Supporting Isolated New Mothers in NSW Using an e-Health Program for Postnatal Depression: A Translational Research Project

A partnership between

Executive Summary

This research project was supported through the NSW Health Translational Research Grants Scheme. It was conducted across two local health districts, Murrumbidgee Local Health District and Western NSW Local Health District to investigate isolated women experience of post natal depression and anxiety. Given these women are isolated from traditional support services, this research explored the facilitators and barriers that exist and impact on the uptake of e-health interventions.

Through a translational research approach using mixed methodology, it was found that multilayered interventions are required to ensure isolated women are able to fully engage in e-health interventions focused on postnatal depression and anxiety. These are articulated further within the report but here a brief summary is provided.

Interventions required from **New South Wales Health** include the provision of technology to ensure the clinicians have the equipment and web access to introduce and work with the mums, introducing them to e-health opportunities. Further, the strategies for introducing mums to e-health are included in the *My Personal Health Record* (The Blue Book).

For **managers** in the Local Health Districts, interventions are the provision of ongoing education and support for their staff especially in the allocation of time for visits with the mums and with information communication technology (ITC) literacy. It cannot be taken for granted that staff interacting with mothers have the skills to engage with e-health programs. The provision of equipment and technology support when troubleshooting is required, assists with engagement in e-health strategies.

PIRI hold the intellectual property for the *MMB* program and feedback has been plentiful about the need for diversity within the program. The need for the inclusion of choice related to differing levels of literacy and diversity of languages is evident in the results. Cultural safety would be enhanced through including women who identify as First Nations and women from diverse cultural backgrounds.

Clinicians are integral to the women accessing the e-health strategies. There is symbiosis between the women and the clinicians in that both need support. The clinicians need support from the health system and their managers so they have the education, the equipment, web access and the time to spend with the mums while guiding the mums through engaging with an e-health program. To facilitate continuity of care and collaborative care for the mums, the clinicians require feedback from referral agencies about the individual mum's response to the program.

Mums are a diverse group whose needs differ. Any support strategy should respect this and be flexible enough to cater for diversity. The isolation felt by the mothers was alleviated by skilled, considerate clinicians and a program that reflected them and addressed their issues in a practical way. Our aim is to ensure facilitators and barriers revealed in this research are addressed providing an optimal environment of care for all mums with perinatal and postnatal depression and anxiety wherever they live.

Table of Contents

List of Tables

List of Figures

Research Project Team

Keryl de Haan
Chief Investigator
Murrumbidgee Local Health District (MLHD)

Associate Professor Maree Bernoth
Researcher
Charles Sturt University

Dr Joanna Carlisle
Project Manager
Charles Sturt University

Alicia Carey
Researcher
Charles Sturt University

Anne Roth
Researcher
Western NSW Local Health District (WNSWLHD)

Christina Hunt
Researcher
Western NSW Local Health District

Professor Jeannette Milgrom
Researcher
Parent-Infant Research Institute (PIRI)

Dr Alan Gemmill
Researcher
Parent-Infant Research Institute (PIRI)

Dr Andre Rodrigues
Researcher
Parent-Infant Research Institute (PIRI)

Research Partners

Robyn Manzie
Director of Mental Health Drug & Alcohol (MHDA) Services
MLHD

Nicole Myers
Manager Child, Youth & Family Health
MLHD

Jason Crisp
Director of Integrated MHDA Services
Western NSW LHD

Associate Professor Maree Bernoth
Academic
Charles Sturt University

Dr Alan Gemmill
Senior Research Fellow
PIRI

Professor Jeannette Milgrom
Director
PIRI and University of Melbourne

Dr Nick Kowalenko
Senior Staff Specialist in Infant, Child and Adolescent Psychiatry
Northern Sydney LHD
President Tresillian Council Board

Debbie Stockton
Director Clinical Service Integration
Tresillian

Acknowledgements

Lisiane Latouche, Director of Social Work/Psychology Services, Tresillian; Executive Member of AAIMHI (NSW), was involved in the early consultation about the design of the project.

The quality and value of the collaborations between the partners in the research were articulated by one of the partner organisations:

> ***The collaboration between the partners and stakeholders has been highly collegial and inclusive. Our staff have remained informed throughout all stages of the project. When concerns arose, these were able to be raised quickly with project staff and/or tabled at Steering Committee for a considered approach with feedback then provided. All staff have felt valued for the part they have played in this collaboration.***

Terminology

Under guidance from the Steering Committee, the terms ‘mum’ and ‘new mums’ are used throughout this report to refer to women who have a new child under the age of 12 months. After consultation with the Indigenous members of the Steering Committee, the terms Aboriginal, Indigenous and First Nation are used interchangeably throughout the document with respect.

Steering Committee

Table 1: Steering Committee membership

Name	Project Role	Organisation	Committee Role	Time on Committee
Keryl de Haan	Chief Investigator	Murrumbidgee Local Health District	Chair	Sept 2018 – July 2020
Associate Professor Maree Bernoth	Researcher	Charles Sturt University	Member	Sept 2018 – July 2020
Dr Joanna Carlisle	Project Manager	Charles Sturt University	Note-taker/ Alternate Chair	Sept 2018 – July 2020
Alicia Carey	Researcher	Charles Sturt University	Member	Sept 2018 – July 2020
Anne Roth	Researcher	Western NSW Local Health District	Member	Sept 2018 – July 2020
Christina Hunt	Researcher	Western NSW Local Health District	Member	Sept 2018 – July 2020
Sabrina Brown	Researcher, Indigenous Health Expert	Murrumbidgee Local Health District	Member— Indigenous Health	Sept 2018 – July 2020
Jodie Bruce	Researcher	Murrumbidgee Local Health District	Member	Sept 2018 – July 2020
Professor Jeannette Milgrom	Researcher	Parent-Infant Research Institute	Member	Sept 2018 – July 2020
Dr Alan Gemmill	Researcher	Parent-Infant Research Institute	Member	Oct 2018 – July 2020
Dr Andre Rodrigues	Researcher	Parent-Infant Research Institute	Member	Nov 2018 – July 2020
Lucinda Jay	Consumer Representative		Consumer Representative	Dec 2018 – July 2020
Deborah Stockton	Researcher	Operational Nurse Manager, Rural & Metro Day Stay Services, Tresillian	Member	May 2019 – July 2020
Karen Griffin	Researcher	Tresillian in Murrumbidgee Family Care Centre	Alternate Tresillian Representative	Sept 2018 – July 2020
Melissa Brooker	Indigenous Health Expert	Safe Start, Murrumbidgee Local Health District	Member— Indigenous Health	Sept 2018 – July 2020

Governance Provided by the Steering Committee

The Steering Committee was comprised of partner organisations and a consumer representative. The Committee met monthly throughout the project and provided support and direction with decisions at key points during the project lifetime. It was the forum for discussion of issues such as the type of language to use in the information to the mothers, optimal ways of communicating with all participants and it proved invaluable in addressing issues related to recruitment. The Steering Committee was the forum for discussion of successes and challenges as they arose and provided guidance for the research team.

One example of this was in relation to the inclusion criteria for the project and the wording of the information sheets for mothers. There was some clarity needed about the interpretation of the Edinburgh Depression Scale question relating to self-harm. The outcomes of productive discussions, articulated by one of the members of the Committee were:

> ***Concerns have been able to be raised and addressed in a timely fashion, enabling refinements to project implementation. This was discussed by the Steering Committee and clarification received on inclusion/exclusion criteria. This was relayed to the clinical staff and enabled an increase in the number of mothers able to participate in the study.***

The consumer representative on the Committee provided input from her lived experience with PND and the research team valued her honesty in giving feedback about the terminology to be used in documents from the mothers. Her feedback to the Committee about her involvement was, *as a consumer advocate I felt the Steering Committee welcomed me and valued my insight and input. Thank you.*

Members of the Steering Committee were asked to provide their experiences of being a member. There were positive comments about the inclusion of a wide range of members from a variety of backgrounds, specialities and experiences. It was appreciated that the meetings were an opportunity to provide feedback, keep up-to-date with the project and discuss ideas for progression of the project.

As the Steering Committee members were from a wide geographical area, the meetings had to use an online meeting platform. This enabled team members to see each other and to get to know each other, even though it was through an e-meeting platform. As isolated health professionals, most of the Committee were very familiar with this mode of interacting. However, as one member pointed out, *meeting virtually provides little opportunity to build relationships as I did not meet anyone face-to-face.*

Significantly, several members commented that the Steering Committee has been highly effective in ensuring that the project remained focused, information was relayed as required and importantly, it enabled the sharing of ideas to facilitate the successful implementation of the project.

Figure 1: Steering Committee's December 2019 meeting

Top row: Anne Roth, Keryl de Haan, Jo Carlisle, Jodie Bruce.
Second row: Christine Hunt, Alicia Carey, Melissa Brooker, Andre Rodrigues.
Bottom row: Alan Gemmill, Lucinda Jay, Deborah Stockton, Sabrina Brown.
Absent: Maree Bernoth, Jeanette Milgrom

Introduction

The *MumMoodBooster* (*MMB*) program is an online cognitive behavioural therapy (CBT) program which has been established as clinically effective (Danaher et al., 2013; Danaher et al., 2012; Milgrom et al., 2016) in providing treatment for new mothers experiencing postnatal depression and anxiety (PNDA). It is an interactive, six-week, self-directed CBT treatment program, closely comparable to therapy delivered in traditional face-to-face psychology sessions. Low-intensity, short message service (SMS) support provides regular contact and encouragement to complete the program. The format is highly interactive and includes: engaging content that can be individually tailored; online exercises and journaling activities; behavioural strategies; video vignettes and animations; tutorials of CBT strategies; online and email reminders for session completion; and supporting information in companion library articles.

There is comprehensive evidence supporting *MMB* as an effective and innovative web-based intervention for postnatal depression. Data gathered also suggests that new mothers reacted positively to the *MMB* online program and its features and the program performed well (Danaher et al., 2013; Milgrom et al., 2016).

In Australia, up to one in five postnatal women experience depression or anxiety in the first year, yet fewer than half seek help and even fewer receive adequate treatment (Milgrom et al., 2016). Data varies regarding the prevalence of PNDA in rural areas with some studies suggesting an increased likelihood and others recognising no difference. However, postnatal women living in regional, rural and remote communities often lack access to coordinated specialist services and trained mental health workers (PANDA, 2019). This, along with fear of stigma, can contribute to disappointingly low rates of treatment (Ross et al., 2016).

The impact of depression can be compounded by isolation and stigma and new mothers not recognising they are experiencing depression or not wanting to seek professional help (Ross et al., 2016). The use of an online treatment has the potential to reduce barriers to treatment uptake resulting in enhanced patient care, service delivery and outcomes for depressed new mothers and for infant development. As such, the focus of this research was to identify what are the facilitators and barriers to their access of the *MMB* program.

Innovative internet-based, self-paced therapies can facilitate moving evidence based interventions into practical health service delivery, including reaching populations in regional, rural and remote communities and can overcome many barriers to the uptake of effective treatment. As well as offering the convenience of engaging with treatment from home, web-based programs provide privacy thus overcoming women's concerns regarding stigma (King et al., 2010). Bringing effective, evidence based, online treatment to women where and when they need it has massive potential to prevent and ameliorate the impact of depression on health and wellbeing at a population level.

Various factors can influence implementation—system complexity, internet reliability, costs, planning, policy concerns, and clinicians' and women's attitudes towards the technology. The aim of this study was to identify the key barriers and facilitators to accessing the online *MMB* program for isolated and hard to reach women in areas of regional, rural and remote NSW, specifically, new mothers living in the Murrumbidgee Local Health District (MLHD) and the Western NSW Local Health District (WNSWLHD).

Providing mental health interventions to help develop more robust mental health for mother and family in the perinatal period is critical for infant development. The NSW Mental Health Commission's (2014) plan, *Living Well: A Strategic Plan for Mental Health in NSW 2014–2024*, recognised that the perinatal period represents a period of particular risk for maternal mental illness. Disruption of the parental relationship can result in delayed social and emotional development and/or significant behavioural problems for the infant. Therefore, providing appropriate care, early detection and intervention along with evidence based treatments is crucial.

The MLHD *Mental Health and Drug and Alcohol Clinical Service Plan* (2014–2019) (MLHD, 2014) recognised the difficulties that geographical location poses with regards to access to services and that utilise the online therapies as an augment to existing clinician services. Further, it acknowledges that such a program would provide more equitable access for consumers across the local health district (LHD) and help redress some of the geographic isolation issues. The *NSW Rural Health Plan: Towards 2021* (NSW Ministry of Health, 2014) also supports the implementation of e-health solutions and strategies to enhance access to health services in rural NSW.

The *MMB* program has been implemented in clinical settings but the focus of this research was to translate the approach to isolated new mothers who may have barriers to accessing the program. The effectiveness and replicability of the online program have already been well established but this project focused on exploring ways to implement the online treatment program within two LHDs with high rates of isolated new mothers (MLHD & WNSWLHD) and look at key factors associated with effective implementation. Recommendations for replicability and sustainability are contained in this report and further enhanced by the use of the *Guidelines for clinicians* manual entitled, *Considerations for the implementation of e-health interventions using MumMoodBooster*.

Ross et al. (2016) recognised that the implementation of e-health interventions as a referral pathway option is complex and characterised with issues that can either support or hinder their uptake. Innovation characteristics such as technology adaptation, complexity and cost can make it difficult for programs to be used. The environment in which the intervention is being offered also influences uptake with factors such as service and intervention compatibility, practitioner attitudes, resource availability, leadership engagement and access to information presenting possible barriers to acceptance of the intervention. In order for an online intervention such as the *MMB* program to be integrated successfully into a health service referral pathway, there needs to be a thorough understanding of the barriers to its utilisation and identification of what supports optimal implementation of the online tool.

The challenges articulated by Ross et al. (2016) were were supported in this research but were extended by seeking to identify strategies to address the challenges. Through the research, as documented in this report, the project team listened to the experts—clinicians and new mothers—and appreciated what facilitated their engagement, made suggestions about addressing challenges and provided support for other clinicians who sought to engage new mothers in an e-health program.

The aims of the research were to:

- Evaluate the implementation of the *MMB* program to support isolated and hard to reach new mothers, identifying the key facilitators and barriers impacting optimal uptake
- Provide information for adjusting the *MMB* program for wide-scale implementation and replication across other rural, remote and isolated areas of NSW.

The question answered in this project is:

- What are the key facilitators and barriers that influence implementation of *MMB* treatment for hard to reach women living in rural, regional and remote areas of NSW?

This research provides data to inform a practice model that enhances the uptake of online therapy for isolated mums and supports clinicians as they promote the use of online therapies to mothers in their care. The aim is to identify facilitators and barriers to mothers in isolated and hard to reach locations, identify solutions to reinforce enablers and overcome barriers to access the e-health program.

Background

The impact of untreated maternal depression is well documented and devastating yet, there is treatment available. So, it is of great concern that up to one in five Australian women experience depression or anxiety in the first year, postpartum yet fewer than half seek help and even fewer receive adequate treatment (Milgrom et al., 2016). Treatment options are well researched and there are even treatment options available for those mothers who are isolated—whether it be due to their geographical location or just because of the practical and emotional/social isolation of being a new mother.

Untreated postnatal depression can significantly affect the developing infant, the mother–infant relationship and the partner relationship as well as the relationships with others in the family. In order for the infant to develop, they require a sensitive and in-tune primary carer to assist with their development of self-regulation and a healthy attachment style. Infants are primed and ready to engage in reciprocal interactions and are also highly sensitive to the quality of care they receive (*BeyondBlue*, 2010).

Research has shown an association between maternal depression and insecure attachment, especially when the maternal depression has occurred for an extended period of time (McMahon et al., 2006). With this in mind, when a primary carer's capacity to engage in joyful parenting is affected by their symptoms of PND such as lowered/non-reactive mood and anxiety, this in turn can affect the interaction between mother and infant.

The cost to society has also been measured and is significantly affected by untreated maternal depression. A PricewaterhouseCooper (PwC) study (Gidget Foundation et al., 2019) reports that health costs associated with PNDA are greatest in the first year (estimate $227 million) due to the increased level of hospital and primary and community health services. Economic and productivity costs during the first few years due to workforce issues such as absenteeism are estimated to be $643 million. Also, social and wellbeing implications of parental depression and anxiety are estimated to total $7 million due to increased likelihood of developmental issues, depression, anxiety and child ADHD diagnoses.

The aim of this research was to determine what the key facilitators and barriers are that impact the uptake of the *MMB* program for isolated women living in regional, rural and remote areas of NSW. To achieve this aim, the strategy involved asking both referring clinicians and new mothers participating in the research, about their experiences. Initially, the new mothers who agreed to participate enrolled in and progressed through the *MMB* program. Their progress was monitored by PIRI and the data was used to inform the quantitative aspects of the research. After engagement with the *MMB*, the new mothers participated in semi-structured interviews. Clinicians attended either focus group interviews or individual interviews conducted at each participating site or online.

The key facilitators and barriers to the implementation of the e-health intervention were identified, recommendations made and strategies developed to address these.

Specifically, this research set out to:

- Determine the utilisation of the online intervention
- Provide information for adjusting the program for wide scale implementation
- Analyse causes for unexpected disengagement with the intervention and recommend appropriate solutions.

Questions answered were:

- What contextual factors facilitated or impeded program implementation (e.g. provider, program, client and geographical factors)?
- Did the program reach and engage the intended target?
- Was the program implemented as intended (program adherence, integrity and usage)?
- Who benefited most from the program and why (e.g. which new mothers, locations, providers)?
- Were new mothers and clinicians satisfied with the implementation of the program?

Literature Review

The literature review section initially provides the evidence base for the use of the *MMB* as an intervention for PND. Subsequent sections cover literature related to PND and the significance of addressing this issue for mothers living in isolated areas especially those who are increasingly vulnerable with the restrictions imposed during the COVID-19 pandemic.

MumMoodBooster Background

The team at PIRI together with Oregon Research Institute developed an online PND intervention program, *MMB*, incorporating low-intensity guided support based on CBT, an established treatment option for depression with its efficacy re-enforced by extensive research (Cuijpers et al., 2009; Cuijpers et al., 2013).

The *MMB* tool is one existing Australian e-treatment for women with a diagnosed perinatal disorder (i.e. moderate to severe depression and anxiety). It is highly effective and achieves a 4-fold improvement in remission from major depression compared to routine care (Milgrom et al., 2016). The best research evidence indicates that early treatment of identified cases is the best proven prevention for subsequent, escalating episodes and for reducing the serious impact on infants. It is also useful as a prevention approach to support any woman experiencing symptoms of PNDA (i.e. those at risk). The online tool with its unique interactive features is a comprehensive CBT treatment program allowing women to work through their issues and is currently available at www.mummoodbooster.com. It can be used in many situations and devices, for example, smartphones for teenage mums.

The *MMB* has been rigorously developed over six years and has a high level of evidence base. It has been trialled nationally and established as an effective treatment for PND (Danaher et al., 2013; Danaher et al., 2012; Milgrom et al., 2016). *MMB* boasts the highest completion rates of any trialled PND program (over 95% of sessions completed by users), is four times as effective as standard care—even for those with severe symptoms of depression—reduces anxiety symptoms, features a support partner website and ensures complete privacy.

Development

Previously, research has reported fully on the formative development and systematic usability testing of the *MMB* program (Danaher et al., 2012). Drawing on the *Getting Ahead of Postnatal Depression* program, run through PIRI (Milgrom et al., 2005), a systematic, iterative development process was used, following the *Science Panel on Interactive Communications and Health* guidelines (Henderson et al., 1999) consistent with a staged approach for the development and testing of behavioural interventions. Two focus groups were conducted in Australia and the US, designed to elicit ideas and opinions about content, structure and aesthetics. Eight participants in Australia and nine participants in America (n=17) were shown the features of the program/screen shots/sample web pages to gain feedback on important features for the target population whilst retaining core content (Danaher et al., 2012). Audio-recorded transcripts were coded and salient constructs, issues and language were then content analysed.

Usability

Twenty-two women (who satisfied inclusion/exclusion criteria) tested user-system interactions. Women were asked to *think aloud* as they viewed screens, videos and engaged in interactive activities. Again, sessions were audio-taped, and coded. Testers completed a widely used system usability scale (SUS). SUS scores can range from 0 to 100 (best). Example SUS items include, *I think that I would like to use this website frequently* and *I felt very confident using the website*. Sessions were held in both Australia (n=14) and in Iowa (n=8). Participant comments were overwhelmingly positive: e.g. “Really hopeful, like you can do something about it,” and “I think this is wonderful, because you can do it at home”. SUS results indicated *MMB* has excellent usability: mean=86.2 (SD=2.13) (Danaher et al., 2012).

Feasibility

Postnatal women (n=15) scoring >12 on the Edinburgh Postnatal Depression Scale (EPDS) were recruited to a feasibility trial. At pre-treatment psychiatric assessment, only one participant did not fully meet DSM-IV criteria for major or minor depression. A fortnightly measure of depressive symptoms was provided by the Patient Health Questionnaire. Growth curve modelling of this data showed that the reduction in participants' symptoms had a significant slope (coefficient=-2.5, $p<0.05$) with a large effect size ($r=0.75$). Further, women had an average symptom reduction (mean=6 points) exceeding the "minimal clinically important difference" on the PHQ-9 (i.e. 2 standard errors of measurement). Review of website usage data indicates that participants have been highly engaged and have adhered to the *MMB* program, having uniformly visited all six online sessions, filled out personal lists, reviewed videos, tracked mood and pleasant activities daily, and received calls from their personal coaches. Over two thirds of participants have also posted their reactions to the program on the Web Forum, e.g. "What the program is saying, is like it's about me. I was comforted knowing there are others with feelings like mine …". Hence, our pilot data provides support for the acceptability, feasibility and efficacy of the *MMB* intervention (Danaher et al., 2013).

Randomised Controlled Trial

A parallel 2-group randomised controlled trial (RCT) (n=43) compared the internet CBT treatment (n=21) to treatment as usual (n=22). At baseline and 12 weeks after enrolment, women's diagnostic status was assessed by telephone with the Standardized Clinical Interview for DSM-IV (SCID-IV) and symptom severity with the Beck Depression Inventory (BDI-II). At the end of the study, 79% of women who received the internet CBT treatment no longer met diagnostic criteria for depression.

This contrasted with only 18% remission in the treatment as usual condition. Depression scores on the BDI-II showed a large effect favouring the intervention group (d=.83, 95% CI 0.20-1.45). Treatment adherence and program satisfaction was very good. Results suggest that our internet CBT program, *MMB*, is an effective treatment option for women clinically diagnosed with PND. This is one of only two controlled evaluations of specialised online psychological depression (Milgrom et al., 2016). A fortnightly measure of depressive symptoms was provided by the Patient Health Questionnaire. Growth curve modelling of this data showed that the reduction in participants' symptoms had a significant slope (coefficient=-2.5, $p<0.05$) with a large effect size ($r=0.75$).

Structure and content

MMB is a self-directed cognitive behavioural PNDA treatment program. *MMB* versions are suitable for both pregnant women (e.g. Mum2BMoodBooster) and new mothers, including those experiencing sub-clinical symptoms and diagnosed cases with major depression and anxiety. Our tool includes ways to recognise and self-assess their depression in line with clinical practice guidelines. *MMB* and its antenatal variant are accessed via a central website, MumSpace.com.au.

Treatment consists of six sequential sessions, as well as additional information in the form of companion library articles that can be accessed 24/7. Users are able to set their own pace to complete sessions and schedule treatment sessions to suit (e.g. around infants). Sessions are supported and encouraged by low-intensity guidance via automated SMS. The program is highly interactive and includes engaging content, personalised tools for tracking mood and activity, video vignettes and tutorials of strategies. *MMB* differs from other available Australian

PND tools in that it is an actual personalised depression treatment program using gold standard CBT targeted and adapted for perinatal women. *MMB* is much more like a traditional face-to-face treatment, allowing women to work through their issues. Sessions are completed anonymously and accessed at home. Motivational/encouraging messages occur throughout the program and help maintain engagement. It is available at a fraction of the cost of traditional psychological sessions.

Self-help antenatal and postnatal versions supported by automated SMS form the core of the online tool for women suffering depression. The postnatal *MMB* program has been successfully adapted for pregnant women (*Mum2BMoodbooster*) (e.g. scoring >14 on the EPDS).

Postnatal Depression

As outlined earlier in the background section of this report, perinatal mental health problems are common, affecting up to 20% of women (NSW Mental Health Commission, 2014). Treatment of perinatal mental health issues is vitally important because if left untreated the implications can be far reaching impacting the mother (parent), the family and the developing infant as well as society.

Infants and children can be adversely impacted by untreated maternal depression and anxiety. Babies thrive when they experience a warm, responsive caregiver which in turn creates a healthy expectation that their physical and emotional needs will be met (*BeyondBlue*, 2010). When a mother is experiencing depression she is less able to demonstrate warmth and a timely response to her infant's cues and cries for help. This can in turn affect the infant's emotional and cognitive development and even result in problems later in childhood and adolescence with language, social and emotional development.

Children of parents who experience depression or anxiety during the perinatal period are also at increased risk of physical health issues such as low birth weight, a reduced immune system, and there is a likelihood of asthma/ respiratory conditions. Transmission of maternal cortisol (produced when the body is under stress) across the placenta is known to play a part in adversely impacting neonatal development resulting in the former adverse health issues (*BeyondBlue*, 2010).

It is also suggested that parents who experience depression are at an increased risk of chronic diseases, substance use and psychological distress and in need of accessing psychological supports. During the perinatal period, this has been found to generate a substantial cost to the health system by way of increased use of primary and community health services including their general practitioner, a psychologist or counsellor and even, for a small number, admission to hospital. The annual financial impact is estimated to be approximately $67 million for primary health services and $8 million in hospital health care (PwC, as cited in Gidget Foundation et al., 2019).

The wider family is also affected by untreated PND with the increased likelihood of family breakdown and family members stepping in to fill the carer role. For the partner, living with a woman experiencing PND can be difficult with partners needing extra support and at risk of developing depression themselves. They can often feel confused, lost and helpless and be the target of their partner's distress and irritability as she attempts to make sense of what is happening to her (Perinatal Anxiety and Depression Australia (PANDA), 2017). The partner's workload can increase as they attempt to continue earning an income and take on more of the household work and care of the children if required. The impact of maternal depression can flow on to parents, siblings and extended family. Some

family members may be included as support people and thus be impacted by the extra workload; others may be excluded from being involved (due to the mother's need for privacy) and thus feel disconnected and conflict in the relationship can result. If the PND continues untreated, these impacts can worsen over time and the toll it takes on family members can increase (*BeyondBlue*, 2010).

Impact of COVID-19 on New Mothers

During the course of the research project the COVID-19 pandemic began and there was an understandable increase in the levels of anxiety and depression experienced by many across Australia, the world, and in particular, new or expecting parents (PANDA, 2020). The PANDA helpline reported receiving 20% more calls for help between February and April, 2020 (Gregory, 2020). Further evidence of the impact of isolation on new mothers is reflected in the response to the Tresillian's *Sleep Well Baby* app. Since the NSW Government made the program freely available in May 2020, there have been over 11,000 downloads of the app. Of those that downloaded the app, 2,900 fit the criteria for PNDA with 576 (20%) of those being at high risk for PNDA.

The pandemic also had implications for the birthing experience of expecting parents. Where a woman was suspected to be positive to COVID-19 or whose husband/partner was suspected to be positive, they were required to birth alone, had no access to pain medication (e.g. gas) during the birth and faced the possibility of not touching their baby for 16 days (Gregory, 2020). Isolation extended further as antenatal check-up appointments at some pregnancy care clinics were limited to being just for the woman on her own. The restrictions on visitors were also more widespread with only one visitor per birthing mother allowed during her hospital admission and this visitor was to be the same person throughout this time. This experience understandably resulted in increased anxiety for parents as they awaited the birth of their baby with parental autonomy over the birthing process (which is best practice as guided by the World Health Organization and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists) being taken over by an attempt to reduce the possible transmission of COVID-19 (Gregory, 2020).

Antenatal anxiety increases vulnerability of the new mother so the additional stressors of the pandemic could significantly see an increase in the 10–15% of women who already experience postnatal anxiety and depression (Buist, 2020). Buist contends that new mothers seeking assistance with PND should be congratulated and that it is critical that support is readily available. Failure to address PND, even mild forms, can have a long term impact on the child. This includes altered reactions to stress, predisposing them to anxiety and depression and, for those who are genetically vulnerable, to auto-immune conditions (Buist, 2020).

Stigma of PND is an inhibiting factor for new mothers to seek help. This was articulated in the interviews for this research, especially for those who identify as Aboriginal. Talking about PND is one step but Buist (2020, p. 9) contends that we need to "understand the ambivalence and anger and fear" that these women experience:

> **No one sets out to be a bad mother, to create a fearful environment for their child. But if they live in fear themselves, a mother cannot create safety for their infant. We need to help and support rather than stigmatise and demonise a mother who is struggling to love and protect her child (Buist, 2020, p. 9).**

Methodology

Theoretical Framework

To answer the question: *What are the key facilitators and barriers that influence implementation of MMB treatment for hard to reach women living in rural, regional and remote areas of NSW*, a translational research framework was used. A translational methodology facilitates understanding of how and why the translation of a health strategy into practice succeeds or fails (Nilsen, 2015). Our focus was on revealing why an evidence based, online CBT program for mums with PND and living in isolated areas was or was not being accessed for therapy.

A translational framework facilitates the enactment of scientifically proven health interventions (in this case the *MMB* program) into the real world, in a wide variety of contexts (Nilsen, 2015); in this research, the context was isolated mums with mild to moderate PND. An essential component of this approach is the establishment of strong relationships with diverse partners (Nilsen, 2015). In translational research, outcomes are enhanced through the inclusion of multiple disciplines to transfer evidence from the theoretical to the practical, real life outcomes that are the hallmark of the methodology (Rubio et al., 2010). The project built multiple layers of partners within the research team, Steering Committee and with the clinicians working with new mothers. Data was collected from surveys, focus groups, interviews as well as quantitative data which initiated, implemented and evaluated the uptake and effectiveness of the program for the target group. Built in to the study were strategies for scalability, sustainability and replication of the project resulting in the *Guidelines for clinicians* manual which can be used as a road map for clinicians supporting mothers to engage with online therapies.

The implementation structure for this project was the Re-AIM Framework based on the work of King et al. (2010) which examines reach, effectiveness, adoption, implementation and maintenance of research. Re-AIM evolved to, 'enhance the impact of health promotion interventions by evaluating the dimensions considered most relevant to real-world implementation, such as the capacity to reach underserved populations and to be adopted within diverse settings' (King et al., 2010, p. 2076). This is congruent with what the research team was trying to achieve here—what were the factors that facilitated or inhibited isolated women with PND accessing an online program that has been proven to be effective in supporting them?

Rubio et al. (2010) acknowledged the role of translational research in leading to a more robust, scientific understanding to enhance standards of care. Further, Rubio et al. contend that this approach to research leads to not just enhance patient care but impacts on 'improved health status in communities' (2010, p. 471). Focus on community health is integral to this research because of the synergies between the health of the mother living in smaller, isolated communities and the immediate and long term health of her baby, her family and her relationships. Parental mental health directly impacts vulnerability to family breakdown and the development of babies and children (Oberklaid et al., 2013) and subsequently the communities to which they belong.

Within the Re-AIM Framework, both qualitative and quantitative methodologies informed data collection and analysis. Phenomenology provided the method for the qualitative phase and gave the opportunity for the women and clinicians to have a voice about their experiences (Creswell, 2014) with accessing the *MMB* program, providing the human experience to enrich the positivist perspective elicited through the quantitative phase.

Ethics

Ethics approval was granted by two Human Research Ethics Committees (HRECs), Charles Sturt University (CSU) and WNSWLHD. The protocol number for the CSU HREC is H19006 and the protocol number for the WNSWLHD is HREC/18/GWAHS/68 (GWAHS 2018–052). An amendment to ethics approval was sought when two potential participants who lived outside the approved geographical area expressed an interest in being part of the project after seeing promotional material related to the project. To support continued oversight of the research, annual progress reports were submitted to and approved by both ethics committees.

Ethics forms and approved information sheets and consent forms are attached to this report (see **Appendices A-D**).

Site specific applications were completed and approved by the WNSWLHD and MLHD.

Intellectual Property

The *MMB* program and its content remain the intellectual property of PIRI. However, the design of any peripheral elements (such as a NSW Health logo appearing on the user interface, or a dedicated web page/entry portal specific to NSW Health) is not considered an integral part of the *MMB* program itself. The *Guidelines for clinicians* manual remains the intellectual property of this research team and NSW Health.

Sampling Criteria

The project used purposive sampling as, in order to answer the research question, it was imperative to invite those with a lived experience of the phenomenon being explored that is, a particular cohort of mothers and the child and family health nurses supporting them (Creswell, 2014). The potential participants were women living in rural, regional and remote areas of the MLHD and WNSWLHD. The mums were 18 years or older who:

- had been screened by child and family health nurse using the EPDS and scored between 13 and 25. This is part of routine screening which already occurs during antenatal appointments and child and family health nurses follow-up at 6-8 weeks and 6-8 months postnatally as part of the NSW SAFE START model of care
- were accessing GP, community mental health, Tresillian, Building Strong Foundations (BSF) services
- were identified as having depressive symptoms.

Mothers who responded to Q10 on the EPDS, which is a question related to the thought of harming themselves, were not automatically excluded based solely on their score. Clinicians would typically assess this risk and potential participants, who had engaged in self-harm in the previous three months and were deemed to be at risk for suicide, were excluded and linked in with other appropriate services. New mums who were considered low risk, were invited to participate in the research. The issue related to self-harm was one that was discussed and clarified by the research team with the Steering Committee and clinicians so that clinical judgement was used by clinicians around the safety of the new mums and their suitability for the research rather than a blanket exclusion for anyone responding positively to the question.

Mothers and clinicians from the following referral sources were invited into the project:

- Child and Family Health Services
- BSF – Aboriginal Children, Families and Communities
- Community Mental Health and Drug and Alcohol Services (in MLHD)
- Tresillian in Murrumbidgee, Family Care Centre.

Mums who participated were drawn from sites within MLHD: Wagga Wagga (Tresillian) (180 births annually), Narrandera (53 births) and Deniliquin (187 births) which represent a recruitment base of approximately 420 births. New mothers were also drawn from sites within WNSWLHD: Bathurst (514 births), Parkes (195 births) and Forbes (131 births)—approximately 840 births per year.

Both Bathurst and Narrandera sites include the BSF service which provides culturally appropriate child and family health services for Aboriginal families. The Tresillian referral site in Wagga Wagga estimates that approximately 60% of women referred to their services present with mild to moderate symptoms of PNDA. The annual estimated 10–20% of birth mothers experiencing mild to moderate symptoms of PNDA (i.e. 100–200 women from Narrandera, Deniliquin, Bathurst, Parkes & Forbes) and the 60% of Tresillian referrals (108 women) give a total referral base for the research of between 200–300 women. From this it was estimated that over the 16 month recruitment period between 60–80 women will participate in the research.

Clinicians delivering the NSW SAFE START psychosocial and depression screening were invited to participate along with community mental health clinicians. Clinicians included those who had referred mothers to the research and those who did not make a referral. The inclusion of the latter group of clinicians was to elicit information about why no referrals had been made by them as this would provide information about barriers to accessing the *MMB* program.

Recruitment

The recruitment process for each geographical area and each cohort of participants involved the following steps.

Child and family health nurses, BSF, Tresillian in Murrumbidgee Family Care Centre and community mental health teams represented in the research footprint were contacted to inform them of the project and co-opt them in the referral of women who fit the profile for the *MMB* program. A poster promoting the research was forwarded to all services to display in waiting areas and other prominent locations where new mothers would encounter them (see **Appendix E**).

All clinicians received instructions regarding the *MMB* program and education on how to access the online tool in a PowerPoint presentation (see **Appendix F**). They were provided with education about the research, about how to recruit new mothers for the research, and about the communication channels to the research team. Education was provided virtually and face-to-face. The face-to-face sessions were conducted at team meetings where a number of clinicians and managers were present. Clinicians and managers provided feedback after the sessions stating that:

> ***The opportunity to meet the principal researchers in person was good from our perspective. I think it was great and what I was interested in was the nurses, particularly I remember down in Deniliquin jumped on board with it quite so quickly and could see the benefit of it immediately.*** **(Kelly, Clinician)**

Individual education was provided for clinicians or managers who were unavailable at team meetings. Some of the clinicians and managers who attended the education sessions were somewhat overwhelmed with the amount of information; this is an aspect that needs future consideration when providing support for the clinicians and managers. One of the managers stated that:

> ***The amount and content of information was a bit overwhelming especially after the first session in Bathurst. It may have been helpful to gauge clinicians' understanding of research more generally and provide information about Translational Research Grants (many are not aware of this process).*** **(Layla, Manager)**

The table below represents the approximate number of education sessions held for clinicians and the relevant LHDs. Individual sessions were largely held via Skype and group sessions were mostly face-to-face.

Table 2: Number and type of education sessions held in LHDs for clinicians

Local Health District	Group sessions	Individual sessions
MLHD	4	9
WNSWLHD	2	3
Total	**6**	**12**

Clinicians identified women who met the criteria, invited them to participate and provided them with information about the project. Initially, clinicians were not confident in approaching the new mothers so this challenge was overcome by providing the clinicians with a preamble that gave them the appropriate words to use to begin the conversation (see **Appendix G**). This strategy was effective and addressed the uncertainty clinicians felt in the beginning stages of their encounter with research and recruitment. A senior clinician shared with us the importance of providing a script for clinicians:

> ***Really, really important because one, you've got a consistent message, two—because people—and I think clinicians, don't know how to explain, you know, when there is research or something new to be offered. They don't know how to go about offering that and what the benefit*** **[is]** ***it brings, so if you've got it scripted for them about why we're asking, what the importance is and what we think the benefit's going to be, if we can help script them with the words, one, we know a consistent message is going out and two, I think it would help prevent avoidance and it would probably really enhance the outcome and the engagement of the clinician let alone the client.*** **(Jenny, Senior Clinician)**

As there were a number of documents to be provided to the new mother and it was recognised that documents could be misplaced or their purpose not clear to the participant, an information pack was compiled. The pack was housed in a CSU folder and included:

a. a letter inviting the new mother to participate in the research
b. information sheets related to ethics approval
c. consent forms
d. a card with the contact numbers for the Project Manager
e. the initial and subsequent questionnaires
f. pre-paid envelopes for the participant to post back questionnaires
g. a brochure identifying other services available to them especially in an emergency
h. information regarding three gift cards that would be sent to the participant when milestones in the project were met. Each gift card was valued at $30.00 and was a small recognition for the time and effort invested in the project by the individual new mother
i. a postcard sized flyer with key points around the *MMB* and the URL to register.

An issue identified in relation to the information packs for the new mothers was the language used in documents. Much of the language was prescribed by the HRECs and as the team, we were obliged to follow the HREC instructions in order to progress the research. Comments from the Steering Committee, especially the consumer representative, were that:

> ***The language could have been more targeted towards the needs of consumers and busy clinicians. We recognised the constraints put upon us re the requirement of the Ethics Committee … it may have been useful for all the Steering Committee members to have met with a representative of the Ethics Committee so we all understood the constraints and/or possibilities up front.*** **(Consumer representative/Steering Committee)**

The information pack evolved over time and as the researchers responded to feedback from the clinicians. The clinicians were generally positive about the usefulness of the information packs with one commenting that:

> ***The information packs clearly outlined what was expected from participants. It also reassured the participant that she may opt out at any time. It was presented in a professional manner.*** **(Brett, Clinician)**

To provide another perspective:

> ***The information packs were a bit overwhelming in regard to the volume of information—too many pieces of paper, repetition of some information.*** **(Margaret, Clinician providing feedback in relation to the information packs for clinicians)**

Once consent was obtained from the mum, the clinician provided a user login for her to begin working through the *MMB* online program. This proved problematic as some participants lost their login and for some there was a delay in receiving their login. Subsequently, some new mothers reverted to the publicly available *MMB* website and capturing their data then became difficult. PIRI and the Project Manager were able to track some of the new mothers who had logged in incorrectly.

Clinicians invited the participants to complete the baseline questionnaires to gather basic demographics and measure symptoms of anxiety and depression. The questionnaires were then posted back to the Project Manager in pre-paid envelopes. On receipt of the document, the Project Manager sent a gift card worth $30.00 to the woman.

Within the PIRI *MMB* program, there are alerts that trigger when new mothers are identified to be at risk. Participants were informed of this service and the new mothers were also informed of other emergency and support services available to them, based on clinical need. This information was in the information packs. The safety of the new mother was of prime concern to the research team so each participant had to have a clinician responsible for her care. Information about the clinician and the new mother they supported was kept by the Project Officer so that if an alert was triggered by the *MMB* program, the Project Officer could contact the relevant clinician for follow-up. This feature was not required to be enacted but clinicians stated in their data that they wanted more feedback from the program.

The individual new mother's engagement with the *MMB* program was tracked through the analytic tools developed by PIRI. This provided the quantitative data for the research.

Ongoing support and education for the clinician and mothers in relation to the program was provided. If telephone calls were not answered by the new mothers, it was found that the most effective way of communicating with these busy, time poor and often exhausted participants was through text messaging. This form of communication enabled the new mother to respond at a time that suited her busy schedule. Supporting clinicians was through emails which kept the clinician involved and informed of the outcomes of Steering Committee meetings and the research process and enabled the clinician to provide feedback.

After approximately nine weeks of being involved with the *MMB* program, the mother's symptoms of depression and anxiety were measured through the PHQ-9 and DASS-42. These forms were included in the participants' information packs. The completed forms were sent to the Project Manager in the pre-paid envelopes. On receipt of the forms, the Project Manager forwarded a second gift card to the new mother.

A follow-up was undertaken with each mother to ask them to complete a second questionnaire following which mothers were invited to participate in a semi-structured interview and/or a focus group to share their experiences.

The project was managed by an onsite Project Officer and data accumulation and participant safety were reviewed monthly by the Steering Committee. The project was approved and ethical oversight was through the WNSWLHD and CSU HRECs for which an Annual Report was submitted to both.

Building a Research Culture

This research was championed by a clinician who was motivated to explore why women who were experiencing PND and lived in isolated areas were not taking advantage of an online therapy. Keryl de Haan was instrumental in bringing a team together that could be successful in accessing funding through the Translational Research Grants Scheme (TRGS) and undertake meaningful and impactful research. Although the first application for funding was not successful, Ms de Haan was determined to get the research underway which meant receiving feedback from the funding body and reapplying the next year. During the two years, the team remained committed to the project and were learning by confronting each challenge and learning how to:

- navigate the grant application process
- develop a research proposal

- apply for ethics approval from two HREC committees –WNSWLHD and CSU
- access site specific approvals for all sites
- manage the budget
- collaboratively function across the clinical, tertiary and industry sectors
- overcome the unexpected issues that arise throughout a research project.

In this research project, the team sought to be inclusive of managers and clinicians who participated in the Steering Committee, attended education sessions, recruited women and participated in the data gathering phase. Notable achievements here were:

- an early career researcher was the Project Manager thus enhancing her skills especially in qualitative research
- one member of the Committee, who participated in the data collection and analysis, is both a midwife and a PhD candidate
- two clinical managers participated in some of the focus groups and individual interviews giving them an insight into the conduct of semi-structured interviews
- linkage with a Professor in the School of Nursing, Midwifery and Indigenous Health (SNMIH) at CSU with an interest in child and family health and the potential for future collaborative partnerships
- building the potential for another project related to encouraging Indigenous mums to breastfeed for longer periods
- that the experience also helped strengthen research partnerships, enabling the subsequent TRGS, EOI (for a totally different project) to consist of a team with partners from MLHD, WNSWLHD, Tresillian and CSU
- that it led to members of the TRGS team identifying an opportunity to develop a proposal for a project submitted in a TRGS round two years after the commencement of the current project
- that the experience of working as part of the TRGS Steering Committee led to improved awareness of the aims and application of translational research.

Engendering a research culture commenced with the education sessions for the clinicians where the project was outlined and the processes were explained. Clinicians had the opportunity to make suggestions about the proposed strategies and the usefulness of documents. To ensure continued communication and inclusion, the clinicians were sent regular emails to keep them informed and to seek feedback about any aspect of the research. Managers played a vital role in information sharing, building excitement about the potential research outcomes and the value of being a part of a research project for the clinician.

As evidenced by comments from participants and Steering Committee members, it was not just the clinicians who were learning about research; this applied to members of the research team under the guidance of the two academics from CSU and the experienced researchers from PIRI. A member of the team commented that they had discovered:

> ***Research is not just about numbers, anything related to the project was seen as valuable information that would be recorded and needed to build the report—this was a benefit to having uni/experienced researchers on the team.*** **(Extract from the reflection sheet issued to Steering Committee members)**

Two senior clinicians involved with the project and who are in a position to instigate further research within the clinical settings, stated that:

> ***We learned A LOT* [sic] *from being involved. It demystified the process of research. It encouraged us to consider doing our own research in the future.* (Extract from the reflection sheet issued to Steering Committee members)**

Being involved in the whole research process gave the members of the research team, the Steering Committee members and the clinicians who agreed to participate, a real world experience of the challenges involved in the processes of research. They were aware of the challenges especially in recruiting mums to the research. A comment indicated how the issues confronted in regards to recruitment could be a deterrent to be involved in research.

> ***It may have caused clinicians to reject the idea of research—especially when difficulties around recruitment appeared. It seemed to be an additional burden to recruit women.* (Extract from the reflection sheet issued to Steering Committee members)**

A member of the Steering Committee whose sole role was an advisory one, stated that she had *very little knowledge* on how to implement a research project. She was motivated by what this project involved and could envisage how a research approach would assist in identifying the most appropriate way to support the mothers she encountered. Currently, she is developing a research project to support Indigenous mums with breastfeeding. She stated that, *I am now going down that track with a project in* [small rural town] *and after meeting with Maree and the Research Manager MLHD, I have some knowledge of the process.* (Member, Steering Committee)

Another Steering Committee member was so motivated about being involved in this project that she enrolled in a Graduate Certificate in Psychotherapy. One of the assessment tasks was to undertake a small research project. The comment shared with the Committee was that she felt confident undertaking the postgraduate study as a result of her membership of this Steering Committee.

Feedback from the clinicians about their role in the research elicited the following response from a manager who was a member of the Steering Committee:

> ***Participation in the study by clinicians, both in terms of participating in promotion, recruitment and being interviewed, has enhanced a sense of inclusion in research, dispelling a sense of mystery regarding research and making it relevant to clinical practice. Clinicians reported seeing the potential benefits of the web-based program and were eager to explore and understand how best to utilise the potential and importantly increase access to help and support for mothers living in regional, rural and remote areas. This link between research and practice was/is important with clinicians reporting they could see that this research had the potential to improve outcomes for women, children and their families.* (Extract from the reflection sheet issued to Steering Committee members)**

Data Collection

To answer the research question, both qualitative and quantitative data collection methods were used with the data from each methodology informing the other. An example is when quantitative data was provided by PIRI that the woman had not completed all modules of the *MMB* program, opportunity to understand why this had occurred was facilitated during the qualitative interview.

Quantitative data

Collection of quantitative data was through baseline questionnaires which measured initial symptoms of depression (Patient Health Questionnaire: PHQ-9) and anxiety (Depression Anxiety and Stress Scales: DASS-42). A second score was elicited after nine weeks when new mothers again completed questionnaires measuring symptoms of depression and anxiety (DASS-42, PHQ-9). Safety monitoring of depressive symptoms was scheduled at regular intervals (at baseline, and nine weeks) using the PHQ-9. If there was a worsening of symptoms or indication of risk of harm, it would have triggered a system 'red flag' to the program administrator, a push notification of emergency resources, and enabled immediate telephone contact for referral to specialist care services. This safety mechanism was not required by any of the participants.

The initial and follow-up DASS-42 and PHQ-9 questionnaires were included in the information packs for the new mothers who had agreed to participate in the research. When completed surveys were returned to the research team and, as a token of appreciation for their time and involvement, the participants were sent a gift card.

Summary of quantitative data sources

- The women received a user login and worked through the online program.
- Baseline questionnaires measured current symptoms of depression (PHQ-9) and anxiety (DASS-42).
- To ensure safety of participants, monitoring of depressive symptoms was scheduled at regular intervals (at baseline, and three, six, and nine weeks) using the PHQ-9. Worsening of symptoms or indication of risk of harm triggered a system 'red flag' to the program administrator, a push notification of emergency resources and enabled immediate telephone contact for referral to specialist care services. This was not required.
- After nine weeks, women again completed questionnaires measuring symptoms of depression and anxiety (DASS-42, PHQ-9).
- Website analytic tools tracked usage throughout the program including session completion, visit frequency and duration.
- A medium-term follow-up of all outcome measures (DASS-42, PHQ-9) was scheduled after a further three months along with a survey of women's and health professionals' satisfaction with the program and its access.

Qualitative data

Qualitative data was collected through semi-structured interviews with mothers and semi-structured interviews and focus groups with clinicians. The mums were interviewed individually rather than in focus groups to enable them to have the opportunity to share emotive experiences and be as open as they felt comfortable with, in answering the questions.

In total, the number of interviews and focus groups was:

- 13 semi-structured interviews with new mothers
- 18 semi-structured interviews with clinicians
- 4 focus groups with clinicians
- 2 semi-structured interviews with managers
- 1 focus group with clinicians which included a manager.

Interviews and focus groups were undertaken predominantly face-to-face so that rapport was optimal and a trust could be established with the participant. However, in March 2020, the COVID-19 pandemic resulted in enforced isolation for the new mothers and clinicians with travel restrictions on the research team. Interviews were then conducted using an online platform for interviews with four clinicians and seven mums.

The interviews focused on the mothers and their experiences in accessing and interacting with the *MMB* program as well as their perspectives about its benefits. The questions included:

- What was the relevance of the program for them?
- How frequently did they engage with the program?
- What factors enticed them to use the program?
- What prevented them from accessing/using the program?
- What was most useful aspect for them?
- What aspects of the program could be improved for other women?
- Any other information/experiences they would like to share?
- Additional questions emerging from the quantitative data being collected.

When interviewing clinicians either individually or in focus groups, the questions to stimulate discussion were:

- What was the clinician's experience with working with mothers experiencing PND?
- How receptive were women to using the program?
- What were the aspects that the clinician found challenging in engaging the women with the program?
- What was most useful about the program?
- What support did they receive in promoting the program?
- What other support would be useful for them to engage women with the program?
- Any comments about the usefulness of the program for isolated women?
- How could they be more prepared to engage women in the program in the future?

In order to capture the experiences of the Steering Committee and the clinicians they encountered or managed, we developed a feedback sheet.

Data Analysis

As a result of the structure of this research and to enable the research questions to be answered, qualitative and quantitative data was collected simultaneously. It is recognised that both types of data will provide information that is different but each contributing to finding the answers to a complex phenomenon (Creswell, 2014). In this research, it was to find the facilitators and barriers for isolated new mothers accessing an online intervention for PND.

Qualitative analysis

Interviews with the mothers and the clinicians were recorded after the participants read the information sheets and signed the consent form. Creswell's (2014) model for thematic analysis was used to structure and provide rigour for the qualitative phase of the data analysis (Creswell & Planto Clark, 2017).

With the participants' approval the interviews were recorded digitally. The recorded data was transcribed verbatim and analysed by three of the researchers.

Transcribed interview documents were sent to three researchers, Associate Professor Maree Bernoth, Ms Keryl de Haan and Dr Jo Carlisle. A template was developed to capture the coding undertaken by each person during their reading of the script to ensure consistency in structuring the first phase of the data analysis. Each of the analysis team members read through the transcripts and coded the data, individually. At this stage the barriers and facilitators started to emerge. As these were clearly expressed by participants and were readily identifiable, they were documented and are the basis of the recommendation section at the end of this report and inform the *Guidelines for clinicians*.

Yet, deeper analysis revealed a much more complex picture that, if explored, would more substantially inform the research outcomes. To explore the themes, the three researchers spent time together in deeper analysis, discussing common threads in their analysis and exploring where themes converged and differed. Because of the number of transcripts, this process needed a dedicated investment of time and deep thought to ensure the integrity of the data was respected and that the voices of the mothers, the clinicians and the managers could be heard.

The figure right diagrammatically represents the analysis process and is adapted from Creswell (2014, p. 197).

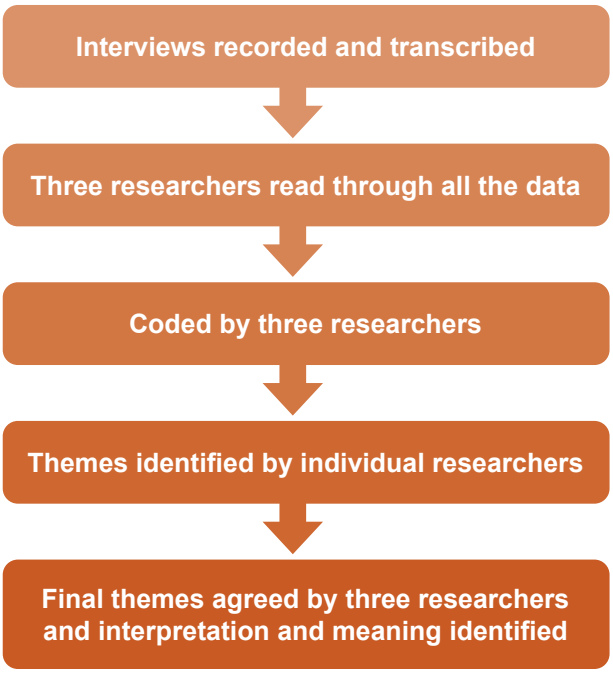


Figure 2: Analysis process for the qualitative data

Qualitative Findings

This section of the report identifies the themes emerging from the interviews with the managers, clinicians and mums who participated in the research. All participants were given a pseudonym to respect their privacy. Differentiation between the informants is provided by nominating the role of the health professional along with a name whereas the mums have a first name only. Although only one mum who identified as Aboriginal and Torres Strait Islander participated in the research, clinicians who are from First Nations peoples shared their experiences to inform the research in relation to culturally safe practice.

Mums

The mums who participated in the research gave of their time and generously shared their thoughts, feelings and experiences. The research team acknowledged the risk for the mums in doing so as it opened them up to revisiting some sad and distressing times in their lives. Yet, an overwhelming sentiment expressed by the participants was a desire to share their story to help other women and prevent peers from experiencing the loneliness and despair they had lived through.

There are a number of themes that emerged from analysing the transcripts, one of which was mums not recognising the symptoms of PND. This was despite some mums with tertiary qualifications in a health discipline. Yet another was the fact that the women had been told about e-health support but they forgot and the uptake of the program only came after several prompts or after reaching desperation.

The following is a representation of the dominant themes that were identified through the analysis process that reveal the facilitators and barriers for mums to engage in e-health programs for PND.

Recognising the symptoms

One of the barriers to accessing the online program was that many women did not recognise the symptoms of depression. They perceived what they were experiencing was fatigue, *just thought I was having a rough patch. I'm just tired, because you're sleeping really badly, it'll be fine, it's not that bad and then you realise "No".* (Rachel)

Yet another comment, *I don't think I was suffering depression at all—it was just normal sleep deprivation coupled with these periods of grief.* (Pippa)

This lack of insight into their depression not only prevented them from accessing assistance, it also put marriages and relationships in peril. *I was angry all the time and I was really irritable. It didn't take very much to really set me off and it sounds terrible, but I was, at one point, I was just thinking as I go, "I want a divorce".* (Pippa)

A clinician added a word of caution about women recognising and managing their own mental health issues after giving birth, *but not many women are sort of really familiar with the concept of counselling your way through your own depression.* (Layla, Clinician)

Yet, one mum shared that, *I think the further you get into the program, the more you realise you actually do need this.* (Isabelle)

Stigma

In conjunction with lack of awareness of symptoms is the stigma, perceived or real, that women feel when they experience depression. If PND is being suppressed or ignored because of the shame attached, the women are not motivated to access the online CBT program.

> ***I didn't feel comfortable talking about it. You feel like everyone else is loving it*** **[motherhood]** ***so you don't want to talk about it. And I know it just perpetuates the myth and the stigma and I was "No, I should talk about it more because people don't talk about it enough".*** **(Zoe)**

This sentiment was supported by a clinician who recognised that although PND is being talked about more, there remains a stigma for some women. The clinician also shared her concern about how women may acknowledge their mental health struggles with a health professional but not with their loved ones.

> ***I think there's a stigma in the community because we'll have clients come here and we'll be the first people that they've ever spoken to about having thoughts of self-harm, but they've been in their relationship with their partner or they say they have a really supportive family. So, they feel like they can tell a health professional, but they feel like they can't tell their own family, the people who are closest to them which is pretty sad.*** **(Frank, Clinician)**

This again would be a barrier to accessing the *MMB* program as the program is accessed through the home computer and could be discovered by other family members.

An Aboriginal health worker said that this reticence to accept help because of the stigma resonated with Aboriginal mums. She felt the women who identified as Aboriginal felt that asking for help was like:

> ***… speaking up at school and saying, "I need help"—people just don't like that. They think other people are going to think bad of them. Like, "Oh, that mother's a bad mother". How do we just break the barriers of getting people to see that getting help is fine?*** **(Elle, Indigenous Health Worker)**

Prompts

Mums felt that they needed reminders about the availability of e-health programs. They received brochures and were told about support services but needed reminders to access these. Some reminders came from clinicians, from friends and from partners. However, others were at the point of total hopelessness before they accessed help. One participant revealed how her distress led to her laying on the kitchen floor, crying before she looked up at her fridge and saw a fridge magnet with a phone number which she called and received the help she needed. *Maybe if I had prompts to remember, like even if it was a message or something like that … I would have thought there are resources there.* (Beth)

Clinicians also recognised the value of having a coordinator to remind mums to engage with the program and then continue to follow-up to ensure the program was meeting their needs and assist where needed.

> ***I mean, I feel like it would be really useful to have a coordinator who they can check in with and checks in with them. That's really what the program needs, is*** **[to have an]** ***essential coordinator who can then just be checking in with clients and giving that phone number.*** **(Frank, Clinician)**

The issue is to get the mums engaged with the e-health program because, once they are registered, it has a prompting mechanism which those mums who used the program found useful.

> ***What I particularly liked was, I got prompting emails saying, "Don't forget to finish this section or don't forget to take a minute for yourself, come check this out on MoodBooster" and I found that really encouraging and helpful, especially if I was having a rough day, I would get an email and go, "Right, I can sit down for five minutes and check in to MumMoodBooster tonight.*** **(Isabelle)**

Isolation

The isolation experienced by the mums was geographical and emotional. The women lived in very small communities, sometimes many kilometres from town where they could access services. Women and clinicians who lived near state borders experienced an unusual isolation in that the service might be just over the bridge but the bridge spanned a state border which precluded them from using the services that exist there or that meant they had a longer wait to access the services than mums who lived in the state.

Another source of geographical isolation came with women who lived close to the boundaries of primary health networks (PHNs). A service may be geographically close but it was inaccessible to the women because it belonged to another PHN.

Unreliability and variances in web access contributed to isolation and to the women's ability to access the e-health program. Location was no indication of web access, *if you're in Wagga, even some places just in Wagga or in Tumut, in town, you can go up the street and not be able to get* [internet access], *so that does certainly have a—an impact.* (Jenny)

Web access impacted the women and the clinicians who were impeded from being able to introduce the e-health program.

Isolation was also caused by when the baby was born. Supportive mothers' groups were scheduled at pre-determined times which meant that women had to wait for a length of time before they could join the subsequent group. Clinicians explained that women could join a group at any time but it was perceived that this was not the case by some mums. *It took me three months before I was in a mother's group. It's a long time to be on your own without connecting in with other mums.* (Beth)

It was the emotional isolation that was a barrier to a mum reaching out for help and engaging with an online CBT therapy.

> ***I think if women are isolated already then, they're not going to be, they already probably have low self-esteem, they've no network, so they're probably not going to their maternal child health nurse appointments or follow-up, they're just going to fall through the cracks.* (Pippa)**

So, from the data, it seems that having services available and giving women information is not enough. It is the ongoing reminders and the constant presence and reassurance of the clinician, the family and partner that are needed to be the impetus for the woman to engage with the therapy available.

> ***I think there's a lot of pressure for women to be happy and excited for their pregnancy and some of them just got through a lot of stress and worry and I think people like that would benefit from knowing there are services to help them get through that. So just talking about this idea you're not alone and there is certainly help available. (Isabelle)***

Role of dads

The significance of the role of the father was raised by the mums and the child and family health nurses. The father was integral to the uptake of the *MMB* for some of the participants but the women recognised that it was not just their own journey through new parenthood, the father was also coming to terms with their new role.

> ***There's a bit of a lightbulb moment that mum has been so engaged in what's happening with her feelings and her baby and the dad is over there with the tears coming down his eyes and nobody has addressed him.* (Kathy)**

One mum spoke of how the anxiety of new fatherhood pushed her partner away from her and their new baby, *my partner was so anxious and that he was just really scared of Loui because he was so little and he thought that I was fine and was coping okay and I thought that he didn't want to be around us.* (Vanessa)

Participants were surprised that there is a section in the *MMB* program for dads/partners. *There was even a quiz that I got Matt to do about males and dads having postpartum depression and what it looks like and he was off the scale on the stress.* (Vanessa)

Another mum spoke about how they included their partner in the *MMB* program by discussing the content as they lay in bed at night. This came about after her partner had a lightbulb moment when he heard an information session on the radio about PND:

> ***There's an anxiety radio ad and it took for my husband to hear the ad, for him to go … "I know what's going on with you now and how your brain's working". So he was and he's really supportive, he was very on board with helping out so I could do some things like that. And then we might go out for lunch or something together to do something nice together or go for a walk with Halley and stuff like that. So he was really good.* (Zoe)**

The inclusion of the father or partner is integral in the woman being involved in the e-health program. By including both partners in pre- and postnatal interventions and education, the clinician has someone invested in reminding mum about the program, supporting her as she engages with it and then encourages her as she progresses through the modules.

Stoicism and self-efficacy

Too many times in the interviews mums shared with us their lack of sense of self. It seems that in taking on a role of a mother, they then become invisible, unworthy and forgotten. *We need all of these things: the cot, everything else but what about mum? You know sometimes you can feel unworthy.* (Beth)

Mums felt they had to be all things to all people, maintaining previous roles as well as taking on new roles and being competent, seen to be managing:

> ***When you're busy you think "Oh I should do this"* [the *MMB* program] *and it just becomes another one of the shoulds that you're beating yourself up for not being able to achieve when you have a baby. Like the washing, the cleaning and I was "Oh it'll take me too long, I have to have the time to actually do it" and so I kept putting it off and then I'd just forget to actually go and do it and it'd be another couple of weeks down the track and I'd think about it.* (Zoe)**

As a result, the program, designed to support them and assist them through their depression, is pushed into the background. Self-care is the aspect that is ignored, they put themselves last. This can be unwittingly reinforced by family, *society and your family all think that you're okay and then that's when it starts getting really tough.* (Beth)

Personhood and agency are found through others such as a partner and a desire to be the best mum they possibly can be.

> ***Enthusiasm and positivity through the program and my knowledge of how it can work, my knowledge of, "Yes, this is exactly what I need to do and wanting," and my desire to want to learn and grow and wanting to get well, and wanting to feel better in myself and wanting to be the best mum and partner that I wanted to be.* (Vanessa)**

> ***... in the end, it's well, Halley deserves to have a functional mother, rather than barely getting through the days, and some days I could just, couldn't.* (Zoe)**

This remains a challenge for health professionals and mums. It is getting a change in focus, developing a sense of self-worth in mums so that their health and wellbeing is a priority, not just to be the best mum or the best partner but because each individual deserves to be supported and enjoy optimal health. If their sense of self is not addressed, they will not reach out to engage with e-health programs.

Learning from the experience of others

The women were very invested in preventing other women experiencing PND. *If there's women that are feeling like even half of what I felt in the last 12 months that makes me so sad.* (Beth)

Some established support groups or expressed an intention to do so:

> ***I just put it out on two mums' groups and yeah, now I have 83 members and there's about six or seven regulars that come and then five to six people that come and go as it is but 83 people that are in the group. I think that that's something that needs to happen as well is like that there's a support network and a support community for new dads and new mums.* (Vanessa)**

The mums spoke about the need for interaction with people in their situation with whom they could share common experiences.

> *I needed a space with other mums that were open and real and not putting on this façade that everything was okay, that you could just sit with and sometimes you didn't even have to talk. Sometimes you could have a cry, sometimes you could have poo humour.* **(Pippa)**

Being involved with a group of women can lead to other support options. One mum had a convoluted journey to accessing e-health interventions but it was the willingness of other women to share information with her that eventually got her to a place where she found support.

> *I wasn't practising self-care, I wasn't taking time out for myself, I wasn't stopping those negative thoughts before they did spiral and I ended up reaching out on a Facebook group called Misfit Mums in Wagga and they said Tresillian's really good and you can go there, and so I did and that was probably the first step that I took in regards to postpartum depression and anxiety.* **(Vanessa)**

The participants suggested that a way to enhance the e-health intervention would be to include a link to groups of participants so they could interact, learn and share with each other.

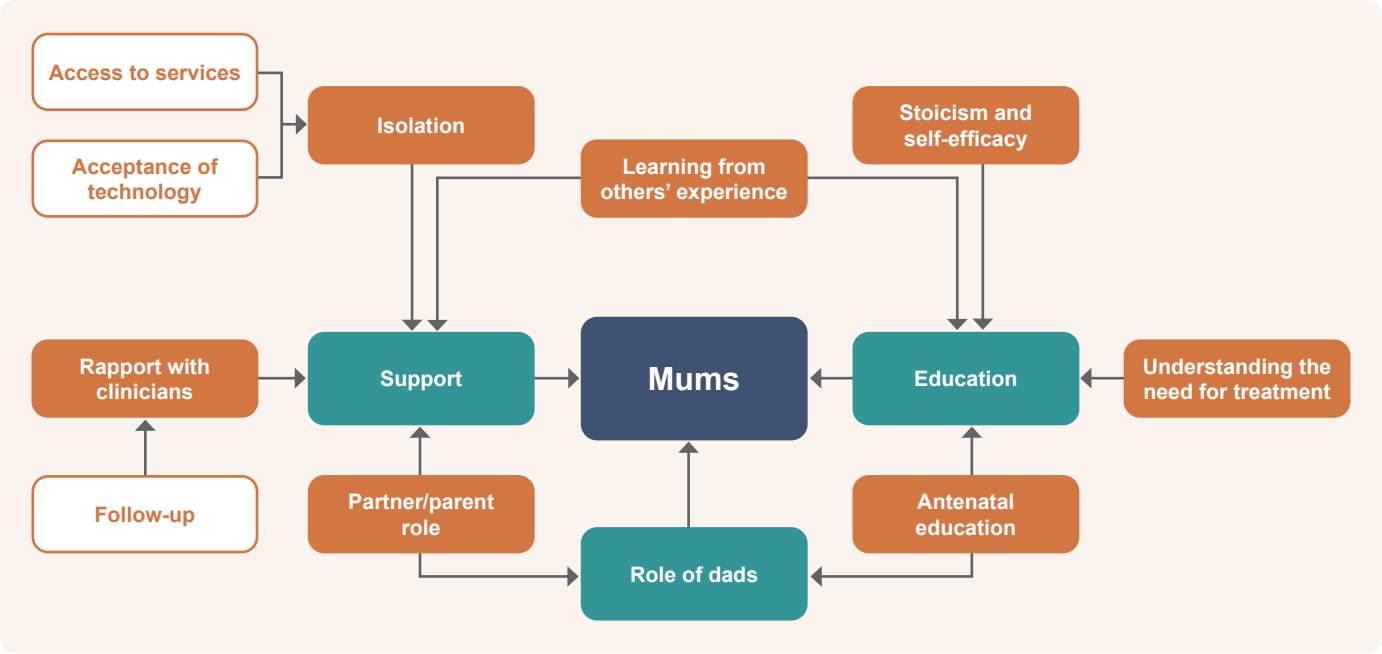


Figure 3: Themes emerging from the interviews with mums

Clinicians

From the initial interaction and assessment, the clinician is building a trusting relationship on which the woman depends for direction, guidance and support as she begins her role as a mother. Clinicians play a pivotal role in whether or not the woman chooses to engage or not with an e-health intervention. The interviews with all participants revealed the means by which the clinician builds an environment which enhances the mums' engagement with e-health programs.

What clinicians need to enable them to engage the mums with e-health programs:

- to be literate in information technology with a commitment to ongoing professional development to maintain awareness, knowledge and skills
- confidence in accessing and using technology that enables access to e-health programs
- awareness of relevant programs, their features and suitability according to the assessed needs of the individual mum
- familiarity with the programs prior to referring mums
- building introduction to e-health into standard practice
- provision of devices on which to access the web and relevant programs
- reliable web access
- ability to build rapport with the woman and build a trusting relationship with her and her partner
- time allocation so that extra time can be spent with women who are vulnerable; extra home visits can be scheduled and referrals can be followed up.

Aspects of the clinician's practice that were inducive to women accessing and using the e-health programs include:

- Skills and approach to the EPDS—whether it is used as a tick box or a conversation to tease out symptoms of depression so the woman's vulnerability could be accurately ascertained.
- Referral and follow-up: the clinician's willingness to refer and then their assertiveness skills in communicating with referral sources to ensure seamless care for the woman.
- Clinical judgement and skills about when to introduce the topic of e-health, how to talk about the program and the relevance for the woman.
- For Indigenous women, establishing a collaborative model of care with the Indigenous woman and a trusted health worker or family member.
- Inclusion and emphasis of the topic of PND in the antenatal birthing classes including the unusual ways PND may present because, *it may not look like what you expect it to look like*. (Zoe)
- Constant conversations and reminders for the woman to access the program.
- Wiliness to spend time with the woman to register in the program and then go through the initial stages of the program to give her confidence about its relevance and to ensure she is able to navigate the website.
- Inclusion of dads and partners in awareness of the e-health program.
- The clinician determining the most relevant way of contacting and communicating with the individual mum.
- Willingness of the clinician to raise concerns the woman may have in seeking help because of fears such as stigma attached to PND: *it also was an opportunity to talk to mum about there's a range of resources out there for you. So just talking about this idea you're not alone and there is certainly help available.* (Kimberly, Clinician)

The diagram below is a graphical representation of the themes emerging from the interviews with clinicians, showing the facilitators and barriers to engaging women in e-health programs.

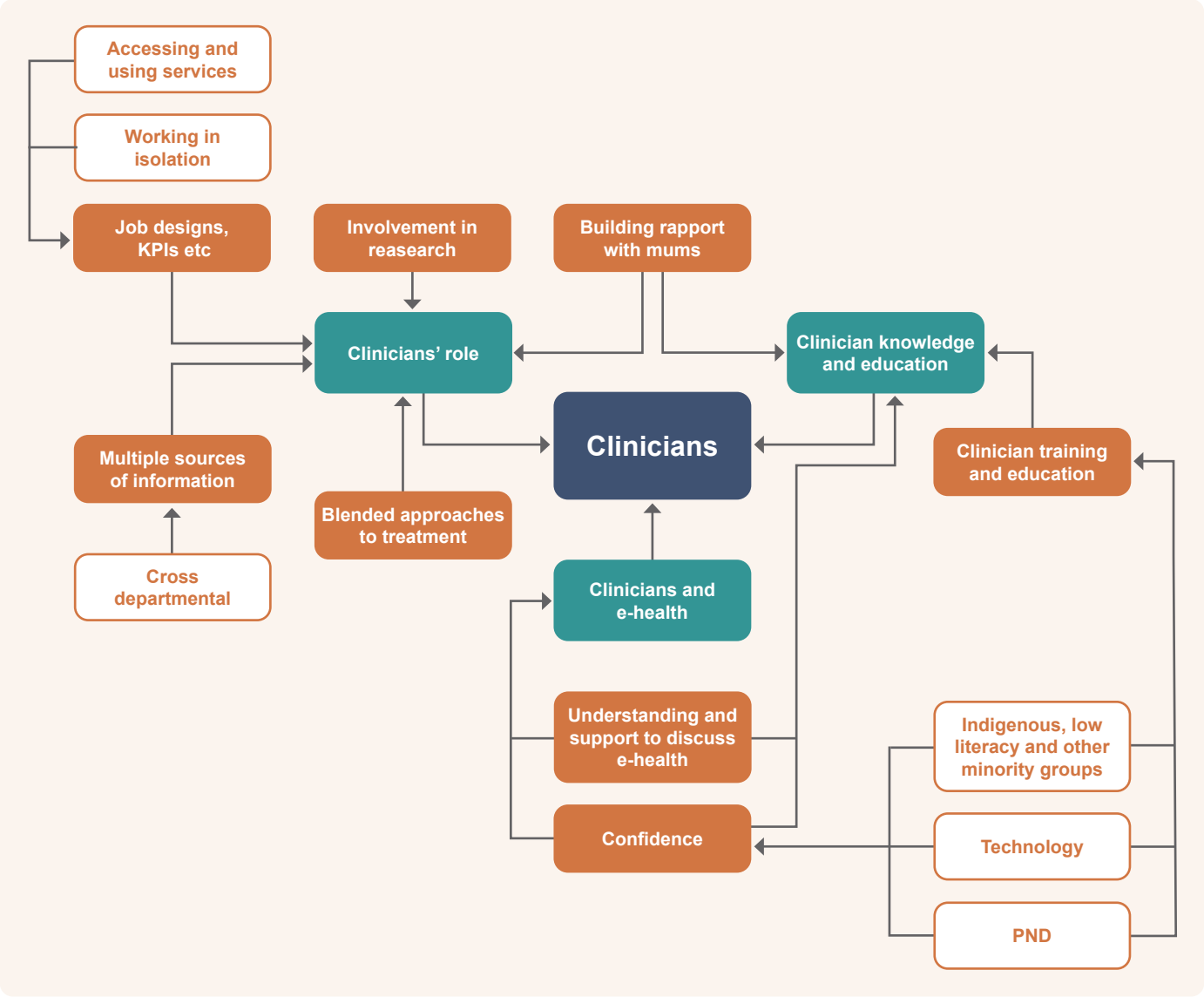


Figure 4: Themes emerging from interviews with clinicians

Managers and Senior Clinicians

Managers and senior clinicians envisaged their role in facilitating access to e-health resources had *been more around developing staff and developing their awareness and developing their skills and understanding around different issues ... It is ensuring staff are aware of policies and referral pathways so clinicians can support vulnerable women and identify PND.* (Jenny, Senior Clinician)

Themes emerging from the interviews with managers and senior clinicians identified the following conditions that enabled or impeded the use of e-health programs:

- **Changing roles of child and family health nurses:** *particularly when working in partnership with families and it was another huge shift to working with the families in a different way just rather than that expert way so there have been great changes and I think now you see the—the new child and family health nurses coming in and they're much more comfortable and confident with looking at families holistically.* (Jenny, Senior Clinician)
- **Development of clinical judgement:** *meetings with the multidisciplinary team have really helped them grow. Maybe in their confidence as well, in their role of identifying complex issues and then their role in the support. It's also been an acknowledgement of their expertise and professionalism and that what they do is so important to help improve health and wellbeing.* (Natasha, Manager)
- **Supporting clinicians as they develop their confidence in the use of technology:** *some staff are not confident, generally speaking, in using the technology. We've had numerous 'show and tells' and demonstrations and user how-to's and guides. Some staff need you to be there with them and stepping them through* [the technology]. *They do struggle to consider e-health technology as one of the options for service delivery.* (Jenny, Senior Clinician)
- **Support for clinicians working with vulnerable families:** *as in the organisation it's making sure that the—the staff have the support and have the skills and knowledge to help them work with vulnerable families and—and engage in vulnerable families because some staff do find that really challenging.* (Jenny, Senior Clinician)
- **Managers trusting staff skills and professionalism:** *I guess as a manager I like to work very much from a supportive base for my staff because they are all clinical professionals, you know, they're all professionals in their field and I like to trust how they do know how to go about the support of mothers with PND is really bread and butter of our business.* (Natasha, Manager)
- **Further**, *trust them professionally, trust what they're recommending, trust what they're offering, trust their support that if you have—if they've got respect and trust for you professionally that gives you a lot of platform to work from.* (Natasha, Manager)
- **Reliable web access.** As articulated by the clinicians, web access impacts on the access to e-health: *we have nurses across the district that don't even bother to take their work devices out because they have tried and tried and tried to get web access and now they just see it as a waste of time, so they don't even worry about it anymore.* (Jenny, Senior Clinician)
- **Availability of devices:** there were differing experiences with access for technological devices to demonstrate the e-health program to the mums. Clinicians and one manager shared that they do not have appropriate devices with the relevant apps to demonstrate these programs to the mums. However, another manager stated that they frequently asked clinicians if they have, *resources and tools to get them structurally set up to get them able to work better. To me the main limitation is maybe their own personal limitations with technology and understanding.* (Natasha, Manager)

The diagrams below encapsulate the themes derived from the interviews with managers, senior clinicians and clinicians, that articulate the optimal work environment to achieve engagement with e-health strategies.

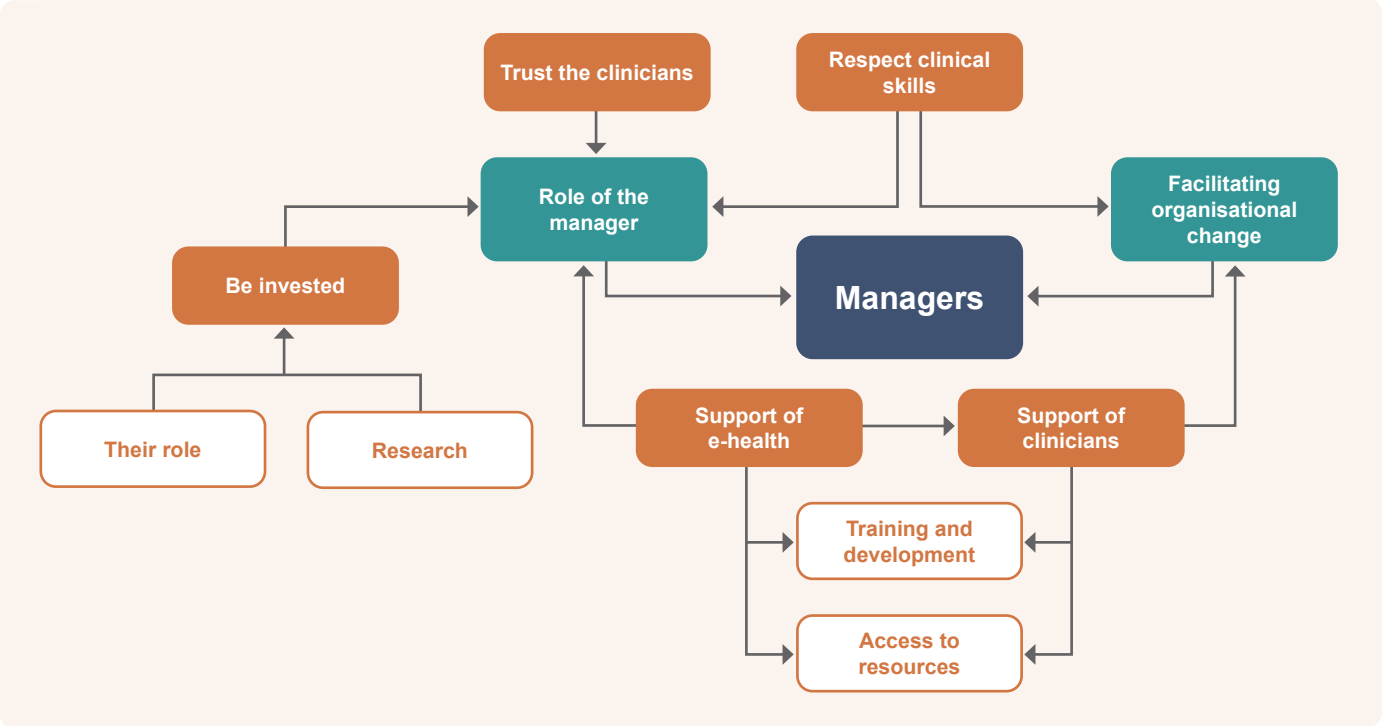


Figure 5: Themes emerging from interviews with managers and senior clinicians

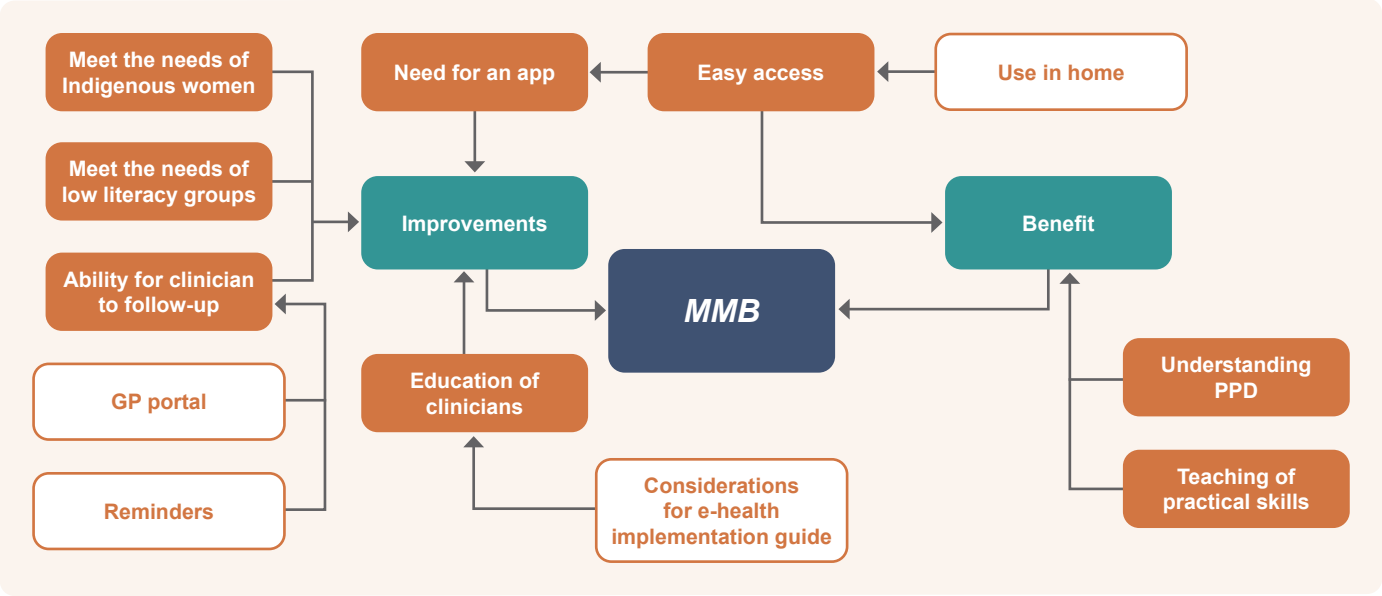


Figure 6: Themes emerging from interviews with clinicians

MumMoodBooster Program

Figure 6 captures the main themes and subthemes that inform the research question in relation to the barriers and facilitators related to the actual *MMB* program. The input from clinicians and from the mums contributed to understanding where the *MMB* program was useful to them and then what aspects could be reviewed to ensure optimal acceptance, usability and benefit to the mums experiencing PND.

The feedback in regards to the *MMB* was varied and depended on the profile of the individual participant. It was perceived that the *MMB* is suitable for women who are engaged through written text. A clinician stated, *literacy levels are an issue too sometimes within our clients, so, that can be a contributing factor* [in preventing engagement]. (Kimberly, Clinician)

The program does not sufficiently cater for women from an Indigenous or culturally diverse background and so it was left to the clinicians to be the voice for the mums who identified more with the marginalised groups.

Accessibility

The strongest message for PIRI is that, if the program is to be accessible to women when they need it, the program must be restructured as an app which can be accessed on an iPhone/Android device. Mums described how they need support at unusual times, for example, in the middle of the night when they are feeding or trying to settle an irritable baby. One mum described how she wanted to engage with the program but found the requirement to open a laptop while breastfeeding was too awkward. However, this mum indicated that she could breastfeed and use her iPhone but it was a different matter when she was breastfeeding and trying to access her computer.

> ***It's really hard to be breastfeeding in the middle of the night and log on to a program on a laptop but you can easily access your phone.* (Beth)**

A clinician shared with us that this had been the case for women she had supported. As an example, the clinician spoke of one mum:

> ***There's no way she could sit in front of a computer, she had a newborn, an 18-month-old and a three-year-old. She was quite depressed because of family origin stuff, but she just said, "There's no way I can sit at a computer every day".* (Layla, Clinician)**

Currently, the woman needs to register through a laptop or over the phone and then she can gain access through her phone but this information is not widely accessible and when registering is complex, the woman is deterred from further engaging with the program. As stated by a senior clinician, *thinking of some of our most vulnerable clients I can see the process being somewhat a bit cumbersome for them and to—to initial set-up.* (Jenny, Senior Clinician)

Literacy

There was commentary about the level of literacy and the amount of reading that was required to engage with the program. It was felt that there needed to be some flexibility so that the program could be adjusted according to varying literacy levels. *The literacy in the program … one woman actually thought it wasn't sort of appropriate.* (Elle, Indigenous Health Worker)

The issues did not just sit with the level of literacy but also incorporated the amount of reading required in each module.

> ***It's very time consuming to sit and read through everything and—yeah, it's just—I don't know, you just start reading and then you'd just be like, "Alright, I'll come—back to that because I have something else to do". So, there's a lot of information to work through and process, it's very wordy.*** **(Elle, Indigenous Health Worker)**

Women gained benefit from the videos where they could relate to the experiences being shared, yet there was concern that all of the women in the videos were well dressed and had hair and makeup attended to, which did not portray the reality of those living with depression. Themes emerged from the mums and the clinicians about the fact that all the faces in the program were white and seemed to fit a middle class profile.

Representing diversity and inclusivity

This theme emerged from the interviews with clinicians. It was pointed out that Indigenous women were not represented in the videos or photos within the program. Further, the demographics of women living in isolated areas are changing. With the Federal Government initiatives to move more of the population to rural areas, with the numbers of migrant labourers and increasing numbers of refugees in our rural areas, there needs to be consideration of the support provided to women who did not speak English or whose language and literacy are variable.

The provision of a portal within e-health programs for feedback

Clinicians shared their frustration in maintaining seamless pathways for the women after referral. It seemed that there was no feedback mechanism for the child and family health nurses so they could monitor and continue appropriate support for vulnerable women. It was suggested that this could be a function of the *MMB* program where alerts and feedback can be sent to the clinician when an alert is triggered with the program that the woman needed additional support.

Themes related to where the program proved to be engaging and beneficial

There is data in the literature review of this document to prove the effectiveness of the *MMB* program which is further substantiated by the quantitative data related to this research. The *MMB* is evidence based but such a program is ineffective if it does not engage the target audience and excite the participants to invest time and effort in moving to wellness.

The mums in this research project shared how useful the *MMB* was to them for a number of reasons. These included:

- Pace of the program – *it was online and that there was a lot of success around it, and I kind of liked the idea that I could do it at my own pace and it was something for me.* (Vanessa)
- Convenient location – *in the comfort and safety of your home and at your own pace then that's probably a preferred way for me.* (Vanessa)

- Reassurance – *this way of thinking isn't normal and this is what you can do to fix it or now focus on this for the next week.* (Zoe)
- Positivity engendered by the program – *I thought it was really good, and I love all the self-care modules in there so I think even as a preventative measure, it is good—I think there is a lot of preventative strategies —most mums can benefit from that self-care component.* (Rose)
- Easy to navigate – *you can go in just to where you want to go pretty easily and I guess it's pretty easy to follow. So, it doesn't matter if you come in and out of it, it's not like you have to go and read all through some heavy information to remember where you were up to or anything like that.* (Zoe)
- Practical, easy to achieve activities – *listing your pleasant activities and make sure you do a variety of things, but try and work those into your day, so do something for yourself, by yourself and then do something you enjoy with the baby.* (Zoe)
- Can be undertaken at the convenience of the individual mum – *there was no set times to go in and get it done, I think that was really good because when you've got a baby, you're never on time anyway. Yeah—I think it was good that it was at your own pace.* (Isabelle)
- Reminders and prompts – *I was impressed at how much there was in the program and how much it was structured and the little prompts and reminders to do things, like I wasn't expecting any of that. It was cool too.* (Ava)
- Relaxation exercises – *I loved the embedded guided meditation, progressive muscle relaxation, the fact that it was embedded in and I was also able to download it.* (Vanessa)
- Sharing the program with a partner – *I would talk to him about, sometimes I'd be sitting in bed in the evening doing the program on the iPad and so I'd talk to him about what I was looking at.* (Zoe)

Quantitative Data

Findings indicate women who registered and completed some or all of the *MMB* treatment program exhibited notable decreases in depression, anxiety and stress symptom severity, as measured by DASS-42 and PHQ-9 questionnaires at baseline and end-of-study. Specifically, women presented with mild to moderate symptoms of depression, anxiety and stress at baseline (according to the DASS-42) while notably presenting with PHQ-9 results within the *moderately severe depression* range. End-of-study measures showed marked improvements in symptom severities as measured by the DASS-42, with average scores in the normal range. Symptom severity also improved to *minimal-mild depression* per the PHQ-9, the lowest diagnosis level of the questionnaire.

As the name suggests, the Depression Anxiety and Stress Scale (DASS-42) is a self-report questionnaire that is designed to measure the negative emotional states of depression, anxiety and stress. In clinical assessment, the DASS-42 is used to clarify a patient's locus of emotional disturbance. The purpose of the DASS-42 is to assess the severity of the core symptoms of depression, anxiety and stress. The scales meet both the needs of researchers and clinicians with its high internal consistency and ability to yield meaningful discriminations in a variety of circumstances. The DASS-42 can be used to measure current state or change in state over time such as during CBT treatment (e.g. the *MMB*). Scoring is determined within depression, anxiety and stress domains, with recommended cut-offs ranging through *normal*, *mild*, *moderate*, *severe* and *extremely severe*.

DASS-42

The graphs below show the scores for the initial DASS-42 screening and follow-up scores at nine weeks. As indicated by the graphs, there was significant improvement in the depression, anxiety and stress scores for all participants and significant reduction in PHQ-9 scores.

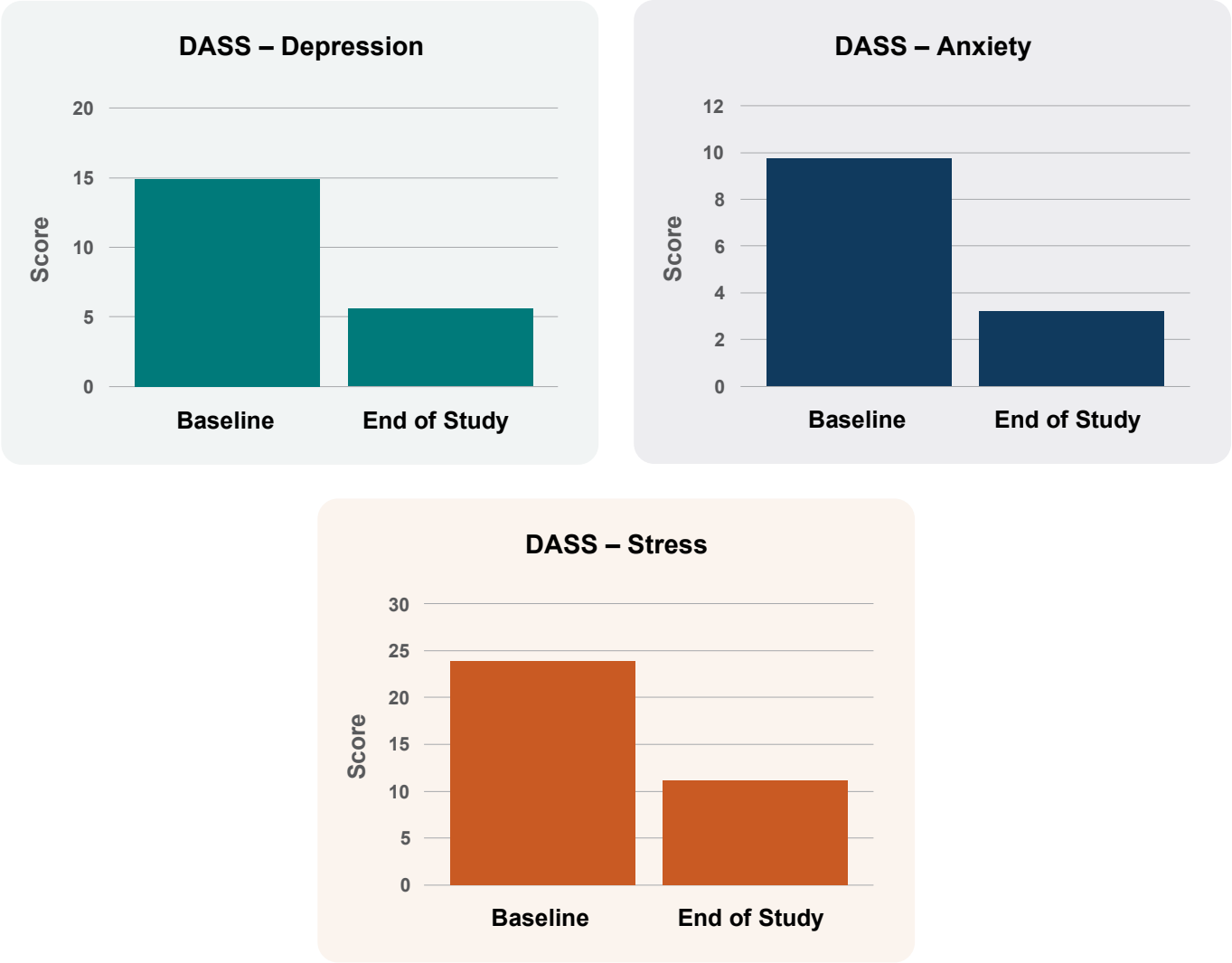


Figure 7: DASS-42 scores for three related negative emotional states of depression, anxiety and stress

PHQ-9

The PHQ-9 offers concise, self-administered items for assessing depression. They incorporate depression criteria with other leading major depressive symptoms into a brief self-report questionnaire that can be used for both screening and diagnosis (Lovibond & Lovibond, 1995). It is one of the most validated tools in mental health research and is a powerful tool in monitoring treatment response. Changes in scores for the participants are presented in the graphs below.

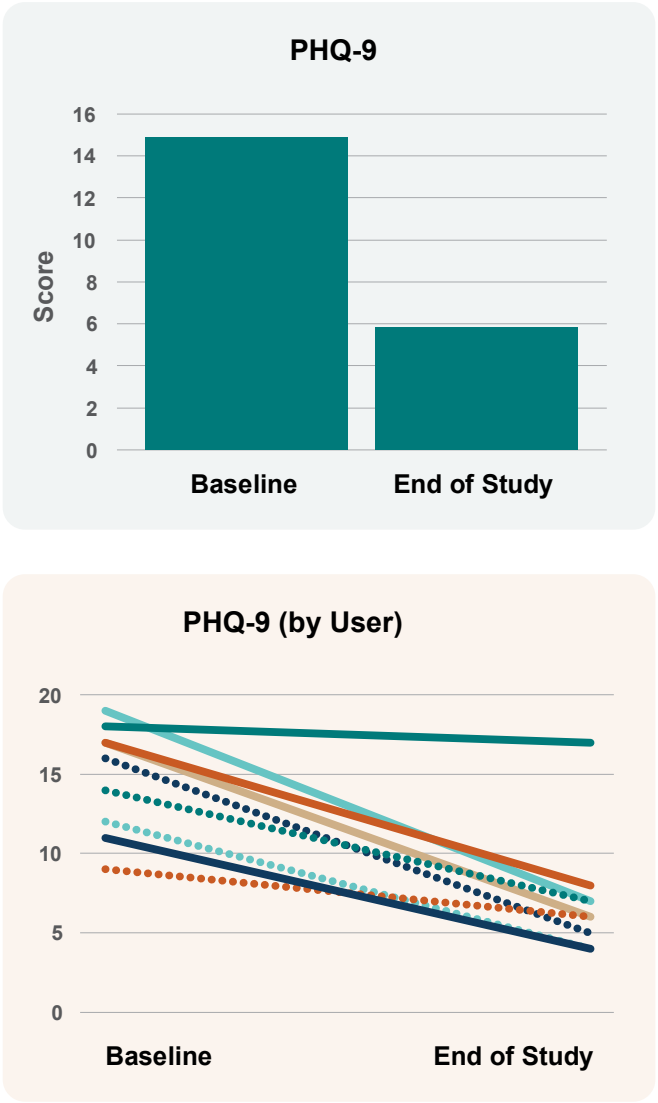


Figure 8: Average and user specific PHQ-9 scores (Baseline – End of Study [Week 9])

PIRI used website analytic tools to track usage throughout the program including session completion, visit frequency and duration. There were three new mothers who completed the full six weeks and seven (7) participants who did not complete all of the modules. Analytical data shows a positive correlation between hours spent on the program and the improvement in PHQ-9 scores as illustrated in the graph below.

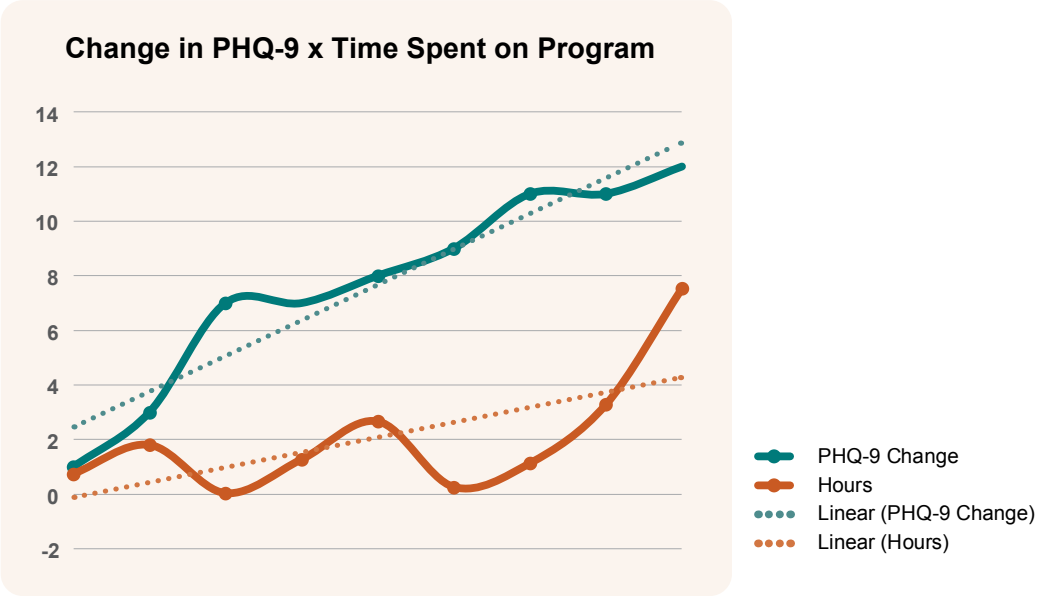


Figure 9: Correlation between changes in PHQ-9 score (Baseline – End of Study) and total time (hours) spent on the program

The table below synthesises data related to the individual participant's EPDS, the mother's age, time spent engaged with the *MMB* program, the number of modules completed and the change in PHQ-9.

Table 3: *MumMoodBooster* user statistics

MMB ID #	EPDS	Baby's Age in Month	Mum's Age	Total Time Spent in Program	Number of Distinct Sessions Visited (out of 6)	Change in PHQ-9
6794	24	9	17	27167	6	-12
7004	15	6	27	4043	2	-11
7141	18	2	25	0	0	No follow-up
7743	16	9	29	11811	6	-11
7880	17	0	26	0	0	No follow-up
8070	19	10	23	2644	6	-1
8092	12	7	17	9590	4	-8
8134	15	8	27	102	1	-7
8135	11	11	19	6477	6	-3
8157	14	9	25	4560	6	-7
8194	13	1	33	914	1	-9

Data analysis showed a negative correlation related to age. The younger the mother giving birth, the higher the score on the EPDS; the more mature mother scored lower on the EPDS. It is important to note the relatively small sample size when generalising these findings.

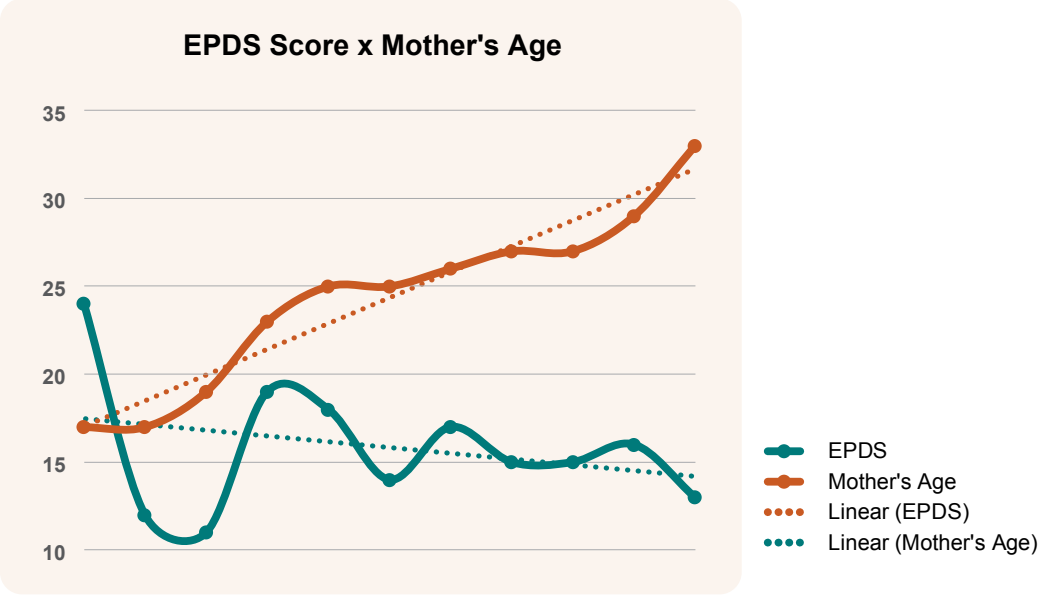


Figure 10: Correlation between EPDS screening score and mother's age

These findings are consistent with previous reports on the efficacy of the *MumMoodBooster* treatment program.

Discussion / Outcomes / Conclusion

This research project provides valuable information for clinicians and policy writers of the unique experiences of regional, rural and remote postnatal women. Specifically, it is about those parents of a newborn baby who are experiencing mild to moderate depression and coping with the isolation that their mental health vulnerabilities and geographical location can impose and exacerbate. This research enabled postnatal women to reveal their realities and struggles to address their mental health needs through an online CBT intervention and any barriers related to the infrastructure required to access the online mental health intervention.

Through interaction with this group of new mothers and their clinicians, we have identified the facilitators and barriers that exist in the implementation of an online evidence based, mental health intervention program to address PND. The research team has utilised the experiences of isolated women who have experienced PND and the child and family health nurses to inform PIRI, the owners of the *MMB* site, of suggested changes to enhance engagement with the *MMB* program. Further participants informed the strategies included in the *Guidelines for clinicians*, the purpose of which is to ensure, as far as possible, that barriers to participate in online health programs are managed or eliminated. The *Guidelines for clinicians* manual which provides support for clinicians has been developed for distribution to all child and family health nurses to enable barriers to be addressed, making online support programs more accessible and useful for isolated women. It is also aimed at supporting clinicians to engage women with e-health interventions thus making therapies accessible to women wherever they live.

The project identified what supports women's access to evidence based intervention for PNDA. It also identified the key barriers that need to be addressed within health services and systems. Bringing effective online treatment to mothers where and when they need it has massive potential to prevent and ameliorate the impact of depression on health and wellbeing at a population level. The increased accessibility of evidence based interventions for isolated/ rural perinatal women will in turn, reduce the impact to the mother, child, family and society, of untreated depression and anxiety. Considering that the financial cost of perinatal depression to the Australian economy in 2012 was estimated to be $433.52 million (NSW Ministry of Health, 2014), a cost effective, easily accessible intervention such as *MMB* is required.

PERINATAL DEPRESSION
COSTS THE AUSTRALIAN ECONOMY
>$433m
(2012)

Addressing the issues identified in this research will ensure systems and strategies are in place to support women experiencing PND to access e-health interventions. Recommendations should be consistently applied across LHDs and integrated into health policies, procedures and clinical practice guidelines and could be replicated and sustained. The outcome of the project has been a model that can be implemented, replicated and sustained within existing services not only for women living in geographically isolated areas but also for women who are isolated from service access for a variety of reasons, including those living in high-population metropolitan areas. Although focused on interventions for women with PND, it also highlighted issues pertinent to the use of e-health implementation in any circumstance.

In 2016, Rossiter et al. identified that child and family health nurses working with women in complex situations needed to engage with education to enhance their clinical skills. However, what we have identified is that, with

online therapies, clinicians supporting mums need more than clinical knowledge: they need education and ongoing support with their ICT skills and awareness. It is a fallacy to take for granted that the clinicians know how to navigate the technologies adopted by various health services (Ridgeway et al., 2011). As stated by one of the managers we interviewed, some child and family health nurses are unwilling to admit to having inadequate skills in engaging with technology and find it hard to keep up with the ever-changing computer programs embraced by health services.

Child and family health nurses also require access to technology and internet access to enable them to demonstrate online therapies to the women they are supporting. Participants (clinicians/child and family health nurses) shared with us their experiences of using their private equipment to show women the online programs or acknowledged they did not take devices to the woman's home as there was no or unreliable internet access.

Of particular concern are women who identify as Indigenous. Initially, a number of Indigenous women consented to participate in the research but only one woman completed the first questionnaire. Invaluable information was derived from the clinicians and Indigenous health workers who support these women but once again we have research without the strong voices of Indigenous mums. What was evident was the need for the Indigenous women to be supported by those they know and trust. Trust is a strong element in securing engagement with Indigenous mums and as researchers who they do not know, it is understandable that they did not engage with us. Even though clinicians who are familiar with the Indigenous mums approached them to be involved in the research, it was the fact that someone they did not know would be visiting them and asking them questions that made the women suspicious and reluctant to be involved. A more effective approach in recruiting Indigenous mums would have been to co-opt the Indigenous health workers to not just invite participation in the research but also undertake all of the follow-up activities, including the interviews.

It was reported that the Indigenous mums were very wary of the judgement of others in their community. Being visited by researchers for interviews may have given the impression that they were being deemed unfit mothers and had to be checked on. This is a demonstration of the importance of community, the impact community can have on health and wellbeing and the responsibility of community to embrace new mums rather than judge them.

Other challenges for the Indigenous mums were insecure housing, not having access to their own mobile phone or iPad and unreliable internet access. Our suggestions are that Indigenous health workers who the mums trust, provide reassurance about seeking help when needed, work with them through the online support program and provide space within the clinic to enable this collaboration to happen.

Clinicians in rural communities revealed that they are supporting women from diverse cultures some of whom are on working visas, others who are refugees and others who have more permanent visas. Despite the length of their stay in Australia, these women are isolated and disadvantaged because of language barriers, previous traumas and distance from family support (Ou et al., 2010), putting them at high risk for PND. These women need consideration in the development of online interventions that are sensitive to diverse cultures as well as the provision of child and family health nurses with the cultural sensitivity and skills to work with these mums as they access and engage with online interventions.

Recommendations

Within NSW this e-health intervention model is potentially relevant to an estimated 19,000 women per annum given that up to one in five women experience PNDA and the NSW annual birth rate is 95,000 babies. So, consideration of recommendations from this research is significant in supporting our mothers, their babies, their families and their communities.

Recommendations relating to each entity are covered separately.

NSW Health

- Each clinician interacting with mums is supplied with an iPhone/Android device or an iPad with sufficient internet connectivity to ensure the clinician can engage the woman with the online therapy in the clinic or in the home.
- Devices are serviced and replaced to provide clinicians with the tools they need to participate with contemporary modes of service delivery.
- iPads are made available for loan to the mums who do not have access to this technology.
- There is an agreement between NSW Health, Libraries NSW and PIRI to make the *MMB* accessible in NSW libraries for women who cannot access the program through any other venue.
- Education: online, face-to-face in groups and individually is provided to support clinicians to develop competence with online therapies and all forms of tele-health.
- ICT troubleshooting mechanisms are available to clinicians and can be accessed wherever the clinician is interacting with a client.
- Treatment options for PND are included in the *My Personal Health Record* book provided to all mums.

Management

- Mandate the introduction to online therapies for PND as part of the universal health home visits.
- The use of e-health programs for PND is discussed at each team meeting.
- Interaction with and promotion of e-health programs are discussed at the annual performance development for each relevant clinician.
- Individual clinicians are assessed for computer literacy and individual programs implemented for each clinician to build skills and provide ongoing support without penalty for their employment or promotion. This can include a mentorship program with ICT competent colleagues.
- Enable flexibility with time and frequency of visits to vulnerable mums.
- Develop referral and feedback pathways with relevant health professionals so the child and family health nurse is able to provide continuity of care.
- Ensure all child and family health staff are provided with functional technology and IT support mechanisms if there are issues.

Clinicians

- All clinicians working with mums complete the relevant e-health program to enable them to promote the relevant program and support the mum to continue through the program.
- Use the clinical guidelines manual developed from this research to support them to support the woman.
- Work collaboratively with managers to continuously grow ICT skills.
- Continue to advocate for women with PND through tailoring visits and follow-ups that fit with the care needs of the individual woman.
- Recognise referral as another step in the pathway of supporting women—not an end to the clinician's responsibility. Seek feedback about the referral and develop a collegial relationship with relevant health professionals, clearly articulating your expectation of feedback so continuity of care exists for each woman.
- Education related to PND for the women and their partner/support commences in antenatal classes.
- Emphasis placed on the wide variety of signs and symptoms related to PND.
- Include partners and families as support to prompt the woman to engage with e-health programs and other strategies to manage and resolve mental health issues.
- The stigma surrounding PND is addressed in the antenatal classes and in postnatal interactions with the women, their partners/family and friends.

PIRI

- The *MMB* program is translated into an app which can be accessed and interacted with through an iPhone/Android device.
- Promotional cards made available through all child and family health clinics and other relevant outlets.
- Magnets provided that can be placed in easily located spaces and be available as prompts to access the program.
- The program be made available in multiple languages.
- A review undertaken of the amount of written text.
- The text accommodates the variety of literacy levels of the users.
- Photos and other images within the program reflect the cultural diversity of users.
- A feedback mechanism for clinicians to enable clear communication related to the new mother's progress through the program and alert the clinicians when issues arise.
- Online support group is established to create perinatal peer-led support from other mums who have completed the *MMB* program. This would help champion mothers to complete the program with relevant referral pathways in place if extra clinical support is needed.
- Videos need to be more current and represent a diverse cultural society. They need to be cognisant of new mothers who relate to YouTube/Instagram etc.

Mums

- Women need reminders about assistance and where it can be accessed, in multiple forms that are easily visible and accessible such as magnets for the fridge.
- Need information, reminders and reassurance about the unexpected signs and symptoms of PND.
- Need to be individually assessed at each interaction with a clinician and a care plan developed in conjunction with the woman that meets her needs.
- A public education awareness strategy developed to de-stigmatise PND and inform families and friends and others who encounter the woman how to assist. An example is the Mental Health First Aid initiative.

Specific Recommendations to Enhance Support for Indigenous Mums

- Collaborative research, including Indigenous mums and relevant health professionals, exploring why Indigenous mums reject referral or do not follow-up when referral is made.
- Awareness campaign for Indigenous health workers about online programs focused on PND.
- Indigenous health workers have time and education to go through e-health programs so they can better support and encourage Indigenous mums to engage with the programs.
- Indigenous health worker the woman trusts spends time doing some of the program with the woman*, to guide them through.* (Elle, Indigenous Health Worker)
- Follow-up discussions about progress through the online program at each visit.
- Indigenous health workers given more time for each visit and more frequent visits with mums and bubs.
- Content of e-health programs created in collaboration with Indigenous health workers and communities so they are relevant to Indigenous women.
- Language and literacy need to be more relevant and accepted by Indigenous women.
- Further collaborative research, including Indigenous mums and relevant health professionals, exploring how there can be more support for Indigenous women from other members of their communities.
- Health workers provided with technology and web access that is available wherever they are meeting the mum—technology that is accessible, transportable and actually works.
- Engage with the Elders of communities to support them to de-stigmatise PND and welcome the support of the health workers for mothers.

Having a much clearer understanding of the barriers and facilitators regarding implementing the e-health intervention in routine referral pathways enables implementation and replication throughout other LHDs within NSW. The outcomes of the research provide a way to incorporate interventions into routine practice, referral and follow-up for isolated, vulnerable women. The *Guidelines for clinicians* document will support clinicians but the interventions require a monitoring process by senior clinicians and managers so barriers are identified and managed if they arise. This approach needs to be flexible in order to respond to any anomalies that may occur within a given population or service area and if required return to the replicability and adaptability stage of the implementation framework.

Where to From Here ...

The findings from this research have been included in a *Guidelines for clinicians* resource, Clinician reference card and key messages video for any clinician working with mums. The resource guides the clinician through the skills in using e-health technology and articulate the significance of engaging the mum with an e-health program and supporting her as she becomes familiar with the program.

The next stage of this project is ensuring the findings are embedded into practice. For the team, this involves revisiting all of the sites where interviews and focus groups were conducted to:

- introduce the *Guidelines for clinicians* document
- distribute the Clinician Reference Card and
- show the support video with key messages.

These strategies are to ensure that the findings of the research are translated into practice. They are designed to support the clinicians and assist them as they incorporate findings into routine interactions between the child and family health nurses and the isolated mothers.

However, the findings clearly show that there are system wide issues to be addressed before isolated mothers can be assured of appropriate and timely interventions to address PNDA. Interventions are required on multiple levels—government, local health district and management—to guarantee that clinicians providing the interventions have the knowledge, equipment, skills and time to be with the mother as she accesses any e-health program.

References

BeyondBlue. (2010). *Perinatal depression and anxiety: Evidence relating to infant cognitive & emotional development*. https://das.bluestaronline.com.au/api/BEYONDBLUE/document?token=BL/0470

Buist, A. (2020, May 9–10). Maternal flame. *Weekend Australian Review*, p. 9.

Creswell, J. W. (2014). *Research design: Qualitative, quantitative, and mixed methods approaches* (4th ed.). SAGE.

Creswell, J. W., & Plano Clark, V. L. (2017). *Designing and conducting mixed methods research* (3rd ed.). SAGE.

Cuijpers, P., Berking, M., Andersson, G., Quigley, L., Kleiboer, A., & Dobson, K. S. (2013). A meta-analysis of cognitive-behavioural therapy for adult depression, alone and in comparison, with other treatments. *Canadian Journal of Psychiatry, 58*(7), 376–385. doi: 10.1177/070674371305800702

Cuijpers, P., Muñoz, R. F., Clarke, G. N., & Lewinsohn, P. M. (2009). Psychoeducational treatment and prevention of depression: The "Coping with Depression" course thirty years later. *Clinical Psychology Review, 29*(5), 449–458. doi: 10.1016/j.cpr.2009.04.005

Danaher, B. G., Milgrom, J., Seeley, J. R., Stuart, S., Schembri, C., Tyler, M. S., Ericksen, J., Lester, W., Gemmill, A., Kosty, D., & Lewinsohn, P. (2013). MomMoodBooster web-based intervention for postpartum depression: Feasibility trial results. *Journal of Medical Internet Research, 15*(11), e242. doi: 10.2196/jmir.2876

Danaher, B. G., Milgrom, J., Seeley, J. R., Stuart, S., Schembri, C., Tyler, M. S., Ericksen, J., Lester, W., Gemmill, A., & Lewinsohn, P. (2012). Web-based intervention for postpartum depression: Formative research and design of the MomMoodBooster program. *Journal of Medical Internet Research, 1*(2), e18. doi: 10.2196/resprot.2329

Gidget Foundation, Perinatal Depression, & Anxiety Australia (PANDA), Peach Tree Perinatal Wellness, and Perinatal Wellbeing Centre. (2019).*The cost of perinatal depression and anxiety in Australia*. Report prepared by PricewaterhouseCooper (PwC) Consulting: Australia.

Gregory, K. (Host). (2020, May 12). Abbey is one of half a dozen women who have given birth in Australia under suspicion of having coronavirus [Radio segment]. On *Background Briefing*. Australian Broadcasting Corporation. https://www.abc.net.au/radionational

Henderson, J., Noell, J., Reeves, T., Robinson, T., & Strecher, V. (1999). Developers and evaluation of interactive health communication applications. The Science Panel on Interactive Communications and Health. *American Journal of Preventive Medicine, 16*(1), 30–34. doi: 10.1016/s0749-3797(98)00106-8

King, D. K., Glasgow, R. E., & Leeman-Castillo, B. (2010). Reaiming RE-AIM: Using the model to plan, implement, and evaluate the effects of environmental change approaches to enhancing population health. *American Journal of Public Health, 100*(11), 2076–2084. doi: 10.2105/AJPH.2009.190959

Lovibond, S. H., & Lovibond, P. F. (1995). *Manual for the depression anxiety stress scales* (2nd ed.). Psychology Foundation of Australia.

McMahon, C. A., Barnett, B., Kowalenko, N., & Tennant, C. (2006). Maternal attachment state of mind moderates the impact of postnatal depression on infant attachment. *Journal of Child Psychology & Psychiatry and Allied Disciplines, 47*(7), 660–669. doi: 10.1111/j.1469-7610.2005.01547.x

Milgrom, J., Danaher, B. G., Gemmill, A. W., Holt, C., Holt, C. J., Seeley, J. R., Tyler, M. S., Ross, J., & Ericksen, J. (2016). Internet cognitive behavioral therapy for women with postnatal depression: A randomized controlled trial of MumMoodBooster. *Journal of Medical Internet Research, 18*(3), e54. doi: 10.2196/jmir.4993

Milgrom, J., Negri, L. M., Gemmill, A. W., McNeil, M., & Martin, P. R. (2005). A randomized controlled trial of psychological interventions for postnatal depression. *British Journal of Clinical Psychology, 44*(Pt 4), 529–542. doi: 10.1348/014466505X34200

Murrumbidgee Local Health District. (2014). Mental Health and Drug and Alcohol Services. *Clinical Service Plan 2014–2019 MLHD*. http://www.mlhd.health.nsw.gov.au/our-services/drug-and-alcohol-services

NSW Mental Health Commission. (2014). *Living Well: A Strategic Plan for Mental Health in NSW 2014–2024*. NSW Mental Health Commission.

NSW Ministry of Health. (2014). *NSW Rural Health Plan: Towards 2021*. http://www.health.nsw.gov.au/rural/Pages/rural-health-plan.aspx

Nilsen, P. (2015). Making sense of implementation theories, models and frameworks. *Implementation Science, 10*, 53. doi: 10.1186/s13012-015-0242-0

Oberklaid, F., Baird, G., Blair, M., Melhuish, E., & Hall, D. (2013). Children's health and development: Approaches to early identification and intervention. *Archives of Disease in Childhood, 98*(12), 1008–1011. doi: 10.1136/archdischild-2013-304091

Ou, L., Chen, J., & Hillman, K. (2010). Health services utilisation disparities between English speaking and non-English speaking background Australian infants. *BMC Public Health, 10*(1), 182. doi: 10.1186/1471-2458-10-182

Parent-Infant Research Institute (PIRI). (2020). MumMoodBooster. https://www.piri.org.au

Perinatal Anxiety and Depression Australia (PANDA). (2017). Partners and carers. https://www.panda.org.au/info-support/for-carers-partners

Perinatal Anxiety and Depression Australia (PANDA). (2019). Living with perinatal anxiety and depression in rural and remote Australia. https://www.panda.org.au/living-with-perinatal-anxiety-and-depression-in-rural-and-remote-australia

Perinatal Anxiety and Depression Australia (PANDA). (2020). PANDA response to coronavirus. https://www.panda.org.au/info-support/panda-response-to-coronavirus

Ridgway, L., Mitchell, C., & Sheean, F. (2011). Information and communication technology (ICT) use in child and family nursing: What do we know and where to now? *Contemporary Nurse, 40*(1), 118–129. doi: 10.5172/conu.2011.40.1.118

Ross, J., Stevenson, F., Lau, R., & Murray, E. (2016). Factors that influence the implementation of e-health: A systematic review of systematic reviews (an update). *Implementation Science, 11*(1), 146. doi: 10.1186/s13012-016-0510-7

Rossiter, C., Schmied, V., Kemp, L., Fowler, C., Kruske, S., & Homer, C. S. (2016). Responding to families with complex needs: A national survey of child and family health nurses. *Journal of Advanced Nursing, 73*(2), 386–398. doi: 10.1111/jan.13146

Rubio, D. M., Schoenbaum, E. E., Lee, L. S., Schteingart, D. E., Marantz, P. R., Anderson, K. E., Platt, L. D., Baez, A., & Esposito, K. (2010). Defining translational research: Implications for training. *Academic Medicine: Journal of the Association of American Medical Colleges, 85*(3), 470–475. https://doi.org/10.1097/ACM.0b013e3181ccd618

There is no such thing as a baby. There is a baby and someone.

Donald Winnicott

Appendices

Appendix A: GWAHS Ethics Approval

12 October 2018
Mrs Keryl de Haan
Coolamon Community Health Centre
Dr Buchanan Place
PO Box 94
COOLAMON
NSW 2701

Greater Western Human Research Ethics Committee (HREC)

The Greater Western HREC has been accredited by the NSW Ministry of Health as a lead committee to provide the single ethical and scientific review of proposals, to conduct research within the NSW public health system. Further, this committee is constituted and operates in accordance with the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research and the CPMP/ICH Note for Guidance on Good Clinical Practice.

Greater Western Human Research Ethics Committee (HREC) HREC/18/GWAHS/68
(GWAHS 2018-052)

What are the key facilitators and barriers impacting optimal implementation of an evidenced based online intervention for isolated women who are experiencing post natal depression and are living in regional, rural and remote areas of New South Wales?

Dear Keryl,

Thank you for responding to the HREC request for further information and clarification for the above project, initially reviewed on 3 October 2018. Your response to the HREC request for further information has been reviewed by the HREC Executive Officer and I am pleased to advise that ethical approval has been granted for this research project.

This HREC approval letter constitutes ethical approval only. You are required to submit a site specific assessment application for each site at which you wish to conduct this project. You must not commence this research project at a site until separate authorisation from the Chief Executive or delegate of that site has been obtained.

The following documentation has been reviewed and approved by the HREC:

- HREA application AU/1/D358311 dated 20/8/2018
- Project Description for Ethics Application
- Participant Information Sheet version 3 dated 21/8/2018
- Participant Consent Form
- Clinician Information Sheet version 2 dated 18/8/2018
- Clinician Consent Form version 2 dated 18/8/2018
- Poster – Clinician Information Session version 2 dated 20/8/2018

Greater Western Human Research Ethics Committee
Incorporating the Western NSW & Far West Local Health Districts
PO Box 143, 39 Hampden Park Road, BATHURST NSW 2795
Tel: (02) 6330 5889

The project is approved to be conducted at the following public health organisation site(s):

- Murrumbidgee Local Health District

Please note the following conditions of approval:

1. The coordinating investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including any unforeseen events that might affect continued ethical acceptability of the project.
2. Proposed changes to the research protocol, conduct of the research, or length of HREC approval will be provided to the HREC for review in the specified format.
3. The HREC will be notified, giving reasons, if the project is discontinued at a site before the expected date of completion.
4. The coordinating investigator will provide an annual report to the HREC and at completion of the study in the specified format.

HREC approval is valid for 5 years from the date of this letter.

Should you have any queries about your project please do not hesitate to contact the Greater Western HREC Executive Officer on (02) 6330 5948 or via email WNSWLHDEthicsCommittee@health.nsw.gov.au

Please quote HREC Reference No. HREC/18/GWAHS/68 (GWAHS 2018-052) in all correspondence.

The HREC wishes you every success in your research.

Yours sincerely,

Phil Sanders

Phil Sanders
Executive Officer
GW HREC

Appendix B: Ethics Application and Response to Ethics Committee

Human Research Ethics Application

Application Management Information
Application ID: 176071
Created date: 18/07/2018
Originating Application ID: AU/1/83F7312
**This is the earliest application from which this application was copied.*
Parent Application ID:
**This is the immediate predecessor from which this application was copied.*
Version Number: HREA V1.3.1 (2018)
Application submitted to: Greater Western Area Health Service, Greater Western Human Research Ethics Committee

The applicant has requested that this ethics application be considered under the Greater than low risk review pathway.

Section 1 – Core Information

Pre-application conditions

Before completing this application, acknowledge that:

1) The HREA has been designed for ethics review of human research, as defined in the National Statement.
2) Adequate resources must be available to conduct this research project.
3) All relevant institutional polices pertaining to the conduct of this research project should be considered and adhered to.
4) Research activities must not commence until ethics approval (and site authorisation, if appropriate) has been provided.
5) The HREA requires the attachment of a Project Description/Protocol.

⊕ Acknowledge and Continue

PROJECT OVERVIEW

Q1.1. What is the project title (as presented in the Project Description/Protocol)?

What are the key facilitators and barriers impacting optimal implementation of an evidenced based online intervention for isolated women who are experiencing post natal depression and are living in regional, rural and remote areas of New South Wales?

Q1.2. Provide a summary of the research project in non-technical language.

The MumMoodBooster (MMB) program, an internet cognitive-behavioural therapy (CBT) program which has been established as clinically effective, will be used to bring treatment to isolated new mothers experiencing mild to moderate depression and anxiety.
The impact of depression can be compounded by isolation, stigma and women not recognising they are depressed or not wanting to seek professional help. The use of an online treatment has been demonstrated to reduce barriers to treatment uptake resulting in enhanced patient care, service delivery and outcomes for women experiencing depression and their infants.
However, despite the widespread agreement of the benefits and importance of e-health strategies, difficulties with implementation has slowed their implementation.
Various factors can influence implementation - system complexity, internet reliability, costs, planning, policy concerns, clinician and women's attitudes towards the technology. This study will aim to identify the key barriers and facilitators to accessing the online MMB for isolated and hard to reach women in areas of regional, rural and remote NSW.

Q1.3. Which category/ies of research best describes the project?

The FOR codes for this project are:
111006, Midwifery, as the research is focused on isolated post natal women who are experiencing postnatal depression.
111005 Mental Health Nursing

Q1.4. In what environment/s will the research be conducted?

- [x] Clinic(s)
- [ ] Community centre(s)
- [ ] Cultural/religious organisation(s)
- [ ] Hospital(s)
- [x] Online
- [x] Private residence(s)
- [ ] Professional organisation(s)
- [ ] Public place(s)
- [x] Research institute(s)
- [ ] School system(s)
- [ ] University(ies)
- [ ] Workplace(s)
- [ ] Other

Q1.5. What organisation/entity has overall responsibility for this project?

Murrumbidgee Local Health District

Q1.6. Describe how this research project is currently, or will be, funded.

The project will be funded through a Translational Research Grant funded by the New South Wales Department of Health. The amount of funding is $322,260 over two years, resulting in completion at the end of June, 2020. This funding has been confirmed and relevant documentation attached to this form.

Q1.7. When do you anticipate starting the research project?

- [x] As soon as ethics and any other relevant approvals have been provided.

Q1.8. What is the anticipated duration of the research project?

2 Years

PROJECT TEAM

Q1.9. Investigator/ Research team

Provide information on the investigator(s)/ researcher(s) conducting the research.

Investigator/ Researcher 1

Q1.9.1 Title

Mrs

Q1.9.2 First Name

Keryl

Q1.9.3 Surname/family name

de Haan

Q1.9.4 Email Address

Keryl.DeHaan@health.nsw.gov.au

Q1.9.5 Is this person the contact person for this application?
◉ Yes ○ No

Q1.9.5.1 Contact Email Address

Keryl.DeHaan@health.nsw.gov.au

Q1.9.5.2 Contact Phone number

0477708100

Q1.9.5.3 Contact Mailing address

Coolamon Community Health Centre
Dr Buchannan Place
PO Box 94
Coolamon, 2701

Q1.9.6 Is this person a student on this project?
○ Yes ◉ No

Q1.9.7 Institutional affiliation and position.

Clinical Leader
Perinatal Mental Health/Substance Use/SAFE START.
Murrumbidgee Local Health District.

Q1.9.8 Staff ID Optional

40032358

Q1.9.9 ORCID Identifier Optional

Q1.9.10 What is the position of this person on the research project?

Chief Investigator/Researcher

Q1.9.11 Does this person have authorisation to sign the application on behalf of all members of the research team?
◉ Yes ○ No

Q1.9.12 Describe the research activities this person will be responsible for.

The Chief Investigator will be involved in coordinating the various project activities, ensuring that tasks and time frames are adhered to and leading the steering committee. The Chief Investigator initiated the grant application and has longstanding working relationships with the project partners and perinatal women. The CI will be involved in the education of the clinicians who will participate in the program and has good rapport and working relationships with the relevant services that will be involved in the project.

Q1.9.13 Describe the person's expertise relevant to the research activity.

The CI is passionate about ensuring vulnerable perinatal women have access to timely and effective treatment and that their isolation does not adversely impact their treatment outcomes. I understand the barriers to accessing services that women living in regional, rural and remote areas in NSW experience. I am a Registered Nurse with:
qualifications in perinatal infant mental health and extensive experience in child and adolescent mental health, drug and alcohol and perinatal infant mental health.

Ms de Haan is a Registered Nurse with qualifications in perinatal infant mental health and extensive experience in child and adolescent mental health, drug and alcohol and perinatal infant mental health. I have worked in the Murrumbidgee Local Health District for over 5 years and have an excellent working knowledge of service availability and referral pathways for vulnerable women in the perinatal period. I have led the development of local perinatal service policy and procedures and various perinatal service delivery projects. I am involved in ongoing collaboration with local health services and non-government organisations regarding perinatal mental health service provision and service responses to vulnerable women in the perinatal period.I have led the development of local perinatal service policy and procedures and various perinatal service delivery projects. I am involved in ongoing collaboration with local health services and non-government organisations regarding perinatal mental health service provision and service responses to vulnerable perinatal women. I have good rapport and working relationships with the relevant services that will be involved in the project.

Investigator/ Researcher 2

Q1.9.1 Title

Associate Professor

Q1.9.2 First Name

Maree

Q1.9.3 Surname/family name

Bernoth

Q1.9.4 Email Address

mabernoth@csu.edu.au

Q1.9.5 Is this person the contact person for this application?
◯ Yes ◉ No

Q1.9.6 Is this person a student on this project?
◯ Yes ◉ No

Q1.9.7 Institutional affiliation and position.

Associate Professor Bernoth is an academic in the School of Nursing, Midwifery and Indigenous Health at Charles Sturt University Wagga Wagga Campus.

Q1.9.8 Staff ID Optional

69000237

Q1.9.9 ORCID Identifier Optional

0000-0002-1788-2674

Q1.9.10 What is the position of this person on the research project?

Co-ordinating Principal Investigator/Researcher

Q1.9.11 Does this person have authorisation to sign the application on behalf of all members of the research team?

◉ Yes ○ No

Q1.9.12 Describe the research activities this person will be responsible for.

Associate Professor Bernoth assisted in writing the grant application and will be responsible for ethics submission and the overall methodological approach of the research. She will provide mentorship to the CI and other members of the team and will ensure congruence, rigour and validity of the project. She will develop the ethics application in conjunction with other team members and will oversee data gathering and analysis, report writing, be a member of steering committee and ensure research governance. Her role will also include contributing to writing the final report, journal articles and conference presentations.

Q1.9.13 Describe the person's expertise relevant to the research activity.

Associate Professor Bernoth has undertaken extensive research and practice development projects. She has led a number of research teams exploring rural ageing, mentoring nurses, authentic partnerships and elder abuse. She has been Chief Investigator in a number of research projects, the most recent projects are exploring the inclusion of older people in teaching ageing and in developing gaming as an approach to engage students learning about ageing. Her external, competitive grants total over $1m. She is an author of numerous peer reviewed publications including a book, chapters texts related to ageing and research and has presented national and international conference papers in China, Sweden and New Zealand. Maree reviews for national and international nursing and education journals and has an extensive media profile. Associate Professor Maree Bernoth is a member of the Australian Association of Gerontology and on the New South Wales AAG committee. She is a member of the Murrumbidgee Primary Health Network Aged Care Consortium and a member of the Institute for Land Water and Society at Charles Sturt University.

Investigator/ Researcher 3

Q1.9.1 Title

Dr

Q1.9.2 First Name

Joanna

Q1.9.3 Surname/family name

Carlisle

Q1.9.4 Email Address

jcarlisle@csu.edu.au

Q1.9.5 Is this person the contact person for this application?

○ Yes ◉ No

Q1.9.6 Is this person a student on this project?

○ Yes ◉ No

Q1.9.7 Institutional affiliation and position.

Joanna Carlisle is a Sessional Academic in the School of Management and Marketing at Charles Sturt University, Wagga Wagga Campus.

Q1.9.8 Staff ID Optional

11354604

Q1.9.9 ORCID Identifier Optional

0000-0002-6849-1083

Q1.9.10 What is the position of this person on the research project?

Investigator/Researcher

Q1.9.11 Does this person have authorisation to sign the application on behalf of all members of the research team?

◉ Yes ○ No

Q1.9.12 Describe the research activities this person will be responsible for.

Joanna Carlisle will act as the On-site project Officer that will be responsible for, assisting in the submission of ethics applications, overseeing the research project, coordinating project promotion, recruiting clinicians. Joanna will also coordinate the distribution and collection of surveys, organising interviews and focus groups. Joanna will be responsible for liaising with the Online Program manager to coordinate access to the online program for the women who consent to participating.
Joanna will also be responsible for the database entry and data reports, and be responsible for preparing the final report in conjunction with the steering committee as well as contributing to writing journal articles and conference presentations.

Q1.9.13 Describe the person's expertise relevant to the research activity.

Joanna conducted her PhD research in the area of training and development in the healthcare management industry. This gave her significant insights into conducting research in the healthcare sector including a sound understanding of ethical practise, healthcare systems and patient sensitivity. Joanna also has experience in project management, both practical workplace experience and as a Lecturer in Business project management.

Investigator/ Researcher 4

Q1.9.1 Title

Ms

Q1.9.2 First Name

Alicia

Q1.9.3 Surname/family name

Carey

Q1.9.4 Email Address

alicarey@csu.edu.au

Q1.9.5 Is this person the contact person for this application?

○ Yes ◉ No

Q1.9.6 Is this person a student on this project?

○ Yes ◉ No

Q1.9.7 Institutional affiliation and position.

Alicia Carey is a registered Nurse and Midwife. Alicia also holds a position as a Lecturer in the School of Nursing, Midwifery and Indigenous Health At Charles Sturt University, Wagga Wagga campus.

Q1.9.8 Staff ID Optional

99977377

Q1.9.9 ORCID Identifier Optional

Q1.9.10 What is the position of this person on the research project?

Investigator/Researcher

Q1.9.11 Does this person have authorisation to sign the application on behalf of all members of the research team?
◯ Yes ◉ No

Q1.9.12 Describe the research activities this person will be responsible for.

Alicia is a novice researcher, who will be part of the team to observe, assist data collection, data analysis and writing the final report. Alicia will be mentored by Associate Professor Maree Bernoth. Alicia brings expertise in maternal mental health, tele health and isolated women.

Q1.9.13 Describe the person's expertise relevant to the research activity.

Alicia has significant clinical experience in rural and remote Nursing and Midwifery including Mental Health. She has current and previous clinical experience in Midwifery in MLHD and WLHD and has mental health postgraduate qualifications and Masters of Midwifery.

Investigator/ Researcher 5

Q1.9.1 Title

Ms

Q1.9.2 First Name

Chirstina

Q1.9.3 Surname/family name

Hunt

Q1.9.4 Email Address

christina.hunt@health.nsw.gov.au

Q1.9.5 Is this person the contact person for this application?
◯ Yes ◉ No

Q1.9.6 Is this person a student on this project?
◯ Yes ◉ No

Q1.9.7 Institutional affiliation and position.

Cristina is the District Clinical Coordinator Perinatal & Infant Mental Health and SAFE START Consultation Liaison at Western NSW Local Health District.
Christina is also a member of the International Marcé Society and the NSW Nurses Association.

Q1.9.8 Staff ID Optional

28002671

Q1.9.9 ORCID Identifier Optional

Q1.9.10 What is the position of this person on the research project?

Investigator/Researcher

Q1.9.11 Does this person have authorisation to sign the application on behalf of all members of the research team?
◯ Yes ◉ No

Q1.9.12 Describe the research activities this person will be responsible for.

Christina will provide specialist PIMH consultation to the steering committee. Further Christina will support the implementation of project tasks and recruitment in the WNSWLHD. Christina will also assist in the development of ethics applications, education of the clinical participants and will contribute the writing of the

development of ethics applications, education of the clinical participants and will contribute the writing of the final report, journal articles and conference presentations.

Q1.9.13 Describe the person's expertise relevant to the research activity.

Christina has experience as a Midwife and Child & Family Health Nurse prior to working in a district perinatal and infant mental health role. She completed her midwifery course in 1993 and has worked continuously with mothers, infants and families since that time. Christina has been in the district clinical coordinator role for 10 years - during that time she have always maintained a clinical role working in the perinatal & infant mental health space. Christina's passion has always been working as part of a multidisciplinary group around supporting families with complex presentations in the perinatal period. Whilst she still carries a small clinical role, her main function these days is helping other clinicians in their work with this client group. Christina has also maintained a longstanding interest in research and has attended a number of workshops in the area of research.

Investigator/ Researcher 6

Q1.9.1 Title

Professor

Q1.9.2 First Name

Jeannette

Q1.9.3 Surname/family name

Milgrom

Q1.9.4 Email Address

jeannette.milgrom@austin.org.au

Q1.9.5 Is this person the contact person for this application?

◯ Yes ◉ No

Q1.9.6 Is this person a student on this project?

◯ Yes ◉ No

Q1.9.7 Institutional affiliation and position.

Jeannette is the Executive Director, Parent Infant Research Institute (PIRI), Melbourne Director, Department of Clinical & Health Psychology, Austin Health
Professorial Fellow, Melbourne School of Psychological Sciences, University of Melbourne.

Q1.9.8 Staff ID Optional

Q1.9.9 ORCID Identifier Optional

0000-0002-4082-4595

Q1.9.10 What is the position of this person on the research project?

Investigator/Researcher

Q1.9.11 Does this person have authorisation to sign the application on behalf of all members of the research team?

◯ Yes ◉ No

Q1.9.12 Describe the research activities this person will be responsible for.

Prof Milgrom (PhD, Professor of Psychology, University of Melbourne)was closely involved in the development of the funding application for this project and will contribute to joint planning and oversight of the research project,including its conduct,analysis,and write up. Together with Dr Gemmill,she will recruit and supervise the work of the Victorian-based online program officer.

Q1.9.13 Describe the person's expertise relevant to the research activity.

Professor Milgrom has an international reputation in perinatal mental health and infant development and has innovated numerous parentinfant interventions and successfully implemented large RCTs in the perinatal period. She has substantial experience in design and implementation of RCTs in the perinatal period and in leading multidisciplinary research teams. She is also Director of Clinical & Health Psychology, Austin Health, and brings extensive clinical psychology experience both with adults and with children. She has a central interest in promoting translation of findings in collaboration with health policy agencies, both nationally and internationally. This specialized interest led her to establish the Parent-Infant Research Institute (PIRI) which over 17 years has developed a suite of evidence-based programs and public health initiatives. PIRI brings together a research team with expert skills in perinatal mental health, evaluating parent-infant interventions and completing RCTs in a timely and rigorous manner. Her track record includes receiving over 70 research grants, including 4 recent NHMRC grants, 2 currently as CIA. She is also a Fellow, Institute for Breathing and Sleep (IBAS). Her outstanding record of translating research to practice means that the trial outcomes are likely to be rapidly disseminated and highly influential. She is well placed to coordinate the Victorian component of the project. She has substantial experience in design and implementation of research in the perinatal period and working in multidisciplinary research teams. She brings extensive clinical psychology and e-mental health experience, having developed and evaluated the MumMoodBooster program with her team at PIRI. Professor Milgrom's links with beyondblue, her advisory role to the government's National Perinatal Depression Initiative (2011 2015), and her immediate past Presidency of the International Marcé Society for Perinatal Mental Health (the key professional society in perinatal mental health) make her central in promoting translation of findings to policy.

Investigator/ Researcher 7

Q1.9.1 Title

Dr

Q1.9.2 First Name

Alan

Q1.9.3 Surname/family name

Germmill

Q1.9.4 Email Address

alan.gemmill@austin.org.au

Q1.9.5 Is this person the contact person for this application?
◯ Yes ◉ No

Q1.9.6 Is this person a student on this project?
◯ Yes ◉ No

Q1.9.7 Institutional affiliation and position.

Alan hold the position of Deputy Director, Parent-Infant Research Institute, Melbourne.

Q1.9.8 Staff ID Optional

Q1.9.9 ORCID Identifier Optional

0000-0002-7753-4110

Q1.9.10 What is the position of this person on the research project?

Investigator/Researcher

Q1.9.11 Does this person have authorisation to sign the application on behalf of all members of the research team?
◯ Yes ◉ No

Q1.9.12 Describe the research activities this person will be responsible for.

Dr Gemmill was involved in the early conception of the MumMoodBooster program of research and is a Senior Research Fellow at the Parent-Infant Research Institute (PIRI). He has contributed to the design of the current project and will contribute to regular research meetings to ensure the scientific integrity of the study and will have a role in interpretation and publication of results along with the other investigators.

Q1.9.13 Describe the person's expertise relevant to the research activity.

Dr Gemmill has worked in perinatal mental health research for 18 years with a specific interest in clinical research studies and preventive intervention programs for maternal mental health problems. He has a specific expertise in the conduct of large cohort studies and RCTs in perinatal mental health. He has been involved in the MumMoodBooster stream of research since the earliest developmental work, through feasibility studies and randomized controlled trials of the program, and up to the current translational project. His research in the last five years has focused on the identification and treatment of perinatal mood disorders and on perinatal e-mental health resources. He was an author, and the lead analyst, on what is probably the largest and most demographically comprehensive study of perinatal risk factors for depression conducted anywhere in the world, determined on a sample of 40,333 women. He has also published work on the neurodevelopmental benefits of early stress reduction for premature infants, and on treatment and prevention of perinatal mood disorders and parenting difficulty. He has contributed to several, successfully completed research projects in the last five years. He has also co-edited an international book on the identification and treatment of perinatal mood disorders.

DISCLOSURE OF INTERESTS

Q1.10. Do any members of the research team (including persons not listed in this application), have any financial or non-financial interests related to this research?

○ Yes ◉ No

RESTRICTIONS

Q1.11. Are there any restrictions or limits on publication of data or dissemination of research outcomes of this project?

○ Yes ◉ No

EVALUATIONS

Q1.12. Has the scientific or academic merit of the research project been evaluated?

◉ Yes ○ No

Q1.12.1. What was the review process and what was the outcome?

The research has been reviewed and approved by Jill Reyment, Robyn Manzie and Jill Ludford from MLHD in February, 2018.
The research was reviewed by the Institute for Land Water and Society at Charles Sturt University in February, 2018.
The grant application was then submitted to the Translational Research Grants Scheme and reviewed and approved by the TRGS Review Panel between March and June, 2018.

The conditions are that the processes outlined in the successful grant application are followed and than the project is completed within two years. The research team and a research assistant will have a project plan to ensure completion within the time frame.

No changes have been made to the project since the review.

Q1.12.2. Attach evidence of the outcome of the scientific or academic review process. Optional

Q1.13. Has this research project had prior ethics review?

◯ Yes ◉ No

Q1.14. Will any further or additional specialised review of this application be sought?

◯ Yes ◉ No

LOCATION

Q1.15. Will this research project be conducted at multiple sites?

◉ Yes ◯ No

Q1.16. Will separate institutional approvals or authorisations be required prior to commencing research at each site?

◉ Yes ◯ No

Section 2 - Research Details and Participants

METHODS

Q1.17. From the list below, select all the research methods that will be used in the research project.

- ☐ Action research
- ☐ Biospecimen analysis research
- ☐ Data linkage research
- ☐ Ethnographic research
- ☐ Epidemiological research
- ☐ Interventional/ Clinical Trial research
- ☐ Observational research
- ☑ Survey/Interview/Focus Group research
- ☐ Textual analysis research
- ☐ None of the above

PARTICIPANTS

Q1.18. Indicate with whom or with what the research will be conducted.

- ◉ Human beings (via active participation), including their associated biospecimens and/or data
- ◯ Human biospecimens only
- ◯ Data associated with human beings only (i.e. as the primary object of research)

Q1.19. Will your research involve participation of any of the following?

- ☐ Women who are pregnant and the human fetus
- ☐ Children and young people
- ☐ People highly dependent on medical care who may be unable to give consent
- ☐ People with a cognitive impairment, intellectual disability or mental illness
- ☐ People in dependent or unequal relationships
- ☐ People who may be involved in illegal activities
- ☐ People in other countries
- ☑ Aboriginal and Torres Strait Islander peoples

Method Specific Questions

ACTION RESEARCH

BIOSPECIMEN ANALYSIS RESEARCH

DATA LINKAGE RESEARCH

ETHNOGRAPHIC RESEARCH

EPIDEMIOLOGICAL RESEARCH

INTERVENTIONAL/CLINICAL TRIALS RESEARCH

OBSERVATIONAL RESEARCH

SURVEY/INTERVIEW/FOCUS GROUP RESEARCH

M8.1. What process/es will your research project use?

- ☑ Surveys
- ☑ Interviews
- ☑ Focus groups

M8.2. How will you engage with your participants?

- ☑ Face to face
- ☑ Via telephone, texting or messaging services, or online collaboration tools
- ☐ Indirectly, via an online provider

M8.3. Will your participants be:

☐ Identifiable

☑ Re-identifiable

☐ Not identifiable

M8.4. Will participants have the opportunity to review or edit their responses or contributions prior to data analysis or publication?

◉ Yes ○ No

M8.4.1.1 Indicate the relevant section/s of your Project Description that details this opportunity.

Data collection/gathering:
The participants will be invited to member check transcriptions of interviews and determine what material may be included and excluded from the data analysis process.

M8.5. Is it foreseeable that your project will explore topics that may cause distress for participants?

◉ Yes ○ No

TEXTUAL ANALYSIS RESEARCH

Participant Specific Questions

Pregnant women and human fetus

Children and young people

People highly dependent on medical care who may be unable to give consent

People with a cognitive impairment, an intellectual disability, or a mental illness

People in dependent or unequal relationships

People who may be involved in illegal activities

People in other countries

Aboriginal and Torres Strait Islander Peoples

P8.1. How have you considered and addressed local Aboriginal and Torres Strait Islander cultural values in the design and conduct of this research?

It is anticipated that, as the research involves isolated women diagnosed with post-natal depression, there will be women who identify as Indigenous or from a Torres Strait Islander background.
Indigenous women will be invited to participate in the Steering Committee to ensure their input in the research and to inform the team about facilitating culturally competence in all aspects of the research. Indigenous women will also contribute by ensuring the research is conducted in keeping with the values of Indigenous and Torres Strait Islander cultures, norms and practices.
Included in the research is the Building Strong Foundations - Aboriginal Children, Families and Communities Team, who will work with the research team as we approach Indigenous women to be participants, as we conduct

interviews and analyse their data. These strategies facilitate respect, enable reciprocity and demonstrate responsibility.
Any Indigenous woman who accepts the invitation to participate in the research and who becomes distressed or indicates that they are not comfortable sharing their experiences with the research team, will be reminded that they are able to withdraw from the research with no penalty and they will be provided with referral to an Indigenous counseling service in their local health area such as Building Strong Foundations. If the Indigenous women prefer to have someone with them during the interview or if they need assistance with using the computer program, appropriate support will be provided. As a sign of gratitude, the research team will pay $30.00 for each interaction.
The outcome of the research, that is, the facilitators and barriers to implementing the on-line resource for isolated, post-natal women, will inform other isolated Indigenous communities and support services so that women in those communities can be adequately supported to achieve optimum benefit from the program into the future. This enables reciprocity and sustainability of the outcomes of this research for Indigenous women.

P8.2. Describe the process that will be used to satisfy the requirements for community consultation, engagement and governance that apply to your research?

The research team is working with the Building Strong Foundations (BSF) - Aboriginal Children, Families and Communities. This organisation has been involved in the development of the research grant so has been consulted throughout the project.
They will be the referral for Indigenous women and will have a team member on the Steering Committee.
Acknowledgement of the Indigenous women will be a significant aspect of the final report.As the aim of this project is to identify facilitators and barriers for isolated women and Indigenous women are a proportion of isolated women, their experiences are integral to the project. It is through this project that Indigenous mothers in the future will be more appropriately supported and the program will be more readily delivered to them without the barriers identified through this project.The Aboriginal Impact Statement will used as a guide for all interactions with Indigenous women.

P8.3. List any relevant ethics guidelines that you have consulted during the development of your research project.

NHMRC Guidelines

ANHMRC Guidelines

CSU Human Research Ethical Guidelines

Greater Western HREC guidelines

Aboriginal Health Impact Statement

Recruitment - General

Q2.1.1. Indicate how you will identify and recruit participants for your research, referencing any relevant section/s of your Project Description/Protocol.

The project will use purposive sampling as the focus is on a particular cohort of women. It involves two groups of participants, clinicians and women who are post natal and have been identified as having mild to moderate post-natal depression.
In relation to Clinicians:
Participants will be invited to be part of the project through information sessions held at the relevant referral services. Clinicians will be provided with information sheets to further explain the project and their role. Clinicians who choose to participate will contact the researchers within one week, sign a consent form and will be provided with education related to the MummoodBooster Program. They will participate in one focus group or one individual interview depending on their circumstances and location. There will be no penalties for the clinicians who choose not to participate.

For women who are post-natal:
Participants will include women living in rural, regional and remote areas of the Murrumbidgee and Western NSW Local Health Districts. The women will be 18 years or older who:
• Have been screened using the Edinburgh Postnatal Depression Scale (EPDS) and have scored between 13 and 25. Routine screening already occurs during Antenatal appointments and Child & Family follow up at 6-8 weeks and 6-8 months postnatally as part of the NSW SAFE START model of care,
• are accessing GP, Community Mental Health, Tresillian, Building Strong Foundations services
• And are identified by clinicians as having mild to moderate post natal depression who will then invite the woman to

participate in the research.
The involvement time for the women will be, three surveys across three months and an interview or focus group. Their time accessing the MumMoodBooster program is determined by the individual woman.

Sample Size:

Across the 16 month recruitment period, approximately 60-80 women scoring 13 to 25 on the EDS will participate. This figure is an estimate based on the prevalence of depression being 10-20% across the perinatal period. Women indicating thoughts of self-harm on the EPDS will be excluded from the project and the team will ensure these women have been referred to appropriate services for immediate risk assessment.

Sites:

Participants from the following referral sources will be invited into the project:
• Child and Family Health services,
• Building Strong Foundations (BSF)- Aboriginal Children, Families and Communities,
• Community Mental Health and Drug & Alcohol Services,
• General Practitioners and
• The Tresillian in Murrumbidgee Family Care Centre.

The sites within MLHD include Wagga Wagga (Tresillian), Narrandera and Deniliquin which represents an annual recruitment base of approximately 420.

The sites within WNSWLHD include Bathurst, Parkes and Forbes this represents an annual birth rate of approximately 840.

This gives a total recruitment base of approximately 1,260.

RECRUITMENT PROCESS:

The progression of recruitment for each geographical area will involve:

1. Contacting the General Practitioners, Mental Health Clinicians, Child and Family Health Nurses, Building Strong Foundations, Tresillian in Murrumbidgee Family Care Centre and Community Mental Health teams to inform them of the project and request their involvement in the referral of women who fit the profile for the MMB program.

2. All clinicians will receive instruction regarding the MMB program and education on how to access the online tool will also be provided. Clinicians will receive additional education regarding screening using the EPDS.

3. Clinicians, who are familiar to the women, will identify women who fit the criteria and invite them to participate and provide them with an information sheet about the project and a consent form. The women will be able to take as much time as they need to consent to participation with the only restriction being the 2 year time frame for the project.

4. Women will receive a user login to begin working through the online program.

5. Clinicians will invite the participants to complete the baseline questionnaires to gather basic demographics and measure symptoms of anxiety and depression.

6. Ongoing support and education for the clinician and the women in relation to the program will be provided. Low-intensity SMS support will provide regular weekly contact and encouragement to complete the program.

Q2.1.2. How will your recruitment strategy take account of the ethical considerations relevant to the specific people you are recruiting?

Each participant will be offered $30.00 for each interaction with the research as a token for their time and to cover any traveling costs.
We acknowledge these are vulnerable women and their mental health will be monitored throughout the research by the research team and the usual support for these women will continue through their post natal support services. Recruitment is through the clinicians so no contact is made with the women by the research team until the women have agreed to have contact. Any questions will be answered to ensure the woman is fully aware of what is involved in their participation.

There will be Indigenous representation on the Steering Committee and clinicians who identify as Indigenous will

interact with women who identify as Indigenous.
Respect for the Indigenous culture will be demonstrated at all interactions and when organising times for visits to the women. When conducting interviews an approach called yarning will be adopted rather than a more formal approach to interviewing.Separate focus groups will be available for the Indigenous women and art work use to promote discussion. Any material deemed as not able to be shared will be identified by the woman and omitted from the data through member checking. The results pertaining to the situation pertinent to Indigenous women will be shared with relevant clinicians who work with Indigenous women and with Indigenous community groups and services.

Recruitment - Action Research

Recruitment - Observational Research

Consent

Q2.2.1. Indicate the relevant section/s of your Project Description/Protocol that address/es consent.

This project proposes to obtain consent from two groups of participants across two area health districts:
1. The women with post natal depression who fit the selection criteria
2. Clinicians who work with post natal women.

1. Women who fit the inclusion criteria will be identified by the clinicians and the clinicians will inform them of the research, ask about their interest in participating and provide the women who respond in the affirmative with an information sheet and contact details of the CI. The woman will be provided with a consent form and after signing will be introduced to the online program.
2. Clinicians will attended an information session and added their name to a list indicated they are willing to participate in the project. Within a week, the potential participant will be contacted about the time and location of the education sessions to support them. At the beginning of each focus group session participants will be given an information sheet to read and retain. A member of the research team will go over the information and respond to questions that arise. Participants will be given a consent form to read and then allowed to ask questions. Participants will be asked to sign and return the consent form to the research team member.

Q2.2.2. Will you be obtaining consent from some or all participants to participate in the research?

- (•) Yes for all participants
- ( ) Yes for some participants
- ( ) Not for any participants

Q2.2.2.1 What is the scope of consent that you will be seeking?

- [x] Specific
- [ ] Extended
- [ ] Unspecified

Q2.2.2.2 How will consent be obtained?

- [x] Written
- [ ] Verbal
- [ ] Implied

Q2.2.2.3 Are you proposing to obtain consent using limited disclosure?

( ) Yes (•) No

Q2.2.3. Are family members, authorised representatives or any others involved in the participants' decision to participate in the research?

◯ Yes ◉ No

Q2.2.4. Will there be an opportunity to confirm or re-negotiate consent during the research project?

◉ Yes ◯ No

Refer to the relevant section/s of your Project Description/Protocol that detail the process for confirming or re-negotiating consent at Q1 (Consent - General)

Q2.2.6. Describe any ethical considerations related to the approach to consent that you will be seeking and your strategies for addressing and managing these issues.

Consent can be renegotiated by the participants at any stage of the research.
For the post natal women:
If a woman has declined the invitation to be part of the project but decides she would like to participate then they will be given the option to be included. If a woman decides to withdraw for what ever reason, they will still have access to the normal clinical services to post natal women.
If it is identified by a clinician or by a woman herself that her level of depression or her physical health is placing her at risk, she will be withdrawn from the program until she is able to continue or, if she chooses, to opt out of the research completely.
Women who have particular needs such as literacy or cultural issues, the clinician working with the woman will address that particular need, refer to any specific service related to her situation and negotiate with the research team on her behalf, if appropriate and if approval is given to act on her behalf.
For the clinicians:
If any clinician has provided consent to participate and their circumstances change or they decide they no longer wish to participate, they may withdraw with no negative consequences.

Q2.2.7. Are you proposing to use an opt-out approach with respect to some or all of the participants?

◯ Yes ◉ No

Q2.2.8. Are you requesting a waiver of the requirement for consent with respect to some or all participants?

◯ Yes ◉ No

Consent - Ethnographic Research

Consent - Children and young people

Consent - People highly dependent on medical care

Consent - People with a cognitive impairment

Consent - Involvement in illegal activities

Risk - General

Q2.3.1. Describe the risks and burdens associated with your research, referencing any relevant sections of your Project Description/Protocol as appropriate.

For the post natal women:
The burden for the women will be that they are required to engage with an on-line program to support them to manage their depression. The participant can access the program whenever they wish and the frequency of use is

manage their depression. The participant can access the program whenever they wish and the frequency of use is also voluntary. The on-line resource is evidence based and has proven to be effective. We are exploring the barriers and facilitators to the use of the program not the program itself. While participants are identified as having minor post natal depression they are not removed from routine follow up with midwives and community health. Further triggers are in place through MumMoodBooster to identify anyone whose condition deteriorates. MumMoodBooster is already evidence based and this project is looking at the barrier to implementation, making the likelihood of the condition worsening minimal.
For the clinicians:
The clinicians:
The clinicians include Mental Health Clinicians, Child and Family Health Nurses, Building Strong Foundations staff, Tresillian in Murrumbidgee Family Care Centre and Community Mental Health teams. They will be invited to participate in the referral of women who fit the profile for the MMB program and to participate in interviews and focus groups to determine facilitators and barriers to the on-line program for isolated women. There will be no repercussions from their service or the MLHD or WNSWLHD, if they decide not to participate in the project.

Q2.3.2. Describe how these risks will be mitigated and managed.

Risks for all participants will be managed by:
1.the ability of the participant to withdraw at any time
2.the interviews being conducted by skilled clinicians and researchers with clinical background
3.cessation of any interviews or focus groups is any participant becomes distressed or physically unwell
4.cultural safety will be enhanced with the inclusion of Indigenous women on the Steering Committee and with the inclusion of clinicians from the Building Strong Foundations (BSF)- Aboriginal Children, Families and Communities
5. If any woman expresses distress in being part of the research, they may withdraw and they will be refereed to their local post natal support clinician.

The mitigation of risk for clinicians is through anonymity of participation. MLHD and WNSWLHD management will be unaware of which staff choose to participate or which staff decline participation. Documents related to staff will be stored by the Research Officer in a locked cabinet at Charles Sturt University. There will be no risk to employment whatever the clinician chooses to participate or refuse to participate.
If they experience distress, the clinician can be referred to the Employee Assistance Program for their service.

Risk - People in dependent or unequal relationships

Benefit

Q2.4.1. Describe the benefits associated with your research, referencing any relevant sections of your Project Description/Protocol as appropriate.

This research project will inform clinicians and policy writers of the unique experiences of regional, rural and remote perinatal women. Specifically those parents of a newborn baby who are experiencing mild to moderate depression and coping with the isolation that their mental health vulnerabilities and geographical location can impose. This research enables perinatal women to take active steps to address their own mental health needs with regards to implementation and delivery of an online CBT intervention mental health and the supporting infrastructure required to make access to online mental health interventions possible.

Through interaction with this group of women and their clinicians, we will develop a model for implementation of an online evidenced based, mental health intervention program within existing services that empowers women to manage their own access to treatment for depression. The model will then be replicable to health services that are responsible for providing interventions for depression and anxiety for perinatal women who are isolated from service access and hard to reach anywhere within NSW.

The outcome of the project will be a model that can be implemented, replicated and sustained within existing services for women living in geographically isolated areas but also applicable to women who are isolated from service access for a variety of reasons, including those living in high-population metropolitan areas. Although focused on interventions for perinatal women the project will also highlight issues to do with eHealth implementation that can be applied to demographically and geographically hard to reach and isolated populations more generally.

Q2.4.2. Explain how the benefits of this research justify any risks or burdens associated with the research.

The project will identify what supports women's access to evidence based intervention for PNDA. It will also identify

The project will identify what supports women's access to evidence based intervention for PNDA. It will also identify the key barriers that need to be addressed within health services and systems. Bringing effective online treatment to women where and when they need it has potential to prevent and ameliorate the impact of depression on health and wellbeing at a population level. The increased accessibility of evidenced based interventions for isolated/rural perinatal women will in turn reduce the impact to the mother, child, family and society of untreated depression and anxiety. Considering that the financial cost of perinatal depression to the Australian economy in 2012 was estimated to be $433.52 million, a cost effective, easily accessible intervention such as MMB is required.
The development of a model to ensure systems are in place to enable depressed perinatal women to access eHealth can be consistently applied across local health districts and integrated into health policies, guidelines and clinical practice guidelines.

Q2.4.3. How will you manage participants' expectations of the perceived benefit of participating in the research?

This research is not evaluating the intervention. MumMoodBooster has been scrutinised through research and has been shown to be effective in supporting and treating women with post natal depression. What we are exploring is the facilitators and barriers to accessing the program by isolated women. The post natal women participating in the project will have explanations, verbal and written, about the aims of the research and that the treatment is the same as what is available to metropolitan women suffering post natal depression. There is no promise of any benefits, just the sharing of their experience in accessing and using the program.

For the clinicians, it will be explained to them that there is no risk to their employment nor is there any benefit to their employment status by participating. Participation does fulfill the requirement for registered nurses to be involved in research but this competency can be demonstrated in other ways and does not solely depend on this project.

Section 3 - Data and Privacy

Data and Privacy - Data Characteristics

Q3.1. Indicate the type of information/data you will be collecting for this project.

- [x] Personal information
- [ ] Sensitive information
- [x] Health information
- [ ] Not personal information

Q3.2. Indicate the type of information/data you will be using in this project.

- [x] Personal information
- [ ] Sensitive information
- [x] Health information
- [ ] Not personal information

Q3.3. Indicate the degree of identifiability of information/data you will be collecting for this project.

- [ ] Individually identifiable information
- [x] Re-identifiable (coded) information
- [ ] Non-identifiable information

Q3.4. Indicate the degree of identifiability of information/data you will be using in this project.

☐ Individually identifiable information

☑ Re-identifiable (coded) information

☐ Non-identifiable information

Q3.5. Describe any ethical considerations relating to the collection and/or use of the information/data in this project.

The majority of the information collected in this research will be non-identifiable information. However given there is a mild risk the depression symptoms of participants could get worse and intervention is need the information of the participants will need to be re-identifiable. While clinicians will hold the majority of this information and intervene if required the Data Manager of the research team will be able to identify participants in the program and raise a 'trigger warning' if required.
In terms of information help by the research team the identifiable information will be stored in a password protected file that will be access only by members of the research team. Participants can then be coded (e.g. Jane Smith is participant 10) and any results documented will be linked only to the coded name. Again this file will be password protected accessed only by the research team. This re-identification is necessary for this project to be completed and to ensure the complete safety of participants. All members of the research team are experienced in ethical practises and understand the importance of maintaining confidentiality. No identifying information will be publish.

Q3.6. Identify the source/s of the information/data that you will be collecting and/or using in this project.

☑ Individual participants

☐ Relatives or associates of participants

☐ Medical/health/mental health record

☐ Electoral roll

☐ Held by a law enforcement agency or judicial body

☐ Publicly held database (Commonwealth)

☐ Publicly held database (State or local)

☑ Privately held database

Q3.7. Describe any ethical considerations relating to the source of information/data as indicated in the response to the previous question.

Information gathered from the individuals and all their data will be stored securely on password protected files with limited access. Identifying data and research results are not kept in the same file/location.
Research participants are informed of research purpose and consent gained. Consent can be withdrawn at anytime without penalty.
Additional support services will be employed as required by participants or identified by clinicians or data analysis (e.g. clinical intervention, translation required, Aboriginal or Torres Straight Islander support).
Data collected through the research will be de-identified with coding and separated from the identifying material.
Clinicians will hold the outcomes of the assessment and thus that information remain confidential.

Q3.8. Was the information/data that you are using previously collected for a purpose other than research?

◉ Yes ○ No

Q3.8.1 Provide a rationale for your use of information/data for a purpose other than that for which it was originally collected.

The EDS is a routine assessment tool used by post natal services. This information is not collected for the purpose of this research however we are using this score to identify potential participants with mild to moderate PND. This is being used under ethical consideration so that women at high risk are not involved in this research. This information is held by the clinicians and not known by the research team.

Data and Privacy - Activities with Data

Q3.9. Do you plan to disclose any personal information/data in this project to a third party?

○ Yes ◉ No

Q3.10. How will you protect the privacy of participants and non-participants in any notes and/or publications arising from your research.

All participants, both women and clinicians will be given a code number so that privacy is respected. Field notes will be in the possession of the researcher while collecting data and then locked in a locked filing cabinet in their office. Interviews and focus groups will be recorded electronically, deposited in Dropbox for the transcription and then files will be kept on password protected computers.
After five years, the files will be deleted and field notes destroyed in locked secure disposal bins for shredding.

Q3.11. Are there any restrictions on your ability to assure the confidentiality of participants?

○ Yes ◉ No

Q3.12. Do you plan to share any individual research results obtained during this research to the participants?

○ Yes ◉ No

Q3.13. Describe how you will handle any secondary or incidental findings that arise from the analysis of personal information/data.

Surveys, focus groups and interviews will be very targeted at the barriers to the implementation of online mental health support in rural and remote areas. As such it is highly unlikely any secondary findings will arise from the personal information, if it does it will be regarded as outside the scope of this research project.

Q3.14. Describe how the information/data will be stored, accessed, archived and/or destroyed.

Three types of information will be collected and stored as part of this study.
1) Surveys - responses will be collected electronically through secure sites. Data will be kept in password protected files. All files will be deleted after 5 years.
2) Interviews - Recordings from interviews will be upload to Dropbox password protected shared files to be transcribes. Transcriptions and raw recordings will be kept for 5 years and then deleted.
3) Focus Group - Notes from focus group sessions will be kept in a locked filing cabinet in the office of a research team member. This office will also be lock when unattended.
All notes will be shredded after 5 years through a secure shredding system and data completely deleted from the computer.

Q3.15. Describe any ethical considerations relating to the storage of, access to or destruction of information/data in this project.

All information is required to be held for 5 years. During this time all data will stored in either password protected files on a password protect computer or in a locked filing cabinet a a researchers office. Identifying data of participants will not be kept in the same location as the data to be analysed.

Q3.16. Will the outcomes of this project be disseminated to the participants?

◉ Yes ○ No

Q3.16.1.1 Describe how the outcomes of the project will be disseminated to the participants, or refer to the

relevant section/s of your Project Description/Protocol which deals with this matter.

The research team will engage in member checking, for the participants that are involved in individual interview to inform the research team of any information they would like excluded.
Those in focus groups will be informed at the start this is not possible for them.
We will also offer participants a copy of the final report if they would like it.

Q3.16.1.2 Describe any ethical considerations relating to any dissemination of outcomes to the participants.

Given that participants are giving informed consent and they will be offered the opportunity to check their transcripts and material will be de-identified, there are no impediments to dissemination of outcome.

Q3.17. Describe any foreseeable future activities for which information/data collected and/or used in this project may be made available.

Data presented in aggregate form can be made available via the form of the final report to clinician and midwives working in rural and remote areas.
There is no need for raw data to be use for any other purpose in the foreseeable future.

Q3.18. Describe any ethical considerations relating to the planned or possible future use of information/data in this project.

There is no need for raw data to be use for any other purpose in the foreseeable future.

Section 4 – Attachments and Declarations

ATTACHMENTS

The following documents have been attached to this HREA.

Document Type	Attachment File Name	Attachment Description

DECLARATIONS

1. DECLARATIONS

I/we certify that:

- All information in this application and supporting documentation is correct and as complete as possible;
- I have read and addressed in this application the requirements of the National Statement and any other relevant guidelines;
- I have familiarised myself with, considered and addressed in this application any relevant legislation, regulations, research guidelines and organisational policies;
- All relevant financial and non-financial interests of the project team have been disclosed; and
- In the capacity of a supervisor, as applicable, I have reviewed this application and I will provide appropriate supervision to the student(s) in accordance with the arrangements specified in this application and those associated with the student's educational program.

Chief Investigator/Researcher, Co-ordinating Principal Investigator/Researcher, Lead Investigator

Chief Investigator/Researcher
Mrs Keryl de Haan
Signature 18/7/18 Date

Co-ordinating Principal Investigator/Researcher
Associate Professor Maree Bernoth
Signature 18/7/18 Date

Principal Investigator

Associate /Assistant/Sub-/Co- Investigator

Investigator and Other

Investigator/Researcher Dr Joanna Carlisle	Signature	18,7,18 Date
Investigator/Researcher Ms Alicia Carey	Signature	18,7,18 Date
Investigator/Researcher Ms Chirstina Hunt	Signature	18,07,18 Date
Investigator/Researcher Professor Jeannette Milgrom	Signature	18,7,18 Date
Investigator/Researcher Dr Alan Gemmill	Signature	18,7,18 Date

Greater Western Human Research Ethics Committee

Researcher Response Template

Project No. HREC/18/GWAHS/68
2018-052
Deferred Decision –

Project Title: **What are the key facilitators and barriers impacting optimal implementation of an evidenced based online intervention for isolated women who are experiencing post natal depression and are living in regional, rural and remote areas of New South Wales?**

HREC Enquiry	Researcher Response
Research merit & integrity **National Statement 1.1 – 1.3**	
• As this is an intervention which has already been shown to be effective, you are asked if women will be able to undertake the program if they do not also wish to be part of the research study. If the program is not available, the Participant Information Sheet (PIS) should advise what alternatives are available.	The Women can still access the program if they withdraw, through a website called Mumspace. Participants who withdraw will be sent a link to that website. The follow sentence has been added to the PIS, under the participation section. "You will still have access to the MumMood Booster Program and the normal support services if you decide to withdraw from the project."
• Please clarify how you will actually identify barriers to participation (e.g. internet access) as the study cohort will only include those who are actually willing, and presumably able, to participate.	These barriers will identified through the data collected from the back end of the program for example – connection dropping out etc. this information is provided by the data manager. Further barriers will also be identified through focus groups and interviews after the program has been completed.
• As the $30 payment will be made for each "interaction", you are asked what constitutes an "interaction". Could you please also advise how the payments will be made.	An interaction will be will be anytime the participant provides data for the research taking place (completes a questionnaire or participates in interviews/focus groups). There is expected to be 3 interactions per participant (2 questionnaires and one interview or focus group). Payments will be made with prepaid Visa debit cards.
• HREA, page 20, Q3.6 indicates that data will be sought from a privately held database. You are asked to give details.	The data collect from the privately held data base in the data collected from the MumMoodBooster program. Data held in the backend of this program will be managed by the Data Manager and where required passed onto the research team to identify barriers (e.g. connection drop outs, participant complaints about access or ease of use etc.).

HREC Enquiry	Researcher Response
National Statement 4.7 Aboriginal and Torres Strait Islander Peoples	
• The HREA, page 13, P8.1 and P8.2, indicates that the study will involve the participation of Aboriginal and Torres Strait Islanders peoples. Please advise whether or not Aboriginality is a focus of the study. If it is, then the study will need to be submitted to the AH & MRC Ethics Committee.	The Aboriginality is not a focus of the study.
Participant Information Statement (PIS) and Consent Form National Statement 2.2	
• The heading on the PISs and Consent Forms (CFs) should be the same as the study title.	This has been updated in the current version of the PISs and CFs
• The section on the PISs relating to "Concerns/Complaints" should be amended to: This study has been reviewed and approved by the Greater Western Human Research Ethics Committee. If you have any concerns or complaints regarding the study please contact the Committee's Executive Officer on (02) 6330 5948 or via e-mail: Phil.Sanders@health.nsw.gov.au	This has been amended on the PIC
• The contact details on the Consent Form should also be amended.	This has been amended on the consent form
• The HREA, page 13, M8.4, indicates that participants will be offered the opportunity to check their transcripts. This information should be included in the PIS.	This has been added to the PIC under participation, point 4.
• The PIS should advise potential participants why they have been asked to take part in the study.	Sentence has been included to explain this at the start of the participation section in the PIC

HREC Enquiry	Researcher Response
• The PISs should contain a statement advising potential participants that if they choose not to take part in the study it will not affect any ongoing treatment they are receiving or their relationship with the health service.	This has been included in the PICs under the participation section
• Please clarify who the advertising poster is aimed at and to give it a version number and date.	Advertising poster is aimed at clinicians. The title has been updated to demonstrate this and the version and date number have been given on the poster.

Appendix C: Participant Information Letter and Consent

Participants' Information Sheet

What are the key facilitators and barriers impacting optimal implementation of an evidenced based online intervention for isolated women who are experiencing post-natal depression and are living in regional, rural and remote areas of New South Wales?

There are three pages in this document.

RESEARCH TEAM

Ms Keryl de Haan, Associate Professor Maree Bernoth, Ms Joanne Carlisle, Ms Chris Hunt, Professor Jeanette Milgrom, Dr. Alan Gemmill, Ms Alicia Carey.

DESCRIPTION

This project is funded by a Translational Research Grant from the New South Wales Health department. The purpose of this study is to find out the key barriers and facilitators to accessing the online *MumMoodBooster* (MMB), Postnatal Depression treatment program for isolated and hard to reach women in areas of regional, rural and remote NSW.

PARTICIPATION

You have been invited to participate in this project because your Edinburgh Depression Scale (EDS) score indicated you are eligible. Your participation in this project is entirely voluntary. If you do agree to participate, you can withdraw from the project at any time without comment or penalty. You will still have access to the *MumMoodBooster* Program and the normal support services from all healthcare providers will remain available if you decide to withdraw from the project. If you initially agree to participate but then change your mind, you can opt out at any stage.

Your participation in the research means:

1. You will be given access to an on-line program that has been shown to be effective in supporting women with post-natal depression, *MumMoodBooster*. You will receive a user login to begin working through the online program and instructions about how to use the program. The research is not about the effectiveness of the program but rather your experiences accessing the program.
2. You will complete a baseline questionnaire to gather basic demographic information and measure you symptoms of anxiety and depression.
3. The questionnaire will be repeated at 9 weeks and again at 3 months after commencing the research.

version 3 21/08/2018

4. You will be invited to participate in an individual interview or a focus group with other participants in the project. This will take approximately one hour. With your consent, the individual interview or focus group will be recorded and the information transcribed. You will have the opportunity to check this transcription.
5. Emergency and support services will be available to you if needed through the clinicians supporting you.

EXPECTED BENEFITS

What information you give us will help to answer questions about uptake of the *MumMoodBooster* program and identify any barriers you had accessing and using the program. This information will then be analysed and outcomes written up identifying recommendations around offering the e-Health intervention MMB as a standard referral pathway in health services for isolated women experiencing perinatal depression and anxiety.

PAYMENT

Each time you participate- completing questionnaires and participating in interview/focus group) you will be reimbursed for your time with a $30 prepaid Visa debit card.

RISKS

If you decide to participate in a focus group, please do not divulge anything you wish to keep confidential or private. If you feel uncomfortable about participating in the discussion, you have the right to not contribute your ideas. You have the right to leave the focus group at any time. However, any contribution you have made prior to withdrawing will become part of the data set.

PRIVACY AND CONFIDENTIALITY

All comments and responses will be treated confidentially. All recorded and transcribed data will be de-identified. Results will also be used for publication and presentations. Your name will not be linked with your responses and you will not be able to be identified in the reported data. Please note that non-identifiable data collected in this project may be used as comparative data in future projects.

CONSENT TO PARTICIPATE

This information sheet is for you to retain so that you have a reminder of what is involved in the research and your rights. It also has the contact details of the researchers and the Research Committee. A consent form will be provided to you if you decide to participate in the focus group. If you agree to participate, the consent form will need to be signed prior to your participation in the focus group.

NSW GOVERNMENT Health
Murrumbidgee
Local Health District

QUESTIONS/FURTHER INFORMATION ABOUT THE PROJECT

If you have any questions or require any further information please contact one of the research team members below.

Joanna Carlisle
Charles Sturt University, Wagga Wagga
Email: jcarlisle@csu.edu.au

Keryl de Haan
Clinical Leader Perinatal Infant Mental Health/Substance Use
Murrumbidgee Local Health District
Phone: 047770810
Email: keryl.dehaan@health.nsw.gov.au

CONCERNS/COMPLAINTS REGARDING THE CONDUCT OF THE PROJECT

This study has been reviewed and approved by the Greater Western Human Research Ethics Committee. If you have any concerns or complaints regarding the study please contact the Committee's Executive Officer on (02) 6330 5948 or via e-mail: Phil.Sanders@health.nsw.gov.au

Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

version 3 21/08/2018

Participant Consent Form

What are the key facilitators and barriers impacting optimal implementation of an evidenced based online intervention for isolated women who are experiencing post natal depression and are living in regional, rural and remote areas of New South Wales?

Principal Investigator
Ms Keryl de Haan
Clinical Leader PIMH/Substance Use
Murrumbidgee Local Health District
Phone: 047770810
Email: keryl.dehaan@health.nsw.gov.au

The purpose of the research has been explained to me, including the potential risks and discomforts. I have read the attached Participant Information Sheet on the above named study, and understand the purpose and the nature of participation. I have been given the opportunity to ask questions about the research and received satisfactory answers.

I understand that I am free to withdraw my participation in the research at any time, and that if I do, I will not be subjected to any penalty or discriminatory treatment, however any comments I have made prior to my withdrawal will remain part of the data set.

There are two pages to this form. If you agree to participate, please sign the second page.

Please read the following statements carefully and tick ☑ the boxes to agree, where applicable:

- ☐ I have been made aware of any known or anticipated inconvenience, risk and discomfort and of their implications as far as the researcher currently knows them.
- ☐ I agree to the use of audio recording equipment during the interviews.
- ☐ I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.
- ☐ I have been advised to retain the Participant Information Sheet.
- ☐ I understand that if I have any complaints or concerns about this research I can contact Greater Western Human Research Ethics Committee: Committee's Executive Officer on (02) 6330 5948 or via e-mail: Phil.Sanders@health.nsw.gov.au

Version 2 17/08/2018

Name of Participant	Signature of Participant	Date

Name of Investigator	Signature of Investigator	Date

Version 2 17/08/2018

Appendix D: Clinician Information Letter and Consent

Clinicians' Information Sheet

What are the key facilitators and barriers impacting optimal implementation of an evidenced based online intervention for isolated women who are experiencing post natal depression and are living in regional, rural and remote areas of New South Wales?

RESEARCH TEAM

Ms Keryl de Haan, Associate Professor Maree Bernoth, Ms Joanna Carlisle, Ms Chris Hunt, Professor Jeanette Milgrom, Dr. Alan Gemmill , Ms Alicia Carey.

DESCRIPTION

This project is funded by a Translational Research Grant from the New South Wales Health department. The purpose of this study is to find out the key barriers and facilitators to accessing the online MMB, Postnatal Depression treatment program for isolated and hard to reach women in areas of regional, rural and remote NSW.

PARTICIPATION

Your participation in this project is entirely voluntary. If you do agree to participate, you can withdraw from the project at any time without comment or penalty. If you initially agree to participate but then change your mind, you can opt out at any stage. However, any comments you make prior to leaving the focus group will remain part of the data set. Withdrawal from the program will not affect you negatively. You are invited to participate in a focus group with other clinicians in your area where your experience with supporting women accessing the online treatment will be shared and discussed. The focus group will take an hour. With your consent, the focus group will be recorded and the information transcribed.

EXPECTED BENEFITS

What information you give us in the focus group will help to answer questions about uptake and identify any barriers you had supporting women accessing and using the program. This information will then be analysed and outcomes written up identifying recommendations around offering the e-Health intervention (MMB) as a standard referral pathway in health services for isolated women experiencing perinatal depression and anxiety.

RISKS

If you decide to participate in a focus group, please do not divulge anything you wish to keep confidential or private. If you feel uncomfortable about participating in the discussion, you have the right to not contribute your ideas. You have the right to leave the focus

version 2 18/08/2018

group at any time. However, any contribution you have made prior to withdrawing will become part of the data set.

PRIVACY AND CONFIDENTIALITY

All comments and responses will be treated confidentially. All recorded and transcribed data will be de-identified. Results will also be used for publication and presentations. Your name will not be linked with your responses and you will not be able to be identified in the reported data. Please note that non-identifiable data collected in this project may be used as comparative data in future projects.

CONSENT TO PARTICIPATE

This information sheet is for you to retain so that you have a reminder of what is involved in the research and your rights. It also has the contact details of the researchers and the Research Committee. A consent form will be provided to you if you decide to participate in the focus group. If you agree to participate, the consent form will need to be signed prior to your participation in the focus group.

QUESTIONS/FURTHER INFORMATION ABOUT THE PROJECT

If you have any questions or require any further information please contact:

Joanna Carlisle
Title: Research Assistant
Charles Sturt University, Wagga Wagga
Email: jcarlisle@csu.edu.au

Keryl de Haan
Title: Clinical Leader Perinatal Infant Mental Health/Substance Use
Murrumbidgee Local Health District
Phone: 047770810
Email: keryl.dehaan@health.nsw.gov.au

CONCERNS/COMPLAINTS REGARDING THE CONDUCT OF THE PROJECT

This study has been reviewed and approved by the Greater Western Human Research Ethics Committee. If you have any concerns or complaints regarding the study please contact the Committee's Executive Officer on (02) 6330 5948 or via e-mail: Phil.Sanders@health.nsw.gov.au

Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

version 2 18/08/2018

Clinician Consent Form

What are the key facilitators and barriers impacting optimal implementation of an evidenced based online intervention for isolated women who are experiencing post natal depression and are living in regional, rural and remote areas of New South Wales?

Principal Investigator
Ms Keryl de Haan
Clinical Leader PIMH/Substance Use
Murrumbidgee Local Health District
Phone: 047770810
Email: keryl.dehaan@health.nsw.gov.au

The purpose of the research has been explained to me, including the potential risks and discomforts. I have read the attached Clinician Information Sheet on related to this research, and understand the purpose and the nature of participation. I have been given the opportunity to ask questions about the research and received satisfactory answers.

I understand that I am free to withdraw my participation in the research at any time and that if I do, I will not be subjected to any penalty or discriminatory treatment, however any comments I have made prior to my withdrawal will remain part of the data set.

There are two pages in this document. Your signature is required on the second page.

Please read the following statements carefully and tick ☑ the boxes to agree, where applicable:

- ☐ I have been made aware of any known or anticipated inconvenience, risk and discomfort and of their implications as far as the researcher currently knows them.
- ☐ I agree to the use of audio recording equipment during the interviews/focus groups.
- ☐ I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.
- ☐ I have been advised to retain the Supporting Clinician Information Sheet.
- ☐ I understand that if I have any complaints or concerns about this research I can contact the Greater Western Health Human Research Ethics Committee's Executive Officer on (02) 6330 5948 or via e-mail: Phil.Sanders@health.nsw.gov.au

Name of Participant	Signature of Participant	Date
Name of Investigator	Signature of Investigator	Date

Version 2 18/08/2018

This page is left blank intentionally

Appendix E: Poster Displayed to Assist Recruitment

MumMood Booster

"Free online treatment for Mums with postnatal depression"

Are you a Mum with a baby less than one year old?

Are you struggling to cope, feel flat, sad or depressed?

This internet CBT treatment program may help you.

MumMoodBooster features:

- Six sequential interactive sessions accessed from home
- Access to lots of online information
- Reimbursement for completion of questionnaires

For more information please contact:

Deniliquin- Child Family Health Nurse or MLHD Mental Health Clinician

Narrandera- Child & Family Health Nurse, MLHD Mental Health Clinician or Aboriginal Maternal Infant Health clinician

Tresillian in Murrumbidgee Family Care Centre, Wagga Wagga- Child & Family Health Nurse

Or email – jcarlisle@csu.edu.au
Research project April - December 2019
Translation Research Collaborative Organisation

Parent-Infant Research Institute · Austin Health · NSW Government · Charles Sturt University · Tresillian in Murrumbidgee

Appendix F: PowerPoint Used in Clinician Information Sessions

Supporting Isolated Women in New South Wales

via an eHealth CBT program

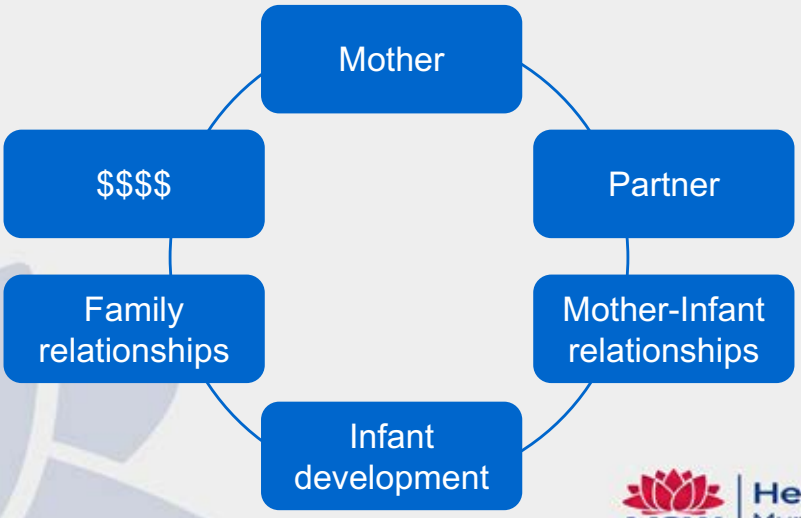
NSW GOVERNMENT Health Murrumbidgee Local Health District

Significance of Perinatal Infant Mental Health

- 10-20% women postnatal depression during the first year after giving birth
- Large proportion go undiagnosed
- Fewer than 50% women receive help for their depression
- Less than 5% receive evidence based treatment!

NSW GOVERNMENT Health Murrumbidgee Local Health District

Impact of untreated Maternal Mental Health



Health
Murrumbidgee
Local Health District

But there is help out there!

Mum Mood Booster

Developed by the Parent Infant Research institute (PIRI)

But how can we support women to access the treatment?

Health
Murrumbidgee
Local Health District

PIRI and MumMoodBooster

You can also sign up and see how *MumMoodBooster* works as a clinician through the Mum Space website.

Instructions on this will also be included in the participant packs.

NSW GOVERNMENT Health Murrumbidgee Local Health District

Let's apply for TRGS!

- Charles Sturt University
- MLHD internal partners – MHDA, CFH, AMHIS, Tresillian
- Western NSW Local Health District
- Parent Infant Research Institute (PIRI)

NSW GOVERNMENT Health Murrumbidgee Local Health District

Research plan!

- Implementation research approach
- Clinicians identified MLHD & WNSWLHD
- Women identified EDS 13-25 (CFHN)
- Invitations to participate & guided to register for *MMB*
- Baseline questionnaires & follow-up 9 weeks
- 3 month follow-up interviews (clinicians and women)

NSW GOVERNMENT Health Murrumbidgee Local Health District

We want to know?

What factors facilitated or impeded *MMB* access

- System complexity
- Internet access & reliability
- Costs
- Clinician/women's attitudes etc.

Target audience

- Did the program reach those in need?

Implementation

- Was the program implemented as intended?
- Integrity & dosage?

Who benefited most

- Location
- Service provider
- Demographic

Satisfaction

- Were clinicians and women satisfied with the MMB online CBT intervention?

NSW GOVERNMENT Health Murrumbidgee Local Health District

Anticipated outcomes

Determine	• The extent of the health problem • Utilisation of the online intervention
Analyse	• Causes for impeded uptake
Recommend	• Appropriate solutions
Upscale	• Provide information for adjusting the MMB program for wide scale implementation

NSW GOVERNMENT Health Murrumbidgee Local Health District

Where are things at?

NSW GOVERNMENT Health Murrumbidgee Local Health District

How can you help?

- The study requires your help to identify women!
- You can help by identifying women who meet the following criteria:
  - 18 years or older
  - Have been screened using the Edinburgh Postnatal Depression Scale (EPDS) and scored between 13-25 by your service.
  - Can be accessing one or more of the following, GP, Community Mental Health, Tresillian, child and family health nurse or Building strong Foundations services
  - And are identified as having signs of anxiety and/or depression.
  - Refer and provide support to these women throughout the research project.

NSW GOVERNMENT Health Murrumbidgee Local Health District

Referring women to participate

- Once a woman has been identified as meeting the criteria they can be invited to participate in the research.
- Provide and go through an information pack and consent form with the woman.
- If a woman consents, forward the details of the participant to Jo Carlisle who will organise a log in for the woman once consent is obtained.
- A weblink will be provided in the information pack to MumMoodBooster.

NSW GOVERNMENT Health Murrumbidgee Local Health District

- Safety monitoring of depressive symptoms is scheduled at regular intervals (at baseline, and 9 weeks) using the PHQ-9. Worsening of symptoms or indication of risk of harm triggers a system ‘red flag’ to the program administrator, an email referring to emergency resources, and enables immediate telephone contact for referral to specialist care services.
- Women are excluded if there are indications or risk or self harm.

Health
Murrumbidgee
Local Health District

- After 9 weeks, women will again complete questionnaires measuring symptoms of depression and anxiety (DASS, PHQ-9). This is co ordinated by Jo or a member of the research team.
- A medium-term follow-up of all outcome measures (DASS, PHQ-9) will be scheduled after a further 3 months along with a survey of women’s and health professionals’ satisfaction with the program. Participants and clinicians will be invited to participate in a semi-structured interview and/or a focus group to share their experiences.

Health
Murrumbidgee
Local Health District

Frequently asked questions (FAQ)

- What if a woman wants to withdraw from the research ?
  - Women can withdraw at any time. Data collected prior to withdrawal will be used in the research.
- Are there any incentives for women participating?
  - Women will be offered $30.00 for each interaction with the research as a token for their time and to cover travel costs.
  - These will be offered at baseline questionnaire, 9 week questionnaire and 3 month follow up.

NSW GOVERNMENT Health Murrumbidgee Local Health District

Frequently asked questions (FAQ)

- Will the woman be able to make direct contact with the research team?
  - Yes, details for Keryl de Haan and Joanna Carlisle are provided in the information pack.
- What is in the participant/clinician information pack?
  - Information about MumMoodBooster program, information sheet, consent form, local support services contact information and a note pad.

NSW GOVERNMENT Health Murrumbidgee Local Health District

Frequently asked questions (FAQ)

- How involved is the program for the woman?
  - Each session is designed to take about 15-20 minutes.
  - There are 6 sessions which should be completed in order (from 1 to 6) using a weekly schedule.
  - These sessions cover the essential steps of the program.
- Can the women start a module and continue it later?
  - Yes, all modules are designed to be able to be started and resumed to allow flexibility.

NSW GOVERNMENT Health Murrumbidgee Local Health District

Frequently asked questions (FAQ)

- Who participates in the focus groups?
  - There will be 2 types focus groups.
  - One where clinicians will be invited to attend and one where women who participate will be invited to attend.
  - These are not mandatory.
  - These will be facilitated by members of the research team.
- What if a women shows signs of depression but does not score between 13 and 25?
  - They can not be in this project but can still use MumMoodBooster through the Mum Space website.

NSW GOVERNMENT Health Murrumbidgee Local Health District

Frequently asked questions (FAQ)

- How old can the child be for the participant to in involved in the project?
  - The child needs to be under the age of 12 months however if older the mother can be referred to the Mum Space site.
- How many women am I expected to refer?
  - There will no expected number, just depends on who you treat and if they are wiling to participate.

NSW GOVERNMENT Health
Murrumbidgee
Local Health District

Frequently asked questions (FAQ)

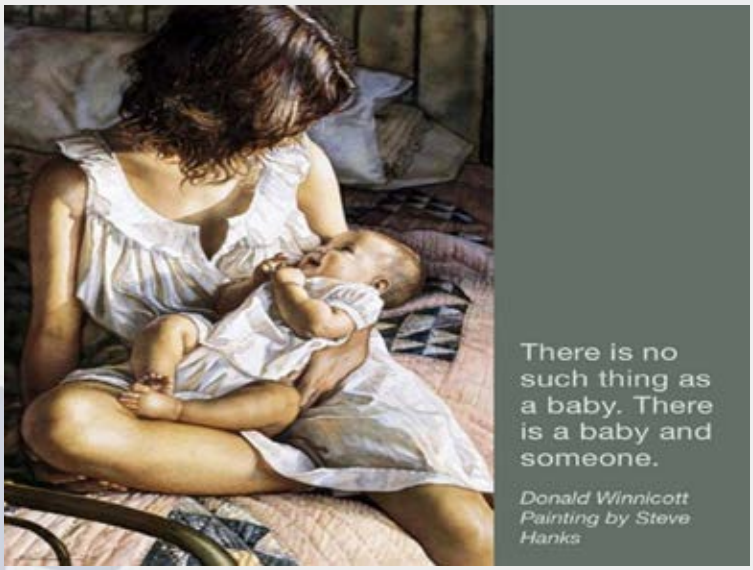
- How do I keep track of my input to the project?
  - A note book will be provide to you.
  - You can keep track of key point that arise in this.
  - We ask you put no identifying data in this book and keep it safe.
- How long is the research project?
  - The project will run for 2 years and has funding for this duration.
  - The end date will be June 2020.

NSW GOVERNMENT Health
Murrumbidgee
Local Health District

Frequently asked questions (FAQ)

- Once the research is over can I find out the outcomes from the research?
  - Yes, a report can be provided.
  - The research team will provide information sessions to the clinicians and present the findings.

NSW GOVERNMENT Health
Murrumbidgee
Local Health District



NSW GOVERNMENT Health
Murrumbidgee
Local Health District

Appendix G: Preamble Provided to Clinicians

Preamble for Clinicians Introducing *MumMoodBooster* Research

Within this Health Service we complete the Edinburgh with all women we see, as we have done with you. When women score between 13 and 25 it indicates possible postnatal depression. So it doesn't mean you have postnatal depression but people in that range often do. So I would like to tell you about some of the supports available to help you manage how you are feeling. Is that OK?

There are many support options available to you, including working with your GP, accessing counselling or online interventions. One of the online options you can do in the comfort of your own home is called *MumMoodBooster.* If you are interested in this option there is currently a research project involving using *MumMoodBooster* that you could participate in. Not only could this help you but could help other rural mums like you. And just for the first step they reward you with a $30 gift card.

This is totally voluntary, is it something you might be interested in?

(If yes go and get a participant pack)

This pack gives you all the information to go through in your own time and the contact details of Jo and Keryl/Chris who are part of the research team, if you have any questions about it. The key steps of participating would be:

- Once you have gone through the pack, you complete the consent and initial questionnaires. This is sent back to the research team in the reply paid envelope. You will receive a $30 gift card for this. Jo will contact you when she receives your consent form to arrange this to be sent to you.
- You participate in the 6 online session – So it is one a week, for 6 weeks. You can start and stop as you please and do at home. This is what will make you feel better.
- Complete 2 questionnaires again in 9 weeks. Jo will contact you about this and you relieve another $30 gift card when this done.
- Jo will contact you in 3 months and ask you to complete the two questionnaires again as well as a short interview with some of the research team. You will receive another $30 gift card when this is done.

You can choose to opt out at any stage and doing this doesn't mean you can't still talk to me, see your GP or counsellor.

So essentially we have 3 options at this stage:

1. You can say no and that's ok.
2. I can help you start and we can sign you up now if you are comfortable.
3. You can take the pack and have a bit of a read and a think.

If **Option 1** is chosen – Continue standard clinical care discussing other options that may suit the women. Let them know they can still use *MumMoodBooster* through the Mum Space website. Make notes in the provided notebook about any reason why or what happened ensuring all information is de identified.

If **Option 2** is chosen – allow women to read pack, complete consent form and 2 questionnaires. Explain that Jo is the project officer on the research project and you will be passing on their name and phone number to Jo who will contact them. It is also useful if you can find out if they prefer a phone call or text message and if there is a better day or time of day for this?

Thank them for signing up and assure them they will be supported and can still access other services. Tell them they are not locked in and just need to tell you/Jo/Keryl/Chris they no longer want to be part of it.

When finished pass details onto Jo – jcarlisle@csu.edu.au.

If **Option 3** is chosen - Book an appointment with them for approximately 1 week later to follow up on the decision – if answer is yes follow option 2 – if no follow option 1.

If there are any questions at any stage please feel free to call Jo on 0428452127 or Keryl 0477708100

This page is left blank intentionally

For further information about this research project
please contact MLHD-Research@health.nsw.gov.au