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## **Participant Information Sheet**

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| **Study title: Public** | Identification of adults with true high blood pressure resistant to drugs and its relationship with breath pauses during sleep. |
| **Study title: Scientific** | The prevalence of true resistant hypertension in Dunedin based adults with resistant hypertension and the association between true resistant hypertension and obstructive sleep apnoea risk. |
| **Principal investigator:** | Name: Dr. M.A. SkinnerDepartment: School of PhysiotherapyPosition: Principal investigator (PI) | Contact phone number:03 479 7466 |
| **Co-investigator:** | Name: Suranga Dassanayake (PhD Candidate)Department: School of PhysiotherapyPosition: Coordinating investigator (CI)  | Contact phone number:03 479 5422  |

**Introduction**

Thank you for showing an interest in this study. Please read this information sheet carefully. If you wish to, feel free to talk with your General Practitioner (GP), family/whanau, other relatives or friends, before deciding whether to participate or not. If you decide to participate we thank you. There will be no disadvantage to you if you decide not to take part in.

**What is the aim of this research project?**

High blood pressure (BP) or hypertension (HT) is a worldwide problem affecting billions of people. Heart disease is the greatest cause of death and hospitalisation in New Zealand. More than 30% of the adult population have HT, with ethnic disparities.

Resistant hypertension (RHT) is a subset of HT. RHT is defined as ‘blood pressure above the minimum level for HT despite concurrent use of three blood pressure reducing (anti-hypertensive) medications (including a diuretic or ‘water pill’). Use of four medications is also considered as ‘resistant’ regardless of blood pressure (BP) values. An accurate account of compliance with medication and recorded BP is important in the diagnosis of RHT to differentiate it from other categories of HT such as pseudo-HT (errors occurring with measurements), white coat HT (high BP values when it is measured by a practitioner but normal BP otherwise) and masked hypertension (normal BP values when it is measured but high BP otherwise). Monitoring BP throughout the day (24 hour ambulatory blood pressure monitoring (24h APMB)) has been shown to be the most effective and valid tool for diagnosing true RHT (TRHT).

The first aim of the study is to investigate the number of individuals with TRHT among Dunedin based adults known to have RHT. We will also be asking questions about levels of sleepiness and whether the individuals have breath pauses during sleep, which may mean they are at risk of obstructive sleep apnoea (OSA). Our second aim is to look at the association between TRHT and high risk of OSA.

**Who is funding this project?**

Investigators have applied for funding from National Heart Foundation and the Otago Medical Research Annual Grant. For the other measurements and procedures, the resources of School of Physiotherapy will be used.

**Who are we seeking to participate in the project?**

Dunedin based adults (18 - 60 years) diagnosed with high blood pressure and on three or more medications to control their BP.

Unfortunately, you will not be able to participate in the study if you have a known kidney disease, are not able to communicate in English, and (for female participants) if you are pregnant.

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

**Initial recruitment**

You will receive a request letter to participate in the study, through your General Practitioner (GP). You will be invited to contact Dr Skinner (Primary Investigator) with any enquiries and to indicate your interest in participating in the study. The coordinating investigator (CI), who is also a PhD candidate, will provide you with an appointment time for the initial assessment. First the CI will obtain written informed consent from you.

**Assessment and measurements**

Appointment 1: At the School of Physiotherapy

The CI will ask you to complete a series of self-administered questionnaires that will be set up on a tablet computer (The technical assistance will be provided if you request it to operate the tablet computer or we could give you paper copies). The questions relate to information about yourself including your age, gender, ethnicity, general health, physical activity level, quality of life and risk of OSA risk (determined from a score called the Epworth Sleepiness Scale (ESS), This section will take approximately 20 minutes.

The CI will then take your resting blood pressure (office blood pressure – (BP)) and heart rate using standardised equipment (in accordance with the American Heart Association 2017 guidelines.) Next, the CI will take your body weight, height and circumferences of neck, waist, hip, measurements using standard guidelines using an electronic weighing scale, the height measuring device (in cm) and measuring tape. This section of the procedure will take about 15 minutes.

If your ESS score is 9 or above, you will be identified as ‘at possible risk for OSA’. If so you will be fitted with 24h ambulatory blood pressure monitor (Figure 1). This small device will be placed on the non-dominant upper arm, at the Cardiology Research Laboratory, on 9th floor in Dunedin Hospital. You will be able to undertake daily activities/sleep as usual over the next 24 hours but from time to time the cuff will automatically inflate to record your BP.



Fig 1. 24h Blood pressure monitor Fig 2. Echocardiogram being taken

<http://www.kelowna_ambulatory-blood-pressure-monitoring/> <http://www.womens-health-advice.com/photos/heart-tests.html>

Appointment 2:

On the following day the device will be removed at the same setting, the Cardiology Research Laboratory. When we review the data for the 24h of monitoring we will be able to confirm if you have true resistant hypertension (TRHT) or not. Where THRT is confirmed you will have another test where a probe is placed on the skin over your heart (Figure 2) and ultrasound is used (echo cardiogram) to confirm the efficiency of your heart structure and function (results to be interpreted by a cardiologist). Apart from the device being put in place you will not feel anything during this test.

After the echocardiogram, the CI will conduct a Six Minute Walk Test (6MWT: walking up and down a 30m corridor as many times as you can in 6 minutes), using the standardised test and safety procedures. Then an Activitrax activity monitor (Figure 3),will be placed on your non-dominant wrist to be worn for seven days/nights to determine your true levels of functional activity during the day and during sleep. You will be able to select the most convenient way to return the monitor, either in person or by post.

Fig 3. Activitrax activity monitor https://www.actigraphcorp.com/activity-monitor-comparison/

**What are the benefits of participating in the study?**

You will be able to receive a report on your cardiovascular health (24h ABPM, echocardiogram, risk of obstructive sleep apnoea (ESS score), physical activity level, and measurements (such as hip to waist ratio).

If you are not found to have TRHT, you will meet with the Primary Supervisor to discuss the outcomes and will be advised to visit your GP to discuss the report on the findings for 24hABPM, and risk of OSA (obtained from the ESS questionnaire), and self-reported physical activity level. Participants with a high risk of OSA but not TRHT will be referred by the co-investigator cardiologist, to the physician at the Sleep Clinic for further sleep analysis.

If you are identified with both TRHT and high risk of OSA, you will be invited to participate in a second study to investigate the outcomes of a supervised physical activity programme on blood pressure levels, but this is not mandatory. Physical activity is known to have a positive effect on cardiovascular health, including BP and we are particularly interested in investigating the effect of physical activity on the subgroup of adults who have TRHT and high risk of OSA.

**Is there any risk of discomfort or harm from participation?**

This study can be categorised as a minimal risk observational study, based on the guidelines of Health and Disability Ethics Committees (HDEC), Ministry of Health, New Zealand. No invasive clinical or non-clinical procedures or equipment and are involved in the proposed study.

All measuring equipment is categorised as low risk (Class I) according to Therapeutic Goods Administration (TGA) guidelines (2011), Australia. Thus, there is no significant risk involved with the procedures or measurements made.

The measurements will be recorded in a research laboratory in the School of Physiotherapy and/or Dunedin School of Medicine Cardiology Research Laboratory located on the 9th floor the Dunedin Hospital building, just one block from the School of Physiotherapy.

All researchers hold at a minimum a current First Aid certificate and AED emergency equipment is available in each location. The risk of an adverse event is low. However, should an adverse event or accident occur, the participant will be covered by ACC under the Accident Compensation legislation. The study population is not a vulnerable one.

During the 6MWT (we will measure the distance which you can cover in six minutes walking back and forth at your own pace, between two marks 30 meters apart). There is a risk of falling or tripping whilst walking or mild muscle soreness/joint pain may be felt the day after the test. The investigator or helper will always be observing and there are facilities to sit and lie-down if you feel any discomfort. There is a possibility of hypoglycaemia (low blood sugar) while the test is being done. Therefore, the test will be carried out in between two main meals to reduce this risk and you should also let us know if you have diabetes. However, you will be advised to do the test at your own pace and you can stop at any time if you feel any discomfort.

In the unlikely event of an accident e.g. a trip, you would be covered by ACC.

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

Only approved data will be collected and no specimens (tissues or body fluid) will be collected in this research. The following data will be collected and will be recorded on a form under a random serial number.

Age, gender, ethnicity, blood pressure, Ambulatory Blood Pressure (24hABPM), names and number of antihypertensive medications, class of antihypertensive medications, height, weight (calculate BMI), hip circumference, waist circumference (calculate waist to hip ratio), neck circumference, quality of Life score (QoL questionnaire), Epworth sleepiness scale (ESS) score, six minute walk test (6MWT) score, activity parameters (step count/physical activity time /sedentary time), sleep parameters (into bed time/out of bed time/sleep onset/latency/total sleep time/wake after sleep onset/ awakenings/ average awakenings, sleep efficiency), heart rate and echocardiography parameters. This information will be used to describe the average age, size, sleep function and activity of the group of adults in the study.

No data for an individual will be presented and no individuals will be identifiable in the published data. Simple statistics will be used to publish the demographic data and no participant will be able to be identified by any other party or in any other publication.

You will be provided with a grocery voucher valued $20 as recognition for being a participant but no other remuneration will be offered for participation in the study.

**What about anonymity and confidentiality?**

A separate list with your name, health number and contact details will be kept for the initial contacts and all the data will be recorded under a random serial number generated by a computer.

Data will be recorded using both hard copy and electronically. The electronic data will be saved on the PIs password protected computer, while the hard copies will be kept under lock and key in the research primary supervisor’s office. A back up computer file will be maintained, and the computer will be password protected.

Only the investigators (4 in number plus a research assistant) will be able to access the data and no third party will be involved in collection, entering or the processing data. In accordance with the requirement, data will be kept for 10 years and after that it will be discarded according to the standard procedures.

**If you agree to participate, can you withdraw later?**

You may withdraw from the study any time with no disadvantage to their health care. However, the data obtained up to the point of withdrawal will be used in the study, as per detail in in the participant information sheet. Throughout the study and in the publications, or in any other material open to public, no individual data relating to a participant/s will be identified.

**Any questions?**

If you have any questions now or in the future, please feel free to contact either:

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| Name: Dr. M.A. Skinner (Primary supervisor)Department: School of PhysiotherapyPosition: Principal investigator | Contact phone number:03 4797466 |
| Name: Suranga Dassanayake (PhD candidate)Department: School of PhysiotherapyPosition: PhD Candidate | Contact phone number: 03 479 5422 |

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**Identification of adults with true high blood pressure resistant to drugs and its relationship with breath pauses during sleep.**

## **CONSENT FORM FOR PARTICIPANTS**

Principal investigator: Dr. Margot Skinner

Phone: 03 479 7466 Email: margot.skinner@otago.ac.nz

Name of the participant:…………………………………………………………………………

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| 01. | I have read the Information Sheet concerning this study and understand the aims of this research project. |  |
| 02. | I have had sufficient time to talk with other people of my choice about participating in the study. |  |
| 03. | I confirm that I meet the criteria for participation which are explained in the Information Sheet. |  |
| 04. | All my questions about the project have been answered to my satisfaction, and I understand that I am free to request further information at any stage. |  |
| 05. | I know that my participation in the project is entirely voluntary, and that I am free to withdraw from the project before its completion. |  |
| 06. | I know that as a participant in the study I will be subjected to an interview and measurements. |  |
| 07. | I know that the interview and measurements will explore my health and related status and that if the line of questioning and /or measurements develops in such a way that I feel hesitant or uncomfortable I may decline to answer any particular question(s), and /or may withdraw from the project without disadvantage of any kind. |  |
| 08. | I understand the nature and size of the risks of discomfort or harm, which are explained in the Information Sheet. |  |
| 09. | I know that when the project is completed all personal identifying information will be removed from the paper records and electronic files which represent the data from the project, and that these will be placed in secure storage and kept for ten (10) years. |  |
| 10. | I understand that the results of the project may be published and agree that any personal identifying information will remain confidential between myself and the researchers during the study and for 10 years after and will not appear in any spoken or written report of the study. |  |
| 11. | I know that there is no remuneration other than a $20 supermarket voucher offered for this study, and that no commercial use will be made of the data. |  |
| 12. | I understand I shall receive a report on my health based on the measurements.  |  |
| 13. | I am aware that I may be requested to participate in a second study based on the results of this study |  |
| 14. | I agree that the principal investigator can send a copy of the report on my health to my GP Yes | No |
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| Signature of participant:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­Name of person taking consent:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Date:\_\_\_\_\_\_\_\_\_\_\_ |