Participant Information & Consent

Record ID _____

POPPIL feasibility study: Participant Information Sheet	
Title: Posture for 'back-to-back' (OP) position in labour	
Formal study title: Does posture for occiput posterior position in labour (POPPIL) reduce operative births? A Feasibility Study	
Locality: Middlemore Hospital & Auckland City Hospital **Lead Investigator:** Dr Jennifer Barrowclough, Department of Midwifery, School of Clinical Sciences, Auckland University of Technology.	Health and Disability Ethics Committee Reference: 2024 FULL 19149 Phone contact: +642102486544

You are invited to take part in research on whether maternal posture can help your labour when your baby is in a 'back-to-back' or posterior position. You need to be at least 16 years of age, plan to labour at Middlemore Hospital or Auckland City Hospital and have a baby in a 'back-to-back position' in labour. 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.

This Participant Information will help you decide if you would like to take part. You may want to talk to family, whānau, friends, or healthcare providers before you decide.

If you choose to participate, your labour and birth information will be used to increase knowledge on the effect of maternal posture when pēpe [baby] is 'back-to-back' with māmā and will inform future research on this topic. Please keep a copy of this Information Sheet.

This document is 4 pages long. Please make sure you read and understand all the pages.

WHAT IS THE PURPOSE OF THE TRIAL?

'Back-to-back' is when your pēpe's [baby's] back lies near māmā's [mother's] back. It is called occiput posterior or OP position by midwives and doctors. At the start of labour, a third of pēpe are in this position but most turn to the front by the end of labour. Those that remain 'back-to-back', may need a caesarean, or instrumental birth. It can also mean backache, longer labour, and longer hospital stay and sometimes pēpe need help breathing or go to intensive care. A māmā's [mother's] posture [position] may help their pēpe turn to the front so they fit through the pelvis for birth, but this needs further study.
The objective is to see how well this trial works before planning a larger trial. For example, whether hapu [pregnant] people join and stay in the trial, find the posture comfortable, are satisfied, and if the posture improves labour and birth.

This study receives funding from the Auckland Medical Research Foundation who have no third-party interests. The researchers are affiliated with Auckland University of Technology (AUT), The University of Auckland, Women's Health at Counties Manukau and Te Toka Tumai, Auckland, and Kids First, Counties Manukau. Researchers and their family or relatives may not take part in the study.
The study has been approved by the Health and Disability Ethics Committee on 13th February 2024. Reference number 19149.
If you have any questions relating to this study please contact Lead Investigator: Dr Jennifer Barrowclough, email: poppil@aut.ac.nz or phone +642102486544.

WHAT WILL MY PARTICIPATION IN THE TRIAL INVOLVE?

Participation is voluntary. Whether you choose to participate in the survey or not, will make no difference to the care you receive. During labour, the research midwife, or doctor (Auckland City Hospital) offers a bedside scan to check if your pēpe is 'back-to-back' [OP]. If your pēpe is OP you can choose to consent to participate in the trial. The research midwife, or midwife (Auckland City Hospital) collects your consent and uses a computer to randomly allocate you to use a side-lying type posture, or free posture. If your baby is not 'back-to-back' [OP] you would not be in the study and would continue your labour as usual.

You are free to choose an epidural or other analgesia as you wish. Use of the side-lying type posture is preferably for 40 minutes or more each hour until birth. The remaining 20 minutes or so each hour you are free to mobilise or use alternative forward type postures e.g. hands and knees. If you are allocated to use free posture, this includes upright, walking, hands and knees, changes from side to side, or use of Swiss and Peanut balls.

The research midwife, or midwife (Auckland City Hospital), will ask your level of discomfort/pain before the trial and approximately 1 hour after. The research midwife, or your birth partner/support person (if they consent), will record your posture use each hour by placing a tick on the form provided. When you return home, the researcher will send an online survey asking about your satisfaction with your labour overall, and your satisfaction with the type of posture you used.

HOW IS THE STUDY DESIGNED?

At least 30 people will take part over a 6-month period. Trial participation is from established labour until birth. You have an equal chance of being randomized to either posture group. Routinely collected information about your labour and birth and your pēpe's [baby's] health will be collected from your maternal and infant hospital records. We request your permission, rather than legal consent, to collect and use your pēpe's information from hospital records. Your posture/s are recorded each hour.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS TRIAL?

The main benefit of the study is the information about using maternal posture for 'back-to-back' position of pēpe [baby] in labour. This can also inform a larger trial later. There are no expected risks to participating in this study. Your information will remain private and confidential. No one will be informed of your participation. Storage of all data will be password protected and only de-identified

data will be used in analysis and reporting. The lead investigator is available if you have any queries about the survey. Contact details are below.

WHO PAYS FOR THE TRIAL?

Participation in the study is free. The research is funded by an independent organisation with no vested interest in the outcome of the trial.

IS THERE ANY REIMBURSEMENT?

Participants will be offered a $50 shopping voucher by the researcher in recognition of their participation.

WHAT WILL HAPPEN TO MY INFORMATION?

Identifiable Information: Your and your pēpe's [baby's] identifiable information e.g., name, date of birth, or address: will only be known to the researchers, maternity care provider in labour, or ethics committee (if study or site audited).

De-identified (Coded) Information: To make sure personal information is kept confidential, information that identifies you or your pēpe will not be included in any report generated by the researcher. Instead, you will be identified by a code. Your pēpe will have a similar code. The researcher will keep a list linking your and your pēpe's codes with your names, so that you can both be identified by your coded data if needed. The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you or your pēpe. Your and your pēpe's coded information may be used for a larger related study by the researchers about use of posture for OP position.

Māori Data Sovereignty: *Māori data sovereignty* is about protecting information or knowledge that is about (or comes from) Māori people. We recognise the taonga of the data collected for this study. To help protect this taonga, we have consulted with Iwi United Engaged (IUE) about the collection, ownership, and use of study data. We allow Māori organisations to access de-identified study data, for uses that may benefit Māori. The study is overseen by IUE's Kaupapa Māori Project Management Plan.

WHAT ARE MY RIGHTS?

Participation is voluntary. Your right to privacy and confidentiality is assured. You have the right to request access to your information held by the research team or request it is corrected if you disagree with it. Whether you choose to participate or not participate makes no difference to the care you are receiving. You may choose to withdraw from the trial at any time.

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

You may withdraw your consent for the collection and use of your information at any time by informing the study's Lead Investigator. If you withdraw, your study participation and collection of data will end. If you agree, information collected up until you withdraw, will continue to be used in the study. You may ask for it to be deleted when you withdraw. All computer stored information is password protected. Paper information will be stored in a secure location within AUT. All researchers sign

confidentiality statements prior to the trial. The lead investigator is responsible for storage and destruction of identified information about you and your pēpe [baby] after 10 years in accordance with AUT, Counties Manukau Health and Te Toka Tumai, Auckland. The following acts and guidelines will also govern the use of data: The Health Act 1956, Health Information privacy Code 1994 and the Privacy Act 2020. A summary of trial results is emailed to you if you consent for this.

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 Jennifer Barrowclough
Lead Investigator,
PhD Midwife
Phone 02102486544
Email: poppil@aut.ac.nz

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate:
Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@advocacy.org.nz
Website: https://www.advocacy.org.nz/

For Māori cultural support please contact:
Iwi United Engaged (IUE)
Email: iue.net.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on:
Email hdecs@health.govt.nz
Phone: 0800 400 569 (Ministry of Health general enquiries)

Approved by the Health and Disability Research Ethics Committee (HDEC) on 13th February 2024.
Reference number 2024 FULL 19149

Consent Form. Please complete after reading the Participant Information Sheet at the top of this form.

a. I have read the Participant Information Sheet (version 9.2) and understand the information.

b. I have had enough time to decide if I want to participate and understand it is my choice.

c. I have had the opportunity to ask questions and I am satisfied with the answers.

d. I have a copy of this consent form and information sheet.

e. I understand I can withdraw any time, give no reason, receive no penalty, and my medical care and birthing plan will not be impacted.

f. Research staff may collect/process information in my maternal records for this pregnancy.

g. I give permission for the collection and use of my baby's information, as described in the Information Sheet.

h. I understand that my participation is confidential, and I will not be identifiable in any reports on this study.

i. I know who to contact if I have any questions about the study in general.

◯ Yes ◯ No

If I withdraw from the study, I consent to previously collected information to be used.

◯ Yes ◯ No

I wish to receive a summary of the results from the study.

◯ Yes ◯ No

I am happy to be contacted for further follow-up studies.

◯ Yes ◯ No

Participant first name:

_____

Participant last name:

_____

I hereby consent to take part in this study (signature)

_____

Participant date & time:

_____

As the partner/support person, I consent to help record posture use each hour until birth by placing a tick on the form provided (optional - see note below).
(Please note: If semi-prone posture is allocated, you would place a tick in one of three boxes each hour. The boxes relate to how much time was spent in the semi-prone posture. If free posture is allocated, you place a tick beside what posture/s were used each hour. Whether you do this or not will not affect the pregnant person's ability to take part in the study.)

◯ Yes ◯ No

Partner/support first name

_____

Partner/support last name

_____

_____
(Partner/support person signature)

Partner/support date & time

_____

Study explained by:

_____
(Study explained by: Midwife/Obstetrician/Researcher Name)

Midwife/Doctor/Researcher signature

_____

Date & time

_____

Upload hard copy PISCF

(Administration only)