TE WHARE WĀNANGA O TE ŪPOKO O TE IKA A MĀUI VICTORIA UNIVERSITY OF WELLINGTON

Centre for Women's Health Research | Te Tātai Hauora O Hine

Participation Information Sheet for Pregnant Women

Study title:	**He Korowai Manaaki Wairoa – A Wrap Around Approach**	
Locality:	**Wellington**	Ethics committee ref: 17/STH/112
Lead investigator:	**Bev Lawton**	Contact phone number: 021 0237 5264

Your GP practice / midwife are taking part in a research project called **He Korowai Manaaki – A Wrap Around Approach**. This project offers extra appointments and additional care to pregnant women. The new appointments are free and you do not have to attend if you don't wish to.

This information sheet will help you decide if you would like to take part and explains why we are doing the study, what your participation would involve, what the benefits and risks might be and what will happen after the study ends. You do not have to decide today whether or not you are happy to be included in this study.

If you agree to participate you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet for Pregnant Women and the Consent Form to keep.

WHAT IS THE PURPOSE OF THE STUDY?

It's important that you and your whare tangata (womb) are well, safe, warm and healthy whilst you are pregnant and growing your baby. These added appointments to your usual maternity care give you and your care providers' opportunities to think of how best to support you and your whānau during and after your pregnancy (including possible free transport to appointments).

Your GP practice / midwife wants to be part of this research so that together we can learn if extra appointments, added services and time provided to women during their pregnancy help to keep mums and babies healthier. It is hoped that in the future other pregnant women can receive this free additional care and that outcomes for women and babies in Aotearoa New Zealand can improve for everyone.

WHAT WILL PARTICIPATION IN THE STUDY INVOLVE?

Your first appointment will check upon your general health and there will be time to talk through what else could support you to stay well and healthy during your pregnancy.

You will be put in touch with a midwife and invited for another appointment to follow up on any results and see how you are at this early stage. Usual care continues with your midwife.

Then at around 32 weeks pregnant you will be booked to see your GP again so that you and your GP can make plans for you and your child's health after the baby is born. Your midwife is welcome to attend any visits with you if you would like.

About 6 weeks after your baby is born another appointment with your GP will be booked and you, your baby and whānau can attend this appointment together to discuss your needs and your baby's. Free contraception is provided if you wish.

All these appointments are free of charge.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

Our research group wants to learn whether this care for pregnant women leads to better health for women and babies. In order to do that we need to look at how you and your baby are in the year that follows the birth of your baby. This information is already collected by the Ministry of Health who will be asked to share this with the research group.

The research group will not receive any information that identifies you. We will not know your name, NHI (national health index number), or your address and we will not be able to identify which GP practice you have received care from.

If this extra assistance is shown to be beneficial, this study will show the Ministry of Health how it can support women and babies to stay well during and after pregnancy. This type of care might then be offered throughout New Zealand to all pregnant women.

WHAT ARE MY RIGHTS?

Your participation in the study is entirely voluntary and you do not have to attend any of the appointments if you do not want to. You can also choose to withdraw from the study at any time, without experiencing any disadvantage.

You are welcome to ask your doctor and midwife more about this study (**He Korowai Manaaki**) and they can answer any questions. If your family, whānau or friends would like to know more they are also welcome to get in touch with the research team on the contact number below.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

This extra type of care for women during pregnancy will be offered by your practice for approximately 1 year – if you choose to not have the health outcomes of you and your baby included in the study, you are still able to receive the extra GP visits if you wish.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

This study is based at the Centre for Women's Health Research (Victoria University of Wellington) and is funded by the Health Research Council of New Zealand.

If you have any questions, concerns or complaints about the study at any stage, you can contact: The Principle Investigator, Professor Bev Lawton:

Tel +64 4 463 5497 Mobile +64 21 463762 Bev.lawton@vuw.ac.nz

The Project Manager, Francesca Storey

Mobile +64 21 0237 5264 Francesca.storey@vuw.ac.nz

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

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

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Individual Consent Form

If you need an INTERPRETER, please tell us.

Please tick to indicate you consent to the following: I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.	Yes ☐	No ☐
I have been given sufficient time to consider whether or not to participate in this study.	Yes ☐	No ☐
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 ☐	No ☐
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 ☐	No ☐
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 ☐	No ☐
I consent to the research staff receiving de-identified information about my and my baby/babies health	Yes ☐	No ☐
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 ☐	No ☐
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 ☐	No ☐
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 ☐	No ☐
I know who to contact if I have any questions about the study in general.	Yes ☐	No ☐
I understand my responsibilities as a study participant.	Yes ☐	No ☐
I wish to receive a summary of the results from the study.	Yes ☐	No ☐

Declaration by participant:

I hereby consent to take part in this study.

Participant's name: _____

Signature: _____ Date: _____

Declaration by member of practice:

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.

Name: _____

Role in Practice: _____

Name of practice group: _____

Signature: _____ Date: _____

SECOND PART OF THE STUDY

We are also interested to learn about your experience with this new wrap-around approach of He Korowai Manaaki.

Separate to your agreement to take part, would you agree to being contacted by a member of the research team in the future to talk about your experience?

More information would be given to you at that time and agreeing to potentially be contacted does not mean that you have to take part.

Agreement by participant:

I hereby agree to be contacted to find out more about sharing my experience.

Participant's name: _____

Signature: _____ Date: _____