ISRCTN88395268 https://doi.org/10.1186/ISRCTN88395268

A feasibility study for attention loss after stroke

Submission date
08/01/2019

Recruitment status
No longer recruiting

Registration date
09/01/2019

Overall study status
Completed

Last Edited
27/10/2022

Condition category
Nervous System Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Current plain English summary as of 12/04/2019:
Background and study aims
Some patients have difficulty taking part in occupational therapy because of attention loss (spatial inattention) after stroke. This means that that awareness of one side of the body and surrounding area is affected causing the person to miss that side. The eyes work but the person does not see. Patients with spatial inattention early after stroke have poor recovery. They can miss out on the full benefits of early stroke care. They are often discharged from hospital needing a lot of help at home. Prism Adaptation Training (PAT) is a possible therapy for inattention. The patient wears glasses with large lenses (prisms) that move their view to one side. The patient points at a target repeatedly for five minutes while wearing prism glasses. The brain adapts temporarily and the patient switches from pointing too far one side to the other, meaning they become more aware of their neglected side. This adaptation may help patients to participate in therapy if it is delivered immediately after wearing the prism glasses. The aim of this study is to investigate how practical it is to use PAT to help patients with spatial inattention to participate in occupational therapy and improve their outcomes. It will also add to existing evidence on the clinical usefulness and value of PAT.

Who can participate?
Stroke patients over 18 years old with spatial inattention, their informal carers and occupational therapy staff

What does the study involve?
Patients are randomly allocated into two groups: one group receives PAT in addition to their normal occupational therapy, the other group just receives normal occupational therapy. The accuracy and acceptability of PAT is assessed through interviews with patients, carers and staff. Patients' functional abilities and the clinical usefulness of PAT on engagement in occupational therapy are also assessed.

What are the possible benefits and risks of participating?
Current research suggests that, when applied correctly, PAT provides some relief from the symptoms of spatial inattention. However, research also suggests that not everyone responds to the training, and that any benefits may be short-lived. Therefore, to suggest that patients would benefit in the long-term by participating in this trial would be misleading. PAT has anecdotal reports of slight motion sickness, vertigo and general discomfort with its prolonged use.

Participants will be encouraged to report any feelings of discomfort arising from the use of optical prisms to their occupational therapist or other medical team members. Questionnaires pertaining to personal thoughts and feelings of patients regarding their stroke and recovery pathway may at times be uncomfortable and distressing for those participating. Staff administering these questionnaires will be suitably trained and will be experienced in performing such tests with patients, who at all times have the right to withdraw. A distress procedure is in place detailing how to manage a situation with distressed participants. Staff participants will be made aware that the decision to participate or not will not affect their employment status in any way.

Where is the study run from?
1. Salford Royal Hospital (UK)
2. Fairfield General Hospital (UK)
3. Manchester Foundation Trust (UK) (Manchester Royal Infirmary
4. Trafford General Hospital
5. Wythenshawe Hospital
6. Stepping Hill Hospital (UK)
7. Royal Albert Edward Infirmary (UK)
8. Royal Blackburn Hospital

When is the study starting and how long is it expected to run for?
July 2018 to April 2020 (updated 08/07/2020, previously: June 2020)

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

Who is the main contact?
Prof. Audrey Bowen
SPATIALstroke@manchester.ac.uk

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Contact information

Type(s)
Scientific

Contact name
Prof Audrey Bowen

ORCID ID
https://orcid.org/0000-0003-4075-1215

Contact details
Chief Investigator
G.800 Stopford Building
University of Manchester
Manchester
United Kingdom
M13 9PL
+44 (0)161 275 1731
SPATIALstroke@manchester.ac.uk

Additional identifiers

Protocol serial number
40626

Study information

Scientific Title
A feasibility Study of Prisms And Therapy In Attention Loss after stroke (SPATIAL feasibility)

Acronym
SPATIAL feasibility study

Study objectives
SPATIAL feasibility will investigate how practical it is to use Prism Adaptation Training (PAT) to help patients with spatial inattention to participate in occupational therapy and improve their outcomes. It will also add to existing evidence on the clinical usefulness and value of PAT.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire & The Humber - Bradford Leeds Research Ethics Committee
NHSBT Newcastle Blood Donor Centre | Holland Drive | Newcastle upon Tyne | NE2 4NQ
Tel: +44 (0)207 1048 088
Email: nrescommittee.yorkandhumber-bradfordleeds@nhs.net
09/01/2019, ref: 18/YH/0480

Primary study design
Interventional

Study design
Randomised; Interventional; Design type: Treatment, Rehabilitation

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Attention loss following stroke

Interventions
Current Interventions as of 10/02/2020:
The trialists are testing how sensible and practical it is to use PAT as part of an occupational therapy session in order to inform a larger trial. This will be done in multiple hospitals. Patients will be split into two groups at random: one will receive PAT in addition to their normal occupational therapy, the other will just receive normal occupational therapy. The entire study will be evaluated to find out what it was like for everyone who was involved. The study will also test whether PAT helps people participate in occupational therapy. The study has been designed in collaboration with stroke service users.

Potential Participant Screening and Recruitment
NHS occupational therapists in six North West stroke sites will identify potential participants who are 1or more weeks post-stroke onset with evidence of spatial inattention. Their details will be given to NHS CRN practitioners/ members of the clinical team for checking eligibility and recruitment before the collection of baseline demographic and clinical data. Patients will be randomized into the groups after this.
Carers will be identified by the participants. They will also be recruited and given the option of consenting by phone (rather than in writing) if this is more convenient for them. Carers will not be randomized or receive any intervention.

Randomization
Randomization will be designed by the trial statistician and arranged by site. Group allocation will be 3:1 (3 PAT plus occupational therapy: 1 occupational therapy alone) to maximize the number of participants in the intervention arm, while retaining a control. The randomization service will be provided by an independent, web-based, third-party professional company (eg: www.sealedenvelope.com). Randomization will take place as soon as possible after informed consent has been obtained. The CRN practitioners/ member of the clinical team will record the group the patient has been allocated to and inform the participant and treating OT of the group allocation.

Baseline assessment
NHS OTs will complete a baseline assessment with consented patient participants which will include OCS hearts and star cancellation tests. The trialists will also see if it is feasible for the therapists to complete the Catherine Bergego Scale/the Kessler Foundation Neglect Assessment Process. They will also record the severity of spatial inattention based on a combination of functional observations, assessment, and their clinical judgment. Should these assessments show that the patient is no longer displaying spatial inattention they will no longer be eligible to take part in the study.

INTERVENTION GROUP
For participants in the intervention group, prism adaptation training (PAT) will be offered at the start of a standardized session OT for up to 3 weeks, 5 days a week. PAT takes no more than 5 minutes plus set up time (seating the participants and fitting the glasses). To perform PAT the participant will be seated at a table in front of a training box that has open ends.
The participant will be fitted with 12.5° prism glasses and the occupational therapist will hold up targets at the opposite end of the box, and ask the participant to reach to the target this will be repeated a maximum of 90 times, or for a maximum of 5 minutes, whichever is the shorter.
When the prism glasses have been removed the session will continue with standardized OT. The effect of prism adaptation training is strongest in the hours soon after treatment; reducing the spatial inattention for long enough to take part in usual OT that aims to increase independence in activities of daily living. The OT staff will record the time that PAT took place, the number of repetitions of pointing, the length and type of therapy intervention.

CONTROL GROUP
Participants in the control group will receive standardized OT without PAT. The OT staff will record the timing and type of therapy intervention.

1ST OT SESSION - BOTH GROUPS
Patients will be asked to perform a brief functional therapy activity (visual search/scanning) with their treating OT twice within the first session, before and after PAT (or at equivalent time points in the non-PAT group). Therapists will explain and feedback to participants as in a typical therapy session. This activity is designed to provide a standardized way of assessing engagement. The tasks will be similar before PAT and after PAT. With the patients' consent, we will video-record these short pre- and post-PAT sections of the first OT session for analysis of engagement at a later date. This analysis will be carried out by an occupational therapist member of the research team who does not know which group each participant is in.

Outcome measurement- patient participant
Outcome measurement will take place at the end of the 3 week intervention period (T1) and three months post-randomization (T2) by research staff/ members of the clinical team trained to conduct outcome measurements. The intended primary outcome for a definitive trial is the Nottingham Extended Activities of Daily Living at T2. Secondary outcomes will be: standardized tests for spatial inattention (e.g. OCS hearts test, BIT star cancellation, Radner reading) at T1 and T2; PRECiS, a patient-reported measure of impact developed for and by people with cognitive difficulties and the EQ5D5L at T2; length of stay, destination on transfer from in-patient care, modified Rankin Scale on transfer and adverse events up until T2. These will be completed by assessors who do not know which group the participant is in (blinded) where possible. Assessors will record which arm they believe the participant to be in and if they have been unblinded.

Outcome measurement- carer participant
Outcome measurements for carers will take place at T2 only. Outcome measures are Carer Experience Scale, modified Carer Strain index and self-reported informal carer costs. These will be collected face to face (in the hospital or home), by phone or by mail by a suitably qualified and trained member of the hospital research or clinical team or a member of the University of Manchester research team.

Process evaluation: interviews
A small sample of carer, patient and staff participants will be invited to take part in a recorded interview. Only participants with capacity (including those who have regained capacity) will be invited to take part in the interviews.

Staff interviews will be conducted by phone by members of the research team based at the University of the West of England, Bristol.

Patient participant and carer interviews will be completed by the University of Manchester research team and may be conducted in person (in hospital, or participant's home) or by phone.

Analysis
Because this study is testing the practicalities of running a trial, analyses will be mostly descriptive. The trialists will establish how many people were recruited, how many people stayed in the trial and the differences in the main participant outcome. In addition, they will estimate participant outcomes based on the number of people within the trial. They will seek outcome data for all participants regardless of whether they received the full amount of PAT unless consent to follow-up is explicitly withdrawn. They recognize that the small size of this study prevents conclusions about the intervention. Standard statistical procedures (regression) will be carried out.

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Potential Participant Screening and Recruitment
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Intervention Type
Other

Primary outcome(s)
Functional ability is measured using EADL at 12 weeks

Key secondary outcome(s)
1. Inattention is measured using star cancellation, Oxford Cognitive Screen, reading test and KF-NAP at baseline, 3 and 12 weeks
2. Impact of cognitive problems is measured using PRECiS at 12 weeks
3. Health status is measured using EQ5D5L at 12 weeks
4. Impact on carers is measured with the Carer Experience Scale, modified Carer Strain Index and self-reported
informal carer costs at 12 weeks

Completion date
30/04/2020

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 10/02/2020:
PATIENT PARTICIPANTS
1. Over 18 years old
2. Confirmed stroke (ischaemic or hemorrhagic)
3. Positive for spatial inattention at routine screening
4. Spatial inattention impacting on functional task performance
5. At least 1 week post-stroke onset
6. Eligible for standard occupational therapy (for at least one session)

7. Able to provide informed consent (or availability of personal/ professional consultee)
8. Able to sit with support and perform brief research intervention (e.g. has sufficient vision, physical mobility and cognition to be able to participate)

CARER PARTICIPANTS
1. Informal carer of a patient in the trial
2. Aged 18 or over
3. Able to provide informed consent

STAFF PARTICIPANTS
1. A member of the NHS occupational therapy team (Occupational therapist, Occupational therapy assistant, rehabilitation assistant)
2. Has been trained in the study processes
3. The staff member has treated a minimum of 1 patient participant from the intervention arm

Previous participant inclusion criteria:
PATIENT PARTICIPANTS
1. Over 18 years old
2. Confirmed stroke (ischaemic or haemorrhagic)
3. Positive for spatial inattention at routine screening
4. Spatial inattention impacting on functional task performance
5. 1 to 4 weeks post stroke onset
6. Eligible for standard occupational therapy (for at least one session)
7. Able to provide informed consent (or availability of personal/ professional consultee)
8. Able to sit with support and perform brief research intervention (e.g. has sufficient vision, physical mobility to be able to participate)

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Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex

All

Total final enrolment
97

Key exclusion criteria
PATIENT PARTICIPANTS
1. Receiving or expected to receive end of life care
2. Discharge anticipated before at least one therapy session

The trialists will begin this feasibility trial with broad inclusion criteria but will monitor and adjust these as recruitment proceeds. For example they will note levels of pre-stroke dependency using the modified Rankin Scale (mRS). They will initially include people regardless of their mRS, including those who were assessed as pre-morbidly dependent ie > 3 on the mRS (an mRS of 4 is defined as: moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance). A mRS of > 3 would only be added as an exclusion criterion should staff feedback and review of patient participation indicate that the intervention appears unsuitable for this group of patients.

CARER PARTICIPANTS
Under 18

STAFF PARTICIPANTS
Have not provided PAT to any patient participants

Date of first enrolment
01/02/2019

Date of final enrolment
31/01/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Salford Royal Hospital (lead centre)
Stott Ln
Salford
United Kingdom
M6 8HD

Study participating centre

Fairfield General Hospital
Rochdale Old Rd
Bury
United Kingdom
BL9 7TD

Study participating centre
Manchester Royal Infirmary
Oxford Rd
Manchester
United Kingdom
M13 9WL

Study participating centre
University Hospital of South Manchester
Southmoor Rd
Wythenshawe
Manchester
United Kingdom
M23 9LT

Study participating centre
Stepping Hill Hospital
Poplar Grove
Hazel Grove
Stockport
United Kingdom
SK2 7JE

Study participating centre
Royal Albert Edward Infirmary
Wigan Ln
Wigan
United Kingdom
WN1 2NN

Study participating centre
Royal Blackburn Hospital
Haslingden Rd

Blackburn
United Kingdom
BB2 3HH

Study participating centre
Trafford General Hospital
Moorside Road
Davyhulme
Manchester
United Kingdom
M41 5SL

Sponsor information

Organisation
The University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-0816-20016

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Audrey Bowen (Audrey.bowen@manchester.ac.uk) via email, fully anonymised from 01/07/2021 for 15 years. Data will be shared at the discretion of the Chief Investigator within reasonable requests.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/10/2022	27/10/2022	Yes	No
HRA research summary			28/06/2023	No	No
Plain English results		04/12/2020	20/06/2022	No	Yes
Protocol file	version 2.0	13/06/2019	02/03/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes