Participant Information Sheet

Study title:	The outcomes of a 12-week physical exercise programme for adults with true resistant hypertension and obstructive sleep apnoea. A single group non-randomised control pragmatic clinical trial.	
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Introduction

Thank you for taking part in the Study I and showing an interest in taking part in the second part of the project, Study II. Please read this information sheet carefully. Feel free to talk with relatives or friends, before deciding whether to take part. If you take part we thank you. If you decide not to take part, there will be no disadvantage to you and thank you for considering our request.

What is the aim of this research project?

The study sample will include people from Study I who wore the blood pressure monitor for 24 hours to confirm they have high blood pressure resistant to drugs and high risk of breath pauses during sleep. The main aim of this study is to see how effective a 12-week physical exercise programme can be to help decrease blood pressure in this group. At the end of the 12 weeks the blood pressure monitor will be worn for 24 hours again and results compared to the levels before the exercise. The other aims are to compare results for activity level, sleep parameters, fitness and quality of life and the heart function taken before and after the exercise programme.

Who is funding this project?

The research team is seeking to get funding from a National Heart Foundation 2018 grants. Other support will come from the School of Physiotherapy.

Who are we seeking to participate in the project?

The participants will be adults who were in Study 1 and were found to have high blood pressure resistant to drugs and a high risk of breath pauses in sleep. The Dunedin based adults of age 18-60 years with high blood pressure who are using 3 or more medication and with risk of breath pauses in sleep. The research team will identify them from Study I. You will be able to take part as long as there is no reason why it would be unsafe for you to exercise.

If you participate, what will you be asked to do?

The exercise program

The research team will give you an appointment to come to the School of Physiotherapy to take part in the exercise programme. The program will run once a week for 12 consecutive weeks.

The physiotherapist who conducts the programme will measure your blood pressure, heart rate and blood oxygen level before each session. First you will do warming up. For warming up you will do activities to a music for five minutes. Then you will do exercises like riding a static cycle, rowing on a machine or walking. This will run for about 15 to 20 minutes. Then you will do some activities such as weight lifting to strengthen your muscles. This task will take 15 to 20 minutes. Warm down exercises for five minutes will be done at the end. The whole programme will take around 45 minutes. The exercise program will design to fit with your capacity.

In addition to that you will be given a home based exercise programme. Because the benefits of exercise are best if you do it several times a week. The exercise will be simple ones such as walking, jogging etc. You will maintain a diary to record your exercise you do at home.

The exercise programmes will altered based on your progress over the 12 weeks. At the end of the 12 weeks the researchers will repeat all the measurements and tests. They will follow the same procedures as they did in study I.

Tests and Measurements:

The procedures are same as they were in the study I. You will come to the School of Physiotherapy, University of Otago, for these...

Appointment 1

You will use a computer to complete the same questionnaires used in the Study I. You can get help from the investigator if you need it. The investigator will then take your blood pressure and heart rate. The digital blood pressure monitor will be used for this task.

Next, the investigator will take your body weight and height. The girth of neck, hip and waist measurements will also be taken. Then the investigator will repeat the walking test over 6 minutes (walking up and down a 30 m corridor as many times as you can in 6 minutes). It will take about 30 minutes for these tasks.

You will also be fitted with the Blood Pressure Monitor which records your blood pressure over 24 hours. You can take part in normal daily activities and sleep during the 24 hours as you did earlier in Study I. We will remove the monitor at School of Physiotherapy the next day. Like last time, you will have a number to call if you have any queries.

Appointment 2:

After removing the blood pressure device you will have a repeat ultrasound scan of the heart. The final part of the study will be wearing the activity monitor, the wrist watch like device on your non-dominant wrist. This will be worn for seven days (day and night) as you did in the Study I. You will select the most convenient way to return the monitor, either in person or by post.

Taking part in of this study is voluntary. The research team will reimburse you with a $20 supermarket voucher to thank you for taking part in the study.

What are the benefits of participating in the study?

You will have the chance to take part in the supervised exercise programme. Exercise is a recommended way to lower the blood pressure. Your blood pressure may be lower by the end of the programme. If it drops your doctor may be able to reduce your medications for blood pressure

You will also get a report on your 24 hour blood pressure, fitness, ultrasound scan of the heart, sleep scores etc. You will be able to compare this report with the previous reports given to you in Study I.

Is there any risk of discomfort or harm from participation?

There will be no harmful clinical or other procedures involved in this study. The measurements will be taken from devices placed on the body. All the devices used in the research are under the 'low risk' category.

There will be no discomfort in assessment procedures and measurements. The risk is minimal in all procedures. During the 6 minute walk test, there is a small risk of a fall, which is same as the natural risk while you are walking. The investigator or helper will always observe and there are facilities to sit or lie down if you feel any discomfort

There is a possibility of joint and muscle pains in the early part of the exercise programme. But this is a normal initial response to exercise.

Falls, minor joint injury and muscle injury are possible risks. The team will take steps to minimize those risks. The team will monitor you and stop the exercise if there is a high risk e.g. very high blood pressure. The team will follow standard procedures in the case of an accident.

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. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

What specimens, data or information will be collected, and how will they be used?

The researchers will collect the approved data only. They will not collect specimens, tissues or body fluid in this research. The researchers will collect data similar to the study I.

[Blood Pressure, Ambulatory Blood Pressure, Number of antihypertensive medications, class of antihypertensive medications, Height, weight (calculate BMI), Hip Circumference, Waist Circumference (calculate ratio), Neck Circumference, Quality of Life score (QoL; SF 36V2), Epworth sleepiness scale (ESS) score, six-minute walk test (6MWT) score, Borg scale score, activity parameters (step count/Physical Activity time /Sedentary time), Sleep parameters (into bedtime/out of bedtime/sleep onset/latency/total sleep time/wake after sleep onset/ Awakenings/ average Awakenings, sleep efficiency), Heart Rate, Echocardiogram]

What about anonymity and confidentiality?

A separate list with your name, health number and contact details will be kept for the initial contacts. All the data will be recorded under a random serial number generated by a computer. The number will be the same one we used in the Study I.

The data recording sheet will not contain your name, address and NIH number. Therefore, no one will identify your details looking at the data sheet. The only way of identification is by matching the random ID number with the initial list which is used to contact you.

Researchers will use the data collected only for the purpose mentioned in the above research. Data will not be published in your name or any identification features. No one will identify you in published data. If pictures are used, we will use standard procedures to get your consent first. Researchers will keep hard copies of data under lock and key. All the electronic data will be kept in a password protected computer. The period for keeping data is 10 years.

The data collection will be done by the PhD student in the team. Only the research team (4 in number) can access data. No third party will be involved in collecting or processing data. Data will be destroyed after 10 years according to the standard procedures.

If you agree to participate, can you withdraw later?

You may withdraw from taking part in the study at any time. It will not cause any disadvantage to yourself. If you withdraw from the study, the data collected at that point may continue to proceed.

Any questions?

If you have questions now or in the future, please contact either:

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