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| Title and Resources |
| **Title**Include the title and version number used on the HREA application |
| PARTICIPATION IN AN ONLINE MINDFULNESS RELATIONSHIP-BASED PROGRAM DURING PREGNANCY: OUTCOMES FOR MATERNAL MENTAL HEALTH, MOTHER-INFANT RELATIONSHIP DURING PREGNANCY, AND MOTHER-INFANT EMOTIONAL AVAILABILITY (STUDY 2).This Research Project Description Protocol refers to HREA application for Study 2. This study is part of a PhD thesis comprising Study 1 (given ethical approval under reference number AS03523) and present Study 2 (program/intervention). The two studies are linked by the investigation of the same maternal variables at the same time points, Study 2 including measurement of baseline, post-intervention, and post-birth outcomes. |
| **Resources**Describe the resources necessary to conduct the project including financial support |
| This project does not require additional physical resources to that currently available to the candidate as a full-time research student. As data will be collected via online surveys, specialised equipment is not necessary. The primary expenditure will be in supporting the candidate to attend and/or present conferences relevant to the research project. |
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| Background to the Project |
| Provide a brief plain language theoretical overview and project rationale.  |
|  Maternal mental health has consequences for the mother-infant relationship and infant development during pregnancy and post birth. Mind-body therapeutic approaches during pregnancy, such as mindfulness-based healthcare practices, have revealed positive outcomes, primarily in reducing parental stress, anxiety and depression. There remains a need for considering the influence of these antenatal approaches on the mother-infant relationship during pregnancy and in the first three months in a single group of pregnant women. This study will explore the associations among mindfulness and other prenatal predictors of maternal-infant relationship (maternal mental health, in particular depression, anxiety and stress, mother-infant relationship during pregnancy, and interoception) via the online Prenatal Mindfulness- Relationship-Based (PMRB) program developed by the candidate through her work with expectant and new parents, including measurement of baseline (20+ weeks gestation), post-intervention (approximately 36-week gestation) and post-partum (10-12 weeks) outcomes. It is believed that this study may provide the first evidence that maternal mindfulness, thus a prenatal mindfulness relationship-based program focused on mother-infant sensorimotor and reflective interactions, can support mother-infant relationship during pregnancy and post-birth, with potential benefits for maternal wellbeing, the transition to parenting, and infant development. Examining prenatal predictors of maternal-infant relationship may provide possible avenues for identification of at-risk women and implementation of timely and appropriate strategies, such as mindfulness-based therapeutic approaches in the prenatal period, to prevent perinatal psychological disorders and their impact on infant development and wellbeing. |
| Describe the research questions, aims, objectives and hypothesis |
| This project addresses the following questions: **RESEARCH QUESTION** **RQ1**: Would participation in the PMRB program lead to higher levels of mindfulness, better  mental health (as indicated by lower levels of anxiety, depression, and stress), more favourable mother-infant relationship, and higher interoception during pregnancy post-intervention, compared to the baseline scores? **RQ1:** Would participation in the PMRB program lead to higher levels of mindfulness, better mental health (as indicated by lower levels of anxiety, depression, and stress), more favorable mother-infant relationship, and higher interoception post-birth, compared to the baseline scores?**RQ3:** Open-ended: “How has the PMRB program supported (oe not supported) you during pregnancy, labour, and birth and the first postpartum trimester?” **AIM** The aim of this project is to pilot the online PMRB program through an e-health feasibility study, comparing post-program and postbirth outcomes in the same variables with baseline scores during pregnancy across three time points. The aim is to test the hypothesis,through an e-health feasibility study, that the PMRB program could enhance the mental health of pregnant and new mothers asmeasured by multiple dimensions of psychological health and the relationship with their infants during pregnancy and post-birth,with positive impacts on gestation, birth, and infant outcomes as reported by the mothers in a Post-Birth Questionnaire. **HYPOTHESIS** 1. It is hypothesized that participation in the PMRB program would lead to higher levels of mindfulness, better maternal mental health

(as indicated by lower levels of anxiety, depression, and stress), more favourable mother-infant relationship, and higher interoceptionduring pregnancy post-intervention, compared to the baseline scores. 1. It was hypothesized that participation in the PMRB program would lead to higher levels of mindfulness, better mental health

(as indicated by lower levels of anxiety, depression, and stress), more favourable mother-infant relationship and higher interoception post-birth, cpmpared to baseline scores1. It was hupotheised that the PMRB program would support women during pregnancy, labour and birth, and the first postpartum period. .
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| Describe the expected outcomes and impacts of the research |
| It is anticipated that the proposed study would add to the limited body of research on prenatal predictors of maternal mental health and maternal-infant relationship and the importance of maternal mindfulness during pregnancy to maternal mental health, and maternal-infant relationship prior and post-birth, and the implications for infant development and wellbeing. It is believed that this study may provide the first evidence that maternal mindfulness, thus a mindfulness-based intervention during pregnancy focused on mother-infant interactions, can support mother-infant relationship during pregnancy and post-birth, with potential benefits for maternal wellbeing and infant development. Evidence of antenatal predictors of maternal mindfulness, mental health and emotional availability may have implications for future research and perinatal mental health practice.  The study may also provide a preliminary understanding of the influence of maternal sensory activities and awareness on mother-infant relationship during pregnancy and in the first postnatal trimester, reconceptualizing the model of prenatal attachment based on the mother’s mental image of the unborn infant, and providing further information regarding the relationship between mother-infant relationship during pregnancy and mother-infant relationship post-birth. One possible implication of this is that development of an infant’s social drive may not emerge after birth (phylogenetic) but commence in utero through an embodied interpersonal relationship (ontogenetic), rather than after birth (phylogenetic).   Improvements in the post-intervention and post-birth outcomes in comparison to the baseline scores may provide evidence that would add to the literature and benefit maternal health care, with government policy implications. Not being limited to the Australian population, this project will also explore the documented impact of the social and physical isolation measures needed to reduce the spread of COVID-19 on the mental health of pregnant women from those countries most affected and the importance of mindfulness-based intervention. Due to the documented effects of maternal mental health challenges on the unborn baby’s development, mother-infant relationship during pregnancy and infant development, exploring mindfulness, maternal mental health, mother-infant relationship and interoception outcomes of the PMRB program may provide important information with clinical implications to guide future research and perinatal mental health practitioners working with pregnant women from community and clinical populations. It is expected that the outcomes of this project may expand the focus of prenatal and perinatal healthcare practitioners to include consideration of the prenatal mother-infant relationship and maternal mindfulness to support maternal-infant relationship in the early postnatal period, in particular maternal emotional availability. Assessment of maternal-infant attachment relationship may help identify those at risk of later maternal-infant relationship difficulties. Mothers may be supported to engage in sensorimotor-reflective interactional activities promoting mindfulness and prenatal attachment, thus improving emotional availability and preparing for a favorable later mother-infant relationship. Assessment of maternal mindfulness may inform intervention approaches to support the development of a prenatal attachment relationship leading to a favourable maternal-infant relationship. Given their involvement in the assessment and promotion of maternal mental health and wellbeing, prenatal and perinatal healthcare professionals could have a key role in the prenatal period in supporting maternal mindfulness and the developing maternal-infant relationship.  This study has the potential to benefit communities of pregnant women, infants, and families by providing preventive strategies to meet complex social and economic challenges related to maternal mental issues during pregnancy and in the perinatal period. It is oriented towards real-world application (strategies to prevent perinatal mental health issues and related mother-infant relationship difficulties impacting on infant development and health), including the development and investigation of an evidence-informed intervention in the earliest phases of human development, influencing government policy, and ultimately improving pre/perinatal healthcare services and communities. This study is expected to contribute to the positive impact Bond University is already making across the world, by expanding into a new focus area (perinatal roots of individual, family and public health) and investing in research on human potential from the beginning of life.  |
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| Provide a brief list of your key references |
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| Project Design |
| Describe the Rationale for your choice of research methods as specified in the HREA. How do these support the research objectives of your research project? |
| The literature review highlighting the gaps, research problem and need for this project has led to the proposal of a research project involving two thrusts, which are Study 1 (separate HREA application) and present Study 2. This feasibility study will use: 1. For the quantitative analysis, a longitudinaly mixed cohort design with pre- and post-intervention online questionnaires and follow-up online survey to collect the data at three time points – baseline at 20+ weeks, post-intervention at approximately

36-week gestation, and 10-12 weeks post-birth and to compare it within subjects and expore changes during pregnancy and from pregnancy to the first trimester postpartum. 1. Qualitative analysis of information voluntarily provided during the sessions of the PMRB program and responding to the open ended question: “How has the PMRB program supported (or not supported) you during pregnancy, labout/birth and the first post-partum trimester?”

Note: This qualitative information provided voluntarily by the study participants during the sessions is within the scope  of the Ethics approval. It turned out it could be used in a qualitative analysis adding to the quantitative analysis of this  intervention study. I have not gathered different data, which would require a new Ethics approval.  |
| Provide a description of the **participants** planned for your study. How many you will need? What are your inclusion/exclusion criteria? How will participants be recruited? What is your estimate and rationale of sample size? |
|  Women are eligible to participate in the studies if they are: (a) aged 18 or older; (b) 20+ weeks gestation; (c) have sufficient English and intellectual proficiency to understand and complete the questionnaires; (d) do not receive antenatal care from specialized clinics, irrespective of parity and ethnicity; (e) from Australia. A minimum of twelve pregnant women (which meets the minimum sample size of a pilot or feasibility study) meeting the inclusion criteria will be invited to participate in an online 9-session Prenatal Mindfulness Relationship-Based (PMRB) program and complete some online questionnairesat three time points - 20-week + gestation, approximately 36-week gestation, and 10-12 weeks post-partum - through advertisements on social media using the snow sampling technique, prenatal organisations, professional and personal networks of the principal investigator, co-investigators, antenatal clinics, university midwifery-led care clinics, and general practitioner clinics.The snow sampling technique will be used to recruit participants through the social network platforms such as Facebook, Instagram, and Twitter. People who receive the invitation will be encouraged to inform their networks about the study by word of mouth and social media. Identifying and recruiting members of this group via snowball sampling is not highly inferior to other methods especially considering that getting to the population targeted is not easy to achieve. The use of social networking sites can be effective for the study of “hard-to-reach” populations that are difficult to study through conventional survey methods (Baltan & Brunet, 2012). The main advantages of this technique are that it can expand the geographical scope and facilitates the identification of individuals with barrier to access. Therefore, the use of virtual social networking sites can increase the sample size and its representativeness (Baltar & Brunet, 2012; Best & Harrison, 2009). From both an ethical and a practical point of view, participants need to be reassured of the protection of the information they provide in order to establish the trust. This method has been increasingly used in other studies of pregnant women. Following ethical approval by the institutional review board, an advertisement for this study will be posted on social media and distributed among prenatal organisations, the professional and personal networks of the Principal Investigator and Co-Investigators, antenatal clinics, general practitioners clinics, university midwifery-led care clinics after obtaining permission via a letter sent to the director by the Principal Investigator. The university survey link (Qualtrics) and some information about the research will be provided on the advert. The link will provide all the needed documents at each stage of data collection to be completed online: A participant information sheet (PIS) informing the women that the study aims to examine infant and mother relationships and mental health and wellbeing; a participant consent form (PCF); a socio-demographic questionnaire to be used in the first survey as part of the consent process to screen/assess the suitability of the potential participants for the study and identify the inclusion and exclusion criteria; a post-birth questionnaire in the third survey; all the questionnaires measuring maternal mental health variables. Particapants will be invited to write an identification code on each document to be identified while securing anonymity and their email address to be contacted for their next survey. The Principal Investigator will reassure the participants by writing, “This (email address) will only be used for data matching and for repeat surveys and will then be deleted”. The Principal Investigator’s name will be displayed and her involvement in the PhD briefly described in the advertisement. It will be made clear in the advertisement that there is no obligation to take part by requesting further information. Potential participants will be informed that each online survey (at three time points) will take approximately 40 minutes. This study is a feasibility trial testing the theoretical framework of the program, so it is not a clinical trial and there is no need for a control group. Recommendations for required sample size for a feasibility trial vary from 10 to 12 per group through to 60-75 per group depending on the main objective of the study. For this study a sample of 30 participants is enough.While all trials should have a sample size justification, not all trials need to have a sample size justification (Billingham et al., 2013). For feasibility and pilot trials a formal calculation may not be appropriate. Thabane et al. (2010) state that assessing the potential efficacy of a novel intervention prior to testing in a main trial can provide data for sample size canculations in the main study.This study procedure was conducted in accordance with the Australian National Code and National Statement and the institutional review board. All participants provided electronic consent at the beginning of the study and were informed that they could discontinue study participation at any time.Billingham, S. A. M., Whitehead, A. L., & Julious, S. A. (2013). An audit of sample sizes for pilot and feasibility trials being  undertaken in the United Kingdom registered in the United Kingdom Clinical Research Network database. *BMC Medical Research*  *Methodology,* 13: 104 .Thabane, L., Ma, J., Chu, R., Cheng, J., Ismaila, A., Rios, L.P., et al. (2010). A tutorial on pilot studies: the what, why and how.  *BMC Medical Research Methodolog*y, 10: 1.     |
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| What instruments / materials are you using? If possible provide validity and reliability of instruments or address the validity of the method. |
| **Sociodemografic Questionnaire** It will be used to gather information from participants to describe the sample.**Post-Birth Questionnaire** It will be used to gather information about the pregnancy, length of gestation, kind of birth,breastfeeding/feeding, mother’s experience of baby’s sleeping and crying.Participants are expected to complete online the following questionnaires regarding maternal variables: mental health, in particular depression, anxiety, and stress, mother-preborn relationship, mindfulness, interoception and emotional availability.**Edinburgh Postnatal Depression Scale (EPDS).** Maternal depression will be measured using theEdinburgh Postnatal Depression Scale (EPDS), which is one of the most widely used self-report instruments designed to detect depression, particularly during the perinatal period (Cox, Holden, & Sagovsky, 1987). The scale consists of 10 Likert-type items scored from 0 to 3 (0 = No, not at all; 1 = hardly ever; 2 = yes, sometimes; 3 = yes, very often), with a maximum score of 30. Women respond to each statement based on their mood over the previous seven days. A higher EPDS score represents an increased risk of depressive symptoms. An example item is, “I have been anxious or worried for no good reason”. The scale has shown a good internal consistency (α = .91) (Alhusen, Hayat, & Gross, 2013). It is simple to score and can be completed in approximately five minutes. Although the instrument is validated to screen for depression in the postnatal period, it can also be used during pregnancy (Vazquez & Miguez, 2019). **Depression Anxiety Stress Scale-21 Short form (DASS-21; Lovibond & Lovibond, 1995).** Maternal anxiety and stress will be measured using theDepression Anxiety Stress Scale-21 (DASS-21). The instrumentis a 21-item self-report assessing depression, anxiety, and stress scales. As this project will use the EPDS to measure depression, only the anxiety and stress subscales will be used. Item are scored on a 4-point Likert scale of 0 (never) to 3 = almost always), with higher scores being indicative of higher levels of depression, anxiety, or stress (Crawford, Cayley, Lovibond, Wilson, & Hartley, 2011). Each scale is scored into categories ranging from normal, mild, moderate, severe, and extremely severe (Lovibond & Lovibond, 1995). The DASS-21 has demonstrated high reliability and internal consistency on each scale (anxiety Cronbach’s α = .84, and stress α = .90; Lovibond & Lovibond, 1995; Crawford et al, 2011). **The Maternal-Foetal Attachment Scale (MFAS; Cranley, 1981).** The Maternal-Foetal Attachment Scale (MFAS) will be used to measure a pregnant woman’s engagement in behaviors indicative of an emotional connection and interaction with her unborn child, such as talking to the baby and massaging the stomach where the baby is (Cranley, 1981). The self-report questionnaire consists of 24 items that are distributed under five subscales: role taking, differentiation of self from the foetus, interaction with the foetus, attributing characteristics to the foetus, and giving of self. Each item is scored on a 5-point Likert-type scale with options ranging from 1 (strongly disagree) to 5 (strongly agree). The total scale score ranges from 24 to 120, with higher scores indicating more favorable maternal-foetal attachment. A sample statements is, “I talk to my unborn baby”. The MFA scale is usually applied to pregnant women during the gestational age of 20-40 weeks. It is a widely used measure of MFA across diverse populations (Ahern & Ruland, 2003). Reliability is good (e.g., test-retest r = .85, Cranley, 1981; r = .88, Alhusen, Hayat, & Cross, 2013). The MFA scale has been favored for the present study because the subscales better match some of the psychological domains fostered by mindfulness, including maternal-foetal interactions. **Five Facets Mindfulness Questionnaire Short Form (FFMQ-SF; Bohlmeijer, ten Klooster, Fledderus, Veehof, & Baer, 2011).)** Maternal mindfulness will be measured using the Five Facets Mindfulness Questionnaire Short Form (FFMQ-SF). This questionnaire contains 24 items, scored on a Likert-scale of 1 (*Never or very rarely true*) to 5 (*Very often or always true*), with higher scores indicating greater mindfulness. These items capture five facets of mindfulness: observing, describing, acting with awareness, nonjudgment of inner experience, and nonreactivity to inner experience. An example question from the Acting with Awareness subscale is “It seems I am ‘running on automatic’ without much awareness of what I am doing”. The measure has shown high levels of internal consistency and convergent and discriminant validity when used in non-clinical samples (Bohlmeijer et al., 2011). **The Emotional Availability Self-Report (EAS) (EA-SR; Vliegen, Bijttebier, Boulpaep, Luyten, Cluckers, & Biringer, 2005)** Maternal emotional availability will be measure using the Emotional Availability Self-Report (EAS) (EA-SR; Vliegen, et al., 2005). The instrumentconsists of 36 items and five subscales: capacity to involve the parent, mutual attunement, affect quality, intrusiveness, and hostility. Each scale is rated on a 5-point Likert scale: (0) not agree at all, to (4) totally agree. Two scales, Intrusiveness and Hostility, refer to the parent contribution to the relationship as perceived by the parent. One scale, Capacity to Involve the Parent, refers to the child’s contribution to the relationship as perceived by the parent. Two other scales, Mutual Attunement and Affect Quality, refer to both parent and child’s contribution to the relationship. The EA-SR has good psychometric properties, with reliability ranging between .71 and .84, except for the affect quality subscale (α = .49) (Vliegen et al., 2005; 2009).**The Multidimensional Assessment of Interoceptive Awareness, Version 2 (MAIA) (Melhing et al., 2012).** Maternal interoceptive awareness will be measured by using the Multidimensional Assessment of Interoceptive Awareness, Version 2 (MAYA). The original version is a 32-item self-report questionnaire used to measure multiple dimensions of interoception, including state and trait (Mehling et al., 2012). It was improved by adding new items to two of the scales (Mehling, Acree, Stewart, Silas, & Jones, 2018), with the new 37-item MAIA-2 confirmed with appropriate fit indices (RMSEA = 0.055 [95% CI 0.052- 0.058]; SRMR = 0.064) and improved internal consistency. The MAIA-2 is a valid measure of interoception. **PMRB Program Outline.**The PhD candidate completed the certified Youth Mindfulness One Year Teacher Training from November 2016 to October 2017, including four five-day retreats at Sharpham House, Devon, UK. The program draws upon the eight-week MBSR developed by Dr Kabat-Zinn in the early 1980s at the University of Massachusetts Medical Center, the first and perhaps the most well-known mindfulness-based intervention to gain empirical support in the treatment of psychological symptoms, which has been taken by thousands of patients and healthcare personnel at the Center for Mindfulness in Medicine, Health Care and Society (CFM). The PMRB program, developed by the researcher through her work with pregnant and new parents and their infants, is an adaptation of the Youth Mindfulness course. Adjustments for the pregnant population to develop the PMRB program were based on previous intervention studies (Dhillon et al., 2017; Dimidjian et al., 2015; Duncan & Bardacke, 2010; Duncan, et al., 2015; Epel et al., 2019; Goodman et al., 2014; Gouveia, 2016; Kabat-Zinn, 1990, 2003a; 2003b; Pickard et al., 2017; van den Heuvel et al., 2015; Waters, 2016), studies of mother-infant relationship during pregnancy (de Cock et al., 2016; McFarland et al., 2011), findings of Prenatal Psychology revealing the effects of maternal mind state on the unborn baby’s bio-behaviour (DiPietro et al., 2008) and sentience (Chamberlain, 2003; Delafield-Butt & Gangopadhayay, 2013; Lagencrantz, 2007; Panksepp & Northoff, 2009; Tashaev, 2007) and sensory modulation strategies to support maternal mental health in a general population (Chalmers, et al., 2012; Novak, et al., 2012) and in pregnancy, and in promoting antenatal and post-natal maternal-infant relationship. (Baillon, et. al., 2002). The input of these studies and the pregnant women the PhD candidate worked with previously helped her when deciding on the duration of the weekly classes, the total program length, and the kind and amount of home exercise it would be wise to ask the pregnant women to do. Based on these studies and the pregnant women’s feedback, the traditional number of weekly meetings – eight - was kept, and the length of each weekly meeting from 20+ weeks to approximately 36-week gestation will be two hours.  A reunion session will be held ten-twelve weeks post-partum, before the third survey. It is supposed to be a group reunion, but the proposed time may be not suitable for all the new mothers busy with their newborn infants. Hence, there might be individual and pair post-partum sessions. The recommended amount of home exercises will be approximately 30 minutes, 6 days a week. The themed progression of the original program will be maintained, and so will the order in which the different types of exercises are introduced. Adaptation to the pregnant population implies that there will be an emphasis upon Prenatal Psychology, Epigenetics and Neuroplasticity, Childbirth Self-Efficacy, Breastfeeding Initiation and Infant Resilience education and cultivation of mother-baby interactions and communication during the meditation session. A content description of each class will be provided to the participants .  The PMRB program is awaiting Ethics approval as an online program to be conducted on a secure Zoom platform to meet the restricted rules about face-to-face social activities related to Covid-19 pandemic. It also aims to respond to the need for support of many pregnant women who experienced extended lockdowns and consequent isolation and mental health challenges in some Australian states. The online platform also allowed recruitment from different states of Australia. In the PMRB program, the teaching of mindfulness is integrated with the following knowledge:* Breathing technique and meditation, mind-body pain and stress coping strategies for childbirth and awareness skills for coping with daily life stress.
* Prenatal and perinatal education, including prenatal development and the infant as a sentience being, basic knowledge of psychobiological processes of pregnancy, childbirth, postpartum adjustment, breastfeeding/ feeding, and psychobiological needs of the infant, and mother-baby sensorimotor modulation techniques during pregnancy using maternal touch, vocalization, and infant’s movements.

Formal mindfulness meditation instruction will be given and practiced in each class for the last 20-25 minutes, followed by the participants feedback of their experience. A key innovative element of the PMRB is the focus on mother-infant connection from a new mindbody perspective based on the mother’s awareness of her body (interoception) as well as of her unborn infant as a sentient being, capable of engaging in bidirectional interactions. This reflects a new concept of prenatal attachment based on shifting attention from when “the baby arrives to the baby is already here and I am connected to my baby”.  In addition to attending the online classes, participants will be asked to commit to practicing some home exercises, including free of charge guided mindfulness meditation videos from YouTube or created by the PhD candidate and particularly designed for pregnancy throughout the course and possibly beyond. Furthermore, as part of the home exercises, participants will be invited to write a diary of their perceptions of the infant’s movements and cues, and a dialogue with the infant to further enhance interoception (embodied awareness and inward focus), sense of presence, sensitivity and reflective functioning, connection with the infant, and relaxation. In addition, they will be invited to reflect upon these experiences and practice mindfulness whenever possibly in their daily life activities. The benefits of these exercises and the importance of continued practice were explained during the sessions. **The Self-Administered Maternal-Baby Engagement Practice Combined with Online Guided Mindfulness Meditation**The self-administered mother-infant connection practices, part of the PMRB program, focus upon sensorimotor interactions aiming to enhance maternal body sensory and baby awareness, present-moment awareness, attention, sensitivity and reflective function, maternal-infant engagement and have calming effects. Sensory-reflective activities include mother’s stroking her pregnant abdomen where the infant’s movements and cues are felt, talking and singing to the unborn infant, and writing in infant journal. The infant nurturing practice is combined with an online brief guided mindfulness meditation program running over the 8-week course for the duration of approximately 30 minutes. The PMRB program aims to further enhance the elements of the practice and develop nonreactive, present-moment awareness. Participants will also learn how to apply the practice of mindfulness to discomfort during pregnancy, labour pain and early parenting. These are some of the core competencies of mindfulness aimed to promote wellbeing in mothers and mother-infant engagement. The simple engagement activities have been traditionally utilised by pregnant women for millennia, as field-studies of African indigenous women has revealed (Sansone, 2023). The PMRB program simply encourages revaluation of these contemplative sensorimotor communication activities through awareness of their importance in nurturing a mother-infant bonding relationship from pregnancy (Sansone, 2021).  The guided as well as self-administered practices of the PMRB program investigated in this project are based on increasing evidence of the unborn infant’s capacity to engage with maternal interactions (Castiello et al., 2010; DiPietro, 2010; Ferrari et al., 2016) and contribute to the prenatal relationship. Studies of prenatal attachment have focused on the mother’s representation or mentalization of the baby. Therefore, prenatal attachment scales refer to the foetus as an internalized image in the mother’s mind, rather than an actual being developing in her womb capable of engaging in an embodied relationship (van der Bergh & Simon, 2009). There is a need for research and prenatal programs which recognize the unborn infant’s capacity to engage in reciprocal interactions (Cannella, 2005; Eichhorn, 2012) and the contribution of mother-infant reciprocal interactions to mother-infant relationship prior and post-birth. The mother-baby engagement practice recognizes the unborn infant as a conscious being capable of engaging in sensorimotor interactions and promotes the contribution of maternal acceptance of prenatal engagement and interactions to mother-infant favourable relationship. This expectation is supported by evidence that the interactions between parent and child provide positive stimulation that promotes development (Klebanov & Travis, 2014).  The prenatal mother-infant engagement practice also draws on evidence of the benefits of sensory modulation strategies in supporting maternal mental health and maternal-infant relationship prior and post-birth. There is growing evidence that use of sensory-based activities with people with mental disorders in an impatient setting may promote development of self-regulatory strategies and improve well-being (Chalmers et. al., 2012; Novak, et al., 2012). Mothers’ use of ‘sensory kits’ (e.g. gently massaging pregnant belly, singing to unborn baby, and writing in baby journal) have revealed to have calming effects thus reduce stress levels, enhance attention, and promote mother-baby relationship during pregnancy (Baillon, et al., 2002). There is a need for further research to support the potential benefit of utilising sensory modulation mindfulness-based nurturing practices to support mother-baby relationship during pregnancy, in particular mother-infant engagement, and thus improve maternal-infant relationship.**Instructor qualifications**  The PhD candidate has training/skill in mindfulness programs. She has more than 20 years of mindfulness practice and received her teaching training in mindfulness at Sharpham House, Devon, UK. She also received a degree in Doctor in Clinical Psychology from the University of Rome La Sapienza, Italy. Although the PMRB program concentrates on mindfulness training, it also combined other health basic information about childbirth, stress coping strategies for labour and childbirth, breastfeeding/feeding, postpartum adjustment and parenting. The teaching and practice of mindfulness mediation integrated with childbirth and parenting education during pregnancy have been found to improve mental health in pregnant women as they transition to parenthood (Byrne et al., 2014; Duncan & Bardacke, 2010; Duncan et al., 2017; Pan et al., 2019).   |

Describe your procedure. What will participants be asked to do? How much time is required of paricipants at a test session and in total? Will there be any follow-up? |
| Participants will be invited to participate in the online prenatal mindfulness relationship-based (PMRB) program and complete some questionnaires online about their pregnancy, mindfulness, mental health, interoception (body awareness), and relationship with their baby before and after birth. If available, a short-form versions of questionnaires will be used to reduce participant burden. Data will be collected at three time points - baseline (20+ weeks’ gestation) post-intervention (approximately 36-week gestation), and 10-12 weeks post-birth.The link to a safe and secure online survey platform called Qualtrics and information about the study will be provided on the advertisement. The link will take those who are interested in the first survey (20+ weeks gestation) to the Participant Information Sheet (PIS) and Participant Consent Form (PCF). Study registration will take place on Qualtrics after the pregnant women have confirmed that they have read the information about the study and have consented to participate. The participants will be then invited to complete a socio-demographic questionnaire and other questionnaires. The next two surveys (approximately 36-week gestation and 10-12 weeks post-birth) involve the same procedure. An email will be sent to each participant who have completed Survey 1 at approximately 36-week gestation after last session of the PMRB program, inviting them to complete Survey 2. The same email will be resent if the participant have not completed Survey 2. Completion of Survey 3 will follow the same procedure. Each participant who has completed the previous surveys, including those who have not completed Survey 2, will receive an email at 10-12 weeks post-partum, inviting them to complete Survey 3. The same email will be resent if the participant has not completed Survey 3.  It will be made clear in the advertisement that there will be no obligation to take part by requesting further information. Potential participants will be informed that each online survey (at three time points) will take approximately 30 minutes. The PIS informed the women that the study aimed to examine infant-mother relationship and mental health and wellbeing at baseline and post-program during pregnancy and post-birth and will be provided at each of the three surveys. Potential participants will be informed about the length of the training program and the benefits of participating, e.g., increased wellbeing and improved mother-infant relationship during pregnancy and post-birth. They will be also given the opportunity to ask questions. The PCF will be also provided at each stage of data collection and completed online. The PIS will make it clear that participants could cease participating in the research and the program at any time. It will explain that should participants experience any physical or emotional discomfort as a result of the research or the program or both, they will be encouraged to seek individual professional support from their general practitioner or other health professional. Contact numbers will be displayed on the PIS. To ensure that the data remained anonymous, each participant will be requested to write an identity (ID) code after consenting. to participate. The same coded ID for each participant will be used in each of the three surveys, thus ensuring matching of the otherwise anonymous respondents. Participants will be also invited to write their email address after consenting to participate. It will be explained on the PIS that the participants’ email address is to be used only to send an email to invite them to the first session of the programme and send the Zoom link for each session, and to invite them to participate in the next survey by providing the new link to the online survey platform Qualtrics. Only the researcherinvolved in the study will have access to the data.After the potential participants have received and read this information, consented to participate and completed the first survey electronically, they will receive an invitation to participate in the PMRB program. A socio-demographic questionnaire will be used in the first survey as part of the consent process to screen/assess the suitability of the potential participants for the study and identify the inclusion and exclusion criteriaThe surveys, including a demographic questionnaires at Time Point 1 and a Post-Birth Questionnaire at Time Point 3 in addition to . the other questionnaires, will take approximately 40 minutes at a test session, a bit less at Time Point 2, when participants won’t be asked to answer the demographic questionnaire or the post-birth questionnaire. The total time required will be approximately 110 minutes.The feasibility trial includes a follow-up online survey post-birth.  |
|  How will you handle the withdrawal/loss of any participants from your study? |
| Capacity is assumed as all participants will be adults and assessed for exclusion criteria, which could alter a participant’s capacity to decide whether or not to participate. Participants will be free to interrupt participation in the online survey and intervention at any time without penalty. Anonymity will be assured.  |
| Describe your data analysis. What are your measures? How will data be coded? **Include any matching and sampling strategies, data linkages, strategies for accounting for potential bias, confounding factors and missing information and statistical power calculation.** |
|  **ANALYSIS**  One-way repeated measures ANOVA to test for statistically significant differences between three timepoints mean scores Thematic analysis using nVivo software to explore participants’ subjective experience of the PMRB program To ensure matching of the otherwise anonymous respondents, each respondent will be granted or selected a coded ID number that will be used on all forms completed by the individual within the one session or the repeated sessions. We don’t plan to disclose information to the participants unless they ask for the information. If so, they will be provided with a lay summary of main results with no identifying information about any participant. Regarding matching, no matching is proposed directly – the project is a 3-part study with known identifiers enabling the same person’s responses at each stage to be linked; the sampling strategy is a convenience sampling study of pregnant women over the 3-stage process; to handle potential bias we are using well-known scales and processes that have been used in previous studies and will be considering the use of a short social desirability responsing scale in stage 1. Other aspects such as confounding factors will be handled via controls (in hierarchical regression) where possible, and missing information will be handled as appropriate in the circumstances such as using mean replacement where there are limited missing items in a scale. Finally, statistical power calculation won’t be needed because the study is a feasibility trial. .  A demographic questionnaire will allow for sampling according to inclusion/exclusion criteria.  There are advantages and disadvantages of online questionnaires. The advantages of online questionnaire include anonymity, low cost, capacity to reach a geographically diverse population, ease of standardization, and the participant’s flexibility and convenience of being able to complete the survey at a time of their choosing (Evans & Mathur, 2005).  **Limitations** frequently occurs in research methods (Ellis & Levy, 2010). They are influences that the researcher cannot control and place restrictions on the methodology and conclusion. The researcher acknowledges that the use of online surveys may result in reduced responses since participants are not being recruited and supported in an active face-to-face manner. The lack of direct contact with the participants may also contribute to reduced completion as participants are not encouraged to complete and submit the survey, and reduced accuracy as they do not have an opportunity to have their questions clarified (Ellis & Levy, 2010). The researcher will consider the above limitations, be cognisant of others that may arise and implement delimitation strategies.  It is anticipated that this project will have a number of strengths, including the collection of data at three time points, allowing to examine some changes in the variables over time (casual inferences) and provide insight into cause-and-effect relationship. Nevertheless, there are several limitations to be considered. While the feasibility trial justifies the small sample size to get meaningful results and the absence of a control group, future studies with larger sample size and control groups are needed to increase the statistical power to identify smaller effect sizes. The data will be collected using self-report questionnaires, therefore there will be no objective measure of these variables in this project. Furthermore, this study will not examine data related to the women’s partner or infant temperament, although evidence reveals that factors related to both infant (Parfitt & Ayers, 2014) and the other partner (Baldoni, 2010; Luz, George, Vieux, & Spitz, 2017; Ramchandani et al., 2008) may influence maternal-infant relationship. Other biases such as social desirability and selection biases also warrant consideration, as participation was voluntary. Further research replicating the findings of this project and examining different community and clinical populations is needed. The principal investigator acknowledges that not having a control group (a group doing the intervention, one not doing the intervention, and even one doing another type of intervention) is a confound. Being the study a feasibility study there is no need for a control group. Future main studies can test the PMRB program by using control groups. While all trials should have a sample size justification, not all trials need to have a sample size justification (Billingham et al., 2013). For feasibility and pilot trials a formal calculation may not be appropriate. Thabane et al. (2010) state that assessing the potential efficacy of a novel intervention prior to to testing in a main trial can provide data for sample size canculations in the main study.The key concern may be the implication of bias that a program that was developed, offered and evaluated by the principal investigator without additional controls could be a biased indicator of outcomes in a self-serving way. Most PhDs have the actual researcher deliver an intervention, and sometimes this intervention has been developed by the researcher (it is usually unavoidable due to costs of employing others to do it etc). The researcher typically needs to do the work as such as it is their PhD. The collected data and statistical analysis and sense of research integrity of the researcher will mitigate the risk for any potential bias. The researcher’s goal is not to validate the efficacy of her own intervention but to explore its outcomes with an open exploratory mind to contribute to the literature and potentially to maternal-infant healthcare. Further research can replicate the findings using an indipendent researcher and an ‘other-intervention’ comparison group. If future evidence demonstrates that mindfulness-based programmes are effective, by recommending these interventions, healthcare professionals can help pregnant women to manage a number of pregnancy-related factors associated with the expectations and uncertainties of becoming a mother.  |
| For research involving an investigational drug or device as part of a clinical trial: What is/are the drug(s) and/or device(s):* + Approved name
	+ Trade name (if any)
	+ Manufacturer
	+ Supplier of drug/device (e.g. manufacturer/pharmacy)
	+ Approved therapeutic indication, dosage/duration in Australia
	+ Believed mode of action
	+ Dosage regimen
	+ Mode of excretion
	+ Known adverse events
	+ Known contra-indications or warnings
	+ If arrangements have been made for the Pharmacy Department to receive or dispense the drugs involved in this project, explain how the drugs will be received and dispensed for the purposes of the research project.
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| n/a |
|  |
| Closure and Dissemination |
| Ethics approval covers not only the collection of data but also issues such as dissemination of data, researchers’ duty of care for participants after data collection, and responsibilities to the institution, professional bodies and research partners/sponsors. This is the closure phase of research. How do you plan to disseminate the results of your research, including to participants and stakeholders? Include any publications that are planned as a result of this research. |
| The results of the research will be disseminated through publishing program or policy briefs; publishing project findings in journals; presenting at national and international conferences and meetings of professional associations; reports; presenting program results to local community groups and other local stakeholders; thesis; subsequent social media.A minimum of four papers for publication will be developed from these studies, which will be submitted to the *Infant Mental* *Health Journal* or A*rchives of Women’s* *Mental Health Journal:* **Manuscript 1.** A literature review gathering the available data on predictors of mother-infant relationship to identify what is known and where the gaps are. Theoretical links between maternal mental health, mindfulness during pregnancy, mother-preborn relationship and mother-infant relationship/emotional availability post-birth are presented, leading to models for how to conceptualise early-in-life protective factors for maternal mental health and mother-infant relationship. The paper aims to contribute important knowledge of prenatal attachment, based on increasing evidence suggesting foetal consciousness and engagement. It also aims to contribute to improving perinatal healthcare practitioners’ way of relating to pregnant mothers and their developing unborn babies. **Manuscript 2.** Detailing outcomes from Study 1. Relationships between maternal mental health, mindfulness, mother-preborn relationship, and interoception and adult attachment will be presented.**Manuscript 3.** It will look at outcomes from the PMRB program and comparisons between mindfulness and other maternal variables within-subjects across three time points.**Manuscript 4.** It will look at outcomes from the qualitative analysis of participants’ subjective experience of the PMRB program, emerging from the open-ended question: “How has the PMRB program supported (or not supported) you during pregnancy, labour/birth and the first postpartum trimester”. |
| Describe the project closure processes and plans for any follow-up research. |
| No follow-up research is planned |
| Data Management and Sharing |
| What will be the format of your research outputs(e.g. survey data,photographs, publications, csv files, etc)? Will they require physical and/or digital storage for the mandatory data retention period? Where will the data be stored? Will the data be automatically or manually backed up? What arrangements have been made to archive the data? What will be done at the end of the mandatory retention period? Will you include measurements from experiments, surveys, photographs, or publications? |
| Electronic files containing the survey data will be stored in password-protected devices on Bond University Research Data Manager website, which is a secure online data system. The data will be kept for 5 years after the submission of the thesis. Paticipants in the online survey will be given a code name. Only the Principal Investigator will have access to the data. Participants’ email addresswill be collected and stored separately from their survey data and is in no way linked to their responses to the online survey. It will be only used to contact the participants for the second and third surveys. Data are non-identifiable and particpants’ confidentiality will be protected. Data will be permanently deleted from the university records at the end of the study, and will not be used for any other purpose.  |
| List any relevant policies and/or legislation that affect your data.  Does any of your data contain personal or commercially valuable information? |
| This project does not imply any intellectual properties or commercialisation which could be used to gain profit. The research will not lead to commercial benefit for the investigator (s) and or the research sponsor (s). |
| Who will own the data? Is there any reason why your data should not be made publicly available? If so, provide a rationale. Who would be interested in your data? |
| The data will be owned by Bond University. The owner of the information or any other party has no right to impose limitations or conditions on the publication of the results. |
| Describe how your data will be shared with other researchers and through what channels. **What provisions have you made to store and share your data via a publicly accessible repository? Will there be an embargo period? If the data cannot be open, will there be negotiated or controlled access to your data?** |
| Should resulting journal article publications request deidentified data, it will be deposited through a public repository (eg CloudStor). Unless a journal requires it, there will be no embargo period |
| How will you ensure the security and integrity of the data and handling of any confidential or sensitive data? |
| I will make sure that there will be no risk that the dissemination of results could cause harm of any kind to individual participants – whether to their physical, psychological, spiritual, emotional, social or financial well-being, or to their employability or professional relationships – or to their communities. The research is not likely to produce information of personal significance to individual participants or any third party. The individual participant’s results will not be recorded with their personal records. Results that relate to a specific participant are not intended to be reported to anyone other than that participant. The research is not likely to reveal a significant risk to the health or wellbeing of persons other than the participant, e.g., family members, colleagues. The confidentiality of participants and their data will be protected in the dissemination of research results. |
| It is a condition of ethical approval that all data created as part of research projects is stored on approved Bond University network storage facilities for a minimum retention period of 5 years. Some data should be retained permanently. Refer to the [University Sector Retention and Disposal Schedule: Research Data](https://www.forgov.qld.gov.au/schedules/university-sector-retention-and-disposal-schedule) for guidance. If data needs to be stored elsewhere, please detail the reason for this and outline security and backup procedures that will be maintained. |
| The research data won’t have permanent archivial value. It will be stored as per the university requirements (see above). |