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The effect of balance training on balance in people with multiple sclerosis using a virtual reality system

Submission date
20/01/2016

Recruitment status
No longer recruiting

Registration date
21/01/2016

Overall study status
Completed

Last Edited
09/08/2016

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Multiple sclerosis (MS) is one of the most common diseases of the central nervous system (brain and spinal cord). Healthy nerves are coated in a fatty casing (myelin sheath) which helps messages to travel quickly and smoothly along nerves. When a person is suffering from MS, the immune system, which normally helps to protect against infection, attacks the myelin sheath, stripping it from the nerves (demyelination). This demyelination means that messages cannot travel along the nerves effectively, causing a range of disabilities. Around 85% of MS sufferers are diagnosed with the relapsing remitting type. This is where the sufferer has sudden flare-ups of symptoms (relapses) followed by periods where the symptoms are very mild or disappear completely. Many people suffering from MS suffer from problems with balance. The aim of this study is to look at the effects of training with a new virtual reality system on balance in people with MS and compare it with traditional physical therapy.

Who can participate?
Adults aged between 25 and 55 who have been diagnosed with relapsing-remitting MS and are moderately disabled.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group complete a 6 week virtual reality training program. The participants take part in two sessions a week which include around 30 minutes of balance training. Participants are asked to stand of a moving platform and look at a screen with a road on it. The road itself includes flat, bumpy and tilting sections and the moving platform moves in sync with the image of the road on the screen (i.e. when the road tilts, the platform tilts). Participants are asked to “walk” along the road whilst keeping their balance. Participants in the second group take part in a conventional exercise program (traditional physical therapy), which consists of balancing on an uneven surface (foam), an unstable base (wobble board) and by catching balls thrown at them from different directions but stepping forward or sideways. At the study of the study and then again at the end of the 6 week training programs, participants in both groups complete a number of assessments and questionnaires in order to find out if their balance has improved.

What are the possible benefits and risks of participating?
Participants may benefit from improved balance as a result of taking part in the study. There are no significant risks of taking part, however some participants may experience nausea because of the moving platform used.

Where is the study run from?
Sheba Medical Center (Israel)

When is the study starting and how long is it expected to run for?
June 2013 to June 2015

Who is funding the study?
National Multiple Sclerosis Society (USA)

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
001

Study information

Scientific Title

The effect of balance training on postural control in people with multiple sclerosis using the CAREN virtual reality system: a pilot randomized controlled trial

Study objectives
Following the intervention period, both groups will demonstrate improved balance capabilities, although greater improvements are expected in the virtual reality (VR) training group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Sheba Medical Center Independent Ethics Committee, ref: 046613SMC

Study design
Pilot randomised parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Multiple sclerosis

Interventions
Participants are randomly allocated to one of two groups.

Virtual reality (VR) group: Patients participate in 12 sessions of CAREN VR over six weeks, with a total of 30 minutes of balance training during each session. Rest breaks are allowed if requested, but are not included in the overall practice time. Typically, the participants take three rest breaks during each practice session, each lasting approximately 3-4 minutes. The training session lasts 45-50 minutes. Participants are instructed to continue their regular physical activities between intervention sessions. The VR system used is the CAREN Integrated Reality System with D-flow software, which works in real-time, enabling the creation of a variety of controlled and repeated simulated environments via dedicated software which includes 3D visual, sound, and proprioceptive stimuli. The following components are incorporated in the system:
1. Motion Platform: CAREN consists of an electro-hydraulic 2m diameter motion platform (Rexroth Hydraudyne, MOTEK, Micro motion) that can be manipulated by 6 degrees of freedom. The movement of the platform is either driven by the subject's movements or pre-programmed in synchrony with function curves that define a specific pathway in the virtual environment.

2. Projection: The virtual scene is projected on a large screen (3m × 2.5m). For the study, a 'road scene' is used which requires subjects to stand on a motion platform while maintaining their balance and advancing along a pre-defined road. The road itself has flat, straight and vertical bumpy sections, right and left tilts and right and left translations. The platform's movement is correlated with the visual stimulus (i.e. when the subject arrives at a bump on the screen, the platform elevates. When the road tilts, the platform tilts accordingly in the same direction). The VR training also includes a secondary task which involves intercepting 18 moving targets (a colored ball of 12.5 cm diameter) appearing above the road. Each target can be intercepted when appearing no further than 20cm from the subject's hands (which are reflected on the screen as a 4.5cm in diameter ball).

Conventional exercise group: Patients participate in 12 sessions of conventional exercise training. In each of the 12 sessions, the participants undergo 10 minutes of stretching exercises and 20 minutes of exercise. In general, the training protocol encompasses 3 dimensions:
1. Static stance: Patients are encouraged to stand on pieces of foam (4 cm thick) with their eyes open or closed for approximately 60 seconds (depending upon the patient’s ability). The difficulty is increased by adding more foam pieces and reducing the support base (shoulder width /partial tandem/tandem).
2. Dynamic weight shifting: A physical therapist throws a ball in numerous directions. The patients have to catch the ball by stepping forward either laterally or squatting for approximately 30 times, depending upon the patient’s tolerance.
3. External perturbations: Patients are encouraged to stand on an unstable base (i.e. a wobble board) while the physical therapist deliberately pushes the top of the board in downward direction, at different places and speeds.

For both groups, during all sessions, the patient is supervised by the physical therapist in order to prevent falls.

Intervention Type
Other

Primary outcome measure
Center of pressure (CoP) trajectories are measuring using posturography measurements taken from the Zebris FDM-T Treadmill data at baseline and 6 weeks.

Secondary outcome measures
1. Stability is measured using the Functional Reach Test (FRT) at baseline and 6 weeks
2. Balance is measured using the Berg Balance Test (BBS) at baseline and 6 weeks
3. Ability to change directions while stepping is measured using the Four Square Step Test (FSST) at baseline and 6 weeks
4. Fear of falling is measured using the Falls Efficacy Scale International (FES-I) at baseline and 6 weeks

Overall study start date
01/06/2013

Completion date
01/06/2015

Eligibility

Key inclusion criteria
1. Diagnosis of definite relapsing-remitting MS according to the revised McDonald criteria 2010
2. Aged between 25 and 55 years
3. Moderate neurological disability as scored by the expanded disability status scale (EDSS), ranging from 3.0 to 6.0 inclusive with a pyramidal functional score of at least 3

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
50

Key exclusion criteria
1. MS clinical relapse or treatment with corticosteroid therapy within 6-months prior to examination
2. Patients experiencing major depression or cognitive decline
3. Orthopedic disorders that could negatively affect balance
4. Pregnancy
5. Blurred vision
6. Cardiovascular disorders

Date of first enrolment
01/06/2014

Date of final enrolment
01/03/2015

Locations

Countries of recruitment
Israel

Study participating centre
Sheba Medical Center
Multiple Sclerosis Center
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Sponsor information

Organisation
Sheba Medical Hospital

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/020rzx487

Funder(s)

Funder type
Charity

Funder Name
National Multiple Sclerosis Society

Alternative Name(s)
National MS Society, The National Multiple Sclerosis Society, The National MS Society, National Multiple Sclerosis Society, Inc., Sociedad Nacional de Esclerosis, Sociedad Nacional de Esclerosis Múltiple, NMSS

Funding Body Type
Government organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication of results in a peer reviewed journal.

Intention to publish date
30/06/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2016		Yes	No