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Testing electrical stimulation during early rehabilitation to manage phantom limb pain and improve walking after below-knee amputation

Submission date
10/11/2026

Recruitment status
Not yet recruiting

Registration date
12/11/2026

Overall study status
Ongoing

Last Edited
11/11/2026

Condition category
Nervous System 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
People who have had a below-knee amputation may experience phantom limb pain, which is pain that feels as though it comes from the missing part of the leg. This pain can affect sleep, daily activities, walking and quality of life.

Functional electrical stimulation (FES) uses small electrical pulses applied through pads placed on the skin to activate muscles. Previous research suggests that using FES during walking may help reduce phantom limb pain and improve walking ability.

The Early MoFit study aims to find out whether FES can be used safely, comfortably and practically during the early stages of rehabilitation after below-knee amputation. The study will also explore whether FES may help reduce phantom limb pain and improve walking and quality of life.

Who can participate?
Adults aged 18–80 years who have had a below-knee amputation on one side within the past two years, have been using a prosthetic leg for less than one year, and currently experience phantom limb pain. Participants must be able to walk using their prosthetic leg, with or without a walking aid, and safely complete the study assessments.

What does the study involve?
Participants will be randomly assigned to start with either six weeks of FES-assisted walking or six weeks of walking without FES. After a six-week break, participants will switch to the other condition. Everyone will therefore experience both conditions.

During the FES period, participants will use a portable electrical stimulation device while walking for at least 20 minutes per day, where safe and comfortable. During the non-FES period, participants will continue their usual walking activities and wear a physical activity monitor.

Participants will complete a short daily pain diary and receive regular telephone calls from the research team.

Assessments will take place before treatment starts and at Weeks 6, 12 and 18. These will include questionnaires about pain and quality of life and short walking assessments using wearable movement sensors. A final telephone follow-up will take place at Week 21.

Each participant will take part for approximately 21 weeks, including the final follow-up.

What are the possible benefits and risks of participating?
Participants may experience improvements in phantom limb pain or walking ability, although these benefits cannot be guaranteed.

FES may cause temporary skin irritation, muscle soreness, fatigue or discomfort during stimulation. The research team will provide training and monitor participants' safety throughout the study.

The findings will help researchers understand whether FES is suitable for use during early rehabilitation and inform the design of a larger clinical trial.

Where is the study run from?
The study is sponsored by the University of Birmingham and will recruit participants from the West Midlands Rehabilitation Centre in Birmingham and Livewell Southwest in Plymouth, United Kingdom.

When is the study starting and how long is it expected to run for?
January 2027 to September 2027.

Who is funding the study?
The study is funded by the Medical Research Council Impact Acceleration Account (MRC IAA), UK.

Who is the main contact?
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Public, Scientific

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Integrated Research Application System (IRAS)
370690

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MR/X502996/1

Sponsor reference
RG_26-079

Study information

Scientific Title
Early intervention with model-driven FES to manage post-amputation phantom limb pain and optimise gait (Early MoFit): a feasibility randomised trial

Acronym
Early MoFit

Study objectives
The primary objective of this study is to evaluate the feasibility, safety, acceptability, and practical delivery of model-driven functional electrical stimulation (FES) during early prosthetic rehabilitation following unilateral transtibial amputation.

The secondary objectives are to obtain preliminary estimates of the effects of FES-assisted walking on phantom limb pain severity, pain interference, walking performance, daily physical activity, and health-related quality of life. The study will also assess recruitment, retention, adherence, intervention usability, and participant and clinician experiences.

The findings will inform refinement of the intervention protocol and the design of a future definitive randomised controlled trial.

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 10/11/2026, Wales Research Ethics Committee 4 (Health and Care Research Wales, Floor 4, Crown Building, Cathays Park, Cardiff, CF10 3NQ, United Kingdom; +44 29 2023 0457; Wales.REC4@wales.nhs.uk), ref: 26/WA/0286

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Crossover

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Phantom limb pain following unilateral transtibial (below-knee) amputation during early prosthetic rehabilitation.

Interventions
This study is a multicentre, randomised, two-period crossover feasibility trial involving eight participants with unilateral transtibial amputation during early prosthetic rehabilitation.

Following screening and baseline assessments, participants will be randomised to one of two treatment sequences:

Group A: Six weeks of functional electrical stimulation (FES)-assisted walking, followed by a six-week washout period and six weeks of walking without FES.

Group B: Six weeks of walking without FES, followed by a six-week washout period and six weeks of FES-assisted walking.

FES intervention:
Participants will receive model-driven FES using the ODFS Pace XL device (Odstock Medical Limited, UK). Electrical stimulation will be delivered to the residual vastus muscle group during the stance phase of walking, synchronised with gait events using a footswitch positioned beneath the insole of the prosthetic footwear.

A trained FES clinician will fit and configure the device, adjust stimulation parameters according to individual needs and comfort, and provide training for safe use. Participants will be instructed to undertake FES-assisted walking for at least 20 minutes per day over six weeks, where safe and tolerated.

Non-FES condition:
Participants will continue their usual walking activities without electrical stimulation while wearing a physical activity monitor.

Washout period:
A six-week washout period will separate the two treatment conditions. No FES treatment will be provided during this period.

Monitoring and follow-up:
Participants will complete daily pain diaries throughout the study and receive weekly telephone reviews during both treatment periods to monitor adherence, symptoms, device use and adverse events.

Outcome assessments will be conducted at baseline and Weeks 6, 12 and 18. A final follow-up telephone call will take place at Week 21 to assess health status, delayed adverse events and participant experiences.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
ODFS Pace XL Functional Electrical Stimulation (FES) device

Primary outcome(s)
1. Feasibility and acceptability of FES-assisted walking measured using recruitment and retention rates, completion of study assessments, adherence to FES and activity monitoring, daily pain diary completion, and participant feedback on intervention acceptability and usability. at baseline and weeks 6, 12, 18 and 21

2. Safety of FES-assisted walking, including the number and nature of adverse events, serious adverse events and device-related issues, measured using study visits, telephone reviews and adverse-event records at baseline and weeks 6, 12, 18 and 21 study visit, weekly for telephone review

Key secondary outcome(s)
1. Phantom limb pain severity and pain interference measured using pain diaries with a 0–10 numerical rating scale and the Brief Pain Inventory–Short Form (BPI-SF), at daily time points for the pain diaries throughout the 18-week study and at baseline and weeks 6, 12 and 18 for BPI-SF

2. Health-related quality of life and participation measured using the EuroQol 5-Dimension 5-Level questionnaire (EQ-5D-5L), World Health Organization Quality of Life – Brief (WHOQOL-BREF) and Patient-Reported Outcomes Measurement Information System Short Form 8a – Ability to Participate in Social Roles and Activities (PROMIS Short Form 8a - Ability to Participate in Social Roles and Activities) at baseline and weeks 6, 12 and 18

3. Walking performance and gait biomechanics measured using repeated 6-metre walking trials and wearable inertial measurement unit (IMU) sensors to measure walking performance and exploratory gait parameters, at baseline and weeks 6, 12 and 18

Completion date
30/09/2027

Eligibility

Key inclusion criteria
1. Adults aged 18–80 years who are able to provide written informed consent
2. Unilateral transtibial (below-knee) amputation within the past two years
3. Fitted with and using a prosthesis for less than one year
4. Current phantom limb pain with a severity of at least 3/10 on a numerical rating scale (NRS)
5. Able to walk with a prosthesis, with or without an additional walking aid
6. Able to safely complete the study walking assessments, as judged by the clinical team
7. Willing and able to comply with study procedures, including use of the FES device or activity monitor, daily pain diary, study visits, and telephone reviews

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Contraindications to functional electrical stimulation (FES), including cardiac pacemakers, implanted defibrillators, other implanted electronic devices, uncontrolled epilepsy, or other conditions considered unsuitable for FES by the clinical team
2. Pregnancy, planned pregnancy during the study, or current breastfeeding
3. Skin conditions, wounds, infections, marked skin sensitivity, or other local issues preventing safe electrode placement on the residual limb
4. Significant medical, neurological, cardiovascular, musculoskeletal, or other conditions that may affect safe participation
5. Inability to safely complete the study walking assessments using the usual prosthesis and walking aid, where required
6. Severe cognitive impairment or other conditions affecting the ability to provide informed consent or follow study instructions
7. Insufficient English language ability to provide informed consent and complete study procedures
8. Current participation in another interventional research study that may affect the study outcomes

9. Any other condition that, in the opinion of the clinical team, makes participation unsafe or inappropriate

Date of first enrolment
04/01/2027

Date of final enrolment
31/03/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
West Midlands Rehabilitation Centre
91 Oak Tree Lane
Selly Oak
Birmingham
England
B29 6JA

Study participating centre
Livewell Southwest
Local Care Centre
200 Mount Gould Road
Plymouth
England
PL4 7PY

Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Anonymised individual participant data supporting published findings may be made available to other researchers upon reasonable request, subject to participant consent, approval by the Chief Investigator and Sponsor, and applicable data protection regulations.

Any data shared will be fully anonymised to ensure that individual participants cannot be identified. Requests for data access will be reviewed in accordance with the University of Birmingham's data-sharing procedures and relevant ethical and regulatory requirements (https://intranet.birmingham.ac.uk/student/libraries/research/rdm/index.aspx).

IPD sharing plan summary
Available on request