Biometrics in Longitudinal Uptake for Early Monitoring and Assessing Perinatal Patterns of Emotions in Depression (BLUESMAPPED)

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STATEMENT OF COMPLIANCE

The Principal Investigator (PI) will assure that no deviation from, or changes to the protocol will take place without prior agreement documented approval from the Research Ethics Board (REB), except where necessary to eliminate an immediate hazard(s) to the study participants.

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the REB for review and approval. Approval of both the protocol and the consent form(s) must be obtained before any participant is enrolled. Any amendment to the protocol or consent materials will require review and approval by the REB before the changes are implemented to the study. All changes to the consent form will be REB approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

WCH Principal Investigator:

Name: Blanca Bolea-Alamanac

Signed: _____ Date: 23 July 2025

<DD Month YYYY>

LIST OF ABBREVIATIONS

EPDS Edinburgh Postnatal Depression Scale

HR heart rate

MDD major depressive disorder

ML machine learning

PD perinatal depression

PI Principal investigator

PMH Postpartum mental health

RC research coordinator

QR quick response

WCH Women's College Hospital

RESEARCH STUDY SUMMARY

Depression affects up to 1 in 5 pregnant and postpartum (perinatal) people. Perinatal depression (PD) is linked to multiple negative outcomes, including poor maternal-infant attachment and child developmental problems. A personal history of depression is the strongest risk factor for PD – with a risk of PD up to 20-fold higher in those with, vs. without, a history of depression. However, how to identify which person with a history of depression will develop PD - and might benefit from preventive interventions - is unclear. If we could provide a pregnant or postpartum person with an individualized prediction of their depression risk, they could start a preventive intervention (such as initiating psychotherapy or restarting their antidepressant medication) that would change their negative illness trajectory into a positive one. Such an approach would help people, and their clinicians weigh the potential benefits and risks of interventions during pregnancy or breastfeeding and substantially improve maternal and child outcomes in this high-risk population. However, making individual actionable predictions in Psychiatry has been an intractable problem so far.

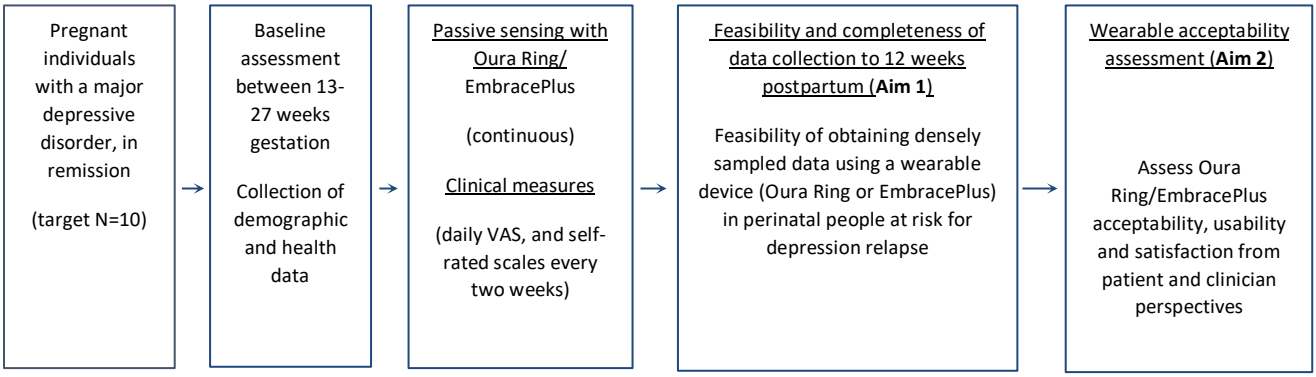
We propose to conduct a **preliminary pilot/proof of concept feasibility study to explore new methods for collecting and analyzing data to determine an individual's risk of developing depression during the perinatal period**. We plan to do this by incorporating **various types of data, including heart rate variability, sleep patterns, and activity levels** obtained from **wearable devices, as well as frequent assessments with user-friendly scales**. If this preliminary pilot is deemed feasible, then we will plan a full-scale pilot study that will combine data from multiple sources, with the aim to identify individual characteristics that may indicate an impending depressive relapse. This data will be integrated and analyzed to determine the

measures that discriminate those who develop perinatal depression from those who do not, enabling them to plan their care and make informed treatment decisions.

In this pre-pilot feasibility and acceptability study, we will recruit 10 participants and follow them for up to 6 months after delivery (main outcome at 3 months). Our study will assess recruitment rates, how many participants complete all the study measures, their point of view about acceptability and satisfaction of the devices and clinicians' perspectives on the use of wearables and their integration in clinical practice. Based on data completeness and adherence, this study will inform the choice of device in a future larger trial, as well as recruitment methods and operational targets such as staff and training required, computing capacity for gathering of data, etc. required for a larger study.

Figure 1. Schematic of Study Design

Figure. 1 Schematic overview of study



Schedule of Activities

Months 0-3: Seek REB approval, hire and train staff.

Months 4-16: Recruit proposed sample (N=10).

Months 17-20: Analyze data and write up results.

Months 21-23: Implement knowledge transfer plan.

1.0 INTRODUCTION

1.1 Background Information

Depression is a mood disorder characterized by significant impairment in one's ability to function, often marked by persistent sadness and loss of interest (9). Depression affects up to one in five pregnant and perinatal people (10). Perinatal depression (PD) can manifest during pregnancy but is more commonly seen within the first three months postpartum (11) as a consequence of endocrine, inflammatory, genetic, and psychosocial factors (12). While the symptoms of PD are similar to those of general depression, individuals with PD are more likely to experience anxiety and irritability during the postpartum period. A distinctive feature of PD is the presence of obsessional thoughts centered on topics like the baby's health or feeding (13,14). PD is linked to multiple negative outcomes from marital conflict to suicide (15). It is strongly linked to impaired mother-infant interactions and poor child developmental and emotional outcomes (16–21), including increased prevalence of anxiety and increased risk of externalizing disorders such as attention deficit hyperactivity disorder (22–25).

1.1.1 PD Prevention

Psychosocial and psychopharmacological interventions can be effective in preventing PD. In a Cochrane review of 28 trials (n~17,000), pregnant persons receiving psychological and psychosocial interventions were 78% less likely to develop PD compared to those receiving standard care (26). Few studies have investigated the preventative effects of antidepressant medications in euthymic individuals (27,28). Within the first 17 weeks postpartum, 7% (1 out of 14) of those who took sertraline developed perinatal depression (PD), compared to 50% (4 out of 8) of those who received a placebo (28). However, preventive interventions have potential drawbacks. Pharmacological treatments exposure may cause concerns with the fetus (cardiac

malformations, prematurity, persistent pulmonary hypertension, neonatal adaptation syndrome (29)) and infant in lactation (e.g. toxicity)(30). Affected individuals and their health care providers must balance these risks against the negative effects of untreated perinatal depression. Common barriers to access non-drug interventions include cost, missing work, and organizing childcare postpartum.

1.1.2 Early Detection of PD

A personal history of depression is the strongest risk factor for perinatal depression (PD), with those affected having up to a 20-fold higher risk compared to those without a history of depression (31). Other contributing factors include young maternal age, single parenthood, poverty, and major life stressors such as intimate partner violence or infant medical complications (31). Despite these known risk factors, accurately predicting whether an individual will develop PD remains challenging.

A Canadian study linking administrative data to clinical birth registry data found a 70% discriminative capacity for identifying postpartum depression (32). This study included 228,134 pregnant persons and used both logistic regression approaches. A risk index for individual-level prediction derived from this data, the Post-Partum Mental Health (PMH)-Careplan, showed probabilities of PD ranging from 1.56% to 40.5%, not being able to inform decisions about preventive treatment or early detection in specific individuals. Thus, existing models to predict PD need to be improved before individual-level prediction of risk can be used clinically (32).

The current study aims to examine the plausibility of collecting densely sampled participant data with wearable devices, as well as examining whether the collected data will be suitable for eventual PD prediction with a machine learning model in a further study.

1.2 Rationale

Early detection of PD can lead to better health outcomes for both pregnant people and their children. The current standard of care is routine screening for depressive symptoms using a validated scale, such as the Edinburgh Postpartum Depression Scale (EPDS), every 3 months. Current indexes of risk provide guidance on identifying individuals with a higher risk of PD, but their clinical value remains limited. Early detection of postpartum depression (PD) through low-burden methods like passive sensing could enable timely preventive interventions such as initiating psychotherapy or resuming antidepressant treatment. This proactive approach can potentially transform a negative illness trajectory into a positive one. This approach would enable individuals and their clinicians to better assess the benefits and risks of interventions during pregnancy or breastfeeding, significantly enhancing maternal and child outcomes in this high-risk population.

1.2.1 The Role of Passive Sensing in Detecting Depression

Data from multiple sources (i.e., multimodal data) is required to improve depression prediction models. Until recently, collecting multimodal data longitudinally had been challenging, as it could only be done at wide time intervals or in institutional settings with specialized equipment. With the rise and widespread use of low-cost passive sensing, it has become possible to examine how people's environment and experiences impact their physiology in situ. A major component in these studies is the notion of ecological momentary assessments, wherein a study participant is asked to periodically self-report what is happening during their day-to-day living (33,34).

Passive sensing holds immense clinical research value. For instance, data on an individual's sleep can assist in predicting their risk of PD, as sleep plays an important role in mood regulation, and sleep deprivation has been proposed as a possible mechanism for PD onset (35).

1.2.2 Wearables

A wearable is defined as a device that the patient carries continuously or semi-continuously and collects information about various physiological parameters (36). Unlike scales or clinical tests, wearables gather information passively and do not require any significant effort by the individual wearing them besides periodic charging. Prior research supports that wearables and e-health interventions are acceptable to patients and clinicians perinatally (21,22). More importantly, these technologies provide an opportunity for pregnant and postpartum individuals to monitor physiological parameters in real-time with little to no burden. It presents a more accessible option in comparison to in-person appointments for PD screening, especially for our target population.

The Oura ring, a lightweight titanium device weighing 4-6 grams, has been utilized in various studies to continuously monitor sleep, activity, and heart rate (37). Designed to be worn on the index finger, the ring is waterproof and is suitable for daily activities like showering. The Oura ring also has a 3D accelerometer and a gyroscope to track sleep and activity. When compared to the results of polysomnography, the ring correctly categorized 93% of events into polysomnography-defined total sleep time and sleep latency (38). Additionally, it employs infrared optical pulse measurement for heart rate assessment. A recent validation study showed that the heart rate data collected by the Oura ring exhibits fewer errors compared to traditional ECG devices (39). More importantly, it has been used for the early detection of pregnancy without any reported adverse outcomes (40).

EmbracePlus is a waterproof smartwatch with medical-grade sensors, enabling the collection of biomarkers such as sleep detection, activity counts, and pulse in a continuous manner (41). Through the use of ventral electrodermal sensors, EmbracePlus detects subtle changes in electrical conductance at the surface of the skin. EmbracePlus also collects clinically validated heart rate

variability using an advanced optical photoplethysmogram (41). Given the potential of the Oura ring and EmbracePlus devices, we propose testing and comparing their feasibility as a passive sensing tool for detecting PD in pregnant persons.

1.3 Potential Risks

Both the Oura Ring and the EmbracePlus use proprietary smartphone apps to stream encrypted data to cloud platforms owned by the respective companies. The companies do not share data with any third parties, and the data can only be accessed on the cloud platforms by those who have access to the account credentials. To avoid the risk that data is linked with individuals in our study, participants will be instructed to avoid creating device accounts with personally identifiable information. Instead, we will create device accounts for them in advance using generic study-specific identifiers (e.g., perinatal-study-p1). Only the research team and the participants will know these credentials.

There are no foreseeable health risks for the participants in the study since the study does not involve any clinical interventions. There is a chance that participants may be misled by data shown through the proprietary apps, but this risk is fairly minimal. The app for EmbracePlus does not show any health information, but rather shows basic indicators like whether the device is charged and connected. While the app for the Oura Ring presents some health information (e.g., sleep quality, readiness score), it has already been designed, tested, and deployed for consumer use. To be clear, we will not be delivering any real-time interventions in this pilot study based on this data, and we will inform participants to take caution in taking action based on any data they see in these apps.

1.4 Potential Benefits

There are multiple benefits to the proposed approach of wearables for perinatal depression prediction, however patients in this pre- pilot study may not benefit from participating in it. Wearables have been successfully used to monitor health status in chronic illness (such as diabetes) and acute care (ICU) (42,43). They have also been used to monitor fetal state and detect preterm labor in pregnant people (44). For participants specifically in our study, the collection of subjective data through self-rated scales allows for close monitoring of one's potential development of depression. Participants diagnosed with depression will be informed, and consent will be sought to communicate the findings with their primary care provider or their psychiatrist allowing them to receive adequate care in a timely manner.

2.0 OBJECTIVES AND PURPOSE

We propose a pre-pilot study protocol to demonstrate the feasibility of a new approach to early detection of PD based on gathering sampled subjective data and passively obtained objective data. We will collect data from 10 euthymic pregnant participants with a history of major depressive disorder (MDD). We posit that we will be able to recruit the sample proposed, that participants will find the wearables acceptable and easy to use and that data will be of enough quality in terms of completeness and accuracy. If these hypotheses are confirmed, we will have the evidence required to conduct a larger study that collects sufficient data for training a predictive ML model.

2.1 Primary Objective

Our primary objective is to determine the feasibility of obtaining densely sampled data using a wearable device (Oura Ring or EmbracePlus) in perinatal people at risk for depression relapse.

2.2 Secondary Objective

Our secondary objective is to assess the acceptability, usability and satisfaction with each wearable.

2.3 Exploratory objectives

We will use conventional statistical methods to analyze the data, compare wearables and explore what changes to the management and protocol of the study would be necessary for a larger pilot study with the ultimate aim of developing and validating a Machine Learning (ML) model to predict perinatal depression.

3.0 STUDY DESIGN

3.1 Overall Study Design

We plan on conducting a pre-pilot observational study to assess the feasibility, acceptability and satisfaction of wearables for collecting data to detect PD in pregnant persons. A total of 10 patients with a history of depression and between 13 and 27 weeks gestation will be included in the study. Participants will be given a wearable device (the Oura Ring or EmbracePlus watch) to wear until minimum 3 months post-partum. During the study period, data will be collected in the forms of passive sensing data from wearable devices and self-reported data from questionnaires. A subset (n=5) will be invited for semi-structured qualitative interviews about their experience in the study.

During the study period, 4 clinicians will also be recruited from Women's College Hospital (WCH) to complete a MS Teams interview on their perspective of wearable acceptability and integration into the electronic medical records (EMR).MS teams be used for interviews, and MS teams auto-transcription services used to generate transcripts. The auto-generated transcript of interview will be stored, on secure password-protected servers at WCH.

3.2 Duration of Study

We anticipate that participation in the pilot study will be from enrollment to at least 3 months post-partum. Patients will have the option to continue using the watch for an additional 12 weeks (3 months) after the primary endpoint. The recruitment process will take approximately 12 months to complete.

3.3 Total Number of Participants and Sites

Our pilot study will be based at WCH, and the target number of participants is 10. Accounting for a potential 50% loss to follow-up, we will be reaching out to at least 20 eligible patients. Participants can be enrolled in person at the main study site at WCH in Toronto, via secure videoconference, or by phone as we have done in other large clinical trials.

4.0 PARTICIPANT SELECTION AND WITHDRAWAL

4.1 Target Population

Our target population is pregnant persons with a history of depression between 13 and 27 weeks gestation, followed from the third trimester until at least 3 months postpartum, the time when most episodes of depression relapse will have occurred (51).Participants will be given the option to receive compensation via wire transfer a cheque or cash following the WCH Research Participant Advance Form instructions for accessibility purposes. Clinicians will be compensated with gift cards.

Pregnant persons:Value: 75 $ for the study and an extra 30 $ for participating in a qualitative interview.

Compensation method: wire transfer/cheque/cash. Participants will be given the option to receive compensation via wire transfer a cheque or cash following the WCH Research Participant Advance form instructions. Clinician participants will be compensated with a $20 gift card for participation.

4.2 Participant Recruitment and Screening

Pregnant persons

Participants will be recruited from antenatal care and specialty reproductive psychiatric clinics across Ontario, including the Reproductive Life Stages (RLS) program at WCH. We will also advertise directly through leafletting in the psychiatry department and advertising on the hospital website. We will advertise through advocacy groups that focus on perinatal mental health and with whom we already have a connection as they have been stakeholders in other studies in the RLS department. Interested participants will be directed to complete an initial eligibility screen in REDCap through a specific Quick Response (QR) code (BLUESMAPPED Eligibility Screen Questionnaire).

Potential participants may be referred to the study by their clinician. The clinician will discuss the study with the patient and provide them with a study leaflet. If the patient shows interest in participating, the clinician will complete a contact information survey using REDCap. The link to this survey will be shared with clinicians via email, mailing lists, or department meetings.

In the survey, the clinician will provide the interested participant's contact information and confirm that the patient has given consent for the clinician to reach out on their behalf. We will specifically ask the following question in the survey: “I am completing this on behalf of my patient, who has consented to be contacted for this research study and is interested in knowing if they are eligible.”

Once the research team receives the contact information from the referring clinician, they will send an eligibility screening form to the potential participant via email using the REDCap system.

For all potential participants deemed eligible (once RC reviews eligibility screenings and confirms this), a member of the research team will follow up via phone, Microsoft Teams, or email to schedule consent call. During this follow-up, the team will explain the study, confirm eligibility, and discuss consent form. If participant wishes to enrol, the link to the e-consent will be emailed to them after consent phone call. Clinicians

Clinicians will be recruited from WCH. The study will be shared during the RLS monthly department meetings with a QR code linking to the study enrollment screening form. The research staff member will reach out to the interested clinicians by email or phone about scheduling a consenting phone call orvirtual meeting.

4.3 Equity, Diversity and Inclusion Considerations

The study does not actively seek to recruit participants from underrepresented groups, but instead seek any potential participants meeting the inclusion criteria. Our recruitment materials will be designed to be accessible to all potential participants.

4.4 Inclusion Criteria

Pregnant Persons

To be eligible to participate in this study as a pregnant person, an individual must meet all the following criteria:

(1) age > 18 years; (2) pregnant, 13 to 27 weeks gestation at enrollment (to allow for sufficient data to be collected before delivery); (3) a previous diagnosis of MDD (the MINI structured clinical interview will be used to ascertain previous MDD episodes, which do not need to have

been of perinatal onset); (4) in remission as per an EPDS score < 9 (unlikely to be currently experiencing current depression in pregnancy); and (5) a smartphone and access to Internet or willingness to use a smartphone loaned by the study. In this feasibility study, we will include people regardless of antidepressant use status. Information about medication use, health resources use (such as psychotherapy), and level of support during pregnancy will be recorded.

If needed, participants will be provided with an iPhone 13 for the duration of the study. A consent iPhone borrowing agreement will be given to the participant borrowing a device (BLUESMAPPED iPhone Borrowing Agreement). Use of the device is restricted to study related activities only. The device will remain the property of the research team, and participants are responsible for its safekeeping. If the device is damaged, participants will need to report the incident to the research team and get a replacement. At the conclusion of the study, participants must return the device within two weeks. If a device is not returned, the research team will send up to two reminder notifications via email or phone.

Clinicians

To be eligible to participate in the study as a clinician, an individual have experience working with women in the area of reproductive life stages and mental health.

4.5 Exclusion Criteria

Pregnant Persons

An individual who meets any of the following criteria will be excluded from participation in this study: (1) active alcohol or substance use disorder within the past 12 months; (2) active suicidal ideation, history of bipolar or primary psychotic disorder; (3) physical condition preventing use of the Oura Ring/EmbracePlus watch (exclusion, for this reason, is expected to be rare); and (4) a

diagnosis of contact or occlusion dermatitis and/or contact dermatitis.

Clinicians

An individual who works outside of WCH or with no experience in the RLS or mental health program will be excluded.

4.6 Screen Failure

Only pregnant persons who meet all the requirements for inclusion will be able to participate. Information such as demographics (i.e., name or contact) and reasons for ineligibility will be recorded in a tracking file for those who are interested but cannot participate.

4.7 Participant Withdrawal Criteria

4.7.1 When and How to Withdraw Participants

Pregnant persons are free to withdraw from participation in the study at any time. The PI may choose to withdraw a participant for significant non-compliance or if the participant is experiencing stress or negative mental health effects. Reasons for the participant or PI's decision to withdraw from the study will be documented in a tracking file.

4.7.2 Withdrawn Participants

Participants can withdraw from the study at any point. Moreover, they can request the removal of any data collected (i.e., any physiological recordings such as HR, or objective recordings of sleep). Once a participant requests to be withdrawn, the reason for withdrawal will be recorded in the tracking file. No other contact will be made with the participant, and no other evaluations will occur.

4.7.3 Participants who are Lost to Follow-up

We will consider a participant lost to follow-up if they miss three scheduled assessments or the members of the research team are unable to contact the participant after three tries. We will make every effort to regain contact with the participant, such as phone calls or emails. If we are still unable to regain communication, we will consider the participant lost to follow-up. All attempts to contact a lost participant will be recorded in the tracking file.

In case of a pregnancy loss, research staff will contact the individual and ask if they would like to continue participating in the study. Resources for bereavement counselling will be shared with the individual if required. The participant may choose to continue wearing the ring/watch and answering questionnaires up to 6 months after the hypothetical delivery date, any questions referring to the pregnancy and fetal outcomes will be withdrawn from the questionnaires if this is the case.

5.0 RESEARCH PROCEDURES

5.1 Research Activities

Participants will be recruited through methods outlined in the *Patient Selection* section (4.0) of the protocol. Once an eligible participant is identified, a research coordinator (RC) will explain the study to potential participants, confirm eligibility, and obtain consent. Participants will be enrolled in person at the main study site at WCH, via secure videoconference, or by phone. Participants will be randomized to be given an Oura Ring or EmbracePlus watch to wear throughout the day so that they collect physiological data as we have done with other adults with mood disorders (48–50).Randomization will be done through REDCap feature after the completion of the consent form.Starting at enrollment, passive data from wearable devices will be collected continuously. Self-ratings of mood, anxiety, and energy levels via a visual analogue

scale (VAS) will be collected daily, and the EPDS and GAD-7 collected every 2 weeks, and concurrent event questionnaires (e.g., life events, pregnancy or infant complications, new health services or treatments used) will be collected every 2 weeks. At 3 months postpartum, participants will complete a final assessment, including a subset (n=5) who will be invited for semi-structured qualitative interviews about their experience in the study.

Clinicians will be given questionnaires and interviews to assess the acceptability and potential integration of wearable devices into clinical practice during the study. We aim to recruit four clinicians affiliated with the RLS Program at Women's College Hospital. Clinicians will participate in a semi-structured MS Teams interview lasting approximately 25 minutes, conducted by the RC or RA (Appendix 1C). The interview will explore their perspectives on the use of wearable devices in health care, including perceived utility, challenges, and considerations for clinical use and EMR integration.MS teams be used for interviews, and MS teams auto-transcription services used to generate transcripts. The auto-generated transcript of interview will be stored, on secure password-protected servers at WCH.

In addition to the interviews, clinicians will also complete an acceptability questionnaire including structured Likert-scale and multiple choice questions lasting approximately 5 minutes during the same MS Teams call session (Appendix 1C). The questionnaire will assess their views on usability, feasibility, and potential barriers or facilitators to the adoption of such technologies in clinical settings. Responses will be analyzed using thematic analysis alongside qualitative interview data to provide a comprehensive understanding of clinician perspectives.

5.2 Questionnaire Administration

Eligibility criteria will be assessed by the RC, and consent phone call, all surveys/questionnaires and interviews will be conducted by trained RAs. Baseline questionnaires include the Antidepressant Treatment History Form (ATHF), the Structured Clinical Interview for DSM-5 (MINI), and level of support during pregnancy will be assessed via the shortened version of the Couple Satisfaction Index (CSI-4). Participant perspectives will be ascertained from the Acceptability Questionnaire and from interviews that will be conducted at the end of the study (3 months postpartum). Heart rate variability and sleep activity will be continuously collected from the Oura Ring/EmbracePlus watch throughout the duration of the study. Participants' mood, anxiety, and energy will be measured using a Visual Analog Scale (VAS) and will be collected daily up to 3 months postpartum. Clinical symptoms such as depression and anxiety will be measured by the EPDS and the generalized anxiety disorder scale GAD-7 every 2 weeks. Concurrent events will be captured using the Life Events Questionnaire, Health Service Use Questionnaire, and Health Complications Questionnaire at baseline, every 2 weeks, and 3 months postpartum. The MINI will be done in participants with:

(i) Score on the Edinburgh Postnatal Depression Scale (EPDS) >13 (i.e., a score associated with a high sensitivity and specificity for depression);

(ii) Two consecutive EPDS scores of 9-12 (i.e., scores with a slightly lower specificity);

(iii) New suicidal ideation,

(iv) The prescription of a new antidepressant; or

(v) An emergency department visit or hospitalization for psychiatric reasons.

Participants who fulfill criteria for relapse will exit the study and receive treatment as usual by their primary care provider or by a perinatal psychiatry service. Birth Outcomes Questionnaire will be administered three months after delivery.

A detailed description of data collected at different timepoints throughout the study is as follows.

At baseline, participants will fill out questionnaires on:

1. Baseline information (baseline questionnaires, antidepressant treatment history, level of support during pregnancy)
2. Depression (MINI)
3. Concurrent events (life events, health service use, health complications)

From enrollment to 3 months postpartum, collected data will include the following:

4. Heart rate variability (HRV), sleep and activity data from the wearables
5. Self-ratings of mood, anxiety, and energy levels reported via a visual analogue scale (VAS) daily,
6. Self-administered EPDS and GAD-7 reported every 2 weeks, and
7. Concurrent event questionnaires (e.g., life events, pregnancy or infant complications, new health services or treatments used) completed every 2 weeks.

After this primary endpoint at 3 months postpartum, participants will complete a final assessment including the following components:

1. Self-ratings of mood, anxiety, and energy levels reported via a visual analogue scale (VAS),
2. Concurrent event questionnaires (e.g., life events, pregnancy or infant complications, new health services or treatments used, birth outcomes)
3. Personal view on the acceptability of wearable devices, and

4. Level of support during pregnancy

A subset (n=5) will be invited for semi-structured qualitative interviews about their experience in the study. Patients can then choose to continue using the wearable for up to 6 months postpartum, undergoing the final assessment again when follow-up is completed.

5.3 Schedule of Events

Study Variable	Measures	Baseline	During Study		3 months post-p.	Use
			Daily	q2wks		
Eligibility	Recruitment Data Questionnaire	Prior to enrollment				F
Baseline Information	Baseline Questionnaires*, ATHF, SCID-5 (MINI), Level of Support During Pregnancy (CSI-4)	X				P
Heart Rate Variability (HRV), Sleep, Activity	Oura Ring, EmbracePlus	Continuously collected				F
Mood, Anxiety, Energy	Visual Analogue Scales (VAS)		X		X	P
Clinical symptoms	EPDS, GAD-7			X		P
Concurrent Events	Life Events Questionnaire	X		X	X	P
	Health Service Use Questionnaire**	X		X	X	P
	Health Complications Questionnaires***	X		X	X	P
	Birth Outcomes Questionnaire/MPAS****		After delivery		X	P
Level of Support during Pregnancy	Level of Support Questionnaire (CSI-4)	X			X	P
Depression Relapse	MINI	X	As indicated*****		X	O
Participant Views	Acceptability Questionnaire and Interviews				X	F
Clinician Views	Acceptability Questionnaire and Interviews	Anytime during the study				F

PP=Postpartum; F=Feasibility; P=Predictor; O=Outcome; SCID-5=Structured Clinical Interview for DSM-5; CSI-4=Couple Satisfaction Index (shortened version); HRV= Heart Rate Variability; ATHF=Antidepressant Treatment History Form; EPDS=Edinburgh Postnatal Depression Scale; GAD=Generalized Anxiety Disorder; *sociodemographic, pregnancy, health service data; ** modified to include questions about new antidepressant prescription, *** pregnancy complications questionnaire until delivery; neonatal and child health questionnaires post-delivery;****Maternal

Postnatal Attachment Scale

6.0 STATISTICAL PLAN

6.1 Sample Size Determination

This initial study is intentionally designed with a small sample size, as it represents the first project within our department involving the collection and analysis of wearable device data. Additionally, this project marks the beginning of an active collaboration with the Department of Engineering at the University of Toronto, as well as with colleagues in the Department of Internal Medicine who have specific expertise in leveraging wearable technologies for disease prediction. Accordingly, we aim to recruit 10 participants to generate preliminary data and assess feasibility. The data collected, including the number of participants who complete the study and the completeness of individual data, will help us estimate a preliminary sample size for a larger pilot study. While we recognize that inter-individual variability may be substantial, we anticipate that this proof of concept pre-pilot will provide valuable insights into the acceptability and usability of the device, which will inform our decision on the appropriate device to use in the larger study and on the assignment of resources for a formal pilot study.

6.2 Statistical Methods

6.2.1 Primary and Secondary Objectives

We will track the recruitment rate of eligible participants and document reasons for non-participation to generate recruitment estimates for future studies and to better understand barriers to participation. Additionally, we will monitor completion rates for follow-up measures and record

reasons for any interruptions in wearable device usage, with completion rates analyzed by participants' demographic data and by group wearable. We will consider the study feasible is we can obtain 70% of the data scheduled for all participants recruited into the study.

Participants' views on the wearable device will be collected during the final assessment via the Acceptability Questionnaire, which includes both quantitative and open-ended questions. We will also evaluate usage patterns from the wearables to identify breaks and instances of complete discontinuation. We will conduct semi-structured interviews with 5 participants. Interview questions will explore acceptability, usability and satisfaction, and they will be guided by Sekhon's (55) acceptability framework.

Qualitative data will be analyzed using a thematic analysis framework as per Braun et al (56). Interview data will be triangulated with responses from the Acceptability Questionnaire. Clinicians will also be asked for their views on the use of wearables using a questionnaire that includes open ended questions.

6.2.2 Exploratory Objective

To assess the potential utility of self-reported and objective wearables data for predicting perinatal depression, we will use multiple statistical tests. For all of the tests listed below, the input covariates will be descriptive statistics that relate to the self-reported and objective wearables data listed in Table 1 (e.g. average sleep during the last 3 months pre-partum, change in average mood rating during the last week pre-partum). Comparisons between groups (according to wearable): For each input variable, we will check its normality using Shapiro-Wilk tests. We will then apply either a t-test or a Mann-Whitney U test as appropriate to determine whether there is a meaningful difference in the variables across groups. Given the small sample, we will not have enough data to ascertain perinatal depression predictors, or differences between

those women that develop depression and those who do not, but in this exploratory objective we aim to check if completeness of data will be of enough quality for further analysis as well as if there are preliminary differences between wearable groups in acceptability and usability.

Table 1. Input variables that will be used in statistical models for exploratory outcomes.

Data Type	Details	Collection Frequency
1. Continuous Wearable Data	Data collected from wearable devices (e.g., heart rate, activity, sleep patterns)	Continuously
2. Self-Ratings (VAS)	Daily ratings of mood, anxiety, and energy levels via a Visual Analogue Scale (VAS)	Daily, 12 weeks post-partum
3. EPDS & GAD-7 Scores	Edinburgh Postnatal Depression Scale (EPDS) and Generalized Anxiety Disorder (GAD-7)	Every 2 weeks (past scores inform future predictions)
4. Event Questionnaires	Life events, pregnancy/infant complications, health services or treatments used	Every 2 weeks, 12 weeks post-partum

7.0 SAFETY AND ADVERSE EVENTS

Adverse events will be recorded from study enrollment until the final follow-up. Serious unanticipated and intervention-related adverse events will be reported to the Women's College Hospital Research Ethics Board. Pregnancy complications that might be considered reportable serious adverse events (SAEs) in medical device intervention studies but are unlikely to be related

to this intervention, including congenital malformations, miscarriage, stillbirth, and prolonged maternal or infant hospitalization and death will be documented if they are reported to us but will not be reported to the REB. Similarly, infant death or hospitalization due to labour/pregnancy complications, congenital malformations, sudden infant death syndrome, illness, or accidents that are unrelated to the intervention will be documented but will not be reported to the REB.

We do not expect incidental findings in the study. However, if incidental findings do present, their seriousness will be assessed by the physicians in the study. If an incidental finding requires further investigation, a decision will be made to either notify the patient and with their permission, the primary care provider, or psychiatrist.

7.1 Definitions

Adverse Event

An adverse event (AE) is any untoward medical occurrence in a research participant administered an investigational product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the investigational product.

Specific to wearable devices, past case studies have shown that wearable devices can sometimes lead to health-related anxiety in some users. If any participant expresses health-related anxiety associated with the wearable (57), they will be invited to discuss their symptoms with the PI. Participants may choose to leave the study if this occurs.

Serious Adverse Event

A serious adverse event (SAE) is any AE that is:

- Fatal;
- Life-threatening;
- Requires or prolongs hospital stay;
- Results in persistent or significant disability or incapacity;
- A congenital anomaly or birth defect; or
- An important medical event (events that may not be life threatening but are of major clinical significance, such as a drug overdose or seizure that did not result in in-patient hospitalization).

7.2 Recording of Adverse Events

The period during which adverse events must be collected is normally defined as the period from the initiation of any research procedures to the final research visit. For this research study, the follow-up period is defined as 3 months after delivery, when the exit visit takes place. If the participant decides to continue using the wearable for another 6 months after delivery, this period will be extended until the exit interview at 6 months after delivery.

7.3 Reporting of Serious Adverse Events

7.3.1 Investigator Reporting: Notifying Applicable Regulatory Agencies

The process for notification to the REB for applicable unanticipated problems will be completed as per REB reporting requirements. Copies of each report and documentation of REB notification and REB receipt/acknowledgement must be kept in study team records.

7.3.2 Safety Management Plan

Participants survey results and data will be monitored regularly. In the event that participants are diagnosed based on self-rated surveys with depression, they will be informed promptly about the result. The research team will ask for the participant's consent in contacting their primary care

provider to provide a referral. If the patient already has a psychiatrist at WCH and with the patient's consent, the specialist that is already looking after the participant will be notified.

Participants will be provided with the research team's contact information. If participants experience heightened health-related anxiety or any other discomfort preventing them from further participation in the study, they can withdraw from the study by contacting the RC.

If participants are suspected to have suicidal ideation, the RC/RA will administer the Columbia protocol a validated screening measure to evaluate risk of self-harm. This protocol asks specific questions about risk (such as suicidal ideation, plans, supports available, etc) and includes a decision tool which ranges from sending information about further supports, to action points to address immediate risk (such as calling 911). Any other safety concerns will be discussed among the clinical team, as it would be in usual clinical practice.

A committee consisting of the PI, study co-investigators, and the RA will hold teleconferences as necessary to discuss study progress, including participant recruitment, and any other unexpected issues.

7.4 Incidental Findings

Participants are given the option to find out and have their primary practitioner notified about incidental findings in the study consent form. If incidental finding occurs, the PI of the study will be notified. The PI will determine if there is clinical relevance to the incidental findings. If there is clinical relevance, a disclosure will be made for those that opted to be informed.

8.0 RESEARCH STUDY DISCONTINUATION AND CLOSURE

This research study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause (i.e. closure based on PI decision). Notification, which includes the reason for study suspension or termination, will be provided to all research participants. If the research study is prematurely terminated or suspended, the PI will promptly inform research participants and the REB, and will provide the reason(s) for the termination or suspension. All communication with participants for this purpose will go through REB review and approval. Research participants will then be contacted, as applicable, and be informed of changes to the study visit schedule

9.0 DATA HANDLING AND RECORD KEEPING

9.1 Data Collection and Management Responsibilities

All data will be kept on WCH servers and will be password protected. Study data will be entered into REDCap (Research Electronic Data Capture), a secure, web-based application designed exclusively to support data capture for research studies. REDCap is developed and maintained by a team at Vanderbilt University and licensed free of charge by the Research Institute at Women's College Hospital (WCH). The application and data are housed on central servers provided by WCH. Local support for REDcap is provided by the WCH REDCap Administrator.

9.2 Source Documents and Access to Source Data/Documents

Access to study records will be limited to REB-approved members of the study team. The PI will permit study-related monitoring, audits, and inspections by the REB and / or University compliance and quality assurance groups of all study related documents (e.g. source documents, data collection instruments, study data etc.). The PI will ensure the capability for inspections of applicable study-related facilities (e.g. pharmacy, diagnostic laboratory, etc.).

9.3 Protocol Deviations

No deviations from or changes to the protocol will be implemented without prior approval from the REB, unless to eliminate an immediate hazard to a participant.

9.4 Record Retention

Data will be kept anonymized for 7 years and then will be destroyed following current data management protocols.

10.0 ETHICAL CONSIDERATIONS

All participants will provide informed consent prior to their involvement in the study. They will be clearly informed that they can withdraw from the study at any time and may also request the withdrawal of their data prior to anonymization. The study will be reviewed and approved by the local hospital's ethics board. All study materials, including informed consent forms, recruitment materials, and questionnaires, will be submitted for ethics approval before the study begins. Data will be securely stored on hospital-based servers in compliance with national personal health information laws.

10.1 Research Ethics Approval

Research Ethics Board (REB) approval will be obtained before initiating any research-related procedures. Following the initial approval, ongoing ethical compliance will be ensured through regular REB reviews, which will occur at least annually in accordance with regulatory and REB guidelines. The study will be conducted in strict adherence to the REB-approved protocol and determinations, including any specified limitations, and in full compliance with REB requirements.

If new information arises that could impact participant consent, a revised consent form or consent addendum will be submitted to the REB for review and approval before implementation. Any updated information provided to participants will also require REB approval prior to distribution.

10.2 Informed Consent Process and Documentation

Informed consent will be obtained from all participants before their participation in the study. For in-person recruitment, a member of the research staff will review the consent form with participants, explaining the study's purpose, potential risks and benefits, and the participant's rights, including the ability to withdraw at any time. Participants will be given ample time to ask questions and review the information before providing consent. A signed copy of the consent form will be be ready for print once the participants electronically signs the consent form on REDCap. (Appendix for BLUESMAPPED WCH Informed Consent Form).

A member of the research staff will email the participant to schedule a phone or virtual meeting (e.g., viaMS Teams) to review the study details and complete the consent discussion process once eligibility has been confirmed. During this meeting, the research staff will discuss the study details and discuss consent from the participant. If the participant is interested in participating in the study, an e-consent form on REDCap will be sent for them to read and sign.

11.0 PRIVACY AND CONFIDENTIALITY

All study-related documents and data will be kept strictly confidential and stored at WCH or on WCH servers, in compliance with WCH policies and procedures to safeguard participant privacy and confidentiality. Data from the Oura ring will be uploaded to WCH servers daily. Data from EmbracePlus will be uploaded continuously to the Empatica Cloud when Wi-Fi is available, and downloaded to the WCH servers daily.

All research activities will take place in a private setting. The participant's contact information will be securely stored at WCH for internal use during the study. Upon the study's completion, all records will remain securely stored in accordance with relevant institutional and regulatory requirements.

MS teams to be used for interviews, and MS teams auto-transcription services used to generate transcripts. The auto-generated transcript of interview will be stored, on secure password-protected servers at WCH.

12.0 RESEARCH STUDY FINANCES

12.1 Funding Source

We plan to apply for an AFP grant (September 2025) which will be matched by internal funds from WCH (Prof. Vigod). Devices will be funded by the CFI grant held by Prof. Vigod.

12.2 Conflicts of Interest

The research team members do not have any foreseeable conflicts in relation to the pilot study.

13.0 PUBLICATION POLICY/DATA SHARING

The results of the study will be disseminated through both academic and non-academic channels. Academic dissemination will include publications in peer-reviewed journals and presentations at relevant academic conferences. Non-academic dissemination will involve lectures for community partners who contributed to recruitment, as well as the publication of an accessible summary of the findings on the hospital's website and other platforms aimed at educating the public about perinatal depression. No patient identifying information will be stored beyond the timeframe of the study. Only de-identified data will be used solely for the purpose of calculating the sample size of future studies.

14.0 REFERENCES

1. Bhalla S, Han T, Gershon A, Wu R, de Lara E, Mariakakis A. Phoneme-Aware Acoustic Analysis of Natural Speech for Lung Function Assessment. In: ICASSP 2025 - 2025 IEEE International Conference on Acoustics, Speech and Signal Processing (ICASSP) [Internet]. 2025 [cited 2025 Jul 6]. p. 1–5. Available from: https://ieeexplore.ieee.org/abstract/document/10888421

2. Bhalla S, Liaqat S, Wu R, Gershon AS, de Lara E, Mariakakis A. PulmoListener: Continuous Acoustic Monitoring of Chronic Obstructive Pulmonary Disease in the Wild. Proc ACM Interact Mob Wearable Ubiquitous Technol. 2023 Sep 27;7(3):86:1-86:24.

3. Liaqat S, Falk T, To T, Andany N, Patel N, Wu R, et al. Predicting Low Oxygen Saturation of COVID-19 Patients Using a Random Forest Classifier. In: B57 CUTTING EDGE COVID RESEARCH [Internet]. American Thoracic Society; 2022 [cited 2025 Jul 6]. p. A3159–A3159. (American Thoracic Society International Conference Abstracts). Available from: https://www.atsjournals.org/doi/abs/10.1164/ajrccm-conference.2022.205.1_MeetingAbstracts.A3159

4. Sedaghat T, Liaqat S, Liaqat D, Wu R, Gershon A, Son T, et al. Unobtrusive Monitoring of COPD Patients using Speech Collected from Smartwatches in the Wild. In: 2022 IEEE International Conference on Pervasive Computing and Communications Workshops and other Affiliated Events (PerCom Workshops) [Internet]. 2022 [cited 2025 Jul 6]. p. 818–23. Available from: https://ieeexplore.ieee.org/abstract/document/9767283

5. Gershon A s., Patel N, Wu R, Liaqat S, Liaqat D, de Lara E, et al. Trends in Oxygen Level During Acute COVID-19 Infection in Patients Quarantining at Home. In: B57 CUTTING EDGE COVID RESEARCH [Internet]. American Thoracic Society; 2022 [cited 2025 Jul 6]. p. A3169–A3169. (American Thoracic Society International Conference Abstracts). Available from: https://www.atsjournals.org/doi/abs/10.1164/ajrccm-conference.2022.205.1_MeetingAbstracts.A3169

6. Lin G, Li B, Li JY, Zhao C, Truong K, Mariakakis A. Users' Perspectives on Multimodal Menstrual Tracking Using Consumer Health Devices. Proc ACM Interact Mob Wearable Ubiquitous Technol. 2024 Sep 9;8(3):116:1-116:24.

7. Lin G, Siddiqui R, Lin Z, Blodgett JM, Patel SN, Truong KN, et al. Blood glucose variance measured by continuous glucose monitors across the menstrual cycle. Npj Digit Med. 2023 Aug 11;6(1):140.

8. Lin G, Li JY, Christofferson K, Patel SN, Truong KN, Mariakakis A. Understanding wrist skin temperature changes to hormone variations across the menstrual cycle. Npj Womens Health. 2024 Oct 4;2(1):35.

9. Chand SP, Arif H. Depression. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 [cited 2024 Aug 26]. Available from: http://www.ncbi.nlm.nih.gov/books/NBK430847/

10. Fisher J, Cabral De Mello M, Patel V, Rahman A, Tran T, Holton S, et al. Prevalence and determinants of common perinatal mental disorders in women in low- and lower-middle-income countries: a systematic review. Bull World Health Organ. 2012 Feb 1;90(2):139-149H.

11. Mughal MK, Giallo R, Arshad M, Arnold PD, Bright K, Charrois EM, et al. Trajectories of maternal depressive symptoms from pregnancy to 11 years postpartum: Findings from Avon Longitudinal Study of Parents and Children (ALSPAC) cohort. J Affect Disord. 2023 May;328:191–9.

12. Yim IS, Tanner Stapleton LR, Guardino CM, Hahn-Holbrook J, Dunkel Schetter C. Biological and Psychosocial Predictors of Postpartum Depression: Systematic Review and Call for Integration. Annu Rev Clin Psychol. 2015 Mar 28;11(1):99–137.

13. Di Florio A, Meltzer-Brody S. Is Postpartum Depression a Distinct Disorder? Curr Psychiatry Rep. 2015 Oct;17(10):76.

14. Johann A, Ehlert U. Similarities and differences between postpartum depression and depression at other stages of female life: a systematic review. J Psychosom Obstet Gynecol. 2022 Jul 3;43(3):340–8.

15. Khalifeh H, Hunt IM, Appleby L, Howard LM. Suicide in perinatal and non-perinatal women in contact with psychiatric services: 15 year findings from a UK national inquiry. Lancet Psychiatry. 2016 Mar;3(3):233–42.

16. Beck CT. The effects of postpartum depression on child development: A meta-analysis. Arch Psychiatr Nurs. 1998 Feb;12(1):12–20.

17. Hammen C, Brennan PA. Severity, Chronicity, and Timing of Maternal Depression and Risk for Adolescent Offspring Diagnoses in a Community Sample. Arch Gen Psychiatry. 2003 Mar 1;60(3):253.

18. Martins C, Gaffan E. Effects of early maternal depression on patterns of infant-mother attachment: a meta-analytic investigation. J Child Psychol Psychiatry. 2000;41(6):737–46.

19. Murray L. The Impact of Postnatal Depression on Infant Development. J Child Psychol Psychiatry. 1992 Mar;33(3):543–61.

20. Weinberg M, Tronick E. The impact of maternal psychiatric illness on infant development. J Clin Psychiatry. 1998;59(Suppl 2):53–61.

21. Sinclair D, Murray L. Effects of postnatal depression on children's adjustment to school: Teacher's reports. Br J Psychiatry. 1998 Jan;172(1):58–63.

22. Pilowsky DJ, Wickramaratne P, Talati A, Tang M, Hughes CW, Garber J, et al. Children of Depressed Mothers 1 Year After the Initiation of Maternal Treatment: Findings From the STAR*D-Child Study. Am J Psychiatry. 2008 Sep;165(9):1136–47.

23. Pilowsky DJ, Wickramaratne PJ, Rush AJ, Hughes CW, Garber J, Malloy E, et al. Children of Currently Depressed Mothers: A STAR*D Ancillary Study. J Clin Psychiatry. 2006 Jan 15;67(01):126–36.

24. Weissman MM, Pilowsky DJ, Wickramaratne PJ, Talati A, Wisniewski SR, Fava M, et al. Remissions in Maternal Depression and Child Psychopathology: A STAR*D-Child Report. JAMA. 2006 Mar 22;295(12):1389.

25. Wickramaratne P, Gameroff MJ, Pilowsky DJ, Hughes CW, Garber J, Malloy E, et al. Children of Depressed Mothers 1 Year After Remission of Maternal Depression: Findings From the STAR*D-Child Study. Am J Psychiatry. 2011 Jun;168(6):593–602.

26. Dennis CL, Dowswell T. Psychosocial and psychological interventions for preventing postpartum depression. Cochrane Pregnancy and Childbirth Group, editor. Cochrane Database Syst Rev [Internet]. 2013 Feb 28 [cited 2025 Jan 15]; Available from: https://doi.wiley.com/10.1002/14651858.CD001134.pub3

27. Cohen LS. Relapse of Major Depression During Pregnancy in Women Who Maintain or Discontinue Antidepressant Treatment. JAMA. 2006 Feb 1;295(5):499.

28. Molyneaux E, Telesia LA, Henshaw C, Boath E, Bradley E, Howard LM. Antidepressants for preventing postnatal depression. Cochrane Common Mental Disorders Group, editor. Cochrane Database Syst Rev [Internet]. 2018 Apr 18 [cited 2025 Jan 15];2018(4). Available from: http://doi.wiley.com/10.1002/14651858.CD004363.pub3

29. Desaunay P, Eude LG, Dreyfus M, Alexandre C, Fedrizzi S, Alexandre J, et al. Benefits and Risks of Antidepressant Drugs During Pregnancy: A Systematic Review of Meta-analyses. Pediatr Drugs. 2023 May;25(3):247–65.

30. Orsolini L, Bellantuono C. Serotonin reuptake inhibitors and breastfeeding: a systematic review: SSRIs AND SNRIs IN BREASTFEEDING. Hum Psychopharmacol Clin Exp. 2015 Jan;30(1):4–20.

31. Silverman ME, Reichenberg A, Savitz DA, Cnattingius S, Lichtenstein P, Hultman CM, et al. The risk factors for postpartum depression: A population-based study: S ILVERMAN ET AL. Depress Anxiety. 2017 Feb;34(2):178–87.

32. Vigod SN, Urbach N, Calzavara A, Dennis CL, Gruneir A, Thombs BD, et al. Clinical index to quantify the 1-year risk for common postpartum mental disorders at the time of delivery (PMH CAREPLAN): development and internal validation. Br J Psychiatry. 2023 Sep;223(3):422–9.

33. Krohn H, Guintivano J, Frische R, Steed J, Rackers H, Meltzer-Brody S. App-Based Ecological Momentary Assessment to Enhance Clinical Care for Postpartum Depression: Pilot Acceptability Study. JMIR Form Res. 2022 Mar 23;6(3):e28081.

34. Omowale SS, Casas A, Lai YH, Sanders SA, Hill AV, Wallace ML, et al. Trends in Stress Throughout Pregnancy and Postpartum Period During the COVID-19 Pandemic: Longitudinal Study Using Ecological Momentary Assessment and Data From the Postpartum Mothers Mobile Study. JMIR Ment Health. 2021 Sep 21;8(9):e30422.

35. Lawson A, Murphy KE, Sloan E, Uleryk E, Dalfen A. The relationship between sleep and postpartum mental disorders: A systematic review. J Affect Disord. 2015 May;176:65–77.

36. Vijayan V, Connolly JP, Condell J, McKelvey N, Gardiner P. Review of Wearable Devices and Data Collection Considerations for Connected Health. Sensors. 2021 Aug 19;21(16):5589.

37. Oura Ring [Internet]. [cited 2025 Jan 17]. How does Oura Ring work: Smart Ring Health Tracking. Available from: https://ouraring.com

38. De Zambotti M, Rosas L, Colrain IM, Baker FC. The Sleep of the Ring: Comparison of the ŌURA Sleep Tracker Against Polysomnography. Behav Sleep Med. 2019 Mar 4;17(2):124–36.

39. Stone JD, Ulman HK, Tran K, Thompson AG, Halter MD, Ramadan JH, et al. Assessing the Accuracy of Popular Commercial Technologies That Measure Resting Heart Rate and Heart Rate Variability. Front Sports Act Living. 2021 Mar 1;3:585870.

40. Grant A, Smarr B. Feasibility of Continuous Distal Body Temperature for Passive, Early Pregnancy Detection [Internet]. medRxiv; 2021 [cited 2024 Sep 9]. p. 2021.08.19.21262306. Available from: https://www.medrxiv.org/content/10.1101/2021.08.19.21262306v1

41. Empatica [Internet]. [cited 2025 Jan 17]. EmbracePlus | The world's most advanced smartwatch for continuous health monitoring. Available from: https://www.empatica.com/embraceplus

42. Phillips SM, Cadmus-Bertram L, Rosenberg D, Buman MP, Lynch BM. Wearable Technology and Physical Activity in Chronic Disease: Opportunities and Challenges. Am J Prev Med. 2018 Jan;54(1):144–50.

43. Kroll RR, McKenzie ED, Boyd JG, Sheth P, Howes D, Wood M, et al. Use of wearable devices for post-discharge monitoring of ICU patients: a feasibility study. J Intensive Care. 2017 Nov 21;5(1):64.

44. Jasinski SR, Rowan S, Presby DM, Claydon EA, Capodilupo ER. Wearable-derived maternal heart rate variability as a novel digital biomarker of preterm birth. PLOS ONE. 2024 Jan 31;19(1):e0295899.

45. Koutsouleris N, Dwyer DB, Degenhardt F, Maj C, Urquijo-Castro MF, Sanfelici R, et al. Multimodal Machine Learning Workflows for Prediction of Psychosis in Patients With Clinical High-Risk Syndromes and Recent-Onset Depression. JAMA Psychiatry. 2021 Feb 1;78(2):195.

46. Ortiz A, Bradler K, Mowete M, MacLean S, Garnham J, Slaney C, et al. The futility of long-term predictions in bipolar disorder: mood fluctuations are the result of deterministic chaotic processes. Int J Bipolar Disord. 2021 Dec;9(1):30.

47. Ortiz A, Bradler K, Hintze A. Episode forecasting in bipolar disorder: Is energy better than mood? Bipolar Disord. 2018 Aug;20(5):470–6.

48. Ortiz A, Bradler K, Moorti P, MacLean S, Husain MI, Sanches M, et al. Reduced heart rate variability is associated with higher illness burden in bipolar disorder. J Psychosom Res. 2021 Jun;145:110478.

49. Ortiz A, Bradler K, Moorti P, MacLean S, Husain MI, Sanches M, et al. Increased sympathetic tone is associated with illness burden in bipolar disorder. J Affect Disord. 2022 Jan;297:471–6.

50. Ortiz A, Hintze A, Burnett R, Gonzalez-Torres C, Unger S, Yang D, et al. Identifying patient-specific behaviors to understand illness trajectories and predict relapses in bipolar disorder using passive sensing and deep anomaly detection: protocol for a contactless cohort study. BMC Psychiatry. 2022 Dec;22(1):288.

51. Munk-Olsen T, Laursen TM, Pedersen CB, Mors O, Mortensen PB. New Parents and Mental Disorders: A Population-Based Register Study. JAMA. 2006 Dec 6;296(21):2582.

52. Vigod SN, Hussain-Shamsy N, Stewart DE, Grigoriadis S, Metcalfe K, Oberlander TF, et al. A patient decision aid for antidepressant use in pregnancy: Pilot randomized controlled trial. J Affect Disord. 2019 May;251:91–9.

53. Vigod SN, Slyfield Cook G, Macdonald K, Hussain-Shamsy N, Brown HK, Oliveira C, et al. Mother Matters: Pilot randomized wait-list controlled trial of an online therapist-facilitated discussion board and support group for postpartum depression symptoms. Depress Anxiety. 2021 Aug;38(8):816–25.

54. Dennis CL, Grigoriadis S, Zupancic J, Kiss A, Ravitz P. Telephone-based nurse-delivered interpersonal psychotherapy for postpartum depression: nationwide randomised controlled trial. Br J Psychiatry. 2020 Apr;216(4):189–96.

55. Sekhon M, Cartwright M, Francis JJ. Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework. BMC Health Serv Res. 2017 Dec;17(1):88.

56. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol. 2006 Jan;3(2):77–101.

57. Rosman L, Lampert R, Zhuo S, Li Q, Varma N, Burg M, et al. Wearable Devices, Health Care Use, and Psychological Well‐Being in Patients With Atrial Fibrillation. J Am Heart Assoc. 2024 Aug 6;13(15):e033750.