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Virtual reality augmented exercise in multiple sclerosis patients

Submission date
10/01/2012

Recruitment status
No longer recruiting

Registration date
01/03/2012

Overall study status
Completed

Last Edited
15/05/2015

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
This study will investigate if using commercially available active gaming technology, or in other words, virtual reality (VR) augmented exercise, can help people affected by multiple sclerosis (MS). Many people with MS have problems with physical function and activity due to balance and muscle problems, as well as pain. This can be a primary factor in the restriction of their activities and therefore has a negative influence on their quality of life. There has been very little research published into the effects of using VR augmented exercise as a rehabilitation tool, and to the knowledge of the researcher there are no published studies investigating the use of this technology for people with MS.

Who can participate?
Men and women aged 18-65 years with a clinical diagnosis of MS.

What does the study involve?
Participants will be randomly allocated to one of three groups:
1. Four weeks of twice-weekly 40-minute sessions of supervised one-to-one visual reality (VR) augmented exercise using the Nintendo Wii™ and Wii Fit™ system.
2. Four weeks of twice-weekly 40-minute sessions of supervised one-to-one 'traditional' physiotherapy prescribed gym-based exercise.
3. Four weeks of usual care.

What are the possible benefits and risks of participating?
Participants may experience improvements in terms of pain and function.

Where is the study run from?
Teesside University (UK).

When is the study starting and how long is it expected to run for?
The study ran from August 2011 to April 2012.

Who is funding the study?
Teesside University (UK).

Who is the main contact?
Mr Jonathan Robinson
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
An investigation of the use of virtual reality based augmented exercise for people with multiple sclerosis

Study objectives
The aims of the study are to investigate the effect of virtual augmented exercise on
1. The management of pain and function in multiple sclerosis (MS) as recorded through the MS walking scale, pain questionnaire and the World Health Organization Disability assessment Schedule II
2. Investigate the mechanisms underlying any effects through centre of pressure measures and physiological measures of electromyography (EMG)
3. Explore the usability and acceptance of the technology through questionnaires of usability and acceptance

Ethics approval required

Old ethics approval format

Ethics approval(s)
1. National Research Ethics Service Committee North East - Newcastle & North Tyneside 1, 21/06/2011, ref:11/NE/0151
2. Teesside University School of Health and Social Care Research Governance and Ethics Committee, 13/04/2011, ref: 097/11

Study design
Exploratory randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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 will be randomly allocated to one of three groups:
1. Four weeks, twice weekly, 40 minute sessions of supervised one-to-one visual reality (VR) augmented exercise using the Nintendo Wii™ and Wii Fit™ system
2. Four weeks, twice weekly, 40 minute sessions of supervised one-to-one 'traditional' physiotherapy prescribed gym based exercise
3. Four weeks of usual care (Control)

Intervention Type
Behavioural

Primary outcome measure
1. Standing balance during quiet unipedal (standing on one foot) and bipedal (standing on two feet) stance recorded by Kistler™ force plate
2. Dynamic balance during sit-to-stand and ground reaction force
3. Temporal distance parameters of gait stride length, cadence, velocity, single and double limb support time
4. Measures of technology acceptance and exercise experience questionnaires

Secondary outcome measures

1. Muscle activity: relationships between electromyography (EMG) and measures of static and dynamic postural stability
2. Self reported walking ability: differences in MSWS12
3. Self reported function: differences in WHODAS II, and pain questionnaires
4. Self reported exertion: Rating of Perceived Exertion

Overall study start date
01/08/2011

Completion date
01/04/2012

Eligibility

Key inclusion criteria
1. Men and women
2. Aged 18-65 years
3. A clinical diagnosis of MS
4. Expanded Disability Status Scale (EDSS) score of one to six (Kurtzke, 1983)
5. Able to read and comprehend written and spoken English (regrettably validated translations of the outcome measure questionnaires are not available)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
66

Key exclusion criteria
1. Currently in acute exacerbation and/or has relapsed within the last three months
2. Diagnoses of any other condition affecting the central nervous system
3. Any musculoskeletal injury or condition for which a health professional has advised the person to refrain from undertaking moderate physical activity
4. Any doubt of ability to give informed consent
5. Currently receiving physical therapy aimed at improvements in fitness and balance
6. Any allergy to conductance gel and/or hypoallergenic tape used during electromyography

Date of first enrolment
01/08/2011

Date of final enrolment
01/04/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Teesside University
Cleveland
United Kingdom
TS1 3BA

Sponsor information

Organisation
Teesside University (UK)

Sponsor details
School of Health and Social Care
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Sponsor type
University/education

Website
http://www.tees.ac.uk

ROR
https://ror.org/03z28gk75

Funder(s)

Funder type
University/education

Funder Name
Teesside University (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	17/04/2015		Yes	No