ISRCTN42229581 https://doi.org/10.1186/ISRCTN42229581

Wii STAR - Wii Stroke Therapy for Arm Rehabilitation

Submission date	Recruitment status	[_] Prospectively registered
28/03/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/04/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/03/2018	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02637791

Secondary identifying numbers
10057

Study information

Scientific Title
A low cost virtual reality system for home based rehabilitation of the upper limb following stroke

Acronym
Wii STAR

Study objectives
Stroke is the third most common cause of mortality and the leading cause of long term disability worldwide (Mackay & Mensah, 2004), with over 900,000 people living in England who have had a stroke (National Audit Office, 2005). 75% of survivors regain their ability to walk again, however a considerable proportion (estimates range between 55 and 75%), fail to regain functional use of their impaired upper limb (Feys et al., 1998). Upper limb motor impairment limits the individuals functional autonomy and activities of daily living, impacting negatively on participation and quality of life (Nichols-Larsen, 2005).

Current rehabilitation for the upper limb has been criticised for lacking the intensity the evidence suggests is necessary for optimal recovery, as in practice the intensity and duration of therapy is limited by resources. Therefore we propose to evaluate the feasibility of home-based Virtual Reality (VR) rehabilitation using a low cost commercially available system as a means to provide exercises to improve upper limb function in patients recovering from a stroke. The VR system tracks infrared light emitting diodes (LEDs) positioned on the fingers: a virtual glove. This translates the actions of reach, grasp and release into game play. The feasibility study involves a two group single blind randomised control design will allow a comparison of changes from baseline to post intervention between the intervention group (virtual glove) and a control group.

It is our future intention to carry out a definitive study to determine the effectiveness of the home-based VR rehabilitation system; before this can be done certain crucial information needs to be collected in order to reach the correct design for the main study. The current study is therefore to determine the feasibility of the main study and to pilot whether the components of the main study can all work together. The study will follow the MRC guidelines for feasibility and pilot testing from the framework for evaluating complex interventions to carry out the primary objectives below.

To further evaluate the feasibility of this VR rehabilitation, a nested qualitative study with the intervention group and with therapists will be conducted. Stroke service providers and commissioners will be interviewed to explore potential barriers and facilitators to the future implementation of the intervention. We will examine feasibility to inform a larger future trial and compare upper limb recovery between both groups to provide initial evidence of effectiveness.

Primary objectives:
1. To develop three games for the virtual glove designed to enhance upper limb function post stroke
2. To evaluate the feasibility of a definitive Randomised Control Trial (RCT) to determine the effectiveness of home use of the virtual glove to improve upper limb function in patients

recovering from a stroke
3. To pilot the components of a definitive study to ensure recruitment, randomisation, treatment, and follow-up assessments are all possible
4. To evaluate feasibility and acceptability to both patients, carers and therapists of the home based VR systems for upper limb rehabilitation in terms of the barriers and facilitators they perceive to the appropriate level of use
5. To understand the organisational, practical and economic barriers to implementation of virtual reality based rehabilitation technologies into community rehabilitation services
6. To develop a user friendly manual for the system incorporating detailed instructions for users, carers and therapists with helpline availability

Secondary objectives:
1. Can we develop games that are acceptable to patients and encourage practice of the movements that underlie activities of daily living?
2. Can we identify patients for whom this would be suitable and recruit sufficient participants?
3. Are potential participants happy to be randomised to one group or the other and can we retain those assigned to the control group thus collecting a complete set of outcome measures from them?
4. Can we provide them with a system that is acceptable to both patients and carers, is easy to set up and use, is reliable and encourages them to play the games at the frequency recommended in the literature for benefits to upper limb function?
5. Do they use the system at the recommended frequency?
6. How much therapist support is needed to train patients and their carers to use the equipment correctly?
7. Can we gather information from the outcomes and drop outs from either group to allow the calculation of the required sample size for a definitive study?
8. What do participants, carers and therapists see as the barriers and facilitators to usage and adoption of such an intervention?

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Nottingham Research Ethics Committee 1, 28/09/2010, Ref: 10/H0403/72
2. A substantial amendment has subsequently been made (our ref/amendment number SA01/11) which was approved by the above committee on 09/02/2011

Study design
Single-centre feasibility study. Two-group single-blind randomised controlled 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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Stroke Rehabilitation

Interventions
Control Group:
Patients in the control group are to receive normal care but will receive no direct intervention from the research team

Intervention Group:
1. Patients will be invited to start the trial six weeks post stroke or once they have returned home, whichever is later and once all other rehabilitation has stopped
2. Patients will be randomly allocated to either the intervention group or the control group by the Clinical Trials Unit (CTU) at the University of Nottingham
3. Patients in the intervention group will receive the virtual glove and games in their homes for a period of 10 weeks
4. In order to achieve the recommended exposure time of 60 hours (Kwakkel et al, 2004) they will be advised to use the system for 20 minutes 3 times a day for 10 weeks to make allowance for missed days or missed sessions
5. An upper threshold for usage of the system will be advised in order to avoid excess exercise of the upper limb
6. Participants will be given sufficient training by the studys Research Therapist (RT) who will subsequently be available to help with any problems that may arise
7. Equipment for intervention group:
7.1. Virtual glove
7.2. Two Nintendo Wii remotes mounted either side of a PC monitor track infrared light emitting diodes (LEDs) mounted on the finger tips using a specially designed glove
7.3. The glove consists of a hand-mounted power unit, with four wired diodes mounted using hook and loop tape on the users finger tips. This system enables the capture of not only the location of the users hand in 3D space but the position of their fingers and thumb
7.4. This will allow the simulation of reach to grasp, grasp and release and rolling motions of the wrist in the games
7.5. In patients homes the games will be displayed on a 24 flat screen monitor
7.6. A suite of 3 games will be provided based on suggestions received from the Nottingham Stroke Research Consumer group and participants in the pilot study that would involve frequent repetitions of upper limb movements (i.e. pull, push, reach, grasp) that are necessary to effect many activities of daily living. Each game will have different levels varying in the standard of the movement required to achieve a score, the speed at which events occur and with which responses are required as well as in complexity of challenge in order to keep the participants motivated to continue to use the system but to ensure that they can achieve some success. Participants scores will be displayed on the screen at the end of a game and there will be a permanent visual display of their progress in terms of scores and levels played.
8. A log of when the system is in use will be collected by the computer as well as what games are being played and what scores the user obtains
9. In order to distinguish between use by the participant and use by any other friends or relatives, a user will be required to enter a code number before they can play so that only the performance metrics of the participant will be logged in the database

Procedure:
1. Four sets of the virtual glove system will be produced
2. The design has already been through several iterative cycles involving users as recommended by USERfit methodology (Poulson, Ashby & Richardson, 1996)
3. The games will be completed and piloted with the Nottingham Stroke Research Consumer Group, patients on the stroke unit and community stroke therapists
4. The data capture software will be produced

Recruitment:
1. The recruitment officer will liaise with staff on the Stroke Unit at Nottingham City Hospital to identify potential participants (i.e. those with some residual movement in the upper limb, no pre-morbid disability in their upper limb function and the ability to follow a two stage command).
2. The initial approach to potential participants will come from a member of the patients usual care team
3. Before they are discharged the recruitment officer will then discuss the study with them 4. They will be asked for permission to be contacted at home by the research team following their discharge and given a study information pack containing:
4.1. An invitation letter asking them if they are still experiencing upper limb problems and inviting them to take part in the study
4.2. An information sheet explaining the study
4.3. A consent form
5. Once discharged, those patients who had been given Information packs will be contacted to arrange a home visit by the Research Associate (RA) to establish that they continue to meet the inclusion criteria to answer any queries they may have, obtain their signature on the consent form and to collect baseline assessments and record any rehabilitation they have already received and other individual information such as:
5.1. Who they live with if anyone
5.2. Whether they have used computers before
5.3. Whether they have any regular commitments that might preclude use of the equipment on some days
6. Participants will also be asked if they are involved in any other current research or have recently been involved in any other research as part of the recruitment screening
7. Prior enrolment in a previous study will not necessarily preclude their enrolment in this research as they may have been involved in medical trials only and not rehabilitation based trials.
8. Establishing what research, if any, patients have previously been involved with will be important to determine if it is appropriate for participants to be included within this study
9. This will also take into account research fatigue of potential participants
10. Those still meeting the inclusion criteria will be randomly allocated to either the intervention or the control group by the CTU at Nottingham University
11. For those assigned to the intervention group, a visit will be arranged to deliver the equipment, set it up and for the research therapist (RT) to demonstrate its use to the participant and their carer
12. The RT will then use the equipment with the participant and then observe them using it independently
13. The RT will then arrange to return within the next two or three days to repeat this demonstration
14. If after this visit the RT feels that the participant has understood how to use the equipment or that there is a carer who understands how to use it, the intervention can commence and the RT will phone the participant after two days to check that they have been able to use the equipment in its intended manner and offer to visit once more to clarify any outstanding matters.
15. If they still seem unsure of how to use it by the end of the second visit the RT will arrange to

visit again in the next 48 hours
16. The RA will then visit fortnightly to retrieve data and check progress
17. The participant will be given a phone number on which a member of the research team can be contacted during working hours if they need any advice or if the equipment fails
18. A record of how many demonstration visits took place and the number and type of requests for help will be recorded as well as the number of extra visits and notes kept of any queries or problems that are raised in each visit or phone call
19. After approximately five weeks all participants will be visited at home by a RT not known to the participant to administer the outcome measures to ensure data are collected from participants who may not continue with the study for the complete period of ten weeks
20. Although the RT will not have had previous contact with the participant it will be difficult to ensure that they do not know to which group the participant belongs: the equipment may be visible in their home and they may wish to talk about it.
21. At the end of the intervention the equipment will be collected from the participants homes by the RA who will conduct a short semi-structured interview with the participant and any carers to determine their experience of using the equipment, barriers to using it in the recommended way and to the recommended levels.
22. Interviews will be audio recorded
23. All participants would be assessed at 10 weeks post randomisation by a RT blind to the group allocation of patients
24. For participants allocated to the control group, they will only have the outcome measures taken as outline for the intervention group

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Wolf Motor Functions Test (WMFT) (Wolf et al, 1989) this is a measure of upper limb functioning that gives both joint specific and total limb information
2. Patients complete 17 timed tasks ordered in terms of complexity involving simple limb movement (such as flipping over cards). It is an outcome measure used in most comparable studies
3. This will be taken at baseline, 5 weeks and 10 weeks (end of intervention period) for both the intervention and control group

Secondary outcome measures
1. Nine-Hole Peg Test (Kellor et al, 1971) - a timed test of fine motor co-ordination. Patients place 9 pegs from a container into a wooden block with 9 empty holes one at a time, once completed the patients then have to remove the pegs and place them back in the container as quickly as possible
2. Nottingham Extended Activities of Daily Living (NEADL) (Nouri & Lincoln, 1987) this is a measure of functional ability that is commonly used in studies of stroke rehabilitation
3. It has four subscales:
3.1. Mobility
3.2. Kitchen tasks
3.3. Domestic tasks
3.4. Leisure activities measured on a Likert scale (0 = not at all, to 3 = on your own easily).
4. Motor Activity Log (MAL) (Taub et al, 1993, 1996) - a structured interview in which participants

are asked a set of standardised questions aiming to examine the extent of (amount of use), and quality of use of their affected upper limb during 30 common ADLs outside of a laboratory or clinical setting. Participants indicate their responses on two set rating scales.
5. These will be taken at baseline, 5 weeks and 10 weeks (end of intervention period) for both the intervention and control group
6. For the intervention group the frequency of use of the equipment will be collected by the software and the frequency of requests for help and type of queries when using the equipment will be logged by the research team to provide information on feasibility of using the equipment and aspects of the intervention that may influence its adoption

Overall study start date
01/09/2009

Completion date
30/09/2013

Eligibility

Key inclusion criteria
1. Aged 18 or over
2. Have a confirmed diagnosis of their first stroke
3. Are no longer receiving any other rehabilitation therapy (community stroke team, intermediate care, early supported discharge)
4. Have residual upper limb dysfunction

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
The target number of participants is 60; 30 in the intervention arm of the trial and 30 in the control arm.

Key exclusion criteria
1. Patients with no detectable movement in the upper limb as research has shown (Parry et al, 1999) that these patients cannot benefit from rehabilitation
2. Patients with pre-morbid disability in upper limb function
3. Patients unable to follow a two stage command
4. Patients living in a care home as their compliance is likely to be compromised by additional factors that would make results difficult to interpret
5. Patients with any of the following:
5.1. Severe symptomatic arm/shoulder pain

5.2. Severe visual impairments
5.3. Other neurological illnesses such as head injury or multiple sclerosis
5.4. Unstable medical condition
5.5. Psychiatric illness
5.6. Epilepsy triggered by screen images
5.7. Cardiac pacemaker
6. Patients unable to tolerate sitting in a chair for 30 minutes
7. Patients unable to complete a baseline test on the VR system (intervention group only)

Date of first enrolment
01/09/2009

Date of final enrolment
30/09/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Nottingham
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
The University of Nottingham (UK)

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Sponsor type
University/education

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
This study is being conducted by CLAHRC-NDL (Collaboration for Leadership in Applied Health Research and Care - Nottinghamshire, Derbyshire and Lincolnshire).

Funder Name
This is an applied health research partnership, funded by the National Institute for Health Research and one of only nine across England.

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	01/03/2017		Yes	No