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Robot assisted training for the upper limb after stroke

Submission date	Recruitment status	[X] Prospectively registered
04/10/2013	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/10/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/05/2021	Circulatory System	

Plain English summary of protocol

Background and study aims
Loss of the ability to use the arm is a common and distressing consequence of stroke. Currently it is unclear how best to provide therapy to improve arm recovery and function. Research suggests that robot-assisted training may be beneficial but this is not yet proven and further research is needed. Robot-assisted training consists of the use of a machine or 'robot' to exercise the arm. The aim of this study is to find out whether robot-assisted training improves arm function after stroke. Robot assisted training is compared to an enhanced upper limb therapy programme consisting of repeated practice of everyday activities using the arm and usual NHS rehabilitation.

Who can participate?
Adults aged over 18 who have had a stroke which has resulted in difficulty using the arm.

What does the study involve?
Participants are randomly allocated to either robot-assisted training, enhanced upper limb therapy or usual NHS rehabilitation. Robot-assisted training and enhanced upper limb therapy are provided for 45 minutes, 3 times per week for 12 weeks. Robot-assisted training uses a machine to exercise the shoulder/elbow, wrist and hand. Enhanced upper limb therapy involves practicing everyday activities. Usual NHS rehabilitation may involve a range of rehabilitation treatments according to individual clinical need. The effects of the treatments are evaluated by comparing the arm function of patients in each group.

What are the possible benefits and risks of participating?
It is not known whether robot assisted training or enhanced upper limb therapy are effective for improving arm function after stroke. However, research has suggested that increasing therapy, in particular repetitive exercise therapy which is used in both robot-assisted training and enhanced upper limb therapy may improve arm function. It is thought that increasing repetitive exercise in rehabilitation may be beneficial, but this is not yet proven.

Where is the study run from?
The study is being run from Newcastle University, Newcastle upon Tyne, UK. Stroke patients from four areas of the UK are invited to take part (Newcastle/Northumbria, Romford, Glasgow and Cambridge).

When is the study starting and how long is it expected to run for?
April 2014 to January 2018

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

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
15309; HTA 11/26/05

Study information

Scientific Title
Robot Assisted Training for the Upper Limb after Stroke (RATULS): a randomised interventional phase III study

Acronym
RATULS

Study objectives
To determine whether robot-assisted training with the InMotion robotic gym system (In Motion commercial version) improves upper limb function post stroke.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service Committee North East - Sunderland, 05/11/2013, ref: 13/NE /0274

Study design
Randomised interventional phase III study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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 rehabilitation

Interventions
This is a three-group randomised controlled trial.

Group 1: Robot-assisted training
Robot-assisted training will use the InMotion robotic gym system which comprises three modules to exercise the shoulder/elbow, wrist and hand. Treatment will be provided for 45 minutes, 3 times per week for 12 weeks.

Group 2: Enhanced upper limb therapy
Enhanced upper limb therapy will consist of upper limb rehabilitation goal setting followed by practice of everyday activities to work towards the goals. Treatment will be provided for 45 minutes, 3 times per week for 12 weeks

Group 3: Usual NHS rehabilitation
This group will continue with usual NHS rehabilitation in accordance with local clinical practice.

Intervention Type
Other

Phase
Phase III

Primary outcome measure
Upper limb function measured using the Action Research Arm Test (ARAT) at 3 months post randomisation

Secondary outcome measures
1. Upper limb impairment, measured using the Fugl-Meyer Test (motor and sensory arm sections)
2. Activities of daily living (measured using the Barthel ADL Index), quality of life (measured using EQ-5D-5L)
3. Upper limb pain, measured using a numerical rating scale
4. Resource use, measured using an adaption of the Client Services Receipt Inventory
5. Adverse events, measured at 3 and 6 months post randomisation

Overall study start date
01/04/2014

Completion date
31/08/2019

Eligibility

Key inclusion criteria
Adults with a first ever stroke who fulfil the following criteria are eligible:
1. Age 18 years and over
2. Clinical diagnosis of stroke (cerebral infarction, primary intracerebral haemorrhage, subarachnoid haemorrhage)
3. Between one week and five years since stroke
4. Moderate to severe upper limb functional limitation (Action Research Arm Test (ARAT) score 0-39) due to stroke
5. Able to provide consent to take part in the study and to comply with the requirements of the protocol

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
UK Sample Size: 720

Total final enrolment
770

Key exclusion criteria
1. More than one stroke (patients with previous transient ischaemic attack (TIA) may be invited to participate)
2. Other current significant impairment of the upper limb affected by stroke e.g. fixed contracture, frozen shoulder, severe arthritis, recent fracture
3. Diagnosis likely to interfere with rehabilitation or outcome assessments e.g. registered blind
4. Previous use of the InMotion robotic gym system or other arm rehabilitation robot
5. Current participation in a rehabilitation trial evaluating upper limb rehabilitation after stroke
6. Previous enrolment in this study

Date of first enrolment
01/04/2014

Date of final enrolment
31/07/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Newcastle University
Newcastle Upon Tyne
United Kingdom
NE2 4AE

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

Sponsor details
Leazes Wing
Royal Victoria Infirmary
Queen Victoria Road
Newcastle Upon Tyne

England
United Kingdom
NE1 4LP

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
31/08/2020

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	20/07/2017		Yes	No
Results article	results	06/07/2019	29/05/2019	Yes	No
Results article	economic evaluation results	25/05/2021	27/05/2021	Yes	No
HRA research summary			28/06/2023	No	No