# Participant Information Leaflet

## A study to investigate the accuracy of a Timed Up and Go Test smartphone application in a population

| | |
|---|---|
| Site | Tara House, MS Ireland, Dooradoyle, Limerick. |
| Principal Investigator and Co-Investigator | **Dr Sean Mc Auliffe:** Assistant Professor, Trinity Health Sciences Centre, Department of Physiotherapy, School of Medicine. Email: mcaulise@tcd.ie<br><br>**Sinéad MacErlane:** Research Assistant, Trinity Health Sciences Centre, Department of Physiotherapy, School of Medicine. Email: smacerla@tcd.ie |
| Study Organiser | Dr. Mc Auliffe/TCD |
| Data Controllers | Trinity College Dublin |
| Data Protection Officer | Data Protection Officer<br>Secretary's Office<br>Trinity College Dublin<br>Dublin 2 |

You are being invited to take part in a research study that is being carried out by Dr. Sean Mc Auliffe, Assistant Professor in Physiotherapy at the School of Medicine in Trinity College Dublin. The study involves taking part in a mobility test named the Timed up and go test. This test is commonly used by physiotherapists to look at mobility in people with a neurological condition. The study aims to determine if, when carried out in a population with a neurological condition, a smartphone application is similar in accuracy to the traditional method of carrying out this timed up and go test.

Before you decide whether or not you wish to take part, please read this information sheet carefully. Feel free to ask Dr Mc Auliffe any questions you may have. Don't feel rushed or under any 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. You may wish to discuss it with your family or friends.

This leaflet has five main parts:

*Part 1 – _The Study*
*Part 2 – _Data Protection*
*Part 3 – _Costs, Funding and Approval*
*Part 4 – _Future Research*
*Part 5 – _Further Information*

## Part 1 – The Study

### Why is this study being done?

• We are undertaking this study to determine if a digital phone application has similar accuracy to a traditional human assessment of the total time taken to perform a timed up and go test in a group of individuals with a neurological condition. The timed up and go test is a commonly used test to assess mobility across a range of health care settings. You will be required to stand up from a standard chair (seat Height between 44 and 47 cm), walk a distance of 3 meters (marked on the floor) at a comfortable pace, turn, walk back and sit down (Figure 1). You will be asked to repeat the same procedure for a distance of 10 meters. You will be asked to perform two trials at each distance (3m and 10m). You are permitted to use walking aids if you currently use one. No physical assistance is given and you are instructed not to use your arms to stand up. The time to complete the task is measured with a stopwatch. Timing commences on the command ‘go’ and stops when the your back is positioned against the back of the chair after sitting down.

**Figure 1**

## Why have I been invited to take part?

We are looking to determine the accuracy of a new smartphone application in measuring mobility in people with neurological conditions. Given you are currently attending the Active Neuro community classes you are a potential candidate to participate in the study if you choose. You are under no obligation to participate if you do not wish to participate you can simply ignore this information sheet.

**Do I have to take part? Can I withdraw?**

You don't have to take part in this study. It is entirely voluntary. You can change your mind about taking part in the study and opt-out at any time even if the study has started. You don't have to give a reason for not taking part or for opting out. If you wish to opt-out, please contact Sinead MacErlane at 0831926295. or on smacerla@tcd.ie and she will organize it for you. Please note that data relating to your performance in the timed up-and-go test will be anonymized once we have completed the analysis. After this point, it is not possible to withdraw this data from the study.

**What happens if I change my mind?**

You can change your mind at any time by informing study investigator Sinead MacErlane, who will be present at the testing or by contacting her on 0831926295. If you wish, you can request that your data stored be destroyed. If you request this, we will destroy all data that are still in our possession. We will no longer use or share your samples or data for research from this point onwards.

**How will the study be carried out?**

The study will take place at the MS Ireland Tara House, Dooradoyle, Co. Limerick. Testing is a once off test and will be arranged at a time of your convenience. During the test you will be asked to perform a mobility test known as the Timed up and go Test. During the test, participants are asked to stand up from a standard chair (seat

Height between 44 and 47 cm), walk a distance of 3m (marked on the floor) at a comfortable pace, turn, walk back and sit down. The time taken to perform the test will be recorded by the smartphone application and by an assessor using a stopwatch. You will repeat the test also for a distance of 10 meters. You will be asked to carry out a survey detailing how you found using the application. The results are recorded and analysed thereafter.

**What will happen to me if I decide to take part?**

If you choose to participate, you will be invited to come, at a time convenient to you, to the MS Ireland Tara House, Dooradoyle, Co. Limerick where the testing will take place. After you have had an explanation of the study and have given written informed consent, you will be asked to perform a mobility test known as the Timed up and go Test. During the test, participants are asked to stand up from a standard chair (seat height between 44 and 47 cm), walk a distance of 3m (marked on the floor) at a comfortable pace, turn, walk back and sit down. You will repeat the test also for a distance of 10 meters. You will be asked to perform the test 2 times for each distance, with a rest provided between tests.

**What will happen to my Data?**

The data (time) collected will be in the form of numerical digits. The data will be stored in an Excel Spreadsheet which will be encrypted and stored on a Trinity college Dublin (TCD) password protected laptop and on TCD's OneDrive. Your data will remain in these two locations at all times. After data analysis has taken place on the TCD laptop the data will be completely anonymised and the code connecting you to the data will be destroyed. It will not be possible to give you your individual data after this.

Dr. Mc Auliffe will have responsibility for encryption and storing of the data and will restrict access to the data to members of the research team only. Data will be stored on TCD one drive and be doubly encrypted on a TCD laptop.

Your data will be destroyed by Dr. Mc Auliffe after a period of seven years.

It will also be necessary to retain the Consent Form (personal data) until the data has been depleted or destroyed in order to provide evidence of consent in accordance with Article 7 GDPR requirements.

**Are there any benefits to taking part in this research?**

Taking part in this study will not directly benefit you. However, research performed with your samples and information may help us to better understand how digital technologies can help enhance the lives of people with mobility problems. It is hoped that if the timed up-and-go smart phone application is accurate it can then be used in clinical trials in the future across a range of conditions such as Multiple Sclerosis or Parkinson's disease.

**Are there any risks to me or others if I take part?**

There is a risk that a connection to your identity could be made. Great care will be taken to ensure the confidentiality of all data and the risk to participants of a breach of confidentiality is considered very low. There is a very low risk that you may experience a fall or related injury during the timed get up and go test. However, the risk is extremely low and the test will be supervised by a qualified Physiotherapist with first aid training.

**What happens if something goes wrong when I'm taking part in the study?**

The study investigator Sinead Mac Erlane, a qualified Physiotherapist will be present during all of the testing. In the unlikely event that you are harmed in any way, the researchers will follow the procedures already in place as part of the Active Neuro project.

**Will I be told the outcome of the study? Will I be told the results of any tests or investigations performed as part of this study that relate to me?**

Any outcome from the research that would impact directly or indirectly on your health will be reported to you. We will report the overall results of the research to you in the form of an email if you wish to receive it. You will need to let Sinead Mac Erlane know at the time of testing if you wish to receive such an email. The results of the study may also be reported in medical/scientific journals and disclosed at medical/scientific conferences. No information which reveals your identity will be disclosed.

**Part 2 – Data Protection**

**What information about me (personal data) will be used as part of this study? Will my medical records be accessed?**

We will only be collecting details regarding your name, age gender, height, weight, phone number, date of birth and email. You will provide us with this information. We will also record your diagnosis of a neurological condition and your current mobility levels. We will then assign you a unique number and will use

that number to identify you on the two testing systems. We need this minimal set of identifiable information for safety and legal purposes. Data relating to your timed get up and go test performance will also be collected and used. Your medical records will not be accessed as part of this study. Beats Medical will have access to anonymised data from the TUG test.

**What will happen to my personal data?**

Your personal data will be doubly encrypted and stored on a TCD laptop and backed up on TCD's secure OneDrive cloud storage system. It will not leave TCD. Your personal data is required to be kept for a period of seven years. After this Dr. Mc Auliffe will destroy this data. The anonymised data on your timed up and go test performance will be kept for a period of up to ten years to assist with the further development of the smartphone application. Beats Medical will not have access to your personal data. .

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

Only the PI Dr Sean Mc Auliffe and Sinead Macerlane will access and use your personal data as part of this study. This personal data will not leave TCD. The paper data (consent form) will be stored in a locked cabinet in Dr Mc Auliffes office. The information will be scanned, encrypted, and stored onto TCD's secure one drive in a folder that only Dr Mc Auliffe and has access to. Once scanned in the paper files will be shredded.

Beats Medical will have access to anonymised data only to help in the development of their application.

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

Your privacy is important to us. The following steps we will take to ensure your data is kept safe.

• All data relating to you that is collected will be stored with double encryption. It will be stored in one of three secure places.

• A locked filing drawer in Dr Mc Auliffes office (paper consent forms)

• In Microsoft Excel or Microsoft Word files that are doubly encrypted on a TCD laptop.

• Backed up all data on TCD's OneDrive also using double encryption.

• A Risk Assessment of the data protection implications of the health research was carried out. The is a very low level of risk that there will be a breach of data protection in this study.

• No presentation or publication arising in relation to this study will identify any individual that takes part in it.

• Dr Mc Auliffe and Sinead Mac Erlane have both completed training in data protection law at TCD.

**What is the lawful basis to use my personal data?**

By law,[3] we can use your personal information for scientific research[4] (in the public interest[5]). We will also ask for your explicit consent to use your data as a requirement of the Irish Health Research Regulations.

**What are my rights?**

You are entitled to:

- The right to access to your data and receive a copy of it
- The right to restrict or object to processing of your data
- The right to object to any further processing of the information we hold about you (except where it is de-identified)
- The right to have inaccurate information about you corrected or deleted
- The right to receive your data in a portable format and to have it transferred to another data controller
- The right to request deletion of your data

*By law you can exercise the following rights in relation to your personal data, unless the request would make it impossible or very difficult to conduct the research. You can exercise these rights by contacting your study Dr Sean Mc Auliffe (email mcaulise@tcd.ie) or the Trinity College Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2, Ireland. Email: dataprotection@tcd.ie. Website: www.tcd.ie/privacy.*

[3] The European General Data Protection Regulation ( GDPR)

[4] *Article 9(2) (j))*

[5] *(Article 6(1)(e)*

**Part 3 – Costs, Funding and Approval**

**Has this study been approved by a research ethics committee?**

• Yes, TCD, Faculty of Health Sciences Research Ethics committee gave ethical approval to this research in April 2023 (Reference number 221201)

• None of the persons carrying out the research have a link to the committee although the researchers are employed by TCD

• A report on this research will be sent to the ethics committee within a year of the start date of the project (May 2024)

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

• Dr. Mc Auliffe is organising the study in his role as Assistant in Physiotherapy at the School of Medicine at Trinity College Dublin. The results of the study will help inform the development of a commercial product by Beats Medical for use in individuals with mobility problems. Dr. Mc Auliffe is not receiving any financial renumeration for his role in the research project.

**Is there any payment for taking part? Will it cost me anything if I agree to take part?**

There is no payment for taking part.

**Part 4 – Future Research**

**Will my personal data and be used in future studies?**

We will not use your data in future studies and will only use and store your data for a maximum of seven years as is required by law.

**Part 5 – Further Information**

**Who should I contact for information or complaints?**

If you have any concerns or questions, you can contact:

• Principal Investigator: Dr Sean Mc Auliffe 0872223564 mcaulise@tcd.ie

• Data Protection Officer, Trinity College Dublin: Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2, Ireland. Email: dataprotection@tcd.ie. Website: www.tcd.ie/privacy.

Under GDPR, if you are not satisfied with how your data is being

processed, you have the right to lodge a complaint with the Office of the Data Protection Commission, 21 Fitzwilliam Square South, Dublin 2, Ireland. Website: www.dataprotection.ie.

**Will I be contacted again?**

If you would like to take part in this study you can contact the researchers using the contact details provided. The research team will organise a time and date to undertake the testing at Tara house at your convenience. You will be asked to sign the Consent Form on the day of testing. You will be given a copy of this information leaflet and the signed Consent Form to keep. You will only be contacted again in future if you have requested to know the results of the study or if you wish to obtain a copy of your data.