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Investigating the feasibility of using electrical stimulation during walking to improve mobility and reduce pain in people with below-knee amputation

Submission date
09/11/2026

Recruitment status
No longer recruiting

Registration date
09/11/2026

Overall study status
Completed

Last Edited
09/11/2026

Condition category
Surgery

[_] 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 often rely more heavily on their unaffected leg when walking. Over time, this may increase the risk of joint problems, muscle weakness, and chronic pain, which can affect mobility and quality of life.
Functional electrical stimulation (FES) is a treatment that uses small electrical impulses to activate muscles. This study aims to investigate whether using FES to stimulate the thigh muscles of the amputated leg during walking can improve walking patterns and reduce pain. It will also assess whether the treatment can be used safely and practically at home and in the community.

Who can participate?
Patients aged between 18 and 70 years who have had an amputation below one knee at least 1 year previously. Participants must have regularly used a prosthetic leg for more than 6 months, be able to walk continuously for 6 minutes without walking aids, and have experienced pain. People with medical conditions that prevent the safe use of FES cannot participate.

What does the study involve?
Participants will be randomly assigned to one of two treatment sequences. Everyone will complete 6 weeks of walking with FES and 6 weeks of walking without FES, separated by a 6-week break. The order of these two treatments will vary between participants.
During the FES period, participants will use a small wearable device called the ODFS Pace XL. The device delivers electrical stimulation to the thigh muscles of the amputated leg during walking. Participants will be asked to use it for at least 20 minutes per day during their normal daily activities.
During the non-FES period, participants will continue their usual walking activities without electrical stimulation and wear an activity monitor.
Participants will attend several appointments at the rehabilitation centre and the University of Birmingham. Researchers will assess walking patterns using movement sensors and laboratory

equipment, and participants will complete questionnaires about their pain and daily activities. Weekly telephone interviews will be used to monitor device use, safety, and participants' experiences.

What are the possible benefits and risks of participating?
Participants may experience improvements in walking and pain management, although these benefits cannot be guaranteed. The study may help researchers develop better rehabilitation treatments for people with lower-limb amputations.
FES is generally considered safe, but some people may experience temporary discomfort from electrical stimulation or mild skin irritation from the adhesive electrodes. Specialist clinicians will provide training and support to ensure that participants can use the device safely.

Where is the study run from?
The study is coordinated by the University of Birmingham (UK), in collaboration with Birmingham Community Healthcare NHS Foundation Trust. Clinical assessments and FES treatment are provided at the West Midlands Rehabilitation Centre, Birmingham, while laboratory-based walking assessments take place at the University of Birmingham.

When is the study starting and how long is it expected to run for?
May 2025 to May 2026

Who is funding the study?
The study is funded by the Medical Research Council Impact Acceleration Account (MRC IAA) through the University of Birmingham (UK)

Who is the main contact?
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Integrated Research Application System (IRAS)
354627

Study information

Scientific Title
Feasibility of community-based gait-synchronised functional electrical stimulation in individuals with transtibial amputation and chronic pain: a randomised crossover study

Acronym
MoFit

Study objectives
The primary objective of this study was to evaluate the feasibility, safety, adherence, and acceptability of repeated, community-based use of gait-synchronised functional electrical stimulation (FES) targeting the residual quadriceps muscles in individuals with unilateral transtibial amputation.

The study also aimed to explore whether prolonged FES-assisted walking could improve gait biomechanics, particularly inter-limb knee kinematic symmetry, and reduce chronic pain intensity and pain-related interference compared with walking without FES.

The findings were intended to inform the development and design of a future definitive randomised controlled trial.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 12/05/2025, West Midlands – Black Country Research Ethics Committee (2 Redman Place Stratford, London, E20 1JQ, United Kingdom; +44 (0)20 7104 8210; blackcountry.rec@hra.nhs.uk), ref: 25/WM/0061

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
Unilateral transtibial amputation (below-knee amputation) associated with chronic pain and gait impairment

Interventions
This study was designed as a randomized, two-period crossover feasibility trial to evaluate the use of gait-synchronised functional electrical stimulation (FES) during daily walking in individuals with unilateral transtibial amputation.

A computer-generated randomisation sequence has been prepared to allocate participants in a 1:1 ratio to one of two intervention sequences:
Sequence A: 6 weeks of FES, followed by a 6-week washout period and 6 weeks of non-FES
Sequence B: 6 weeks of non-FES, followed by a 6-week washout period and 6 weeks of FES

FES intervention:
Participants received FES using the ODFS Pace XL device (Odstock Medical Limited, UK), targeting the quadriceps muscles of the residual limb. Stimulation was triggered by a heel-mounted footswitch and delivered during the stance phase of walking. The stimulation frequency was set at 40 Hz, with a 200 ms ramp-up time, 300 ms ramp-down time, and 2500 ms timeout. Pulse width (45–126 μs) and current amplitude (35–80 mA) were individually adjusted by specialist FES physiotherapists to achieve a comfortable and functionally visible muscle contraction.

Participants received device fitting, familiarisation, and instructions on safe use before beginning the intervention. They were instructed to use FES during their habitual walking activities at home and in the community for a minimum of 20 minutes per day.

Non-FES control:
Participants continued their usual daily activities without FES and were advised to walk for at least 20 minutes per day.

Assessments and follow-up:
Gait and pain assessments were conducted immediately before and after each intervention period. Gait kinematics were evaluated using wearable inertial measurement units (IMUs), while pain intensity and interference were assessed using the Brief Pain Inventory (BPI). All gait assessments were performed without concurrent FES stimulation.

Weekly telephone interviews were conducted to monitor adherence, device use, adverse events, and participant experiences. An additional follow-up interview was conducted at Week 22 to evaluate overall acceptability, perceived benefits, and practical challenges associated with FES use.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
ODFS Pace XL (Odstock Medical Limited)

Primary outcome(s)
1. Musculoskeletal dynamics during walking measured using residual-limb vastus muscle forces and intact-limb knee joint contact forces, estimated using musculoskeletal modelling based on gait data collected with wearable inertial measurement units (IMUs), marker-based motion capture, and force plates. Gait assessments were planned at baseline (week 0), week 6, week 13, and week 18 using wearable IMUs, with additional laboratory-based biomechanical assessments at weeks 2 and 14 using motion capture and force plates.

Key secondary outcome(s)
1. Pain-related interference with walking ability measured using the walking ability item of the Brief Pain Inventory–Short Form (BPI-SF) at baseline (week 0), week 6, week 13, and week 18.

2. Feasibility, adherence, and safety of community-based FES use measured using the recruitment and retention rates, adherence to prescribed FES use (at least 20 minutes per day), and the occurrence of device-related adverse events, assessed using study recruitment records and structured weekly telephone interviews with participants, throughout the 18-week crossover study, with adherence and safety monitored weekly during each 6-week intervention period and retention assessed at week 18.

Completion date
14/05/2026

Eligibility

Key inclusion criteria
1. Adults with unilateral transtibial amputation more than 1 year previously
2. Regular use of a prosthesis for at least 6 months
3. Ability to walk continuously for 6 minutes without a walking aid
4. Current chronic pain, or chronic pain experienced within the previous 6 months, affecting mobility, walking, or prosthetic use, as indicated by a positive response to Question 1 of the Brief Pain Inventory–Short Form (BPI-SF) at baseline

Healthy volunteers allowed
No

Age group

Mixed

Lower age limit
18 Years

Upper age limit
70 Years

Sex
All

Total final enrolment
14

Key exclusion criteria
1. Contraindications to functional electrical stimulation (FES), including cardiac pacemakers, implanted defibrillators, or other implanted electronic devices
2. Self-selected walking speed greater than 1.25 m/s
3. No current or recent experience of chronic pain (pain level = 0)
4. Insufficient English language proficiency to provide informed consent

Date of first enrolment
22/05/2025

Date of final enrolment
16/10/2025

Locations

Countries of recruitment
United Kingdom

England

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

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

IPD sharing plan summary
Not expected to be made available