

# Development of a Musculoskeletal Model to Understand Changes in Lumbopelvic Pain during Pregnancy

## *Participant Information Sheet*

### **Study Investigators**

Dr Julie Choisne (Principal investigator)

Professor Patria Hume (Co-investigator)

Dr Hannah Wyatt (Co-investigator)

Jie Chen (Research student)

### **Introduction**

You are invited to take part in this study, which aims to develop a musculoskeletal model to better understand the changes in lumbopelvic pain during pregnancy. This research is collaboratively conducted by researchers from the Auckland Bioengineering Institute (ABI), the Sports Performance Research Institute New Zealand (SPRINZ) of the Auckland University of Technology (AUT) and The University of Canterbury. The study will be overseen by Dr Julie Choisne, a senior research fellow and primary investigator at the ABI, Prof. Patria Hume, a specialist in biomechanics and kinanthropometrist, Dr Hannah Wyatt, a specialist in gait and injury prevention biomechanics and Mr Jie Chen, a PhD student at the ABI.

This informational sheet is designed to help you determine whether you wish to participate in the study. It outlines the purpose of the research, the procedures involved, potential benefits and risks, and what happens after the study concludes. We will review this information with you and address any questions you may have. You are encouraged to discuss the study with others, such as family/ whānau, friends, midwives, or healthcare providers. Participation in the study is entirely voluntary, and you are free to decline without providing a reason and without any impact on your healthcare. If you decide not to participate, there are no consequences. Your decision will not affect your relationship with any member of the research team or any of the institutions involved. If you initially agree to participate but change your mind later, you may withdraw from the study at any time; no explanation is necessary. If you decide to participate, you will be asked to complete and sign a Consent Form, and you will receive copies of both the Participant Information Sheet and the Consent Form for your records.

This document is 6 pages long. Please make sure you have read and understood all the pages.

### **Why are we doing the study?**

Pain in the lower back, pelvis, or both, which are collectively called as lumbopelvic pain, is the most common musculoskeletal complaint during pregnancy. Pain in these regions typically increases with advancing pregnancy, interfering with work, daily activities and sleep.

Through computer simulation, we can estimate the lumbopelvic joint and muscle loads of pregnant women during functional activities (e.g., walking, standing up and sitting down) to better understand the development of lumbopelvic pain during pregnancy, and potentially enabling us to predict the onset and severity of pain. However, the computer model of pregnant women we have now is not adequate. Unfortunately, it doesn't consider how pregnant women move and how muscles change during pregnancy, even though they play a crucial role in the calculation of joint loads. Therefore, we have developed a more detailed pregnancy-specific model to understand contributors to lumbopelvic pain so interventions can be developed and assessed adequately.

We will use a 3D whole-body imaging scanner to get your body shape at each of your visits. The 3D body imaging scanner uses safe light to capture the external shape of your body and has been used in various other projects by our staff and at other institutions. This technology is now widely used for clothing shopping and muscle to fat ratio measurement at the gym and has also been used for the study of over 2,000 women throughout pregnancy. With these 3D images, we'll create a new model that shows how a woman's body changes during pregnancy.

Understanding how pregnant women move is important to understanding the loads applied to the joints throughout computer modeling. To investigate the movement and muscle forces needed for each task, we will use motion capture cameras that can track retroreflective markers moving in space (just like in the movie and gaming industry). Therefore, small reflective markers will be adhered to some specific parts of your skin so we can track your movements. You will be asked to walk and do simple daily activities such as standing torso rotation and sit-to-stand. From this data, we can calculate things like how your joints rotate and move, and even estimate the forces of the muscles and joint loads inside your body during these activities. Don't worry, the camera can only detect the marker location and will not record any other information that could identify you.

### **What will participation in the study involve?**

The study will involve longitudinal data collections of participants pre- (if feasible), during- and post-pregnancy. You will be invited to attend at least 3 times at AUT Millennium, one time in each trimester (1-12 weeks, 13-26 weeks, and 27 to the end) of your pregnancy. You will also have the option of attending a visit before becoming pregnant if you are trying to conceive and a visit within 6 months after delivery. The data collection process will be the same for each visit.

The visit involves three data collection phases: questionnaires, movement analysis and 3D whole-body scanning.

1. You will first have your heart rate, temperature, and blood pressure checked to ensure that you are safe to take part. This data will not be stored or used for the research, but it will act as a pre-test health check. If you qualify for the study, you will be asked to fill

out a questionnaire about pregnancy-related lumbopelvic pain. You will then be offered a private space for you to change into the standardise data collection wear – a sports bra and shorts. The room has an automatic locking door, and access is limited to specific personnel. The sizes of the apparel will be revised as the participant progresses through the study. Before the motion capture session, you can choose to get surface electromyography (EMG) placed on your belly and back muscles to record your muscle activity. This process involves placing small electrodes on the skin to measure the electrical activity of your muscles while you perform certain movements. The electrodes will only be placed on the skin surface and will not cause any harm or penetration. These selected participants will comfortably sit on the examination bed and get 4 sets of surface electrodes placed on the skin by a trained researcher (can be requested to be female). The operator will observe the participant for any signs of discomfort or adverse reactions throughout the electrode placement process.

2. You will then be guided to the next room (side-by-side, approximately 2 steps between) for the motion capture. A set of 67 reflective markers (little grey balls of 6.35 mm diameter) will be placed by a trained researcher on your skin at specific landmarks to record your movement. The markers' trajectories will be tracked by several cameras. The markers will be attached to the skin using double-sided hypoallergenic tape. This technology captures body movement without emitting any radiation or direct impact on the body. During the motion capture, we will ask you to walk barefoot several times. We'll also guide you through some extra movements, such as standing torso rotation and stand-to-sit-to-stand. You can talk during the experiment and give us verbal statements of discomfort at any moment. You can request to stop the collection process or not complete certain movements at any point without giving a reason.
3. After the motion capture, you will be escorted to the next room for 3D whole-body imaging. You will be given a dressing gown to wear for the transition from one room to the other. You will then be directed to the 3D imaging pose and scanned (1 minute) by the 3D scanner. The 3D body scanner is entirely radiation-free, ensuring that no harmful exposure affects the mother or the fetus, providing a safe, non-invasive solution for capturing the body shape. The entire visit will last no longer than 2 hours. Once the data collection is completed, the markers (and electrodes if you participate in EMG recording) will be carefully removed from your skin, and you will be escorted back to a room where you can change back into your own clothes. You will be given the opportunity to discuss your experience and ask any final questions you may have.

### **What are the possible risks to your participation?**

As in everyday life, there is a chance of accidental falls during the collection process. However, we will make sure the risk is minimized. The researchers will check with you during the collection process, and you will be encouraged to stop if you experience any discomfort. All equipment used for the experiment meets clinical safety standards and will be tested normally. All researchers will be well trained, safety precautions will be in place and every session will be closely monitored during the data collection.

### **What will happen when incidental findings are a possibility?**

Unanticipated medical conditions in the mother that were previously undiagnosed may happen during pregnancy, such as hypertension, infections, physical pains other than lumbopelvic pain, and mental illness. Any incidental findings that could impact the health of the mother or

fetus will be communicated promptly to the participant. The participant will be advised to seek further evaluation from their healthcare provider. If the participant consents, we will assist in facilitating communication with their healthcare provider to ensure they receive appropriate care. If an incidental finding significantly alters the risk profile of the study, the research team will collaborate with the participant's healthcare provider to determine whether it remains safe for the participant to continue in the study, and participants should be re-consented, with a discussion about whether they wish to continue in the study.

### **What are the benefits of this study?**

You will receive the results of this study if you desire to. You will be offered a \$20 gift voucher at the end of each visit. This study will provide researchers and clinicians with a better biomechanical understanding of pregnancy-related lumbopelvic pain, also providing ideas for physios and midwives to prevent and treat lumbopelvic pain during pregnancy. Ultimately, the goal is to enhance the pregnancy experience by alleviating pain and supporting the well-being of pregnant mothers.

### **Can I bring any companion during the experiment?**

We recognize the importance of support from family, friends, and whānau during your participation in this study. You are welcome to have a member of your whānau or a support person present during data collection sessions if this would make you feel more comfortable. We encourage you to let us know in advance if you would like someone to accompany you so we can make any necessary arrangements.

### **Withdrawing from the study**

Your participation is completely voluntary. You are free to decline to participate or withdraw from the research at any time without experiencing any disadvantage and without giving a reason.

### **What will happen to my information?**

All gathered data will remain de-identified, with privacy guaranteed throughout the research process, from collection to storage and dissemination. All gathered data will be stored by REDCAP (University of Auckland managed secure, web-based research data capture tool) and securely retained for ten years following the project's conclusion. To make sure your personal information is kept confidential, identifiable information will not be included in any report generated by the research group. Instead, you will be identified by a key code (i.e. de-identified). The study investigators will keep a list that links your key code to your name, ensuring your identification through your coded data, if necessary, for instance, in case of your withdrawal from the study, but this will not be available to anyone other than the research team listed on this information sheet. The results of the study may be published or presented, but not in a form that would identify you.

### **What will happen to the results of this research?**

During or upon completion of the study, research findings will be used in PhD thesis and submitted for publication in international journals that report medical and scientific research, including internal reports, journal papers, and conference presentations. There is the potential that research from this and/or future studies could contribute to developing a commercial product in the future. Your data will not make up any part of any product (identifiable or de-

identified data), but your de-identified data may be used for research to develop a product that can support pain reduction for women during pregnancy.

### **What will happen after the study ends or if you decide to pull out?**

Participants are allowed to pull out of the study at any time without giving a reason and to withdraw any data traceable to them up to 13 months after signing the consent form. You can contact anyone other than the research team listed on this information sheet to inform you of your intention to pull out.

### **Where can you go for more information for cultural support?**

Our research is committed to respecting the cultural values and individual dignity of all participants. We understand that participation in a study may bring unique cultural considerations, and we aim to support each participant in a manner that honors their background and beliefs. For any cultural support or guidance during your participation, you may contact Iwi United Engaged at [misty@iue.net.nz](mailto:misty@iue.net.nz) or by phone (0274890804). They are available to discuss any cultural concerns you may have to ensure a comfortable and respectful experience throughout the study.

### **Where can you go for more information about the study or to raise concerns or complaints?**

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

Principal Investigator: Dr. Julie Choisne  
The University of Auckland  
Auckland Bioengineering Institute  
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For any queries regarding ethical concerns, you may contact: The Chair, The University of Auckland Human Participants Ethics Committee, Office of the Vice Chancellor, Level 10, 49 Symonds Street, Auckland 1142. Telephone: 3737599 ext 83711. Email address: [ro-ethics@auckland.ac.nz](mailto:ro-ethics@auckland.ac.nz)

If you require Māori cultural support, talk to your Whānau in the first instance. If you have any questions or complaints about the study, you may contact:

Misty Edmonds  
Email: [misty@iue.net.nz](mailto:misty@iue.net.nz)  
Phone: 0274 890 804

### **Statement of Approval**

APPROVED BY THE AUCKLAND HEALTH RESEARCH ETHICS COMMITTEE ON 27/11/2024 FOR A PERIOD OF 3 YEARS. REFERENCE NUMBER 27603.