

Visual impairment in stroke: intervention or not (VISION)

Submission date 08/04/2011	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 08/04/2011	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 23/04/2019	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
10134

Study information

Scientific Title

Visual Impairment in Stroke: Intervention Or Not (VISION) - a randomised controlled trial to investigate whether prism glasses or visual search training are more effective than information only (standard care) in patients with a homonymous hemianopia follow stroke

Acronym

VISION

Study objectives

The aim of this trial is to be the first step in determining the effectiveness of Fresnel Prisms and Visual Search Strategies compared to standard care in patients with homonymous hemianopia (HH) following a stroke. The trial will be a multicentre three arm individually randomised controlled trial with independent assessment at 6, 12 and 26 weeks post randomisation. Recruitment will occur in hospital and outpatient settings in Bath, Nottingham, Oxford, Salford and Sheffield. 105 patients with HH and without ocular motility impairment, visual inattention or pre-existent visual field impairment will be randomised to 3 groups using an online randomisation system. Allocation will be revealed to the treating clinician, patient and trial coordinator, maintaining blinding for the assessors. The primary outcome will be visual field assessment. Secondary measures will include the Rivermead Mobility Index, VFQ25/10, Nottingham EADL, EQ5D and SF12 questionnaires. Analysis will be by intention to treat. This study has been developed and supported by the UKSRN CSG working with service users. The findings will support a future HTA application.

Website: www.strokevision.org.uk (under construction)

Ethics approval required

Old ethics approval format

Ethics approval(s)

10/H1003/119

Primary study design

Interventional

Study design

Randomised interventional screening trial

Study type(s)

Screening

Health condition(s) or problem(s) studied

Stroke Research Network; Rehabilitation

Interventions

1. After assessment of eligibility patients will be randomised to either treatment with Fresnel prisms, visual search strategies or control group (information only)
2. Prisms will be worn for a minimum of 2 hours per day and visual search strategies will be done for a minimum of 30 minutes per day, both for a minimum of 6 weeks
3. Patients will then be followed up at 6, 12 and 26 weeks post treatment start
4. At baseline and follow up visits participants will have their visual fields will be assessed (primary endpoint) and complete a participant completed outcome measures questionnaire pack along with a reading accuracy test (secondary endpoints)
5. Total duration of participant involvement: 26 weeks

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Visual field

Key secondary outcome(s)

1. Visual function questionnaire (VFQ 25-10) change in perceived ability relating to activities of daily living
2. Rivermead mobility index change in functional mobility
3. Nottingham extended activities of daily living (NEADL) change in extended daily living index
4. EQ-5D change in health related quality of life
5. SF-12 change of general health status
6. Assessment of reading speed and accuracy (Radner Test)

Completion date

31/08/2013

Eligibility**Key inclusion criteria**

1. 18 years of age and older
2. Best corrected visual acuity of 6/18 in either eye
3. Homonymous hemianopia
4. Refractive error within ± 5 Dioptres
5. Vision measures will be established by orthoptic assessment
6. Male or female

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Total final enrolment

87

Key exclusion criteria

1. Inability to consent due to severe cognitive impairment
2. Unwilling to participate in the study
3. Ocularmotility impairment and visual inattention in addition to the visual field impairment (as

assessed by the orthoptist)

4. Preexisting visual field impairment

Date of first enrolment

01/03/2011

Date of final enrolment

31/08/2013

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Thompson Yates Building

Liverpool

United Kingdom

L69 3GB

Sponsor information

Organisation

University of Liverpool (UK)

ROR

<https://ror.org/04xs57h96>

Funder(s)

Funder type

Charity

Funder Name

The Stroke Association (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	19/01/2016		Yes	No
Results article	results	01/10/2017		Yes	No
Results article	results	01/09/2019		Yes	No
Protocol article	protocol	17/07/2014		Yes	No