Does virtual reality training give an improved balance and stability in elderly?

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Validation of a VR system with validated questionaires The aim of our study is to determine if balance training with a VR application with real time feedback can improve balance. Furthermore, it is determined whether VR training results in improved...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON38825

Source
ToetsingOnline

Brief title
Virtual Reality and Stability Control (VReSCo)

Condition

- Other condition
- Joint disorders

Synonym
Balancetraining Fall prevention

Health condition

Propriocepsis en balansproblemen

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Fall prevention, Stability, Training, Virtual Reality

Outcome measures

Primary outcome

Crossectional as inventory of population and validation of the VR system with known questionnaires

Dates of stability from the VR system (STABLE) and data from validated questionnaires and tests regarding balance and stability.

The parameters that will be measured are:

1) the time that it takes to complete a required training task

2) the number of times that a subject has to apply a stepping out strategy to restore balance

3) variation of the centre of pressure during quiet stance and task performance.

Diminishment of 1), 2) and 3) will be assumed to be beneficial and as such an improvement of balance. Endpoints will be defined after each training session and at the end of the training period.

The endpoint will be reached after 12 weeks. Two training sessions each week for 30 minutes.

Secondary outcome

Part I

Crossectional research: identification of patients with an extreme score on

questionnaire and tests, and associate it with the VR output variables

Part II

Secondary study parameters/endpoints

Berg Balance Scale, Short Physical Performance battery, Falls efficacy scale.

Handgrip strength. Will be performed at baseline and at the end of the training

period.

Study description

Background summary

Hip fractures are common and associated with high rates of morbidity and mortality. In the United States alone, over 300.000 hip fractures occur each year. There are many preventive strategies described. Balance training has been shown to help to prevent hip fractures in elderly. Osteoarthritis (OA) of the knee is characterized by a sense of instability of the affected leg, pain and thus mobility limitations. In knee OA, proprioceptive accuracy ("giving way" sensation) is reduced and might be associated with pain and activity limitations (kinesiofobia).
Recently a virtual reality (VR) stability and balance learning environment was introduced. The MOTEK STABLE® is a therapeutically Virtual Reality application using real-time feedback to improve balance.

Study objective

Validation of a VR system with validated questionaires
The aim of our study is to determine if balance training with a VR application with real time feedback can improve balance. Furthermore, it is determined whether VR training results in improved mobility in patients with symptomatic knee osteoarthritis.

Study design

Part I, crossectional as inventory of population and validation of the VR system with known questionnaires
Part II as a VR pilot intervention in 2 x 10 patients (knee osteoarthritis and consolidated wrist fractures)

Study burden and risks

The volunteers will have to come to the LUMC Leiden to take part of the assessment and some (n=20) eventually a training. Physical effort will be required. Falling hazard will be minimized by using a safety harness. A research nurse or student physiotherapy swill be present at all times. In total there will be 12 visits in 6 weeks. The volunteers will possible benefit from a better balance control.

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

Distal antebrachii fracture in the recent past.
Symptomatic knee osteoarthritis

Exclusion criteria

Walking aids , BMI > 30, severe impairment of sight, cognitive dysfunction

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-07-2013
Enrollment:	250
Type:	Actual

Ethics review

Approved WMO

Date:	27-05-2013
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL43767.058.13