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Research Title:

The post-operative review as an opportunity to intervene for postnatal depression in mothers undergoing Caesarean section: A randomised controlled trial performed at North Shore Hospital, Auckland, New Zealand.

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Research Proposal

Summary

- Postnatal depression (PND) is a common disease affecting many mothers with serious health and social consequences.
- New Zealand data put the prevalence of maternal PND between 10-20%, although it is unclear how reliable these figures are.
- RANZCOG and international colleges firmly assert the value of screening early in the pregnancy and again in the early postnatal period with a validated tool such as the Edinburgh Postnatal Depression Scale (EPDS). Despite this, screening in the local population is conducted to varying standards.
- This randomised controlled trial seeks to determine whether a brief, standardised intervention, delivered by a Senior House Officer at the post-Caesarean section review, can reduce the rates of undiagnosed and untreated PND in the early postnatal period for mothers undergoing Caesarean section.
- Mothers randomised to the intervention group will be educated about PND, and given the resources to conduct their own PND screening using the EPDS, which is then linked to local support services with text message reminders
- Evaluation will be at postnatal week-8 where the EPDS will be applied to both the intervention and control arms, and mothers will be asked about PND therapy they may have accessed over the 8-week period.
- If the results are positive, the hope would be to extend the study to look at earlier and wider intervention, incorporating all modes of delivery, as well as the paternal/maternal partner population.

Introduction

Global data show the prevalence of maternal postnatal depression (PND) between 10-20%, a figure that changes by many variables including definition of severity, timing of onset, location of population, and socioeconomic status [1, 2]. The 2015 RANZCOG statement, 'Perinatal Anxiety and Depression', quotes Australian data to give a figure of up to 16% [3]. These figures are generally supported by New Zealand research, but robust evidence is lacking.

Major risk factors for the development of PND include: depression and anxiety in the pregnancy; psychiatric illness outside of pregnancy; relationship difficulties with one's partner; partner mental illness; lack of support structures; and pessimistic outlook towards the pregnancy [1, 3, 4]. From New Zealand data we can add

to these: relative youth; non-European ethnicity; low household income; and low parental education [5-7].

The question of whether obstetric complications and factors affect the rate of PND, particularly if the infant was delivered by Caesarean section, is contentious. One early study found that compared to those who delivered by either assisted or unassisted vaginal birth, those with an emergency Caesarean section had almost six times the risk of PND at three months postnatal [8]. A more modest association has been found in Australian data, which concludes differences in mode of delivery do not reach statistical significance for the development of PND [9]. This is supported by a recent international literature review that determined the link between Caesarean section and PND has not been conclusively established [10].

Consequences of PND can be substantial: as a result many will develop chronic illness, suffer from recurrent depression, and have poor relationships with their partners and children [3, 5]. It is sadly noted that suicide is now the leading cause of maternal mortality in New Zealand, and there is growing concern in the public arena that not enough attention is being given to identify and support those affected [11, 12].

PND in New Zealand: A Literature Review

Issues with New Zealand PND data make defining the scope of the problem very difficult. Furthermore, much of the local work on PND has gone into risk stratification, which is not a significant concern for this study, which seeks to apply a PND intervention in a non-risk stratified fashion.

These issues are clearly demonstrated by the following literature review. The databases used were Ovid, Scopus, PubMed, and Google Scholar. Key search terms were ("postnatal depression" or "postpartum depression") and (New Zealand). The eight relevant studies reviewed below are listed in descending chronological order.

1. Slykerman, R. F., Hood, F., Wickens, K., Thompson, J. M. D., Barthow, C., Murphy, R., ... & Stanley, T. (2017). Effect of lactobacillus rhamnosus HN001 in pregnancy on postpartum symptoms of depression and anxiety: a randomised double-blind placebo-controlled trial. *EBioMedicine*, 24, 159-165 [13].

This study, partially funded by Fonterra, evaluated the effectiveness of probiotics in preventing eczema in offspring as a primary outcome, and preventing maternal postnatal depression and anxiety as a secondary outcome. It was conducted in Auckland and Wellington, with women self-registering for the study following an advertising campaign. From 768 assessed for eligibility, 423 women were randomised to probiotic or placebo. Exclusion criteria included: non-English speaking; not

planning to breastfeed; serious medical or health problems relating to the pregnancy; and, geographical mobility during the pregnancy. The EPDS was applied at 6-12 months postnatally when the woman was asked to think back to 1-2 months postnatally and “complete the questions based on how they were feeling at the time”. The prevalence of PND (defined as an EPDS of 13+) in the treatment and placebo arms was 16.5% (n=32) and 23.5% (n=44) respectively. In terms of an accurate prevalence of PND, there are major concerns here regarding recruitment, population, exclusion criteria, and the retrospective way the EPDS was applied.

2. Underwood, L., Waldie, K. E., D’Souza, S., Peterson, E. R., & Morton, S. M. (2017). A longitudinal study of pre-pregnancy and pregnancy risk factors associated with antenatal and postnatal symptoms of depression: evidence from growing up in New Zealand. *Maternal and child health journal, 21*(4), 915-931 [14].

This study looked at 5,301 women, screened for EPDS in the third trimester, and then again at nine-months postnatal. Rates of antenatal depression (AND) and PND (defined as an EPDS of 13+) were 8.5% and 5% respectively. Concerns for this study include the time at which the postnatal screen was conducted (late in the postnatal period) and attrition rates that likely understate the prevalence of PND. As the study authors themselves admit, those known to have fewer risk factors for PND, in particular European ethnicity, well educated, and wealthy, were more likely to remain in the study.

3. Signal, T. L., Paine, S. J., Sweeney, B., Muller, D., Priston, M., Lee, K., ... & Huthwaite, M. (2017). The prevalence of symptoms of depression and anxiety, and the level of life stress and worry in New Zealand Māori and non-Māori women in late pregnancy. *Australian & New Zealand Journal of Psychiatry, 51*(2), 168-176. [15]

Women were recruited from 51 sites across New Zealand for this study focused on depression in the third trimester. Of the 1,837 women approached, 1,144 filled in the questionnaire. This found AND rates (defined as an EPDS of 13+) of 22.4% in Maori, and 15.3% in non-Maori. As this scale was not repeated in the postnatal period, it is not possible to calculate true PND prevalence, but the numbers are interesting to compare to the Growing Up in New Zealand AND figure of 8.5%, demonstrating large variation between the studies.

4. Health Promotion Agency. Postnatal Depression in New Zealand: Findings from the 2015 New Mothers’ Mental Health Survey. (2015). Website. [6]

This was an online cross-sectional survey of 805 women, recruited from a pool of 2,407 who had delivered within 2 years, with names provided by the organisation www.bounty.co.nz. This website provides a combination of information, advertising, and products to New Zealand mothers. From this pool, 1,770 were contacted by a fieldwork company, and incentivised to participate in the survey by being put in a draw to win electronic goods. Of these, 805 women completed the survey, and 14% screened positive for PND (defined as an EPDS of 13+). Significant issues regarding the recruitment process and participant retention make these numbers difficult to evaluate. Also, the timing of the EPDS, out to 2 years postnatally, with no ante-natal screen, is well outside of college guidelines, and makes any meaningful interpretation of the data problematic.

5. Thio, I. M., Browne, M. A. O., Coverdale, J. H., & Argyle, N. (2006). Postnatal depressive symptoms go largely untreated. *Social psychiatry and psychiatric epidemiology, 41*(10), 814-818. [16]

This study describes itself as a “one-wave postal survey” where the EPDS was mailed to a sample of all women in the Greater Auckland Metropolitan Region four months postnatally. The population was derived from perinatal care provider data. 744 women were contacted, 322 usable surveys were returned, and then all non-European responders were excluded due to concerns about language comprehension to leave a total of 225 replies. Of these 225 mothers, the rate of PND, (defined as an EPDS of 13+) was 16%. The issues with this study are multiple. The numbers analysed represent just over 30% of the original population, and the decision to exclude non-European responders would certainly understate the prevalence of PND. The timing is outside of college guidelines, and there is no baseline PND rate.

6. Abbott, M. W., & Williams, M. M. (2006). Postnatal depressive symptoms among Pacific mothers in Auckland: prevalence and risk factors. *Australian and New Zealand Journal of Psychiatry, 40*(3), 230-238. [5]

This study was part of the much larger Pacific Islands Families Study, which looked at 1,398 infants born at Middlemore Hospital in the year 2000 as well as their parents. The eligible population included all infants where at least one parent was of both Pacific Island descent and a New Zealand permanent resident. The recruitment rate was an impressive 87% of the total eligible population. The EPDS was applied 6 weeks postnatally, in the mother’s preferred language, as part of a 1-hour interview. The prevalence of PND (defined as an EPDS of 13+), was 16.4%. This was an excellent study, but there are difficulties with applying this figure to the population at North Shore Hospital, where the prevalence of Pacific Island mothers is substantially less. The study also did not contain a baseline measure.

7. McGill, H., Burrows, V. L., Holland, L. A., Langer, H. J., & Sweet, M. A. (1995). Postnatal depression: a Christchurch study. *The New Zealand Medical Journal*, 108(999), 162-165. [17]

This study was performed by way of postal questionnaires sent to and then returned by women 6 months after the delivering at Christchurch Women's Hospital in a year spanning 1991/1992. Participants were invited to join the study by a research assistant visiting the hospital every second day for 6 months until 2,000 consents were obtained. These 2,000 women were all contacted, and 1,330 replied (66%). There is no information given about who and how many refused to consent, or the characteristics of those women who did not return the questionnaire. Using the definition of PND as an EPDS of 14+, 13% screened positive. Using a score of 12-13, an additional 7% were considered to be on the threshold for depression. Concerns with this study include the poor rate of responders from the consented 2,000 patients, the inability to determine the actual population number due to the study not reporting the number of non-consenters, the lack of PND baseline measurement, and the significant time period between when the study was conducted and now (22+ years).

8. Webster, M. L., Thompson, J. M., Mitchell, E. A., & Werry, J. S. (1994). Postnatal depression in a community cohort. *Australian and New Zealand journal of psychiatry*, 28(1), 42-49. [18]

This was a longitudinal cohort study of Auckland women screened for PND by the Plunket Society and public health nurses at 4 weeks postnatally. The population pool was mothers who gave birth within a one-week period in the Auckland region. Of the 340 eligible mothers, 101 were excluded because English was a second language (mainly Pacific Island and Asian ethnicities), and a further 33 did not respond, leaving a total of 206 replies (60%). Using the definition of PND as an EPDS score of 13+, the prevalence of major depression in these women was 7.8%, with 13.6% experiencing more minor symptoms. This study was significant, in that it was the first New Zealand study to use the EPDS. It also demonstrated that the known significant risk factors for PND only predicted about 21% of those who developed either a major or minor depressive disorder, emphasising the need for global rather than risk stratified screening. Concerns with this study include the relatively poor response rate when compared to the total eligible population, the deliberate exclusion of ethnicities known to have higher rates of PND, the lack of PND baseline measurement, and the significant time period between when the study was conducted and now (23+ years).

PND Screening: The Australasian Context and the Edinburgh Postnatal Depression Scale

We turn now to a consideration of PND screening in the Australasian setting, and the primary screening tool for PND, the Edinburgh Postnatal Depression Scale (EPDS).

Despite various local guidelines, the observation made in the 2008 Health Services Assessment Collaboration (HASC) statement is still valid today; within the WDHB as nationally, there is not standardised and comprehensive screening for PND, with significant variations in practice [19]. During the exploratory phase of this proposal, an informal, open response survey was conducted among mothers via a local parent centre and playcentre. In 51 pregnancies, formal screening was applied by the LMC in 5 cases, the Plunket nurse in 2 cases, and the GP in 3 cases. A direct quote from one of the mothers spoke to this point: "It's actually quite amazing how inconstant the approach is to dealing with PND when you look at our responses. No wonder there are mums struggling out there!!"

At WDHB, the protocol, 'Maternal Mental Health Screening and Referral', recommends screening once in early pregnancy then again at 10-14 days postnatal [20]. In reality, this falls outside the practice of many hospital midwives and doctors, where patients come in after and leave before these times. Additionally, awareness of this protocol is low, with many midwives and all the obstetric registrars polled in focus groups not knowing of the protocol's existence. The WDHB booking form has a section for maternal mental health, shared with past medical and surgical history, but no designated space to record the implementation of PND screening. (There is a tick box for domestic violence screening). Whether a Lead Maternity Carer (LMC) decides to formally screen for PND is optional; while some do so rigorously, anecdotal and personal experience again suggest this is not universally the case. There have been suggestions that the Well Child Provider should make this a formal part of their practice, although this remains a little-implemented suggestion [19]. Whether or not the GP performs a formal screen is again recommended, but not routine [21].

The New Zealand College of Midwives (NZCOM) has no specific policy for screening for PND. A focus group conducted with NZCOM members suggests that while this may be forthcoming, there is little information available. At the time of writing, the NZCOM information on PND links to the now defunct webpage, www.mothersmatter.co.nz [22].

The RANZCOG statement referenced above states clearly that, "All pregnant women should be screened for psychosocial risk factors. Screening for perinatal mood disorders, in the form of a psychosocial assessment or

administration of a validated tool, such as the EPDS, should be considered part of routine antenatal and postpartum care” [3]. This is mirrored in the British National Institute for Health and Care Excellence (NICE) guidance that the screen be conducted at both the booking visit and the “early postnatal period” [2, 3].

In Australia, the National Perinatal Depression Initiative, instituted in 2008, started the process of universal screening for depression in the antenatal and postnatal period [23]. The expectation is that routine screening for PND, including the EPDS, is conducted at least once during pregnancy and then again around 4-6 weeks postnatally. The Queensland “Pregnancy Health Record”, for example, has specific boxes to record initial and repeat EPDS scores, with further boxes for additional EPDS applications, as well as mental health and social worker referrals [24].

Key to this study is the intent to identify and make the EPDS available to mothers in the early postnatal period. Endorsed by both RANZCOG and NICE, and included in Appendix F, the EPDS is the primary tool used globally to screen for PND [2, 3]. The EPDS 10-item questionnaire has been employed since 1987 and is available and validated in over 50 languages [25, 26]. Although typically self-administered, its application via phone is also supported in the literature [27, 28].

Sensitivity and specificity of a positive EPDS screen (a score of either 12+ or 13+ depending the study) is considered to be in the 80-90% range [29]. The EPDS is not strictly diagnostic, which requires formal psychiatric evaluation, but it does provide a quantitative result for the mother that is easily applied to care algorithms [6].

As demonstrated in the literature review above, a key variable in the New Zealand data for prevalence of EPDS-PND is the timing of screening: The Mental Health Survey looked at a postnatal population spanning a two year period; Abbott & Williams applied the scale at 6 weeks; Thio et al at 4 months; McGill et al at 6-9 months [5, 6, 16, 17]. For the intervention arm of this study, in lieu of an antenatal screen, the EPDS will be recommended to the mother at day one postnatal, and then again at 6 weeks postnatal.

The reason for choosing the 6-week mark to recommend self-screening to mothers, when the WDHB protocol suggests 10-14 days, is twofold. First, as argued by Thio et al, screening too early in the postnatal period can unfairly label as depression various emotions that are a normal response to having a new infant [16]. Second, the 6-week mark represents the intersection of midwifery and general practice care and is a clear temporal landmark where the mother is far more likely to access medical professional input.

For both the intervention and control arm of the study, the EPDS will be applied and recorded by study authors at the 8-week mark. This is within college guidelines.

We have not found any study to date, evaluating the post-Caesarean section debrief as an opportunity to intervene and screen for PND. One study considered a GP debrief in the first week postnatally and found that this did not improve mental health outcomes [30]. A more recent meta-analysis also found no benefit to early-postnatal follow up for maternal mental health [31]. Neither have we found any study looking at a package provided in the hospital setting and linked in with hospital resources designed to enable mothers to self-screen for PND. The value of such an intervention is therefore currently unclear.

Study Aims

The aim of this study is to see whether a brief, standardised intervention, delivered by a Senior House Officer (SHO) at the post-Caesarean section review, can reduce the rates of undiagnosed and untreated PND in the early (up to 8 weeks) postnatal period. The hope is to engage mothers of babies born by Caesarean section from the time of delivery and empower them to take ownership of their mental health care. The focus is not simply to prevent PND but also to make sure those at risk access the help they need.

There are several reasons for targeting this population. First, anecdotal evidence suggests that doctors do not routinely or adequately cover the issue of PND, despite evidence they are well positioned to do so [3, 32]. This may represent significant lost opportunity.

Second, the post-Caesarean section review offers doctors unique opportunities to intervene in the lives of the infant and its parents. Whether elective or acute, the time spent with the mother and her family usually allows the medical team to build high levels of trust. At the post-Caesarean section review, advice is routinely proffered on issues such as breastfeeding and future pregnancy planning, which is typically well received. For the hospital doctor, this often stands in contrast to physiological deliveries where the role of advisor is often exclusively held by the midwife LMC.

Third, there is some evidence that the post-Caesarean section population is at higher risk of PND, meaning that any interventions in a small study like this could yield higher returns than otherwise.

Fourth, the early postnatal period represents a time of maximal engagement with the medical profession. Mothers are under the immediate care of doctors and midwives at the hospital. This care is then picked up in the form of home visits by the LMC. At six weeks, the General Practitioner takes over with the routine baby check, and the Well Child provider, often a Plunket

nurse, comes into the picture. Rather than looking to introduce more opportunities for mothers to engage with the health system, it makes sense to utilise those already on offer.

Beyond this current study, the goal would be to make the case for implementing a postnatal PND intervention more widely. Getting buy-in would be a large undertaking. If the case is proved that a post-Caesarean section review intervention is effective, the argument would be more persuasive to expand the target population to consider all methods of delivery, include the antenatal period, and incorporate the maternal partner.

This study was originally intended to be an EPDS-PND prevalence study. As is clear from the local literature review, there are numerous problems with the data, meaning the prevalence of PND in the target population cannot be accurately estimated. However, we believe that a study such as this would unlikely be able to overcome the same difficulties. An attempt will be made to estimate the prevalence of early postnatal EPDS-PND by using the responses of the control group at week 8, but it is not anticipated that this will produce an accurate figure. In addition, the major drawback to a prevalence study is that even if the numbers were accurately obtained, this brings us no closer to having a meaningful intervention to employ.

Research Methodology

Setting, Population, Design, and Recruitment

This will be a randomised controlled study, conducted at the Maternity Suite, North Shore Hospital, Waitemata District Health Board, New Zealand (NSH, WDHB), from 2019-2020.

The eligible population will be mothers of infants delivered by public Caesarean section identified from the Maternity Ward postnatal register.

The exclusion criteria will be: mothers transferred out of NSH (for example to a primary birthing unit) prior to being seen on the maternity ward; mothers not immediately admitted from the operating theatre to the maternity ward (for example those requiring admission to the intensive care unit); mothers unable to sign the operative consent form without use of an interpreter; mothers directly cared for in labour or during delivery by the study authors; mothers currently under the care of WDHB mental health services.

