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

Submission date
26/05/2011

Recruitment status
No longer recruiting

Registration date
28/06/2011

Overall study status
Completed

Last Edited
17/12/2020

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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
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Study website
http://www.envisagerehab.co.uk

Contact information

Type(s)
Scientific

Contact name
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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 anaylsis 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
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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