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WAVES: Wristband accelerometers to motivate arm exercises after stroke

Submission date	Recruitment status	[_] Prospectively registered
07/07/2016	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/07/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/05/2021	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). One of the most common complications of a stroke is weakness on one side of the body (hemiparesis), which is particularly common in the arms or legs. Stroke survivors report that services do not pay enough attention to loss of arm movement, which affects many people and has a large impact on their quality of life. There is increasing evidence that performing many extra practice movements can help arm recovery as long as these reflect useful activities such as washing or dressing. Despite national clinical recommendations, the NHS lacks sufficient therapists to supervise this additional practice, and so therapy programmes have been developed which patients can complete by themselves with regular checks by a therapist. However, as experienced by many people who start to exercise regularly, it is a challenge for patients to measure how much activity has been done and to remain motivated. This study will test a new piece of technology (a movement sensor or “accelerometer” which is worn of the affected arm which gives feedback to prompt patients to move their arm more) to improve the effectiveness of a daily arm therapy programme. The aim of this study is to investigate the feasibility of conducting a study of wrist worn accelerometers with vibrating-alert and visual feedback to prompt exercise of the arm during rehabilitation after stroke.

Who can participate?

Adults who have had a stroke between 48 hours and three months ago which has led to loss of arm function, who are within an NHS stroke rehabilitation service.

What does the study involve?

Participants are randomly allocated to one of two groups. Both groups undertake a four week therapy programme of arm exercises. The therapist will suggest appropriate arm activities to practice at home to support therapy sessions and discuss how their arm can be used in normal daily activities. Participants also receive a wristband to wear on the stroke side from 8am to 8pm during this four week period. Participants in the first group wear the active wristband (accelerometer) with an integrated vibrating-alert function and visual display feedback (the CueS device) which provides feedback (via vibrations and a light up display) to prompt more limb use if activity falls below a personalised threshold. The device also provides visual feedback on

achievement towards the threshold so well as a twice weekly objective report of movement and prompts. Participants in the second group wear a 'sham' CueS device for four weeks which will monitor impaired limb activity but will not provide prompts, feedback or reports to guide therapy. Participants in both groups complete a number of questionnaires at the start of the study and then after four and eight weeks in order to find out if there have been any changes to their arm function. At the end of the study, the amount of participants that have been recruited and the number who saw the study through are recorded to find out if a larger study would be feasible.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
1. Wansbeck General Hospital (UK)
2. North Tyneside General Hospital (UK)
3. University of North Tees Hospital (UK)
4. Queen Elizabeth Hospital (UK)
5. Royal Victoria Infirmary (UK)

When is the study starting and how long is it expected to run for?
January 2016 to December 2017

Who is funding the study?
Stroke Association (UK)

Who is the main contact?
Ms Ruth Da Silva
Ruth.Da-Silva@ncl.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Ruth Da Silva

ORCID ID
http://orcid.org/0000-0002-8897-4090

Contact details
Stroke Research Group
Newcastle University
3-4 Claremont Terrace
Newcastle Upon Tyne
United Kingdom
NE2 4AE
+44 (0)191 208 3842
Ruth.Da-Silva@ncl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
31066

Study information

Scientific Title
Wristband Accelerometers to motiVate arm Exercise after Stroke, a pilot randomised controlled trial (WAVES)

Acronym
WAVES

Study objectives
The aim of this study is to assess the feasibility of a multi-centre, observer blind, randomised controlled trial of wrist worn accelerometers with vibrating-alert and visual feedback to prompt functional exercise of the upper limb during rehabilitation after stroke.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North East – Newcastle & North Tyneside, 29/03/2016, ref: 16/NE/0063

Study design
Observer blind parallel group pragmatic pilot randomised controlled 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
Specialty: Stroke, Primary sub-specialty: Rehabilitation; UKCRC code/ Disease: Stroke/ Cerebrovascular diseases

Interventions
Participants are randomly allocated to one of two study groups in a 1:1 ratio using a computer generated randomisation system will be used to randomise participants via a central telephone service hosted by Newcastle University Stroke Research Group. The randomisation process will be conducted by a member of the clinical team in order to conceal group allocation from the local research support staff who will be assessing the outcome measures.

Study intervention treatment: An NHS therapist will review participants twice weekly and agree a programme of upper limb activities for the participant to practice in addition to usual care. Intervention participants will be provided with a wrist worn movement detector (accelerometer) with an integrated vibrating-alert function and visual display feedback (the CueS device) to:
1. Constantly sense impaired limb movement
2. Gently vibrate to prompt more limb use if activity falls below a personalised threshold
3. Provide visual feedback on achievement towards the threshold
4. Provide patients and therapists with a twice weekly objective report of movement and prompts.
Participants will wear the CueS device for four weeks.

Study control treatment: An NHS therapist will review participants twice weekly and agree a programme of upper limb activities for the participant to practice whenever they choose in addition to usual care. Control participants will wear a 'sham' CueS device for four weeks which will monitor impaired limb activity but will not provide prompts, feedback or reports to guide therapy.

Outcomes will be assessed at 4 weeks and 8 weeks following start of therapy. Assessments will be undertaken by research staff blinded to group allocation.

Intervention Type
Other

Primary outcome measure
Feasibility outcome measures:
1. Recruitment is measured by enrolment of one patient per month from each study centre
2. Attrition rate is measured by the number of participants who consent to participate in the study and remain in the study until the end of the 8 week follow up assessment.
3. Participant adherence to the study is measured by participants wearing the wristband for >80% of the recommended hours
4. Report on the frequency of usual rehabilitation care received is measured by completion of daily log sheets
5. Success of outcome assessor blinding as measured by the number of participants who complete the 4 week outcome assessment without unblinding the outcome assessor to participant group allocation.
6. Report on serious adverse events related to the study as measured by completion of the SAE report forms
7. Completeness of data will be measured by completion of baseline, 4 week and 8 week assessments and number of complete days of accelerometer data from the wristband

Secondary outcome measures
The clinical outcomes will be recorded at Baseline, 4 weeks and 8 weeks:
1. Stroke impairment and dependency, measured by the Modified Rankin Scale, Barthel Index and National Institutes of Health Stroke Scale (NIHSS)
2. Upper limb pain and overall fatigue, measured by a numerical visual analogue scale (0-10)
3. Upper limb function, measured by the Action Research Arm Test
4. Real world upper limb activity, measured by the Motor Activity Log
5. Upper limb strength, measured by the Motricity Index
6. Objective measurement of affected upper limb activity, measured by a standard wrist worn accelerometer worn for three days after the 4 and 8 week outcome visits
7. Unilateral spatial neglect, measured by the star cancellation test

Overall study start date
03/01/2016

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Aged 18 years and over
2. More than 48 hours but less than 3 months post stroke onset
3. New reduced upper limb function on one side.
4. Able to provide individual consent to participate in the study.
5. Living within the community services catchment area of a participating study centre
6. Receiving at least twice weekly NHS therapy which is planned to continue for four weeks from the start of the intervention

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Total final enrolment
33

Key exclusion criteria
1. Severely reduced upper limb function which results in inability to lift the affected hand off the lap when sitting

2. Unable to follow the programme due to significant cognitive impairment or communication difficulties
3. Other significant upper limb impairment e.g. fixed contracture, frozen shoulder, severe arthritis, upper limb pain that inhibits participation in the programme
4. Diagnosis likely to interfere with rehabilitation e.g. registered blind, severe visual problems as a result of stroke, palliative treatment approach being provided
5. Unable to sense both Cues device vibratory prompts and visual display

Date of first enrolment
24/05/2016

Date of final enrolment
31/08/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Wansbeck General Hospital
Woodhorn Lane
Ashington
United Kingdom
NE63 9JJ

Study participating centre
North Tyneside General Hospital
Rake Lane
Tyne and Wear
United Kingdom
NE29 8NH

Study participating centre
University of North Tees Hospital
Hardwick Road
Stockton-on-Tees
United Kingdom
TS19 8PE

Study participating centre

Queen Elizabeth Hospital
Queen Elizabeth Avenue
Gateshead
United Kingdom
NE9 6SX

Study participating centre
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

Sponsor information

Organisation
Northumbria Healthcare NHS Foundation Trust

Sponsor details
Research and Development Department
North Tyneside General Hospital
Rake Lane
North Sheilds
England
United Kingdom
NE29 8NH

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01gfeyd95

Funder(s)

Funder type
Charity

Funder Name
Stroke Association

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication of the study protocol (by December 2016) and study results (by March 2018) to an open access peer reviewed journal.

Intention to publish date
31/03/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	21/10/2016		Yes	No
Other publications	activity data	01/07/2018	07/05/2021	Yes	No
Results article		01/08/2019	07/05/2021	Yes	No
HRA research summary			28/06/2023	No	No