**Usability study for the AID (Adams Independent Dynamic) Foot Splint in stroke patients.**

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# Background

Stroke patients can present with weakness on one side of their body. Commonly, their ankle muscles can be weak and they are unable to pick their foot up. This is a tripping hazard and a falls risk. Due to this weakness, they may need assistive devices to help them to walk.

The Dictus splint is a popular splint to use for this population as it allows the patient to use their available muscle strength during the activity. It consists of a leather strap around the ankle, which is attached to the person’s shoe by an elastic band and pins. The splint has small components that often fall off e.g. metal pins. The pins can also cause marking on the person’s foot if they have decreased sensation and this can lead to pressure sores or the person choosing not to use the splint due to pain. Additionally, the splints are difficult to put on, and patients may need carer assistance to get the splint on. Some patients discontinue use due to these difficulties, leading to an increased falls risk.

This research study will test a new dynamic foot splint (Adams Independent Dynamic foot splint or AID foot splint) that has been designed to be put on independently by patients who have weakness on one side of their body meaning they use one handed dressing strategies. The new splint will not have any loose pins and so should be more cost effective as it will not need regular replacement of parts.

# Research aims

1. To assess whether the AID Foot Splint can be put on independently, using one hand by stroke patients.
2. To compare the time taken to put the splint on between the AID Foot and Dictus splints.
3. To compare the AID Foot Splint with the dictus splint when the participant is walking (timed walk test).
4. To seek feedback from participants regarding the AID Foot Splint’s usability during dressing and walking and compare this to their feedback for the Dictus splint

# Methodology

## Research design

A usability study of the AID foot splint in participants following stroke. The participants will have a functional assessment and answer a brief questionnaire.

## Participants

Inclusion criteria:

1. Aged 18 years or older
2. Have suffered a stroke causing weakness on one side of the body
3. Have a functional level where they can dress their lower body without assistance e.g. able to sit and reach down to their feet.
4. Have reduced function in their affected arm meaning that they need to adopt one-handed dressing strategies.
5. Be able to walk 6 metres.
6. Able to answer the study questionnaires (English speaking, no aphasia, and no important cognitive issues).

Screening of the patients for these issues will be undertaken by the principal investigator by liaising with ward staff regarding the participant.

## Sample

Participants will be selected by communicating with CDHB stroke services at wards CG and DG at Burwood Hospital. Potential participants will be approached by a member of their treating rehabilitation team initially. If they are interested in participating in the research project, they will then be contacted by the research team.

# Testing procedure

Key tasks;

* + - * 1. Times to put the foot splint on – AID foot splint vs. Dictus splint. The order of testing of the splints will be randomly generated using online randomisation software (<https://www.random.org/>). These measurements will be followed by a short usability questionnaire.

Participants will sit on a supportive surface and then shown how to put on the splint using one hand. They will then have two practice trials with the splint and receive feedback from the assessor regarding their technique. After the two practice trials, they will put the splint on whilst being timed and, after a rest, take the splint off while being timed. *They will have help getting the shoe on/off if needed.*

Please see appendix 1 and 3 for full testing procedures

* 1. Walking with the foot splint – AID foot splint vs. Dictus splint. The order of testing will follow the same sequence as the time to put the splint on trial. Followed by short usability questionnaire.

The same walk test will be used for both splints. The participants can use their usual walking aid, if applicable, and receive assistance as needed to remain safe. The participant will have one practice walk of the test course followed by a rest. They will then participate in the timed trial.

Please see appendix 1 and 3 for full testing procedures

## Questionnaire

The study questionnaire (Appendix 3) will ask participants about their experience using the splints during two key tasks; (i) putting the splint on and taking it off, and (ii) walking with the splint.

The response (agree/ disagree ) of the participants to the questions will be graded using a likert scale ranging from strongly agree to strongly disagree.

## Data analysis

The timed tests for putting the splints on will be compared to assess whether there is a difference between the two splints and the average difference calculated.

For the timed walking tests, statistical significance will be tested in the first instance, with the clinical significance of any differences then being assessed objectively.

SPSS or other similar software will be used for data analysis.

The results of the questionnaires will be collated and feedback from the participants compared.

## Scientific rigour

The research protocol will be reviewed by a clinician-researcher with experience in the Neurological Physiotherapy field.

# Ethical considerations

## Ethics proposal

Ethical approval has been received by the Health and Disability Ethics Committee with assistance from the CDHB Research Office. The study has also been approved by Te Komiti Whakarite at the CDHB.

**Informed consent**

Informed consent will be obtained from all participants in the study. A participant information sheet will be provided and discussed, followed by signing of the consent form.

## Confidentiality

Participants’ participation in the study will be kept confidential and all data collected will be secured safely. The research team will know all the participants and will have access to all data. All the participants will be allocated a participant number to maintain anonymity. Only the research team will be aware of the number allocation to participants. All electronic data will be stored on a password protected computer. All hard copies of data/health information will be kept in a locked filing.

## Ethical concerns

### Respect for people

Respect for people, and for their rights, including autonomy, confidentiality and protection of people with impaired or diminished autonomy. Only people who are considered to have the capacity to participate in the study will be asked to take part so as not to impact vulnerable people.

### Justice

Justice requires that, within a population, there is a fair distribution of the benefits and burdens of participation in a study, and for any participant, a balance of burdens and benefits.

Accordingly, this study will:

a) have fair inclusion and exclusion criteria

b) not discriminate in the selection and recruitment of participants by including or excluding them on the grounds of ethnicity, age, sex, disability, or religious or spiritual beliefs, except when such exclusion or inclusion is essential to the purpose of the study.

### Beneficence and non-maleficence

This study is within the range of minimal risk as potential participants can reasonably be expected to regard the probability and magnitude of possible harms from participation in the study as no greater than those encountered in aspects of everyday life that relate to the study. The study does not include activities that are a departure from normal care for this group of participants.

All participants will receive information regarding the study aims and will be asked whether they wish to receive the study results on completion.

Confidentiality will be ensured for participant’s information through the use of anonymous participant paper questionnaires.

Information regarding support services will be included in the participant information sheet.

# Required resources

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| --- | --- | --- |
| **Expense** | **Cost** | **Source** |
| **Shoes x 10** | $120 | [www.thewarehouse.co.nz](http://www.thewarehouse.co.nz) |
| **AID Foot Splints x 4** | $260 | [www.twinneedle.co.nz](http://www.twinneedle.co.nz) |
| **Dictus Splints x 4** | $496 | [www.alliedmedical.co.nz](http://www.alliedmedical.co.nz) |
| **TOTAL** | $876 |  |

# Projected timeline for this study

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| --- | --- | --- |
| ***Event*** | *Planned start date* | *Planned finish date* |
| Submit for ethical approval | Jan 2018 | Jan 2018 |
| Set up database  Set up back-up system for data | Jan 2018 | Jan 2018 |
| Undertake study | Jan 2018 | July 2018 |
| Enter and analyse results | July 2018 | August 2018 |
| Write up study | August 2018 | Sept 2018 |
| Complete study |  | Oct 2018 |