

# STEPFORWARD: Patient acceptability of a novel prosthetic device

<b>Submission date</b> 16/04/2018	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 19/04/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/04/2023	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Annually, 6,000 people in the UK are referred for fitting of an artificial lower leg (known as a prosthesis) after the surgical removal of their limb (lower-limb amputation). These are mostly patients over 50 years and usually have diabetes and/or blood vessel (vascular) problems. Older patients are often prescribed standard foot-ankle prostheses which are rigid at the “ankle”, unlike those often given to younger people which can adjust to slopes and stairs. It is unknown which is the best prosthesis for older patients. The aim of this study is to see whether it is possible to do a large study comparing the standard foot-ankle prosthesis to a new version, by first carrying out a smaller study.

### Who can participate?

Patients aged over 50 with a below-knee amputation because of vascular problems and who find walking difficult

### What does the study involve?

Participants are randomly allocated into one of two groups to wear either their existing prosthesis or a new prosthesis for 12 weeks. One-to-one interviews are held to ask patients how they felt about participating in the study. The researchers measure how far patients can walk, how long they wear their prosthesis daily, and ask them to score their pain, health and well-being. This is done with questionnaires, simple exercise tests and a wearable device which measures activity.

### What are the possible benefits and risks of participating?

Participants may not directly benefit from this study but taking part could help build up the evidence about how beneficial the new prosthesis is compared to standard prostheses. No risks are expected, but participants in the new prosthesis group may find that it can take them some time to adjust to the new prosthetic, therefore they could slip or stumble as they adjust to it.

### Where is the study run from?

1. Hull & East Yorkshire NHS Trust (UK)
2. Nottingham University Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?  
April 2018 to March 2020

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

Who is the main contact?  
Dr Natasha Mitchell

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Natasha Mitchell

**Contact details**  
York Trials Unit  
Lower Ground Floor  
ARRC Building  
Department of Health Sciences  
University of York  
Heslington  
York  
United Kingdom  
YO10 5DD

## Additional identifiers

**Protocol serial number**  
37815

## Study information

**Scientific Title**  
STEPFORWARD: Patient acceptability of a novel prosthetic device: a randomised feasibility study in older patients with vascular-related amputations and multimorbidities

**Acronym**  
STEPFORWARD

**Study objectives**  
To assess the feasibility of conducting a future, full scale randomised controlled trial into the effectiveness and cost-effectiveness of a novel prosthesis for older patients with vascular-related amputations and other health issues compared to a standard prosthesis.

**Ethics approval required**  
Old ethics approval format

## **Ethics approval(s)**

Yorkshire & the Humber - Leeds West, 09/03/2018, ref: 18/YH/0089

## **Study design**

Randomised; Both; Design type: Treatment, Process of Care, Device, Rehabilitation, Qualitative

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

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

Disorder of arteries and arterioles, unspecified

## **Interventions**

Multi-centre, randomised controlled, open feasibility study, using a 1:1 randomisation ratio, patients will be block randomised, stratified by prosthetics centre.

The study will look at the randomisation process, recruitment and whether patients found the study processes acceptable. Over two years, the trialists want to recruit 90 older people with a below-knee amputation because of vascular problems and who find walking difficult. They will invite patients from three prosthetics centres across England to participate and they will be placed randomly into one of two groups by a computer: wearing 1) their existing prosthesis or 2) a new prosthesis for 12 weeks. There will be one-to-one interviews to ask how patients felt about participating in the study. The trialists will measure how far patients can walk, how long they wear their prosthesis daily, and ask them to score their pain, health and well-being. They will do this with questionnaires, simple exercise tests and a wearable device which measures activity.

## **Intervention Type**

Other

## **Primary outcome(s)**

The feasibility of conducting a future, full scale RCT into the effectiveness and cost-effectiveness of a novel prosthesis for older patients with vascular-related amputations and other health issues compared to a standard rigid prosthesis. This will be assessed based on whether:

1. Study consent/retention rates and proposed sample sizes indicate recruitment for the full-scale RCT is plausible within a 24-month period
2. Outcome measures and fidelity evaluation data are successfully collected
3. There are no significant barriers to delivery of the trial identified by participants or recruiting centres

## **Key secondary outcome(s)**

1. Patient recruitment rate
2. Barriers to recruitment, how these might be overcome from the perspective of patients, and the most important outcomes to them
3. The acceptability of the study procedures to both participants and recruiting centres
4. Patient use of NHS resources over the study period related to the research
5. Identify a primary outcome measure(s) for a future main trial (if feasibility is established)

6. The completeness of follow-up to establish how feasible it is to collect patient-reported outcome measures including data related to patient function, health status, adverse events and use of the NHS
7. Day-to-day use of the prosthesis in both groups and measure normal physical activity through the use of wearable technologies (activity monitors)

**Completion date**

31/03/2020

## Eligibility

**Key inclusion criteria**

Current inclusion criteria as of 10/05/2018:

1. Aged over 50 years
2. Has a unilateral amputation
3. Has a below-knee amputation only
4. Has an amputation due to vascular reasons (diabetes, peripheral vascular disease), neurological disorders (i.e. diabetic neuropathy) or life-limiting illness (i.e. tumour, cancer)
5. Is categorised as 'limited mobility' (K2 classification or SIGAM mobility grade C or D)
6. Is currently using a standard prosthetic foot-ankle (e.g. SACH, uniaxial, multiflex or other K1 /K2 feet) that does not adjust to sloped surfaces and is not self-aligning
7. Has been using a prosthesis for at least 12 months, with the same socket for a minimum of 3 months
8. Has had a stable residual limb for at least 3 months (i.e. stable in volume and without cuts or wounds; daily management of volume with socks and liners is acceptable)
9. Is willing to trial a new prosthesis for a 12-week period (if allocated to intervention arm)
10. Is able to self-complete the English language outcome measure tools (or complete with assistance)
11. Is able to follow the detailed verbal instructions required for the functional/clinical tests
12. Is able to provide written informed consent

Previous inclusion criteria:

1. Aged over 50 years
2. Has a unilateral amputation
3. Has a below knee amputation only
4. Has an amputation due to vascular reasons (diabetes, peripheral vascular disease), neurological disorders (i.e., diabetic neuropathy) or life-limiting illness (i.e. tumour, cancer)
5. Is categorised as 'limited mobility' (K2 classification or SIGAM mobility grade C or D)
6. Is currently using a standard prosthetic foot-ankle (e.g., SACH, uniaxial, multiflex or other K1 /K2 feet) that does not adjust to sloped surfaces and is not self-aligning
7. Has been using a prosthesis for at least 12 months
8. Has had a stable residual limb for at least 3 months (i.e. stable in volume and without cuts or wounds)
9. Is willing to trial a new prosthesis for a 12-week period (if allocated to intervention arm)
10. Is able to self-complete the English language outcome measure tools (or complete with assistance)
11. Is able to follow the detailed verbal instructions required for the functional/clinical tests
12. Is willing to have their GP informed of their involvement in the study
13. Is able to provide written informed consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

55

**Key exclusion criteria**

A patient will be excluded for the following reasons:

1. Has contraindications of wearing their current prosthesis (e.g., open wound, infection)
2. Has contraindications of wearing the novel prosthesis according to manufacturer's instructions (i.e., a long residual limb - intact side measurement from mid patella tendon to ground minus the socket measurement from mid patella tendon to distal end of socket female-pyramid-adaptor should be at least 115mm)
3. Has had a recent cerebrovascular event, such as a stroke
4. Has a disease that severely affects their memory, such as dementia or Alzheimer's

**Date of first enrolment**

01/05/2018

**Date of final enrolment**

31/08/2019

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

Hull & East Yorkshire NHS Trust

United Kingdom

HU16 5JQ

**Study participating centre**

**Nottingham University Hospitals NHS Trust**  
United Kingdom  
NG5 1PJ

**Study participating centre**  
**Lancashire Teaching Hospitals NHS Foundation Trust**  
United Kingdom  
PR2 9HT

## Sponsor information

**Organisation**  
Hull & East Yorkshire NHS Trust

**ROR**  
<https://ror.org/01b11x021>

## Funder(s)

**Funder type**  
Government

**Funder Name**  
NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-0816-20029

## Results and Publications

### Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

### IPD sharing plan summary

Data sharing statement to be made available at a later date

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		18/03/2021	22/03/2021	Yes	No
<a href="#">Protocol article</a>	protocol	20/09/2019	06/01/2021	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No

[Other publications](#)

Qualitative experience	23/04/2023	24/04/2023	Yes	No
------------------------	------------	------------	-----	----