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Visual impairment in stroke: intervention or not (VISION)

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised interventional screening trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
Visual field

Secondary outcome measures
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)

Overall study start date
01/03/2011

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 ±5Dioptres
5. Vision measures will be established by orthoptic assessment
6. Male or female

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 105; UK Sample Size: 105

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
England

United Kingdom

Study participating centre
Thompson Yates Building
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Sponsor information

Organisation
University of Liverpool (UK)

Sponsor details
c/o Ms Lindsay Carter
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Sponsor type
University/education

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Charity

Funder Name
The Stroke Association (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	17/07/2014		Yes	No
Results article	results	19/01/2016		Yes	No
Results article	results	01/10/2017		Yes	No
Results article	results	01/09/2019		Yes	No