BMJ Open

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Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-018140
Article Type:	Protocol
Date Submitted by the Author:	08-Jun-2017
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Primary Subject Heading:	Evidence based practice
Secondary Subject Heading:	Ophthalmology
Keywords:	functional vision assessment, orientation and mobility, OMO and VROOM tools, co-rated measures, embedded mixed methods, translational research

Optimising technology to measure functional vision, mobility, and service outcomes for people with low vision or blindness: Protocol for a prospective cohort study in Australia and Malaysia

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Word count: 5142 words, excluding title page, abstract, references, figures and tables.

ABSTRACT

Introduction: Orientation and mobility (O&M) specialists assess the functional vision and O&M skills of people with mobility problems, usually relating to low vision or blindness. There are numerous O&M assessment checklists, but no measures that reduce qualitative assessment data to a single comparable score, suited for assessing any O&M client, of any age or ability, in any location. Functional measures are needed internationally to align O&M assessment practices, guide referrals, profile O&M clients, plan appropriate services, and evaluate outcomes from O&M programs (e.g., long cane training), assistive technology (e.g., hazard sensors) and medical interventions (e.g., retinal implants). This study aims to validate two new measures of functional vision (VROOM) and O&M (OMO) in the context of ordinary O&M assessments in Australia, with cultural comparisons in Malaysia, also developing phone apps and online training to streamline professional assessment practices.

Methods and analysis: This multiphase observational study will employ embedded mixed methods with a QUAL/quan priority: co-rating measures during social inquiry. Australian O&M agencies (n=15) provide the sampling frame. Heterogeneous O&M specialists will use quota sampling to generate cross-sectional assessment data (up to n=400) before investigating selected cohorts in outcome studies. Cultural relevance of the VROOM and OMO tools will be investigated in Malaysia, where the tools will inform the design of assistive devices and evaluate prototypes. Confirmatory factor analysis, Rasch modelling, cluster analysis and analysis of variance (ANOVA) will be undertaken along with descriptive analysis of measurement data. Qualitative findings will be used to interpret VROOM and OMO scores, filter statistically significant results, warrant their generalisability, and identify additional relevant constructs that could also be measured.

Ethics and dissemination: Ethical approval has been granted by the Human Research Ethics Committee at Swinburne University (SHR Project 2016/316). Dissemination of results will be via agency reports, journal articles and conference presentations.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This study aims to compare the functional vision and functional mobility skills of people of any age or abilities, addressing an international shortage of performance measures for use in dynamic, everyday environments.

- The co-rated measurement tools employ a constructivist approach to knowledge that aligns with O&M assessment practice, rather than assuming objectivity when assessing everyday human behaviour.
- The VROOM and OMO tools aggregate ratings to a single comparable score on the spot.
- Words and number data require mixed analyses, with authenticity presiding over standardisation and statistical power when evaluating data quality.
- The study design depends on industry partners generating data with clients during ordinary O&M assessments.

INTRODUCTION

Globally, there are 285 million people with low vision or blindness, including 20 million Asians with visual acuity less than 3/60.[1] In Australia and New Zealand, an estimated 605,300 people have visual acuity less than 6/12,[2 3] making them ineligible to drive.[4] Orientation and mobility (O&M) specialists work in the community with non-drivers whose mobility problems are usually related to low vision or blindness. They assess a client's functional vision and orientation and mobility skills, then teach visual efficiency, mobility aid use (e.g., long cane, dog guide, Miniguide) and practical travel strategies to maximise independence.

O&M clients are diverse, making it difficult to compare their functional status and prioritise needs. They include people with intellectual and physical disabilities who live locally supported by a carer, and people who live independently, work full-time and travel internationally. Functional O&M assessment precedes any O&M intervention. This qualitative assessment is often supported by checklists or rating scales to evaluate a client's general O&M skills and confidence,[5] or more targeted considerations such as children's O&M,[6] body concepts,[7] or mobility challenges with tunnel vision.[8] However, the only tool designed to reduce qualitative assessment data to a single comparable score on the spot is specific to children with cortical vision impairment (CVI) whose co-morbidities such as hemiparesis can limit their independent mobility. The "CVI Range" considers mobility, but is primarily used to rate a child's functional vision out of ten, and thereby guide appropriate, timely intervention to stimulate the child's visual development.[9 10]

The international O&M community needs a similarly efficient way to score the functional vision and O&M skills of all clientele, to profile and compare different client

groups, interpret their mobility choices, guide program design, and evaluate the outcomes of O&M training, assistive devices and interventions such as a bionic eye.[11 12] Previous O&M outcome studies have tended to use anthropometrics such as visual acuity and walking speed to measure elements of O&M performance, but these isolated measures have been unable to capture the more holistic benefits from O&M training[13] or vision-related interventions[14] that participants report anecdotally. Functional O&M assessment using robust social research methods is needed to evaluate the everyday outcomes that a person gains from a vision- or mobility-related intervention, including O&M training;[15] but then functional measures are also needed that reduce complex qualitative data to a single score so that findings from infinitely diverse clients and circumstances can be more easily compared.

The VROOM and OMO tools

During 2015, two new tools were developed for use in ordinary O&M assessment, during which defined ordinal scales are co-rated and then ratings are aggregated on the spot, reducing qualitative assessment data to a score out of 50. The VROOM tool measures Vision-Related Outcomes in O&M (functional vision for mobility), and the OMO tool measures functional O&M Outcomes (supplementary information, appendix 1). These tools share the same measurement template and are designed to be used together, but vision does not neatly predict functional abilities[16] so the two constructs need to be measured separately during functional O&M assessment.

The VROOM and OMO tools (see supplementary information, appendix 1) were developed following bionic vision research (2011-2015),[17 18] where grounded theories about functional vision and mobility were derived from the lived experience of people with advanced retinitis pigmentosa (n=43).[19] These theories indicated what to measure, and suggested how constructs could be rated and weighted in the measurement template that includes Part A: observed travel and Part B: wellbeing. In Part A ten rating decisions are made using a single rating scale after observing the client's visual behaviours and travel skills in both static and dynamic environments (maximum score 30). In Part B, five relevant constructs, each with defined performance indicators, are co-rated while discussing wellbeing with the client (maximum score 20). Comments from clients and stakeholders are noted alongside these ratings, providing precise, embedded mixed data[20] about each client's functional abilities at the time of assessment.

To test proof of concept, the VROOM tool was retro-scored with a convenience sample (n=13), drawing on live observations of people selected from across the visual spectrum and

video data from the bionic eye project. This process showed that the measurement template worked – the VROOM tool could be used with drivers, people with low vision and people with light perception only, yet was precise enough to capture subtle functional improvements in vision. The three retinal implant recipients each showed a 12-16% (6-8 point) increase in their VROOM scores when their retinal implant device was switched on.[19]

The VROOM and OMO tools were then co-rated during interviews with O&M clients who have a guide dog (n=51). During the co-rating conversation, participants were also invited to critique the constructs being assessed in the tools, and suggest improved wording of performance indicators. The VROOM tool inadvertently captured a 60% (30 point) improvement in one man's vision that resulted from corneal transplant surgery in between his initial VROOM rating and a re-scoring conversation several months later.

Statistical analyses of these pilot data suggested that the subscales in the VROOM tool are measuring the one construct (functional vision for mobility), but that O&M is a more complicated phenomenon which needs further investigation during ordinary O&M assessment. A statistically powered study with embedded comments from diverse O&M clients and O&M specialists is needed to review the sufficiency and redundancy of subscales in the OMO tool. A priority is to balance user-friendliness of the tool during professional practice, with its ability to generate meaningful measurement data on the spot.[21]

The VROOM and OMO tools are intended to assess a person's functional skills upon initial referral, pre-post O&M training, or at any time that comparisons need to be made. They could be used to capture the functional impact of deteriorating vision (repeated measures over time), the range of fluctuation experienced by clients (e.g., comparing day and night vision), and the range of benefit that might be gained from different types of interventions (e.g., long cane training, or a retinal implant). Over time, this practice-based evidence has the potential to inform referral criteria for O&M services and vision-related interventions, warrant funding applications for client services and assistive devices, evaluate new assistive technologies, and shape social policies impacting eligibility criteria for pensions, urban planning for pathways, public transport and safety, and communication technologies that improve access to information.

The role of technology in O&M

Since World War II, specialised electronic mobility aids have been developed for people with low vision or blindness, to increase their range of preview during travel, to avoid collisions and support fluent wayfinding; to gain and maintain orientation, and manage travel

information.[22 23] Wearable, or implantable vision restoration devices include retinal prostheses,[17] computer mediated head-mounted displays [24], and sensory substitution devices.[25] In the longer term, autonomous robot guidance is also proposed as an alternative to a dog guide to support wayfinding.[26]

Each of these technologies is remarkable for its innovation and fit for purpose. However, each is suited to a narrow clientele: blindness is already a low incidence disability, O&M clients have diverse needs, and aids and devices differ in their cultural acceptability. Specialist technology is costly to develop – some devices never make it past the prototype stage, and most that reach commercialisation tend to be superseded in a few years.[27]

Since GPS and accessibility features have become common inclusions, many O&M clients now prefer mainstream technologies such as a smartphone or tablet to support their travel (figure 1). Voiceover means that people who cannot see print, can access information without needing braille. Clients venture to unknown places, equipped with GPS apps (e.g., blindsquare.com). The camera function serves as a low vision aid, bringing distant landmarks close for detailed scrutiny. Mainstream devices are multi-purpose and synchronised so the traveller needs to carry less equipment. New iterations are affordable and easy to upgrade. Accessibility features help to reduce social barriers as people with full vision, low vision, and no vision can enjoy the same technology.

[insert figure 1]

O&M specialists, some with low vision or blindness, also use smartphones and tablets to support their professional practice – to organise caseloads, facilitate appointments, and make referrals, then access apps, maps, timetables, online directions and voice recording functions to plan, implement and review travel with clients. Video provides evidence of the client's O&M skills to show relevant stakeholders after an O&M session. FaceTime between city-based professionals and rural or remote clients can be used to consult about real-time travel challenges in between regional visits.[28] O&M case notes can be uploaded to the office database, and the internet makes professional development opportunities available to isolated or time-poor practitioners.

Technologies scheduled for development in this project include a mobile phone app to support and streamline O&M assessment, and online training for O&M specialists in the use of the VROOM and OMO tools.

Life-logging in O&M research once meant keeping a handwritten or audio-recorded mobility diary, but affordable, accessible technologies are providing new ways to measure everyday travel. Personal activity monitors (e.g., Fit-bit, Smart-watch, mobile phone apps) combine accelerometer and GPS technology to measure aspects of free-roaming mobility (e.g., speed, distance, sedentary periods, heart-rate). These monitors are readily available, discreetly integrated into a wristwatch or mobile phone, so they don't make the user stand out in public. Accessibility features and synchronisation with other devices enable the user to manage personal data, which furthers the self-determining purpose of O&M intervention. However, accessibility differs between different platforms and devices, and improvements are needed to increase the user-friendliness of personal activity monitors for people with low vision or blindness.

Another approach to life-logging is to capture egocentric vision with a video-camera (e.g., gopro.com) mounted on the head or body. Such devices are already worn by skiers and cyclists attached to a safety helmet. They can record the challenges encountered during travel, including self-talk and commentary. When eye tracker technology such as Tobii (www.tobii.com) or SMI (www.eyetracking-glasses.com) is also used to measure mobile gaze direction during travel, then state-of-the-art computer vision techniques can analyse the eye-tracker data in conjunction with the video/audio data and generate precise information about visual behaviour during travel. These data help to inform the iterative development of new vision-related technologies, but when the aim of O&M research is to capture a participant's everyday responses to everyday situations, it is important to consider appearances. In some communities, snatch-theft is a risk when costly equipment is on display, and devices that make the traveller look unusual can change the way that passers-by interact so that something other than ordinary functional performance is measured. Life-logging technologies that are not so obviously visible seem likely to generate more authentic data about everyday activities.

Aims of this study

The aims of this study are to:

1. Validate the VROOM and OMO tools during ordinary O&M assessment, to profile O&M clients and compare their functional abilities through:
    a. statistically-powered cohort studies in Australia, and
    b. cultural investigations in Malaysia.

2. Optimise technology to measure functional vision, mobility, and service outcomes of people with low vision or blindness, by
    a. analysing the technology use and needs of O&M agencies, O&M specialists and O&M clients in Australia and Malaysia, then
    b. developing phone apps and online training that enable O&M specialists and O&M clients to generate and manage practice-based evidence from O&M assessments.

METHODOLOGY and METHODS

Study design

This study will employ a multi-phase, mixed methods design (figure 2), beginning with a cross-sectional study, then extending to cohort studies in relation to selected vision- and mobility-related interventions.

[insert figure 2]

The VROOM/OMO validation study (solid-line boxes) depends on establishing industry partnerships with O&M service providers (called agencies) in Australia and Malaysia. At the same time, technology will be investigated and developed to support O&M assessment practices (dashed-line boxes).

To that end, online surveys of the technology use, and needs, of O&M clients and O&M specialists will inform the design and optimisation of technologies. A mobile phone app that streamlines VROOM/OMO data collection and upload will be developed and piloted in Australia, then refined at the end of first-round data collection as the VROOM and OMO tools are revised. Accessible online VROOM/OMO training will be developed to facilitate the widespread, consistent use of the tools by O&M professionals internationally. Assistive devices that support independent travel with low vision or blindness will be developed in two PhD projects, using the VROOM and OMO tools to evaluate prototypes.

The validation study is an embedded, mixed methods design with a QUAL/quan priority,[20] which means that measurement data will be generated in the context of social inquiry in the participants' lived environments, not from standardised tasks and venues. The objectives, methods, facilities/ resources, and expected outcomes of the validation study are detailed in Table 1.

Table 1: VROOM/OMO Validation Study details – objectives, methods, facilities/resources and expected outcomes

Objectives	Methods	Facilities/resources	Expected outcomes
1. Feasibility Establish the feasibility of co-rating clients' skills using the VROOM/OOMO tools during ordinary O&M assessments.	Train O&M specialists in Australia to use the VROOM/OMO tools. Seek post-pilot feedback though focus groups, email, phone. Revise VROOM and OMO tools in collaboration with client consultants.	O&M industry partnerships Client reference group Data collection app Evaluation questions[a.]	Guidelines which streamline the use of VROOM and OMO tools in ordinary O&M assessments.
2. Scope of application Evaluate whether the VROOM and OMO tools can generate meaningful data about functional vision and mobility with people of any age or dis/abilities, travelling in diverse circumstances.	Generate at least 50 assessments for each 10-point group within the 50-point scoring range in VROOM and OMO. Recruit additional participants as needed to achieve statistical power. Evaluate cultural relevance of VROOM and OMO tools in Malaysia.	Additional participants will be recruited through corporate sponsors (e.g., banks) which volunteer staff for community service, disability services, and aged care facilities.	Parameters for use of VROOM and OMO tools indicating - Applications - Limitations - Modifications for selected contexts Identify functional constructs that warrant development of separate measures.
3. Reliability Investigate whether stakeholders are interpreting the measures consistently.	With each industry partner, a sample of assessments representing different client cohorts, will be observed by a second professional or selected stakeholder who notes alternative interpretations of the rating scales, for subsequent discussion and qualitative analysis.	Where appropriate, video data from a sample of assessments representing different client cohorts will be generated for inter-rater review.	Guidelines for managing challenging relationships and contention when co-rating the VROOM and OMO tools, to be built into online VROOM/OMO training.
4. Content validity Evaluate the content validity, sufficiency, and redundancy of the VROOM and OMO subscales with diverse O&M clients.	Use qualitative data to: - Develop interpretation tables for VROOM and OMO scores - Evaluate the relevance of VROOM and OMO tools to different cohorts - Identify relevant constructs that haven't yet been measured.	Evaluation questions[b.]	VROOM and OMO tools provide a common language for tacit knowledge about low vision and mobility, that can be shared between O&M clients, family, friends, professionals and community members.

Objectives	Methods	Facilities/resources	Expected outcomes
5. Construct validity Evaluate whether the VROOM and OMO tools measure unidimensional phenomena.	Analyse the VROOM/OMO data to review the relevance and weighting of constructs through: - Qualitative coding - Text mining - ANOVA - Rasch analysis - Mixed analyses Check findings/queries with experts.	Expert consultants: - Client reference group - Industry partners - O&M Association of Australasia	O&M professionals equipped to generate meaningful, comparable measures of client capabilities from ordinary professional practice that can be used to manage referrals, design programs, and evaluate outcomes.
6. Criterion validity* Evaluate the concurrent validity of the VROOM and OMO tools.	Compare VROOM and OMO scores with their embedded qualitative data. Compare VROOM scores with clinical visual acuity in the better eye (n=65). Compare OMO scores with CET[c] scores (n=85).	Selected industry partners to generate CET scores in addition to VROOM/OMO data during functional assessments. Source clients' clinical visual acuities measured within 1 year of VROOM assessment from agency files (where available).	Identify areas of similarity, difference and overlap between clinical and functional measures of vision, orientation and mobility that might influence vision-related policies, such as eligibility for driving, pensions, assistive equipment, or support services.
7. Predictive validity* Evaluate whether VROOM and OMO scores can predict benefits gained from particular vision- or mobility-related interventions.	Measure VROOM and OMO scores before and after selected interventions (e.g. long cane training, dog guide training, electronic travel aids). Identify patterns in referral status and program outcomes for selected interventions.	Industry partners to identify interventions of particular interest. Combine data from different industry partners to create intervention cohorts of >50 participants where possible.	Develop guidelines for referral to selected services or interventions that are informed by VROOM and OMO data.

a. Feasibility Evaluation Questions: What did you gain from using the VROOM and OMO tools? What was frustrating or unhelpful about the process? How could the tools/process be improved? Who else could benefit from these measures?
b. Content Validity questions: What is important to you about your functional vision and mobility? Is anything important missing from the VROOM/OMO tools? Do the tools measure anything that's not important to you?
c. CET = Client Evaluation Tool[5]
* Objectives 6 and 7 will be addressed after the initial cross-sectional data collection is completed.

The first five objectives (establishing the feasibility, scope of application, reliability, content and construct validity of the tools) will be addressed during the first round of data collection, expected to take one year.

Data collection to address objectives 6 and 7 (establishing concurrent and predictive validity) will take longer for several reasons. Using multiple assessment tools in addition to the VROOM and OMO tools to establish their concurrent validity will extend assessment times and O&M specialists will need to fit this in as their workloads allow. Some O&M programs can last twelve months or more, so it can take a long time to complete data collection pre-post intervention. Then the heterogeneous nature of O&M practice means it can take a long time to accrue data about a selected intervention.

The research team

The research team includes an O&M specialist, a psychologist, statisticians, and experts in human-computer interaction, with team members located in Melbourne, Australia and in Sarawak, Malaysia.

Participants and eligibility

Vision and mobility are generic human functions so the VROOM and OMO tools are designed to encompass the skills of anyone, of any age or abilities, in any location. The scope of application of the VROOM and OMO tools will be tested by O&M specialists in this study (table 1, objective 2) through purposive heterogeneous sampling to include children (minimum n=50 aged <20), adults (minimum n=50 aged 21-59) and seniors (minimum n=50 aged 60+) with a wide range of comorbidities who are living and travelling in varied locations. There are no exclusion criteria for people being assessed, except their unwillingness to participate.

Sampling frame

The Australian O&M industry, which employs qualified O&M specialists, will provide the main sampling frame for this study. O&M specialists, including dog guide instructors, are uniquely skilled in assessing the functional vision and O&M skills of diverse clients. Ultimately, they will determine whether the VROOM and OMO tools are feasible for routine use and enhance ordinary O&M practice (table 1, objective 1).

Malaysian agencies providing services for people with low vision or blindness provide a second sampling frame to test the international relevance of the VROOM and OMO tools.

The inclusive design of the VROOM and OMO tools means that O&M clients and non-clients can be compared using the same scales and these assessment tools have potential application beyond the O&M profession. Community-based rehabilitation (CBR) fieldworkers (employed in developing countries) and occupational therapists also provide travel training to clients, but are not necessarily skilled in assessing functional vision for mobility. Occupational therapists and CBR fieldworkers employed by agencies in this study will be invited to participate in VROOM/OMO training sessions, trial the tools in collaboration with O&M specialists, and provide feedback to the research team. However, their findings will be analysed separately from the data generated by O&M specialists.

Sampling strategy and sample size

The validation study will use quota sampling to assess a minimum of 50 participants[29] in each of the ten point categories in both the VROOM and OMO scales (Table 2). Many clients will score differently on the two measures, and we estimate that up to 400 O&M assessments will be needed to fill these quotas by the end of first-round data collection.

Table 2: Quota of participant assessments needed in each category of the VROOM and OMO scales to make statistical comparisons.

VROOM integers	0 blind	1-10	11-20	21-30	31-40	41-50	TOTAL
Quota	50	50	50	50	50	50	**300**
OMO integers	-	1-10	11-20	21-30	31-40	41-50	
Quota	-	50	50	50	50	50	**250**

O&M specialists will select who to assess, beginning with convenience sampling as their workloads allow, then moving to purposive sampling to fill the quotas. We anticipate needing to recruit an additional convenience sample of adults with near-full vision and a purposive sample of people with profound mobility limitations (from aged care facilities or disability services), to supplement participant numbers in the VROOM 41-50 and the OMO 1-10 categories, because people with excellent vision and people who will always travel with a carer seldom refer for O&M services in Australia.

Recruitment

We identified fifteen agencies in Australia that provide O&M services, including five paediatric O&M services. These agencies employ around 224 O&M specialists, including 55

dog guide instructors. The number of O&M clients across Australia is unclear but Guide Dogs Victoria alone worked with 1380 clients in a 12 month period, delivering 2390 programs.[30] However, there are several reasons why it is not feasible to validate the VROOM and OMO measures through one agency within the time frame of the study.

The agencies are perpetually under-resourced and can have long waiting lists.[2] The roll-out of the National Disability Insurance Scheme (www.ndis.gov.au) is changing referral pathways, service profiles and reporting procedures in O&M agencies, requiring substantial new learning for staff. Then the VROOM/OMO study design calls for maximum diversity to test whether the VROOM and OMO tools can be used with anyone anywhere (table 1, objective 1). Diverse participation of agencies, O&M specialists and clients will share the work of data collection and maximise collaboration and critique of the VROOM and OMO tools. The number of VROOM/OMO assessments undertaken by each agency will depend on the agency's size, service profile, referral rates and likely client characteristics; competing research priorities; the number of O&M specialists employed, their availability, workloads and interest; and the informed consent of clients.

Through industry contacts, we identified seven organisations in Malaysia providing services to people with low vision or blindness. Several of these agencies offer community based rehabilitation (CBR) services, but the availability and extent of O&M services is unclear, and there is only one guide dog in the country (https://youtu.be/lqZBp8TsGj). Contact will be established with Malaysian agencies prior to a field trip in early 2018 to explore understandings of low vision and attitudes to disability and independent travel in Malaysia, then evaluate the relevance of the VROOM and OMO tools for use by Malaysian CBR fieldworkers and O&M specialists.

Collaboration with O&M specialists and clients will occur throughout the project. O&M specialist are available through industry partnerships and through the professional body (O&M Association of Australasia). An O&M client reference group (n=10) has been recruited through industry contacts, to critique the VROOM and OMO tools and associated technologies during the project.

Data collection

Ordinary O&M assessment, comprising interview and observed travel in the client's lived environments, provides the context for implementing the VROOM and OMO tools. O&M assessment is tailored to the individual client, because each client's unique life-space and priorities affect their mobility choices and how they deploy their vision during travel. During

their initial VROOM/OMO training, O&M specialists will be encouraged to integrate the tools into their existing assessment practices in whatever way works best for the client. This means that co-rating decisions might be discussed through the initial interview, during observed travel, or in a focused conversation at the end of the assessment.

O&M specialists will be encouraged to use the VROOM and OMO tools at any time during their contact with clients in a year-long phase of data collection – at initial assessment, mid-training or upon completion of an O&M program. This process will enable assessors and clients to gain confidence using the VROOM and OMO tools, test their application in a wide range of circumstances, and evaluate their feasibility for routine use (table 1, objectives 1 and 2).

We will use these data to generate interpretation tables that describe the functional implications for each ten-point category in the VROOM and OMO tools. We will profile Australian O&M cohorts, describing relationships between their functional vision and mobility, and their vision condition/s, life circumstances and mobility aid choices. Feedback from clients and assessors after this period will also indicate the most effective ways to implement the tools and inform guidelines for long term data collection.

Examining the cultural relevance of the VROOM and OMO tools in Malaysia is part of establishing the generalisability of these tools for international use.

The second phase of data collection is longitudinal, measuring VROOM and OMO scores pre-post O&M training that might include a long cane, dog guide or Miniguide, wheeled mobility (e.g., powerchair, scooter, bicycle), public transport, navigational devices (e.g., GPS apps, Trekker Breeze), visual efficiency training and orientation to new places, in individual or group programs. The VROOM and OMO tools will be used to evaluate the functional outcomes of assistive technologies developed for O&M clients in this study (piloting with n=7).

After interpretation tables are developed, the VROOM and OMO tools will be available to research groups internationally as outcome measures for vision- or mobility-related interventions. These intervention-specific cohort studies depend on continuing relationships with industry partners, and securing ongoing funding.

Primary measures: VROOM and OMO tools

The ordinal scales in the VROOM and OMO tools that aggregate to a score out of 50, and the associated comments that support these rating decisions, provide the primary data about functional vision and mobility in this study (supplementary information, appendix 1).

Secondary measures

Socio-demographic questions built into the VROOM/OMO assessment provide additional information about clients and their travel contexts (supplementary information, appendix 2).

O&M Environmental Complexity Scale

O&M specialists will use the six-level O&M Environmental Complexity Scale to identify the most challenging settings observed during assessment, assuming the client can manage all environments below this level.[31] The first two levels are uninhabited places, either (1) clear and safe like an empty corridor, or (2) cluttered with obstacles and changes underfoot; then pedestrian-paced environments can be (3) relatively clear like a residential footpath or (4) crowded like a busy market or playground; and traffic-paced environments can involve (5) infrastructure that controls crossing decisions, such a traffic lights and islands, or (6) uncontrolled priority roads where the onus is on the traveller to make a safe crossing decision.

Vision

When a client's visual acuities (and fields) are available on file, measured within a year of the VROOM assessment, these measures will be compared with VROOM scores to explore equivalence between clinical and functional vision measures. However, clinical vision testing with every client assessment is not part of this protocol.

Client Evaluation Tool (CET) [5]

The CET measures a client's O&M skills and confidence during functional O&M assessment from the separate perspectives of client and O&M specialist. A sample of participants (n=85) will be assessed using both the OMO tool and the CET to establish concurrent validity.

O&M technology surveys

Two online surveys will investigate the technology that O&M clients (supplementary information, appendix 3) and O&M professionals (supplementary information, appendix 4) already use, as well as identifying needs and ideas for optimising technology to support travel, O&M professional practice and research.

Data monitoring and management

Time-frames and frequency of follow up

The first round of data collection to profile Australian O&M clientele (n=400) will be completed in a one year period (mid 2017 to mid 2018). Then agencies will be invited to continue data collection pre-post training according to their own follow-up schedules. The timing and frequency of follow-ups will depend on the intervention/s received and the service profile of the Agency. For example, a client who has trained with a dog guide might receive follow up at one, three, six and twelve months post training, whereas a Miniguide client might be assessed immediately before and after training, then twelve months later to gauge the long-term impact of the device.

Managing bias and subjectivities

O&M agencies in Australia have asserted the need for outcome measures and they affirm the VROOM/OMO project, but they are perpetually under-resourced, vie for government and charity funding, and their ability to collect data is subject to competing priorities. The O&M specialist negotiating industry partnerships will encourage personnel to implement the VROOM and OMO tools according to their own resources and service profiles. This means that O&M clientele across Australia will not be equally represented according to their agency affiliations or geographical location. Nevertheless, the combination of purposive and quota sampling methods will ensure that the VROOM/OMO data-set represents the full range of functional vision and O&M abilities seen in O&M professional practice.

Long term, larger agencies will be encouraged to target their VROOM/OMO outcome assessments in key services that might render data from 50 or more clients. At the same time, the research team will draw together isolated assessment data from different agencies into groups that share like characteristics so that wherever possible, statistical comparisons can be made in addition to mixed methods analyses.

The VROOM and OMO tools are designed to represent what O&M specialists discover about the clients' capabilities and choices in the clients' environments, not to project what should happen. Thus, O&M specialists will be encouraged to follow the client's cues about what is meaningful to assess, just as they ordinarily do during functional O&M assessment.

O&M specialists already navigate differences of opinion during O&M sessions, and power shifts dynamically between the client's priorities, professional opinions, and the concerns of other stakeholders. An impasse while co-rating might indicate that more information or further functional assessment is needed before VROOM/OMO measurement decisions can be made.

Data analyses

In addition to comparing each ten-point group in the VROOM and OMO scales, O&M assessment data will be compared on the basis of age, vision condition/s, comorbidities, occupation and mobility aid use.

Qualitative data will be coded and categorised with the support of NVIVO software, Excel spreadsheets and mind-mapping software.

Confirmatory factor analysis and Rasch modelling will be used to refine the OMO and VROOM scales using reflective models. In Part B of the OMO scale a formative model is required due to the range of elements that constitute mobility-related wellbeing. Structural equation modelling will be used to predict travel-related wellbeing from these items' responses with confirmation from sociodemographic and CET data.

Cluster analysis will be used to identify groups of clients exhibiting similar O&M patterns. Chi-Squared tests will be used to compare these clusters with other client groupings defined in terms of vision, employment status and other demographics.

Between Groups ANOVA will be undertaken to compare the skills of different O&M client groups, and with non-client participants if appropriate. An invariance test of the measurement models derived for Australia and Malaysia will determine whether these measures are likely to be transferable between cultures and languages.

Longitudinally, repeated measures analyses will be performed with the OMO and VROOM outcome data collected pre-post intervention, to evaluate the effectiveness of these interventions.

In embedded mixed data analyses, qualitative findings will be used to review the personal relevance of measures and identify any salient aspects of functional vision or O&M that have not been measured; to build interpretation tables for the VROOM and OMO scales; and to filter, interpret, and warrant the generalisability of statistically significant results.

Data quality assurance

Co-rated data are different to independently rated data, requiring alternative approaches to data management than are typically used in the development of psychometrics. Validation of the VROOM and OMO tools does not depend entirely on statistical power. Rather, statistical results must be integrated with qualitative data in mixed analyses to generate robust findings.[32] The QUAL/quan priority during data collection ensures that co-rated measurement data represent what matters to participants. Practices that support the trustworthiness of qualitative data are built into the assessment and co-rating process, including collaboration

between the researcher and the researched, triangulation of multiple observations and opinions, member-checking, and reflexivity.[33]

During assessment, clients' opinions are evident both in their words and actions, and relevant stakeholders can speak for clients whose insight, voice or actions might be limited. During their VROOM and OMO training, O&M specialists will be encouraged to justify their professional reasoning during assessments, and minimise the influence of their own biases during co-rating conversations.

ETHICS AND DISSEMINATION

Ethical approval has been granted by the Human Research Ethics Committee at Swinburne University (SHR Project 2016/316). Informed consent will be obtained from all participants, and express written permission sought before any identifiable data (e.g., names of agencies or people, photos, video) are used in conversations, presentations, or publications. However, O&M assessment happens in public places, so it is impossible to guarantee anonymity in this project.

Due to industry sensitivities, the research team will not publish data from this study that compares agencies; rather VROOM and OMO data across agencies will be reported along with cohort profiles defined by these data.

VROOM and OMO assessments will add a little time, but no additional risk to ordinary O&M assessments. O&M agencies already have safeguards in place (e.g., health action plans, procedures and insurance policies) to manage risk and any incidents that might arise during O&M assessments.

Dissemination of results will be via individual agency reports, journal articles and conference presentations.

Acknowledgements

Dean Johnson and Mel Stevens have been valued collaborators in the development of O&M theory, the VROOM and OMO tools and the technology surveys.

Funding

This project is supported by Swinburne University of Technology through the Melbourne-Sarawak Research Collaboration Scheme - Digital Health Project (October 2016-September 2018).

Competing interests

All authors have completed the ICMJE uniform disclosure form at http://www.icmje.org/coi_disclosure.pdf Dr. Deverell reports personal fees from Bionic Vision Australia (2014) and Guide Dogs Victoria outside the submitted work, and is an executive member of the Orientation and Mobility Association of Australasia. The remaining co-authors declare: no support from any organisation for the submitted work, no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, and no other relationships or activities that could appear to have influenced the submitted work.

Exclusive Licence

Authors' contributions

LD conceived the VROOM and OMO tools, then collaborated with the research team (co-authors) to draft the research protocol.

Transparency

The lead author affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; no important aspects of the study have been omitted.

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Figure captions

Figure 1: O&M client uses GPS and public transport apps on her mobile phone to support travel with her guide dog. Photo by Lil Deverell, used with client's permission.

Figure 2: Workflow between different parts of the study. Dashed-line boxes indicate technology developments

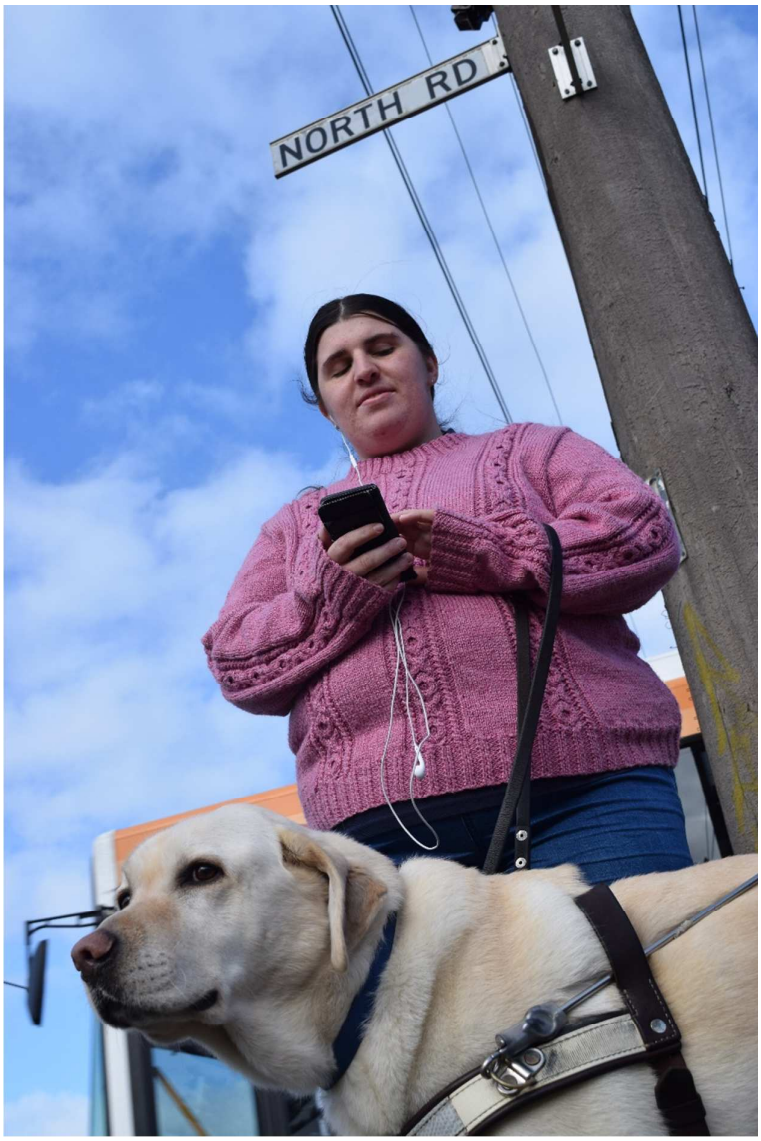

Figure 1: An O&M client uses GPS and public transport apps on her mobile phone to support travel with her guide dog. Photo by Lil Deverell, used with client's permission.

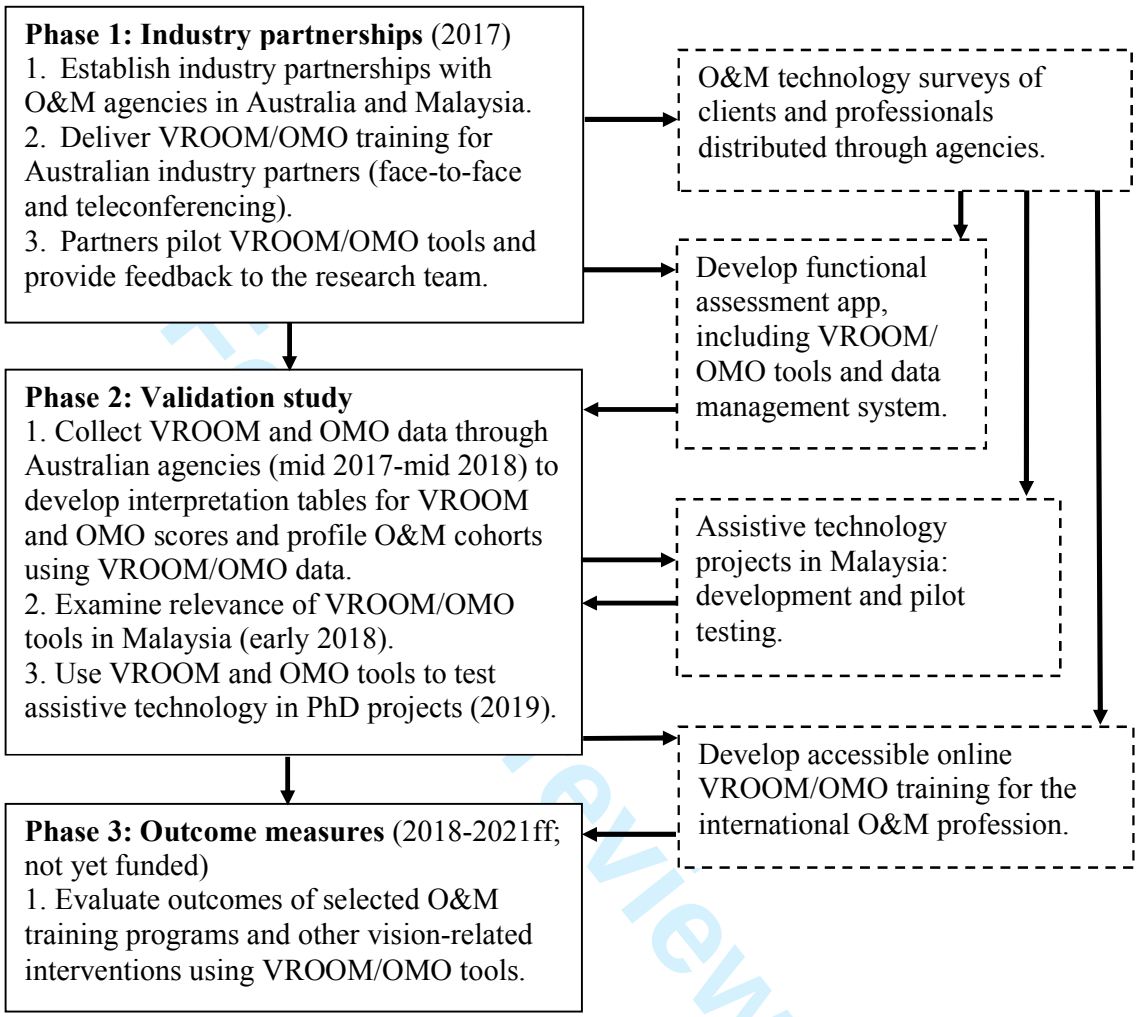

Figure 1: Workflow between different parts of the study. Solid line boxes indicate VROOM/OMO validation study. Dashed-line boxes indicate technology developments.

Supplementary Information

Optimising technology to measure functional vision, mobility, and service outcomes for people with low vision or blindness: Protocol for a prospective cohort study in Australia and Malaysia

Appendix 1: The VROOM/OMO tools

The VROOM (table 1) and OMO (table 2) tools are intended for use by an orientation and mobility (O&M) specialist or dog guide instructor who is assessing a client's functional vision and mobility status during travel in the community. Both assessment tools are co-rated by the assessor, the client, and any other relevant stakeholders present (e.g. family members, professionals).

The tools use the same measurement template: Part A measures elements of observed travel (out of 30), and Part B measures elements of wellbeing (out of 20). Subscales are aggregated to a score out of 50 on the spot so that scores can be discussed with the client.

When to assess VROOM and OMO

The VROOM and OMO tools can be scored multiple times in different situations, facilitating functional comparisons:

- At Referral. Benchmark the client's functional skills, explore relationships between vision, mobility, and wellbeing, identify service options, and define program goals.
- To measure fluctuations. If the client's skills are known to vary in different conditions, assess in daytime or in best conditions and again at whatever time the client's skills are worst (e.g., light: compare day/night travel; fatigue: compare morning/late afternoon travel).
- To measure program outcomes. Assess before and after training/intervention in the same conditions (e.g., without, then with a new mobility aid).
- To measure change over time. Assess at regular intervals over time to measure functional deterioration (e.g., progressive vision or medical conditions) or functional improvement (e.g. consolidating new functional vision or mobility skills).

Instructions for assessors

1. During ordinary O&M assessment, interview the client about functional vision and mobility, then go for a walk together. Start the functional assessment in a familiar place (e.g., client's home, school) and observe the client engaged in at least three travel-related tasks, then move to more dynamic places relevant to the client and observe at least three more travel tasks.

2. Discuss patterns and variations in behaviour with the client as you score each VROOM and OMO subscale together in any order. The co-rating conversation can be woven throughout your ordinary assessment, or happen at the end. Work out your own style.
3. The rating process is shared, but the weight of opinion can shift: the assessor might initiate ratings in Part A Observed Travel after seeing the client in action; the client's opinion might weigh more in Part B Wellbeing, which considers action in the previous month.
4. Differences of opinion might be due to lack of information or lack of insight. You might need to observe the client in more situations and/or involve other stakeholders in co-rating.
5. When there is indecision between two levels on a sub-scale, always choose the lower rating (before and after intervention). This captures the client's worst performance and gives room to improve.
6. Ratings need to be justified, so where possible, record brief comments from the client, the assessor, and other stakeholders near the relevant ratings.
7. Once you have scored every cell, aggregate the total VROOM and OMO scores, then discuss implications with the client.

O&M Environmental Complexity Scale (ECS)[1]

The VROOM and OMO tools use the ECS to compare different travel environments (figure 1). The six levels of scale assume that travel challenges are cumulative, so the assessor only needs to note the highest level of complexity encountered during assessment.

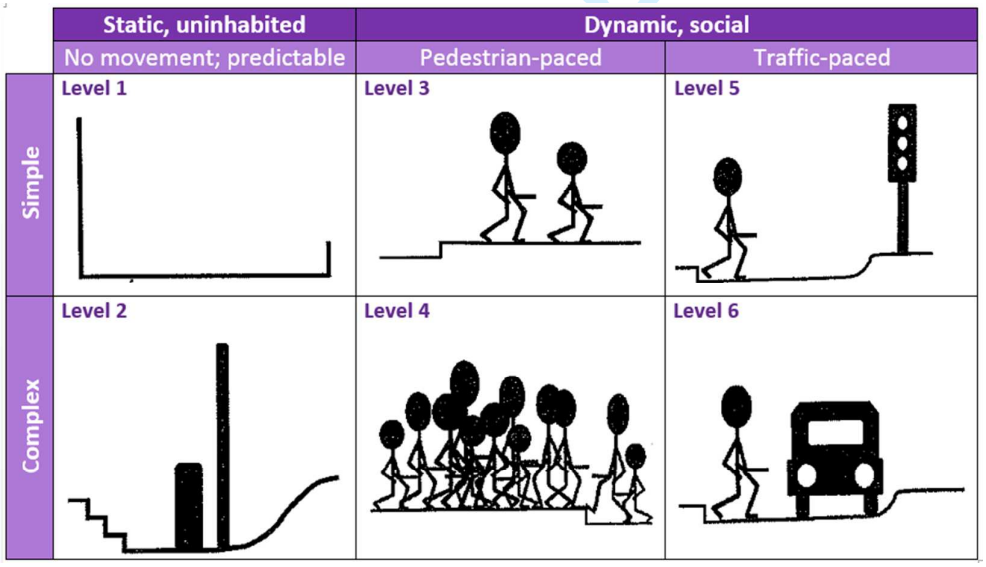

Figure 1: O&M environmental complexity scale

[1] Deverell L. O&M environmental complexity scale. *International Journal of Orientation & Mobility* 2011;4(1):64-77.

Level 1: Static, uninhabited places with level groundplane, no obstacles e.g., empty corridor, gymnasium or sports ground

Level 2: Static, uninhabited places with varying groundplane and/or obstacles e.g., steps, ramps, loose surfaces, furniture, poles

Level 3: Pedestrian-paced places (no faster than jogging) with a clear, continuous path of travel e.g., quiet residential footpath, workplace, or school corridors during class-time

Level 4: Pedestrian-paced places where the pathway is repeatedly obstructed and wayfinding is tiring e.g., market, busy car park

Level 5: Traffic-paced places where infrastructure supports crossing decisions e.g. traffic lights, islands, chicanes, crossing guards, zebras

Level 6: Traffic-paced places where the traveller must judge when it is safe to cross the road, e.g., mid-block priority roads, or places where traffic ignores the road rules

Abbreviations in the VROOM and OMO tools

ECS: O&M Environmental Complexity Scale

Aids: SG=sighted guide; dog=dog guide; LC=long cane; SC=support cane; ID=identification cane; WC=wheelchair; Sc=motorised mobility scooter; MG=miniguide; GPS=global positioning system (e.g. Trekker Breeze, phone app); Ph=phone; Other=might include low vision aids.

Table 1: VROOM tool

VROOM Part A: Route Travel Vision-Related Outcomes in O&M Date: Starting time: Client: Visual acuities: Assessor:		**Stable, familiar conditions; no hurry** e.g., home, local block Venues: _____ ECS: 1 2 3 4 5 6 Light: Day Dim Night Aids: NoAid SG Dog LC SC ID WC Sc MG GPS Ph Other:	**Dynamic conditions; timeliness needed** e.g., road crossings, shops, crowds Venues: _____ ECS: 1 2 3 4 5 6 Light: Day Dim Night Aids: NoAid SG Dog LC SC ID WC Sc MG GPS Ph Other:
SCORING **3 = Vision is primary** No touch or aid is needed **2 = Vision needs back-up** Rely on vision; use non-visual strategies to confirm **1 = Vision is secondary** Rely on non-visual strategies Vision sometimes useful **0 = Vision is useless** Use non-visual strategies	**Getting your bearings** Where am I? Which way do I go?	/3	/3
	Checking groundplane What's underfoot? Is it safe to step out?	/3	/3
	Wayfinding Is this the path? Is anything in the way?	/3	/3
	Recognising moving parts Who is around? Do I seek or avoid them?	/3	/3
	Finding things What am I looking for? How do I find it?	/3	/3

VROOM Part B: Wellbeing	Score together from observations and discussion about activities **within the past month**	Comments & Score
Reading	0 I have no useful vision for reading text 1 If I'm close enough, I can identify large signs (e.g., stop sign) by text, size, shape, colour 2 I can sometimes read vehicle number plates & shop signs 3 I can sometimes identify different foods by looking at text and packaging (e.g., milk) 4 I can read regular print (i.e., letters, N12)	/4
Visual certainty	0 My vision is never useful when I'm moving around; too little, too late 1 I can't rely on my vision when I'm doing things 2 My vision causes hesitation and frustration; it undermines confidence when I'm moving 3 My vision has its limitations, but I know how to work with it 4 My vision is reliable for travel; I don't really have to think about it much	/4
Mobility aids (beyond home)	0 I use non-visual skills (cane/dog/guide) beyond home – my vision is useless 1 I rely on my cane/dog/guide – vision provides some extra information 2 I need non-visual skills sometimes (e.g., night travel, fluctuating vision) 3 I can go without, but a mobility aid gives me confidence, relieves fatigue, expands options 4 My vision is good enough for travel – I don't need a mobility aid	/4
People	0 I can't see people's shapes or movement; or see if a conversation partner moves away 1 I can see a body moving past, but I can't tell who it is; I sometimes collide 2 I can recognise people by their shape, colours, size or gait; I can usually avoid collisions 3 I can see faces, but not details; I do miss some social cues 4 I can recognise faces, read facial expressions and social cues	/4
Pleasure	0 My vision is un-motivating; it rarely or never prompts a closer look 1 My vision is limited or frustrating; often more trouble than it is worth 2 My vision is useful for some things, but not for others 3 I can see interesting things; it is usually worth the time it takes to look 4 I can see beautiful or engaging things that bring calm, contentment, excitement, even bliss	/4
RECOMMENDATIONS Part A: _____/30 Part B: _____/20 **Total Score: _____/50**		

Table 2: OMO tool

OMO Part A: Route Travel O&M Outcomes Date: Starting time: Client: Visual acuities: Assessor:		**Stable, familiar conditions; no hurry** e.g., home, local block Venues: _____ ECS: 1 2 3 4 5 6 Light: Day Dim Night Aids: NoAid SG Dog LC SC ID WC Sc MG GPS Ph Other:	**Dynamic conditions; timeliness needed** e.g., road crossings, shops, crowds Venues: _____ ECS: 1 2 3 4 5 6 Light: Day Dim Night Aids: NoAid SG Dog LC SC ID WC Sc MG GPS Ph Other:
SCORING **3 = Elite skills** Graceful, fluent, safe & effective in most places **2 = Competent skills** Safe & effective, but not always graceful & fluent **1 = Basic skills** Limited effective skills; needing consolidation **0 = Beginner skills** Unsafe/inadequate for the context	**Getting your bearings** Where am I? Which way do I go?	/3	/3
	Checking groundplane What's underfoot? Is it safe to step out?	/3	/3
	Wayfinding Is this the path? Is anything in the way?	/3	/3
	Recognising moving parts Who is around? Do I seek or avoid them?	/3	/3
	Finding things What am I looking for? How do I find it?	/3	/3

OMO Part B Wellbeing	Score according to discussion about skills, attitudes and activities **within the past month**	Comments & Score
Activities	0 I find activities overwhelming 1 My mix of activities is not quite right; I don't know how to fix it, or I'm not yet ready for change 2 I like some of my activities, but I'm ready for new directions 3 I'm satisfied with my current mix of activities 4 I find my mix of activities challenging and enriching	/4
Connections	0 I feel isolated and lonely much of the time; I find it hard to connect with others 1 The people I know all do things for me; I feel quite dependent on others; I feel I have little to offer 2 I know where to find people; I'm linked in with some people or groups 3 I meet with people regularly; I feel welcomed and included 4 I have mutual friendships; we're there for each other; I actively contribute	/4
Life-space	0 I'm house-bound; I rarely go beyond the front gate 1 I do routine travel, only in well-known local areas (e.g., home block, local shops) 2 I explore in my local community; I like to try different routes 3 I travel to known places beyond the local community (e.g. commuting for work, visiting friends) 4 I like to explore beyond the local community, discovering new places	/4
Orientation	0 Even at home, I get disorientated; I have trouble understanding shapes, angles and distances 1 I can find the way at home by myself; beyond home, I need a companion or I get lost 2 I travel independently beyond home; if I get anxious or lost, I rely on help from other people 3 I travel independently beyond home; if I get anxious or lost, I can usually work it out by myself 4 I can go anywhere independently; I use mental mapping and I'm rarely disorientated for long	/4
Self-determination	0 My travel is managed by other people; I don't make the decisions 1 I need travel restrictions – I'm not always aware of what's safe and what is not 2 I'm aware of my own limitations, but I limit my travel rather than learning new skills 3 I'm aware of my own limitations; I plan ahead, source information and get help with my travel skills 4 I'm in charge; I evaluate my travel and learn from experience as I go; I develop my own skills	/4
RECOMMENDATIONS Part A: _____/30 Part B: _____/20 **Total Score: _____/50**		

Appendix 2: Socio-demographic and health questions

1. Age
2. Gender
3. Highest level of education (no formal schooling, primary/secondary school, post-secondary certificate/diploma, bachelor's degree, post-graduate certificate/diploma/ masters/PhD).
4. Occupation (full-time paid work, part-time paid work, unpaid work – home & family duties, volunteer work – community, student).
5. Monthly income (mainly from own assets or earnings, social services/government/ NGO, family).
6. Is your income enough to meet your goals (sufficient, some compromises needed, insufficient)?
7. What are the main cultural issues/values that affect your goals and lifestyle choices (e.g., country of origin, ethnicity, religion)?
8. Language/s spoken at home
9. Vision condition/s
10. Onset of first vision condition/s (congenital: birth-first year, childhood: 1-18 years, adult >18 years), and pace of onset (gradual, abrupt).
11. Current visual status (full vision, low vision/no pension, low vision/pension, no light perception).
12. Clinical vision measures if available (visual acuity, visual fields).
13. Where do you live (city, country town/village, isolated property or farm)?
14. Who you live with (alone, with immediate family members, with friends, relatives or acquaintances, in supported accommodation/aged care facility/hostel)?
15. Do you have physical or mental health issues? If so, what?
16. In the past six months, considering wellbeing and medical appointments, how often have health issues affected you, (daily/most days, weekly, monthly, occasionally/rarely) and are they predictable or unpredictable?
17. Rate your overall physical fitness (very poor, poor, OK, good, very good).
18. In the past month, what places have you been travelling accompanied and solo?
    - Static, level, clear places (empty corridor, sports ground)
    - Static places with surface changes & obstacles (furnished room)
    - Quiet pedestrian-paced places (house, residential footpath)

- Busy, crowded, pedestrian-paced places (market, shops)
- Quiet or controlled road crossings (traffic lights, zebra crossing)
- Busy, uncontrolled road crossings (main road, mid-block)

19. Other than vision, what are your main barriers to travel (limited goals/motivation, disorganisation, family dynamics/demands, poor health/fatigue, finances, inaccessible physical environment, limited access to information, limited access to transport (public or private), safety concerns, get lost easily, self-conscious in public, other)?
20. Have you used any of the following to support your travel in the past month (private transport, public transport, taxi/Uber, sighted guide/travel companion, dog guide, long cane, id cane, support cane, Miniguide, braille, print, audio/voice-over, computer/ internet, GPS, mobile phone/platform, best apps)?

Appendix 3: Technology survey for O&M clients

Q1. Gender

- ☐ Male
- ☐ Female

Q2. Age

- ☐ Less than 10
- ☐ 10-19
- ☐ 20-29
- ☐ 30-39
- ☐ 40-49
- ☐ 50-59
- ☐ 60-69
- ☐ 70 +

Q3. How would you describe your sight?

- ☐ No light perception
- ☐ Low vision and legally blind (eligible for pension)
- ☐ Low vision, but not eligible for pension
- ☐ Full vision

Q4. How do you travel beyond home?

- ☐ Long cane
- ☐ Dog guide
- ☐ Sighted guide
- ☐ Taxis/Ubers
- ☐ Public transport
- ☐ Private car
- ☐ Wheelchair
- ☐ Scooter
- ☐ Bicycle
- ☐ Other. Please explain: _____

Q5. Do you use any of the following devices? (can choose more than one)

- ☐ Mobile phone/s. Make and model:
- ☐ Tablet. Make and model:
- ☐ Portable braille notetaker Make and model:
- ☐ Laptop computer. Make and model:
- ☐ Desktop computer. Make and model:
- ☐ Standalone GPS. Make and model:
- ☐ Standalone OCR (optical character recognition) device. Make and model:
- ☐ CCTV (closed circuit television). Make and model:
- ☐ Personal activity monitor (e.g, Fitbit, SmartWatch). Make and model:
- ☐ Handheld sonar (e.g., Miniguide). Make and model:
- ☐ Sonar built into another device (e.g., Ultracane) Make and model:
- ☐ Barcode Reader. Make and model:
- ☐ Other. Please describe:

Q6. What formats do you use to support your travel? (can choose more than one)

- ☐ Print on paper
- ☐ Screen magnifier (zoom)
- ☐ Screen reader (voice-over)
- ☐ Voice recorder
- ☐ Braille
- ☐ I plan and/or travel with someone else
- ☐ Other. Please explain

Q7. Which apps do use to plan or carry out travel?

- ☐ Please list: .
- ☐ I don't use apps.

Q8. What features do you particularly like in the apps you use?

- ☐ Please explain.
- ☐ I don't use apps.

Q9. Do you have access to technology training for travel purposes?

- ☐ Yes. Please describe: .
- ☐ I would like more training. Please describe:
- ☐ No

Q10. Do you have ideas about how technology could be developed or enhanced to support your travel?

- ☐ Yes. Please explain:
- ☐ No.

Q11. Are you happy to be contacted by a Swinburne researcher to discuss your technology ideas?

- ☐ Your name:
- ☐ Best phone number:
- ☐ Best email address:

Q12. How did you respond to this survey?

- ☐ Independently
- ☐ With some assistance

Appendix 4: Technology survey for O&M professionals

Q1. Gender

- ☐ Male
- ☐ Female

Q2. Age

- ☐ Less than 10
- ☐ 10-19
- ☐ 20-29
- ☐ 30-39
- ☐ 40-49
- ☐ 50-59
- ☐ 60-69
- ☐ 70 +

Q3. What is your vision like?

- ☐ Full vision
- ☐ Low vision, but not legally blind
- ☐ Low vision, and legally blind (< 6/60 acuity and/or <10° fields)
- ☐ No light perception

Q4. What is your role? (you might have more than one)

- ☐ O&M specialist
- ☐ Dog guide instructor
- ☐ CBR fieldworker
- ☐ Other. Please explain: _____

Q5. What clients do you work with? (you may choose more than one)

- ☐ Adults
- ☐ Children
- ☐ People with neurological limitations / acquired brain injury

- ☐ People with intellectual disability
- ☐ People with physical limitations (e.g., use a support cane, wheelchair, scooter)
- ☐ People with mental health problems
- ☐ People with multisensory limitations (e.g., deafblind)
- ☐ Other. Please explain:

Q6. What devices do you use to support your O&M client work? (you may choose more than one)

- ☐ Mobile phone/s. Make and model:
- ☐ Tablet. Make and model:
- ☐ Portable braille notetaker Make and model:
- ☐ Laptop computer. Make and model:
- ☐ Desktop computer. Make and model:
- ☐ Standalone GPS. Make and model:
- ☐ Standalone OCR (optical character recognition) device. Make and model:
- ☐ CCTV (closed circuit television). Make and model:
- ☐ Personal activity monitor (e.g, Fitbit, SmartWatch). Make and model:
- ☐ Handheld sonar (e.g., Miniguide). Make and model:
- ☐ Sonar built into another device (e.g., Ultracane) Make and model:
- ☐ Barcode Reader. Make and model:
- ☐ Other. Please describe:

Q7. What O&M assessment resources have you used with clients?

- ☐ Agency assessment forms
- ☐ Checklists or rating scales. Please list:
- ☐ Books or theoretical approaches. Please list:
- ☐ Electronic resources (e.g., devices, apps). Please list:
- ☐ Physical materials. Please list:
- ☐ Other. Please explain:

Q8. What features do you like in the apps you use?

- ☐ Please describe.
- ☐ Not applicable

Q9. Do you use any accessibility features with a mobile phone? (list as many as you like)

- ☐ No
- ☐ Zoom/large print
- ☐ Reverse contrast
- ☐ Voice-over
- ☐ Other. Please describe.

Q10. Do you have concerns about using a mobile phone app to collect O&M assessment information?

- ☐ No.
- ☐ Yes. Please explain:

Q11. Do you have ideas about how technology could be developed or enhanced to support O&M practice (for you or the client)?

- ☐ Yes. Please explain:
- ☐ No.

Q12. Are you happy to be contacted by a Swinburne researcher to discuss your technology ideas?

- ☐ Your name:
- ☐ Best phone number:
- ☐ Best email address:

STROBE Statement—checklist of items that should be included in reports of observational studies

Re: *Optimising technology to measure functional vision, mobility, and service outcomes for people with low vision or blindness: Protocol for a prospective cohort study in Australia and Malaysia*

Please note: the results and discussion sections are not cross-referenced to the main document because this is a protocol paper not a research report.

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract **(p1)**
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found **(p2)**
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported **(p3-7)**
Objectives	3	State specific objectives, including any prespecified hypotheses **(p7-8, table 2)**
Methods		
Study design	4	Present key elements of study design early in the paper **(p8, figure 2)**
Setting	5	Describe the setting, locations **(p8-9, p15, supplement),** and relevant dates including periods of recruitment **(figure 2)**, exposure, follow-up **(p16)**, and data collection **(figure 2)**
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up **(p14, 16)** *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls **(p12)** *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants **p11-13**
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed **(N/A)** *Case-control study*—For matched studies, give matching criteria and the number of controls per case **(N/A)**
Variables	7	Clearly define all outcomes **(p5)**, exposures, predictors **(p16)**, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group **(p14, 15, supplement)**
Bias	9	Describe any efforts to address potential sources of bias **(p 16)**
Study size	10	Explain how the study size was arrived at **(p12)**
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why **(p17)**
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding **(p17)**
		(*b*) Describe any methods used to examine subgroups and interactions **(p17)**
		(*c*) Explain how missing data were addressed **(N/A)**
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed **(N/A)**

		Case-control study—If applicable, explain how matching of cases and controls was addressed **(N/A)** *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy **(p17)**
		(*e*) Describe any sensitivity analyses **(to be determined post hoc)**
Results (N/A)		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
		(b) Indicate number of participants with missing data for each variable of interest
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time
		Case-control study—Report numbers in each exposure category, or summary measures of exposure
		Cross-sectional study—Report numbers of outcome events or summary measures
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
		(*b*) Report category boundaries when continuous variables were categorized
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion (N/A)		
Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based **(p18)**

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Optimising technology to measure functional vision, mobility, and service outcomes for people with low vision or blindness: Protocol for a prospective cohort study in Australia and Malaysia

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-018140.R1
Article Type:	Protocol
Date Submitted by the Author:	22-Sep-2017
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Primary Subject Heading:	Evidence based practice
Secondary Subject Heading:	Ophthalmology
Keywords:	functional vision assessment, orientation and mobility, OMO and VROOM tools, co-rated measures, embedded mixed methods, translational research

Optimising technology to measure functional vision, mobility, and service outcomes for people with low vision or blindness: Protocol for a prospective cohort study in Australia and Malaysia

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Word count: 5786 words, excluding title page, abstract, references, figures and tables.

ABSTRACT

Introduction: Orientation and mobility (O&M) specialists assess the functional vision and O&M skills of people with mobility problems, usually relating to low vision or blindness. There are numerous O&M assessment checklists, but no measures that reduce qualitative assessment data to a single comparable score, suitable for assessing any O&M client, of any age or ability, in any location. Functional measures are needed internationally to align O&M assessment practices, guide referrals, profile O&M clients, plan appropriate services, and evaluate outcomes from O&M programs (e.g., long cane training), assistive technology (e.g., hazard sensors) and medical interventions (e.g., retinal implants). This study aims to validate two new measures of functional vision (VROOM) and O&M (OMO) in the context of ordinary O&M assessments in Australia, with cultural comparisons in Malaysia, also developing phone apps and online training to streamline professional assessment practices.

Methods and analysis: This multiphase observational study will employ embedded mixed methods with a QUAL/quan priority: co-rating functional vision and O&M during social inquiry. Australian O&M agencies (n=15) provide the sampling frame. O&M specialists will use quota sampling to generate cross-sectional assessment data (n=400) before investigating selected cohorts in outcome studies. Cultural relevance of the VROOM and OMO tools will be investigated in Malaysia, where the tools will inform the design of assistive devices and evaluate prototypes. Exploratory and confirmatory factor analysis, Rasch modelling, cluster analysis and analysis of variance (ANOVA) will be undertaken along with descriptive analysis of measurement data. Qualitative findings will be used to interpret VROOM and OMO scores, filter statistically significant results, warrant their generalisability, and identify additional relevant constructs that could also be measured.

Ethics and dissemination: Ethical approval has been granted by the Human Research Ethics Committee at Swinburne University (SHR Project 2016/316). Dissemination of results will be via agency reports, journal articles and conference presentations.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This study addresses an international shortage of functional vision and O&M measures that facilitate comparisons of different people and assistive devices in infinitely diverse circumstances. No such versatile assessment tools have been available to date.

- The co-rated measurement tools employ a constructivist approach to knowledge that aligns with O&M assessment practice. This resolves previous problems with O&M data quality that arise from assuming objectivity is possible in functional inquiry.
- Each assessment tool aggregates ratings to a single comparable score on the spot so that results are immediately accessible to clients and O&M specialists to support person-centred practice, low vision education and professional decision making.
- The assessment tools generate words and number data from the same context so that the resulting performance measures are precise and their relevance is warranted by individual participants. However, there are no established guidelines in the literature to evaluate the quality of co-rated data, and these guidelines need to be developed.
- A limitation is that the study depends on recruiting sufficient industry partners to generate data with their clients during ordinary O&M assessments when the O&M industry is in a period of tumultuous change and there is a limited pool of O&M specialists in Australia to draw upon.

INTRODUCTION

Globally, there are 285 million people with low vision or blindness, including 20 million Asians with visual acuity less than 3/60.[1] In Australia and New Zealand, an estimated 605,300 people have visual acuity less than 6/12,[2 3] making them ineligible to drive.[4] Unfortunately, clinical vision measures (e.g., acuity, fields, contrast sensitivity) do not predict a person's everyday functional capability in the real world.[5] Clinical and functional phenomena are fundamentally different, therefore different measures are needed in translational research to evaluate clinical and functional outcomes.[6 7]

Clinical inquiry seeks to reduce confounding factors and measure single variables in controlled conditions, then statistically compare these variables post hoc. In contrast, functional inquiry is intrinsically complex; power shifts from the researcher to the participant who decides what matters in the real world, then integrates multiple variables with priorities changing in transit; these simultaneous changes and associated responses are easier to show than to tell. Six characteristics define functional inquiry: authenticity, embodiment, community, diversity, integration and learning.[8]

We propose that functional vision has three manifestations: vision for reading, near tasks and orientation and mobility (O&M), each with implications for assessment and measurement (figure 1). Reading and near tasks can be assessed in controlled settings because they involve

limited lower body movements and task materials are within easy reach. However, functional vision for O&M is irreducibly complex. O&M necessitates full body movement through changing environments that include unpredictable moving elements, while integrating multiple visual functions to achieve one or more purposes.

[insert figure 1]

Many clinical O&M studies have been designed to investigate individual elements of O&M in controlled conditions[9] – avoiding obstacles on a prescribed course[10], following a white line on a dark floor, and locating a contrasting door,[11]or a sign on a door.[12] Walking speed and obstacle tallies provide clean repeatable data in clinical trials, but their relevance as functional outcome measures of O&M training or vision-related interventions is based on surmise and has been inadequately justified in the literature.[13] Not surprisingly, these measures have failed to capture the more holistic, lifestyle benefits gained from O&M training[9] or vision-related interventions[14] that participants report anecdotally. O&M clients have indicated they care about travel fluency and minimising fatigue while achieving their purpose and avoiding falls.[15 16]

Clinical O&M trials are often conducted in an uninhabited environment, rating only Level 2 on the six level O&M Environmental Complexity Scale (Supplementary information, appendix 1).[17] They rarely investigate free-roaming mobility in pedestrian-paced environments (levels 3 and 4) or traffic environments (levels 5 and 6) that require social skills, knowledge of the road code and timely responses to unpredictable events.

In contrast, O&M specialists undertake person-centred practice in the community with non-drivers whose mobility problems are usually related to low vision or blindness.[18 19] They assess a client's functional vision and O&M skills qualitatively, then teach visual efficiency skills, mobility aid use (e.g., long cane, dog guide, Miniguide) and practical travel strategies to maximise the client's independence.

O&M clients are diverse, making it difficult to compare their functional status and prioritise needs. There are checklists and rating scales to support aspects of functional O&M including general skills and confidence,[20] children's skills,[21] body concepts,[22] and mobility challenges with tunnel vision.[23] The "CVI Range" is designed to measure cortical vision impairment in children.[24 25] But there are no measures for use in general O&M assessment that reduce qualitative assessment data to a single comparable score. Internationally, O&M professionals needs an efficient way to rate the functional vision and the O&M skills of any

client they encounter, to profile and compare different client groups, interpret their mobility choices, guide program design, and evaluate the outcomes of O&M training, assistive devices and interventions such as a bionic eye.[26 27]

The VROOM and OMO tools

During 2015, two new functional assessment tools were developed for use in ordinary O&M practice. The VROOM tool measures Vision-Related Outcomes in O&M (functional vision for mobility), and the OMO tool measures functional O&M Outcomes (Supplementary information, appendix 1).

The VROOM and OMO tools are designed to be used in the same assessment event, but they measure different phenomena, producing a separate score for functional vision and for functional O&M. These tools are built on the same measurement template. Each is a suite of behaviourally-anchored rating scales, with Part A scoring observed behaviours out of 30, and Part B scoring elements of self-reported wellbeing out of 20. Rather than measuring opinions separately, the VROOM and OMO tools are scored together during a co-rating conversation between the assessor, the client and any other relevant stakeholders. Conversation about the client's abilities leads to accord about how to score each construct, and disagreement can mean that more observation and detailed discussion is needed. When there is indecision between levels on a scale, the rule is to choose the lower rating. The sub-scores are then aggregated for each tool on the spot, resulting in a score out of 50 for vision, and 50 for mobility.

The VROOM and OMO tools were developed following bionic vision research (2011-2015),[16 28] where grounded theories about functional vision and mobility were derived from the lived experience of people with advanced retinitis pigmentosa (n=43).[8] To test proof of concept, the VROOM tool was retro-scored with a convenience sample (n=13), drawing on live observations of people selected from across the visual spectrum and video data from the bionic eye project. This process showed that the measurement template worked with a broad spectrum of people including drivers and people with light perception only, yet was precise enough to capture subtle functional improvements in vision. The three retinal implant recipients each showed a 12-16% (6-8 point) increase in their VROOM scores when their retinal implant device was switched on.[8]

The VROOM and OMO tools were then piloted during interviews with O&M clients who have a guide dog (n=51).[29] During their co-rating conversation, participants were invited to critique the constructs being assessed in the tools, and suggest improved wording of

performance indicators. The VROOM tool inadvertently captured a 60% (30 point) improvement in one man's functional vision from corneal transplant surgery in between his initial VROOM rating and a re-scoring conversation several months later.

Rating decisions in Part A are made after observing the client travelling in multiple settings, with attention to five universal travel functions: Getting your Bearings, Checking Groundplane, Wayfinding, Recognising Moving Parts and Finding Things. The rating scale for the OMO tool focuses on travel competence regardless of vision as: (3) elite, (2) competent, (1) basic or (0) beginner, regardless of visual status, whereas the VROOM tool rates sensory preferences as: (3) predominantly visual, (2) vision first confirmed by other senses, (1) other senses first, confirmed by vision (0) non-visual.

In Part B of the template, five relevant constructs, each with defined performance indicators, are co-rated while discussing wellbeing and lifestyle choices with the client. OMO-Part B explores Activities, Connections, Life-space, Orientation and Self-Determination (sense of agency), which are drawn from the Effective Mobility Framework,[15] whereas VROOM-Part B explores vision for Reading, Visual Certainty, Mobility Aid choices, People and Pleasure, which are drawn from new theory about visual purposes.[8]

Comments from the client, the assessor and other stakeholders are noted alongside these ratings, providing precise, embedded mixed data[30] about each client's functional abilities at the time of assessment.

Exploratory factor analysis of the pilot data suggested that the subscales in the VROOM tool are measuring the one construct (functional vision for mobility). However, O&M is a more complicated phenomenon involving the mechanics of travel, spatial cognition and psychosocial factors, as indicated in the Effective Mobility Framework.[15] OMO-Part A works well, scored after observing travel, but a larger data-set is needed to explore the sufficiency and relationships between the OMO-Part B constructs in accounting for O&M. In addition to grounded theory methodology,[31] Rasch analysis of a larger VROOM and OMO data-set generated from more diverse clients will be used to review the subscales, calibrate the weighting of constructs, and thereby convert the ordinal scales to interval measures.

The VROOM and OMO tools are not just created for use by researchers, but are intended to support and streamline professional O&M practice, so a priority is to balance their user-friendliness during client assessments, with their ability to generate precise, meaningful measurement data on the spot.[32]

The VROOM and OMO tools are designed to

- benchmark functional skills upon initial referral,

- measure the range of normal fluctuations (e.g., day/night vision, morning/evening travel)
- track deterioration of skills with aging or specific conditions
- compare skills pre-post O&M training (e.g., long cane)
- evaluate new assistive technologies (e.g., smart-cane, bionic eye)

Over time, this practice-based evidence has the potential to inform referral criteria for O&M services and vision-related interventions, warrant funding applications for client services and assistive devices, and shape social policies impacting eligibility criteria for pensions, urban planning for pathways, public transport and safety, and communication technologies that improve access to information.

The role and design of O&M technology

There are three ways that technology is related to this project: to support independent travel for O&M clients, to streamline O&M professional practices, and to support the measurement of O&M outcomes.

Since World War II, specialised electronic mobility aids have been developed for people with low vision or blindness, to increase their range of preview during travel, to avoid collisions and support fluent wayfinding; to gain and maintain orientation, and manage travel information.[33 34] Wearable, or implantable vision restoration devices include retinal prostheses,[11 28] computer mediated head-mounted displays,[35] and sensory substitution devices.[36] Autonomous robot guidance is also proposed as an alternative to a dog guide to support wayfinding.[37]

Each of these technologies is remarkable for its innovation and fit for purpose. However, each is suited to a narrow clientele and devices differ in their cultural acceptability. Specialist technology is costly to develop, some devices never make it past the prototype stage, and most that reach commercialisation tend to be superseded in a few years.[38] Since GPS apps (e.g., blindsquare.com) have become widely available and accessibility features such as voiceover, zoom and camera functions have become common inclusions, many O&M clients now prefer mainstream technologies such as a smartphone or tablet to support their travel (figure 2).[29] Mainstream devices are affordable and easy to upgrade, multi-purpose and synchronised so the traveller needs to carry less equipment. They reduce social barriers as people with full vision, low vision, and no vision enjoy the same technology.

[insert figure 2]

O&M specialists, some with low vision or blindness, also use smartphones and tablets to support their professional practice – to organise caseloads, access apps, maps, timetables, online directions and voice recording functions to plan, implement and review travel with clients. Video provides evidence of the client's O&M skills to show relevant stakeholders. FaceTime connects city-based professionals and rural or remote clients to deal with real-time travel challenges in between regional visits.[39] The internet makes diverse professional development opportunities available to isolated or time-poor practitioners.

Life-logging in O&M research has become easier with an increase in personal activity monitors (e.g., Fit-bit, Smart-watch, mobile phone apps), discreetly integrated into a wristwatch or mobile phone. However, accessibility differs between different platforms and devices, and improvements are needed to increase their user-friendliness for people with low vision or blindness. Egocentric vision can be captured with a video-camera (e.g., gopro.com) mounted on the head or body to record travel challenges, combined with eye tracker technology such as Tobii (www.tobii.com) or SMI (www.eyetracking-glasses.com) to measure mobile gaze direction, then state-of-the-art computer vision techniques can generate precise information about visual behaviour during travel.[40] These data help to inform the iterative development of new vision-related technologies, but in functional research, it is important to consider appearances. In some communities, snatch-theft is a risk when costly equipment is on display, and devices that make the traveller look unusual can change the way that passers-by interact so that something other than ordinary functional performance is measured.

In human factors engineering, there is growing awareness of the need for user-centred design when developing technologies. Ethnographic analysis is a method that draws observations from the practical use of devices in the context of their intended use, accounting for both practical and cultural influences on usage and acceptance.[41] Then, co-design is a participatory method, which places the user needs, desires and opinions at the centre of the design process.[42] Consumers, researchers and designers all play a role in generating ideas, developing concepts and iteratively testing and modifying prototypes.

Aims of this study

The aims of this study are to:

1. Validate the VROOM and OMO tools during ordinary O&M assessment, to profile O&M clients and compare their functional abilities through:

a. quota sampling in Australia, and
b. cultural investigations in Malaysia.

2. Optimise technology to measure functional vision, mobility, and service outcomes of people with low vision or blindness, by
   a. analysing the technology use and needs of O&M agencies, O&M specialists and O&M clients in Australia and Malaysia, then
   b. developing assistive technology prototypes to support clients' O&M through student projects
   c. developing phone apps and online training that enable O&M specialists and O&M clients to generate and manage practice-based evidence from O&M assessments.

METHODOLOGY and METHODS

Study design

This study will employ a multi-phase, mixed methods design (figure 3), beginning with a cross-sectional study of O&M clients, extending to O&M cohort studies defined in relation to selected vision- and mobility-related interventions.

[insert figure 3]

The VROOM/OMO validation study (solid-line boxes) is an embedded, mixed methods design with a QUAL/quan priority,[30] which means that measurement data will be generated in the context of social inquiry in the participants' lived environments (i.e., ordinary O&M assessments) not from standardised tasks and venues. The validation study depends on establishing industry partnerships with O&M service providers (called agencies) in Australia and Malaysia. The objectives, methods, facilities/ resources, and expected outcomes of the validation study are detailed in table 1.

At the same time, technology will be investigated and developed to support clients' independent mobility and professional O&M assessment practices (figure 3, dashed-line boxes). First, online surveys of the technology uptake and needs of O&M clients and O&M specialists will inform the design and optimisation of technologies. A mobile phone app that streamlines VROOM/OMO data collection and upload will be developed and piloted in Australia, then refined at the end of first-round data collection as the VROOM and OMO tools are revised. Accessible online VROOM/OMO training will be developed to facilitate

the widespread, consistent use of the tools by O&M professionals internationally. Parallel to this project, assistive devices that support independent travel with low vision or blindness will be developed in two PhD projects, using the VROOM and OMO tools to evaluate prototypes.

Table 1: VROOM/OMO Validation Study details – objectives, methods, facilities/resources and expected outcomes

Objectives	Methods	Facilities/resources	Expected outcomes
1. Feasibility Establish the feasibility of co-rating clients' skills using the VROOM/OOMO tools during ordinary O&M assessments.	Train O&M specialists in Australia to use the VROOM/OMO tools. Seek post-pilot feedback though focus groups, email, phone. Revise VROOM and OMO tools in collaboration with client consultants.	O&M industry partnerships Client reference group Data collection app Evaluation questions[a.]	Guidelines which streamline the use of VROOM and OMO tools in ordinary O&M assessments.
2. Scope of application Evaluate whether the VROOM and OMO tools can generate meaningful data about functional vision and mobility with people of any age or dis/abilities travelling in diverse circumstances.	Generate at least 50 assessments for each 10-point group within the 50-point scoring range in VROOM and OMO. Recruit additional participants as needed to achieve these quotas. Evaluate cultural relevance of VROOM and OMO tools in Malaysia.	Additional participants will be recruited through corporate sponsors (e.g., banks) which volunteer staff for community service, disability services, and aged care facilities.	Parameters for use of VROOM and OMO tools indicating - Applications - Limitations - Modifications for selected contexts Identify functional constructs that warrant development of separate measures.
3. Reliability Investigate whether stakeholders are interpreting the measures consistently.	With each industry partner, a sample of assessments representing different client cohorts, will be observed by a second professional or selected stakeholder who notes alternative interpretations of the rating scales, for subsequent discussion and qualitative analysis.	Where appropriate, video data from a sample of assessments representing different client cohorts will be generated for inter-rater review.	Guidelines for managing challenging relationships and contention when co-rating the VROOM and OMO tools, to be built into online VROOM/OMO training.
4. Content validity Evaluate the content validity, sufficiency, and redundancy of the VROOM and OMO subscales with diverse O&M clients.	Use grounded theory methodology to: - Develop separate interpretation tables for VROOM and OMO tools - Evaluate the relevance of VROOM and OMO tools to different cohorts - Identify relevant constructs that have not yet been measured.	Evaluation questions[b.]	VROOM and OMO tools provide a common language for tacit knowledge about low vision and mobility, that can be shared between O&M clients, family, friends, professionals and community members.

Objectives	Methods	Facilities/resources	Expected outcomes
5. Construct validity Evaluate whether the VROOM and OMO tools measure unidimensional phenomena.	Analyse the VROOM/OMO data to review the relevance and weighting of constructs through: - Qualitative coding - Exploratory/confirmatory factor analysis - Text mining - ANOVA - Rasch analysis - Mixed analyses Check findings/queries with experts.	Expert consultants: - Client reference group - Industry partners - O&M Association of Australasia	O&M professionals equipped to generate meaningful, comparable measures of client capabilities from ordinary professional practice that can be used to manage referrals, design programs, and evaluate outcomes.
6. Criterion validity[c.] Evaluate the concurrent validity of the VROOM and OMO tools.	Compare VROOM and OMO scores with: - embedded qualitative data - lifestyle data also generated during O&M assessment - clinical visual acuity in the better eye (n=65).	Source clients' clinical visual acuities measured within 1 year of VROOM assessment from agency files (where available).	Identify areas of similarity, difference and overlap between clinical and functional measures of vision, orientation and mobility that might influence vision-related policies (driving eligibility, pensions, assistive equipment, or support services).
7. Predictive validity [c.] Evaluate whether VROOM and OMO scores can predict benefits gained from particular vision- or mobility-related interventions.	Measure VROOM and OMO scores before and after selected interventions (e.g. long cane training, dog guide training, electronic travel aids). Identify patterns in referral status and program outcomes for selected interventions.	Industry partners to identify interventions of particular interest. Combine data from different industry partners to create intervention cohorts of >50 participants where possible.	Develop guidelines for referral to selected services or interventions, informed by VROOM and OMO data.

a. Feasibility Evaluation Questions: What did you gain from using the VROOM and OMO tools? What was frustrating or unhelpful about the process? How could the tools/process be improved? Who else could benefit from these measures?
b. Content Validity questions: What is important to you about your functional vision and mobility? Is anything important missing from the VROOM/OMO tools? Do the tools measure anything that's not important to you?
c. Objectives 6 and 7 will be addressed after the initial cross-sectional data collection is completed.

The first five objectives (establishing the feasibility, scope of application, reliability, content and construct validity of the tools) will be addressed during the first round of data collection, expected to take one year.

Data collection to address objectives 6 and 7 (establishing concurrent and predictive validity) will take longer and the following considerations will affect progress:

- There are no gold standard measures of functional vision for mobility or O&M to establish criterion validity, but some agencies might use related tools that can be compared: the Stuart Tactile Maps test[16 43] to investigate spatial cognition, and the Client Evaluation Tool[20] to evaluate travel skills and confidence.
- Adding assessment tools to VROOM and OMO will extend assessment times; O&M specialists will only fit this in as their workloads allow.
- Some O&M programs can last twelve months or more, so it can take a long time to complete data collection pre-post intervention.
- The heterogeneous nature of O&M practice means it can take a long time to accrue data about a defined cohort or selected intervention.

The research team

The research team includes an O&M specialist, a psychologist, statisticians, and experts in design and human-computer interaction, with team members located in Melbourne, Australia and Sarawak, Malaysia.

Participants and eligibility

Vision and mobility are generic human functions so the VROOM and OMO tools are designed to encompass the skills of anyone, of any age or abilities, in any location, not just O&M clients. The scope of application of the VROOM and OMO tools will be tested by O&M specialists in this study (table 1, objective 2) through purposive heterogeneous sampling to include children, adults and seniors with a wide range of comorbidities who are living and travelling in varied locations. There are no exclusion criteria for people being assessed, except their unwillingness to participate.

Sampling frame

The Australian O&M industry, which employs qualified O&M specialists, will provide the main sampling frame for this study. O&M specialists, including dog guide instructors, are uniquely skilled in assessing the functional vision and O&M skills of diverse clients who

have low vision or blindness. Ultimately, they will determine whether the VROOM and OMO tools are feasible and enhance ordinary O&M practice (table 1, objective 1).

Malaysian agencies providing services for people with low vision or blindness provide a second sampling frame to explore the international relevance of the VROOM and OMO tools.

The VROOM and OMO tools have potential application beyond the O&M profession. Occupational therapists and community-based rehabilitation CBR fieldworkers employed by industry partners will be invited to participate in VROOM/OMO training sessions, trial the tools in collaboration with O&M specialists, and provide feedback to the research team (table 1, part of objective 3). However, their findings will be analysed separately from the data generated by O&M specialists.

Sampling strategy and sample sizes

In this mixed-methods study we consider sampling from two perspectives: data saturation and statistical power. First, data saturation is needed to ensure that the VROOM and OMO tools adequately account for the functional phenomena they purport to measure, which will be evident in their respective interpretation tables (table 1, objective 4). Superficially data saturation means collecting qualitative data until no new behaviours are identified. According to grounded theory methodology, theoretical data saturation is more dependent on theoretical sampling and theoretical adequacy than sample size,[31] which is why sampling diversity is important in this study.

Statistically, we are aware that larger samples will more accurately represent any group subject to comparisons, but we need to strike a balance between available resources in the O&M industry, and ideal sample sizes. Some useful rules of thumb have guided our sample size decisions: Measuring group differences (e.g., t-test, ANOVA) – 30 per cell for 80% power, and if decreased, no lower than 7 per cell; Relationships (e.g., correlations, regression) – around 50; Chi-square – at least 20 overall, with no cell smaller than 5; Factor analysis – around 300.[44] Thus, our purposive quota sampling will aim for minimum numbers of:

- 50 children (aged <20 years); 50 adults (aged 21-59); and 50 seniors (aged 60+)
- 50 participants in each of the ten-point categories in both VROOM and OMO (table 2)
- 30-50 participants in mainstream O&M groups (e.g. long cane, dog guide users)
- 7 participants in specialist groups (e.g., wheelchairs, assistive technologies)

- 300 participants for exploratory and confirmatory factor analysis
- 300 participants for Rasch analysis

We estimate that 300-400 O&M assessments will be needed to fill these quotas by the end of first-round data collection.

Table 2: Quota of participant assessments needed in each category of the VROOM and OMO scales to make statistical comparisons.

VROOM integers	0 blind	1-10	11-20	21-30	31-40	41-50	TOTAL
Quota	50	50	50	50	50	50	**300**
OMO integers	-	1-10	11-20	21-30	31-40	41-50	
Quota	-	50	50	50	50	50	**250**

O&M specialists will select who to assess, beginning with convenience sampling as their workloads allow, then moving to purposive sampling to fill the indicated quotas. We anticipate needing to recruit additional purposive samples of adults with near-full vision to supplement participant numbers in the VROOM 41-50 category, and people with profound mobility limitations to supplement participant numbers in the OMO 1-10 category, because people with full vision and people who will always travel with a carer seldom refer for O&M services in Australia.

Recruitment

We identified fifteen agencies in Australia that provide O&M services, including five paediatric O&M services. These agencies employ around 224 O&M specialists, including at least 55 dog guide instructors.[2] The number of O&M clients across Australia is unclear but Guide Dogs Victoria alone worked with 1380 clients in a 12 month period, delivering 2390 programs.[45] However, it is not feasible to validate the VROOM and OMO measures in one location. The agencies are perpetually under-resourced and can have long waiting lists.[2] The roll-out of the National Disability Insurance Scheme (www.ndis.gov.au) is changing referral pathways, service profiles and reporting procedures, resulting in agency turmoil and substantial new learning for staff. Spreading the workload across agencies will give O&M specialists more choice to opt in when they are able, and maximise diversity and collaboration in critiquing the VROOM and OMO tools. The number of VROOM/OMO assessments undertaken by each agency will depend on the agency's size, service profile,

referral rates and likely client characteristics; competing research priorities; the number of O&M specialists employed, their availability, workloads and interest; and the informed consent of clients.

Through industry contacts and the internet, we identified seven organisations in Malaysia providing services to people with low vision or blindness. Several of these agencies offer community based rehabilitation (CBR) services, but the availability and extent of O&M services is unclear. The one guide dog handler in the country, Stevens Chan is repeatedly refused access to taxis, buses, shopping centres and parks, due to lack of legal frameworks, policies and community education in the country (e.g., https://www.youtube.com/watch?v=G9Mh55TER7Y). Contact will be established with Malaysian agencies prior to a field trip in early 2018 to explore understandings of low vision and attitudes to disability and independent travel in Malaysia, then evaluate the relevance of the VROOM and OMO tools for use by Malaysian CBR fieldworkers and O&M specialists. Any formal VROOM/OMO data collection in Malaysia followed by Item Response Theory/Rasch modelling needs to follow this grounded theory research phase and is beyond the scope of the current protocol.

Collaboration with O&M specialists and clients will occur throughout the project through industry partnerships, the professional body (O&M Association of Australasia) and an O&M client reference group (n=10), to critique the VROOM and OMO tools and associated technologies.

Data collection

Ordinary O&M assessment, comprising interview and observed travel in the client's lived environments, provides the context for implementing the VROOM and OMO tools. O&M specialists will be encouraged to integrate the tools into their existing assessment practices in whatever way works best for the client. This means that co-rating decisions might be discussed through the initial interview, during observed travel, and in a focused conversation at the end of the assessment.

O&M specialists will be encouraged to use the VROOM and OMO tools at any time in the initial phase of data collection – at initial assessment, mid-training or upon completion of an O&M program. This process will enable assessors and clients to gain confidence using the VROOM and OMO tools, test their application in a wide range of circumstances, and evaluate their feasibility as professional assessment tools (table 1, objectives 1 and 2).

The research team will use these data to generate interpretation tables that describe the functional implications for each ten-point category in the VROOM and OMO tools. We will profile Australian O&M cohorts, describing relationships between their functional vision and mobility, and their vision condition/s, life circumstances and mobility aid choices. Feedback from clients and assessors after this period will also indicate the most effective ways to implement the VROOM and OMO tools and inform guidelines for long term data collection.

Examining the cultural relevance of the VROOM and OMO tools in Malaysia is part of establishing the generalisability of these tools for international use.

The second phase of data collection is longitudinal, measuring VROOM and OMO scores pre-post O&M training that might include a long cane, dog guide or Miniguide, wheeled mobility (e.g., powerchair, scooter, bicycle), public transport, navigational devices (e.g., GPS apps, Trekker Breeze), visual efficiency training and orientation to new places, in individual or group programs. The VROOM and OMO tools will be used to evaluate the functional outcomes of assistive technologies developed for O&M clients in this study (piloting with n=7). The question of what constitutes meaningful change in functional outcome research will be explored in this phase, building grounded theory from participants' comments and descriptive statistics derived from the VROOM and OMO data-sets.

After interpretation tables are developed, the VROOM and OMO tools will be available to research groups internationally as outcome measures for vision- or mobility-related interventions. These intervention-specific cohort studies depend on securing relationships with industry partners, and ongoing funding.

Primary measures: VROOM and OMO tools

The ordinal scales in the VROOM and OMO tools that aggregate to a score out of 50 for each tool, and the associated comments that support these rating decisions, provide the primary data about functional vision and mobility in this study (Supplementary information, appendix 1).

Secondary measures

Socio-demographic questions built into the VROOM/OMO assessment provide additional information about clients and their travel contexts (Supplementary information, appendix 2).

O&M Environmental Complexity Scale

O&M specialists will use the six-level O&M Environmental Complexity Scale to identify the most challenging settings observed during assessment, assuming the client can manage all environments below this level.[17]

Vision

When a client's visual acuities (and fields) are available on file, measured within a year of the VROOM assessment, these measures will be compared with VROOM scores to explore equivalence between clinical and functional vision measures. However, clinical vision testing with every client assessment is not part of this protocol.

O&M technology surveys

Two online surveys will investigate the technology that O&M clients (Supplementary information, appendix 3) and O&M professionals (Supplementary information, appendix 4) already use, as well as identifying needs and ideas for optimising technology to support travel, O&M professional practice and research.

Data monitoring and management

Time-frames and frequency of follow up

We aim to complete the first round of data collection to profile Australian O&M clientele (n=300-400) in a one year period (late 2017 to late 2018). Then agencies will be invited to continue data collection pre-post training according to their own follow-up schedules. The timing and frequency of follow-ups will depend on the intervention/s received and the service profile of the Agency. For example, a client who has trained with a dog guide might receive follow up at one, three, six and twelve months post-training.

Managing bias and subjectivities

O&M agencies in Australia have asserted the need for outcome measures and they affirm the VROOM/OMO project, but they are perpetually under-resourced, vie for government and charity funding, and their ability to collect data is subject to competing priorities. As industry partnerships implement the VROOM and OMO tools according to their own resources and service profiles, O&M clientele will not be equally represented according to their agency affiliations or geographical location. Rather, the combination of purposive and quota

sampling methods will ensure that the VROOM/OMO data-set represents the range of functional vision and O&M abilities seen within and beyond O&M professional practice.

Long term, larger agencies will be encouraged to target their VROOM/OMO outcome assessments in key services that might render data from 50 or more clients. At the same time, the research team will draw together isolated assessment data from different agencies into groups that share like characteristics so that wherever possible, statistical comparisons can be made in addition to mixed methods analyses.

The VROOM and OMO tools are designed to represent what O&M specialists discover about the clients' capabilities and choices in the clients' environments, not to project what should happen. Thus, O&M specialists will be encouraged to follow the client's cues about what is meaningful to assess, just as they ordinarily do during functional O&M assessment.

O&M specialists already navigate differences of opinion during O&M sessions, and power shifts dynamically between the client's priorities, professional opinions, and the concerns of other stakeholders. An impasse while co-rating might indicate that more information or further functional assessment is needed before VROOM/OMO measurement decisions can be made.

Data analyses

In addition to comparing each ten-point group in the VROOM and OMO scales, O&M assessment data will be compared on the basis of age, vision condition/s, comorbidities, occupation and mobility aid use.

Qualitative data will be coded and categorised with the support of NVIVO software, Excel spreadsheets and mind-mapping software.

Exploratory/confirmatory factor analysis and Rasch modelling will be used to refine the OMO and VROOM scales using reflective models. In Part B of the OMO scale a formative model is required due to the range of elements that constitute mobility-related wellbeing. Structural equation modelling will be used to predict travel-related wellbeing from these items' responses with confirmation from sociodemographic data.

Cluster analysis will be used to identify groups of clients exhibiting similar O&M patterns. Chi-Squared tests will be used to compare these clusters with other client groupings defined in terms of vision, employment status and other demographics.

Between Groups ANOVA will be undertaken to compare the skills of different O&M client groups, and with non-client participants if appropriate. An invariance test of the

measurement models derived for Australia and Malaysia will determine whether these measures are likely to be transferable between cultures and languages.

Longitudinally, repeated measures analyses will be performed with the OMO and VROOM outcome data collected pre-post intervention, to evaluate the effectiveness of these interventions.

In embedded mixed data analyses, qualitative findings will be used to review the personal relevance of measures and identify any salient aspects of functional vision or O&M that have not been measured; to build interpretation tables for the VROOM and OMO scales; and to filter, interpret, and warrant the generalisability of statistically significant results.

Data quality assurance

Co-rated data are different to independently rated data, requiring alternative approaches to data management than are typically used in the development of psychometrics. Validation of the VROOM and OMO tools does not depend entirely on statistical analyses. In a mixed methods study, statistical results must be integrated with qualitative data in mixed analyses to generate robust findings.[46] The QUAL/quan priority during data collection ensures that co-rated measurement data represent what matters to participants. Practices that support the trustworthiness of qualitative data are built into the assessment and co-rating process, including collaboration between the researcher and the researched, triangulation of multiple observations and opinions, member-checking, and reflexivity.[47 48]

During assessment, clients' opinions are evident both in their words and actions, and relevant stakeholders can speak for clients whose insight, voice or actions might be limited. O&M specialists will be encouraged to justify their professional reasoning during assessments, and minimise the influence of their own biases during co-rating conversations.

ETHICS AND DISSEMINATION

Ethical approval has been granted by the Human Research Ethics Committee at Swinburne University of Technology (SHR Project 2016/316). Informed consent will be obtained from all participants, and express written permission sought before any identifiable data (e.g., names of agencies or people, photos, video) are used in conversations, presentations, or publications. However, O&M assessment happens in public places, so it is impossible to guarantee anonymity in this project.

Due to industry sensitivities, the research team will not publish data from this study that compares agencies; rather VROOM and OMO data across agencies will be reported along with client cohort profiles defined by these data.

VROOM and OMO assessments will add a little time, but no additional risk to ordinary O&M assessments. O&M agencies already have safeguards in place (e.g., health action plans, procedures and insurance policies) to manage risk and any incidents that might arise during O&M assessments.

Dissemination of results will be via individual agency reports, journal articles and conference presentations.

Acknowledgements

Dean Johnson and Mel Stevens have been valued collaborators in the development of O&M theory, the VROOM and OMO tools and the technology surveys.

Funding

This work is supported by Swinburne University of Technology, Melbourne-Sarawak Research Collaboration Scheme - Digital Health Project (October 2016-September 2018).

Competing interests

All authors have completed the ICMJE uniform disclosure form at http://www.icmje.org/coi_disclosure.pdf Dr. Deverell reports personal fees from Bionic Vision Australia (2014) and Guide Dogs Victoria outside the submitted work, and is an executive member of the Orientation and Mobility Association of Australasia. The remaining co-authors declare: no support from any organisation for the submitted work, no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, and no other relationships or activities that could appear to have influenced the submitted work.

Data sharing statement

No additional data are available.

Exclusive Licence

Authors' contributions

All authors contributed to the design of the study. LD conceived the VROOM and OMO tools and led the mixed methods and qualitative designs. DM, JB and FI led the quantitative design. BTL, AAM, SS, AC, CM and PZ led the integration of technologies. AP advised on psychosocial elements. LD and FI led the drafting of the manuscript which was reviewed and commented on by all authors.

Transparency

The lead author affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; no important aspects of the study have been omitted.

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Figure captions

Figure 1: Three manifestations of functional vision

Figure 2: O&M client uses GPS and public transport apps on her mobile phone to support travel with her guide dog. Photo by Lil Deverell, used with client's permission.

Figure 3: Workflow between different parts of the study. Solid line boxes indicate VROOM/OMO validation study. Dashed-line boxes indicate technology developments.

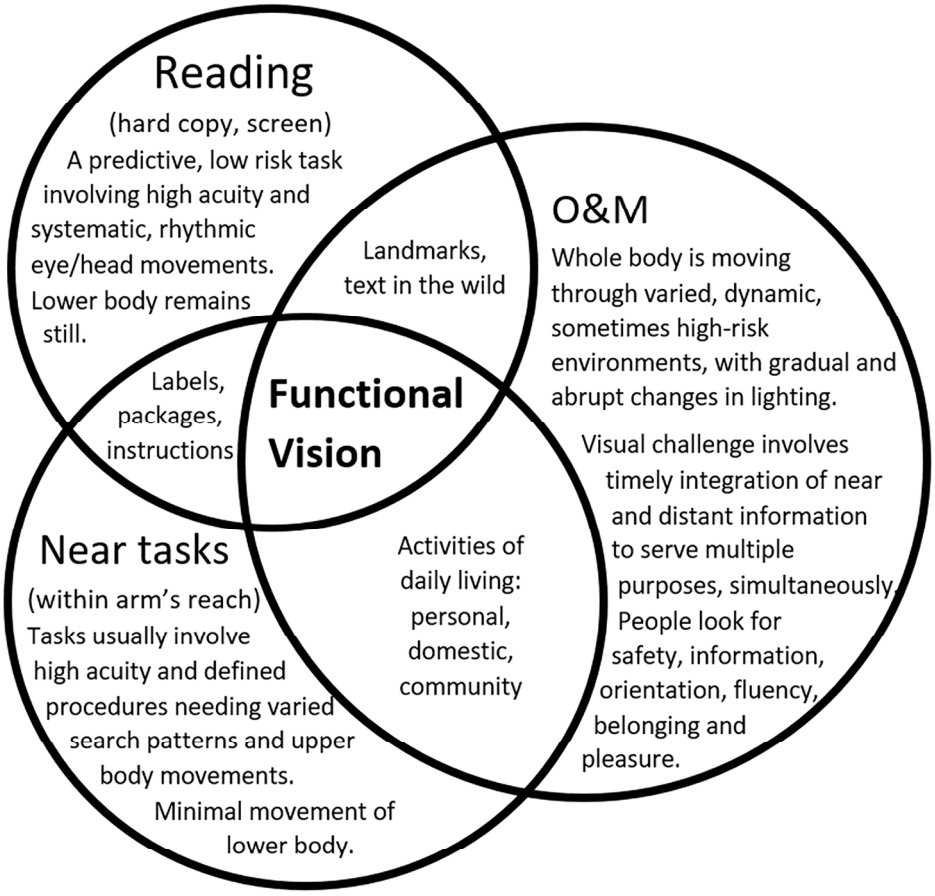

Figure 1: Three manifestations of functional vision

97x93mm (600 x 600 DPI)

Figure 2: O&M client uses GPS and public transport apps on her mobile phone to support travel with her guide dog. Photo by Lil Deverell, used with client's permission.

508x338mm (300 x 300 DPI)

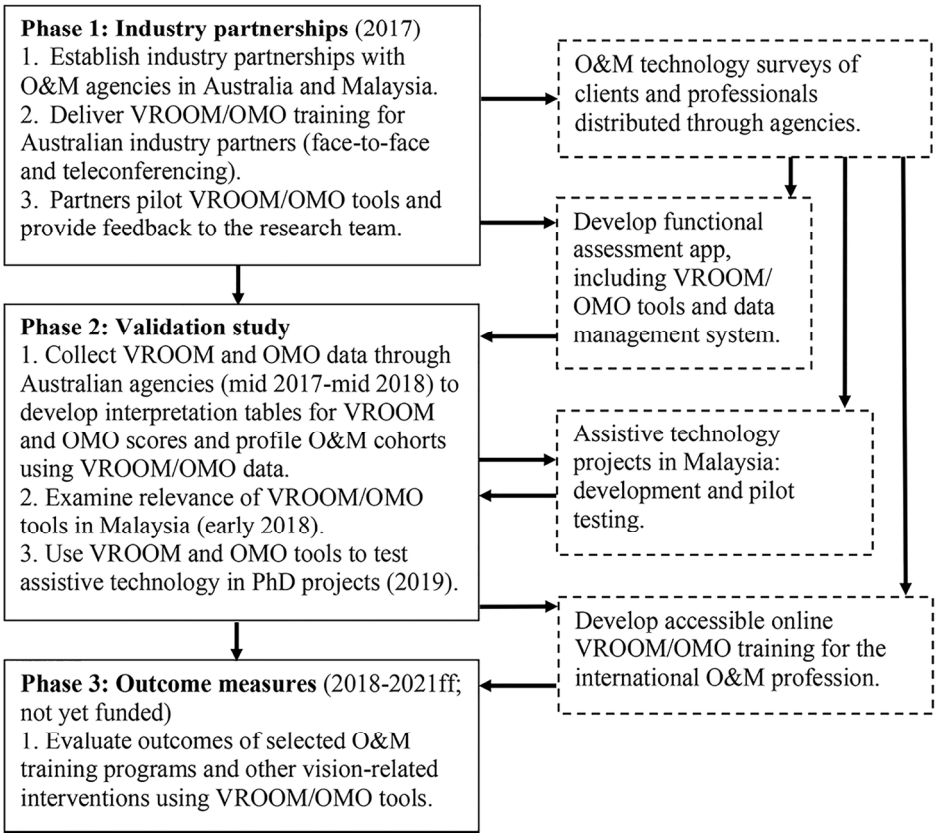

Figure 3: Workflow between different parts of the study. Solid line boxes indicate VROOM/OMO validation study. Dashed-line boxes indicate technology developments.

91x82mm (600 x 600 DPI)

Supplementary Information

Optimising technology to measure functional vision, mobility, and service outcomes for people with low vision or blindness: Protocol for a prospective cohort study in Australia and Malaysia

Appendix 1: The VROOM/OMO tools

The VROOM (table 1) and OMO (table 2) tools are intended for use by an orientation and mobility (O&M) specialist or dog guide instructor who is assessing a client's functional vision and mobility status during travel in the community. Both assessment tools are co-rated together by the assessor, the client, and any other relevant stakeholders present (e.g. family members, professionals).

The tools use the same measurement template: Part A measures elements of observed travel (out of 30), and Part B measures elements of wellbeing (out of 20). Subscales within each tool are aggregated to a score out of 50 on the spot so that scores can be compared and discussed with the client.

When to assess VROOM and OMO

The VROOM and OMO tools can be scored multiple times in different situations, facilitating functional comparisons:

- At Referral. Benchmark the client's functional skills, explore relationships between vision, mobility, and wellbeing, identify service options, and define program goals.
- To measure fluctuations. If the client's skills are known to vary in different conditions, assess in daytime or in best conditions and again at whatever time the client's skills are worst (e.g., light: compare day/night travel; fatigue: compare morning/late afternoon travel).
- To measure program outcomes. Assess before and after training/intervention in the same conditions (e.g., without, then with a new mobility aid).
- To measure change over time. Assess at regular intervals over time to measure functional deterioration (e.g., progressive vision or medical conditions) or functional improvement (e.g. consolidating new functional vision or mobility skills).

Instructions for assessors

1. During ordinary O&M assessment, interview the client about functional vision and mobility, then go for a walk together. Start the functional assessment in a familiar place (e.g., client's

home, school) and observe the client engaged in at least three travel-related tasks, then move to more dynamic places relevant to the client and observe at least three more travel tasks.

2. Discuss patterns and variations in behaviour with the client as you score each VROOM and OMO subscale together in any order. The co-rating conversation can be woven throughout your ordinary assessment, or happen at the end. Work out your own style.
3. The rating process is shared, but the weight of opinion can shift: the assessor might initiate ratings in Part A Observed Travel after seeing the client in action; the client's opinion might weigh more in Part B Wellbeing, which considers action in the previous month.
4. Differences of opinion might be due to lack of information or lack of insight. You might need to observe the client in more situations and/or involve other stakeholders in co-rating.
5. When there is indecision between two levels on a sub-scale, always choose the lower rating (before and after intervention). This captures the client's worst performance and gives room to improve.
6. Ratings need to be justified, so where possible, record brief comments from the client, the assessor, and other stakeholders near the relevant ratings.
7. Once you have scored every cell, aggregate the total VROOM and OMO scores, then discuss implications with the client.

Abbreviations in the VROOM and OMO tools

ECS: O&M Environmental Complexity Scale

Aids: SG=sighted guide; dog=dog guide; LC=long cane; SC=support cane; ID=identification cane; WC=wheelchair; Sc=motorised mobility scooter; MG=miniguide; GPS=global positioning system (e.g. Trekker Breeze, phone app); Ph=phone; Other=might include low vision aids.

O&M Environmental Complexity Scale (ECS)[1]

The VROOM and OMO tools use the O&M Environmental Complexity Scale to compare different travel environments (figure 1). The six levels of scale assume that travel challenges are cumulative, so the assessor only needs to note the highest level of complexity encountered during assessment.

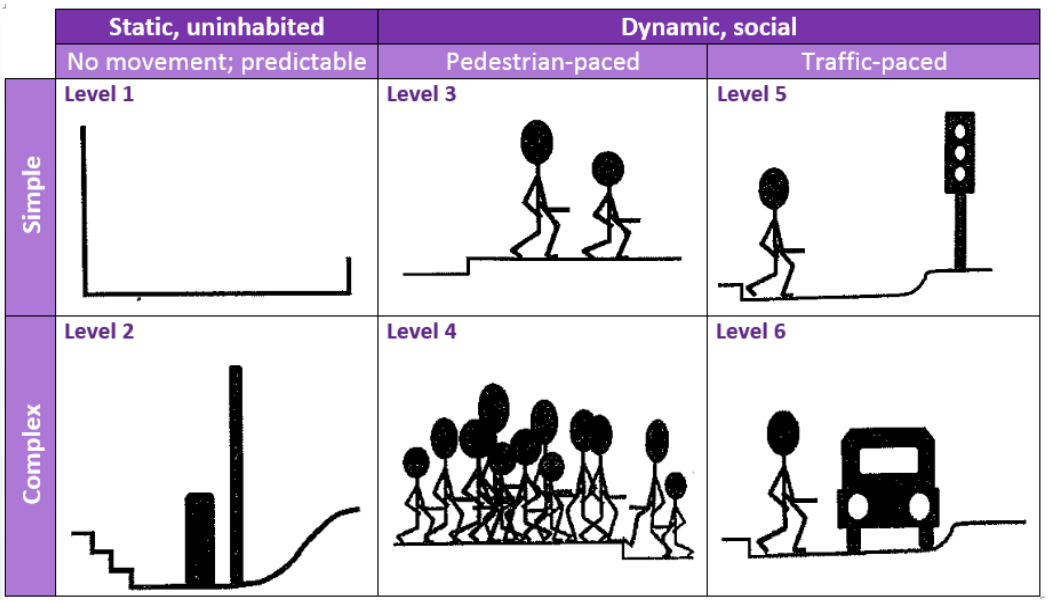

Figure 1: O&M environmental complexity scale

Level 1: Static, uninhabited places with level groundplane, no obstacles e.g., empty corridor, gymnasium or sports ground

Level 2: Static, uninhabited places with varying groundplane and/or obstacles e.g., steps, ramps, loose surfaces, furniture, poles

Level 3: Pedestrian-paced places (no faster than jogging) with a clear, continuous path of travel e.g., quiet residential footpath, workplace, or school corridors during class-time

Level 4: Pedestrian-paced places where the pathway is repeatedly obstructed and wayfinding is tiring e.g., market, busy car park

Level 5: Traffic-paced places where infrastructure supports crossing decisions e.g. traffic lights, islands, chicanes, crossing guards, zebras

Level 6: Traffic-paced places where the traveller must judge when it is safe to cross the road, e.g., mid-block priority roads, or places where traffic ignores the road rules

[1] Deverell L. O&M environmental complexity scale. *International Journal of Orientation & Mobility* 2011;4(1):64-77.

Table 1: VROOM tool

VROOM Part A: Observed Travel Vision-Related Outcomes in O&M Date: Starting time: Client: Assessor: Observed / Interview only		**Stable, familiar conditions; no hurry** e.g., home, local block Venues: _____ ECS: 1 2 3 4 5 6 Light: Bright Dim Dark Aids: NoAid SG Dog LC SC ID EWC MWC Sc MG GPS Ph Other:	**Dynamic conditions; timeliness needed** e.g., road crossings, shops, crowds Venues: _____ ECS: 1 2 3 4 5 6 Light: Bright Dim Dark Aids: NoAid SG Dog LC SC ID EWC MWC Sc MG GPS Ph Other:
SCORING **3 = Vision is primary** No touch or aid is needed **2 = Vision needs back-up** Rely on vision; use non-visual strategies to confirm **1 = Vision is secondary** Rely on non-visual strategies Vision sometimes useful **0 = Vision is useless** Use non-visual strategies	**Getting your bearings** Where am I? Which way do I go?	/3	/3
	Checking groundplane What's underfoot? Is it safe to step out?	/3	/3
	Wayfinding Is this the path? Is anything in the way?	/3	/3
	Recognising moving parts Who is around? Do I seek or avoid them?	/3	/3
	Finding things What am I looking for? How do I find it?	/3	/3
ECS=O&M Environmental Complexity Scale; Aids: SG=sighted guide; dog=dog guide; LC=long cane; SC=support cane; ID=identification cane; EWC=electric wheelchair; MWC=manual wheelchair; Sc=motorised mobility scooter; MG=miniguide; GPS=global positioning system (e.g. Trekker Breeze, phone app); Ph=phone			

VROOM Part B: Wellbeing	Score together from observations and discussion about activities **within the past month**	Comments & Score
Reading	0 I have no useful vision for reading text 1 If I'm close enough, I can identify large signs (e.g., stop sign) by text, size, shape, colour 2 I can sometimes read vehicle number plates & shop signs 3 I can sometimes identify different foods by looking at text and packaging (e.g., milk) 4 I can read regular print (i.e., letters, N12)	/4
Visual certainty	0 My vision is never useful when I'm moving around; too little, too late 1 I can't rely on my vision when I'm doing things 2 My vision causes hesitation and frustration; it undermines confidence when I'm moving 3 My vision has its limitations, but I know how to work with it 4 My vision is reliable for travel; I don't really have to think about it much	/4
Mobility aids (beyond home)	0 I use non-visual skills (cane/dog/guide) beyond home – my vision is useless 1 I rely on my cane/dog/guide – vision provides some extra information 2 I need non-visual skills sometimes (e.g., night travel, fluctuating vision) 3 I can go without, but a mobility aid gives me confidence, relieves fatigue, expands options 4 My vision is good enough for travel – I don't need a mobility aid	/4
People	0 I can't see people's shapes or movement; or see if a conversation partner moves away 1 I can see a body moving past, but I can't tell who it is; I sometimes collide 2 I can recognise people by their shape, colours, size or gait; I can usually avoid collisions 3 I can see faces, but not details; I do miss some social cues 4 I can recognise faces, read facial expressions and social cues	/4
Pleasure	0 My vision is un-motivating; it rarely or never prompts a closer look 1 My vision is limited or frustrating; often more trouble than it is worth 2 My vision is useful for some things, but not for others 3 I can see interesting things; it is usually worth the time it takes to look 4 I can see beautiful or engaging things that bring calm, contentment, excitement, even bliss	/4
RECOMMENDATIONS Part A: _____/30 Part B: _____/20 **Total Score: _____/50**		

Table 2: OMO tool

OMO Part A: Observed Travel O&M Outcomes Date: Starting time: Client: Assessor: Observed / Interview only		**Stable, familiar conditions; no hurry** e.g., home, local block Venues: _____ ECS: 1 2 3 4 5 6 Light: Bright Dim Dark Aids: NoAid SG Dog LC SC ID EWC MWC Sc MG GPS Ph Other:	**Dynamic conditions; timeliness needed** e.g., road crossings, shops, crowds Venues: _____ ECS: 1 2 3 4 5 6 Light: Bright Dim Dark Aids: NoAid SG Dog LC SC ID EWC MWC Sc MG GPS Ph Other:
SCORING **3 = Elite skills** Graceful, fluent, safe & effective in most places **2 = Competent skills** Safe & effective, but not always graceful & fluent **1 = Basic skills** Limited effective skills; needing consolidation **0 = Beginner skills** Unsafe/inadequate for the context	**Getting your bearings** Where am I? Which way do I go?	/3	/3
	Checking groundplane What's underfoot? Is it safe to step out?	/3	/3
	Wayfinding Is this the path? Is anything in the way?	/3	/3
	Recognising moving parts Who is around? Do I seek or avoid them?	/3	/3
	Finding things What am I looking for? How do I find it?	/3	/3
ECS=O&M Environmental Complexity Scale; Aids: SG=sighted guide; dog=dog guide; LC=long cane; SC=support cane; ID=identification cane; EWC=electric wheelchair; MWC=manual wheelchair; Sc=motorised mobility scooter; MG=miniguide; GPS=global positioning system (e.g. Trekker Breeze, phone app); Ph=phone			

OMO Part B Wellbeing	Score according to discussion about skills, attitudes and activities **within the past month**	Comments & Score
Activities	0 I find activities overwhelming 1 My mix of activities is not quite right; I don't know how to fix it, or I'm not yet ready for change 2 I like some of my activities, but I'm ready for new directions 3 I'm satisfied with my current mix of activities 4 I find my mix of activities challenging and enriching	/4
Connections	0 I feel isolated and lonely much of the time; I find it hard to connect with others 1 The people I know all do things for me; I feel quite dependent on others; I feel I have little to offer 2 I know where to find people; I'm linked in with some people or groups 3 I meet with people regularly; I feel welcomed and included 4 I have mutual friendships; we're there for each other; I actively contribute	/4
Life-space	0 I'm house-bound; I rarely go beyond the front gate 1 I do routine travel, only in well-known local areas (e.g., home block, local shops) 2 I explore in my local community; I like to try different routes 3 I travel to known places beyond the local community (e.g. commuting for work, visiting friends) 4 I like to explore beyond the local community, discovering new places	/4
Orientation	0 Even at home, I get disorientated; I have trouble understanding shapes, angles and distances 1 I can find the way at home by myself; beyond home, I need a companion or I get lost 2 I travel independently beyond home; if I get anxious or lost, I rely on help from other people 3 I travel independently beyond home; if I get anxious or lost, I can usually work it out by myself 4 I can go anywhere independently; I use mental mapping and I'm rarely disorientated for long	/4
Self-determination	0 My travel is managed by other people; I don't make the decisions 1 I need travel restrictions – I'm not always aware of what's safe and what is not 2 I'm aware of my own limitations, but I limit my travel rather than learning new skills 3 I'm aware of my own limitations; I plan ahead, source information and get help with my travel skills 4 I'm in charge; I evaluate my travel and learn from experience as I go; I develop my own skills	/4
RECOMMENDATIONS Part A: _____/30 Part B: _____/20 **Total Score: _____/50**		

Appendix 2: Socio-demographic and health questions

1. Age
2. Gender
3. Highest level of education (no formal schooling, primary/secondary school, post-secondary certificate/diploma, bachelor's degree, post-graduate certificate/diploma/ masters/PhD).
4. Occupation (full-time paid work, part-time paid work, unpaid work – home & family duties, volunteer work – community, student).
5. Is your income enough to meet your goals (sufficient, some compromises needed, insufficient)?
6. Language/s spoken at home
7. Vision condition/s
8. Onset of first vision condition/s (congenital: birth-first year, childhood: 1-18 years, adult >18 years), and pace of onset (gradual, abrupt).
9. Clinical vision measures if available (visual acuity, visual fields).
10. Where do you live (city, country town/village, isolated property or farm)?
11. Who you live with (alone, with immediate family members, with friends, relatives or acquaintances, in supported accommodation/aged care facility/hostel)?
12. Do you have issues that make your life complicated? If so, what?
13. Rate your overall physical fitness (very poor, poor, OK, good, very good).
14. Other than vision, what are your main barriers to travel (limited goals/motivation, disorganisation, family dynamics/demands, poor health/fatigue, finances, inaccessible physical environment, limited access to information, limited access to transport (public or private), safety concerns, get lost easily, self-conscious in public, other?
15. Have you used any of the following to support your travel in the past month (private transport, public transport, taxi/Uber, sighted guide/travel companion, dog guide, long cane, id cane, support cane, Miniguide, braille, print, audio/voice-over, computer/ internet, GPS, mobile phone/platform, best apps, other)?

Appendix 3: Technology survey for O&M clients

Q1. Gender

- ○ Male
- ○ Female

Q2. Age

- ○ Less than 10
- ○ 10-19
- ○ 20-29
- ○ 30-39
- ○ 40-49
- ○ 50-59
- ○ 60-69
- ○ 70 +

Q3. How would you describe your sight?

- ○ No light perception
- ○ Low vision and legally blind (eligible for pension)
- ○ Low vision, but not eligible for pension
- ○ Full vision

Q4. How do you travel beyond home?

- ☐ Long cane
- ☐ Dog guide
- ☐ Sighted guide
- ☐ Taxis/Ubers
- ☐ Public transport
- ☐ Private car
- ☐ Wheelchair
- ☐ Scooter
- ☐ Bicycle
- ☐ Other. Please explain: _____

Q5. Do you use any of the following devices? (can choose more than one)

- ☐ Mobile phone/s. Make and model:
- ☐ Tablet. Make and model:
- ☐ Portable braille notetaker Make and model:
- ☐ Laptop computer. Make and model:
- ☐ Desktop computer. Make and model:
- ☐ Standalone GPS. Make and model:
- ☐ Standalone OCR (optical character recognition) device. Make and model:
- ☐ CCTV (closed circuit television). Make and model:
- ☐ Personal activity monitor (e.g, Fitbit, SmartWatch). Make and model:
- ☐ Handheld sonar (e.g., Miniguide). Make and model:
- ☐ Sonar built into another device (e.g., Ultracane) Make and model:
- ☐ Barcode Reader. Make and model:
- ☐ Other. Please describe:

Q6. What formats do you use to support your travel? (can choose more than one)

- ☐ Print on paper
- ☐ Screen magnifier (zoom)
- ☐ Screen reader (voice-over)
- ☐ Voice recorder
- ☐ Braille
- ☐ I plan and/or travel with someone else
- ☐ Other. Please explain

Q7. Which apps do use to plan or carry out travel?

- ☐ Please list:
- ☐ I don't use apps.

Q8. What features do you particularly like in the apps you use?

- ☐ Please explain.
- ☐ I don't use apps.

Q9. Do you have access to technology training for travel purposes?

- ☐ Yes. Please describe: _____
- ☐ I would like more training. Please describe: _____
- ☐ No

Q10. Do you have ideas about how technology could be developed or enhanced to support your travel?

- ○ Yes. Please explain: _____
- ○ No.

Q11. Are you happy to be contacted by a Swinburne researcher to discuss your technology ideas?

- ☐ Your name: _____
- ☐ Best phone number: _____
- ☐ Best email address: _____

Q12. How did you respond to this survey?

- ☐ Independently
- ☐ With some assistance

Appendix 4: Technology survey for O&M professionals

Q1. Gender

- ○ Male
- ○ Female

Q2. Age

- ○ Less than 10
- ○ 10-19
- ○ 20-29
- ○ 30-39
- ○ 40-49
- ○ 50-59
- ○ 60-69
- ○ 70 +

Q3. What is your vision like?

- ○ Full vision
- ○ Low vision, but not legally blind
- ○ Low vision, and legally blind (< 6/60 acuity and/or <10° fields)
- ○ No light perception

Q4. What is your role? (you might have more than one)

- ☐ O&M specialist
- ☐ Dog guide instructor
- ☐ CBR fieldworker
- ☐ Other. Please explain: _____

Q5. What clients do you work with? (you may choose more than one)

- ☐ Adults
- ☐ Children
- ☐ People with neurological limitations / acquired brain injury
- ☐ People with intellectual disability

- [ ] People with physical limitations (e.g., use a support cane, wheelchair, scooter)
- [ ] People with mental health problems
- [ ] People with multisensory limitations (e.g., deafblind)
- [ ] Other. Please explain:

Q6. What devices do you use to support your O&M client work? (you may choose more than one)

- [ ] Mobile phone/s. Make and model:
- [ ] Tablet. Make and model:
- [ ] Portable braille notetaker Make and model:
- [ ] Laptop computer. Make and model:
- [ ] Desktop computer. Make and model:
- [ ] Standalone GPS. Make and model:
- [ ] Standalone OCR (optical character recognition) device. Make and model:
- [ ] CCTV (closed circuit television). Make and model:
- [ ] Personal activity monitor (e.g, Fitbit, SmartWatch). Make and model:
- [ ] Handheld sonar (e.g., Miniguide). Make and model:
- [ ] Sonar built into another device (e.g., Ultracane) Make and model:
- [ ] Barcode Reader. Make and model:
- [ ] Other. Please describe:

Q7. What O&M assessment resources have you used with clients?

- [ ] Agency assessment forms
- [ ] Checklists or rating scales. Please list:
- [ ] Books or theoretical approaches. Please list:
- [ ] Electronic resources (e.g., devices, apps). Please list:
- [ ] Physical materials. Please list:
- [ ] Other. Please explain:

Q8. What features do you like in the apps you use?

- [ ] Please describe.
- ( ) Not applicable

Q9. Do you use any accessibility features with a mobile phone? (list as many as you like)

- ☐ No
- ☐ Zoom/large print
- ☐ Reverse contrast
- ☐ Voice-over
- ☐ Other. Please describe.

Q10. Do you have concerns about using a mobile phone app to collect O&M assessment information?

- ○ No.
- ○ Yes. Please explain:

Q11. Do you have ideas about how technology could be developed or enhanced to support O&M practice (for you or the client)?

- ○ Yes. Please explain:
- ○ No.

Q12. Are you happy to be contacted by a Swinburne researcher to discuss your technology ideas?

- ☐ Your name:
- ☐ Best phone number:
- ☐ Best email address:

STROBE Statement—checklist of items that should be included in reports of observational studies

Re: *Optimising technology to measure functional vision, mobility, and service outcomes for people with low vision or blindness: Protocol for a prospective cohort study in Australia and Malaysia*

Please note: the results and discussion sections are not cross-referenced to the main document because this is a protocol paper not a research report.

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract **(p1)**
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found **(p2)**
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported **(p3-7)**
Objectives	3	State specific objectives, including any prespecified hypotheses **(p7-8, table 2)**
Methods		
Study design	4	Present key elements of study design early in the paper **(p8, figure 2)**
Setting	5	Describe the setting, locations **(p8-9, p15, supplement),** and relevant dates including periods of recruitment **(figure 2)**, exposure, follow-up **(p16)**, and data collection **(figure 2)**
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up **(p14, 16)** *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls **(p12)** *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants **p11-13**
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed **(N/A)** *Case-control study*—For matched studies, give matching criteria and the number of controls per case **(N/A)**
Variables	7	Clearly define all outcomes **(p5)**, exposures, predictors **(p16)**, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group **(p14, 15, supplement)**
Bias	9	Describe any efforts to address potential sources of bias **(p 16)**
Study size	10	Explain how the study size was arrived at **(p12)**
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why **(p17)**
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding **(p17)**
		(*b*) Describe any methods used to examine subgroups and interactions **(p17)**
		(*c*) Explain how missing data were addressed **(N/A)**
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed **(N/A)**

		Case-control study—If applicable, explain how matching of cases and controls was addressed **(N/A)** *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy **(p17)**
		(*e*) Describe any sensitivity analyses **(to be determined post hoc)**
Results (N/A)		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
		(b) Indicate number of participants with missing data for each variable of interest
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time
		Case-control study—Report numbers in each exposure category, or summary measures of exposure
		Cross-sectional study—Report numbers of outcome events or summary measures
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
		(*b*) Report category boundaries when continuous variables were categorized
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion (N/A)		
Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based **(p18)**

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Optimising technology to measure functional vision, mobility, and service outcomes for people with low vision or blindness: Protocol for a prospective cohort study in Australia and Malaysia

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-018140.R2
Article Type:	Protocol
Date Submitted by the Author:	26-Oct-2017
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Primary Subject Heading:	Evidence based practice
Secondary Subject Heading:	Ophthalmology
Keywords:	functional vision assessment, orientation and mobility, OMO and VROOM tools, co-rated measures, embedded mixed methods, translational research

Optimising technology to measure functional vision, mobility, and service outcomes for people with low vision or blindness: Protocol for a prospective cohort study in Australia and Malaysia

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Word count: 5786 words, excluding title page, abstract, references, figures and tables.

ABSTRACT

Introduction: Orientation and mobility (O&M) specialists assess the functional vision and O&M skills of people with mobility problems, usually relating to low vision or blindness. There are numerous O&M assessment checklists, but no measures that reduce qualitative assessment data to a single comparable score, suitable for assessing any O&M client, of any age or ability, in any location. Functional measures are needed internationally to align O&M assessment practices, guide referrals, profile O&M clients, plan appropriate services, and evaluate outcomes from O&M programs (e.g., long cane training), assistive technology (e.g., hazard sensors) and medical interventions (e.g., retinal implants). This study aims to validate two new measures of functional vision (VROOM) and O&M (OMO) in the context of ordinary O&M assessments in Australia, with cultural comparisons in Malaysia, also developing phone apps and online training to streamline professional assessment practices.

Methods and analysis: This multiphase observational study will employ embedded mixed methods with a QUAL/quan priority: co-rating functional vision and O&M during social inquiry. Australian O&M agencies (n=15) provide the sampling frame. O&M specialists will use quota sampling to generate cross-sectional assessment data (n=400) before investigating selected cohorts in outcome studies. Cultural relevance of the VROOM and OMO tools will be investigated in Malaysia, where the tools will inform the design of assistive devices and evaluate prototypes. Exploratory and confirmatory factor analysis, Rasch modelling, cluster analysis and analysis of variance (ANOVA) will be undertaken along with descriptive analysis of measurement data. Qualitative findings will be used to interpret VROOM and OMO scores, filter statistically significant results, warrant their generalisability, and identify additional relevant constructs that could also be measured.

Ethics and dissemination: Ethical approval has been granted by the Human Research Ethics Committee at Swinburne University (SHR Project 2016/316). Dissemination of results will be via agency reports, journal articles and conference presentations.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This study addresses an international shortage of functional vision and O&M measures that facilitate comparisons of different people and assistive devices in infinitely diverse circumstances. No such versatile assessment tools have been available to date.

- The co-rated measurement tools employ a constructivist approach to knowledge that aligns with O&M assessment practice. This resolves previous problems with O&M data quality that arise from assuming objectivity is possible in functional inquiry.
- Each assessment tool aggregates ratings to a single comparable score on the spot so that results are immediately accessible to clients and O&M specialists to support person-centred practice, low vision education and professional decision making.
- The assessment tools generate words and number data from the same context so that the resulting performance measures are precise and their relevance is warranted by individual participants. However, there are no established guidelines in the literature to evaluate the quality of co-rated data, and these guidelines need to be developed.
- A limitation is that the study depends on recruiting sufficient industry partners to generate data with their clients during ordinary O&M assessments when the O&M industry is in a period of tumultuous change and there is a limited pool of O&M specialists in Australia to draw upon.

INTRODUCTION

Globally, there are 285 million people with low vision or blindness, including 20 million Asians with visual acuity less than 3/60.[1] In Australia and New Zealand, an estimated 605,300 people have visual acuity less than 6/12,[2 3] making them ineligible to drive.[4] Unfortunately, clinical vision measures (e.g., acuity, fields, contrast sensitivity) do not predict a person's everyday functional capability in the real world.[5] Clinical and functional phenomena are fundamentally different, therefore different measures are needed in translational research to evaluate clinical and functional outcomes.[6 7]

Clinical inquiry seeks to reduce confounding factors and measure single variables in controlled conditions, then statistically compare these variables post hoc. In contrast, functional inquiry is irreducibly complex;[8] in the participant's everyday environments, power shifts from the researcher to the participant who decides what matters then integrates multiple variables with priorities changing in transit; these simultaneous changes and associated responses are easier to show than to tell.[9]

We propose that functional vision has three manifestations: vision for watching and reading, vision for near tasks, and vision for orientation and mobility (O&M). These manifestations increase in cephalocaudal involvement and task challenge, requiring different assessment conditions (figure 1).

[insert figure 1]

Watching and reading primarily involve head and neck work to locate, scan and interpret information – looking for a familiar person around a table, browsing a magazine, watching television, a sunset, a play or a sporting event. Near tasks involve head and upper body work to locate task materials within arm's reach, and manage hand-eye coordination – making a sandwich or managing medications. Watching, reading and near tasks involve limited lower body movement, so they can be assessed in controlled settings, seated or standing. However, functional vision for O&M is dynamic and irreducibly complex. O&M necessitates full body movement through changing environments that can include unpredictable moving elements, adjusting to changes in lighting, while integrating multiple visual functions to achieve multiple purposes – cleaning the house, going to the playground, navigating work or school.

Many clinical O&M studies have been designed to investigate individual elements of O&M in controlled conditions[10] – avoiding obstacles on a prescribed course,[11 12] following a white line on a dark floor, and locating a contrasting door,[13] or a sign on a door.[14] Walking speed and obstacle tallies provide clean repeatable data in clinical trials, but their relevance as functional outcome measures of O&M training or vision-related interventions is based on surmise and has been inadequately justified in the literature.[15] Not surprisingly, these measures have failed to capture the more holistic, lifestyle benefits gained from O&M training[10] or vision-related interventions[16] that participants report anecdotally. O&M clients have indicated they don't mind contacting obstacles, but they care about travel fluency, fatigue and avoiding falls.[17 18]

Clinical O&M trials are often conducted in an uninhabited environment, rating only Level 2 on the six level O&M Environmental Complexity Scale (Supplementary information, appendix 1).[19] They rarely investigate free-roaming mobility in pedestrian-paced environments (levels 3 and 4) or traffic environments (levels 5 and 6) that require social skills, knowledge of the road code and timely responses to unpredictable events.

In contrast, O&M specialists undertake person-centred practice in the community with non-drivers whose mobility problems are usually related to low vision or blindness.[20 21] They assess a client's functional vision and O&M skills qualitatively, then teach visual efficiency skills, mobility aid use (e.g., long cane, dog guide, Miniguide) and practical travel strategies to maximise the client's independence.

O&M clients are diverse, making it difficult to compare their functional status and prioritise needs. There are checklists and rating scales to support aspects of functional O&M

including general skills and confidence,[22] children's skills,[23] body concepts,[24] and mobility challenges with tunnel vision.[25] The "CVI Range" is designed to measure cortical vision impairment in children.[26 27] But there are no measures for use in general O&M assessment that reduce qualitative assessment data to a single comparable score. Internationally, O&M professionals needs an efficient way to rate the functional vision and the O&M skills of any client they encounter, to profile and compare different client groups and travel environments, interpret clients' mobility choices, guide program design, and evaluate the outcomes of O&M training, assistive devices and interventions such as a bionic eye.[28 29]

The VROOM and OMO tools

During 2015, two new functional assessment tools were developed for use in ordinary O&M practice. The VROOM tool measures Vision-Related Outcomes in O&M (functional vision for mobility), and the OMO tool measures functional O&M Outcomes (Supplementary information, appendix 1).

The VROOM and OMO tools are designed to be used in the same assessment event, but they measure different phenomena, producing a separate score for functional vision and for functional O&M. These tools are built on the same measurement template. Each is a suite of behaviourally-anchored rating scales, with Part A scoring observed behaviours out of 30, and Part B scoring elements of self-reported wellbeing out of 20. Rather than measuring opinions separately, the VROOM and OMO tools are scored together during a co-rating conversation between the assessor, the client and any other relevant stakeholders. Conversation about the client's abilities leads to accord about how to score each construct, and disagreement can mean that more observation and detailed discussion is needed. When there is indecision between levels on a scale, the rule is to choose the lower rating. The sub-scores are then aggregated for each tool on the spot, resulting in a score out of 50 for vision, and 50 for mobility.

The VROOM and OMO tools were developed following bionic vision research (2011-2015),[18 30] where grounded theories about functional vision and mobility were derived from the lived experience of people with advanced retinitis pigmentosa (n=43).[9] To test proof of concept, the VROOM tool was retro-scored with a convenience sample (n=13), drawing on live observations of people selected from across the visual spectrum and video data from the bionic eye project. This process showed that the measurement template worked with a broad spectrum of people including drivers and people with light perception only, yet was precise enough to capture subtle functional improvements in vision. The three retinal implant

recipients each showed a 12-16% (6-8 point) increase in their VROOM scores when their retinal implant device was switched on.[9]

The VROOM and OMO tools were then piloted during interviews with O&M clients who have a guide dog (n=51).[31] During their co-rating conversation, participants were invited to critique the constructs being assessed in the tools, and suggest improved wording of performance indicators. The VROOM tool inadvertently captured a 60% (30 point) improvement in one man's functional vision from corneal transplant surgery in between his initial VROOM rating and a re-scoring conversation several months later.

Rating decisions in Part A are made after observing the client travelling in multiple settings, with attention to five universal travel functions: Getting your Bearings, Checking Groundplane, Wayfinding, Recognising Moving Parts and Finding Things. The rating scale for the OMO tool focuses on travel competence regardless of vision as: (3) elite, (2) competent, (1) basic or (0) beginner, regardless of visual status, whereas the VROOM tool rates sensory preferences as: (3) predominantly visual, (2) vision first confirmed by other senses, (1) other senses first, confirmed by vision (0) non-visual.

In Part B of the template, five relevant constructs, each with defined performance indicators, are co-rated while discussing wellbeing and lifestyle choices with the client. OMO-Part B explores Activities, Connections, Life-space, Orientation and Self-Determination (sense of agency), which are drawn from the Effective Mobility Framework,[17] whereas VROOM-Part B explores vision for Reading, Visual Certainty, Mobility Aid choices, People and Pleasure, which are drawn from new theory about visual purposes.[9]

Comments from the client, the assessor and other stakeholders are noted alongside these ratings, providing precise, embedded mixed data[32] about each client's functional abilities at the time of assessment.

Exploratory factor analysis of the pilot data suggested that the subscales in the VROOM tool are measuring the one construct (functional vision for mobility). However, O&M is a more complicated phenomenon involving the mechanics of travel, spatial cognition and psychosocial factors, as indicated in the Effective Mobility Framework.[17] OMO-Part A works well, scored after observing travel, but a larger data-set is needed to explore the sufficiency and relationships between the OMO-Part B constructs in accounting for O&M. In addition to grounded theory methodology,[33] Rasch analysis of a larger VROOM and OMO data-set generated from more diverse clients will be used to review the subscales, calibrate the weighting of constructs, and thereby convert the ordinal scales to interval measures.

The VROOM and OMO tools are not just created for use by researchers, but are intended to support and streamline professional O&M practice, so a priority is to balance their user-friendliness during client assessments, with their ability to generate precise, meaningful measurement data on the spot.[34] O&M assessment apps and online training will be developed to support O&M specialists and clients to use the VROOM and OMO tools.

The VROOM and OMO tools are designed to

- benchmark functional skills upon initial referral,
- measure the range of normal fluctuations (e.g., day/night vision, morning/evening travel)
- track deterioration of skills with aging or specific conditions
- compare skills pre-post O&M training (e.g., long cane)
- evaluate new assistive technologies (e.g., smart-cane, bionic eye)

Over time, this practice-based evidence has the potential to inform referral criteria for O&M services and vision-related interventions, warrant funding applications for client services and assistive devices, and shape social policies impacting eligibility criteria for pensions, urban planning for pathways, public transport and safety, and communication technologies that improve access to information.

The role and design of O&M technology

There are three ways that technology is related to this project: to support independent travel for O&M clients, to streamline O&M professional practices, and to support the measurement of O&M outcomes.

Since World War II, specialised electronic mobility aids have been developed for people with low vision or blindness, to increase their range of preview during travel, to avoid collisions and support fluent wayfinding; to gain and maintain orientation, and manage travel information.[35 36] Wearable, or implantable vision restoration devices include retinal prostheses,[13 30] computer mediated head-mounted displays,[37] and sensory substitution devices.[38] Autonomous robot guidance is also proposed as an alternative to a dog guide to support wayfinding.[39]

Each of these technologies is remarkable for its innovation and fit for purpose. However, each is suited to a narrow clientele and devices differ in their cultural acceptability. Specialist technology is costly to develop, some devices never make it past the prototype stage, and most that reach commercialisation tend to be superseded in a few years.[40] Since GPS apps (e.g., blindsquare.com) have become widely available and accessibility features such as

voiceover, zoom and camera functions have become common inclusions, many O&M clients now prefer mainstream technologies such as a smartphone or tablet to support their travel (figure 2).[31] Mainstream devices are affordable and easy to upgrade, multi-purpose and synchronised so the traveller needs to carry less equipment. They reduce social barriers as people with full vision, low vision, and no vision enjoy the same technology.

[insert figure 2]

O&M specialists, some with low vision or blindness, also use smartphones and tablets to support their professional practice – to organise caseloads, access apps, maps, timetables, online directions and voice recording functions to plan, implement and review travel with clients. Video provides evidence of the client's O&M skills to show relevant stakeholders. FaceTime connects city-based professionals and rural or remote clients to deal with real-time travel challenges in between regional visits.[41] The internet makes diverse professional development opportunities available to isolated or time-poor practitioners.

Life-logging in O&M research has become easier with an increase in personal activity monitors (e.g., Fit-bit, Smart-watch, mobile phone apps), discreetly integrated into a wristwatch or mobile phone. However, accessibility differs between different platforms and devices, and improvements are needed to increase their user-friendliness for people with low vision or blindness. Egocentric vision can be captured with a video-camera (e.g., gopro.com) mounted on the head or body to record travel challenges, combined with eye tracker technology such as Tobii (www.tobii.com) or SMI (www.eyetracking-glasses.com) to measure mobile gaze direction, then state-of-the-art computer vision techniques can generate precise information about visual behaviour during travel.[42] These data help to inform the iterative development of new vision-related technologies, but in functional research, it is important to consider appearances. In some communities, snatch-theft is a risk when costly equipment is on display, and devices that make the traveller look unusual can change the way that passers-by interact so that something other than ordinary functional performance is measured.

In human factors engineering, there is growing awareness of the need for user-centred design when developing technologies. Ethnographic analysis is a method that draws observations from the practical use of devices in the context of their intended use, accounting for both practical and cultural influences on usage and acceptance.[43] Then, co-design is a participatory method, which places the user needs, desires and opinions at the centre of the

design process.[44] Consumers, researchers and designers all play a role in generating ideas, developing concepts and iteratively testing and modifying prototypes.

Aims of this study

The aims of this study are to:

1. Validate the VROOM and OMO tools during ordinary O&M assessment, to profile O&M clients and compare their functional abilities through:
    a. quota sampling in Australia, and
    b. cultural investigations in Malaysia.
2. Optimise technology to measure functional vision, mobility, and service outcomes of people with low vision or blindness, by
    a. analysing the technology use and needs of O&M agencies, O&M specialists and O&M clients in Australia and Malaysia, then
    b. developing assistive technology prototypes to support clients' O&M through student projects
    c. developing phone apps and online training that enable O&M specialists and O&M clients to generate and manage practice-based evidence from O&M assessments.

METHODOLOGY and METHODS

Study design

This study will employ a multi-phase, mixed methods design (figure 3), beginning with a cross-sectional study of O&M clients, extending to O&M cohort studies defined in relation to selected vision- and mobility-related interventions.

[insert figure 3]

The VROOM/OMO validation study (solid-line boxes) is an embedded, mixed methods design with a QUAL/quan priority,[32] which means that measurement data will be generated in the context of social inquiry in the participants' lived environments (i.e., ordinary O&M assessments) not from standardised tasks and venues. The validation study depends on establishing industry partnerships with O&M service providers (called agencies) in Australia and Malaysia. The objectives, methods, facilities/ resources, and expected outcomes of the validation study are detailed in table 1.

At the same time, technology will be investigated and developed to support clients' independent mobility and professional O&M assessment practices (figure 3, dashed-line boxes). First, online surveys of the technology uptake and needs of O&M clients and O&M specialists will inform the design and optimisation of technologies. A mobile phone app that streamlines VROOM/OMO data collection and upload will be developed and piloted in Australia, then refined at the end of first-round data collection as the VROOM and OMO tools are revised. Accessible online VROOM/OMO training will be developed to facilitate the widespread, consistent use of the tools by O&M professionals internationally. Parallel to this project, assistive devices that support independent travel with low vision or blindness will be developed in two PhD projects, using the VROOM and OMO tools to evaluate prototypes. Agencies might also choose to investigate the impact of particular assistive devices using VROOM and OMO assessments.

Table 1: VROOM/OMO Validation Study details – objectives, methods, facilities/resources and expected outcomes

Objectives	Methods	Facilities/resources	Expected outcomes
1. Feasibility Establish the feasibility of co-rating clients' skills using the VROOM/OOMO tools during ordinary O&M assessments.	Train O&M specialists in Australia to use the VROOM/OMO tools. Seek post-pilot feedback though focus groups, email, phone. Revise VROOM and OMO tools in collaboration with client consultants.	O&M industry partnerships Client reference group Data collection app Evaluation questions[a.]	Guidelines which streamline the use of VROOM and OMO tools in ordinary O&M assessments.
2. Scope of application Evaluate whether the VROOM and OMO tools can generate meaningful data about functional vision and mobility with people of any age or dis/abilities travelling in diverse circumstances.	Generate at least 50 assessments for each 10-point group within the 50-point scoring range in VROOM and OMO. Recruit additional participants as needed to achieve these quotas. Evaluate cultural relevance of VROOM and OMO tools in Malaysia.	Additional participants will be recruited through corporate sponsors (e.g., banks) which volunteer staff for community service, disability services, and aged care facilities.	Parameters for use of VROOM and OMO tools indicating - Applications - Limitations - Modifications for selected contexts Identify functional constructs that warrant development of separate measures.
3. Reliability Investigate whether stakeholders are interpreting the measures consistently.	With each industry partner, a sample of assessments representing different client cohorts, will be observed by a second professional or selected stakeholder who notes alternative interpretations of the rating scales, for subsequent discussion and qualitative analysis.	Where appropriate, video data from a sample of assessments representing different client cohorts will be generated for inter-rater review.	Guidelines for managing challenging relationships and contention when co-rating the VROOM and OMO tools, to be built into online VROOM/OMO training.
4. Content validity Evaluate the content validity, sufficiency, and redundancy of the VROOM and OMO subscales with diverse O&M clients.	Use grounded theory methodology to: - Develop separate interpretation tables for VROOM and OMO tools - Evaluate the relevance of VROOM and OMO tools to different cohorts - Identify relevant constructs that have not yet been measured.	Evaluation questions[b.]	VROOM and OMO tools provide a common language for tacit knowledge about low vision and mobility, that can be shared between O&M clients, family, friends, professionals and community members.

Objectives	Methods	Facilities/resources	Expected outcomes
5. Construct validity Evaluate whether the VROOM and OMO tools measure unidimensional phenomena.	Analyse the VROOM/OMO data to review the relevance and weighting of constructs through: - Qualitative coding - Exploratory/confirmatory factor analysis - Text mining - ANOVA - Rasch analysis - Mixed analyses Check findings/queries with experts.	Expert consultants: - Client reference group - Industry partners - O&M Association of Australasia	O&M professionals equipped to generate meaningful, comparable measures of client capabilities from ordinary professional practice that can be used to manage referrals, design programs, and evaluate outcomes.
6. Criterion validity[c.] Evaluate the concurrent validity of the VROOM and OMO tools.	Compare VROOM and OMO scores with: - embedded qualitative data - lifestyle data also generated during O&M assessment - clinical visual acuity in the better eye (n=65).	Source clients' clinical visual acuities measured within 1 year of VROOM assessment from agency files (where available).	Identify areas of similarity, difference and overlap between clinical and functional measures of vision, orientation and mobility that might influence vision-related policies (driving eligibility, pensions, assistive equipment, or support services).
7. Predictive validity [c.] Evaluate whether VROOM and OMO scores can predict benefits gained from particular vision- or mobility-related interventions.	Measure VROOM and OMO scores before and after selected interventions (e.g. long cane training, dog guide training, electronic travel aids). Identify patterns in referral status and program outcomes for selected interventions.	Industry partners to identify interventions of particular interest. Combine data from different industry partners to create intervention cohorts of >50 participants where possible.	Develop guidelines for referral to selected services or interventions, informed by VROOM and OMO data.

a. Feasibility Evaluation Questions: What did you gain from using the VROOM and OMO tools? What was frustrating or unhelpful about the process? How could the tools/process be improved? Who else could benefit from these measures?
b. Content Validity questions: What is important to you about your functional vision and mobility? Is anything important missing from the VROOM/OMO tools? Do the tools measure anything that's not important to you?
c. Objectives 6 and 7 will be addressed after the initial cross-sectional data collection is completed.

The first five objectives (establishing the feasibility, scope of application, reliability, content and construct validity of the tools) will be addressed during the first round of data collection, expected to take one year.

Data collection to address objectives 6 and 7 (establishing concurrent and predictive validity) will take longer and the following considerations will affect progress:

- There are no gold standard measures of functional vision for mobility or O&M to establish criterion validity, but depending on the interests of agencies and clients, comparable data might be generated from the Stuart Tactile Maps test[18 45] (spatial cognition), the Client Evaluation Tool[22] (travel skills and confidence) or personal activity monitors (distance, roaming range, activity type, travel related stress).
- Adding assessment tools to VROOM and OMO will extend assessment times; O&M specialists will only fit this in as their workloads allow.
- Some O&M programs can last twelve months or more, so it can take a long time to complete data collection pre-post intervention.
- The heterogeneous nature of O&M practice means it can take a long time to accrue data from multiple clients about a defined cohort or selected intervention.

The research team

The research team includes an O&M specialist, a psychologist, statisticians, and experts in design and human-computer interaction, with team members located in Melbourne, Australia and Sarawak, Malaysia.

Participants and eligibility

Vision and mobility are generic human functions so the VROOM and OMO tools are designed to encompass the skills of anyone, of any age or abilities, in any location, not just O&M clients. The scope of application of the VROOM and OMO tools will be tested by O&M specialists in this study (table 1, objective 2) through purposive heterogeneous sampling to include children, adults and seniors with a wide range of comorbidities who are living and travelling in varied locations. There are no exclusion criteria for people being assessed, except their unwillingness to participate.

Sampling frame

The Australian O&M industry, which employs qualified O&M specialists, will provide the main sampling frame for this study. O&M specialists, including dog guide instructors, are

uniquely skilled in assessing the functional vision and O&M skills of diverse clients who have low vision or blindness. Ultimately, they will determine whether the VROOM and OMO tools are feasible and enhance ordinary O&M practice (table 1, objective 1).

Malaysian agencies providing services for people with low vision or blindness provide a second sampling frame to explore the international relevance of the VROOM and OMO tools.

The VROOM and OMO tools have potential application beyond the O&M profession. Occupational therapists and community-based rehabilitation CBR fieldworkers employed by industry partners will be invited to participate in VROOM/OMO training sessions, trial the tools in collaboration with O&M specialists, and provide feedback to the research team (table 1, part of objective 3). However, their findings will be analysed separately from the data generated by O&M specialists.

Sampling strategy and sample sizes

In this mixed-methods study we consider sampling from two perspectives: data saturation and statistical power. First, data saturation is needed to ensure that the VROOM and OMO tools adequately account for the functional phenomena they purport to measure, which will be evident in their respective interpretation tables (table 1, objective 4). Superficially data saturation means collecting qualitative data until no new behaviours are identified. According to grounded theory methodology, theoretical data saturation is more dependent on theoretical sampling and theoretical adequacy than sample size,[33] which is why sampling diversity is important in this study.

Statistically, we are aware that larger samples will more accurately represent any group subject to comparisons, but we need to strike a balance between available resources in the O&M industry, and ideal sample sizes. Some useful rules of thumb have guided our sample size decisions: Measuring group differences (e.g., t-test, ANOVA) – 30 per cell for 80% power, and if decreased, no lower than 7 per cell; Relationships (e.g., correlations, regression) – around 50; Chi-square – at least 20 overall, with no cell smaller than 5; Factor analysis – around 300.[46] Thus, our purposive quota sampling will aim for minimum numbers of:

- 50 children (aged <20 years); 50 adults (aged 21-59); and 50 seniors (aged 60+)
- 50 participants in each of the ten-point categories in both VROOM and OMO (table 2)
- 30-50 participants in mainstream O&M groups (e.g. long cane, dog guide users)

- 7 participants in specialist groups (e.g., wheelchairs, assistive technologies)
- 300 participants for exploratory and confirmatory factor analysis
- 300 participants for Rasch analysis

We estimate that 300-400 O&M assessments will be needed to fill these quotas by the end of first-round data collection.

Table 2: Quota of participant assessments needed in each category of the VROOM and OMO scales to make statistical comparisons.

VROOM integers	0 blind	1-10	11-20	21-30	31-40	41-50	TOTAL
Quota	50	50	50	50	50	50	**300**
OMO integers	-	1-10	11-20	21-30	31-40	41-50	
Quota	-	50	50	50	50	50	**250**

O&M specialists will select who to assess, beginning with convenience sampling as their workloads allow, then moving to purposive sampling to fill the indicated quotas. We anticipate needing to recruit additional purposive samples of adults with near-full vision to supplement participant numbers in the VROOM 41-50 category, and people with profound mobility limitations to supplement participant numbers in the OMO 1-10 category, because people with full vision and people who will always travel with a carer seldom refer for O&M services in Australia.

Recruitment

We identified fifteen agencies in Australia that provide O&M services, including five paediatric O&M services. These agencies employ around 224 O&M specialists, including at least 55 dog guide instructors.[2] The number of O&M clients across Australia is unclear but Guide Dogs Victoria alone worked with 1380 clients in a 12 month period, delivering 2390 programs.[47] However, it is not feasible to validate the VROOM and OMO measures in one location. The agencies are perpetually under-resourced and can have long waiting lists.[2] The roll-out of the National Disability Insurance Scheme (www.ndis.gov.au) is changing referral pathways, service profiles and reporting procedures, resulting in agency turmoil and substantial new learning for staff. Spreading the workload across agencies will give O&M specialists more choice to opt in when they are able, and maximise diversity and collaboration in critiquing the VROOM and OMO tools. The number of VROOM/OMO

assessments undertaken by each agency will depend on the agency's size, service profile, referral rates and likely client characteristics; competing research priorities; the number of O&M specialists employed, their availability, workloads and interest; and the informed consent of clients.

Through industry contacts and the internet, we identified seven organisations in Malaysia providing services to people with low vision or blindness. Several of these agencies offer community based rehabilitation (CBR) services, but the availability and extent of O&M services is unclear. The one guide dog handler in the country, Stevens Chan is repeatedly refused access to taxis, buses, shopping centres and parks, due to lack of legal frameworks, policies and community education in the country (e.g., https://www.youtube.com/watch?v=G9Mh55TER7Y). Contact will be established with Malaysian agencies prior to a field trip in early 2018 to explore understandings of low vision and attitudes to disability and independent travel in Malaysia, then evaluate the relevance of the VROOM and OMO tools for use by Malaysian CBR fieldworkers and O&M specialists. Formal VROOM/OMO data collection in Malaysia followed by Item Response Theory/Rasch modelling needs to follow this grounded theory research phase, but is beyond the scope of the current protocol.

Collaboration with O&M specialists and clients will occur throughout the project through industry partnerships, the professional body (O&M Association of Australasia) and an O&M client reference group (n=10), to critique the VROOM and OMO tools and associated technologies.

Data collection

Ordinary O&M assessment, comprising interview and observed travel in the client's lived environments, provides the context for implementing the VROOM and OMO tools. O&M specialists will be encouraged to integrate the tools into their existing assessment practices in whatever way works best for the client. This means that co-rating decisions might be discussed through the initial interview, during observed travel, and in a focused conversation at the end of the assessment.

O&M specialists will be encouraged to use the VROOM and OMO tools at any time in the initial phase of data collection – at initial assessment, mid-training or upon completion of an O&M program. This process will enable assessors and clients to gain confidence using the VROOM and OMO tools, test their application in a wide range of circumstances, and evaluate their feasibility as professional assessment tools (table 1, objectives 1 and 2).

The research team will use these data to generate interpretation tables that describe the functional implications for each ten-point category in the VROOM and OMO tools. We will profile Australian O&M cohorts, describing relationships between their functional vision and mobility, and their vision condition/s, life circumstances and mobility aid choices. Feedback from clients and assessors after this period will also indicate the most effective ways to implement the VROOM and OMO tools and inform guidelines for long term data collection.

Examining the cultural relevance of the VROOM and OMO tools in Malaysia is part of establishing the generalisability of these tools for international use.

The second phase of data collection is longitudinal, measuring VROOM and OMO scores pre-post O&M training that might include a long cane, dog guide or Miniguide, wheeled mobility (e.g., powerchair, scooter, bicycle), public transport, navigational devices (e.g., GPS apps, Trekker Breeze), visual efficiency training and orientation to new places, in individual or group programs. The VROOM and OMO tools will be used to evaluate the functional outcomes of assistive technology prototypes developed for O&M clients in this study (piloting with n=7). The question of what constitutes meaningful change in functional outcome research will be explored in this phase, building grounded theory from participants' comments and descriptive statistics derived from the VROOM and OMO data-sets.

After interpretation tables are developed, the VROOM and OMO tools will be available to research groups internationally as outcome measures for vision- or mobility-related interventions. These intervention-specific cohort studies depend on securing relationships with industry partners, and ongoing funding.

Primary measures: VROOM and OMO tools

The ordinal scales in the VROOM and OMO tools that aggregate to a score out of 50 for each tool, and the associated comments that support these rating decisions, provide the primary data about functional vision and mobility in this study (Supplementary information, appendix 1).

Secondary measures

Socio-demographic questions built into the VROOM/OMO assessment provide additional information about clients and their travel contexts (Supplementary information, appendix 2).

O&M Environmental Complexity Scale

O&M specialists will use the six-level O&M Environmental Complexity Scale to identify the most challenging settings observed during assessment, assuming the client can manage all environments below this level.[19]

Vision

When a client's visual acuities (and fields) are available on file, measured within a year of the VROOM assessment, these measures will be compared with VROOM scores to explore equivalence between clinical and functional vision measures. However, clinical vision testing with every client assessment is not part of this protocol.

O&M technology surveys

Two online surveys will investigate the technology that O&M clients (Supplementary information, appendix 3) and O&M professionals (Supplementary information, appendix 4) already use, as well as identifying needs and ideas for optimising technology to support travel, O&M professional practice and research.

Data monitoring and management

Time-frames and frequency of follow up

We aim to complete the first round of data collection to profile Australian O&M clientele (n=300-400) in a one year period (late 2017 to late 2018). Then agencies will be invited to continue data collection pre-post training according to their own follow-up schedules. The timing and frequency of follow-ups will depend on the intervention/s received and the service profile of the Agency. For example, a client who has trained with a dog guide might receive follow up at one, three, six and twelve months post-training.

Managing bias and subjectivities

O&M agencies in Australia have asserted the need for outcome measures and they affirm the VROOM/OMO project, but they are perpetually under-resourced, vie for government and charity funding, and their ability to collect data is subject to competing priorities. As industry partnerships implement the VROOM and OMO tools according to their own resources and service profiles, O&M clientele will not be equally represented according to their agency affiliations or geographical location. Rather, the combination of purposive and quota

sampling methods will ensure that the VROOM/OMO data-set represents the range of functional vision and O&M abilities seen within and beyond O&M professional practice.

Long term, larger agencies will be encouraged to target their VROOM/OMO outcome assessments in key services that might render data from 50 or more clients. At the same time, the research team will draw together isolated assessment data from different agencies into groups that share like characteristics so that wherever possible, statistical comparisons can be made in addition to mixed methods analyses.

The VROOM and OMO tools are designed to represent what O&M specialists discover about the clients' capabilities and choices in the clients' environments, not to project what should happen. Thus, O&M specialists will be encouraged to follow the client's cues about what is meaningful to assess, just as they ordinarily do during functional O&M assessment.

O&M specialists already navigate differences of opinion during O&M sessions, and power shifts dynamically between the client's priorities, professional opinions, and the concerns of other stakeholders. An impasse while co-rating might indicate that more information or further functional assessment is needed before VROOM/OMO measurement decisions can be made.

Data analyses

In addition to comparing each ten-point group in the VROOM and OMO scales, O&M assessment data will be compared on the basis of age, vision condition/s, comorbidities, occupation and mobility aid use.

Qualitative data will be coded and categorised with the support of NVIVO software, Excel spreadsheets and mind-mapping software.

Exploratory/confirmatory factor analysis and Rasch modelling will be used to refine the OMO and VROOM scales using reflective models. In Part B of the OMO scale a formative model is required due to the range of elements that constitute mobility-related wellbeing. Structural equation modelling will be used to predict travel-related wellbeing from these items' responses with confirmation from sociodemographic data.

Cluster analysis will be used to identify groups of clients exhibiting similar O&M patterns. Chi-Squared tests will be used to compare these clusters with other client groupings defined in terms of vision, employment status and other demographics.

Between Groups ANOVA will be undertaken to compare the skills of different O&M client groups, and with non-client participants if appropriate. An invariance test of the

measurement models derived for Australia and Malaysia will determine whether these measures are likely to be transferable between cultures and languages.

Longitudinally, repeated measures analyses will be performed with the OMO and VROOM outcome data collected pre-post intervention, to evaluate the effectiveness of these interventions.

In embedded mixed data analyses, qualitative findings will be used to review the personal relevance of measures and identify any salient aspects of functional vision or O&M that have not been measured; to build interpretation tables for the VROOM and OMO scales; and to filter, interpret, and warrant the generalisability of statistically significant results.

Data quality assurance

Co-rated data are different to independently rated data, requiring alternative approaches to data management than are typically used in the development of psychometrics. Validation of the VROOM and OMO tools does not depend entirely on statistical analyses. In a mixed methods study, statistical results must be integrated with qualitative data in mixed analyses to generate robust findings.[48] The QUAL/quan priority during data collection ensures that co-rated measurement data represent what matters to participants. Practices that support the trustworthiness of qualitative data are built into the assessment and co-rating process, including collaboration between the researcher and the researched, triangulation of multiple observations and opinions, member-checking, and reflexivity.[49 50]

During assessment, clients' opinions are evident both in their words and actions, and relevant stakeholders can speak for clients whose insight, voice or actions might be limited. O&M specialists will be encouraged to justify their professional reasoning during assessments, and minimise the influence of their own biases during co-rating conversations.

ETHICS AND DISSEMINATION

Ethical approval has been granted by the Human Research Ethics Committee at Swinburne University of Technology (SHR Project 2016/316). Informed consent will be obtained from all participants, and express written permission sought before any identifiable data (e.g., names of agencies or people, photos, video) are used in conversations, presentations, or publications. However, O&M assessment happens in public places, so it is impossible to guarantee anonymity in this project.

Due to industry sensitivities, the research team will not publish data from this study that compares agencies; rather VROOM and OMO data across agencies will be reported along with client cohort profiles defined by these data.

VROOM and OMO assessments will add a little time, but no additional risk to ordinary O&M assessments. O&M agencies already have safeguards in place (e.g., health action plans, procedures and insurance policies) to manage risk and any incidents that might arise during O&M assessments.

Dissemination of results will be via individual agency reports, journal articles and conference presentations.

Acknowledgements

Dean Johnson and Mel Stevens have been valued collaborators in the development of O&M theory, the VROOM and OMO tools and the technology surveys.

Funding

This work is supported by Swinburne University of Technology, Melbourne-Sarawak Research Collaboration Scheme - Digital Health Project (October 2016-September 2018).

Competing interests

All authors have completed the ICMJE uniform disclosure form at http://www.icmje.org/coi_disclosure.pdf Dr. Deverell reports personal fees from Bionic Vision Australia (2014) and Guide Dogs Victoria outside the submitted work, and is an executive member of the Orientation and Mobility Association of Australasia. The remaining co-authors declare: no support from any organisation for the submitted work, no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, and no other relationships or activities that could appear to have influenced the submitted work.

Data sharing statement

No additional data are available.

Exclusive Licence

Authors' contributions

All authors contributed to the design of the study. LD conceived the VROOM and OMO tools and led the mixed methods and qualitative designs. DM, JB and FI led the quantitative design. BTL, AAM, SS, AC, CM and PZ led the integration of technologies. AP advised on psychosocial elements. LD and FI led the drafting of the manuscript which was reviewed and commented on by all authors.

Transparency

The lead author affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; no important aspects of the study have been omitted.

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Figure captions

Figure 1: Three manifestations of functional vision

Figure 2: O&M client uses GPS and public transport apps on her mobile phone to support travel with her guide dog. Photo by Lil Deverell, used with client's permission.

Figure 3: Workflow between different parts of the study. Solid line boxes indicate VROOM/OMO validation study. Dashed-line boxes indicate technology developments.

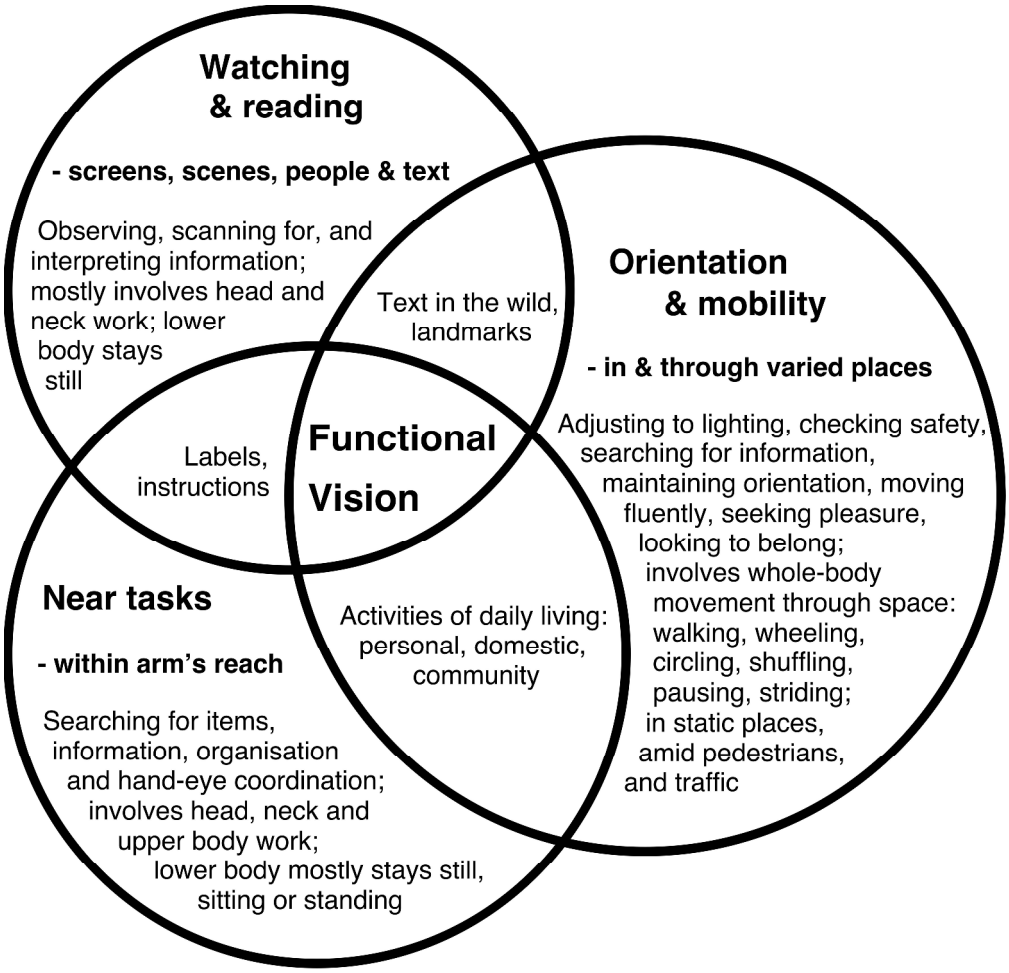

Figure 1: Three manifestations of functional vision

502x484mm (300 x 300 DPI)

Figure 2: O&M client uses GPS and public transport apps on her mobile phone to support travel with her guide dog. Photo by Lil Deverell, used with client's permission.

508x338mm (300 x 300 DPI)

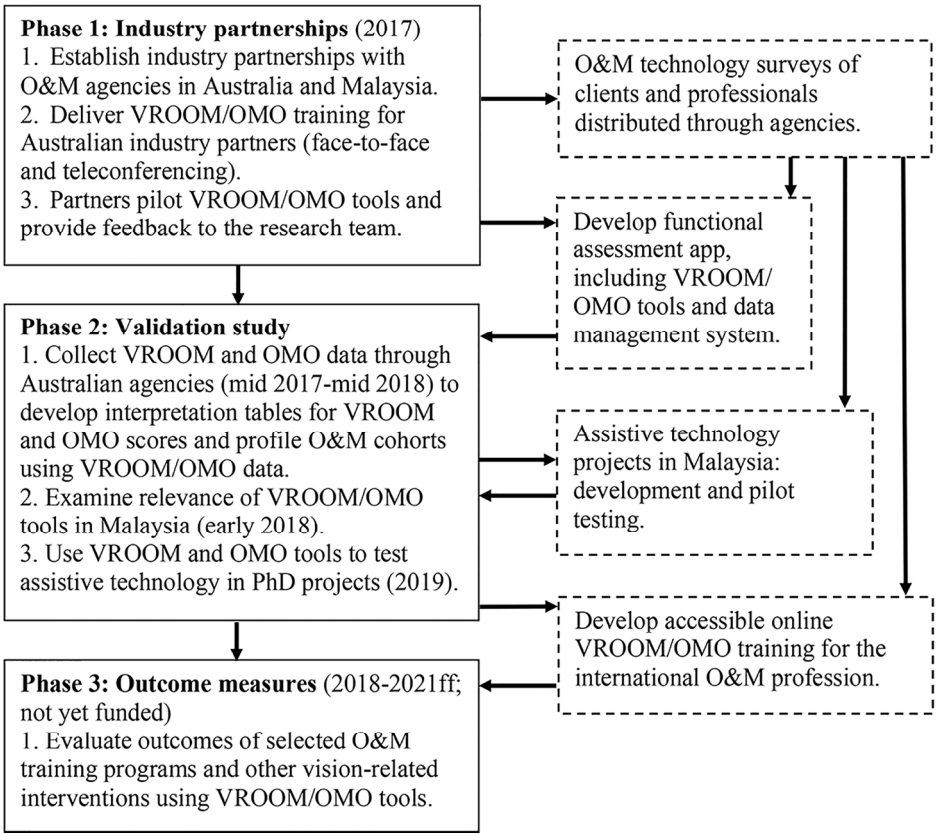

Figure 3: Workflow between different parts of the study. Solid line boxes indicate VROOM/OMO validation study. Dashed-line boxes indicate technology developments.

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Supplementary Information

Optimising technology to measure functional vision, mobility, and service outcomes for people with low vision or blindness: Protocol for a prospective cohort study in Australia and Malaysia

Appendix 1: The VROOM/OMO tools

The VROOM (table 1) and OMO (table 2) tools are intended for use by an orientation and mobility (O&M) specialist or dog guide instructor who is assessing a client's functional vision and mobility status during travel in the community. Both assessment tools are co-rated together by the assessor, the client, and any other relevant stakeholders present (e.g. family members, professionals).

The tools use the same measurement template: Part A measures elements of observed travel (out of 30), and Part B measures elements of wellbeing (out of 20). Subscales within each tool are aggregated to a score out of 50 on the spot so that scores can be compared and discussed with the client.

When to assess VROOM and OMO

The VROOM and OMO tools can be scored multiple times in different situations, facilitating functional comparisons:

- At Referral. Benchmark the client's functional skills, explore relationships between vision, mobility, and wellbeing, identify service options, and define program goals.
- To measure fluctuations. If the client's skills are known to vary in different conditions, assess in daytime or in best conditions and again at whatever time the client's skills are worst (e.g., light: compare day/night travel; fatigue: compare morning/late afternoon travel).
- To measure program outcomes. Assess before and after training/intervention in the same conditions (e.g., without, then with a new mobility aid).
- To measure change over time. Assess at regular intervals over time to measure functional deterioration (e.g., progressive vision or medical conditions) or functional improvement (e.g. consolidating new functional vision or mobility skills).

Instructions for assessors

1. During ordinary O&M assessment, interview the client about functional vision and mobility, then go for a walk together. Start the functional assessment in a familiar place (e.g., client's

home, school) and observe the client engaged in at least three travel-related tasks, then move to more dynamic places relevant to the client and observe at least three more travel tasks.

2. Discuss patterns and variations in behaviour with the client as you score each VROOM and OMO subscale together in any order. The co-rating conversation can be woven throughout your ordinary assessment, or happen at the end. Work out your own style.
3. The rating process is shared, but the weight of opinion can shift: the assessor might initiate ratings in Part A Observed Travel after seeing the client in action; the client's opinion might weigh more in Part B Wellbeing, which considers action in the previous month.
4. Differences of opinion might be due to lack of information or lack of insight. You might need to observe the client in more situations and/or involve other stakeholders in co-rating.
5. When there is indecision between two levels on a sub-scale, always choose the lower rating (before and after intervention). This captures the client's worst performance and gives room to improve.
6. Ratings need to be justified, so where possible, record brief comments from the client, the assessor, and other stakeholders near the relevant ratings.
7. Once you have scored every cell, aggregate the total VROOM and OMO scores, then discuss implications with the client.

Abbreviations in the VROOM and OMO tools

ECS: O&M Environmental Complexity Scale

Aids: SG=sighted guide; dog=dog guide; LC=long cane; SC=support cane; ID=identification cane; WC=wheelchair; Sc=motorised mobility scooter; MG=miniguide; GPS=global positioning system (e.g. Trekker Breeze, phone app); Ph=phone; Other=might include low vision aids.

O&M Environmental Complexity Scale (ECS)[1]

The VROOM and OMO tools use the O&M Environmental Complexity Scale to compare different travel environments (figure 1). The six levels of scale assume that travel challenges are cumulative, so the assessor only needs to note the highest level of complexity encountered during assessment.

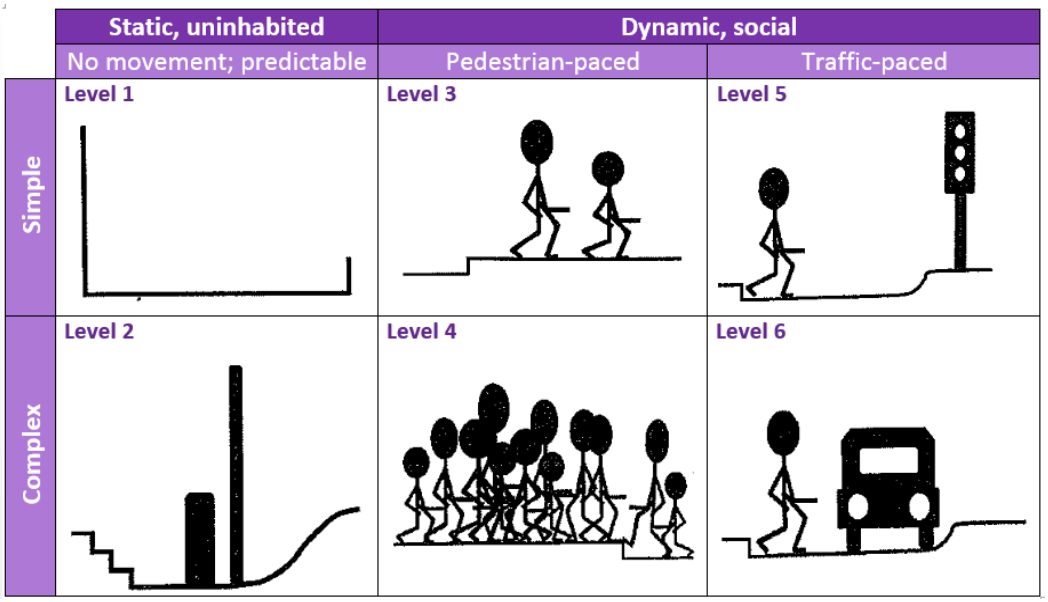

Figure 1: O&M environmental complexity scale

Level 1: Static, uninhabited places with level groundplane, no obstacles e.g., empty corridor, gymnasium or sports ground

Level 2: Static, uninhabited places with varying groundplane and/or obstacles e.g., steps, ramps, loose surfaces, furniture, poles

Level 3: Pedestrian-paced places (no faster than jogging) with a clear, continuous path of travel e.g., quiet residential footpath, workplace, or school corridors during class-time

Level 4: Pedestrian-paced places where the pathway is repeatedly obstructed and wayfinding is tiring e.g., market, busy car park

Level 5: Traffic-paced places where infrastructure supports crossing decisions e.g. traffic lights, islands, chicanes, crossing guards, zebras

Level 6: Traffic-paced places where the traveller must judge when it is safe to cross the road, e.g., mid-block priority roads, or places where traffic ignores the road rules

[1] Deverell L. O&M environmental complexity scale. *International Journal of Orientation & Mobility* 2011;4(1):64-77.

Table 1: VROOM tool

VROOM Part A: Observed Travel Vision-Related Outcomes in O&M Date: Starting time: Client: Assessor: Observed / Interview only		**Stable, familiar conditions; no hurry** e.g., home, local block Venues: _____ Highest ECS: 1 2 3 4 5 6 Light: Bright Dim Dark Aids: NoAid SG Dog LC SC ID EWC MWC Sc MG GPS Ph Other:	**Dynamic conditions; timeliness needed** e.g., road crossings, shops, crowds Venues: _____ Highest ECS: 1 2 3 4 5 6 Light: Bright Dim Dark Aids: NoAid SG Dog LC SC ID EWC MWC Sc MG GPS Ph Other:
SCORING **3 = Vision is primary** No touch or aid is needed **2 = Vision needs back-up** Rely on vision; use non-visual strategies to confirm **1 = Vision is secondary** Rely on non-visual strategies Vision sometimes useful **0 = Vision is useless** Use non-visual strategies	**Getting your bearings** Where am I? Which way do I go?	/3	/3
	Checking groundplane What's underfoot? Is it safe to step out?	/3	/3
	Wayfinding Is this the path? Is anything in the way?	/3	/3
	Recognising moving parts Who is around? Do I seek or avoid them?	/3	/3
	Finding things What am I looking for? How do I find it?	/3	/3
ECS=O&M Environmental Complexity Scale; Aids: SG=sighted guide; dog=dog guide; LC=long cane; SC=support cane; ID=identification cane; EWC=electric wheelchair; MWC=manual wheelchair; Sc=motorised mobility scooter; MG=miniguide; GPS=global positioning system (e.g. Trekker Breeze, phone app); Ph=phone			

VROOM Part B: Wellbeing	Score together from observations and discussion about activities **within the past month**	Comments & Score
Reading	0 I have no useful vision for reading text 1 If I'm close enough, I can identify large signs (e.g., stop sign) by text, size, shape, colour 2 I can sometimes read vehicle number plates & shop signs 3 I can sometimes identify different foods by looking at text and packaging (e.g., milk) 4 I can read regular print (i.e., letters, N12)	/4
Visual certainty	0 My vision is never useful when I'm moving around; too little, too late 1 I can't rely on my vision when I'm doing things 2 My vision causes hesitation and frustration; it undermines confidence when I'm moving 3 My vision has its limitations, but I know how to work with it 4 My vision is reliable for travel; I don't really have to think about it much	/4
Mobility aids (beyond home)	0 I use non-visual skills (cane/dog/guide) beyond home – my vision is useless 1 I rely on my cane/dog/guide – vision provides some extra information 2 I need non-visual skills sometimes (e.g., night travel, fluctuating vision) 3 I can go without, but a mobility aid gives me confidence, relieves fatigue, expands options 4 My vision is good enough for travel – I don't need a mobility aid	/4
People	0 I can't see people's shapes or movement; or see if a conversation partner moves away 1 I can see a body moving past, but I can't tell who it is; I sometimes collide 2 I can recognise people by their shape, colours, size or gait; I can usually avoid collisions 3 I can see faces, but not details; I do miss some social cues 4 I can recognise faces, read facial expressions and social cues	/4
Pleasure	0 My vision is un-motivating; it rarely or never prompts a closer look 1 My vision is limited or frustrating; often more trouble than it is worth 2 My vision is useful for some things, but not for others 3 I can see interesting things; it is usually worth the time it takes to look 4 I can see beautiful or engaging things that bring calm, contentment, excitement, even bliss	/4
RECOMMENDATIONS Part A: _____/30 Part B: _____/20 **Total Score: _____/50**		

Table 2: OMO tool

OMO Part A: Observed Travel O&M Outcomes Date: Starting time: Client: Assessor: Observed / Interview only		**Stable, familiar conditions; no hurry** e.g., home, local block Venues: _____ Highest ECS: 1 2 3 4 5 6 Light: Bright Dim Dark Aids: NoAid SG Dog LC SC ID EWC MWC Sc MG GPS Ph Other:	**Dynamic conditions; timeliness needed** e.g., road crossings, shops, crowds Venues: _____ Highest ECS: 1 2 3 4 5 6 Light: Bright Dim Dark Aids: NoAid SG Dog LC SC ID EWC MWC Sc MG GPS Ph Other:
SCORING **3 = Elite skills** Graceful, fluent, safe & effective in most places **2 = Competent skills** Safe & effective, but not always graceful & fluent **1 = Basic skills** Limited effective skills; needing consolidation **0 = Beginner skills** Unsafe/inadequate for the context	**Getting your bearings** Where am I? Which way do I go?	/3	/3
	Checking groundplane What's underfoot? Is it safe to step out?	/3	/3
	Wayfinding Is this the path? Is anything in the way?	/3	/3
	Recognising moving parts Who is around? Do I seek or avoid them?	/3	/3
	Finding things What am I looking for? How do I find it?	/3	/3
ECS=O&M Environmental Complexity Scale; Aids: SG=sighted guide; dog=dog guide; LC=long cane; SC=support cane; ID=identification cane; EWC=electric wheelchair; MWC=manual wheelchair; Sc=motorised mobility scooter; MG=miniguide; GPS=global positioning system (e.g. Trekker Breeze, phone app); Ph=phone			

OMO Part B Wellbeing	Score according to discussion about skills, attitudes and activities **within the past month**	Comments & Score
Activities	0 I find activities overwhelming 1 My mix of activities is not quite right; I don't know how to fix it, or I'm not yet ready for change 2 I like some of my activities, but I'm ready for new directions 3 I'm satisfied with my current mix of activities 4 I find my mix of activities challenging and enriching	/4
Connections	0 I feel isolated and lonely much of the time; I find it hard to connect with others 1 The people I know all do things for me; I feel quite dependent on others; I feel I have little to offer 2 I know where to find people; I'm linked in with some people or groups 3 I meet with people regularly; I feel welcomed and included 4 I have mutual friendships; we're there for each other; I actively contribute	/4
Life-space	0 I'm house-bound; I rarely go beyond the front gate 1 I do routine travel, only in well-known local areas (e.g., home block, local shops) 2 I explore in my local community; I like to try different routes 3 I travel to known places beyond the local community (e.g. commuting for work, visiting friends) 4 I like to explore beyond the local community, discovering new places	/4
Orientation	0 Even at home, I get disorientated; I have trouble understanding shapes, angles and distances 1 I can find the way at home by myself; beyond home, I need a companion or I get lost 2 I travel independently beyond home; if I get anxious or lost, I rely on help from other people 3 I travel independently beyond home; if I get anxious or lost, I can usually work it out by myself 4 I can go anywhere independently; I use mental mapping and I'm rarely disorientated for long	/4
Self-determination	0 My travel is managed by other people; I don't make the decisions 1 I need travel restrictions – I'm not always aware of what's safe and what is not 2 I'm aware of my own limitations, but I limit my travel rather than learning new skills 3 I'm aware of my own limitations; I plan ahead, source information and get help with my travel skills 4 I'm in charge; I evaluate my travel and learn from experience as I go; I develop my own skills	/4
RECOMMENDATIONS Part A: _____/30 Part B: _____/20 **Total Score: _____/50**		

Appendix 2: Socio-demographic and health questions

1. Age
2. Gender
3. Highest level of education (no formal schooling, primary/secondary school, post-secondary certificate/diploma, bachelor's degree, post-graduate certificate/diploma/ masters/PhD).
4. Occupation (full-time paid work, part-time paid work, unpaid work – home & family duties, volunteer work – community, student).
5. Is your income enough to meet your goals (sufficient, some compromises needed, insufficient)?
6. Language/s spoken at home
7. Vision condition/s
8. Onset of first vision condition/s (congenital: birth-first year, childhood: 1-18 years, adult >18 years), and pace of onset (gradual, abrupt).
9. Clinical vision measures if available (visual acuity, visual fields).
10. Where do you live (city, country town/village, isolated property or farm)?
11. Who you live with (alone, with immediate family members, with friends, relatives or acquaintances, in supported accommodation/aged care facility/hostel)?
12. Do you have issues that make your life complicated? If so, what?
13. Rate your overall physical fitness (very poor, poor, OK, good, very good).
14. Other than vision, what are your main barriers to travel (limited goals/motivation, disorganisation, family dynamics/demands, poor health/fatigue, finances, inaccessible physical environment, limited access to information, limited access to transport (public or private), safety concerns, get lost easily, self-conscious in public, other?
15. Have you used any of the following to support your travel in the past month (private transport, public transport, taxi/Uber, sighted guide/travel companion, dog guide, long cane, id cane, support cane, Miniguide, braille, print, audio/voice-over, computer/ internet, GPS, mobile phone/platform, best apps, other)?

Appendix 3: Technology survey for O&M clients

Q1. Gender

- ○ Male
- ○ Female

Q2. Age

- ○ Less than 10
- ○ 10-19
- ○ 20-29
- ○ 30-39
- ○ 40-49
- ○ 50-59
- ○ 60-69
- ○ 70 +

Q3. How would you describe your sight?

- ○ No light perception
- ○ Low vision and legally blind (eligible for pension)
- ○ Low vision, but not eligible for pension
- ○ Full vision

Q4. How do you travel beyond home?

- ☐ Long cane
- ☐ Dog guide
- ☐ Sighted guide
- ☐ Taxis/Ubers
- ☐ Public transport
- ☐ Private car
- ☐ Wheelchair
- ☐ Scooter
- ☐ Bicycle
- ☐ Other. Please explain: _____

Q5. Do you use any of the following devices? (can choose more than one)

- ☐ Mobile phone/s. Make and model:
- ☐ Tablet. Make and model:
- ☐ Portable braille notetaker Make and model:
- ☐ Laptop computer. Make and model:
- ☐ Desktop computer. Make and model:
- ☐ Standalone GPS. Make and model:
- ☐ Standalone OCR (optical character recognition) device. Make and model:
- ☐ CCTV (closed circuit television). Make and model:
- ☐ Personal activity monitor (e.g, Fitbit, SmartWatch). Make and model:
- ☐ Handheld sonar (e.g., Miniguide). Make and model:
- ☐ Sonar built into another device (e.g., Ultracane) Make and model:
- ☐ Barcode Reader. Make and model:
- ☐ Other. Please describe:

Q6. What formats do you use to support your travel? (can choose more than one)

- ☐ Print on paper
- ☐ Screen magnifier (zoom)
- ☐ Screen reader (voice-over)
- ☐ Voice recorder
- ☐ Braille
- ☐ I plan and/or travel with someone else
- ☐ Other. Please explain

Q7. Which apps do use to plan or carry out travel?

- ☐ Please list:
- ☐ I don't use apps.

Q8. What features do you particularly like in the apps you use?

- ☐ Please explain.
- ☐ I don't use apps.

Q9. Do you have access to technology training for travel purposes?

- ☐ Yes. Please describe: _____
- ☐ I would like more training. Please describe: _____
- ☐ No

Q10. Do you have ideas about how technology could be developed or enhanced to support your travel?

- ○ Yes. Please explain: _____
- ○ No.

Q11. Are you happy to be contacted by a Swinburne researcher to discuss your technology ideas?

- ☐ Your name: _____
- ☐ Best phone number: _____
- ☐ Best email address: _____

Q12. How did you respond to this survey?

- ☐ Independently
- ☐ With some assistance

Appendix 4: Technology survey for O&M professionals

Q1. Gender

- ○ Male
- ○ Female

Q2. Age

- ○ Less than 10
- ○ 10-19
- ○ 20-29
- ○ 30-39
- ○ 40-49
- ○ 50-59
- ○ 60-69
- ○ 70 +

Q3. What is your vision like?

- ○ Full vision
- ○ Low vision, but not legally blind
- ○ Low vision, and legally blind (< 6/60 acuity and/or <10° fields)
- ○ No light perception

Q4. What is your role? (you might have more than one)

- ☐ O&M specialist
- ☐ Dog guide instructor
- ☐ CBR fieldworker
- ☐ Other. Please explain: _____

Q5. What clients do you work with? (you may choose more than one)

- ☐ Adults
- ☐ Children
- ☐ People with neurological limitations / acquired brain injury
- ☐ People with intellectual disability

- [ ] People with physical limitations (e.g., use a support cane, wheelchair, scooter)
- [ ] People with mental health problems
- [ ] People with multisensory limitations (e.g., deafblind)
- [ ] Other. Please explain:

Q6. What devices do you use to support your O&M client work? (you may choose more than one)

- [ ] Mobile phone/s. Make and model:
- [ ] Tablet. Make and model:
- [ ] Portable braille notetaker Make and model:
- [ ] Laptop computer. Make and model:
- [ ] Desktop computer. Make and model:
- [ ] Standalone GPS. Make and model:
- [ ] Standalone OCR (optical character recognition) device. Make and model:
- [ ] CCTV (closed circuit television). Make and model:
- [ ] Personal activity monitor (e.g, Fitbit, SmartWatch). Make and model:
- [ ] Handheld sonar (e.g., Miniguide). Make and model:
- [ ] Sonar built into another device (e.g., Ultracane) Make and model:
- [ ] Barcode Reader. Make and model:
- [ ] Other. Please describe:

Q7. What O&M assessment resources have you used with clients?

- [ ] Agency assessment forms
- [ ] Checklists or rating scales. Please list:
- [ ] Books or theoretical approaches. Please list:
- [ ] Electronic resources (e.g., devices, apps). Please list:
- [ ] Physical materials. Please list:
- [ ] Other. Please explain:

Q8. What features do you like in the apps you use?

- [ ] Please describe.
- ( ) Not applicable

Q9. Do you use any accessibility features with a mobile phone? (list as many as you like)

- ☐ No
- ☐ Zoom/large print
- ☐ Reverse contrast
- ☐ Voice-over
- ☐ Other. Please describe.

Q10. Do you have concerns about using a mobile phone app to collect O&M assessment information?

- ○ No.
- ○ Yes. Please explain:

Q11. Do you have ideas about how technology could be developed or enhanced to support O&M practice (for you or the client)?

- ○ Yes. Please explain:
- ○ No.

Q12. Are you happy to be contacted by a Swinburne researcher to discuss your technology ideas?

- ☐ Your name:
- ☐ Best phone number:
- ☐ Best email address:

STROBE Statement—checklist of items that should be included in reports of observational studies

Re: *Optimising technology to measure functional vision, mobility, and service outcomes for people with low vision or blindness: Protocol for a prospective cohort study in Australia and Malaysia*

Please note: the results and discussion sections are not cross-referenced to the main document because this is a protocol paper not a research report.

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract **(p1)**
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found **(p2)**
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported **(p3-7)**
Objectives	3	State specific objectives, including any prespecified hypotheses **(p7-8, table 2)**
Methods		
Study design	4	Present key elements of study design early in the paper **(p8, figure 2)**
Setting	5	Describe the setting, locations **(p8-9, p15, supplement),** and relevant dates including periods of recruitment **(figure 2)**, exposure, follow-up **(p16)**, and data collection **(figure 2)**
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up **(p14, 16)** *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls **(p12)** *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants **p11-13**
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed **(N/A)** *Case-control study*—For matched studies, give matching criteria and the number of controls per case **(N/A)**
Variables	7	Clearly define all outcomes **(p5)**, exposures, predictors **(p16)**, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group **(p14, 15, supplement)**
Bias	9	Describe any efforts to address potential sources of bias **(p 16)**
Study size	10	Explain how the study size was arrived at **(p12)**
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why **(p17)**
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding **(p17)**
		(*b*) Describe any methods used to examine subgroups and interactions **(p17)**
		(*c*) Explain how missing data were addressed **(N/A)**
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed **(N/A)**

		Case-control study—If applicable, explain how matching of cases and controls was addressed **(N/A)** *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy **(p17)**
		(*e*) Describe any sensitivity analyses **(to be determined post hoc)**
Results (N/A)		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
		(b) Indicate number of participants with missing data for each variable of interest
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time
		Case-control study—Report numbers in each exposure category, or summary measures of exposure
		Cross-sectional study—Report numbers of outcome events or summary measures
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
		(*b*) Report category boundaries when continuous variables were categorized
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion (N/A)		
Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based **(p18)**

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.