# Biomechanics visualisation in ankle-foot orthoses (AFO) tuning for stroke

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
26/05/2011		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
28/06/2011 Last Edited	Completed  Condition category	Results		
		Individual participant data		
17/12/2020	Circulatory System	[] Record updated in last year		

#### Plain English summary of protocol

Background and study aims

A stroke is a serious condition where the blood supply to a part of the brain is cut off, usually by a blood clot blocking an artery or a bleed (haemorrhage). One of the most common complications of a stroke is paralysis on one side of the body (hemiplegia). This can make movements such as walking very difficult and so patients often need extensive physiotherapy to help them recover. An ankle-foot orthosis (AFO) is a brace that is worn on the lower leg and foot. It helps to support the ankle and foot in the correct position, preventing the foot from dragging along the ground. The "tuning" of an AFO describes personalised adjustment so that it helps a person to achieve the best gait (manner of walking) possible. Improving the tuning process of AFO's could help to improve patient outcomes such as walking speed and posture. Traditionally, tuning of AFO's is done "by eye" (observation technique), however computers could potentially be used to perfect this process. The aim of this study is to find the most effective way of tuning AFO's for stroke patients.

#### Who can participate?

Adults who have had a stroke and have been suffering from hemiplegia within the past year.

#### What does the study involve?

Participants are randomly allocated into one of two groups which are looked after by a team made up of a physiotherapist, an orthotist (who is responsible for providing the orthosis) and a bioengineer (who will collect data throughout the study). Participants in the first group (intervention group) are shown computerised visualisations in order to help to demonstrate their gait problems and their AFO's are tuned in line with the visualisations. Participants in the second group (control group) are not shown any visualisations, and their AFO's are tuned by the team using the traditional observation technique. After 3 and 6 months, all participants have their gait measured using 3D motion analysis software (showing a persons' movement on a computer in 3D using reflective spots). For participants in the first group, their progress is discussed with their care team using the information from the gait measurements.

What are the possible benefits and risks of participating?

Participants could potentially benefit from an improvement in their gait and the distance they can walk after wearing the AFO. Risks of participating are minor but may include skin irritation

from the reflective spots stuck to the skin for the 3D motion analysis. Another possible risk includes the possibility of falling during the walking practice.

Where is the study run from? University of Strathclyde (UK)

When is the study starting and how long is it expected to run for? August 2011 to August 2013

Who is funding the study? Medical Research Council (UK)

Who is the main contact? Dr Bruce Carse bruce.carse@strath.ac.uk

#### Study website

http://www.envisagerehab.co.uk

#### Contact information

#### Type(s)

Scientific

#### Contact name

Dr Bruce Carse

#### Contact details

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### Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers** GN10OR216

# Study information

#### Scientific Title

Visualisation to enhance biomechanical tuning of ankle-foot orthoses (AFO) in stroke - a randomised controlled trial

#### **Study objectives**

Can visualisation of biomechanical data improve the tuning of ankle-foot orthoses (AFOs) for stroke patients?

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

NHS West of Scotland Research Ethics Committee 4, 01/04/2011, ref: 11/AL/0166

#### Study design

Single-centre single-blind randomised controlled trial

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Hospital

#### Study type(s)

Treatment

#### Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

#### Health condition(s) or problem(s) studied

Stroke

#### **Interventions**

- 1. Patients will be randomised (in blocks of six) to either the intervention or control arm of the study
- 2. Each arm will have its own multidisciplinary team (MDT)
- 3. Each of these MDTs will consist of a physiotherapist, orthotist and bioengineer
- 4. The relevant orthotist will then cast and fit an AFO to to the patient prior to baseline measures being taken
- 5. Baseline measures: All patients to have baseline gait measurements taken using 3D motion analysis
- 6. Intervention arm: AFO tuning aided by 3D motion analysis and biomechanics visualisation software
- 7. Control arm: AFO tuning by observation (standard care)
- 8. Three month measures: all patients to have baseline gait measurements taken using 3D motion analysis

- 9. Six month measures: all patients to have baseline gait measurements taken using 3D motion analysis
- 10. Duration from baseline measures will be 6 months

#### Intervention Type

Device

#### Primary outcome measure

- 1. Walking velocity
- 2. Time taken to complete 10m walk test

#### Secondary outcome measures

- 1. Lower limb joint kinematics (thigh and shank global orientations) & kinetics (knee and hip flexion/extension moments
- 2. Ground reaction force Fz2 peak magnitude
- 3. Step length
- 4. Gait symmetry
- 5. Modified Ashworth Scale
- 6. Abbreviated Rivermead Mobility Index
- 7. EuroQol (EQ-5D)

#### Overall study start date

30/08/2011

#### Completion date

28/08/2013

# Eligibility

#### Key inclusion criteria

- 1. In patients who have suffered a recent hemiplegia (within 1 12 months)
- 2. Aged 16 80 years
- 3. Have difficulty walking, but able to walk with/without assistance
- 4. Have difficulty flexing knee and extending hip during walking
- 5. Meet the criteria for AFO referral as outlined in AFO screening tool (Appendix 9 of NHS Scotland Best Practice Statement 'Use of AFO follwoing stroke')
- 6. Able to give informed consent
- 7. Able to attend for follow-up at 3 and 6 months

#### Participant type(s)

**Patient** 

#### Age group

Adult

#### Sex

Both

#### Target number of participants

70

#### Key exclusion criteria

- 1. Unable to give informed consent
- 2. Unable to walk, even when assisted
- 3. Suffer from significant peripheral vascular disease not suitable for fitting of AFO
- 4. Have any other significant medical problems likely to preclude use of AFO or follow-up

#### Date of first enrolment

30/08/2011

#### Date of final enrolment

28/08/2013

#### Locations

#### Countries of recruitment

Scotland

United Kingdom

# Study participating centre University of Strathclyde

Glasgow United Kingdom G4 0NW

# Sponsor information

#### Organisation

University of Strathclyde (UK)

#### Sponsor details

c/o Ms Louise McKean (Contracts Manager) Research & Knowledge Exchange Services 50 George Street Glasgow Scotland United Kingdom G1 1QE

#### Sponsor type

University/education

#### Website

http://www.strath.ac.uk/

#### **ROR**

https://ror.org/00n3w3b69

# Funder(s)

#### Funder type

Research council

#### **Funder Name**

Medical Research Council

#### Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

#### **Funding Body Type**

Government organisation

#### **Funding Body Subtype**

National government

#### Location

**United Kingdom** 

## **Results and Publications**

#### Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not provided at time of registration

#### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	05/12/2011		Yes	No