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Functional strength training to improve walking and upper limb function in stroke patients

Submission date 12/01/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/01/2009	**Overall study status** Completed	
Last Edited 15/08/2014	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Jane Cross

Contact details
School AHP
University of East Anglia
Norwich
United Kingdom
NR4 7TJ
j.cross@uea.ac.uk

Additional identifiers

Protocol serial number
TSA 2008/08

Study information

Scientific Title
Functional strength training to improve walking and upper limb function in people at least one year after stroke: a phase II trial

Study objectives

The hypothesis is that providing functional strength training (FST) to people who are at least one year after stroke will improve motor function and ability to perform everyday functional activity. The first step towards testing this hypothesis in a definitive phase III clinical trial is to address the following questions:
1. Is there sufficient efficacy to justify subsequent trials of FST for upper and lower limb motor recovery in people at least one year after stroke?
2. Is FST delivered in the community acceptable to stroke survivors one year and more after stroke?
3. What is the probable recruitment rate to a subsequent phase III trial?
4. What sample size is needed for subsequent phase III trial (effect size, attrition rate, response variation)?
5. What cost-effectiveness data should be collected in subsequent trials?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Norfolk Ethics Committee approval pending as of 12/01/2009

Primary study design
Interventional

Study design
Randomised placebo-controlled observer-blind phase II trial with embedded qualitative investigation

Study type(s)
Treatment

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

Interventions
Functional strength training is hands-off progressive resistive exercise during functional activity whilst directing participants attention to the activity being performed and providing appropriate verbal feedback to enhance knowledge of performance. FST is designed to increase ability to produce voluntary muscle force throughout joint range, increase ability to modulate force in muscles/muscle groups appropriate for the activity being trained and improve functional ability. Activities are progressed by increasing the number of repetitions, increasing range of joint motion required and increasing the load to be moved. Intervention will be provided by a Research Physiotherapist for 1 hour/day, 4 days/week. Portable equipment (e.g. free weights and steppers) will be used as appropriate. Participants will be encouraged to use the paretic limb (upper or lower as allocated) in everyday functional activity. Standardised treatment schedules will be used (as in our earlier trials) to record the amount and type of intervention provided (compliance).

FSTLL will focus on functional activities e.g. sit-to-stand using body weight as resistance and progressively lowering the height of the supporting surface as participants improve. Equipment such as portable steppers will be used as appropriate but only with physiotherapy supervision for safety reasons.

FSTUL will focus on reaching for, retrieval of and manipulation (use) of everyday objects for activities such as pouring water from a jug, opening jars and lacing a shoe.

Both treatment schedules will include resistive exercise to strengthen specific muscles/muscle groups where weakness is hampering functional activity. The scientific papers describing these treatment schedules are currently in preparation.

Intervention Type
Other

Phase
Phase II

Primary outcome(s)
1. Functional Ambulatory Category for lower limb function
2. Action Research Arm Test for upper limb function

All measured on days 43 and 88.

Key secondary outcome(s)
1. Modified Rivermead Mobility Index for lower limb function
2. Nine Hole Peg Test for upper limb function

All measured on days 43 and 88.

Completion date
01/03/2012

Eligibility

Key inclusion criteria
1. Adults aged 18 years and above, either sex, one to five years after stroke in anterior circulation (infarct or haemorrhage) not receiving formal therapy for their upper or lower limb
2. Have a walking ability on the Functional Ambulatory Category between 1 and 49 and have some voluntary activity in the paretic upper limb scoring 12+/57 on the Action Research Arm Test but unable to complete the Nine Hole Peg Test in 50 seconds or less
3. Can follow a one-stage command, i.e. sufficient communication/orientation for interventions in this trial

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Known pathology precluding them participating in functional strength training

Date of first enrolment
01/03/2009

Date of final enrolment
01/03/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
School AHP
Norwich
United Kingdom
NR4 7TJ

Sponsor information

Organisation
The Stroke Association (UK)

ROR
https://ror.org/05mgfq941

Funder(s)

Funder type
Charity

Funder Name
The Stroke Association (UK) (ref: TSA 2008/08)

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?
Results article	results	12/08/2014		Yes	No
Protocol article	protocol	01/07/2013		Yes	No