Participant Information Sheet

Study title:	*Improving obesity via exercise- IMPROVE trial*		
Locality:	South Auckland	Ethics ref.: 12/NTB/24	
Lead investigators:	**Dr Paul Hofman** **Dr Sumudu Seneviratne**	Contact phone number:	Dr Sumudu Seneviratne 09 9231531 / 0277066263

You are invited to take part in a study on improving mothers and babies risk of developing obesity by, exercising during pregnancy. Whether or not you take part is your choice. If you do not want to take part, you do not have to give a reason. It will not affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you would like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. We expect this will take about 10 minutes. You may also want to talk about the study with other people such as family, whānau, friends, or healthcare providers. Feel free to do so.

If you agree to take part in this study, you will be asked to sign the Consent Forms on the last pages of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is five pages long and additionally has 2 Consent Forms. Please make sure you have all the pages.

Why are we doing the study?

We are planning to look at the effects of exercise in pregnancy in overweight mothers. Regular exercise is recommended for pregnant women without any medical or pregnancy related problems. There is evidence that exercise is good for the health of you and your baby.

We believe exercise will help reduce your baby's birth weight a little and protect it from later obesity and obesity related problems. We think there will be benefits for you as well with less weight gain during pregnancy and less risk of pregnancy related diabetes. You may also have an easier labour and delivery. The results of this study will help plan a way of reducing risk of obesity for all communities.

There will be two groups in this study, an intervention group and a control group. Selecting the group you belong to will be on chance (randomised). You, your midwife or the research team cannot decide which group you will belong to. The intervention group will be asked to do regular exercise. The women in the control group can do their normal activities.

This study is approved and supported by the National Research Council for Growth and Development (NRCGD). It will be conducted by the Liggins Institute, University of Auckland.
The principal study investigators are Dr Paul Hofman – Consultant Paediatric Endocrinologist and Associate Professor and Dr Sumudu Seneviratne, Clinical Research Fellow in Paediatric Endocrinology - Liggins Institute, University of Auckland

This study has received ethical approval from the health and disability ethics committee on 16.10.2012.

If you are interested in joining this research please contact the following investigators.You can call or e-mail them with questions you may have regarding this study

Dr Paul Hofman - 09 923 6453 / 021 938897 or email - p.hofman@auckland.ac.nz
Dr Sumudu Seneviratne - 09 9231531 or email - s.seneviratne@auckland.ac.nz

What would your participation involve?
To join in this study

- You must be in less than 20 weeks pregnant
- You must be between 18 and 40 years of age
- You must be overweight - Body mass index (BMI) above 25
  (Contact your lead maternity carer/midwife to check this, or contact us directly with your current weight and height)
- You must not smoke during this pregnancy
- You must not have any major medical illness
- You must not be taking any medication that affects baby's growth.

If you decide to join this study, the following tests will be done on you and your baby.

- Your baby will have fetal ultrasound scans for growth every 4 weeks at Middlemore hospital. You will be able to get a copy of these scan reports for yourself if you wish.

You will need to visit the Liggins Institute in Auckland three times: (duration 2 hours each)

- Once at the 5th month and once at the 8th month of pregnancy. At this time we will take some measurements, blood tests, a fitness assessment on an exercise cycle and you will need to fill in several questionnaires. This should take about 1-2 hours.

- Lastly, two weeks (14 days) after childbirth when your baby is approximately 2 weeks old, a test called a DXA will be performed. This is a safe and painless test and takes less than 5 minutes. It is a good way of measuring the muscle and fat content of you and your baby.

You will receive travel vouchers to cover the cost of each of these trips by petrol vouchers. Free parking is available at the institute. We will provide you with detailed directions and meet you on arrival at each visit.

Ideally, we would like to collect a small sample of blood from the umbilical cord just after delivery. This is to measure your baby's hormones. In addition, if you agree, we will also collect a few samples from the placenta (afterbirth) and umbilical cord to look at how exercise may change your baby's growth. However, this is your choice weather we obtain these samples.

Intervention group

The participants in the intervention group will need to exercise 30-40 minutes 3- 5 times a week from 20 weeks to 36 week (5^{th} to 8^{th} month) of pregnancy.
You can exercise at home on an exercise cycle which we will provide for you. It is necessary to exercise regularly at a given heart rate. You will get a heart rate monitor to wear during exercise and will maintain exercise diaries. You can keep the cycle at study completion.

Control group

The participants in the control group do not need to exercise.You can do any physical exercise if you wish, and maintain an exercise diary that we will provide. You will not receive exercycles at the beginning of the study, but can receive a free exercycle bike with instructions at study completion.

What are the possible benefits and risks to you of participating?

We believe that regular exercise will help to improve your health, and the long-term health of your baby. Our past experience in pregnant women suggests that it is is safe and well tolerated. We hope that the provision of exercycle to exercise at home, will help improve the amount of exercise you do regularly, longterm.

Close communication will occur between your maternity caregiver/midwife and the research team. If there are any health concerns during the study, we will inform your maternity caregiver. If you develop any medical problems after joining in the study where exercise is not good for you, you will stop exercising.

If you are not used to exercising regularly, there is a chance that you may feel some muscle pains at first. However, we will be starting exercise slowly and increasing gradually to reduce this.

You may feel mild pain/ bruising at the site of blood testing.

