Feasibility of in-home monitoring for people with glaucoma: the I-TRAC mixed-methods study

Carrie Stewart,[1] Hangjian Wu,[2] Uma Alagappan,[1] Augusto Azuara-Blanco,[3] Anthony J King,[4] Andrew J Tatham,[5] Rodolfo Hernández,[2] Bruce Lowe,[6] Darian Shotton,[6] Nana Appiah,[1] Taylor Coffey,[1] Thenmalar Vadiveloo,[1,7] Graeme MacLennan[1,7] and Katie Gillies[1*]

[1]Health Services Research Unit, University of Aberdeen, Aberdeen, UK
[2]Health Economics Research Unit, University of Aberdeen, Aberdeen, UK
[3]Centre for Public Health, Queen's University Belfast, Belfast, UK
[4]Ophthalmology, Nottingham University Hospitals NHS Trust, Nottingham, UK
[5]Princess Alexandra Eye Pavilion, NHS Lothian, Edinburgh, UK
[6]Patient Partner
[7]The Centre for Health Randomised Trials (CHaRT), University of Aberdeen, Aberdeen, UK

[*]Corresponding author k.gillies@abdn.ac.uk

Published August 2024
DOI: 10.3310/GTWD6802

Scientific summary

Feasibility of in-home monitoring for people with glaucoma: the I-TRAC mixed-methods study

Health Technology Assessment 2024; Vol. 28: No. 44
DOI: 10.3310/GTWD6802

NIHR Journals Library www.journalslibrary.nihr.ac.uk

Scientific summary

Background

Glaucoma is a chronic neurodegenerative eye disease and the second commonest cause of severe visual loss in the UK. Diagnosed patients require regular, lifelong monitoring to detect progression and assess effectiveness of treatment, with monitoring typically delivered within the hospital eye services (HES). Ophthalmology is the busiest NHS outpatient specialty, accounting for 10% of all outpatient visits, and glaucoma represents a significant part of this workload. In England alone there are over 1 million clinic visits per year for patients with glaucoma. Providing regular surveillance and treatment is already a major challenge for the NHS but as the prevalence of glaucoma increases with age, demand for glaucoma care is increasing (and will continue to do so) due to the ageing population.

The two main measurements used in the assessment of glaucoma are intraocular pressure (IOP) measurement and visual field (VF) testing. Recent advances in technology mean it is now possible for patients with glaucoma to measure their IOP and test their VFs in their own home. Home monitoring could theoretically replace or supplement standard care, perhaps allowing patients to require fewer outpatient visits, while increasing convenience and potentially reducing costs and increasing capacity for the NHS. It is also possible that frequent home testing may lead to better outcomes than achieved with standard infrequent visits to HES, potentially leading to earlier detection of progression or highlighting high IOP undetected through conventional outpatient clinic-based tests.

Currently though, it is not known if home monitoring is acceptable to people with glaucoma, or if home monitoring in the general glaucoma population is feasible. The main aim of this study was to assess acceptability and feasibility of home monitoring, and to make recommendations about future research to test how the NHS could use home monitoring.

Objectives

The aim of In-home Tracking of glaucoma: Reliability, Acceptability, and Cost (I-TRAC) was to determine the feasibility and acceptability of digital technologies to monitor glaucoma at home and inform the possible need for and design of a definitive evaluative study. The specific research objectives were to:

- identify which patients with glaucoma are most appropriate for home monitoring (e.g. all patients, those with stable disease, or those with severe glaucoma?)
- understand the views of key stakeholders (patients, clinicians, researchers) on whether home monitoring is feasible and acceptable
- develop a conceptual framework for the economic evaluation of home monitoring for glaucoma
- explore the need for and provide evidence on the design of a future study to evaluate the clinical and cost-effectiveness of digital technologies for home monitoring of glaucoma.

Methods

Design

The I-TRAC study was a multiphase mixed-methods feasibility study with key components informed by theoretical (i.e. the Theoretical Framework of Acceptability and Theoretical Domains Framework) and conceptual [A process for Decision-making after Pilot and feasibility Trials (ADePT)] frameworks, utilising various data sources from a survey, interviews, focus groups, an observational intervention study, and literature reviews.

Recruitment

Recruitment to each of the I-TRAC study phases was as follows:

- Expert glaucoma specialists from the UK were recruited through a professional glaucoma society and invited to participate in a survey. Those who responded were asked to indicate their willingness to participate in a follow-up focus group or interview.
- Patient participants for the intervention study were recruited through three secondary care ophthalmology glaucoma clinics.
- All site staff involved in the patient-facing delivery of I-TRAC across the three sites were invited to participate in a focus group or interview.
- External researchers, such as Chief Investigators and Trial/Study Managers, who had been involved in evaluating digital technologies for home monitoring of eye disease or other diseases (as either feasibility, pilot or full-size trials) and who were either known to the I-TRAC team or identified through published literature were invited to participate in an interview.

Intervention

Patient participants were asked to use two home monitoring technologies to measure IOP and visual function (through a contrast sensitivity assessment) on a weekly basis for a duration of 12 weeks. Participants were provided with an iCare HOME 2 handheld tonometer (iCare Oy, Vantaa, Finland) to measure IOP, and the OKKO Visual Health App (OKKO Health, Bristol, UK) was used to measure visual function on a tablet computer. Site staff and patient participants received training in how to use the devices in hospital in advance of the home monitoring period. Participants received a prompt each week to remind them to use their home monitoring equipment; they could opt between receiving e-mail or text message electronic reminders.

Results

The key findings from I-TRAC are presented below in relation to the study objectives.

Objective 1: Identify which glaucoma patients are most appropriate for home monitoring

The online survey, completed by 49 expert glaucoma clinicians, aimed to determine which glaucoma patients may be most suitable for home monitoring using digital technology. The survey findings demonstrated agreement among expert glaucoma clinicians that there is a place for home monitoring of glaucoma patients using digital technology. However, based on the scenarios used in this study, there is limited agreement among clinicians about which glaucoma patients are most suitable for home monitoring using digital technologies to measure IOP and visual function. Clinicians reported that they were generally not supportive of the home monitoring of high-risk patients as a replacement for standard care, due to the fear of missing disease progression or unreliable readings. However, they were generally supportive of home monitoring having a role within low-risk scenarios. Clinicians anticipated that the integration of home monitoring into the current healthcare system could act as an adjunct to increase hospital capacity for glaucoma patients who require face-to-face assessment. The survey highlighted a range of issues and challenges related to the home monitoring of glaucoma patients using digital technologies. A central theme was clinicians' lack of trust in home monitoring technologies, related to concerns about the reliability, accuracy and clinical usefulness of these technologies. Clinicians expressed concerns about patient safety (if standard care were to be replaced with home tonometry), decreased rather than increased glaucoma progression detection, and concerns about how resource efficient (time and financial) this approach could be in comparison to current provision.

Objective 2: Understand the views of key stakeholders on whether home monitoring is feasible and acceptable

Several key stakeholder groups were included in various I-TRAC phases in order to achieve this objective.

Firstly, three focus groups (*n* = 2, *n* = 4, *n* = 4) and five individual interviews with expert glaucoma clinicians suggested there is cautious optimism about the use of digital technologies to monitor patients' glaucoma at home. Clinicians reported that they are interested and enthused by the potential of glaucoma home monitoring, but there are several areas of concern that need to be addressed before they would feel reassured to buy-in to this approach. They believe home monitoring could meet an existing clinical need, addressing the present difficulties of inadequate capacity to meet increasing demand. They can see potential patient and service benefits, but they require reassurances about the technologies and how such a service would be implemented into routine care. Contextually, the influence of the coronavirus disease discovered in 2019 pandemic was evident; clinicians' experiences throughout the pandemic have both prompted a need to adapt and change the way they monitor patients with glaucoma and highlighted that monitoring outside the clinic is possible and, in many ways, can be done safely. The current care backlog post pandemic is driving enthusiasm for innovative solutions.

The multiphase mixed-methods study exploring the intervention's acceptability demonstrated that for both patient participants and site staff tasked with delivering I-TRAC there were many positives and the intervention was deemed broadly acceptable. Overall, the I-TRAC study recruited well, recruiting 95% of its proposed sample size (42 patient participants of 45) in the planned recruitment period (November 2021–August 2022, 10 months). Retention and completion of follow-up procedures was also successful, with 95% (*n* = 40) completing the 3-month follow-up clinic visits. Adherence to the interventions was generally high, especially considering that our predetermined adherence levels were above 80%, and satisfaction with the process and the training were also scored highly by patient participants. However, 48% (*n* = 20) of patient participants contacted site staff at least once when at home, resulting in additional input from site staff regarding study process or intervention delivery.

The qualitative data from the interviews and focus groups with patient participants (*n* = 10) and site staff (*n* = 9) did corroborate some of these findings (e.g. stating recruitment worked well and study processes were easy to follow and low burden). Yet the qualitative data also highlighted important areas not identified through the quantitative pilot, such as: the need for a refinement of eligibility criteria and associated recognition of limited sample diversity in I-TRAC; issues relating to inadequate training (for both site staff and patients); a lack of confidence in the technology (and their ability) in relation to the purpose of home monitoring; familiarity with the device and physical dexterity issues; and some anxieties in relation to a lack of clinical oversight when monitoring at home. These findings highlight that several key factors need to be deliberated when considering the feasibility of future trials evaluating digital technology for home monitoring of glaucoma.

Finally for this objective, we interviewed researchers from external teams (*n* = 8) who had been involved in the evaluation of digital technologies for home monitoring patients' health. Although researchers reported multiple challenges encountered while carrying out digital health technology studies/trials, they also had many suggestions as to how these could be prevented or overcome. The common barriers were low stakeholder acceptability, lack of understanding of digital technologies, poor resource planning, insufficient peripheral infrastructure, problematic relationships with commercial partners, and the unsolved dilemma of digital exclusion. The findings illustrate that researchers in the UK carrying out digital health technology studies encounter a number of challenges impacting on the successful design, conduct, and delivery of digital health technology studies/trials and potentially leading to wasted research efforts. This broader exploration of feasibility issues surrounding digital health technology studies/trials highlights significant agreement about critical trial design and conduct issues that require consideration in studies/trials of this type.

Objective 3: Develop a conceptual framework for the economic evaluation of home monitoring for glaucoma

Several methods were used to develop a conceptual framework to consider the future economic evaluation of home monitoring for glaucoma. Data sources used included evidence from two systematic reviews conducted for the I-TRAC project and secondary analysis of the data collected through all

previous I-TRAC phases to identify resource use and patient preference components. Overall, the key categories of intervention costs of glaucoma home monitoring identified in this study include equipment cost, patient training, ongoing patient support during home monitoring, potential spill-over costs (e.g. high readings trigger hospital visits) and costs of data integration (to the existing medical records) and evaluation by artificial intelligence, while key sources of patient utilities of glaucoma home monitoring are categorised as health-related quality of life (HRQoL)-related (e.g. more frequent disease monitoring and faster identification of disease progression) and non-HRQoL related (e.g. convenience). Given the complexity and scarcity of relevant evidence in the literature, it is recommended that further qualitative/quantitative research needs to be conducted to better understand the study population, care pathways of the compared interventions, cost categories and benefits of home monitoring, before a formal economic evaluation can be conducted. A step-by-step approach is then recommended to carefully explore what economic evaluation approach can be suitable in the context of glaucoma home monitoring.

Objective 4: Explore the need for and provide evidence on the design of a future study to evaluate the clinical and cost-effectiveness of digital technologies for home monitoring of glaucoma

The data from across all phases of the I-TRAC study were mapped to the ADePT framework in order to establish the feasibility of a future evaluative study of the clinical and cost-effectiveness of digital technologies for home monitoring of glaucoma. Many of the 14 items in ADePT were successfully achieved (e.g. 93% of sample size was recruited in the original recruitment window, and overall acceptability of the home monitoring technologies was good). The mixed-methods data collection and analysis allowed in-depth investigation of key areas and highlighted uncertainties that need to be addressed before moving to an evaluative study. Some of these focused on aspects related to the population; that is, clarity is still required on which glaucoma patients would be most suitable for home monitoring, and this is linked to whether home monitoring is considered as an additional service (i.e. in addition to routine monitoring through HES) or as a replacement service (i.e. patients would not attend HES and instead would be monitored at home). While the interventions were broadly deemed as acceptable to patients and clinicians, further refinement of the intervention is required (e.g. frequency and duration) and consideration of how it 'fits' within the healthcare system is required before evaluation. As well as the intervention, considerations about an appropriate comparator were not explored in I-TRAC but should be. Lastly, determination of appropriate outcomes (and their importance for a range of stakeholders) for the evaluation of digital technologies for glaucoma home monitoring also requires attention.

Conclusions

The I-TRAC study has demonstrated 'cautious optimism' when considering patients' and healthcare professionals' views on the acceptability of digital technologies for home monitoring patients with glaucoma. Much of the caution from clinicians related to concerns around the reliability of the technologies and the potential to miss progression of the disease if patients were not monitored in clinic. The study evidenced sufficient fidelity, good adherence to the interventions among the patient population, and feasibility of delivery of both the interventions and the study processes. However, I-TRAC also highlighted several unknowns relating to the research question and design of a future evaluative study that require addressing before progression to a randomised controlled trial. The I-TRAC study has also considered the wider ecosystem challenges of running digital health technology trials through evidencing the views of external research teams experienced in digital home monitoring technology delivery. Further research is required to determine the appropriate population (i.e. glaucoma patients with low vs. high risk of progression) and further refine intervention components and their delivery, to allow future evaluation studies to be planned.

Study registration

This study is registered as Research Registry #6213.

Funding

This award was funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme (NIHR award ref: NIHR129248) and is published in full in *Health Technology Assessment*; Vol. 28, No. 44. See the NIHR Funding and Awards website for further award information.

Health Technology Assessment

ISSN 2046-4924 (Online)

Impact factor: 3.6

A list of Journals Library editors can be found on the NIHR Journals Library website

Launched in 1997, *Health Technology Assessment* (HTA) has an impact factor of 3.6 and is ranked 32nd (out of 105 titles) in the 'Health Care Sciences & Services' category of the Clarivate 2022 Journal Citation Reports (Science Edition). It is also indexed by MEDLINE, CINAHL (EBSCO Information Services, Ipswich, MA, USA), EMBASE (Elsevier, Amsterdam, the Netherlands), NCBI Bookshelf, DOAJ, Europe PMC, the Cochrane Library (John Wiley & Sons, Inc., Hoboken, NJ, USA), INAHTA, the British Nursing Index (ProQuest LLC, Ann Arbor, MI, USA), Ulrichsweb™ (ProQuest LLC, Ann Arbor, MI, USA) and the Science Citation Index Expanded™ (Clarivate™, Philadelphia, PA, USA).

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: journals.library@nihr.ac.uk

The full HTA archive is freely available to view online at www.journalslibrary.nihr.ac.uk/hta.

Criteria for inclusion in the *Health Technology Assessment* journal
Manuscripts are published in *Health Technology Assessment* (HTA) if (1) they have resulted from work for the HTA programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

HTA programme

Health Technology Assessment (HTA) research is undertaken where some evidence already exists to show that a technology can be effective and this needs to be compared to the current standard intervention to see which works best. Research can evaluate any intervention used in the treatment, prevention or diagnosis of disease, provided the study outcomes lead to findings that have the potential to be of direct benefit to NHS patients. Technologies in this context mean any method used to promote health; prevent and treat disease; and improve rehabilitation or long-term care. They are not confined to new drugs and include any intervention used in the treatment, prevention or diagnosis of disease.

The journal is indexed in NHS Evidence via its abstracts included in MEDLINE and its Technology Assessment Reports inform National Institute for Health and Care Excellence (NICE) guidance. HTA research is also an important source of evidence for National Screening Committee (NSC) policy decisions.

This article

The research reported in this issue of the journal was funded by the HTA programme as award number NIHR129248. The contractual start date was in January 2021. The draft manuscript began editorial review in March 2023 and was accepted for publication in January 2024. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' manuscript and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this article.

This article presents independent research funded by the National Institute for Health and Care Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, the HTA programme or the Department of Health and Social Care. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, the HTA programme or the Department of Health and Social Care.

This article was published based on current knowledge at the time and date of publication. NIHR is committed to being inclusive and will continually monitor best practice and guidance in relation to terminology and language to ensure that we remain relevant to our stakeholders.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Newgen Digitalworks Pvt Ltd, Chennai, India (www.newgen.co).