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Augmented visual feedback in upper limb stroke rehabilitation

Submission date	**Recruitment status**	[X] Prospectively registered
10/08/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/09/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
02/10/2017	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
A stroke is a serious, life-threatening medical condition that occurs when the blood supply to part of the brain is cut off. Many stroke survivors have limited arm function, decreasing their independence and quality of life. Rehabilitation to encourage functional arm recovery is based on practice of everyday tasks and feedback. Visual feedback is known to support relearning and is already used by therapists with the aid of mirrors or video. However, neither method is optimal as both rely on subjective observation rather than an accurate analysis of the patient's movement. Stroke survivors can also be distracted or distressed by their appearance. In this study we propose to provide improved visual feedback by recording a patient's arm movements using motion capture technology to create a stick-like figure that will mimic the patient's movements on a computer screen. The simple feedback will highlight the success and quality of those movements. The aim of this study is to assess the effectiveness of this additional visual feedback as part of stroke rehabilitation.

Who can participate?
Adults aged 18 or over up to 3 months from time of onset of stroke and with limited arm function

What does the study involve?
Participants are randomly allocated into one of three groups. The first group receive the usual therapy that would be provided from the Early Supported Discharge (ESD) team. The second group receive arm therapy focusing on reach and grasp, the same exercises as for the third group but without visual feedback. This takes place at a community-based clinic, one hour twice a week for six weeks, in addition to standard care. The third group receive one hour of enhanced arm therapy with improved visual feedback twice a week at a community-based clinic for 6 weeks, in addition to any standard care. All participants are followed up for 6 months.

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

Where is the study run from?
University of Strathclyde (UK). Participants are recruited at discharge from acute stroke wards across NHS Lanarkshire

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

Who is funding the study?
Lifelong Health and Wellbeing (LLHW): a cross-research council initiative in partnership with the UK health departments and led by the Medical Research Council (MRC) (UK)

Who is the main contact?
Lucy Jones
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Study website
http://www.envisagerehab.co.uk/content/wp4a-envisage-stroke-rehabilitation-upper-limb

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
G0900583

Study information

Scientific Title
The impact of augmented visual feedback in upper limb rehabilitation in sub-acute stroke: a pilot randomised controlled trial

Study objectives
Does the use of augmented visual feedback of biomechanical movement performance in upper limb rehabilitation improve functional outcomes after stroke?

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS West of Scotland Research Ethics Committee 2, 15/06/2011, REC ref: 11/AL/0260

Study design
Interventional single-blind single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Interventions
Stroke patients with upper limb impairments who meet inclusion criteria will be randomised into one of three groups:

1. Control group: This is standard care (SC) only and is usual therapy that would be provided, i.e. from the Early Supported Discharge (ESD) team.
2. Placebo group: Upper limb therapy focusing on reach and grasp, the same exercises as for the intervention group but without visual feedback. This will take place at a community-based clinic, one hour twice a week for six weeks, in addition to any received SC.
3. Intervention Group: One hour of enhanced upper limb therapy twice a week at a community-based clinic for 6 weeks, in addition to any SC. During the sessions patients will receive augmented visual feedback during upper limb exercises.

Intervention Type
Behavioural

Primary outcome measure
Arm function assessed by the Action Research Arm Test (ARAT) at baseline, six weeks and six months

Secondary outcome measures
1. Kinematic (temporal and spatial parameters) assessment measured using sensors worn during a section of the ARAT
2. Hand function measured by the 9 Hole Peg Test
3. Stroke Impact Scale - to evaluate quality of life and disability changes
Measured at baseline, six weeks and six months

Additional outcome measures:
1. A patient and therapist questionnaire at 6 weeks to assess the acceptance of the visualisation system from their perspective
2. The safety of intervention assessed by number and nature of adverse events at end of intervention period and at follow up
3. Acceptance of the visualisation system will be assessed by withdrawal or dropout rates from study

Overall study start date
01/10/2011

Completion date
01/04/2013

Eligibility

Key inclusion criteria
1. Aged more than or equal to 18 years
2. Clinical diagnosis of stroke
3. Sub-acute stage of stroke (up to three months from time of onset of stroke)
4. Some movement in affected arm and/or hand - Action Research Arm Test (ARAT) score of 4-56 (57 max score)
5. Medically stable hence suitable for physical rehabilitation
6. Ability to understand and follow simple instructions
7. Able to give informed consent when assisted to do so with suitable communication aids

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
45

Key exclusion criteria
1. Pre-existing upper limb deficits
2. Bilateral arm impairments
3. Severe visual or cognitive problems precluding participation in study protocol
4. Involved in any other intervention study

Date of first enrolment
01/10/2011

Date of final enrolment
01/04/2013

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
University of Strathclyde
Glasgow
United Kingdom
G4 0NW

Sponsor information

Organisation
University of Strathclyde (UK)

Sponsor details
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Sponsor type
University/education

Website
http://www.strath.ac.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

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