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Eye movement training in visual field defect patients by using a 3D game

Submission date
04/11/2022

Recruitment status
Recruiting

Registration date
14/11/2022

Overall study status
Ongoing

Last Edited
06/02/2026

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Hemianopia or homonymous hemianopia (HH) is a visual field defect causing partial or complete blindness in one side (left or right) of the visual field. A common cause of hemianopia is cerebral infarction (stroke). A significant population of stroke patients, estimated at between 20% and 57%, are affected by this condition. 8% to 10% of stroke patients have permanent hemianopia. Visual field defects affect the quality of life and functional ability in daily activities such as driving, mobility and reading. In addition, visual field defects may cause anxiety, depression and social isolation which affects the ability to participate in conventional rehabilitation programmes. The study is designed to present visual stimulus sequences that replicate a conventional visual search scanning with additional audio cues to simulate real-life environments and turn the task into a 'game' where patients are awarded performance-related points.

Who can participate?
Participants who meet the eligibility criteria, particularly, MRI safety and residual homonymous hemianopia following stroke, partially or completely.

What does the study involve?
The participant will complete the 30 min VR training for 6 weeks, 5 days weekly, 30 sessions in their home, while other behavioural tasks and MRI scan will take place in our medical imaging centre which include; Digital VISION, Bell task, interview and MRI scan.

What are the possible benefits and risks of participating?
Participants may notice improvement in the daily life activities after the training. The commercial VR system is enjoyable for most people with no risks. Some people may, however, find the VR headset uncomfortable or may experience a headache or eyestrain after long term use (Simulator sickness). Participants will be instructed to train for 30 mins per day and given the opportunity to take breaks as required. Participants will be scanned in a 3 Tesla magnet; there is therefore a potential risk of injury to participants and researchers because of the strong magnetic field in the scanner room. The initial assessment will be conducted by the MRI radiologist at LiMRIC, who will ensure MRI compatibility for all participants. There is also the risk

of missile hazards from objects being bought into the scanner room that are magnetic. A further risk comes from the audible noise of the scanner. The psychologically adverse risk of note is that participants may become uncomfortable or claustrophobic in the scanner.

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

When is the study starting and how long is it expected to run for?
September 2021 to April 2026

Who is funding the study?
King Saud bin Abdulaziz University for Health Sciences (Saudi Arabia)

Who is the main contact?
Dr Georg Meyer, georg@liverpool.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)
321304

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 321304

Study information

Scientific Title

Examination of brain plasticity through structural and functional MRI during the audio-visual training in hemianopia patients with virtual reality (VR)

Study objectives
The objective of the proposed research is to test whether VR rehabilitation for hemianopia leads to measurable subjective and objective behavioural performance measures and to test whether these changes are linked to functional and structural brain imaging metrics.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Observational cohort study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Hemianopia (partial or complete)

Interventions
The study is designed to present visual stimulus sequences that replicate a conventional visual search scanning with additional audio cues to simulate real-life environments and turn the task into a 'game' where patients are awarded performance-related points.
The proposed study closely follows recent work at the University of Liverpool that demonstrated the outcomes listed above in a healthy population (Aloufi, Rowe & Meyer, 2021). We will report functional and structural brain changes by using fMRI, DTI and structural imaging sequences.
Data analysis will follow a previously developed and validated analysis pathway optimised using healthy controls. Three main measurements will be reported: behavioural, functional and structural measurements, before and after the training period. Details are given below that it has been also used in Aloufi, Rowe and Meyer (2021), with additional behavioural tests.

The study participants will take part in MRI scanning, training and behavioural tasks:
1. VR training in the participant's home for 30-minute daily sessions, 5 days a week and for 6 consecutive weeks, the participants will perform the VR audio-visual training.
2. Behavioural tests will be conducted in our imaging centre (LiMRIC), before (week 0) and after the training (week 7) which include:
2.1. Digital VISION visual searching training:
Participants will be asked to perform standardised tests in a lab environment that enables us to measure eye gaze to establish changes in fixation patterns with training.
2.2. Bell task:
Behavioural performance on a visual search task (Bells task - Basagni et al., 2017) will be collected before and after the intervention. Participants will be asked to find printed objects on a monochrome printed (A0 size) poster to provide a wide-field assessment.

2.3. QFV-25 questionnaire interview:
The National Eye Institute Visual Function Questionnaire-25 (NEI VFQ-25) was designed to measure the quality of life for people who have a chronic eye disease (Mangione, 2001). The NEI VFQ-25 questionnaire consists of 25 vision-targeted questions which include 11 vision-related constructs, and one general health rating question. These 25 questions are divided into two categories; 16 rate difficulty with activities and 9 ask for level of agreement to describe the severity of problems associated with visual loss.
3. MRI scanning:
We will scan participants at two points of their training programme using sequences that are widely used: functional imaging, DTI and structural (T1 and T2 weighted) imaging, functional MRI (fMRI).

Intervention Type
Behavioural

Primary outcome(s)
1. Mean response time and number of correct targets measured using a VR headset during the 30-minute daily sessions, 5 days a week and for 6 consecutive weeks
2. Mean response time and number of correct targets measured in the Digital VISION search at baseline and post training

Key secondary outcome(s))
1. Mean response time will be measured in Bell task at baseline and post training.
2. Brain activity and connectivity will be observed using MRI scanning at baseline and post training.

Completion date
30/04/2026

Eligibility

Key inclusion criteria
1. Participants are required to be residual homonymous hemianopia (partial or complete following stroke.
2. Participants must have normal hearing and no speaking/communication difficulty.
3. Participants must speak English fluently - in order to understand all training and test instructions.
4. Participants must be 18 years or older.
5. Participants must be able to perform the behavioural tasks, for which training will be provided.
6. Participants must be sufficiently mobile to attend scanning at the imaging centre/LiMRIC

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
15

Key exclusion criteria
1. Participant who cannot sign the consent form or cannot read the participants' information sheet and consent form.
2. Participants who cannot perform the task (the screening takes place before participants are invited to join the study to ensure that, participants can perform the task and to exclude vulnerable adults).
3. MR exclusion criteria: Standard MR exclusion criteria will apply (e.g. claustrophobia (fear of tight spaces), cardiac pacemaker, metal in the eye, vascular clips, actual or possible pregnancy).
4. COVID-19 check: if the participant has any symptoms before the first visit to LiMRIC for the MRI scan and before the training starts (Cough, fever, loss or change in the smell or taste https://www.nhs.uk/conditions/coronavirus-covid-19/symptoms/#symptoms), there is a flexibility to delay the starting of study, but this delaying can not be offer after the study is started. they will be excluded. We will be followed the COVID-19 procedure for LiMRIC at the recruitment period.

Date of first enrolment
29/04/2024

Date of final enrolment
28/02/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Aintree University Hosiptal
Stroke unit
Liverpool
England
L9 7AL

Sponsor information

Organisation
University of Liverpool

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
University/education

Funder Name
King Saud bin Abdulaziz University for Health Science

Alternative Name(s)
, King Saud bin Abdulaziz University for Health Sciences, KSAU-HS

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Saudi Arabia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		06/01/2026	06/02/2026	Yes	No
Participant information sheet	version 1	01/04/2022	14/11/2022	No	Yes
Plain English results			06/02/2026	No	Yes