

STUDY PROTOCOL

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Effectiveness of an online biopsychosocial cognitive-behavioural preventive intervention to improve wellbeing and mental health during pregnancy. Randomized controlled trial (BienGestar)

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Abstract

Background Pregnancy is a period of significant psychological, physiological, and social change, which can increase vulnerability to emotional distress. While many interventions focus on detecting and treating symptoms of anxiety and depression during pregnancy, fewer target the promotion of wellbeing. The BienGestar study aims to evaluate the effectiveness of a digital, biopsychosocial, cognitive-behavioural intervention designed to promote mental health, wellbeing, and physical health during pregnancy and the postpartum period in a community-based sample of healthy pregnant women.

Methods The study is a randomized controlled trial with two parallel arms: an intervention group and a control group. Participants will be recruited through public health centers in Catalonia, Spain. Eligible participants are pregnant women less than 15 weeks of gestation, aged 18 or older, with access to an internet-connected device and able to understand and read Spanish. After providing informed consent and completing baseline assessments, participants will be randomized into one of the two groups. The intervention consists of a 20-week structured program delivered through a secure online platform, with daily activities and psychoeducational content adapted to the gestational stage. Outcomes will be assessed at baseline (gestational week 15), post-intervention (gestational week 36), and postpartum (45 days after delivery). Primary outcomes include mental wellbeing, life satisfaction, and symptoms of anxiety and depression. Secondary outcomes include prenatal attachment, self-efficacy, birth experience, and infant health indicators. Obstetrical and neonatal data will be collected from medical records. All analyses will follow the intention-to-treat principle, and a per-protocol analysis will also be conducted to assess the intervention's efficacy among participants who adhered to the program.

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Discussion This study introduces a novel, health-promotion-focused approach to perinatal mental health care. By targeting psychological wellbeing rather than emotional distress, and by offering a fully online, self-guided intervention integrated into primary care, BienGestar may contribute to scalable, preventive strategies to support women throughout pregnancy. If effective, the intervention could be implemented broadly as part of routine prenatal care to enhance maternal wellbeing and infant outcomes.

Trial registration ClinicalTrials.gov: NCT06871397. Prospectively registered on March 11, 2025.

Keywords Perinatal mental health, Wellbeing, Online intervention, Pregnancy, Mental health promotion, Preventive care.

Background

Pregnancy is a critical period in a person's life, characterized by significant physical, hormonal, and psychological changes. These transformations often bring physical discomfort, increased stress, emotional uncertainty, as well as concerns and fears related to pregnancy, childbirth, and the transition to parenthood [1–4]. Collectively, these factors contribute to a higher incidence of emotional disorders, even in healthy, low-risk pregnancies. Recent studies report that up to 40% of pregnant individuals experience symptoms of anxiety, and up to 25% exhibit symptoms of depression [5–8]. These emotional difficulties have been associated to a range of negative outcomes both for mother and infant, including physical complications, more frequent obstetric consultations [9, 10], increased sick leave, delivery difficulties, higher cesarean section rates, and increased incidences of prematurity, low birth weight [11, 12], postpartum mental health problems [13] and later child development problems [11, 14–19].

Despite the growing body of evidence linking perinatal emotional disorders to adverse outcomes, addressing mental health problems during this period remains particularly challenging. Social stigma surrounding mental health, combined with the widespread belief that pregnancy and motherhood should be states of joy and fulfillment, often prevents individuals from seeking psychological help or leads them to avoid pharmacological treatments out of concern for fetal development. These barriers highlight the need for the implementation of accessible, non-pharmacological intervention options to support perinatal mental health [20].

While research has mainly focused on the impact of emotional symptoms, considerably less attention has been given to positive psychological states, such as mental wellbeing. Some studies indicate that pregnant women who experience higher levels of wellbeing and emotional stability tend to report more positive childbirth experiences and have a lower risk to have a difficult delivery [12, 21], as well as, their infants show better neurodevelopmental outcomes at the short term [12, 21–23] and at the long term [21, 24].

Mental wellbeing denotes a state of mental health, happiness, life satisfaction and quality of life [25–27]. Emerging evidence suggest that mental wellbeing is not merely the absence of mental illness; rather, it represents a distinct therapeutic target. States of mental wellbeing can occur regardless of the presence of mental illness, offering an alternative and complementary pathway to promoting mental health and preventing emotional distress [28, 29].

Psychologically oriented interventions, primarily using cognitive-behavioral therapy (CBT) techniques, have been widely implemented to address emotional problems during pregnancy. These interventions focus on preventing symptom onset or escalation through methods such as psychoeducation, cognitive restructuring, problem-solving, stress inoculation, self-monitoring, progressive muscle relaxation, visualizations, and mindfulness [30–34]. Some of these techniques, such as progressive muscle relaxation and mindfulness, have been used independently during pregnancy, showing effectiveness in increasing wellbeing, reducing stress and anxiety, improving sleep quality, and even lowering the risk of birth complications [35–39]. The growing prevalence of online interventions offers a promising tool for promoting wellbeing and preventing the onset of mental health issues during pregnancy and CBT techniques have been adapted for online delivery, demonstrating effectiveness in reducing symptoms of depression, anxiety, stress, and insomnia [40–48]; and lowering the risk of prematurity and birth complications [36, 49–51]. However, relatively few studies have specifically tailored digital interventions to pregnant individuals [52].

The objectives of this study are to evaluate the effectiveness of a biopsychosocial preventive psychological intervention delivered online in promoting life satisfaction, wellbeing and mental health during pregnancy and postpartum in healthy pregnant women from the community. Specifically, the study aims to prevent the onset of anxiety and depression symptoms during pregnancy and postpartum, as well as prevent the escalation of symptoms in pregnant individuals with subclinical symptoms at the start of the intervention. The study will also investigate the impact of the intervention on the incidence of

T0 <15 GW	Participant eligibility Informed consent – Recruitment Registration – Data Collection Questionnaire Allocation to control or experimental group	
T1 15 GW	BASAL ASSESSMENT Sociodemographical data; WHO-5; SWLS; PWS; EPDS; Whooley; STAI; PRAQ-R2; Habits healthy lifestyle; EVAP.	
T2 16-35 GW	CONTROL GROUP Care as usual	EXPERIMENTAL GROUP Care as usual BienGestar online intervention
T3 36 GW	POST-INTERVENTION ASSESSMENT WHO-5; SWLS; PWS; EPDS; Whooley; STAI; PRAQ-R2; Habits and healthy lifestyle; EVAP.	
T5 45 PPD	FOLLOW-UP ASSESSMENT WHO-5; SWLS; PWS; EPDS; Whooley; STAI; PSOC.	

Fig. 1 Diagram and flowchart of the study. GW: Weeks of gestation; WHO-5: World Health Organization Well-Being Index; SWLS: Satisfaction With Life Scale; PWS: Psychological Wellbeing Scale; EPDS: Edinburgh Postnatal Depression Scale; Whooley: Whooley Anxiety Questionnaire; STAI: State-Trait Anxiety Inventory; PRAQ-R2: Pregnancy Related Anxiety Questionnaire; EVAP: Escala para la Evaluación de la Vinculación Afectiva y la adaptación Prenatal; PPD: Postpartum days; PSOC: Parenting Sense of Competence Scale

difficult delivery and on the infants health as well as on the incidence of postpartum depression, maternal role satisfaction and self-efficacy.

Methods

Study design

The BienGestar study is a randomized controlled trial with two parallel arms: an experimental and a control group. The experimental group is offered access to a biopsychosocial preventive psychological intervention delivered online, in addition to care-as-usual. The control group receives care-as-usual with no additional intervention. Participants in both groups may also use any concurrent healthcare services routinely available during pregnancy, which will be monitored throughout the study.

The study protocol, participant information sheet and informed consent were approved by the Clinical Research Ethics Committee (CEIC) of IDIAP Jordi Gol (23/125-P) and registered in clinicaltrials.gov (NCT06871397). Figure 1 displays the flowchart of the study design.

Inclusion and exclusion criteria

Participants eligible for inclusion in the study are pregnant women less than 15 weeks of gestation at the time of recruitment, aged 18 years or older, who are able to read, write, and understand Spanish. Additionally, participants must have access to an electronic device with internet

connectivity (e.g., smartphone, tablet, or computer) and demonstrate the ability to use web-based platforms. All participants must provide signed written informed consent.

Exclusion criteria include high-risk pregnancies requiring referral to a specialized healthcare center, a history of central nervous system disorders (e.g., brain pathology or traumatic brain injury), the presence of psychiatric diagnoses or acute psychiatric conditions (e.g., substance use disorders, schizophrenia or other psychotic disorders, or suicide risk), and current use of psychopharmacological medication or undergoing psychopharmacological treatment.

Recruitment

Participants will be recruited through the Sexual and Reproductive Health Assistance Services (ASSIR) located in Primary Care Centres within the Reus-Altebrat area (Catalonia, Spain), which serve a mixed urban, peripheral, and rural population and attend approximately 1,000 childbirths annually. Recruitment will be carried out by the midwives responsible for routine prenatal care. Informational posters and brochures about the study will be available in the waiting areas, and pregnant women will have the opportunity to express interest and request additional information.

During the initial prenatal visit (before 15 weeks of gestation), eligible women will be informed about the study by their referring midwife. Those interested will receive detailed information and sign a written informed consent form (on paper or electronically, if needed). The midwife will then complete a digital Data Collection Questionnaire (DCQ) to assess inclusion and exclusion criteria. Once the DCQ is submitted, the participant is automatically randomized by the system and assigned a study code. All participants will subsequently receive an email with a link to complete the baseline assessment questionnaires. Women allocated to the intervention group will also receive access credentials and a link to the online intervention platform.

The recruitment and study data collection will take place from March 2025 to June 2027.

Randomization

Participants will be randomly assigned to either the experimental or control group in a 1:1 ratio using a computer-generated randomisation sequence integrated into the Data Collection Questionnaire (DCQ). Upon completion of the eligibility assessment and informed consent, the referring midwife enters participant data into the digital DCQ, which automatically performs the random allocation and assigns a unique study code. The randomisation sequence is managed and securely stored by the technical personnel responsible for the digital

platform at the university. The research team will remain blind to group allocation throughout the recruitment and data collection phases. Access to the randomisation outcomes will be restricted until the end of the study and completion of the primary statistical analyses. Due to the nature of the intervention, participants cannot be blinded to group assignment.

Sample size

Sample size was calculated to detect statistically significant differences between the experimental and control groups on primary psychological outcomes related to subjective well-being, anxiety, and depressive symptoms, as measured by the Satisfaction With Life Scale (SWLS), the WHO-5 Well-Being Index, the Edinburgh Postnatal Depression Scale (EPDS), and the State-Trait Anxiety Inventory (STAI). Assuming a two-tailed test with an alpha level of 0.05, a statistical power of 80% ($\beta = 0.20$), and a moderate effect size (Cohen's $d = 0.5$), a minimum of 128 participants (64 per group) would be required. Accounting for a potential dropout rate of up to 40%, based on prior experience with similar digital interventions in pregnant populations, the target sample size was increased to 300 participants (150 per group) to ensure adequate power and allow for secondary and subgroup analyses. GRANMO Sample Size Calculator v.7.12 (available at <https://www.datarus.eu/aplicaciones/granmo/>) was used.

Intervention

The intervention is part of the BienGestar program, a structured, web-based, biopsychosocial preventive psychological intervention designed to promote wellbeing, mental health, and physical health in healthy pregnant women from the general population. The intervention is grounded in evidence-based cognitive-behavioral therapy (CBT) principles and techniques and is intended to complement routine prenatal care.

The intervention is delivered through a secure online platform accessible via any internet-connected electronic device (e.g., smartphone, tablet, or computer). It consists of 20 weekly modules, corresponding to gestational weeks 16 to 36. Each module provides daily content over five days, with each day's activity designed to require approximately 10 min to complete. A new module becomes available each week based on the participant's gestational age. Participants can access and revisit content from previous weeks at any time, but future modules remain locked until the corresponding week of gestation. This sequential and progressive access is designed to align with the natural course of pregnancy and support sustained engagement with the program.

Each weekly module includes the following components: (1) A psychoeducational text addressing a specific

theme related to pregnancy and psychological wellbeing. The content covers a broad range of topics including: promotion of physical health during pregnancy (e.g., healthy habits, physical activity, nutrition recommendations, and management of early pregnancy symptoms); promotion of mental health (e.g., emotional regulation, self-care, and cognitive strategies); fetal development and prenatal attachment, with week-by-week updates on fetal growth designed to support emotional bonding; preparation for childbirth, including both physiological and psychological aspects as well as common fears and concerns; promotion of partner relationship and family dynamics during the transition to parenthood; and early parenting, with information on infant capabilities, bonding, and caregiving practices; (2) a section titled How is your baby?, offering developmentally appropriate information on fetal growth, aimed at supporting prenatal bonding and emotional connection; (3) a self-observation or reflective question to foster self-awareness; (4) a practical exercise rooted in CBT strategies (e.g., values clarification, behavioral activation); (5) a brief breathing or relaxation technique (e.g., coherence breathing, guided visualization, progressive muscle relaxation); (6) a symbolic or experiential element (e.g., drawing, letter writing, meaningful gestures) to facilitate emotional expression and connection with the pregnancy.

The content is designed to be self-guided and accessible, intentionally avoiding the generation of guilt or pressure. It includes a variety of written, experiential, and sensory exercises to adapt to the needs and capacities of different users. Additionally, the intervention reinforces the supportive role of midwives and promotes maternal confidence in seeking professional help when necessary.

Participants allocated to the intervention group will receive individualized access credentials in the recruitment process and will have unrestricted access to all previously completed content. Usage data (e.g., log-ins, module completions) will be collected to evaluate adherence to the intervention.

Participants in the control group will receive standard prenatal care as defined by the Catalan Institute of Health, which includes emotional health screening with the Whooley questionnaire at gestational weeks 12–14 and 29–30 (Departament de Salut, 2018). They will not receive access to the online intervention during the study period to prevent contamination between groups.

Assessments

All assessments will be based on self-report techniques and will be administered online. Measurements will be conducted at baseline (T1), corresponding to gestational week 15, after randomization and prior to the start of the intervention. Post-intervention assessments will take place at gestational week 36 (T2), following the

completion of the 20-week intervention period. A follow-up assessment will be conducted 45 days after delivery (T4) to evaluate the maintenance of effects during the postpartum period.

Clinical and obstetric data will be obtained from medical records once the participants have given birth and delivery-related information is available.

Figure 1 provides an overview of the assessment schedule and specifies which instruments will be administered at each time point.

Instruments

World Health Organization-Five Well-Being Index (WHO-5) [53]. The WHO-5 is a brief, 5-item self-report questionnaire designed to assess current mental wellbeing. It has demonstrated adequate validity for screening depressive symptoms and for evaluating outcomes in clinical trials. Furthermore, the instrument has shown good psychometric properties when used in pregnant populations [54].

The Satisfaction With Life Scale (SWLS) [55]. The SWLS is a brief, 5-item self-report instrument designed to assess global cognitive evaluations of one's life satisfaction. It is one of the most widely used scales in intervention studies to measure subjective wellbeing [29]. The scale has been adapted for the Spanish population, including pregnant women, and has demonstrated good psychometric properties [56]. A total score can be calculated, with higher scores indicating greater life satisfaction.

Psychological Wellbeing Scale (PWS) [57]. The PWS is a 65-item self-report questionnaire designed to assess psychological wellbeing across four domains: subjective psychological wellbeing, material wellbeing, job-related wellbeing, and wellbeing in couple relationships. The instrument has been validated in the Spanish population and shows good psychometric properties.

Edinburg Postpartum Depression Scale (EPDS) [58]. The EPDS is a 10-item self-report questionnaire originally developed to detect symptoms of depression in the postpartum period. However, its use has also been validated for screening depressive symptoms during pregnancy [59], including in Spanish pregnant populations [60].

Whooley Anxiety Questionnaire (Whooley) [61]. The Whooley is a brief, 4-item self-report screening tool used to detect core symptoms of anxiety. It is recommended by the National Institute for Health and Care Excellence (NICE) as a standard screening instrument in perinatal mental health care.

State-Trait Anxiety Inventory (STAI) [62]. The STAI is a 40-item self-report questionnaire designed to assess two distinct dimensions of anxiety: state anxiety (a temporary emotional condition influenced by situational factors) and trait anxiety (a stable predisposition to experience

anxiety across time and situations). The STAI is widely used internationally, including in studies involving pregnant populations [63].

Pregnancy Related Anxiety Questionnaire (PRAQ-R2) [64]. The PRAQ-R2 is a brief, 10-item self-report questionnaire derived from the original 55-item version of the Pregnancy-Related Anxiety Questionnaire. It assesses three specific dimensions of pregnancy-related anxiety: fear of childbirth, concerns about the integrity of the baby, and worries about changes in physical appearance. The PRAQ-R2 has been validated in the Spanish population, demonstrating good psychometric properties [65].

Escala para la Evaluación de la Vinculación Afectiva y la adaptación Prenatal (EVAP) [66]. The EVAP is a 21-item self-report questionnaire that assesses two key dimensions of the psychological experience of pregnancy: prenatal attachment and psychosocial adaptation to pregnancy. The scale was developed using selected items from the most widely used instruments in this field—the Antenatal Attachment Scale and the Prenatal Self-Evaluation Questionnaire—and has demonstrated good psychometric properties in Spanish pregnant women.

Habits and healthy lifestyle. Habits and lifestyle will be assessed using an adapted version of the Mediterranean Lifestyle (MEDLIFE) Index [67], modified by the research team for the BienGestar study. This index evaluates dietary patterns, physical activity, and other lifestyle habits. Six items from the original scale—primarily related to dietary recommendations—were revised to align with current guidelines for pregnant women. These modifications were based on the *Guide for Pregnant Women* (Generalitat de Catalunya) and the *Practical Guide to Pregnancy and Postpartum Care* (Spanish Ministry of Health). Additionally, participants will be asked whether they currently smoke.

Parenting Sense of Competence Scale (PSOC) [68]. The PSOC is one of the most widely used self-report measures for assessing parental self-efficacy. It consists of 16 items and yields two factors: parental satisfaction, referring to the emotional quality and gratification associated with parenting, and parental efficacy, reflecting the perceived competence and confidence in managing parenting challenges. A Spanish version of the PSOC has been adapted and validated, demonstrating good psychometric properties in the Spanish population [69].

Sociodemographic data. Sociodemographic data will be collected through an ad-hoc questionnaire specifically designed for this study. Information will be obtained for both members of the couple and will include age, highest level of completed education, current occupation, and household composition. Relevant clinical and obstetrical data. Relevant clinical and obstetrical data of pregnant women and their fetus/newborns data will be obtained from medical records.

Obstetrical and Clinical data. Relevant obstetrical and clinical data of pregnant women and their fetus/newborns will be obtained from the participants' medical records at their reference primary care centers. The following information will be collected: type of delivery (vaginal, instrumental, elective or emergency cesarean), duration of labor (in hours), use of analgesia or anesthesia (e.g., epidural), gestational age at birth, and presence of obstetric complications (e.g., labor induction, postpartum hemorrhage, or episiotomy). Neonatal variables will include birth weight, length, head circumference, Apgar scores at 1, 5 and 10 min, neonatal medical complications (e.g. Neonatal Intensive Care Unit admission), and feeding method at discharge (exclusive breastfeeding, mixed, or formula feeding).

Statistical approach

All analyses will follow the intention-to-treat (ITT) principle. Descriptive statistics will be used to characterize the sample at baseline. Continuous variables will be expressed as means and standard deviations, while categorical variables will be presented as frequencies and percentages. Baseline comparisons between groups will be performed using independent samples t-tests for continuous variables and chi-square tests for categorical variables.

To evaluate the effectiveness of the intervention on primary and secondary outcomes, linear mixed-effects models will be used. These models will include group (intervention vs. control), time (T1, T3, T5), and the group $\times$ time interaction as fixed effects, with random intercepts to account for within-subject correlations over time. Analyses will be adjusted for relevant baseline covariates when appropriate.

In addition to the ITT analysis, a per-protocol (PP) analysis will be conducted to assess the intervention's efficacy among participants who adhered to the program. Adherence will be defined as having accessed at least 70% of the weekly modules (i.e., 14 out of 20) and having engaged with the content on at least three days per week, on average. The same linear mixed-effects models will be applied to this subgroup to examine whether the effects are consistent with or differ from those observed in the ITT analysis.

All statistical tests will be two-tailed, with an alpha level of 0.05. Analyses will be performed using SPSS statistical software.

Discussion

The present study protocol describes the design and methodology of a randomized controlled trial whose aim is to test the effectiveness of BienGestar, a web-based preventive intervention designed to promote mental wellbeing, emotional balance, and both physical and

mental health in healthy pregnant women from the general population.

Most psychological interventions during pregnancy focus primarily on symptom management in women at risk of, or already experiencing, emotional distress [30, 31, 70]; however, BienGestar takes a distinct approach by adopting a health promotion framework, rather than a deficit-oriented or strictly clinical model and by targeting positive mental health rather than symptom reduction. In this framework, positive mental health is recognized as an independent dimension of mental health, characterized by the presence of wellbeing, life satisfaction, and self-efficacy [27] and several studies have demonstrated that these components can enhance mental health [28, 71, 72]. Higher self-efficacy, in particular, has been associated with greater psychological wellbeing, better emotional adjustment, and fewer postnatal depressive symptoms [73], making it a key protective factor to be addressed in psychological interventions. BienGestar has been designed with this perspective in mind, aiming to promote these positive psychological resources to strengthen maternal mental health and resilience throughout pregnancy, and to enhance adaptation to motherhood.

On the other hand, as BienGestar is not a symptom-oriented intervention, it is designed to be implemented in a community-based context, offering support to all pregnant women in the general population, regardless of their clinical symptomatology. This represents a shift toward universal prevention and may contribute to reducing stigma, reinforcing protective psychosocial resources, and facilitating help-seeking and access to care when symptoms or distress are present. In this way, BienGestar intervention positions psychological wellbeing as a central component of standard prenatal care and this approach promotes a more inclusive, preventive, and health-promoting model of maternal care, as recommended by the World Health Organization [74].

To further support this inclusive approach, BienGestar is delivered in a digital format, helping to overcome well-documented barriers to mental health care during the perinatal period—such as fear of judgment, lack of time, geographical limitations, and reluctance to seek in-person support [20, 52]. In addition to improving access, the digital format offers greater flexibility, continuity of support across pregnancy, and enhanced privacy—allowing participants to engage with the content at their own pace and in their preferred environment, which may further increase adherence and emotional safety [75].

In many countries, routine antenatal education programmes—most commonly termed childbirth education, prenatal education or parent-craft classes—are scheduled in the third trimester and centre on labour physiology, pain-management techniques, breastfeeding initiation,

newborn care and immediate postpartum recovery [76, 77]. While such classes provide valuable late-gestation support, their timing limits opportunities to influence psychological adjustment earlier in pregnancy. BienGestar, by contrast, is deliberately initiated at the start of the second trimester, when many women experience greater physical stability and are more receptive to sustained psychosocial engagement. The program's structure aligns weekly content with gestational development and includes components such as prenatal bonding, preparation for childbirth, promotion of partner relationships, and early parenting reflecting a biopsychosocial understanding of perinatal wellbeing. Moreover, the intervention intentionally avoids language or strategies that may induce guilt or perfectionism, promoting instead emotional self-awareness, flexible coping, and compassion toward oneself and others.

The effectiveness of the BienGestar intervention in improving key psychological and obstetric outcomes—including life satisfaction, psychological wellbeing, prenatal attachment, self-efficacy, and birth-related indicators—will be evaluated through a randomized controlled trial. This study is expected to contribute to the growing field of positive perinatal psychology and to strengthen the evidence base for scalable, theory-driven digital interventions that can be integrated into routine prenatal care practices.

Nonetheless, the study is not without limitations. As with any self-administered online program, participant adherence may vary, and differential engagement could influence outcomes. To address this, the study will implement both intention-to-treat (ITT) and per-protocol analyses. The ITT approach ensures that all randomized participants are included in the analysis according to their original group assignment, regardless of their level of adherence, thus preserving the benefits of randomization and reducing bias. Complementarily, per-protocol analyses will be conducted including only those participants who complete the intervention as intended, allowing a more accurate estimation of the intervention's efficacy under ideal adherence conditions. Additionally, while the intervention is based on cognitive-behavioral techniques with proven efficacy, its combination and delivery in a fully automated digital format will need careful evaluation.

If the intervention proves effective, it could offer a valuable low-cost, scalable solution for promoting mental health in pregnancy through existing primary care structures. It may also contribute to improved obstetrical and neonatal outcomes, reduced emotional suffering, and enhanced quality of life during the transition to parenthood. Its public health orientation makes it particularly relevant for integration into maternal care policies

aiming to promote mental health equity and population-level wellbeing.

In conclusion, the BienGestar study introduces a novel, preventive approach to perinatal mental health that emphasizes the promotion of wellbeing rather than the management of pathology. By targeting a community-based sample of healthy pregnant women and offering an accessible, web-based format, the intervention aims to strengthen protective factors, increase emotional regulation, and support positive maternal and infant outcomes.

Abbreviations

ASSIR	Sexual and Reproductive Health Assistance Services
CBT	Cognitive-Behavioral Therapy
CEIC	Clinical Research Ethics Committee
DCQ	Data Collection Questionnaire
EPDS	Edinburgh Postnatal Depression Scale
EVAP	Escala para la Evaluación de la Vinculación Afectiva y la adaptación Prenatal
ITT	intention-to-treat
PP	per-protocol
PRAQ-R2	Pregnancy Related Anxiety Questionnaire
PSOC	Parenting Sense of Competence Scale
PWS	Psychological Wellbeing Scale
STAI	State-Trait Anxiety Inventory
SWLS	Satisfaction With Life Scale
Whooley	Whooley Anxiety Questionnaire
WHO-5	World Health Organization Well-Being Index

Authors' contributions

CHM conceived the study design, obtained funding, coordinated the implementation of the study, and led the writing of the manuscript. She contributed to all stages of manuscript preparation and revision. JCS participated in the study design, is a project investigator and contributed to the critical review and editing of the manuscript. DP, IS, and FR are project investigators and participated in the review and editing of the manuscript. CR is a project investigator and contributed to the manuscript revision. All authors read and approved the final manuscript.

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The study protocol has undergone full external peer review by the funding body as part of the peer review process. This funding source had no role in the design of this study and will not have any role during its execution, analyses, interpretation of the data, or decision to submit results.

Data availability

The datasets used and analysed during the current study will be available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

This study will be conducted in agreement with the principles of the Helsinki Declaration, as revised and updated, and the Good Clinical Practice. The protocol has been approved to the Clinical Research Ethics Committee (CEIC) of the Primary Care Research Institute (IDIAP) Jordi Gol (23/125-P; 17/05/2024).

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests. Data confidentiality will be protected under the Spanish law governing the protection of personal data (Ley Orgánica de Protección de Datos de Carácter Personal y garantía de los

derechos digitales; 03/2018, 5 December). Only the participants who signed the informed consent form were included in the study.

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