|  |
| --- |
|  |
|  | Department of Psychological Medicine, School of Medicine, Building 507, 22-30 Park AvenueGrafton, Auckland, New Zealand 1023**T**+64 9 373 7599**The University of Auckland** Private Bag 92019Auckland 1142New Zealand |

**PARTICIPANT INFORMATION SHEET**

|  |  |
| --- | --- |
| **Project Title:**  | Can social support change the impact of stress on gastric functioning? |
| **Supervisor:** | Professor Elizabeth Broadbent, Department of Psychological Medicine, University of Auckland. |
| **Co-Investigators:** | Dr Mikaela Law, University of Auckland.Dr Stefan Calder, Alimetry Ltd. |
| **Researcher:** | Christopher Roper, University of Auckland. |
|  |  |

You are invited to participate in a study that investigates the relationship between stress and gastric activity (stomach electrical activity) in people without gastrointestinal disorders. Whether or not you take part is your choice. If you don’t want to take part, you don’t have to give a reason, and it won’t affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you’d like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign a Consent Form that will be provided separately. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 8 pages long.

**It is important that you carefully read this information sheet,** so that you can make an informed decision about whether or not you would like to take part.

You will be asked to sign a consent form prior to participating, which will be provided separately.

**Voluntary Participation and Withdrawal from This Study**

Participation in this study is **entirely voluntary**, you are free to decline to participate, or withdraw from the research at any given time, without providing a reason, and this will in no way impact the care you receive. You also have the right to withdraw any information collected from you during the study, although data withdrawal is limited for up to one month after you have completed the recording and questionnaires.

You have the right to access any information that is collected about you during your enrolment in this study. The information that is gathered from you during your participation in the study will be de-identified to ensure your privacy. No material which could personally identify you will be used in any reports on this study. We are happy to send you a summary of the results of this study upon its completion. Please note it may take time to collect data and provide results for this study.

**Purpose of this study:**

Disorders of Gut-Brain Interaction (DGBI) have a high prevalence of 40% worldwide, causing a significant burden for the individual and wider healthcare systems. There is no clear underlying cause, however evidence suggests that biological, psychological and social factors can contribute to symptoms. The purpose of the current study is to investigate if social support influences the impact of stress on gastric activity. This involves inducing a stress response and measuring changes in gastric activity in healthy people who have experienced varying levels of social support. Our study will add to the growing body of research about the relationships between social support, acute stress and gastric activity.

**How is the study designed?**

This study will recruit 48 participants. Participants will be required to attend a single 120-minute in-person session at either Alimetry Ltd (85 Symonds Street, Grafton) or the University of Auckland Grafton Campus (22/30 Park Avenue, Grafton). The experiment involves completing questionnaires and doing a stressful task that involves placing your hand in ice-cold water and doing mental arithmetic. Social support will be measured using questionnaires and simulated through the behaviour of the researcher. Full details of what to expect are outlined below.

**Who can take part in the study?**

We are looking to recruit participants who are 18-years or older and are fluent in English. You must be able to fully understand the risks and benefits of the research procedures and provide informed consent prior to participating.

This research involves undergoing Body Surface Gastric Mapping (BSGM), a non-invasive method that measures the electrical activity of your stomach. Therefore, participants must be able to remain relaxed in a reclined position for the duration of the procedure. This method involves placement of electrodes on surface of your abdomen. Preparation for BSGM also involves refraining from taking certain medications for at least 48-hours prior to the study. The exclusion criteria outlined below minimises factors that may interfere with measuring your gastric activity, as well as minimising potential adverse effects.

You will not be able to participate in BSGM if:

* You have chronic gastrointestinal disorders.
* You have a history of gastrointestinal surgeries.
* You are pregnant or lactating.
* You have allergies to adhesives.
* You have extreme skin sensitivities to cosmetic lotions.
* You are a regular user of cannabis.
* You have open abdominal wounds.
* You have fragile skin that tears/breaks/bruises easily.
* You are unable to safely refrain from taking any of the following medications for a period of at least 48-hours: drugs that affect gastric emptying (e.g., metoclopramide, domperidone, erythromycin), antispasmodics (e.g., dicyclomine, atropine, flavoxate), pain medications which contain opiates (e.g., codeine, oxynorm, morphine, and tramadol), and sedatives (e.g., diazepam, xanax, alprazolam).

You will need to lift your shirt to show your abdomen for the test; however, you will not be required to remove the clothing on your chest. The study will also involve the researcher touching your abdomen in order to place the electrode array.

This study also involves completing a stress test. This task involves placing your hand in ice-cold water several times for durations of up to 90 seconds at a time and doing mental arithmetic exercises. The exclusion criteria outlined below is designed to minimise potential adverse effects in individuals who may have sensitivities to cold water or stress.

You will not be able to participate in the stress test if you have a current injury on either of your arms/hands, or if you have received a diagnosis of any of the following conditions:

* A cardiovascular condition (e.g., heart disease, high blood pressure, or a stroke).
* Raynaud’s syndrome.
* A metabolic or endocrine disorder (e.g., hypothyroidism).
* A neurogenic disorder (e.g., Parkinson’s disease).
* A terminal illness.

Furthermore, you will be asked to fast (not eat or drink) from midnight the night prior to your session. This includes not drinking coffee on the morning of the study day. If you feel that this would cause you notable discomfort or stress, you are advised not to participate.

**What to expect if you participate:**

If you indicate that you are interested in participating in this study, you will be asked to complete an online screening questionnaire to determine your eligibility. You will be asked questions that cover the exclusion criteria mentioned described above. The researcher will then contact you to inform you of your eligibility.

If you agree to take part in this research project you will be asked to attend an in-person, 120-minute session at either Alimetry Ltd (86 Symonds Street, Grafton) or the University of Auckland Grafton Campus. The researcher will arrange a suitable time and date for an appointment with you via email, and clarify whether you use any mobility devices (e.g., wheelchair, mobility scooter, or walking aids) that would require the scheduling of your appointment at the site with disability access options. You have the right to bring one or more support persons with you to the appointment.

Before you attend your session:

In preparation, you will be asked to fast (not eat or drink) from midnight the night prior to your session (including tea, coffee, water). You will also be asked to refrain from taking the following medications for at least 48-hours before your appointment as they can affect normal stomach actions: drugs that affect gastric emptying (e.g., metoclopramide, domperidone, erythromycin), antispasmodics (e.g., dicyclomine, atropine, flavoxate), pain medications which contain opiates (e.g., codeine, oxynorm, morphine, and tramadol), and sedatives (e.g., diazepam, xanax, alprazolam).

On your research day:

On arrival, the researcher will review the information sheet with you and clarify any concerns you may have. You are required to read and sign the informed consent form prior to continuing with the research.

Phase 1:

1. The BSGM recording will be set-up.
	* You will need to expose your abdomen for a sensor array of electrodes to be set in place. Clothing covering your chest area does not need to be removed.
	* Excess abdominal hair may be removed and skin will be prepped using NuPrep. This reduces skin impedance for enhanced test results.
	* A sensor array (up to 29cm x 17cm patch) will be applied to the skin overlaying your stomach and we will start recording your stomach activity (see Figure 1). There may be minor adjustments to the placement to ensure optimal conductance.
2. Additional sensors and electrodes will be set-up.
* To measure your body’s response to the stressor, additional electrodes and sensors will be placed on your left hand and shoulders (See Figure 1). This a non-invasive process that poses minimal risk.



**Figure 1.** Photograph of a person wearing the electrode array and stress sensors.

1. You will be guided to sit in a reclined chair and the researcher will start recording gastric activity and other parameters. This recording will continue for your full session.
2. A baseline period of 15-minutes will be observed. During this time, you will complete several questionnaires that will include questions about your demographics, your perceptions of the social support you currently receive in your everyday life, and your perceptions of the social support you received during your childhood. You will also complete the Alimetry Gut-Brain Wellbeing Survey, which enquires about your general mental health over the past two weeks.
3. A 10-minute meal time will then follow. You will be provided with a meal of approximately 452kCal consisting of a protein bar and nutritional shake. Several options are available to accommodate specialised requirements for individuals who follow gluten-free, vegan and/or diabetic diets. You are asked to take the full 10-minutes to consume your meal.
4. You will then sit reclined in the chair for a 30-minute waiting period.

Phase 2:

1. You will receive a short instructional briefing explaining the procedure of the stress task and the effects it has on the body. This will take approximately 5 minutes.
2. You will complete the stress task over a 10-minute period. You will be asked to insert your hand into ice-cold water several times for varying durations of no more than 90 seconds at a time. During the periods of time where your hand is outside the water, you will be asked to do continuous mental arithmetic exercises. You will be filmed during the task to enable analysis of your facial expressions as a further measure of your stress levels. Please note that you can stop the stress test at any time if it becomes too unpleasant. There will be no negative consequences for stopping early, and the researcher will monitor you throughout the test to ensure your safety.

Phase 3:
1. You will remain reclined in the chair for a further 30 minutes to enable the measurements to continue while your body recovers from the task.

2. At the end of this phase, you will be disconnected from all equipment and asked to complete an additional questionnaire about social support.

Additional notes:

* At specific times during your session, you will be asked how stressed and relaxed you feel, and how much pain you are experiencing. It is important that your answer reflects how you feel at that moment in time.
* The social support components of the study involve the use of questionnaires and simulated behaviours enacted by the researcher running the session. Although you may bring a support person if you wish, this is not the focus of the study.

**What are the possible risks and benefits of this study?**

This study is not designed to directly benefit participants. However, the outcomes of this research may benefit the wider community by providing new knowledge about the relationship between social support and gastric functioning.

There is minimal risk associated with the BSGM procedure as it is a non-invasive test. However, there may be slight irritation and soreness of the skin at the site of the electrode array after removal. You will receive a follow-up call or text 24-hours, 48-hours and a week after your participation to monitor any adverse skin reactions. You will be directed to seek additional assistance from your GP should reactions not self-resolve.

There is minimal risk associated with the stress test, as it is comprised of well-established methods for inducing temporary stress in laboratory settings. The cold water can produce painful sensations, however the pain will subside quickly after removal of your hand from the water. In the unlikely event of an adverse reaction or pain that does not resolve quickly, you will be advised to contact your GP.

You will be asked to respond to several questionnaires that enquire about different aspects of your life. The Alimetry Gut-Brain Wellbeing Survey enquires about your mental health over the previous two weeks, and the social support questionnaires enquire about your experiences of social relationships in your adulthood and childhood. Should you find any of the questions distressing, the researcher will provide assistance on the day. This may involve referring you to appropriate support services, including mental health services, helplines, and online coping resources. The researcher may also recommend that you seek assistance from your GP or community support services.

Incidental findings:

The BSGM procedure used in this study is not intended for diagnostic purposes. However, in the unlikely event that incidental findings emerge, you will be advised to contact your GP.

**Will any costs be reimbursed?**

Participants will not incur any costs. As a thank-you for participating, you will receive a $50 shopping voucher.

**What if something goes wrong?**

In the highly unlikely situation that you were injured in this study, you would be eligible to apply for compensation via ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. 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 will happen to my information?**

During this study the research team will record information about you and your study participation. This includes screening information, BSGM, stress information, and questionnaires about your experiences of social support and general wellbeing. You cannot take part in this study if you do not consent to the collection of this information.

Identifiable Information

Identifiable information is any data that could identify you (e.g., your name or date of birth). Only members of the research team that are affiliated with the University of Auckland will have access to your identifiable information. This information will be stored securely and remain separate from de-identified data. You will be assigned a unique participant number on enrolment, which will be used to convert your data into a de-identified form. Confidentiality will be maintained throughout with no reference to personal details through data collection and analysis thereof. At completion of the study, data will be kept for at least 10 years to accommodate future review and analysis if needed. At that time, all files will be disposed of securely.

The screening questionnaire that determines your eligibility for the study will collect identifiable information, and your responses will be reviewed by the researcher. If you are ineligible or choose not to participate, this information will be immediately deleted.

De-identified (Coded) Information

To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by the research team or in any study information sent to the sponsor. Instead, you will be identified by a numerical code. The research team will keep a list linking your code with your name, so that you can be identified by your coded data if needed.

The following groups may have access to your coded information:

* The sponsor, for the purposes of this study.
* People working with or for the sponsor, for the purposes of this study (this may include approximately 20 people).

The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you.

Security and Storage of Your Information.

Your identifiable information is securely held at the University of Auckland and Alimetry Ltd during the study. After the study it is transferred to a secure archiving site and stored for at least 10 years, then destroyed. Your coded information will be entered into electronic case report forms and sent through a secure server to the sponsor. Coded study information will be kept by the sponsor in secure, cloud-based storage. All storage will comply with local and/or international data security guidelines.

BSGM, participant information and digital survey data will be stored on the Alimetry Cloud. This is a secure storage system owned by Alimetry Ltd. All manual survey data will be stored securely in a locked filing cabinet at the University of Auckland, and digital entry of de-identified manual data will occur on secure servers managed by the University of Auckland. Access to data will be restricted to the research team.

Risks.

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is currently very small, but may increase in the future as people find new ways of tracing information.

This research includes basic information such as your ethnic group, age, and sex. It is possible that this research could one day help people in the same groups as you. However, it is also possible that research findings could be used inappropriately to support negative stereotypes, stigmatize, or discriminate against members of the same groups as you.

Rights to Access Your Information.

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected.

Please ask if you would like to access the results of your screening and tests during the study.

If you have any questions about the collection and use of information about you, you should ask the researcher or members of the research team.

Rights to Withdraw Your Information

You may withdraw your consent for the collection and use of your information at any time, by informing any member of the research team.

If you withdraw your consent, your study participation will end, and no more information will be collected from you. However, information collected up until your withdrawal from the study will continue to be used and included in the study. This is to protect the quality of the study.

Ownership Rights.

Information from this study may lead to discoveries and inventions or the development of a commercial product. The rights to these will belong to Alimetry Ltd. You and your family will not receive any financial benefits or compensation, nor have any rights in any developments, inventions, or other discoveries that might come from this information.

Māori Data Sovereignty.

Māori data sovereignty is about protecting information or knowledge that is about (or comes from) Māori people. We recognise the taonga of the data collected for this study. To help protect this taonga:

* Cultural consultation has been undertaken with advisors in the Department of Psychological Medicine at the University of Auckland.

**Can I find out the results of the study?**

After the outcomes of the study have been finalised, you are able to request a copy for your perusal. It is important to note that results may only be available from 6 to 12 months after your session.

**Who is funding the study?**

This study is funded by the University of Auckland and Alimetry Ltd.

**Who has approved the study?**

The study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. HDECs only approve ethical aspects of studies. The Northern A Health and Disability Ethics Committee has approved this study.

**Who do I contact for more information or if I have concerns?**

If you have any questions, concerns or complaints about the study at any stage, you can

contact:

Christopher Roper

Master of Health Psychology Candidate

University of Auckland

E: crop723@aucklanduni.ac.nz

M: 022 522 4185

If you want to talk to someone who isn’t involved with the study, you can contact an

independent health and disability advocate on:

Phone: 0800 555 050

Fax: 0800 2 SUPPORT (0800 2787 7678)

Email: advocacy@advocacy.org.nz

Website: https://www.advocacy.org.nz/

If you require Māori or Pacific cultural support, talk to your whānau/family in the first

instance. Alternatively, you contact the primary researcher who will put you in touch with appropriate services

You can also contact the health and disability ethics committee (HDEC) that approved this

study on:

Email: hdecs@health.govt.nz

Phone: 0800 400 569 (Ministry of Health general enquiries)