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Repetitive Arm Functional Tasks After Stroke (RAFTAS) study II

Submission date
04/04/2013

Recruitment status
No longer recruiting

Registration date
04/04/2013

Overall study status
Completed

Last Edited
05/09/2016

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Loss of the ability to use an arm affects up to 85% of people who have recently had a stroke. People report that losing the use of their arm is one of the most distressing long term symptoms of stroke. Some people feel that rehabilitation does not focus enough on arm recovery. At the moment it is unclear how to best provide therapy to improve arm recovery. Recent research has suggested that recovery may be improved by practising activities a lot of times, especially if the activity is for a specific functional purpose. An example of an activity for a functional purpose is use your affected hand to touch your cheek with a flannel'. This type of therapy is called Repetitive Functional Task Practice (RFTP). Previous research about RFTP therapy has not allowed us to say for sure that this treatment will improve recovery of arm function. In order to test whether RFTP therapy will improve arm recovery, we need to conduct a large research study. However, before we do a large clinical trial its important to do a small version of the trial (a pilot trial) to check that the design and logistics of the trial are acceptable. This study is a small pilot trial which will enable us to design the large clinical trial to determine if RFTP therapy will improve arm recovery after stroke.

Who can participate?
We are inviting people to take part who have recently had a stroke which has caused problems with how they can use their arm.

What does the study involve?
In this pilot trial, people are randomly allocated to one of the two groups, one group the new treatment (called the intervention group) and the other group standard treatment (called the control group). Results and feedback from both groups are examined. In this pilot trial, the new treatment is a RFTP therapy programme and standard treatment is usual rehabilitation. Everybody who agrees to take part in the study will be asked to undertake three research assessments. Assessment 1 will take place after they agree to take part in the study, assessment 2 one month after they enter the study and assessment 3 three months after they enter the study. At each assessment a member of the research team will ask participants some questions about how their stroke is affecting their everyday life and ask them to perform some movements with their arms. People who are placed into the group which receive the RFTP therapy programme will be asked to follow the RFTP programme. This will include practising

activities independently, twice each day for four weeks. In addition, people who receive the RFTP programme will be seen by a therapist twice per week for four weeks. The therapist will review progress, adjust activities if needed and ask for comments on how they are finding the programme. The programme is in addition to the usual rehabilitation they normally receive. People who are placed into the group which receive usual rehabilitation will continue with the usual post stroke rehabilitation.

What are the possible benefits and risks of participating?
All participants taking part in this research study will be provided with advice and information about stroke, rehabilitation and positioning of the arm and hand after stroke which we hope they will find interesting and useful. Participants provided with the RFTP programme will receive arm therapy (RFTP programme) which is extra to the therapy they are receiving. Research has suggested that arm recovery may be faster when extra treatment is given early after stroke. This could possibly speed up how quickly they can use their arm again. Having this programme to practise at this early time after stroke will hopefully make the most of the time where potential recovery of the arm is greatest. Research has also suggested (but not proven) that people who have had a stroke are helped most by practising everyday activities. These are the types of activities we are using in the RFTP programme. All participants in this research project will be asked to take part in research assessments which examine how their stroke has affected their arm and the effects their stroke is having on their everyday life. Some participants may find this tiring or upsetting. Participants who receive the RFTP programme may notice some discomfort in their arm when practising the programme but this should be no greater than the discomfort they may feel during usual rehabilitation therapy. It is very common for people to feel tired after a stroke. Participants who receive the RFTP programme will be practising the programme in addition to their usual rehabilitation which could make them feel more tired.

Where is the study run from?
The study coordinating Centre is Newcastle University. We have three study sites who are recruiting participants for our study; North Tees and Hartlepool NHS Foundation Trust, Gateshead Health NHS Foundation trust and South Tees Hospitals NHS Foundation Trust, all based in the UK.

When is the study starting and how long is it expected to run for?
November 2012 to August 2014

Who is funding the study?
The Stroke Association (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
14134

Study information

Scientific Title
Repetitive Arm Functional Tasks After Stroke (RAFTAS) study II: a randomised controlled trial

Acronym
RAFTAS Study II

Study objectives
Loss of the ability to use an arm affects up to 85% of people who have a stroke and patients report that this is one of the most distressing long term symptoms after stroke. At the moment it is unclear how best to provide therapy to improve arm recovery. Recent research has suggested that recovery may be improved by a type of therapy called Repetitive Functional Task Practice (RFTP) but this is not yet proven. RFTP involves practising everyday functional activities.

In order to test whether RFTP therapy will improve arm recovery, a large randomised controlled trial (RCT) needs to be conducted. In a RCT, a new treatment is compared with the standard treatment available. People are put into two groups at random and one group given the new treatment (RFTP therapy) and the other group the standard treatment (usual stroke rehabilitation). However, before a large clinical trial is conducted, its important to do a small version of the trial (a pilot trial) to check that the design and logistics of the trial are acceptable and feasible.

This research study is a small pilot trial which will enable us to design a large clinical trial to determine if RFTP therapy will improve arm recovery after stroke. Patients who agree to take part in the pilot trial will be randomised to a four week programme of RFTP therapy or to continue with usual post stroke rehabilitation. Eligibility for the study, recruitment rate, adherence to therapy, feedback about therapy and clinical measurements at 1 month and 3 months (eg arm function) will be recorded.

The RFTP therapy programme consists of twice daily independent practice of participant selected functional activities. A therapist will review progress twice per week and activities will be modified according to progress.

Ethics approval required
Old ethics approval format

Ethics approval(s)
13/NE/0074

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Topic: Stroke Research Network; Subtopic: Stroke / Rehabilitation

Interventions
1. A four week RFTP programme for patients with upper limb impairment due to acute stroke OR
2. Usual post stroke rehabilitation

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The aim of the study is to assess the feasibility of a multi-centre, observer blind parallel group randomised controlled trial of a RFTP programme for the upper limb early after stroke. The study design is a pilot randomised controlled trial and interventional.

Key secondary outcome(s))
1. To determine whether it is possible to enrol 1-2 patients per month from each study centre
2. To report the proportion of study eligible patients in each study centre
3. To report the proportion of study eligible patients enrolled in the study
4. To report the main reasons why patients were not eligible for study inclusion
5. To report the attrition of participants in control and intervention groups
6. To report participant adherence to the RFTP programme
7. To report therapist adherence to the RFTP programme
8. To report the usual rehabilitation care received by control and intervention groups within the study intervention period
9. To report the success of outcome assessor blinding to participant group allocation
10. To report adverse events in control and intervention groups during the study
11. To report completeness and summary statistics of data to inform the design of a future multi-centre RCT. Data will be recorded at baseline, 1 and 3 months:
11.1. Upper limb function (measured by the Action Research Arm Test)
11.2. Grip strength (measured using a dynamometer)
11.3. Arm strength (measured by the Motricity Index)
11.4. Ability to perform extended activities of daily living (measured by the Nottingham Extended Activities of Daily Living Index)
11.5. Bilateral arm activity (measured using a GENEActiv™ accelerometer
12. To seek and report the views and experiences of study participants about undertaking the

RFTP programme
13. To seek and report the views and experiences of therapists about delivery of the RFTP programme

Completion date
30/04/2014

Eligibility

Key inclusion criteria
1. Age >= 18 years, male and female
2. Within 14 days of stroke onset
3. New reduced upper limb function due to acute stroke but with retained ability to lift the affected hand off their lap
4. Capable of undertaking the RFTP therapy programme and adhering to the study protocol
5. Able to provide informed consent to participate in the study
6. Lives within the community services catchment area of a participating study site

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Severe reduced upper limb function which results in inability to lift the affected hand off their lap
2. Unable to follow the RFTP programme for example due to cognitive impairment or receptive aphasia
3. Other significant upper limb impairment e.g. fixed contracture, frozen shoulder, severe arthritis, and upper limb pain that inhibits participation in the RFTP programme
4. Diagnosis likely to interfere with rehabilitation e.g. registered blind, palliative care

Date of first enrolment
01/03/2013

Date of final enrolment
30/04/2014

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
Northumbria Healthcare NHS Foundation Trust (UK)

ROR
https://ror.org/01gfeyd95

Funder(s)

Funder type
Charity

Funder Name
Stroke Association (UK)

Alternative Name(s)
TheStrokeAssociation, TheStrokeAssoc

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2016		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes