Use of the Auditory Biofeedback system to improve a patient*s partial weight bearing compliance: 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 incorrect steps. Incorrect steps are the steps exceeding the maximum allowed load or being below the minimum load.The specific research question that...

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

Summary

ID

NL-OMON41762

Source
ToetsingOnline

Brief title
Improving partial weight bearing compliance using auditory feedback device

Condition

- Bone and joint injuries
- Bone and joint therapeutic procedures

Synonym
Anterior Cruciate ligament reconstruction

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: anterior cruciate ligament reconstructie, auditory biofeedback device, Partial weight bearing compliance

Outcome measures

Primary outcome

The percentage of incorrect steps, exceeding the maximum or minimum allowed load, will be used to determine the difference in a patient's partial weight bearig compliance with and without the use of the Auditory BioFeedback (ABF) device. The timedifference between warning signals will be used to determine the learning curve by use of the ABF device.

Secondary outcome

After the second session an interview will be performed, to give an indication of the user's opinion about the auditory feeback in general and about the use of the auditory biofeedback 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.

Several biofeedback devices have been developed to provide the patient with feedback when overloading their limb. However due to high costs, they are

mainly used in clinical settings. It has been shown that patients are not able to apply the prescribed PWB after training, when they walk unsupervised without a biofeedback device.

The Auditory Biofeedback (ABF) device "Parbel" is a cheap and wearable system for providing biofeedback on PWB on a daily basis. This device uses a load measuring insole combined with an app for data display and feedback on weight bearing. The allowed load can be programmed into the device by the physician. When the allowed load is exceeded a warning signal is sounded. Using the ABF device, patients will have an indication of allowed load during walking relative to the applied load. In the present study it will be investigated whether it is feasible to improve a patient's PWB compliance, when using the improved ABF device.

A previous version of this device was tested in a study with healthy subjects. Here it was shown that the ABF system could improve the partial weight bearing compliance of a patient. However from a study with patients recovering from anterior cruciate ligament (ACL) reconstruction, it became clear, that the ABF device should be improved. After surgery patients often land on their forefoot, without heel contact. Because the previous version of the ABF device, only had a sensor in the heel, no or less load was measured during walking. Also it was questioned whether the then used piezo electric sensors are the correct sensors to measure the ground reaction force. Slow pressure changes will not be observed and patients often load their limb more slowely than healthy subjects. Furthermore, when wearing the ABF device patients tried to reach the warning signal as a reassurance that they were applying sufficient load, because they were instructed not to apply too little load. Therefore it was suggested to implement a lower threshold, to warn the patient when too little load is applied.

Now instead of piezo electric sensors, hall sensors in combination with magnets with the material D30 in between are used. This sensor can measure slow changes in loading. Hall sensors are transducers that vary in output voltage in response to a magnetic field. By applying load on the sensor the distance of the magnet to the hall sensor changes and so the output voltage of the hall sensor changes. The output voltage can be coupled to the applied load. Five distance sensors are placed under the ball of the foot and 2 sensor are placed under the heel of the foot, one under the lateral side and one under the big toe, to make sure loading of the foot is measured. Also it will be possible to set a lower threshold to provide the patient from feedback when too little load is applied.

The hypothesis is, that using this improved ABF system, the patients quickly learn to apply the right load during walking with feedback and will not be able to apply the correct amount of load without feedback from the ABF device. During the learning curve, the interval of the sounded alarms will decrease when the ABF device is used. Furthermore it is expected that after training

with the ABF device, the patients will not be able to retain their compliance to PWB. Compliance to PWB will 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 incorrect steps. Incorrect steps are the steps exceeding the maximum allowed load or being below the minimum load.
The specific research question that the study aims to answer is:

- Is it possible to increase partial weight bearing compliance using the 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 an 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 instructions of the device?

Study design

First session
Prior to the patients normal physiotherapy 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. This way also the minimum allowed force will be determined. The amount of loading of the limb to achieve these forces, is demonstrated to the patient using a scale. The Auditory BioFeedback (ABF) device will be set to this maximum and minimum 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. The crutches will be set on the proper height.
The subjects will be randomly divided into two groups. Subjects assigned to group one will first walk for five minutes with crutches and the ABF device turned on, but no feedback will be given to the patient. During this time, patients will try to apply no more than the maximum allowed load, but more

than the minimum amount of 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, because the sound on the smartphone is turned off. After five minutes of walking, the subjects will take a short break while the sound is turned on on the smartphone, so the ABF device can provide the patient with feedback. An explanation of the functioning of the ABF device is given. After this, the patients will again walk with crutches for five minutes while forces are again recorded by the ABF device. During this time, they are encouraged to change the load on their limb, when the ABF device gives a warning indicating too much or too little load is applied.
Subjects assigned to the second group (the control group) will participate in the same measurements but without feedback from the ABF device. The group will walk two times for 5 minutes as well, with breaks in between, but no feedback will be provided.

Second session:
Prior to the patients following normal physiotherapy session will participate in the second session of this research. The allowed force is again determined using the previous weight measurement and the current maximum and minimum percentage load assigned to the patient by their physician. The amount of loading of the limb to achieve these forces, is demonstrated to the patient using a scale. The Auditory BioFeedback device will also be setup to these forces.
The patients assigned to the first group will first walk for five minutes with the ABF device, without feedback and after a short break they will walk for five minutes with feedback from the ABF device. The patients assigned to the control group will walk two times with a short break in between with no feedback given by the ABF device. As in the first session, measurements of the forces while walking will be recorded by the ABF system and patients do not receive feedback on these measurements.
After the two five minute walking tests, a short interview will be conducted with the subjects of both groups. In this interview, subjects from the first group 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. The subjects from the control group will be asked whether they think they were able to comply to the PWB instructions or not, if it was difficult for them to apply the correct amount of load and if they would be interested to have feedback during walking.

Study burden and risks

The subjects will participate in two sessions before normal physiotherapy, part of the prescribed rehabilitation, is conducted. During these sessions, body weight will be measured one time. First the subjects will be assigned to two groups. One group receiving Auditory feedback from the ABF device and one control group, also wearing the ABF device but not receiving feedback. At the first session, subjects will walk for ten minutes equipped with an ABF device

and crutches. At the second session, subjects will walk for ten minutes equipped with an ABF device using crutches as well and a short interview will be conducted afterwards. To avoid fatigue, subjects will be encouraged to take breaks as needed throughout the sessions. The risks involved are no greater than normal walking with crutches. Knowledge will be gained about the effectiveness of the ABF device to improve a patient's partial weight bearing compliance. When effective, the ABF device might be the first cheap device, which can be used outside of clinical settings on a daily basis by the patient. This would lead to better partial weight bearing of the limb and could be beneficial for the rehabilitation process of patients. Future patients that are required to use partial limb loading, can therefore benefit from this research. If the ABF device is able to improve partial weight bearing, a large scale Randomized Controlled Trial can give more insight into the effect of partial weight bearing after surgery. This knowledge will benefit all future patients in this group.

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

- Patients recovering from ACL reconstruction
- Younger than 65 years of age
- Able to walk with crutches
- Able to speak Dutch

Exclusion criteria

- Significant orthopeadic disturbances or pain
- serious co-morbidities
- Clinically significant hearing problems
- Clinically significant neurological problems

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2016
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	05-05-2015
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	NL52008.042.15