Evaluation of body fat content by DEXA scanning requires brief exposure to radiation. Radiation carries a small possibility of promoting neoplastic tumours. The radiation from a DEXA scan is extremely low. It is only one tenth of that of a chest X-ray and less than what you would get on a short international flight to Australia.

What would happen if you were injured in the study?

If you were injured in this study, which is unlikely, you would be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study will not affect your cover.

What are the rights of participants in the study?

The decision to participate in this exercise study is voluntary. You are free to decline to participate or to withdraw from the research at any time. You will not face any disadvantage. You will continue to get your routine health care.

If you decide to participate in this study, you will have the right to access information collected as part of the study about you and your baby, if you wish to do so. You will be told of any health information related to the study that may have an impact on your or the health of your baby

All information collected about you and your baby will be available only to the investigators of this study. This information will be kept safe for 7 years. It will then be destroyed.

What will happen after the study ends, or if you pull out?

At the end of this study, we may also be looking at the long-term health benefits of exercise during pregnancy on yourself and your baby. This will be part of a different research project. You will be invited to join in this study later if you wish to.

The study data will be stored in a protected mode accessible only by the investigators of this study for 7 years. Contact details of the study participants will be retained for possible future use. This will be under the care of Dr Paul Hofman, who will be responsible for their secure storage. All data will be stored electronically and be deleted at 7 years, or earlier if requested by you.

Several tissue samples may be collected as part of the study. These will include blood and placental samples. These will be stored for up to 7 years after the initial study.This is to complete analysis on them. Once this is done, they will be destroyed by incineration.

Individual results as well as the study's overall findings will be sent to all participants on completion of the study. The study will take about 3 years to complete. We will be sending out results at this time.

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:

Dr Paul Hofman 09 923 6453 / 027 7066 263, email - p.hofman@auckland.ac.nz

Dr Sumudu Seneviratne - 09 923 1531, email - s.seneviratne@auckland.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 on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

You can also contact Whanau support workers should you require their support on:

CMDHD Middlemore Hospital: (Te Kaahui Ora Maori Health) Phone: 09 276 0044, ext 8138
Waitemata and Auckland : (Maori Health Gains team) Phone: 09 376 7056

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

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

CONSENT FORM FOR MATERNAL PARTICIPATION

LIGGINS INSTITUTE
THE UNIVERSITY OF AUCKLAND
NEW ZEALAND
Te Whare Wānanga o Tāmaki Makaurau

The University of Auckland
Private Bag 92019
Auckland
New Zealand

Telephone: 64 9 373 7599
Facsimile: 64 9 373 8763

Study Title **IMPROVE trial-Improving maternal and progeny risk of obesity via exercise**

Principal Investigators Paul Hofman, Sumudu Seneviratne

Declaration by participant:

I have read and I understand the Participant Information Sheet. I have had the opportunity to ask questions and I am satisfied with the answers I have received. I have had the opportunity to discuss the study with my Whaanau/ family. I freely agree to participate in this study. I have been given a copy of the Participant Information Sheet and Consent Form to keep.

YES / NO

I agree to my maternity carer being informed of my participation in this study YES / NO

I consent to the researchers storing a specimen of my blood (for up to 7 years) for its later use as a part of this study YES/ NO

I wish to receive a copy of my results YES / NO

OPTIONAL

I consent to the researchers storing a specimen of my placenta and fetal umbilical cord after delivery (for up to 7 years) for its later use as a part of this study or for future research into fetal growth subject to ethical approval being given by an accredited ethics committee YES / NO

Participant's name: _____

Signature: _____ Date: _____

Declaration by member of research team:

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.

Researcher's name: _____

Signature: _____ Date: _____

If you have any concerns, you may contact: Dr Paul Hofman 09 9236453 or Dr Sumudu Seneviratne – 09 9231531

CONSENT FORM FOR OFFSPRING PARTICIPATION

LIGGINS INSTITUTE
THE UNIVERSITY OF AUCKLAND
NEW ZEALAND
Te Whare Wānanga o Tāmaki Makaurau

The University of Auckland
Private Bag 92019
Auckland
New Zealand

Telephone: 64 9 373 7599
Facsimile: 64 9 373 8763

Study Title **IMPROVE trial- Improving maternal and progeny risk of obesity via exercise**

Principal Investigators Dr Paul Hofman, Dr Sumudu Seneviratne

Declaration by participant:

I have read and I understand the Participant Information Sheet. I have had the opportunity to ask questions and I am satisfied with the answers I have received. I have had the opportunity to discuss this study with my Whaanau/family. I understand that taking part in this study is voluntary (my choice), and that I may withdraw from the study at any time and this will in no way affect my baby's continuing health care.
I understand that my baby's participation in this study is confidential and that no material, which could identify them, will be used in any reports on this study. I understand that the treatment (exercise programme) will be stopped if it should appear harmful to my unborn child

YES / NO

.....

I consent to the researchers storing a specimen of my baby's cord blood (for up to 7 years) for its later use as a part of this study or follow-up research involving my child YES / NO

I wish to receive a copy of my baby's results YES / NO

Participant's name:

Signature: Date:

Declaration by member of research team:

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.

Researcher's name:

Signature: Date:

If you have any concerns, you may contact: Dr Paul Hofman 09 9236453 or Dr Sumudu Seneviratne – 09 9231531