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Wii balance training in stroke patients

Submission date 12/04/2018	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/08/2018	**Overall study status** Completed	
Last Edited 21/09/2018	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Balance impairments are frequently seen following a stroke. Conventional balance therapy (exercise therapy) has been shown to be effective at improving balance during the rehabilitation of patients with subacute stroke. However, most conventional balance exercises rely on the repetition of specific movements and postures, which patients may perceive as monotonous, dull and not challenging. This can lead to a lack of motivation and interest, which eventually can result in a decrease of exercise adherence, which is an important factor for successful therapy. Video game based technology has become popular for use in rehabilitation settings, due to its motivational character, usability and costs. The aim of this study is to compare the effectiveness of Wii Fit balance training with conventional balance therapy on balance in patients with subacute stroke, conducted in an outpatient setting.

Who can participate?
Patients aged over 18 with subacute stroke (between 6 weeks and 6 months ago), discharged from the rehabilitation center

What does the study involve?
Participants are randomly allocated to twice a week 30 minutes of conventional balance therapy or Wii Fit balance training under the supervision of a physical therapist. For the rest of the week, the patients are instructed to exercise according to their allocated group for at least 30 minutes a day at home (more was allowed). The intervention lasts for 8 weeks. With Wii Fit balance training, the Wii Balance board is used. At the sessions under supervision, the physical therapist selects, in consultation with the patients, one or more games for the patients to exercise in that session. This selection is based on whether the patients enjoy the game and if the game is feasible for the patients. At home the patients are allowed to select one or more games for their balance exercises. For safety reasons, the patients are allowed to use a walker during the exercise when they need it. The conventional balance therapy consists of dynamic and static exercises in which the base of support is reduced in steps (e.g. walking on a straight and narrow line and standing on two legs, standing on one leg, respectively). Also, the surface on which the exercises are performed could be changed (solid, foam and wobble). Balance and gait instability are measured before and directly after the eight-week intervention.

What are the possible benefits and risks of participating?
There are no possible benefits for the participants, as the results are used for future therapy and patients. The risks of participating are small to none, and no side effects were reported.

Where is the study run from?
The study is initiated from the Erasmus MC in Rotterdam, The Netherlands, which was the lead center. Participating centers for inclusion of the patients were: Laurens Antonius IJsselmonde, Rijndam Revalidatiecentrum locatie Vlietlandplein, and Maasstad Ziekenhuis Rotterdam.

When is the study starting and how long is it expected to run for?
December 2009 to August 2017

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NL29213.078.09

Study information

Scientific Title
Wii Fit balance training is not more effective than conventional balance therapy in outpatients with subacute stroke

Study objectives
The hypothesis was that the Wii Fit balance training is more effective than conventional balance therapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The local ethics committee of the Erasmus MC Rotterdam, The Netherlands, 26/09/2009, ref: MEC-2009-337, and the CCMO, The Netherlands, ref: NL29213.078.09

Study design
Randomized clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Subacute stroke patients in an outpatient setting

Interventions
Randomization was performed by using ‘random permutated blocks’ using blocks of 2 patients for each of the 2 treatments (Pocock, 1994). Using this method and a randomization table, the 2 treatments were put in random order and placed in dense , numbered envelopes. One person who was not involved in any of the other study procedures conducted the randomization. Blinding was applied to the researcher who performed the measurements and who analyzed the data. It was not possible to blind the patient or the therapist, because both knew which balance therapy was given.

According to group allocation, patients were provided twice a week 30 minutes of conventional balance therapy or Wii Fit balance training under supervision of a physical therapist. For the residual days of the week, the patients were instructed to exercise, in conformity with the allocated group, for at least 30 minutes a day at home (more was allowed). The intervention lasted for eight weeks.

Nintendo Wii Fit
With Wii Fit balance training, the Wii Balance board was used, which consists of 4 transducers to

assess force distribution and the resulting movements in the Center of Pressure (CoP). Eleven games to exercise balance (Table Tilt (plus), Ski Slalom, Balance Bubble (plus), Penguin Slide, Heading, Tilt City, Segway Circuit, Perfect 10, Snowball Fight, Muscle Workouts and Step Basics) were selected in accordance with the physical therapist. At the sessions under supervision, the physical therapist selected, in consultation with the patients, one or more games for the patients to exercise in that session. This selection was based on two conditions: whether the patients enjoyed the game and if the game was feasible for the patients. At home the patients were allowed to select one or more games for their balance exercises. For safety reasons, the patients were allowed to use a walker during the exercise when he/ she needed it.

Conventional balance therapy
The conventional balance therapy consisted of dynamic and static exercises in which the base of support was reduced in steps (e.g. walking on a straight and narrow line and standing on two legs, standing on one leg, respectively). Also, the surface, on which the exercises were performed, could be changed (solid, foam and wobble).

Intervention Type
Other

Primary outcome measure
1. Balance measured using the Berg Balance Scale (BBS) prior to and directly after the eight-week intervention
2. Gait instability measured using the Dynamic Gait Index (DGI) prior to and directly after the eight-week intervention

Secondary outcome measures
1. Walking speed measured using the 5 Meter Walk Test (5MWT) prior to and directly after the eight-week intervention
2. Fatigue measured using the Fatigue Severity Scale (FSS) prior to and directly after the eight-week intervention
3. Fatigue measured using the VAS-Fatigue Severity Scale (VAS-f) prior to and directly after the eight-week intervention
4. Independence of Activities of Daily Living measured using the Barthel Index (BI) prior to and directly after the eight-week intervention
5. Physical activity measured using the actigraph (GT1M-1 and GT1M-2) prior to and directly after the eight-week intervention
6. Physical activity measured using the Physical Activity Scale for Individuals with Physical Disabilities (PASIPD) prior to and directly after the eight-week intervention
7. Individuals perceived functioning in daily activities and social participation measured using the Life Habits prior to and directly after the eight-week intervention
8. Individual perceived general health (quality of life) measured using the Short-Form 36 (SF-36) prior to and directly after the eight-week intervention

Overall study start date
01/12/2009

Completion date
01/08/2017

Eligibility

Key inclusion criteria
1. Patients with subacute stroke (>6 weeks and <6 months)
2. Discharged from the rehabilitation center
3. Ischemic, hemorrhagic or recurrent stroke (diagnosed by a neurologist)
4. Aged >18 years
5. Continued outpatient physical therapy
6. Functional Ambulation Category (FAC) independence level of ≥4
7. Berg Balance Scale (BBS) score <56 or a BBS score of 56 and a score of 0 or 1 at item 5 of the Dynamic Gait Index (DGI)
8. Understanding of simple exercises
9. None of the included patients used the Wii for at least the last four weeks before the trial started
10. All participants provided written informed consent before the start of the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
34

Key exclusion criteria
1. Traumatic intracranial hemorrhage
2. History of disorders that might have an influence on balance
3. Serious deviations in muscles or anatomy of the lower limbs
4. Unable to perform the tasks as a consequence of serious visual, sensory, cognitive and linguistic impairments

Date of first enrolment
01/06/2010

Date of final enrolment
01/12/2016

Locations

Countries of recruitment
Netherlands

Study participating centre

Erasmus MC
's Gravendijkwal 230
Rotterdam
Netherlands
3015 CE

Sponsor information

Organisation
Erasmus MC

Sponsor details
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Sponsor type
University/education

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ROR
https://ror.org/018906e22

Funder(s)

Funder type
Charity

Funder Name
Fonds NutsOhra

Alternative Name(s)
NutsOhra Foundation, NutsOhra Fund, Stichting Nuts Ohra

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location

Netherlands

Results and Publications

Publication and dissemination plan
The trialists are currently at the end phase of writing the article, and are planning to submit the article within 2 months to a high-impact peer reviewed journal within the field of rehabilitation /physical therapy.

Intention to publish date
16/06/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr H. (Henri) L.P. Hurkmans (h.hurkmans@erasmusmc.nl).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		21/09/2018	21/09/2018	No	No