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Prevalence of psychiatric disorders during pregnancy—a feasibility study at second trimester ultrasound in the general population (GROUP study): study protocol

Lucie Knabe ,[1] Camille Tanaka,[1] Sarah Tebeka,[2,3] Samantha Neilson,[4] Clothilde Cauvin,[1] Nicolas Mercier,[1] Daphné Cayron,[1] Morane Savelli,[5] Philippe Deruelle,[6] Florent Fuchs,[6,7,8] Joana Pissarra,[9] Nicolas Molinari,[10] Raoul Belzeaux[1,11]

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For numbered affiliations see end of article.

Correspondence to
Dr Lucie Knabe;
l-knabe@chu-montpellier.fr

ABSTRACT

Introduction During the perinatal period, women have an increased risk for psychiatric disorders, which are highly prevalent in this context. In addition, there are significant delays in diagnosing these conditions, worsening their prognosis and increasing their societal burden. Studies describing psychiatric disorders in the perinatal period often focus on specific disorders; only postpartum depression and, to a lesser extent, anxiety disorders are studied. There are also very few evaluations conducted by clinicians based on a semistructured interview, relying on the diagnostic criteria of international nosography.

Methods and analysis This multicentric prospective study will recruit 140 adult pregnant women based on randomly selected second trimester (T2) ultrasound consultations. The primary outcome is the prevalence of any psychiatric disorder assessed with a standardised psychiatric assessment, the Mini-International Neuropsychiatric Interview (M.I.N.I.). Within 10 days after the T2 ultrasound appointment, we will conduct the M.I.N.I., collect demographic data, evaluate suicidal behaviour with the Columbia-Suicide Severity Rating Scale, describe negative life events from the past year using the Paykel questionnaire and evaluation of social deprivation (Evaluation of the Deprivation and Inequalities of Health in Healthcare Centres score). Participants will also complete self-administered psychiatric questionnaires that screen for specific pathologies. We will build a biological sample collection. At two months post partum, we will repeat the questionnaires, adding an assessment of mother-child bonding. Patients can choose between in-person or telemedicine visits on both occasions.

Ethics and dissemination All participants will be required to provide written informed consent. The study has received ethical approval from the French National Committee ('Comité de Protection des Personnes Ouest VI') (approval number: 23.03919.000236). Results will be disseminated through peer-reviewed journal publications and at scientific conferences and meetings.

Trial registration number NCT06297252.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Uses a standardised diagnostic interview for diagnosing main psychiatric disorders, including suicide behaviours, ensuring validated and reproducible results.
⇒ Recruitment and analysis of 140 patients (number of subjects needed) in two distinct hospitals will allow for conclusions on the prevalence of psychiatric disorders.
⇒ Potential selection bias as women experiencing psychiatric symptoms may be more likely to participate in the study.
⇒ Establishes an innovative biobank.

INTRODUCTION

Young women, particularly those between the ages of 15 and 25 years, are at a heightened risk for psychiatric disorders, which often first manifest during this period. These disorders are primarily identified in primary care and are typically managed by general practitioners, with psychiatrists intervening in severe or treatment-resistant cases. These psychiatric disorders represent a significant source of disability and healthcare costs and frequently coexist with several other psychiatric, addictive or non-psychiatric disorders,[1] potentially increasing suicidal behaviour.[2] Diagnosis delays are common, extending over several years, significantly worsening outcomes and escalating societal costs.[3] Notably, the annual prevalence of psychiatric disorders among women is estimated to be at least 20%, including major depressive episodes (14%), bipolar disorder (3%), anxiety disorders (13%) and post-traumatic stress disorder (PTSD) (2%), some disorders

being associated with one one another.[4] The perinatal period—spanning pregnancy and the *postpartum* phase up to 1 year after childbirth—marks a time of increased psychiatric vulnerability. During this period, women are at a higher risk of developing or exacerbating psychiatric disorders. Accordingly, there is an increased risk of admission to a psychiatric hospital after childbirth.[5 6] According to a recent review of anxiety disorders, certain symptoms specific to pregnancy have been identified as risk factors for this pathology,[7] including gestational vomiting and sleep disorders. Perinatal depression is a common complication,[8–10] with 16.7% of French women exhibiting symptoms of a major depressive episode 2 months post partum, according to the latest National Perinatal Survey.[11] This is very similar to the rates observed in other international studies.[12] Also, 3% of women experience PTSD during pregnancy, and 4% of women experience it during *post partum*.[13] Moreover, though rare, postpartum psychosis also occurs.[14] Lastly, death by suicide is the leading cause of maternal mortality in several countries[15]: suicide is responsible for around 20% of *postpartum* deaths.[16]

Disorders or symptoms that emerge during pregnancy often worsen in the *postpartum* period, significantly risking decompensation or recurrence.[17–19] Also, untreated mental illness in pregnant women increases the risk of high-risk behaviours such as exposure to sexually transmitted diseases, smoking, alcohol and other substance use disorders, as well as inadequate prenatal care.[20] These disorders have an impact not only on the patient's quality of life but also on early interactions with the newborn.[21] As a matter of fact, psychiatric disorders during the perinatal period may have a significant impact on fetal and infant development. The mother sets not only an intrauterine and postpartum environment, which can contribute to the child's psychopathology, but also typically plays a crucial role in shaping his emotional, social and cognitive development.[21]

Despite the intensive multidisciplinary monitoring during the perinatal period, including consultations with general practitioners, gynaecologists or midwives, and comprehensive screening throughout pregnancy and postpartum, psychiatric disorders remain largely underdiagnosed and undertreated.[22] Clinical diagnosis in routine practice lacks sensitivity in comparison with standardised assessments,[23 24] such as the Mini-International Neuropsychiatric Interview (M.I.N.I.),[25] which is administered by a psychiatric professional and provides a structured, reproducible diagnostic approach, though it is more time-consuming and costly.

Surprisingly, few studies have thoroughly investigated the prevalence of all psychiatric disorders in a prospective way during pregnancy using standardised and reliable clinical assessments. Most research focused narrowly on depression, neglecting the complex interplay of comorbid conditions, including the relationship between PTSD and depression, as well as undiagnosed bipolar disorders. One significant American study[26] has used a validated semi-structured questionnaire to assess all psychiatric disorders among approximately 36 000 pregnant women. In this study, the prevalence of at least one psychiatric disorder in the preceding year ranged from 33.7% among pregnant women with no obstetric complication to 40.1% among those with obstetric complications. Also, Jacquelin *et al*[27] used cross-sectional data from the National Epidemiologic Survey on Alcohol and Related Conditions-III to determine the prevalence of psychiatric disorders in women with obstetric complications. The presence of obstetric complications was associated with a significantly higher prevalence of mood disorders and anxiety disorders during the perinatal period compared with women without obstetric complications.

The main strength of our study, compared with earlier ones, is its innovative character. Two of these earlier studies are quite similar but have major differences—some of which may be considered weaknesses—that we shall try not to reproduce. The first, published in 2003, is a Swedish multicentric observational study. It was undertaken to determine the prevalence of psychiatric disorders during the second trimester (T2) of pregnancy.[28] To illustrate just how unsupported the literature is, the authors described their work as a 'probably unique study'. A validated semistructured questionnaire to assess psychiatric disorders was completed by 1734 pregnant women who had taken part in routine ultrasound screening. Psychiatric disorders were present in 14.1% of women. Major depression was present in 3.3%, and anxiety disorders in 6.6%. Only 5.5% received treatment. The second, a Brazilian study conducted in 2013, was also observational. It involved 239 women who benefited from M.I.N.I. during their first-trimester ultrasound,[29] focusing on risk factors associated with suicide. They demonstrated that generalised anxiety disorder, major depressive disorder and multiparity were associated with suicidal risk in the first trimester of pregnancy.

These two studies provide us with epidemiological data from geographical areas, and therefore, healthcare systems differ from those in France. Our study, on the other hand, will enable us to describe the landscape of perinatal psychiatry, first locally and then nationally.

Another major strength of our protocol is that it involves repeating the questionnaires at 2 months *post partum*. Indeed, it is interesting to study the dynamics of symptoms to identify elements that may be associated with the development of pathology after pregnancy. For example, Evans *et al*[30] noted an increase in depression scores between the 18th and 32nd week of pregnancy, but it is not clear whether this same phenomenon applies to other psychiatric disorders.

The originality of our project also lies in the establishment of a biological collection, which will serve as a foundational resource for numerous future research projects. These projects will focus on identifying novel biomarkers not only in psychiatry and obstetrics but also across various other disciplines. Emerging biomarkers offer hope for enhancing diagnostic precision,[31 32] though their efficacy requires further validation through replicated studies.

Thus, the aim of this study is to determine the prevalence of at least one diagnosed psychiatric disorder (among all Diagnostic and Statistical Manual of Mental Disorders-5 (DSM-5) diagnoses), whether in remission or active, during pregnancy at the time of the T2 ultrasound. We will evaluate the occurrence of psychiatric disorders and the feasibility and acceptability of studying such disorders in a general population of adult women with ongoing pregnancies.

METHODS AND ANALYSIS

Study design and setting

This is an observational, prospective, multicentric study. The study will be conducted in the gynaecology-obstetrics departments of the Montpellier University Hospital and Beziers Hospital. Briefly, these are the two main public maternities in our region, performing over 3500 and 1000 births per year, respectively.

This study aims to include all pregnant women, regardless of comorbidities and other characteristics. Nevertheless, baseline characteristics will be used to classify participants during analyses.

The choice to perform the first visit during the T2 ultrasound appointment was carefully considered. First, this time period allows the detection of complications arising during pregnancy: a first-trimester ultrasound evaluation may not be able to identify disorders that worsen or appear during pregnancy. Also, patient care management is already welldefined in the T2 (women have selected their obstetrics specialist, follow-up and birth clinic).

A 2-month *postpartum* follow-up visit (V2) will allow for assessing the evolution and consequences of the diagnoses identified during the initial assessment. Previous studies and national surveys screened for postpartum depression 2 months after delivery.[33–36] Lastly, the 2-month V2 will also allow early detection of postpartum psychiatric

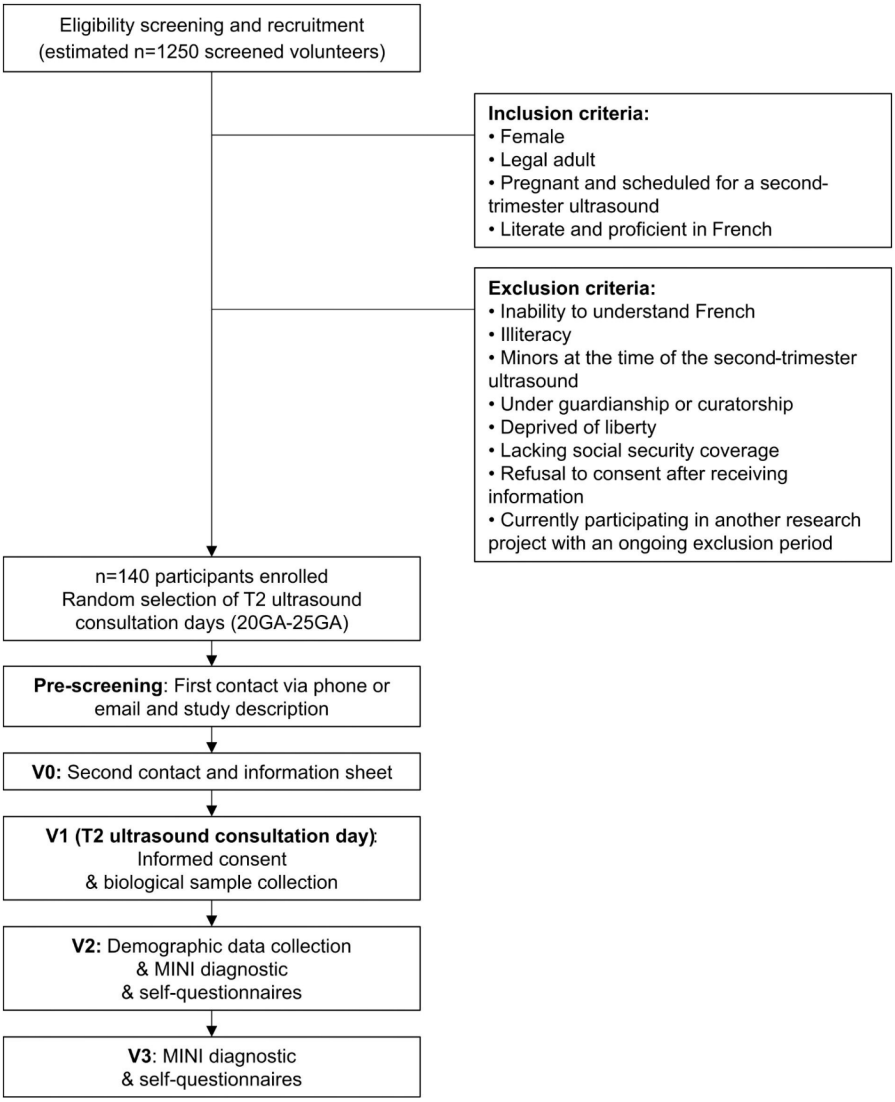

Figure 1 Study flowchart detailing recruitment, inclusion/exclusion criteria and visits. GA, gestational age; T2, second trimester; V0, screening visit; V1, inclusion visit, V2, follow-up visit; V3, postpartum visit.

disorders, avoiding delays in treatment and, therefore, improving prognosis.

Study population and eligibility criteria

Figure 1 shows the flowchart diagram of the study. Participants will be pregnant women undergoing a T2 ultrasound, regardless of known clinical history and normal or pathological pregnancy). Participants must meet the following inclusion criteria: female sex, legal adult, pregnant and scheduled for a T2 ultrasound and able to read and communicate in French (figure 1). Patients will not be included if they meet any of the following exclusion criteria: inability to understand French, illiteracy, minors at the time of the T2 ultrasound, under guardianship or curatorship, deprived of liberty, lacking social security coverage, refusal to consent after receiving information or currently participating in another research project with an ongoing exclusion period (figure 1). Participation is voluntary and participants can withdraw from the study at any time.

Patient and Public Involvement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

Recruitment and study timeline

The participant timeline is presented in figure 2. After recruitment, participants will undergo two visits within a 6-month follow-up period, including the final visit.

A total of 1250 volunteers will be approached to enrol approximately 140 participants. To limit sampling bias, the recruitment will involve a random selection of days for T2 ultrasound at the maternity units of Montpellier University Hospital and Beziers Hospital. On the randomly selected days, initial contact will be made between 28 and 21 days before the T2 ultrasound appointment, by email or post, with a brief presentation of the study. Patients will also be informed that a psychiatrist will contact them to present the study in greater detail and answer any questions they may have.

Screening visit (V0)

A screening visit (V0) will be offered to all women scheduled for a T2 ultrasound on random preselected days. If they consent to participate, they will receive detailed study information. A V0 will be scheduled no later than 15 days before their ultrasound consultation. A psychiatrist will contact patients by telephone to introduce himself/herself and describe the study. The psychiatrist will answer

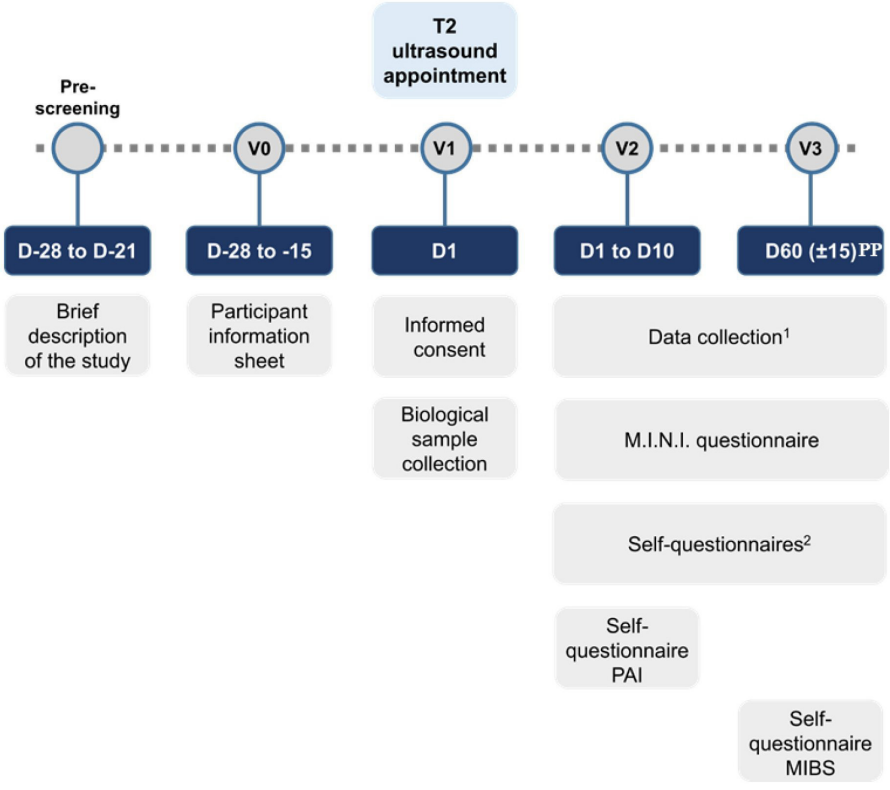

Figure 2 Participant timeline and patient path. [1]Collected data: medical and socio-demographic characteristics, Evaluation of the Deprivation and Inequalities of Health in Healthcare Centres and Columbia-Suicide Severity Rating Scale questionnaire and Paykel inventory. [2]Self-questionnaires: Edinburgh Postnatal Depression Scale, Mood Disorder Questionnaire, DSM-5 post-traumatic stress disorder checklist, Eating Disorder Examination Questionnaire, Medication Adherence Report Scale and Beliefs about Medicines Questionnaire. D, day; DSM-5, Diagnostic and Statistical Manual of Mental Disorders- 5; MIBS, Mother-to-Infant Bonding Scale; M.I.N.I., Mini-International Neuropsychiatric Interview; PAI, Personality Assessment Inventory and T2, second trimester; PP, postpartum; V0, screening visit; V1, inclusion visit, V2, follow-up visit; V3, postpartum visit.

any questions participants may have and suggest considering taking part in the protocol. Following this call, the study information note will be sent to the participants. If they wish to have more information, or if they have agreed to the call by a psychiatrist, a few days after this initial contact, a clinical research associate will call patients back to provide more details about the study, particularly to enlighten them on practical aspects of their participation.

Consent (inclusion visit (V1))

An inclusion visit (V1) will be scheduled on the day of their T2 ultrasound appointment. A psychiatrist will explain the study, answer any questions and ask the patient to sign a consent form (online supplemental file 1) if she wishes to participate. If, at this time, the patient expresses the wish not to participate in this research or not to be contacted about this project, solicitations will cease.

Biological sample collection

If participants provide specific consent for the contribution to the biobank, a blood test will be conducted during the V1. The collection will include a 2.5 mL Paxgene tube for whole-blood RNA, a 6 mL dry tube for serum and a 6 mL EDTA tube for native DNA (retained for 5 years). These samples will be anonymised and sent to the Biological Resource Centre at Montpellier University Hospital.

Follow-up visit (V2)

Follow-up visit (V2) will be scheduled at the hospital or via teleconsultation (videoconference or telephone) on the same day or within 10 days of the T2 ultrasound, based on the patient's preference, which will be noted. This session will primarily focus on completing the M.I.N.I. diagnostic interview with trained psychiatrists. To achieve a high inter-rater reliability, assuring a high degree of agreement, fewer than five examiners will be involved. They will also collect additional data such as medical and obstetrical history, expected pregnancy term and family medical history (standardised questionnaires and Electronic Case Report Form (e-CRF) (online supplemental file 2)). Given the epidemiological significance of suicide in the perinatal period, suicidal behaviour will be evaluated using the Columbia-Suicide Severity Rating Scale (CSSR-S).[37] The last 12 months' negative life events will be assessed using the Paykel questionnaire. Given its impact on psychological well-being, multiple dimensions of individual deprivation (eg, 'home-owning', 'financial difficulties' and 'sports activities') will be assessed using the Evaluation of the Deprivation and Inequalities of Health in Healthcare Centres (EPICES) questionnaire. Participants are required to complete self-administered questionnaires online on the same day or within 10 days: the Edinburgh Postnatal Depression Scale (EPDS)[24] for depression, the Mood Disorder Questionnaire (MDQ)[38] for bipolar disorder, the DSM-5 PTSD Checklist (PCL-5)[39] and the Eating Disorder Examination Questionnaire (EDEQ).[40] Additionally, the Beliefs about Medicines Questionnaire (BMQ)[41] and the Medication Adherence Report Scale (MARS)[42] assess medication beliefs and adherence, respectively. The Personality Assessment Inventory (PAI)[43] evaluates mother-child bonding as the questionnaire is about the relationship between mother and unborn child.

Studies suggest that teleconsultation does not affect the quality of results compared with face-to-face interviews, supporting their equivalence.[44–46]

Psychiatric medical history

Known psychiatric diagnoses will also be collected from the attending physician and the maternity records. Diagnoses explicitly recorded (eg, 'generalised anxiety disorder') and those inferred (eg, 'anxious patient') will be distinguished. This approach will highlight the discrepancies between unknown and newly established diagnoses, as identified using the M.I.N.I.

Postpartum visit (V3)

The postpartum visit (V3) will occur in person or via teleconsultation around 2 months post partum (±2 weeks), aligned with the patient's preference and the expected delivery date, which may be reassessed by reviewing the patient's medical file at that time. During this visit, medical, obstetrical and paediatric information will be collected, a new M.I.N.I. assessment will be conducted and the initial self-questionnaires will be administered again, with the addition of the Mother-to-Infant Bonding Scale (MIBS)[47] to assess mother-child bonding, without the PAI.

Outcomes and measures

The primary outcome is the presence of at least one psychiatric disorder of any kind (assessed by the M.I.N.I. questionnaire), in remission or not, during pregnancy at the T2 ultrasound.

Secondary outcomes at the two assessment stages (V2 and V3) include:

- The presence of each psychiatric disorder individually, including a history of suicidal behaviour disorder assessed with the CSSR-S. CSSR-S results will be interpreted according to each subsection's scores. If a positive score for questions 3 and 5 is observed, or if suicidal behaviour is confirmed, patients need immediate clinical intervention. If suicidal risk is present, the patient will need further evaluation and potential intervention. These interventions will be managed by our perinatal psychiatry team.
- The presence of postnatal depression assessed by the EPDS. The threshold for postpartum depression diagnosis will be an EPDS total score of over 13.
- The presence of bipolar disorders determined by the MDQ. The threshold for a bipolar disorder diagnosis will be at least 7 positive responses (out of 13 questions).
- The presence of PTSD determined by the PCL-5. Participants with a PCL-5 total score of at least 31 will be diagnosed with PTSD.

- The presence of eating disorders evaluated with the EDEQ. The cut-off to determine the presence of an eating disorder will be an EDEQ score of at least 4 (out of 6).
- The presence of diagnoses unknown to the obstetric team and/or not documented in the obstetric record.
- The presence of diagnoses unknown to the patient.
- The presence of diagnoses unknown to the attending physician.
- The presence of postpartum diagnoses.
- Medication compliance evaluated with the MARS. A MARS score of at least 6 (in 10) will indicate poor compliance.
- Beliefs about treatment assessed with the BMQ. The different BMQ subscores (all ranging from 1 to 5) will be used independently to interpret the participants' beliefs.
- Mother-child bond assessed by the MIBS and PAI. A disturbance in the mother-child bond will be detected if an MIBS total score is at least 2. PAI standardised scores ranging from 60 to 69 or 70 and above will indicate moderate or severe clinical disturbances, respectively.
- The sensitivity, specificity and positive and negative predictive values of the self-questionnaires (EPDS, MDQ, PCL-5 and EDEQ) compared with the gold standard (M.I.N.I.).

Sample size

This study aims to estimate the prevalence of psychiatric disorders, anticipated to be around 20%. To achieve a precision of ±8% at 95% CI, 97 evaluable participants would be needed. Considering a potential 30% dropout rate, the target will be to enrol 140 participants.

Data collection

During the visits V1 and V2, data will be collected based on the participants' declarations:

- Administrative and socio-demographic details such as marital status, residence, educational level, employment status and social security coverage, along with an evaluation of social deprivation (EPICES score).
- Medical history, including somatic, gynaecological and psychiatric conditions, associated treatments and substance use.
- Psychiatric family history among first-degree relatives.
- Current pregnancy data, including dates, gestational term, characteristics, follow-up and any obstetric complications.
- Clinical care characterisation, such as early prenatal interviews and support from perinatal professionals.
- Assessment of suicidal ideation and behaviour using the CSSR-S.
- Review of significant life events from the past 12 months using the Paykel inventory.
- Self-questionnaires cited above.

The data collected during visit V3 will be the following:

- Delivery and postpartum information.
- Newborn metrics such as weight, height, aspect (colouration), pulse, grimace (when excited), activity (tonus) and respiration score, previous hospitalisations and diagnoses.
- Data concerning the mother-child bond.
- Information on breastfeeding and feeding methods.
- Experiences related to care and childbirth.
- Self-questionnaires cited above.

Data management

Data will be collected and recorded on e-CRF (online supplemental file 2) by trained local research coordinators or physicians. A REDCap-based electronic case report form will be used to gather and deposit patient data. For confidentiality purposes, participants will be identified with a unique identifier number, the name and family name initials, sex and age. If needed, source data will be made available for inspection purposes by the principal investigator.

Collected data should be: (1) correctly recorded in the e-CRF (online supplemental file 2) at the moment of collection; (2) pseudonymised and (3) validated by the principal investigator's electronic signature. All documents will be kept for the duration of the study in a secured physical location and a secured REDCap server until perennial archiving.

Data analysis plan

The baseline features of the overall population and of each group will be described. Categorical variables will be reported as frequencies and percentages and continuous variables as either means with SD or medians with IQR.

The primary outcome and most secondary outcomes will be assessed with the M.I.N.I. questionnaire. Suicidal behaviour disorders will be evaluated with the CSSR-S questionnaire. The remaining secondary outcomes will be assessed using the scores of the self-questionnaires EPDS, MDQ, PCL-5, EDEQ, MARS and BMQ.

Participants' socio-demographic characteristics will be described using frequencies and percentages for qualitative variables or mean and SD or median and IQR, according to their distribution.

For the primary endpoint analysis, the prevalence of any psychiatric disorder during pregnancy will be described using frequencies, percentages and 95% CIs. For secondary endpoint analysis, specific disorders will be detailed similarly. The analysis will include subgroup evaluations based on known psychiatric histories. The diagnostic performance of self-administered questionnaires (EPDS, MDQ, PCL-5 and EDEQ) in identifying depression, mood disorders, PTSD and eating disorders, respectively, will be compared against the M.I.N.I. subdomains, with sensitivity, specificity and positive and negative predictive values computed along with 95% CIs.

Clustering methods will be applied to create homogeneous subgroups of participants based on comorbidities. No interim analysis is planned; preliminary data analysis will occur post-V2 completion, with comprehensive

analysis following the final V3. All analyses will be conducted by the medical statistical department of the Montpellier University Hospital using statistical software (SAS, V.9.4, SAS Institute and R, V.4.4.0).

ETHICS AND DISSEMINATION

The project is part of the 'AOT TREMPLIN' initiative funded by the Montpellier University Hospital.

This research involving humans will be conducted in compliance with French 'Loi no 2012–300 du 5 mars 2012 relative aux recherches impliquant la personne humaine' (Loi Jardé), 'Loi No 78–17 du 6 janvier 1978 modifiée relative à l'Informatique, aux fichiers et aux Libertés'. This study will be conducted in accordance with Good Clinical Practice, as defined by the International Conference on Harmonisation. The study project has been approved by the ethics committee 'Comité de Protection des Personnes Ouest VI 23.03919.000236'. The study is conducted in accordance with the Declaration of Helsinki and was prospectively registered at ClinicalTrials.gov (NCT06297252) on 7 March 2024.

The results will be submitted for publication in a peer-reviewed journal and presented at one or more scientific conferences.

Author affiliations
[1]Department of Psychiatry and Addictology, University Hospital Center, Montpellier, France
[2]Université Paris Cité, INSERM UMR1266, Institute of Psychiatry and neurosciences, Team 1, Paris, France
[3]Department of Psychiatry, AP-HP, Louis Mourier Hospital, Colombes, France
[4]INT-UMR 7289, CNRS Aix-Marseille University, Marseille, France
[5]Clinical Research Unit, CH Beziers, Beziers, France
[6]Department of Obstetrics and Gynecology, University Hospital Center, Montpellier, France
[7]INSERM, Center for research in Epidemiology and Population Health, U1018, Reproduction and Child Development, Villejuif, France
[8]Desbrest Institute of Epidemiology and Public Health (IDESP), INSERM, Montpellier, France
[9]Clinical Research and Epidemiology Unit, University Hospital Center, Montpellier, France
[10]IDESP, INSERM, PreMEdical INRIA, University Hospital Center, Montpellier, France
[11]IGF, CNRS, INSERM, Montpellier, France

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, conduct, reporting or dissemination plans of this research.

Patient consent for publication Consent obtained directly from patient(s).

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ORCID iD
Lucie Knabe http://orcid.org/0000-0003-4560-4273

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