Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

Participant Information Leaflet

An Investigation of the Active Stand Protocol in eliciting Heart Rate Recovery

Principal Investigator and Co-investigators: Prof. John Gormley, Caitríona Quinn

Introduction:

You are being invited to take part in a research study to be carried out at the Clinical Research Facility in St. James's Hospital by researchers from the School of Physiotherapy in Trinity College Dublin. Before you decide whether you wish to take part, you should read the information provided in this leaflet carefully. Take time to ask questions – don't feel rushed or under pressure to make a quick decision. You should understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. To take part you must be available for three testing sessions. To be eligible to participate you must be at least 18 years old. You may wish to discuss it with your family, friends or GP.

Part 1 – The Study

Who is carrying out this research?

Researchers from the School of Physiotherapy in Trinity College Dublin are carrying out this study to investigate the repeatability of heart rate recovery in response to the Active Stand protocol in healthy adults.

Why is this study being done?

The Active Stand assessment is used to identify various cardiovascular and neural responses to standing. During the test, blood pressure and heart rate are monitored to identify any unusual changes. This assessment is used for research purposes and clinically to identify various health conditions including orthostatic hypotension, causes of falls and fainting and autonomic dysfunction. Much of the research available regarding the Active Stand is conducted on those over 50 years old due to the nature of the associated conditions and how well the test compares over several assessments is not well known.

Aim: The aim of this research is to perform the active stand protocol in a healthy adult population of all ages in order to determine the repeatability of the test.

Why am I being asked to take part?

You have been invited to take part in this study because you are attending/working at Trinity College Dublin or St James's Hospital and may be eligible to take part in this study. The researchers intend to test 125 volunteers from staff and students of Trinity College Dublin/ St James's Hospital, who are healthy adults between the ages of 18 and 75.

Do I have to take part?

You have volunteered to participate in this study. You may quit at any time. If you decide not to participate, or if you quit, you will not be penalised and will not give up any benefits which you had before entering the study. You should not feel in any way obliged to take part in this study. If you wish to seek more information about this study Ms. Caitríona Quinn will be able to provide you with information. Contact details for Ms. Quinn are provided overleaf.

How will the study be carried out?

Participants will be recruited from Trinity College Dublin and St. James's Hospital. This study is aiming to determine how repeatable measurement of heart rate recovery in response to the Active Stand protocol is. This will be achieved by conducting repeat assessments of the Active Stand over three sessions, a week apart.

What will happen to me if I agree to take part?

If you decide to take part in this study you will be asked to visit the Clinical Research Facility in St. James's Hospital on three occasions. During your first visit you will be asked to complete a demographic questionnaire. You will also undergo body composition analysis and complete an Active Stand. In the following two visits you will complete the Active Stand assessment. During one of these visits you will conduct the Active Stand three times at 30-minute intervals. You will be asked to fast for at least 12 hours, to refrain from caffeine and nicotine for 4 hours, alcohol and taurine-containing beverages and vigorous exercise for 12 hours.

Body Composition Analysis

You will be asked to fast for at least 12 hours before testing. Upon arrival to the Clinical Research Facility your standing height will be measured. The amount of fat, water and muscle in your body will be estimated using a machine that analyses measurements including details of body weight, body mass index (BMI), percentage body fat, muscle mass and fat mass. This machine is non-invasive and will not cause any pain.

Blood Pressure and Vascular Stiffness Assessment

You will be seated in a supportive chair with both feet on the ground. A blood pressure cuff will be used to take your blood pressure and measure your vascular stiffness. This is a non-invasive procedure.

The Active Stand

Prior to testing, the procedure and equipment used will be explained to you. You will be asked to lie down for 5 to 10 mins without moving or speaking. A heart rate monitor will be attached to you while you are lying down. You will then be asked to stand up as quickly as possible and to remain standing unassisted for 3 minutes. You will be asked to describe any symptoms at 1 and 3 minutes after standing. You will then be asked to sit back down to allow your blood pressure to return to its original level. Your blood pressure and heart rate will be monitored constantly throughout the test. If you feel unwell in any way at any stage during the test you may stop the test.

Are there any benefits to me or others if I take part in the study?

This study has minimal benefits to you personally but will greatly benefit research pertaining to the Active Stand protocol. Full analysis of body composition measurements will be available to participants on completion of testing procedures in the form of an individualised health report, which may be of potential benefit.

Are there any risks to me or others if I take part in the study?

As with all clinical research there is risk involved, however the lead investigator will strive to ensure all risk is minimised. During the active stand, participants may experience dizziness, light headedness or weakness. There is a risk of falling or fainting upon doing the active stand. These risks will be minimised by the researcher ensuring the environment is set up properly and assessments are conducted in a correct and safe manner. Testing will be terminated immediately by the investigator if this occurs. Blood pressure and heart rate will be monitored closely throughout the procedures. Participants will be provided with a seat if they feel unwell. Onsite nursing staff will be available.

In the unlikely event of sudden cardiac arrest, the researcher is trained in Basic Cardiac Life Support and will apply the skills necessary in such an event. A crash trolley including an Automated External Defibrillator will be available on site and the procedures according to the standard of the CRF will be carried out. Access to a crash team is also available if required.

Exclusion from participation: You cannot be in this study if any of the following applies to you:

- Non-fluent in English
- Poor brain function that would affect your ability to give informed consent
- Cardiac, respiratory or metabolic conditions
- Neuro-musculoskeletal disorders
- Acute musculoskeletal injury
- Malignancy
- Mental illness
- Chronic infectious disease
- Acute systemic infection or illness
- Taking medication that affects cardiovascular function
- Exclusion for any other reason deemed appropriate by the research team

What should I expect on the day of testing, if I do consent to take part in this study?

If you consent to taking part, the following points explain how to prepare for your testing day.

- Please fast from midnight on the night before your assessment days. Limit your liquid intake while fasting: you may drink water but refrain from caffeinated drinks for 4 hours prior to testing and alcohol and energy drinks for 12 hours prior to testing. Fasting ensure more accurate results of body composition analysis and heart rate recovery. Please bring a snack and drink to have after each assessment.
- Please refrain from strenuous physical activity for at least 12 hours prior to each assessment.

Part 2 – Data Protection

What information about me will be used as part of this study?

Information regarding your gender, age and relevant medical history will be collected as part of this study. Height and body composition will be measured during the first session. Blood pressure, heart rate and vascular stiffness will be assessed as part of this study. Access to your medical records is not required for this study.

What will happen to my personal data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task for scientific research purposes in the public interest.' Trinity College Dublin is the data controller and is responsible for looking after your information and using it properly. We will use the minimum personally-identifiable information possible. All data will be pseudo-anonymised during data processing. That means, we will not be using your name or any identifiable data but will instead give your dataset a numerical ID code. This data will be securely stored on a password protected computer in a locked research office that is only accessible by the research team. All hard copy data will be stored securely in this office in locked filing cabinets.

We will keep anonymised information about you for up to 10 years after the study has finished. This excludes any research documents with personal information, such as consent forms, which will be held securely at Trinity College Dublin, which will be held for 10 years after the end of the study. After this period, all data related to the study will be destroyed.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate.

You can find out more about how we use your information by contacting Ms. Caitríona Quinn (Tel: 01 8963613, email quinnc18@tcd.ie)

Who will access and use my personal data as part of this study?

The Research Physiotherapist (Ms. Caitríona Quinn) will have access to your personal details and results from the study. The Principal Investigator (Prof. John Gormley) will have access to coded (pseudonymised) data only. Your personal data will not be shared with anyone outside of the research team at Trinity College Dublin. The Research Physiotherapist and Principal Investigator have undergone training in data protection law and practice, prior to starting this research. The researchers in this project are bound by our Professional Code of Conduct to maintain confidentiality regarding all data gained during this research. The data processor for this study is Trinity College Dublin.

Will my personal data be kept confidential? How will my data be kept safe?

Data will be pseudonymised and subsequently anonymised to ensure confidentiality. The Research Physiotherapist will be the only person who can access the data and will be the only person to know the passwords on the electronic database. Hardcopy data will be stored in locked filing cabinets, accessible to the study investigators only.

What is the lawful basis to use my personal data?

We are collecting and storing this personal identifiable information in accordance with General Data Protection Regulation (GDPR) legislation (Article 6 and 9) which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is "a public interest task" and "a process necessary for research purposes".

What are my rights?

You have a number of rights under data protection law regarding your personal information. For example, you can request a copy of the information we hold about you, including audio recordings or photographs.

If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our Privacy Notice for Research at http://www.stjames.ie/InformationGovernance/PrivacyPolicyFull/.

A list of your rights is below

- Right to access data held
- Right to restrict the use of the data held
- Right to correct inaccuracies
- Right to have information deleted
- Right to data portability
- Right to object to profiling

You can exercise these rights by contacting any member of the research team, or the Trinity College Data Protection Officer (see contact details below). If you are not satisfied with how your data is being used, you can also lodge a complaint to the Data Protection Commissioner (Tel: +353578684800 or +353(0)761104800; website: www.dataprotection.ie; address: Office of the Data Protection Commission, 21 Fitzwilliam Square South, Dublin 2).

Part 3- Costs, Funding and Approval

Will it cost if I agree to take part?

There is no cost to participate in this study.

Has this study been approved by a research ethics committee?

This research project has the approval of the Tallaght University Hospital/ St James's Hospital Research Ethics committee on 20/01/2021. Further information of the conditions of this approval can be obtained by contacting research.ethics@tuh.ie

Who is organising and funding this study? Will the results be used for commercial purposes?

This research project is self-funded by Trinity College Dublin, as part of postgraduate research. The results will not be used for commercial purposes. You will not be paid to take part in this research.

Part 4 – Future Research

Will my personal data be used in future studies?

As part of this form we are seeking consent to have the option to use your anonymous data for comparative purposes in other studies of a similar nature examining the Active Stand Protocol However, your data will remain coded and your personal identifiers will never be published or disclosed to anyone outside of the current research team. Your data will only be used for comparative purposes in other studies which have Research Ethics Committee approval. Further research may be conducted by the current research team or other researchers here in Trinity College Dublin. If you would prefer for this not to happen, please make this known to the research team in your consent form. This will not affect your participation in this study.

Will I be contacted again?

We may contact you regarding future research regarding the Active Stand Protocol. If you agree to your details being held to be contacted regarding future research, we will retain a copy of your consent form until such time as your details are removed from our database but will keep the consent form and your details separate.

Part 5 – Further Information

Who should I contact for information or complaints?

For more information or answers to your questions about the study, your participation in the study and your rights, please contact the research team:

- Principal Investigator/Research Supervisor: Prof. John Gormley, Discipline of Physiotherapy, Trinity College Dublin. Tel: (01)8962121. Email: jgormley@tcd.ie
- Research Physiotherapist: Ms. Caitríona Quinn, PhD Physiotherapy (candidate), Trinity College Dublin. Tel: (01)8963613. Email: quinnc18@tcd.ie
- Data Controller: Trinity College Dublin

For information regarding your rights under data protection law, please contact:

- Data Protection Officer: Website: www.tcd.ie/privacy Tel: 01 8961892. Address: Secretary's Office, Trinity College Dublin, Dublin 2. Email: dataprotection@tcd.ie

Thank you for taking the time to read this information.