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A study to find out whether a remouldable prosthetic socket is acceptable and practical for people who have had a below-knee amputation and are being fitted with their first prosthesis

Submission date
17/11/2026

Recruitment status
Not yet recruiting

Registration date
26/11/2026

Overall study status
Ongoing

Last Edited
26/11/2026

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
When someone has a below-knee amputation, they may be offered an artificial leg (prosthesis) to help them stand, walk and move around. The prosthesis is attached to the remaining part of the leg (called the residual limb) using a specially made socket. At the moment, most sockets are made using a plaster cast of the residual limb. The socket is then manufactured, which can take around 3-4 weeks. During the first year after an amputation, the shape and size of the residual limb can change as swelling reduces and muscles change. This can mean that several new sockets are needed, causing further delays and hospital appointments.
The ASSIST study will look at a new type of socket called a remouldable socket. This socket can be heated and reshaped to fit changes in the size and shape of the residual limb, rather than making a completely new socket each time.
The study aims to find out whether it is possible and acceptable to carry out a larger research study to compare the remouldable sockets with the usual NHS sockets.
In particular, this study will look at:
1. Whether people are willing to take part in the study and be randomly allocated to one of two types of socket;
2. Whether the remouldable socket is acceptable to people using it;
3. Whether the study procedures and assessments work well;
4. Whether it is possible to collect information about quality of life, comfort, mobility, adjustment to the prosthesis and healthcare costs;
5. How patients and healthcare professionals feel about the study and how it could be improved.
The findings will help researchers decide if a larger study should be carried out to find out whether remouldable sockets offer benefits to patients and value for money for the NHS.

Who can participate?
Patients aged 18 years or older who have had a below-knee amputation, are waiting to receive

their first prosthesis, are expected to be able to walk using a prosthesis, and are receiving physiotherapy at one of the participating prosthetics centres or its associated community rehabilitation service.

What does the study involve?
Participants are expected to be involved in the study for approximately 5 months. They will be randomly allocated to one of two groups, with an equal chance of being allocated to either group:
1. Remouldable socket group: participants will receive a remouldable socket. This socket can be heated and reshaped as the size and shape of residual limb changes.
2. Usual care group: participants will receive the standard NHS socket, which is made using the usual plaster-casting and manufacturing process.
All participants will continue to receive usual physiotherapy and rehabilitation throughout their participation in the study regardless of group allocation.
There will be four main study visits, which will take place during usual routine appointments:
1. First appointment – before the socket is made: The study team will check the participant is eligible to take part, ask them to answer some questions about their quality of life, and collect information about their health and mobility.
2. Second appointment – when the socket is cast: The residual limb will be measured and cast for the allocated type of socket and the participant will be asked some questions about their quality of life.
3. Third appointment – 2 months after socket casting: Participants will be asked to complete some questionnaires and take part in a simple mobility test.
4. Fourth appointment – 4 months after socket casting: Participants will repeat the questionnaires and mobility test, and will also be asked to rate any changes in their quality of life, socket comfort, ease of movement using the prosthesis and adjustment to using the prosthesis, during study participation.
The questionnaires will ask about:
1. General health and quality of life
2. How comfortable the socket is
3. How easy it is to move around using the prosthesis
4. Feelings about adjusting to life with the prosthesis
5. Any healthcare appointments or services used
Some participants will also be invited to take part in an interview to talk about their experiences of the study and, where relevant, using the remouldable socket. Taking part in an interview is optional.

What are the possible benefits and risks of participating?
Taking part in the study may provide some potential benefits, although these cannot be guaranteed. Possible benefits for participants allocated to the remouldable socket group include receiving their prosthesis more quickly; having a socket that can be adjusted as the shape and size of the residual limb changes; potentially needing fewer replacement sockets and appointments; and improved socket comfort and mobility. Taking part will also help researchers understand how best to support people following an amputation and improve prosthetic services for future patients.
Patients with a below-knee amputation who are using a new prosthesis may all experience falls, blistering due to wearing the prosthetic limb or skin damage to the remaining limb or foot. The chance of experiencing one of these events is not increased by taking part in the study. There is a small chance participants in the remouldable socket group might experience a skin reaction to the silicone liner. This would be managed as per usual care by the clinical team.

Taking part will involve completing some short questionnaires and study assessments. There is a possibility that answering some of the questions may cause distress. Participants do not have to answer all of the questions and will be supported by the research team.

Where is the study run from?
The host NHS organisation is Hampshire and Isle of Wight Healthcare NHS Foundation Trust and the lead research organisation is the University of Hull. The study is coordinated by Hull Health Trials Unit (UK).

When is the study starting and how long is it expected to run for?
1 July 2026 to 30 June 2028, with recruitment expected to open from January 2027.

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

Who is the main contact?
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Integrated Research Application System (IRAS)
350022

Central Portfolio Management System (CPMS)
65028

National Institute for Health and Care Research (NIHR)
209197

Study information

Scientific Title
ASSIST: A randomised feasibility trial to assess the Acceptability of a remouldable Socket System in the Immediate rehabilitation phase of people with a tranSTibial amputation

Acronym
ASSIST

Study objectives
1. Determine how long it takes to set up prosthetics sites; determine participant recruitment rates and drop outs, and recruitment times across prosthetics centres
2. Do interviews with participants to understand if the study processes were acceptable to them, including the randomisation process, the remouldable socket fitting and comfort (for participants in that group only), and what health outcomes were important to them
3. Do interviews with clinicians to understand their views on future study design
4. Identify the NHS resource use costs and patient waiting times for a full economic analysis in a future full trial, and estimate the cost of the remouldable socket vs traditional socket
5. Identify a primary outcome measure(s) to inform sample size calculations for the future full trial
6. Understand the feasibility of collecting patient-reported outcomes, including data on function, health status, adverse events, and resource use

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 26/10/2026, West Midlands – South Birmingham Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; southbirmingham.rec@hra.nhs.uk), ref: 26/WM/0210

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Transtibial amputation

Interventions
This is a pragmatic, parallel group, multicentre RCT feasibility study to evaluate, in a group of primary patients with a new transtibial amputation who are being fitted for their first prosthesis, the feasibility of recruitment, acceptability of randomisation and other study processes, and adherence to the intervention.

Recruitment and randomisation:
Potentially eligible patients will be identified by their physiotherapy team during routine appointments in the usual care, pre-prosthetic phase of the pathway. Once screened, eligible and consented, participants will complete a baseline pre limb-casting assessment (taking ~20-30 minutes) during a routine appointment, including: participant demographics, comorbidities, pre-prosthesis mobility level and quality of life with the EQ-5D-5L.

Afterwards, participants will be randomly allocated, using a web-based data capture and randomisation system (REDCap Cloud) provided by Hull Health Trials Unit (HHTU), using a 1:1 ratio with random permuted blocks, to either the remouldable (intervention) or usual care (control) socket group. We will use prosthetic centre and age as stratification factors in the randomisation. Patients below 50 years are more likely to have an amputation unrelated to disease and therefore better mobility; patients aged over 50 years are more likely to have an amputation related to disease and have lower mobility. Participants randomised to the remouldable socket will be given a silicone liner to practice donning and doffing. All participants will continue with the usual pre-prosthetic physiotherapy until their primary limb-fitting appointment. Blinding of investigator and participant is not possible due to differences between the sockets.

Procedure:
At their primary limb-casting appointment, participants in the control group will be fitted with a usual care socket using the traditional plaster of Paris casting method, followed by manufacturing of the polypropylene/laminate definitive socket, then delivery of the socket and prosthetic leg. Participants in the intervention group will be fitted with the remouldable socket

made of thermoplastic material, which will be moulded directly onto their residual limb. The clinicians will endeavour to fit the full prosthesis on the same day (pending delivery/availability of other prosthetic parts) for those receiving the remouldable socket.

Participants in both groups will continue to receive a usual care prosthetic ankle-foot appropriate to their mobility level, followed by routine prosthetic interventions and physiotherapy treatment.

Clinical outcomes:
2 months and 4 months after the primary limb-casting appointment, all participants will complete the same set of five questionnaires and one clinical test. They include:
1. EQ-5D-5L health-related quality of life, a generic instrument to measure health outcomes and health economics (Ernstsson et al., 2022)
2. Socket comfort score (SCS) (Hanspal et al., 2003)
3. Use of prosthesis with the Locomotor Capabilities Index-5 (LCI-5) questionnaire, self-reported perceived capability to perform 14 different locomotor activities with a prosthesis (Franchignoni et al., 2004)
4. Physical and psychosocial adjustment to a prosthesis with the Trinity Amputation and Prosthesis Experience Scales – Revised (TAPES-R). This tool measures a person's adjustment to their prosthesis, prosthetic satisfaction and pain (phantom limb, residual limb) related to their amputation (Gallagher et al., 2010)
5. Bespoke health resource use questionnaire. Self-reported data will be collected regarding participants' visits to health-related practitioners over the intervention period due to their prosthesis or its interaction with other comorbidities via a bespoke health resource use questionnaire. Participants will also be asked to report falls or near misses and circumstances surrounding the fall(s), and skin irritation and/or pressure sores related to wearing their prosthesis.
6. Timed Up and Go test time, a functional measure to assess balance, ability to transfer to and from seated positions and gait (Podsiadlo & Richardson, 1991).

At the 4-month appointment, participants will additionally be asked to complete a single-question global rating of change (GRC) scale for each of the validated questionnaires (i.e., EQ-5D-5L, SCS, LCI-5 and TAPES-R) to provide a measure of participant-rated change during study participation.

Participants are expected to be involved in the study for approximately 5 months, as primary limb-casting is expected to take place approximately 1 month after randomisation.

Following their involvement in the trial, all participants will continue to receive usual care in terms of completing rehabilitation with a prosthesis followed by management of life-long amputation-related needs. Participants with the intervention socket will continue using that socket as long as they are satisfied with it, and the socket has not exceeded the number of possible remoulds (five remoulds). Once that occurs, or once the person's residual limb has stabilised (usually after 12-18 months), whichever is later, the patient may be cast for a new socket using the traditional socket method (as NHSE is unlikely to allow for routine commissioning of the direct mould technology until a full trial demonstrates clinical and cost-effectiveness). A patient who has been using a silicone liner should have the option to continue using that type of liner if clinically indicated and in line with the patient's preference, even with a traditional socket.

Prosthetists and physiotherapists will record the number of prosthetic (including re-casting and / or remoulds) and physiotherapy appointments for each socket system throughout the trial via

audio-journal case report forms (CRFs), noting staff grade and title, length of appointment, and other resources required to cast and fit either socket. The CRF, designed as a structured prompt sheet, will guide clinicians in recording their impressions of consultations via an audio-journal after each patient interaction. These data will contribute to the health economic analysis. These outcomes, as well as time since primary limb-casting, will be collected. The feasibility of capturing this information will be important to assess the environmental impact of using materials during the different casting methods for the future full trial. We will also include the time and consumables spent in training for the remouldable socket. We will seek input from clinicians, including a group independent to the trial, in the design of the CRF to reduce clinician burden.

Qualitative data collection:
Understanding the experiences and perspectives of both patients and clinicians is crucial for assessing the feasibility and acceptability of the remouldable socket technology before progressing to a full trial. Qualitative research will provide in-depth insights into all aspects of use, which cannot be fully captured through quantitative measures alone. To achieve this, an independent researcher will conduct semi-structured interviews with participants and clinicians, enabling an open and flexible exploration of their views. This approach allows us to identify both anticipated and unforeseen barriers and facilitators to implementation, ensuring that any future trial is designed to maximise recruitment, retention and clinical effectiveness.

To ensure a broad range of perspectives, we will use a purposive sampling approach, interviewing 15-25 patients across all participating sites to ensure sufficient information power. A sampling matrix will guide participant selection to ensure diversity across key demographics, such as age, gender, level of mobility, and ethnicity.
Participants will be interviewed after completing the trial to explore:
1. Their perceptions of the recruitment process and clarity of recruitment materials
2. The factors influencing their decision to participate
3. Their experience of socket fitting and real-world use of the prosthesis
4. Their overall involvement in the study and any recommendations for improvement

Additionally, to understand potential barriers to participation, patients who decline to take part in the study will be invited to complete a short survey outlining their reasons for non-participation. This will help us refine recruitment strategies for a larger trial and identify any concerns that may need to be addressed.

Up to 10-15 clinicians across all participating sites will be interviewed. We will consider experience and previous exposure to direct mould sockets in our sampling approach. We will explore their views on the acceptability of the remouldable socket technology within NHS care pathways and their feedback on the training they received to:
1. Fit the remouldable sockets
2. Undertake research within prosthetics therapies

We will ask about their views on:
1. The CRF to capture health economics data
2. Future trial and any recommendations for improvement

Participant and clinician interviews, and audio-journal CRFs, will be recorded, transcribed verbatim and managed using NVivo software for coding and data management. The qualitative data will be analysed using a reflexive thematic approach to identify key themes and insights.

Intervention Type

Other

Primary outcome(s)
The primary outcomes are the following feasibility outcomes which will be assessed against pre-defined progression criteria at the end of the study:
1. Recruitment rates will be measured as the number of patients meeting eligibility criteria at each site, and the proportion of these who provide consent, on a monthly basis and at the end of the study
2. Retention will be measured by recording the proportion of participants who withdraw from the study and their reasons why, on a monthly basis and at the end of the study
3. Data completeness will be measured by calculating the proportion of missing data of patient-reported outcomes at the end of the study
4. Acceptability of the intervention and to random allocation to trial arms will be explored in qualitative interviews with participants at the end of their study participation
5. Acceptability of study processes will be explored in qualitative interviews with both participants and healthcare professionals at the end of the study
6. Adverse events will be reported via the study database within 24 hours of the site team being made aware

Key secondary outcome(s)
The secondary outcomes will explore candidate outcome measures to be used in a future full trial. Collection feasibility of the following measures:
1. The feasibility of collecting patient-reported outcome measures and a functional performance outcome measure will be determined using the EQ-5D-5L, Socket Comfort Score (SCS), Locomotor Capabilities Index-5 (LCI-5) and Trinity Amputation and Prosthesis Experience Scales-Revised (TAPES-R) questionnaires at 2 and 4 months after the primary limb-casting appointment
2. The feasibility of collecting health economic data will be measured using a bespoke Health Resource Use Questionnaire at 2 and 4 months after the primary limb-casting appointment, and audio journal CRFs completed by clinicians after each participant interaction during the intervention period

Completion date
30/06/2028

Eligibility

Key inclusion criteria
Patients will be included if they:
1. Have a major unilateral below-knee amputation, of any aetiology
2. Are awaiting their first prosthesis
3. Are expected to ambulate with a prosthesis, as measured with the Amputee Mobility Predictor
4. Are receiving physiotherapy at the limb-fitting centre or in the community at the main primary continuing care sites
5. Are able to provide informed consent
6. Are willing to trial remouldable socket in case they are randomised into that group

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
0

Key exclusion criteria
Patients will be excluded if they:
1. Have a life-limiting illness unrelated to amputation
2. Have a bulbous residual limb at the time of casting (circumference at distal end is >2 cm compared to circumference at tibial tuberosity) as it may not be possible to fit the remouldable socket if the participant is randomised into that group
3. Have a body mass greater than 80 kg with a distal circumference of 16-23 cm (small socket) OR have a body mass greater than 125 kg with a distal circumference of 20-38 cm (medium socket)
4. Have a residual limb greater than 27 cm as per manufacturer's recommendations
5. Are receiving physiotherapy in the community OUTSIDE OF the primary continuing care sites
6. Have any contraindication to wearing a silicone liner
7. Have severe upper limb dysfunction (due to strength requirement to don/doff the silicone liner)
8. Have a known allergy to silicone liner and/or inability to visually inspect the residual limb by themselves or with the help of a caregiver (in case of allergic reaction to silicone liner)
9. Have a disease affecting memory (Abbreviated Mental Test Score of 3 or less, indicative of severe impairment)

Date of first enrolment
20/01/2027

Date of final enrolment
31/10/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Portsmouth Enablement Centre
St Mary's Community Health Campus
Milton Road
Portsmouth
England
PO3 6AD

Study participating centre
Dorset Prosthetic Centre
Royal Bournemouth Hospital, Castle Lane East
Bournemouth
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H7 7DW

Study participating centre
Royal National Orthopaedic Hospital NHS Trust
Brockley Hill
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Sponsor information

Organisation
University of Hull

ROR
https://ror.org/04nkhwh30

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website			17/11/2026	No	No