

Participant Information Sheet



SCHOOL OF MEDICINE

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How Does Choice Influence Drug Response?

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Researcher introduction

The project is being conducted by Chantelle Bond, a master's candidate from the Department of Psychological Medicine; and Professor Keith Petrie (Psychological Medicine) who is supervising the project in collaboration with Dr Kate Faasse from the University of New South Wales in Australia.

Project Description and Invitation

You are invited to take part in a research study investigating the usefulness of two fast acting beta blocker medications (Lopressor and betacarm) with the same active ingredient (metoprolol) for reducing pre-examination anxiety.

This research is investigating the effectiveness of two different formulations of fast acting beta blocker medications for relief of pre-exam anxiety. Participants will be randomly assigned to either choose which beta blocker they take, or to be assigned a beta blocker to take. Participants will complete a baseline questionnaire which requests information on current anxiety, feelings about control and any symptoms experienced in the last week, in addition to some basic information such as age, sex and ethnicity. After taking the medication, participants will be asked to complete three brief tasks to simulate an examination. During the research session, participants will be asked to report anxiety experienced, any side effects of the medication, feelings about control, and will have their heart rate and blood pressure recorded.

The day after the session, participants will also receive an email with a link to a follow-up questionnaire. This questionnaire will again ask for anxiety symptoms experienced over the previous day.

Please note that this research involves taking a beta blocker tablet.

What the Research Involves:

Taking part in this study will involve participating in one 50-minute session at the Clinical Research Centre at the University of Auckland Medical School, as well as a brief follow up online questionnaire the day following the research session.

You will have one beta blocker medication to take at the start of the session and will be asked to complete three short tasks which will simulate an exam. You will also be asked to complete written questionnaires which include rating your anxiety levels, and any physical symptoms or sensations. Your blood pressure and heart rate will also be recorded.

Eligibility

To take part in this research you must be aged 18 years old or over, able to read and write in English, and be able to attend one 50-minute session at the Clinical Research Centre at the Grafton Campus of the University of Auckland.

People who are already taking beta blocker medications prescribed by a doctor are not eligible to take part in the current study. Because of the risk of medication interactions, anyone currently taking calcium channel blocker medications or digoxin should not take part.

Because of health concerns, people with asthma, diabetes, bronchospasms, low blood pressure, low heart rate or known reactions to any beta blocker medication are not eligible to participate in the study. Those who are pregnant or trying to get pregnant are also not eligible to participate.

In addition to this, anyone with known allergies to the inert components of the tablets, including anhydrous lactose, sodium starch glycolate, magnesium stearate, lactose monohydrate, micro crystalline cellulose, polyvinyl pyrrolidone, hydroxyl propyl methyl cellulose or FD&C yellow no.5 are not eligible to take part in this research.

Data Retention

Participants are able to request that the data they have provided be withdrawn until December 2021, when data analysis will begin. To withdraw your data, please contact one of the researchers with your request to withdraw the data that you provided.

The collected written data will be stored on University of Auckland property in a locked filing cabinet, and all computerised data will be stored on the University of Auckland computer system, in a password protected file, with the password known only to the researchers involved in the study. After six years, the written data will be destroyed by shredding and the computer files will be erased.

Confidentiality

All the information you provide is confidential and will be available only to the researchers involved in this project.

The data you provide will be coded and your identity will be kept in confidence to the researchers. When you participate in the study, you will be assigned a number between 1 and 100, and a separate list will be kept linking your name to the data you provide. All data provided will be reported only in aggregate form and no data that could identify any individual participant will be reported.

You do not have to take part in this research if you do not want to. You can also stop participating in the research at any time and your data will not be included in the analyses.

Your participation or non-participation in this research will not affect your academic relationships with the researchers and University of Auckland staff members who are involved in this study, nor will it affect university grades received from any papers taught by such University of Auckland staff member.

Beta Blockers

This research uses two different beta blockers, Lopressor and betacarm, which both have the same active component, metoprolol. Because both beta blockers have the same active ingredient, they will both work

comparatively well at combating anxiety, as well as have the same potential side effects.

There are small and insignificant differences between the two pills available. Lopressor is made in Switzerland by the drug company Novartis, while betacarm is manufactured in Canada by the drug company GSK (GlaxoSmithKline). The inert components of the pills are not identical either; Lopressor is primarily anhydrous lactose while betacarm is primarily lactose monohydrate. These differences should not have any effect on how well each beta blocker works for anxiety.

Adverse Effects

Both Lopressor and betacarm have the same active ingredient and share the same benefits and potential side effects. Beta blocker medications are commonly used to treat high blood pressure, rapid heart rate, migraine, and anxiety. Their primary physical effect is to block the effects of the hormone epinephrine (adrenaline), resulting in a reduced heart rate and lowered blood pressure.

Beta blocker medicines are associated with a variety of adverse effects. Common side effects include headache, drowsiness, dizziness, sore throat, dry mouth, skin itching, nausea, stomach pain, and cold hands or feet.

You may experience some, all or none of these adverse effects. If you do experience mild adverse effects, they will be short-term and should be gone within four hours as the medicine exits your system.

Beta blockers are not recommended for use in people with asthma or diabetes. If you have either of these conditions you are not eligible to take part in the current study.

Anxiety

This research involves answering questions about your anxiety levels before and after you take a beta blocker medication. However, the questionnaires used in this study are not meant for diagnosing anxiety problems.

If you are experiencing anxiety to the degree that it is impacting on your life and causing you distress, we encourage you to contact your GP or

Auckland University Student Counselling services at Level 3, Student Commons Building, 2 Alfred Street, Phone: 09 373 7599 ext 87681.

Blood Pressure

This study involves monitoring blood pressure throughout the session. It is possible that during the course of this research we may discover hypertension (high blood pressure) in a small number of participants. Any participants who are found to have consistently high baseline blood pressure (i.e. two readings over 140/90 mmHg) will be informed of this finding, and advised to make an appointment to see their GP.

If desired, participants can be provided with the average of their two baseline blood pressure readings once they have completed the study session.

Study Results

After the research has been completed and the data has been analysed, you will be sent an email containing information about the study including results of the research. Should you wish to discuss this further, a telephone call or face-to-face meeting will be arranged with the one of the study investigators. The study results will be used for a master's thesis and be written for publication in a major medical journal.

Compensation

As compensation for the time involved in research participation, all participants who complete this research will receive a \$50 Westfield gift card.

We appreciate the time you have taken to read this information. If you have any additional questions, please contact:

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For any queries regarding ethical concerns, you may contact:

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For cultural support and queries, you may contact:

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Cultural Liaison
Level 5, Building 532
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Grafton, Auckland

For any concerns regarding ethical issues you may contact:

Chair, The University of Auckland Human Participants Ethics Committee,
Office of Research Strategy and Integrity, The University of Auckland,
Private Bag 92019, Auckland 1142. Telephone 09 373-7599 ext. 83711.
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