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Augmented visual feedback with gait training in sub-acute stroke

Submission date
14/06/2011

Recruitment status
No longer recruiting

Registration date
21/09/2011

Overall study status
Completed

Last Edited
27/09/2018

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
This study aims to address the following question: will providing stroke survivors with a visual representation of how they move during rehabilitation improve their walking ability?
Two thirds of stroke survivors encounter problems in walking after stroke. This can have a strong impact on their independence. We propose to use a rehabilitation aid that will improve walking ability after stroke by providing visual feedback (VF) of survivors movement performance. Currently used methods of providing VF involve mirrors or video footage. However, neither method is optimal for stroke survivors as they can be distracted by their appearance, confused by mirror images, or are unable to observe their movement adequately. Our rehabilitation aid proposes to provide VF without such distractions.

Who can participate?
Adults within 3 months of stroke onset, who have been discharged from hospital in NHS Lanarkshire are be eligible for this trial. Participants must be able to walk short distances with a walking aid and supervision if required.

What does the study involve?
We will record the participants walking movements using motion analysis technology. This involves using video cameras to track the position of small reflective markers placed on the participants legs and pelvis. The use of this technology will provide the movement data required to create the visual representation. Our proposed visualisation comprises of a sticklike figure that we will show to patients on a large computer screen. The sticklike figure will be able to mimic the motion of the user either in real-time or post hoc, depending on the task. This will provide participants with simple yet meaningful feedback of their movement performance. We anticipate that such feedback will give stroke survivors an improved understanding of their rehabilitation and, in turn, enhanced mobility outcomes.
We will compare the effects and experiences of 3 groups of stroke survivors: a control group, a group that receives gait training, and a group that receives gait training with our VF method. Participants standard care will not be affected. Gait training will consist of 1 hour sessions, twice a week for 6 weeks. Assessments will be taken before and after the study to assess the effect of VF on mobility outcomes. Each participant will be involved in the trial for a total of 6 months.

What are the possible benefits and risks of participating?
The risks of this study are not felt to be any greater than those associated with standard care.

Where is the study run from?
University of Strathclyde (UK)

When is study starting and how long is it expected to run for?
September 2011 to March 2013

Who is funding the study?
This study is funded by the Medical Research Council under the research programme Lifelong Health and Wellbeing (LLHW).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Augmented visual feedback of biomechanical movement performance to enhance walking recovery after stroke: a pilot randomised controlled trial

Study objectives
Can visualisation of biomechanical movement performance during rehabilitation enhance mobility outcomes after stroke?

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland Research Ethics Committee 4 approved on 26 April 2011, Ref: 11/AL/0184

Study design
Single blind single centre randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
1. All participants to have baseline gait measurements
1.1. This will involve recording participants walking over a high contrast grid mat whilst wearing small bullseye markers on their lower body
1.2. Video footage will allow for assessment of clinical outcomes and temporal and spatial parameters
2. Impairment levels of memory, attention and neglect will also be assessed
3. Randomisation: participants will randomised into 1 of the 3 following arms:
3.1. Control: usual routine standard care (SC) only
3.2. Placebo: SC + gait training
3.3. Experimental: SC + gait training with augmented visual feedback
4. Gait training in the placebo and experimental groups will consist of a selection of pre-designed walking related exercises, from which the study therapist will be able to choose depending on the individual participants level of impairment
5. 3D motion analysis will be used to measure the movements of both groups, however only the experimental group will be provided with feedback
6. Augmented visual feedback will be in the form of a stick-like figure that will mimic the movements of the participant
7. This will allow the participant to see how they move, either in real-time or post hoc, during walking and related exercises

Intervention period:
1. Participants in the placebo and experimental groups will attend their respective gait training sessions twice a week for 6 weeks
2. Each session will last 1 hour
3. Participants in the control group will be expected to attend their usual routine care only
4. 6 week measures: All patients to have gait measurements as described for baseline
5. 6 month measures: All patients to have gait measurements as described for baseline
6. A questionnaire will also be given to assess the participants experiences of the study
7. Participants will be involved in the study for 6 months in total

Intervention Type

Other

Phase
Not Applicable

Primary outcome(s)
Walking speed (time taken to complete 5m walk test)

Key secondary outcome(s))
1. Functional ambulation classification
2. Timed up and go
3. Rivermead visual gait assessment
4. Temporal and spatial parameters associated with walking
5. Stroke impact scale-16
6. Adherence (attendance and drop-out rate)
7. Safety (number and nature of adverse events)

Completion date
01/03/2013

Eligibility

Key inclusion criteria
1. Patients in early supported discharge (ESD) service with clinical diagnosis of stroke
2. In sub-acute stage of stroke (up to three months from time of onset)
3. Aged more than or equal to 18 years
4. Exhibit an abnormal gait pattern
5. Able to walk with/without assistance Functional Ambulation Categories (FAC) score 1 or more
6. Medically stable and hence suitable for physical mobility rehabilitation
7. Able to understand and follow simple instructions
8. Able to give informed consent when assisted to do so with suitable communication aids if required

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria

1. Severe visual or cognitive problems precluding participation study
2. Pre-existing lower limb deficits or any other medical comorbidities which interfere significantly with gait
3. Involved in any other research trials

Date of first enrolment
01/09/2011

Date of final enrolment
01/03/2013

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Bioengineering
Glasgow
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Sponsor information

Organisation
University of Strathclyde (UK)

ROR
https://ror.org/00n3w3b69

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)- Lifelong Health and Wellbeing (Phase 2) Ref number: G0900583, Grant ID: 91021

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?
Protocol article	protocol	11/09/2012		Yes	No
Abstract results	Results	01/06/2014		No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes