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A clinical investigation of a novel functional electrical stimulation system

Submission date
28/11/2016

Recruitment status
No longer recruiting

Registration date
13/01/2017

Overall study status
Completed

Last Edited
13/01/2017

Condition category
Nervous System Diseases

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

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). Around 150,000 experience a stroke each year in the UK, leaving large numbers of people living with the consequences of a stroke. Many stroke victims suffer from long-term complications depending on the area of the brain that is affected, which can affect their ability to move, speak or even their cognitive function (memory loss, difficulty reasoning and confusion). One of the most common complications of a stroke is weakness or paralysis on one side of the body. At least half of the people who survive a stroke experience reduced function in one of their arms. A number of studies show that repeating arm exercises can help to restore function, however this not much time is spent on this in current therapy on offer. Functional electrical stimulation is a treatment that uses small electrical pulses to cause muscle contractions, sequenced in such a way as to assist with the performance of functional tasks. This technology offers the potential to deliver high doses of therapy, but without needing a therapist to be continuously present. A number of studies have shown that its use may help to improve arm function following a stroke. However, there are limitations with current FES devices. For instance, many of the devices are difficult to use effectively with people who have weakness in multiple joints, while others are inflexible in the way in which they are controlled. To address this, a new FES system (FES-UPP system) has been designed to support people with arm problems following a stroke to practice functional tasks. The system has sufficient channels of stimulation to generate muscle contractions around all arm joints, and it uses information from movement sensors to decide which muscles to stimulate and when, offering flexibility in control. The aim of this study is to explore whether this FES system is able to support people with stroke to perform arm exercises they would otherwise be unable to perform unaided and how usable therapists find the system.

Who can participate?
Practicing therapists working with stroke patients and adults who have had a stroke and are experiencing arm weakness.

What does the study involve?
People with stroke take part in up to six sessions using the FES-UPP system. During one of the sessions (whichever is most convenient for the participant) participants are asked how they are

finding the system and are assessed to find out how well they can perform arm exercises both when using the system and when not using the system, to see whether the system is effective in supporting people to practice these activities. Information on how much practice can be delivered using the system and any practical issues, such as how long it takes to set up the system, are also recorded.
Therapists are training to use the FES-UPP system. At the end of the training, they are invited to complete two questionnaires, one on the training process and one on the system itself. They are then invited to use the FES-UPP system as required with up to 10 stroke patients. At the end of the study, they are invited to attend an interview addressing their perceptions of the system and the study design, as well as complete another questionnaire on the system design.

What are the possible benefits and risks of participating?
There are no notable benefits or risks involved with participating.

Where is the study run from?
1. Salford Royal Hospital (UK)
2. Bury Community Stroke Team (UK)
3. Salisbury District Hospital (UK)

When is the study starting and how long is it expected to run for?
June 2013 to September 2017

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

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
32126

Study information

Scientific Title
A clinical investigation of a novel functional electrical stimulation system (FES-UPP) for early post-stroke upper limb rehabilitation in 3 clinical settings

Study objectives
The aim of this study is to:
1. Verify that, under normal conditions of use, the performance characteristics of the device are those intended by the manufacturer
2. Determine any undesirable side effects and assess whether these constitute risks when weighed against the intended performance of the device

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire & The Humber - Leeds West Research Ethics Committee, 07/09/2016 , ref: 16/YH/0258

Study design
Non-Randomised; Interventional; Design type: Treatment, Device

Primary study design
Interventional

Secondary study design
Non randomised study

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

People with stroke (PwS)
PwS will be recruited at one of the three clinical sites. Each participant will take part in up to eight sessions, lasting approximately one hour over a period of up to six weeks from the first session. There will be two types of session, Type A and Type B. In a Type A session, the therapist and PwS will first agree on one or more activities to be practiced using the FES-UPP system. An activity may be one that has been used in a previous session (where applicable), or may be a new one. Activities will be selected based on clinical assessment to be difficult, or impossible for the PwS to perform unaided. The therapist will then use the FES-UPP system to set up the sequenced patterns of stimulation to multiple muscles to support the PwS in performing each of the functional activities, and to provide appropriate feedback and/or instruction to the PwS. The PwS will then be encouraged to practice, under supervision, each of the FES-supported activities, until the PwS indicates a desire to stop, or 1 hour has passed (whichever is shorter). During each session, the system will log the nature and amount of FES therapy delivered. At site A, for PwS 6-10, a de-weighting system will be made available for use, at the therapist's discretion, in combination with FES-UPP. Type B: Under normal circumstances this will take place on the second, third or fourth of the sessions with FES-UPP. At this session, in addition the PwS and the therapist, a member of the research team will also be present. The purpose of the type B session is to address the primary research question "does use of the FES-UPP enable PwS to perform a wider range of functional activities, and/or perform the same activities in an improved way?" During this session, the researcher will video each attempt at each activity for later analysis. The researcher, therapist and PwS will agree on two suitable unilateral activities, one or both of which may have been used in a previous session. The researcher, in consultation with the therapist, will then use the FES-UPP system to fine tune the setups to allow a robust attempt at the activity that is suitable for recording on video. They will then use the software to set all stimulation levels in each phase to zero and ask the PwS to attempt the activity unaided (note that the attempt should be completely unaided by FES, therapist or de-weighting system). Next, the therapist will re-instate the FES stimulation levels and invite the PwS to attempt the activity with FES support (note that the attempt should be with only FES support i.e. without therapist or de-weighting support). The process will then be repeated for the second activity. In addition, at a convenient session, each PwS will be assessed on upper limb spasticity, impairment, as well as neglect and cognitive ability. At the end of the last session, each PwS will be invited to complete a short questionnaire on the system.

Therapists
Therapist participants will report their be trained to use the FES-UPP system. At the end of the training they will be invited to complete two questionnaires, one on the training process and one on the system itself. They will then be invited to use the FES-UPP system as required with up to 10 PwS (see above). Research team members will observe one session per participant for later usability analysis. At the end of the study, therapist participants will be invited to attend an interview addressing their perceptions of the system and the study design, as well as complete another questionnaire on the system design.

Intervention Type
Device

Primary outcome measure
Upper limb function, is assessed with and without FES at a convenient time over the course of the planned therapy sessions (ideally sessions 2, 3 or 4).

Secondary outcome measures

Patient outcomes:
1. Spasticity is measured using the Modified Ashworth Scale at week 1
2. Upper limb impairment is measured using the Fugl-Meyer UE Scale at week 1
3. Neglect is measured using the Star Cancellation Test at week 1
4. Cognitive ability is measured using the Montreal Cognitive Assessment at week 1
5. Therapy delivered is measured using the FES-UPP software at all sessions
6. User perception of the system is measured using the Patient Participant Questionnaire at week 6 (or earlier, if completed 8 sessions before 6 weeks, or exit study for other reason)

Therapist outcomes:
1. Therapist characteristics are measured using the therapist profiling questionnaire at baseline
2. Views on the training is measured using the Training Questionnaire at baseline
3. Perceptions of the system is measured using the Technology Acceptance Model at the end of training and at the end of training and at the end of study baseline and 5 months
4. User perspective is measured using a semi-structured interview at 5 months

Overall study start date
01/06/2013

Completion date
01/09/2017

Eligibility

Key inclusion criteria
Therapist participants inclusion criteria:
1. Practicing therapist working with stroke patients
2. Successfully completed the training to use FES-UPP

Person with stroke participant inclusion criteria:
1. Aged 18 or over
2. Evidence of a clinical stroke, as defined by the WHO " rapidly developing clinical signs of focal (or global) disturbance of cerebral function, lasting more than 24 hours or leading to death, with no apparent cause other than that of vascular origin"
3. Impairment of one or both upper limbs, for which they are, or plan to be, participating in therapy
4. Medically fit to engage in active therapy sessions
5. Less than 6 months post-stroke
6. Sufficient level of cognition and communication to comply with the assessments and participate in the study. This will be assessed in the informed consent process, either involving the person with stroke themselves, or declaration of personal consultee where the consent trained professional, therapist and personal consultee are in agreement that it is appropriate for that person to take part in the study
7. Potential person with stroke (pws) participant expected to remain under the care of one of the services (See above for details on the three services) for sufficient time to allow at least 2 sessions with FES-UPP to be completed

Participant type(s)
Mixed

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 30; UK Sample Size: 30

Key exclusion criteria
Participant with stroke exclusion criteria:
1. Any neurological condition that effects voluntary control of upper limb movements, such as Myotonic Muscular Dystrophy, Polio, Multiple Sclerosis, unresolved peripheral nerve injuries
2. Complex regional pain syndrome
3. Orthopaedic conditions that restrict joint range
4. Severe Rheumatoid Arthritis
5. Epilepsy not adequately controlled by medication
6. Cardiac pacemaker or other active implanted device
7. Metal external fixator implant
8. Cancerous tissue/malignancy in the region of stimulation
9. Pregnancy
10. Skin rash, allergy, broken skin, wound or poor skin condition in an area where electrodes are to be placed
11. Requiring an interpreter

Criteria to be discussed with the Research Team:
1. Painful shoulder, or pain in the upper limb
2. Participating in another study
3. Fixed flexion contracture or excessive spasticity in more than 2 muscles
4. Any medical condition other than those listed above that may affect the response to ES

Date of first enrolment
27/10/2016

Date of final enrolment
31/03/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Salford Royal Hospital
Stroke services

Stott Lane
Salford
United Kingdom
M6 8HD

Study participating centre
Bury Community Stroke Team
Holcombe House
Fairfield Hospital
Rochdale Old Road
Bury
United Kingdom
BL9 7TD

Study participating centre
Salisbury District Hospital
Outpatient services
Odstock Medical Ltd
The National Clinical FES Centre
Salisbury
United Kingdom
SP2 8BJ

Sponsor information

Organisation
University of Salford

Sponsor details
Allerton Bldg
University of Salford
Salford
England
United Kingdom
M6 6PU

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01tmqtf75

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
The study team intends to use the results to support the CE marking of the system. Planned publication of two papers on the results in relevant rehabilitation journal.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from l.p.j.kenney@salford.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No