

Orthoses for people with stroke (AFOOT)

Submission date 08/12/2014	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 06/05/2015	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 21/12/2015	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Stroke is a serious, life-threatening medical condition that usually happens when a blood clot or haemorrhage cuts off the blood supply to an area of the brain. Symptoms vary according to how much of the brain is affected and where in the brain the stroke occurs, but includes paralysis, muscle weakness and speech difficulties. For most patients a stroke causes a weakness down one side of the body which often makes it difficult to walk. One way to manage this is to use a splint, called an ankle-foot orthosis or AFO, which supports the foot and ankle so the toes don't catch when stepping forwards. Although research shows that an AFO can improve walking there is none comparing different types of AFO to tell us which is the best to use. We want to compare two commonly used types of AFO; a custom made, and an 'off-the-shelf' one. We want to find out:

1. Whether the AFOs work, what effects they have and how big the effects are .
2. Which type of patient the AFOs work for.
3. Whether they cause side effects and how serious the side effects are.
4. Information about recruitment, adherence and completion rates.

Who can participate?

Adults who have had a stroke, able to walk 5m with or without a walking aid and fulfil the criteria to be referred to an orthotics service.

What does the study involve?

Participants are randomly allocated into one of three different groups. Those in group 1 are given standard care. Those in group 2 are given an off-the-shelf AFO. Those in group 3 are given a custom made AFO. Each participant is followed-up to measure the effects of the AFO six weeks and three months after they have been referred to their local orthotics service. Patient satisfaction with their AFO, how much they use it, how mobile wearing it makes them, how it affects the way in which they walk (walking pattern) and any side effects (such as pain or falls) are all assessed.

What are the possible benefits and risks of participating?

Not provided at time of registration.

Where is the study run from?

Stroke & Vascular Research Centre, University of Manchester (UK)

When is the study starting and how long is it expected to run for?
January 2012 to June 2015

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Professor Sarah Tyson
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Contact information

Type(s)

Public

Contact name

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Additional identifiers

Protocol serial number

59338/GM

Study information

Scientific Title

Which is the better ankle foot orthosis for people with stroke?

Acronym

AFOOT

Study objectives

Using the model in the MRC Framework for Developing and Evaluating Complex Interventions, patients' satisfaction with the two most commonly prescribed types of AFO; bespoke and off-the-shelf will be evaluated, to:

1. Establish the feasibility of the off-the-shelf AFO for people with stroke
2. Compare the acceptability and clinical effectiveness of bespoke and off-the-shelf AFOs
3. Identify the patient groups for whom each AFO is effective
4. Identify the outcomes affected by the AFOs and the effect sizes
5. Obtain information about recruitment, adherence and completion rates to inform a definitive Phase III trial.

Ethics approval required

Old ethics approval format

Ethics approval(s)

North West 12 Research Ethics Committee - Lancaster, 19/07/2011, ref: 11/NW/0352

Primary study design

Interventional

Study design

UK multicentre RCT feasibility Ttrial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Stroke

Interventions

Two types of ankle foot orthosis (AFO) prescribed to correct foot drop. Participants are randomised to either an off-the-shelf, commonly used medium priced Leaf Spring AFO; or a custom made AFO, where the design is decided by the clinical orthotist. Both AFO are offered as standard care.

Intervention Type

Device

Primary outcome(s)

Patient Satisfaction Questionnaire

Measured at week 6 and 12.

Key secondary outcome(s)

1. Walking speed and gait analysis, measured by the GAITRite automated walkway & manual counts of speed and step count over 5m (measured at baseline, 6 weeks and 12 weeks)
2. Modified Functional Walking Categories (MFWC) (measured at baseline, 6 weeks and 12 weeks)
3. Falls Efficacy Scale - International (FES-I) (measured at baseline, 6 weeks and 12 weeks)

Completion date

30/06/2015

Eligibility

Key inclusion criteria

1. Have a diagnosis of stroke
2. Be living at home or residential care (or in hospital with discharge plans confirmed)
3. Satisfy the referral criteria to their local Orthotics Service
4. Have impaired dorsiflexion – which limits heel strike (the heel hits the ground first when taking a step forwards)
5. Have no contractures at the ankle (sufficient range of movement at the affected ankle for the heel to be in contact with the floor while standing)
6. Be able to walk 5m (approx across a typical living room), without the assistance of another person but maybe with the assistance of a walking aid
7. Be able to consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Any co-morbidities of sufficient severity to limit mobility
2. Any condition which precludes them from wearing an AFO (e.g., severely oedematous ankles /feet; severe skin conditions/abrasions; inability to wear footwear)

Date of first enrolment

01/07/2012

Date of final enrolment

30/09/2014

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Stroke & Vascular Research Centre
School of Nursing, Midwifery & Social Work
Jean McFarlane Building
University of Manchester
Oxford Road
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Sponsor information

Organisation

University of Manchester

ROR

<https://ror.org/027m9bs27>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	18/12/2015		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes