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Does early targeted trunk training improve mobility outcome at 6 months for patients who are unable to sit unsupported at admission?

Submission date
23/12/2015

Recruitment status
No longer recruiting

Registration date
23/12/2015

Overall study status
Completed

Last Edited
19/09/2016

Condition category
Nervous System Diseases

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
A stroke is a serious condition where the blood supply to a part of the brain is cut off, usually by a blood clot blocking blood flow (ischemia) or a bleed in the brain (intracerebral haemorrhage). The majority of strokes are ischemic strokes, in which the arteries that supply the brain with oxygen (carotid arteries) become narrowed or blocked. Intracerebral haemorrhages (ICH) are much less common than ischemic strokes, and occur when a diseased blood vessel in the brain bursts, causing bleeding which causes a sudden increase of pressure on the brain. One of the most common complications of a stroke is weakness on one side of the body (hemiparesis). This can involve weakness in the arms and/or legs, as well as loss of control over the torso (trunk deficit). Previous studies have shown that in individuals with poor trunk control, such as the ability to sit unsupported (poor sitting balance), are less likely to regain their mobility at six months. Despite this, physiotherapy that specifically targets trunk performance is often neglected during early rehabilitation. It is well recognized that more extensive physical rehabilitation following stroke significantly improves a person's chance of regaining their mobility. Given that trunk function is a good predictor of future mobility, including specific trunk training in early physiotherapy could play an important role. The aim of this study is to look at the effects of providing additional trunk training during early rehabilitation after stroke in order to find out whether a large-scale study would be possible.

Who can participate?
Adults who have suffered a stroke three to seven days previously who are experiencing hemiparesis in the arm and leg and are unable to sit unsupported for 30 seconds (severe trunk deficit). Adults who have suffered a stroke three to seven days previously who are experiencing hemiparesis in the arm and leg and are unable to sit unsupported for 30 seconds and are unable to make their own decisions (lacking mental capacity).

What does the study involve?
All participants undergo 16 additional hours of trunk training over a period of six to eight weeks as well as standard physiotherapy. This involves functional exercises, such as moving in bed, sitting up and standing, as well as exercises designed to strengthen muscles. At the start of the

study, and then again after the trunk training programme and six months later, participants complete a number of questionnaires and movement tests in order to find out whether their condition has improved. The amount of participants who could be recruited to take part is also recorded to find out if it is feasible to conduct a larger study. In a sub-study, ten participants who lack the mental capacity (ability to make decisions) to decide if they want to take part who meet the other inclusion criteria also complete the same training program and follow up assessments, to see if there is any difference.

What are the possible benefits and risks of participating?
Participants benefit from receiving additional therapy sessions which could help to improve their recovery. There are no notable risks of participating, although the extra exercise sessions could make participants feel tired.

Where is the study run from?
Mark ward, St Thomas' Hospital (UK)

When is the study starting and how long is it expected to run for?
December 2015 to June 2017

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
20256

Study information

Scientific Title
Additional Trunk Training in Early Stroke Trial (ATTEST): A mixed method feasibility study

Acronym
ATTEST

Study objectives
The aim of this study is to carry out a study to determine the feasibility and acceptability of delivering additional trunk training during early rehabilitation after stroke for adults with significant trunk weakness 72 hours post stroke.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East of England-Essex NHS committee, 13/11/2015, ref: 15/EE/0317
Significant amendment approved 21/06/2016 (HRA approval received 04/08/2016).

Primary study design
Interventional

Study design
Non-randomised feasibility study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Stroke; Subtopic: Rehabilitation; Disease: Therapy type

Interventions
The patient will receive a minimum of 16 hours of additional trunk training over a 6-8 week period, focussing on strengthening and functional exercises. Specific trunk strength training exercises will be prescribed following an initial assessment of muscle strength. The functional training element will consist of practising functional movements such as bed mobility, lying to sitting, independent sitting, standing and transitions. Sessions will take place daily (as far as possible) and will last for approximately 30 minutes. The training will be in addition to the patient's usual physiotherapy and take place on the stroke ward, in the hospital gym or in the patient's place of residence if discharged from acute care before the training is completed.

Participants will be followed up post intervention and at six months.

Sub-study:
Ten participants meeting the main study inclusion/exclusion criteria as detailed above, but who do not have mental capacity to give informed consent will be recruited to participate in this sub-study. Participants will be assessed for capacity by the research nurse as detailed below to comply with the Mental Capacity Act, 2005. If a participant does not have capacity to consent, a personal or nominated consultee will be sought to make a decision on their behalf in their interest.
All other aspects of the study will be identical to the main study.

Intervention Type
Other

Primary outcome(s)
Feasibility measures of recruitment, retention and attrition will be determined through screening and completion data to measure the number of admitted patients that fulfil the study inclusion/exclusion criteria; consent to take part in the study; complete the trunk training intervention; and complete baseline, post intervention and 6 month follow up assessments of the secondary outcome measures.

Key secondary outcome(s)
1. Trunk impairment is measured using the Trunk Impairment Scale at baseline, post intervention and at 6 months follow-up
2. Mobility is measured using the Modified Rivermead Mobility Index at baseline, post intervention and at 6 months follow-up
3. Quality of life is measured using the Stroke Specific Quality of Life Scale and SF-6D at baseline, post intervention and at 6 months follow-up
4. Quality of life and health costs (QALYs) are measured using the EQ5D-5L at baseline, post intervention and at 6 months follow-up

Completion date
30/06/2017

Eligibility

Key inclusion criteria
Inclusion criteria (updated on 19/09/2016):
1. Aged 18 years or over
2. Between day 3 and day 7 of a supra tentorial lesion associated with an ischaemic or haemorrhagic stroke
3. With hemiparesis involving the arm and leg
4. Able to understand and follow a one-stage command
5. With significant trunk deficit evidenced by an inability to sit independently for 30 seconds
6. Able to provide informed consent in accordance with the Mental Capacity Act (2005)
7. Patients with mild aphasia can be included, the consent procedure will be facilitated using pictorial aphasia-friendly participant information booklets and communication other than spoken language (for example, gestures, strategic use of environmental cues) in line with Connect recommendations
8. Non-English speakers will be included if the aid of an interpreter is available via the NHS

Sub-study:
1. Those meeting inclusion criteria (above)
2. Lacking mental capacity to give informed consent

Original inclusion criteria:
1. Aged 18 years or over
2. Between day 3 and day 7 of a first supra tentorial lesion associated with an ischaemic or haemorrhagic stroke
3. With hemiparesis involving the arm and leg
4. Able to understand and follow a two-stage command
5. With significant trunk deficit evidenced by an inability to sit independently for 30 seconds

6. Able to provide informed consent in accordance with the Mental Capacity Act (2005)
7. Patients with mild aphasia can be included, the consent procedure will be facilitated using pictorial aphasia-friendly participant information booklets and communication other than spoken language (for example, gestures, strategic use of environmental cues) in line with Connect recommendations
8. Non-English speakers will be included if the aid of an interpreter is available via the NHS

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Exclusion criteria (updated on 19/09/2016):
1. Individuals with brainstem or cerebellar strokes associated with severe symptoms of dizziness or positional vertigo exacerbated by exercise. Screening for severe dizziness will be ascertained by the medical staff before recruiting.
2. Clinically significant pre-morbid levels of disability
3. Not medically stable as defined by the medical team

Original exclusion criteria:
1. Individuals with brain stem, cerebellar or multiple stroke lesion
2. Previous neurological disease affecting motor performance
3. Not medically stable

Date of first enrolment
01/02/2016

Date of final enrolment
30/08/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

St Thomas' Hospital
Mark ward
Guy's and St Thomas' NHS Foundation Trust
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	version V2		13/04/2016	No	Yes