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Early electrical stimulation to the wrist extensors and wrist flexors to prevent the post-stroke complications of pain and contractures in the paretic arm

Submission date
14/01/2015

Recruitment status
No longer recruiting

Registration date
15/01/2015

Overall study status
Completed

Last Edited
25/07/2019

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Stroke is a serious, life-threatening medical condition that usually happens when a blood clot or haemorrhage cuts of the blood supply to an area of the brain. Symptoms vary according to how much of the brain is affected and where in the brain the stroke occurs, but includes paralysis, muscle weakness and speech difficulties. A stroke can also have an impact on the sufferers emotions and can lead to anxiety, depression and personality changes. It is the largest cause of disability in adults in the United Kingdom. Not being able to use their hands, muscle weakness, pain, and joint deformities are long-lasting and disabling problems for nearly half of all stroke survivors. This can, in part, result from patients not getting adequate therapy focusing on the hand and arm in the very early stages of rehabilitation (just after their stroke). It is vital that rehabilitation therapy begins as soon as possible after a person has had a stroke. Although the damage is to the brain rather than the limbs, muscle wastage (atrophy) can happen soon after stroke through them not being used.
Muscle atrophy can even occur in those who have retained some degree of active arm movement. Electrical stimulation (ES) is a treatment in which small pulses of electrical current from a battery operated portable device are used to activate a paralysed muscle and produce a strong muscle contraction. ES has been shown to increase brain activity and can hence influence the formation of new nerve pathways (known as neuroplasticity) to replace those damaged by stroke. We plan to build on previous research by training clinical therapists to operate ES devices; starting ES much earlier after stroke; applying a higher intensity treatment to more of the forearm muscles (i.e. both the front and back of the forearm) and providing treatment for a longer period of time than previously carried out. We will test how possible it is to incorporate ES into a patient self-management programme to enable independent use outside of routine therapist led rehabilitation sessions.

Who can participate?
Adults who have had a stroke affecting their upper limbs (arms) and their carers.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 receive usual care. Those in group 2 are given electrical stimulation to the stroke-affected arm, twice a day (morning and afternoon), five days a week for 3 months.

What are the possible benefits and risks of participating?
Participants may not benefit directly from taking part in the study but possible benefits do include the recovery of arm function and prevention of post-stroke complications such as pain and contractures in the arm. Some people may find the initial sensation of their hand moving involuntarily during treatment slightly disturbing. It is possible that participants may see faint redness of the skin under or surrounding the electrode pad following treatment and this is nothing to be concerned about. However, in the unlikely event that the redness persists participants should inform the treating therapist or their doctor/nurse. They may also experience a tingling sensation when the ES device is switched on.

Where is the study run from?
University of Nottingham (UK)

When is the study starting and how long is it expected to run for?
April 2015 to March 2018

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

Who is the main contact?
Mrs Joanna Fletcher-Smith

Contact information

Type(s)
Scientific

Contact name
Mrs Joanna Fletcher-Smith

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT02324634

Protocol serial number

18168

Study information

Scientific Title
Early electrical stimulation to the wrist extensors and wrist flexors to prevent the post-stroke complications of pain and contractures in the paretic arm - a feasibility study

Acronym
ESCAPS study version 1.0

Study objectives
Aim of this study is to evaluate the feasibility of incorporating electrical stimulation (ES) into a stroke patient self management programme to enable independent use outside of routine therapist led rehabilitation sessions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee: East Midlands Nottingham 1, ref: 15/EM/0006

Primary study design
Interventional

Study design
Randomised; Interventional

Study type(s)
Treatment

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

Interventions
1. Feasibility RCT:
Participants will be randomly allocated to one of two groups: intervention or control.

Those assigned to the intervention group will receive electrical stimulation (ES) applied to the wrist extensors and wrist flexors twice a day, 5 days a week, for 3 months. The therapist (occupational therapist or physiotherapist) will identify the motor points for the forearm flexors and the extensors, and will place the electrode pads on these motor points using sticky pads. They will then connect the electrodes to the respective channels in the electrical stimulator. The ES will be set to deliver a 450µs pulse at a frequency of 40-60Hz (as per patient convenience). The intensity of the current will be increased to produce an alternating contraction of the flexors and extensors using a flex-hold-extend-hold pattern. A single stimulation and hold cycle will last 20 seconds and this will be cyclically repeated for 30 minutes after which the device can be removed.

Those assigned to the control group will receive usual care only and will not receive any ES treatment.

Participants in both arms of the trial will complete outcome assessments at baseline, 3, 6, and 12 months.

2. Patient and carer interviews:
Intervention group: 10 pairs of patient participants and their nominated carers will be interviewed about their experience of using or supporting a loved one to use electrical stimulation therapy as part of a research study. The interviews will be used to examine issues regarding compliance with the ES treatment regime, acceptability of the ES treatment, experience of supporting a stroke survivor in using the ES treatment, any perceived treatment effects, the training that was provided and the ongoing support needs and any issues related to recruitment and consent. The purpose of these interviews is to identify issues related to delivering ES as part of a randomised controlled trial. The findings from these interviews will contribute to the final content and design of the research protocol for the definitive trial.

Each interview will last for around one hour in total and will take place in the participants' homes, or clinic if preferred, and will be recorded, transcribed verbatim and analysed thematically. Interviews will be conducted following completion of the 3 month follow-up assessments.

Control group: 5 pairs of patient participants from the control group and their nominated carers will be interviewed to examine any issues from the perspective of the control group participants.

3. Therapist Focus discussion Groups:
4 Physiotherapists and 4 occupational therapists from the Nottingham Stroke Unit will be invited to participate in a minimum of one and a maximum of three focus discussion groups during the course of the feasibility RCT. The focus groups will discuss the barriers and facilitators to successfully implementing the intervention and study protocol into clinical practice.

Intervention Type
Procedure/Surgery

Primary outcome(s)
The primary objective of the research is to evaluate the feasibility of running a randomised controlled trial that will test the efficacy of delivering early, intensive ES to prevent post stroke complications (such as pain and contractures) to the paretic (weak) upper limb after stroke.

The primary outcome measures:
1. Feasibility of the trial design (12 months) - Recruitment rates: number / % of participants recruited within 72 hours post-stroke; time post-stroke that participants received their first treatment; recruitment strategy: number / % of patients screened, number / % eligible and approached, number / % who consented, number / % excluded after screening; Completion rates: number / % of participants who completed the intervention; Number / % of participants who received ES twice a day, 5 days a week whilst in hospital, and number / % who continued with the treatment regime after discharge. Mean, min and max number of ES treatments that participants received during the 3 month intervention period; Recruitment of patients lacking mental capacity to consent for themselves: consultee consent rates (number / % of patients unable to give informed consent, and number consented by a consultee, number of consultees who declined consent).
2. Tolerability (12 months) – Proportion of participants who withdraw or decline intervention;

records of interventions declined and why.
3. Integrity of the study protocol (12 months) – Measured by examining how many participants are able to complete the study, % of missing data, and % of people who completed each of the outcome measures at 3, 6 and 12 month follow-up, calculation of the cost of running the study.

Key secondary outcome(s)
1. NIHSS score (0, 3, 6, 12 months) – neurological outcome and degree of recovery
2. Barthel ADL Index score and modified Rankin score (0, 3, 6, 12 months) – Independence (functional ability) in basic daily activities
3. Scale of Pain Intensity (SPIN) (0, 3, 6, 12 months) – Pain in the affected arm
4. Muscle contractures (reduction in range of movement and spasticity) (0, 3, 6, 12 months) – muscle contractures will be monistored by measuring muscle activity during assessments using Biometrics equipment
5. Action Research Arm Test (ARAT) (0, 3, 6, 12 months) – arm function
6. Stroke Specific Quality of Life scale (SS-QOL) (0, 3, 6, 12 months) – stroke related quality of life
7. EuroQoL-5D (EQ-5D) (0, 3, 6, 12 months) – health status
8. Patient resource use (cost) questionnaire (0, 3, 6, 12 months) – a measure of resource use and health related costs
9. Caregiver strain Index (CSI) (0, 3, 6, 12 months) – Carer strain
10. Nottingham Extended ADL (NEADL) (0 months) – pre-morbid functional state
11. The Montreal Cognitive Assessment (MoCA) (0 months) – Cognitive status at baseline

Completion date
31/03/2018

Eligibility

Key inclusion criteria
Eligibility criteria – patient participants for the feasibility RCT
1. Patients with a confirmed clinical diagnosis of stroke AND it is their first stroke event to affect their upper limb
2. Patients aged 18 years or over
3. Impaired arm movement and strength resulting in reduced function, caused specifically by the stroke. (as determined by the arm subsection score of the National Institute for Health Stroke Scale (NIHSS)

Carer participants for the feasibility RCT Inclusion criteria
1. Nominated carer for a patient participating in the feasibility RCT
Eligibility criteria – Patient and carer interviews
1. Participating in the main feasibility RCT
2. Mental capacity to consent and take part in the interview
3. Able to understand English
4. Nominated carer supporting a participant in the main feasibility RCT
5. Mental capacity to consent and take part in the interview
6. Able to understand English

Therapist Focus Discussion Groups
1. HCPC registered occupational therapist or physiotherapist
2. Currently employed by NUH NHS Trust and working on the Nottingham Stroke Unit
3. Experience of supporting at least one participant to use the ES intervention

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Patient participants for the feasibility RCT
1. Patients with a previous history of stroke affecting their upper limb will be excluded as a chronic limb condition from a previous stroke could affect the results
2. Patients will also be excluded with peripheral nerve injury of the upper limb; an existing orthopaedic condition affecting the upper limb; fixed contractures at the elbow, wrist or fingers; malignancy in the area of the ES electrode placement; or epilepsy
3. Patients with a cardiac pacemaker or similar implanted device.
4. Pregnancy
5. Undiagnosed pain or skin conditions (i.e. not related to the stroke)

Carer participants for the feasibility RCT
1. Non English speaking

Patient and carer interviews
Patient
1. Individual is unable to communicate verbally or in written form
2. NonEnglish speaking
3. Aged younger than 18 years
Carer
1. Individual is unable to communicate verbally or in written form
2. NonEnglish speaking
3. Aged younger than 18 years

Date of first enrolment
01/05/2015

Date of final enrolment
30/09/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Nottingham
Division of Rehabilitation and Ageing
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
University of Nottingham

ROR
https://ror.org/01ee9ar58

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

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	04/01/2016		Yes	No
HRA research summary			28/06/2023	No	No