Development of core outcome sets for vision screening and assessment in stroke: Protocol.

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Contributions

All authors drafted this protocol and contributed to the development of the selection criteria and data extraction criteria.

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Introduction

Visual impairment is common in stroke occurring in up to 73% of stroke survivors [1]. Visual impairment is typically categorised into impairments of central vision, eye movements, visual fields and visual perception [2]. Vision is arguably our most important sense. Visual impairment results in impaired activities of daily living with reduced quality of life through loss of independence, greater risk of trips and falls,

and accidents [3-6]. This leads to loss of independence and potentially results in social isolation and depression [5,6].

The primary focus of stroke rehabilitation is often occupational therapy and physiotherapy to mobilise patients, improve limb function and balance, and engage in activities of daily living plus speech and language therapy for communication difficulties [7]. Many rehabilitation strategies require visual input; for example, to safely mobilise around potential obstacles, recognise depth and position of objects, and recognise visual cue cards. Given so many stroke survivors have visual impairment it is important to screen for this at an early time point post-stroke onset with the aim to optimise the rehabilitation process.

The recent IVIS study reported specialist orthoptist vision screening is possible at a median of 3 days post stroke onset with the majority of stroke survivors being assessed within one week of stroke onset [1]. This study used standardised visual assessment methods with portable equipment to be used at the patient's bedside. There is, however, no standardised visual screening assessment for post-stroke visual impairment. In one UK survey it was found that 45% of stroke services provided no formal vision assessment for stroke patients [8]. A further survey of practice identified that only 7% of stroke units had a policy relating to vision assessment and management [9]. Both surveys showed lack of standardisation for vision assessment and treatment for stroke survivors. The National Stroke Strategy argues that vision and visual perceptual difficulties are components requiring multi-faceted stroke specific rehabilitation and support [10]. The Royal College of Physicians recommend that every patient with stroke has a practical assessment of vision and examination of the visual field [11].

On the basis that there is no consensus on how to adequately screen for visual impairment after brain injury, the aim of this study is to achieve consensus on the content of vision screening and full vision assessment for stroke survivors in order to better identify visual impairment. Screening and/or full vision assessments are to be undertaken at any time point post-stroke onset with the intention that identification of visual impairment enables prompt access to earlier visual rehabilitation options. One approved process to reach consensus on screening and assessment for specific conditions is through the development of core outcome sets (COS) [12]. COS indicate the minimum that should be measured and reported in all studies of a

specific condition. The overall purpose of a vision screening and full assessment COS is to improve routine care in the NHS through standardisation of assessments.

Review aim and objectives

The primary aim of this review is to generate an item bank of relevant outcomes previously reported by researchers and clinicians in studies of screening and assessment of stroke-related visual impairment.

Vision screening is defined as the assessments considered important for use by clinicians not working in eye care settings and without formal experience or training in performing eye tests. Full vision assessment is defined as the assessments considered important for use by clinicians who had formal eye care training and were principally based in eye clinics.

Methods

The systematic review will be carried out by conducting a search of the primary literature.
Subjects of all ages with target conditions will be included.

The target conditions are stroke-related:

1. Central visual impairment
2. Ocular alignment and movement deficits
3. Visual field loss
4. Visual perception deficits.

We will include any reported outcome and outcome measure that was recorded at any point of time from vision screening and assessment using any possible instrument or method.

Examples of types of **outcomes** expected to be found from the review for each of the conditions include:

- Central visual impairment: Visual acuity, Contrast sensitivity, Colour vision
- Ocular alignment and movement deficits: Angle of deviation, net change in angle, +/- 8/10 prism dioptres (PD) of orthotropia/phoria, range of ductions and versions
- Visual field loss: Static perimetry, Kinetic perimetry
- Visual perception deficits:Agnosia, alexia, simultanagnosia.

Examples of types of **outcome measures** expected to be found from the review include:

- Visual acuity: Snellen's, LogMar
- Ocular alignment and movement deficits: Prism cover test (PCT), prism reflection test (PRT), stereo-acuity, fusional amplitude, smooth pursuits, saccades
- Visual field loss: Area, mean sensitivity, mean deviation, pattern standard deviation
- Visual perception deficits: Line bisection, cancellation task.

Examples of types of **patient-reported outcome measures (PROMS)** expected to be found from the review include:

- VFQ-25
- AS20
- EQ5D
- SF12
- NEADL

Study search

The following types of studies will be included in the review:

- Systematic reviews (with or without meta-analysis) inclusive of diagnostic test accuracy reviews
- Randomised controlled trials
- Controlled clinical trials
- Prospective cohorts

- Retrospective cohorts
- Case series (with more than 10 patients)

Case reports and letters will be excluded.

Search methods for identification of studies

We will search a range of electronic databases including MEDLINE, SCOPUS, Cochrane Library of systematic reviews, AMED and PsycINFO. In an effort to identify further published data, we will search electronic registers in Google Scholar. Additionally, we will perform citation tracking using Web of Science Cited Reference Search for all included studies and search the reference lists of review articles up to 2016.

We will use the orthoptic search facility web link (http://pcwww.liv.ac.uk/~rowef/index_files/page646.htm) to search in orthoptic journals and conference transactions which are not electronically listed: British and Irish Orthoptic Journal, American Orthoptic Journal, Australian Orthoptic Journal, European Strabismus Association, International Strabismus Association and the International Orthoptic Association. Lastly the reference list of identified reports and articles will be searched for additional studies. Search terms to be used are described in table 1.

All languages will be included and translations will be obtained when necessary.

Eligibility of studies

All researchers (FR, LH) will independently screen the titles and abstracts identified from the search using a screening proforma based on the eligibility criteria. The full papers of any studies considered potentially relevant will be considered and the selection criteria applied independently by each of the reviewers. We will resolve disagreements by discussion between the review authors. If a disagreement remains, we will seek the opinion of a third reviewer. This process will be undertaken using the Cochrane software for reviews COVIDENCE (https://www.covidence.org).

For the purpose of this study there will be no synthesis of outcome data from the included studies as we seek to create an item bank of all utilised outcomes and outcome measurements. Hence a critique of the methodological quality of the studies is not necessary.

Data extraction

LH will extract the data using a pre-determined data extraction form which will be verified by FR to ensure that all the outcomes have been identified. Disagreement will be resolved through discussion and where resolution is not possible, a third reviewer will be consulted.

The following data will be extracted from each study:

Demographics:

1. Study type
2. Author details
3. Year and journal of publication
4. Origin of primary investigator
5. Condition(s) under investigation
6. Age of participants in the study population.

Outcomes:

1. The designated primary outcome
2. Methods of measurement(s)
3. The time points at which they were measured.

Data analysis and presentation

For analysis purposes the data will be tabulated so that for each study the outcomes will be listed alongside the measurement instrument. The outcome domains will then be determined following a review of the extracted outcomes by the authors (FR, LH). The outcomes will be grouped under these domains. We will aim to combine outcomes if they differ in nomenclature across studies but essentially are the same.

End output

We will generate an item bank of relevant outcomes for vision screening and assessment of stroke-related visual impairment. We will generate an inventory of measurements for each of these relevant outcomes. We will source time points at which these outcomes are measured.

Conflicts of interest

The authors report no conflicts in relation to this study.

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Table 1 Search terms

Terms	Boolean operator	Terms
Outcome*		*Central vision* [Mesh term]
		- Visual acuity
Measur*		- Colour vision
		- Contrast sensitivity
Assess*		- Ischemia
Treat*		*Strabismus* [Mesh term]
		Ocular motility disorders [Mesh term]
Interven*		- Heterophoria/heterotropia
		- Esotropia/esophoria
Manag*		- Exotropia/exophoria
		- Hypertropia/hyperphoria
Diagnos*		- Hypotropia/hyperphoria
		- Cyclotropia/cyclophoria
Test*		- Convergent strabismus
		- Divergent strabismus
Screen*		- Acquired nystagmus (all types)
		- Horizontal gaze palsy
Therap*	AND	- Vertical gaze palsy
		- Third nerve palsy
Evaluat*		- Fourth nerve palsy
		- Sixth nerve palsy
Clinic*		- Convergence paralysis
		- Divergence paralysis
Stroke*		- Skew deviation
Cerebrovasc*		*Visual field loss* [Mesh term]
		- Hemianopia
		- Quadrantanopia
		- Homonymous
		- Altitudinal
		Visual perception [Mesh term]
		- Visual inattention
		- Visual neglect
		- Visual agnosia
		- Alexia
		- Simultanagnosia
		- Visual hallucinations