

# Orthoses for people with stroke (AFOOT)

<b>Submission date</b> 08/12/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/05/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/12/2015	<b>Condition category</b> Circulatory System	<input type="checkbox"/> 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 a 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 a 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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**Study website**  
[www.strokeresearch.org.uk](http://www.strokeresearch.org.uk)

## Contact information

**Type(s)**  
Public

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

**Study design**

UK multicentre RCT feasibility Ttrial

**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 below to request a participant information sheet

**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 measure**

Patient Satisfaction Questionnaire

Measured at week 6 and 12.

**Secondary outcome measures**

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)

**Overall study start date**

01/01/2012

**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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

166

**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**

England

United Kingdom

**Study participating centre****Stroke & Vascular Research Centre**

School of Nursing, Midwifery & Social Work

Jean McFarlane Building

University of Manchester

Oxford Road

Manchester

United Kingdom

M13 9PL

## **Sponsor information**

**Organisation**

University of Manchester

**Sponsor details**

Oxford Road

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44 (0) 161 275 7583

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**Sponsor type**

University/education

**ROR**

## 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

### Publication and dissemination plan

1. Data Analysis to be completed January 2015
2. Report and publications depending on the results

### Intention to publish date

30/06/2015

### 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?
<a href="#">Results article</a>	results	18/12/2015		Yes	No