FULL TITLE OF THE STUDY

Organisation of eye care services for adults and children following acquired brain injury and for children with cerebral visual impairment.

PROTOCOL VERSION NUMBER AND DATE

Version 1 30th January 2024

RESEARCH REFERENCE NUMBERS

Funders Number: NIHR157622

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ii. LIST OF ABBREVIATIONS

ABI	Acquired brain injury
CEA	Cost effectiveness analysis
CENTRAL	Cochrane Central Register of Controlled Trials
CERQual	Confidence in the Evidence from Reviews of Qualitative Research
CSDR	Cochrane Database of Systematic Reviews
CVI	Cerebral visual impairment
EPOC	Cochrane Effective Practice and Organisation of Care taxonomy
ERIC	Education Resources Information Center
HMIC	Health Management Information Consortium
OECD	Organisation for Economic Co-operation and Development
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analysis
QTVI	Qualified teachers of the visually impaired
VI	Visual impairment

STUDY SUMMARY

Study Title	Organisation of eye care services for adults and children following acquired brain injury and for children with cerebral visual impairment.
Study Design	Evidence synthesis
Planned Study Period	24 months
Research Aim	To inform care pathways and service design to improve assessment practice and the commissioning/delivery of eye care services. To provide the evidence base for quality eye care and support across all aspects of the patient pathway through primary, secondary and tertiary NHS and social care services.

KEY WORDS: Visual impairment
Brain Injury
Cerebral Visual Impairment
Care pathways

ROLE OF STUDY FUNDER

The funder of this study is the NIHR Health and Social Care Delivery Research who is providing financial funding of £560,209.99. The funder will ensure there is proper use of the funds they have allocated to provide value for money.

ROLES AND RESPONSIBILITIES OF STUDY OVERSIGHT GROUP

A study oversight group will convene regularly (monthly for the first six months of the study and then every two months) for on-going advice and support of the conduct, governance and finances of the research study to ensure milestones are met. The group will consist of all members of the research team including the employed research associates.

STUDY TEAM

Chief Investigators

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Co-investigators

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STUDY PROTOCOL

Organisation of eye care services for adults and children following acquired brain injury and for children with cerebral visual impairment.

1 BACKGROUND

Sight is necessary for many daily life activities. Vision problems are common in patients with acquired brain injury (ABI) and are a defining characteristic of cerebral visual impairment (CVI). However, visual problems are not obviously apparent therefore detection relies on specific testing and holistic patient care relies on integrated provision of services.

These evidence syntheses will address how services can be best organised and delivered to inform, assess and care for patients with visual impairment due to ABI or CVI.

Our evidence synthesis reviews address important research questions relevant to two populations. The first includes adults and children with visual impairment (VI) as a result of ABI. We define ABI as being caused by acute events occurring after the peri-natal period (i.e. >1 month old) inclusive of focal injury (stroke, tumours), traumatic injury and central nervous system infections, but not genetic, congenital, pre- or peri-natal causes. The second includes children with CVI. We define CVI as verifiable visual impairment caused by disturbance of the central visual pathways whatever their mode of presentation [1].

For both cohorts if visual impairment is diagnosed, adults and children are typically assessed by eye care clinicians in the UK. Visual impairment occurring as a result of ABI and CVI can be categorised into ocular motility disorders, central and/or peripheral visual field loss, reduced acuity and visual perceptual disorders. There can be combined anterior and posterior visual pathway problems in ABI e.g. as with hydrocephalus secondary to haemorrhagic stroke or brain tumour, or with traumatic optic neuropathy with accommodative and convergence problems following traumatic brain injury, or with retinal haemorrhages and ocular cranial nerve palsy following non-accidental head injury. Whilst anterior visual pathway problems can co-occur, a diagnosis of CVI is the presence of visual dysfunction which is not attributable to these [1].

Ocular motility disorders are conditions that affect eye movement. They can be congenital or develop as acquired conditions due to neurological, endocrine or traumatic causes [2]. Strabismus is a misalignment of the two eyes. Untreated, this may cause double vision, visual confusion, eye strain and headaches [3]. In the UK, strabismus affects 2.4% of children and about 4% of adults [4,5]. Visual impairment (e.g. reduced visual acuity, visual field loss, visual perception disorders) in children or adults occurs commonly. For example, CVI related vision problems were reported in at least 3% of primary school children, including in 40% of children recognised as having a need for additional educational support, almost all of which were previously undiagnosed [6]; visual impairment is reported in 60% of stroke survivors [7]. Visual impairment is not always obvious therefore detection relies on specific tests appropriate to age and ability [8,9].

Whilst hospital-based assessment and management are well documented for many of these visual conditions, assessment and/or models of care can vary widely. There also are gaps in high quality evidence relating to the assessment and measurement of the psychosocial impact of these conditions, and to the organisation of health care to detect and manage these conditions, as well as how to better integrate care across NHS and partner services such as social services, education and charity sectors.

Ideally, for ABI and CVI, service provision is needs-driven and meets the requirements of the individual. For ABI, this warrants early assessment, management and support, and in the context of ABI, is often first needed as part of inpatient bedside care. However, inpatient eye care is *ad hoc* in the UK. Once patients with ABI are discharged from hospital care, community eye care and liaison with community and social care services is typically non-standardised and frequently leads to substantial unmet needs for patients.

For CVI, early assessment, management and support is required to maximise the child's visual capabilities and promote engagement and interaction with their environment. Delayed visual diagnosis and management for children carries lifelong consequences. Hospital eye care is often focused on acute signs and variances can occur after discharge where eye care is managed across a mix of secondary or community eye care services. Therefore, children with CVI may struggle to access appropriate assessment and therefore management, especially if they have not been admitted with an acute illness. Critically, because of the age and developmental immaturity of children, liaison is required among many professionals, family and other services (e.g. education).

2 PURPOSE

The purpose is to establish how services can be best organised and delivered to assess and care for patients with visual impairment due to ABI or CVI.

3 RESEARCH AIMS AND OBJECTIVES

Aim

To establish how can services be best organised and delivered to assess and provide high-quality care for patients with visual impairment due to ABI or CVI.

Objectives

1) identify and map elements of service delivery models for adults and children with visual impairment due to ABI and children with CVI
2) identify barriers and facilitators to ABI and CVI integrated service delivery
3) explore patient/carer experience of ABI and patient/family experience of CVI service delivery and impact on quality of life
4) identify and map health and social care resources involved in ABI and CVI service delivery models and their cost implications.

4 STUDY DESIGN AND PLAN OF INVESTIGATION

Informed by the assessment of unmet priorities, two evidence synthesis reviews will be conducted, using a selected range of methods that will assess key components of service delivery and patient experience for the following topics:

1. Methods of service delivery for children and adults with visual impairment due to **acquired brain injury**

ABI for the purposes of this study is defined as being caused by an acute event occurring after the peri-natal period (i.e. >1 month old) inclusive of focal injury (stroke, tumours), traumatic injury and central nervous system infections, but not genetic, congenital, pre- or peri-natal causes.

2. Methods of service delivery for children with **cerebral visual impairment**

CVI for the purposes of this study is defined as verifiable visual impairment caused by disturbance of the central visual pathways whatever their mode of presentation [1].

Each review will synthesise the evidence for care throughout the patient's pathway/journey of care. A mixed-method synthesis is proposed for each pathway allowing for an integration of evidence around methods of effective service delivery with a recognition of implementation issues and patient experience.

It may be possible for ABI and CVI to co-exist in children. Thus, it is acknowledged that there will be a certain degree of overlap between the two evidence synthesis reviews.

Table 1 summarises our mixed-method synthesis approach and focuses on the features of service delivery to be analysed. Each mixed-methods synthesis will comprise of several reviews. Whilst the scope is similar for the two pathways (ABI and CVI), there is a distinction between the conditions of ABI and CVI along with some differences in the types of visual impairment encountered in each condition and the specific needs of the patient in each condition.

Table 1: Approach to review components

Review component	**Objective**	**Review approach**
1. Detection of visual impairment	To identify and map elements of ABI/CVI service delivery models around detection of visual impairment (objective 1 and 4)	Scoping review
2. Management and delivery of care	To identify and map elements of ABI/CVI service delivery models around management and delivery of care (objective 1 and 4)	Scoping review
3. Barriers & facilitators	To identify barriers and facilitators to ABI/CVI integrated service delivery (objective 2)	Mixed-methods synthesis
4. Patient experience	To explore patient experience of ABI/CVI service delivery and their impact on quality of life (objective 3 and 4)	Mixed-methods synthesis
5. Collaborative practice	To identify and map elements of ABI/CVI service delivery models around collaborative practice (objective 1)	Scoping review
6. Care costs	To understand which health and social care resources are involved, the magnitude and frequency of their involvement, and in what care setting (objective 4)	Scoping review

4.1 Stakeholder group

A stakeholder group will be established at the start of the study to shape and support the reviews. They will meet quarterly with directed contact between meetings if consultation is required to progress. The group will comprise patients with either visual impairment as a result of ABI or CVI, carers, charity representatives e.g. RNIB, the CVI Society, Headway, Child Brain Injury Trust, Stroke Association, relevant professional groups from the vision team e.g. ophthalmologists, orthoptists, optometrists, eye clinic liaison officers, qualified teachers of the visually impaired (QTVIs) and the wider care team e.g. occupational therapists, physicians, GPs, social care workers, as well as NHS and social care managers.

Recruitment of stakeholder group members will use advertisements via charities and professional societies e.g. Royal College of Ophthalmologists, BIOS, Association of Optometrists, Royal College of Occupational Therapists, Royal College of Physicians, Royal College of GPs. The stakeholder group will provide critical input and oversight for all stages of the review process including search terms, sources of grey literature, data synthesis and co-production of outputs. This group will also help to provide context to findings, in view of how ways of working may have changed due to the external factors e.g. pandemic.

4.2 Review methods

For each pathway (ABI/CVI) an overarching mixed methods synthesis will be conducted in accordance with the latest guidance on mixed methods (e.g. JBI Manual for Evidence Synthesis) [10]. Both mixed-method syntheses will adopt an overall segregated convergent design in which an overall review question is addressed by several objectives for which "quantitative and qualitative evidence address different aspects or dimensions of a phenomenon of interest and therefore they can neither confirm nor refute each other but rather only complement each other". Both reviews will collate data to form a pathway through healthcare, social care, education and other sector care across the lifespan of individuals with VI due to ABI or CVI. For each pathway (ABI and CVI) the mixed-methods in evidence syntheses 1 and 2 will consist of:

1. A scoping review will be undertaken in accordance with appropriate guidance (e.g. JBI) to identify and map common elements of ABI/CVI service delivery models around the detection and management of visual impairment and collaborative practice [11]. Capturing care resources involved to scope potential care costs. Scoping reviews are useful for systematically mapping research findings across a body of research evidence that is heterogeneous and/or complex in nature. (objective 1 and 4).

2. An integrated, convergent mixed-methods synthesis will be undertaken in accordance with appropriate guidance (e.g. JBI methodological guidance) to identify barriers and facilitators to the implementation of integrated ABI/CVI service delivery (objective 2) [10].

3. A mixed methods evidence synthesis will be undertaken in accordance with appropriate guidance to explore patient experience of ABI/CVI service delivery and their impact (objective 3) [12].

4.2.1 Search strategy

A comprehensive and wide-ranging search will explore services across the spectrum of hospital, community, social care, and other related settings for ABI and CVI. We will search MEDLINE, CINAHL, Embase, APA PsycINFO, Social Care Online, Cost-Effectiveness Analysis (CEA), Health Technology

Assessment database, ERIC, British Education Index, Education Research Complete, and The Cochrane Library (CENTRAL and CDSR) from inception onwards restricted to English language publications only. An initial exploratory search will be developed in an iterative manner in MEDLINE from keywords relevant to the two topics (ABI and CVI) identified by the review team, stakeholder group and published topic-relevant systematic reviews. Keywords will include brain injury terms OR child terms AND vision disorder terms. Subject headings (e.g. MeSH), free text and advanced search techniques (e.g. truncation, proximity operators) will be used. As with all systematic review searches, the initial search for each topic will evolve during discussions with the wider research team and stakeholder group to ensure that the search terms are relevant.

A sample of relevant records will be used to conduct sensitivity analysis on search terms in order to check the sensitivity of the searches and amend as required. An iterative approach to searching will be undertaken as our understanding of the literature increases. Once the searches are tested and validated in MEDLINE, we will translate them across other sources. No date or study design limitations will be applied to the search strategies but we will exclude animal studies.

Depending on the volume of evidence retrieved, relevant studies identified by the searches will either be filtered into the appropriate review workstream, or, in the event of a large volume of evidence, we will look to adapt the searches to identify relevant studies to include using appropriate search filters e.g. therapy/RCT filters, qualitative filters [13].

In addition, we will contact topic experts to seek unpublished/ongoing studies, check reference lists of included studies and carry out forward citation searching.

Supplementary searches will also be undertaken for a UK focused search of grey literature such as: Health Management Information Consortium (HMIC), websites of selected relevant organisations e.g. RNIB, Stroke Association, The CVI Society, SeeAbility, Headway, Brain Charity, etc. and targeted Google Scholar searches [14]. Search results will be downloaded into a review management system (e.g. Endnote) and de-duplicated before uploading for screening and selection using a review screening software package (e.g. Rayyan).

4.2.2 Eligibility criteria

The inclusion and exclusion criteria will be refined in consultation with the wider review team, stakeholders and PPI. Example criteria are:

Types of studies

- *Service delivery models (detection and management of VI) scoping review*

For the scoping reviews we will include any study that describe or evaluate ABI/CVI service delivery models around the detection or management of visual impairment (e.g. systematic reviews, randomised controlled trials, surveys, process evaluations, etc.).

- *Barriers and facilitators mixed-methods synthesis*

For the mixed-methods synthesis of barriers and facilitators to the implementation of ABI/CVI service delivery models we will include quantitative, qualitative or mixed-methods studies.

- *Quality of life and patient experience evidence synthesis*

For the mixed methods evidence synthesis of quality of life and patient experience of ABI/CVI service delivery models we will include quantitative, qualitative or mixed-methods studies.

- *Grey literature and stakeholder evidence*

Gaps will be filled and evidence contextualised using grey literature (e.g. reports/guidelines) that detail service delivery models and expert input. A NICE call for evidence process may be used to help focus areas for submission of evidence for consideration against inclusion criteria and comment.

Protocols, non-English language publications, conference abstracts, editorials and letters will be excluded.

Participants and setting

Participants of all ages for the ABI synthesis (these ABI visual conditions affect all ages) and children aged 0-17 years for the CVI synthesis (scoping review/mixed methods review/barriers and facilitators) and carers or professionals involved in the delivery of services for the ABI/CVI syntheses (scoping review/barriers and facilitators) will be included. Some conditions can cause ABI or childhood CVI post-natally, therefore there is a need for the overlap of ages to capture both aetiologies.

Studies conducted in hospital and community settings will be included, which may also include educational and home settings. We will include studies from countries with membership of the Organisation for Economic Co-operation and Development (OECD).

Interventions

Care pathways or service delivery for individuals with VI due to ABI or CVI which address any area of early assessment, detection, management or support.

Outcomes

Outcome measures will include descriptions of service components, effectiveness e.g. time to diagnosis/treatment, patient experience, barriers, facilitators, cost and inequalities to address components described in Table 1.

