Improving partial weight bearing compliance of patients after lower limb surgery using an auditory feedback device: a feasibility study

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Primary Objective: To determine whether it is feasible to use an ABF device to lower the amount of steps that exceed the maximum allowed force.The specific research question that the study aims to answer is:- Is it possible to increase partial…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint injuries
Study type	Observational non invasive

Summary

ID

NL-OMON36177

Source
ToetsingOnline

Brief title
Improving partial weight bearing compliance using auditory feedback device

Condition

- Bone and joint injuries
- Bone and joint therapeutic procedures

Synonym
leg surgery, lower limb surgery

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: auditory feedback device, lower limb surgery, partial weight bearing compliance

Outcome measures

Primary outcome

Parameters will be used to evaluate the difference in fractions of steps that exceed the maximum allowed load with or without the use of an Auditory BioFeedback (ABF) device. Pa-rameters will be used to indicate the learning curve involved in adapting to the use of an ABF device.

Secondary outcome

An interview will be conducted after the second session, giving an indication of user accep-tance of the biofeedback training in general and the tested ABF device.

Study description

Background summary

After some types of surgery on the lower extremity of a patient, partial weight bearing is instructed by the surgeon or physician. During the course of rehabilitation, usually several weeks, the allowed load is slowly increased until full weight can be applied. The partial weight bearing on the affected limb, is achieved by the use of crutches or a walking frame. The assessment of the applied load on the limb in case of partial weight bearing is often difficult. The instruction of the allowed load consists of indicating the allowed static load on the limb using scales. Patients are often unable to translate this static force when walking. In the present study, the feasibility of a wearable system for providing biofeedback of the maximum allowed load is investigated. The Auditory BioFeedback (ABF) device used in this study, uses a

load measuring insole combined with a battery powered data analy-sis ankle brace. The allowed load can be programmed into the ankle brace by the physician. When this load is exceeded, an alarm is sounded warning the patient of overloading. Using the ABF device, patients will have an indication of allowed load during walking opposed to the now used static load. Furthermore, the patients will be warned every time the allowed load is exceeded. The hypothesis is, that using this system, the patients quickly learn to apply the right load during walking. During the learning curve, the interval of the sounded alarms will decrease. This less often overloading of the limb, could be beneficial to the rehabilitation process.

Study objective

Primary Objective:
To determine whether it is feasible to use an ABF device to lower the amount of steps that exceed the maximum allowed force.
The specific research question that the study aims to answer is:
- Is it possible to increase partial weight bearing compliance using an Auditory BioFeedback device?

The present study is conducted in preparation of a future randomized controlled trial, investigating the ability of an Auditory BioFeedback (ABF) device for partial weight bearing to reduce rehabilitation time of patients that have undergone leg surgery.

Secondary Objective:
To determine whether the use of a ABF device is satisfactory for patients.
Specific research questions that the study aims to answer are:
- Is the use of biofeedback technology easy to use for therapists and patients?
- Does the biofeedback signal provide the patient with usable information?
- Is there user acceptance and satisfaction of complying with partial weight bearing instruc-tions of the device?

Study design

Prior to the patients normal physical therapy session, a normal part of their rehabilitation process after surgery, subjects will participate in the study.
First their weight will be determined using a scale. With this measurement, and the percentage allowed maximum load assigned to the patients by their physician, the maximum allowed force will be determined. The amount of loading of the limb to achieve this force, is demonstrated to the patient using a scale. The Auditory BioFeedback (ABF) device will be setup to this maximum force.
At the start of the measurements, subjects will be equipped with the ABF device and explained how to walk with crutches to achieve partial limb loading.
Subjects will first walk for five minutes on the treadmill with the ABF device

turned off. During this time, patients will try to apply no more than the maximum allowed load to the affected limb. The ground reaction force of walking will be recorded by the ABF device. Patients will not receive feedback on the forces that are recorded. After five minutes of walking the subjects will take a short brake while the ABF device is turned on and an explanation of the functioning of the device is given. After this, patients will again walk with crutches for five minutes while forces are again recorded. During this time, they are encouraged to reduce the load on their limb when the ABF device gives a warning. After the five minutes walking a second short brake takes place. After this second short brake while the ABF device is turned off, subjects will again walk for five minutes. During this time no feedback is given from the ABF device, the forces will be recorded.
After the walking tests, a short interview will be conducted with the subjects. In this interview, subjects will be asked about their experience with the ABF device and asked if they feel the use of the device made a difference in their partial weight bearing.

Study burden and risks

All measurements are non-invasive and place the patient at no risk other than normal walking on a treadmill. During all evaluations, the researcher will guard the subject to minimize the risk of falls. During training, the potential risks are minimal since the subjects perform the training under supervision.

Potential benefits of the proposed research to the subjects and others:
Subjects that participate in this study are better guided in the process of partial limb loading af-ter they have undergone surgery. This might lead to less overloading of the limb, achieving a bet-ter rehabilitation process. If less overloading of the affected limb is a benefit in the rehabilitation process is not known. Past studies suggest that patient are not able to comply with the weight bearing instructions. This study intended to find if a Auditory BioFeedback (AFB) device is able to assist patients in complying to the instructions. In case the ABF device is able to achieve this, a subsequent large scale Randomized Controlled Trial will have to prove the benefit of partial limb loading on the rehabilitation process. The results of this study could benefit all future patients that undergo surgery on the lower extremities.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Indicated for partial limb load bearing
- Younger than 65 years of age
- Able to walk with the aid of crutches
- Able to speak Dutch

Exclusion criteria

- Significant orthopaedic disturbances or pain
- Serious co-morbidities
- Clinically significant hearing problems
- Clinically significant neurological problems

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-05-2012
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	29-09-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL36826.042.11