Health and disability research

These screening questions will help determine whether HDEC review is required for your study. They are based on the rules contained in section three of the *Standard Operating Procedures for Health and Disability Ethics Committees*.

Don't hesitate to contact us if you'd like help answering these questions, or any others in the HDEC form.

A. Health and disability research

Does your study aim to improve health outcomes, or outcomes for disabled people?

- (•) Yes
- ( ) No

Human reproductive research

B. Will your study involve the creation or use of a human gamete, a human embryo or a hybrid embryo?

- ( ) Yes
- (•) No

Type of study

C. Is your study:

- (•) an intervention study?

In intervention studies, the investigator controls and studies the preventive, diagnostic or therapeutic intervention(s) provided to participants for the purpose of adding to knowledge of the health effects of the intervention(s). Many intervention studies are clinical trials.

- ( ) an observational study?

In observational studies the researcher has no control over study variables, and merely observes outcomes.

Main Criteria

D. Will your study involve **human participants** recruited in their capacity as:

- consumers of health or disability support services, or
- relatives and/or caregivers of consumers of health or disability support services, or
- volunteers in clinical trials (including bioequivalence and bioavailability studies)?

- (•) Yes
- ( ) No

E. Does your study involve the use, collection or storage of **human tissue** (as defined by section 7 of the Human Tissue Act 2008)?

Examples of human tissue include:

- *all or any part of a body*

- *whole human organs or parts of them*
- *human stem cells or other human cells*
- *human blood*
- *human bone marrow*
- *human hair, nails, and skin*
- *human mucus, sputum, or urine.*

○ Yes
◉ No

G. Will your study involve the use or disclosure of **health information** (as defined by section 4(1) of the Health Information Privacy Code 1996)?

Health information is about identifiable individuals. It includes:

- *information about the health of an individual, including his or her medical history*
- *information about any disabilities that individual has, or has had*
- *information about any health services or disability services that are being provided, or have been provided, to that individual*
- *information in connection with the donation of any body part or any bodily substance of that individual*
- *information derived from the testing or examination of any body part, or any bodily substance of that individual*
- *information about the individual which is collected before or in the course of, and incidental to, the provision of any health service or disability service to that individual.*

◉ Yes
○ No

H. *You don't need HDEC approval to use health information for research if:*

- *informed consent to this use has already been obtained*
  or
- *the health information won't be disclosed* to researchers in a form that would allow them to identify the individual(s) concerned, or to match the information with other datasets through a non-encrypted identifier (eg, an NHI number).*

Does one of these exceptions to the need to obtain HDEC approval apply to your study?

○ Yes
◉ No

* See rule 11 of the Health Information Privacy Code 1996.

Exemptions

I. *Exemption for low risk medical devices*

Does your study involve evaluating a low-risk (class I) medical device?

Low-risk (class I) medical devices are defined from page 77 of the Australian Therapeutic Goods Administration's Australian Regulatory Guidelines for Medical Devices.

○ yes
◉ no

INCLUSIONS

HDEC REVIEW

O. Your study requires HDEC review

The question below will determine the review pathway appropriate to your study.

Does your study involve any of the following? (select all that apply)

- ☐ a new medicine
- ☐ an approved medicine being used for a new indication or through a new mode of administration
- ☐ a medical device that is or would be classified as a class IIb, class III, or active implantable medical device by the Therapeutic Goods Administration (TGA)
- ☐ a new surgical intervention
- ☐ one or more participants who will not have given informed consent to participate
- ☐ one or more participants who are vulnerable (that is, who have a restricted ability to make independent decisions about their participation)
- ☐ standard treatment being withheld from one or more participants
- ☐ the storage, preservation or use of human tissue without consent
- ☐ Future Unspecified Use of Tissue
- ☑ none

Exp.

*Your study will be reviewed by the **expedited review** pathway described at section 6 of the Standard Operating Procedures for Health and Disability Ethics Committees.*

a.1 Title and summary

a.1.1.

Short study title: Postnatal depression in mothers of babies born by Caesarean section

a.1.2.

Formal study 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.

a.1.3. A protocol must be uploaded in the “Documents” tab before submission to an HDEC.

If this protocol has a unique identifier, please enter this below.

Protocol number (if applicable): none

a.1.4. Please provide the dates on which you plan to commence and conclude your study in New Zealand

Planned commencement date: 01/01/2019
Planned conclusion date: 31/12/2020

a.1.5. Please provide a brief, plain English summary of your study.

[< 2000 characters]

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

a.1.6. Please provide a brief summary of the main ethical issues that you believe your study may raise.

[< 1200 characters]

The study authors have identified five main ethical issues raised by this study, listed below. They are discussed in detail in the attached protocol, with explanations and justifications, pp.8-10

1. The intent to mask the exact subject matter of the study from mothers during the recruitment phase. Because of similarities to the intervention, it is likely that a full consent process would seriously compromise this study, confounding data from the outset.

2. Providing the EPDS to mothers to complete themselves. There is potential for them to make a positive diagnosis of PND and not follow up appropriately, or to incorrectly make a negative diagnosis and be falsely reassured.

3. Not discussing mental health issues at the post-Caesarean section review with mothers in the control group.

4. Appropriately managing those mothers who screen positive for PND at the week 8 follow up phone call.

a.2.1. Does your study aim to improve knowledge of:

- ○ diagnosis
- ◉ early detection / screening
- ○ prevention
- ○ treatment
- ○ rehabilitation
- ○ lifestyle/behaviour
- ○ other:

a.2.1.1. Which of the following best describe your intervention study?

Blinding:	◉ open-label	○ single-blind	○ double-blind		
Arms:	◉ two-arm	○ multi-arm			
Design:	◉ parallel	○ crossover	○ dose-ranging	○ cluster	○ factorial
Control:	○ placebo-controlled	◉ active-controlled	○ uncontrolled		
Randomisation:	◉ randomised	○ non-randomised			
Aim:	◉ superiority	○ equivalence	○ non-inferiority		
	○ none of the above				

a.2.2. Please select the ANZSRC field of research that best describes your study from the drop-down menus.

Level 1: 11 Medical and Health Sciences

Level 2: Paediatrics and Reproductive Medicine

Level 3: Obstetrics and Gynaecology

a.3 Investigators

Co-ordinating Investigator (CI)

The CI has overall responsibility for the conduct of the study, including adherence to established ethical standards.

In student research, the student him- or herself is the CI.

a.3.1. Are you the CI for this study?

◉ Yes

○ No

a.3.1.1. *The CI must authorise this application (through the "Authorisations" tab) before it can be submitted to an HDEC for review. You should request authorisation once you have completed all questions in the Online Form, or sign this form as the Co-ordinating Investigator in the Authorisations tab.*

Please provide the following information on the study's CI.

	Title:	Forename/Initials:	Surname:
	Dr	Richard	Carpenter
Mailing Address:	124 Shakespeare Rd		
Suburb/Town:	Takapuna		
Postcode:	0620		
Country:	New Zealand		
Organisation:	Waitemata District Health Board		

Department*:	Department of Women's Health
Position:	Obstetrics and Gynaecology Registrar
E-mail:	richard.carpenter@waitematadhb.govt.nz
Phone (BH):	021 233 8867
Phone (AH)*:	
Mobile*:	
Fax:	

Other Investigator(s)

Other than the Co-ordinating Investigator, Investigators at all localities in a multi-centre intervention study must be listed as Investigators. Supervisors of student research must also be listed as Investigators.

You may list any other Investigators at your discretion.

a.3.2. Will any co-investigators be involved in conducting your study?

- (●) Yes
- ( ) No

a.3.2.1. *You should request authorisation from each Investigator in your study (using the "Authorisations" tab) once you have completed all questions in the Online Form.*

(For each co-investigator:)

Other CI 1

Title:	Forename/Initials:	Surname:
Dr	Alyssa	Page

Mailing Address:	124 Shakespeare Rd
Suburb/Town:	Takapuna
Postcode:	0622
Country:	New Zealand
Organisation:	Waitemata District Health Board
Department*:	Department of Women's Health
Position:	Obstetrics and Gynaecology Senior House Officer
E-mail:	alyssa.page@waitematadhb.govt.nz
Phone (BH):	021 169 8227
Phone (AH)*:	
Mobile*:	
Fax:	

Other CI 2

Title:	Forename/Initials:	Surname:
Ms	Eleanor	McQueen

Mailing Address:	124 Shakespeare Rd
Suburb/Town:	Takapuna
Postcode:	0622
Country:	New Zealand

Organisation:	Waitemata District Health Board
Department*:	Department of Women's Health
Position:	Midwife
E-mail:	Eleanor.McQueen@waitematadhb.govt.nz
Phone (BH):	021 150 4840
Phone (AH)*:	
Mobile*:	
Fax:	

a.4 Primary contact person

a.4.1. Are you the primary contact person for this study?

- (•) Yes
- ( ) No

Title:	Forename/Initials:	Surname:
Dr	Richard	Carpenter

Mailing Address:	124 Shakespeare Rd
Suburb/Town:	Takapuna
Postcode:	0620
Country:	New Zealand
Organisation:	Waitemata District Health Board
Department*:	Department of Women's Health
Position:	Doctor, Obstetrics and Gynaecology Registrar
E-mail:	richard.carpenter@waitematadhb.govt.nz
Phone (BH):	021 233 8867
Phone (AH)*:	
Mobile*:	
Fax:	

a.5 Sponsor

The sponsor has overall responsibility for the initiation, management, and financing arrangements of a study.

a.5.1. Which of the following best describe the sponsor(s) of your study?

- [ ] pharmaceutical company
- [ ] medical device company
- [ ] academic institution
- [ ] collaborative research group
- [ ] district health board (DHB)
- [ ] other government agency
- [ ] non-governmental organisation (NGO)
- [ ] other

☑ no sponsor

Third party performing sponsor's duties or functions in New Zealand

a.6 Localities and participants

New Zealand

It is a standard condition of HDEC approval that locality authorisation be obtained (through the "Authorisations" tab) ***before a study commences at a locality****. This authorisation confirms that the locality has addressed research governance issues that may arise as a result of the study.*

However, locality authorisation ***does not*** *have to be obtained prior to submission of your application to an HDEC.*

Other organisations involved in studies may prefer or require that their involvement in studies be recorded as an authorisation. You should check with these organisations before proceeding with your study.

Contact details for DHB research offices are available here

a.6.1. At which type(s) of locality do you intend to conduct your study?

- ☑ district health board
- ☐ tertiary education institution
- ☐ primary health care centre
- ☐ private organisation
- ☐ other - please specify:

a.6.2. Approximately how many participants do you intend to recruit in New Zealand?

450

Other countries

a.6.3. Will your study also involve participants recruited in countries other than New Zealand?

- ○ Yes
- ◉ No

a.7 Prior review

a.7.1. Is this application related to one or more previous applications for HDEC review?

- ○ Yes
- ◉ No

a.7.2. Has an application for this study (or a substantially similar study) previously been declined approval by an HDEC in New Zealand?

○ Yes
◉ No

a.7.3. Has an application for this study (or a substantially similar study) previously been declined approval by an overseas ethics committee?

○ Yes
◉ No

a.8 Clinical trials of new medicines

You can apply for HDEC approval and regulatory approval(s) in any order. The PI and study sponsor are responsible for ensuring that all necessary regulatory approvals have been obtained before the study commences.

a.8.1. Is your intervention study a clinical trial of a new medicine (as defined by the Medicines Act 1981)?

○ Yes
◉ No

a.9 Open/closed meeting

HDECs are public administrative bodies, and their meetings are open to the public. Your study may be reviewed in a closed meeting only if grounds may exist to withhold information about it under the Official Information Act 1982.

a.9.1. Do you want your application to be considered in a closed meeting?

○ Yes
◉ No

a.10 HDEC review preference

b.1 Research should be based around a clear study question that can produce benefits.

b.1.1. Briefly and in plain English, what is the principal study question (hypothesis) that your study will test?
You can refer to page numbers of your study's protocol for further detail if you need to.

[< 2000 characters]

Can a brief, standardised intervention, delivered by a Senior House Officer (SHO) at the post-Caesarean section review, reduce the rates of PND and increase the rates of treated PND in the early postnatal period for mothers undergoing Caesarean section?

b.1.2. Please briefly describe the scientific basis for your study (including, where appropriate, brief discussion of previous research).
You can refer to page numbers of your study's protocol for further detail if you need to.

[< 2000 characters]

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 (ref to literature review pp.3-5)

Screening in the local population is conducted to differing standards, although 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)(ref to review pp.5-6)

b.1.3. Please briefly explain how your study will contribute to new knowledge and improve health outcomes.

[< 2000 characters]

We have not found any study to date, evaluating the role of the post-Caesarean section debrief as a potential intervention and screening tool for PND. One study considered early GP debrief in the first week postnatally and found that this did not improve outcomes including breastfeeding and mental health. One study considered a GP debrief in the first week postnatally and found that this did not improve mental health outcomes. A more recent meta-analysis also found no benefit to early-postnatal follow up for maternal mental health. 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 (ref p.6).

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 maternal-partner population

Direct benefits for participants: therapeutic and non-therapeutic studies

b.1.4. *Therapeutic studies are studies that examine interventions or procedures that hold the prospect of direct diagnostic, therapeutic or preventative benefit for individual participants.*

Is your intervention study a therapeutic study?

(●) Yes ( ) No

b.1.4.1. Please briefly describe the direct diagnostic, therapeutic or preventative benefits that your intervention study may have for participants.

[< 600 characters]

1) Prevent the progression of EPDS-PND to true PND by identifying at risk mothers and supporting them to receive proper care.

2) Preventing mothers from developing EPDS-PND, by educating and supporting them in the early post-natal period around the issue of PND, warning signs to watch for, and where to access strategies to manage with the stress of a new baby.

b.2 Research should be well-designed, so that it can answer the study question.

b.2.1. Please briefly describe and justify the design of your study.

[< 1200 characters]

Please ref pp.7-8.

Open-label: unavoidable

Two-arm: one intervention versus treatment as usual

Parallel: appropriate for randomisation to ensure low risk of confounding.

Active-controlled: no appropriate placebo for the intervention.

Randomised: to minimise effects of confounding

Superiority: aim is to demonstrate that the intervention is superior to treatment as usual

b.2.2. Please indicate whether peer review of the scientific and statistical quality of your study has been obtained from one or more of the following.

- ☐ the Standing Committee on Therapeutic Trials (SCOTT)
- ☐ the study's funder (e.g. the Health Research Council)
- ☐ the study's sponsor
- ☑ experts within the research team
- ☐ senior colleague(s) in the field
- ☐ other

b.2.2.1. *Evidence of favourable peer review for this study must be uploaded in the "Documents" tab before submission to an HDEC.*

Please briefly describe the peer review process that has been carried out for your study.

[< 1200 characters]

Expert advice from study supervisors:
- Dr Aram Kim, FRANZCP (review and letter of support attached)
- Dr Wendy Burgess, FRANZCOG

Expert advice from WDHB Research and Knowledge Centre:
- Dr Wayne Miles (Director)
- Hamish Neave (Bio-statistical Analyst)

b.3 Research should be conducted by an appropriate Principal Investigator, to ensure that the study protocol is respected and followed.

b.3.1. *A CV for the study's Co-ordinating Investigator must be uploaded in the "Documents" tab before submission to an HDEC.*

Please briefly summarise the Co-ordinating Investigator's qualifications and experience relating to conducting studies of this nature.

[< 1200 characters]

Professional Affiliation:

• RANZCOG Training Registrar
• MCNZ

Qualifications:

• Postgraduate Diploma in Obstetrics and Medical Gynaecology, 2017 [UoA]
• Bachelor of Medicine and Bachelor of Surgery (Distinction), 2015 [UoA]
• Master of Arts, First Class Honours, 2010 [UoA]
• Bachelor of Arts (Honours), First Class Honours, 2008 [UoA]
• Bachelor of Arts, 2007 [UoA]

Thesis/Publications/Conference Presentations:

• Martin, R., Rolfe, G., Carpenter, M., & Carpenter, R. Rationale and Design of a New Zealand-wide Electronic Registry for Complex Basal Cell Carcinoma. Clinical Skin Cancer 1.2 (2016): 82-87.
• Carpenter R, Mola GL. Audit of singleton and twin breech deliveries over a ten-year (2005 to 2014) period at two rural hospitals in Papua New Guinea's Gulf Province. Pacific Journal of Reproductive Health 2015; 1.2 (2015).
• Carpenter R. The military character of Plato's Republic. 2010. (Available at University of Auckland Library

BID2048026)

b.4 Where possible, research should generate material that is useful for future research.

Reporting and dissemination of results

b.4.1. How do you intend to report or disseminate the results of your study?

- [x] article(s) in peer-reviewed scientific journals
- [x] internal reports
- [x] conference presentations
- [x] publication on website
- [ ] other publications
- [ ] submission to regulatory authorities (e.g. Medsafe, TGA, FDA, EMA)
- [ ] other
- [ ] no plans to report or disseminate results

b.4.2. Will any restrictions be placed (for example, by your study's sponsor or funder) on the publication of the results of your study?

○ Yes ◉ No

Future research using data generated in your study

b.4.4.

Might data generated in your study be made available for use in future research?

○ Yes ◉ No

b.4.6. ***Intervention studies must be registered prior to commencement.***
Has your intervention study already been registered in a clinical trials registryapproved by the World Health Organisation?

○ yes
◉ no

b.4.7. You can obtain HDEC approval prior to registration, as long as you have obtianed a Universal Trial Number (UTN) for your study.

UTN: U1111-1219-9639

r.1 Risk of physical harm to participants

r.1.1. Briefly and in plain English, please describe:

- the procedures to be undertaken by participants in your study, and
- any risks associated with these procedures that potential participants may reasonably wish to be informed of.

***Do not** describe procedures that will be undertaken as part of normal clinical care regardless of participation in your study, or the risks of such procedures.*

[< 2500 characters]

Intervention Group: Read an information package on PND and self-complete the Edinburgh Postnatal Depression Scale (EPDS).

Intervention and Control Groups: 5-minute phone call following self-completion of online EPDS.

Nil significant associated risks.

r.1.2. Will you seek consent from participants to inform health practitioners with responsibility for their health care that they are taking part in your study?

(•) Yes ( ) No

r.1.3. Will your study involve withholding standard treatment from participants?

( ) Yes (•) No

Arrangements for monitoring serious adverse events

r.1.4. How will serious adverse events occurring in your study be monitored?

- [x] independent data safety monitoring committee
- [ ] internal data safety monitoring committee
- [ ] other data safety monitoring arrangements
- [ ] no formal data safety monitoring arrangements

r.1.5. Please briefly explain *either*:

- the monitoring arrangements in place for your study, and explain why they are appropriate (including reference to your study's protocol where appropriate), or
- why you do not consider formal monitoring arrangements to be necessary for your study.

[< 1200 characters]

An independent data safety monitoring committee 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, and a WDHB Maternity Ward Charge Midwife. 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.

r.1.6. Please briefly outline the criteria (if any) for terminating your intervention study, including reference to your study's protocol where appropriate.

[< 600 characters]

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

Compensation for injury to participants

r.1.7. Will any participants seek or be given treatment by or at the direction of a registered health professional (as defined in the Accident Compensation Act 2001) as part of your intervention study?

○ Yes ◉ No

r.1.8. Please briefly explain your answer(s) to questions r.1.7 above.

[< 1200 characters]

Patients identified at risk of PND will be referred to an appropriate care provider (GP or WDHB Mental Health Services), as per pp. 10 & 27-9. Treatment (either appropriate psychological or appropriate pharmacological therapy) will not be administered by the study authors.

Ionising radiation not needed for normal clinical management

r.1.13. Will your study involve the administration of ionising radiation that is not needed for participants' normal clinical management?

○ Yes ◉ No

r.2 Risk of breach of privacy and confidentiality

Before the study

r.2.1. Will your study involve reviewing or screening health information, for example in order to identify potential participants?

The term "health information" is defined in the Health Information Privacy Code

◉ Yes ○ No

r.2.1.1. Please briefly explain how you will ensure the confidentiality of this health information before the study.

[< 600 characters]

Hard copy clinical records will only be reviewed on the ward and not be taken off-site.

During the study

r.2.2. During your study, who will have access to health information used in your study?

[< 600 characters]

Study authors and supervisors

r.2.3. Please briefly explain how you will ensure the confidentiality of this health information during the study.

[< 600 characters]

Data is likely to be processed at both the hospital and authors' private residences. To ensure confidentiality of health information transmission of information from hospital to private residence will be via secure email, retrieved via remote access, or transported in a sealed container or USB not leaving the authors' possession. At both locations, information will be kept in a secure location not accessible to the general public

r.2.3.1. Will your study involve the use of surveys or questionnaires?

(●) Yes ( ) No

r.2.3.2. *Copies of these surveys or questionnaires must be uploaded in the "Documents" tab before submission to an HDEC.*

After the study

r.2.4. Which of the following best describes the form in which data generated in your study will be stored after the study has finished?

(●) identified
( ) potentially identifiable
( ) partially de-identified
( ) de-identified
( ) anonymous
( ) other – describe:

r.2.4.1. Please briefly explain your answer above.

[< 600 characters]

Information will be identified by NHI as per Appendix C: Study Enrolment Form, p.17.

r.2.5. *The Health (Retention of Health Information) Regulations 1996 require that **some** health information be retained for a period of ten years.*

For how long will health information generated in your study be stored?

[< 600 characters]

In accordance with the Health (Retention of Health Information) Regulations 1996, information will be stored for 10 years. This will be on an encrypted USB in the co-ordinating author's private safe, after which time the USB will be irreversibly destroyed.

Publication of results

r.2.6. Will the results of your study be published in a form that identifies (or could reasonably be expected to identify) individual participants?

( ) Yes (●) No

r.3 Risks associated with the use of human tissue

r.4 Risk of unexpected clinically significant findings

r.4.1. Might any aspect of your study produce findings that may be both unexpected and clinically significant for participants, donors of existing stored human tissue, or their families?

◉ Yes ○ No

r.4.1.1. What might these findings be, and how will participants, donors of existing stored human tissue, or their families be informed of them?

[< 600 characters]

The diagnosis of EPDS-PND.

In the intervention arm, this may be a self identified finding in the first 6 weeks post intervention. The intervention package will explained what this finding means and how to act on it.

In the intervention and control groups, this may occur at the week 8 phone call. The patient will be informed via phone, the finding explained, and then appropriate referral offered.

r.5 Risk of potential conflict of interest

Funding and remuneration

r.5.1. Please briefly describe the main source(s) of funding for your study.

[< 600 characters]

Essentially unfunded. Photocopying by WDHB. Other costs that may be incurred (for example study phone sim card and charges) to be covered by primary author.

Financial approval has been given by WDHB Chartered Accountant, Heidi Zhang.

r.5.2. Does the Co-ordinating Investigator, any Co-Investigator, or any direct member of their families have any commercial interest in the intervention(s) to be studied, or any financial relationship to the study sponsor or funder(s), that may inappropriately influence his or her conduct in the study?

○ Yes ◉ No

r.5.3. Will the Co-ordinating Investigator or any Co-Investigator 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)?

○ Yes ◉ No

Health or disability support service providers

r.5.4. Will the Co-ordinating Investigator or any Co-Investigator also be the usual health or disability support service provider for one or more participants in your study?

○ Yes ◉ No

r.5.5. Will the usual health or disability service provider for one or more participants in your study receive any remuneration (or any other valuable consideration) for referring potential participants to the research team in your study?

○ Yes ◉ No

Other potential conflicts of interest

r.5.6. Please briefly describe any other potential conflicts of interest that may arise for researchers in your study, and describe how they will be minimised and managed.

[< 600 characters]

Nil. Exclusion criteria expressly forbid study authors from being involved in labour cares of patient.

r.6 Risk of stigmatisation

r.6.1. Please briefly indicate whether the results of your study may risk stigmatising individuals or population groups, and if so, how this risk will be minimised and managed.

[< 600 characters]

No.

r.7 Risks to researchers and third parties

r.7.1. Please briefly indicate whether your study may pose any significant risks to researchers and/or third parties, and briefly explain how such risks will be minimised and managed.

[< 600 characters]

No.

r.8 Summary: the risks of research should be proportional to its expected benefits.

r.8.1. Please briefly explain why you consider the risks of your study to be proportional to its expected benefits.

[< 1200 characters]

The intervention is keeping with College guidelines that clearly endorse early identification and support of those mothers at risk of PND.

Concerns about exposing patients to the EPDS without direct supervision are the reality of the current situation with all information freely available on the internet.

The intervention is low cost, can be readily implemented, and if results are positive, may have a significant opportunity to improve outcomes for a very at risk population.

Participants should consent to their participation in research.

p.1.1. Briefly and in plain English, please describe what taking part in your study will involve for participants.

[< 1200 characters]

Intervention group:
- receiving a 1 minute breif on PND at the postnatal review
- receiving a handout with information on PND, where to seek help, and two EPDS questionnaires to fill out immediately and 6 weeks later
- receiving 3 text reminders about PND and the EPDS questionnaires
- receiving a text request to complete an online 5 minute EPDS and a follow up 5 minute phone call at 8 weeks postpartum, to evaluate the primary outcomes, and the intervention.

Control group:
- receiving a text request to complete an online 5 minute EPDS and a follow up 5 minute phone call at 8 weeks postpartum, to evaluate the primary outcomes, and the intervention.

p.1.2. Will **all** participants in your study give their informed consent to participate?

- (•) yes, all participants will give informed consent
- ( ) no, one or more participants will not give informed consent

p.1.9. Will informed consent be recorded in writing?

(•) Yes ( ) No

Consent should be informed by adequate understanding of relevant information.

p.2.1. Briefly explain the process by which potential participants in your study will be provided with information on the study, have the opportunity to ask questions, and asked to give their informed consent.

[< 1200 characters]

Study authors will identify potential participants, apply the inclusion and exclusion criteria, then recruit in person to the study using the 'Participant Information Sheet", Appendix A, and "Participant Consent Form', Appendix B. Ref pp.12-16. Please refer to the discussion on p.9 for why Appendix (V1) is the preferred method.

p.2.2. A**generic** version of the participant information sheet and consent form (PIS/CF) that you will provide to potential participants must be uploaded in the "Documents" tab before submission to an HDEC. You don't need to submit information sheets specific to each study locality.
A suggested pro forma for your PIS/CF can be found here.

p.2.3. How have you checked that the participant information sheet is appropriate for your study population?

[< 600 characters]

Feedback from WDHB mothers who are not part of the medical profession.

p.2.4. How many words does your participant information sheet contain?

905

p.2.5. What is the Flesch Reading Ease Score for your participant infornation sheet?
You can use Microsoft Word to calculate this score.
While there are no hard and fast rules for the readability of information sheets, a score of 65 or above usually indicates that a document is written in plain English.

69

Withholding or concealing information from participants

p.2.6. Does your study involve deliberately withholding or concealing information from participants?
Blinding procedures in randomised controlled trials are not normally considered to involve withholding or concealing information from participants.

(•) Yes ( ) No

p.2.6.1. Please explain why it is appropriate to withhold or conceal information from participants in your study.

[< 600 characters]

There is good reason to think that a full consent process would seriously compromise this study, confounding data from the outset. A fully informed consent process as outlined in Appendix A (Version 2) p.14 bears much resemblance to the intervention outlined in Appendix F, pp.20-23.

This cannot be explained fully here. Please refer to ethical consideration 1 p.9.

Information that becomes available during the study and that may be relevant to continued participation

p.2.7. How will you ensure that participants receive information that becomes available during the study and that may be relevant to their continued participation?

[< 1200 characters]

Contact details gathered during screening for eligibility. Will be able to contact patients via this means.

Information about the results of the study

p.2.8. Will you inform participants of the results of your study?

(•) Yes ( ) No

p.2.9. Please *either* explain how you will inform participants or explain why you do not intend to do so.

[< 600 characters]

Via hard or soft copy, at their request, as informed by patient at recruitment

Consent should be voluntary.

p.3.1. *Generic copies of any advertising that you intend to use to encourage potential participants to take part in your study must be uploaded in the "Documents" tab before submission to an HDEC.*
Please explain how potential participants will be identified and approached in a way that ensures they can give informed consent free from undue influence.

[< 1200 characters]

NA

Potentially vulnerable people

p.3.2. Will your study involve potentially vulnerable people – that is, people who may have a restricted ability to make independent decisions about their participation?

( ) Yes (•) No

Inducements

p.3.3. Will participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in your study?

○ Yes ◉ No

P.4 Population groups, particularly Māori, should be consulted in the design and conduct of research that is of relevance to them.

Consultation with Māori

p.4.1. Please describe whether and how your study may benefit Māori.

[< 1200 characters]

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. If discrepancies between Maori and Pakeha are discovered, we intend to work further with Dr Wihongi to redesign, more appropriately our intervention

p.4.2. Please identify the main cultural issues that may arise for Māori who may participate in your study, and explain how these issues will be managed.

If Māori will be excluded from participating, please state this. You will be asked to explain your inclusion/exclusion criteria in the next section of the Form.

[< 1200 characters]

Nil significant.

p.4.3. According to the Health Research Council's Guidelines for Researchers on Health Research Involving Māori, is formal consultation with Māori required for your study?

◉ Yes ○ No

p.4.3.1. Please either describe your study's consultation process, or explain why you do not consider that formal consultation with Māori is required.

[< 1200 characters]

Consultation has occurred and approval given, by the Director of Maori Health Research across the Waitemata and Auckland DHBs, Dr Helen Wihongi.

Please refer to pp.10-11

p.4.4. Does your study involve kaupapa Māori research methodologies?

○ Yes ◉ No

Consultation with other relevant population groups

p.4.5. Will any other population groups be specifically targeted for recruitment into your study?

○ Yes ◉ No

Collection of ethnicity status

p.4.6. Will participants' ethnicity status be collected as part of your study?

◉ Yes ○ No

Community intervention studies

p.4.7. Is your study a community intervention study?

○ Yes ◉ No

f.1 Where possible, research should reduce health inequalities.

f.1.1. Might your intervention study contribute to reducing inequalities in health outcomes between different populations, and particularly between Māori, Pacific peoples and other New Zealanders?

◉ Yes ○ No

f.1.2. Please explain your answer above.

[< 1200 characters]

Currently data do not exist for the prevalence of PND in the specific study population. Identifying an inequality is essential to address and reduce inequality.

f.2 Participants and non-participants should be treated fairly compared to each other

Inclusion and exclusion criteria

f.2.1. Please briefly describe the inclusion and exclusion criteria for your study.
You can refer to page numbers of your study's protocol where further detail is required.

[< 2000 characters]

The eligible population will be mothers of infants delivered by public Caesarean section identified from the Maternity Ward Clinical Charge Midwife's (CCM) register of mothers requiring a doctor's review.

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 under the care of the private services operating within NSH; 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.

f.2.2. Please explain how these inclusion and exclusion criteria ensure that the risks and benefits of your study are distributed fairly.

[< 1200 characters]

The exclusion criteria are largely a matter of practicality and appropriateness. E.g. not appropriate to intervene in women who are already receiving care, or where the study authors were involved in labour cares.

The only significant concern is around the exclusion of those who could not consent without an interpreter. Anecdotally, this is estimated to represent a very small minority of the total population, but is a study limitation. If the study proves to be beneficial, and rolled out to all patients, then the intervention can be given in written form in the appropriate language, to fairly reach the population. The verbal nature of evaluation makes this very difficult though for the current study.

Placebo-controlled Studies

f.2.3. Does your study involve the use of placebo?

○ Yes ◉ No

Impact on health and disability support service provision

f.2.4. Might your study adversely impact on the provision of health and disability services?

○ Yes ◉ No

Best intervention standard

f.2.5. *An intervention study meets the best intervention standard if the intervention(s) in the study are tested against the best proven intervention(s) available outside the study.*
Please explain how your study meets the “best intervention standard”.

[< 600 characters]

There is currently no best proven intervention in the study population for this specific disease. The intervention is hoped to be the "best intervention" based on extrapolation, population research, and educated discussion.

f.3 Different groups of participants should be treated fairly compared to each other

Post-study access for participants to best-proven intervention

f.3.1. Will all participants have continued access to the best-proven intervention after the end of your intervention study?

◉ Yes ○ No

Equipoise Standard

f.3.2. *An intervention study meets the equipoise standard if the evidence is ‘equally poised’ as to the overall balance of risks and benefits of each of the interventions offered in the study, so that it cannot be determined in advance which of the groups in a proposed study will be better off.*

Please briefly explain how your intervention study meets the equipoise standard.

[< 600 characters]

As discussed, we have not found any study evaluating the role of the post-Caesarean section debrief as a potential intervention and screening tool for PND. Related studies have been equivocal. 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.