- *Service delivery models (detection and management of VI) scoping review*

Outcomes relating to characteristics on what services are delivered, how services are organised and how they are delivered to assess and manage patients with visual impairment due to ABI or CVI will be included. These will include (but are not limited to), screening and specialist tests, settings of delivery, staff involvement, timing of assessment and follow-up, referral pathways and clinical and cost outcomes.

- *Barriers and facilitators mixed-methods synthesis*

Outcomes for barriers and facilitators to implementation relating to patient and carer or healthcare professionals' capabilities and service dimension will be included.

- *Patient experience mixed methods evidence synthesis*

Outcomes relating to patient experience of services (e.g. patient satisfaction) will be included.

- *Collaborative practice*

Evidence of engagement in quality improvement, communication enhancement programmes and training or education needs will be included.

4.2.3 Selection of studies and data extraction

Studies will be selected for inclusion through a 2-stage process i.e. title/abstract screening followed by full text screening using the predefined explicit criteria. Title/ abstract screening will be completed independently by two reviewers to exclude records that do not meet the inclusion criteria and select records that may meet inclusion criteria for further review at the full text stage. Full texts of those selected will be retrieved and independently screened by two reviewers against the inclusion criteria. Any disagreements on eligibility decisions will be resolved through consensus and, if necessary, by discussion with a third reviewer.

Data to be extracted will be informed by discussions with our stakeholder group. Data relating to study characteristics (e.g. author, date, country, study design), sample (e.g. patient demographics, sample size), models of service delivery (e.g. types of services/test/intervention provided, format, delivery, intensity, frequency, duration, underlying framework or theories, etc.), effectiveness (e.g. clinical effectiveness, test performance), experience, barriers, facilitators, cost and equity will be extracted by one reviewer into a piloted data extraction form and independently checked for accuracy by a second reviewer.

4.2.4 Quality assessment

For the barriers and facilitators and patient experience reviews, studies will be quality assessed using an appropriate quality assessment tool, (e.g. Cochrane Risk of Bias assessment for RCTs, MMAT for mixed-methods, CASP Qualitative tool). Two reviewers will independently assess risk of bias. Disagreements will be resolved by discussion or by involving a third reviewer. (N.B. Quality assessment is not a requirement for scoping reviews).

4.2.5 Data synthesis

- *Service delivery models (detection and management of VI) and Collaborative practice scoping reviews*

Descriptions of service delivery models or interventions will be mapped onto an appropriate framework agreed with our stakeholders (e.g. the Cochrane Effective Practice and Organisation of Care taxonomy (EPOC)). We will highlight common elements of what works and what doesn't work in relation to service delivery models. Statistics on the effects of service delivery models will be extracted as reported, but, where data allows, standardised in evidence tables (noting any calculations). Evidence will be summarised in tables and synthesised narratively [15].

- *Barriers and facilitators mixed methods synthesis*

The latest guidance e.g. JBI guidance, for a mixed-methods synthesis will be followed [10]. Following current guidance, a convergent integrated approach to synthesis will be adopted which "involves integration of transformed data referred to as direct assimilation, which rests on the assumption that quantitative and qualitative data can both address the same research question. As such they can be combined once data have been transformed in the same format (i.e. 'quantitized' or 'qualitized')" [10]. Quantitative data will be transformed into qualitative data.

A theory-led approach to analysis and synthesis will be adopted. Extracted data will be coded, followed by grouping of codes [12]. Identifying barriers and facilitators is enhanced by the use of theoretical frameworks to guide the process [16,17]. A theory-led thematic best-fit framework synthesis is planned to identify and analyse affective, cognitive, social and environmental barriers and facilitators using appropriate frameworks e.g. the Theoretical Domains Framework (a framework of behaviour change theories) and Normalization Process Theory (a theory of implementation) as a priori coding frameworks. Evidence will be summarised in tables and synthesised narratively [18].

- *Patient experience qualitative evidence synthesis*

The Thomas and Harden's three step approach for thematic synthesis of qualitative data will be followed: i) coding of text line by line, ii) development of descriptive themes, iii) development of analytical themes [12]. Firstly, text will be coded on a line-by-line basis. An iterative approach to coding will be undertaken with codes reviewed and revised as new data emerged. A single reviewer will code the data with a second reviewer checking the assigned codes. Any discrepancies will be resolved by discussion. All coded data will then be reviewed for consistency. Secondly, the codes will be reviewed and arranged into related descriptive themes. Finally, analytical themes will be derived from the related descriptive themes in collaboration with the wider review team.

- *Cost*

Eye care service delivery models for ABI and CVI populations may improve service utilization and patient experience, potentially reducing the cost of care and ultimately create better value for the healthcare system. Flowing from the mapped service delivery component, we will summarise the relevant cost-related literature, its methodology and identify challenges in the cost evaluation of services. Information collected from identified studies relating to service delivery model, setting, clinical and economic outcomes/endpoints, study design, analytical approach and framework, time horizon and, if possible, methods employed to characterise uncertainty, will contribute to achieve such goals. Bespoke extraction forms for each review will be used. Identified studies will be critically reviewed and evidence will be summarised in tables and synthesised narratively.

- *Inequalities*

An equality impact assessment will be conducted across the different review processes, to include stakeholder engagement, data analysis and dissemination strategies using the NIHR ARC-EM Equality Impact Assessment Toolkit for Systematic Reviews [19]. In recognition of our intention to include all adults and children with ABI, and all post-natal causes of childhood CVI, inclusion and exclusion criteria are deliberately minimal. There will be no restriction on gender, ethnicity, age, religion, socioeconomic status or access to healthcare. We will use PROGRESS+ to extract data on health inequalities within the included studies across all reviews [20]. The extent to which disadvantaged populations are included in

ABI/CVI research and how health inequalities were assessed within the included studies will be examined, that is descriptive (reporting of baseline characteristics only) versus analytical (equity impact assessed via targeted, gap, gradient approaches) [20].

4.2.6 Overarching synthesis

An overarching synthesis will be conducted to integrate the findings for each pathway (ABI and CVI). The findings from each review will be integrated in a narrative synthesis to investigate the linkages between effective components of service delivery, patient experience and barriers and facilitators to implementation. We will provide a graphical representation of our data within a conceptual framework for each pathway (ABI and CVI). This will be in the form of staged system-based logic models, supported by guidance on the use of logic models in complex health interventions [21]. Alongside this, an abductive analysis of the review findings will be used to draw on organisational theory and further enhance understandings of the management of complex integrated service delivery [22]. The abductive analysis will be conducted at three levels: professional, organizational and institutional to provide a rich narrative explanation of the facilitators and barriers to the delivery of integrated care for ABI and CVI [23-25]. The stakeholder group will support the research team to establish the relevance and transferability of findings to a wider audience, fill in the evidence gaps and highlight implications for practice. Findings will be used to generate key messages about service models and evidence-based care for patients with VI as a result of ABI or CVI.

4.2.7 Summary of findings and assessment of confidence in the evidence

Currently, there is no guidance on how to assess confidence/certainty in mixed-methods reviews. For the qualitative synthesis however, we will use the Confidence in the Evidence from Reviews of Qualitative Research (CERQual) approach to assess confidence in the review findings [26]. One reviewer will independently assess each CERQual component (1) methodological limitations of included studies, (2) relevance of contributing studies to the research question, (3) coherence of study findings, and (4) adequacy of the data supporting the study findings) individually and across the four components to make a final assessment and a second reviewer will cross-check. We will rate overall assessment of confidence as high, moderate, low, or very low and provide a reason for this judgement. We will assign high confidence if it is highly likely, moderate confidence if likely, low confidence if it is possible, and very low confidence if it is not clear that the review finding is a reasonable representation of the phenomenon of interest. Judgements related to the four CERQual components will be summarized in a CERQual Qualitative Evidence Profile [26].
Reviews will adhere to appropriate reporting checklists such as the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA 2020) statement [27], relevant extensions (e.g. PRISMA extension for Scoping Reviews [28]) and the Enhancing transparency in reporting in the synthesis of qualitative research (ENTREQ) [29]. A PRISMA flow diagram will be used to summarise study selection.

4.3 Timetable

The study timeline (uploaded material) specifies the activities over 24 months.

Months 1-3; project set-up procedures, establish stakeholder group
Months 4-19; protocol publication and search/analysis process for ABI review
Months 7-22; protocol publication and search/analysis process for CVI review

Month 19; publication of ABI review
Month 22; publication of CVI review
Months 19-24; Publication of lay/public reports

Throughout; regular oversight meetings, 3-monthly stakeholder group meetings and 6-monthly activity reports

Study timeline

Project Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Calendar Month	Mar-24	Apr-24	May-24	Jun-24	Jul-24	Aug-24	Sep-24	Oct-24	Nov-24	Dec-24	Jan-25	Feb-25	Mar-25	Apr-25	May-25	Jun-25	Jul-25	Aug-25	Sep-25	Oct-25	Nov-25	Dec-25	Jan-26	Feb-26
Set-up	x	x	x																					
Establish Stakeholder Group	x																							
Submit ABI protocol to registry				x																				
Refine and conduct ABI search strategies				x	x																			
Study selection					x	x																		
Analysis and synthesis							x	x	x	x	x	x	x	x										
Submit ABI review for publication															x									
Submit CVI protocol to registry				x																				
Refine and conduct CVI search strategies				x	x																			
Study selection													x	x										
Analysis and synthesis															x	x	x	x	x	x	x			
Submit CVI review for publication																						x		
Lay/public review publications																			x	x	x	x		
Dissemination																				x	x	x	x	x
Stakeholder group meetings		x	x			x			x			x			x			x			x			x
Project oversight meetings	x	x	x	x	x	x		x		x		x		x		x		x		x		x	x	x

5 ETHICAL AND REGULATORY CONSIDERATIONS

5.1 Assessment and management of risk

We do not foresee any risks involved with the conduct of this study.

5.2 Peer review

This study was peer reviewed by independent experts as part of the application for funding to NIHR Health and Social Care Delivery Research.

5.3 Patient & Public Involvement

The inclusion of the stakeholder group (section 4.1) and VISable, are a core part of the research study. The VISable PPI group has three meetings per year and the chair and members are all stroke survivors with visual impairment. The group will act as a separate monitoring group for the study to ensure independent checking of patient and public involvement at all stages. A frequent feedback process to and from the users in this group will be implemented to provide lay governance for the conduct of each phase followed by an evaluation of how our results are viewed to benefit users in lay terms.

6 DISSEMINATION POLICY

The protocols of the reviews planned will be published, for the scoping reviews in open access journals or the Open Science Framework (OSF) and for non-scoping reviews on PROSPERO.

Two new NIHR monographs will be published. Each review monograph will provide a comprehensive, cohesive review that outlines an evidence-informed organisation of care. In line with NIHR guidance we will disseminate in a coordinated set of formats and channels, e.g. easy-read articles targeted at the general public. Materials will be promoted on social media with our stakeholder groups and other patient and public partners (VISable PPI panel). Sub-sections of each monograph as review articles are expected to be published in peer reviewed journals.

In addition to these established dissemination formats, we will seek to translate our mapping of service delivery to an interactive graphic, visual mapping and diagramming software to present our refined, evidence informed logic model. Effectiveness and barriers/facilitators evidence will be included in the model using hypertext and layering functions. The model will also be configured to be able to focus on particular service perspectives (such as community or specialist care). Drafts of the model will be presented at stakeholder meetings and refinements made based on expert feedback.

Findings will be presented to health professionals and wider audiences through stakeholder events. We will provide lay summary reports in both written and audio versions which will be circulated through the networks of the stakeholder group. All lay reports will be placed on a study website for open public access.

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8 APPENDICIES

8.1 Appendix 1 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
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