Plan Overview

A Data Management Plan created using DMPonline

Title: Feasibility of Integrating Home-Based Perimetry for Glaucoma Patients into Clinical Care: Examining Acceptability, Usability, and Implementation Challenges Across Diverse Populations

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Project abstract:

Glaucoma is a leading cause of irreversible blindness that require lifelong monitoring to prevent progression. Home-based perimetry tools like tablets-based, web-based, and VR headsets offer remote monitoring to reduce hospital visits. However, these tools are largely limited to research or private hospitals, restricting insight into their effectiveness in real-world specifically among underserved populations. This study will adopt a patient-centred approach to evaluate the usability, acceptability, and trust in these technologies across diverse groups, ensuring variation in ethnicity, socioeconomic status, digital literacy, age, gender, educational levels and variation in vision loss. Engaging individuals with limited access to eye care, this research will uncover what matters most to them and what is needed to ensure such innovations do not widen health disparities. It will also explore how home test results can be integrated into clinical decision-making. Conducting this study in Bradford, a city known for its ethnical and socioeconomic diversity, the study will address a critical gap in evidence beyond clinical trials. It will generate practical insights into barriers, enablers, and implementation challenges and deliver recommendations for equitable and inclusive healthcare access. The findings will support sustainable, patient-driven models of care that aligns with NHS digital health priorities and net zero ambitions.

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Feasibility of Integrating Home-Based Perimetry for Glaucoma Patients into Clinical Care: Examining Acceptability, Usability, and Implementation Challenges Across Diverse Populations

Data and software outputs

The data and software outputs your research will generate and/or re-use

This study will generate qualitative, quantitative, and device-generated data across three phases:

- **Phase 1**: Interview and focus group transcripts, thematic codes (NVivo), and a systematic review matrix on digital glaucoma tools and related conditions (e.g., diabetic retinopathy). Existing data sources (e.g., published literature and grey literature) will be accessed via databases such as PubMed, Scopus, and CINAHL. All records will be documented using PRISMA-ScR guidelines, with full bibliographic metadata retained. There are no known constraints on re-using published literature beyond standard licensing; however, care will be taken to adhere to any copyright or embargo restrictions when referencing proprietary sources.
- **Phase 2**: Clinical test results, user interaction data from a home-based glaucoma device, System Usability Scale (SUS) scores, and observational data (e.g., think-aloud protocol transcripts).
- **Phase 3**: Workshop transcripts, design artefacts, workflow diagrams, and co-designed implementation strategies for NHS integration.

For all phases, data provenance will be clearly documented through metadata files, version-control documentation, and a data inventory register. Transcripts will be timestamped and linked to unique participant IDs. Data generation and transformations (e.g., pseudonymisation, aggregation) will be tracked using structured logs to ensure transparency and traceability.

The metadata and documentation that will accompany the outputs

In alignment with the Wellcome Trust’s open research policy, this project will be sharing data in a timely and responsible manner to maximise reuse and transparency. Primary outputs will be published in open access journals such as BMJ Open Ophthalmology, JMIR Human Factors, and the British Journal of Ophthalmology. Data associated with these publications will be shared in accordance with each journal’s data availability policy and best practice guidelines for open science.

Where required, datasets will be made available as supplementary material or deposited in reputable open-access repositories (e.g., Zenodo, Dryad, or the University of Bradford Research Repository), with persistent identifiers (e.g., DOIs) and appropriate metadata. All shared datasets will include licensing terms that allow for broad reuse while ensuring proper attribution. Sensitive or identifiable data that cannot be shared (e.g., raw clinical outputs) will be summarised in aggregate form within publications and personal data excluded from public release.

All datasets will be described using appropriate metadata, following FAIRsharing.org standards and the Dublin Core or Data Documentation Initiative (DDI) schemas where applicable. Quantitative data will be documented with variable names, units, and codebooks. Qualitative data (transcripts and coded themes) will be accompanied by context, coding structure, and thematic maps. All files will include readme.txt files to describe content, version control, structure, and licensing.

When you intend to share your data and software

In line with the Wellcome open research policy, research outputs will be published in open access journals (e.g. *BMJ Open Ophthalmology*, *JMIR Human Factors*, *British Journal of Ophthalmology*). Where possible, anonymised datasets will be shared in reputable open repositories (e.g. Zenodo, Dryad, or the University of Bradford Research Repository) and assigned DOIs. All shared data will be accompanied by licensing information (e.g. CC BY 4.0) and rich metadata to enable discoverability, reuse, and citation. Sensitive or identifiable data (e.g. clinical test outputs) will not be publicly shared. Instead, aggregate summaries will be reported in publications.

For unpublished datasets or toolkits not directly linked to a specific article, data will be made available within 12 months of project completion, allowing for analysis, validation, and initial dissemination. This schedule adheres to established good practice in digital health and HCI research, balancing openness with a reasonable period of exclusive use. All data sharing will remain consistent with ethics approvals and participant consent regarding secondary use and public release. There will be limitations associated with intellectual property (IP), particularly in relation to proprietary aspects of the home-based glaucoma device and clinical integration toolkits.

In cases where data cannot be publicly shared (e.g., sensitive health records especially the ones from patient's test results or identifiable device output), clear justifications will be provided, and aggregate summaries will be included in the publication.

Where your data and software will be made available

To ensure maximum discoverability and long-term preservation, all shareable datasets will be deposited in the university of Bradford repository which aligns with FAIR data principles and are appropriate for Wellcome-funded research. Qualitative and usability datasets (coded interview summaries, SUS scores, observation logs) will also be deposited in the University of Bradford Research Repository or Zenodo, both of which support DOI assignment, versioning, and open licensing (e.g. CC BY 4.0). Systematic review matrices and literature outputs will be archived in open platforms such as (Open Science Framework) or Dryad, depending on publisher. Implementation toolkits and co-designed frameworks developed in Phase 3 will be shared via Zenodo ensuring persistent identifiers, open access, and citation tracking.

All repositories will be selected from those listed in FAIRSharing, Re3Data, or the Wellcome Open Research curated list of approved repositories, to ensure compliance with Wellcome's open research policy.

How your data and software will be accessible to others

All shareable data will be made openly accessible to the research community through Zenodo, the University of Bradford Research Repository, Dryad, or OSF, depending on the data type and publisher requirements. Each dataset will be assigned a persistent identifier (DOI) and made available under a Creative Commons licence (e.g. CC BY 4.0), to ensure reuse and attribution.[VP1]

Due to legal and ethical constraints, raw clinical data containing identifiable patient information (e.g. visual field results linked to patient IDs or health records) will not be shared publicly. Instead, aggregate summaries and anonymised excerpts will be included in the publications. Researchers interested in accessing controlled data (e.g. pseudonymised clinical records or qualitative transcripts) may submit a data access request via the University of Bradford, subject to review by the study's Principal Investigator and the institutional ethics committee. Access will be granted for non-commercial academic purposes, subject to a FAIRsharing signed data-sharing agreement.

Whether limits to data and software sharing are required

Yes, limits to data sharing are required in this project due to ethical and privacy considerations. Specifically, raw test results and device-generated data from individual glaucoma patients will not be shared publicly, as they may contain sensitive personal health information that could potentially be re-identified, even after pseudonymisation.

However, these results will be aggregated, anonymised, and summarised for dissemination in publications, presentations, and reports. Where applicable, de-identified findings will be shared in open access journals, and high-level summaries will be included in usability and clinical relevance datasets to support transparency.

Anonymised datasets from this study will be made available via the University of Bradford Research Repository or Zenodo, with a persistent DOI and shared under a CC BY 4.0 licence. All data will include appropriate metadata in line with FAIR principles. Due to ethical and privacy considerations, raw device outputs and individual clinical data will not be publicly shared. Instead, aggregated and de-identified results will be provided in open-access publications. Participants will give informed consent outlining data use and confidentiality. Access to restricted data may be granted for academic purposes under a data sharing agreement.

How datasets and software will be preserved

All datasets generated during the project will be preserved in accordance with the University of Bradford's Data Management Policy and in full compliance with the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018.

Research materials

What materials your research will produce and how these will be made available

This research will produce several materials, including:

- Systematic review datasets and evidence matrices
- Transcripts and coded data from interviews, focus groups, and workshops
- Usability data, including SUS scores, task observations, and device logs
- Co-designed implementation toolkits and clinical integration frameworks
- Software/scripts used for data analysis

Where appropriate, anonymised and non-sensitive materials will be made openly available through trusted repositories such as Zenodo, the University of Bradford Research Repository, or OSF. Each resource will include persistent identifiers (DOIs) to support reuse. Sensitive materials (e.g., raw clinical outputs like test results) will be summarised and shared in aggregate form only.

Resources required

You should consider what resources you may need to deliver your plan and outline where dedicated resources are required.

To effectively implement this data management and sharing plan, dedicated research support will be required. A Research Assistant will be employed to support the following:

- Data preparation and organisation, including transcription, anonymisation, and formatting of qualitative and quantitative data
- Metadata creation and documentation using recognised standards (e.g. Dublin Core, COREQ, PRISMA-ScR)
- Repository submission, ensuring datasets are properly archived, assigned DOIs, and licensed appropriately
- Compliance monitoring, ensuring that data handling follows the University of Bradford's data policy and UK GDPR
- Supporting controlled access requests and managing data sharing agreements where sensitive data is involved

Intellectual property

What IP your research will generate

This research will not generate intellectual property in form of commercial products, patents, or proprietary software. The primary research output will be anonymised data from eye tests, which will be used solely for academic research purposes.

How IP will be protected

While no commercial IP will be generated, the research outputs will be protected by the University of Bradford policies on data management and ethical use. Anonymised data will be stored securely, and access will be governed by data-sharing agreements (FAIRsharing) where applicable.

How IP will be used to achieve health benefits

The anonymised data will contribute to scientific knowledge and inform future research on eye testing and monitoring. Findings from the study will be used to enhance clinical understanding and improve monitoring methods, potentially influencing healthcare practices and policies related to vision care.

Provide the name and contact details for the person in your organisation (e.g. Technology Transfer Officer or Business Development executive) who can act as a point of contact for Wellcome in connection with the protection and commercialisation of this IP

Russell Hodgetts