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Home based reach to grasp training after stroke

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Registration date 20/10/2011	**Overall study status** Completed	
Last Edited 29/10/2018	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
This initial study is a preparation for a larger study that will answer the question 'Is task-specific training for reach-to-grasp at home, more effective than the standard care given to the patient with poor arm function following stroke'. This is an important study because:
1. Reach-to-grasp (reaching to grasp an object) is the most common arm activity we do in everyday life, so it is very important to find treatments which can give people the ability to do this movement after stroke
2. More treatment is being given to people in their homes, because they have shorter length of stay in hospital, but we do not yet know if arm treatment is effective when delivered at home
3. There is not currently enough evidence to know whether task-specific training is an effective treatment for the arm after stroke

Task-specific training involves the practice of either whole or part movements of the arm, which are as much like the actual movement as possible but the physiotherapist can make the movements easier according to the ability of the patient.

We will design a treatment manual that describes the principles of task-specific training, and a menu of all the training ideas a therapist could use to train certain movements in a task-specific way. The manual will include ideas for practice of the whole movement, and for parts of reach-to-grasp such as opening the fingers and thumb.

This study aims to:
1. Describe the treatment for both standard care and task-specific reach-to-grasp therapy
2. See if people with stroke find the task-specific training acceptable
3. Find out how many people we can recruit into the study
4. Measure how many people complete the training programme
5. To calculate how many people will be needed in a larger trial
6. Gather the opinions of participants about how the trial was conducted and the treatment they received.

Who can participate?
People who live in Bristol, North Bristol, South Gloucestershire and North Somerset can be considered for the study if they:
1. Have had a stroke in the last 12 months

2. Have been discharged home (i.e. permanent address, may include care home/sheltered accommodation)
3. Are not able to pick up a small ball bearing from the table top, between index finger and thumb, and place it on shelf above a table

People will not be able to join the study if any of the following apply
1. Their arm or hand movement is affected because of other conditions like arthritis
2. The person doesn't have any arm movement at all, so that they are not able to lift their hand off their lap
3. They have a very stiff or tight arm or fingers so that the joints cannot be easily moved by someone else
4. More than 12 months have passed since the stroke

What does the study involve?
The participants will be randomly placed in either to 'reach to grasp' training at home or 'standard care'. In standard care the number of times and content of physiotherapy is variable according to the individual's circumstances and the range of community services available but on the whole it is not intense. Participants in the 'reach to grasp' training group will receive 14 hours of treatment from the therapist over six weeks and will also be asked to practice exercises for up to an hour a day.

Assessments to measure arm and hand use will take place when participants join the study, six weeks later and then again at 3 months and 6 months. At these later visits the researcher will also ask questions to find out participant's views of the therapy received and how they have used various health and social services.

What are the possible benefits and risks of participating?
The reach to grasp training may improve arm and hand function and participants may also benefit from the contact with the research physiotherapist and research nurses.

At present, we do not know if Reach to Grasp training is any better than standard care and we cannot guarantee that it will help anyone. The information we get from this study is to help us to develop better treatment for future patients with poor arm and hand movements after stroke. It is important to be aware that:
1. The reach to grasp training is quite intensive; some people might find the number of visits to the house difficult
2. The physiotherapy treatments being tested in this study are not known to produce any harm. Unfortunately some people develop shoulder or hand pain after stroke and this happens to people who receive physiotherapy as well as to those who don't.

Where is the study run from?
The study is being organised by Dr Turton who is an Occupational Therapist and a Senior Research Fellow from the University of the West of England, Bristol. It is hoped that 60 people who live in Bristol, South Gloucestershire or North Somerset will be able to take part in the study over the course of a year. These people will be referred by NHS therapists who have been working with them.

When is study starting and how long is it expected to run for?
The study commenced on the 13 June 2011 and will continue for 26 months. Recruitment started in December 2011 and will continue for 15 months.

Who is funding the study?
The Stroke Association UK

Who is the main contact?
Dr Ailie Turton
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
9226

Study information

Scientific Title
Pilot randomised controlled trial of home based reach to grasp training after stroke

Study objectives
Following a stroke, up to 85% of people experience lasting impairments of their arm, which may affect daily activities, such as grooming and food preparation. There is a clear need to improve arm rehabilitation after stroke. Research on skill learning and neuroscience suggests that task specific practice could be an effective method for improving the use of the arm. This means that the person practices their target task in the manner and context and with the objects they use in everyday life.

A recent high quality review of the literature concluded that there is insufficient evidence to recommend task specific training for the arm after stroke. The most common arm movement needed in everyday life is to reach to grasp objects. Therefore it is important to know the effect of arm training on this action in particular. Also, arm rehabilitation is usually provided in the home, but there is little evidence to show that arm treatment at home is effective. A randomised controlled trial is therefore needed to investigate whether task specific training at home is an effective treatment to improve reach to grasp. Prior to conducting such a trial, information is needed about the treatment itself: detailed description, acceptability to patients, and about the practicalities of running such a trial: e.g. recruitment rates, matching treatment intensity, sample sizes

This study is a pilot single blind randomised controlled trial to gather the information needed to plan a subsequent definitive trial. Over a period of 6 weeks, participants allocated to the intervention group will receive 14 hours task specific reach to grasp training at home with up to 40 hours of guided self practice. Those allocated to the control group will receive usual care. Upper limb function will be assessed at baseline, at 6 weeks, 3 months and 6 months after baseline.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West Research Ethics Committee (UK), 03/02/2011, ref: 10/H0102/83

Study design
Interventional randomised controlled trial

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
Stroke Research Network, rehabilitation - a community study

Interventions
Reach to grasp training
Task-specific training involves the practice of either whole or part movements, which are as much like the actual movement as possible. The exercises are graded according to the participants ability.

Intervention Type
Behavioural

Primary outcome measure
Action Research Arm Test measured 6 weeks after baseline assessment is primary time point. Assessed again at 3 and 6 months after baseline.

Secondary outcome measures
1. Motor Activity log measured 6 weeks after baseline and 3 & 6 months after baseline
2. Stroke Impact Scale measured 6 weeks after baseline and 3 & 6 months after baseline
3. Wolf Motor Function Test measured 6 weeks after baseline assessment and 3 & 6 months after baseline

Overall study start date
01/11/2011

Completion date
31/12/2012

Eligibility

Key inclusion criteria
A participant may enter the study if ALL of the following apply:
1. Diagnosis of stroke
2. Patient discharged home (i.e. permanent address, may include care home/sheltered accommodation)
3. Has remaining upper limb movement deficit defined as being unable to pick up a 6mm ball bearing from the table top, between index finger and thumb, and place it on a shelf 37 cm above table
4. Informed written consent

Non-English speakers will be included with the aid of family or friends to translate. Aphasic patients will be included because the trial steering committee knows from previous clinical experience that task-specific training can be delivered to aphasic patients via the use of communication other than spoken language (e.g. gestures, strategic use of environmental cues).

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Key exclusion criteria

A participant may not enter the study if ANY of the following apply:
1. Upper limb movement deficits attributable to non-stroke pathology
2. Unable to lift hand off lap when asked to place hand behind head
3. Severe fixed contractures of elbow or wrist (i.e. grade 4 on the modified Ashworth scale)
4. Shoulder pain
5. More than 12 months post-stroke

Date of first enrolment
01/11/2011

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of the West of England
Bristol
United Kingdom
BS16 1QY

Sponsor information

Organisation
University of the West of England (UK)

Sponsor details
Frenchay Campus
Coldharbour Lane
Bristol
England
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BS16 1QY

Sponsor type
University/education

Website
http://www.uwe.ac.uk/

ROR
https://ror.org/02nwg5t34

Funder(s)

Funder type
Charity

Funder Name
The Stroke Association (UK)

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?
Protocol article	protocol	25/04/2013		Yes	No
Results article	results	01/07/2017		Yes	No