Fracturerehabilitation.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29415

Source
NTR

Brief title
Feetb@ck

Health condition

Keywords: lower extremity, lower leg, fracture, bone healing, pressure measurement, parameters.
Sleutelwoorden: botbreuk, fractuur, onderste extremiteiten, belasting, drukparameters

Sponsors and support

Primary sponsor: University Medical Centre Utrecht
Evalan, Almere
Source(s) of monetary or material Support: ZonMw Rehabilitation Innovation

Intervention

Outcome measures

Primary outcome

1. Bouts of axial dynamic loading;

2. Number of dynamic loadings;

3. Average amplitude;

4. Duration per unit of time.

Secondary outcome

1. Convenience;

2. Ease.

For these measurements questionnaires are used.

Study description

Background summary

Feetb@ck supports fracture rehabilitation by collecting pressure measurements and transform them into specific parameters, easy to use for health care givers. Real-time monitoring is possible by using a communication device and an in-shoe plantar pressure measurement sensor. Data is collected and stored at a central database. Information about the amount of steps and axial pressure are helpful for caregivers to give feedback to the patients by phone. With this objective method it is easier to show the patient load and load.

In this project prototypes are made and will be used by 20 different patients with a lower leg fracture. The aim is to test the applicability of this concept. Using a website makes it possible for patients as well as care-givers to follow the patient. It might be possible to give insight into their activity level and to compare it with people of their age and gender. The advantage for the patient is that they don't have to travel to the hospital.

The multidisciplinary projectteam has already performed some research in this field of fracture rehabilitation and we are eager to share the results with others.

Study objective

The aim of this programm is to stimulate people to follow the medical instructions and therefore to optimise the rehabilitation process and the bonehealing.

In this project a prototypes was fabricated and will be used in twenty patients with a specific type of lower extremity fracture to investigate the use of the technical device.

Study design

During twelve weeks real-time monitoring.

Intervention

With a special communication device and an in-shoe pressure sensor beneath the foot, data will be collected and sent to a central database. Pressure data provides information about the amount of steps, the axial pressure beneath the leg, and caregivers are able to provide feedback to the patients. Usual care is subjective 'time writing', but with this method objective data are available about load.

Contacts

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Eligibility criteria

Inclusion criteria

Fracture of the lower extremity.

Exclusion criteria

1. Not able to communicate in Dutch;

2. Not instructable;

3. Without an address.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Factorial
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2010
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-11-2010
Application type:	First submission

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
NTR-new	NL2511
NTR-old	NTR2629
Other	ZonMw : 335020004
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A