

**Participant Information Sheet**

**Study title: Usability study of the AID (Adams Independent Dynamic) Foot Splint in stroke patients**

Locality: Burwood Hospital, CDHB (Canterbury District Health Board)

Lead investigator: Mark Adams; Contact phone number: 03 3836836

Ethics committee ref: 18\_STH\_12

You are invited to take part in a study on the usability of a new foot splint. 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 the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 6 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

## What is the purpose of the study?

Stroke can cause weakness on one side of the body. A stroke may cause weakness of the ankle muscles leading to a foot drop. A stroke may also result in the inability to use the arm affected by the stroke. Splints can be used to help with foot drop, although many are difficult to put on using one hand. This can lead to people not wearing their splints. Not wearing a splint after being recommended to do so by a physiotherapist, can place people at an increased risk of falls.

Participants will be timed putting on the new dynamic foot splint and then another popular foot splint, the Dictus splint. They will then be asked about their experience of putting each of these on. Following this, they will perform a short timed walking test with each splint and again asked about their experience using the splint to walk with.This study is being conducted by the innovator of the new splint, Mark Adams. He is also a Burwood Hospital physiotherapist. He can be contacted to answer questions at:

Mark Adams,

Canterbury District Health Board

Telephone Number: 03 383 6836

Email Address: mark.adams@cdhb.health.nz

The study is being funded by a grant from Via Innovations through the Canterbury District Health Board.

The study has been approved by the Health and Disability Ethics Committee of New Zealand

## What will my participation in the study involve?

You have been chosen to participate in this study because you are:

1. Aged 18 years or older.

2. Have suffered a stroke causing weakness on one side of the body.

3. Able to sit and reach down to your feet safely.

4. Have reduced function in one arm, so you need to get dressed using only one hand.

5. Able to walk 6 metres

6. Considered by the Principal Investigator and also by Ward Staff, to be able to answer the study questionnaires.

Should you agree to take part in the project, you will be asked to complete timed tests of you putting the splint on, and then walking with the splint on. You will also be asked to answer questions about your experience using the splint. All these requests fall outside usual clinical care.

The investigator estimates that taking part in the study will take up about half an hour of your time at the beginning of the study, to sign the consent form and learn how to use the foot splint. The study will take part during your usual physiotherapy clinic sessions or another time during the day.

We plan to collect information about the type and the location of your stroke from your health records. You will be assigned a project number so that your name will be removed from the results. Names of people, places or organisations will be removed from the questionnaires also.

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There will be no impact on your usual health care either by your refusal or agreement to participate in this study.

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

There is a very low risk of physical harm or discomfort from participation in this study. The new splint should not place you at any greater risk of falling than usual. Also, the environment will be set up by the researchers to keep you as safe as possible and you will be offered the assistance you need.

## Who pays for the study?

The study is being funded by a grant from Via Innovations through the Canterbury District Health Board.

## What if something goes wrong?

If you were injured in this study, which is unlikely, you would be eligible **to apply** for compensation from 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 are my rights?

Taking part in the study is voluntary (your choice). You are free to decline to participate, or to withdraw from the research at any practicable time, without experiencing any disadvantage.

You have the right to access the information collected about you, as part of the study.

Your study information will be stored on a password protected computer. The investigator plans to present the final study results to other physiotherapists and interested clinicians. When this happens, information from all participants will be grouped together so no-one will be able to identify you as an individual.

## What happens after the study or if I change my mind?

Data from the study will be stored for 10 years, within a password protected computer system.

The investigator plans to present the findings of the study to clinical colleagues and also plans to publish study findings. Study findings will also be sent to those participants who have indicated an interest in receiving this information. These study findings should be available within one year of you taking part in the study.

You are free to decline to participate, or to withdraw from the research at any practicable time, without experiencing any disadvantage.

## 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:

Mark Adams,

Canterbury District Health Board

Telephone Number: 03 383 6836

Email Address: mark.adams@cdhb.health.nz

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@hdc.org.nz

For Maori health support please contact :

Ranga Hauora Team at Burwood Hospital (03 383 6873).

If you are in the community, please contact He Waka Tapu (0800 HEWAKA or text 0272 HEWAKA).

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

 Phone: 0800 4 ETHICS

 Email: hdecs@moh.govt.nz



**Consent Form**

**Please tick to indicate you consent to the following**

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| --- | --- | --- |
| I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.  | □ |  |
| I have been given sufficient time to consider whether or not to participate in this study. | □ |  |
| I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study. | □ |  |
| I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet. | □ |  |
| I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care. | □ |  |
| I consent to the research staff collecting and processing my information, including information about my health. | □ |  |
| If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed. | Yes 🞏 | No 🞏 |
| I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study. | Yes 🞏 | No 🞏 |
| I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study. | □ |  |
| I understand the compensation provisions in case of injury during the study. | □ |  |
| I know who to contact if I have any questions about the study in general. | □ |  |
| I wish to receive a summary of the results from the study. | Yes 🞏 | No 🞏 |

**Declaration by participant:**

I hereby consent to take part in this study.

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| Participant’s name: |
| Signature: | Date: |

**Declaration by member of research team:**

I have given a verbal explanation of the research project to the participant, and have answered the participant’s questions about it.

I believe that the participant understands the study and has given informed consent to participate.

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| Researcher’s name: |
| Signature: | Date: |