##

## **Participant Information Sheet**

|  |
| --- |
| **Walking to better health after stroke** |

**Introduction**

Thank you for showing an interest in this project. Please read this information sheet carefully. Take time to consider and, if you wish, talk with relatives or friends, before deciding whether or not to participate.

If you decide to participate we thank you. If you decide not to take part, there will be no disadvantage to you and we thank you for considering our request.

**What is the aim of this research project?**

The aim of this research project is to determine whether a 12-week walking programme, provided and monitored by a physiotherapist, is a practical and reasonable way of improving the health and wellbeing of people following stroke.

**Who is funding this project?**

Funding for this project comes from a University of Otago Research Grant.

**Who are we seeking to participate in the project?**

People with stroke, living in the community, who can walk by themselves (with or without walking aids) and, are over the age of 17 years will be eligible to take part in the project. This includes people living in residential care and those still receiving rehabilitation. The time or distance individuals can walk is not important. Participants may have experienced their stroke recently or many years before.

**If you participate, what will you be asked to do?**

You will be asked to attend a 90-minute appointment at the School of Physiotherapy where you will complete a range of questionnaires and undergo measures of height, weight, blood pressure and walking endurance. You will also be fitted with a device (an accelerometer) that records daily activity. The device will need to be worn for the next seven days. Instructions on how to wear this small device will be provided. After seven days’ you will be asked to return the accelerometer in person or by prepaid post.

Participants will then be randomly allocated to a control (usual care) group or a walking group.

**Control group:** If you are allocated to the control group, you will continue your usual day-to-day routine. After 12-weeks, you will be asked to return to the School of Physiotherapy and repeat the questionnaires and measures including wearing the accelerometer device for another seven days. Following this, you will be offered an 8-week version of the walking programme based at the School of Physiotherapy. It is up to you whether you want to participate in this programme or not.

**Walking group**: If you are allocated to the walking group, you will be contacted by a physiotherapist to arrange a meeting, either at your home or at the School of Physiotherapy, to start a 12-week walking programme.

|  |  |
| --- | --- |
| Week 1(1 hour) | Your physiotherapist will provide you with a Fitbit™ tracker to monitor how many steps you take each day and show you how to use the Fitbit™ App on a suitable smartphone, tablet or computer (you can choose to use your own device or we will provide a smartphone for the duration of the programme). It is essential that you wear the Fitbit™ everyday so that you and your physiotherapist can get an accurate idea of how many steps you take each day. However, it is not essential that you use a smartphone or equivalent device should you feel uncomfortable with this. You will be given a walking diary in which to record the number of steps registering on the Fitbit™ each day. |
| Week 2(45 mins) | You will meet your physiotherapist again to review your step count, how you are finding the Fitbit™ and discuss any concerns. A daily step target for the following week will then be agreed and you and your physiotherapist will discuss how ‘hard’ you should walk and how best to fit this into your week. Again, it is essential that you wear the Fitbit™ everyday to get an accurate idea of how many steps you take each day. |
| Weeks 3-12(30 mins) | You will be in weekly contact with your physiotherapist, at a prearranged time, to discuss progress, document daily step count for the previous week (as recorded from the Fitbit™ in the walking diary or on the Fitbit™ App), and agree a new daily step target for the following week. In this way the walking programme will be tailored to suit your needs and progressed on a weekly basis. The weekly contact with your physiotherapist can be in person (for a maximum of six visits), by phone or through a video-conferencing platform similar to Skype™. |
| After 12-weeks, you will be asked to return to the School of Physiotherapy and repeat the questionnaires and measures you completed at the start, including wearing the accelerometer device for another seven days. |
| *Optional*: At the end of the walking programme, you will be invited to take part in a focus group discussion about your experiences in the study, the walking programme and how you found the Fitbit™. The discussion will be audio-recorded and later transcribed for analysis. The researcher will undertake to safeguard the confidentiality of the discussion, but cannot guarantee that other members of the group will do so. We will discuss this option with you at the end of the walking programme. |

**Is there any risk of discomfort or harm from participation?**

This study will assess your walking. As such there is a risk that you could fall. Assessors are experienced physiotherapists used to assessing people with movement disorders and will always stand close by. To further minimise your risk of falling during the assessment procedures, the assessor may use a safety belt positioned around your waist with easy to grab handles, may ask a second physiotherapist to be available during testing, stop the test or leave out any items of the test if it is judged to be too high a risk for falling. Should a fall occur, the assessor will follow usual first aid procedures and University safety policies.

Some of the questionnaires regarding quality of life and overall health and wellbeing may address issues you feel uncomfortable with. All responses are confidential, however, you do have the option to leave questions blank, at no disadvantage, should you desire.

As part of the assessment procedure you will be asked to wear an accelerometer device throughout the day for seven consecutive days. If you experience a skin reaction (rare) you will be asked to remove the device and contact the Principal Investigator.

If you are allocated to the walking group, the risks to you are minimal. You will be in charge of your walking programme and it is up to you where you walk, when you walk and whether you want to use a walking aid, hand rail or the support of another person. You may experience some muscle discomfort from unaccustomed exercise; skin reaction from Fitbit™ contact (rare); or fatigue. You will be encouraged to discuss these issues and any others you experience, with your physiotherapist. If symptoms persist, or concern remains, advice will be given for you to attend an appropriate health practitioner and you can decide whether to continue with the programme or withdraw.

**What specimens, data or information will be collected, and how will they be used?**

Information will be collected on your age, gender, ethnicity and medical condition (including current medications) along with your responses to our questionnaires on quality of life, wellbeing and confidence in walking. Measurements of physical activity, blood pressure, endurance, your height and weight, will also be collected. If you are allocated to the walking group, your physiotherapist will document each meeting in her/his clinical notes as required by law. Information relating to your daily step count will be collected for analysis, along with any information you provide regarding the programme should you choose to participate in the optional focus group discussions. This information will be analysed to evaluate the feasibility of the walking programme as an intervention for people with stroke. All information will be retained in secure storage for 10 years, as required by the University's research policy, after which it will be destroyed.

**What about anonymity and confidentiality?**

Any information collected during this study will be forwarded to the primary investigator, Dr Lynne Clay. A unique participant code number will be assigned to you at the start and used on your study records instead of your name. The master list linking your name and number will be kept in a secure location and will be destroyed upon completion of the data collection period. Although we plan to publish the findings of this study and present at conferences, the data will be reported in group form, so that it will not be possible to identify individuals. The consent forms will be stored separately from the completed questionnaires so that it will not be possible to associate a name with any given set of responses. No information that discloses your identity will be released or published without your specific consent to the disclosure. A summary of the final results will be available to you on request.

**If you agree to participate, can you withdraw later?**

You may withdraw from participation in the study at any time and without any disadvantage to yourself. Please make the primary investigator, assessor or physiotherapist aware at the time if this is the case.

Your participation in this study is voluntary and no aspect of any ongoing care will be affected should you either decline or agree to participate. Should you wish to participate, you will be asked to provide written consent. Unfortunately, we are unable to reimburse you for any expenses you may incur during the period of your participation.

**Any questions?**

If you have any questions now or in the future, please feel free to contact the Principal Investigator:

|  |  |
| --- | --- |
| **Dr Lynne Clay,****Centre for Health, Activity and Rehabilitation Research, School of Physiotherapy**lynne.clay@otago.ac.nz  | Contact phone number:03 479 4979/ 0800 687489 |

*This study has been approved by the Health and Disability Ethics Committee (HDEC) Number ###. If you have any concerns about the ethical conduct of the research you may contact the Committee by phone on* 0800 4 38442 (0800 4 Ethic) or *email* *hdecs@moh.govt.nz* *. Any issues you raise will be treated in confidence and investigated and you will be informed of the outcome.*