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Standing practice in rehabilitation early after stroke

Submission date	Recruitment status	[X] Prospectively registered
04/07/2016	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/12/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
31/10/2022	Circulatory System	

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 an artery (ischaemic stroke) or a bleed (haemorrhagic stroke). A large proportion of stroke victims suffer from long-term complications depending on the area of the brain that is affected, affecting their ability to speak, think and move. People with severe stroke experience significant muscle weakness which means that they spend much of their time in bed or sitting. This inactivity can cause their muscles to become even weaker and stiffer and may lead them to experience sudden drops in blood pressure when they move from lying to standing (orthostatic hypotension (OH). This further interferes with their ability to participate in intensive stroke rehabilitation, overall recovery and quality of life. Currently physiotherapy for people with severe stroke concentrates on practicing tasks such as getting in and out of bed into a chair that are important for independence and achieving safe discharge home. Standing up early after a stroke may help strengthen muscles, reduce OH and minimise or prevent muscles becoming stiff and weaker. A standing frame has the ability to assist people with severe stroke safely into a supported standing posture, however there are not given to patients when discharged and are not often used in stroke rehabilitation units. This study aims to assess whether it is possible for people with severe stroke to use a standing frame to practice functional movements such as standing and moving between sitting and standing during their hospital-based rehabilitation.

Who can participate?

Adults with severe stroke who are patients in participating Stroke Rehabilitation Units in Cornwall and Devon.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group take part in the functional standing frame programme. This involves a maximum of 30 minutes using the standing frame plus an additional 15 minutes to provide time for usual physiotherapy where participants may practise transfers, arm activities or activities chosen by participants or guided by physiotherapists. Participants will undertake the functional standing frame programme for ideally up to five days per week for a total of three weeks. Those in the second group practice routine physiotherapy stroke rehabilitation for 45 minutes per day (or as long as a tolerated) ideally up to five days per week for three weeks. Participants in both groups complete a range of

assessments and questionnaires at the start of the study and then again after three, six and twelve months to assess their function and ability to undertake activities of daily living.

What are the possible benefits and risks of participating?
Participants who use the standing frame may benefit from improvements to their symptoms and enhanced recovery. There are no notable risks involved with participating.

Where is the study run from?
1. Camborne Redruth Community Hospital (UK)
2. Bodmin Community Hospital (UK)
3. Skylark Ward, Stroke Rehabilitation Unit (UK)
4. Elizabeth Ward, Stroke Rehabilitation Unit (UK)

When is the study starting and how long is it expected to run for?
April 2016 to March 2019

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

Who is the main contact?
Miss Angie Logan
angie.logan@plymouth.ac.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

ICA-CDRF-2015-01-044

Study information

Scientific Title
A randomised controlled feasibility study to investigate the effects of a functional standing frame programme versus usual physiotherapy in people with severe sub-acute stroke on function, quality of life and neuromuscular impairment

Acronym
SPIRES

Study objectives
The aim of this study is to find out whether a functional standing frame programme for people with severe stroke is feasible to implement in a sub-acute inpatient rehabilitation setting and if it leads to an improvement in functional ability and quality of life, orthostatic hypotension and a reduction in neuromuscular impairment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West Research Ethics Committee, 03/08/2016, ref: 16/WA/0229

Study design
Multi-centre randomised controlled feasibility 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 to request a patient information sheet

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

Interventions
Participants will be randomised using a secure web-based system and a minimisation algorithm. The minimisation procedure will minimise group imbalance among the two intervention groups. Groups will be matched for:

1. Fatigue (fatigue vs no/minimal fatigue)
2. OH (hypotension vs no hypotension)

Functional standing frame programme (intervention group):
The intervention will occur for a period of three weeks and will start as early as possible after randomisation to ensure that the treatment can be completed whilst an inpatient. The functional standing frame programme will occur in a SRU gym/therapy room which is private. The functional standing frame programme involves a maximum of 30 minutes using the standing frame plus an additional 15 minutes to provide time for usual physiotherapy where participants may practise transfers, upper limb activities or activities chosen by participants or guided by physiotherapists. Participants will undertake the functional standing frame programme for ideally up to five days per week which is aligned with the Royal College of Physicians Guidelines.

Usual physiotherapy (control group):
This is defined as routine physiotherapy stroke rehabilitation for 45 minutes per day (or as long as a tolerated) ideally up to five days per week for three weeks, which is aligned with Royal College of Physicians Guidelines.

Participants in both groups are followed up after 3, 6 and 12 months.

Intervention Type
Other

Primary outcome measure
Function/ability to undertake activities of daily living is measured using the Barthel Index of Activities of Daily Living and Edmans Activities of Daily Living Index for Stroke Patients at baseline, 3, 6 and 12 months.

Secondary outcome measures
1. Blood pressure is measured using sphygmomanometer at baseline, 3, 6 and 12 months
2. Knee muscle strength is measured using hand held dynamometer at baseline, 3, 6 and 12 months
3. Length of muscles at hip, knee and ankle is measured using Goniometry at baseline, 3, 6 and 12 months
4. Muscle tone is measured using the Modified Ashworth Scale at baseline, 3, 6 and 12 months
5. Balance/trunk control is measured using the Trunk Control Test at baseline, 3, 6 and 12 months
6. Mood is measured using the PHQ-9/SAD-Q10 at baseline, 3, 6 and 12 months
7. Quality of life is measured using the Stroke & Aphasia Quality of Life Scale-39 at baseline, 3, 6 and 12 months
8. Quality of life is measured using the EQ-5D-5L at baseline, 3, 6 and 12 months
9. Fatigue is measured using the Fatigue Visual Analogue Scale at baseline, 3, 6 and 12 months

Overall study start date
01/04/2016

Completion date
31/03/2019

Eligibility

Key inclusion criteria

1. New (first/recurrent) clinical diagnosis of stroke, cerebral haemorrhage or infarct confirmed by consultant or CT scan leading to admission to the SRU
2. Aged 18 years and over
3. Graded as mRS 4 or 5 and/or NIHSS≥16 (severe or very severe stroke and unable to stand without support/mechanical aid and assistance of two people)
4. Able to give informed consent or assent from a consultee
5. Conscious and responsive to verbal commands

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50 in total (25 in each group)

Total final enrolment
45

Key exclusion criteria
1. Systolic blood pressure ≤100mmHg or ≥220mmHg at rest lying or sitting
2. Oxygen saturation ≤87% with or without supplementary oxygen (e.g. severe acute/chronic cardiorespiratory disease)
3. Resting heart rate of ≤40 or ≥110 beats per minute (e.g. cardiovascular instability)
4. Temperature ≥38.5 degrees centigrade or ≤35 degrees centigrade
5. Orthopaedic impairments which prevent full weight bearing in standing
6. Malnutrition Universal Screening Tool score of ≥2, or not meeting nutritional demands for therapeutic interventions
7. Documented clinical decision for receiving end of life care
8. Unstable coronary or other medical condition that is judged by the PI/CI or clinical team to impose a medical risk to the patient by involvement in the study
9. Severe communication and/or cognitive deficit which affects their ability to follow instructions (e.g. assessed functionally by specialist clinicians as being a risk to themselves or others due to their inability to follow non-verbal prompts or are behaving erratically)
10. Immobile and not weight bearing pre-stroke
11. Additional neurological deficits unrelated to the current or past stroke (e.g. peripheral neuropathy or Multiple Sclerosis), because these impairments are not related to the condition of interest
12. Weight of 115kg or more, this is the weight limit on the standing frames
13. Being discharged out of county, e.g. admitted during holiday/visit to Cornwall or Devon because they would be unable to participate in follow-up assessments
14. Already registered in an intervention trial

Date of first enrolment

20/12/2016

Date of final enrolment
31/10/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Camborne Redruth Community Hospital
Lanyon Ward, Stroke Rehabilitation Unit
Cornwall Partnership Foundation NHS Trust
Barncoose Terrace
Redruth, Cornwall
United Kingdom
TR15 3ER

Study participating centre
Bodmin Community Hospital
Woodfield Ward, Stroke Rehabilitation Unit
Cornwall Partnership Foundation NHS Trust
Boundary Road
Bodmin, Cornwall
United Kingdom
PL31 2QT

Study participating centre
Skylark Ward, Stroke Rehabilitation Unit
Mount Gould Community Hospital
Livewell Southwest
Plymouth
United Kingdom
PL4 7PY

Study participating centre
Elizabeth Ward, Stroke Rehabilitation Unit
Bideford Community Hospital
North Devon Healthcare
Abbotsham Rd

Bideford
United Kingdom
EX39 3AG

Sponsor information

Organisation
Royal Cornwall Hospitals NHS Trust

Sponsor details
Knowledge Spa
Royal Cornwall Hospitals
Truro
England
United Kingdom
TR1 3HD

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/026xdcm93

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

Publication and dissemination plan

Current publication and dissemination plan as of 19/04/2021:
A manuscript for publication was submitted in March 2021 following revisions. The outcome is pending.

Previous publication and dissemination plan:
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

31/08/2021

Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		01/12/2018		Yes	No
Results article		03/03/2022	31/10/2022	Yes	No
HRA research summary			26/07/2023	No	No