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Supporting women's role integration and identity during the emotional transition to motherhood

Submission date
10/11/2025

Recruitment status
No longer recruiting

Registration date
10/12/2025

Overall study status
Ongoing

Last Edited
13/11/2025

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Becoming a mother is a major life change that can affect a woman’s sense of identity. While many support programs focus on physical health or treating depression after birth, few help women understand and integrate their new role as a mother into their personal identity. This study aims to test a new psychological program called I-Materna, designed to support pregnant women in Spain from early pregnancy through the postpartum period. The goal is to help women feel more confident and emotionally well by supporting their transition into motherhood and reducing the risk of postpartum depression.

Who can participate?
Women aged 18 or older who are pregnant (between 10 and 14 weeks), speak and understand Spanish, and have no serious medical or psychological conditions can take part. Women must not be receiving psychological treatment or have used substances recently. They must also be able to attend at least 80% of the sessions.

What does the study involve?
Participants will be randomly placed into one of two groups. One group will receive usual care, while the other will take part in the I-Materna program. This program includes 24 sessions over 12 months, starting early in pregnancy and continuing until five months after birth. Each session lasts 90 minutes and covers topics like managing emotions, building a bond with the baby, balancing personal and professional roles, and coping with stress. Women in both groups will also continue with their regular medical check-ups.

What are the possible benefits and risks of participating?
The program may help women feel more emotionally balanced, confident, and better prepared for motherhood. It could also reduce symptoms of postpartum depression. There are no known risks from participating, and all sessions are designed to be safe and supportive.

Where is the study run from?
The study is based at the Faculty of Health Sciences at Universidad Rey Juan Carlos in Madrid, Spain. It is supported by local hospitals and health centers.

When is the study starting and how long is it expected to run for?
Recruitment began in January 2026 and is expected to continue until May 2026. The program itself runs for 12 months for each participant.

Who is funding the study?
The study is funded by a research grant from the Community of Madrid and Rey Juan Carlos University, as part of a program to support emerging researchers.

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
I-MATERNA: Identity and Maternal Adjustment for the Emotional Transition and Role integration in New Adulthood. Study protocol for a multicenter randomized controlled trial in pregnant women, comparing a psychosocial intervention with standard care to improve role integration, identity consolidation and emotional wellbeing

Acronym
I-MATERNA

Study objectives
The aim of this study is to assess the effectiveness of a specifically psychological intervention programme designed for Spanish pregnant women, beginning between weeks 10 and 14 of gestation and continuing through the postpartum period. The primary aim of the programme is to support the integration of the motherhood experience into women's personal identity. In addition to outlining the intervention design, the study seeks to evaluate its effects on postpartum depression (PPD) and overall psychological well-being. Furthermore, it explores the role of identity-related role integration in mediating these outcomes, as well as the influence of other relevant psychological and contextual variables.

H1. Program participants (I-Materna) will demonstrate greater integration of the motherhood experience into their personal identity at the end of the follow-up period compared to the control group.
H2: Pregnant women who participate in the psychological intervention program (I-Materna) will show significantly lower levels of postpartum depression (PPD) symptoms compared to a control group without intervention.
H3: Participants in the program (I-Materna) will exhibit higher levels of general psychological well-being (e.g., life satisfaction, positive affect) during the postpartum period compared to the control group.
H4: The effect of the program on reducing PPD will be mediated by a higher degree of integration of motherhood into personal identity.
H5: The effect of the program on enhancing psychological well-being will be mediated by increased maternal self-efficacy and a stronger self-esteem.
H6: Program participants will show greater emotional regulation during the postpartum period compared to the control group.
H7: Active participation in the program sessions (attendance, emotional engagement) will be positively associated with the psychological benefits obtained.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 16/03/2023, Ethics Committee of the Rey Juan Carlos University (Calle Tulipán, s/n, Móstoles, 28933, Spain; +34 646040114; investigacion.comite.etica@urjc.es), ref: 0103202312023

Study design
Interventional randomized controlled trial with parallel assignment open-label (no masking)

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pregnancy and motherhood

Interventions
We invite the training group to participate in the I-Materna program that we have specially designed for pregnancy, to prevent psychological symptoms and promote psychological well-being through the integration of their new role as mothers into their identity. We conduct training groups of 24 biweekly sessions of 90 minutes each (from 10-14 weeks of gestation to 5 months postpartum, establishing a total duration of the program of 12 months. Taking as a central variable the integration of the maternal role in the identity of women, the intervention program will also take into account the needs expressed by pregnant women in relation to this topic (identity and pregnancy) in a study prior to the intervention protocol carried out by the research team (Catalá et al., 2025).

The main topics that will be addressed in the intervention program are the following: presentation of the program, exploration of expectations and emotions surrounding motherhood, implications of the maternal role in personal identity, the importance of self-care and acceptance of emotions, the creation of self-care habits aimed at physical and emotional well-being, strengthening prenatal attachment and emotional connection with the baby, tools for managing stress and anxiety during adaptation to the maternal role, managing unrealistic expectations about motherhood, identifying and managing negative thoughts related to motherhood, fostering self-compassion versus excessive self-criticism, addressing changes in the relationship after motherhood, assessing the importance of social support and learning to ask for help, learning to balance different roles, fostering flexibility to adapt to the changing demands of motherhood, building a healthy bond with the baby, accepting the personal transformation that motherhood entails, reducing maternal guilt and promoting self-acceptance, evaluating progress and setting medium-long term goals. Attendance at least 80% of the sessions will be required.

The sessions follow a similar structure, dedicating 15 minutes to reviewing the tasks from the previous session, 60 minutes to working with the core contents of the session, and 15 minutes to questions, reflections, closing the session, and setting out consolidation tasks.

Most of the topics mentioned are addressed in a single session, with the exception of implications of the maternal role in personal identity, tools for managing stress and anxiety during adaptation to the maternal role, fostering self-compassion versus excessive self-criticism, learning to balance different roles, fostering flexibility to adapt to the changing demands of motherhood, accepting the personal transformation that motherhood entails, which were addressed in two sessions.

Women in the control group will attend a systematic childbirth preparation program throughout the Community of Madrid that includes six sessions: 1) Care in the final stretch of pregnancy (carried out at the end of the second trimester of pregnancy), 2) Holistic alternatives for pain management and tools for a positive childbirth experience (addressing topics such as pain physiology, pain perception, pharmacological and non-pharmacological pain relief methods), 3) Childbirth (the different types of childbirth assistance and types of delivery, the hospital environment and the resources available during childbirth are indicated), 4) Postpartum (prediction of these health and symptoms...tears, stitches, life at home with a newborn, the importance of the environment, mother's care, 5) Feeding the baby (breastfeeding), 6) Newborn care (normal baby behavior, usual signs and warning signs).
Sessions will begin at the end of the second semester, beginning the third trimester, with weekly sessions lasting one hour. They are voluntary but recommended and are taught in person by midwives.
Since this is a free, voluntary program offered by the public health system in Madrid, Spain, the experimental group could also participate in this program. Their participation (if it occurs) will be included as an additional covariate in the study.
Women in both the experimental and control groups will have the customary regular consultations with midwife, general practitioner or obstetrician. In Spain, pregnancy care is fully covered by the public healthcare system. Routine prenatal visits are conducted following a standardized schedule for low-risk pregnancies. Although there is some variation among autonomous communities and public and private hospitals, in general terms, we can establish 14 medical follow-up appointments: 1) first trimester biochemical screening (9 weeks), 2) prenatal screening (week 12), 3) first trimester ultrasound (week 12), 4) pelvic floor midwife consultation (week 12), 5) in-person results (week 12), 6) second trimester ultrasound (week 20), 7) second trimester blood tests (week 24), 8) second trimester obstetrics consultation (week 26), 9) 28-week midwife consultation (week 26), 10) third trimester blood tests (week 34), 11) third trimester ultrasound (week 36), 12) third trimester consultation (week 36), 13) 36-week delivery room visit (week 36), 14) 40-week consultation (week 40).

