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STEPFORWARD: A comparison between usual care “rigid” prosthetic feet and hydraulic “flexible” feet for quality of life in patients with a below-knee amputation who have limited mobility

Submission date
20/01/2026

Recruitment status
Recruiting

Registration date
16/03/2026

Overall study status
Ongoing

Last Edited
10/08/2026

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Every year in the UK, more than 2,000 people have a lower-leg (below-knee) amputation, most often because of diabetes or problems with blood flow. Many of these people are over 50 and find walking difficult, especially outdoors or on uneven ground. Everyday activities such as walking on slopes, using stairs, or moving over uneven pavements can feel unsafe or uncomfortable.
Most people with these difficulties are given a standard NHS prosthetic foot. This type of foot is quite stiff and does not adjust to different surfaces, which can increase the risk of trips and falls and may reduce comfort and confidence when walking. There are newer prosthetic feet that can adapt to the ground, but at the moment there is not enough clear evidence to show whether they really improve people’s lives or are good value for the NHS. Because of this, they are not often offered.
This study aims to find out whether a newer, flexible prosthetic foot can make everyday life easier and safer. This foot uses a hydraulic system that allows it to automatically adjust when walking on slopes, stairs, or uneven ground. The researchers want to understand whether this type of foot improves comfort, confidence, quality of life, and safety compared with the standard rigid foot.

Who can participate?
About 266 adults with a below-knee amputation and limited mobility will take part.

What does the study involve?
The study will be carried out in around 12 NHS prosthetic centres across the UK. Everyone who joins will already be using a prosthesis. Participants will be randomly assigned (like flipping a coin) to use either the flexible hydraulic foot or the usual rigid foot.
Participants will take part in the study for 12 months. During this time, they will be asked to

complete questionnaires about their quality of life, comfort, confidence, and mental wellbeing. Walking ability, activity levels, and any trips or falls will also be recorded. Some participants will wear a small activity monitor to measure how much they walk. The study will also look at whether the new foot offers good value for money for the NHS.
A smaller number of participants, as well as prosthetic staff, will be invited to take part in interviews. These interviews will help the researchers understand people's real-life experiences of using the new foot and how practical it is in everyday care.
The results of this study will help decide whether flexible, self-adjusting prosthetic feet should be offered more widely to people with limited mobility after a below-knee amputation, with the aim of improving comfort, safety, and quality of life.

What are the possible benefits and risks of participating?
If you are in the flexible foot group, you may find that your comfort or movement improves. However, this cannot be guaranteed, and you may not benefit directly from taking part. The information we collect from this study may help improve care for other people with a below-knee amputation and limited mobility in the future.
There are no extra risks or disadvantages from taking part in this study. Your usual care will not change, and no treatment will be stopped or withheld. You will continue to receive routine care for your socket and prosthesis.
If you are in the flexible foot group, you may experience some temporary discomfort when changing to the new prosthetic foot. This should be similar to the normal adjustment period when changing to any new prosthesis.
During the study, we will ask you to complete six short questionnaires. Some questions may feel upsetting or uncomfortable. You do not have to answer any questions you do not want to, and a member of the research team will be available to support you if needed.

Where is the study run from?
Hull University Teaching Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
August 2026 to December 2029

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

Who is the main contact?
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Contact information

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Public

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Additional identifiers

Integrated Research Application System (IRAS)
346857

Central Portfolio Management System (CPMS)
64481

National Institute for Health and Care Research (NIHR)
169127

Study information

Scientific Title
STEPFORWARD: A randomised controlled trial and economic evaluation of the impact of a hydraulic self-aligning ankle-foot on quality of life for patients with a below-knee amputation who have limited mobility

Acronym
STEPFORWARD

Study objectives
Primary
1. To conduct a randomised controlled trial to estimate difference between groups in health-related QOL at 12 months
Secondary
1. To evaluate the cost-effectiveness of a flexible vs. rigid foot
2. To estimate difference between groups in a range of secondary outcome measures, including use of prosthesis, mental wellbeing, functional mobility and falls at 12 months
3. To conduct a qualitative interview study as part of an internal pilot and process evaluation to assess acceptability of trial processes and intervention to patients and staff
4. To develop an intervention implementation strategy

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 21/04/2026, West of Scotland REC 4 (Research Ethics – Room 29, 2nd Floor, Administration Building, Gartnavel Royal Hospital, 1055 Great Western Road, Glasgow, G12 0XH, United Kingdom; +44 0141 314 4485/0213; ggc.wosrec4@nhs.scot), ref: 26/WS/0035

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Device feasibility

Study type(s)

Health condition(s) or problem(s) studied
Patients with a below-knee amputation categorised as having limited mobility

Interventions
People taking part in this study will be randomly assigned by the research team, using a secure computer system, to one of two groups. One group will continue using their usual rigid prosthetic foot, and the other group will receive a flexible prosthetic foot. Each participant has an equal chance of being placed in either group. The research team will not know which group a participant is in until they have completed the initial assessments and eligibility checks.
Because the type of prosthetic foot is visible, neither participants nor clinicians can be blinded to

the group assignment. However, the researchers who analyse the study results will not know which group participants were in.
Before group allocation, all participants will attend a baseline clinic visit. At this visit, they will complete questionnaires about their health, wellbeing, comfort, and mobility, carry out simple walking tests, and have basic measurements taken (such as height, weight, and blood pressure). Participants will also wear a small activity monitor for seven days to measure their daily steps while using their usual prosthetic foot.
After this monitoring period, participants will be informed of their group assignment. Those allocated to receive the flexible foot will attend an additional clinic visit about two to three weeks later. At this visit, a prosthetist will fit the new foot at no cost, and a physiotherapist will provide guidance to ensure the foot is used safely and comfortably. Participants can return to their usual foot at any time if they wish.
All participants, regardless of group, will then take part in the same follow-up assessments. These will mostly be completed remotely at 3, 6, and 9 months and will include questionnaires and wearing an activity monitor for seven days. A final clinic visit will take place at 12 months, including walking tests, questionnaires, and physical measurements.
Participants will receive payment for attending clinic visits and for completing questionnaires, as well as reimbursement for travel costs when needed.

Intervention Type
Device

Phase
Phase III

Drug/device/biological/vaccine name(s)
Hydraulic ankle prosthesis

Primary outcome(s)
1. Health related Quality of Life measured using EQ5D-5L-VAS at 12 months

Key secondary outcome(s)
1. Cost-effectiveness of a flexible vs. rigid foot measured using Health resource use through HRUQ questionnaires at 12 and 42 months

2. Socket comfort score and self-reported falls measured using questionnaire at baseline, 3, 6, 9 and 12 months

3. Self-reported use of prosthesis measured using Locomotor Capabilities Index-5 at baseline, 3, 6, 9 and 12 months

4. Self-reported mental wellbeing measured using Warwick-Edinburgh Mental Well-being Scale at baseline, 3, 6, 9 and 12 months

5. Self-reported prosthetic foot preference, walking activity importance and frequency measured using Prosthetic Foot Preference Rating Scales at baseline, 3, 6, 9 and 12 months

6. Participant demographics; self-reported use of health services, medications, aids and accessories, and work and leisure activities measured using Bespoke health resource use questionnaire (for health economics evaluation) at baseline, 3, 6, 9 and 12 months

7. Acceptability of trial processes and intervention to patients and staff measured using Focus group and interview synthesis and analysis at 12 months

Completion date
31/12/2029

Eligibility

Key inclusion criteria
1. Adults aged 18 years and over.
2. Have a major unilateral below-knee amputation, of any aetiology.
3. Are prosthesis users categorised as having limited mobility in the community.
4. Have an MFCL K2-level classification.
5. Have a SIGAM mobility grade of C (can walk on level ground only, less than or up to 50 metres, with or without walking aids) or D (can walk outdoors on level ground only and in good weather, more than 50 metres, with or without walking aids).
6. Are using a usual care rigid, non-hydraulic, non-self-aligning prosthetic foot (for example: solid ankle cushioned heel, uniaxial, multiaxial, or multiflex).
7. Have completed initial prosthetic rehabilitation.
8. Have an appropriately fitting socket and/or a socket comfort score (SCS) of 7 or higher.
9. Are deemed suitable to use a flexible foot based on multidisciplinary team (MDT) clinical decision-making.
10. Are willing to trial the hydraulic self-aligning flexible foot if randomised to the intervention group.

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
99 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Have a contraindication to wearing their current prosthesis (e.g., open wound, infection on residual limb)**
2. Have a contraindication to the intervention flexible hydraulic self-aligning foot (this relates to body mass > 100 kg, long residual limb)
3. Have a clinical diagnosis of disease affecting memory or score ≤3 on the Abbreviated Mental Test indicating severe cognitive impairment

** If a patient is undergoing initial prosthetic rehabilitation or has an inappropriately fitting socket or contraindication to wearing their prosthesis, they can be reconsidered for inclusion once they satisfy the eligibility criteria (i.e., they complete initial prosthetic rehabilitation, or have their socket modified/remanufactured to fit correctly and/or have no contraindication, respectively).

Date of first enrolment
01/09/2026

Date of final enrolment
30/06/2028

Locations

Countries of recruitment
United Kingdom

England

Scotland

Study participating centre
Hull University Teaching Hospitals NHS Trust
Hull Royal Infirmary
Anlaby Road
Hull
England
HU3 2JZ

Study participating centre
Portsmouth Hospitals University NHS Trust
Queen Alexandra Hospital
Southwick Hill Road
Cosham
Portsmouth
England
PO6 3LY

Study participating centre
Royal National Orthopaedic Hospital NHS Trust
Brockley Hill
Stanmore
England
HA7 4LP

Study participating centre
Livewell Southwest Prosthetic Service
The Thornberry Centre
1 Brest Way
Plmouth
England
PL6 5XW

Study participating centre
The Queen Elizabeth University Hospital Glasgow
1345 Govan Road
Glasgow
Scotland
G51 4TF

Study participating centre
Birmingham Community Healthcare NHS Foundation Trust
3 Priestley Wharf
Holt Street
Birmingham Science Park, Aston
Birmingham
England
B7 4BN

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Cambridge Biomedical Campus
Hills Road
Cambridge
England
CB2 0QQ

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
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Herries Road
Sheffield
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S5 7AU

Study participating centre
Nottingham University Hospitals NHS Trust - Queen's Medical Centre Campus
Nottingham University Hospital
Derby Road
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NG7 2UH

Study participating centre
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Pillars Building
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Infirmary Street
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Wirral University Teaching Hospital NHS Foundation Trust
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Arrowe Park Road
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North London NHS Foundation Trust
4th Floor, East Wing
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4 St. Pancras Way
London
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NW1 0PE

Sponsor information

Organisation
Hull University Teaching Hospitals NHS Trust

Funder(s)

Funder type

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

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
Not expected to be made available