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# Orthoses for people with stroke (AFOOT)

**Submission date**
08/12/2014

**Recruitment status**
No longer recruiting

**Registration date**
06/05/2015

**Overall study status**
Completed

**Last Edited**
21/12/2015

**Condition category**
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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 of 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

# Contact information

### Type(s)
Public

### Contact name
Dr Sarah Tyson

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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-morbities 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
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## Sponsor information

### Organisation
University of Manchester

### Sponsor details
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### Sponsor type
University/education

### 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

**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? |
|---|---|---|---|---|---|
| Results article | results | 18/12/2015 | | Yes | No |