Intervention Type
Behavioural

Primary outcome(s)
Measured at (T1) during the initial session between gestational weeks 10 and 14, prior to intervention and group allocation; (T2) between gestational weeks 35 and 40; (T3) within the first week postpartum; and (T4) at five months postpartum:
1. Identity Scale (ad hoc). Developed by the research team
2. Maternal Role Integration Scale (ad hoc). Developed by the research team
3. Life satisfaction assessed using the Satisfaction with Life Scale (SWLS) (Diener, Emmons, Larsen, & Griffin, 1985)

Key secondary outcome(s))
1. Age is measured using an ad-hoc questionnaire at baseline (first trimester)
2. Gender is measured using an ad-hoc questionnaire at baseline (first trimester)

3. Country of origin is measured using an ad-hoc questionnaire at baseline (first trimester)
4. Educational level is measured using an ad-hoc questionnaire at baseline (first trimester)
5. Current employment status is measured using an ad-hoc questionnaire at baseline (first trimester)
6. Annual income is measured using an ad-hoc questionnaire at baseline (first trimester)
7. Marital status is measured using an ad-hoc questionnaire at baseline (first trimester)
8. History of previous abortions is measured using an ad-hoc questionnaire at baseline (first trimester)
9. Number of children previously delivered is measured using an ad-hoc questionnaire at baseline (first trimester)
10. Pregnancy planning status is measured using an ad-hoc questionnaire at baseline (first trimester)
11. Time taken to conceive is measured using an ad-hoc questionnaire at baseline (first trimester)
12. Parity status (primiparous or multiparous) is measured using an ad-hoc questionnaire at baseline (first trimester)
13. Biological origin of the baby is measured using an ad-hoc questionnaire at baseline (first trimester)
14. Current gestational week is measured using an ad-hoc questionnaire at baseline (first trimester)
15. Intention to breastfeed is measured using an ad-hoc questionnaire at baseline (first trimester)
16. Intended duration of breastfeeding in months is measured using an ad-hoc questionnaire at baseline (first trimester)
17. Gestational week at delivery is measured using an ad-hoc questionnaire at childbirth
18. Type of delivery is measured using an ad-hoc questionnaire at childbirth
19. Multiple birth status is measured using an ad-hoc questionnaire at childbirth
20. Use of analgesia is measured using an ad-hoc questionnaire at childbirth
21. Duration of labor is measured using an ad-hoc questionnaire at childbirth
22. Traumatic birth experience is measured using an ad-hoc questionnaire at childbirth
23. Satisfaction with the birth is measured using an ad-hoc questionnaire at childbirth
24. Newborn’s age is measured using an ad-hoc questionnaire at childbirth
25. Birth weight is measured using an ad-hoc questionnaire at childbirth
26. Skin-to-skin contact is measured using an ad-hoc questionnaire at childbirth
27. Neonatal unit admission is measured using an ad-hoc questionnaire at childbirth
28. Hours of companionship with the baby is measured using an ad-hoc questionnaire at childbirth
29. Hours of active interaction with the baby is measured using an ad-hoc questionnaire at childbirth
30. Baby’s sleep duration is measured using an ad-hoc questionnaire at childbirth
31. Breastfeeding status is measured using an ad-hoc questionnaire at childbirth
32. Months of breastfeeding is measured using an ad-hoc questionnaire at childbirth
33. Enjoyment of breastfeeding is measured using an ad-hoc questionnaire at childbirth
34. Maternal ambivalence is measured using the Maternal Ambivalence Scale at third and fourth time points (postpartum)
35. Prenatal distress is measured using the Prenatal Distress Questionnaire at third and fourth time points (postpartum)
36. Maternal-fetal attachment is measured using the Maternal Fetal Attachment Scale at third and fourth time points (postpartum)
37. Anxiety symptoms are measured using the Hospital Anxiety and Depression Scale at third and fourth time points (postpartum)
38. Depression symptoms are measured using the Hospital Anxiety and Depression Scale at third and fourth time points (postpartum)

39. Self-esteem is measured using the Rosenberg Self-Esteem Scale at third and fourth time points (postpartum)
40. Loneliness is measured using the UCLA Loneliness Scale (Version 3, 6 items) at third and fourth time points (postpartum)
41. Postpartum-specific anxiety is measured using the Postpartum Specific Anxiety Scale at third and fourth time points (postpartum)
42. Maternal role adoption is measured using the Adopción del Rol Materno Scale at third and fourth time points (postpartum)
43. Mother-infant bonding is measured using the Postpartum Bonding Questionnaire at third and fourth time points (postpartum)
44. Maternal parenting self-efficacy is measured using the Perceived Maternal Parenting Self-Efficacy Tool at third and fourth time points (postpartum)
45. Session adherence (attendance and punctuality) is measured using a session attendance log and punctuality checklist completed by facilitators at all intervention sessions.
46. Level of active participation is measured using a facilitator-rated participation scale (e.g., 5-point Likert scale assessing verbal contributions, engagement in activities) at all intervention sessions.
47. Comprehension of the session content is measured using brief post-session quizzes or comprehension checklists tailored to each session's objectives at all intervention sessions.
48. Emotional engagement is measured using a short self-report item (e.g., "I felt emotionally involved in today's session") rated on a 5-point Likert scale at all intervention sessions.
49. Perceived relevance and usefulness of the intervention is measured using a brief post-session questionnaire with items such as "The content was relevant to my needs" and "I found today's session useful" at all intervention sessions, rated on a 5-point Likert scale at all intervention sessions.
50. Motivation to apply learned strategies is measured using a self-report item (e.g., "I feel motivated to use what I learned today") rated on a 5-point Likert scale at all intervention sessions.
51. Contextual barriers to participation are measured using an ad-hoc checklist of potential barriers (e.g., childcare, transportation, emotional state) completed by participants or facilitators at all intervention sessions.
52. Quality of interaction with facilitators is measured using a brief participant-rated scale (e.g., "The facilitator was supportive and respectful") at all intervention sessions rated on a 5-point Likert scale at all intervention sessions.
53. Group cohesion is measured using a short version of the Group Environment Questionnaire (GEQ) or an ad-hoc item such as "I felt connected to the group today" rated on a 5-point scale at all intervention sessions.
54. Perceived peer support is measured using a self-report item (e.g., "I felt supported by other participants today") rated on a 5-point Likert scale at all intervention sessions.
55. Maternal fatigue is measured using a single-item fatigue scale (e.g., "How fatigued do you feel today?") rated from 0 (not at all) to 10 (extremely) at all intervention sessions.
56. Presence of social or familial support is measured using a self-report item (e.g., "I feel supported by my family or close others") rated on a 5-point Likert scale at all intervention sessions.

Completion date
30/01/2027

Eligibility

Key inclusion criteria

1. Women aged 18 years or older
2. Sufficient spoken and written comprehension of Spanish
3. Pregnancy without physiological complications that may compromise fetal development
4. No prior diagnosis of maternal psychological disorders before pregnancy
5. Voluntary acceptance of participation in the study
6. Inclusion in the intervention program between 10 and 14 weeks of gestation, at the first ultrasound medical visit

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
45 years

Sex
Female

Total final enrolment
60

Key exclusion criteria
1. Development of severe medical conditions during the study that may compromise the pregnancy
2. Current psychological treatment
3. Problematic substance use in the past 6 months
4. Participation in similar therapeutic programs in the past year
5. Withdrawal from the study after enrollment
6. Failure to attend at least 80 percent of the intervention sessions

Date of first enrolment
19/01/2025

Date of final enrolment
18/05/2025

Locations

Countries of recruitment
Spain

Study participating centre
Universidad Rey Juan Carlos. Facultad de Ciencias de la Salud
Avenida de Atenas, s/n
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Sponsor information

Organisation
Universidad Rey Juan Carlos

ROR
https://ror.org/01v5cv687

Funder(s)

Funder type
University/education

Funder Name
Comunidad de Madrid and Universidad Rey Juan Carlos

Results and Publications

Individual participant data (IPD) sharing plan
Individual participant data (IPD), including de-identified responses to questionnaires and relevant outcome measures, will be made available upon reasonable request to qualified researchers for the purpose of scientific collaboration and secondary analysis. Data will be anonymized to ensure participant confidentiality and stored in a secure institutional repository. Access will be granted following approval by the principal investigators and contingent upon signing a data-sharing agreement that outlines ethical use, data protection standards, and intended research objectives. No personal identifiers will be shared, and data will not be used for commercial purposes.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes