

The efficacy of virtual reality on gait and stair descending in patients with an Anterior Cruciate Ligament reconstruction.

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The aim of this study is to investigate the efficacy of virtual reality on gait and stair descending in patients with an Anterior Cruciate Ligament reconstruction.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Tendon, ligament and cartilage disorders
Study type	Observational non invasive

Summary

ID

NL-OMON36660

Source

ToetsingOnline

Brief title

The efficacy of virtual reality on gait and stair descending .

Condition

- Tendon, ligament and cartilage disorders
- Soft tissue therapeutic procedures

Synonym

ACL reconstruction, Anterior Cruciate Ligament reconstruction

Research involving

Human

Sponsors and support

Primary sponsor: Interfacultair centrum voor Bewegingswetenschappen

Source(s) of monetary or material Support: Ministerie van Defensie

Intervention

Keyword: Anterior Cruciate Ligament, Anterior Cruciate Ligament surgery or reconstruction, Virtual reality

Outcome measures

Primary outcome

Biomechanical measurements: angles and moments of force of joints of the lower extremities and ground reaction forces. Main points of interests are:

- the differences in biomechanical outcome measurements between the test with no interaction effect and the test with an interaction effect with virtual reality.
- the difference in biomechanical outcome measurements between the patient and control group per test.

Angles and moments of force of joints of the lower extremities and ground reaction forces during heel strike, mid stance and pre-swing phases of the gait cycle will be calculated. The angles and moments of force of joints of the lower extremities and ground reaction forces during stair descending on the force plate will be calculated.

Secondary outcome

Not applicable

Study description

Background summary

Patients with an ACL reconstruction have developed an adaptive locomotion pattern after the traumatic injury of the ACL and the reconstruction surgery in comparison with healthy individuals after one year. Nowadays perturbation (balance and coordination exercises) rehabilitation programs on the CAREN system are being developed for patients with an ACL reconstruction. The expected results of a perturbation program using CAREN in patients with an ACL reconstruction is a decrease in fear of movement, to facilitate a more normal movement pattern during virtual reality activities, to facilitate patients in activities to widen their cognitive limitations and to increase the stability of the knee. The effect of virtual reality on the neuromechanics (control and biomechanics) of the lower extremity during gait and stair descending in patients with an ACL reconstruction has not been studied systematically, nor published. The benefits of the study are to have more knowledge about the adapting strategies of the patients with an ACL reconstruction in a virtual environment, inhibit fixed motor programs so that patients start to function better and to shorten rehabilitation programs. The test results of this study could be used to improve the rehabilitation program of patients with an ACL reconstruction.

Study objective

The aim of this study is to investigate the efficacy of virtual reality on gait and stair descending in patients with an Anterior Cruciate Ligament reconstruction.

Study design

observational study with open-label trial

Study burden and risks

The only potential risk factor for the subjects during the tests is falling. This risk factor will be minimized for the subjects by wearing a safety harness which will be attached on the safety frame. In the past no patients have felled. Safety instructions of the CAREN system will be followed by the investigators. The benefits of the study are to acquire more knowledge about the adapting strategies of the patients with an ACL reconstruction in a virtual environment, inhibit fixed motor programs so that patients start to function better and to shorten rehabilitation programs. The test results of this study could be used to improve the rehabilitation program of patients with an ACL reconstruction.

Contacts

Public

Interfacultair centrum voor Bewegingswetenschappen

A. Deusinglaan 1
9713 AV Groningen
NL

Scientific

Interfacultair centrum voor Bewegingswetenschappen

A. Deusinglaan 1
9713 AV Groningen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

patient group:

- First unilateral ACL reconstruction between the seven to ten weeks post-surgery
- Age: 18 - 45 years old
- Male
- Military
- Patients who have been operated in the Central Military Hospital and who are rehabilitating in the Military Rehabilitation Centre *Aardenburg* or Central Military Hospital. ;control group:
- Age: 18 - 45 years old
- Male
- Military
- No history of knee or ankle injuries in the last 6 months

Exclusion criteria

For the patient group:

- contralateral ACL reconstruction
 - Medial collateral ligament injury grade 3
 - Major hydrops in the operated knee
 - Neurological or orthopaedic dysfunctions which will have a negative influence on the test results.
 - Weight >130 kg, because of the maximum load on the platform
- Experience with the Computer Assisted Environment (CAREN) system ;Control group:
- Neurological or orthopaedic dysfunctions which will have a negative influence on the test results.
 - Weight >130 kg, because of the maximum load on the platform
 - Experience with the CAREN-system

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	18-03-2011
Enrollment:	68
Type:	Actual

Ethics review

Approved WMO

Date: 27-01-2011
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	NL34113.042.10