

Participant Information Sheet

Date Information Sheet Produced:

February 18th 2021

Project Titles

Te Kukunetanga: Developing Cycle of Life Research Programme

Project 1: Physical Evolution through Pregnancy (PEP)

Project 2: Running Evolution through Pregnancy (REP)

Project team

- Professor Patria Hume – AUT SPRINZ Professor, Principal Investigator
- Dr Hannah Wyatt - AUT SPRINZ Post-doctoral Fellow, PEP Biomechanics Lead
- Ms Sabina Just - AUT SPRINZ PhD scholar, certified and practicing midwife
- Dr Kelly Sheerin - AUT Millennium SPRINZ Clinics Manager and Senior Lecturer, PEP Kinanthropometry Lead
- Dr Heather Donald - AUT Clinical Lecturer, PEP Midwifery Lead
- Dr Dean Mahuta - AUT Senior Lecturer, Vision Matauranga and Engagement Lead
- Dr Sarah-Kate Millar - AUT Senior Lecturer, PEP dynamic movement collaborator
- Professor Judith McAra-Couper - AUT Professor, PEP Midwifery collaborator
- Dr Nimisha Waller - AUT Clinical Lecturer, PEP Midwifery collaborator
- Professor Susan Crowther - AUT Professor, PEP Midwifery collaborator
- Dr Sally Britnell – AUT Senior Lecturer, PEP Nursing Lead & Data Management Lead
- Dr Bridget Munro - NIKE Scientist - PEP Biomechanics collaborator
- Dr Jane Cappaert - NIKE Scientist - PEP Biomechanics collaborator
- Dr Emily Emily Lawrence - NIKE Scientist - PEP Biomechanics collaborator
- Dr Cailee Caldwell - NIKE Scientist - PEP Biomechanics collaborator
- Oliver Viant – Research Intern – University of Bath

Te Kukunetanga - Developing Cycle of Life Physical Evolution Through Pregnancy Project (PEP)



Close coordination and engagement of this multidisciplinary team in the Te Kukunetanga – Physical Evolution through Pregnancy project has successfully established procedures and systems for balancing the competing project and ethical needs.

An Invitation

My name is Professor Patria Hume, and I'm a researcher at AUT University. Together with my colleagues at AUT and our partners at Nike (who are partially funding this research), I would like to invite you to participate in a research programme that will assess: 1) how body shape and size change during pregnancy and postnatally; 2) how these changes influence balance, walking and running function.



What is the purpose of this research?

A women's body undergoes unique progressive changes in shape and size throughout pregnancy and in the six months after the birth. Although it is generally accepted that the physical changes experienced throughout this time affect the way women walk, run, balance, exercise and carry out daily tasks, we currently have limited insight into how these relationships evolve across time, and how they differ between women. By monitoring physical and functional changes of women throughout pregnancy and post-natal, we can develop foundational knowledge of the pregnancy journey which will provide an opportunity to inform health-related practices for pregnant woman. Therefore, the aim of this research programme is to monitor changes in body shape and size, walking and running gait and balance throughout pregnancy and in the 6 months after the birth, in addition to understanding factors which may contribute to the physical changes experienced.

How was I identified and why am I being invited to participate in this research?

We are seeking women at any stage of pregnancy, or those who are currently trying to become pregnant, who are willing and able to visit the Te Kūketanga rooms in the AUT Millennium Clinics at Antares Place on Auckland's North Shore at intervals throughout their pregnancy and in the 6 months post-natal.

Are there any women that can not participate in this research?

- If you are under the age of 18 years and over the age of 40 years.
- If you have existing medical conditions and do not receive permission to participate from your doctor/midwife.
- If you have a history of substantial foot, ankle, knee, musculoskeletal or neuromuscular trauma/disease.
- Women who develop pregnancy-related complications may need to be withdrawn from the study but may re-enter when these complications subside.
- Participants who suffer an injury may still participate in parts of the study should this not affect their injury and with permission from their health professional.
- If you have been advised by your general practitioner not to participate for any health-related reason.
- To be included within the running aspect of this study individuals must;
 - Have run prior to pregnancy
 - Have run a minimum of once per week
 - Currently be able to run for a minimum of 20 minutes during each session

How do I agree to participate in this research?

