

Home-training for hemianopia (partial blindness)

Submission date 15/05/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/05/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 23/04/2021	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

People often develop problems with their vision after a brain injury, such as a stroke. This happens because the visual pathway that carries information from the eye to the brain becomes damaged. The resulting loss of vision can be temporary or permanent and any recovery of a person's sight may only be partial. Hemianopia is the term used to describe partial blindness in both eyes caused by damage to the visual pathway. This condition is one of the most common and disabling consequences of brain damage, with numerous negative effects on the everyday life of a person with the condition. We have been investigating visual field defects such as hemianopia and have developed rehabilitation training programs for these conditions. The aim of the program is not to restore the lost vision but rather to help people develop strategies to help them overcome the problems they experience due to their disability. Our most recent training program is called Durham Reading and Exploration training (DREX). It is a computer-based and self-adjusted program that allows people to train themselves in their own home. The training involves a series of tasks encouraging visual exploration which become progressively more difficult, helping the patient to develop improvements in their eye-movements and visual awareness. Here, we want to see how well the DREX program works when used as touchscreen tablet app or as a computer program by comparing any changes in visual search and reading speeds of patients before and after they have used the program with another group of patients who are given standard care. If successful, this free and accessible app could benefit many patients, helping them to overcome the disabilities they experience due to visual loss.

Who can participate?

Adults (aged at least 18) suffering with a non-progressive visual field defect for at least 3 months caused by a brain injury.

What does the study involve?

Participants are randomly allocated into one of three groups. Those in group 1 (intervention group 1) use the DREX program on a touchscreen tablet. Those in group 2 (intervention group 2) use the DREX program on a computer. Those in group 3 (control group) are given their usual care and any treatments given by their doctors or therapists. Participants in all three groups are asked to complete assessments before and after the intervention groups have completed the DREX program to measure their reading and visual search abilities and also their quality of life.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Wolfson Research Institute at Durham University Queen's Campus (UK)

When is the study starting and how long is it expected to run for?
June 2015 to December 2017

Who is funding the study?
Durham University (UK)

Who is the main contact?
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3. Dr Alison Lane (scientific)

Study website
www.durham.ac.uk/drex

Contact information

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Efficacy of visuomotor compensation training for individuals with a visual field defect

Study objectives

1. Participants receiving visuomotor training will perform significantly better on measures of reading and visual search than those allocated to standard care
2. Participants receiving computer training will perform significantly better on measures of reading and visual search than those allocated to standard care
3. Visuomotor training is equally effective as computer training on the measures of reading and visual exploration

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Ethics Advisory Sub-Committee in Department of Psychology, Durham University, 12/05/2015, ref: 14/32
2. NRES Committee North East – Newcastle & North Tyneside 1, 09/12/2015, ref: 15/NE/0351

Study design

Randomised controlled and parallel trial with three study arms

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Home

Study type(s)

Treatment

Participant information sheet

Please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Hemianopia following acquired post-chiasmatic brain injury such as stroke

Interventions

1. Two intervention groups, namely visuomotor training and computer training, will do visual exploration and reading training using the DREX (Durham Reading and Exploration) program. The visuomotor training group will do the training on a touchscreen tablet, while the computer training group will run the training using a laptop independently at their home
2. A control group (standard care) will continue any existing treatment given by their doctors or therapists
3. All study groups are required to complete pre- and post-training assessments to measure the reading and visual search ability as well as a several quality of life scales

Intervention Type

Behavioural

Primary outcome measure

1. Reading is measured using an in-app reading task* and a reading task using a modified passage from 'The Grey Gentlemen' (Ende, 1974; Aimola et al., 2014) at baseline, 6 weeks, 12 weeks and 3 months follow up
2. Visual Exploration is measured using an in-app visual exploration task* and the 'Find-the-Number' visual search task (Aimola et al., 2014) at baseline, 6 weeks, 12 weeks and 3 months follow up

* Those described as being 'in-app' are part of the Durham Reading and Exploration (DREX) app.

Secondary outcome measures

1. Short-term memory is measured using an in-app short-term memory task* at baseline, 6 weeks, 12 weeks and 3 months follow up
2. Mood and depression is measured using the 21-item Beck Depression Inventory II (BDI II) at baseline, 6 weeks, 12 weeks and 3 months follow up
3. Motivation towards rehabilitation is measured using the 31-item Motivation for Traumatic Brain Injury Rehabilitation Questionnaire (MOT-Q) at baseline, 6 weeks, 12 weeks and 3 months follow up
4. Activities of Daily Living (ADL) is measured using an in-app 6-item ADL questionnaire* and the 10-item Visual Impairment Questionnaire at baseline, 6 weeks, 12 weeks and 3 months follow up
5. Attitude and goals towards rehabilitation is measured using the 10-item Self-Ability and Attitude Questionnaire at baseline, 6 weeks, 12 weeks and 3 months follow up

* Those described as being 'in-app' are part of the Durham Reading and Exploration (DREX) app.

Overall study start date

01/01/2015

Completion date

31/12/2017

Eligibility

Key inclusion criteria

1. Adults aged 18 years or above who have been diagnosed with a non-progressive visual field defect (for at least 3 months) due to post-chiasmatic injury
2. Good cognitive ability
3. Able to give consent

Participant type(s)

Patient

Age group

Mixed

Lower age limit

18 Years

Sex

Both

Target number of participants

120

Key exclusion criteria

1. Individuals with visual field loss due to prechiasmatic or chiasmatic damage, or neurodegenerative disease
2. Aged under 18 years
3. Have comorbid oculomotor disorders

4. Severe physical problems
5. An unstable medical illness
6. Unable to provide informed consent

Date of first enrolment

01/06/2015

Date of final enrolment

30/06/2017

Locations

Countries of recruitment

England

United Kingdom

Study participating centre**Wolfson Research Institute**

Cognitive Neuroscience Research Unit

Department of Psychology

Durham University Queen's Campus

Stockton-on-Tees

United Kingdom

TS17 6BH

Sponsor information

Organisation

Ministry of Education Malaysia

Sponsor details

Blok E8, Kompleks E

Pusat Pentadbiran Kerajaan Persekutuan

Putrajaya

Malaysia

62604

Sponsor type

Government

ROR

<https://ror.org/05v8z6a72>

Funder(s)

Funder type

University/education

Funder Name

Durham University

Alternative Name(s)

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

1. Publication of study results in international peer reviewed journal planned
2. The protocol and trial results of the study may be disseminated in the form of poster or oral presentation at both national and international conferences and meetings. Planned dissemination of the preliminary results in the 12th International Low Vision Research and Rehabilitation (ISLRR) congress, June 2017, in The Netherlands.

Intention to publish date

31/12/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Thesis results			23/04/2021	No	No
HRA research summary			28/06/2023	No	No