

Online Prevention of Emotional Disorders During the Reproductive Period



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Online prevention of emotional disorders during the reproductive period

Prevención online de alteraciones emocionales durante la etapa reproductiva

Memoria presentada por Verónica Martínez Borba para optar al grado de doctora por la Universitat Jaume I

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“I used to think I was the strangest person in the world but then I thought there are so many people in the world, there must be someone just like me who feels bizarre and flawed in the same ways I do. I would imagine her, and imagine that she must be out there thinking of me too. Well, I hope that if you are out there and read this and know that, yes, it’s true I’m here, and I’m just as strange as you”

Frida Kahlo

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PRESENTATION

The reproductive period covers the stage in which women can become pregnant and give birth. According to the World Health Organization (WHO), it begins approximately at 15 years of age with menarche and finishes with menopause around the age of 49. During this vital period, some women may have a desire to have children, while others may not. The former will be the focus of the present thesis dissertation.

Two different situations emerge when women are at a preconception stage planning to conceive. It is possible that women get pregnant spontaneously, but it is also possible that other women face difficulties when trying to conceive and ask for Assisted Reproductive Techniques (ART). Both scenarios may impose a great challenge for women that need to adapt to the new role as a mother or as a woman in need of fertility treatments. Emotional suffering is highly prevalent in both populations, and, when not addressed, this may negatively impact the women, their significant others (e.g., romantic partner, family, and friends), and the babies.

In the last decades, scientific research has focused on the development of psychosocial strategies that help women to overcome the difficulties that may arise during the reproductive period, particularly the struggles that emerge due to ART or the challenges imposed during pregnancy and motherhood. These initiatives, however, have had low reach and real practice evidences that psychosocial components are still rare in multidisciplinary management addressed to women undergoing ART or to women in the perinatal period (i.e., during pregnancy and up to one year in the postpartum). Additional efforts should be undertaken to guarantee that all women have access to healthcare systems that promote not only physical, but also psychological and social well-being. Therefore, the present dissertation aims to develop a new model of care that can be applied during particularly challenging episodes during the reproductive period (i.e., women who present fertility problems and those in the perinatal period). To achieve this goal, we will benefit from the advantages that Information and Communication Technologies (ICTs) have offer, ultimately to prevent the onset and aggravation of emotional disorders (hereafter, EDs; anxiety, depression, and related disorders; Bullis et al., 2019).

This research project is presented in the form of a compendium of five scientific articles arranged in seven chapters. **Chapter 1** serves to introduce and contextualize the difficulties and demands that women face during the reproductive period (e.g., difficulties in becoming pregnant or problems in the perinatal period). The focus is, therefore, on pregnant and postpartum women, as well as on a subgroup of women who face important distress during their reproductive period because they want to become pregnant but they have some difficulties in the process, and, as a consequence, might undergo ART. Next, I explain how challenges related to motherhood that might occur during the reproductive period of women may impact women's mental health.

Difficulties in the access to mental health services are explained and limitations of current face-to-face psychological programs are discussed. In this project, ICTs are proposed to facilitate a new model of care that could help to disseminate psychological interventions at any stage during the reproductive period in a cost-effectiveness manner. At the end of the first chapter, the general and specific objectives of the thesis are explained.

Following this introductory section, five scientific articles are presented in five chapters (from **Chapter 2 to Chapter 6**). As exposed in Table 1, four of these studies have been already published in international peer-reviewed journals indexed in Journal Citations Reports, while the last manuscript was submitted for publication on May 25th 2022 and is currently under consideration for publication in the journal of Patient Education and Counseling. These studies aimed to improve the assessment of EDs during the reproductive period, as well as to develop a preventive intervention for women undergoing ART and perinatal women considering their opinions and needs. Originally, the focus of the present dissertation were pregnant and postpartum women (perinatal period). However, after the development of the first three studies with perinatal women, difficulties in conducting further investigations with this type of population due to financial restrictions and the impact of the pandemic on research in general forced a change in our goals from that stage on. Thus, in the last studies of this thesis, which are focused on the implementation of an intervention and the analysis of users' opinions, we changed our target population to women who were undergoing ART due to availability and feasibility reasons. The lessons learned in the first steps of the dissertations were incorporated, but new research was also conducted for this novel purpose.

Finally, **Chapter 7** offers a discussion section including the main conclusions of the aforementioned five studies with a special emphasis on their strengths, limitations, and practical implications for clinical practice.

Table 1. Doctoral dissertation as a compendium of publications.

Chapter	Article
2	Martínez-Borba, V. , Suso-Ribera, C., & Osma, J. (2018). The Use of Information and Communication Technologies in Perinatal Depression Screening. <i>Cyberpsychology, Behavior and Social Networking</i> , 21(12), 741–752. doi.org/10.1089/cyber.2018.0416 [Impact factor = 2.65 (Q2)]
3	Martínez-Borba, V. , Suso-Ribera, C., Osma, J., & Andreu-Pejó, L. (2020). Predicting postpartum depressive symptoms from pregnancy biopsychosocial factors: A longitudinal investigation using structural equation modeling. <i>International Journal of Environmental Research and Public Health</i> , 17(22), 1–15. doi.org/10.3390/ijerph17228445 [Impact factor = 3.39 (Q1)]
4	Osma, J., Suso-Ribera, C., Martínez-Borba, V. , & Barrera, A. Z. (2020). Content and format preferences of a depression prevention program: A study in perinatal women. <i>Anales de Psicología</i> , 36(1), 56–63. doi.org/10.6018/analesps.356051 [Impact factor = 2.05 (Q3)]
5	Martínez-Borba, V. , Osma, J., Crespo-Delgado, E., Andreu-Pejó, L., & Monferrer-Serrano, A. (2022). Prevention of Emotional Disorders and Symptoms Under Health Conditions: A Pilot Study using the Unified Protocol in a Fertility Unit. <i>Anales de Psicología</i> , 38(1), 25–35. doi.org/10.6018/analesps.356051 [Impact factor = 2.33 (Q3)]
6	Martínez-Borba, V. , Andreu-Pejó, L., & Osma, J. (submitted). First step to design a smartphone application to provide psychological care during reproductive treatments: A qualitative study including patients' and professionals' perspective. [Submitted to Patient Education and Counseling; Impact factor = 3.47 (Q1)].

This thesis has been accepted by the co-authors of the publications listed above that have waved the right to present them as a part of another PhD thesis.

SUMMARY

The reproductive period refers to the time when women can become pregnant and give birth. Most women adapt adequately to the challenges that might emerge during the reproductive period, including the difficulties inherent to the perinatal period (i.e., pregnancy and postpartum), as well as to the physical and emotional burden derived from fertility problems when these occur. However, there is also a percentage of women who experience EDs, such as anxiety and depression, associated with motherhood during this vital period. If these anxious-depressive symptoms/disorders are not adequately addressed, they can have important negative consequences both for women, their close relationships and the offspring, which helps understand why numerous organizations have claimed the need to pay attention to EDs of women during the reproductive period.

It has been proposed that women in the reproductive period, particularly women in the perinatal period and women facing potentially stressful experiences like facing fertility problems and undergoing ART, should receive longitudinal assessments of their psychosocial status. This would allow to offer them prevention and treatment programs, especially to the women who present clinical symptomatology or are at risk of developing clinical disorders. Monitoring of emotional status during the reproductive period, however, is rare.

Numerous barriers at all levels (e.g., health system, professionals, the women, and the societies in general) may difficult the adequate evaluation and management of EDs during this vital stage. An important challenge results from the overreliance on face-to-face individual evaluations and treatments, which are financially demanding for health systems, time-consuming for the professionals, difficult to disseminate to end users (i.e., women), and are often associated with the social stigma of receiving overt mental health support. Conducting health assessments and delivering psychological preventive and treatment programs using ICTs has emerged as a good alternative to face-to-face evaluations and interventions because of the advantages they offer. ICTs allow us to reach a greater number of women in a cost-effective manner, as they reduce travel to health centers, shorten or eliminate waiting lists, reduces the stigma associated with psychological problems thanks to anonymity, and facilitates health care in the women's own context, which makes family conciliation more feasible.

There are now several ICT-psychological based programs addressed to women in the reproductive period, including perinatal women and also populations with fertility problems, but important limitations in these programs have been detected. For example, the heterogeneity of psychological programs makes it difficult to choose one over the other and symptom-focused programs make it difficult to address comorbid symptomatology (e.g., women presenting anxiety and depression at the same time). Many of these do not explain how content was selected and

whether professionals with expertise in the field were involved. Also importantly, there has been an excessive focus on postpartum interventions and preventive programs are scarce compared with treatment protocols. Finally, there are no programs available for Spanish women for the assessment and prevention of EDs during the reproductive period.

The general aim of this doctoral dissertation is to develop a new model of care to be implemented during the reproductive period. As a novelty, this approach will be supported by the use ICTs to help prevent the onset and maintenance of EDs during the perinatal period, as well as during fertility treatments.

When designing assessment and intervention programs, it is important to explore the opinions, preferences, and recommendations of both women who receive these programs and professionals who attend them. The design of assessment and intervention protocols in accordance with these preferences is fundamental since it could favor a more positive attitude towards the programs, as well as greater satisfaction with them, which could result in increased adherence and efficacy of these psychological programs. It is also important to select the key variables to be included in such programs according to the scientific literature. With the previous in mind, the development of the intervention program will first include a series of steps that will be described in more detail in the following sections.

RESUMEN

La etapa reproductiva abarca el periodo en el que las mujeres pueden quedarse embarazadas y dar a luz. La mayoría de mujeres se adaptan adecuadamente a los retos que pueden surgir durante la etapa reproductiva, incluyendo las dificultades inherentes a la etapa perinatal (embarazo y parto) así como al impacto físico y emocional de los problemas de fertilidad cuando estos ocurren. Sin embargo, también existe un porcentaje de mujeres que presenta alteraciones emocionales, como ansiedad y depresión, asociadas a la maternidad durante esta etapa. Si estos síntomas ansioso-depresivos no son abordados adecuadamente pueden tener marcadas consecuencias negativas tanto para las mujeres como para su entorno más cercano y descendencia, lo que podría explicar el por qué numerosas organizaciones han postulado la necesidad de atender a estos problemas emocionales durante la etapa reproductiva.

Se ha propuesto que todas las mujeres en etapa reproductiva, especialmente las mujeres en la etapa perinatal, pero también aquellas que se enfrentan a situaciones potencialmente estresantes como los problemas de fertilidad y los tratamientos de reproducción asistida (TRA), deberían recibir evaluaciones longitudinales sobre su estado psicosocial. Esto permitiría ofrecer programas preventivos y de tratamiento a aquellas mujeres que presentan sintomatología clínica o están en riesgo de desarrollar problemas emocionales. A pesar de esto, los problemas emocionales raramente son explorados y abordados durante la etapa reproductiva.

Se han detectado numerosas barreras a diferentes niveles (p.ej., sistema sanitario, profesionales, las mujeres y la sociedad en general) que impiden una adecuada atención a los problemas emocionales durante esta etapa vital. Destacan las barreras que tienen que ver con la dependencia exclusiva de las evaluaciones y tratamientos individuales cara a cara, que son económicamente exigentes para el sistema sanitario, consumen mucho tiempo de los y las profesionales, son difíciles de diseminar entre las mujeres y a menudo se asocian con el estigma social de recibir apoyo en materia de salud mental.

La posibilidad de dispensar programas a través de las tecnologías de la información y la comunicación (TIC) ha surgido como una buena alternativa a las intervenciones cara a cara por las ventajas que presentan. Parece que las TIC son capaces de ofrecer programas que alcancen a un mayor número de mujeres de manera coste-efectiva ya que reducen desplazamientos hasta los centros de salud, permiten acortar o eliminar las listas de espera para poder acceder a cuidados psicológicos, reducen el estigma asociado a los problemas psicológicos gracias al anonimato y permiten el cuidado de la mujer en su propio contexto lo que facilita la conciliación familiar.

Existen numerosos programas basados en TIC destinados a mujeres en la etapa reproductiva, es decir mujeres embarazadas, en el parto o en TRA. Sin embargo, también

debemos destacar las limitaciones que presentan. Por ejemplo, la heterogeneidad de los programas psicológicos dificulta la elección de uno de estos protocolos frente a otros y los programas centrados en síntomas dificultan el abordaje de la sintomatología comórbida (por ejemplo, mujeres que presentan ansiedad y depresión al mismo tiempo). Además, muchos de estos programas no aportan información extensa sobre los contenidos proporcionados ni sobre la implicación de los y las profesionales en los mismos. De igual manera, existe una mayor atención a las intervenciones postparto y existe una menor atención a las intervenciones preventivas en comparación a los programas de tratamiento. Por último, no existen en España programas de evaluación y prevención de problemas emocionales durante la etapa reproductiva.

El objetivo general de la presente tesis doctoral es desarrollar un nuevo modelo de atención durante la etapa reproductiva basado en el uso de TIC para prevenir la aparición y mantenimiento de problemas emocionales durante la etapa perinatal, así como durante TRA.

Al diseñar programas de evaluación e intervención es importante explorar las opiniones, preferencias y recomendaciones tanto de las mujeres que reciben estos programas, como de las profesionales que les atienden. El diseño de protocolos de evaluación e intervención acordes a estas preferencias es fundamental ya que podría favorecer una actitud más positiva hacia los programas, así como una mayor satisfacción con los mismos, que se podría traducir en una mayor adherencia y eficacia de los programas psicológicos. Además, también resulta relevante incluir en estos programas variables de interés acorde a la evidencia científica. Con este objetivo en mente, el desarrollo del programa de intervención incluirá una serie de pasos que serán descritos con mayor detalle en los siguientes capítulos.

CHAPTER 1.
GENERAL INTRODUCTION

1. General Introduction

1.1 Challenges experienced by women during the reproductive period

According to the WHO, the reproductive period comprises the years in which women can become pregnant and give birth, which ranges approximately from 15 to 49 years of age (WHO, 2006). During this vital cycle, some women may feel the desire to become mothers and thus begin planning to become pregnant, either with their partners or alone.

Conceiving a child can be one of the most vital desires for many women. However, the reproductive period is not always as smooth as believed. Women face multiple changes and challenges while seeking to become pregnant and during the perinatal period, including both physical and psychological demands (Devi Ramalingam et al., 2021; Emmanuel & St John, 2010). In the next lines, I describe some of the most frequent challenges that women experience when attempting to become pregnant, with a particular emphasis on ART, as well as on difficulties that may arise during the perinatal period, once they are pregnant.

1.1.1 Challenges experiences by women who have become pregnant and clinical recommendations during the perinatal period

Motherhood is a major life transition that requires women to develop a new identity as a mother and to adapt themselves to physical changes, but also leads to alterations in relationships and roles (Emmanuel & St John, 2010). Traditionally, it has been socially and culturally believed that the perinatal period is a protective phase for the development of EDs. While this is true for many women who cultivate adequate coping skills and adapt to the transition to motherhood, some others may experience important emotional suffering during the perinatal period (Clifton & Domar, 2022; Grzesik- Gašior et al., 2019).

In particular, EDs are the most frequent mental illness during pregnancy and the postpartum (Janik et al., 2018). In Spain, it is estimated that between 16.8% and 20.9% of women suffer perinatal anxiety symptoms (González-Mesa et al., 2019; Soto-Balbuena et al., 2018). Additionally, between 4% and 23% of women are estimated to experience perinatal depressive symptoms in Spain (González-Mesa et al., 2019; Míguez & Vázquez, 2021a). Also alarmingly, recent meta-analytic studies informed of an increased tendency in the onset of perinatal depressive symptoms during the last years with high comorbidity rates between both anxiety and depressive symptoms particularly aggravated during the COVID-19 pandemic (Cena et al., 2021; González-Mesa et al., 2020; Luo et al., 2021; Motrico et al., 2022; Nisar et al., 2020).

Suffering from an ED is associated with negative consequences not only for the individual but also for the most proximal and distal context (König et al., 2020; Vieta et al., 2021; WHO, 2021). Particularly in the perinatal period, EDs result in high burden for the women, but also for the baby, partner, relatives, friends, and the society. Women who suffer depressive or anxiety symptoms/disorders during the perinatal period and do not receive an adequate support are at greater risk of presenting low self-esteem, decreased quality of life, increased sleep disturbances, more relationship' problems (social, partner-related, and sexual), more addictive behaviors (smoking and drinking), suicidal ideation, adverse birth outcomes, difficulties in mother-infant relationship and problems with breastfeeding (Dadi et al., 2022; Fanti et al., 2022; Li et al., 2022; Slomian et al., 2019). In terms of child development, different meta-analytic studies have reported that, when not addressed, maternal depressive symptoms/disorders are associated with development problems in their offspring in several areas, including socioemotional, behavioral, cognitive, language and motor domains (Martucci et al., 2021; Rogers et al., 2020; Slomian et al., 2019). All these negative consequences have also an important economic impact from the society, derived from healthcare utilization and medical expenditures (Pollack et al., 2022). What do clinical guidelines suggest in this scenario?

Some of the most relevant **international guidelines** in the field of perinatal healthcare recommend that all women should be monitored about EDs and their risk factors during pregnancy and the postpartum period (first year after delivery). A set of basic initial screening questions about depressive and anxiety symptoms have been proposed (i.e., Whooley Questions; Whooley et al., 1997) followed by the administration of a complete questionnaire when needed (i.e., the Edinburg Postnatal Depression Scale, EPDS; Cox et al., 1987). Professionals suggest that all women suspected to have a severe mental health condition or with personal history of mental illness should be referred to a perinatal mental health specialist (Austin et al., 2017; National Institute for Health and Clinical Excellence, 2020; Scottish Intercollegiate Guidelines Network, 2012; The American College of Obstetricians and Gynecologists, 2018). Regarding prevention and treatment of EDs during the perinatal period, international guidelines recommended to provide early stepped-care interventions based on manualized psychosocial protocols (i.e., Cognitive-Behavioral Therapy, CBT) including self-help, face-to-face, telephone or e-mental health interventions according to the particular case (Austin et al., 2017; National Institute for Health and Clinical Excellence, 2020).

In our most immediate context, the Spanish **national guideline** for women during pregnancy and the postpartum also establishes that women should be assessed about prenatal depressive symptoms and other risk factors during these periods (Ministerio de sanidad Servicios Sociales e Igualdad, 2014). This guideline, however, has an excessive focus on the postpartum period and does not provide a detailed description of prenatal assessment and intervention

recommendations, which contrasts with the well-established argument that prenatal depressive symptoms is the best predictor of postpartum depression (Hutchens & Kearney, 2020; Qi et al., 2021). Therefore, additional efforts are required to systematize perinatal mental care.

A special mention in this direction should be acknowledged to the autonomic proposal of Catalonia (Generalitat de Catalunya. Departament de salut, 2018), which is more aligned with international recommendations, including the assessment of EDs and its risk factors both during pregnancy and postpartum and suggesting the referral of women who present mental health issues to the psychologist.

In sum, institutional guidelines discuss the relevance of EDs and other psychosocial risk factors during the perinatal period and generally propose that all pregnant women should be longitudinally checked on their mental well-being during pregnancy or at the postpartum and should be offered the appropriate treatment if emotional suffering is detected. How do these treatments protocols tend to address EDs during the perinatal period?

To manage EDs, a first step requires adequate evaluation of mental health status. In this sense, different efforts have been conducted to develop an assessment protocols that allow the identification of EDs during the perinatal period. Most recent systematic reviews that analyzed **screening** programs for perinatal mental health (Bhat et al., 2022; Míguez & Vázquez, 2021b; Waqas et al., 2022) conclude that:

- Assessment protocols are more often provided at the postpartum compared to pregnancy.
- The Edinburg Postnatal Depression Scale is the most frequent instrument for mental health screening, but the variety of cutoffs and time of assessment periods used difficult comparability of studies.
- Increased attention has been paid to screening for EDs, the relevance of their risk factors is underestimated. Risk factors for EDs are usually explored separately in small subsets which difficult the comprehensive analysis of this phenomenon and the early identification of women who present higher risk for the development of EDs.
- There are difficulties on the referral and follow-up of women with positive mental health screening results. It has been reported that 60% of women who are referred to other services after positive screening do not actually consult with the psychological service (Xue et al., 2020), which reflects the difficulties in the provision of continuity of care.

In relation to psychological **intervention** programs, recent meta-analyses revealed that several interventions to prevent and treat depressive symptoms during perinatal period exist (Cuijpers et al., 2021; Li et al., 2022; Yasuma et al., 2020). Although CBT seems to be an effective

treatment to address depressive symptoms in the short and the long term (Branquinho et al., 2021; Cuijpers et al., 2021; Li et al., 2022; Shortis et al., 2020), results also indicated that preventive programs are less frequently offered compared with treatment interventions once the problem has already emerged (Li et al., 2022). This contrasts with current evidence showing that perinatal depression could be prevented by enhancing attitudes and behaviors that promote physical and mental health which decrease the cost of care in the healthcare system (American Psychological Association [APA], 2014; Muñoz et al., 2021).

Similar to what has been indicated for assessment protocols, one important limitation of current intervention programs during perinatal care is that they tend to focus on isolated pregnancy or postpartum periods, as opposed to the recommended longitudinal intervention studies during the whole perinatal period (Cuijpers et al., 2021; Huang et al., 2020; Li et al., 2022). In addition, intervention designs, have been very diverse and generally ignore the transdiagnostic nature of EDs (Prom et al., 2022).

In sum, while current perinatal assessment and treatment protocols have made some advances in the past decades, they still do not fully align with clinical guidelines. In particular, the most recent scientific evidence revealed that studies for perinatal mental health are still almost exclusively focused on the postpartum period, and assessment efforts often ignore the simultaneous role of a comprehensive set of biopsychosocial risk factors. Also alarming, preventive protocols are underrepresented, programs are highly heterogeneous in their content and format, and few studies have been conducted in Spain.

1.1.2 Challenges experienced by women who seek to become pregnant and clinical recommendations for women undergoing fertility treatments

The previous section described the difficulties identified during the reproductive period, specifically when women are pregnant or have given birth in the last 12 months. However, infertility and ART can also be associated with important challenges in the women. This section exposes the emotional challenges faced by women who desire to get pregnant, but this did not happen spontaneously and are receiving ART.

While 84% of women get pregnant during the first year of unprotected sexual relationships (NHS-UK, 2018), other women face multiple difficulties when trying to conceive. Infertility, understood as the inability to get pregnant after 12 months of unprotected sexual intercourse, affects approximately 8-12% of couples worldwide (Vander Borcht & Wyns, 2018). Fertility problems impact directly on the women's life and, the sole diagnosis breaks with personal

expectancies and is considered to be a critical life event (Chow et al., 2016). After the diagnosis, women usually start ART, commonly intrauterine inseminations (IUI).

Although ART offers the possibility to achieve pregnancy, it also implies high emotional, physical, and economic burden (Chow et al., 2016). According to recent systematic reviews and meta-analyses, the most common challenges of ART have been found in sexual function, marital and social relationships, and emotional well-being. Experiencing EDs during ART is highly frequent (Kiani et al., 2021), which increases according to the duration of infertility and the number of ART received (Milazzo et al., 2016; Sater et al., 2022).

These EDs experienced during ART have important consequences that should not be overlooked because they can compromise women' health. Recent studies have found positive associations between anxiety and depressive symptoms during ART and sexual dysfunction, sleep disturbances, and ART discontinuation (Fernandez-Ferrera et al., 2022; Pedro, Sobral, et al., 2016; Sater et al., 2022). The discontinuation with ART is associated with important economic loss, both for the healthcare system and for the women (Chambers et al., 2009; van Eekelen et al., 2020).

Women undergoing ART are a greater risk of developing EDs both during ART and during the subsequent perinatal periods. EDs not only are highly prevalent during fertility problems, but also have a negative impact on different areas of women's life. National and international organizations have recently noticed the relevance of providing psychological care during ART and have summarized this in clinical guidelines. What do these guidelines suggest for care during ART?

The **international** European Society of Human Reproduction and Embryology (ESHRE) has developed a guide for fertility staff to offer psychosocial care before, during, and after ART (ESHRE Psychology and Counselling Guideline Development Group, 2015). According to this guideline, professionals should assess behavioral, social, emotional, and cognitive needs of women under this treatment. Once the assessment is performed, the ESHRE recommends to provide women with information about lifestyle behaviors, ART procedures and ART options, offer additional psychosocial care to women at risk of relational-social distress or negative emotional reactions, ask patients about their ART concerns, discuss with women who do not get pregnant the implications of ending unsuccessful treatments, and talk with pregnant women about pregnancy worries.

At a **national** level, the Spanish Fertility Society (Sociedad Española de Fertilidad) has established a guideline with some references to the aforementioned ESHRE protocol. According to these recommendations, infertile patients should be longitudinally screened on several psychological factors such as anxiety, depression, stress, anger, coping skills, social support, and personality, among others, during the first contact with the professionals, prior and after each ART, and after pregnancy (Grupo de Interés en Psicología. Sociedad Española de Fertilidad, 2009). After the assessment, specific cognitive-behavioral psychological abilities to address clinical symptomatology should be instructed. These include techniques like relaxation, cognitive restructuring, assertive communication, and planning pleasant activities. As a final remark, this guideline suggest that women should continue with psychological care even if they get pregnant, because women may still experience high levels of stress and anxiety associated with worries about the baby's health (Grupo de Interés en Psicología. Sociedad Española de Fertilidad, 2009).

Thus, recommendations during ART indicate that all women undergoing fertility treatments should be assessed about EDs and referred to the most convenient healthcare service when necessary. Guidelines postulate that continuity of care should be guaranteed even if women get pregnant after ART. What are the specific components that have been incorporated into this continuous care?

During the last decades, there has been an increased interest in developing and validating psychosocial instruments to be applied during screening of women undergoing ART. For instance, the Fertility Quality of life tool (FertiQoL; Boivin et al., 2011) was developed in 2011 and has been translated to more than 40 languages already. Mental health **screening** protocols and studies that evaluate the utility and feasibility of implementations research in human reproduction units, however, are still rare. To the best of our knowledge, just one research team in The Netherlands has explored the feasibility of conducting screening of emotional risk factors before ART. The study by Van Dongen et al. (2012) evaluated the implementation of a screening program throughout the instrument SCREENIVF instrument by exploring uptake rate and participants' satisfaction. They found that around 80% of patients completed the screening questionnaire and between 30-33% of them were at risk for emotional problems. Regarding satisfaction, 90% of the participants reported that the screening was useful and most participants considered that time consumption was not excessive. The authors concluded that emotional assessments prior to ART are feasible (Van Dongen et al., 2012), which is important to recommend further diagnosis and psychological interventions when necessary (Verhaak et al., 2010).

Contrary to the aforementioned screening programs, systematic reviews and meta-analyses have showed that psychological **interventions** are already available and are effective in the improvement of mental health during fertility treatments. It is well documented that CBT, coping skills, training and mind-body interventions (including relaxation, mindfulness, and healthy behaviors) can improve anxiety, depression, stress, social support, marital relationship, and quality of life during ART (Chow et al., 2016; Chu et al., 2017; Frederiksen et al., 2015; Gaitzsch et al., 2020; LoGiudice & Massaro, 2018; Masoumi et al., 2019; Zhou et al., 2021), even in group format (Warne et al., 2022). Regarding format and length, it has been suggested that better and more credible results are found in group formats lasting 6-12 weeks (Chow et al., 2016; Chu et al., 2017; Clifton & Domar, 2022; Frederiksen et al., 2015).

To sum up, while different well-designed and validated psychosocial instruments already exist to be used during ART (Pedro, Frederiksen, et al., 2016), their inclusion in routine care in human reproduction units is not established. More encouraging results have been found in terms of intervention programs at an international level. However, public human reproduction units in Spain rarely have psychologist to provide psychosocial support during ART. Thus, EDs during ART are underdiagnosed and undertreated in our country. What are some of the barriers that limit our ability to adequately monitor and provide effective interventions to women seeking to become pregnant and during the perinatal period?

1.2 The problem of relying on face-to-face care only and the potential of Information and Communication Technologies to change the current model of care

As explained in the previous sections, clinical guidelines recommend the assessment and diagnosis of EDs and their risk factors during the whole reproductive period, from the time women seek to become pregnant, especially when infertility problems arise, through the whole perinatal period. However, the aforementioned scientific evidence, which summarizes the practices that are implemented in our immediate context, shows a different reality. As exposed in preceding lines, women do not usually ask about mental health services when having difficulties to become pregnant and during the perinatal period, and consequently, intervention programs are not available cross-culturally. Some authors have wondered why women are not receiving the adequate mental care during the reproductive period, considering that women are indeed interested in receiving psychological care during the reproductive period (Clifton & Domar, 2022; Martin-Key et al., 2021), there must be other possible contributors to the inadequate management of these women.

1.2.1 Barriers for adequate mental care during the critical reproductive period: from women having problems to become pregnant to the postpartum

In the light of the most relevant scientific evidence (Aarts et al., 2013; Huppelschoten et al., 2019; Jones, 2019; Sambrook Smith et al., 2019; van Dongen et al., 2016; Waqas et al., 2022; Webb et al., 2021; Xue et al., 2020; Zhu et al., 2022), barriers to access to mental care during the reproductive period include individual as well as professional, organizational/political, and social/cultural factors. As shown in Table 1.2, most of these barriers are the consequence of providing traditional face-to-face care, which is highly expensive, in terms of personal, economic, and material consumption of resources.

Table 1.2 Barriers to access to mental healthcare during the reproductive period.

Domain	Barriers to receive mental healthcare
Individual	Normalization of symptoms, stigma, fear of losing maternal rights, worries about confidentiality, lack of time, difficulties with childcare and transport, previous negative experiences, beliefs about medication and health, and lack of family support.
Professionals	The prioritization of physical care, inadequate knowledge and skills training, lack of time, poor communication with other professionals, lack of supervision, lack of confidence, and negative attitudes towards reproductive mental issues.
Organizational and political	Lack of human health resources, long waitlists, scheduling issues, limited access to services, complex referral pathways, lack of follow-up protocols, inflexible and non-patient-centered care, inappropriate treatment according to women needs, and high costs.
Social and cultural	Mental health stigma, cultural pressure, and language differences.

Not surprisingly, during the last decades there has been an increasing interest in developing new models of care that could help to reduce the burden of face-to-face psychological programs and facilitate the dissemination of more affordable evidence-based protocols (da Fonseca et al., 2021). It has been postulated that the use of ICTs would serve this purpose.

1.2.2 Relevance of technologies on the society. Impact of technologies in the healthcare system

The widespread use of technologies in our daily tasks has also reached the medical context. E-Health is defined as the use of electronic technologies (i.e., the Internet, mobile devices, computers, and information technologies) for health purposes (da Fonseca et al., 2021; Eysenbach, 2001). Among all technologies that could be employed to provide psychological care, Internet-based web- and app-based interventions are the mainstream.

Internet-based assessments and interventions present numerous advantages when compared with traditional models of care. ICTs may help to provide more available and accessible evidence-based evaluations and treatments by reducing logistic barriers (i.e., traveling to the consultation or combining visits with child care), reducing costs, and saving the patients' and the professionals' time. It also has the potential to reduce the stigma associated with mental health issues (increased anonymity and privacy), reduce missing data, provide automatic feedback to patients and therapists, and help therapists in decision making (Andersson & Titov, 2014; Kerst et al., 2020; Przeworski & Newman, 2012).

In addition to the previous advantages of ICTs, research has also revealed that Internet-based psychological interventions, especially those based on CBT, could be at least as effective as face-to-face programs and are more cost-effective (Andersson, 2018; Andersson et al., 2019; Andersson & Titov, 2014). Not surprisingly, it has been postulated that Internet interventions could act as an alternative or complement to face-to-face services (Andersson, 2018; Schröder et al., 2016). Nowadays, Internet-based programs have reached different physical and mental health conditions (Denecke et al., 2022; White et al., 2022) including mental care during the reproductive period (Sparidaens et al., 2021; Yunus et al., 2022).

1.2.3 Use of Information and Communication Technologies during the reproductive period

Indeed, the use of ICTs during the reproductive period, especially during the postpartum, has increased exponentially in the past years. Overall, a large amount of research suggests that Internet-based interventions are effective and acceptable in the treatment of perinatal anxiety and depression (Hussain-Shamsy et al., 2020; Loughnan et al., 2019; Yunus et al., 2022). In the field of fertility treatments, the amount of research is far more limited. For instance, a few studies have used web-based interventions to reduce stress during ART (Sexton et al., 2010) or to monitor patients' treatment trajectory and provide lifestyle advices during ART (Sparidaens et al., 2021). Others have developed mobile apps to provide mindfulness-based interventions (Boedt et al., 2022), to favor positive reappraisal coping when waiting for the results of fertility treatments (Schick et al., 2019), or to provide obstetric information during ART (Timmers et al., 2021).

While research to date utilizing ICTs to enhance management of EDs in women during the reproductive period is encouraging, especially during the postpartum, important challenges still need to be addressed. First, no study has yet addressed comorbid anxiety and depressive symptoms in the same investigation because disorder-specific treatments have been used, which is problematic given the high comorbidity between the two. Second, interventions do not offer continuity of care with longitudinal programs that cover preconception, especially ART, pregnancy, and postpartum periods and they generally focus on the postpartum or, to a lesser extent, in pregnancy (Hussain-Shamsy et al., 2020; Loughnan et al., 2019). Third, there is not a

consensus about the optimal number of sessions, their duration, and the amount of support that multidisciplinary treatments should incorporate (Loughnan et al., 2019; Yunus et al., 2022) and the inclusion of an active psychological therapy such as CBT or interpersonal psychotherapy in such programs is scarce. In addition, current programs are very heterogeneous in terms of the content included, the ICT platform used, and the homework provided, to name some examples (Clifton & Domar, 2022; Gaitzsch et al., 2020). Finally, recent studies have indicated that some apps are not developed by trusted health care companies, are not regularly updated, or do not include perinatal risk factors (Spadaro et al., 2022; Tsai et al., 2022).

There are different ICT-based programs to be used during the reproductive period, especially in the postpartum. Preliminary results found that the Internet could be a useful tool to prevent and treat depressive symptoms in the reproductive period. However, some issues have been raised, namely the increased attention to one of the perinatal periods (generally the postpartum), the difficulties in addressing comorbid disorders, or the lack of professionals' and users' involvement in the development of technologies. There is a need to develop modern, well-designed, and conceptually-relevant ICT-based programs to be used during the reproductive period, particularly in women with fertility problems. What are the steps that need to be taken to develop such programs?

1.2.4 Development of Internet-based programs: the need to consider the users' opinions and preferences

A frequent barrier with e-Health refers to the lack of motivation and poor opinion of stakeholders about e-Health as the development process often ignores the professionals' and users' needs (Kerst et al., 2020; Schreiweis et al., 2019).

The acceptability of new models of interventions by healthcare professionals plays a fundamental role in e-Health implementation (Andersson & Titov, 2014; Kerst et al., 2020). It has been suggested that professionals who remain skeptic or feel threatened by the inclusion of technology-based solutions for mental health will never implement these programs in their daily practice (Andersson, 2018; Granja et al., 2018; Sprenger et al., 2017). As a solution to this barrier, it has been proposed that professionals should be involved in the development of such technologies to better fit their preferences and to discuss with them the benefit of using e-Health solutions (Schreiweis et al., 2019).

In addition to the professionals, the opinion of users has also been acknowledged as an important barrier for e-Health implementation. Users who do not perceive a benefit from using e-Health may refrain from their use. In fact, one of the most remarkable issues with Internet-based programs, particularly mobile applications for the management of depressive disorders, is the lack of user adherence in the general population (Kerst et al., 2020) and during the reproductive period (Aarts et al., 2011; Yunus et al., 2022). It is possible that technologies are not developed following a patient-centered approach which may discourage women and people in general to use them. Involving women in the development of such new technologies is fundamental as an indicator of quality of healthcare and to contribute to the successful implementation of e-Health programs (Granja et al., 2018).

Despite the benefits of e-Health programs, negative attitudes by the professionals and users may impede the correct implementation of this services in public health services. To solve this problem, users and professionals need to be more involved in the design and update of interventions (Andersson, 2018). It has been proposed that satisfaction, adherence, and probably efficacy will increase if e-Health is designed according to the professionals' and the users' needs (Arsenijevic et al., 2020).

1.3 General aims and research questions of the thesis

In the last decades, there has been an increased interest in the assessment, prevention, and treatment of EDs during the reproductive period. A number of milestones have been reached in the amelioration of healthcare programs for women who seek to become pregnant but face difficulties and ask for ART, as well as during pregnancy and in the postpartum. However, in this attempt to develop more affordable approaches to care, there are some issues that need to be improved. This doctoral dissertation, as described in Figure 1, has been developed as an attempt to address the limitations identified by previous research studies at different levels:

ASSESSMENT:

- Programs designed to evaluate and help prevent perinatal EDs are focused on isolated moments during pregnancy or in the postpartum instead of including longitudinal protocols.
- There is a lack of comprehensive assessment protocols that facilitate the identification of EDs and their risk factors on women during the reproductive period.

INTERVENTION:

- Psychological interventions during the perinatal period do not align with women preferences.
- Treatments for EDs are largely focused on the perinatal period, especially in the postpartum, so resources for women with fertility problems undergoing ART are an urge, particularly in Spain. Existing psychological programs designed to address EDs during ART are focused on specific symptoms or conditions, which difficult the management of comorbid anxiety and depressive conditions.

USER EXPERIENCE:

- Current Internet-based protocols generally ignore the professionals' and the women's needs. Assessment and treatment protocols do not consider their opinion when designing technology-based interventions, which may compromise program adherence and efficacy.

Considering these literature gaps, the **main aim** of this thesis is to explore and propose a new model of care based on ICTs that facilitates the evaluation and prevention of EDs in women who are undergoing ART, those who are pregnant, and women at the postpartum.

More specifically, the **research questions** that will be addressed during the present dissertation are:

- ASSESSMENT:

1. What do we know about the use of ICTs on the longitudinal assessment of perinatal depressive symptoms?
2. What risk factors should we consider when developing psychological screening protocols during the perinatal period?

- INTERVENTION:

3. How should we design interventions focused on the prevention of EDs to better meet the women's needs?
4. Can we implement a transdiagnostic online intervention to prevent the onset of EDs during ART? Could it be useful and well accepted?

- USER EXPERIENCE:

5. What is the opinion and preferences of women undergoing ART and the professionals who attend them about this transdiagnostic psychological intervention? How can we translate this online intervention into a complete self-administered m-Health program?