Study authors will assemble the list of publicly performed post-Caesarean section mothers prior to morning handover, apply the exclusion criteria, then recruit to the study using the 'Participant Information Sheet', Appendix A, and 'Participant Consent Form', Appendix B. Consenting mothers will then be

randomised to either the control or intervention group using a validated randomisation app with simple randomisation technique, namely a coin toss with heads to the control group, and tails to the intervention group [33]. Mothers will be informed of their allocation immediately

Basic demographic information will be gathered for the index pregnancy from the hospital booking form and the online record. This will be recorded on the 'Study Enrolment Form', Appendix C. This form will also act as the cover page to each study case, outline the details of the delivery, record the randomisation allocation, record the SHO conducting the debrief, and ultimately record the details from the Week 8 follow up and beyond. Basic demographic information will also be collected on patients who decline to take part in the study, to ensure that any conclusions drawn are not inappropriately generalised to groups of patients who may have been more likely to decline.

The maternity ward SHO of the day, with appropriate instruction and supervision from a study author, will then conduct the post-Caesarean section review. Those in the control group will receive the standard review that does not mention maternal mental health, as outlined in Appendix D. Mothers in the intervention group will receive the same review with the addition of specific PND education and advice, Appendix E, and an information pack, Appendix F. These information packs are largely adapted from the WDHB protocol and have been customised in response to feedback from focus groups with local mothers, many of whom have personally dealt with PND. Feedback was also incorporated from WDHB Pacific, Asian, and Maori mental health services, with Maori input discussed in further detail below. Before conducting the study, Appendix F as it currently stands will be re-packaged by an advertising specialist with an interest in maternal mental health, with the content remaining largely unchanged.

Three reminders will be sent to mothers in the intervention group via text message at Day 2, Week 3 and Week 6 postnatally. For this study, text messages will be sent manually by a study author from a dedicated cell phone, which will also be used study contact number. This process could easily be automated if results lead later to a larger scale implementation of the intervention. These text messages will remind the mother to complete the two EPDS questionnaires and link to online resources via hypertext. They are contained in Appendix G.

Evaluation will be conducted by a study author at 8 weeks post-Caesarean section with a +/- 6-day period of leeway. The reason for conducting the recruitment at 8 weeks is to account for mothers who may book late for their child's 6-week GP check. A text message will be sent to the mother, informing her that a study author will phone her at a pre-determined time that evening, or at an

alternative time of her choosing, as per Appendix G. A hyperlink to an online EPDS will be sent to the mother in the text message, and she will be asked to follow the link and complete the questionnaire prior to the phone call. If she is unable to follow the link, then the EPDS may be administered verbally via phone.

Participants will be considered lost to follow up if they are unable to be reached on three successive days by a confirmed valid contact phone number, or if they decline at any stage to participate further in the study.

A debrief letter will be sent via email, or post if they chose, to all mothers who receive a follow up phone call, as per Appendix L and Appendix M. The main purpose of this debrief is to address the first of the ethical considerations discussed below, namely the gap between the recruitment statement “aspects of maternal mental health”, and the actual focus of the study, PND. Those in the intervention group will be asked further questions to evaluate the intervention. Those in the control arm will receive a copy of the complete intervention (discussion, information package, and text messages). This debrief letter will be customised depending on whether the mother has required a referral to primary or hospital services.

Outcomes

This study has two primary outcomes.

1. The prevalence of EPDS-PND, defined as a score of 13 or more, in mothers at 8 weeks post-Caesarean section.
2. The incidence of mothers started on evidence-based treatment for PND, namely appropriate psychological or pharmacological therapy as outlined in the BPAC NZ article “Postnatal Depression”, in the 8 weeks following Caesarean section [21].

Subgroup analysis of the results will be made with regards to Caesarean category, maternal age, maternal ethnicity, parental relationship status, maternal residency status, maternal mental health history status, family violence screen status, maternal parity and whether she had a previous Caesarean section. With regards to ethnicity, the prioritisation order will be Maori, then Pacific, then Asian, and then New Zealand European/Other, as recommended by the New Zealand Ministry of Health [6, 34].

An attempt will be made to estimate prevalence of EPDS-PND in the early postnatal period based on the results of the control arm week 8 EPDS.

Self-completed EPDS scores will be obtained where possible, to see if the immediate postnatal EPDS has any positive predictive power for the week 8 EPDS-PND.

Statistical Considerations

The information and considerations in this section have been developed in consultation with Dr Wayne Miles (Director) and Hamish Neave (Biostatistical Analyst) at the WDHB Research and Knowledge Centre.

To power this study for an 80% chance of a statistically significant result for an estimated risk ratio of 0.5, and assuming a control group incidence of 20% PND as supported by the literature, the minimum sample required will be 430 participants completing follow up, with at least 215 participants in each arm of the trial. This calculation was completed with the OpenEpi Version 3, open source calculator [35].

To calculate the length of time required to gather study data, a two-month review of Maternity Ward records was conducted, which showed the average number of eligible cases per working week to be 16. This will mean a total of around 30 study weeks, or around 140 study days. The study is planned to be run over a 2-year period.

Results for the primary outcomes will be presented using Chi-squared analysis. It is likely that this format will also be used for sub-group analysis; however, it may also be possible to use a logistic model which is preferred but cannot be confirmed until data is gathered.

Information and Privacy

On each study day, study authors will be involved reviewing and screening health information to identify potential participants and to collect demographic information. For confidentiality and safety, these hard-copy clinical records will only be reviewed on the ward.

During the study, only study authors and supervisors will have access to the information gathered. Hard copy data will be kept in a secure filing cabinet at Northshore Hospital. Electronic data will be kept on the WDHB hospital database

After the study, hard copies of the study data will be kept in WDHB clinical records, and electronic copies kept on the WDHB hospital database. There will be a linking document where identifying information is coded, and the code kept in the database. The coded information and the code will be physically separated. In accordance with the Health (Retention of Health Information) Regulations 1996, information will be stored for 10 years.

Publication of results will not be in a form that identifies or could reasonably be expected to identify individual participants.

Ethical Considerations

The study authors have identified five main ethical issues raised by this study.

First, is the plan not to state in the recruitment phase that this research is looking at PND specifically, rather to use the more general term “maternal mental health”. There is good reason to think that a consent process that explained PND would seriously compromise this study, confounding data from the outset. As discussed above, the proposed intervention package centres on increasing a mother’s awareness of PND and then using this to promote access to support resources. Explaining PND to any extent in the recruitment phase would achieve this outcome. To prove that the intervention does or does not work, it cannot be the case that the intervention is essentially applied by study authors to both groups prior to a mother even consenting to be part of the study

The request for a degree of concealment in the recruitment phase was taken on advice from Dr Wayne Miles and presented openly to the New Zealand Health and Disability Ethics Committee (HDEC) for their consideration. Originally, a higher degree of concealment was requested, to be able to explain the study as being about the evaluation of post-Caesarean section discharge planning and follow up, without specifying that mental health or PND was the focus. This was considered a reasonable request as we considered the intervention to have an extremely low risk of causing harm to participants. Following discussion with HDEC, it was agreed that this approach had the potential to cause mothers to feel deceived and undermine confidence in the health system. It was also agreed that using the term “maternal mental health” generally was a fair compromise. To further alleviate any concerns, a written debrief will be provided to all women following the Week 8 Follow Up, whether in the intervention or control arm, re-explaining the purpose of the study, and providing an opportunity to feed back any concerns or questions they may have (Appendix L and Appendix M). This was considered essential by HDEC to bridge any gap a patient may have felt between recruitment and the conduct of the study. In the case that a woman feels unhappy with this process, and as the PIS makes clear, the woman is free to withdraw from the research at any time, and to withdraw their data at any time.

A second ethical issue is the process of providing the EPDS to mothers to complete and score themselves. There is potential for mothers to make a positive diagnosis of PND and not follow up appropriately, or to incorrectly make a negative diagnosis and be falsely reassured. This concern is raised by HASC who argue that screening “creates an expectation of care”; it may be considered unethical to identify potential cases of PND if they are not adequately followed up [19]. A related concern, raised in the South Australian Maternal and

Neonatal Clinical Network, is that questionnaires should only be used by psychometrically trained staff [36].

In response to these concerns, we note that that all the information contained in the information package is readily available and freely accessible to any patient using a basic internet search engine. The first six entries returned on Google searching for ‘Postnatal depression NZ’ are: depression.org.nz; mentalhealth.org.nz; plunket.org.nz; health.govt.nz; healthnavigator.org.nz; and bpac.org.nz. To briefly consider each: depression.org.nz contains PND screening questions, and online PHQ-SADS and GAD-7 questionnaires; mentalhealth.org.nz contains PND screening questions, references the EPDS, and links to online PHQ-SADS, and GAD-7 questionnaires; Plunket contains PND screening questions and links to depression.org.nz which in turn contains the online PHQ-SADS, and GAD-7 questionnaires; health.govt.nz contains PND screening question and links to postnataldistress.co.nz where an online EPDS questionnaire is available; healthnavigator.org.nz contains PND screening questions and an online EPDS questionnaire; bpac.org.nz contains in-depth discussion of all aspects of PND, with screening questions, discussion of treatment, and an online EPDS questionnaire. The EPDS itself is available in many iterations with accompanying information simply by Googling, “EPDS”. It is clear then, that the information package contains no more potentially dangerous information than is freely and publicly accessible on any computer or smartphone. What the package does offer is proper context for the information, linking into local support structures and networks, and within the natural timeframes of ongoing midwifery and doctor support.

Further measures to address this concern include an independent data safety monitoring committee who will oversee study results at regular intervals. This is to ensure that the study is neither demonstrating poorer outcomes for the intervention group compared to the control group, nor are the outcomes for the intervention group so positive that the study should be terminated early and the intervention immediately become standard care. The panel will consist of a WDHB psychiatrist, Dr Frederick Sundram and a WDHB Maternity Ward Charge Midwife, Bronagh Scott. Results will be submitted to the committee by the study authors at intervals of 50 data sets. The data will be presented as the percentage positive for the outcome in each arm of the trial, as a running total. After discussion with the WDHB statistical team, it has been decided that it is not currently possible to determine strict criteria for when study termination should occur. Rather than artificially, and somewhat arbitrarily set parameters, this will be left to the discretion of the expert committee. If either committee member has concerns, then they agree to contact the WDHB Research and Knowledge Centre, who will analyse the data, determine if the differences reach statistical significance, and whether or not the trial

should be stopped. On the advice of the WDHB Clinical Governance Committee, if a woman feels unable to access help so that she contacts the authors directly, this will be considered an adverse outcome and be recorded and reported discretely. All study participants will be given an email address to contact the authors directly, and this will be reemphasised through the study.

A third ethical issue raised is deliberately not discussing mental health issues, and withholding the information package, from those in the control group.

In response we note that this is the reality of the SHO post-Caesarean section review as it currently stands, and so represents treatment as usual. We point out that the study design does not prevent a midwife or anyone else asking about a mother's mental wellbeing or administering the EPDS as they see appropriate. It in no way stops any mothers in the control group from accessing the care that they would otherwise have received. By conducting the study in the proposed fashion, the hope is that there will be an evidential base for insisting that the intervention occurs at every review, a base that is currently lacking. In addition, at the Week 8 mark, the intervention will be offered to all patients in the study, which is still considered early postnatal and therefore within college guidelines.

A fourth ethical issue raised by the study is that of excluding mothers unable to sign the operative consent form without use of an interpreter. While criticism has been levelled at other studies in the literature review above for taking similar measures, this is considered appropriate in the current setting for two reasons: One, the study is not a prevalence study, so excluding these mothers will not influence the primary outcomes; Two, the financial backing required to use interpreters and translators is inhibitive in an unfunded study. The fundamental question of whether the post-Caesarean section review is suitable for PND intervention is the focus at this stage, as opposed to reaching all mothers who may benefit. If the intervention is proved to be worthwhile, then the next stage would involve procuring funding to make the intervention accessible to all WDHB mothers. We also note that this measure does not go as far as Webster et al, for example, who excluded all mothers for whom English was not their primary language [18].

A fifth ethical issue raised by this study is how appropriately to manage those mothers who screen positive for EPDS-PND at the 8-week postnatal follow up.

During the recruitment process, consent will have been obtained for a mother's GP or WDHB services to be informed about her participation in, and of any significant abnormal results obtained during, the study. Therefore, the process outlined in the WDHB protocol referenced above, 'Maternal Mental Health Screening

and Referral', will be followed with verbal confirmation of consent from the mother.

Women with an EPDS score of 10-13 (note that this includes the study-designated EPDS positive score of 13) will be referred to their GP via a prioritised WDHB referral letter copied to the patient who will be advised to see their GP within the next week, as per Appendix J. The referral letter will reiterate the community resources available to the woman, as outlined in Appendix F.

Women with an EPDS score of 14 or more and those who score strongly positive answers to Question 10 indicating serious risk of harm to self or others will have a prioritised WDHB referral letter sent to the WHB Mental Health Services, copied to the GP and the patient, as per Appendix K

Those considered at immediate risk of harm to self or others will be referred via phone, with or without the patient's express consent, to the appropriate WDHB mental health crisis team and potentially emergency services. This will be backed up by a referral letter to the WHB Mental Health Services as described above, noting that the patient will have already been referred to the crisis team.

Oversight and supervision will be provided Dr Aram Kim, FRANZCP, and Dr Wendy Burgess, FRANZCOG.

The New Zealand Health and Disability Ethics Committee process for receiving ethical approval as well as the WDHB research approval process have been followed.

Tikanga Maori and the Treaty of Waitangi

The study authors recognise that Maori do not experience equitable mental health outcomes compared to Pakeha generally, and with regards to PND specifically [15, 37]. This represents a significant failing under Treaty of Waitangi obligations.

The methodology of this study is underpinned by the principles enshrined in the Treaty, both for the population generally, and Maori specifically. Partnership and participation are guaranteed in Articles One and Two of the Treaty, working with Maori to achieve good health outcomes and involving Maori in the planning and delivery of health services [37]. This study explicitly seeks to partner with all mothers in the study population, and actively encourages their participation in their mental health care. The Director of Maori Health Research across the Waitemata and Auckland DHBs, Dr Helen Wihongi, was consulted during the research proposal stage, and her advice has been incorporated into the final proposal. WDHB Maori Mental Health services are linked into the information package, along with other cultural services.

Article Three of the Treaty guarantees protection, including at least equal health care outcomes for Maori compared to Pakeha; Article Three also emphasises respect for taonga, cultural treasure, and Tikanga Maori, the “Maori Way” [37]. One of the important data sets from this study will be outcomes by ethnicity; data that are not currently available for the study population. Ethnicity will be collected as part of the patient information, and sub-group analysis by Maori and other ethnicities is planned. A review of recent WDHB data indicates that the number of study participants who will be Maori is likely to be low. In the calendar year 2017, 85 of the 1,472 mothers undergoing Caesarean section were Maori, making the prevalence around 6%. Despite this, if discrepancies between Maori and Pakeha are discovered, we intend to work further with Dr Wihongi to redesign, more appropriately our intervention. The authors are aware of the work by Te Kani Kingi and Mason Durie, “Hua Oranga: A Maori Measure of Mental Health Outcomes”, and appreciate that this could be a very valuable resource to guide future study and intervention [37].

Declaration of Potential Conflicts of Interest

The study has no external source of funding. Financial approval has been given by WDHB Chartered Accountant, Heidi Zhang.

Neither the Co-ordinating Investigator, nor any Co-Investigators, nor any direct members of their families have any commercial interest in the intervention to be studied, or any financial relationship to the study sponsor that may inappropriately influence his or her conduct in the study.

Neither the Co-ordinating Investigator nor any Co-Investigator will be remunerated for their involvement in the study in a way that may inappropriately influence his or her conduct in the study, for instance, bonuses for favourable results or high recruitment rates.

Appendix A: Participant Information Sheet (PIS)

Study Title: Mental health post-Caesarean section
 Locality: North Shore Hospital, New Zealand
 HDEC Ethics Committee Reference: 18/NTB/162
 Lead Investigator: Dr Richard Carpenter
 Contact Phone Number: 021 0838 8437

You are invited to take part in a study looking at aspects of mental health and wellbeing for women who have had a Caesarean section after they have leave hospital and return to the community.

Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document.

This document is 2 pages long, including the Consent Form. You will be given a copy of this document to keep. Please make sure you have read and understood all the pages.

What is the purpose of the study?

The purpose of this study is to look at how we support the mental health and wellbeing of women who have had a Caesarean section over the first 8 weeks from the operation. We know this can be a time of significant adjustments and want to see if we can improve the care in this period.

What will my participation in the study involve?

You have been chosen to participate in this study, because you have given birth via Caesarean Section at North Shore Hospital. The extent of your participation will depend on whether you are randomly assigned to the intervention or the control group. This will in no way affect the normal postnatal care given to you by the ward staff, your midwife, your GP, or any other health professional.

If you are assigned to the intervention group, you will receive an information package to read through in hospital, which should not take more than 10 minutes. We will then send three text reminders during the 6-week period after you leave hospital linking back to this information. To protect the study, we ask please that you do not share this information with other mothers either on the Maternity Ward or in the community.

Whichever group you are allocated to, we will contact you 8 weeks from now via text message and ask you to answer a 5-minute online questionnaire, which will be followed up with a 5-minute phone call. A written study debrief will be sent to you following this phone call by email, or letter if you prefer.

Health information will be collected from these questionnaires and by accessing medical records. All information will be treated with the highest respect for privacy and confidentiality.

What are the possible benefits and risks of this study?

If you are in the intervention group, there is good reason to think that the information and follow up you receive will help you in the first months of your new baby's life. If you are in the control group, we will provide you with the same information 8 weeks from now and expect that it will still be of significant use.

Although we do not think there will be any substantial risks by taking part in this study, the results will be monitored to ensure that those in the intervention group are not in any way disadvantaged compared to those receiving standard care.

If you were injured in this study, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

Who pays for the study?

You will not incur any costs by taking part in this study. This study is not funded by any external agency, and the study authors are in no way financially benefiting from this research.

What are my rights?

Taking part in this study is voluntary, you are free to decline to participate. You are also free to withdraw from the research at any time, and to withdraw your data at any time. No decision you make will compromise your relationship between the healthcare community and the investigators and the research. You have the right to access information collected about you as part of the study. You will be told of any new information about adverse or beneficial effects related to the study that may have an impact on your health. You have the right to privacy and confidentiality as guaranteed under the Code of Health and Disability Services Consumers' Rights.

What happens after the study?

The study findings will hopefully be published in a peer-reviewed medical journal, as well as discussed at scientific conferences and distributed within the Waitemata District Health Board. The final copy of this research should be completed by 2021. If you want, it can be sent to you via email or post.

Study data will be stored in the hospital records system. The co-ordinating investigator will be responsible for its storage and destruction after 10 years, as is standard for such research.

