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Spatial inattention grasping therapy for neglect post-stroke

Submission date
12/06/2025

Recruitment status
Recruiting

Registration date
07/07/2025

Overall study status
Ongoing

Last Edited
07/07/2025

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
A stroke is caused by the blood supply being cut off to part of the brain, killing brain cells. This can affect the brain's ability to interpret information. In some cases, this can make the stroke survivor lose attention to things on one side of the body. This disabling condition is called spatial neglect or inattention. Spatial inattention affects 1 in 3 stroke survivors. People affected by spatial inattention often have poor recovery and long-term disability. They tell us: "It's terrifying, I bump into people" and "there's not enough support". Healthcare staff follow national stroke guidelines but currently there is no effective treatment for spatial inattention. Stroke survivors and NHS staff prioritised research into improving how the brain interprets information. They suggested focusing on conditions like spatial inattention. We worked with stroke survivors, carers, and healthcare staff to create a therapy for spatial inattention called SIGHT (Spatial Inattention Grasping Therapy). SIGHT requires people to grasp and balance rods with their less affected hand. Because of spatial inattention, the rods tilt in the first attempts. This improves when they see and feel the rods tilt. In our earlier small studies, patients found SIGHT to be acceptable. It showed promise in improving spatial inattention. We will conduct a bigger study to see if SIGHT can help spatial inattention after stroke. We will also find out which patients benefit most.

Who can participate?
Any adult who is in hospital because of a confirmed stroke and experiencing signs of spatial inattention. They should be between 1 week and 60 days post-stroke and be able to follow instructions and sit with or without support in front of a table for 30 minutes.

What does the study involve?
We will split stroke survivors with spatial inattention into two groups. One group will receive SIGHT and usual care. The other group will only receive usual care. Usual care does not include SIGHT. To compare the effect of the therapy, we will assess patients' ability to attend to objects and to carry out daily life tasks. We will assess patients before the therapy starts, after therapy, and 3 months after the end of therapy. We will also study why some people benefit more from therapy than others. People who have inattention are better at grasping the middle of objects than judging where the middle is. This shows that different parts of the brain control grasping and perceiving things. People with damage to the parts of the brain used for grasping may

benefit less. To help identify who might benefit we will measure grasping, vision, cognition, and stroke severity; where possible and with the consent of patients, some will have an MRI scan.

What are the possible benefits and risks of participating?
There are no direct benefits to participants and no known risks to taking part.

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

When is the study starting and how long is it expected to run for?
January 2025 to February 2028

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

Who is the main contact?
Dr Stephanie Rossit, s.rossit@uea.ac.uk

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
335220

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 58911; Grant Code: NIHR159047

Study information

Scientific Title
Spatial Inattention Grasping Therapy (SIGHT) for rehabilitation of spatial neglect post-stroke: a randomised-controlled multicentre efficacy trial with embedded mechanistic study of determinants of therapy response

Acronym
SIGHT

Study objectives
When added to treatment as usual (TAU), 30 minutes per day of SIGHT for 7 days (over a 10-day period) will produce a greater reduction in neglect than TAU alone.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 11/06/2025, London – Queen Square Research Ethics Committee (Floor 2, 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8225, +44 (0)207 104 8227, +44 (0)207 104 8284; queensquare.rec@hra.nhs.uk), ref: 25/LO/0391

Study design
Randomized; Interventional; Design type: Treatment, Complex Intervention, Rehabilitation

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied

Stroke

Interventions

Initial screening of potentially eligible participants will include a check of patients' notes to confirm:
1. Evidence of stroke including review of radiology reports to confirm stroke lesion is visible on clinical scan
2. Patient meets remaining eligibility criteria where information is available

Potentially eligible participants will be provided with a participant information sheet. All patients pre-screened will be
recorded in the screening log. Once initial screening is complete, the following activities will be undertaken:
1. Written informed consent or consultee assent will be obtained to participate
2. Star Cancellation sub-test of the Behavioural Inattention Test (BIT)
3. Line bisection sub-test of the BIT
4. Cancellation Task of Oxford Cognitive Screen
5. For sites participating in the mechanistic study only, if the patient is suitable and consents for MRI, complete screening for MRI (according to local procedures)

Patients providing consent and meeting all of the inclusion criteria, including the minimum definition for spatial neglect
(Star Cancellation ≤51, Oxford Cognitive Screen cancellation <42 or BIT Line Bisection score ≤7) will complete the
baseline measures and have relevant data collected as listed below:
1. Clinical and Demographic data collected by site staff
2. If baseline measures are not being undertaken on the same day as eligibility confirmation, these measures are repeated, including:
2.1. Star Cancellation sub-test of the BIT
2.2. Line Bisection sub-test of the BIT
2.3. Cancellation Task of Oxford Cognitive Screen (CT-OCS)
3. Endpoint weightings line bisection task
4. Oxford Cognitive Screen (OCS)
5. Catherine Bergego Scale KF-NAP (CBS KF-NAP)
6. NIH Stroke Scale/Score (NIHSS) extracted from clinical records (most recent only)
7. Perception-Grasping Dissociation task
8. Visual field assessment sub-test of the Vision Impairment Screening Assessment (VISA) tool
9. Gesture Recognition sub-test of the Birmingham Cognitive Screen (BCoS)
10. Optional: Computerised Extrapersonal Neglect Test (CENT)
11. Pseudonymised clinical brain imaging scans (CT and/or MRI) uploaded to UEA via the Image Exchange Portal
12. Pseudonymised clinical brain imaging scan reports uploaded to the REDCap database
13. Confirmation of yes/no of lesion in the Intraparietal Sulcus (IPS)
14. MRI-eligible patients at sites participating in the mechanistic study will have the following MRI neuroimaging sequences before baseline measures are obtained:
14.1. Localisation/setup scans
14.2. T1-weighted whole brain scan
14.3. T2 FLAIR
14.4. Diffusion-weighted imaging scan (DTI)
14.5. Resting-state functional MRI (rsfMRI)

The completion and submission of the baseline measures will enable the database randomisation, notifying the trial team and local SIGHT intervention delivery staff of the patient' s trial arm. Randomisation stratification will use trial site, age of patient, neglect severity (according to the Star Cancellation) and whether a lesion is present or not on the Intraparietal Sulcus (IPS). If a patient is allocated to the intervention arm, the SIGHT-trained staff will deliver the SIGHT intervention over a 10-day period following randomisation. Treatment as usual will be recorded during this 10-day period for all patients on both arms of the trial.

All participants will have a visit from a blinded assessor on Day 11 (+5 days) post-randomisation. The blinded assessor will collect the efficacy measures: Star Cancellation test; endpoint weighting line bisection, OCS and the Catherine Bergego Scale KF-NAP.

All participants will have a visit from a blinded assessor at 12 weeks (±10 days) post-randomisation. The blinded assessor will collect the efficacy measures: Star Cancellation test; endpoint weighting line bisection, OCS; the Catherine Bergego Scale KF-NAP and the Stroke Impact Scale (SIS).

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Neglect measured using the Star Cancellation sub-test of the Behavioural Inattention Test (BIT) at baseline, Day 11 and 12 weeks post-randomisation

Key secondary outcome(s))
Measured at baseline, Day 11 and 12 weeks post-randomisation:
1. Neglect measured using the Oxford Cognitive Screen (OCS) cancellation task, the Endpoint weightings line bisection task (LB) and the Catherine Bergego Scale KF-NAP(CBS KF-NAP).

Measured only at 12 weeks post-randomisation:
2. Self-reported stroke outcomes will be measured using the Stroke Impact Scale (SIS).

Measured only at baseline:
3. Stroke severity determined from data extracted from patients' notes using the NIH Stroke Scale/Score (NIHSS)
4. Dissociation between grasping and pointing measured using the Perception-Grasping Dissociation task
5. Visual field deficits measured using the visual field assessment sub-test of the Vision Impairment Screening Assessment (VISA) tool
6. Stroke-specific cognitive deficits assessed using the full Oxford Cognitive Screen
7. Apraxia detected using the Gesture Recognition sub-test of the Birmingham Cognitive Screen (BCoS)
8. For sites that are able, the (optional) Computerised Extrapersonal neglect test (CENT) will be used to measure neglect for far space, or extrapersonal neglect.
9. Clinical brain imaging scans and reports (CT and/or MRI) will be used to map the stroke lesion location to determine if this impacts therapy response.
10. For those who are able and consent to MRI the following neuroimaging sequences will be acquired to map the stroke lesion and provide a neuroimaging dataset of neglect post-stroke:

10.1. Localisation/setup scans to harmonise the data
10.2. T1-weighted whole-brain scan for alignment
10.3. T2 FLAIR to provide good lesion contract
10.4. Diffusion-weighted imaging scan (DTI) for white matter tractography
10.5. Resting-state functional MRI (rsfMRI) to measure changes in blood oxygenation associated with intrinsic brain activity

Completion date
29/02/2028

Eligibility

Key inclusion criteria
1. Aged at least 18 years at the time of consent
2. Stroke confirmed with clinical brain imaging (CT and/or MRI), not neck or brain vessel imaging (CTA, MRA, DSA)
3. Between 1 week and 60 days post-stroke
4. Able to read and understand English (those with aphasia will be supported)
5. Signs of neglect on at least one of the following:
5.1. Star Cancellation <= 51, or
5.2. BIT line bisection score <= 7), or
5.3. Oxford Cognitive Screen Cancellation accuracy score < 42 and either OCS Cancellation Object Score > 1 or < -1, or OCS Cancellation Space score >3 or <-2
6. Able to follow a one-stage command “grasp this pencil/pen with your less affected arm” as demonstrated by another
7. Able to sit with or without support in front of a table for 30 continuous minutes

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Being discharged from inpatient hospital facility to home, or to an inpatient hospital facility that is not part of the regional participating hub within the next 7 days
2. Enrolled on another interventional study targeting neglect
3. Limited life expectancy due to another illness or chronic condition making the 3-month follow-up difficult (e.g. widespread malignancy)
4. For mechanistic neuroimaging study only: Contraindications to taking part in the MRI study as assessed by the local MRI safety questionnaire (e.g., non-MRI compatible pacemaker)

Date of first enrolment
01/07/2025

Date of final enrolment
30/04/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Norfolk Community Health and Care NHS Trust
Norwich Community Hospital
Bowthorpe Road
Norwich
United Kingdom
NR2 3TU

Study participating centre
Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Lane
Colney
Norwich
United Kingdom
NR4 7UY

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Cambridge Biomedical Campus
Hills Road
Cambridge
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CB2 0QQ

Study participating centre
Northern Care Alliance NHS Foundation Trust
Salford Royal
Stott Lane

Salford
United Kingdom
M6 8HD

Study participating centre
St George's Healthcare Nhst
Blackshaw Road
London
United Kingdom
SW17 0QT

Study participating centre
Birmingham Community Healthcare NHS Foundation Trust
3 Priestley Wharf
Holt Street
Birmingham Science Park, Aston
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B7 4BN

Study participating centre
Imperial College Healthcare NHS Trust
The Bays
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South Wharf Road
London
United Kingdom
W2 1BL

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital
Herries Road
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S5 7AU

Sponsor information

Organisation

University of East Anglia

ROR
https://ror.org/026k5mg93

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository after publication of results, from February 2028. Participants have consented to this, and all data will be fully anonymised.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes