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Clinical efficacy of functional strength training for upper limb motor recovery early after stroke: neural correlates and prognostic indicators

Submission date
12/09/2012

Recruitment status
No longer recruiting

Registration date
13/09/2012

Overall study status
Completed

Last Edited
02/10/2018

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Weakness of the arm and hand after stroke affects peoples' everyday lives. Some treatments may be beneficial but this largely depends on a patients ability to actively participate in repetitive practice of everyday (functional) tasks. Patients with substantial weakness may not be able to do this. We know that the recovery of the central nervous system (CNS) after stroke involves reorganisation of nerve networks in the brain and spinal cord. We do not yet know how to use physical therapies to encourage beneficial reorganisation to improve outcomes after stroke. We also do not know which stroke survivors should receive which physical therapies. This study will investigate whether a new therapy (functional strength training - FST) can reduce weakness and improve outcomes for patients.

Who can participate?
Adults aged 18 or over between 2-60 days after stroke when they provide informed consent.

What does the study involve?
In addition to receiving conventional physical therapy (CPT), all participants will be randomly allocated to receive 6 weeks of FST or movement performance therapy (MPT), up to 5 days per week for up to 1.5 hours per day. We measure the participants ability to use the weaker arm and hand for functional tasks such as lifting a pencil and the ability to produce voluntary contraction of weak muscles against resistance. These measures will be made before treatment begins, after the 6 weeks of treatment, and at 6 months after the stroke. Participants will also undergo brain imaging to define the extent of damage, recovery and activity during hand movement; magnetic brain stimulation to measure how well the brain is connected to weakened muscles of the affected arm and hand; and health economics.

What are the possible benefits and risks of participating?
All participants, whichever extra therapy they receive, may benefit from a more comprehensive assessment of their ability to use their weaker arm and hand than is available in routine clinical

practice. Also, all participants will receive extra therapy that might enhance recovery of their arm and hand. The results of you having a magnetic resonance imaging (MRI) scan and transcranial magnetic stimulation (TMS) investigation for research purposes may have possible personal benefits. For example, if we discover something that your medical team may benefit from knowing, we will bring it to their attention. This detailed information could provide new information about you. We cannot promise that the study will help you but the information we get from the study may help improve the treatment of people who have survived a stroke. There is a small risk that you may experience some discomfort caused by overworking muscles during the extra therapy. This is caused by natural processes associated with muscle training. If you tell us you are in discomfort we will stop the extra therapy that day. Before all of the assessments we will ask you questions to ensure it is safe for you to proceed. For example, before the MRI scans you will be asked whether you have particular forms of metal in your body. If we think that it is not safe for you to proceed then you will not have that particular assessment. We will make every effort to minimise any risk to you as we follow a range of safety standards and best practice policies.

Where is the study run from?
University of East Anglia, Norwich, Norfolk, England (UK).

When is the study starting and how long is it expected to run for?
The study started in September 2012 and will run until May 2015.

Who is funding the study?
NIHR Efficacy and Mechanism Evaluation (UK).

Who is the main contact?
Mr Andrew Walker
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Study website
http://www.fastindicate.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
12967

Study information

Scientific Title
Clinical efficacy of functional strength training for upper limb motor recovery early after stroke: neural correlates and prognostic indicators

Acronym
FAST INdICATE

Study objectives
Weakness of the arm and hand after stroke affects everyday lives. People with substantial weakness may not be able to participate in proven treatment which requires repeated practice of functional tasks such as pouring water from a jug. The present study will investigate whether a new therapy we have developed called Functional Strength Training (FST) can reduce weakness and thereby improve recovery.
This is a two-group randomised clinical trial in three clinical centres. All 288 participants will receive their conventional physiotherapy (CPT). In addition they will be randomised to receive extra treatment either as CPT or FST. The measures of clinical outcome that will be used to compare the effects of the two extra therapies will be: the ability to use the weaker arm and hand for functional tasks such as picking up a pencil; and the ability to produce voluntary contraction of weak muscles against resistance. These measures will be made before treatment begins, after 6 weeks of treatment and at 6 months after the stroke.
The trial is designed to find whether the benefits of FST justify a subsequent large scale trial. Embedded in the trial are measures to increase understanding of how central nervous system (CNS) recovers after stroke. We know that CNS recovery involves reorganisation of nerve networks in the brain and spinal cord. We do not yet know how to use physical therapies to encourage beneficial reorganisation to improve outcomes after stroke. We also do not know which stroke survivors should receive which physical therapies. To answer these questions we will combine: brain imaging and magnetic brain stimulation to find out how the biological mechanisms underpinning arm use change over time in the two groups of participants and whether these changes are associated with improvements in the ability to perform everyday tasks.

More details can be found at http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=12967

Ethics approval required
Old ethics approval format

Ethics approval(s)

Norfolk Research Ethics Committee, 22/02/2012, ref: 11/EE/0524

Study design
Randomised interventional 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

Interventions
Protocol-driven Conventional Physical Therapy (CPT) emphasises a therapist facilitating movement (therapist-dependent) whereas Functional Strength Training (FST) involves repetitive progressive resisted exercise during goal-directed functional activity (therapist independent). Experimental FST and CPT will be delivered by different research therapists for up to 1.5 hours a day for 6 weeks. All participants will continue to receive routine CPT delivered by clinical therapists.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Primary efficacy measure is change in the Action Research Arm Test (ARAT) from pre-treatment, measured at baseline

Secondary outcome measures
1. Wolf Motor Function Test (WMFT)
2. Hand grip Force and Pinch Grip Force

Overall study start date
17/09/2012

Completion date

16/05/2015

Eligibility

Key inclusion criteria
Current inclusion criteria as of 02/08/2013:

1. Adults aged 18+ years
2. 2-60 days after stroke
3. Have a cerebral infarction in anterior cerebral circulation territory, cortical and/or subcortical, confirmed by clinical neuroimaging
4. Have obvious motor dyspraxia or communication deficits as assessed by ability to imitate action with the nonparetic upper limb
5. Have sufficient voluntary muscle contraction in the paretic upper limb to generate the beginning of prehension i.e score at least 11/33 for Motricity Index pinch section

Previous inclusion criteria:

1. Adults aged 18+ years
2. 14 - 60 days after stroke
3. Have a cerebral infarction in anterior cerebral circulation territory, cortical and/or subcortical, confirmed by clinical neuroimaging
4. Have obvious motor dyspraxia or communication deficits as assessed by ability to imitate action with the nonparetic upper limb
5. Have sufficient voluntary muscle contraction in the paretic upper limb to generate the beginning of prehension i.e score at least 11/33 for Motricity Index pinch section

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 288; UK Sample Size: 288

Key exclusion criteria
1. Able to complete the Nine Hole Peg Test (9HPT) in 50 seconds or less
2. Have obvious spatial neglect
3. Unable, prior to the index stroke, to use the paretic upper limb to lift a cup and drink from it

Date of first enrolment
17/09/2012

Date of final enrolment

16/05/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of East Anglia
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Sponsor information

Organisation
University of East Anglia (UK)

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Sponsor type
University/education

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ROR
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Funder(s)

Funder type

Government

Funder Name
NIHR Efficacy and Mechanism Evaluation (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	01/02/2014		Yes	No
Results article	results	01/06/2018		Yes	No