Who do I contact for more information or if I have concerns?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Dr Richard Carpenter,
Obstetrics Registrar and Co-ordinating Investigator
Phone: 021 0838 8437
Email: MMH.Research@waitematadhb.govt.nz

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

For Maori health support please contact :

He Kamaka Waiora
Phone: (09) 486 8324 ext 3553
Email: hekamakawaiora@waitematadhb.govt.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS
Email: hdecs@moh.govt.nz

Appendix B: Participant Consent Form

Please tick to indicate you consent to the following

I have read or have had explained to me and I understand the Participant Information Sheet.	Yes <input type="checkbox"/>	
I have been given sufficient time to consider whether or not to participate in this study.	Yes <input type="checkbox"/>	
I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.	Yes <input type="checkbox"/>	
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.	Yes <input type="checkbox"/>	
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.	Yes <input type="checkbox"/>	
I consent to the research staff collecting and processing my information, including information about my health.	Yes <input type="checkbox"/>	
If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
I consent to my GP or current care provider being informed about my participation in the study and of any significant abnormal results obtained during the study.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.	Yes <input type="checkbox"/>	
I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.	Yes <input type="checkbox"/>	
I know who to contact if I have any questions about the study in general.	Yes <input type="checkbox"/>	
I understand my responsibilities as a study participant.	Yes <input type="checkbox"/>	
I wish to receive a summary of the results from the study.	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Declaration by participant:

I hereby consent to take part in this study.

Participant's name:

 Signature: _____ Date: _____

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it. I believe that the participant understands the study and has given informed consent to participate.

Researcher's name:

 Signature: _____ Date: _____

Appendix C: Study Enrolment Form

Inclusion/Exclusion Criteria:

Inclusion Criteria:	Public Caesarean section
Exclusion Criteria:	Transferred prior to review; Not admitted directly to maternity ward; Unable to sign consent without interpreter; Author directly involved in labour care; Currently under WDHB MMH

Participant Identifiers:

Study Case Number:	
Maternal NHI:	
Cell Phone Number:	
Preferred Contact Address (Email or Post):	

Recruitment, Consent, & Allocation

Date Recruited	
Recruiter	RC / EM / AP
Study Allocation Group	Control / Intervention / Declined
SHO Conducting Review:	
Request Copy of Study Results	Post / Email / No
Consents to GP or WDHB Notification	Yes / No

Demographic Information from WDHB Booking Form:

Caesarean Section Category:	Elective / Emergency
Prioritised Maternal Ethnicity:	Maori / Pacific / Asian / NZ European or Other
Maternal Age:	<25 / 25-34 / >34
Maternal Residency Status:	NZ citizen / NZ permanent resident / 2 year work permit / Other
Parental Relationship Status:	Married or Civil Union / Defacto / Separated / No relationship / Other
LMC:	WDHB / Self-employed
Maternal Mental Health History:	Yes / No / Not completed
Family Violence Screen	Yes / No / Not completed
Parity:	1 / 2 / 3 / 4+
Previous Caesarean Section:	No / 1 / 2 / 3 / 4+

Week 8 Follow Up: Control Group

Days +/- W8 Contact Made	-6-4 / -3-1 / 0-2 / 3-5 / 6-8, 9-11 / Lost / Withdraw
Outcome 1: Total EPDS Score	
Outcome 1: Q10 EPDS Score	
Referral Required to MMH or GP	Compulsory / Yes / Declines / No / Completed
Outcome 2: Appropriate PND Treatment?	Medication / Therapy / Both / No

Week 8 Follow Up: Intervention Group

Days +/- W8 Contact Made	-6-4 / -3-1 / 0-2 / 3-5 / 6-8, 9-11 / Lost / Withdraw
Outcome 1: Total EPDS Score	
Outcome 1: Q10 EPDS Score	
Referral Required to MMH or GP	Compulsory / Yes / Declines / No / Completed
Outcome 2: Appropriate PND Treatment?	Medication / Therapy / Both / No
D1 EPDS	
W6 EPDS	

Debrief Feedback/Other:

Used Study Email as Felt Unable to Get Help	Yes / No
Appropriate Debrief Sent	
Concerns with Recruitment Process	Yes / No / No Reply
Package Helpful?	1 / 2 / 3 / 4 / 5 / Not Read
Texts Helpful?	1 / 2 / 3 / 4 / 5 / Not Received
Mind the Bump Helpful?	1 / 2 / 3 / 4 / 5 / Not Downloaded
Other Feedback:	

Appendix D: Standard Caesarean Section Review for Control Group

Operation Details:

- Date and time of operation
- Category and indication
- Complications including estimated blood loss and specific post-operative instructions
- Suitability for VBAC

Patient Background:

- Relevant medical history
- Relevant complications in the pregnancy
- Pre-operative haemoglobin and blood group

Observations:

- Full set of current vitals and any concerning readings or trends

Subjective History:

- Maternal concerns and questions. Debrief and explain operation as indicated
- Check mobility, whether eating and drinking, whether passed urine and flatus, whether pain controlled and if managed to get sleep, whether initiated breastfeeding, whether any concerning vaginal bleeding or vaginal discharge

Objective History:

- General examination as indicated: Checking at least level of distress, level of consciousness, peripheral perfusion, presence of TED stockings, and the presence of any medical devices such as drains, IDCs, and IVLs.
- Abdomen: Inspect, palpate, percuss, auscultate, noting especially location and tone of uterus, whether any abdominal distension or pain, whether bowel sounds are active, and whether there is any excessive ooze or bleeding from wound
- Pad check: Check lochia and vaginal bleeding

Assessment:

- Specific concerns
- Whether or not to remain under obstetric care or if suitable for discharge to midwifery care

Hospital Plan:

- Arrange for operator to review patient as needed
- Assess for MDT involvement, for example social work, physiotherapist.
- VTE prophylaxis
- Analgesia instructions including need for on-going pain team involvement
- Advice regarding mobility, eating and drinking, urine and bowel monitoring
- Assess the need for iron or blood replacement
- Indication of length of stay required in hospital

Discharge Advice:

- Explain indications for return to hospital including increasing pain, increasing bleeding, foul discharge, and symptoms of systemic infection
- Wound cares and follow up required
- No heavy lifting for 6 weeks, initially nothing heavier than baby
- No driving for at least 2 weeks, and up to 6 weeks depending on insurance policy
- Advice regarding suitability for VBAC and least an 18-month interval between pregnancies to allow uterine healing. At same time, provide contraceptive advice, with consideration to breastfeeding
- Advise to breastfeed exclusively for at least 6 months due to maternal and fetal benefits, and mixed feeding up to a year if possible. Explain midwives are available for help and further advice with this.
- Any specific advice due to index pregnancy complications, for example regarding diabetes or hypertensive disorders of pregnancy, their implications for the postnatal period, future pregnancies, and long term maternal health.

Appendix E: Modified Caesarean Section Review for Intervention Group

[Initially as per Appendix D, with the addition of the following]

- Explain that PND is a common condition affecting up to 20% of mothers. Explain that early recognition is key and that there is good help available. Provide the information package to mother. Explain that the package contains links to information and advice for where to get help if needed. Encourage her to read the package and complete the relevant sections at the appropriate time. Inform her that if she has any questions about the package, she can ask to speak to the on-call SHO at any time while in hospital.

Appendix F: Intervention Group Hand-out

Introduction:

Congratulations! This is an exciting time as you adjust to the addition of new life, with all the joys and challenges he or she will bring. During this period, it is our job to make sure that you and your family are kept well in all respects, including your mental health and wellbeing. We thank you for agreeing to be part of our study looking at how we can do this better.

Most women go through the first year after giving birth with no significant concerns for their mental health. However, some mothers have symptoms that do cause trouble, such as:

- feeling low or sad
- losing interest and pleasure in doing normal things
- feeling irritable or angry for no reason
- feeling worthless or guilty
- experiencing excessive worry and even panic attacks.

Between 60-90% of mothers experience some of these symptoms early in the postnatal period, typically around days 3-5, which is known as the 'baby blues'. However, when these symptoms persist, they can mean a mother is suffering from postnatal depression (PND) which affects up to 20% of mothers in the year after giving birth. If this happens to you, it is not your fault, you are not alone, and we do care.

The purpose of this package is to educate you how on to monitor your own mental health and wellbeing, and to show you where to get help if it is needed. We use a questionnaire called the Edinburgh Postnatal Depression Scale that is very good at identifying mothers at risk of having PND. A negative result (12 or less) is about 90% accurate for ruling it out, and a positive result (13+) about 90% accurate for ruling it in.

What to Do:

1. In the next few days, ideally before you leave hospital, please read over this booklet and answer the questions on Page 2.
2. In six weeks' time, ideally before baby's GP check-up, please answer the questions on Page 3.
3. It may help to set a reminder on your phone or calendar now to help you remember to do the six-week questionnaire. We understand that papers can be difficult to keep track of and may get lost among all the information you have been given. Fortunately, the questionnaires are available online, and an explanation for how to access this will be sent to you via text in the next week.
4. A good strategy to help reduce the risk of developing PND is to download and work through the mobile app, "Mind the Bump", which is available on Google Play Store, and The App Store. This is a free mindfulness meditation program for new parents, designed to help you see more clearly and deal more skillfully with the pressures of being a new (or again!) mother.

If the results of your answers prompt you to seek help, you can be assured that this is the best available advice linking you into the best available resources. If you have any questions about this package while you are in hospital, please ask to speak to the maternity ward Senior House Officer, who will be happy to assist. You are surrounded by people who want the very best for you, your baby and your family. Again, congratulations, and good luck!

The Day One Edinburgh Postnatal Depression Scale

As soon as possible after receiving this booklet, please read over the list below and circle the that comes closest to how you have felt in the past seven days, not just how you feel today, then add up the numbers for your total score.

1. I have been able to laugh and see the funny side of things.	As much as I always could Not quite so much now Definitely not so much now Not at all	0 1 2 3	6. Things have been getting on top of me.	Yes, most of the time I haven't been able to cope at all Yes, sometimes I haven't been coping as well as usual No, most of the time I have coped quite well No, I have been coping as well as ever	3 2 1 0
2. I have looked forward with enjoyment to things.	As much as I ever did Rather less than I used to Definitely less than I used to Hardly at all	0 1 2 3	7. I have been so unhappy that I have had difficulty sleeping.	Yes, most of the time Yes, sometimes Not very often No, not at all	3 2 1 0
3. I have blamed myself unnecessarily when things went wrong.	Yes, most of the time Yes, some of the time Not very often No, never	3 2 1 0	8. I have felt sad or miserable.	Yes, most of the time Yes, sometimes Not very often No, not at all	3 2 1 0
4. I have been anxious or worried for no good reason.	No not at all Hardly ever Yes, sometimes Yes, very often	0 1 2 3	9. I have been so unhappy that I have been crying.	Yes, most of the time Yes, quite often Only occasionally No, never	3 2 1 0
5. I have felt scared or panicky for no very good reason.	Yes, quite a lot Yes, sometimes No, not much No, not at all	3 2 1 0	10. The thought of harming myself has occurred to me.	Yes, quite often Sometimes Hardly ever Never	3 2 1 0

Score 0-9

Score 10-12

Score 13+ or
Q.10 = 2-3

This is a low risk score for PND. We encourage you to be mindful of your mental health and wellbeing and remember to repeat this questionnaire in six weeks' time.

This predicts mild to moderate risk of significant anxiety and depression. Please discuss this result with your midwife or ask to speak to the on-call Senior House Officer. It may be useful to look at the online resources listed on Page 4.

This predicts a high chance of significant anxiety and depression and requires follow up. Our strong advice is talk to a doctor (in hospital or your GP), as well as your midwife. The online resources listed on Page 4 may also be beneficial.

The Week Six Edinburgh Postnatal Depression Scale

Six weeks after giving birth and before seeing the GP for baby's check-up, please read over the list below and circle the that comes closest to how you have felt in the past seven days, not just how you feel today, then add the numbers for your total score.

1. I have been able to laugh and see the funny side of things.	As much as I always could Not quite so much now Definitely not so much now Not at all	0 1 2 3	6. Things have been getting on top of me.	Yes, most of the time I haven't been able to cope at all Yes, sometimes I haven't been coping as well as usual No, most of the time I have coped quite well No, I have been coping as well as ever	3 2 1 0
2. I have looked forward with enjoyment to things.	As much as I ever did Rather less than I used to Definitely less than I used to Hardly at all	0 1 2 3	7. I have been so unhappy that I have had difficulty sleeping.	Yes, most of the time Yes, sometimes Not very often No, not at all	3 2 1 0
3. I have blamed myself unnecessarily when things went wrong.	Yes, most of the time Yes, some of the time Not very often No, never	3 2 1 0	8. I have felt sad or miserable.	Yes, most of the time Yes, sometimes Not very often No, not at all	3 2 1 0
4. I have been anxious or worried for no good reason.	No not at all Hardly ever Yes, sometimes Yes, very often	0 1 2 3	9. I have been so unhappy that I have been crying.	Yes, most of the time Yes, quite often Only occasionally No, never	3 2 1 0
5. I have felt scared or panicky for no very good reason.	Yes, quite a lot Yes, sometimes No, not much No, not at all	3 2 1 0	10. The thought of harming myself has occurred to me.	Yes, quite often Sometimes Hardly ever Never	3 2 1 0

Score 0-9

Score 10-12

Score 13+ or
Q.10 = 2-3

This is a low risk score for PND. We encourage you to be mindful of your mental health and wellbeing over the coming months and wish you all the best.

This predicts mild to moderate risk of significant anxiety and depression. It would be a good idea to mention this to your GP when you go for baby's check-up; they can organise appropriate follow up which may consist of repeat this questionnaire in a few weeks' time. It may be useful to look into the online resources listed on Page 4 if you have not done so already.

This predicts a high chance of significant anxiety and depression and requires follow up. Please take this questionnaire to your doctor when you go for baby's check-up. It may be useful to look into the online resources listed on Page 4 if you have not done so already.

Important Information:

- If at any stage you are unable to contact your GP or midwife, or it is not possible to get an appointment in good time, then you can call the WDHB Mental Health Services, preferably in business hours. The numbers are 09 487 1400 (North), 09 427 0360 (Rodney), and 09 822 8601 (West)
- The study authors are available at MMH.Research@waitematadhb.govt.nz. This email is checked daily, and we will get in contact immediately if you are unable to access help.
- If at any stage you feel at immediate risk to yourself or to others, if you feel that your baby or you are at risk from others, or if you have caused or experienced actual harm, then call 111 immediately, ask to speak to the police and the ambulance services, and explain the situation to them. You and your baby will be taken to a safe place until the situation can be resolved. You can also contact the WDHB crisis team on 09 487 1414 (North) and 09 822 8501 (West).

Useful Websites:

PND specifically: www.plunket.org.nz; www.health.govt.nz/your-health/pregnancy-and-kids;
www.pada.nz; www.mothershelpers.co.nz

Depression and anxiety generally: www.depression.org.nz; www.beyondblue.org.au;
www.beatingtheblues.co.nz;

Mindfulness and meditation: www.calm.auckland.ac.nz

Community support services: www.raeburnhouse.org.nz/information/directory-mobile-app

Useful Phone Numbers:

Lifeline (open 24/7) - 0800 543 354; Depression Helpline (open 24/7) - 0800 111 757; Healthline (open 24/7) - 0800 611 116; Samaritans (open 24/7) - 0800 726 666; Suicide Crisis Helpline (open 24/7) - 0508 828 865; Youthline (open 24/7) - 0800 376 633 (or text 234 for free between 8am and midnight, or email talk@youthline.co.nz); Alcohol Drug Helpline (open 24/7) - 0800 787 797 (or text 8691 for free; Mental Health Foundation's Resource and Information Service (09 623 4812).

Cultural Support:

WDHB Maori Mental Health Support Services: (09) 822 8555
 WDHB Asian Mental Health Support Services: (09) 486 8900 ext. 47321
 WDHB Pacific Health Support Services: (09) 837 1780

Other Questions to Consider:

If you are currently experiencing family violence please talk to a hospital doctor, your GP, your midwife, or visit www.areyouok.org.nz, also available via phone on 0800 456 450.

If you have concerns about your or a family member's drug or alcohol misuse please talk to a hospital doctor, your GP, your midwife, or visit www.cads.org.nz, also available via phone on 09 845 1818.

If there has there been a recent change in in your social situation and you feel unable to cope – such as isolation from support structures, a recent break-up or bereavement, or financial stress – your doctor or midwife can refer you to the WDHB Women's Health Social Work team on fax number 09 4868928 (North), and 09 837 6619 (West).

Appendix G: Text Message Reminders

Day Two Postnatal: Intervention Group

Hello. This is a friendly reminder from the WDHB Research Team to “check in” with your mental health using our information pack. If you have not done so already, please complete the questionnaire on Page 2. You can find an online copy of the questionnaire by following this link: <https://psychology-tools.com/epds>. To receive a copy of the information package electronically, email mmh.research@waitematadhb.govt.nz. We wish you all the best until we touch base again in a few weeks. Please do not reply to this text message; if you have any concerns please talk to your GP or midwife. If you are still in hospital, then you can also ask to see the on-call Senior House Officer.

Week Three Postnatal: Intervention Group

Hello from the WDHB Research Team. It is now about 3 weeks since you gave birth. We hope that the process of adjusting to life at home with your new baby is going well. If you get a moment, we encourage you to look at the mobile app, “Mind the Bump”, which is available on the Google Play Store (Android), and the App Store (Apple). This is a free mindfulness mediation program for parents. If you have downloaded this already, then well done, and we encourage you to continue practicing the techniques and skills it covers. Take care, and we will be in touch again in another few weeks. Please do not reply to this text message; if you have any concerns please talk to your GP or midwife.

Week Six Postnatal: Intervention Group

Hello again from the WDHB Research Team. It is now about 6 weeks since you gave birth. This is a reminder to please complete the questionnaire on Page 3 of the information pack. You can find an online copy of the questionnaire by following this link: <https://psychology-tools.com/epds>. To receive an electronic copy of the information package you were given in hospital, email mmh.research@waitematadhb.govt.nz. You will soon be seeing your GP for baby’s 6 week examination. This is a great time to touch base with a doctor to discuss any concerns you may have about your mental health. We will be in touch again in a week or two to get your thoughts on this study. Please do not reply to this text message; if you have any concerns please talk to your GP or midwife.

Week Eight Postnatal Follow Up, Concealed Recruitment and Consent: Control Group and Intervention Group

Hello from the WDHB Research Team. It is now 8 weeks since you gave birth. While in hospital you met with one of our doctors or midwives, and kindly agreed to participate in a research project looking at maternal mental health. The focus of this study was Postnatal Depression (PND). One of the study authors will call you this evening around 8 pm and ask you some questions that will not take more than 5 minutes. We ask that you please follow this link prior to 8pm, tick the box for each question that is most accurate for you, and remember your total score: <https://psychology-tools.com/epds>. If 8pm is not good for you, please reply to this text with a more convenient time. We thank you again for agreeing to participate in this research project aimed at improving health care for mothers in the Waitemata DHB.

Appendix H: Control Group Week 8 Follow Up

Primary Outcomes:

- The mother has EPDS-PND as defined by a score of 13+ on the phone-delivered EPDS at week 8

Select the answer that comes closest to how you have felt **IN THE PAST 7 DAYS**, not just how you feel today.

1. I have been able to laugh and see the funny side of things.	As much as I always could Not quite so much now Definitely not so much now Not at all	0 1 2 3	6. Things have been getting on top of me.	Yes, most of the time I haven't been able to cope at all Yes, sometimes I haven't been coping as well as usual No, most of the time I have coped quite well No, I have been coping as well as ever	3 2 1 0
2. I have looked forward with enjoyment to things.	As much as I ever did Rather less than I used to Definitely less than I used to Hardly at all	0 1 2 3	7. I have been so unhappy that I have had difficulty sleeping.	Yes, most of the time Yes, sometimes Not very often No, not at all	3 2 1 0
3. I have blamed myself unnecessarily when things went wrong.	Yes, most of the time Yes, some of the time Not very often No, never	3 2 1 0	8. I have felt sad or miserable.	Yes, most of the time Yes, sometimes Not very often No, not at all	3 2 1 0
4. I have been anxious or worried for no good reason.	No not at all Hardly ever Yes, sometimes Yes, very often	0 1 2 3	9. I have been so unhappy that I have been crying.	Yes, most of the time Yes, quite often Only occasionally No, never	3 2 1 0
5. I have felt scared or panicky for no very good reason.	Yes, quite a lot Yes, sometimes No, not much No, not at all	3 2 1 0	10. The thought of harming myself has occurred to me.	Yes, quite often Sometimes Hardly ever Never	3 2 1 0

Total Score =

Score to Question 10 =

- The mother has received evidence-based treatment for PND, including either appropriate psychological or appropriate pharmacological therapy as outlined in the BPAC.org.nz article "Postnatal Depression" since her Caesarean section [21].

For example:

- six to eight weeks of non-directive counselling, interpersonal therapy (IPT) or cognitive behavioural therapy (CBT), whether in group therapy, or individual personal or computer-based therapy
- an appropriate antidepressant such as a serotonin re-uptake inhibitor (SSRI) or tricyclic antidepressants (TCA).

Additional Follow Up Required?

- EPDS scores of 10-13 require GP referral letter
- EPDS scores of 14 or more and those who score 2-3 for Question 10 indicating serious risk of harm to self or others require referral sent to the WHB Mental Health Service
- Women considered at immediate risk of harm to self or others require immediate phone referral to WDHB mental health crisis team +/- police/ambulance services, backed up with referral to the WHB Mental Health Service.

Appendix I: Intervention Group Week 8 Follow Up

Primary Outcomes:

1. The mother has EPDS-PND as defined by a score of 13+ on the phone-delivered EPDS at week 8

Select the answer that comes closest to how you have felt **IN THE PAST 7 DAYS**, not just how you feel today.

1. I have been able to laugh and see the funny side of things.	As much as I always could Not quite so much now Definitely not so much now Not at all	0 1 2 3	6. Things have been getting on top of me.	Yes, most of the time I haven't been able to cope at all Yes, sometimes I haven't been coping as well as usual No, most of the time I have coped quite well No, I have been coping as well as ever	3 2 1 0
2. I have looked forward with enjoyment to things.	As much as I ever did Rather less than I used to Definitely less than I used to Hardly at all	0 1 2 3	7. I have been so unhappy that I have had difficulty sleeping.	Yes, most of the time Yes, sometimes Not very often No, not at all	3 2 1 0
3. I have blamed myself unnecessarily when things went wrong.	Yes, most of the time Yes, some of the time Not very often No, never	3 2 1 0	8. I have felt sad or miserable.	Yes, most of the time Yes, sometimes Not very often No, not at all	3 2 1 0
4. I have been anxious or worried for no good reason.	No not at all Hardly ever Yes, sometimes Yes, very often	0 1 2 3	9. I have been so unhappy that I have been crying.	Yes, most of the time Yes, quite often Only occasionally No, never	3 2 1 0
5. I have felt scared or panicky for no very good reason.	Yes, quite a lot Yes, sometimes No, not much No, not at all	3 2 1 0	10. The thought of harming myself has occurred to me.	Yes, quite often Sometimes Hardly ever Never	3 2 1 0

Total Score =

Score to Question 10 =

2. The mother has received evidence-based treatment for PND, including either appropriate psychological or appropriate pharmacological therapy as outlined in the BPAC.org.nz article "Postnatal Depression" since her Caesarean section [21].

For example:

- six to eight weeks of non-directive counselling, interpersonal therapy (IPT) or cognitive behavioural therapy (CBT), whether in group therapy, or individual personal or computer-based therapy
- an appropriate antidepressant such as a serotonin re-uptake inhibitor (SSRI) or tricyclic antidepressants (TCA).

Additional Questions for Intervention Group:

1. Did you complete one or both EPDS questionnaires as recommended in the package? If so, can you please provide the scores?

Additional Follow Up Required?

1. EPDS scores of 10-13 require GP referral letter
2. EPDS scores of 14 or more and those who score 2-3 for Question 10 indicating serious risk of harm to self or others require referral sent to the WHB Mental Health Service
3. Women considered at immediate risk of harm to self or others require immediate phone referral to WDHB mental health crisis team +/- police/ambulance services, backed up with referral to the WHB Mental Health Service.

Appendix J: Week 8 Follow Up Referral Letter to GP

Dear Colleague:

[PATIENT'S NAME] has been participating in a WDHB study looking at postnatal depression in mothers of babies born by Caesarean Section. This study has been supervised by WDHB clinicians, Dr Aram Kim, FRANZCP, and Dr Wendy Burgess, FRANZCOG,

As part of the study, [PATIENT'S NAME] received a follow up phone call on [date] approximately 8 weeks after giving birth. She scored an EPDS of [EPDS SCORE]. As per WDHB protocol 'Maternal Mental Health Screening and Referral', we are referring her to your service for further follow up and have advised her to see you within the week to discuss the issues raised. It may be that she would benefit from psychological or pharmacological therapy as appropriate.

If you would like further information about this condition and its treatment, I would direct you to the BPAC.org.nz article "Postnatal Depression", <https://bpac.org.nz/BPJ/2010/nataldep/postnatal.aspx>.

This letter is copied to [PATIENT'S NAME]. To this end, we are including the information below for her reference, and we thank you for your ongoing care.

Important Patient Information:

If at any stage you are unable to contact your GP or midwife, or it is not possible to get an appointment in good time, then you can call the WDHB Mental Health Services, preferably in business hours. The numbers are 09 487 1400 (North), 09 427 0360 (Rodney), and 09 822 8601 (West)

If at any stage you feel at immediate risk to yourself or to others, if you feel that your baby or you are at risk from others, or if you have caused or experienced actual harm, then call 111 immediately, ask to speak to the police and the ambulance services, and explain the situation to them. You and your baby will be taken to a safe place until the situation can be resolved. You can also contact the WDHB crisis team on 09 487 1414 (North) and 09 822 8501 (West).

Useful Websites:

PND specifically:	www.plunket.org.nz ; www.health.govt.nz/your-health/pregnancy-and-kids ; www.pada.nz ; www.mothershelpers.co.nz
Depression and anxiety generally:	www.depression.org.nz ; www.beyondblue.org.au ; www.beatingtheblues.co.nz ;
Mindfulness and meditation:	www.calm.auckland.ac.nz
Community support services:	www.raeburnhouse.org.nz/information/directory-mobile-app

Useful Phone Numbers:

Lifeline (open 24/7) - 0800 543 354; Depression Helpline (open 24/7) - 0800 111 757; Healthline (open 24/7) - 0800 611 116; Samaritans (open 24/7) - 0800 726 666; Suicide Crisis Helpline (open 24/7) - 0508 828 865; Youthline (open 24/7) - 0800 376 633 (or text 234 for free between 8am and midnight, or email talk@youthline.co.nz); Alcohol Drug Helpline (open 24/7) - 0800 787 797 (or text 8691 for free; Mental Health Foundation's Resource and Information Service (09 623 4812).

Cultural Support:

WDHB Maori Mental Health Support Services:	(09) 822 8555
WDHB Asian Mental Health Support Services:	(09) 486 8900 ext. 47321
WDHB Pacific Health Support Services:	(09) 837 1780

Yours Sincerely

Dr Richard Carpenter
Obstetrics and Gynaecology Registrar
Waitemata District Health Board

Appendix K: Week 8 Follow Up Referral Letter to WDHb Mental Health Services

Dear WHB Community Mental Health Services:

[PATIENT'S NAME] has been participating in a WDHb study looking at postnatal depression in mothers of babies born by Caesarean Section. This study has been supervised by WDHb clinicians, Dr Aram Kim, FRANZCP, and Dr Wendy Burgess, FRANZCOG,

As part of the study, [PATIENT'S NAME] received a follow up phone call on [DATE] approximately 8 weeks after giving birth.

*** EITHER ***

She scored an EPDS of [EPDS SCORE]. As per WDHb protocol 'Maternal Mental Health Screening and Referral', we are referring her to your community services for further follow up.

*** OR *** She is considered to be at risk based on her EPDS Question 10 score of [EPDS QUESTION 10 SCORE]. For the record her EPDS score was [EPDS SCORE]. As per WDHb protocol 'Maternal Mental Health Screening and Referral', we are referring her to your community services for further follow up.

*** OR ***

At this phone call she was considered at immediate risk of harm to herself and/or others and was referred to the WDHb crisis team +/- police/ambulance services by phone. This referral letter is to document this event and ensure that she is picked up by the appropriate service. For the record her EPDS score was [EPDS SCORE] and her EPDS Question 10 score was [EPDS QUESTION 10 SCORE].

This letter is copied to [PATIENT'S NAME] and her GP. To this end, we are including the information below for the patient's reference.

Important Patient Information:

If at any stage you feel at immediate risk to yourself or to others, if you feel that your baby or you are at risk from others, or if you have caused or experienced actual harm, then call 111 immediately, ask to speak to the police and the ambulance services, and explain the situation to them. You and your baby will be taken to a safe place until the situation can be resolved. You can also contact the WDHb crisis team on 09 487 1414 (North) and 09 822 8501 (West).

Useful Websites:

PND specifically:	www.plunket.org.nz ; www.health.govt.nz/your-health/pregnancy-and-kids ; www.pada.nz ; www.mothershelpers.co.nz
Depression and anxiety generally:	www.depression.org.nz ; www.beyondblue.org.au ; www.beatingtheblues.co.nz ;
Mindfulness and meditation:	www.calm.auckland.ac.nz
Community support services:	www.raeburnhouse.org.nz/information/directory-mobile-app

Useful Phone Numbers:

Lifeline (open 24/7) - 0800 543 354; Depression Helpline (open 24/7) - 0800 111 757; Healthline (open 24/7) - 0800 611 116; Samaritans (open 24/7) - 0800 726 666; Suicide Crisis Helpline (open 24/7) - 0508 828 865; Youthline (open 24/7) - 0800 376 633 (or text 234 for free between 8am and midnight, or email talk@youthline.co.nz); Alcohol Drug Helpline (open 24/7) - 0800 787 797 (or text 8691 for free; Mental Health Foundation's Resource and Information Service (09 623 4812).

Cultural Support:

WDHB Maori Mental Health Support Services: (09) 822 8555
WDHB Asian Mental Health Support Services: (09) 486 8900 ext. 47321
WDHB Pacific Health Support Services: (09) 837 1780

Yours Sincerely

Dr Richard Carpenter
Obstetrics and Gynaecology Registrar
Waitemata District Health Board

Appendix L: Intervention Group Debrief Letter

Version 1: No referral made post week-8 follow up phone call

Hello [Name]:

Thank you for participating in our study looking at postnatal depression (PND) in mothers who deliver by Caesarean section. The purpose of this study was to see whether a brief, standardised intervention, delivered by a Senior House Officer at the post-Caesarean section review, could reduce the rates of undiagnosed and untreated PND.

As you were in the intervention group, the junior doctor who checked in on you after your operation briefly discussed PND and gave you an information package. This package was designed to educate about PND, give you the resources to self-screen for PND, and explain how to seek support if you needed it. You also received three text message reminders linking back to this information.

Because a significant part of this study was raising awareness of PND, we did not use the term “Postnatal Depression” when we recruited you to the study, instead using the more general term “maternal mental health”. We felt that explaining PND to any extent during recruitment would have made the effect of the intervention impossible to distinguish from the effect of the recruitment.

The decision to not mention PND specifically was made after discussion with senior WDHB doctors and New Zealand Health and Disabilities Ethics Committee members. We hope that you understand and accept the reason behind this decision. If you have any issues with this, we sincerely apologise, and would ask that you feedback to us via return email.

If you have a moment, we would also ask that you please provide some feedback on the following questions, to make sure our intervention was as effective as possible, as we seek to improve the care we provide women moving ahead.

1. Did you read through the information package provided when you were at NSH? Please rate its value from 1 (not at all) to 5 (very).
2. Did you receive text messages from us after giving birth? Please rate their value in helping you focus on your mental health and wellbeing from 1 (not at all) to 5 (very).
3. Did you download and use the “Mind the Bump App”? Please rate its value from 1 (not at all) to 5 (very).
4. Do you have any feedback to improve the information package?

Thank you again for your participation, and we wish you all the best.

Kind Regards,

Dr Richard Carpenter
Obstetrics Registrar and Co-ordinating Investigator

Version 2: Referral made post week-8 follow up phone call

Hello [Name]:

Thank you for participating in our study looking at postnatal depression (PND) in mothers who deliver by Caesarean section. The purpose of this study was to see whether a brief, standardised intervention, delivered by a Senior House Officer at the post-Caesarean section review, could reduce the rates of undiagnosed and untreated PND.

As you were in the intervention group, the junior doctor who checked in on you after your operation briefly discussed PND and gave you an information package. This package was designed to educate about PND, give you the resources to self-screen for PND, and explain how to seek support if you needed it. You also received three text message reminders linking back to this information.

EITHER

GP Referral

Because of our recent phone call, we have referred you to your GP to follow up the results of your PND screen. You and your GP will receive a copy of this referral shortly, and we encourage you see them soon.

OR

WDHB MH Referral

Because of our recent phone call, we have referred you to our mental health services to follow up the results of your PND screen. If they have not done so already, they will be in touch soon, and we encourage you to stay engaged with them

One further thing we will like to discuss is how the recruitment to this study was done.

Because a significant part of this study was raising awareness of PND, we did not use the term “Postnatal Depression” when we recruited you to the study, instead using the more general term “maternal mental health”. We felt that explaining PND to any extent during recruitment would have made the effect of the intervention impossible to distinguish from the effect of the recruitment.

The decision to not mention PND specifically was made after discussion with senior WDHB doctors and New Zealand Health and Disabilities Ethics Committee members. We hope that you understand and accept the reason behind this decision. If you have any issues with this, we sincerely apologise, and would ask that you feedback to us via return email.

If you have a moment, we would also ask that you please provide some feedback on the following questions, to make sure our intervention was as effective as possible, as we seek to improve the care we provide women moving ahead.

1. Did you read through the information package provided when you were at NSH? Please rate its value from 1 (not at all) to 5 (very).
2. Did you receive text messages from us after giving birth? Please rate their value in helping you focus on your mental health and wellbeing from 1 (not at all) to 5 (very).
3. Did you download and use the “Mind the Bump App”? Please rate its value from 1 (not at all) to 5 (very).
4. Do you have any feedback to improve the information package?

Thank you again for your participation, and we wish you all the best.

Kind Regards,

Dr Richard Carpenter
Obstetrics Registrar and Co-ordinating Investigator

Appendix M: Control Group Debrief Letter

Version 1: No referral made post week-8 follow up phone call

Hello [Name]:

Thank you for participating in our study looking at postnatal depression (PND) in mothers who deliver by Caesarean section. The purpose of this study was to see whether a brief, standardised intervention, delivered by a Senior House Officer at the post-Caesarean section review, could reduce the rates of undiagnosed and untreated PND.

Because a significant part of this study was raising awareness of PND, we did not use the term “Postnatal Depression” when we recruited you to the study, instead using the more general term “maternal mental health”. We felt that explaining PND to any extent during recruitment would have made the effect of the intervention impossible to distinguish from the effect of the recruitment.

The decision to not mention PND specifically was made after discussion with senior WDHB doctors and New Zealand Health and Disabilities Ethics Committee members. We hope that you understand and accept the reason behind this decision. If you have any issues with this, we sincerely apologise, and would ask that you feedback to us via return email.

As you were in the control group, you received standard care while in hospital. A junior doctor would have checked on you the day after your operation and discussed issues such as contraception and breastfeeding. For the women in the intervention group, the junior doctor also talked about PND and provided them with an information package. This package was designed to educate about PND, give the resources to self-screen for PND, and explain how to seek support needed. Three text message reminders linking back to this information were also sent over a six-week period.

The advice given by the junior doctor to woman in the intervention group, the information package provided while in hospital, and a copy of the text messages sent, are all attached to this email. The information is still relevant, and we really encourage you to read through it in your own time.

Thank you again for your participation, and we wish you all the best.

Kind Regards,

Dr Richard Carpenter
Obstetrics Registrar and Co-ordinating Investigator

Version 2: Referral made post week-8 follow up phone call

Hello [Name]:

Thank you for participating in our study looking at postnatal depression (PND) in mothers who deliver by Caesarean section. The purpose of this study was to see whether a brief, standardised intervention, delivered by a Senior House Officer at the post-Caesarean section review, could reduce the rates of undiagnosed and untreated PND.

EITHER

GP Referral

Because of our recent phone call, we have referred you to your GP to follow up the results of your PND screen. You and your GP will receive a copy of this referral shortly, and we encourage you see them soon.

OR

WDHB MH Referral

Because of our recent phone call, we have referred you to our mental health services to follow up the results of your PND screen. If they have not done so already, they will be in touch soon, and we encourage you to stay engaged with them

One further thing we will like to discuss is how the recruitment to this study was done.

Because a significant part of this study was raising awareness of PND, we did not use the term “Postnatal Depression” when we recruited you to the study, instead using the more general term “maternal mental health”. We felt that explaining PND to any extent during recruitment would have made the effect of the intervention impossible to distinguish from the effect of the recruitment.

The decision to not mention PND specifically was made after discussion with senior WDHB doctors and New Zealand Health and Disabilities Ethics Committee members. We hope that you understand and accept the reason behind this decision. If you have any issues with this, we sincerely apologise, and would ask that you feedback to us via return email.

As you were in the control group, you received standard care while in hospital. A junior doctor would have checked on you the day after your operation and discussed issues such as contraception and breastfeeding. For the women in the intervention group, the junior doctor also talked about PND and provided them with an information package. This package was designed to educate about PND, give the resources to self-screen for PND, and explain how to seek support needed. Three text message reminders linking back to this information were also sent over a six-week period.

The advice given by the junior doctor to woman in the intervention group, the information package provided while in hospital, and a copy of the text messages sent, are all attached to this email. The information is still relevant, and we really encourage you to read through it in your own time.

Thank you again for your participation, and we wish you all the best.

Kind Regards,

Dr Richard Carpenter
Obstetrics Registrar and Co-ordinating Investigator

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