The effect of water drinking on orthostatic tolerance

**Does a drink of water help prevent fainting?**

We are conducting a research study to find the answer. We are looking for **men and women aged 19-50 years** to take part in a study examining the effect of water drinking on blood pressure control and fainting.

Your participation will help improve the treatment and management of fainting spells.

As a thank you for your participation, you will receive $75 in compensation.

Your participation in this study will involve three tests, on three separate days, of your blood pressure control and susceptibility to fainting. On each day you will be asked to drink a glass of water. The temperature of the water will change on the different test days.
INFORMED PARTICIPANT CONSENT FORM

The effect of water drinking on orthostatic tolerance

You are invited to take part in investigations conducted under the supervision of:

Dr. Victoria Claydon, Associate Professor with the Department of Biomedical Physiology and Kinesiology, Simon Fraser University.

Major (Dr) Iain Parsons, Cardiology Registrar and PhD student with Kings College London.

Dr Nick Gall, Honorary Senior Lecturer with Kings College London, Consultant Cardiologist with Kings College Hospital.

Prof Phil Chowienczyk, Professor of Cardiovascular Clinical Pharmacology with Kings College London. Honorary Consultant Physician with Kings College Hospital.

Colonel (Professor) David Woods, Professor of Military Medicine with the Royal Centre for Defence Medicine.

Brooke Hockin (PhD Candidate) and Natalie Heeney (MSc Candidate), graduate researchers in the Department of Biomedical Physiology and Kinesiology, Simon Fraser University.

What are the overall goals of the study?

The primary purpose of this investigation is to determine whether drinking water can improve orthostatic tolerance in healthy control volunteers. Orthostatic tolerance refers to the ability to maintain an adequate blood pressure when standing. In some individuals blood pressure can fall when standing, predisposing to dizzy spells or fainting episodes. Drinking water can boost blood pressure and make fainting episodes less likely to occur. However, it is not clear whether the temperature of the water has an impact on the blood pressure response. We will test whether warm water and cold water have the same effect on blood pressure responses.

Is my participation in the study voluntary?

Your participation in these procedures is entirely voluntary and therefore it is up to you to decide whether or not to participate in this study. Before you decide, it is important that you understand what the procedures involve. You are under no obligation to participate in this study, and you may withdraw from it at any time. If you decide not to participate, or if you decide to withdraw from the study part way through, you do not need to provide any reasons for your decision.
What if I have questions about the study?

Please ask the investigator, Dr Claydon, to explain any information that is not clear to you. You will be given a copy of this consent information to keep should you wish to refer to it later. Research results can be obtained upon request from Dr Claydon (E-mail: victoria_claydon@sfu.ca; telephone: 778 782 8513).

Who can I contact if I have any concerns about the study?

If you have concerns about the study you can contact Dr. Jeff Toward, Director of the Office of Research Ethics (E-mail: jtoward@sfu.ca; telephone: 778-782-6593).

What will participants be required to do?

You will be asked to undergo a “tilt test”. This test measures your blood pressure control, and your susceptibility to fainting spells. You will undergo this test on three separate days. On each day you will be given a drink of water: either a 500ml drink of room temperature water, a 500ml drink of ice cold water, or a 500ml drink of warm water. The order in which you receive the water will be determined randomly.

Before you start the test one of the study team will ask you some questions about your medical history, and your general health. There will also be questions about cardiovascular risk factors such as smoking, exercise levels, and alcohol consumption. They will measure your height and weight. You will be asked to empty your bladder prior to testing. We will take a urine measurement of the amount of salt in your urine – a marker of your salt intake and hydration. So that we can make measures of your heart, you will be asked to remove any clothing on your upper body. You can choose to either do the testing bare-chested, or to wear a hospital gown to cover your chest. You can change into the gown in privacy.

For the test procedure, you will be asked to lie down on a bed while we attach monitoring equipment to your body. This will include:

1. An electrocardiogram (ECG). This is a monitor that will measure your heart beat (how fast and how regularly your heart is beating). We will attach three adhesive electrodes (stickers) to the skin of your chest (on your left and right shoulder, and the left side of your belly button) and connect them to the ECG machine. If you have a hairy chest, it may be necessary to shave three small areas of your chest in order to help the electrodes stick to your skin. An alcohol swab will be used to clean the skin prior to electrode placement.

2. A blood pressure monitor. A small Velcro cuff will be placed around your middle finger that pulses gently against the small arteries along the side of the finger, and records your blood pressure with every heart beat. This measurement is non-invasive and painless.

3. We will measure your breathing rate and the gases in the air you are breathing out with a small nasal cannula (a flexible tube). This small plastic tube will be placed under your nose, on your top lip, and will sample your breathing. You will be able to breathe and talk normally while wearing this device.

4. We will measure the blood flow to your brain in an artery called the middle cerebral artery. We will do this using ultrasound (imaging device). We will place a little ultrasound gel on your temple and will position an ultrasound probe overlying the gel. The probe will be held in place with a head band. This means the investigators will not need to touch you to hold the probe. You can move your head freely when wearing the ultrasound probe. You will not be able to feel the ultrasound.
5. We will also measure blood flow in your arm, in the brachial artery, also with ultrasound. Your arm will be placed on a support with a probe positioned over a little ultrasound gel near the elbow. We will ask you to keep your arm still during the test.

6. We will measure the amount of blood that your heart is pumping. To do this we will hold an ultrasound probe on top of some ultrasound gel on the left side of your chest, over your heart. These measures will be taken intermittently at various times during the test. The ultrasound probe will be touching your skin, but you will not be able to feel the ultrasound. The ultrasound probe needs to be placed on bare skin, so it will not be possible to wear a bra during the measurement. You can choose whether to be bare chested, or whether you would prefer to wear a hospital gown to cover your chest. During these measurements the person holding the ultrasound probe will need to adjust the position of the gown and to touch or look at your chest in order to put the probe in the correct position on your chest. The person making these measurements will be a male cardiologist (heart doctor).

7. We will place a strap over your knees and a box over your legs that seals against your waist (a bit like a canoe skirt). The strap is to help you stand in a relaxed position without fidgeting your legs too much. The box is placed over your legs so that we can apply lower body negative pressure to your legs later on in the test without disturbing the monitoring. Once the monitors are in place we will make recordings from them for 15 minutes while you lie on your back and rest. You will then be given the water to drink. After a further 15 minutes of resting, we will tilt the table into an upright position (at 60 degrees). This is like standing, but leaning backwards slightly. We will make recordings from the monitors for a further 20 minutes. We will ask you not to move your legs much during the test. After 20 minutes of standing, we will apply lower body negative pressure to the box over your legs (by removing some of the air from the box). This will feel a little bit drafty, and may be a little noisy, but is not painful or unpleasant. The effect mimics prolonged standing. We will apply the lower body negative pressure at three different levels for 10 minutes each (-20mmHg, -40mmHg and -60mmHg).

The test will be stopped immediately if:

- You complete the whole procedure (30 minutes lying down, 20 minutes standing, and 30 minutes of lower body negative pressure).
- You experience symptoms of dizziness or lightheadedness and/or your blood pressure or heart rate begin to decrease.
- You request the test to stop.

You will then be returned to the supine position (lying on your back). If you experienced dizziness at the end of the test, lying down will quickly resolve this. The monitors will be removed and any residue from the ultrasound gel will be removed. It is common to feel a bit hot and sweaty at the end of the test. There are showers near to the lab, and we can provide clean towels etc for you to freshen up after the test if you wish.

**Who is eligible to take part in the study?**

We are looking for healthy English speaking men and women aged 19-50 years to take part in this study. You should not participate in this study if you are pregnant, or think you might be. Individuals who suffer from recurrent fainting episodes (≥2 episodes of fainting with loss of consciousness in the prior 6 months) will be excluded. Volunteers may include members of the community at large, as well as staff and students at Simon Fraser University.
How should I prepare for the procedure?

You do not need to make any special preparations for these procedures. Tests will usually be conducted in the mornings and you will be asked to have only a light breakfast before the test, without caffeine. You will also be asked to avoid strenuous exercise for at least 12 hours prior to testing. Women should make a note of the date of their last period. We will try to schedule testing over three consecutive days for women in case there is any effect of cyclical hormone changes on your test results. Where this is not possible, tests will be scheduled at the same phase of your cycle in separate months.

Who will be present during the study tests?

The study will be supervised by either the principal study investigator, Dr Victoria Claydon, and/or Dr Iain Parsons. Ms Hockin and Ms Heeney will assist with testing. There will always be at least two study team members present during testing. Undergraduate or graduate research students supervised by Dr Claydon may also assist with testing.

What are the potential advantages to taking part?

There are no direct benefits to you from taking part in the study. It is hoped that the results of this study will ultimately aid in the treatment and management of fainting spells in patients who are prone to these episodes, and so improve quality of life for those affected by recurrent fainting episodes. You will receive up to $75 to compensate you for your participation in the study ($25 per test). Free parking is available on request.

What are the potential disadvantages to taking part?

The study will take place in a controlled laboratory environment and most participants do not find the assessments unpleasant. Every effort will be made to ensure your safety, privacy and comfort. The following are discomforts or risks that may be associated with your procedures.

1. During the tilt table test you may experience some dizziness or lightheadedness associated with reduced blood pressure and/or heart rates. Rarely, participants have been known to faint briefly. Actual fainting is unusual and is always very short in duration with rapid return to consciousness.

2. These assessments will take time to perform and you will be asked to keep still during the assessments. You may find that you become uncomfortable or bored during the course of these investigations. Every effort will be made to maintain your comfort throughout the study. You will be provided with pillows, blankets etc as appropriate to ensure your comfort. To compensate you for your time, you will be paid $25 for each of the three tests that you complete.

3. Preparing the skin for electrode placement may cause minor irritation or redness. It is possible that you will experience an allergic reaction to the electrode gel or adhesive.

4. You may feel embarrassed about having the ultrasound measurements of your heart because they must be made on your bare chest. If you like you can wear a gown to help maintain your modesty. The person making these measures is a cardiologist (a heart doctor) and makes these measurements all the time.

What if you learn new information about my health during the study?

It is possible we will gain information about your health during this study. Some of the data being collected are new, and we don’t yet know what a normal or abnormal response might be. In other cases there are well established typical values (such as for healthy levels of blood pressure). Where
typical values are known, if any of your data fall outside of these typical values, Dr Claydon or Dr Parsons will let you know. However, please note that this does not constitute a diagnosis. Any deviation observed may or may not be significant, and only your physician can provide you with medical advice as to whether or not further investigation is required. You should follow up with your physician to determine the best course of action, if any, for you.

**How will confidentiality and anonymity be assured?**

All information that is retained by the researchers will be identified by code number, rather than using your name. Your data will be stored in the principal investigator’s office for a period of twenty years and will be password protected. You will not be identified on any research publications arising from this study. A list of the participant codes will be kept by the principal investigator in order to maintain integrity of the study details over time. This list will be kept in a locked cabinet, in the investigators’ office.

No information that discloses your identity will be released or published without your specific consent to the disclosure. However, research records may be inspected, in the presence of the principal investigator, or her designate, by representatives of the Simon Fraser University Research Ethics Board, provided that it is done in the presence of the principal investigator or her designate and that the records will not be copied and nor will your name be recorded. However, no records, which identify you by name or initials, will be allowed to leave the investigator’s offices. Your personal information may be disclosed if required by law (such as in cases of reported abuse).

**INFORMED PARTICIPANT CONSENT**

I have received a copy of the consent form. I consent to participation in this study by signing this consent form. I have read and understand all the preceding information describing this study and all my questions have been answered to my satisfaction. I voluntarily consent to participate in this study.

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