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Attentional therapy for the treatment of neglect disorder

Submission date
29/01/2021

Recruitment status
No longer recruiting

Registration date
09/02/2021

Overall study status
Completed

Last Edited
18/08/2025

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
This study will investigate the treatment of a specific syndrome that can occur following a cerebrovascular accident (Stroke) or brain tumour. Neglect is a complex syndrome characterized by a failure to attend to, look at and respond to stimuli (objects, food, people) located on the side of space or of the body opposite to the side affected by a brain lesion. There is a estimated 3-5 million new cases of neglect world-wide per year but no standard treatment for patients with neglect has been established.

Who can participate?
Adults over 18 years, with any type of acute stroke and evidence of clinically significant neglect

What does the study involve?
We will ask you to take part in up to 15 sessions, face to face, spread out over 12 weeks. Some sessions will be spent testing your responses on thinking tasks and questionnaires and some will be spent in virtual reality stimulation. Throughout we will check for any side effects from the virtual stimulation therapy. If these persist you can withdraw at any time.
This study will START while you are in hospital and will END when we follow you up 12 weeks after the last stimulation session.
The study will require intensive practice with ATTEND, completing 4 sessions of 10 minutes virtual reality stimulation per day. It will continue for 5 days a week for up to three weeks, whilst you are in hospital.
In summary, during the intensity practice time you will be asked to spend just over 1½ hours with our research team per day for a continuous 5 days (Monday – Friday only).
We would like to interview you about your experience of the virtual reality stimulation in a face-to -face interview with one of the researchers. These interviews will be either filmed or audio recorded.

What are the possible benefits and risks of participating?
The study will provide information useful to the study of stroke recovery.
The study MAY improve your ability to look and respond to the left (or right) and improve some of your inattention symptoms, but this CANNOT BE GUARANTEED. If you are in the control group your symptoms may not get better.

Since we are asking you to complete an intensive therapy programme you will spend a lot of time using a virtual reality headset. The effects of prolonged use of virtual reality can include eye strain, nausea or virtual reality sickness and sometimes a feeling of anxiety.
If you experience any of these side effects we will strongly encourage you to STOP using the virtual reality headset and take a break. The research team will be with you throughout the stimulation.

Where is the study run from?
UCL Queen Square Institute of Neurology (UK)

When is the study starting and how long is it expected to run for?
August 2020 to July 2024

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

Who is the main contact?
1. Dr Catherine Doogan, c.doogan@ucl.ac.uk
2. Professor Alex Leff, a.leff@ucl.ac.uk

Study website
https://www.ucl.ac.uk/icn/research/research-groups/neurotherapeutics

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 46866

Study information

Scientific Title
ATTEND: Attentional Therapy for the TrEatment of Neglect Disorder

Acronym
ATTEND

Study objectives
This study will investigate the treatment of a specific syndrome that can occur following a cerebrovascular accident (Stroke) or brain tumour. Neglect is a complex syndrome characterized by a failure to attend to, look at and respond to stimuli (objects, food, people) located on the side of space or of the body opposite to the side affected by a brain lesion. There is a estimated 3-5 million new cases of neglect world-wide per year (Corbetta, Kincade, Lewis, Snyder, & Sapir, 2005) but no standard treatment for patients with neglect has been established.

The primary objective is to ascertain if immersive virtual reality stimulation that induces smooth pursuit eye movements improves score on impairment-based and function-based outcome measures of neglect in patients with this syndrome, caused by an acute stroke. There will be a control stimulation, delivered by the same VR hardware, which does not induce smooth pursuit eye movements ‘control’.

Secondary outcomes will include reduction in length of stay in an inpatient setting, improvements in social activity and participation, and participant and/or carer reported outcome measures (PROMS/CROMS).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/11/2020, London-Bromley Research Ethics Committee (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)207 104 8063; Bromley.rec@hra.nhs.uk), ref: 20/LO/1061

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Neglect disorder following stroke

Interventions
Participants will be randomised into two groups; 1) Therapy VR, 2) Control VR.
Both groups will receive the same exposure to VR stimulation. Therapy VR will induce smooth pursuit eye movements and encourage spatial attention to the affected side (usually left) while Control VR will consist of playing a game using vertical eye movements only so no expectation that this will improve neglect.
The VR stimulation will be delivered 5 days a week for 2 (min)-3 (max) weeks.
Participants will be assessed on our outcome measures twice before, once during and twice after the intervention.
Participants will complete 5 assessment sessions (T1-T5).Assessments all relate to behavioral tests, eye movement tests, functional questionnaires (for attending staff or carers).

Intervention Type
Behavioural

Primary outcome measure
1. Neglect measured using Free Exploration test (based on eye movements when viewing standardised images) at baseline, pre-intervention, daily during the intervention, and at post-intervention follow up
2. Neglect measured by behavioural inattention cancellation test at baseline
3. Neglect measured using Catherine Bergego Scale at baseline, pre-intervention, and at post-intervention follow up by questionnaire for staff

Secondary outcome measures

1. Length of stay in an inpatient setting measured using statistics about length of stay during the two groups from patient records
2. Participant reported outcome measures (PROMS) involving a semi-structured interview

Overall study start date
03/08/2020

Completion date
31/07/2024

Eligibility

Key inclusion criteria
1. 18 years or older
2. Any type of acute stroke
3. Evidence of clinically significant neglect
4. Able to tolerate the use of Virtual Reality hardware and software
5. Willing and able to provide written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 24; UK Sample Size: 24

Total final enrolment
34

Key exclusion criteria
1. No major co-existing neurological or psychiatric diagnosis
2. Patients who have difficulty adequately understanding verbal or written explanations as a result of communication impairment follow their stroke, will be excluded from the study

Date of first enrolment
02/02/2021

Date of final enrolment
30/06/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London Hospital
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
United Kingdom
NW1 2PG

Study participating centre
St Mary's Hospital
Imperial College Healthcare NHS Trust
South Wharf Road
London
United Kingdom
W2 1BL

Study participating centre
North Middlesex University Hospital NHS Trust
Sterling Way
London
United Kingdom
N18 1QX

Study participating centre
Central and North West London NHS Foundation Trust
Stephenson House
75 Hampstead Road
London
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Study participating centre
Royal Free Hospital
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Study participating centre
University College London
UCL Queen Square Institute of Neurology
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Sponsor information

Organisation
University College London

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Sponsor type
University/education

Website
http://www.ucl.ac.uk/

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name

NIHR Academy; Grant Codes: RP-2015-06-012

Funder Name
National Institute for Health Research (NIHR) (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/07/2025

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V4	23/11/2020	09/02/2021	No	Yes
HRA research summary			28/06/2023	No	No
Basic results		18/08/2025	18/08/2025	No	No