

**Ultrasonographic Assessment of Gastric Emptying  
Following Water Ingestion in Healthy Volunteers –  
Feasibility Study**

**Participant Information Leaflet**

Helping you decide whether or not to join our research project.

We would like to invite you to join our research project, but first we want to be sure you know what it is about.  
Please read this leaflet carefully at home.

If there is anything you do not understand or if you would like further information, please contact Dr Chris Thompson at  
[at17585@bristol.ac.uk](mailto:at17585@bristol.ac.uk)

**You are being invited to take part in a feasibility study that is being conducted by the Musculoskeletal Research Unit at the University of Bristol. Before you decide to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully**

**Part 1** tells you the purpose of the project and what will happen if you take part

**Part 2** gives you more detailed information about the conduct of the project

## **Part 1**

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### **1. What is the purpose of the project?**

In this study we are interested in seeing how quickly a drink of water leaves the stomach of healthy people. We plan to give participants drinks of water and measure the volume of their stomachs using ultrasound, both before and after the drink. This will allow us to see how quickly the water exits the stomach. Eventually we hope to continue this research in patients.

### **2. Why have I been chosen?**

To take part in this study, participants must:

- Be an adult (aged over 18 years)
- Be able to attend on two separate days for study interventions
- Not be pregnant, trying to get pregnant or think you might be pregnant
- Not be taking medication that may influence appetite and/or digestion of food (except oral contraceptive pills).
- Not have a history of any medical condition that may affect appetite and/or digestion of food e.g. previous gastro-duodenal surgery, diabetes mellitus, advanced liver or renal disease, recent gastrointestinal infection (within one month).
- Not have a condition that reduces the ability to obtain accurate data with ultrasound e.g. obesity (BMI>35), previous gastro-duodenal surgery

### 3. Do I have to take part?

It is up to you to decide whether or not to take part in this research project. Taking part in this project is completely voluntary.

### 4. What will happen to me if I take part?

If you decide to take part:

- We would ask you to have an early breakfast and then fast from food and calorie-containing drinks for 4 hours. You may need to get up earlier than usual to have a light breakfast, to ensure you are adequately fasted before you arrive for the study. You may drink water and we would ask you to record any intake prior to arrival.
- We would then ask you to attend the University of Bristol Musculoskeletal Research Unit in the Learning and Research Building at Southmead Hospital for 2-4 hours. We would need you to repeat this process on two separate days.
- When you arrive, you will be briefed about the use of ultrasound and have an opportunity to discuss any concerns. In order to locate the stomach, an ultrasound probe will need to be placed on the skin around the abdomen. Therefore, it is important that suitable clothing is worn (i.e. easy to expose the abdomen).
- We will take some basic details and then perform an ultrasound scan of your stomach. This will give us a baseline value of the area of your stomach. Following

this, you will either be designated to follow a protocol of having drinks of water over a period of two hours, or to have no drinks at all. At various points during the protocol we will perform additional ultrasound scans.

- You will be asked to provide ratings of your comfort, thirst, hunger and anxiety levels at various time points during the session.
- Following completion of the protocol you can eat and drink immediately.

### 5. What is ultrasound?

Ultrasound scanning, or sonography, is a method of obtaining pictures or images from inside the human body. It involves sending very high frequency sound waves through the body. The sound waves are directed at the body from a small, vibrating crystal in a hand-held scanner (called a transducer). These sound waves are reflected off the internal organs to create an image. Ultrasound images are captured in real time and displayed on a television monitor.

### 6. What to expect from the ultrasound scan.

An ultrasound examination is a painless, non-invasive procedure. You will be taken into the scanning room and asked to take a seat next to the ultrasound machine. It is recommended to wear comfortable, loose-fitting clothing as you will need to lift your top to expose your abdomen. A clear, water-based gel will be spread onto your skin over the scanning

site. This helps to transmit the sound waves to the microphone in the transducer (probe). The researcher will press the transducer onto your skin and move it back and forth to locate your stomach. At the end of the scan, the researcher will wipe away the gel and place a number of small marks on your skin in the vicinity of your stomach. These will be used as a reference point for subsequent scans. These marks will fade/wash off with showering or bathing.

Please note that this is not a medical or disease diagnostic scan and therefore your scan will not be examined for abnormalities. The scan will not benefit you directly, and does not form part of any medical diagnosis or treatment. However, very occasionally, when we look at an ultrasound scan from a healthy volunteer, unexpected potential abnormalities are discovered and if appropriate your GP will be contacted. The staff involved in this research study doing the scanning do not have expertise in medical diagnosis, as they do not have the relevant specialist medical training. You should not regard this scan as a medical screening procedure.

#### **7. What risks are associated with ultrasound?**

Ultrasound scanning has been shown to be one of the safest medical techniques, and is routinely used to scan babies, both before and after birth, children and adults. It has been widely used in clinical practice for over 40 years, providing valuable pictures and information with no evidence of any harm. However, just as ordinary sounds that are too loud can damage our hearing, so very high levels of ultrasound can produce

undesirable effects, for example by warming the tissue through which the ultrasound passes. Because of this there are strict guidelines about the level of ultrasound that can be used. This study will operate well within these guidelines.

#### **8. What will I have to do?**

If you agree to take part, you will be asked to fast from food and calorie-containing drinks for 4 hours, and then attend the Musculoskeletal Research Unit for an ultrasound examination of your stomach. We may give you some water to drink during the examination. We would ask you to attend on two separate days so we can repeat the study with different amounts of water during the ultrasound examination. We expect that the examination should take about 2 hours to complete, and we would not keep you beyond 4 hours on any given day.

#### **9. What are the possible disadvantages and benefits of taking part?**

There will not be any direct benefits to you, but there will be potential benefits to those undergoing surgery in the future.

There are no major risks of being involved. The study will only require you to undergo a period of fasting, to drink water at set intervals and to undergo ultrasound scans. You may feel thirsty or uncomfortable during the fasting period, although the times will be kept as short as possible. Someone will monitor your

comfort levels at all times and should you wish to stop participating you may do so at any time.

#### 10. Is the research project confidential?

We will ask you to give consent to include your data in further analysis. All data collected in this study will be kept confidential and will be anonymised on completion of the study. There will be no record that links the data collected from you with personal data from which you could be identified (i.e. the consent form). You are free to withdraw your data from the study whilst the study is in progress. Once you have given consent, and the study is completed, we cannot withdraw data at a later stage because of the anonymised nature of the study.

**This completes Part 1 of the Information Booklet.**

**If the information in Part 1 has interested you and you are considering taking part, please continue to read the additional information in Part 2 before making any decisions.**

## Part 2

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#### 11. What will happen if I don't want to carry on with the research project?

Your participation is voluntary and if you decide to take part you are still free to withdraw at any time, without giving a reason, and without your legal rights being affected. If you do decide not to continue with the study, or lose capacity\* during the course of the study, we would keep and use any information you have given us up to that point, unless you tell us that you would like your information removed from the study.

*\* "Capacity" means the ability to use and understand information to make a decision, and communicate any decision made. A person lacks capacity if their mind is impaired or disturbed in some way, and this means the person is unable to make a decision at that time.*

#### 12. What will happen to the results of the project?

You will be provided with a brief report of the findings of this research project once the project has finished, if you so wish. The results of this project will be published in reports, scientific journals and presented at conferences.

### 13. Who is organising and funding this project?

Researchers in the Musculoskeletal Research Unit, at the University of Bristol, are conducting the project.

The project is funded by a grant from the David Telling charitable Trust.

### 12. How to make a complaint

Should you need general advice about taking part in this research, please contact:  
Musculoskeletal Research Unit, University of Bristol  
Level 1, Learning and Research Building, Southmead Hospital  
Westbury-on-Trym, Bristol, BS10 5NB or email  
[at17585@bristol.ac.uk](mailto:at17585@bristol.ac.uk)

If you wish to make a formal complaint please write to:  
[research-governance@bristol.ac.uk](mailto:research-governance@bristol.ac.uk)

### 14. Who has reviewed this research project?

This research has been looked at by an independent group of people at the University of Bristol called the Faculty of Health Sciences Research Ethics Committee, to protect your interests.

### 15. What happens next?

If you are interested in taking part, please complete the enclosed questionnaire and consent form. A researcher will then be in touch with you about the study.

If you have any questions about the project before then, please feel free to contact:

Dr Chris Thompson by email at [at17585@bristol.ac.uk](mailto:at17585@bristol.ac.uk)

**Thank you very much for taking the time to read this  
information booklet. Please keep a copy of this information  
booklet.**