We encourage you to read the information provided to learn more about the details of the study, as well as consult with your whānau, lead maternity carer midwife, GP or obstetrician (where appropriate). If you are keen to participate, you can indicate this by contacting us via phone or email on the details provided at the end of this information sheet. For those who are interested in being involved with the running aspect of this study, please specify when contacting us. We will guide you through a series of questions to confirm your eligibility for this research before booking your first session. Before progressing with this initial session, you will have the opportunity to ask any additional questions; once you have all the information you require, you will be asked to provide written consent via a form which will be provided to you. At this stage, we will also check your vital signs (i.e. heart rate, blood pressure, respiration rate, temperature, oxygen saturation) to ensure you are safe to participate on the day.

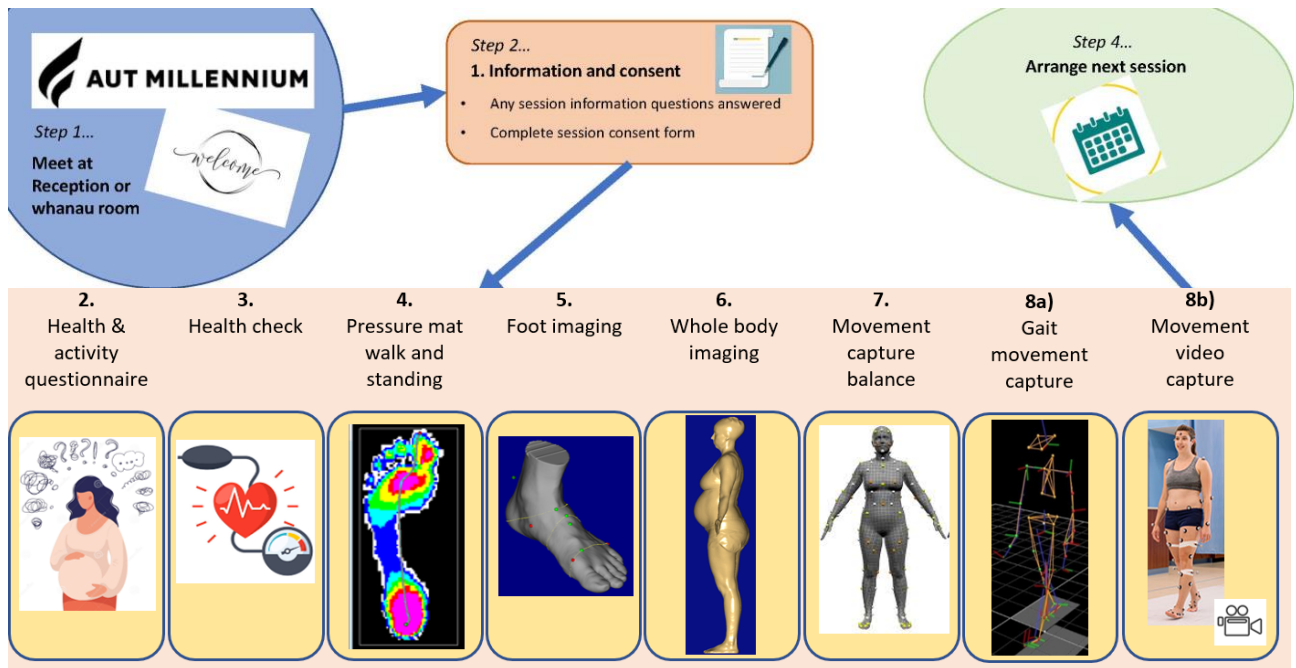
Please note your participation in this research is voluntary (it is your choice) and whether or not you choose to participate will neither advantage nor disadvantage you. You can withdraw from the study at any time. If you choose to withdraw from the study, then you will be offered the choice between having any data that is identifiable as belonging to you removed or providing your permission for its continued use within this research study. However, once the findings have been produced, removal of your data may not be possible.

For Māori participants in these research studies, there may be cultural considerations associated with the collection and storing of your information. These considerations should be discussed with your family/whānau as appropriate, citing the protection of whakapapa. Controlling access to your data and limiting unauthorised use of your information are important questions that you may need to think about before consenting to the research. It is also acknowledged that people have the right to choose whether they participate or not in a research study. You may also like to think about the direct benefits that this research will have for yourself, your whānau and for Māori as a people. We advise participants to consult with their whānau prior to consenting to participate in a research study and suggest that your family/whānau are involved with you at all stages of the research.



What will happen in this research?

Below is an outline of the session collection process. Sessions will take approximately 30 minutes every month and one hour every trimester. For those who take part in the running portion of the study, each monthly session will last one hour.



During each session visit you will be given the option to participate in any or all the assessments you would like to by selecting Yes or No on a "Session data collection consent and health check" form.

Data collection options include:

- Health and activity-related questionnaire(s)
- Health checks (i.e. blood pressure, oxygen saturation, temperature, respiration rate)
- Foot and whole-body imaging (non-hazardous)
- Body movements during walking and balance
- Running questionnaires and movement capture.

Details of data collection

Depending on what you consent to, we will be collecting up to eight types of information as part of this study in each assessment session: 1) Consent to start the day's assessments; 2) Health and physical activity questionnaires (completed online); 3) Health check of vital signs; 4) Pressure under your feet as you walk and stand on a mat; 5) Foot imaging to gain measures of foot size and shape; 6) Whole body imaging to measure whole body size and shape; 7) Movement capture while you balance; 8) Movement capture as you walk via marker tracking (a) and/or video (b) (9) Running-related questionnaires and movement capture as you run via marker tracking.

Only those who ran before getting pregnant and run for a minimum of once/week for at least 20 minutes will be invited to take part in the running aspect of this study. The running collections will be held at monthly intervals (aligning with the reduced collections). During the monthly visits you will be asked to perform a short warm up, followed by the completion of five ~20 meter overground running trials at your own self-selected pace. After the collection period, time will be given to cool down for as long as required. You will be given the option of running barefoot, wearing a pair of standardised running shoes as supplied by Nike, or doing both.

None of the processes or the movements involved will increase risk to yourself or your baby beyond what you would experience in daily living. You will be given the opportunity to take part in short assessment session every month lasting approximately 30 minutes (these exclude motion capture assessments #7 & 8) and full sessions every trimester lasting approximately one hour (includes all the assessments #1-8). Running study collections (all assessments #1-9) will take approximately 90 minutes every month. The monthly questionnaires are anticipated to take between 10 and 25 minutes to complete.



You will be invited to return for monthly reassessment until 6 months post birth. Further details of each section of the collection indicated in the flow figure are provided in the "TK-PEP data collection rooms and protocol information package".

What are the benefits?

A primary benefit of the research will be to inform understanding of how changing body dimensions throughout pregnancy impact on stability, walking and running ability. The insight we gain will allow us to better inform health-related practices during this phase of life. It is anticipated that this understanding will help in the design of clothing and footwear that better supports pregnant women, to help prevent discomfort and pain associated with standing, walking, running and to reduce the risk of falls during pregnancy.

Potential benefits during the project

- Get monthly health checks (heart rate, blood pressure, temperature, respiration rate, oxygen saturation, body mass).
- See how your body shape changes over pregnancy.
- Receive personal reports of how your body is changing to support the growth of your baby.
- An opportunity to connect with health professionals between your scheduled appointments.
- Attend participant only wellbeing seminars from a variety of experts e.g. nutrition, exercise and physical activity.
- Opportunities for personalised exercise plans to meet your needs and those of your whanau.
- Many women have a fall during pregnancy because of a loss of balance. It is hoped that as you learn more about how your body changes during pregnancy it will give you more confidence in how you move and help you in your balance to reduce your risk of falling.
- Gain an outlook on how your running technique changes as you move through pregnancy (if applicable)
- Have a better understanding of when to stop running during your pregnancy as well as safely returning to running post- pregnancy (if applicable).

Potential benefits at the end of your data collection sessions

- Receive a figurine (3D print) of yourself while you are pregnant from your whole-body image assessment if you would like.

Potential benefits at the end of the PEP project

- Post study there will be the ability to predict changes in body shape, size and vital signs to allow future wahine to have appropriate information and education when required throughout their pregnancy.
- Your participation will help us to build our understanding of changes women undergo during and post-pregnancy. We hope this will lead to advanced health care outcomes, both physical and mental.
- Currently, there is a large body of unsupported information stating that running during pregnancy can be harmful for both the mother and foetus. However, a recent international literature review has stated that exercise throughout pregnancy is beneficial unless there are contraindicated medical conditions. Your participation will allow us to add to the current gaps in the literature by gaining evidence.
- Your participation will help us to create robust guidelines for women wanting to continue running during their pregnancy as well as returning to running after birth.
- In New Zealand there is a trend of over half women having a baby via an instrumental birth or a caesarean section. We hope to find ways to change this trend so more women can have a vaginal birth. By participating in this study, you can help us find out how a woman's body changes in shape and size affect walking, balance, and emotion that may contribute to the birth outcome.
- NIKE are additionally developing a way of capturing motion data without using markers (i.e. markerless motion capture), for which they need many videos of people walking. The videos are used to develop their markerless motion capture model, so that the technique can be applied for motion capture in the future. This will ultimately lead to a quick and efficient way for us to collect movement data in the future.

What are the discomforts and risks and how will these be alleviated?

There should be no significant risk to you during the study, however some minimal risk in the way of potential discomfort is acknowledged. Standing in minimal clothing for the 3D whole body image assessment may introduce discomfort for some women. To minimise any discomfort, the imaging equipment has been housed in a private room and surrounded by a curtain; therefore, you will not be seen by anyone during the testing. A single operator will be present in the room during the scan; you may indicate if you wish for the researcher to be a female. It is



important for you to note that the researchers will be able to see the digital images that are obtained during the collection. You will be offered the chance to see the image of yourself on the computer if you would like to.

We have provided a Walk Through of the assessment rooms, and a video that shows the assessment stages. Please go to [Te Kūketanga: Developing Cycle of Life Research Programme - SPRINZ - AUT](#) for these videos.

In summary, the assessments will take place in three spaces at AUT Millennium, two are side-by-side (health check & foot image room is next to the 3D whole-body image room) and the biomechanics laboratory adjoins the health check & foot image room. The only time you will need to walk in the corridor is for approximately 2 steps from the health check & foot image room to the 3D whole-body image room, and back. The corridor is typically quiet, however, it is accessible by staff and students at AUT. We will ask you to change into clothing that is provided for the whole-body imaging and motion capture. So that we can collect measures of your body shape and size, this clothing will be minimal, although options with ranging skin exposure will be available. As you will be required to move from the whole-body image room to the motion capture room, a robe and slippers will be provided for you to wear, or should you wish to, you can change into your own clothes for this period of time. Each of the collection spaces contain private changing areas. You will also have the option of having a support person with you throughout the testing to assist in any way you should need.

The full-body imaging measurements are collected via a visible red light, which is not harmful to the body or eyes of the woman or fetus. We have provided a fact sheet for this which contains statements which have been supported by neonatal and physician experts.

The walking and balance activities are no more demanding than would be experienced during normal daily activities. If you experience discomfort at any stage, you are encouraged to inform the researcher with you at the time so that they can quickly address the problem.

If eligible to take part in the running portion of this study, a researcher will stand next to you during the running trials.

There is always the risk of the spontaneous loss of pregnancy. At an appropriate time, researchers will discuss with participants whether they are happy for data collected to date to remain in the dataset, or if they would prefer it were removed. In these circumstances, the woman will be encouraged to consult their GP and/or lead maternity carer, if they have not already. They will also be offered up to three counselling services through the AUT Counselling and Mental Health Support, at no cost. These sessions are only available for issues that have arisen directly as a result of participation in the research and are not for other general counselling needs. To access these services, you will need to:

- drop into our centre at WB203 City Campus, email counselling@aut.ac.nz or call 921 9998.
- let the receptionist know that you are a research participant, and provide the title of this research project research and the name and contact details of either researcher as given in this Information Sheet.

You can find out more information about AUT counsellors and counselling on <https://www.aut.ac.nz/student-life/student-support/counselling-and-mental-health>

All laboratory staff have first aid certification, and there are four experienced licenced midwives and one experienced licenced nurse as the clinical staff in the team that you will be able to call for advice:

1. Midwife Sabina Just (027 227 3187)
2. Midwife Nimisha Wheller (921 9999 ext 7210)
3. Midwife Judith McAra-Cooper (921 9999 ext 7193)
4. Midwife Susan Crowther (921 9999 ext 7912)
5. Nurse Sally Britnell (921 9999 ext 7539 / 021 846 200)

What compensation is available for injury or negligence?

In the unlikely event of a physical injury because of your participation in this study, Accident Compensation equivalent cover will be provided by Newline Australia Insurance Policy No AUS20987880A.

How will my privacy be protected?

Original raw information (e.g. images and video) where you are identifiable will only be accessible to AUT researchers directly connected to this project. Throughout the data collection and analysis process all data will be stored on password-protected computers or in locked filing cabinets. The raw data will be processed at AUT, and



as part of this, the information will be coded to protect your privacy. We will de-identify your data using a unique code assigned to you upon entry to the study.

The de-identified extracted data will be made available to Nike Inc. who are our research project partners, only if you give specific consent in the consent form for each data type. For the optional video collection for markerless data analysis, we are providing the options of not having this video collected, having the video collected while wearing a face mask, or having the video collected and provided with full facial recognition. This enables you to have complete control over what options you would like for the data collection and analyses.

Following the analysis of the data, all images and information obtained as part of the study will be placed in an AUT Ethics secure storage and will no longer be available to anyone other than Prof. Patria Hume and the Sport Performance Research Institute New Zealand (SPRINZ) ethics coordinator. The data will be stored for ten years, after the completion of the study, following which time it will be destroyed, unless you consent to its indefinite storage. Your de-identified data may be used to inform future research, including postgraduate theses.

Your name, contact number or email address and emergency contact information that you will be asked for upon submission to the study will be kept in a password protected file in a secure room. This information will only be used to contact you regarding an upcoming appointment or if needed in the case of an emergency.

What are the costs of participating in this research?

There are no monetary costs associated with participating in this research. Your time-cost associated with this research will be 0.5 to 1 hour each month for your visits to AUT Millennium.

Koha will be provided to thank you for your time and travel to each session. There will also be an additional koha for those participants who complete at least 12 sessions in the study. There is a potential maximum of 16 sessions over a 2 year timeframe.

What opportunity do I have to consider this invitation?

We would appreciate if you could let us know within 14 days whether you would be available to take part in the study or not, however, should you wish to join later, this is also welcomed.

Will I receive feedback on the results of this research?

You will be provided with an option of receiving personal reports of how your body is changing to support the growth of your baby.

What do I do if I have concerns about this research?

Any concerns regarding the nature of this project should be notified in the first instance to the Project Supervisor,
Professor Patria Hume patria.hume@aut.ac.nz **021805591**

Concerns regarding the conduct of the research should be notified to the Executive Secretary of AUTEK,
ethics@aut.ac.nz, (+649) 921 9999 ext 6038.

Whom do I contact for further information about this research?

Please keep this Information Sheet and a copy of the Project Consent Form for your future reference. You are also able to contact the research team as follows:

Project Supervisor Contact Details:

Prof. Patria Hume
Sport Performance Research Institute New Zealand, Auckland University of Technology,
Ph 021805591 or patria.hume@aut.ac.nz

Project researchers available daily for questions

Sabina Just contact@sabinamidwife.com 027 227 3187
Hannah Wyatt hannah.wyatt@aut.ac.nz 027 556 6228
Dean Mahuta dean.mahuta@aut.ac.nz 021 913 498