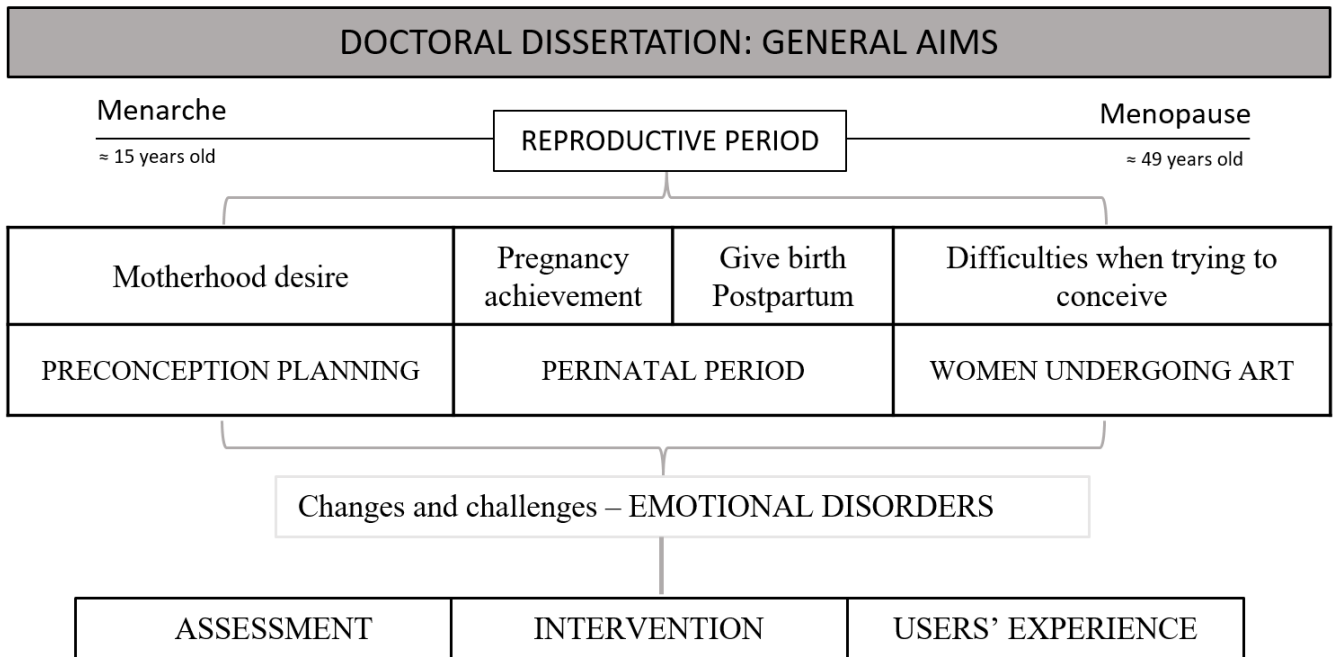


Figure 1. Description of the doctoral dissertation.

1.4 Outline of the thesis

To respond the questions above, five studies have been conducted as part of this doctoral dissertation.

First, **Chapter 2** presents a systematic review that will serve to contextualize how ICTs has been used in the field of perinatal depression screening and to discuss to what extent ICTs might help to overcome some of the barriers presented by traditional face-to-face models of care.

Second, because the evaluation of risk factors for mental distress is fundamental to better develop preventive programs during the reproductive period, **Chapter 3** will show an empirical study that explored the unique contribution of a set of risk and protective biopsychosocial factors for postpartum depression in perinatal women when considered altogether in a structural equation model. This study will help us to obtain a parsimonious model that could guide prevention programs in a more effective way.

After the previous exploration of the factors (i.e., contents) that healthcare programs during the reproductive period should include, we conducted an experimental study to examine the preferences of women regarding the contents and formats that these psychological programs to prevent perinatal depressive symptoms should consider (**Chapter 4**).

With all the information from Chapters 2 to 4, the next step was to develop and implement an Internet-based program to provide a preventive psychological intervention during the perinatal period. However, because funding was not obtained for this purpose and the pandemic had an important impact on research funding lines and potential research practices, we had to adjust our goals. We had a close contact with an infertility service that was very interested in receiving psychological treatment for women under ART and were open to use an online format. Thus, because treatments for women undergoing ART due to fertility problems, who are a particularly vulnerable population during the reproductive period, are very rare, this was our new target population. **Chapter 5** shows the development of a transdiagnostic preventive program applied in an online group format to prevent the onset of EDs during ART. This study reports preliminary results in terms of clinical utility (prevention of EDs) and acceptability (adherence rates and satisfaction). The knowledge acquired in the previous steps of the dissertation was used for this purpose, but adaptations were made to this specific population by revising the literature.

Difficulties found in the implementation of the aforementioned transdiagnostic prevention program (i.e., women's availability to compose the groups) evidenced the need to develop completely self-administered programs. Thus, **Chapter 6** reflects the first step in this direction. Two focus groups were conducted to explore the opinion and preferences of women undergoing ART and professionals who attend them about the use of ICTs for reproductive mental health and the adaptation of this preventive psychological program to be delivered through a mobile application.

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CHAPTER 2.

THE USE OF INFORMATION AND COMMUNICATION
TECHNOLOGIES IN PERINATAL DEPRESSION SCREENING:
A SYSTEMATIC REVIEW

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2. The use of Information and Communication Technologies in Perinatal Depression Screening: A Systematic Review

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2.1 Abstract

Objective: Perinatal mental illness refers to psychiatric disorders that exist during pregnancy and up to 1 year after childbirth. The aim of this systematic review was to discuss the use of Information and Communication Technologies (ICTs) on perinatal depression (PeD) screening in the past three decades. **Method:** Published articles were searched between 1990 and 2018, both in English and Spanish. In the search, we used different keywords, such as “pregnancy”, “depression”, or “technology” in ScienceDirect, PubMed-NCBI, and Web of Science. **Results:** We found 10 articles that combined the use of ICTs and a focus on PeD screening. Studied periods included pregnancy ($n = 2$) and postpartum ($n = 8$). The telephone was the most commonly used communication method ($n = 5$), followed by the Internet ($n = 4$). One investigation used both, the telephone and the Internet. The Edinburgh Postnatal Depression Scale was the most frequently used screening measure ($n = 8$). The proportion of depressed perinatal women varied across studies depending on the pregnancy status and the cutoff values used, showing a very broad range between 5.8 and 51.9 percent. **Conclusion:** Despite the increasing popularity of ICTs in health settings, their use in perinatal mental health screening is still rare. Overall, encouraging findings have been reported when using ICTs for screening of PeD, such as eliminating the need to travel to the health center to conduct the screening and allowing for a wider dissemination. However, more research is needed to support their inclusion in perinatal care.

Keywords: ICTs pregnancy, postpartum, depression, screening.

2.2 Introduction

Perinatal mental illness refers to “psychiatric disorders that are prevalent during pregnancy and as long as 1 year after delivery.”¹ Although a number of mental disorders have been reported during pregnancy and postpartum, depression and anxiety are the most prevalent problems worldwide.² This review will focus on depression, which has received most attention in perinatal research.

Perinatal depression (PeD) is estimated to affect between 3 and 6 percent of women.³ During pregnancy, depression prevalence in different studies and countries has ranged from 6 to 12 percent.^{4,5} In the postpartum, depression has been estimated to affect between 7 and 25 percent of women.⁶⁻¹⁰

PeD is a major public health concern because of its negative consequences for the mother, the fetus, and the baby.¹¹ For instance, depression during pregnancy has been linked to increased childbirth complications, including premature birth, low birth weight, and preeclampsia. Moreover, postpartum depression (during the first year after delivery) is associated with poor performance in the babies’ behavioral, cognitive, and emotional domains.¹²⁻¹⁴ Not surprisingly, identification and management of PeD and other mental health disorders have become a fundamental goal of the World Health Organization.¹⁵

Fortunately, the perinatal period provides a unique opportunity for the detection of depressive symptoms because of the continuous medical monitoring of women, especially during pregnancy. Also encouragingly, previous studies and guidelines have shown that assessment of PeD can be carried out quickly with only one or two brief screening questions, which might be as valid and effective as long, structured mental health assessment methods.¹⁶⁻²⁰

In this scenario, an early detection of depressive symptoms in the perinatal period, which reduces the impact of mental illness on the mother, the baby, and the family,²¹ should be feasible. Unfortunately, despite the benefits of early detection and intervention of pregnant women with depressive symptoms are well known and although we have instruments to measure them, PeD is often undetected and, consequently, undertreated or addressed after its onset.^{22,23}

There might be several reasons to explain why the identification of PeD is still unsuccessful, including difficulties in the health care professional and the mothers. On the one hand, some factors explaining why prompt and adequate screening by health care professionals is rare might include a reduced awareness about the problem, time constraints for exhaustive assessments during and between consultations, lack of established policies for care, or unclear referral networks.^{4,24-27}

On the other hand, barriers in perinatal women have also been reported. For instance, some maternal and pregnancy characteristics, such as being a young mother with an intermediate education level, being born abroad, and being in the first trimester of pregnancy are related to lower consultation of a mental health specialist.²² Other barriers in the mother are related to sociocultural and environmental factors. Some of these include difficulties in combining child care and face-to-face psychological interventions, not knowing where to go to receive treatment, time limitations, transportation difficulties, social stigma associated with mental illness, and fear that their baby could be removed from their care.^{28–32}

In the light of the previous findings, the goal of this study was to review how Information and Communication Technologies (ICTs) have been used in PeD screening and to discuss to which extent they might help overcome some of the barriers presented previously. During the past years, the use of ICTs in the health service industry (e-Health) has increased spectacularly, arguably because of the decrease in their cost and their increased availability in the general population.³³ For instance, in 2017 Internet access and portable electronic devices connected to the Internet (e.g., smartphones, laptops, and tablets) were available to 87 and 65 percent of Europeans, respectively.^{34,35} Also importantly, 51 percent of individuals used the Internet to seek health-related information in 2017.³⁶

The use of ICTs in PeD might minimize some of the aforementioned barriers experimented by perinatal women when looking for mental health advice. For instance, ICTs allow a flexible access to screening and treatment, which can be performed anytime and anywhere, eliminating travel costs and facilitating the combination of child care and self-care.^{37–39} In addition, ICTs offer anonymous help, which can minimize stigmatization,⁴⁰ improve help-seeking behaviors among perinatal women,⁴¹ and decrease participants' inclination to give a socially desirable response, thus encouraging more honest answers because of a sense of privacy and lack of perceived judgment.⁴² In fact, anonymity seems to be a key aspect in the assessment of PeD, as higher prevalence rates of PeD have been obtained when women filled out a questionnaire at home on their own compared with phone calls by nurses.⁴³

ICTs could also be useful for health professionals to communicate with patients and colleges in a more effective and immediate manner, as well as to support their decisions or to seek information.⁴⁴ Moreover, ICTs could make consultations more efficient if screenings completed by the mothers at their homes remotely informed the clinicians of important undesired events, such as an increase in depressive symptoms, without the need to have on-site consultations for such assessments.⁴⁵ In fact, health care professionals believe that the use of ICTs in PeD screening has important benefits, such as eliminating language barriers reducing redundancy and human errors, and increasing the client's privacy.⁴⁶

This study will review the contributions of ICTs in the field of PeD screening in the past three decades (since 1990). In doing so, we will report the sample characteristics (e.g., pregnancy period), type of ICTs employed (e.g., phone calls or the Internet), procedures and instruments used for screening, and the main findings in the perinatal literature. In addition to providing an overview of existent research using ICTs for PeD screening, the implications of the findings and future lines of research will be discussed.

2.3 Methods

Scientific articles including the use of ICTs for depression screening during the perinatal period were consulted after an extensive literature search using vertical search options.

2.3.1 Literature research

The systematic search for scientific articles was carried out in March 2018. The information was consulted on the following databases: ScienceDirect, PubMed-NCBI, and Web of Science. Key terms used are in line with previous reviews on ICTs and health^{47,48} and included: “perinatal”, “pregnant”, “pregnancy”, “prenatal”, “postnatal”, “postpartum”, “depression”, “depressive symptoms”, “technology”, “technologies”, “Internet”, “eHealth”, “mHealth”, “ICT”, “mobile”, “app”, “application”, “phone”, “telephone”, “smartphone”, “tablet”, “PDA”, and “screening.” The search was limited to articles published between 1990 and March 2018. Key terms were searched in the abstract. The specific search terms used in ScienceDirect are reported in Appendix 2.1. We used the same search strategy for all databases.

Two of the authors, namely V.M.B. and C.S.R, conducted the research independently and selected the articles (see a more detailed description in section “Literature selection”). The results obtained by each researcher were compared to ensure that the final database included all the articles. The agreement in the number of articles found between both researchers was 89 percent.

2.3.2 Literature selection

A prerequisite to select a study was that any form of ICTs was used in the screening of PeD. The review includes articles published in English and Spanish to provide an overview of the use of ICTs for PeD screening in the past decades and to discuss its current state of the art. The eligibility of studies was assessed following a series of steps according to eligibility criteria (Table 2.1). First, a selection was made by looking at the article title and abstract. Then, the full text was read for the selected articles and additional references were searched within the text. A flow diagram of the selection process is given in Figure 2.1. The diagram will only be presented for one researcher (V.M.B.) to facilitate the readability of the text. As described previously, the same procedure was followed by C.S.R.

Table 2.1 Inclusion and exclusion criteria.

Inclusion	Exclusion
Articles	Full text not being an article, Reviews, Protocols
English or Spanish	Full text no available in English or Spanish
Focused on human	Animal studies
Using ICTs for screening	Including face-to-face session
Focused on screening	Result no showing proportion of depressed women
Focused on depression	Evaluation not including depression measure
Perinatal women	Studies focused on general population, no pregnant women, with a focus on fathers or babies and perinatal women after 12 months postpartum

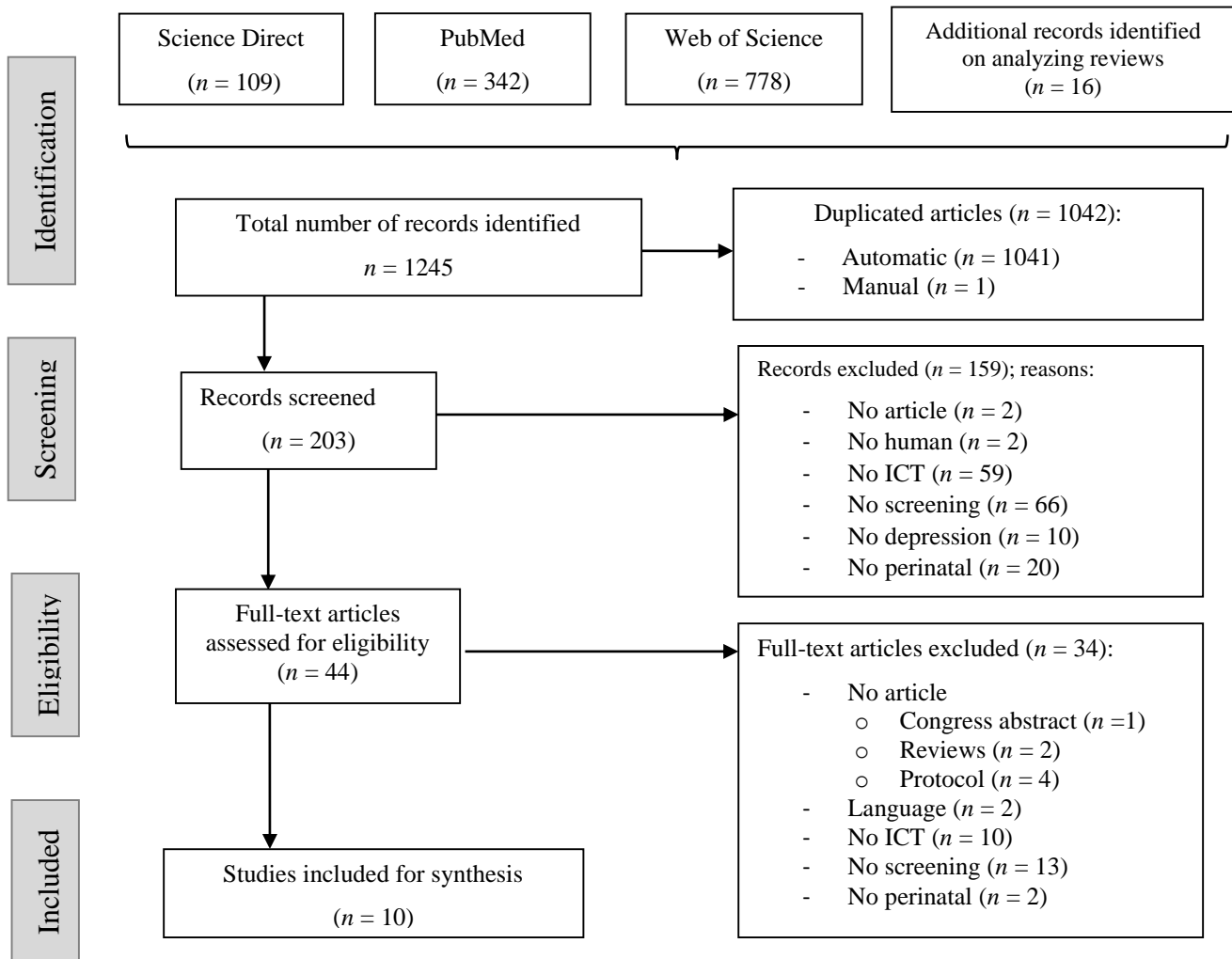


Figure 2.1 Flow Diagram of study selection.

2.4 Results

2.4.1 Sample characteristics

After comparing the findings from both researchers, the first search yielded 203 results. Of these, 10 articles met the inclusion criteria (Table 2.2).

Sample characteristics are given in Table 2.2. The majority of studies ($n = 8$) have been conducted in the United States.^{28,39,41,43,49–52} The remaining two investigations were from England⁵³ and Canada.⁵⁴ Most studies have included women older than 18 years of age, but four articles also recruited adolescent mothers.^{43,51,52,54}

Regarding the period of interest, most investigations focused on postpartum ($n = 8$, 80 percent).^{28,41,43,49–52,54} Only two articles (20 percent) screened for depression during the prenatal period.^{39,53} Also interestingly, we observed that the moment in which screening was conducted varied widely across investigations. For instance, in the prenatal period, studies included women at any gestational stage.^{39,53} Similarly, the period of interest during the postpartum varied from 7 days after childbirth to 6 months postpartum depending on the study ($n = 7$; 70 percent),^{28,41,43,49,51,52,54} whereas one investigation included screening up to 1 year after delivery.⁵⁰

2.4.2 Type of ICTs

As given in Table 2.2, ICTs have included the phone ($n = 5$, 50 percent)^{39,41,49,51,54} and the Internet ($n = 4$, 40 percent).^{28,50,52,53} One investigation used both types of ICTs.⁴³ For those using the telephone, screening was carried out through telephone calls ($n = 4$, 40 percent)^{41,43,51,54} or through an interactive voice response system ($n = 2$, 20 percent).^{39,49} By contrast, studies that preferred the Internet as a way of screening for PeD, have used web pages ($n = 3$, 30 percent),^{28,50,52} a tablet application ($n = 1$, 10 percent),⁵³ or e-mails ($n = 1$, 10 percent).⁴³

2.4.3 Instruments used to assess depressive symptomatology

The Edinburgh Postnatal Depression Scale (EPDS)⁵⁵ has been the most frequently selected tool for depression screening across studies ($n = 8$, 80 percent).^{28,39,41,43,49,52–54} Some authors used the Postpartum Depression Screening Scale (PDSS)⁵⁶ as an alternative to the EPDS ($n = 2$, 20 percent),^{50,51} whereas others administered the Whooley questionnaire²⁰ or the DSM-IV (Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition) Structured Clinical Interview for Axis I Disorders—Clinician Version (SCID-CV)⁵⁷ as a complement to the EPDS ($n = 2$, 20 percent).^{53,54}

Although screening tools were similar in the majority of studies, the selected cutoff points were very diverse. The screening cutoff for the EPDS ranged from 8 to 13 across investigations. For instance, three studies (30 percent) used a single cutoff score of 8,⁴¹ 10,⁴³ or 13,⁵² whereas

other authors ($n = 5$, 50 percent)^{28,39,49,53,54} established two cutoff points, one for moderate (EPDS $\geq 10-11$) and another for severe (EPDS $\geq 12-13$) depressive symptoms. Taking the PDSS, selected cutoffs for moderate and severe depression were 60–80 and >80 , respectively.^{50,51}

2.4.4 Study findings

When screening occurred during pregnancy, the proportion of women with depressive symptoms varied considerably across studies. Some authors³⁹ reported that 9.3 percent women presented with mild depressive symptoms (EPDS $>10 \leq 11$), whereas 29.6 percent were categorized as experiencing major depressive symptoms (EPDS ≥ 12). A most recent study revealed a lower proportion of severely depressed women, that is, a 7.2 percent of women with EPDS scores of between 10 and 12 and only 5.8 percent of women indicating EPDS scores >13 .⁵³

The proportion of depressed women in the postnatal period was somewhat higher than those reported during pregnancy. However, results varied greatly across investigations, arguably as a result of the different cutoffs used. Not surprisingly, the more restrictive the cutoff was, the fewer depressed women were reported. For instance, one study using an EPDS cutoff of 8 obtained that 51.9 percent of participants were depressed.⁴¹ By contrast, when the EPDS cutoff was set to ≥ 10 , the proportion of depressed women decreased to between 6.2⁵⁴ and 17 percent.⁴⁹ The most recommended cutoff of 12 yielded a proportion of depressed women of between 3.4⁵⁴ and 11.1 percent.⁴⁹ Finally, when using the most restrictive cutoff of EPDS >13 , the proportion of women depressed ranged from 5.5²⁸ to 16 percent.⁵²

During the postpartum, depression screening using the PDSS with a cutoff of 80 indicated that between 9⁵¹ and 23 percent⁵⁰ of women met criteria for major postpartum depression. When authors used a lower cutoff (between 60 and 80), the prevalence of depression was found to be 15 percent.⁵¹

Table 2.2 Main characteristics of the studies included ($n = 10$).

Author ^a , year	Pregnancy status	Sample, nationality Mean age (<i>SD</i> , range)	Screening tool, cutoff	Method	Outcomes
BenDavid (2016).	Postpartum, 2-3 weeks after delivery.	N = 27, 26 (6.23; 18-42) USA, Hispanic, Guatemalan.	EPDS >8.	Phone: Calls.	51.9% ($n = 14$) of participants screened positive (EPDS mean = 11.6; $SD = 1.86$).
Drake (2014).	Postpartum, 2-3 months after delivery.	N = 18, age range 18-29 years old. USA, Caucasian.	EPDS $\geq 12/13$.	Internet: Web-page.	EPDS ranged from 0 - 13 (mean = 8.0; $SD = 4.76$). 5.5% ($n = 1$) of participants had EPDS score > 13.
Horowitz (2011).	Postpartum, 4 weeks after delivery.	N = 5169, 32.2 (5.4; 14-49) USA, white and Hispanic (78%).	EPDS ≥ 10 .	N=3806, Phone: Calls. N=1363, Internet: Mail.	13% ($n = 674$) had EPDS scores ≥ 10 .
Kim (2007).	Prenatal, any gestational age.	N = 54, 25.5 (6.1). USA, African-American or Caucasian (79.6%).	EPDS >10 \leq 11. EPDS ≥ 12 .	Phone: Interactive voice response.	EPDS scores range from 1 to 24 (mean = 8.8). 9.3% ($n = 5$) had EPDS scores >10 \leq 11. 29.6% ($n = 16$) had EPDS scores ≥ 12 .
Kim (2012).	Postpartum, 7-10 days after delivery.	N = 324, 87% ≥ 20 years. USA, African American, Hispanic or Caucasian (91.4%).	EPDS ≥ 10 . EPDS ≥ 12 .	Phone: Interactive voice response.	17% ($n = 55$) had EPDS scores ≥ 10 . 11.1% ($n = 36$) had EPDS scores ≥ 12 .
Le (2009).	Postpartum, <12 months after delivery.	N = 333, around 31 years. USA, Caucasian.	PDSS = 60-79. PDSS ≥ 80 .	Internet: Web-page.	23% of the Internet study vs. 12% of in-person sample met criteria for risk of major postpartum depression ($z = 2.53$; $p < .05$).
Marcano-Belisario (2017).	Prenatal, any gestational age.	N = 530 (273 scrolling layout; 292 paging layout) England.	Whooley questions. EPDS $\geq 10 \leq 12$. EPDS ≥ 13 .	Internet: Tablet application.	23.02% ($n = 122$) participants answered <i>Yes</i> to at least one Whooley question. 7.2% ($n = 38$) had EPDS $\geq 10 \leq 12$. 5.8% ($n = 31$) had EPDS ≥ 13 .
Mitchell (2006).	Postpartum, 8 weeks after delivery.	N = 106, 30.4 (5.3, 17-43), 93.1% USA, Caucasian.	PDSS $\geq 60 \leq 80$. PDSS >80.	Phone: Calls.	15% ($n = 18$) had PDSS $\geq 60 \leq 80$. 9% ($n = 11$) had PDSS $\geq 80 \leq 128$.
Teaford (2015).	Postpartum, 1-6 months after delivery.	N = 469, 29.3 (5.3, 17-44). USA, white (86%).	EPDS ≥ 13 .	Internet: Web-page.	EPDS scores ranged 0-27 (mean = 7.0). 16% ($n = 75$) had EPDS scores ≥ 13 .
Zelkowitz (1995).	Postpartum, 6-8 weeks after delivery.	N = 1559, age range 17- 44 years old. Canada.	EPDS ≥ 10 . EPDS ≥ 12 . SCID.	Phone: Calls.	6.2% had EPDS scores ≥ 10 . 3.4% had EPDS scores ≥ 12 .

EPDS Edinburgh Postnatal Depression Scale, SCID-I Structured Clinical Interview for Disorders, PDSS Postpartum Depression Screening Scale.

^a We have included only the last name of the first author.

2.5 Discussion

This study aimed at reviewing the existing literature into the use of ICTs for PeD. The importance of the topic lies in the fact that use of these tools, which has boosted in health settings in the past decades because of their increased availability in the population,³³ has been argued to overcome some of the existent barriers in screening for PeD.⁴⁰⁻⁴² For instance, health care professionals have reported time constraints that make active, repeated assessment unfeasible.⁴⁴ In addition, perinatal women have indicated that anonymity and flexibility in the time to perform the assessment or to receive treatment are important factors influencing their decision to search for mental health assistance.^{58,59}

Despite the potential of ICTs in PeD screening, this review evidenced that the integration of ICTs in this field is still very rare. In addition, our study revealed some strengths (e.g., the consensus about the screening tool to be used) and weaknesses (e.g., inconsistency in the cutoffs used, infrequent use of apps for telemonitoring, exclusion of teenage mothers, and a major focus on the postpartum period) of the existent literature.

One important finding in this study was that the EPDS seems to be the preferred tool in studies using ICTs for PeD screening,^{28,39,41,43,49,52-54} followed by the PDSS.^{50,51} Readers should keep in mind that the EPDS and the PDSS are not diagnostic tools, so women scoring above the cutoff should undergo a formal diagnosis assessment by a mental health specialist.^{56,60,61} However, investigations have shown that brief screening questions have a good diagnostic validity compared with structured mental health assessment and are recommended before a more in-depth evaluation is made.¹⁶⁻²⁰

In contrast to the popularity of the EPDS, our review revealed that the ICTs use to perform the final diagnostic assessment has been very rare,⁵⁴ which suggests that health care professionals still rely on face-to-face interaction for the diagnosis of PeD. A recent study supports this idea, as sanitarians (psychologists and psychiatrists) seem to trust e-mental health applications for screening, prevention, follow up, and positive psychology intervention, but they are skeptical with regard to their use in other forms of treatment and diagnosis of maternal depression.⁴⁵

Another interesting result in this investigation was that, despite the consensus about the use of the EPDS for PeD screening using ICTs, the cutoff to be used is not well established. Specifically, a number of studies selected the recommended cutoff of 12 for severe depressive symptoms,^{28,39,49,53,54} but less (EPDS >8 or EPDS \geq 10)^{41,43} and more restrictive cutoffs have also been utilized (EPDS \geq 13).⁵² This is problematic, as prevalence scores will likely differ as a function of the cutoff used and, most importantly, this will affect the recommendation made to the mothers. According to the existent literature on the EPDS, the recommended cutoff of 12⁵⁵

should be preferred unless clearly justified. In support of this, studies using this cutoff have reported prevalence scores between 3.4 and 11.1 percent, which are similar to the prevalence reported by the American Psychiatric Association.³

An important goal in this study was to explore the types of ICTs used by researchers. The past decades have seen a surge in the number tools available, from the first fixed devices (e.g., phones and computers) to smartphones and wearable technology that have made ecological, momentary assessment feasible. Despite the current advances in ICTs, research into PeD has mostly relied on phone calls and, to a lesser extent, web pages for screening.^{28,41,43,50–52,54} In fact, our search indicated that only one study used an application for a portable device, that is, a tablet⁵³ and no investigation included a smartphone app to ecologically screen for depression.

At this point, some considerations should be made. Recent reports have repeatedly indicated that the proportion of individuals owning a portable electronic device connected to the Internet³⁵ and the use of the Internet to seek for health-related information³⁶ have grown spectacularly. Similarly, the use of smartphone applications by perinatal women is becoming more and more frequent.⁶² In fact, the use of smartphone apps is argued to be the current gold standard assessment method in health settings as it reduces costs (phone calls by the health care professional are substituted for a continuous assessment with the app), it allows for telemonitoring (it captures and communicates data in real time), it is ecological (mothers can answer wherever they are removing the need to connect to their computer at home or to travel to the clinic), and it is minimally invasive (mothers can decide when to answer to the app, which is more difficult when phone calls are used for assessment).⁶³ Also importantly, there is recent evidence to suggest that the use of mobile devices when administering validated screening scales does not affect data equivalence compared with traditional assessment modes, such as paper^{64,65} and that less personal assessment tools (e.g., mail as opposed to phone calls) result in higher PeD prevalence rates,⁴³ supporting the use of more impersonal screening tools, such as smartphone apps, in PeD.

In addition to the infrequent use of modern, anonymous ICTs screening tools, our review of the literature also evidenced a tendency to exclude teenage mothers in studies using ICTs for PeD screening. This is alarming because young mothers are less likely to consult a mental health specialist.²² Furthermore, teenager mothers seem to present with higher depression prevalence rates than adult mothers (17 and 3.3 percent, respectively) and many of them (up to 20 percent) report having committed suicide attempts during pregnancy.⁶⁶ For these reasons and also because this population arguably has a high knowledge of ICTs, teenage mothers are good candidates to benefit from ICTs screening programs for PeD and should not be excluded from future research into this topic.

A final shortcoming revealed by the present investigation is that the majority of reviewed studies had a focus on the postnatal period, despite the well-established benefits of early screening during pregnancy.^{37–39} Considering the existing link between prenatal and postpartum depression,^{67–69} the high prevalence rates of prenatal depression obtained in this review (between 5.8 and 29.6 percent), and the consequences of prenatal depression on the fetus and later on the baby,^{12–14} routine depression screening throughout the pregnancy period should be an urge.

Related to this, we found that the majority of reviewed investigations have been cross-sectional studies with a single screening point, with no consensus about the best time for screening during pregnancy or postpartum and with no follow-up. In our opinion, the fact that prenatal depressive symptoms often persist at least during the first year postpartum,^{70–72} future research and screening programs should be characterized by a more frequent assessment starting early during pregnancy and finishing no sooner than 1 year after delivery. We believe that the use of ICTs will surely facilitate this repeated screening of depressive symptoms during obstetric (pregnancy) and pediatric (postpartum) revisions.⁴¹ However, further research is needed to determine the optimal quantity and timing of evaluations to rapidly and efficiently detect the onset of PeD.

2.5.1 Implications for future research and clinical practice

The use of e-health and m-health will surely change the way screening will happen in the future in perinatal care. There are, however, some challenges to their implementation that will need to be addressed in future developments. Engagement, for instance, is a critical element that will determine whether individuals are willing to use these technologies. There are some characteristics intrinsic to ICTs that may favor engagement in perinatal women. For instance, ICTs give the control and responsibility of medical care to the patient, who can decide when and how to perform the evaluation.

Making the technology customizable is another way of enhancing engagement, as reported by women.^{38,58} Virtual and augmented reality might serve this purpose,^{73,74} as both technologies make customization feasible. To date, however, the utility of virtual and augmented reality for mental health screening in perinatal women remains unexplored. Other strategies to promote engagement in self-monitoring using ICTs are gamification and social interactions.^{75,76} For instance, participating women could be allowed to share their experiences with other women using the same technologies and could obtain rewards in the form of unlocking treatment content (i.e., a module on emotion regulation or psychology quotes) as they respond to the assessments.

As a final remark, we would like to draw attention to perceived utility and ease of use as key factors that should be considered in future developments of ICTs in perinatal care, as both elements are excellent predictors of technology use.⁷⁷ Some strategies in this direction would

include involving the target population in technology development and providing immediate feedback to the individual and the health care provider.⁷⁸⁻⁸⁰ To sum, what this study indicates is that the use of ICT in perinatal screening is very limited and mostly represented by old-fashioned tools that make repeated, self-monitoring and telemonitoring almost impossible. There is a need to adopt more modern screening strategies that eliminate common barriers for seeking mental care in the perinatal period.

2.5.2 Conclusions

Routine screening for perinatal mental health is crucial both for the mother and the baby.⁵¹ However, barriers in the mother (e.g., difficulties travelling to the clinic, the stigma of mental health, and combining childcare and face-to-face consultations) and the health care professional (e.g., lack of time) make repeated assessment difficult. The use of ICTs, especially smartphones, has been argued to overcome some of the limitations described previously as it allows for telemonitoring without the need for face-to-face interactions and eliminates the need to involve a human evaluator.⁸¹ Not surprisingly, smartphone apps are perceived by many as the current gold standard assessment tools in health settings.^{44-46,65}

Despite the aforementioned potential advantages of using smartphone apps for routine screening of depression in perinatal women, our review underlined that (a) ICTs used to date tend to require a human evaluator (e.g., phone calls), (b) repeated screening to explore the evolution of mothers is very rare (frequently only once), (c) the cutoffs used for depression have been inconsistent, (d) the focus has been mostly on postpartum mental health, and (e) teenage mothers have been frequently ignored. In the light of these findings, we believe that there is an important gap in the literature into screening for PeD using ICTs. Future research should explore the feasibility and utility of routine screening from early pregnancy periods to at least 1 year postpartum using smartphone apps, so that the onset of depression can be rapidly detected at any stage during the perinatal period.

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Appendix 2.1

Final Search Terms in Science Direct

Search	Keywords	Results
1	“perinatal” AND “depression” AND “technology” AND “screening”	0
2	“perinatal” AND “depression” AND “technologies” AND “screening”	0
3	“perinatal” AND “depression” AND “Internet” AND “screening”	4
4	“perinatal” AND “depression” AND “eHealth” AND “screening”	1
5	“perinatal” AND “depression” AND “mHealth” AND “screening”	0
6	“perinatal” AND “depression” AND “ICT” AND “screening”	0
7	“perinatal” AND “depression” AND “mobile” AND “screening”	0
8	“perinatal” AND “depression” AND “app” AND “screening”	0
9	“perinatal” AND “depression” AND “application” AND “screening”	0
10	“perinatal” AND “depression” AND “phone” AND “screening”	2
11	“perinatal” AND “depression” AND “telephone” AND “screening”	3
12	“perinatal” AND “depression” AND “smartphone” AND “screening”	0
13	“perinatal” AND “depression” AND “tablet” AND “screening”	1
14	“perinatal” AND “depression” AND “PDA” AND “screening”	0
15	“perinatal” AND “depressive symptoms” AND “technology” AND “screening”	0
16	“perinatal” AND “depressive symptoms” AND “technologies” AND “screening”	0
17	“perinatal” AND “depressive symptoms” AND “Internet” AND “screening”	3
18	“perinatal” AND “depressive symptoms” AND “eHealth” AND “screening”	1
19	“perinatal” AND “depressive symptoms” AND “mHealth” AND “screening”	0
20	“perinatal” AND “depressive symptoms” AND “ICT” AND “screening”	0
21	“perinatal” AND “depressive symptoms” AND “mobile” AND “screening”	0
22	“perinatal” AND “depressive symptoms” AND “app” AND “screening”	0
23	“perinatal” AND “depressive symptoms” AND “application” AND “screening”	1
24	“perinatal” AND “depressive symptoms” AND “phone” AND “screening”	0
25	“perinatal” AND “depressive symptoms” AND “telephone” AND “screening”	1
26	“perinatal” AND “depressive symptoms” AND “smartphone” AND “screening”	0
27	“perinatal” AND “depressive symptoms” AND “tablet” AND “screening”	0
28	“perinatal” AND “depressive symptoms” AND “PDA” AND “screening”	0
29	“pregnant” AND “depression” AND “technology” AND “screening”	0
30	“pregnant” AND “depression” AND “technologies” AND “screening”	0
31	“pregnant” AND “depression” AND “Internet” AND “screening”	2
32	“pregnant” AND “depression” AND “eHealth” AND “screening”	0
33	“pregnant” AND “depression” AND “mHealth” AND “screening”	0
34	“pregnant” AND “depression” AND “ICT” AND “screening”	0
35	“pregnant” AND “depression” AND “mobile” AND “screening”	0
36	“pregnant” AND “depression” AND “app” AND “screening”	0
37	“pregnant” AND “depression” AND “application” AND “screening”	3
38	“pregnant” AND “depression” AND “phone” AND “screening”	2
39	“pregnant” AND “depression” AND “telephone” AND “screening”	2
40	“pregnant” AND “depression” AND “smartphone” AND “screening”	0
41	“pregnant” AND “depression” AND “tablet” AND “screening”	2
42	“pregnant” AND “depression” AND “PDA” AND “screening”	0
43	“pregnant” AND “depressive symptoms” AND “technology” AND “screening”	0

44	“pregnant” AND “depressive symptoms” AND “technologies” AND “screening”	0
45	“pregnant” AND “depressive symptoms” AND “Internet” AND “screening”	1
46	“pregnant” AND “depressive symptoms” AND “eHealth” AND “screening”	0
47	“pregnant” AND “depressive symptoms” AND “mHealth” AND “screening”	0
48	“pregnant” AND “depressive symptoms” AND “ICT” AND “screening”	0
49	“pregnant” AND “depressive symptoms” AND “mobile” AND “screening”	0
50	“pregnant” AND “depressive symptoms” AND “app” AND “screening”	0
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53	“pregnant” AND “depressive symptoms” AND “telephone” AND “screening”	0
54	“pregnant” AND “depressive symptoms” AND “smartphone” AND “screening”	0
55	“pregnant” AND “depressive symptoms” AND “tablet” AND “screening”	0
56	“pregnant” AND “depressive symptoms” AND “PDA” AND “screening”	0
57	“pregnancy” AND “depression” AND “technology” AND “screening”	1
58	“pregnancy” AND “depression” AND “technologies” AND “screening”	1
59	“pregnancy” AND “depression” AND “Internet” AND “screening”	2
60	“pregnancy” AND “depression” AND “eHealth” AND “screening”	0
61	“pregnancy” AND “depression” AND “mHealth” AND “screening”	0
62	“pregnancy” AND “depression” AND “ICT” AND “screening”	0
63	“pregnancy” AND “depression” AND “mobile” AND “screening”	0
64	“pregnancy” AND “depression” AND “app” AND “screening”	0
65	“pregnancy” AND “depression” AND “application” AND “screening”	5
66	“pregnancy” AND “depression” AND “phone” AND “screening”	3
67	“pregnancy” AND “depression” AND “telephone” AND “screening”	7
68	“pregnancy” AND “depression” AND “smartphone” AND “screening”	0
69	“pregnancy” AND “depression” AND “tablet” AND “screening”	0
70	“pregnancy” AND “depression” AND “PDA” AND “screening”	0
71	“pregnancy” AND “depressive symptoms” AND “technology” AND “screening”	0
72	“pregnancy” AND “depressive symptoms” AND “technologies” AND “screening”	0
73	“pregnancy” AND “depressive symptoms” AND “Internet” AND “screening”	1
74	“pregnancy” AND “depressive symptoms” AND “eHealth” AND “screening”	0
75	“pregnancy” AND “depressive symptoms” AND “mHealth” AND “screening”	0
76	“pregnancy” AND “depressive symptoms” AND “ICT” AND “screening”	0
77	“pregnancy” AND “depressive symptoms” AND “mobile” AND “screening”	0
78	“pregnancy” AND “depressive symptoms” AND “app” AND “screening”	0
79	“pregnancy” AND “depressive symptoms” AND “application” AND “screening”	0
80	“pregnancy” AND “depressive symptoms” AND “phone” AND “screening”	0
81	“pregnancy” AND “depressive symptoms” AND “telephone” AND “screening”	2
82	“pregnancy” AND “depressive symptoms” AND “smartphone” AND “screening”	0
83	“pregnancy” AND “depressive symptoms” AND “tablet” AND “screening”	0
84	“pregnancy” AND “depressive symptoms” AND “PDA” AND “screening”	0
85	“prenatal” AND “depression” AND “technology” AND “screening”	0
86	“prenatal” AND “depression” AND “technologies” AND “screening”	0
87	“prenatal” AND “depression” AND “Internet” AND “screening”	0
88	“prenatal” AND “depression” AND “eHealth” AND “screening”	0
89	“prenatal” AND “depression” AND “mHealth” AND “screening”	0
90	“prenatal” AND “depression” AND “ICT” AND “screening”	0
91	“prenatal” AND “depression” AND “mobile” AND “screening”	0
92	“prenatal” AND “depression” AND “app” AND “screening”	0

