Use of auditory feedback to improve a patients compliance with partial weight bearing

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Use of the auditory biofeedback device, will improve partial weight bearing compliance

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29061

Bron
NTR

Verkorte titel
Improving partial weight bearing compliance using an auditory biofeedback device

Aandoening

Anterior cruciate ligament reconstruction

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: University Medical Center Groningen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Percentage of incorrect steps: This parameter will be used to evaluate the difference in fractions of incorrect steps, with or without the use of the ABF device.

2. Time interval between incorrect steps (exeeding either the maximum or minimum allowed weight): This parameter will be used to indicate the learning curve involved in adapting to the use of an ABF device.

Toelichting onderzoek

Achtergrond van het onderzoek

After surgery or injury of the lower extremity, partial weight bearing (PWB) is often instructed to the patient. However it is very difficult for patients to comply with given PWB instructions. Currently available methods to improve a patient's PWB compliance are either insufficient or too expensive. The cheap and portable Auditory biofeedback device tested in this study, can give feedback about a patient's weight bearing during walking. It will be investigated whether it is feasible to improve a patient's PWB compliance with help of the ABF device. In case feedback from the ABF device can indeed improve a patient's PWB compliance, the device can also be used at home, due to the low costs of the device. Then a large scale RCT can be performed to investigate the effect of PWB after surgery on the rehabilitation process. All future patients to whom PWB is instructed, will benefit from this knowledge.

Doel van het onderzoek

Use of the auditory biofeedback device, will improve partial weight bearing compliance

Onderzoeksopzet

Two weeks after surgery the first session will be conducted.

Three weeks after surgery the second session will be conducted.

Onderzoeksproduct en/of interventie

In this study an auditory biofeedback (ABF) device, giving feedback about partial weight bearing (PWB) to the paient will be tested. The device consists out of a measurement insole embedded in a sandal. Via a bluetooth connection this insole is connected to a smartphone. When the patient applies too much or too little force on his/her limb an auditory signal is given by the smartphone. To test whether an ABF device can improve a patient's PWB complicance 2 groups of 10 patients will be formed. the "feeback group" will receive feedback by an auditory signal from the ABF device. The control group will wear the ABF device as well but will not receive feedback from it. All patients will enroll in two sessions to test repeatability.

Contactpersonen

Publiek

University Medical Center Groningen, University of Groningen

Iris Bokkes
A. Deusinglaan 1, Building 3215, room 1105B

Groningen 9713 AV
The Netherlands

Wetenschappelijk

University Medical Center Groningen, University of Groningen

Iris Bokkes
A. Deusinglaan 1, Building 3215, room 1105B

Groningen 9713 AV
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Patients recovering from ACL reconstruction

- Younger than 65 years of age

- Able to walk with crutches

- Able to speak Dutch

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Significant orthopeadic disturbances or pain

- serious co-morbidities

- Clinically significant hearing problems

- Clinically significant neurological problems

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2015
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5295
NTR-old	NTR5404
Ander register	METC number: METc 2015/141 : ABR Number: 52008

Resultaten