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Does the use of Nintendo WiiTM Sports improve dominant arm function and is it acceptable to patients after stroke?

Submission date
25/11/2011

Recruitment status
No longer recruiting

Registration date
25/11/2011

Overall study status
Completed

Last Edited
16/03/2016

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
A stroke occurs when the blood supply to part of the brain is cut off. The injury to the brain can lead to weakness or paralysis in one side of the body. The aim of this study is to find out whether people who have arm weakness after a stroke can benefit from exercising with a Nintendo WiiTM for six weeks in addition to their usual rehabilitation programme. We want to find out if using the WiiTM improves arm function, how the participants feel about using it and if this use can reduce costs for the health service over time.

Who can participate?
Stroke patients aged 18 and over who have weakness in their dominant arm (the arm they used to do most things like writing or using a knife).

What does the study involve?
Patients are approached about the study in hospital or a clinic following a stroke but the rest of the study takes place in their own homes, except for the 6-week and 6-month follow-up visits which take place either in the patient's home or in the outpatient clinic or research unit at the convenience of the participant. Participants are randomly allocated to one of two groups. Participants in one group each receive a WiiTM game and console to use at home with their own TV to exercise their arm for six weeks. Participants in the other group are taught personalised arm exercises. Both groups are asked to exercise daily for six weeks. There are questionnaires and simple, painless tests at the start, after 6 weeks and again after 6 months. Twenty five of the participants who use a WiiTM for 6 weeks may be asked for a further interview so that we can understand fully how using the WiiTM affected their condition. In all cases, the study should last no more than 6 months.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
This study is conducted in a number of stroke centres in the South West of England.

When is the study starting and how long is it expected to run for?
November 2011 to July 2013

Who is funding the study?
NIHR Research for Patient Benefit Grant (UK)

Who is the main contact?
Dr Katja Adie
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
11030

Study information

Scientific Title
Does the use of Nintendo WiiTM Sports improve dominant arm function and is it acceptable to patients after stroke?

Acronym
Trial of WiiTM in STroke (TWIST)

Study objectives
The aim of this research study is to find out whether people who have arm weakness after a stroke can benefit from exercising with a Nintendo WiiTM for six weeks in addition to their usual rehabilitation programme.

Ethics approval required
Old ethics approval format

Ethics approval(s)

11/SC/0405

Study design
Randomised; Interventional; Design type: Not specified

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Stroke Research Network; Subtopic: Rehabilitation; Disease: Device used

Interventions
Patients are likely to be approached about the study in hospital or a clinic following a stroke but the rest of the study will take place in their own homes, except for the 6 week and 6 months follow-up visits which can take place either in patients home, or in outpatient clinic or research unit at the convenience of the participant. The WiiTM game and console will be lent to 120 participants to use at home with their own TV to exercise their arm for six weeks. The other 120 will be taught personalised arm exercises. Both groups will be asked to exercise daily for six weeks. There are questionnaires & simple, painless tests at the start, after six weeks and again after six months. Twenty five of the participants who have a WiiTM for six weeks may be asked for a further interview to make sure the researchers understand fully how using the WiiTM affected their condition. In all cases, the study should last no more than six months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Arm strength and function as measured by the Action Research Arm Test at six weeks

Key secondary outcome(s))
Not provided at time of registration

Completion date
31/07/2013

Eligibility

Key inclusion criteria
1. Clinical diagnosis of new stroke within the previous six months at time of consent
2. Aged 18 years or older
3. Participants living at home at the start of their participation in study with suitable home environment (consider enough space, plus suitable TV, electricity supply and telephone)
4. Weakness in the dominant arm Medical Research Council (MRC) scale less than 5 in any joint plane of movement) due to stroke

6. Able to manipulate WiiTM remote control
7. Able to understand and follow two stage commands and able to give written or verbal consent
Target Gender: Male & Female ; Lower Age Limit 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Comorbidity which impairs ability to participate (e.g. severe arthritis, severe cognitive impairment, severe cardiorespiratory
disease)
2. Hemianopia or visual inattention
3. Concurrent participation in another interventional study
4. Pacemaker or Implantable cardioverter defibrillator (ICD) device (possible interference from the WiiTM)
5. In, or likely to be discharged to, long term care

Date of first enrolment
01/11/2011

Date of final enrolment
31/07/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Treliske
Truro
United Kingdom
TR1 3LJ

Sponsor information

Organisation
Royal Cornwall Hospitals NHS Trust (UK)

ROR
https://ror.org/026xdcm93

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit Grant (ref. pb-pg-0110-20332)

Results and Publications

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	01/03/2015		Yes	No
Results article	results	01/02/2017		Yes	No
Protocol article	protocol	09/10/2014		Yes	No