

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

<b>Submission date</b> 25/11/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 25/11/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/03/2016	<b>Condition category</b> Circulatory System	<input type="checkbox"/> 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 Wii™ for six weeks in addition to their usual rehabilitation programme. We want to find out if using the Wii™ 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 Wii™ 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 Wii™ for 6 weeks may be asked for a further interview so that we can understand fully how using the Wii™ 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  
katja.adie@rcht.cornwall.nhs.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Katja Adie

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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 Wii™ 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

**Secondary study design**

Randomised controlled 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**

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 Wii™ 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 Wii™ for six weeks may be asked for a further interview to make sure the researchers understand fully how using the Wii™ affected their condition. In all cases, the study should last no more than six months.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Arm strength and function as measured by the Action Research Arm Test at six weeks

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/11/2011

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 240; UK Sample Size: 240

**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**

England

United Kingdom

**Study participating centre**

Treliske

Truro

United Kingdom

TR1 3LJ

## **Sponsor information**

**Organisation**

Royal Cornwall Hospitals NHS Trust (UK)

**Sponsor details**

Treliske

Truro

England

United Kingdom

TR1 3LJ

**Sponsor type**

Hospital/treatment centre

**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

**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?
<a href="#">Protocol article</a>	protocol	09/10/2014		Yes	No
<a href="#">Results article</a>	results	01/03/2015		Yes	No
<a href="#">Results article</a>	results	01/02/2017		Yes	No