ISRCTN30210699 https://doi.org/10.1186/ISRCTN30210699

Exercise for falls prevention in lower limb amputees

Submission date
16/07/2015

Recruitment status
No longer recruiting

Registration date
27/07/2015

Overall study status
Completed

Last Edited
23/11/2020

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
In the UK, there are approximately 5-6,000 new referrals to prosthetic services centres every year. Approximately 70% of lower-limb amputations are related to vascular disease (e.g., vascular-related diabetes) and typically occur in men over 60 years of age. Moreover, 52% of lower limb amputees fall each year, and 75% fall two or more times. There has been a lot of work done on exercise for improved function in older adults but no published journal articles about exercise as a tool for falls prevention and better function in lower-limb amputees. Moreover, many prosthetic rehabilitation centres do not offer structured exercise classes for lower-limb amputees.
The aim of this study is to undertake a targeted exercise programme in lower-limb amputees and assess how well it helps preventing falls and improving daily function and performance.

Who can participate?
Adult below-knee and above-knee amputees who wear their prosthesis on a daily basis and have completed a gait retraining or rehabilitation programme at some point.

What does the study involve?
Participants will be placed into either an exercise group or a control group. Those in the exercise group will take part in an exercise programme (exercises becoming progressively difficult), partly supervised (once or twice a week) and partly home-based (once or twice a week). Participants in the control group will be asked not to change their normal weekly physical activity levels.
All participants will undergo biomechanical testing before and after the exercise period. Quality of life, prosthetic function and satisfaction, and balance confidence will also be monitored.

What are the possible benefits and risks of participating?
The biomechanical testing will not provide direct benefit to the participants. However, it will inform the individualised design of the exercise programme and thus provide important information regarding the effectiveness of the intervention and potentially impact on future exercise programmes. Participants may request lay feedback on their performance on the biomechanical tests, and this will be provided upon request.
Participants allocated to the exercise group will benefit directly from participation in this study,

as they will be given an exercise programme designed for lower limb amputees may experience one or more of the following: improved gait, balance, muscle strength and flexibility; reduced falls over a 1-year period; improved mental well-being and quality of life. Participants may also benefit from weekly social interaction with other lower limb amputees during the group-based exercise sessions.
Participants in the non-exercise (control) group may still benefit as knowledge gained through our study will be shared, and an exercise programme may be designed for them upon completion of the study. Participants in the control group are very important as their results will inform the findings of this research and help us establish whether our exercise programme was successful. Our goal is to encourage the development of a community-based exercise group that will directly benefit participants in this study and other similar individuals. Following the completion of the study, and if the exercise intervention proves beneficial, the establishment of a long-term, falls prevention group-based programme could be developed in the local area, and all participants are likely to benefit from this, from a musculoskeletal and quality of life perspective.
There are some small risks and burdens when participating in this study, including: an additional time commitment will be required by all participants to complete the biomechanical testing, weekly exercise diaries, and questionnaires, including at 12 months follow-up; participants in the exercise group are also asked to commit more free time to participate in the study (on average over 2.5-3 hours per week for 12 weeks); all participants may be inconvenienced somewhat by filling in the weekly exercise diaries during the 12-week exercise period (all participants will complete this, even those in the non-exercise group). This will come at no cost to the participants, as pre-paid return envelopes will be provided; participants in the exercise group may experience muscle/joint soreness after each exercise session if they are not used to physical activity. Participants are at somewhat higher risk of falling as they perform activities that challenge their balance as part of the exercise intervention. However, the group-based sessions will be supervised by a suitably trained exercise instructor with first aid training.
To control for these risks, the investigators promise that: all health and safety risks will be minimised during the biomechanical testing by adherence to correct health and safety guidelines in the laboratory, including adequate lighting, walkways free from obstructions, nonslip surfaces, the presence of handrails on staircases and armrests on chairs, safety harness during the balance test. proximity of first aid kit and first aid trained personnel; we will ensure that participants understand these risks and that they minimise risk of falling by performing the exercises gently at first, in an area free from obstruction, whilst wearing proper footwear and clothing, and within close contact of another person or mobile phone in case they were to fall during home-based exercise. Most importantly, participants will be asked to demonstrate that they know how to get up off the floor in case of a fall and to seek medical attention if needed; we will maintain weekly contact with the participants and ask for feedback about their progress. If any exercise causes them discomfort, it may be modified or replaced with another exercise.

Where is the study run from?
Hull and Yorkshire area (UK).

When is the study starting and how long is it expected to run for?
August 2014 to January 2017

Who is funding the study?
British Association of Chartered Physiotherapists in Amputee Rehabilitation (London, UK) and the Help for Health Trust (Hull, UK)

Who is the main contact?
Prof. Natalie Vanicek
n.vanicek@hull.ac.uk

Contact information

Type(s)
Public

Contact name
Prof Natalie Vanicek

Contact details
University of Hull
Department of Sport Health and Exercise Science
Cottingham Rd
Hull
United Kingdom
HU67RX
+44 (0)1482 463607
n.vanicek@hull.ac.uk

Type(s)
Scientific

Contact name
Prof Natalie Vanicek

Contact details
University of Hull
Department of Sport Health and Exercise Science
Cottingham Rd
Hull
United Kingdom
HU67RX
+44 (0)1482 463607
n.vanicek@hull.ac.uk

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Exercise training to maximise musculoskeletal function for falls prevention in lower limb amputees

Study objectives
Current study hypothesis as of 23/11/2020:
This study aims to evaluate the effectiveness of an individualised exercise intervention at improving musculoskeletal function and reducing falls in lower limb amputees. The null (H0) and alternative (H1) hypotheses are as follows:

Research hypothesis 1:
H0: a 12-week individualised exercise intervention will not reduce falls or improve musculoskeletal function over a 12-month period in lower limb amputees.
H1: a 12-week individualised exercise intervention will reduce falls and improve musculoskeletal function over a 12-month period in lower limb amputees.

Research hypothesis 2:
H0: a 12-week individualised exercise intervention will not improve self-reported quality of life, fear of falling and general well-being over a 12-month period in lower limb amputees
H1: a 12-week individualised exercise intervention will improve self-reported quality of life, fear of falling and general well-being over a 12-month period in lower limb amputees.

Previous study hypothesis:
This study aims to evaluate the effectiveness of an individualised exercise intervention at improving musculoskeletal function and reducing falls in lower limb amputees. The null (H0) and alternative (H1) hypotheses are as follows:

Research hypothesis 1:
H0: a 12-week individualised exercise intervention will not improve musculoskeletal function or reduce falls over a 12-month period in lower limb amputees.
H1: a 12-week individualised exercise intervention will improve musculoskeletal function and reduce falls over a 12-month period in lower limb amputees.

Research hypothesis 2:
H0: a 12-week individualised exercise intervention will not improve self-reported quality of life, fear of falling and general well-being over a 12-month period in lower limb amputees.
H1: a 12-week individualised exercise intervention will improve self-reported quality of life, fear of falling and general well-being over a 12-month period in lower limb amputees.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS Health Research Authority NRES Committee Yorkshire & The Humber - Leeds East, 05/05/2015, Reference number: 14/YH/1138

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Individuals with lower limb amputation due to vascular or traumatic reasons and wearing a prosthetic limb.

Interventions
Current interventions as of 23/11/2020:
The intervention will be a personalised exercise programme consisting of group-based (supervised, circuit-training style) and home-based physical activities lasting 12 weeks. The exercises will consist of walking-based activities, functional strength tasks, flexibility and balance; should be performed 3 times a week, progressing to 4 times a week; and starting from 30 minutes and progressing to 1 hour. Thus, the exercises will be evidence-based, graded (becoming progressively more difficult) and designed specifically for below- and above-knee amputees.

The control group will not alter their levels of daily activity and will not engage in a supported exercise programme/intervention.

Previous interventions:
The intervention will be a supported exercise programme consisting of group-based (supervised, circuit-training style) and home-based physical activities lasting 12 weeks. The exercises will consist of walking-based activities, functional strength tasks, flexibility and balance; should be performed 3 times a week, progressing to 4 times a week; and starting from 30 minutes and progressing to 1 hour. Thus, the exercises will be evidence-based, graded (becoming progressively more difficult) and designed specifically for below- and above-knee amputees.

The control group will not alter their levels of daily activity and will not engage in a supported exercise programme/intervention.

Intervention Type
Other

Primary outcome(s)
Falls history over a 12 month period and musculoskeletal parameters (e.g., walking speed and gait function, muscle strength and balance profiles).

Key secondary outcome(s))
Quality of life, fear of falling and general well-being parameters.

Completion date
15/01/2017

Eligibility

Key inclusion criteria
Inclusion criteria have been considered to include all community-dwelling, lower limb amputees patients aged 18-85 years, both males and females, who have had a unilateral below-knee or above-knee amputation for reasons related to either dysvascularity (e.g., diabetes mellitus), trauma, infection, neurological disorder (e.g., diabetic neuropathy) or neoplasia (e.g. benign or malignant growth). Participants who have had one or more falls within the last 2 years will be included in the study. Prospective participants must wear their prosthesis on a daily basis and have completed a gait retraining or rehabilitation programme at some time.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
85 years

Sex
All

Total final enrolment
15

Key exclusion criteria
1. The presence of ‘non-lifestyle’ chronic disease (e.g., multiple sclerosis, Parkinson’s disease, genetic disorders, neurological disorders other than cause of amputation (e.g., diabetic neuropathy, acquired brain injury, autoimmune disorders)
2. Have any cardiac complications, such as a previous heart attack, angina, or have had a coronary artery bypass
3. Severe infections and fever
4. Uncontrolled asthma
5. Uncontrolled diabetes
6. Systolic blood pressure of more than 180 mmHg or diastolic blood pressure of more than 105 mmHg (as measured upon entry into the study)
7. Currently on hypertensive medication AND with a systolic blood pressure of more than 160 mmHg or a diastolic pressure greater than 90 mmHg (as measured upon entry into the study)
8. Recent cerebrovascular accident or stroke
9. Pregnancy
10. Severe osteoporosis
11. Presence of diseases severely affecting memory (e.g. dementia)
12. Presence of current life-limiting illness (e.g. cancer)
13. Current musculoskeletal injury in the lower limbs, including severe lower back pain
14. The inability to give informed consent
15. Unwillingness to allow their GP to be informed of their participation in the study
16. Participants unable to understand English will be excluded, as all instructions will be given in English only
17. Participants currently involved in a falls prevention or structured exercise programme will also be excluded

Date of first enrolment
18/05/2015

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Sport, Health and Exercise Science, University of Hull
Cottingham Rd
Hull
United Kingdom
HU67RX

Sponsor information

Organisation
University of Hull

ROR
https://ror.org/04nkhwh30

Funder(s)

Funder type
Charity

Funder Name
British Association of Chartered Physiotherapists in Amputee Rehabilitation

Funder Name
Help for Health Trust

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2018	03/09/2020	Yes	No
Basic results		03/09/2020	03/09/2020	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes