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SWIFT Cast: efficacy and neural-biomechanical correlates of response

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Registration date 18/05/2010	**Overall study status** Completed	
Last Edited 05/12/2017	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Protocol serial number
EME 08/43/25

Study information

Scientific Title
Clinical efficacy of the Soft-Scotch Walking Initial FooT (SWIFT) Cast on walking recovery early after stroke and the neural-biomechanical correlates of response

Acronym
SWIFT Cast

Study objectives
The primary driver for this research is the clinical hypothesis, generated by our pilot work, that an individualised and rapidly produced ankle-foot cast (SWIFT CAST) used in addition to protocol-driven conventional physical therapy (CPT) early after stroke is more cost-effective than protocol-driven CPT alone for walking recovery. The scientific premise driving this research is that detailed understanding of how the central nervous system recovers after stroke will enable physical therapies to be targeted at recovery mechanisms in those stroke survivors most likely to respond. Progress is hampered as the predominant means of investigation, functional magnetic resonance imaging (fMRI), has technological limitations and physical therapies used to investigate the central nervous system have been poorly defined. Neuro-biomechanics together with well-defined physical therapies provides a novel way forward. This research will determine clinical efficacy of a SWIFT CAST, as a precursor to a subsequent phase III trial, and use this and protocol-driven CPT to investigate neuro-biomechanical correlates of clinical improvement.

Specific questions are:
1. Does the use of a SWIFT CAST provided as an adjunct to CPT enhance walking recovery early after stroke more than CPT given alone? (clinical efficacy)
2. What are the biomechanical correlates of clinical improvement in walking in response to SWIFT CAST and protocol-driven CPT? (understanding biological and behavioural mechanisms)
3. Is site of stroke lesion (structural MR) and/or biomechanical characteristics sufficiently predictive of improvement in walking to enable targeting therapy at stroke survivors likely to respond? (new scientific and clinical principles)

In addition, the combination of structural imaging, biomechanics and protocol-driven physical therapy is a novel combination in stroke rehabilitation research and we are therefore also asking:
4. Should neuro-biomechanics and protocol-driven physical therapy be used together with structural neuroimaging to enhance knowledge generated by stroke rehabilitation research? (development/testing of new methodologies)

Link to EME project website: http://www.eme.ac.uk/projectfiles/084325info.pdf
Link to protocol: http://www.eme.ac.uk/projectfiles/084325protocol.pdf

On 15/08/2013 the anticipated end date was changed from 01/09/2013 to 01/12/2012.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Norfolk Research Ethics Committee approved on the 24th December 2009 (ref: 09/H0310/87)

Study design
Multicentre randomised controlled observer-blind phase II trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
After completion of baseline measurements the intervention phase will last for six weeks. All participants will receive conventional physical therapy (CPT) deemed appropriate for their presentation by the clinical physiotherapists using a standardised treatment schedule. The treatment schedule consists of a recording form and explanatory manual describing the treatment and we have used this successfully with clinical physiotherapists in our recently completed trials comparing CPT and functional strength training for the upper limb and lower limb. The clinical physiotherapists providing CPT will be trained to use the treatment schedule and will document content and amount of treatment provided each day. The records of treatment provided for all participants will be collected by Research Physiotherapists each week.

Control intervention:
Participants allocated to the control group will receive CPT. A SWIFT CAST will not be provided. They will, however, have a video analysis of their gait (described in experimental intervention) to ensure that assessment is exactly the same as in the experimental group. If participants discontinue CPT before the end of the 6-week intervention period then every effort will be made to include individuals in the outcome and follow-up measures (intention to treat principle).

Experimental intervention:
Participants allocated to the experimental group will receive a soft-scotch ankle-foot cast (SWIFT Cast) in addition to CPT. A SWIFT Cast is a lightweight, semi-rigid cast extending from the metatarsal heads to the head of the fibula. It positions the paretic foot in relation to the shank so that plantarflexion and/or excessive pronation/supination of the foot is minimised during walking so that the ground reaction force vector assumes the normal direction: passing in front of the knee at floor contact, through the knee in mid-stance and behind the knee in terminal stance. It is made from Soft Cast and Scotch (3M PLC UK). The SWIFT Cast is lightweight (100 - 200 g), semi-rigid and porous.

Intervention Type
Other

Phase
Phase II

Primary outcome(s)
Walking speed: during walking forwards in a straight line at participant-selected speed. Each participant will be asked to undertake 4 walks. Walking speed will be measured in the middle of the walkway using 2 inexpensive infra-red light beams placed 3 metres apart on shoulder-high stands and connected to an electronic timer. Subjects who cannot walk without support, i.e. a FAC score of 2 or less (support of 1 person), will be deemed to have a walking speed of zero.

Key secondary outcome(s))
Ability to walk independently, functional mobility, ability to walk with a normal gait pattern and structural brain imaging:
1. Functional Ambulation Category (FAC) ranges from unable to walk (score 0) to able to walk independently on level/non-level surfaces (score 5). This measure is clinically relevant to walking function and has been found to have strong inter-rater and test-retest reliability.
2. Modified Rivermead Mobility Index: This reliable and clinically relevant scale measures functional mobility including turning over in bed, standing up, walking indoors and ascending stairs. This measure is used widely in stroke rehabilitation research.
3. Efficiency of gait measured by:

3.1. Peak angular velocity of the knee during walking as a sensitive objective measure of gait performance
3.2. The ratio of step times on the paretic and non-paretic lower limbs as a measure of temporal symmetry
3.3. The ratio of step lengths on the paretic and non-paretic lower limbs as a measure of spatial symmetry
3.4. The ratio of sagittal angular velocity of the knee of the paretic and contra-lateral lower limbs as a measure of joint symmetry
3.5. The angle of the tibia with respect to the vertical at initial contact, foot flat, mid stance and terminal contact as a measure of smooth forward progression of the lower leg. These measures are made simultaneously with walking speed using the clinical gait analysis equipment (see primary outcome). They can be undertaken easily in a clinical environment using a technique developed by Wall and applied by Rowe and others in which the participant walks across a 10 metre long mat on which a high contrast grid has been printed while being video recorded from the side view. The resultant video can be played back in slow motion and timed using a multi-lap stopwatch to determine the step times. It can also be viewed frame by frame and using the grid the spatial location of the feet during the walk can be determined to give step lengths. The average angular velocity of the knee during stance can be estimated for the gait cycle in which the participant is perpendicular to the camera by measuring the angle of the maximum and minimum knee angles using a computer generated goniometer, subtracting one from the other and then dividing them by the time between the two occurrences. Finally the angle of the tibia with respect to vertical can be determined by using the freeze frame mode and the computer generated goniometer.
4. MR scan (baseline only): in order to have an accurate delineation of the cerebral lesion, the structural neuroimaging will be done 3 - 8 weeks after onset. To achieve accurate delineation of the lesion will mean that, for some participants, the structural neuroimaging will not be undertaken at exactly the same time point as other baseline measures. Standard FLAIR and T1-weighted SPGR high-resolution "volume" data sets will be obtained prospectively from all subjects at baseline using a standardised acquisition sequence including field inhomogeneity correction and identical voxel size; data sets will be collected and processed in a single laboratory under J-CB's supervision. Following harmonisation of image characteristics for different scanners lesions will be automatically segmented on the FLAIR data set using appropriate seeding and then the lesion contours will be projected onto the T1-SPGR data set following reslicing. All T1-SPGR data sets will then be spatially normalised to the MNI template (including lesion masking if necessary) using SPM2.

Completion date
01/12/2012

Eligibility

Key inclusion criteria
Participants will be recruited from in-patient stroke services and will be followed up until 6 months after stroke wherever they are living. Study criteria are:
1. Aged 18+ years (either sex), 3 - 42 days after stroke, infarct or haemorrhage, confirmed through routine clinical imaging
2. Fit for rehabilitation, i.e., peripheral oxygen saturations 90%+ on air, resting pulse less than 101 beats/minute
3. Walking ability from FAC score 1 to FAC score 5 (section 5) but with:
3.1. Abnormal initial floor contact, and/or
3.2. Impaired ability to take full body weight through the paretic lower limb in stance

4. No contractures at hip, knee, ankle or forefoot or loss of skin integrity
over the paretic foot or lower limb. Contracture is defined as persistent loss of full passive range of motion at a joint resulting from structural changes in connective tissues and measured using manual goniometry using the non-paretic lower limb as the comparator.
5. Can follow a 1-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
Does not meet inclusion criteria

Date of first enrolment
01/06/2010

Date of final enrolment
01/12/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Queens Building
Norwich
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Sponsor information

Organisation
University of East Anglia (UK)

ROR
https://ror.org/026k5mg93

Funder(s)

Funder type
Government

Funder Name
Medical Research Council (MRC)/National Institutes of Health Research (NIHR) (UK) - Efficacy and Mechanism Evaluation (EME) Programme (ref: EME 08/43/25)

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	01/01/2016		Yes	No
Protocol article	protocol	01/01/2012		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes