Wii-balance therapy for patients after stroke

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To determine whether Wii balance therapy is more effective than the conventional balance therapy for the standing and walking balance of patients with a stroke.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Neurological disorders NEC
Study type	Interventional

Summary

ID

NL-OMON33001

Source
ToetsingOnline

Brief title
Wii-balance therapy

Condition

- Neurological disorders NEC

Synonym
cerebrovascular accident, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Fonds NutsOhra

Intervention

Keyword: balance therapy, RCT, stroke, Wii

Outcome measures

Primary outcome

The primary outcome parameter of the study is balance measured with the Berg balance scale and the Dynamic gait Index.

Secondary outcome

Intensity of exercising:

The intensity of exercising is the duration and frequency in which the patient performs the balance exercises. The intensity is determined by means of a diary in which the patient records when and how long (minutes) he / she performs the balance exercises, and by using a self-questionnaire that asks patients how often per week and for how long (minutes) they have practiced.

Prognostic factors:

Prognostic factors are the factors that may affect the restoration of balance. The prognostic factors age, sex, social status are derived from the patient file. Therapy adherence is measured with a diary and a self-questionnaire.

Activities of daily living:

Activities of daily living (ADL) are the basic tasks of everyday life. The extent to which the patient independently perform ADL is measured with the Barthel index.

Participation:

Participation is a person's actual involvement in society. Participation is measured with the Life Habits questionnaire.

Quality of life:

Quality of life is being defined and measured as the functioning of persons in the physical, psychological and social field (or dimension), and its subjective evaluation. Quality of life is measured with the SF-36.

Study description

Background summary

Patients with a stroke often have impaired balance. Therefore, these patients have an increased risk of falling, which can lead to serious complications such as hip fractures. Balance training leads to a reduction (41-65%) of the number of falls. The problem is that balance therapy, which mostly consists of home exercises, is often considered as boring. This requires a lot of the patient's discipline to consistently carry out the prescribed balance exercises. The result is that a significant number of patients (20-60%) don't perform the exercises or only partially, which leads to a significant decrease of the therapeutic effect. Hence, the therapeutic effect depends largely on the intensity (duration and frequency) in which the patient perform the exercises. A possible solution to improve the effectiveness of balance therapy is the use of interactive 'video games'. We know from research and our own experience that patients are more motivated to perform exercises with interactive video games. This may have a positive effect on the intensity of exercising and therefore the therapeutic effect.

Study objective

To determine whether Wii balance therapy is more effective than the conventional balance therapy for the standing and walking balance of patients with a stroke.

Study design

It is a randomized single-blind parallel clinical trial to determine the effectiveness of Wii balance therapy for the restoration of balance in patients

with stroke. The study population comprises 56 patients with a cerebrovascular accident (CVA), which are randomized over the intervention (= Wii balance therapy) and control (= conventional balance therapy) group. Measurements are performed before and after the balance therapy. Patient's balance is measured with the Berg balance scale and the dynamic gait index. Activities of daily living, participation and quality of life are measured with respectively the Barthel index, the Life Habits questionnaire and RAND36.

Intervention

The subjects receive balance training for 8 weeks. The intervention group will exercise daily for 8 weeks with Wii-Fit: 2x per week 30 minutes under the guidance of a physiotherapist, and on the other days 30 minutes at home. The control group receives standard 8-week balance training for patients with stroke: 2x per week under the guidance of a physiotherapist, and on the other days 1x per day for 30 minutes at home.

Study burden and risks

The risks associated with this study are minimal. There is a slight physical load when performing the Wii balance exercises, however, this corresponds with the physical load of the standard balance therapy.

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 with a stroke, longer than 6 weeks and shorter than 6 months, diagnosed by a neurologist
- Minimal age of 18 years
- Sum score < 56 points on Berg Balance scale
- can be instructed to perform simple tasks
- Written Informed Consent

Exclusion criteria

- A medical history of neurological disorders, other than mentioned in the inclusion criteria
- Musculoskeletal disorders that influence the lower extremities

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2009
Enrollment:	56
Type:	Actual

Ethics review

Approved WMO Date:	26-10-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL29213.078.09