2. The use of ICT in perinatal depression screening: A systematic review

93	“prenatal” AND “depression” AND “application” AND “screening”	0
94	“prenatal” AND “depression” AND “phone” AND “screening”	1
95	“prenatal” AND “depression” AND “telephone” AND “screening”	0
96	“prenatal” AND “depression” AND “smartphone” AND “screening”	0
97	“prenatal” AND “depression” AND “tablet” AND “screening”	2
98	“prenatal” AND “depression” AND “PDA” AND “screening”	0
99	“prenatal” AND “depressive symptoms” AND “technology” AND “screening”	0
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101	“prenatal” AND “depressive symptoms” AND “Internet” AND “screening”	0
102	“prenatal” AND “depressive symptoms” AND “eHealth” AND “screening”	0
103	“prenatal” AND “depressive symptoms” AND “mHealth” AND “screening”	0
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106	“prenatal” AND “depressive symptoms” AND “app” AND “screening”	0
107	“prenatal” AND “depressive symptoms” AND “application” AND “screening”	0
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109	“prenatal” AND “depressive symptoms” AND “telephone” AND “screening”	0
110	“prenatal” AND “depressive symptoms” AND “smartphone” AND “screening”	0
111	“prenatal” AND “depressive symptoms” AND “tablet” AND “screening”	0
112	“prenatal” AND “depressive symptoms” AND “PDA” AND “screening”	0
113	“postnatal” AND “depression” AND “technology” AND “screening”	1
114	“postnatal” AND “depression” AND “technologies” AND “screening”	1
115	“postnatal” AND “depression” AND “Internet” AND “screening”	2
116	“postnatal” AND “depression” AND “eHealth” AND “screening”	0
117	“postnatal” AND “depression” AND “mHealth” AND “screening”	0
118	“postnatal” AND “depression” AND “ICT” AND “screening”	0
119	“postnatal” AND “depression” AND “mobile” AND “screening”	0
120	“postnatal” AND “depression” AND “app” AND “screening”	0
121	“postnatal” AND “depression” AND “application” AND “screening”	2
122	“postnatal” AND “depression” AND “phone” AND “screening”	3
123	“postnatal” AND “depression” AND “telephone” AND “screening”	6
124	“postnatal” AND “depression” AND “smartphone” AND “screening”	0
125	“postnatal” AND “depression” AND “tablet” AND “screening”	1
126	“postnatal” AND “depression” AND “PDA” AND “screening”	0
127	“postnatal” AND “depressive symptoms” AND “technology” AND “screening”	1
128	“postnatal” AND “depressive symptoms” AND “technologies” AND “screening”	1
129	“postnatal” AND “depressive symptoms” AND “Internet” AND “screening”	1
130	“postnatal” AND “depressive symptoms” AND “eHealth” AND “screening”	0
131	“postnatal” AND “depressive symptoms” AND “mHealth” AND “screening”	0
132	“postnatal” AND “depressive symptoms” AND “ICT” AND “screening”	0
133	“postnatal” AND “depressive symptoms” AND “mobile” AND “screening”	0
134	“postnatal” AND “depressive symptoms” AND “app” AND “screening”	0
135	“postnatal” AND “depressive symptoms” AND “application” AND “screening”	0
136	“postnatal” AND “depressive symptoms” AND “phone” AND “screening”	0
137	“postnatal” AND “depressive symptoms” AND “telephone” AND “screening”	1
138	“postnatal” AND “depressive symptoms” AND “smartphone” AND “screening”	0
139	“postnatal” AND “depressive symptoms” AND “tablet” AND “screening”	1
140	“postnatal” AND “depressive symptoms” AND “PDA” AND “screening”	0
141	“postpartum” AND “depression” AND “technology” AND “screening”	2

142	“postpartum” AND “depression” AND “technologies” AND “screening”	2
143	“postpartum” AND “depression” AND “Internet” AND “screening”	5
144	“postpartum” AND “depression” AND “eHealth” AND “screening”	0
145	“postpartum” AND “depression” AND “mHealth” AND “screening”	0
146	“postpartum” AND “depression” AND “ICT” AND “screening”	0
147	“postpartum” AND “depression” AND “mobile” AND “screening”	0
148	“postpartum” AND “depression” AND “app” AND “screening”	0
149	“postpartum” AND “depression” AND “application” AND “screening”	3
150	“postpartum” AND “depression” AND “phone” AND “screening”	3
151	“postpartum” AND “depression” AND “telephone” AND “screening”	13
152	“postpartum” AND “depression” AND “smartphone” AND “screening”	0
153	“postpartum” AND “depression” AND “tablet” AND “screening”	0
154	“postpartum” AND “depression” AND “PDA” AND “screening”	0
155	“postpartum” AND “depressive symptoms” AND “technology” AND “screening”	1
156	“postpartum” AND “depressive symptoms” AND “technologies” AND “screening”	1
157	“postpartum” AND “depressive symptoms” AND “Internet” AND “screening”	2
158	“postpartum” AND “depressive symptoms” AND “eHealth” AND “screening”	0
159	“postpartum” AND “depressive symptoms” AND “mHealth” AND “screening”	0
160	“postpartum” AND “depressive symptoms” AND “ICT” AND “screening”	0
161	“postpartum” AND “depressive symptoms” AND “mobile” AND “screening”	0
162	“postpartum” AND “depressive symptoms” AND “app” AND “screening”	0
163	“postpartum” AND “depressive symptoms” AND “application” AND “screening”	0
164	“postpartum” AND “depressive symptoms” AND “phone” AND “screening”	0
165	“postpartum” AND “depressive symptoms” AND “telephone” AND “screening”	2
166	“postpartum” AND “depressive symptoms” AND “smartphone” AND “screening”	0
167	“postpartum” AND “depressive symptoms” AND “tablet” AND “screening”	0
168	“postpartum” AND “depressive symptoms” AND “PDA” AND “screening”	0
		109

ICT, Information and Communication Technologies

CHAPTER 3.

**PREDICTING POSTPARTUM DEPRESSIVE SYMPTOMS FROM
PREGNANCY BIOPSYCHOSOCIAL FACTORS: A LONGITUDINAL
INVESTIGATION USING STRUCTURAL EQUATION MODELING**

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3. Predicting Postpartum Depressive Symptoms from Pregnancy Biopsychosocial Factors: A Longitudinal Investigation Using Structural Equation Modeling

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3.1 Abstract

Objective: The prediction of postpartum depression (PPD) should be conceptualized from a biopsychosocial perspective. This study aims at exploring the longitudinal contribution of a set of biopsychosocial factors for PPD in perinatal women. **Methods:** A longitudinal study was conducted, assessment was made with a website and included biopsychosocial factors that were measured during pregnancy ($n = 266$, weeks 16–36), including age, affective ambivalence, personality characteristics, social support and depression. Depression was measured again at postpartum ($n = 101$, weeks 2–4). The analyses included bivariate associations and structural equation modeling (SEM). **Results:** Age, affective ambivalence, neuroticism, positive, and negative affect at pregnancy were associated with concurrent depression during pregnancy (all $p < 0.01$). Age, affective ambivalence, positive affect, and depression at pregnancy correlated with PPD (all $p < 0.05$). Affective ambivalence ($\beta = 1.97$; $p = 0.003$) and positive ($\beta = -0.29$; $p < 0.001$) and negative affect ($\beta = 0.22$; $p = 0.024$) at pregnancy remained significant predictors of concurrent depression in the SEM, whereas only age ($\beta = 0.27$; $p = 0.010$) and depression ($\beta = 0.37$; $p = 0.002$) at pregnancy predicted PPD. **Conclusions:** Biopsychosocial factors are clearly associated with concurrent depression at pregnancy, but the stability of depression across time limits the prospective contribution of biopsychosocial factors. Depression should be screened early during pregnancy, as this is likely to persist after birth. The use of technology, as in the present investigation, might be a cost-effective option for this purpose.

Keywords: pregnancy, postpartum, depressive symptoms, risk factors, biopsychosocial, longitudinal studies, information and communication technologies.

3.2 Introduction

Postpartum depression (PPD) is one of the most prevalent emotional disorders worldwide, with global estimates ranging from between 5% to 25% [1]. PPD is associated with both personal and economic burden [2]. First, negative health consequences for the women and the baby have been reported, such as inadequate gestational weight gain, low birth weight, preterm birth, inadequate weight gain in the baby, under-utilization of prenatal care services, increased substance use in the women, and increased maternal mortality [3,4]. Second, the economic costs of PPD include loss of productivity and health care expenses [5]. Not surprisingly, the American Psychiatric Association has indicated that all perinatal women should be assessed for both the presence of and risk for psychiatric disorders during pregnancy (twice), and during the first six months postpartum [6].

The biopsychosocial model of PPD is an attempt to comprehensively understand the risk for the onset of depressive symptoms, but also the protective factors associated with this disorder, so that prevention and treatment efforts can be developed in a more effective manner [7]. Several meta-analyses and systematic reviews have supported this biopsychosocial approach to PPD [8,9]. As a result of this, factors such as low educational and income level, ambivalence toward pregnancy, personal and family history of depression, perceived social support, and personality characteristics, among others, are now frequently investigated in the PPD literature [8,9]. Specifically, variables related to the increased risk of PPD are pregnancy ambivalence, neuroticism, negative affect and prenatal depressive symptoms [10–12]. On the contrary, positive affect and extraversion seem to be protective factors for PPD development [11,12]. There is sufficient evidence, however, that the best predictor of PPD is depressive symptomatology during pregnancy [8,9,13].

The research to date has clearly contributed to the development of the biopsychosocial approach to PPD. Nevertheless, there are a number of shortcomings in the literature on PPD that are yet to be addressed. For instance, most studies tend to investigate the contribution of only one or two risk factors altogether (e.g., Hetherington, McDonald, Williamson, Patten and Tough, 2018 [14]), so the communalities between biopsychosocial factors are not controlled and the unique contribution of each variable remains unclear [15]. This is important as it might help reduce the number of therapeutic targets to a more manageable set. Additionally, studies exploring the relationship between biopsychosocial factors and perinatal depressive symptoms are generally cross-sectional (e.g., Adamu and Adinew, 2018 [16]), so the predictive value of these variables in the evolution of depressive symptoms across the perinatal period is unclear. Research has shown that both the spontaneous remission and intensification of depressive symptoms exist [17],

so longitudinal studies are fundamental if prevention and treatment programs are to be effectively developed.

In addition to the aforementioned shortcomings, previous research has revealed the important barriers to face-to-face evaluation in the perinatal period, including insufficient time for care providers, availability of mental health services, lack of time for the women, difficulties in combining child care with onsite appointments, geographical distance, and the high economic costs of traveling to academic or health care institutions [18]. The use of information and communication technologies (ICTs) in the field of health (e-health) has emerged as an alternative to traditional face-to-face methods in response to these barriers. To the best of our knowledge, there is only one longitudinal study that used ICTs (e-mail) to explore emotional disorders in perinatal women [19]. However, a biopsychosocial approach to PPD was not adopted in this investigation, and complex associations between variables, for example via structural equation modeling (SEM), were not investigated.

With the aim of providing more robust evidence for the development of screening, prevention, and treatment programs for PPD, we have conducted a study exploring the unique contribution of a set of risk and protective biopsychosocial factors for PPD in perinatal women using SEM. A longitudinal design was implemented, and prenatal and postpartum assessments were conducted using ICTs (i.e., a website). After a thorough literature research, the biopsychosocial factors included in the prediction of PPD were psychosocial factors with robust support in the literature (ambivalence toward pregnancy, neuroticism, extraversion, positive and negative affect, social support, and prenatal depressive symptoms) and a biological variable, namely age, with limited but promising evidence [8].

On the basis of previous research, we hypothesize that the perinatal risk factors for concurrent and prospective PPD will include age (i.e., being younger), affective ambivalence, neuroticism, and negative affect. On the contrary, we expect that extraversion, positive affect and social support will be protective factors for depressive symptoms. We anticipate that prenatal depressive symptoms will be the best predictors of PPD. We also expect that psychosocial factors will be intercorrelated, so that only a small subset of them will uniquely contribute to PPD in the SEM. The unique contribution of these variables is difficult to anticipate from the existing literature, and will be investigated in an exploratory manner. By testing these hypotheses, we expect to achieve our study goal, that is, explore the unique prospective contribution of a set of biopsychosocial factors in the mother in the prediction of PDD. To make the text more readable, we will interchangeably use the terms pregnancy and prenatal when referring to the assessments made before delivery.

3.3 Methods

3.3.1 Participants

The study was conducted between 2012 and 2015. The sample included 266 women who voluntarily registered on the MamáFeliz (HappyMom, hereafter MMF) website for assessment and completed the first evaluation (during pregnancy). These women were asked to respond to two assessments: one during pregnancy (between week 16 and week 36) and one at postpartum (between weeks 2 and 4 after delivery, according to the women's availability). During pregnancy, depression has been shown to be more prevalent during the second and the third trimesters [20]. At postpartum, the highest prevalence rates of depression were found between weeks 2 and 7 after delivery [21,22]. As observed in Figure 3.1, from the initial sample, 101 women also provided information in the postpartum (completers' sample). Sociodemographic characteristics of the sample, divided by group (completers vs. non-completers), will be described in the results section. Several guidelines have been proposed in the multiple regression literature for deciding the sample size required for analyses. For example, Harrell (2001) proposed a minimum of 10 participants for each predictor in the model. Our SEM included 8 predictors, and therefore we would require 80 participants according to this rule of thumb. Harris (2001) proposed at least $n = 50 + p$, where n is sample size and p is number of predictors. According to this, the minimum n would be 58 participants. Based on previous recommendations on required sample sizes when conducting multiple regressions [23,24], the current sample size was sufficient for the analyses conducted.

3.3.2 Procedure

All the procedures described in the present study were approved by the ethical committees of the Hospital Universitario La Plana de Villareal (Castellón) and the Gobierno de Aragón (CP12/2012). The health professionals at the specialized public gynecology centers collaborating in the study disseminated the investigation with all consecutive potential participants meeting the eligibility criteria (see Table 3.1) and gave women a document with a unique code and the link to the MMF website. Once on the website, the women that voluntarily agreed to participate in the study had to accept the data protection and confidentiality policies and had to sign the online informed consent form before completing the online assessments. Health professionals participating in the study gave the information on how to participate to pregnant women meeting the inclusion criteria. However, the number of women not meeting the criteria or not willing to participate was not reliably collected by the health care providers due to time restrictions during consultations.

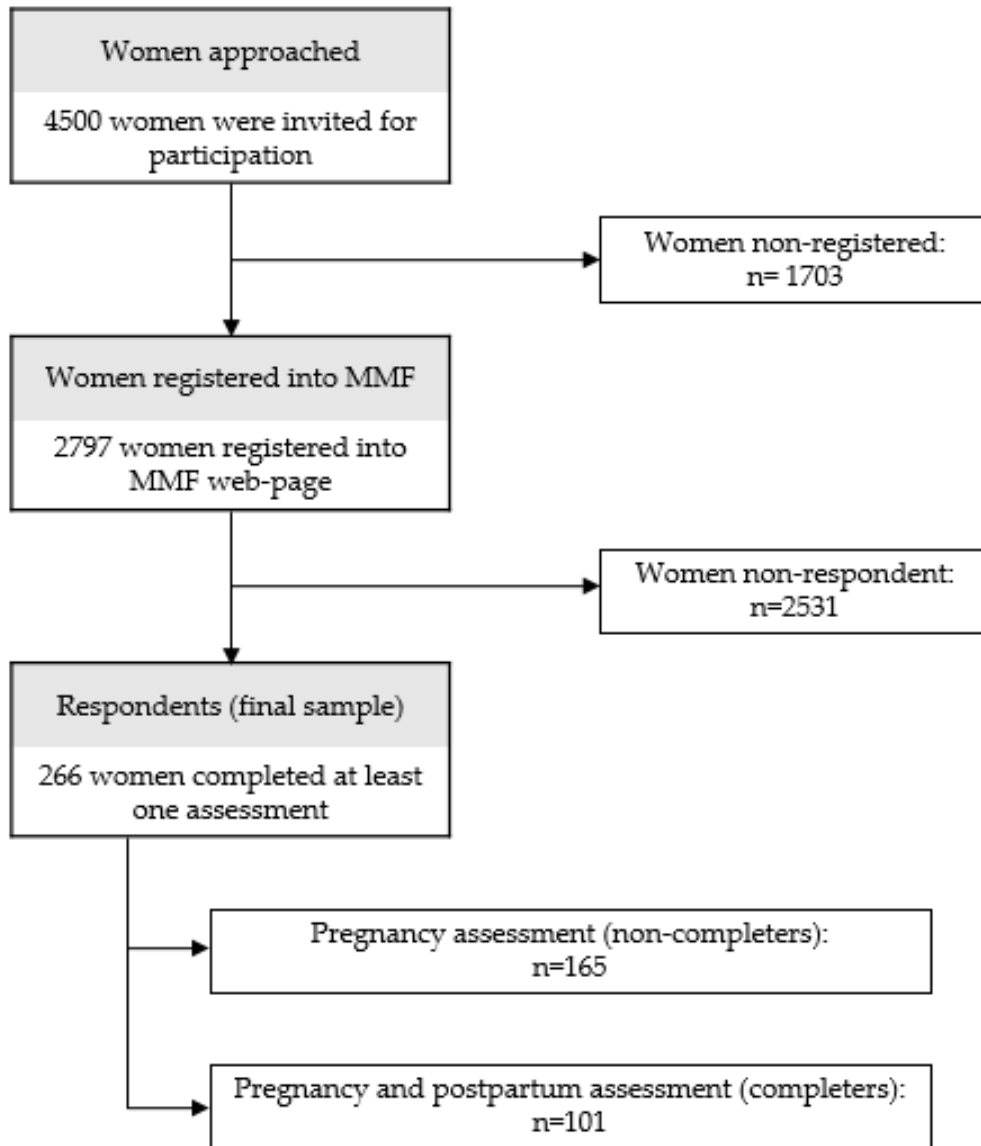


Figure 3.1 Flow diagram of participants.

Table 3.1 Inclusion and exclusion criteria to participate in the study.

Inclusion	Exclusion
Being pregnant (weeks 16 to 36)	
Over 18 years of age	Not being able to read and answer questions in Spanish
Having internet access	
Signing the informed consent form	

The assessments were carried out entirely via the MMF website, which evaluated the most important biopsychosocial factors associated with perinatal depressive symptoms. E-mail reminders were used for the prospective assessments. At the end of each assessment, women received feedback about their present mental well-being as a result of their evaluation. If depressive symptoms were detected after the assessments, they received an e-mail recommending a consultation with their doctor for a more in-depth evaluation of their emotional state.

3.3.3 Measures

All sociodemographic and biopsychosocial data were assessed online via the MMF website. All the questionnaires mentioned below were administered in their full length.

Demographic and biologic

We asked for nationality, educational level, relationship status and age; *ad hoc* questions were developed. To report on their nationality, women had to indicate the country (Spain only) or the region (i.e., South America or Central America, North America, Western Europe, Eastern Europe, North Africa, South Africa, Middle East countries, Far East countries, Southeast Asia, and Oceania) they were born in. Regarding educational level, women responded as to whether they had no studies, basic studies, secondary studies, bachelor studies, technical studies, university studies, a master's degree or doctorate studies. Women also indicated their marital status as follows: single, unmarried (with a stable partner), married, divorced, or widowed.

Psychological

Ambivalence toward pregnancy: This *ad hoc* item evaluated mixed feelings about pregnancy; “How often have you experienced feelings of ambivalence and/or contradiction about your pregnancy (for example, I have sometimes experienced joy, but also sadness or hope, but also worry)”. This item has 4 response options ranging from 0 = “never” to 3 = “very often”. Higher scores represent more ambivalence toward pregnancy.

The Beck Depression Inventory (BDI-II) [25,26]: This comprises 21 items and evaluates depressive symptoms and cognitions experienced during the last two weeks. Each item has 4 response options (0 = “not at all” and 3 = “severely”), so the total score can range from 0 to 63. Higher scores indicate more severe depressive symptomatology. The recommended BDI-II cutoffs for women in Spain are 0–13 for minimal depressive symptoms, 14–19 for mild depressive symptoms, 20–28 for moderate depressive symptoms, and 29–63 for severe depressive symptoms [25,27]. In our sample, the reliability was good during both pregnancy ($\alpha = 0.81$) and postpartum ($\alpha = 0.85$).

The Positive and Negative Affect Schedule (PANAS) [28,29]: This evaluates positive and negative emotional experiences. It consists of 20 adjectives, 10 for each affect scale (i.e., Positive and Negative). Each item is divided into 5 grades (1 = “very slightly/not at all” and 5 = “extremely”) and total scores for each scale can range from 10 to 50. In our sample, Cronbach alphas were very good (0.89 and 0.86 for positive and negative affect, respectively).

The Eysenck Personality Questionnaire revised (EPQ-R) [30,31]: This assesses patterns of behaviors, thoughts, and feelings (i.e., personality). The questionnaire is composed of 48 dichotomous (Yes/No) items (12 for extraversion, 12 for neuroticism, 12 for psychoticism, and 12 for lie). For this study we only used the neuroticism ($\alpha = 0.79$) and extraversion ($\alpha = 0.77$) scales.

Social

The Multidimensional Scale of Perceived Social Support (MSPSS) [32,33]: This is composed of 12 items that evaluate perceived social support in three domains (family, friends, and others). Each item has 7 response options (1 = “completely disagree” and 7 = “completely agree”). Total scores have a 12–84 range. Higher scores represent a higher perception of social support. In our sample, the psychometric properties of the three subscales were very good ($0.91 \leq \alpha \leq 0.94$), but the total MSPSS score was preferred to reduce the number of statistical comparisons between biopsychosocial variables included in this study and to reduce the risk of type I errors.

3.3.4 Data analysis

First, we conducted a descriptive analysis comparing completers and non-completers using a Chi-squared test for categorical variables and a Mann–Whitney *U* test for continuous factors (a non-parametric test was selected due to the distribution of scores). This comparison between completers and non-completers was made to evaluate whether there were baseline differences between both samples that would help us understand dropouts and therefore would compromise the generalizability of the findings. This comparison, however, is not related to the main goal of the present work (i.e., to predict postpartum depressive symptoms from a biopsychosocial perspective). For the same reason, we calculated Spearman and not Pearson correlations to explore the relationship between prenatal psychosocial factors (age, affective ambivalence, personality, affect, and social support) and prenatal and PPD, considering the completers’ sample only. Finally, SEM analyses were conducted to test a model that accounts for PPD from prenatal characteristics in the sample of completers. SEM has become a technique of choice when exploring complex associations between variables because of its advantages [34]. To name some examples, SEM allows the exploration of several relationships at the same time and facilitates the simultaneous use of a construct both as a dependent (i.e., prenatal depressive symptoms predicted by prenatal psychosocial factors) and as an independent variable (i.e., prenatal depressive symptoms predicting PPD) [35]. The fit for the proposed model was assessed with the Chi-square test, the root mean square error of approximation (RMSEA), the standardized root mean square residual (SRMR), the Tucker–Lewis index (TLI), and the comparative fit index (CFI). RMSEA and SRMR values smaller than 0.05 and TLI and CFI values greater than 0.95 reflect an excellent fit [36]. As recommended in the literature [37], maximum likelihood parameter estimation with standard errors and a mean-adjusted Chi-square test that is robust to non-normality (Satorra–Bentler MLM estimation) was used in the SEM.

Past research has indicated that adjustment to the alpha level is not necessary when exploratory studies include simple rather than intricate sets of hypotheses [38]. The present study’s hypothesis is simple in the sense that we only anticipate that a reduced number of

predictors will emerge from the SEM, while the exact unique contributions and their directions are not hypothesized (this would be a more intricate and confirmatory analysis). As a consequence, an uncorrected alpha level of 0.050 was used in the analyses.

3.4 Results

3.4.1 Demographic and Biopsychosocial Characteristics of the Participants: Comparison between Completers and Non-Completers

The demographic and biopsychosocial characteristics of the whole sample are presented in Tables 3.2 and 3.3. There were no significant differences in demographic and biopsychosocial characteristics between completers and non-completers, which supports the generalizability of the study results. Our sample (completers; $n = 101$) was composed of primiparous Spanish perinatal women between 16 and 36 weeks of gestation (mean = 24.42; $SD = 8.62$) of approximately 33 years of age, who were in a stable relationship and were well-educated. Most women had some degree of ambivalence toward pregnancy. Three out of four had minimal depressive symptoms, 24% had mild depressive symptoms, 4% had moderate depressive symptoms, and no participants had severe depressive symptoms.

In the postpartum period, 82.2%, 14.8% and 3% of completers presented minimal, mild, and moderate depressive symptoms, respectively. No participant presented severe depressive symptoms in the postpartum.

Table 3.2 Biopsychosocial variables during pregnancy and postpartum.

Variable	Non-Completers		Completers		Comparison	
	Mean (SD; Range)	N	Mean (SD; Range)	N	<i>U</i>	<i>p</i>
Age	32.59 (4.39; 18–42)	165	33.54 (3.88; 23–42)	101	7474.00	0.157
Affective Ambivalence	0.93 (0.73; 0–3)	165	0.86 (0.74; 0–3)	101		
No	26.1%	43	30.7%	31	7869.00	0.390
Yes	73.9%	122	69.3%	70		
Neuroticism	3.77 (3.43; 0–12)	165	3.69 (2.99; 0–12)	101	8191.00	0.815
Extraversion	8.10 (2.93; 0–12)	165	8.54 (2.67; 1–12)	101	7678.00	0.279
Positive Affect	29.70 (9.78; 0–50)	139	29.68 (8.92; 0–50)	101	6735.00	0.592
Negative Affect	16.50 (7.00; 0–40)	139	15.88 (5.82; 0–32)	101	6754.40	0.617
Social Support	75.13 (10.92; 12–84)	123	76.97 (7.84; 42–82)	101	5927.00	0.551
Pregnancy Depressive Symptoms	11.37 (7.40; 2–33)	134	10.21 (5.49; 1–26)	101	6499.50	0.603
Minimal	73.9%	99	72.3%	73	3446.00	0.602
Mild	11.2%	15	23.7%	24	169.50	0.765
Moderate	9.7%	13	4%	4	21.00	0.563
Severe	5.2%	7		0		
Postpartum Depressive Symptoms			8.54 (5.53; 0–25)	101		
Minimal			82.2%	83		
Mild			14.8%	15		
Moderate			3%	3		
Severe				0		

3.4.2 *Cross-Sectional and Longitudinal Bivariate Associations between Pregnancy Biopsychosocial Factors and Pregnancy and Postpartum Depressive Symptoms in the Sample of Completers*

Table 3.4 shows Spearman correlations between prenatal psychosocial factors and prenatal and PPD symptoms in the sample of completers ($n = 101$). Prenatal depressive symptoms were positively associated with concurrent age ($r = 0.21$; $p = 0.032$), affective ambivalence ($r = 0.38$; $p < 0.001$), neuroticism ($r = 0.34$; $p < 0.001$), and negative affect ($r = 0.36$; $p = 0.004$). Conversely, prenatal depressive symptoms were negatively linked to positive affect ($r = -0.49$; $p < 0.001$). PPD symptoms were related to prenatal age ($r = 0.27$; $p = 0.006$), affective ambivalence ($r = 0.20$; $p = 0.042$), positive affect ($r = -0.21$; $p = 0.033$) and depressive symptoms ($r = 0.47$; $p < 0.001$). Being older, experimenting with more affective ambivalence, reporting less positive affect, and presenting depressive symptoms during pregnancy were associated with increased postpartum depressive symptoms. These correlations were between weak and moderate in strength. Social support and extraversion were not associated with concurrent and prospective depressive symptoms.

Table 3.3 Sociodemographic variables of the sample.

Variable	Non-Completers	Completers	Comparison	
	Frequency (%)	Frequency (%)	χ^2	p
Nationality				
Spanish	154 (93.3)	94 (93.1)	0.07	0.934
Other	11 (6.7)	7 (6.9)		
Educational Level				
<12 years	23 (13.9)	15 (14.9)	0.04	0.837
>12 years	142 (86.1)	86 (85.1)		
Parity				
Primiparous	122 (73.9)	79 (78.2)	0.62	0.429
Multiparous	43 (26.1)	22 (21.8)		
Relationship Status				
Not in a Relationship	42 (25.5)	17 (16.8)	2.70	0.100
In a Relationship	123 (74.5)	84 (83.2)		

Note: sample size was 165 for non-completers and 101 for completers.

As observed in Table 3.4, there were some significant associations between the biopsychosocial variables included in the study. Neuroticism was positively related to affective ambivalence ($r = 0.26$; $p = 0.009$) and negative affect ($r = 0.49$; $p < 0.001$), as well as negatively linked to extraversion ($r = -0.21$; $p = 0.038$), social support ($r = -0.26$; $p = 0.010$), and positive affect ($r = -0.38$; $p < 0.001$). Positive affect was positively associated to extraversion ($r = 0.28$; $p = 0.004$) and social support ($r = 0.23$; $p < 0.001$). Extraversion correlated positively with social support ($r = 0.23$; $p = 0.022$). Finally, affective ambivalence had a positive relationship with negative affect ($r = 0.29$; $p = 0.003$).

Table 3.4 Bivariate correlations between psychosocial variables and depressive symptoms in the sample of completers.

Variable	Age	AM	N	E	PA	NA	SS	PRE Dep	POST Dep
Age	-	0.14	0.17	-0.8	-0.15	0.13	-0.18	0.21 *	0.27 **
AM		-	0.26 **	-0.01	-0.13	0.29 **	-0.17	0.38 ***	0.20 *
N			-	-0.21 *	-0.38 ***	0.49 ***	-0.26 **	0.34 ***	0.16
E				-	0.28 **	-0.05	0.23 *	-0.15	-0.18
PA					-	-0.17	0.34 ***	-0.49 ***	-0.21 *
NA						-	-0.03	0.36 ***	0.10
SS							-	-0.16	-0.10
PRE Dep								-	0.47 ***
POST Dep									-

Note: AM, affective ambivalence; N, neuroticism; E, extraversion; PA, positive affect; NA, negative affect; SS, social support; PRE Dep, pregnancy depressive symptoms; POST Dep, postpartum depressive symptoms. *** $p < 0.001$; ** $p < 0.010$; * $p < 0.050$. Sample size is 101.

3.4.3 Structural Equation Model Predicting Postpartum Depressive Symptoms from Prenatal Biopsychosocial Factors in the Sample of Completers

In the model, psychosocial variables were placed according to their expected proximity with PPD (Figure 3.2). For instance, personality is, theoretically, the most distal factor related to PPD, while pregnancy depressive symptoms would be the most proximal factor to it.

As shown in Figure 2, distal psychological factors (i.e., neuroticism) were associated with more proximal psychological constructs (i.e., positive and negative affect). Specifically, neuroticism positively contributed to negative affect ($\beta = 0.84$; $p < 0.001$) and was negatively associated with positive affect ($\beta = -0.87$; $p = 0.003$). Contrary to neuroticism, extraversion contributed to more positive affect ($\beta = 0.73$; $p = 0.018$). In an intermediate level, positive affect was associated with more social support at pregnancy ($\beta = 0.22$; $p = 0.041$).

A number of cross-sectional associations with prenatal depressive symptoms also emerged. Specifically, positive associations were revealed for affective ambivalence ($\beta = 1.97$; $p = 0.003$) and negative affect ($\beta = 0.22$; $p = 0.024$), while positive affect was inversely linked to depressive symptoms ($\beta = -0.29$; $p < 0.001$). When exploring the longitudinal, prospective associations between study variables and PPD, only age ($\beta = 0.27$; $p = 0.010$) and prenatal depressive symptoms ($\beta = 0.37$; $p = 0.002$) predicted PPD. The proposed model showed an excellent fit ($\chi^2 = 5.072$, $p = 0.535$; degrees of freedom = 6; RMSEA < 0.001 ; 90% RMSEA CI < 0.001 –0.118; CFI = 1.000; TLI = 1.045).

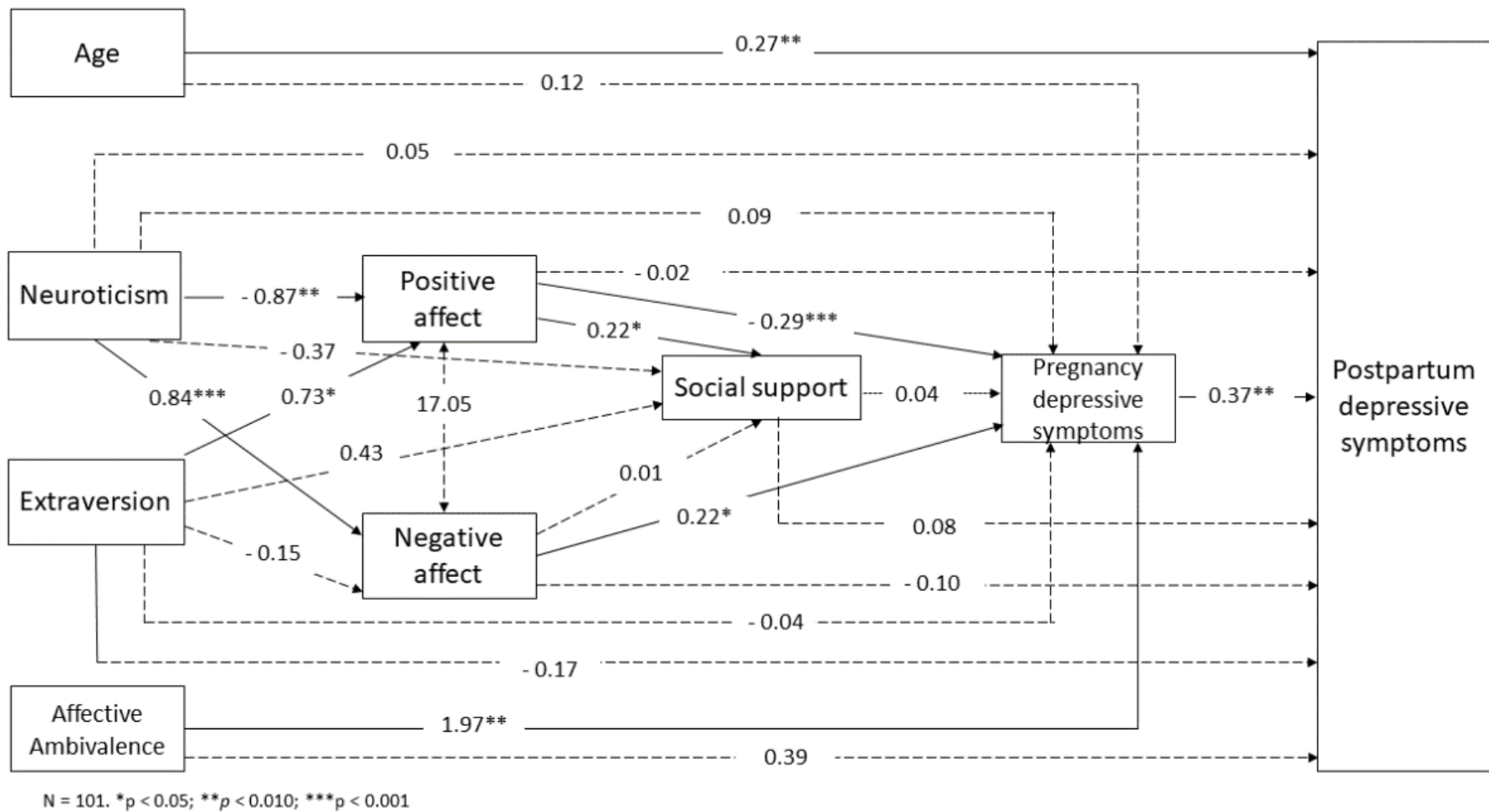


Figure 3.2 Structural Equation Model predicting depressive symptoms in the sample of completers.

3.5 Discussion

The present study aimed at investigating a relatively comprehensive set of biopsychosocial factors associated with perinatal depressive symptoms. Similar to previous research, the biopsychosocial factors included in the study (i.e., age, ambivalence and personality) were cross-sectionally linked to depressive symptoms during pregnancy [8,9,39], and prenatal depressive symptoms were the best predictors of PPD [9,13]. New to this investigation, we observed that the predictive ability of prenatal biopsychosocial factors when predicting PPD becomes negligible, with the exception of age, when prenatal depressive symptoms were accounted for.

3.5.1 Factors Cross-Sectionally Associated with Prenatal Depressive Symptoms

As hypothesized, age, affective ambivalence, neuroticism and negative affect appear to be risk factors for concurrent depressive symptoms, while positive affect is likely to be a protective factor for concurrent prenatal depressive symptoms. A surprising finding was that extraversion and social support did not correlate with concurrent and PPD.

The relationship between age and perinatal depressive symptoms is not well established in the literature [8]. Our results are consistent with studies suggesting that older women are at higher risk of pregnancy depressive symptoms [40]. However, the strength of the cross-sectional associations found in the present investigation was weak, so the results should be interpreted with caution and replication should be encouraged.

Previous research has supported the association between neuroticism, which is defined as a tendency to experience negative affect when facing a stressor [41], and depressive symptoms [11]. These findings are important because pregnancy is a period in which important challenges are likely to occur due to the changes in the body and the environment [42], so women scoring high in neuroticism are likely to be at higher risk for presenting perinatal depressive symptoms. A similar finding was obtained with negative affect, a personality characteristic closely related to neuroticism. These results are consistent with past research in the perinatal literature [12], and again suggest that there are personality profiles associated with an increased risk of emotional distress in this population that should be taken into consideration in prevention and treatment programs.

In addition to these two risk psychological factors for depressive symptoms, this study investigated the role of two arguably protective factors for depressive symptoms, namely, extraversion and positive affect. Consistent with our expectations, positive affect was inversely associated with the severity of depressive symptoms, which is consistent with the idea that this personality characteristic is a protective factor against depressive symptoms in perinatal women [12]. Surprisingly, though, extraversion, which has been linked to decreased emotional distress in

past research [11], and social support [43,44] were not significantly associated with depressive symptoms in our study. It is possible that the role of social support is more evident in disadvantaged populations. Our sample is not likely to be representative of such populations, as participants were generally well-educated adults that reported being in a stable relationship. In the light of the present investigation's findings, intrapersonal processes (i.e., experienced emotions) appear to be more important for prenatal depressive symptoms than interpersonal elements (i.e., social interactions and support). Another explanation could be that structural social support as measured in the present study (i.e., family support, friends support, and support from others) is negligible compared with functional social support (i.e., instrumental, emotional, informational, etc.). Because the literature in this regard is still scarce, the study results will require replication in similar (i.e., well-educated and maritally stable women) and different populations (i.e., less educated or single women for whom social support can play a more important role). Additionally, it would also be advisable to include different domains of social support (e.g., instrumental and emotional support). As recently suggested, social support to perinatal women should be provided by the right person, delivered at the right time, and should be of the right kind [45].

Overall, the aforementioned cross-sectional findings revealed in the bivariate analyses were supported by SEM, with the exceptions of age and neuroticism. As we predicted, when all biopsychosocial factors were included in a single model, a number of them ceased to significantly contribute to concurrent depressive symptoms, arguably due to shared variance, as indicated by the moderate bivariate associations between psychological variables included in the study. These findings are important as they might guide interventions and research in a more effective way (i.e., reducing the number of target variables due to redundancies and selecting the most robust predictors of outcomes). There is evidence to suggest that neuroticism and negative affect share important variance [46], so the burden of assessment and treatment might be reduced by selecting one of the factors only for research and treatment practices (i.e., negative affect according to the present study findings).

3.5.2 Factors Predicting Postpartum Depressive Symptoms

Consistent with past research [47], our bivariate analyses revealed that the association between psychosocial factors and depressive symptoms decreased with time. Affective ambivalence and positive affect did contribute to depressive symptoms prospectively, but only when investigated in a bivariate manner.

There is previous evidence to suggest that affective ambivalence is associated with perinatal depressive symptoms [10]. In a context wherein women are forced to view pregnancy as a positive process [11], negative emotions appear to have no or little place. However, as

evidenced by the large number of perinatal women who presented some degree of ambivalence in the present investigation (around 70% of respondents), the reality is quite different. Therefore, normalizing and destigmatizing ambivalence toward motherhood should be not only therapeutic goals, but societal aims, so that false negatives are minimized.

Positive affect was also longitudinally associated with prospective depressive symptoms. There is evidence to suggest that the promotion of positive emotions in perinatal women can be achieved via their participation in pleasant activities [48] and, consistent with the present study findings, this appears to reduce PPD symptoms [49]. Therefore, psychological treatments that encourage the induction of positive emotions or the inclusion of positive-induction modules in existent interventions should be recommended in perinatal women presenting low positive affect.

An interesting longitudinal finding was that only our biological factor, namely age, significantly contributed to PPD above and beyond prenatal depressive symptoms and the remaining psychosocial factors. This is a novel finding which might be attributable to a number of factors that are age-related. For instance, it is possible that older women had unrealistic expectations about motherhood, more difficulties in combining job or house-care duties with maternity, or more risk factor for obstetric and perinatal complications in both the women and the children [50,51], which might lead to increased postpartum depressive symptoms. Because providing information about the changes that occur in the perinatal period appears to be a good intervention for perinatal women [52], adjusting the expectations of older women, anticipating the challenges associated with pregnancy and motherhood, and providing them with abilities to deal with this new situation might be of special interest for older women. Research has shown that women face different stressors during the perinatal period depending on their parity status (i.e., primiparous or multiparous) [53]. Overall, multiparous women appear to experience higher concerns about their lack of social support, while primiparous are more worried about negative body changes or the maternal role [54]. Therefore, the information that should be provided to them and the adjustment of their expectations during pregnancy should consider the woman's parity status.

Our results showed that, when all biopsychosocial factors are included in a single model, only age and prenatal depressive symptoms were significant predictors of PPD. As anticipated and in line with previous research [8,9], prenatal depressive symptoms were the best predictors of PPD. What these findings suggest is that the intensity of depressive symptoms might remain relatively stable across time [17], so early detection and management should be a priority. Women regularly attend visits with the midwives during the perinatal period, so these appointments would represent good opportunities for mental health assessment and referral to a specialized mental health service when necessary.

Two of the strengths of the present investigation were the implementation of a longitudinal design and the use of technology for assessment. Current clinical practice guidelines recommended longitudinal assessments to detect and identify women at risk for PPD [6]. However, the high costs associated with extensive longitudinal evaluations make the implementation of such screening programs in the current public health systems difficult. While there is some promising evidence on the utility of ICTs in this field to overcome dissemination- and cost-related barriers [55], there are research gaps in programs of these characteristics, as the technologies used tend to be old-fashioned (i.e., SMS texts or phone calls) and little research has been conducted in the prenatal period [56]. The use of app-based or web-based screening and treatment methods should be encouraged in this population to maximize the benefits associated with the use of technology, especially during the prenatal period to ensure an early detection and treatment of this problem.

3.5.3 Limitations

The present study certainly has limitations. In our sample, the women were Spanish, well-educated, and predominantly were in a stable couple, so our results may not be generalized to all pregnant women populations. Sample size and dropout rates were also a problem. In this study, the participants were initially 266 perinatal women, but the longitudinal nature of the investigation and the number of included measures likely influence negatively the response rates (i.e., some women responding to a part of the assessment only) and dropouts. In fact, one of the present study goals was to explore whether communalities between constructs exist. This represents important information for reducing assessment protocols to a more manageable set. Another solution to long assessments is the validation of single-item measures against full-length traditional scales, which appears to be feasible and important when using technology (i.e., apps) for repeated assessment [57]. Gamification or gift cards are additional methods to increase adherence to longitudinal assessments. It is important to note that several measures exist to assess depressive symptoms during the perinatal period. Some authors found that the BDI-II, the measure used in the present study, could overestimate the prevalence of depressive symptoms in this population due to its extensive assessment of somatic symptoms [58]. Somatic symptoms are indeed prevalent and underestimated during the perinatal period, which explains why some authors recommended their assessment [59]. Given that both the Edinburgh Postnatal Depression Scale (EPDS) and the BDI-II seem to be accurate in evaluating depressive symptoms [60], future studies should explore whether the prevalence of symptoms in perinatal women is inflated when the BDI-II is administered. An additional limitation in the study was the focus on self-report measures. While this is a frequent practice and provides important information about the subjective state of the individual, the fidelity of the data (i.e., honesty, bias, or understanding and interpretation of items) cannot be guaranteed. This is important when assessing sensitive information, such as

ambivalence. However, it is also possible that the assessment procedure used (i.e., online as opposed to face-to-face) actually promoted a sense of anonymity and, thus, enhanced honesty. Another potential problem in the study refers to the use of *post hoc* questions. The majority of questionnaires administered were full-length scales validated in Spanish populations. However, an important construct, namely pregnancy ambivalence, was measured using an *ad hoc* item. This practice might represent a threat to the comparability of results. Finally, it is important to note that, despite the fact that a set of important biopsychosocial factors associated with perinatal depressive symptoms was selected, the list is far from complete. For example, biological factors, such as reproductive and stress hormones, psychological variables, such as beliefs and perceived anxiety control, social factors such as marital satisfaction and peer support, and contextual information (i.e., seasonal time frame or seasonal light exposure), have also been linked with depressive symptomatology in perinatal research [15,61], but were not included in the present study for feasibility reasons.

3.5.4 Conclusions

The assessment of a set of biopsychosocial factors in the present study provides a broader picture of the relationship between biological (age), psychological (affective ambivalence and personality characteristics), and social (social support) factors, and concurrent and prospective depressive symptoms in perinatal women. Our results confirm the need to repeatedly evaluate depressive symptoms in perinatal women. Our SEM analyses revealed that (a) prenatal depressive symptoms were the best biopsychosocial predictors of PPD, (b) for adult women (>18 years old), being younger appears to be a protective factor against perinatal depressive symptoms, especially in the postpartum period, (c) ambivalence about pregnancy and negative affect are related to increased concurrent but not prospective depressive symptoms, and (d) positive affect is associated with reduced concurrent depressive symptoms. The study findings suggest that biopsychosocial longitudinal assessments and intervention protocols that begin during pregnancy and continue in the postpartum are required for this population. In the light of our results, such treatment programs should emphasize the importance of emotional regulation strategies to increase positive affect and to reduce negative affect in women. A recent example is the Unified Protocol for the transdiagnostic treatment of emotional disorders [62,63], but it also includes educational components to help adjust the women's expectations and face the challenges associated with motherhood, especially in older women. From this study and past experience, we recommend the use of ICTs in such programs (i.e., blended treatments combining onsite and online treatment and ecological momentary assessment with apps) to minimize some of the dissemination and stigma barriers of traditional assessments methods.

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CHAPTER 4.

**CONTENT AND FORMAT PREFERENCES OF A DEPRESSION
PREVENTION PROGRAM: A STUDY IN PERINATAL WOMEN**

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4. Content and format preferences of a depression prevention program: A study in perinatal women

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4.1 Abstract

Objective: this study investigated ethnic differences in the preferred content and delivery method of a depression prevention program for perinatal women. **Method:** participants were 163 pregnant (66.9%) and postpartum (33.1%) women. Women identified themselves as Latinas (45.4%) or non-Latinas (54.6%). **Results:** overall, women preferred individual and onsite therapy across contents. Only when the content was related to improving communication, they were willing to incorporate the partner. There were no ethnic differences in the preferred format. Regarding content, women preferred to receive “information on the pregnancy process including physical and psychological changes.” Non-Latinas had a higher preference for “receiving regular check-ins on their emotional state” than Latinas. **Conclusions:** these results should be considered when developing future perinatal depression prevention programs and evidence that work needs to be done if we want online interventions to be viewed more favorably by perinatal women.

Keywords: Depression prevention, Information and Communication Technologies, Latina, Perinatal, Treatment preferences.

4.2 Introduction

Published reports on the global prevalence of perinatal depression suggest that we are currently facing an important mental health challenge. With respect to prenatal depression, global rates are between 6% and 38%, with high prevalence rates in Western nations like Canada (20%), England (31%), and the United States (38%; Field, 2011). Similarly, high prenatal incidence rates have been reported in Latin countries and territories, ranging from 16% to 30% in Mexico, the Dominican Republic and, in the United States, Puerto Rico (i.e., Lara et al., 2015). Unfortunately, the global rate of postpartum depression (PPD) is not any more encouraging. 9.3% of women residing in United States (Vesga-López et al., 2008) met criteria for PPD, compared to 13.3% of Mexican women (Lara et al., 2015) and 53% of Dominican and Puerto Rican women (Zayas, Jankowski, & McKee, 2003). Lower rates have been reported in Germany (6%) and Spain (8%), as well as in Belgium, Poland, and Italy (between 13-16%; Grote et al., 2010). Given the global impact, countries ought to provide women with appropriate prevention and intervention programs that are easy to disseminate, widely accepted, and adjusted to the women's daily lives and needs (Vázquez, Blanco, Torres, Otero, & Hermida, 2014).

Pregnant and postpartum women are interested in mental health prevention and intervention programs. A recent study demonstrated that 85% of pregnant women were interested in psychological approaches that helped them to prepare for motherhood, such as methods to improve their well-being (Dimidjian & Goodman, 2014). Also, a majority of childbearing age women agreed/strongly agreed that prenatal (79.2%) and postnatal (88.5%) mental health screening should be routinely conducted (Kingston et al., 2014). Despite the overwhelming endorsement, mental health services remain underutilized and most women do not benefit from any type of formal psychological support during the perinatal period (Hewitt & Gilbody, 2009), thus suggesting that barriers to maternal mental health services need to be identified and addressed.

Some mothers experience barriers like difficulties in transportation and feelings of guilt and stigma about being depressed (i.e., Byatt, Simas, Lundquist, Johnson, & Ziedonis, 2012), barriers which have been argued to decrease with the use of alternate options such as technology-based resources (e.g., online treatment; Donker, Cuijpers, Stanley, & Danaher, 2015). However, while online treatments appear to be well accepted in general (Maloni, Przeworski, & Damato, 2013), perinatal women have consistently preferred face-to-face interventions as the treatment format of choice (Dimidjian & Goodman, 2014) and only a small proportion of women (1.5%) appear to prefer web-based Internet support (Goodman, 2009) and would rather receive treatment individually than in group (Goodman, 2009).

What previous investigations suggest is that treatment preferences should not be ignored in the context of perinatal depression, as they might have important implications for help-seeking behaviors and related barriers, utilization of psychological resources, and access to care (Mallou, Boubeta, & Cueto, 2003; Supplee, Parekh, & Johnson, 2018). Unfortunately, however, important shortcomings in the existing literature make the current conclusions limited and difficult to generalize. Specifically, the preferences are rarely explored together in the same study and cultural differences are rarely investigated, thus, leading to inconclusive results. In sum, while the study of treatment preferences might be important when developing new psychological interventions for perinatal women, there is a need to combine all the aforementioned elements together in one study, while accounting for ethnic differences. Therefore, this investigation aims to examine depression prevention intervention preferences (online vs. onsite, individual vs. group, and alone vs. with their partner) among women who identify as Latinas compared to non-Latinas across four different treatment content areas. Although this is a cross-sectional preliminary study, we expected to replicate some of the findings reported previously. More specifically, we hypothesized that, while some participants would accept online treatment options, onsite treatment would remain a higher order preference. Additionally, we anticipated that individual treatment would be preferred over group interventions and that intervention content addressing general information to prepare women for motherhood would be preferred over a more targeted program on depression prevention due to the stigma associated with mental health. Finally, we hypothesized that ethnic differences, if evident, would be modest with the direction of such differences to be analyzed in an exploratory manner.

4.3 Methods

4.3.1 Participants and procedures

Google AdWords campaigns were used to advertise and recruit perinatal women interested in providing information about their sociocultural, emotional, and pregnancy experiences. Women who were at least 18 years old, currently pregnant or within one year postpartum, and able to read English or Spanish were invited to complete an anonymous and voluntary online survey. Data for participants in this study were recruited via the Internet using an online survey available in English and Spanish between October 16, 2014 and March 30, 2015. Of eligible women ($n = 1,805$), 509 consented to participate. Of these, 81 did not indicate their ethnic identity and 265 failed to provide data on the content format preferences outcome variables, so they were excluded from the study analysis. The final sample analyzed in this report was comprised of 163 perinatal women with a mean age = 28.36 years ($SD = 6.20$). A majority were pregnant (66.9%) and almost equally identified as Latina (45.4%) or non-Latinas (54.6%). There were no group differences in education level ($\chi^2(1,163) = 0.93, p = .418$), marital status ($\chi^2(1,163) = 2.51, p = .113$), or number

of children ($t = 1.29, p = .200$). Countries of origin were diverse and, therefore, categorized into representative groups. Women who identified themselves as Latinas were mostly from South America ($n = 55$). The remaining Latina participants identified their region or country of residence as Caribbean ($n = 6$), Central America ($n = 4$), Spain ($n = 2$), or other ($n = 6$). On the other hand, the majority of non-Latinas were originally from North America ($n = 40$). Other regions included South America ($n = 12$), South and South-East Asia ($n = 16$), Central and South Africa ($n = 8$), and other ($n = 7$). Almost all Latinas completed the study survey in Spanish (90.5%), while the majority of non-Latinas chose to complete the study survey in English (84.3%). See Table 4.1 for their demographic characteristics. The Institutional Review Board at the sponsoring university approved all study procedures.

Table 4.1 Sociodemographic characteristics of Latina and non-Latina pregnant and postpartum women.

Sociodemographic	Latina	Non-Latina	t/χ^2	p
<i>Age</i> ^a	27.23 (5.99)	29.29 (6.24)	2.13	.035
<i>Number of children</i> ^a	1.92 (0.89)	2.15 (1.28)	1.29	.200
<i>Perinatal period</i> ^b			12.35	<.001
Pregnant	60 (55.0)	49 (45.0)		
Postpartum	14 (25.9)	40 (74.1)		
<i>Marital status</i> ^b			2.51	.113
Married/Cohabiting	58 (42.6)	78 (57.4)		
Single/Divorced	16 (59.3)	11 (40.7)		
<i>Socioeconomic status</i> ^b			4.60	.032
Middle	61 (42.4)	83 (57.6)		
Low	13 (68.4)	6 (31.6)		
<i>Educational level</i> ^b			0.93	.334
< 12 years	16 (53.3)	14 (46.7)		
> 12 years	58 (43.6)	75 (56.4)		
<i>Language</i> ^b			90.46	<.001
English	67 (90.5)	14 (15.7)		
Spanish	7 (9.5)	75 (84.3)		

^a Means and standard deviations are shown and independence is explored with a t -test;

^b Frequencies and percentages are shown and independence is investigated with a χ^2 test.

4.3.2 Instruments

The survey was created *ad hoc* for this study and have included the following sections:

Demographic Characteristics

Participants provided information on their age, language preference, perinatal status, number of children, country of residence, racial background, marital status, employment status, socioeconomic status, and educational level.

Program Content

Four content areas were presented to participants based on mental health guideline recommendations related to depression prevention that target the need for ongoing assessment of depression (content a; Haga, Drozd, Brendryen, & Slinning, 2013), the most common components included in programs to prepare for motherhood (contents b and c; O'Mahen et al., 2014; Parker, Dmitrieva, Frolov, & Gazmararian, 2012), and recommendations for healthy communication and social support from partners (content d; Elsenbruch et al., 2007). Each content area was framed as follows:

Content a. Conducting regular check-ins on their emotional state during pregnancy and postpartum using a questionnaire (depression prevention content).

Content b. Providing information about the pregnancy process, including physical and psychological changes, as well as information about the development of the baby (preparing for motherhood content).

Content c. Providing information about the health and care of their baby in the first year postpartum and later on when raising their child (preparing for motherhood content).

Content d. Providing information and tips on how to communicate with their partner to increase collaboration and support during pregnancy and postpartum (depression prevention content).

Intervention Preferences

A set of questions to assess preferred methods of delivery (e.g., "Would you like to receive regular check-ins on your emotional state during pregnancy and postpartum using a questionnaire?") and preferred format (e.g., online vs. onsite, individual vs. group, and alone vs. with their partner) were created for each content area (e.g., "Individually, on my cell phone using an application developed by psychologists" or "In a group, with other pregnant women in a Health Center and a psychologist/health professional"). In total, eight format preferences were presented to participants. All preferences were introduced with the sentence, "How would you like to receive this resource or information." Each preference option was categorized into three dichotomous groups (online vs. onsite, individual vs. group, alone vs. with your partner). Content areas were introduced with the sentence, "Where would you like to receive this resource or information." For a full description of the questions and how they were categorized refer to Table 4.2.

Table 4.2 Format preferences and their corresponding classification.

How would you like to receive the [insert one of the four contents] content?	Individual/ Group	Online/ On site	Alone/ Partner
1. Individually, in a Health Center or with a psychologist	Individual	On site	Alone
2. Individually, at home through an online program (computer) developed by psychologists	Individual	Online	Alone
3. Individually, on my cell phone using an application developed by psychologists	Individual	Online	Alone
4. With my partner, in a Health Center or with a psychologist	Individual	On site	With partner
5. With my partner, at home through an online program (computer) developed by psychologists	Individual	Online	With partner
6. With my partner, on my cell phone using an application developed by psychologists	Individual	Online	With partner
7. In a group, with other pregnant women in a Health Center and a psychologist/health professional	Group	On site	Alone
8. In a group, with my partner and other couples in a Health Center and a psychologist/health professional	Group	On site	With partner

Note: The table shows all study questions and how they were categorized (online vs. onsite, individual vs. group, alone vs. with your partner). Items 1 to 8 represent the answers about preferences for each question.

4.3.3 Statistical analysis

First, we investigated whether both groups (Latinas and non-Latinas) were similar demographically by means of a Student's *t*-test (for continuous variables) or a Chi-square test (for categorical variables). Second, a comparison between Latinas and non-Latinas' preferences for each of the proposed content areas was examined using a Chi-square test for group differences. A final analysis of independence was planned for each content type to calculate differences in format preferences (online vs. onsite, individual vs. group, and alone vs. with their partner) across the two ethnic groups (e.g., format preference independent of ethnic group for a given content). However, because we observed that the sample was segmented into two arguably different groups (pregnant vs postpartum), we conducted an additional analysis to explore content preferences as a function of the perinatal period of participants. All analyses were completed with the Statistical package SPSS version 22 (IBM Corp, 2013).

4.4 Results

4.4.1 Sample characteristics

As seen in Table 4.1, an examination of differences across the two ethnic groups revealed that Latinas were younger than non-Latinas ($t = 2.13, p = .035, 95\% \text{ CI} = 0.15, 3.97$), more likely to be pregnant ($\chi^2 (1,163) = 12.35, p < .001$), and perceived their socioeconomic status as lower ($\chi^2 (1,163) = 4.60, p = .032$).

4.4.2 Intervention content preferences

For each of the four content areas, preference differences were examined between Latinas and non-Latinas (i.e., if the proportion of women who would like that content to be included in a depression intervention program for perinatal women was different across ethnic groups). No statistical differences were revealed for content areas b to d, indicating similar levels of interest irrespective of ethnic background (see Figure 4.1). The data revealed a higher interest in regular check-ins on emotional state during the perinatal period among non-Latinas ($\chi^2 (1, 163) = 7.08, p = .008$). Content b and c (information about pregnancy and health care of the baby) were the most frequently preferred by all participants (73.6% and 68.1%, respectively). By contrast, the two remaining content areas, a and d (regular check-ins on their emotional state and communication with partner), were only selected by approximately 57% of the sample.

4.4.3 Format preferences across ethnic groups content areas

As seen in Table 4.3, there were no ethnic differences in the format preferences (individual vs. group, online vs. on site, alone vs. with the partner) across the four content areas. We found a non-significant trend in the proportion of Latina and non-Latina women who preferred to receive check-ins on their emotional state individually as opposed to in group ($\chi^2 (1, 106) = 3.62, p = .057$). That is, Latina women demonstrated a slight preference for participating in a group format when compared to non-Latinas.

4.4.4 Format preferences across content areas in the whole sample

In addition to examining differences in format preferences as a function of ethnic group, we also conducted exploratory analyses to examine whether certain content areas were preferred in a particular format, irrespective of ethnic group (see Table 4.4). Our results indicated that the individual format ($\chi^2 (3, 383) = 2.54, p = .468$) and onsite delivery ($\chi^2 (3, 382) = 4.76, p = .190$) were clearly preferred irrespective of the treatment content area. By contrast, the preference for receiving contents alone or with their partner was content-dependent ($\chi^2 (3, 383) = 11.79, p = .008$). Specifically, the *post hoc* analyses indicated that the company of the partner would be frequently selected when “receiving information and tips about how to communicate with the

partner”, but rare when “receiving regular check-ins on the emotional state” (adjusted, standardized residuals were 3.0 and -2.5, respectively).

4.4.5 Content preferences as a function of the perinatal period

As reported in Table 4.5, postpartum women were more interested than pregnant participants in receiving “Regular check-ins on their emotional state” ($\chi^2 (1, 163) = 4.19, p = .041$). We did not find differences in the interest towards the remaining contents as a function of the perinatal period (all $p > .05$).

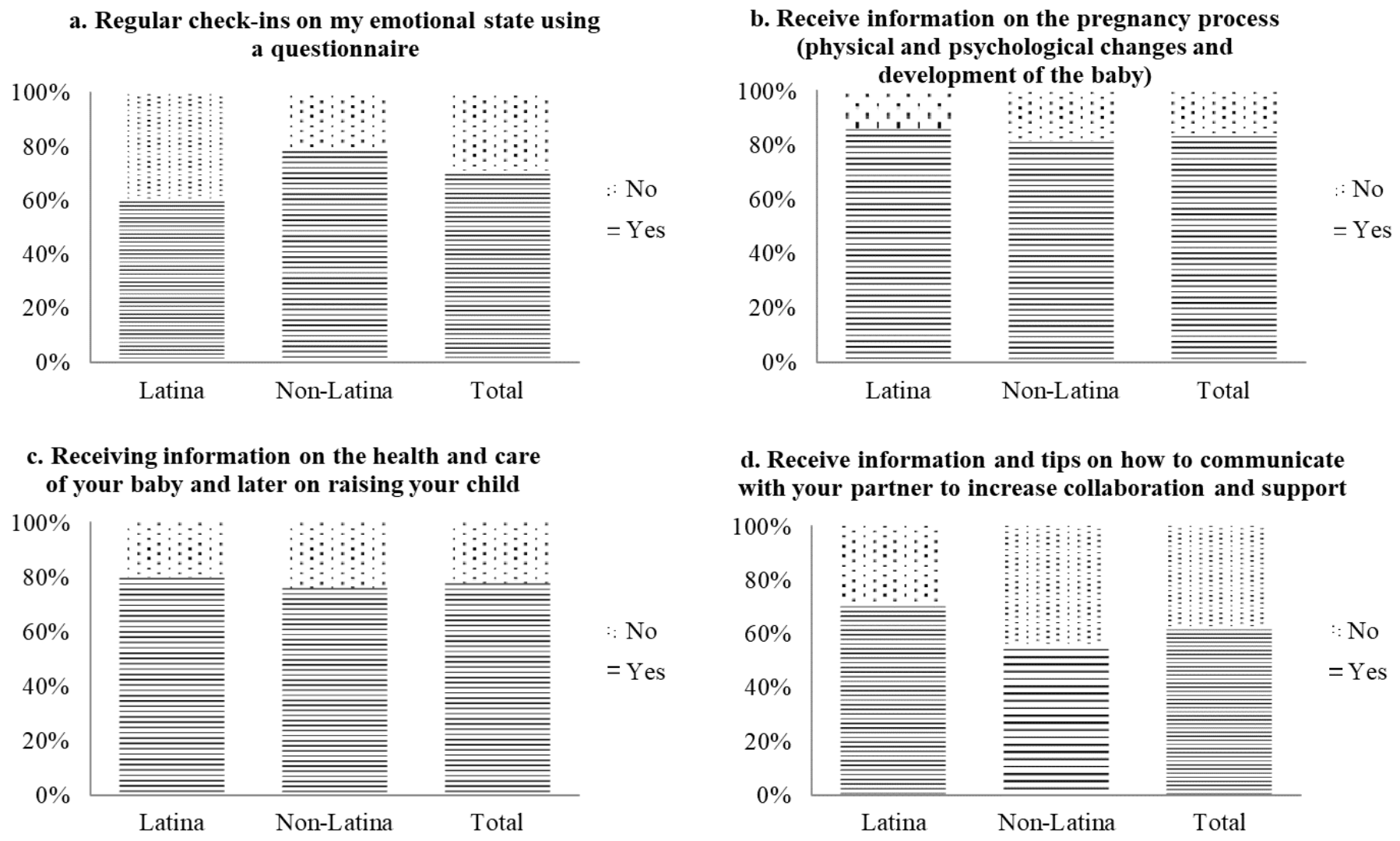


Figure 4.1 Intervention content area preferences of Latina and non-Latinas perinatal women.

Table 4.3 Preferences for intervention content area by format of delivery among perinatal Latina and non-Latina women.

	<i>Regular check-ins on emotional state...</i>				<i>Physical & psychological changes...</i>				<i>Health & care of my baby...</i>				<i>Communicate with my partner...</i>			
	Latina n=40	non-Latina n=66	χ^2	p	Latina n=49	non-Latina n=61	χ^2	p	Latina n=38	non-Latina n=54	χ^2	p	Latina n=40	non-Latina n=35	χ^2	p
<i>Individual vs group</i>			3.62	.057			0.48	.488			0.26	.609			0.73	.393
Individual	87.5	97.0			91.8	95.1			88.9	92.1			85.0	91.4		
Group	12.5	3.0			8.2	4.9			11.1	7.9			15.0	8.6		
<i>Online vs on site</i>			<.001	.999			0.39	.531			1.55	.213			0.14	.709
Online	33.3	33.3			46.9	41.0			31.6	44.4			27.5	31.4		
On site	66.7	66.7			53.1	59.0			68.4	55.6			72.5	68.6		
<i>Alone vs partner</i>			1.99	.159			1.54	.215			3.01	.083			0.10	.757
Alone	70.0	81.8			59.2	70.5			52.6	70.4			55.0	51.4		
With the partner	30.0	18.2			40.8	29.5			47.4	29.6			45.0	48.6		

Note: Differences in sample sizes are reflective of not all individuals reporting a preferred format for all content areas. Values in the cells are percentages.

Table 4.4 Preferences for delivery format across content area in the whole sample.

	<i>Regular check-ins on emotional state...</i> n=106	<i>Physical & psychological changes...</i> n=110	<i>Health & care of my baby...</i> n=92	<i>Communicate with my partner...</i> n=75	χ^2	p
<i>Individual vs group</i>					2.54	.468
Individual	93.4	93.6	90.2	88.0		
Group	6.6	6.4	9.8	12.0		
<i>Online vs on site</i>					4.76	.190
Online	33.3	43.6	39.1	29.3		
On site	66.7	56.4	60.9	70.7		
<i>Alone vs partner</i>					11.79	.008
Alone	77.4*	65.5	63.0	53.3*		
With the partner	22.6*	34.5	37.0	46.7*		

Note: Differences in sample sizes are reflective of not all individuals reporting a preferred format for all content areas. Values in the cells are percentages. *Adjusted, standardized residuals are > 1.96.

Table 4.5 Content preferences as a function of the perinatal period in the whole sample.

	<i>Regular check-ins on emotional state....</i> (n=106)		<i>Physical & psychological changes..</i> (n=110)		<i>Health & care of my baby...</i> (n=92)		<i>Communicate with my partner...</i> (n=75).	
	χ^2	p	χ^2	p	χ^2	p	χ^2	p
<i>Perinatal</i>	4.19	.041	0.61	.434	0.44	.509	1.82	.178
Pregnancy	66.1		81.9		76.0		66.3	
Postpartum	81.5		86.8		80.8		54.9	

Note: Differences in sample sizes are reflective of not all individuals reporting a preferred format for all content areas. Values in the cells are percentages.

4.5 Discussion

This study set out to examine depression prevention intervention content and delivery format preferences among a global sample of Latina and non-Latina perinatal women. Given the low utilization of psychological services among perinatal women (Bales et al., 2015) and the growing societal trend to rely on electronic information using mobile devices and computers (Internet World Stats, 2017), data from this study has the potential to influence the development of technology-based mental health resources that can be accessed by pregnant and postpartum women all around the world.

4.5.1 Intervention content preferences

The content options included in this study mainly focused on depression prevention and mood management (contents b and c) or on preparing for motherhood and parenting (contents a and d). All content options were acceptable by the perinatal women with a noticeable reduced preference for content related to depression prevention relative to content on preparing for motherhood. Our hypothesis, which was confirmed, was that the latter would be preferred, arguably due to the existence of maladaptive beliefs and misconceptions about depression and because of the negative stigma associated with perinatal depression (Byatt et al., 2012). In addition to the stigma, these results could also be explained by the characteristics of the content areas, which are focused on women's needs (emotional state screening and communication tips) instead of the babies' needs.

While depression prevention content was considered less important than information on baby care, the least preferred content was that of "tips on how to communicate with your partner". Additionally, women frequently reported that they would prefer to participate in the treatment components without the company of their partner. These results are surprising despite the importance of social support during the perinatal period (Elsenbruch et al., 2007). One possible explanation is that mothers are not aware of the key role of social support during pregnancy and after delivery or maybe they believe that existing levels of communication and support from their partners are already in place. Another possibility is that certain parenting stereotypes or expectations may exist in the society, such as baby care being the sole responsibility of women, which might explain the prioritization of baby-care content over psychological and social ones (Georgas, Berry, van de Vijver, Kagitcibasi, & Poortinga, 2006). Given this assumption, depression prevention plans should first tap into increasing women's interest in improving their psychological and social skills in order to contribute to their own well-being and, consequently, that of the baby.

4.5.2 Format preferences

In relation to ethnic differences, we had hypothesized that differences in preference between Latinas and Non-Latinas, if present, would be very modest. Indeed, our study revealed that preferences were comparable across the two ethnic groups. Some studies have reported ethnic differences in treatment preferences (pharmacological vs. psychotherapy; Dimidjian & Goodman, 2014; Goodman, 2009) type of health professional (Kingston et al., 2014), or type of setting (O'Mahen & Flynn, 2008). However, to the best of our knowledge, none of the previous published reports investigated the interplay between content, format, and ethnicity. What our results suggest is that Latina and non-Latina perinatal women tend to agree about content and format preferences of prevention programs for perinatal depression. Specifically, all perinatal women preferred to receive a depression prevention program individually, onsite, and principally alone, regardless of

ethnic identity. These results are similar to those reported by Goodman (2009) who found a clear preference for individual psychotherapy (72.5%), which is usually delivered onsite and alone with the mental health professional.

An interesting finding in the present study was that group delivery format was rarely listed as preferred by perinatal women. The use of a group intervention format has multiple advantages for public and private health systems, which make it a very frequent delivery, format in clinical and research settings (Ickovics et al., 2011). However, in light of our results, this format could function as an initial barrier to participation, adherence, and maintenance of pregnant and postpartum women in a depression prevention program, and should be explored and discussed whenever an intervention is proposed. By aligning the delivery format with the mother's preferences or by changing some misconceptions about group format delivery, we might be able to reduce the barriers associated with depression prevention treatments.

As hypothesized, perinatal women showed a preference for onsite delivery format. Other studies have found the same results (Goodman, 2009). These findings remain speculative at this point given that perinatal women may perceive onsite interventions with health professionals as the most common format of health service delivery. However, research suggests that there are still some concerns with regards to the use of e-Health resources, especially in relation to privacy and a lack of clarity over how e-Health works and the services it provides (Peeters, Krijgsman, Brabers, Jong, & Friele, 2016).

An additional finding in the study was that postpartum women were more keen on receiving regular check-ins on their emotional state when compared to their pregnant counterparts. No more differences in content preference were revealed between pregnant and postpartum women. These results are interesting as they indicate that women experience different needs across the perinatal period. One possible explanation for these findings is that the focus of attention during check-ins is likely to change from pregnancy (mostly the mother's well-being) to the postpartum (mostly the newborn's well-being). However, research has shown that emotional distress in the postpartum is not infrequent (Patel et al., 2012; Vliegen, Casalin, & Luyten, 2014), which might explain why more attention to the mother's emotional state is appreciated at this stage. Note, however, that this is merely hypothetical and further conclusions cannot be drawn from the present study results.

This is not the first study to explore women's opinions about information and communication technologies (ICTs) in the context of perinatal care. So far, research has indicated an open attitude by perinatal women towards technology tools for maternal health and mental health (Osma, Barrera, & Ramphos, 2016). While acknowledging this, when compared to onsite treatment and program options, the numbers are discouraging. Thus, as researchers and clinicians,

we are urged to consider how to increase the willingness to consider online program options in perinatal care. Given the limited access and utilization of maternal mental health programs and resources, the open attitude of perinatal women towards online format, and the increased global use of the ICTs in healthcare (Internet World Stats, 2017), efforts should be directed toward developing and effectively disseminating digital treatments for perinatal depression prevention in order to impact perinatal women worldwide.

This study has a number of limitations that must be taken into account. First, the sample is limited to women who are active Internet users and who already have a certain level of comfort using technology and accessing information electronically. Second, there was significant number of women who declined to participate or who discontinued participation just after registering, so the generalization of results should be viewed with caution. Third, we used a closed answer option system to facilitate participation and to reduce the burden associated with online data collection. A qualitative study would surely provide rich information, but the low participation rate obtained with the current version of the study protocol suggests that some strategies to encourage participation should be conducted (e.g., economic compensation). Despite these shortcomings, this study represents an important preliminary step towards understanding what perinatal women prefer in terms of mental health support.

To the best of our knowledge, no other investigation has specifically examined technology-based preferences among perinatal women or the intersection between preferred type of content and method of delivery. The use of ICTs, especially online format and mobile applications is becoming a feasible alternative delivery format of prevention and treatment interventions for perinatal depression. While, perinatal women appear to be open to receiving depression prevention content using online and mobile technologies, our study evidenced that there is still a gap we need to bridge if we want online interventions to be viewed more favorably by perinatal women. As mental health researchers and providers, we must consider these preferences when developing needed resources to address the global burden of perinatal depression.

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CHAPTER 5.

**PREVENTION OF EMOTIONAL DISORDERS AND SYMPTOMS
UNDER HEALTH CONDITIONS: A PILOT STUDY USING THE
UNIFIED PROTOCOL IN A FERTILITY UNIT**

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5. Prevention of Emotional Disorder and Symptoms Under Health Conditions: A Pilot Study using the Unified Protocol in a Fertility Unit

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5.1 Abstract

Objective: Emotional Disorders (EDs) are common in women who undergo fertility treatments. The Unified Protocol (UP) is a transdiagnostic intervention that has demonstrated efficacy in preventing EDs under different health conditions. The aim of this pilot study is to: 1) improve emotional dysregulation for the prevention of anxiety and depressive symptoms in women undergoing intrauterine inseminations (IUI); 2) assess their acceptability (e.g., satisfaction and adherence rates). **Methods:** Five women undergoing IUI, with no clinical diagnoses, responded to measures of mood (anxiety and depression), affect, quality of life and emotional dysregulation in the pre- and post-assessments, and at the 1-, 3- and 6-month follow-ups. The UP was adapted to be applied during six face-to-face group sessions lasting 2 h. The COVID-19 pandemic situation implied changing to an online format to end the program. **Results:** The results showed that women did not develop EDs, and no statistically significant pre-post and pre-follow-up differences were found for anxiety, depression, quality of life and emotional dysregulation (all $p > .050$). A tendency towards improvement in the post-assessment evaluation was noted. Satisfaction with the format and UP program was high. **Conclusions:** It would seem that programs focusing on therapeutic common factors like the UP could have an emotional preventive effect during IUI.

Keywords: Unified Protocol, Assisted Reproduction Techniques, Group format, e-health, Emotional Disorders, Emotion Regulation, Health Prevention.

5.2 Introduction

According to the World Health Organization (WHO), infertility is defined as a chronic disease of the reproductive system characterized by the impossibility of achieving pregnancy after 12 months or more of regular sexual relations without using any contraceptive method (Zegers-Hochschild et al., 2010). It is estimated to affect between 1.9% and 27.1% of women worldwide (Mascarenhas et al., 2012). The most recent data confirm that demand for Assisted Reproductive Techniques (ART) is globally increasing (Adamson et al., 2018). For example, in Europe more than 600,000 treatment cycles were performed in 2011 and 918,159 treatment cycles in 2016 (Calhaz-Jorge et al., 2020; European IVF-Monitoring Consortium et al., 2016).

Generally, ART could be divided into different stages. They usually begin with simple lifestyle changes or programmed sexual relations, and then progress to complex treatments like controlled ovarian hyperstimulation plus intrauterine insemination (IUI), or to increasingly more complex techniques like in vitro fertilization (IVF; Smith et al., 2011). All these procedures, whether they are effective or not, come with an associated series of risks and possible complications (Ávila & Moreno-Rosset, 2008) that, together with uncertainty about treatment effectiveness, make the ART process an extremely stressful event (Greil et al., 2011).

Some studies report that between 25% and 65% women undergoing fertility treatments present some psychopathology type such as anxiety or depression symptomatology, often with high comorbidity rates between both disorders (i.e., Cox et al., 2006). Recent studies conducted with women undergoing ART report higher depression and anxiety rates than before treatment (Lakatos et al., 2017), which could negatively impact their quality of life, as well as the cost-effectiveness of ART and its continuity (i.e., Kiesswetter et al., 2020). These data have worsened with the COVID-19 pandemic because infertility ART stopped from March 15th 2020, and this delay stresses the population undergoing ART (Vaughan et al., 2020).

These data highlight the need to develop and implement programs to prevent the onset of emotional disorders (EDs; anxiety, depression and related disorders; Bullis et al., 2019) in women who are involved in ART. Several review studies have analyzed those interventions with proven efficacy in reducing stress, anxiety and depressive symptoms in couples undergoing ART (i.e., Ying et al., 2016). Some studies report positive results in the reduction of anxiety and depressive symptoms (Boivin, 2003), while others indicate no beneficial effect of psychological interventions on infertile patients' mental health (Hämmerli et al., 2009). These differences may be the result of the varying psychological interventions applied. Boivin (2003) suggests that group interventions based on education and skills training are more effective. Some studies indicate that symptoms-focused psychosocial interventions based on CBT, mindfulness techniques, stress management and emotion regulation programs could be effective in reducing psychological stress

or anxiety and depressive symptoms, and in improving the quality of life of women undergoing ART (Heredia et al., 2020; Li et al., 2019).

Despite the proven efficacy of these symptoms-focused interventions, it remains unclear which of them is more suitable for women undergoing ART. An alternative to the symptoms-focused approach is to implement a transdiagnostic prevention program to improve women's emotion regulation strategies. The Unified Protocol (UP) is a cognitive-behavioral transdiagnostic intervention that focuses on the shared aetiological and maintenance factors underlying EDs, which are related to difficulties in emotion regulation. The UP facilitates the learning of emotional regulation skills to improve tolerance to discomfort deriving from intense emotions, such as sadness, guiltiness or anxiety (Barlow et al., 2017). Previous studies have shown preliminary data for the efficacy of the UP in treating EDs that are comorbid with different health conditions, and are especially prevalent in women (e.g. chronic pain or breast cancer; Payne 2018; Weihs et al., 2019; Osma et al., 2021). Recent studies report promising data about applying the UP in a group format (e.g., Reinholt et al., 2017) and for preventing EDs in different populations (Sauer-Zavala et al., 2020).

Despite such evidence, it would appear that women and couples with fertility problems neither receive the necessary psychological care nor are referred to adequate mental health services (Pasch et al., 2016). Some barriers come down when asking for help, such as the stigma associated with mental health, logistical or financial limitations or health professionals' lack of knowledge and skills (van Dongen et al., 2016; Wischmann, 2008). In this scenario, the use of Information and Communication Technologies (ICTs) can provide important advantages that help to overcome the limitations of traditional face-to-face systems (Burger et al., 2020). For instance, it is more anonymous and can reduce the stigma related to mental health consultations, it can be delivered at home and has no travelling barriers, and allows treatments to be continued even when unexpected negative events occur and impede face-to-face interventions, such as the COVID-19 pandemic situation (e.g., Vaughan et al., 2020). Furthermore, ICT-based interventions have shown good results for women's acceptability of fertility problems (i.e., van Dongen et al., 2016).

Therefore, the objective of our study focuses on: 1) improving emotional regulation skills to prevent anxiety and depressive symptoms/disorders in women undergoing IUI; 2) assessing the acceptability (e.g., satisfaction and adherence rates) of this program. By taking into account our program's preventive nature, we expected to maintain non-clinical levels of anxiety and depressive symptoms and negative affect after the UP-preventive program (UP-PP), and at the 1-, 3- and 6-month follow-ups. We also expected to observe the positive affect, quality of life, and improvements in emotion dysregulation to remain. Finally, we expected to find a high level of satisfaction with the program in terms of the participants' quantitative and qualitative reports and their high adherence rates.

5.3 Methods

5.3.1 Participants

Figure 5.1 shows the flow diagram of our participants. Twenty-five women treated for fertility problems in a Human Reproductive Unit (HRU) in the General University public Hospital from Castellón, consented to participate in this study. Of these women, 22 were contacted by a psychologist to arrange the first interview during which inclusion criteria were assessed. As some women did not meet the inclusion criteria (see Figure 5.1), eight women participated in the study (mean age = 32.88, $SD = 3.56$, range 28-39). All the women were Spanish, most were in a relationship ($n = 7$), currently employed ($n = 8$) and had more than 12 years of education ($n = 8$). The time period during which they had attempted pregnancy ranged between 12 and 36 months (mean = 20.50, $SD = 7.84$), and the cause of infertility was mainly unknown ($n = 4$), female factor ($n = 2$) and no male partner ($n = 2$). The number of IUI received upon the first assessment was between 1 and 3 cycles (mean = 1.63, $SD = 0.92$). Six women received IUI using their partner's sperm, while two did so with anonymous donations. None had previous children.

5.3.2 Procedure

All the procedures were approved by the Ethics Committee of the General University Hospital from Castellón. The study was conducted between September 2019 and November 2020 in the HRU of the aforementioned public hospital.

The women attending the HRU to receive IUI were invited by the doctor responsible for the HRU to voluntarily participate in the UP-PP in face-to-face groups. After providing written informed consent, psychologists conducted the first face-to-face appointment at the hospital where the Mini-International Neuropsychiatric Interview (MINI; Sheehan et al., 1998) was administered to evaluate the exclusion (i.e., diagnostic of mental health disorder or suicide risk at the time of the assessment) and inclusion criteria (i.e., aged over 18 years, undergoing IUI treatment, fluent in Spanish or Catalan, and able to attend all the programmed group sessions). As the women who do not receive fertility treatment usually report fewer distress and depressive symptoms than those receiving these treatments (Lakatos et al., 2017), one inclusion criterion to participate in group sessions was having undergone at least one IUI. The women who had not begun IUI at the time of the first assessment with a psychologist were informed about the possibility of being included in the next groups.

If the women met the inclusion criteria ($n = 8$), before they started UP-PP they completed an online pre-assessment on the *Qualtrics* platform, a session that lasts approximately 30 minutes. The same instruments were also administered at the post- and three follow-up assessments (1-, 3- and 6-month follow-ups).

To ensure proper UP-PP implementation, the psychologist went on a UP training course with clinical supervision by J.O author, who has been certified by the Unified Protocol Institute and has ample experience in applying the UP.

5.3.3 Unified Protocol Prevention Program (UP-PP)

Table 5.1 shows the original UP sessions, as well as the adaptations made to this pilot study. The prevention program consisted of weekly sessions during 6 weeks, distributed as one 1-hour individual session and five 2-hour group sessions. The first individual face-to-face session focused on motivation and adjusting expectancies. The second session was also conducted at the hospital with all the women. However, the remaining sessions (program sessions 3 to 6) were held online as a result of the COVID-19 pandemic. These sessions were offered over the Zoom platform by maintaining the 2-hour duration of sessions. After each session, the women received an *ad hoc* manual by email with the information they had learned during every session, including worksheets to register their homework.

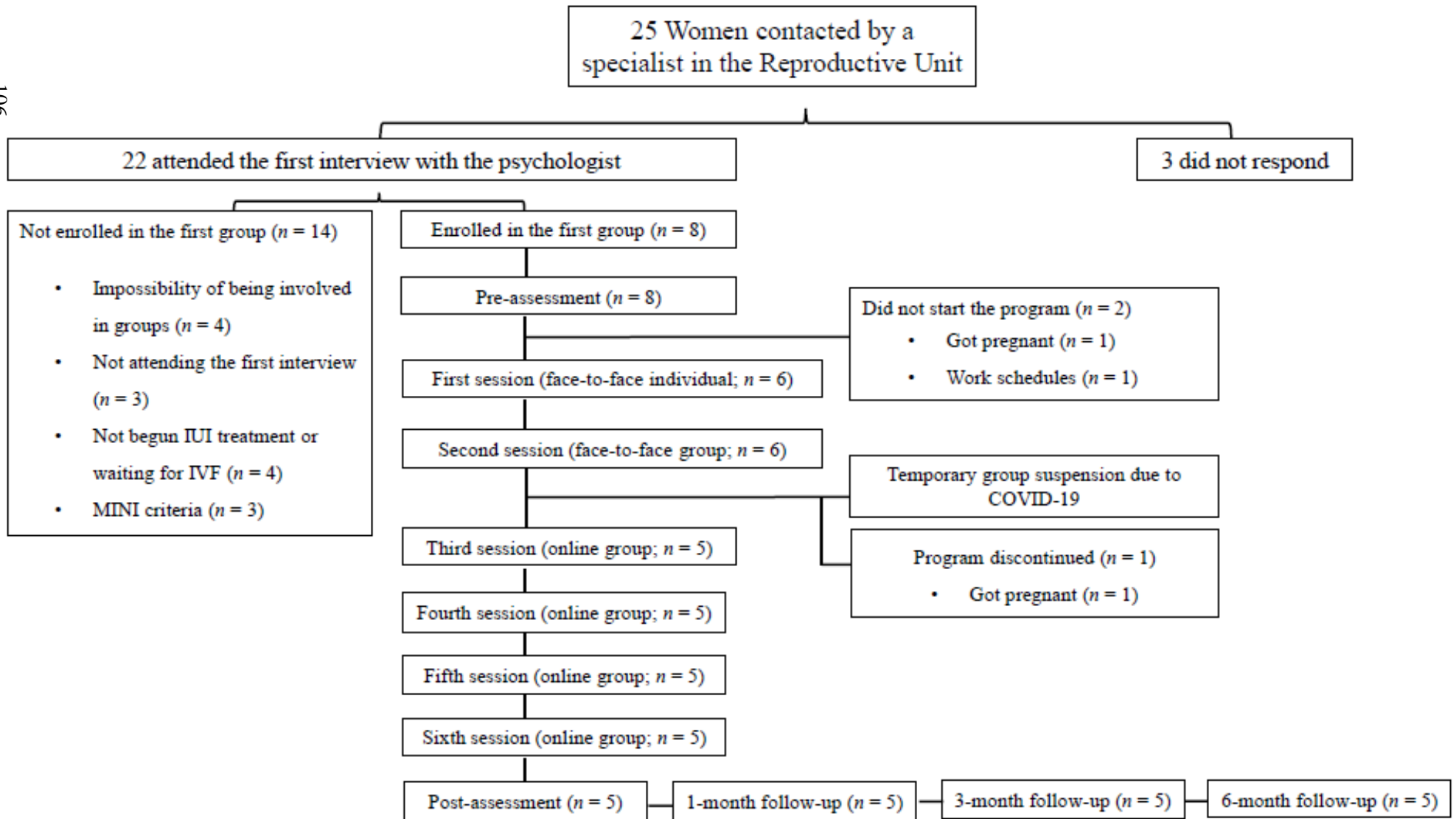


Figure 5.1 Flow diagram of the study participants.

Table 5.1 Unified Protocol adaptations to the preventive program for the women undergoing IUI.

UP original	Adapted UP-PP modules	Description of adaptations
Setting goals and maintaining motivation	Adjusting expectations: emotional changes and emotional regulation during ART (INDIVIDUAL AND FACE-TO-FACE)	This module was adapted to talk about emotional changes during fertility treatments, as well as the importance of emotion regulation before, during and after pregnancy. Finally, expectations of IUI, UP-PP and motherhood myths were worked out.
Understanding emotions	What do our emotions tell us? Analysis of emotional experiences (FACE-TO-FACE GROUP)	This was applied following the UP original structure. Psychoeducation about emotions and their functions were presented using specific examples of the fertile treatment process.
Mindful Emotion Awareness	Living in the present to facilitate change (ONLINE GROUP)	This module was applied following the same contents described in the original UP.
Cognitive flexibility	My head doesn't help me: worries, doubts and fears (ONLINE GROUP)	Here the focus on thoughts was worked on. Women learned how to identify maladaptive thought patterns and how to be more flexible with specific fertility examples: <i>“Everybody gets pregnant except me”</i> , <i>“I will never get pregnant”</i> or <i>“I should be happier about my sister’s pregnancy”</i> .
Countering Emotional Behaviours	My Ladder of Opportunity: Behaviour guided by my goals and values (ONLINE GROUP)	We adapted this module by explaining Emotion Behaviours and changing them for Alternative Actions guided by their own goals. In this way, women thought about their values and planned some behaviours to be used when emotions were intense, and directed behaviours allowed them to continue with their personal goals. A problem-solving solution was added to help women to differentiate whether emotions were justified or not, and when they needed to be more flexible or evaluate their options and choose more appropriate ones at that time.
Recognizing Accomplishments and looking to the Future	Emotional release valves: maintaining reinforcing and meaningful activities and assertive communication (ONLINE GROUP)	During this session, we adapted the UP programming future pleasant activities to increase their well-being. As difficult conversations may emerge in the following months, women learned to anticipate them, and also learned assertive communication techniques to be used with family relations, friends and coworkers.

5.3.4 Instruments

The Mini-International Neuropsychiatric Interview (MINI; Sheehan et al., 1998; Ferrando et al., 1998): it evaluates 16 diagnostic categories according to the Diagnostic and Statistical Manual of Mental Disorders Fourth Edition – Text Revision (DSM-IV-TR; American Psychiatric Association [WHO], 2000) and the ICD-10 Classification of Mental and Behavioural Disorders (World Health Organization [WHO], 1993). The DSM-IV-TR version of MINI was used because it was the only one that psychologists had at the time the assessment was made. Questions about the presence or absence of the symptom were closed and had to be asked by the interviewer. The kappa value for interobserver reliability was around .75, while test-retest reliability was less than .75 for the DSM-IV-TR version.

Overall Anxiety Severity and Impairment Scale (OASIS; Norman et al., 2006; Osma et al., 2019): it evaluates frequency, intensity and interference of anxious symptomatology in the last week. It consists of five items that are rated on a Likert scale ranging from 0 (*I didn't feel anxious*) to 4 (*Constant anxiety*). The total score ranges from 0 to 20. Higher scores indicate greater anxious symptomatology severity. In the Spanish version, the cutoff point set in the clinical sample was 10 points (Osma et al., 2019). OASIS has good internal consistency ($\alpha = .87$; Osma et al., 2019).

Overall Depression Severity and Impairment Scale (ODSIS; Norman et al., 2006; Osma et al., 2019): it evaluates frequency, intensity and interference of depressive symptoms in the past week. It consists of five items with responses ranging between 0 (*I didn't feel depressed*) and 4 (*Constant depression*). Total scores, ranging from 0 to 20, indicate depressive symptomatology severity. In the Spanish version, the cutoff point in the clinical sample was 10 points (Osma et al., 2019). ODSIS displays excellent psychometric properties ($\alpha = .94$; Osma et al., 2019).

Positive and Negative Affect Schedule (PANAS; Watson et al., 1988; Sandín et al., 1999): it comprises 10 positive affect and 10 negative affect descriptors. These items are rated on a Likert-type scale ranging from 1 (*Nothing or almost nothing*) to 5 (*Very much*). Each scale scores from 10 to 50. Higher scores indicate a more positive or negative affect. In Spanish women, the normative data for positive and negative affect were mean = 32.52 ($SD = 8.46$) and mean = 20.61 ($SD = 7.73$), respectively (López-Gómez et al., 2015). The Spanish version has shown good internal consistency on both the positive ($\alpha = .87$) and negative affect ($\alpha = .89$; Sandín et al., 1999) scales.

The Fertility Quality of Life tool (FertiQoL; Boivin et al., 2011): it consists of 36 items that assess quality of life related to fertility treatments. Questions are rated on a 5-point Likert scale from 0 (*Very poor/very dissatisfied/always/an extreme amount/completely*) to 4 (*Very good/very satisfied/never/not at all*). The total score can be calculated by summing all 34 items, two FertiQoL items measure overall physical health and satisfaction with quality of life and are not

used in FertiQoL scoring. Total scores ranged between 0 and 136. Higher scores mean better quality of life. For the Spanish women undergoing ART, the mean FertiQoL score is 68.00 (range 46.00 - 87.00; Heredia et al., 2013). Good psychometric properties are found ($.72 \leq \alpha \leq .92$; Boivin et al., 2011).

Difficulties in Emotion Regulation Scale (DERS; Gratz & Roemer, 2004; Hervás & Jódar, 2008): it contains 28 items with 5-point Likert answers from 1 (*Never*) to 5 (*Always*) that estimate emotional dysregulation severity. Total scores range from 28 to 140. Higher scores indicate more difficulties in emotion regulation. In Spanish women, the normative data is mean = 59.10 ($SD = 17.50$; Hervás & Jódar, 2008). Internal consistency is high in the Spanish version ($\alpha = .74$; Hervás & Jódar, 2008).

Participants' satisfaction: an *ad hoc* questionnaire was developed to assess participants' satisfaction with five domains: assessments, online format, emotion regulation, general UP-PP satisfaction and UP-PP specific content satisfaction. Each question was rated from 0 (*Not satisfied/ not important at all/ any technological issues/ therapeutic alliance maintained/ not helpful*) to 10 (*Completely satisfied/ very important/ high technological issues/ therapeutic alliance not maintained/ completely helpful*).

5.3.5 Statistical analyses

Firstly, the participants' socio-demographic characteristics were explored. Given the sample distribution, the non-parametrical Mann-Whitney U test was performed to explore the differences in the socio-demographic and psychological variables between completers and non-completers.

Secondly, the evolution of the psychological variables (anxiety and depressive symptoms, affect, quality of life, emotion dysregulation) was analyzed according to the pre-post assessment and the pre- follow-up assessments (1-, 3-, and 6-month follow-ups). The non-parametric Saphiro-Wilcoxon test was used.

Finally, satisfaction with the emotion regulation program and the adherence rates were analyzed in order to assess users' acceptability. The quantitative analyses included satisfaction with assessments, satisfaction with online group sessions, satisfaction with the UP-PP and adherence rates (attended sessions compared to programmed ones). In addition, qualitative reports of women were presented. All the statistical analyses were performed with SPSS, version 22.0 (IBM Corp, 2013).

5.4 Results

5.4.1 Comparison of Completers and non-completers

At the beginning, eight women opted to participate in group sessions and then completed the pre-assessment. However, when the first program session began, two women dropped out, which left six women who attended the first individual program session. One additional woman got pregnant between the second and third program sessions and declined the option of continuing in the group.

Comparisons between completers and non-completers were made to determine if the socio-demographic or psychological variables could favour discontinuation with this prevention program. As observed in Table 5.2, there were no statistical differences at the pre-assessment between the women who completed all the sessions ($n = 5$) and those who discontinued ($n = 3$) for either sociodemographic or psychological status (all $p > .050$).

Table 5.2 Socio-demographic and psychological characteristics of completers and non-completers.

Variable	Completers ($n = 5$)	Non-completers ($n = 3$)	Comparison	
	Mean (SD); range	Mean (SD); range	U	p
Age	33.80 (4.09); 28 - 39	31.33 (2.31); 30 - 34	4.00	.291
Number of received IUI	2 (1.00); 1 - 3	1 (0.00); 1 - 1	3.00	.121
Time trying to get pregnant in months	19.5 (13.30); 6 - 36	20 (4.00); 16 - 24	5.50	.858
	N (%)	N (%)	χ^2	p
In a relationship	4 (80)	3 (100)	0.60	.439
Currently employed	5 (100)	3 (100)	-	-
More than 12 years of education	5 (100)	3 (100)	-	-
Infertility cause				
Female	1 (20)	1 (33.30)	0.16	.694
Unknown	2 (40)	2 (66.67)	0.47	.494
No male partner	2 (40)	0	-	-
Type of donation				
Partner	3 (60)	3 (100)	1.40	.237
Anonymous	2 (40)	0	-	-
	Mean (SD); range	Mean (SD); range	U	p
Anxiety symptoms	2.60 (2.88); 0 - 7	1.67 (2.08); 0 - 4	7.00	.878
Depressive symptoms	1.80 (2.49); 0 - 5	3.00 (4.36); 0 - 8	5.50	.525
Positive affect	38.40 (10.19); 27 - 49	35.00 (1.00); 34 - 36	6.00	.655
Negative affect	21.00 (8.86); 14 - 33	16.67 (3.21); 13 - 19	6.00	.653
Quality of life	91.25 (26.17); 58 - 120	101.67 (19.86); 86 - 124	4.50	.593
Emotion dysregulation	52.80 (20.92); 36 - 89	51.00 (25.24); 34 - 80	5.00	.453

5.4.2 Mood, affect, quality of life and emotion dysregulation results

Mood and affectivity over time

Table 5.3 shows the mean scores and standard deviations of the psychological variables assessed before the program (pre), at the end of the program (post) and at the three follow-up points (1-, 3-, and 6-month follow-ups).

Both anxiety and depressive symptoms remained relatively stable under the clinical cutoff set for the Spanish population (≥ 10) during all the assessments. Anxiety and depressive symptoms decreased from the pre- to the post-assessment, and then increased at the 1-, 3- and 6-month follow-ups. However, these differences were non-significant (all $p > .050$).

Positive affect remained from the pre- to the post-assessment, and slightly decreased at the follow-up assessments (1-, 3-, and 6-month follow-ups). However, as Table 5.3 shows, all the differences were non-significant (all $p > .050$). The women included in our study maintained a high positive affect at the end of the program and at the follow-up assessments. The mean score and standard deviation in our sample were higher than the normative data in all five assessments.

The changes in negative affect between the pre- and post-assessment, the pre- and 1-month follow-up and the pre- and 6-month follow-up were non-significant (all $p > .050$). However, statistically significant differences were found in the scores from the pre- to the 3-month follow-up ($Z = -2.03$, $p = .042$, $d = 0.75$), which means that women had lower negative affect at the 3-month follow-up than for the pre-assessment scores. Compared to normative data for Spanish women, our sample obtained higher scores for negative affect at the pre-assessment and the 1-month follow-up. In contrast, this tendency changed at the 3- and 6-month follow-up assessments, when our sample's mean score was lower than the scores reported by Spanish women with no clinical diagnosis of mental disorders.

Quality of life and emotion dysregulation over time

Quality of life tended to increase from the pre- to the post-assessment, and continued to rise at the 1-month follow-up. The lowest quality of life score was obtained at the 3-month follow-up, when most women had finished their fertility treatment without positive results. Finally, at the 6-month follow-up, women reported similar quality of life scores as they did at the pre-assessment. As seen in Table 5.3, none of these differences was significant (all $p > .050$). Moreover, women gave higher quality of life scores across all five assessments than those reported by other Spanish women undergoing ART.

Emotion dysregulation improved when the program ended (post-assessment) and remained relatively stable at the 1-, 3- and 6-month follow-ups. Once again, these differences were non-significant (all $p > .050$). Additionally, emotion dysregulation in our sample was lower

at the pre-assessment (mean = 52.80, $SD = 20.92$) compared to normative data for Spanish women (mean = 59.10, $SD = 17.50$), and this difference was also observed at the post-assessment and the 1-, 3- and 6-month follow-ups.

5.4.3 UP-PP acceptability

UP-PP satisfaction

Firstly, as observed in Table 5.4, high program satisfaction was indicated. Regarding assessment satisfaction, women reported that the questions were easy to understand and answer. Women generally trusted *Qualtrics* as a reliable tool to make assessments.

Secondly, women were asked about their satisfaction with the online emotion regulation program. High satisfaction was indicated for their participation in groups (i.e., interacting with other women during online sessions). Four participants were satisfied with both the face-to-face and online formats. One participant favoured the face-to-face format over the online sessions. As regards format preferences in a future emotion regulation program, three women preferred the group and face-to-face format, while two women did not mind the format.

Regarding emotion regulation in the fertility process, all the women considered it important to learn emotion regulation skills during IUI. The participants generally considered that the UP-PP helped them to manage their emotions and to solve their problems more adaptively. When they contemplated the whole program, they found it useful and would recommend it to women in a similar situation. The participants specifically rated all the skills they had learned in the six program modules. The highest scores were for learning about emotion components, thoughts identification and assertive communication.

Finally, qualitative reports were also analyzed. Some women reported that they would like to alternate individual and group sessions with couple sessions. Three women stated that they would prefer it if the program included longer sessions and more sessions during fertility treatment. Other comments included: *“I like the structure of sessions; sharing our week’s experiences, learning new skills and putting them into practice in real life”*, *“Now I realize the importance of being accompanied by women who are in the same situation”*, *“Thank you so much for thinking of us and seeing that emotion well-being is also important during fertility treatments”*, *“This program helped me to make an appropriate adaptation to not only fertility problems, but also to the pandemic situation”*.

5.4.4 Adherence rates

Six women started the emotion regulation program, and only one woman dropped out after the two initial sessions when she got pregnant. This means that 80% of them completed all six program sessions and the three follow-up assessments.

Table 5.3 Mean, standard deviation and changes across UP-PP in psychological variables.

Psychological variables	PRE		POST		1m FU		3m FU		6m FU		Comparisons							
											PRE-POST		PRE-1m FU		PRE-3m FU		PRE-6m FU	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Z	p	Z	p	Z	p	Z	p
Anxiety symptoms	2.60	2.88	2.20	1.48	4.40	3.05	4.00	3.08	5.40	2.88	-0.56	.577	-0.95	.343	-0.81	.416	-1.22	.223
Depressive symptoms	1.80	2.49	0.80	1.79	1.80	4.02	2.80	4.76	2.40	2.88	-1.34	.180	0.00	.999	-0.45	.655	0.00	.999
Positive affect	38.40	10.19	38.40	12.54	36.60	7.30	36.40	9.29	37.40	11.48	0.01	.999	-0.37	.715	-0.67	.500	-0.27	.786
Negative affect	21.00	8.86	18.00	8.97	22.40	8.20	15.80	4.09	19.00	5.52	-1.84	.066	-0.41	.686	-2.03	.042	-0.67	.500
Quality of life	91.25	26.17	95.00	11.40	100.25	13.10	85.75	17.44	91.50	18.84	-0.73	.465	-0.37	.715	-0.37	.715	-0.37	.713
Emotion dysregulation	52.80	20.92	44.00	7.11	44.60	11.44	45.00	8.80	45.20	11.58	-0.67	.500	-0.94	.345	-0.95	.343	-0.94	.345

Note: 1m FU = 1-month follow-up after the program ended; 3m FU = 3-month follow-up after the program ended; 6m FU = 6-month follow-up after the program ended.

Table 5.4 Unified Protocol Preventive Program satisfaction.

UP-PP evaluation	Mean; SD; range
Satisfaction assessment	
To what extent did you find the assessment questions through <i>Qualtrics</i> easy to understand?	8.00; 1.73; 5-9
To what extent did you find the assessment questions through <i>Qualtrics</i> easy to answer?	8.40; 1.95; 5-10
To what extent did you feel comfortable answering evaluation questions through <i>Qualtrics</i> ?	10
To what extent did you trust the adequate HANDLING of the information collected through <i>Qualtrics</i> ?	9.8; 0.44; 9 - 10
To what extent did you have technical difficulties using <i>Qualtrics</i> ?	0.20; 0.45; 0-1
To what extent were you able to contact the psychologists responsible for the program if you needed to?	10
Satisfaction online format	
To what extent did you feel you have been listened to during the online group sessions?	10
To what extent did you feel you have been able to participate actively in the online group?	9.40; 0.89; 8-10
To what extent were you able to interact with the other women in the group during the online sessions?	9.0; 1.00; 8 - 10
To what extent were you able to maintain concentration and attention during online sessions?	9.0; 1.00; 8 - 10
To what extent did you feel that the online system had affected the therapeutic alliance?	2.8; 2.68; 0 - 7
Emotion regulation during the fertility process	
To what extent did you feel that it is important to learn emotional regulation strategies during ART?	9.8; 0.45; 9 - 10
To what extent did you feel that the UP-PP helped you to regulate your emotions in an adaptive manner?	9.0; 1.73; 6 - 10
To what extent did the contents you learned helped you to solve your problems effectively?	9.8; 0.45; 9 - 10
General UP-PP satisfaction	
In general, how would you rate the quality of the program you received?	9.8; 0.45; 9 - 10
In general, how would you rate the usefulness of the program you received?	10
To what extent did this program cause you any discomfort?	0.60; 0.89; 0 - 2
Overall, how satisfied are you with the program?	10
Would you recommend this program to a family relative or friend in your situation?	10
UP-PP specific content satisfaction	
<i>To what extent did each skill learned in the UP-PP help you to adequately regulate your emotions?</i>	
Thoughts identification	9.4; 0.55; 9 - 10
Learning about emotion components, thoughts, physical sensations and behaviours	9.4; 0.89; 8 - 10
Assertive communication skills	9.4; 1.34; 7 - 10
Recognising emotional experiences	9.2; 0.83; 8 - 10
Cognitive flexibility	9.2; 0.84; 8 - 10
Emotional driven behaviours identification	9.2; 0.84; 8 - 10
Problem-solving skills	9.2; 0.84; 8 - 10
Mindfulness techniques	9.2; 1.30; 7 - 10
Opposed behaviours technique	8.8; 1.30; 7 - 10

0 = Not satisfied/ not important at all/ any technological issues/ therapeutic alliance maintained/ not helpful - 10 = Completely satisfied/ very important/ high technological issues/ therapeutic alliance not maintained/ completely helpful

5.5 Discussion

Due to the importance of emotion regulation during fertility treatments (Galhardo et al., 2013), and the fact that standardised protocols for EDs prevention are lacking, the objectives of the present study were to: 1) improve emotional dysregulation for the prevention of anxiety and depressive symptoms/disorders in women undergoing IUI; 2) assess their acceptability (e.g., satisfaction with and adherence rates to the program). Our results confirmed our hypothesis because no participant presented clinical symptoms or EDs at the end of the program or after the 6-month follow-up assessment, and negative affect continued at non-clinical levels. In addition, the scores for positive affect and quality of life remained, and emotion dysregulation decreased. Finally, the adherence rates and satisfaction reported by the women who participated in this study were both high. However, given the novelty of this program and its pilot nature, we broadly discuss our results below.

Firstly, as regards EDs prevention, the women at the pre-assessment presented no clinical anxiety and depression symptoms, and scores were similar at the post- and follow-up assessments. These preliminary results are encouraging because the participants had high distress levels (during the program and follow-ups) not only because of the IUI treatments itself (Cox et al., 2006), but because they did not achieve their goals while other women did, and also because the pandemic stopped treatments, which increased their uncertainty, along with other consequences of the pandemic (e.g. restricted mobility, health concerns, economic difficulties, etc.). Despite all these factors, the women participating in this brief prevention program were able to tolerate their intense emotional responses and adhered to their goals. Thus, we suggest that the brief UP-PP could be a useful preventive program to reduce the probability of EDs or clinical symptoms onset during IUI treatments.

Overall, affect seems an important factor to be considered in infertile populations given its relation to quality of life (Kiesswetter et al., 2020). Our results indicated that the brief UP-PP could help to maintain positive affect across IUI sessions. In addition, our preventive program brought about a significant decrease in negative affect, especially from the pre-assessment to the 3-month follow-up. While previous studies have found that negative affect increased in women with repeated ART failure (Coughlan et al., 2014), our result seemed to indicate that if women learned emotion regulation skills, they would be able to maintain lower negative affect scores even though they did not get pregnant, suffered miscarriages or fertility treatments were discontinued due to external events (i.e., COVID-19 pandemic). As previously suggested, programs based on improving cognitive coping skills could improve depressive symptoms as well as positive and negative affect (Kraaij et al., 2009). In light of our results, the brief UP-PP could serve this purpose.

The literature has recently focused on not only impaired psychological functioning, but also on maintaining and promoting a positive perception of quality of life as an intervention target (Gallagher et al., 2013). For this reason, our objective was to maintain the quality of life of the women undergoing IUI. Our results indicated an improved quality of life tendency from the pre- to the post-assessment and the 1-month follow-up, but a decreased tendency was observed at the 3-month follow-up. At the end of the assessments (at the 6-month follow-up), women reported comparable quality of life scores to those recorded at the pre-assessment. This is congruent with previous studies, which have proposed the UP as a useful intervention for this purpose (Sakiris & Berle, 2019). As we found in our study at the 3-month follow-up, quality of life maintenance is especially relevant at the end of IUI treatments. At this stage, women without a satisfactory result (i.e., not getting pregnant, miscarrying) should consider looking for other treatment options (i.e., IVF in public or private centres), which could lead to lower quality of life scores. For this reason, future studies should consider that if the prevention program finishes before IUI treatments end, a follow-up session must be held at around this time because it is when women need special support.

The latest variable included in our study was emotion dysregulation. Previous studies have found that emotional regulation processes are important for the psychological functioning of people with infertility (Galhardo et al., 2013). For this reason, we suggest that, throughout our brief adapted UP-PP, the women undergoing IUI can learn adaptive emotional strategies to better cope with stressful situations and the intense emotions related to them. Our results revealed an improvement in emotion dysregulation from the pre- to the post-assessment, and this improvement continued at the 1-, 3- and 6-month follow-ups. Despite these differences being non-significant, an improvement tendency was observed.

Regarding our second objective, and in line with previous studies (e.g., Martínez-Borba et al., 2019), high satisfaction with assessments made over Internet was herein noted. However, we should consider that the women in our study had a high level of education, which might imply that our sample found the questions easier to understand and respond than women with a lower level of education.

In addition, satisfaction with the online delivery format was also assessed. Despite the change in format delivery, the interaction between the participants, and also between the participants and the therapist, was not altered. Therefore, women reported having no trouble with maintaining the therapeutic alliance. As a result, only one woman preferred face-to-face sessions over online contact. Despite the advantages reported by online interventions, it would seem that some women still prefer face-to-face programs (Osma et al., 2020). This can be explained by it not being common for the Spanish public health system to offer such services with online tools.

Although women would consider a computer-based therapy as their top choice (Hantsoo et al., 2017), public services still rely on face-to-face interventions. So future efforts should promote the use of online interventions in public health settings.

Regarding the relevance of emotion regulation during IUI and satisfaction with the UP-PP, all the women agreed that emotion regulation during fertility programs is particularly important and rated the UP-PP as a high-quality program. They also considered it helpful to manage their emotions and to solve their problems. These results are congruent with previous studies, which have found high satisfaction levels with a brief preventive UP application in the online format (Sauer-Zavala et al., 2020), and suggest that an adapted UP-PP is well accepted by women undergoing IUI. It is really important because preventive programs need to be accepted and adjusted to the women's needs (Vázquez et al., 2014).

The women's qualitative reports were also included in this study. As previously mentioned, the women who participated in this group had experienced stressful situations associated with the pandemic situation (i.e., involuntarily discontinuing fertility treatments, economic difficulties, mobility restrictions, etc.). In relation to these additional difficulties, the women reported "we appreciate that you have continued the UP-PP during COVID-19 because we need it more than ever, especially because fertility treatments are discontinued". The women also valued being in contact with other women undergoing IUI "we need to talk about this with other women". These qualitative opinions indicated that the group format is extremely useful for facilitating peer support, symptoms validation and vicarious learning (Yalom & Leszcz, 2005). As previous research has found, peer support is fundamental in infertile populations and can be delivered via online devices (Grunberg et al., 2018). The women's quantitative and qualitative reports indicated their good acceptability of the online group sessions. Thus including the Internet group format in future prevention programs seems feasible and needs to be developed particularly in smaller settings, such as rural practices or small towns (Bennett & Glasgow, 2009) where healthcare access equity may not be guaranteed.

Previous UP online studies have found difficulties in maintaining the sample throughout sessions (45% of the participants completed the program; Sauer-Zavala et al., 2020). Our adherence rates were high because 80% of the women who started the program attended the whole program and all the follow-up sessions. While some studies indicate that depressive symptoms can result in discontinuing ART (Pedro et al., 2017), adjusting expectancies about IUI outcomes is important to appropriately adapt to negative results and to lower dropout rates. According to our experience, women do not abandon fertility treatments because they change their objective (i.e., no longer wanting to get pregnant), but because of emotionally driven behaviours (i.e., "I am sad and anxious, and I decided to stop fertility treatment to avoid experiencing these

emotions”). Hence the brief adapted UP-PP can help women to learn about emotionally driven behaviours and might prevent them from dropping out.

All these results highlight the preventive utility of the brief UP-PP for those women undergoing IUI. However, findings from this pilot study should be interpreted according to its limitations. This is a pilot study with a small sample size and no comparison group, which limits the generalisation of its results, and hypothesis testing should be considered preliminary and interpreted cautiously. Future efforts should be made to recruit a bigger sample size or to even conduct a randomised controlled study with a control group. While acknowledging the limitations of pilot studies, they are considered an essential step in a research project because they allow issues and deficiencies to be identified in the research protocol and instruments before conducting a larger study (Lancaster et al., 2004). In our case, it allowed us to perform a preliminary study on the “utility and acceptability” of implementing a preventive program in an HRU with an online format, and to develop a manualized protocol including the UP contents adapted to specific infertile women to be used in the next groups. It also allowed us to make changes according to the pilot study results. For instance, in line with the women’s reports and their experience in group sessions, we decided to add another session, which means that the future brief UP-PP will comprise seven sessions. In addition, and in accordance with women’s reports, future efforts should be made to include couples in preventive interventions.

Secondly, those women undergoing IVF were excluded, as this treatment was delivered in another public hospital and in a different city. Future studies should be conducted to prove whether the results herein obtained are replicable in other health services for women with infertility, such as IVF treatments. In addition, our participants were recruited in a public health unit so, once again, our results are not necessarily generalizable to all women and all services. Thirdly, our sample was entirely Spanish. New studies must be conducted with a culturally-sensitive approach to care, and must include migrant communities to study the intercultural efficacy and viability of this prevention program or if adaptations made with these relevant aspects must be contemplated. Finally, only completers provided satisfaction feedback on the UP program and format delivery, which could be interpreted as positive qualifications being overrepresented.

5.5.1 Conclusion

This is the first study to offer preliminary data about the mid-term (6-month follow-up) utility and acceptability of a brief adapted UP-PP application with an online group format in a public HRU. As recently suggested, moving face-to-face UP programs to the online context is urged (Sauer-Zavala et al., 2020) to reduce healthcare access disparities. The pandemic situation brought about the chance to implement this brief UP-PP online, which is especially relevant in our context because the women undergoing IUI usually work and might find it complicated to spend free time attending face-to-face sessions. In addition, the women who attended the HRU came from different places. The online program avoids travelling to group sessions. Overall, our preliminary outcomes suggest that a brief emotional regulation-based preventive program delivered with an online group format is feasible and useful for preventing clinical symptoms/EDs, and also for maintaining affect, quality of life and emotion regulation in women during IUI. The results of this pilot study also indicated that the women who attend an HRU should benefit from a multidisciplinary approach because it would take into account both their physical and emotional necessities. Healthcare providers and managers must consider these encouraging preliminary results to guarantee comprehensive health interventions for all the women attending this specific HRU.

Conflict of interest: The authors declare that they have no conflict of interest.

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CHAPTER 6.

FIRST STEP TO DESIGN A SMARTPHONE APPLICATION TO PROVIDE PSYCHOLOGICAL CARE DURING REPRODUCTIVE TREATMENTS: A QUALITATIVE STUDY INCLUDING PATIENTS' AND PROFESSIONALS' PERSPECTIVE

This chapter has been submitted as:

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6. First step to design a smartphone application to provide psychological care during reproductive treatments: A qualitative study including patients' and professionals' perspective

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6.1 Abstract

Objective: Internet-based interventions may help reduce the emotional burden of assisted reproductive techniques (ART) although some concerns regarding its use need to be addressed. Could patient-centered care help to improve Internet-based interventions? The aim of this study is to explore the opinion, preferences and recommendations of women undergoing ART and professionals who care for them about how to turn a face-to-face preventive psychosocial program into a mobile application. **Methods:** 6 patients and 12 professionals were involved in two semi-structured focus group. After the transcription, two independent researchers coded the information in order to extract Areas, Subcategories, and Categories discussed during focus groups. **Results:** analyses of the content indicated that both patients and professionals agree that m-Health should be developed by professionals, ensure data protection, combine online and face-to-face sessions, connect women with peers, offer the inclusion of the partner or a relative, include a variety of educational content, provide personalized content adapted to women's needs and provide fast responses and immediate feedback. **Conclusion:** these results may help to guide the development of m-Health programs. Exploring opinions and preferences of simultaneous stakeholders, patients and professionals is important because patient-centered care may help to increase users' satisfaction with psychosocial interventions and, therefore, improve adherence rates and treatment effectiveness.

Keywords: Assisted Reproductive Techniques, Focus group, m-Health, Patient-centered care, Prevention, Qualitative.

6.2 Introduction

Approximately 19.4% of women face fertility problems when trying to achieve a pregnancy [1]. Fortunately, assisted reproductive techniques (ART) such as intrauterine insemination (IUI) offer the possibility to get pregnant. Despite some women receive these ART with optimism and hope [2], it is also well documented that ART are also associated with high unpleasant emotions such as shame, frustration or impatience [2]. The emotional burden of ART may result not only in high suffering in women with elevated rates of anxiety and depressive symptoms [3], but also in the discontinuation of ART. Around 20% of women discontinue fertility treatment due to psychological factors [4] with depression being one of the best predictors of ART discontinuation [5].

Despite these alarming data, women rarely receive psychological care during ART [3,6]. Reasons for not consulting with fertility units and psychosocial care include not having access to specialized fertility health services, psychosocial programs are not offered to women, the high costs associated with these consultations, women choice of not to talk about their concerns and lack of skills and time on professionals to provide psychosocial assessments and referrals [7–9].

Different efforts have been conducted in the field of mental health to overcome the aforementioned limitations. E-Health, defined as health services delivered through the Internet [10], has emerged as a potential way to provide patients with psychosocial interventions with important advantages for the health care system, professionals and women. For instance, e-Health services may result in a reduction in the use of professional resources and, consequently, in a decline in the costs of psychological interventions [11,12]. Apart from this, Internet-based programs offer increased privacy and anonymity, availability and flexibility so women can use the platform according to their needs regardless of time and place [12–15]. Also importantly, couples with fertility problems, and especially women, use Internet mainly for seeking fertility-related information [16–19] so it seems feasible to include e-Health services in fertility care.

Different e-Health and m-Health programs (i.e., the use of mobile phone in medical care) have been applied in the reproductive care context [20]. Overall, randomized controlled trials found positive results in the reduction of general stress, fertility problems (e.g., sexual concerns, rejection of a childfree lifestyle and social concerns), depressive and anxiety symptoms [21–23]. Although Internet-based programs seem to be useful, feasible and acceptable, some issues regarding its integration in the current healthcare systems are still present.

It has been suggested that Internet-based interventions are not always effective in infertile populations [20,22]. Furthermore, dropouts are the main concern in psychological Internet-based programs [22,24,25] with attrition rates for infertile populations ranging between 16 and 68% [26]. Finally, professionals sometimes express skepticism and concerns regarding the inclusion

of e-Health in some professional activities (i.e., assessment and treatment) [27,28]. Professionals' attitudes towards e-Health applications are directly related to their intention to use and future recommendation [27] and this recommendation may motivate infertile couples to engage with Internet-based devices [16,29]. In this context, patient-centered online programs that better address women and professional's needs and preferences would help to improve adherence rates, programs efficacy as well as attitudes and intention to use it in women and professionals.

The most widespread definition of patient-centered care is the one provided by the Institute of Medicine (2001), which postulates that clinical decisions in the context of healthcare should take into account individual patient preferences, needs, and values. In the specific context of obstetric care, it has been recently stated that patient-centered care should encompass better the needs and priorities of women, encouraging respect, decision-making, therapeutic alliance, effective communication, social relationships, autonomy and empowerment [31,32]. It has been suggested that patients' experience of care may reduce the physical and emotional burden associated to ART [33]. Specifically, patient-centered care has been associated with an increased well-being, quality of life and satisfaction with treatment, but also with intention to comply with ART [5,34]. According to these positive results, there is no doubt that patient-centered care should be always guaranteed. For that purpose, women should be involved in the design of e-Health and m-Health services from the first step of its development [35]. However, it is important to consider that patients and healthcare providers sometimes disagree when asked about perceptions of patient-centered care [33] so it is also important to include health professional perspectives [36].

In light of this information, the aims of the present study are (a) to explore the opinion, preferences and recommendations of women undergoing ART about how to convert a face-to-face preventive psychosocial program into a completely self-administered mobile-based intervention and (b) to explore professionals' opinions, preferences and recommendations on how to include m-Health in the reproductive care of women undergoing ART. All this information will guide authors in the adaptation of a face-to-face psychological prevention intervention to a mobile application-based intervention.

6.3 Methods

6.3.1 Participants

Participants in this study were patients undergoing ART at the General University public Hospital from Castellón who have already participated in a pilot psychological prevention program called "Unified Protocol Preventive Program (UP-PP)" and also health professionals who care for them. Consequently, participants' sample size was determined by sample convenience.

In a first attempt, 20 women were contacted. Two of them could not engage in the study due to schedules difficulties. The patients' subgroup was composed by 6 women (mean age = 36.33; $SD = 4.46$) who were undergoing IUI. Patients had been undergoing ART during 6–36 months (mean = 22.17; $SD = 9.89$). Most women were in a heterosexual stable relationship ($n = 5$) while one was single. None of them had previously had children. All women had received a previous UP-PP before their participation in the focus group session. The Unified Protocol is a psychological intervention based on Cognitive and Behavioral therapy (CBT) principles developed by Barlow et al. [37] which focusses on improving emotion regulation skills to address emotional disorders (i.e., anxiety, depression and related disorders) and its comorbidity in a wide range of populations and conditions [38]. In our adapted version, the UP-PP was composed by 6 synchronic videoconference sessions delivered in group format once a week (for a detailed description of the program see chapter 5).

The professionals' subsample comprised of 12 women (mean age = 43.25, $SD = 9.24$) who provided healthcare to women undergoing ART. Of these, 6 women specialized in obstetrics and gynecology, 2 were nurse aides, 3 were psychologist and 1 was a psychiatrist. Years of expertise range from 5 to 25 years (mean = 12.00; $SD = 7.95$). Most professionals work in public hospitals ($n = 8$) followed by a public university ($n = 3$) and private hospitals ($n = 1$).

6.3.2 Procedure

The Ethics Committee of the General University Hospital from Castellón approved this study and all its procedures. The present work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki).

Before the focus groups, all participants were telephoned by the research team (V.M.B, PhD student and L.A.P, PhD) to assess their interest in participating in this study. Women who agreed to participate received an email with an information sheet and a detailed description of the study and its procedures. All women gave written informed consent and agreed to participate in the online focus group.

A focus group is a qualitative research method that consist of semi-structured interviews with a reduced number of participants that share a common background or intervention [39]. It allows to explore participants' thoughts and feelings to better understand their perspective about a particular subject [39]. In this study, two separate focus groups were conducted (one for patients and one for professionals, interviews were not repeated). Both focus groups lasted 2 hours each and were mediated by the same researcher (J.O., PhD), who is a male associate professor in a public University with experience in conducting focus groups. The mediator did not have previous contact with participants in the focus groups. Focus groups were conducted online through the platform *Cisco Webex* which can be safely used in a medical context, complies with the Health

Insurance Portability and Accountability Law (Ley de Portabilidad y Responsabilidad del Seguro Médico; HIPAA) and has a security certificate (ISO/IEC 27001:2013).

At the beginning of the focus group, the mediator briefly introduced himself, his research interest, the aim of the study and the rules for the development of the session. Questions and doubts about the study were solved. Two engineers were connected during the focus groups, with neither camera nor microphone activated; they did not participate in the interview and only took notes about the most relevant recommendations for app design. Focus groups were video recorded in order to later analyze participants' responses. After the focus groups, researchers revised that all records were correct. As no problem with the recording was detected, no additional field notes were taken after the interview. Despite all women having agreed to participate and consented to the recording of the session, for ethical purposes, after the transcription of the talks, the recordings were deleted.

6.3.3 Measures

Two semi-structured *ad hoc* interviews were developed to explore patients' and professionals' use and opinions about apps as well as preferences and recommendations for m-Health technology development. First, the researcher team discussed the principal themes that would be addressed during the focus groups. Then, questions were elaborated by the leader of the study (J.O.) to cover these themes. The first draft of these interviews was revised by the entire research team, trying to maintain the questions to the minimum possible to address all themes. The final version of the interview was revised by external professionals with experience in focus groups development (see Appendix 6.1).

6.3.4 Data analysis

First, the Statistical Package for Social Sciences (SPSS) software was employed to analyze sociodemographic characteristics of the sample.

Next, qualitative data was analyzed with the MAXQDA software [40]. A recent standardized approach to qualitative content analysis of focus groups was followed to conduct the analysis of the content [41]. First, a word for word transcription of the recordings was carried out. The transcripts were not returned to participants. Second, to ensure accuracy, content analyses were conducted by two independent female researchers in a public University (V.M.B and L.A.P). Both researchers were previously trained in the use of qualitative research for social sciences. In the first step, researchers highlighted phrases that captured the main ideas discussed as a response to research questions. Then researchers assigned codes to them according to pre-specified content area. Content areas were then grouped according to their similarity in Subcategories. The same procedure was followed to group similar Subcategories in general Categories. A hierarchical

structure was followed from specific units (Areas) to more general classifications (Categories). Thus, general Areas, Subcategories and Categories were finally presented. Participants do not provide feedback on the findings. Data saturation was not possible due to convenience sampling.

After this classification, an investigator triangulation was performed [42]. The two aforementioned researchers discussed the coding system (draft version) and consulted with an additional supervisor to establish the final classification (final version). As a final step, to analyze the inter-rater reliability between the first draft and the final version of the data extraction, a Cohen’s Kappa was calculated. Additionally, agreement between patients and professionals was explored. Proportion of Areas that were discussed by both groups as well as the proportion of Areas discussed just by one of the subsamples (patients or professionals) were presented. The consolidated criteria for reporting qualitative research (COREQ) [43] was followed to report results derived from this study (see Appendix 6.2).

6.4 Results

6.4.1 Areas, Subcategories and Categories extracted

Extraction of Areas, Subcategories and Categories for the patients’ focus group can be consulted in table 6.1. As observed in table 6.2, good agreement between researchers (from data extraction draft to final version) was obtained.

Table 6.1 Extraction of Areas, Subcategories and Categories for patients’ focus group ($n = 6$).

Category ($n = 2$)	Subcategory ($n = 13$)	Description	Areas ($n = 69$)
ICTs use.	*Devices.	Technological devices used in daily tasks.	Smartphone (6) Tablet (2) Computer (4)
	Apps use.	Mobile applications used in routine activities and used for health improvement.	Fertility (3) Nutrition (4) Mental health (4) Physical health (4) Payments (3) Languages (1) Microsoft (1) Social media (1) Healthcare assistance (1) Driver’s license (1)
m-Health advantages.		Benefits from using mobile applications to provide psychological care.	Accessibility (6) Time (2) Ease (2) Stigma (2) Cost (1)
m-Health concerns.		Worries regarding the use of m-Health.	Development (1) Data protection (1)
Face-to-face benefits.		Positive aspects of face-to-face therapies with professional interaction.	Human contact (3) Reliability (1) Non-verbal information (1)

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	m-Health efficacy.	Opinion about the usefulness of m-Health solutions.	Symptoms' severity (5) Acute moments of discomfort (3) Personal characteristics (3) Engagement (1)
App design	Format.	Aesthetic aspect of the application. Elements that should include a mobile application.	Videos (1) Figures (1) Letters-numbers (2) Music-color (2) Virtual assistant (1) Schematic (1) Smartwatch (1)
	Contents.	Intervention components that should be included in a m-Health preventive program.	Forum (5) Partner (4) ART (2) Daily activities (5) Emotions (2) Psychological abilities (5) Professionals' training (3) Theoretical-practical (2) Similar cases (1) Myths (1)
	Personalization.	Mobile applications designed to better meet users' needs.	Treatment personalized to ART (4) Treatment personalized to women's needs (3) Module flexibility (2)
	Applications uses.	Suggestions for different uses of the app.	Complement (1) Professionals' contact (1) Prevention (1)
	Barriers.	Obstacles for providing mental health-related programs via the use of the app.	Perceived utility-stigma (2) Professionals' involvement (2) Complexity (1) Motivation (1) Quality (1)
	Adherence.	Improvements in the design of the app to reduce dropout rates.	Ease (2) Personalized (1) Fast (1) Feedback and gamification (3) Peers comparison (2) Notifications (2) Appearance (2) Fun (2) No malfunctions (1) Unblock modules (1) Separate videos (1) Name (1) Professionals' involvement (1)
	Intention of use.	Comments regarding whether apps could be used by stakeholders.	Recommendation (5)

Note: * Subcategory extracted only on patients' focus group.

Table 6.2 Inter-rater reliability between the first draft and the final data extraction.

Focus group	Areas		Subcategories		Categories	
	% agreement	K	% agreement	K	% agreement	K
Patients	92.69	0.73, substantial	86.66	0.42, moderate	75.00	0.50, moderate
Professionals	87.50	0.50, moderate	75.00	0.50, moderate	81.25	0.45, moderate

K = Cohen's Kappa.

Table 6.3 shows the results of Areas, Subcategories and Categories extractions for the professionals' focus group. As shown in table 6.2, acceptable agreement between the two aforementioned phases was obtained.

We calculated the agreement between patients and professionals in Areas mentioned during the focus group. Thirty point forty-three per cent of Areas proposed by participants were also mentioned by professionals and 47.73% of Areas discussed by professionals matched those mentioned by participants. An extensive explanation of these results will be presented below.

Table 6.3 Extraction of Areas, Subcategories and Categories for professionals' focus group ($n = 12$).

Category ($n = 2$)	Subcategory ($n = 13$)	Description	Areas ($n = 44$)
ICTs use.	Apps use.	Mobile applications used in routine activities and used for health improvement.	Fertility (1) Drugs (2) Eating disorders (1) Postpartum depression (1) Breastfeeding (1)
	m-Health advantages.	Benefits from using mobile applications to provide psychological care.	Accessibility (5) Time (1) Ease (2) Learning (3) Reliability (1)
	m-Health concerns.	Worries regarding the use of m-Health.	Development (3) Human contact (2) Updates (1)
	Face-to-face benefits.	Positive aspects of face-to-face therapies with professional interaction.	Human contact (2)
	m-Health efficacy.	Opinion about the usefulness of m-Health solutions.	Useful (3)
App design.	Format.	Aesthetic aspect of the application. Elements that should include a mobile application.	Video (2) Icons (1) Interactive (2) Subtitles (1) Timetable (1)
	Contents.	Intervention components that should be included in a m-Health preventive program.	Forum (11) Partner (3) ART (8) Daily activities (5) Emotions (5) Staff / healthcare environment (5) Antecedents (1)
	Personalization.	Mobile applications designed to better meet users' needs.	Treatments personalized to ART (3) Treatment personalized to women needs (5)
	Application uses.	Suggestions for different uses of the app.	Complement (5) Professionals' contact (1)
	Barriers.	Obstacles for providing mental health-related programs via the use of apps.	Perceived utility (1) Socioeconomic (3)

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Adherence.	Improvements in the design of the app to reduce dropout rates.	Ease (3) Personalized (2) Fast (2) Feedback (2) Useful information-gadgets (2) Physical-Psychological (2) No charge (1)
*App benefits.	Benefits of receiving psychological care during ART.	Wellbeing (2) Reduce ART Dropouts (1)
Intention of use.	Comments regarding whether apps would be used by stakeholders.	Recommendations (4) Women's acceptance (9)

Note: * Subcategory extracted only on professionals' focus group.

6.4.2 Participants' reports

Textual reports of patients and professionals can be consulted in Appendices 6.3 and 6.4. Regarding Information and Communication Technologies (ICTs) use and opinion (Category 1), both subsamples, patients and professionals, used apps related to the fertility process. Additionally, patients mentioned the use mental health applications ($n = 4$), and professionals used applications related to the prescription of drugs ($n = 2$).

In relation to participants' opinion about the use of ICTs for mental health interventions, most of them, in both focus groups, stated advantages were time, accessibility and ease. Patients also highlighted m-Health helping to reduce the stigma ($n = 2$) and reducing costs ($n = 1$). Professionals also perceived as a benefit of m-Health increasing in learning ($n = 3$). The development of technologies was reported as a concern during both focus groups. An additional fear reported by patients was data protection ($n = 1$) while professionals expressed concerns about losing human contact ($n = 2$) and technology updates ($n = 1$). One of the benefits of using a face-to-face format for psychological interventions most mentioned in both focus groups was human contact.

In general terms, professionals had positive attitudes towards the usefulness of these applications ($n = 3$). However, patients commented on some factors influencing m-Health efficacy. Broadly speaking, patients believed that m-Health could serve to support women in simple and specific situations of emotional suffering whereas complex treatments and severe mental health conditions would require face-to-face interventions.

With respect to App design (Category 2), it seems that patients and professionals would appreciate it if the format of the app could include visual aspects, namely videos and figures or icons. Patients mentioned the inclusion of letters-numbers ($n = 2$) and music-colors ($n = 2$) but professionals were more interested in including interaction ($n = 2$), subtitles ($n = 1$), or a timetable ($n = 1$). With regards to content development, the most discussed Areas in both focus groups were those related to social support (forums and partner inclusion), information about ART, daily

activities and emotional assessments. Patients expressed their desire to also include contents about learning psychological abilities ($n = 5$; problem solving, cognitive flexibility, positive mood) and professionals training ($n = 3$). The professionals focus group suggested the inclusion of information about staff/healthcare environment ($n = 5$) and antecedents' assessment ($n = 1$).

Some advice about how to personalize treatments was suggested, with a consensus between patients and professionals regarding the need to personalize psychological interventions both according to ART stage and individual women's needs. All participants considered m-Health as a potentially useful tool to be used as a complement to face-to-face interventions with a therapist. Patients added that m-Health could provide preventive interventions ($n = 1$).

Some barriers for using the App in a health context also emerged, participants in both focus groups reported that not feeling engaged with the App could be a barrier for its use. Patients also believed that lack of professionals' involvement could act as a barrier for m-Health implementations ($n = 2$). Socioeconomic barriers ($n = 3$) for the use of mobile applications were mentioned by professionals. As a solution to increase engagement with the App, patients and professionals recommended designing personalized, fast and easy-to-use applications as well as providing women with feedback. Additional recommendations to increase adherence mentioned by patients were showing information to allow peer comparison ($n = 2$) or sending notifications ($n = 2$). Suggestions from the professionals were to provide useful information and gadgets ($n = 2$), include both physical and psychological content ($n = 2$) and design a free-of-charge app ($n = 1$).

Finally, all comments regarding intention of use indicated that women would recommend the use of applications that include the aforementioned elements. Professionals suggested that m-Health could help patients to increase their wellbeing ($n = 2$) and reduce ART dropouts ($n = 1$). However, professionals did not reach an agreement with respect to women's intention of use of this technology-based solutions. Some professionals argued that women's acceptability of applications and its elements (i.e., forums) could be high, but others remained skeptical and explained that adherence rates when these devices are used are generally low.

6.5 Discussion

The main aim of this study was to explore the opinion, preferences and recommendations of patients and healthcare providers about how to develop m-Health to be used in the context of reproductive care.

As expressed in our focus group, and consistent with previous findings [18,44], both women and professionals use mobile applications for fertility-related issues. It is relevant in terms

of feasibility and may facilitate that both parties involved agree in the collaborative use of m-Health for fertility-related issues.

This widespread use of mobile applications can be explained by the perceived advantages of ICTs. Patients and professionals agree that m-Health is an easy and accessible solution that offers increased frequency of sessions and reduces time during consultations. Incorporating technologies may benefit a greater number of women accessing psychological care as frequently as they need, with no limitations associated with patients and professionals' schedules.

While acknowledging the benefits of ICT-based programs, participants also reported some concerns about the use of m-Health solutions. Similar with previous studies [36] patients and professionals in our focus groups were worried about app development. Future work should be undertaken to better develop, test, validate and disseminate evidence-based mobile applications [45] and to ensure that sensitive information is collected in a safe context and is not transferred to external parties [36].

Regarding m-Health efficacy, patients in our study believe that m-Health could serve to reduce acute moments of emotional discomfort but suggest that severe mental health conditions should be addressed in face-to-face sessions. This model of care is not new in psychology. In the context of reproductive care, it has been proposed that self-help programs may help to address the stress experienced by most women while more intense clinical programs could be offered to those likely to benefit from them [22]. Attending to our results, online preventive programs should be offered to all women starting ART and subsequent psychosocial assessments could be used to monitor women's progress and recommend additional, more intensive interventions when needed.

Patients in our focus group also highlighted that human contact is one of the most substantial benefits of face-to-face interventions. Not surprisingly, patients and professionals consider that m-Health should be understood as a complement to face-to-face consultations. As digital technologies have been proposed to be a complement in healthcare fertility services [46], programs offered in Human Reproduction Units should rely on technology-based interventions that include regular contacts with a therapist (i.e., blended programs), which may increase participants' adherence and satisfaction.

With regards to recommendations about how to adapt the UP-PP to be completely self-administered (Category 2), the most discussed content in both focus groups was the inclusion of social support, for example throughout forums and partner support. Patients undergoing ART usually request to be in contact with other peers and professionals [29,47] although concerns with misinformation from social media has been also reported [48]. As a solution, and as previously recommended by literature [18,36], professionals in our focus group suggested that the forum could be voluntary, anonymous and mediated by a professional. Regarding partner inclusion, a

recent study revealed that male spouses are motivated to participate in an Internet-based fertility intervention [49] so psychosocial programs should offer the possibility to engage the partner if the woman agrees to it. Also importantly, given that almost half of the women who gave birth over the last few years in Spain were unmarried [50], the alternative inclusion of a friend or a relative in the program should be considered.

Apart from social support, patients and professionals would like the App to provide information about ART procedures and daily activities (i.e., nutrition or exercise). Previous studies have found that some women perceive they do not have enough information about ART [2,51]. According to patients' comments and previous findings [52], mobile applications can be a highly useful tool to provide this information. To better meet patients' and professionals' demands, this educational information should be accompanied by training in psychological abilities (i.e., problem solving, cognitive flexibility or pleasant activities) that help patients to better manage unpleasant emotions during ART.

The women also provided some suggestions about App aesthetics; patients and professionals expressed the need to include visual aspects. Previous studies have found that App users appreciate the App when includes elements as color, music, graphs and charts [36]. These results indicate that not only the content should be designed carefully, but also the features of the App. Given that interface personalization seems to be important to increase App usage [53], the app could offer a variety of colors and formats to allow users to select the most convenient choice according to their preferences.

Related to this idea of App personalization, participants in our focus group also suggested that App content should be adapted according to the ART stage and women's personal needs. Integrating a feature suggested by our participants, a timetable, may help to monitor ART stages and emotional status and offer specific psychological abilities according to the assessment outcomes.

Despite the possibility of including all these elements in an App, participants also mentioned some barriers for its use. Consistent with previous findings [29,54], both focus groups mentioned that women who feel well in themselves would not perceive a need to participate in a preventive psychological intervention. Participants also stated that women who were suffering and logged into the App, would not want to answer questionnaires. As a solution, the participants proposed that the App offers personalized feedback and a fast response when detecting high suffering.

The results of this study must be understood in the context of some limitations. First, while focus groups may present numerous advantages when personal experiences need to be explored, they also have some limitations. Focus groups cannot generate statistical explanations

or predictions and sample size is generally small and not representative [55]. The small sample size, especially for the patients' subgroup, may also limit the generalizability of the results. Convenient sample selection was required in our study because we were interested in exploring the opinion of women who have participated in a previous preventive psychological program so no additional patients focus groups, that could have facilitated data saturation, could be conducted. For the same reason, as the partner was not included in the aforementioned program they could not participate in the focus group. Given the valuable information that the partner could provide to design self-applied interventions in the context of ART, future studies should explore their opinion and preferences and integrate it in intervention design. Second, our sample of patients were receiving IUI in a public hospital. This may limit the generalizability of our results, as women undergoing ART in private centers may not have the same needs. For instance, psychological care could be more easily offered in private centers.

6.5.1 Practice Implications

While acknowledging the aforementioned limitations, the present work contributes to previous literature in many aspects. First, to the best of our knowledge, this is the first study that explores the opinions and preferences of women undergoing ART and professionals who care for them to develop an UP-PP to be delivered through a mobile application. The inclusion of both parties that are simultaneously involved in ART, women with fertility problems and professionals who care for them, is an important innovation because patients and healthcare providers are not always involved in the development of mental health mobile applications [56,57]. Second, the results of this study will help to guide the development of a mobile application which helps to disseminate a psychological intervention that has previously demonstrated its usefulness in emotional disorder prevention during ART. Third, including the users' perspective may help to overcome the barriers of previous m-Health solutions increasing usability and users' satisfaction and, therefore, adherence rates and effectiveness.

6.5.2 Conclusions

In light of the recommendations analyzed in this qualitative study, fertility m-Health solutions should: (a) be developed by professionals; (b) ensure data protection; (c) be regularly updated; (d) propose a step model of care; (e) offer blended interventions, combining online and face-to-face sessions; (f) connect women with peers; (g) offer the inclusion of the partner or a relative; (h) include a variety of educational content (i.e., ART, daily activities, emotion regulation, etc.); (i) provide visual information and personalized interface; (j) be adapted to women's needs (according to ART stage and personal needs); (k) provide fast responses and immediate feedback.

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Statement: “I confirm all participant identifiers have been removed or disguised so the participant described are not identifiable and cannot be identified through the details of the story”.

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Appendix 6.1

Semi-structured interviews used during focus groups sessions.

- The patients' interview was composed by 15 questions which can be grouped in 2 categories:
 - o Patients' use of and opinion about mobile applications (10 questions): What kind of technologies do you usually use?; Do you know how much time you spend every day on you mobile phone?; What mobile applications do you usually employ?; Do you have any mental health mobile applications downloaded on you mobile phone?; What do you know about psychological treatment delivered through mobile applications?; Do you think it works?; Do you have any experience with this kind of program?; What differences do you find between face-to-face and mobile-based interventions?; What advantages and disadvantages do you perceive?; Do you think that these interventions could be complementary?
 - o Patients' recommendation to adapt a psychological program to m-Health (5 questions): What elements do you think are needed to develop effective mobile applications?; What are your recommendations to develop a mobile application that applies the UP-PP?; Would you recommend the use of a mobile application to receive the UP-PP to people who are at risk of suffering anxiety or depressive symptoms?; Would you download this mobile application if you needed it?; Do you have any ideas about how to prevent mobile application users from dropping out once they have installed the application?

- The professionals' interview had very similar questions to those included in the patients' interview. It also had 15 questions grouped in 2 different categories:
 - o Professionals' use of and opinion about mobile applications (7 questions): What experience do you have with the use of Information and Communication Technologies (telephone, videoconference, web pages, mobile applications, etc.) for psychological intervention delivery?; What do you know about the specific use of mobile applications to provide psychological care?; Do you think it could work?; Do you have any experience with this kind of program?; What differences do you find between face-to-face and mobile-based interventions?; What advantages and disadvantages do you perceive?; Do you think that these interventions could be complementary?

- Professionals' recommendation to adapt a psychological program to m-Health (8 questions): What elements do you think are needed to develop effective mobile applications?; What are your recommendations to develop a mobile application that applies the UP-PP?; What would you like this application to include to facilitate your work with your patients?; Would you recommend the use of a mobile application to receive the UP-PP to the women you care for?; Do you offer it to all women?; Do you think that there is a specific patient profile that could be unsuitable to recommend to them the use of the mobile application?; Overall, how do you think women would receive this mobile application-based program?; Do you have any ideas about how to prevent mobile application users from dropping out once they have installed the application?

Appendix 6.2

Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist.

Domain 1: Research team and reflexivity		
<i>Personal characteristics</i>		
Topic	Guide question /Description	Page No.
1. Interviewer/ facilitator.	Which author/s conducted the interview or focus group?	130
2. Credentials.	What were the researcher's credentials? E.g. PhD, MD.	130
3. Occupation.	What was their occupation at the time of the study?	130
4. Gender.	Was the researcher male or female?	130
5. Experience and training.	What experience or training did the researcher have?	130, 131
<i>Relationship with participants</i>		
6. Relationship established.	Was a relationship established prior to study commencement?	130
7. Participant knowledge of the interviewer.	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research.	131
8. Interviewer characteristics.	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic.	131
Domain 2: study design		
<i>Theoretical framework</i>		
9. Methodological orientation and Theory.	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis.	131
<i>Participants selection</i>		
10. Sampling.	How were participants selected? e.g. purposive, convenience, consecutive, snowball.	129-130
11. Method of approach.	How were participants approached? e.g. face-to-face, telephone, mail, email.	130
12. Sample size.	How many participants were in the study?	130
13. Non-participation.	How many people refused to participate or dropped out? Reasons?	130
<i>Setting</i>		
14. Setting of data collection.	Where was the data collected? e.g. home, clinic, workplace.	130
15. Presence of non-participants.	Was anyone else present besides the participants and researchers?	131
16. Description of sample.	What are the important characteristics of the sample? e.g. demographic data, date.	130

Data collection

17. Interview guide.	Were questions, prompts, guides provided by the authors? Was it pilot tested?	131, Appendix 6.1
18. Repeat interviews.	Were repeat interviews carried out? If yes, how many?	130
19. Audio/visual recording.	Did the research use audio or visual recording to collect the data?	131
20. Field notes.	Were field notes made during and/or after the interview or focus group?	131
21. Duration.	What was the duration of the interviews or focus group?	130
22. Data saturation.	Was data saturation discussed?	132, 139
23. Transcripts returned.	Were transcripts returned to participants for comment and/or correction?	131

Domain 3: analysis and findings

Data analysis

24. Number of data coders.	How many data coders coded the data?	131
25. Description of the coding tree.	Did authors provide a description of the coding tree?	131-132
26. Derivation of themes.	Were themes identified in advance or derived from the data?	131-132
27. Software.	What software, if applicable, was used to manage the data?	131
28. Participant checking.	Did participants provide feedback on the findings?	132

Reporting

29. Quotations presented.	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. participant number.	Appendix 6.3 and 6.4
30. Data and findings consistent.	Was there consistency between the data presented and the findings?	132-136
31. Clarity of major themes.	Were major themes clearly presented in the findings?.	132-136
32. Clarity of minor themes.	Is there a description of diverse cases or discussion of minor themes?	132-136

Appendix 6.3

Extraction of Areas, Subcategories and Categories for patients' focus group (n = 6) including textual examples.

Category (n = 2)	Subcategory (n = 13)	Description	Areas (n = 69)	Examples
ICTs use.	*Devices.	Technological devices used in daily tasks.	Smartphone (6) Tablet (2) Computer (4)	"I use a smartphone, an iPad, a laptop and a computer" (Pa.1), "I also use a smartphone, an iPad, a laptop and a computer" (Pa.2), "I use a smartphone and a computer" (Pa.3), "I use a smartphone, a laptop and a computer" (Pa.4).
	Apps use.	Mobile applications used in routine activities and used for health improvement.	Fertility (3) Nutrition (4) Mental health (4) Physical health (4) Payments (3) Languages (1) Microsoft (1) Social media (1) Healthcare assistance (1) Driver's license (1)	"I have downloaded too many applications. For fertility, there are applications to know when you are going to have your period. Applications to learn English, I usually download a lot of apps because of my job. There are many applications, to pay for goods, to pay the rent, for your driver's license" (Pa.1), "I carry my job on my mobile phone, I have all the Microsoft apps, exercise, fertility, medical insurances, to make payments. I use my mobile phone to fulfill all my responsibilities, without it I would die. I even have the bar of my job" (Pa.2), "I have social media, receipts, fertility" (Pa.3), "I have an app that notifies me about daily activities" (Pa.5), "I have the scale connected to my mobile" (Pa.3), "I also have Radar COVID app" (Pa.2), "COVID app is also important" (Pa.1), "I had one that included challenges related to drinking water, meditation, healthy food, relaxation, etc. you can choose challenges and it offers motivational sentences, I do not use it so long" (Pa.4), "The smartwatch sends reminders to take deep breaths, it notifies you of your heart rate, etc." (Pa.5), "I have a fear of flying and I used a mobile application to help me during the take-off, it works without Internet connection and it recommends breathing or visualizing images to focus your attention" (Pa.1).
	m-Health advantages.	Benefits from using mobile applications to provide psychological care.	Accessibility (6) Time (2) Ease (2) Stigma (2) Cost (1)	"During reproductive treatments, we have new doubts every week, you can be guided with the app as it is always available; with a face-to-face therapist, you need an appointment with the psychologist or psychiatrist and this is not always possible. With the app you can have sessions more frequently" (Pa.4), "One advantage is the availability, it no longer depends on people's schedules" (Pa.1), "It could be always available" (Pa.5), "If a mobile application offers people some tips, it could be more accessible" (Pa.4), "You can reach more people and not only a small group of participants" (Pa.1), "People recording videos could say a lot of things that could be understood by many people" (Pa.5). "Time consultations are limited, the app could help to provide important information that cannot be offered in face-to-face interventions" (Pa.5), "It could be more accessible in terms of time" (Pa.4). "Some exercises, like problem solving, that could be difficult to do, could be more easily done by a mobile application, I would do it throughout an app" (Pa.1), "We use Internet a lot, if we have everything in a mobile application it would make our life easier" (Pa.2). "It is easier because with an app there are no taboos, it is more difficult to call your health center because you have to explain that you have a problem, with the app you avoid this" (Pa.5), "It could be great because with the app you can overcome this barrier and feel free to express your emotions and concerns" (Pa.4). "It is more affordable from a financial point of view. You can save money because psychological treatments are expensive" (Pa.4).
	m-Health concerns.	Worries regarding the use of m-Health.	Development (1) Data protection (1)	"I will trust an app depending on who has developed it. I will trust a mobile application if there is support behind its development" (Pa.5). "Free apps or use a lot of publicity or they give your data to third parties. For me, it is so important to know who can access my data in such a sensitive and private matter as assisted reproduction" (Pa.1).

Face-to-face benefits.	Positive aspects of face-to-face therapies with professional interaction.	Human contact (3) Reliability (1) Non-verbal information (1)	<p>“Face-to-face interventions are more personal. I needed to have contact with a therapist who helps me” (Pa.6) “If you want psychological treatment, you prefer a person who interacts with you and you can feel is listening to you” (Pa.1), “During therapy you need someone who guides you and tells you if you are doing well” (Pa.2).</p> <p>“Face-to-face interventions are more reliable” (Pa.6).</p> <p>“In face-to-face interactions, therapist can see the patients’ non-verbal language and infer what is happening” (Pa.6).</p>
m-Health efficacy.	Opinion about the usefulness of m-Health solutions.	Symptoms’ severity (5) Acute moments of discomfort (3) Personal characteristics (3) Engagement (1)	<p>“It depends on the symptoms’ severity. If it is a complex treatment, you may appreciate having therapist support to guide you and provide feedback on whether you are doing it well. For a complex treatment, I need more help” (Pa.2), “If it is something more difficult or if you want to have a treatment you may prefer a person who interacts with you and is listening to you” (Pa.1), “It depends on how severe the case is” (Pa.4), “It is not helpful for everything, if it is a severe condition you should have a more urgent way to receive psychological care” (Pa.5), “With an app you are the one who uses the app. I do not know whether a psychological problem could be treated by a person who is not a psychologist. I need a therapist who helps me to overcome my suffering” (Pa.6).</p> <p>“I think that the app could be useful for specific moments in which you need help and you can access it easily. I think that the app could be helpful if it guides you to breath or meditate in specific situations. You can avoid having a panic attack or feeling down previous to specific moments like before consultations or treatments” (Pa.1), “I think it could be useful for simple demands” (Pa.2), “When you have depression you do not have motivation to do anything. It could be more useful for anxiety symptoms; you can do meditation before sleeping or in situations of high anxiety” (Pa.6).</p> <p>“It depends on the patient, there are many people that do not improve despite going to therapy with a psychologist, maybe it is not his/her moment. Suffering a mental health condition is linked to other external variables different from the psychologist or the application” (Pa.6), “There are people who stop smoking by reading a book but the same therapies are not equally effective for everybody” (Pa.5), “The symptoms that women face during ART are similar, with the app you can see what is applicable to your case and what not, but the way it will evolve depends on the person” (Pa.2).</p> <p>“People who use the app more could improve” (Pa.5).</p>
App design	Format. Aesthetic aspect of the application. Elements that should include a mobile application.	Videos (1) Figures (1) Letters-numbers (2) Music-color (2) Virtual assistant (1). Schematic (1) Smartwatch (1)	<p>“I imagine it with a professional recording informative videos” (Pa.5).</p> <p>“I imagine it like a set I saw with no human people but with abstract figures” (Pa.1).</p> <p>“I think that the theoretical part should include letters that go forward” (Pa.1), “To do the problem solving technique, screens could appear where you can assign punctuation to different options” (Pa.1).</p> <p>“With music that guides you” (Pa.1), “The aesthetics should be well developed with colors” (Pa.1).</p> <p>“I can imagine it as a virtual assistant who addresses you because you have written your personal information, such as name, how many cycles you have undergone, etc.” (Pa.1).</p> <p>“I think it could be designed to be schematic” (Pa.2).</p> <p>“It could be nice if you could link the app with smartwatches. It could calculate your beats during meditation” (Pa.6).</p>
Contents.	Intervention components that should be included in a m-Health preventive program.	Forum (5)	<p>“The app should include a forum where women can share messages and be in contact. We all have a shared objective, getting pregnant, but it is important that forums are controlled by a professional” (Pa.1), “When you are frustrated, it could be useful to participate in a forum, but it could also create a vicious circle because you focus your attention on the negative experiences that other women share, it needs a professional to moderate it” (Pa.5), “In forums, a language could be used that does not represent you (fighters). In our group, we provide great support to each other, but in our case it is the result of having</p>

		learned it with the guide of a therapist; forums should be mediated by a professional to build a constructive and respectful support network” (Pa.4), “I think forums could be so ambitious and big. I think maybe it is not the forum, but being in contact with other women in small groups, like a group intervention but online” (Pa.6), “I would like the app to offer the chance to connect with other women. When I use the fertility app, I always look at users’ comments and experiences to see whether the side effects that I am feeling are also experienced by other women. When you see that other women are feeling the same things that you, you feel a sense of belonging” (Pa.3).
Partner (4)		“The emotional and physical burden on the women is not comparable to that suffered by our partner. Sometimes they say “it is better this way”. They should learn how to support the women. I think it should be a specific content for partners about how to be supportive” (Pa.6), “Maybe the partner should be included, the partner also suffers, but it should be the women who choose if she wants their partner using the app” (Pa.2), “I think it is important for them to feel included, in the pandemic context they cannot be present when doctors share relevant information with us. They feel they are excluded in this process and they say “it does not matter” because they do not know the suffering behind the ART. However, I also think that partners are a different matter, they need it, but maybe there should be a separate study and they need a different app. The way to connect with treatments is different, I think he would not benefit from the same strategies as me. I think that women should decide at the beginning of the intervention if she prefers to do it with her partner or not” (Pa.1), “I also think that partners have other thoughts related to fertility and ART” (Pa.3).
ART (2)		“I would like it if the app could explain the different ART that we are undergoing. Scientific data and information can help reduce doubts and fears” (Pa.5), “App could include information about the ART. It could be useful if we know how IUI or IVF works” (Pa.1).
Daily activities (5)		“During the program we do not always talk about the same topics. This way, the app should also include nutrition information. The app could include a midwife talking about nutrition” (Pa.5), “I have changed mi diet and I have noticed an incredible change, I think it is very important to focus on this” (Pa.6), “I would like it if the app included other things like doing exercise” (Pa.5), “It was hard for me not knowing if I could do exercise” (Pa.6), “Personal training is crucial” (Pa.2).
Emotions (2)		“No one asks you how you are feeling, despite emotional states being relevant in hormonal aspects. I would like the app to ask how you are feeling at this moment in time” (Pa.1), “I was remembering a mobile application to record your menstruation which allows the user to register physical and emotional symptoms” (Pa.4).
Psychological abilities (5)		“For and against exercises (problem solving) could be integrated in a mobile application” (Pa.1), “Mobile application could help you in a given situation when you need some rapid advice to solve a specific problem” (Pa.2), “Information that helps you to be cognitively flexible (things are not so wrong, there are scientific data)” (Pa.5), “When you are feeling down and thinking that everything goes bad, you can have the app to help you to discuss these thoughts” (Pa.3), “It is important that the app focusses also on positive aspects, for instance suggesting you see a film. When you are frustrated, not only meditation is helpful, but also other things. The app should help your general wellbeing and not only your fertility” (Pa.5).
Professionals’ training (3)		“Professionals do not make eye contact, I feel just like a number, they conduct medical procedures and we do not know what these interventions are” (Pa.1), “It could be very helpful if the professionals could learn how to communicate with patients, it is important to connect with the professional in order for these procedures to be less impersonal” (Pa.3), “Professionals should learn how to interact with women, smile and make eye contact” (Pa.6).
	Theoretical-practical (2)	

		Similar cases (1)	“It could be possible to provide a general introduction of the program which shows what the program is about” (Pa.2), “I imagine a theoretical part (what the emotions are, how they can be identified, etc.) and another practical part (sharing and explaining your feelings)” (Pa.1).
		Myths (1)	“All women could be reflected on this app” (Pa.5). “It could also include some information to debunk myths. During fertility treatment, I did not want to exercise or go out because I thought it was harmful. No one tells you that after the first IUI you can feel your baby. It falls off when you get your period. When you have to begin a new cycle you have to rebuild yourself.” (Pa.6).
Personalization.	Mobile applications designed to better meet users’ needs.	Treatment personalized to ART (4)	“The app should be different if it is designed for women who are starting the first cycle of ART or if it is for women who are in the third cycle of ART. The app should take into account that every month is different” (Pa.2), “The app should offer different things according to the ART. Are you awaiting the results of your last insemination or did it fail? We do not need the same advice when we have our period than when we are starting the cycle. Maybe I am not able to explain that I am sad, but I can say that I have received a negative result” (Pa.1), “In apps for pregnancy monitoring you can register your symptoms and the app tells you what is happening. In the fertility app it could be similar and explain the feelings that we all usually feel in specific moments” (Pa.4), “The app should consider what is your infertility diagnosis because if you have endometriosis maybe your diet should be different to reduce period cramps” (Pa.6).
		Treatment personalized to women’s needs (3)	“The app should assess your emotional state in order to know what to offer you. The app should ask how you feel and then adapt the contents to the specific moment in which we are or to our current feelings” (Pa.1), “It is possible that women prefer not to receive some information. It would be very useful if women could personalize the app (i.e., not receiving notifications). Depending on your symptoms, the app should provide a recommendation” (Pa.2), “It is interesting that the app assesses your evolution, and it offers you specific content like relaxation” (Pa.4).
		Module flexibility (2)	“ART are cyclic and recurrent; we do four IUI. In the app you can select if you prefer to do all modules included in the program but when you finish it and still have one year of ART, it is not necessary to repeat all the program, unless it is to remember you favorite activities and modules” (Pa.1), “You can use the app for specific moments of suffering, but you can have also the option to do the complete intervention” (Pa.2).
Application uses.	Suggestions for different uses of the app.	Complement (1)	“I think that the App could serve as a complement to therapy guided by a professional. You can use the App to do your homework and routines like meditation or thought analyses” (Pa.5).
		Professionals’ contact (1)	“I do not know what an app could do to help me. Maybe the app could recommend me to contact someone who understand me, I do not know if it could do anything else” (Pa.4).
		Prevention (1)	“In our context of ART, if there is no pre-existent mental health problem, the app could be useful from the beginning” (Pa.2).

Barriers.	Obstacles for providing mental health-related programs via the use of apps.	Perceived utility-stigma (2)	and	“Not feeling identified with the app. Feeling that I do not have a problem and I do not need to use the app. Prejudge mental health issues. Also, you will use the app when you are feeling bad, I think you will not use the app when you are happy” (Pa.1), “App not satisfying the needs of every woman” (Pa.2).
		Professionals’ involvement (2)		“It is important how professionals offer it to women. If they write the information in a paper and do not explain the importance of this program, you will not use it. On the other hand, if gynecologists offer it like it is something that could be helpful to your fertility, you will probably download the app” (Pa.5), “Professionals not recommending its use because of reduced time during consultations could be a barrier” (Pa.3).
		Complexity (1)		“Too many functions, not knowing how to use the app” (Pa.4).
		Motivation (1)		“Not having the pressure to meet the therapist can lead to lack of motivation to do the exercises. Not receiving professionals’ feedback may encourage women not to engage with the app” (Pa.5).
		Quality (1)		“I believe that an app is worse when including videos because their reproduction could be slow and of low quality” (Pa.1).
Adherence.	Improvements in the design of the app to reduce dropout rates.	Ease (2)	and	“The App must be easy to use. If you need to follow a lot of complex steps to download and use the app, you will lose interest, the app should be simple” (Pa.5), “It should be easy, I stop using a mobile application when I do not know how it works” (Pa.4).
		Personalized (1)		“It is important to personalize and individualize treatments to ensure the success of the app. The app could have a calendar and the woman can choose if they want to receive notifications and when to receive them.” (Pa.2).
		Fast (1)		“When you are suffering you do not want to do a test. The app should be fast, you can open it to report your symptoms and the app should provide a rapid response” (Pa.2).
		Feedback gamification (3)		“Women should perceive they are having some benefit from using the app” (Pa.6), “The app should encourage women (i.e., you are doing it right). We need to see that we are better and better every day. If the app shows you results, it is easier to get motivated and engage with the app. If I see that this week I have cried twice instead of five times, it motivates me” (Pa.1), “The app should provide reinforcements to motivate you. Apps to stop smoking shows you how much money you have saved or how many days you have been without smoking” (Pa.3).
		Peers comparison (2)		“The app can show you the result of other users to motivate you. I think it is interesting that you can see the results of other women, it could motivate you to use the app more” (Pa.6), “I liked it when, during sessions, we can see how others solve their problems” (Pa.5).
		Notifications (2)		“Some messages could emerge when the app detects low engagement” (Pa.4), “I would like the app to send me notifications” (Pa.2).
		Appearance (2)		“Include a nice app design” (Pa.1), “The appearance of the app and how information is arranged is crucial to capture the user” (Pa.2).
		Fun (2)		“It is important to use humor” (Pa.4), “The app should be fun to be attractive” (Pa.1).
		No malfunctions (1)		“It should be well-designed with no errors in the functioning” (Pa.5).
		Unblock modules (1)		“In order to not get bored, the app should encourage you to practice and reach different phases of the program. Sessions should be scheduled to persuade you to connect and complete the modules” (Pa.5).
		Separate videos (1)		“Videos could be supported by external web pages (i.e., youtube)” (Pa.1).
Name (1)	“To reduce stigma, the name of the app should be something like <i>skills to manage your emotions</i> ” (Pa.1).			
Professionals’ involvement (1)	“Professionals should offer this program like something that could help you in the process of fertility” (Pa.5).			

Intention of use.	Comments regarding whether apps could be used by stakeholders.	Recommendation (5)	“I actually have recommended the program” (Pa.5), “Yes, of course I would recommend this” (Pa.3), “I would recommend this program. It is more necessary that progesterone. I cannot understand how it is not universally offered to all women. I consider myself lucky to be able to participate, I do not know how I would manage my emotions without this support” (Pa.1), “I would recommend it. It is important that all women know the reality of the process and dispelling myths” (Pa.6), “Yes, psychological aspects are crucial” (Pa.2).
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Note: * Subcategory extracted only on patients' focus group. (Pa. 1) = Patient number one; (Pa. 2) = Patient number two; (Pa. 3) = Patient number tree; (Pa. 4) = Patient number four; (Pa. 5) = Patient number five; (Pa. 6) = Patient number six.

Appendix 6.4

Extraction of Areas, Subcategories and Categories for professionals' focus group ($n = 12$) including textual examples.

Category ($n = 2$)	Subcategory ($n = 13$)	Description	Areas ($n = 44$)	Examples
ICTs use.	Apps use.	Mobile applications used in routine activities and used for health improvement.	Fertility (1)	“Every week we conducted a group session and women saw a video explaining aspects related with ART, then women took the video home” (Prof. 1).
			Drugs (2)	“Different pharmacy units collaborated to develop a web page to show patients how to administer drugs” (Prof. 2), “Sometimes we send Internet links to access explicative videos in order to show them drug-related information” (Prof. 3).
			Eating disorders (1)	“In the eating disorders unit, professionals use a mobile application that helps to monitor patients' emotional state and eating behaviors” (Prof. 1).
			Postpartum depression (1)	“In our hospital, we conduct online postpartum depression assessments” (Prof. 1).
			Breastfeeding (1)	“I used a mobile application called <i>Latcapp</i> during breastfeeding” (Prof. 4).
	m-Health advantages.	Benefits from using mobile applications to provide psychological care.	Accessibility (5)	“It is accessible” (Prof. 4), “I think that one of the most remarkable advantages of apps is the accessibility. With an app you can have all the information and check it when you need it. This tool is available 24h a day.” (Prof. 3), “Patients are usually very nervous during medical appointments, we give so much information; with mobile applications, women can remember all the information that professionals explain during the face-to-face appointments” (Prof. 5), “We share information with women but maybe they do not begin the ART until a month later. In this period of time, they may forget most of the information. With apps, the information is always available” (Prof. 6), “The apps are highly accessible” (Prof. 7).
			Time (1)	“Patients have a lot of questions and doubts, but appointments last just 15-20 minutes. The app could serve to share information that it is usually difficult to address during face-to-face sessions. We do not always have the time we would like to provide more extensive attention” (Prof. 4).
			Ease (2)	“It is convenient and easy” (Prof. 4), “The convenience of apps is an advantage” (Prof. 7).
			Learning (3)	“Videos integrated in a mobile application could help women to understand the different procedures they are undergoing (i.e., how IUI works)” (Prof. 2), “Videos are useful and rapid. It can show a lot of information that explained in writing may be difficult to understand” (Prof. 1), “The app will allow women to solve doubts that could be left unresolved during face-to-face appointments” (Prof. 3).
			Reliability (1)	“These technologies are reliable” (Prof. 3).
m-Health concerns.	Worries regarding the use of m-Health.	Development (3)	“I would trust in a app if it is evidence-based and it has been developed by professionals. It is necessary to offer this information in order for women to be able to trust it. When I used Lactapp, I first checked that it was developed by midwives who followed the principles of scientific evidence” (Prof. 4), “It is crucial to explain to women how the app works, who has developed it. In this case, women should know that behind the app there is a group of psychologists, it is evidence-based. If it is explained in reproductive units, I think women will trust in the app” (Prof. 7), “These tools could be useful for women if they have been developed by professionals” (Prof. 3).	
		Human contact (2)	“I think an app is more impersonal” (Prof. 6), “I saw a problem with the degree of interaction. Women undergoing ART need lots of interaction, sometimes they may need an interaction with a professional. A rapid response from the app may not be enough to solve the doubt” (Prof. 1).	
		Updates (1)	“I believe that there are different devices developed, but some of them are not well-maintained. I have logged in some web pages and I feel that information is not adapted to the current situations and advances. It is a changing topic, it is not just about developing devices, but to be useful it also requires to be updated” (Prof. 2).	

	Face-to-face benefits.	Positive aspects of face-to-face therapies with professional interaction.	Human contact (2)	“Human contact is important and it helps to build a good relationship between the patient and the doctor which is not possible to reach with a mobile application” (Prof. 6), “I feel that human contact is important in reproductive care” (Prof. 2).
	m-Health efficacy.	Opinion about the usefulness of m-Health solutions.	Useful (3)	“In our unit, these devices work very well” (Prof. 1), “It is a useful tool because women can access all the information they need” (Prof. 3), “It could be very useful also for us to be familiar with how to monitor pregnancies or how to take appointments in different services” (Prof. 2).
App design.	Format.	Aesthetic aspect of the application. Elements that should include a mobile application.	Video (2)	“It could include videos about how sperm moves into the fallopian tubes when artificial insemination is performed” (Prof. 2), “Women should have a video to learn about her own bodies and know what they can expect during ART” (Prof. 5).
			Icons (1)	“It could include some icons or something similar” (Prof. 8).
			Interactive (2)	“It is important that you can interact with the app” (Prof. 7), “If a mobile app could be interactive, it would be perfect” (Prof. 1).
			Subtitles (1)	“Information could be presented with subtitles including different language options” (Prof. 8).
			Timetable (1)	“Especially for women undergoing IVF, it could be helpful to have a calendar that reminds women of all the procedures (i.e., drugs intake) and appointments. A mobile application that register all the prescriptions would be perfect” (Prof. 1).
Contents.	Intervention components that should be included in a m-Health preventive program.	Forum (11)	“Include a peer support group. Throughout the app create a chat, something coordinated. Feeling integrated in a group is positive” (Prof. 6), “In my opinion, if the app is evidence-based, it could not include a forum” (Prof. 4), “I do not know if it is appropriate to create a forum of patients. I think that not all women would like to know about others’ issues and doubts. We work in a small village and women would appreciate their privacy” (Prof. 5), “A forum should be something voluntary, women can choose to participate or decline” (Prof. 9), “The forum could also be anonymous” (Prof. 8), “I agree that a forum should be anonymous, without showing the name or the image of the participant; it may help to reduce the taboo and make them feel free to talk” (Prof. 6), “The possibility to include a chat to contact with an assessor like bank apps, it could be ideal” (Prof. 7), “We can include a professionals’ group who respond to doubts in a scientific way” (Prof. 6), “Some forums used to solve doubts that are not supervised and are non-evidence based work well. Maybe it could work in fertility. It could be optional; woman participate if they want to. Professionals can see what comments are being made and they solve doubts” (Prof. 10), “I think the same, it could be a peer chat and a professionals chat” (Prof. 11), “I think that group and peer support are crucial during ART, I suggest not losing it in an app. It could be developed to encourage people from different countries to participate and share experience in a controlled context” (Prof. 1).	
		Partner (3)	“Another aspect that we should consider is partner functioning, it has been demonstrated that the best support is provided when the partner functioning is adequate” (Prof. 1), “We always focus on women, but reproduction involves a couple. A lot of couples break up during this process” (Prof. 8), “Women suffer all the procedures, but both should be implicated in the process. Sometimes partners feel detached and it could be a good option to make them feel engaged” (Prof. 11).	
		ART (8)	“How to administer drugs. Explain symptoms and complications associated with drug administration” (Prof. 3), “Before the initiation of ART, couples should know information about ART procedures to better understand it in the first appointment in the HRU” (Prof. 2), “Women should know the process of fertility since she contacts with the HRU, including diagnostic tests, treatment options, differences between different ART and pregnancy rates” (Prof. 3), “There are so many causes of infertility, I would like the app to include some basic concepts, simple and easy definitions, to help women understand their infertility diagnoses” (Prof. 4), “Without a doubt, we need to include information about inclusion and exclusion criteria to receive ART in the public healthcare system” (Prof. 3), “A lot of women do not know their body, how ovarian and fallopian tubes works, it would be useful if the app were to show it in a video” (Prof. 5), “Information about how to ask for help” (Prof. 4), “At the end, they can find information about all the available fertility services in their country. Offer women alternatives according to their	

			economic resources” (Prof. 2).
		Daily activities (5)	“I can also think of including complementary information about nutrition and physical exercise that are not addressed during face-to-face appointments” (Prof. 9), “Information about practicing sports or real information about basic and common activities such as travelling” (Prof. 1), “I completely agree that this kind of information is essential” (Prof. 8), “Talk about sexual functioning that is usually impaired during ART” (Prof. 5), “There are patients that stop having sex from the beginning of ART because of lack of knowledge” (Prof. 9).
		Emotions (5)	“We can link the calendar of medical procedures to emotional states and explain to women the emotions they may feel depending on the ART phase” (Prof. 11), “Including a space to register how women feel and provide information that helps them normalize their symptoms” (Prof. 7), “To teach women how to manage hard situations” (Prof. 2), “Strategies to better manage frustration” (Prof. 8), “I agree with the idea of giving advice on how to manage frustration” (Prof. 1).
		Staff/healthcare environment (5)	“Apart from all the things that have been mentioned, I consider relevant that women meet the professionals who will be carrying out the ART. Sometimes one professional confirms the diagnosis and a different one delivers the treatment, it is important that women meet us as a group to increase their confidence” (Prof. 8), “Knowing the staff is highly relevant because women perceive that different professionals are responsible for their care and they are worried about missing information between professionals” (Prof. 2), “Related to this, in my opinion the app should include an environment tour, this way women may perceive the context as less invasive” (Prof. 11), “Knowing the environment is especially important in IVF, where women need to go into surgery, it is part of what we do in our unit” (Prof. 1), “IVF is a complex process, it would be very interesting if women can see some images of the facilities” (Prof. 8).
		Antecedents (1)	“Information about traumatic experiences. Psychoeducation about how these experiences can negatively impact in the present when women are trying to get pregnant and some advice about how to manage it. Also conduct screening about violence to detect problematic situations” (Prof. 8).
Personalization.	Mobile applications designed to better meet users’ needs.	Treatments personalized to ART (3)	“The period of time from IUI to the pregnancy test is very difficult, all these techniques of emotional management could be especially useful at this moment and after a negative pregnancy test” (Prof. 8), “We need to help women to overcome not getting pregnant both when they have their period or when they get a negative result on a pregnancy test” (Prof. 2), “I feel it is quite interesting because the period of time waiting for the pregnancy results seems to be the most difficult” (Prof. 1).
		Treatment personalized to women’s needs (5)	“It would be like providing emotional information according to women needs” (Prof. 11), “App could be adapted to the language of the user. I think that culture also plays a role” (Prof. 9), “Language is an important handicap; it would be important to adapt it” (Prof. 10), “Sometimes women come alone to medical appointments and it is difficult for them to learn some relevant aspects about drug administration, language is important” (Prof. 2), “The app should be inclusive in order to include the highest percentage of women possible, culture adaptations are required” (Prof. 7).
Application uses.	Suggestions for different uses of the app.	Complement (5)	“Technologies are good, but I also think that it is very important to have face-to-face contact, we should not allow one to replace the other. Apps are highly commendable and useful as support, they are an incredible breakthrough, but we cannot stop onsite appointments” (Prof. 6), “I would say that onsite sessions are fundamental. Technologies do not have to be exclusive” (Prof. 4), “It could also be blended” (Prof. 7), “I prefer it to be complementary. The best scenario would be having both options available” (Prof. 11), “Combined format would be ideal” (Prof. 9).
		Professionals’ contact (1)	“To facilitate the process, it could be possible even to recommend to arrange psychological care previous to the start of ART” (Prof. 8).
Barriers.	Obstacles for providing mental health-related programs via the use of apps.	Perceived utility (1)	“Women who feel that they are not suffering emotional distress probably will not log into the app” (Prof. 1).
		Socioeconomic (3)	“Problems with the language” (Prof. 8), “Cultural differences” (Prof. 6), “Not having Internet access” (Prof. 3).

Adherence.	Improvements in the design of the app to reduce dropout rates.	Ease (3)	“If the app is easy to understand it may facilitate that people with low sociocultural knowledge can understand better all the contents” (Prof. 11), “It should consist of videos and a few letters. It could make it more comprehensible” (Prof. 7), “Then the app should also be very practical and intuitive” (Prof. 8).
		Personalized (2)	“We need to think a lot about what women exactly need” (Prof. 4), “Addressing the needs of the women, if you address women’s needs they will adhere to the app” (Prof. 1).
		Fast (2)	“Women will no use the app if it requires so much time, you need to adjust the investment of time. The access should be fast. We use more the applications in which we can receive a solution quickly” (Prof. 1), “The app should be fast” (Prof. 12).
		Feedback (2)	“You can create a profile where woman can follow their treatment and emotional state. Provide feedback in the app” (Prof. 4), “Women would use the app if they perceive that they are receiving some benefits” (Prof. 1).
		Useful information-gadgets (2)	“Women will log into the app but they will continue to use it depending on the information that you provide to them. Providing daily useful information to them, women usually ask <i>Can I have this drugs?</i> Solving this kind of question may encourage women to use the app” (Prof. 4), “Providing a gadget to organize the information, like a calendar to register medical appointments. It is something that can help women to better organize their schedules. Using it daily may encourage them to adhere” (Prof. 10).
		Physical-Psychological (2)	“You can combine the two dimensions, the physical and psychological aspects. You can capture women by providing information about ART and then they will feel more motivated to continue with psychological contents” (Prof. 8), “Professionals may recommend the use of the app for fertility issues, when women see that they are receiving the information they need, they will link with other things like their emotions” (Prof. 4).
*App benefits.	Benefits of receiving psychological care during ART.	No charge (1)	“Being free of charge, of course” (Prof. 8).
		Wellbeing (2)	“To be more adapted to ART, positive results in emotional wellbeing” (Prof. 1), “It would allow women to be more relaxed” (Prof. 8).
Intention of use.	Comments regarding whether apps would be used by stakeholders.	Reduce ART Dropouts (1)	“Women usually drop out during ART, most of the time because of the emotional burden. If you could demonstrate that this psychological program decreases dropout in ART, it would be wonderful even for HRU who are interested in women being strong to endure ART until they get pregnant” (Prof. 1).
		Recommendations (4)	“I do not like to recommend, but I recommended the app about breastfeeding because I have used it, I liked it and then I recommended it” (Prof. 4), “We already recommend psychological therapy previous to ART” (Prof. 8), “If you can demonstrate that the use of the app is linked to a reduction in ART dropouts, professionals would recommend it” (Prof. 1), “We would like to recommend your app for psychological care during ART (<i>all participants agreed</i>)” (Prof. 3).
		Women’s acceptance (9)	“In my experience, acceptance is low, but I saw publications that show it is normal, just half of the women logged into the app during quarantine. All women had the link but only 50% of them logged in, it is the experience I have” (Prof. 1), “Everybody has a mobile phone, I can see it in my unit, they use it a lot and they use Internet. All women read forums so I think 99.9% of women would use it” (Prof. 8), “I also think that women would use it” (Prof. 3), “I agree; app would be used by women” (Prof. 10), “I do not think people are going to go into forums” (Prof. 5), “It is a very motivated population. It is a profile of patient that trust professionals, if you recommend it, they will use it” (Prof. 4), “There are individual differences, some women may prefer face-to-face while others may choose online” (Prof. 7), “Forums could be very useful for some women and not work for others” (Prof. 2), “Whether women decide to register or not depends on personality factors” (Prof. 11).

Note: * Subcategories extracted only in professionals’ focus group. (Prof. 1) = Professional number one; (Prof. 2) = Professional number two; (Prof. 3) = Professional number three; (Prof. 4) = Professional number four; (Prof. 5) = Professional number five; (Prof. 6) = Professional number six; (Prof. 7) = Professional number seven; (Prof. 8) = Professional number eight; (Prof. 9) = Professional number nine; (Prof. 10) = Professional number ten; (Prof. 11) = Professional number eleven; (Prof. 12) = Professional number twelve.

CHAPTER 7.
GENERAL DISCUSSION AND CONCLUSIONS

7. General discussion and conclusions

For many years, it has been believed that women are protected against the development of EDs during the reproductive period in general and in the perinatal period and during fertility treatments in particular. In the light of clinical evidence contradicting this idea, different scientific evidence and important national and international organizations have made important efforts to demonstrate that this is not always the case and have made the reality of many women who suffer EDs during the reproductive period visible (Clifton & Domar, 2022; ESHRE Psychology and Counselling Guideline Development Group, 2015; Generalitat de Catalunya. Departament de salut, 2018; Kiani et al., 2021; National Institute for Health and Clinical Excellence, 2020).

Enormous efforts have been made to develop assessment, preventive, and treatment protocols which serve to address EDs during the reproductive period (Bhat et al., 2022; Clifton & Domar, 2022; Li et al., 2022). However, these protocols hardly meet clinical guidelines as they are mainly focused on the postpartum, do not draw from a biopsychosocial approach to EDs, and do not usually consider preventive programs (Cuijpers et al., 2021; Huang et al., 2020; Li et al., 2022; Prom et al., 2022). Also alarmingly, Spanish public services that attend women during pregnancy and in the postpartum and who provide fertility treatments rarely have specialized psychologists to conduct routine psychosocial assessments and to offer the most convenient intervention according to the women's needs.

Additional limitations inherent to traditional face-to-face models of care have also raised as contributors to the difficulties in the access to reproductive mental healthcare (Waqas et al., 2022; Webb et al., 2021; Zhu et al., 2022). Women who access face-to-face services have to overcome multiple impediments, such as individual (i.e., stigma), professional (i.e., lack of time), organizational-political (i.e., lack of human health resources), and social-cultural barriers (i.e., cultural pressure). The use of ICTs and more precisely e-Health and m-Health has emerged as a cost-effective and reliable solution to overcome the limitations of face-to-face services and to provide psychological care in different health problems (Denecke et al., 2022; White et al., 2022). Well-designed ICT-based protocols have been developed during the reproductive period (Sparidaens et al., 2021; Yunus et al., 2022). However, the attention is still focused mainly on postpartum women, programs do not provide a transdiagnostic approach that allow the treatment of comorbid conditions with anxiety and depressive symptoms/disorders, and end users are rarely involved in the development of such ICT-based programs (Clifton & Domar, 2022; Gaitzsch et al., 2020; Hussain-Shamsy et al., 2020; Loughnan et al., 2019; Spadaro et al., 2022; Tsai et al., 2022; Yunus et al., 2022).

In the light of the previous research and clinical gaps, the broad aim of this doctoral dissertation was to propose and develop a new ICT-based model of care that facilitates the assessment of EDs, the development of preventive interventions, and includes the user's opinions during the reproductive period. The specific objectives of this work were (1) to review the scientific literature in the field of ICTs use for the assessment of perinatal depressive symptoms, (2) to explore the role of biopsychosocial factors in the prediction of perinatal depressive symptoms, (3) to analyze women's preferences regarding content and format of a psychological program to prevent depressive symptoms during the perinatal period, (4) to provide a preventive psychological intervention to women undergoing ART, and (5) to explore the opinions and preferences of women undergoing ART and professionals who attend them about the design of a mobile application to provide a self-management preventive psychological intervention during fertility treatments. To accomplish this general and specific goals, five empirical studies were conducted.

In this final chapter, a summary of the key findings of these studies will be exposed. Only the main conclusions of the five manuscripts included in this dissertation will be summarized instead of a discussion of the results for each study to avoid overlapping with information provided in studies presented from Chapter 2 to Chapter 6. Finally, in this section I will critically present the main strengths and limitations of this research and I will conclude with some practical implications for future research and clinical practice.

7.1 Key findings

The articles included in this compendium-based thesis dissertation have been arranged in three different domains related with reproductive care, which are: (1) assessment protocols to identify women in the reproductive period suffering EDs and risk/protective factors associated with EDs, (2) design of an intervention to offer psychological care during the reproductive period, and (3) users' experience analysis. The main results of the scientific studies that have been developed in each domain are summarized in next lines:

7.1.1 *Findings on the assessment of reproductive mental health and associated risk/protective factors*

Research question 1: What do we know about the use of ICTs for the longitudinal assessment of perinatal depressive symptoms?

Chapter 2: The use of Information and Communication Technologies in Perinatal Depression Screening: A systematic Review.

Main aim: Review and discuss the use of ICTs on perinatal depression screening.
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Conducting longitudinal assessments about EDs during the reproductive period is essential to detect psychological suffering and offer the adequate intervention program to pregnant women (Austin et al., 2017; National Institute for Health and Clinical Excellence, 2020; Scottish Intercollegiate Guidelines Network, 2012; The American College of Obstetricians and Gynecologists, 2018). However, in our current clinical practice, longitudinal assessments covering a wide range of EDs as well as their risk factors requires a high investment of personal and material resources, which makes these assessments very difficult. The use of ICTs could facilitate a reasonable alternative to the traditional model of care because of its benefits compared with face-to-face programs (Andersson, 2018; Schröder et al., 2016). Despite the well-known advantages of using ICTs in the context of reproductive care, their implementation for perinatal depression screening is still partial. The main results of this systematic review evidenced that:

- Most studies have been conducted in United States.
- While some studies reported that adolescent mothers have increased risk for the development of EDs, this population is usually excluded in research studies.
- There is a lack of longitudinal assessment protocols: most studies were conducted only at the postpartum.
- The most widespread use of technologies on perinatal depression assessment is relatively old-fashioned as it relies on phone calls.
- Very few studies employed the Internet (i.e., web pages, tablet applications, or e-mails) to conduct the assessments.
- The use of the Edinburg Postnatal Depression Scale to screen for depressive symptoms is well established, but its cutoff and time of assessment varied across studies.
- The proportion of women with depressive symptoms varied across studies.
- The integration of ICTs on perinatal depression screening is still rare.

Research question 2: What risk/protective factors should we consider when developing psychological screening protocols during the perinatal period?

Chapter 3: Predicting Postpartum Depressive Symptoms from Pregnancy Biopsychosocial Factors: A Longitudinal Investigation using a Structural Equation Modeling.

Main aim: Explore the unique contribution of a set of biopsychosocial factors in the prediction of perinatal depressive symptoms.

The longitudinal assessment of a wide range of risk factors for the development of perinatal depression facilitates the early detection of women who are suffering or are at risk of developing EDs during the perinatal period (Míguez & Vázquez, 2021). It would be reasonable to think that research has captured this perinatal depression scenario. However, the existing literature does not

assess the longitudinal contribution of diverse risk factors on pregnancy and postpartum depressive symptoms (Míguez & Vázquez, 2021) and, therefore, it is difficult to establish what are the most relevant risk factors so as to select them to be included in screening programs. Our empirical study conducted in this direction indicated that:

- Protective and risk factors for the development of perinatal depression are intercorrelated, so parsimonious models with a reduced number of critical predictors would be recommended. For instance, neuroticism largely contributed to negative affect.
- The structural equation model indicated that, when all protective and risk factors are considered altogether, depressive symptoms during pregnancy are the best predictors of depressive symptoms at postpartum, so early detection and intervention is crucial.
- Younger women had reduced risk of developing depressive symptomatology, especially at the postpartum, so this should be a target population of preference in screening programs.
- Both ambivalence towards pregnancy and negative affect seem to increase the risk of prenatal depressive symptoms.
- Increased positive affect reduces the risk of prenatal depressive symptoms.
- Social support and extraversion were not linked with prenatal and postpartum depressive symptoms.

7.1.2 *Findings in the design and implementation of preventive interventions during the reproductive period*

Research question 3: How should we design interventions focused on the prevention of EDs to better meet the women's needs?

Chapter 4: Content and format preferences of a depression preventive program: A study in perinatal women.

Main aim: To investigate the preferences about content and delivery format of a psychological program to prevent depressive symptoms in perinatal women while acknowledging ethnic differences.

A high proportion of women are interested in psychological programs (Clifton & Domar, 2022; Martin-Key et al., 2021) and their specific preferences should be explored and considered when interventions are designed because women's preferences may have implications for help-seeking behaviors (Granja et al., 2018). Although previous studies have attempted to explore these preferences, both content and format preferences have been rarely explored as a whole and cultural differences are omitted. This study tries to overcome these problems. Some of the main results of this investigation revealed that:

- Cultural differences emerged in content preferences. Non-Latinas women showed an increased interest in receiving regular check-ins about their emotional state than Latinas.
- All women preferred contents related with “receiving information about pregnancy” and “receiving information on the health and care of the baby”.
- The least preferred contents were “receiving regular check-ins on emotional state” and “receive tips on communication with their partner”.
- No cultural differences in format preferences were found. Non-Latinas as well as Latinas indicated they would prefer to receive a perinatal program individually and face-to-face.
- Only when content is related with communication with the partner, women may chose including their partner in the program.
- With regards to differences according to the perinatal period, most women at the postpartum are interested in receiving regular check-ins on their emotional state.

Research question 4: Can we implement a transdiagnostic online intervention to prevent the onset of EDs during ART? Could it be useful and well accepted?

Chapter 5: Prevention of Emotional Disorders and Symptoms Under Health Conditions: A pilot Study Using the Unified Protocol in a Fertility Unit.

Main aim: Provide a transdiagnostic psychological intervention to women undergoing ART and explore its preliminary feasibility, clinical utility, and acceptability.

EDs are highly prevalent during fertility treatments (Kiani et al., 2021), so different efforts have been conducted to develop and implement psychological programs to address them (Clifton & Domar, 2022). However, the scientific literature has postulated that these programs are quite heterogeneous, which makes difficult to establish which of these programs are more suitable for this specific population of women (Koumparou et al., 2021; Verkuijden et al., 2016). A number of issues regarding face-to-face programs and symptoms-focused approaches emerged when implementing psychological care during ART. This study proposed a transdiagnostic program to prevent the onset of EDs during ART. In general terms, the preliminary results of this study showed that:

- The implementation of a preventive program in group online format can be useful to prevent the development of depressive and anxiety symptoms during ART.
- These results were maintained at a mid-term period (at post-program and at one, three, and six months follow-ups).
- This program also helped to maintain subclinical levels in affect, quality of life, and emotion dysregulation at all assessment points.

- High satisfaction rates were found regarding the programs' online format and its contents, which makes this program feasible and highly acceptable.

7.1.3 Findings related with the users' opinions and recommendations

Research question 5: What is the opinion and preferences of women undergoing ART and the professionals who attend them about this transdiagnostic psychological intervention? How can we translate this online intervention into a complete self-administered m-Health program?

Chapter 6: First step to design a smartphone application to provide psychological care during reproductive treatments: A qualitative study including patients' and professionals' perspective.

Main aim: Explore the opinion, preferences, and recommendations of women undergoing ART and the professionals about the design of a mobile application to provide psychological care during ART.

Different face-to-face and online interventions already exist to be applied during ART (Boedt et al., 2022; Gaitzsch et al., 2020). However, it has also been claimed that there is a need to better integrate patient-centered care during ART as a gold standard care (Dong et al., 2022). Studies in this direction should consider individual patient preferences, needs and values, and should involve stakeholders in the design of m-Health solutions (Alqahtani & Orji, 2020; Garrido et al., 2019). A first step in this direction was done as a part of this research project. The results derived from our study suggest that:

- Women undergoing ART and professionals would like to use and recommend a mobile application if it includes the formats and contents discussed during the focus groups. This suggests that psychological programs provided throughout a mobile application could be feasible and well accepted in the ART context.
- The perceived advantages of m-Health solutions reported by professionals and patients were time, accessibility, and ease of use.
- The concern regarding the use of m-Health claimed in both focus groups was technologies not being developed by professionals.
- Women and professionals agreed that some benefit of relying on face-to-face programs was maintaining human contact.
- Barriers for m-Health implementations include lack of perceived utility by users.
- Based on the recommendations provided in both focus groups, mobile applications should: be developed by professionals, be regularly updated, provide stepped care programs, provide blended interventions with online and face-to-face sessions, be provided with peer support, include social support from a close relationship (partner or a

relative), offer a variety of contents, provide visual material, be adapted and personalized according to the women's needs, and provide women with instant feedback.

7.2 Strengths

The studies developed under this doctoral dissertation have a number of strengths that reinforce the current knowledge, understanding, and practices developed to address EDs during the reproductive period. The most remarkable innovations of this project are listed below:

7.2.1 Innovations regarding reproductive mental health assessment

First, while most systematic reviews have focused on ICT-based preventive and treatment interventions for perinatal depression (Lara-Cinisomo et al., 2021; Loughnan et al., 2019; Silang et al., 2022), our systematic review was focused on screening protocols. This is extremely important because psychological assessments are a core component of psychological practice and allow to reach a diagnosis and guide subsequent intervention plans (APA, 2020). This research also stands out for including all the studies that have used ICTs regardless of their novelty (i.e., including from telephone calls to Internet-based programs). This helped us to understand current practices and propose a new model of care more aligned with the current use of technologies in our society.

The second study was conducted taking into account the results found in the aforementioned systematic review. As a reminder, studies in our review were found to be conducted mostly in United States, they did not include longitudinal follow-ups, and usually involved old-fashioned ICTs such as phone calls. As a response to these limitations, the study exposed in Chapter 3 was conducted in Spain, was focused on the longitudinal assessment of perinatal women, and used a web-page. Thus, the methodology and the results of this investigation present important innovations. First, this methodology allowed us to assess a set of biopsychosocial factors which contrast with evidence that pointed that studies used to assess the role of isolated psychological or social risk factors for prenatal depressive symptoms (Míguez & Vázquez, 2021) without a comprehensive inclusion of several biopsychosocial factors. In this sense, we followed national and international guidelines by including measures of EDs and associated factors (i.e., social support and personality traits). However, we extended this knowledge by including additional risk and protective factors not included in this guidelines but extremely important during the perinatal period, namely ambivalence towards motherhood and negative and positive affect. Second, the inclusion of modern technologies is also an innovative proposal. This Internet-based method allowed us to conduct longitudinal assessments with no human involvement which reduces notably the time and efforts employed. Also importantly, the

use of a web-page allowed us to reach an increased number of participants and let them to respond according to their schedules.

7.2.2 Innovations regarding design and implementation of preventive interventions during the reproductive period

The third study included in this dissertation (Chapter 4) expands the current knowledge by exploring several format and content preferences altogether in the same study. While most studies investigated the content and format preferences as independent constructs (Ride & Lancsar, 2016; Simhi et al., 2019), our work covers several format options (online / on site; individual / group; alone / with partner) as well as content preferences (regular check-ins, information about pregnancy, information about healthcare of their baby, communication with partner) and the relation between both variables (i.e., women indicating a clear preference for including their partner when assertive communication was discussed). Moreover, all women in the perinatal period, namely pregnant and postpartum women, participated in our study and cultural differences were analyzed. There are some studies exploring women's opinions, but many of them have focused on a very specific perinatal period (pregnancy or postpartum) or in a specific Latina population (Demirci et al., 2016; Lara-Cinisomo et al., 2014). This is problematic because needs of minorities and women from diverse ethnic backgrounds should be considered in the perinatal period (Pilav et al., 2022). Our work could be a first step in this direction.

An additional strength of our study has to do with the design and implementation of a preventive intervention to be applied during the reproductive period, specifically in women undergoing ART (Chapter 5). The most recent findings from systematic reviews conducted in this field revealed that no preventive intervention was conducted in Spanish human reproduction units (Chow et al., 2016; Frederiksen et al., 2015; Gaitzsch et al., 2020). Under our project, this problem was solved by providing an intervention to Spanish women undergoing ART in a public hospital. For the development of this preventive program, we brought together all the knowledge acquired during the previous stages of this project (Chapter 2 to Chapter 4). By doing so, the findings of these studies, focused on perinatal women, were adapted to be integrated in a preventive intervention for women undergoing ART. As exposed in next lines, the assessment protocol as well as the format of the sessions were planned according to results from our previous studies.

First, the protocol assessment applied previously, during and after the preventive program included measures that demonstrated its relevance on perinatal women, namely, depressive symptoms and affect (Chapter 3). Additional measures were included because of their relevance according to the sample characteristics and the objective of the intervention. For instance, anxiety was measured because of its high comorbidity with depressive symptoms during ART (Cox et al., 2006), quality of life was selected as a measure of well-being related with ART, and emotion

dysregulation was added because it is the focus of the preventive intervention. Furthermore, the implementation of longitudinal assessments also represents a strength of this dissertation because intervention programs during ART are usually focused on pre and post intervention assessments (Gaitsch et al., 2020).

Second, the format of the preventive intervention also integrated the opinion reported by perinatal women in Chapter 4, who reported a preference for face-to-face and individual interventions. In a first attempt, the preventive program was designed to be conducted in face-to-face sessions. However, the pandemic situation forced and also provided us the chance to conduct it online through video calls. Additionally, although the program was designed to be applied in group format, the first session was conducted individually to better meet women preferences and to allow them to discuss some sensitive information about motherhood and ART.

7.2.3 Innovations regarding users' opinions and recommendations

The last study included as a part of this doctoral dissertation (Chapter 6) contributes to scientific evidence because it explores the opinion of the two key stakeholders involved in ART, that is, women undergoing fertility treatments and professionals who provide these treatments. This investigation goes beyond studies which focus predominantly on isolated opinions of participants or professionals (Rowland et al., 2020; Stawarz et al., 2018). It is important because psychological programs during ART must be developed taking into consideration the preferences and needs of both agents to better meet their needs and encourage its use (Gameiro et al., 2013; Pedro et al., 2016).

Exploring these opinions prior to the development of a mobile application also strengthened this research. While technology improvements usually involve exploring preferences of women once the intervention has been already developed and tested (i.e., Ramphos et al., 2019), the inclusion of stakeholders in the very early stage of its development may help to better address users' preferences and consequently to reduce costs associated with technology adaptations after their initial development.

Finally, methodological strengths of this study have to do with the analyses of qualitative reports. The study presented in Chapter 4 highlighted the need to explore qualitative opinion of the participants, so this methodology was integrated in the last study of this dissertation.

7.3 Limitations

Despite the numerous strengths that have been exposed in the previous section, we should also acknowledge some limitations that emerged from the aforementioned studies and may limit the generalization, comparability, and interpretation of findings.

First, with regards to the systematic review described in Chapter 2, it was conducted and published in 2018. Since then, a large number of scientific studies have been published in the field of ICTs use during the perinatal period. This may suggest that data from or systematic review could reveal some novel research if it was replicated now. Additionally, the words used for the search and database selection may limit the number of articles that were found to be included in the systematic review. Similarly, while a broad set of risk and protective factors were selected in Chapter 4, this list could be completed and extended with other biopsychosocial variables.

Second, the participants included in the empirical studies (Chapter 3 to 6) were mostly highly educated, employed, Spanish women in a stable relationship who were attended in public hospitals and receiving intrauterine inseminations as opposed to in vitro fertilization (Chapter 5 and 6). Furthermore, while the use of technologies is a strength of this dissertation, this reliance on technology also has some challenges which affected all studies in some degree. For example, sample recruitment was online (Chapter 3 and 4), the intervention was conducted using video calls (Chapter 5), and opinions were explored with an online focus group (Chapter 6). This means that all women were active Internet users and sufficiently proficient with technologies, which might have left aside women without Internet access or with limited ability to use technologies. Also related with sample characteristics, it is important to note that only women were included in our studies without the participation of their partners or relatives at any stage.

Third, sample retention and participation were also an issue that needs to be mentioned in studies described in Chapters 3 to 6. Longitudinal retention of participants was complex and some women refused to participate once they had registered (Chapters 3 and 4), so interpretation of our results should be considered with caution. Again, only participants who completed the intervention were able to provide quantitative satisfaction feedback (Chapter 5), so reasons for dropout were not analyzed. Additional limitations of sample size should be highlighted (especially remarkable in Chapters 5 and 6). A pilot study with no comparison group was conducted in Chapter 5, so only preliminary results can be extracted and the conclusions should be interpreted cautiously. In the same direction, only women who participated in the transdiagnostic intervention explained in Chapter 5 could participate in subsequent focus groups, so a small sample size was reported in Chapter 6.

An additional set of intrinsic limitations related with psychosocial assessments should be mentioned. Chapters 3 to 5 are affected by questionnaire selection, the use of self-reported measures only, and the inclusion of *ad hoc* questions to assess psychosocial symptomatology and preferences. Self-reported measures could result in biased information (i.e., difficulties in understanding questions) and may difficult the comparability of results. Furthermore, opinion analyses in Chapter 4 are supported by quantitative, closed answer options without an open space that would have allowed a qualitative reports analyses, although this was improved in the Study reported in Chapter 6.

7.4 Implications for future research, health policies, and clinical practices

Despite its limitations, information derived from the present dissertation has the potential to influence reproductive care specially in Spain and in our Spanish Health System. It entails changes not only in future research studies, but also has the potential to impact health policies that change clinical practices in public and private services.

7.4.1 Future research recommendations

The results and limitations of the studies presented in this doctoral dissertation may serve to guide future research in the field of reproductive mental health. Table 7.4 summarizes the efforts that should be undertaken to extend the knowledge in the field of variable selection, sample coverage, sample retention, sample size, assessment protocols, and technology development.

Table 7.4 Recommendations for future research according to our studies.

Domain	Research recommendations
Variable selection	Test the role of a diverse set of biopsychosocial and obstetric variables that have demonstrated their relevance in reproductive mental health and were not included in our project. For example, motherhood beliefs, perceived control, peer support, etc.
Sample coverage	<p>Conduct studies with diverse populations (i.e., adolescents, poorly educated, without a romantic partner or same-sex couples, unemployed, with low income or low technology proficiency, etc.).</p> <p>Develop culturally-sensitive programs which include intercultural analyses. In our closest context, we have to consider women from Rumania, Morocco, and South America.</p> <p>Test whether the results obtained are replicable in other health services for women in the reproductive period (i.e., women undergoing in vitro fertilization, perinatal women receiving reproductive care at private services, etc.).</p> <p>Include the opinion of the partner or a relative when designing psychological interventions during the reproductive period.</p>
Sample retention	<p>Provide gamification and immediate feedback to encourage adherence with psychological assessment programs.</p> <p>Explore reasons for discontinuation with psychological assessment programs and characteristics of individuals who dropout.</p> <p>Increase women's interaction with online programs.</p>
Sample size	Recruit bigger samples and conduct controlled studies with comparison groups.
Assessment	<p>Validate single-item measures to be included in online ecological momentary assessments.</p> <p>Explore whether different results are obtained when different questionnaires are administered (i.e., comparison between the Edinburg Postnatal Depression Scale and the Beck Depression Inventory).</p> <p>Develop and validate instruments that allow the assessment of common variables that remain unexplored (i.e., ambivalence towards motherhood, fertility-related problems).</p>
ICTs development	Develop evidence-based e-Health and m-Health solutions and validate them with scientific studies that allow to enhance the confidence of users' on online psychological programs

7.4.2 Changes in health policies and clinical practice

The results derived from the present work may have some relevant clinical implications for healthcare providers who work in the field of reproductive mental health, specifically with women in the perinatal period and women undergoing ART. The main clinical implication resulting from this dissertation is the evidence supporting the potential of technology to transform the reproductive mental health model of care. The proposed model of care derived from our project could be consulted in Figure 7.1 and will be explained in the following lines.

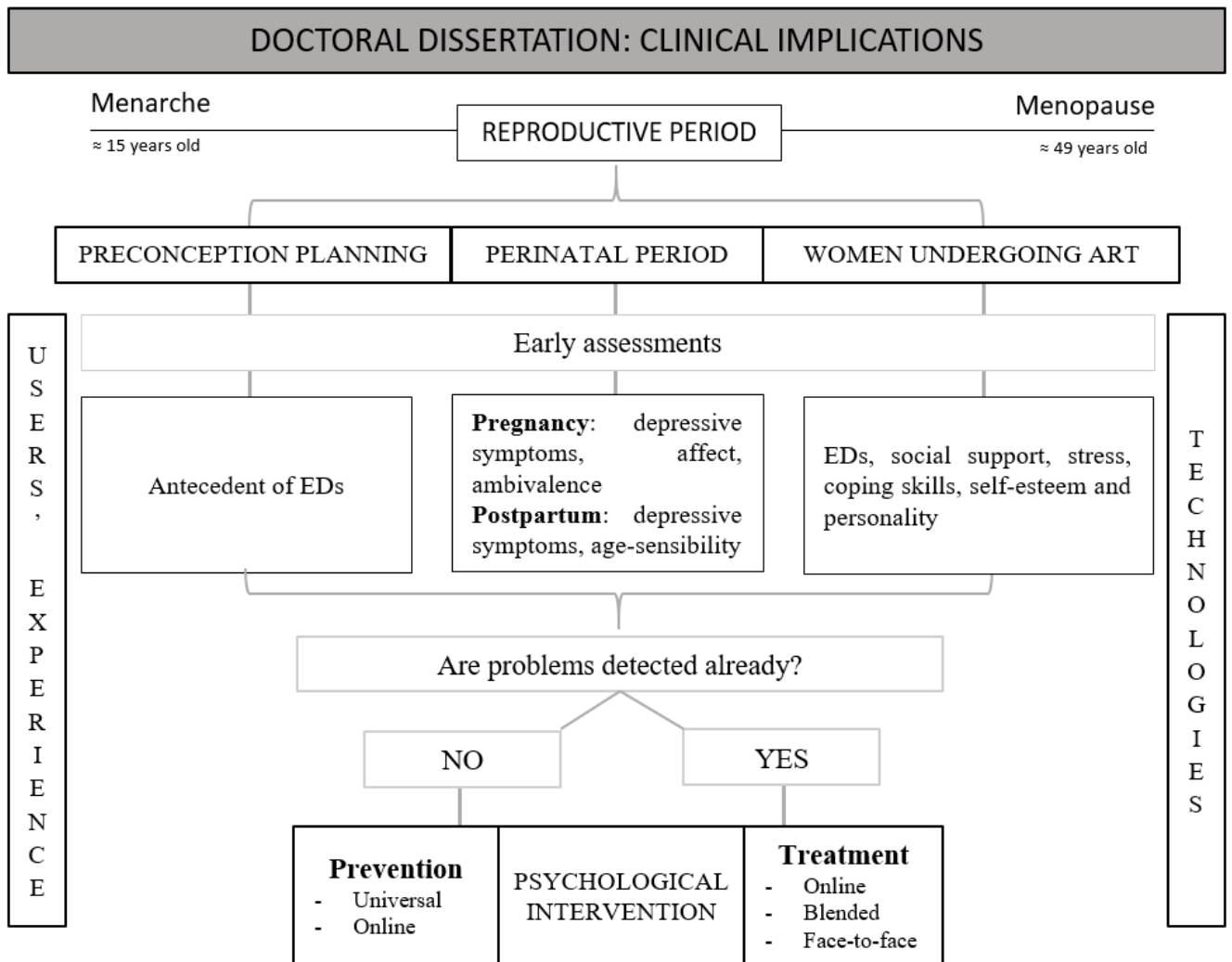


Figure 7.1 Clinical implications derived from this doctoral dissertation.

Currently, there are no universal psychosocial screening and intervention programs as part of routine reproductive care in Spain. We really need screening and intervention protocols to be developed in a near future. Clinical guidelines have postulated the need to better assess EDs and related risk factors during all the reproductive period. In the light of our results, conducting these kind of assessments is feasible, well-accepted, and highly useful. These encouraging results could be used by policy makers to design and implement assessment protocols in Spanish public services who attend women in the reproductive period.

When and what should be assessed during the reproductive period?

According to our proposal (Figure 7.1), women should be assessed across all the reproductive period, which in our study included perinatal women and women undergoing ART. However, we will briefly focus on some recommendations to be considered at the preconception stage. Previous studies have indicated that personal and familiar antecedents of EDs are good predictors of prenatal depressive symptoms (Míguez & Vázquez, 2021). In this scenario, we encourage that all women who express their desire to get pregnant and consult with healthcare providers should be assessed at least for personal and familiar history of EDs. By doing so, women who present risk factors for the development of EDs during the reproductive period could be early detected when planning for pregnancy and a preventive or treatment intervention could be recommended to them. Different types of psychological interventions will be described in the next paragraphs.

After this preconception planning, two possible scenarios may occur: some women can get pregnant spontaneously and other may find difficulties and ask for ART. With regards to the former, we propose that all women who get pregnant should be screened about the presence of EDs and their risk factors. As indicated by our results (Chapter 3), at least depressive symptoms, pregnancy ambivalence, and affect should be assessed at pregnancy. In the postpartum, depressive symptoms should be evaluated and different protocols as a function of women age should be developed. Note that, while our results indicated that being older is associated with experiencing more severe prenatal depressive symptoms, contradictory results have been found in literature. Extended research will probably be needed to solve these inconsistent findings and to analyze how to include this variable as a measure of risk for depression. Timing of these assessments should start early at pregnancy and it should be maintained at least during the first year after delivery (Chapter 1).

In the case of women undergoing ART, the Spanish Fertility Society (Grupo de Interés en Psicología. Sociedad Española de Fertilidad, 2009) have recommended that women should be assessed about anxiety and depressive symptoms, social support, stress, coping skills, self-esteem, and personality. Congruent with this recommendation, we also believe that these variables should be included in early assessment programs. In relation with timing of assessments, it should be preferable that assessments of EDs begin before women start ART and they remain active longitudinally during the course of ART (previous and after each fertility treatment).

How can the clinicians conduct these psychosocial assessments?

As a first recommendation, we suggest that psychological assessments should be offered as a part of women health care. The routinely and universal inclusion of such protocols could facilitate that women may not feel judged as a “bad mother” or as a weak person and, consequently, mental health stigma during the reproductive period could be reduced and more honest responses could be found.

Second, based on our findings, we suggest to develop and use well-designed and short instruments. In this case, although different instruments are available to assess depressive and anxiety symptoms during the reproductive period, our proposal is to validate short and psychometrically-sound measures such as the Overall Anxiety Symptoms Scale (OASIS; Norman et al., 2006; Osma et al., 2019) and de Overall Depressive Symptoms Scale (ODSIS; Norman et al., 2006; Osma et al., 2019) that include only 5 items of anxiety and depression each, respectively, and have been successfully used in the study reported in Chapter 5.

Third, to reduce the burden of psychological assessments, it could be reasonable to select only the most relevant protective and risk factors to be included in assessment protocols. Findings exposed in Chapter 3 indicated that some psychological variables are intercorrelated. For instance, women who experience intense negative affect tend to present higher neuroticism. Additionally, in our study negative affect seems to be more related with perinatal depressive symptoms than neuroticism. These results highlighted that, to select risk factors for EDs in a more efficient manner, the number of questionnaires could be reduced. Based on our results, we propose the inclusion of positive and negative affect as an indicator of protective and risk factors for the development of EDs during the reproductive period.

What should we do after these psychosocial assessments?

Once early assessments have been carried out, women should be derived to the most convenient psychological intervention according to the results of the assessments (i.e., questionnaire scores):

- Women **with negative screening results** could benefit from online universal preventive programs. Based on our experience (Chapter 5 and 6), women undergoing ART could benefit from a preventive program focused on learning emotion regulation skills (i.e., mindfulness or cognitive flexibility) and other coping skills (i.e., assertive communication skills and problem solving). We believe that the Unified Protocol could serve this purpose. As women in these programs have no clinical symptomatology, the reduced version of this program, composed of 7 sessions (Chapter 5) could serve to learn emotion regulation skills during ART. According to our experience, this preventive program could also be useful for women in the perinatal period, but future studies may

test this hypothesis. In the case of women at a preconception stage, it could be possible to offer a very brief psychoeducational program about lifestyle behaviors, difficulties that may emerge when trying to conceive, challenges imposed by future motherhood, and recommendations when difficulties actually arise. Given the non-clinical characteristics of these samples, we propose the use of a mobile application to provide preventive psychological care. Implementing these preventive psychological interventions as a part of reproductive care could bring important benefits to the health system. To name an example, if universal preventive programs are offered, 50% of potential cases of perinatal depression could be prevented and the remaining 50% of women who developed depressive symptoms could be treated. By doing this, prevalence and negative consequences of depression could be notably reduced (Muñoz, 2001; Muñoz et al., 2021).

- Women **with positive screening results** should be offered a treatment program according to their personal characteristics and needs. Thanks to the comments provided by patients in Chapter 6, a stepped model of care is proposed in this dissertation. Stepped models of care try to maximize efficiency of resource allocation in therapy by delivering low-intensity, evidence-based interventions initially and moving to more intensive and costly interventions for those patients who not respond to this first stage (Haaga, 2000). It has been proposed that this model of care could be applied to provide transdiagnostic programs with an initial online intervention (Cross & Ian Hickie, 2017). Our proposal is that low-risk women should be referred to completely online or blended interventions (i.e., combined automated and online sessions with some therapist-guidance) according to their schedules and preferences. Contrary to this, high-risk women could benefit from face-to-face interventions. It is important to note that the inclusion of human professionals in such interventions (blended and face-to-face programs) may difficult the implementation of psychological programs, especially while services attending women during the reproductive period do not have a psychologist. In all cases, a complete an adapted Unified Protocol Treatment Program could be offered with a longer duration (between 12 and 16 sessions) and including modules that were omitted or modified in the preventive program (i.e., setting goals & maintaining motivation or emotional expositions).

How can the clinicians address EDs during the reproductive period?

Clinicians need to account for some considerations when providing psychological interventions during the reproductive period. Results from our project could help in this purpose.

With regards to contents, the information derived from our studies (Chapter 4 and 6) indicated that women are more interested in receiving general information about the reproductive period than receiving psychological contents. Thus, the aforementioned preventive and treatment programs could start with some general information (i.e., medical procedures) and then proceed with the psychological contents. Additional lessons learned from our work lead us to propose that all the contents included in psychological interventions should be adapted to the target populations. For instance, women who are at the preconception stage should be given information to help them break some myths about pregnancy and motherhood (i.e., you can get easily pregnant or motherhood is one of the best moments in a woman's life). In the case of perinatal women, examples exposed to women should differentiate between pregnant and postpartum women (i.e., worries during pregnancy could be related with baby's health or labor pain, while worries in the postpartum could be associated with being a good mother or losing their identity as a woman). Finally, programs for women undergoing ART should include a variety of scenarios. In Chapter 5, we learnt that information provided to women undergoing ART should reflect the diversity of these women. Thus, examples should include heterosexual as well as homosexual relationships and should also be representative of single women undergoing ART. Moreover, regardless of civil status, psychological programs during the reproductive period should include the figure of the partner or a relative. To better meet women's needs (Chapter 4 and 6), women should be asked at the beginning of the programs about the possibility to involve an important person in the psychological intervention and, depending on the women's preferences, they could be included across all the program or only at given modules (i.e., partner communication).

How can we better address and meet the user's preferences?

During the development of the present doctoral dissertation we have explored the women's opinions to integrate their preferences before the development of psychological interventions (Chapter 4 and 6). Not surprisingly, in the model of care presented in Figure 7.1 the role of users' experience emerged as a fundamental element at different levels (when assessments are conducted and also when implementing intervention programs) and with women in different moments or situations (from women at a preconception stage to perinatal women and women undergoing ART). In an ideal context, women in the reproductive period would be asked prior to (i.e., *What contents would you like to receive during the reproductive period?*), during (i.e., *Do you think this module helped you to better manage your emotions?*), and after a psychological program has been offered (i.e., *How satisfied are you with the psychological program you have received?*).

This would allow professionals to develop interventions according to “previous” reports, adapting these interventions according to “during” valuations and extend programs according to “after” comments.

What is the role of technologies in assessment and intervention programs?

We encourage that the use of e-Health and m-Health should lead to the implementation of both assessment and intervention programs. In the light of findings from Chapter 2, we postulate the need to develop modern technologies such as mobile applications because they are highly integrated in our daily routines and women usually use them for health-related purposes and also during the perinatal period (Zhang et al., 2022). The inclusion of technologies in public health services may help reduce the burden of psychological programs. If all women are offered a mobile application, cost of interventions would probably decrease. In this sense, after this doctoral dissertation our future efforts will be addressed to develop a mobile application which allows us to get even closer to our ideal model of care during the reproductive period, more precisely to offer a self-applied preventive psychological program to women undergoing ART.

Unfortunately, ICT-based programs are not usually offered in our public health system, which probably contributed to the poor preference for online programs found in Chapter 3. What this result suggests is that, when interventions are conducted online, women should be informed about the benefits and potential problems of using these technologies. In relation to the latter, women perceived that barriers for not using m-Health is lack of perceived utility. When clinicians provide information about m-Health solutions it is important that they mention the relevance of this specific tool during the reproductive period and how its use could help women to better adapt to the changes and challenges imposed by motherhood and ART. Related with this idea, the results in Chapter 6 also indicated that clinicians should be more involved in recommending m-Health to ensure its implementation in routine care. Finally, as women exposed in Chapter 6, online psychological programs should be developed by professionals and should guarantee data protection. Including information about technology development and privacy policies in dissemination campaigns could probably help encourage women to develop a more favorable attitude towards technologies.

7.5 Conclusions

Reproductive mental health needs to be urgently addressed. The results obtained in this research represents a contribution to the field of mental health during the reproductive period, not only by adding evidence-based knowledge in this field, but also by proposing a new model of care that can be useful for clinical practice.

For a long time, EDs have remained underdiagnosed and undertreated during the reproductive period because it was assumed that during this period women only experienced pleasant emotions and negative experiences had no place. Consequently, women who presented EDs during pregnancy, postpartum or ART have remained silenced for decades. These women have felt inadequate and embarrassed because they thought they were the only woman who feels overwhelmed by feelings of sadness and anxiety.

Fortunately, during the last decades EDs during the reproductive period have been more and more visible. Nowadays, it is well-know that we need to address these psychological problems and to develop new models of care that allow all women to express their suffering and to receive mental healthcare when needed. It is our responsibility as a researchers and clinicians to normalize the experience of unpleasant emotions and suffering during the reproductive period and to guarantee an equal access to healthcare resources in perinatal women as well as women undergoing ART. Hopefully, the results of this doctoral dissertation may help policy making decisions about the development and implementation of e-Health and m-Health solutions that help to disseminate assessment and intervention protocols that could be integrated in routine reproductive healthcare services.

7.6 References

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CHAPTER 8.
APPENDICES

8. APPENDICES

Appendix 8.1 Ethical approvals



CEIC Aragón (CEICA)

**Informe Dictamen Favorable
Proyecto Investigación Biomédica**

C.P. - C.I. PI12/0055

20 de junio de 2012

Dña. María González Hinjos, Secretaria del CEIC Aragón (CEICA)

CERTIFICA

1º. Que el CEIC Aragón (CEICA) en su reunión del día 20/06/2012, acta CP12/2012 ha evaluado la propuesta del investigador referida al estudio:

Título: Mamáfeliz una aplicación informática para la evaluación y la prevención de la depresión postparto

Versión protocolo: abril 2012

Versión hoja de información al paciente: junio 2012

Investigador: Dr. Jorge Javier Osma López; Universidad de Zaragoza

1º. Considera que

- El proyecto se plantea siguiendo los requisitos de la Ley 14/2007, de 3 de julio, de Investigación Biomédica y su realización es pertinente.
- Se cumplen los requisitos necesarios de idoneidad del protocolo en relación con los objetivos del estudio y están justificados los riesgos y molestias previsibles para el sujeto.
- Son adecuados tanto el procedimiento para obtener el consentimiento informado como la compensación prevista para los sujetos por daños que pudieran derivarse de su participación en el estudio.
- El alcance de las compensaciones económicas previstas no interfiere con el respeto a los postulados éticos.
- La capacidad de los Investigadores y los medios disponibles son apropiados para llevar a cabo el estudio.

2º. Por lo que este CEIC emite un **DICTAMEN FAVORABLE**.

Lo que firmo en Zaragoza, a 20 de junio de 2012

Fdo:



Dña. María González Hinjos
Secretaria del CEIC Aragón (CEICA)



COMITÉ ÉTICO DE INVESTIGACIÓN
CLÍNICA DE ARAGÓN (CEICA)
Avda. Gómez Laguna, 25 planta 11
50009 Zaragoza

COMPOSICIÓN DEL COMITÉ ÉTICO DE INVESTIGACIÓN CLÍNICA DE ARAGÓN

Dra. María González Hinjos, Secretaria del Comité Ético de Investigación Clínica de Aragón,

CERTIFICA

1º En la reunión celebrada el día 20 de junio de 2012, correspondiente al Acta nº CP12/2012, se cumplieron los requisitos establecidos en la legislación vigente -Real Decreto 223/2004 y Decreto 26/2003 del Gobierno de Aragón, modificado por el Decreto 292/2005- para que la decisión del citado CEIC sea válida.

3º El CEIC de Aragón, tanto en su composición, como en sus PNT, cumple con las normas de BPC.

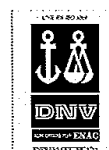
4º La composición del CEIC de Aragón en la citada fecha, era la siguiente:

- **Presidente:** Carlos Albar Remón; Médico. Servicio de Medicina Preventiva y Salud Pública. Hospital Clínico Universitario Lozano Blesa. Profesional Sanitario experto en epidemiología clínica.
- **Vicepresidente:** Cesar Loris Pablo; Médico. Servicio de Pediatría. Hospital Universitario Miguel Servet. Representante de Comisión de Investigación.
- **Secretaria:** María González Hinjos; Farmacéutica.
- Pilar Comet Cortés; Enfermera. Unidad Mixta de Investigación. Hospital Clínico Universitario Lozano Blesa.
- Marina Heredia Ríos; Representante de las Organizaciones de Consumidores y Usuarios.
- Gabriel Hernández Delgado; Médico. Servicio de Radiología. Hospital Universitario Miguel Servet. Representante de Comisión de Investigación.
- Angela Idoipe Tomás; Farmacéutica. Servicio de Farmacia. Hospital Universitario Miguel Servet. Farmacéutica de Hospital.
- María Jesús Lallana Álvarez. Farmacéutica de Atención Primaria de Zaragoza Sector III.
- Jesús Magdalena Belío; Médico. Centro de Salud de Azuara. Médico con labor asistencial y representante del Comité de Ética Asistencial del Área de Atención Primaria II y V.
- Mariano Mateo Arrizabalaga; Médico. Servicio de Farmacología Clínica. Hospital Clínico Universitario Lozano Blesa.
- Elisa Moreu Carbonell; Jurista. Profesora de la Facultad de Derecho, Universidad de Zaragoza.
- Javier Perfecto Ejarque; Médico. Centro de Salud Arrabal. Médico con labor asistencial.
- Alexandra Prados Torres; Médico. Instituto Aragonés de Ciencias de la Salud. Representante de Comisión de Investigación.
- José Puzo Foncillas; Médico. Servicio de Bioquímica. Hospital General San Jorge. Representante de Comisión de Investigación.
- Mónica Torrijos Tejada; Médico. Instituto Aragonés de Ciencias de la Salud.

Para que conste donde proceda, y a petición del promotor,

Zaragoza, a 20 de junio de 2012


Firmado: María González Hinjos





CONFORMIDAD DE LA DIRECCIÓN DEL CENTRO

Don Javier Peñarrocha Nebot, Gerente del Departamento de Salud La Plana y vista la autorización del Comité Ético de Investigación Clínica reunido el 25 de octubre de 2011.

DECLARA

Que conoce la propuesta realizada por D. Jorge Javier Osma Lopez, para que realice en el Hospital de la Plana el proyecto de investigación titulado: "**Mama Feliz: una aplicación para la evaluación y la prevención de la depresión post-parto en la C.V**"

Que acepta la realización de dicho proyecto de investigación en el Hospital de la Plana en colaboración con el Servicio de Partos.

Lo que firmo en Vila-real, a 26 de octubre de 2011

EL GERENTE DEL DEPARTAMENTO DE LA PLANA

D. Javier Peñarrocha Nebot



CEIm



GENERALITAT
VALENCIANA



CASTELLÓ
DEPARTAMENT DE SALUT

**INFORME COMITÉ DE ÉTICA DE LA INVESTIGACIÓN CON MEDICAMENTOS (CEIm)
HOSPITAL GENERAL UNIVERSITARIO DE CASTELLÓ**

Doña Berta Claramonte Clausell, Secretaria del Comité de Ética de la Investigación con Medicamentos del Hospital General Universitario de Castelló,

CERTIFICA

Que el Comité de Ética de la Investigación con medicamentos (CEIm) del HOSPITAL GENERAL UNIVERSITARIO DE CASTELLÓ en su reunión del día 30 de septiembre de 2019, acta 8/2019, tras la evaluación de la respuesta de aclaraciones realizada por: Alba Monferrer y Jorge Javier Osma del Proyecto de Investigación: "Mejora de las habilidades de regulación emocional para la prevención de síntomas ansiosos y depresivos en mujeres con problemas de fertilidad" Protocolo versión 1, 23 de septiembre 2019. HIP/CI versión 1, 23 de septiembre 2019

Servicio: Unidad de Reproducción Humana de HGUCS.
Investigador Principal: Alba Monferrer Serrano. Jorge Javier Osma

Y teniendo en consideración las siguientes cuestiones:

1. Cuestiones relacionadas con la idoneidad del investigador y sus colaboradores.
2. Cuestiones relacionadas con la idoneidad de las instalaciones.
3. Cuestiones relacionadas con la idoneidad del protocolo en relación con los objetivos del estudio y se consideran justificados los riesgos y las molestias previsibles para el sujeto.
4. Consideraciones generales del estudio.

EMITE UN INFORME FAVORABLE.

El Comité tanto en su composición como en los PNT cumple con las normas de BPC (CPMP/ICH/135/95) y con el Real Decreto 1090/2015, de 4 de diciembre, por el que se regulan los ensayos clínicos con medicamentos, los Comités de Ética de la Investigación con medicamentos y el Registro Español de Estudios Clínicos, siendo su composición la siguiente:

Presidente	D. Mario Ferrer Vázquez Facultativo Especialista Pediatría
Vicepresidente	D. Raimundo García Boyero Facultativo especialista Hematología
Secretaria	D^a Berta Claramonte Clausell Facultativo Especialista Neurología
Vocales	D^a Amparo Andrés Pruñonosa Graduada en Enfermería D. José Vicente Castelló Carrascosa Facultativo Especialista Alergología D. Juan Vicente Esplugues Mota Farmacólogo Clínico D^a Ana Fernández Herrero

CEIm



GENERALITAT
VALENCIANA



CASTELLÓ
DEPARTAMENT DE SALUT

Miembro ajeno a la profesión sanitaria. Licenciada en Derecho

D^a Amparo Ferrandiz Selles

Jefe de Servicio UCI

D. Raúl Ferrando Piqueres

Farmacéutico Hospitalario

D. Jesús Lucas García

Facultativo Especialista Pediatría

D^a Eufemia Marcos González

Diplomada en Trabajo Social

D^a Estel Ortells Ros

Facultativo Especialista en Medicina Familiar y Comunitaria

D^a María Teresa Pitarch Saborit

Miembro lego

D^a Rocío Ramos Aparici

Facultativo Especialista Anestesiología y Reanimación

D^a María Esther Roselló Sastre

Facultativo Especialista Anatomía Patológica

D^a Ana Sánchez Llopis

Facultativo Especialista en Urología

D. Carlos J. Soriano Navarro

Facultativo Especialista Cardiología

D. Juan Francisco Tosca Flores

Licenciado en Medicina y Cirugía. Experto en BPC

Que en dicha reunión del Comité de Ética de la Investigación con medicamentos se cumplió el quórum preceptivo legalmente

Que en el caso de que se evalúe algún proyecto del que un miembro sea investigador/colaborador, éste se ausentará de la reunión durante la discusión del proyecto.

Lo que firmo en Castellón a 12 de noviembre de 2019

Fdo. Berta Claramonte
Secretaría Técnica del CEIm



GENERALITAT
VALENCIANA

Conselleria de Sanitat
Universal i Salut Pública

Comité Ètic d'Investigació
amb Medicaments (CEIm)

Comité Ético de Investigación con Medicamentos

Hospital General Universitari de Castelló



**INFORME COMITÉ DE ÉTICA DE LA INVESTIGACIÓN CON MEDICAMENTOS (CEIm)
HOSPITAL GENERAL UNIVERSITARIO DE CASTELLÓ**

Doña Berta Claramonte Clausell, Secretaria del Comité de Ética de la Investigación con Medicamentos del Hospital General Universitario de Castelló,

CERTIFICA

Que el Comité de Ética de la Investigación con medicamentos (CEIm) del HOSPITAL GENERAL UNIVERSITARIO DE CASTELLÓ en la reunión telemática de la Comisión Permanente, el día 2 de marzo de 2021, tras la evaluación de la ADENDA presentada por el Dr. Jorge Osma López del Proyecto de Investigación: "Mejora de las habilidades de regulación emocional para la prevención de síntomas ansiosos y depresivos en mujeres con problemas de fertilidad".

Protocolo versión 1 del 23 de septiembre de 2019.

Hoja de Información y Consentimiento informado (participantes) versión 3 del 11 de febrero de 2021

Hoja de Información y Consentimiento informado (profesionales) versión 1 del 11 de febrero de 2021

Investigador Principal: Dra. Alba Monferrer Serrano

Servicio: Unidad de Reproducción Humana del Hospital General Universitario de Castellón

Y teniendo en consideración las siguientes cuestiones:

1. Cuestiones relacionadas con la idoneidad del investigador y sus colaboradores.
2. Cuestiones relacionadas con la idoneidad de las instalaciones.
3. Cuestiones relacionadas con la idoneidad del protocolo en relación con los objetivos del estudio y se consideran justificados los riesgos y las molestias previsibles para el sujeto.
4. Consideraciones generales del estudio.

EMITE UN INFORME FAVORABLE

El Comité tanto en su composición como en los PNT cumple con las normas de BPC (CPMP/ICH/135/95) y con el Real Decreto 223/2004, y su composición actual es la siguiente:

Presidente	D. Mario Ferrer Vázquez Facultativo Especialista Pediatría
Vicepresidente	D. Raimundo García Boyero Facultativo especialista Hematología
Secretaria	D^a Berta Claramonte Clausell Facultativo Especialista Neurología

Que en dicha reunión del Comité de Ética de la Investigación con medicamentos se cumplió el quórum preceptivo legalmente

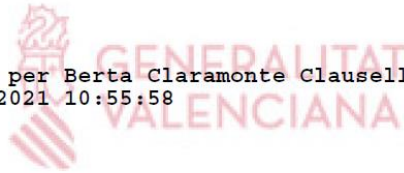
Avgda. Benicàssim, s/n 12004 Castelló - Tel. (+34) 964 725 000 - www.castello.san.gva.es

CEIm



Que en el caso de que se evalúe algún proyecto del que un miembro sea investigador/colaborador, éste se ausentará de la reunión durante la discusión del proyecto.

Firmat per Berta Claramonte Clausell el
04/03/2021 10:55:58



Fdo. Berta Claramonte Clausell
Secretaria Técnica.

Appendix 8.2 Co-authors agreements



Alinne Z. Barrera, como coautora doy mi **autorización** a Verónica Martínez Borba para la presentación de la siguiente publicación como parte de su tesis doctoral.

Relación de publicaciones:

- Content and format preferences of a depression prevention program: A study in perinatal women.

Asimismo, **renuncio** a poder utilizar estas publicaciones como parte de otra tesis doctoral.

Y para que conste firmo el presente documento,

A handwritten signature in black ink, appearing to be 'Alinne Barrera'.

Alinne Barrera, Ph.D.
Professor
Palo Alto University

1 de junio del 2022

Castellón de la Plana

Todo ello, atendiendo al artículo 28 del Reglamento de los estudios de doctorado de la Universitat Jaume I de Castelló, regulados por el RD 99/2011, en la Universitat Jaume I (Aprobado en la sesión nº 8/2020 del Consejo de Gobierno de 02 /10/2020):

“(…)

4. En el caso de publicaciones conjuntas, todas las personas coautoras deberán manifestar explícitamente su autorización para que la doctoranda o doctorando presente el trabajo como parte de su tesis y la renuncia expresa a presentar este mismo trabajo como parte de otra tesis doctoral. Esta autorización se adjuntará como documentación en el momento del inicio de evaluación de la tesis.

Laura Andreu Pejó, como coautora doy mi autorización a Verónica Martínez Borba para la presentación de las siguientes publicaciones como parte de su tesis doctoral.

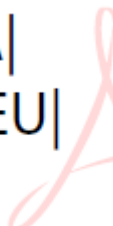
Relación de publicaciones:

- Predicting postpartum depressive symptoms from pregnancy biopsychosocial factors: A longitudinal investigation using structural equation modeling.
- Prevention of Emotional Disorders and Symptoms Under Health Conditions: A Pilot Study using the Unified Protocol in a Fertility Unit.
- First step to design a smartphone application to provide psychological care during reproductive treatments: A qualitative study including patients' and professionals' perspective

Asimismo, renuncio a poder utilizar estas publicaciones como parte de otra tesis doctoral.

Y para que conste firmo el presente documento,

LAURA|
ANDREU|
PEJO



Firmado digitalmente
por LAURA|ANDREU|
PEJO
Fecha: 2022.06.07
13:26:44 +02'00'

Castellón de la Plana

Todo ello, atendiendo al artículo 28 del Reglamento de los estudios de doctorado de la Universitat Jaume I de Castelló, regulados por el RD 99/2011, en la Universitat Jaume I (Aprobado en la sesión nº 8/2020 del Consejo de Gobierno de 02 /10/2020):

“(…)

4. En el caso de publicaciones conjuntas, todas las personas coautoras deberán manifestar explícitamente su autorización para que la doctoranda o doctorando presente el trabajo como parte de su tesis y la renuncia expresa a presentar este mismo trabajo como parte de otra tesis doctoral. Esta autorización se adjuntará como documentación en el momento del inicio de evaluación de la tesis.



Elena Crespo Delgado, como coautora doy mi **autorización** a Verónica Martínez Borba para la presentación de la siguiente publicación como parte de su tesis doctoral.

Relación de publicaciones:

- Prevention of Emotional Disorders and Symptoms Under Health Conditions: A Pilot Study using the Unified Protocol in a Fertility Unit.

Asimismo, **renuncio** a poder utilizar estas publicaciones como parte de otra tesis doctoral.

Y para que conste firmo el presente documento,

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NIF:***4706** el día 01/06/2022 con
un certificado emitido por ACCVCA-
120

Castellón de la Plana, 01 de junio de 2022.

Todo ello, atendiendo al artículo 28 del Reglamento de los estudios de doctorado de la Universitat Jaume I de Castelló, regulados por el RD 99/2011, en la Universitat Jaume I (Aprobado en la sesión nº 8/2020 del Consejo de Gobierno de 02 /10/2020):

“(…)

4. En el caso de publicaciones conjuntas, todas las personas coautoras deberán manifestar explícitamente su autorización para que la doctoranda o doctorando presente el trabajo como parte de su tesis y la renuncia expresa a presentar este mismo trabajo como parte de otra tesis doctoral. Esta autorización se adjuntará como documentación en el momento del inicio de evaluación de la tesis.



Alba Monferrer Serrano, como coautora doy mi **autorización** a Verónica Martínez Borba para la presentación de la siguiente publicación como parte de su tesis doctoral.

Relación de publicaciones:

- Prevention of Emotional Disorders and Symptoms Under Health Conditions: A Pilot Study using the Unified Protocol in a Fertility Unit.

Asimismo, **renuncio** a poder utilizar estas publicaciones como parte de otra tesis doctoral.

Y para que conste firmo el presente documento,

ALBA|
MONFERRER|
SERRANO

Firmado digitalmente
por ALBA|MONFERRER|
SERRANO
Fecha: 2022.06.01
08:35:32 +02'00'

Castellón de la Plana

Todo ello, atendiendo al artículo 28 del Reglamento de los estudios de doctorado de la Universitat Jaume I de Castelló, regulados por el RD 99/2011, en la Universitat Jaume I (Aprobado en la sesión nº 8/2020 del Consejo de Gobierno de 02 /10/2020):

*“(…)
4. En el caso de publicaciones conjuntas, todas las personas coautoras deberán manifestar explícitamente su autorización para que la doctoranda o doctorando presente el trabajo como parte de su tesis y la renuncia expresa a presentar este mismo trabajo como parte de otra tesis doctoral. Esta autorización se adjuntará como documentación en el momento del inicio de evaluación de la tesis.*

