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iPAM (robot) Stroke Intervention Trial (iSIT) for arm weakness

Submission date 08/08/2012	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 22/08/2012	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 02/10/2017	**Condition category** Circulatory System	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Stroke is the most common cause of severe disability in the UK. About 150,000 have a stroke in the UK each year and up to 85% of these people experience arm paresis (impaired movement). Studies show that increasing the level of physical therapy can improve some aspects of recovery, but resources are limited. One approach to improve rehabilitation treatment for the weak arm is to use robotic devices to provide extra arm exercise. The iPAM robot system imitates the arm exercise that would normally be delivered by a physiotherapist and allows people to undertake independent whole arm exercise. The aim of this study is to find out whether or not it is possible to use this iPAM robotic exercise system in hospitals to improve arm function in people with stroke.

Who can participate?
People aged 18 or over who are admitted to hospital with stroke, have arm weakness and are able to benefit from ongoing rehabilitation to improve arm function.

What does the study involve?
Participants are randomly allocated to either the iPAM treatment group or the control group while they are in hospital receiving their usual rehabilitation treatment. The iPAM treatment group receive up to 30 iPAM robot treatment sessions over 6 weeks or for however long they are in hospital alongside their normal NHS treatment. The control group receive normal NHS treatment and some extra therapy equivalent to the time that the therapist spends setting up the iPAM robot system. Clinical assessments are undertaken of the participants' arm movement and how much use they have before the study starts and after 10 weeks to see if the use of the iPAM robot improves arm movement. Questionnaires are also used to get feedback from NHS therapists and patients involved in the study about their experiences of using the iPAM robot system.

What are the possible benefits and risks of participating?
This is a research study so there may be no benefits associated with the study treatments. However, the information from this study may help us to improve treatments that are available to people with stroke. No harmful side effects have been observed from using iPAM in a previous study. Nevertheless, there are some potential risks associated with use of iPAM as well

as excessive arm exercise within a routine therapy session. These may include repetitive or jerky movements which may cause arm muscle or joint ache/strain; shoulder pain may occur while the exerciser moves the arm; the arm might feel stiffer with excessive exercise; and participants might become tired due to the exercises.

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

When is the study starting and how long is it expected to run for?
January 2012 to December 2012

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

Who is the main contact?
Prof. Bipin Bhakta

Contact information

Type(s)
Scientific

Contact name
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Study information

Scientific Title
Phase 2 clinical study of iPAM robot-assisted arm rehabilitation in acute stroke

Acronym
iSIT

Study objectives

1. To investigate the effect of iPAM assisted exercise on upper limb movement compared to usual care in people with early stroke.
2. To obtain information about the practicalities of delivering intensity and duration of iPAM intervention within NHS stroke rehabilitation service.
3. To assess safety of device use within an NHS stroke rehabilitation environment.
4. To obtain end user opinion (person with stroke, NHS therapy staff) about the use of iPAM to treat people in the early stages of stroke recovery within a NHS stroke rehabilitation service.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. NRES Committee Yorkshire & The Humber - Leeds West, 17/10/2011, ref: 10/H1307/131
2. Medicines and Healthcare products Regulatory Agency (MHRA), 29/11/2011, ref: CI/2011/0031

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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

Interventions
Active group:
iPAM will be set up by the patient's treating therapist to deliver upper limb exercises based on clinical assessment. iPAM, uses a computer screen [Patient User Interface] to present targets towards which the patient is asked to reach; this is the 'patient workspace'. The patient's movement is assisted at the upper arm and forearm by the iPAM system in three dimensions, simulating a therapist's hands. iPAM delivers assistance according to the therapist's prescription (SILCK Clinic) and the clinical state of the patient. The iPAM control system uses clinical rules (SILCK Clinic) to adapt the assistance according to the patient's progress. It also varies the representation of the computer targets to maintain interest. iPAM adjusts the targets during sequential exercises autonomously within predefined therapy prescriptions. iPAM is intended to be operated under indirect therapy supervision. For example, the patient may exercise using the iPAM in the rehabilitation therapy area while the therapist is treating another patient nearby. The system has several safety protocols for safe use of the system within a rehabilitation ward environment. Should adverse events arise these will be managed in accordance with agreed research governance processes. We anticipate that each patient recruited to the iPAM group will receive one to two exercise sessions of iPAM delivered therapy per day for up to 30 days. Each exercise session will be approximately 45-60 minutes or as low as 10 minutes depending on the patient's clinical state. The decision about need for rehabilitation interventions (when to start, finish and type) will be made by the treating clinicians, therapists and nurses in consultation with patients and families as part of the routine management of the patient. The patient's usual rehabilitation treatment will continue as clinically indicated.

Control group
The control group will receive usual therapy plus additional therapy time (equivalent to the time it takes for a therapist to set a patient up in the iPAM system - approximately 15 minutes). This extra time therapy may be combined to make extra or longer usual therapy sessions.

Adherence to treatment
The iPAM system will automatically log the frequency, duration and type of exercises undertaken by patients randomised to the active group. At the end of the trial the therapy staff will be asked to complete a form with details about how a patient has responded to iPAM treatment and the reasons for stopping treatment. The usual rehabilitation treatment that is focused on improving motor function (e.g. dressing, hand function, transfers, standing, walking) delivered by the therapist in both the active and control groups will be documented using a tick box intervention record.

The baseline assessment (approximately 1-6 weeks post stroke) will be undertaken by the ward based physiotherapist / research physiotherapist / stroke research network staff who is not involved in the treatment allocation. The 10 weeks (post randomisation) assessment will be undertaken by a research physiotherapist or appropriately trained person who is not involved in the treatment allocation or in direct clinical care of trial participant. NHS ward based therapists delivering treatment to the recruited patients and the patients themselves will not be masked to the treatment allocation.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Fugl Meyer (Upper limb section) change score from baseline to 10 weeks post randomisation

Key secondary outcome(s)
1. Proportion of subjects showing a clinically meaningful response (defined as >=3 point improvement in Fugl Meyer upper limb score; Barthel Index; Stroke Impact Scale; ABILHAND; EQ-5D
2. Safety: Safety issues will be reported by the treating therapist to the recruiting centre Principal Investigator according to MHRA processes.
3. Implementation outcomes: Standardised Likert response questionnaire will be used. Questions include ease of implementation, nature of exercise, fit with routine clinical service

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Aged 18 years or above
2. New clinically diagnosed ischaemic or haemorrhagic stroke (excluding subarachnoid haemorrhage) in the 1-6 weeks prior to randomisation
3. Reduced arm movement due to stroke - Patient unable to turn palm face up and face down, keeping elbow straight, thumb pointing up and shoulder flexed between 30° and 90°

4. Expected to need ongoing in-patient rehabilitation treatment for at least 3 - 6 weeks after stroke (clinical judgement)
5. Expected to be able to comply with treatment schedule post randomisation
6. Able to sit safely in supportive wheelchair with harness for 30-60 minutes
7. Able to participate in an assisted upper limb exercise session at least 10 minutes
8. Able to summon help and able to press the patient stop button on the iPAM system wheelchair with the non paretic arm

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Not expected to survive for 2 months following stroke
2. Medically unstable (e.g. cardiac or respiratory conditions or epilepsy)
3. Could not use the arm affected by stroke prior to stroke (e.g. because of other conditions)
4. Weight over 125kg (19 stone 9.6lbs / 275.6lbs) (weight restrictions on the orthoses and seating system for iPAM)

Date of first enrolment
02/01/2012

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Leeds Institute of Molecular Medicine
Leeds
United Kingdom
LS2 9NZ

Sponsor information

Organisation
University of Leeds (UK)

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) - Health Technology Devices Program (UK) ref: 475

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration