# Attentional therapy for the treatment of neglect disorder

Submission date	Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>		
29/01/2021		∐ Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
09/02/2021		[X] Results		
Last Edited	Condition category	Individual participant data		
18/08/2025	Nervous System Diseases			

#### 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  $1\frac{1}{2}$  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

### Contact information

#### Type(s)

Scientific

#### Contact name

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**Prof Alex Leff** 

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### Additional identifiers

#### Clinical Trials Information System (CTIS)

Nil known

#### ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

**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

#### Study type(s)

Treatment

#### 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(s)

- 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

#### Key secondary outcome(s))

- 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

#### 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** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

All

#### 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

**United Kingdom** 

England

# 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 United Kingdom NW1 2PL

#### Study participating centre Royal Free Hospital

Pond Street London United Kingdom NW3 2QG

# Study participating centre University College London

UCL Queen Square Institute of Neurology 17-19 Queen Square London United Kingdom WC1N 3AZ

## **Sponsor information**

#### Organisation

#### University College London

#### **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**

#### 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?
Basic results		18/08/2025	18/08/2025	No	No
HRA research summary			28/06/2023	No	No
Participant information shee	version V4	23/11/2020	09/02/2021	No	Yes

Participant information sheetParticipant information sheet11/11/202511/11/2025NoYesStudy website11/11/202511/11/2025NoYes