SenseCog Home Care Study (Phase 2)

**Title:** Implementation and evaluation of a home hearing and vision care program to improve quality of life for frail older Australians

* **Lay Title:** Evaluating the impact of hearing and vision support in home care settings

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# Project Team Roles and Responsibilities

## Research Team

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| Name | Affiliation | Role | Responsibility |
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| Dr Helen Gurteen | School of Health and Rehabilitation Sciences, University of Queensland, Brisbane, QLD, 4072, Australia | Expert in hearing research | Development of research protocol and intervention materials  Participant recruitment  Data collection  Data analysis  Dissemination of research findings |
| Professor Nancy A. Pachana | Director, Healthy Ageing Initiative, University of Queensland, Brisbane, QLD, 4072, Australia.  Email: [n.pachana@psy.uq.edu.au](mailto:n.pachana@psy.uq.edu.au) | Expert in healthy ageing | Development of research protocol and intervention materials  Data analysis  Dissemination of research findings |
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| Dr John Newall | Department of Linguistics, Faculty of Medicine, Health and Human Sciences, The Australian Hearing Hub, 16 University Avenue, Macquarie University, NSW 2109, Australia.  Email: john.newall@mq.edu.au | Expert in hearing care | Development of research protocol and intervention materials  Data analysis  Dissemination of research findings |
| Dr Sabrina Lenzen | Centre for the Business and Economics of Health, University of Queensland, Brisbane, QLD, 4072  Email: s.lenzen@uq.edu.au | Expert in health economics | Development of research protocol and intervention materials  Data analysis  Dissemination of research findings |
| Professor Judy Lowthian | Bolton Clarke Research Institute, 347 Burwood Highway, Forest Hill, VIC, 3131  Email: jlowthian@boltonclarke.com.au | Expert in aged care research | Development of research protocol and intervention materials  Data analysis  Dissemination of research findings |
| Dr Smriti Raichand | Macquarie University Centre for the Health Economy, Macquarie Business School & Australian Institute of Health Innovation, Macquarie University, NSW 2109, Australia  Email: smriti.raichand@mq.edu.au | Expert in health economics | Development of research protocol and intervention materials  Data analysis  Dissemination of research findings |
| Bronwyn Franco | School of Health and Rehabilitation Sciences, University of Queensland, Brisbane, QLD 4072, Australia.  Email: b.franco@uq.edu.au | Expert in hearing research | Development of research protocol and intervention materials  Participant recruitment  Data collection  Data analysis  Dissemination of research findings |
| Lana Wilson | School of Health and Rehabilitation Sciences, University of Queensland, Brisbane, QLD 4072, Australia.  lana.wilson@uq.net.au | PhD Candidate | Development of research protocol and intervention materials  Participant recruitment  Data collection  Data analysis  Dissemination of research findings |

## Associate Investigators

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| Name | Affiliation | Role | Responsibility |
| Ms Emma Scanlan | Hearing Australia  [Emma.Scanlan@hearing.com.au](mailto:Emma.Scanlan@hearing.com.au) | Audiology liaison | Development of research protocol and intervention materials  Data analysis  Dissemination of research findings |
| Ms Carrie Lidscombe | Ballycara, Service Excellence Manager, Scarborough, QLD, 4020  clipscombe@ballycara.com | Age care partner liaison | Development of research protocol and intervention materials. Participant recruitment |
| Dr Dayna Cenin | Brightwater Group, Manager Brightwater Research Centre, Ingelwood, WA, 6052  Dayna.Cenin@brightwatergroup.com | Aged care partner liaison | Development of research protocol and intervention materials. Participant recruitment |
| Dr Leander Mitchell | School of Psychology, The University of Queensland, Brisbane, QLD, 4072  Email: [leander@psy.uq.edu.au](mailto:leander@psy.uq.edu.au) | Expert in re-enablement and access & equity advisor | Development of research protocol and intervention materials  Data analysis  Dissemination of research findings |
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| Ms Tiffany Militano | Wesley Mission, General Manager Community Aged Care, Community Aged Care Administration  Email: tmilitano@wmq.org.au | Aged care partner liaison | Development of research protocol and intervention materials  Participant recruitment  Data analysis  Dissemination of research findings |
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# Resources

* Resources required:
  + Sensory Support Worker
  + Professional transcription of interviews
* Funding secured from NHMRC MRFF (#MRF2024352) ($1,361,891.80)

# Background

Home care provided by professional caregivers enables older Australians to remain engaged and connected to their communities and to carry on living in their own homes rather than moving to residential aged care. The Royal Commission into Aged Care Quality and Safety found a strong preference by Australians to be able to remain living in their own home compared to residential age care if they ever required support or care.1 Health issues likely have a major effect on the quality of life and the ability to age in place. However, the health needs of Australian home care populations are not well characterised, particularly with respect to levels of cognitive and hearing/vision impairments. Hearing and/or vision impairments interact to significantly exacerbate the impact of cognitive impairments on quality of life, increasing behavioural and psychological symptoms, communication barriers and social isolation, cognitive decline, higher care needs and care costs.

Hearing and vision impairments often go under-identified and under-treated, particularly in people with dementia.2 In addition, as most home care providers do not include hearing/vision in care packages, there is a lack of routine assessments of hearing and vision or links to care pathways for people receiving home care. Thus, hearing/vision problems often go un-detected among people receiving care services due to prioritisation of other care needs and lack of staff expertise.3, 4 Furthermore, as onset is gradual, people may not realise they have a hearing/vision problem, or they view hearing/vision problems as an inevitable consequence of ageing, and so place less importance on preventing or treating the hearing/vision impairment. Cognitive impairments may result in someone being less likely to identify and report hearing/vision needs, less able to access hearing/vision services and require additional support for hearing/vision intervention.5 Further, sensory impairments, and resulting reactions, may be mistaken for behaviours associated with dementia, rather than investigated and addressed.6

Informal caregivers play a critical role by supporting activities of daily living, mobility and overall well-being of older adults with hearing and vision impairments.7, 8 Caregiving often leads to detrimental effects on the physical and mental health of family members who provide informal care to older adults.9 In particular, hearing and vision impairments in people with dementia impact their caregivers by increasing their social isolation, depression, relationship stress and care burden.10

Hearing and vision interventions are effective in improving health and wellbeing outcomes for older adults,5, 11 including people with dementia.5 Improved sensory healthcare approaches have been identified as an urgent priority by health professionals,12 consumer and community stakeholders,10 and in national reports,1, 4, 13 Effective management and support of hearing/vision health in home care settings requires a multi-faceted approach that considers the individual, home care service providers, the local environment, as well as the wider care ecosystem, which is currently not consistently integrated with community allied health services.1

To address this need, Investigators Dawes and Leroi developed the SENSEcog sensory support intervention for people with dementia in European homecare populations to improve outcomes for people with dementia and caregivers.14 Through a codesign process we have adapted the SENSEcog sensory support intervention for the Australian homecare context. The multi-faceted sensory support intervention is individualised to the recipient and provides a coordinated approach to support their hearing and vision needs. The intervention comprises of assessment and correction of hearing or vision impairments (or both) and home-based sensory support sessions to facilitate adherence to devices, enhance communication, foster social inclusion, and organise referrals to relevant support services.

## Research Questions

1. What is the prevalence of cognitive impairments, hearing/vision loss and other psychiatric disorders among people receiving home care services (Part 1)
2. What is the impact of the sensory support intervention on the quality of life of homecare recipients and their family members/informal caregivers? (Part 2)
3. What is the impact of the sensory support intervention on the homecare recipients’ functional ability, visual function, hearing function, mental and social wellbeing? (Part 2)
4. How does the cognitive status of the homecare recipient mediate the outcomes of the sensory support intervention and what are the additional supports required for people with dementia (Part 2).
5. What is the impact of the sensory support intervention on family member/informal caregiver mental well-being and quality of relationship with homecare recipient? (Part 2)
6. What are the costs and cost-effectiveness of the sensory support intervention compared to usual care? (Part 2)
7. To what extent was the intervention implemented as intended and what were the contextual issues that influenced intervention delivery and causal mechanisms through which the intervention achieved or did not achieve impact? (Part 2)
8. Is the intervention feasible, appropriate, and acceptable to participant? (Part 2)

## Expected outcomes

This project will implement a sensory support intervention for older adults in community populations to improve outcomes for Australians receiving home care services. The sensory support intervention was informed by extensive European work and was adapted to the Australian context through a co-design process with consumer representatives and key stakeholders. This project will determine the sensory support intervention's impact on quality of life, feasibility, acceptability, appropriateness, implementation considerations and cost-effectiveness.

# Project Design

## Research Project Setting

Part 1 of this study will be conducted in South-East Queensland metropolitan area, and Part 2 in the greater Brisbane metropolitan area. Our aged-care partners BallyCara, Wesley Mission, and Bolton Clarke, provide home care services to over 7,000 people in Brisbane. The setting of this research involves a combination of in-person and online methods for data collection. The epidemiological study will be conducted in participants’ homes or central locations (e.g., community centre). The intervention will be delivered to participants at their homes and in clinic settings (audiology and optometry). Participants will be interviewed at locations that are convenient for them, such as their homes or workplaces. Online surveys will also be utilised as a means of gathering data. This approach aims to maximise participant convenience and accessibility.

## Methodological Approach

### Part 1

A descriptive cross-sectional study to characterise and estimate the prevalence of cognitive impairment, hearing/vision loss and psychological disorders in older adults who receive homecare services.

### Part 2

Multiple theoretical and applied perspectives inform the conceptual framework underlying the SENSEcog AU study design. A type 1 effectiveness-implementation trial design will be used to test the effectiveness of the sensory support intervention while exploring implementation-related factors.15 Effectiveness will be investigated by a pragmatic, prospective pre-post intervention trial using mixed methods to evaluate (i) the impact of the intervention on homecare recipient’s quality of life and wellbeing; functional ability, behaviours; and sensory environment, (ii) the impact of the intervention on caregiver’s quality of life, well-being and relationship with the home care recipient and (iii) the cost related to, and cost-effectiveness of the intervention. Implementation-related factors will be investigated through a mixed-methods process evaluation underpinned by a theoretical framework derived from the UK Medical Research Council’s guidance on process evaluations.16

There are two streams to this research that will be investigated concurrently:

* **Stream 1 Effectiveness and Health Economics Evaluation:** To evaluate the impact of the sensory support intervention on (a) homecare recipient’s quality of life and wellbeing, functional ability, behaviours, and sensory environment, and (b) the caregiver’s quality of life, well-being and relationship with the homecare recipient and (c) to determine the costs associated with, and the cost-effectiveness of the sensory support intervention for homecare recipients with hearing/vision impairment compared to pre-intervention (usual care). ***Method:*** Pre-and-post intervention trial using mixed methods with health economic evaluations such as a within-trial analysis, economic modelling, and a budget impact analysis
* **Stream 2 Process Evaluation:** To determine the feasibility, appropriateness, fidelity, and acceptability of the sensory support intervention for people with dementia and hearing/vision impairment. ***Method:*** Mixed methods that include logbooks and semi-structured interviews (qualitative) and program adherence monitoring (quantitative).

## Participants

### Part 1 Participants

1. People aged > 65 years receiving home care services
   1. *Sample size:* For expected prevalence of hearing impairment (60%),17 vision impairment (21.8%),2 or dementia (67.7%),18 the required sample sizes are 369 (95% Confidence Interval (CI) 55%,65%), 262 (95% CI 17%,27%) and 342 (95% CI 62%, 72%), respectively for the margin of error or absolute precision of ±5% in estimating the prevalence with 95% confidence. Thus, approximately 369 home care recipients will be recruited. This sample size is calculated using the Scalex SP calculator.19
   2. *Inclusion/exclusion criteria:* People will be eligible to participate if they received home care services are aged 65 years or older, able to provide consent, and have adequate conversational English. We will exclude any person who is unable or unwilling to consent or has been hospitalised in the previous 2 weeks following acute illness, delirium, or major infection.
   3. *Sampling strategy:* We will aim for representation across the Brisbane region.

### Part 2 Participants

Participants will comprise home care recipients with hearing and/or vision loss and their family member / informal caregiver.

1. People aged > 65 years receiving home care services:
   1. *Sample size:* Approximately 87 home care recipients from part 1 who meet the inclusion will be recruited to part 2. The evaluation is powered to detect a standardised effect size of d=0.3 (because hearing/vision interventions are associated with small-to-medium but meaningful effects on health-related quality of life outcomes20, 21) in the primary treatment group (i.e. people with hearing or vision loss). Assuming a correlation of 0.6 between baseline and 12-week follow-up Health Utility Indiex-3 scores and an attrition rate of 20% at follow-up (a conservative estimate based on the 12%–15% rates observed in previous similar studies), we will need to recruit 87 people with vision and/or hearing impairment at baseline to achieve 80% power to detect the effect size at the two-sided 5% level of significance.
   2. *Inclusion/exclusion criteria:* People will be eligible to participate if they: i) have a range of cognition from normal until the moderately-advanced stage of dementia (Stage 6, defined by the 7-stage FAST Score22), ii) are a resident in their own home and receiving home care services; iii) have capacity to provide informed consent to participate, iv) have adult-acquired hearing and/or vision impairment ( hearing worse than 20 dB HL at 1000Hz or worse than 35 dB HL at 3000Hz in the better ear; presenting monocular visual acuity of not more than 6/12 in the better eye. People will be ineligible to participate if they have cataract(s) requiring surgical management within study period.
   3. *Sampling strategy:* Consecutive sampling will be used. Participants from part 1 who meet the inclusion criteria will be systematically invited to participate in part 2. This method ensures that all eligible participants are given an equal opportunity to participate in part 2, thereby minimising selection bias.
2. Family members/informal caregivers of a person aged 65 years and older receiving home care services:
   1. *Sample size:* Approximately 87 family members/informal caregivers of people receiving home care services will be recruited at baseline based on the power calculation outlined above (see point 1a).
   2. *Inclusion/exclusion criteria:* People will be eligible to participate if they are aged 18+ years; are an informal caregiver of the home care recipient who is participating in this study, are able to provide consent; and have adequate conversational English. People will be excluded if they are not in regular contact (less than weekly) with the person receiving home care services.

## Recruitment Strategies and Timeframes

* Participant recruitment is expected to take place between Jan 2024 and May 2025
* *Home care recipients and family members:* Participants will be recruited through home care providers.
* Study information will be disseminated using the following strategies:
  + Email distribution via home care providers (i.e., Wesley Mission, BallyCara, Bolton Clarke, etc.)
  + Advertisements in newsletters,on social media platforms, retirement village bulletin boards, and retirement village social clubs
  + Face-to-face information sessions facilitated by a member of the research team
  + Approached directly by a home care provider staff member.
* Example advertisements are available in Appendix A. Similar text may be presented in different formats as necessary for the dissemination mode.
* Potential participants will be asked to (1) contact a member of the research team if they are interested in participating in the study and would like further information or (2) be directed to a QR code or link to an online survey which will include a copy of the participant information sheet and the contact details of the research team. Participants may be asked to provide their contact details if they would like to speak to one of the researchers prior to consenting to the study (see Appendix B). For home care recipients and family members, they may give permission for a member of staff to pass on their contact information to the research team.
* Participants will be screened against the inclusion and exclusion criteria after they have had a chance to review the participant information sheet but prior to giving written informed consent. This will involve responding to a series of questions in an online survey or speaking to a research team member, depending on how the person initiates engagement with the research team (see Appendix C).

## Approach/es to the provision of Participant Information Statements and/or Consent

* All participants will receive a participant information sheet (see Appendix D) and will have the opportunity to discuss the project with a member of the research team and/or a family member before providing written, informed consent (see Appendix E). Consent may be obtained in paper form for electronically using Qualtrics or similar.
* All participants will be informed that they are not obligated to participate and are free to withdraw at any time without giving a reason; and that withdrawal will not impact services or the delivery of care from their provider.
* Individuals participating in qualitative interviews will be informed that they will be audio- or video-recorded and will be asked to consent to this explicitly.
* Additional considerations for older adults with dementia and hearing and/or vision impairment:
  + Persons with dementia will receive an information sheet written in accessible language and will meet with a member of the research team who will explain the purpose of the project and what they will be required to do (see Appendix F). All individuals taking consent will have received training in checking capacity in accordance with the legal requirements for conducting research and be asked to document their assessment (see Appendix G).
  + Persons with capacity to give informed consent for participation will be provided clear and appropriate explanations of the project and given adequate time for consideration and decision making.
  + For persons with dementia who are not able to consent, we will obtain proxy consent from their legal guardian who can provide consent on their behalf and assent from the person with dementia themselves.
  + Both participants and family members/caregivers will be reassured that there will be no negative implications should they choose not to participate. Consent will be regarded as a continuing process, as opposed to a single decision, and willingness to continue participating will be discussed at each separate data collection time point.
  + Some participants may not be able to complete the printed consent form for themselves, particularly those participants with low vision, although all forms will be made accessible using large font and digital forms. In this instance, a family member, friend, or person nominated by the participant can complete the form on their behalf and in their presence, but this must be witnessed and countersigned by the researcher taking consent. The consent form should be read verbatim to the participant to agree verbally to in these cases.

## Research Activities and Data Collection

Data collection will occur between March 2024 and December 2025.

### Part 1

Following informed consent, participants will complete a survey about demographic characteristics (age, gender, marital status, living status, current or former occupation, and years in formal education (Appendix H). In addition, the survey will capture the following information for home care recipients: health status (including hearing/vision needs), medication use, co-morbidities and healthcare resource use, date of most recent hearing and vision examination, and key aged care metrics (e.g., date of commencement of home care services and assessed level of care needs). The survey can be completed online using Qualtrics (or similar platform) or in paper form. The survey is expected to be brief and take 5-10 minutes to complete. For people with dementia or vision impairment, there will be the option to participate in a structured interview instead, either over the telephone/Internet or in-person (depending on where they are living).

A researcher will conduct the baseline assessment visits on the home care recipient at a central location (e.g., community meeting rooms) or at the participants’ home at a time convenient to the participant. The baseline assessment will assess hearing, visual and cognitive functioning and well-being using the methods described in Section 10 (Outcome measures). The baseline assessment is anticipated to take approximately 2 hours. Those that meet the inclusion criteria will be invited to enter Part 2 and the data collected in Part 1 becomes the baseline assessment for Part 2.

### Part 2

#### Stream 1: Effectiveness and Health Economic Evaluation

Target participant groups: Home care recipients, family members/caregivers

##### Description of the Intervention

The sensory support intervention was developed in accordance with the UK’s Medical Research Council’s (MRC) guidelines on the development and testing of complex interventions.23 Our previous research adapted the European SENSEcog sensory support intervention to the Australian context using codesign. The existing European SENSEcog sensory support intervention14, 24, 25 has been field-tested and trialled over five years in the SENSE-Cog program.

The sensory support intervention targets people aged 65 years and older with a range of cognition and hearing and/or vision impairments receiving home care services. The sensory support intervention is a complex intervention, meaning there is variation in how it is carried out with each participant. The principle aim of the intervention is to provide sensory support to older people with a range of cognition so that they might be able to continue living in their own homes. This aim be achieved through correcting their sensory impairment, supporting the correct use of devices, modifying their existing environment, accessing relevant support services, enhancing communication between the participant and their companion, and promoting social inclusion. The intervention will be delivered by specialist trained sensory support workers employed on the project in conjunction with referral to community hearing/vision clinicians (e.g., audiologists, optometrists). The intervention will be delivered over 3 months with 4 to 6 sessions (duration 1 to 2 hours) in the participants’ home. Each intervention step will be tailored to meet the participant’s individual needs dependent on their cognitive ability, current knowledge and skills, access to services and environmental factors. The complete intervention comprises three components with eight sub-components (Table 1). Component A and B of the intervention will be delivered in that order while the remaining components may be delivered in a flexible order dependent on participants’ needs.

Table 1. Description of the Sensory Support Invention components.

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| Component | Sub-Component & Description |
| A. Decision Support | **1. Identify any vision and hearing concerns and discuss support options**  *Key Component – (Time: 60 minutes)*  The Sensory Support Worker (SSW) discusses hearing and vision concerns and support options with participant and arranges hearing and/or vision assessments. |
| B. Correction of Sensory Impairment | **2. Optimisation of any vision or hearing impairment (arrange transport to and from hearing/vision appointment)**  *Key Component - (Time: 60 minutes)*  Vision and hearing assessments will be undertaken by an audiologist or optometrist according to standard procedures.  Optometrical services will be provided by the participant’s usual optometrist. Participants will be reimbursed for the cost of their spectacles up to a $250 amount.  Audiological services will be provided by Hearing Australia. Starkey Hearing Technologies will provide the hearing aids free of charge for the study. |
| C. Sensory Support | **3. Continuous training in correct use of sensory devices**  *Key Component - (Time: 60 minutes)*  The SSW will work with participants to enhance adherence and correct usage of the prescribed hearing aids and spectacles. This will include advice given on wearing times, handling, maintenance, cleaning, and storage of devices. The following tests will be administered to monitor participants' ability to manage their sensory equipment: Hearing Aid Skills and Knowledge test,26 SENSE-Cog Glasses Skills and knowledge test for vision,27 |
|  | **4. Home-based functional assessment and goal setting**  *Key Component - (Time: 120 minutes)*  A functional checklist will be used to ascertain how the home care recipient’s cognition ability and sensory impairments impact on a broad range of daily living activities. The outcomes of the assessment will help to shape other components of the Sensory Support intervention, including referral for support, social inclusion, and supplementary devices. The SSW will incorporate the results of the hearing and/or vision assessments and results the functional assessment to set personalised goals by the participants and their study partner using the Bangor Goal Setting Inventory.28 Goal setting is a highly successful strategy for use in this population.29 Goals will be revisited at each visit and the SSW will explore facilitators, barriers and resources to the goals and introduce skills and strategies to support progress. |
|  | **5. Communication training**  *Key Component - (Time: 60 minutes)*  The SSW will work with participants to enhance communication between the home care recipient and their family member / informal caregiver using the SENSE-cog Communication Manual which was adapted from existing evidence-based resources relating to hearing/vision loss and dementia to provide guidance and strategies to enhance communication in different settings. Copies of pre-existing materials such as leaflets will be provided to the participants. |
|  | **6. Referral to health and social services**  *Supplemental component - (Time: 20 minutes)*  Based on the functional assessments and goals set in sub-component 4, the SSW may refer participants to health or social care services in the community (e.g., psychological services, low vision services, geriatric psychiatry services, falls clinic, etc.) |
|  | **7.** **Fostering social inclusion through hobbies / interests / social groups**  *Supplemental component - (Time: 20 minutes)*  In line with participant’s goals set in sub-component 4, the SSW will provide information and guidance on opportunities to develop their own hobbies and interest or attend local social groups. |
|  | **8.** **Environmental modifications and assistive devices**  *Supplemental component - (Time: 20 minutes)*  Based on the functional assessment and goals set in component 4, the SSW may arrange and support the use of environmental modifications (e.g., lighting, placement of objects) or assistive devices (e.g., magnifiers). |
| *SSW, Sensory Support Worker* | |

##### Causal Assumptions about how change will be enacted

As the aim of the intervention is to improve the quality of life of people with dementia by improving sensory function through correction and behaviour change the COM-B component of the Behaviour Change Wheel (BCW) has been selected to explain how the intervention might work. The BCW and its COM-B component is an evidence-based behaviour change model.30 The central posit of the BCW is that for a behaviour change to occur an individual needs to have the capability “C” (psychological and physical capacity to engage in the activity), the opportunity “O” (a conducive environment that supports the behaviour change), and the motivation “M” (the conscious and sub-conscious process direct behaviour and decision-making).30 The theoretical basis and logic model for how the sensory support intervention might work is provided in Table 2.

Table 2. Theoretical basis and logic model for how the sensory support intervention might work.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Activities** | **Outcomes - Impact** | | |
| **COM-B domain** | **Component of the sensory intervention** | **Short-term**  **(Behaviour change (B) due to the intervention)** | **Medium-term**  **Immediate impact of the behaviour change (secondary outcomes of interest)** | **Long-term**  **Primary outcome of interest** |
| Capability (C) | Correct hearing / vision impairment  Training in correct use of hearing aids / spectacles  Communication training with dyad  Home-based functional assessment and tailored interventions to address support care needs enabled | Hear and see better  Improved uptake and adherence  Greater understanding of impairment  Improved relationships with caregiver  Enhanced cognitive stimulation | Enhanced cognitive functioning (MoCA)  Reduced neuropsychiatric symptoms  Less loneliness  Enhanced social interactions  Greater independence for person with dementia  Greater companion respite  Enhanced self-efficacy  Improved communication  Greater functional ability  Reduced apathy  Relationship satisfaction is higher in both home care recipient and caregiver  Improved caregivers health & well-being | Quality of life of home care recipient |
| Opportunity (O) | Provision of sensory devices  Environmental modification  Referral to health and social care services  Referral to social / hobby / interest activities | Hear and see better  Appropriate levels of support from caregiver  Uptake of health and social care services  Uptake of social / hobby / interest opportunities |
| Motivation (M) | Individualised goal setting  Referral to social / hobby / interest | Enhanced cognitive stimulation  Achievement of set goals  Enhanced uptake and adherence of sensory aids and social opportunities  Uptake of meaningful and enjoyable social/ hobby / interest activities |

##### Effectiveness and Health Economics Evaluation Data Collection

Following informed consent, participants who have not already completed the demographic survey in Part 1 will complete a survey about demographic characteristics (age, gender, marital status, living status, current or former occupation, and years in formal education) (Appendix H). Quantitative and qualitative outcomes will be captured at baseline, at the completion of the intervention and 3-months post-intervention completion. For home care recipients, data collected in Part 1 becomes their baseline data for Part 2. Data will be derived by a variety of methods, including self-or proxy-report questionnaires and semi-structured interviews. An overview of all outcome measures pertaining to home care recipients and informal caregivers is provided in Section 10 with outcome measure questionnaires provide in Appendix I.

Participants will have the option to complete self-reported questionnaires online, in paper format, or verbally via structured interview either in-person or over the phone. For people with dementia, questionnaires may be completed by a proxy (informal caregiver). It is anticipated that the questionnaires will take 70 and 55 minutes for home care recipients and their family member / informal caregivers to complete, respectively.

During and after the intervention delivery, a sub-sample (approximately 20%) of participants will be purposively selected based on a variety of intervention components undertaken to participate in a semi-structured, in-depth interview designed to complement the quantitative measures (quality of life, hearing and vision function, etc.). This interview will collect experiential data to understand acceptability of the intervention (see Stream 2). For further details on semi-structured interviews see Section 4.6.2 Stream 2 Process Evaluation.

At 6 months after the conclusion of the intervention, home care providers will be contacted to check on the vital and residence status of the participant. If the participant had been discharged from home care to residential care, information will be obtained on the date and reason for the discharge.

#### Stream 2: Process Evaluation

A process evaluation study based on the UK Medical Research Council’s guidance will be used to explore potential discrepancies between expected and observed outcomes and to understand how context may influence the outcomes. 16, 23 The process evaluation will employ logbooks, reflections, document review, surveys and semi-structured interviews to: i) determine the feasibility, appropriateness, fidelity and acceptability of the sensory support intervention which will be essential to scale the intervention in real-world populations;31 ii) characterise the contextual issues which may shape the delivery and the impact of the intervention; and iii) investigate possible causal mechanisms through analyses of potential moderators and mediators. This process evaluation will be embedded throughout the data collection process, capturing aspects of adherence, fidelity, barriers, and facilitators to the intervention.

##### Visit Logbooks

Visit logbooks will capture visit details, sensory support goals and actions, and survey data (Appendix J). The Sensory Support Worker will assist the home care recipient in filling in their logbook. Specifically, the homecare recipient logbook will contain Likert style ratings for feasibility, appropriateness, and acceptability. The family member/informal caregiver logbook will contain Likert style ratings for how the homecare recipient engaged with the visit, how the homecare recipient is adapting to their sensory device, and how confident the family member/informal caregiver feels in supporting the homecare recipient in using the device(s). It is anticipated that it should take 10 minutes to complete the logbooks. The sensory support workers will record in their logbook their experiences, ideas, and personal reactions to delivering the intervention, as well as make observations of uptake and use of the intervention by participants and note any barriers and enablers to the intervention delivery.

##### Semi-structured interviews

The interviews may be conducted online (e.g., using Zoom), via telephone, in person at a location convenient to the participant (e.g., home or work), or in-person at a central location (e.g., University, community meeting room). Open-ended questions will explore (1) quality of life, hearing and vision function, (2) acceptability of the intervention, (3) contextual issues and (4) barriers and enablers to intervention implementation were developed by the investigator team (Appendix K)). The interview topic guides will be piloted and reviewed by the consumer and community involvement advisory group for ease of administration, use of language, and level of understanding and minor adjustment will be made if necessary. Interviews are anticipated to go for one hour. All interviews will be audio or video-recorded to ensure we have an accurate record of what was said for analysis purposes. We will provide participants the option of (1) reviewing the interview transcript for accuracy and/or (2) reviewing the synthesised data in the form of member checking.

Necessary accommodation will be made for people living with dementia. All participants with dementia will be invited to have a significant other person accompany them to the interview for emotional and practical support. Interview questions directed at the person with dementia will be reframed to be more structured in line with the person’s communication abilities. For example, they might be asked a series of closed-ended questions in place of an open-ended question; and questions will be kept short and simple. Significant others will have the opportunity to elaborate on what the person with dementia has said.

# Participant withdrawal

Participants will be informed that they are free to withdraw from the research project at any time if they desire to do so. Participants who wish to discontinue will be asked to contact a member of the research team who will discuss the possibility of including their data that has already been collected in the analysis. However, for those participants who do not want their data included in the analysis, their data will be destroyed securely (e.g., electronic files deleted). Participants will not be disadvantaged in any way for deciding to withdraw from the research project. This statement appears on the Participant Information Sheets and Consent Form and will be emphasised verbally by the researcher when explaining the projects to the participants.

# COVID-19 Safety Protocol

Data collection will take place at a location convenient to the participant (e.g., home, work, community meeting room) or online (e.g., Zoom video meeting). Federal and state government and any service provider health requirements for density limits / spacing requirements, vaccination status, mask requirements and all other health directives will be followed according to each state health jurisdiction.

On the day prior to the study visit/interview, and again on the day of the study visit/interview, the participants and researchers conducting the study visit/interview will be asked the following health screening questions:

1. Do you have a high temperature/fever?
2. Do you have a cough, runny nose, sore throat, sneezing, or shortness of breath?
3. Do you have nausea or loss of smell?

If the participant/researcher answers 'yes' to any of the questions, the study visit/interview will be rescheduled for a new date at least seven days after the original scheduled date and/or via Zoom as appropriate.

Immediately prior to the commencement of the study visit/interview, participants will be provided with hand sanitiser.

# Data Management Plan

All electronic data will be downloaded and stored securely on The University of Queensland’s Research Data Management System and only members of the research team will have access. All hardcopy data will be stored securely in a locked filing cabinet in the School of Health and Rehabilitation Sciences or participating institution during the study and will be digitised for long-term storage; once digitised hardcopy data will be destroyed using the UQ Secure Destruction service. Audio-visual recordings may be sent securely to a professional transcription service for transcription, at which point all personal identifiers will be removed from the transcript and replaced with a participant number. A separate, password protected document will link participants numbers to their personal information (names, contact information, demographic information). All identifiable information (e.g., name, address, phone numbers, emails) will be deleted within 6 months of the end of the study, allowing time for feedback of results to participants. With the informed consent of participants, non-identifiable research data will not be destroyed. Following NHMRC Open Access Policy (2022; https://www.nhmrc.gov.au/about-us/publications/nhmrc-open-access-policy-2022), FAIR (Findable, Accessible, Interoperable and Reusable) Principles and UQ recommendations, (https://guides.library.uq.edu.au/for-researchers/publish-a-dataset-with-uqrdm-and-uq-espace), the non-identifiable research dataset will be archived in the UQRDM, a publicly accessible repository.

# Data Analysis

**RQ1. What is the prevalence of cognitive impairments, hearing/vision loss and other psychiatric disorders among people receiving home care services (Part 1)**

Descriptive statistics, such as frequencies and percentages, will be used to report prevalence for each variable of interest. Appropriate inferential statistical tests will be applied to compare prevalence of cognitive, hearing and vision across different sub-groups of home care recipients.

**RQ2. What is the impact of the sensory support intervention on the quality of life of homecare recipients and their family members/informal caregivers? (Part 2)**

Missingness of data and variability of the outcomes (baseline, 3- and 6-months) and point estimates, and difference in outcomes at 6-months post intervention will be calculated. The precision of estimates will be assessed using 95% confidence intervals. Change in outcome measures from baseline to 3- and 6-months will be estimated using multilevel linear or logistic regression models with a random effect of person to account for the repeated measures on individuals over time.

**RQ3 & 4. What is the impact of the sensory support intervention on the homecare recipients’ functional ability, visual function, hearing function, mental and social wellbeing? How does the cognitive status of the homecare recipient mediate the outcomes of the sensory support intervention and what are the additional supports required for people with dementia? (Part 2)**

A series of generalised linear models will be applied for each dependent variable: functional ability, visual function, hearing function, mental and social well-being; the independent variable will be time. Potential covariates will include demographic variables, health status, cognitive status, sensory functioning, and use of sensory support intervention. The nested structure of the data will be taken into consideration in the modelling.

**RQ5. What is the impact of the sensory support intervention on family member/informal caregivers’ mental well-being and quality of relationship with homecare recipient? (Part 2)**

Two generalised linear models will be applied for each dependent variable: family member / informal caregiver’s wellbeing and relationship with home care recipient; the independent variable will be time. Potential covariates will include demographic variables, home care recipient’s health status, home care recipient’s cognitive and sensory functioning and use of sensory support intervention. The nested structure of the data will be taken into consideration in the modelling.

**RQ6. What are the costs and cost-effectiveness of the sensory support intervention compared to usual care? (Part 2)**

We will model the cost-effectiveness of the intervention compared with pre-intervention (care as usual) alternatives and the budget impact of its implementation at a national level. This evaluation will inform policy makers on the total cost associated with, and value of investing in sensory support interventions in home care settings in Australia. The health economic evaluation will entail a within-trial analysis, economic modelling, and a budget impact analysis. These results will be reported according to the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) checklist.32

The within-trial analysis will include i) health benefits associated with quality of life outcomes for participants, as well as informal carers, and ii) healthcare resource use in patients and informal carers ascertained through a questionnaire based on the modified Resource Utilization in Dementia - Lite Version (RUD-Lite).33

Home care recipients’ quality of life will be measured using the Health Utility Index 3 (HUI3)34 and the Quality of Life – Aged Care Consumers (QOL-ACC) instruments.35 The HUI3 captures the sensory quality of life attributes and therefore will be more sensitive to the intervention’s effect. The HUI’s interviewer administered 40-question questionnaire will be used to capture quality of life and then mapped to the HUI3. We will use both self-assessment, which will be completed by the home care recipient, and the proxy assessments, which will be completed by the informal carer/family member. HUI3 will be used to estimate utilities using an available algorithm.34 The QOL-ACC will also be used to capture quality of life as the HUI3 has showed inconsistencies in persons with dementia. The QOL-ACC has been validated both for people with dementia and home care populations.35 QOL-ACC answers will be used to estimate utilities with an Australian algorithm. Utilities will be used to estimate quality adjusted life years (QALYs) which combine the utility of a health state with the time spent in that health state. QALYs will be used as the benefit measure in the cost-effectiveness analyses. Healthcare resource utilisation for patients will be measured using an instrument based on the RUD-Lite questionnaire.

Regarding the informal carer/family members, we will measure their resource utilisation costs using an instrument based on the RUD- Lite questionnaire, and the quality of life using the European Quality of Life 5-dimension 5-level (EQ-5D-5L) questionnaire. The RUD lite, a shortened version of the RUD questionnaire is a validated tool for capturing resource use in caregivers of dementia patients, in institutional36 and community care settings.33 The RUD lite is used to assess resource use in terms of caregivers’ time, hospital care and outpatient visits. Importantly, caregivers time is divided into three main categories: personal activities of daily living (PADL) e.g., bathing and dressing, instrumental activities of daily living (IADL) e.g., shopping and housekeeping, and supervision of the patient. This tool is a questionnaire and is not scored. It will be administered at baseline and during follow-up. The EQ-5D-5L questionnaire is a self-rated scale, which will assess the informal caregiver’s health-related quality of life (HRQoL) before and after the SENSEcog intervention. The EQ-5D-5L measures five health aspects and has five response levels of severity for each dimension. We will use a published Australian algorithm to derive the utility values for the cost-effectiveness analyses.37

The economic evaluation outcome will be the incremental cost-effectiveness ratio (ICER), which will determine whether the intervention is cost-effective using Australia’s cost-effectiveness threshold for QALYs.38 The ICER represents the incremental cost associated with a unit gain of health outcome of interest (e.g., a QALY), between two interventions. The ICER will be estimated as the difference between the costs of SENSEcog home care model and usual care (numerator), divided by the difference between the QALYs gained through the SENSEcog home care model and usual care (denominator).

The equation for ICER can be described as:

where C1 and C0 represent the costs associated with the SENSEcog home care model and the usual care, respectively, while E1 and E0 represent the difference of the SENSEcog home care model and the usual care, respectively.

The numerator and denominator for the ICER calculation will be estimated using generalised linear models accounting for data distribution and covariates. Sampling uncertainty will be handled by non-parametric bootstrap sampling. Bootstrap iterations will be plotted in the cost-effectiveness plane and cost-effectiveness acceptability curves.

The lifetime cost-effectiveness of the intervention will be estimated using economic modelling (e.g., Markov modelling). A literature review will inform the model structure and parameters not sourced from the trial. Uncertainty around the lifetime cost-effectiveness results will be explored using deterministic and probabilistic sensitivity analyses.

A budget impact analysis will determine the financial implications of implementing the sensory support intervention for the federal and/or state governments This overall cost to the Australian healthcare system will be estimated using projected utilisation estimates of sensory support interventions in home care setting over a relevant time horizon.

**RQ7 & 8 To what extent was the intervention implemented as intended and what were the contextual issues that influenced intervention delivery and causal mechanisms through which the intervention achieved or did not achieve impact? Is the intervention feasible, appropriate, and acceptable to the participant? (Part 2)**

Descriptive statistics will be used to examine feasibility, appropriateness, and acceptability. We will analyse the process evaluation data quantitatively and qualitatively, using descriptive statistics and content analytic approaches. Data from semi-structured interviews will be transcribed, independently coded with inductive and deductive approaches, with thematic analysis of the material. The thematic analysis will follow Braun and Clarke’s method (data familiarisation, generate initial codes, search for themes, review themes, define themes, writing up).39

# Data Linkages

Not applicable

# Outcome measures

**Outcome measures and data collection instruments used in Part 1 and Part 2 pertaining to home care recipients.**

Table 3. Baseline sample description – Part 1

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Variable | Instrument | Description | Estimated time |
| Demographic and health status | Age  Sex  Ethnicity  Level of home care  Number and type of co-morbidities  Medication | Purposefully developed questionnaire | Participants will be asked about their demographic and health status. | 5 mins |
| Cognitive and sensory functioning | History of hearing, vision, and cognitive function / management | Purposefully developed questionnaire | Participants will be asked if they have been diagnosed with hearing, vision or cognitive impairment/dementia and subsequent management for the conditions (e.g., use of hearing/vision devices, surgeries) | 5 mins |
|  | Hearing function | Automated audiometry by HearX | Each ear will be tested at pure tone frequencies of 0.5 to 8 kHz | 5 mins |
|  |  | Examination of the external auditory canal, tympanic membrane, and middle ear by Otoscopy | Each ear will be examined by an audiologist using an otoscope to detect abnormalities of the ear anatomy and wax build-up. | 5 mins |
|  | Vision function | Visual acuity screen by Peek Acuity | A smartphone-based vision check app provides a measure of visual acuity and a visual representation of the result.  Scores are provided in standard units of Snellen – including metric (6/6) and imperial (20/20) – and LogMAR (0.0) | 2 mins |
|  |  | Contrast Sensitivity by SPARCS40 | This online, computer-based test assesses contrast sensitivity in five areas of the visual field. Vertical square wave gratings of varying contrast are presented to the subject in each of the five test areas to establish contrast using a staircase strategy. Low contrast scores may indicate ocular disease and require follow-up with an optometrist. | 5 -10 mins |
|  |  | Central vision test using Amsler grid41 | Participants will be presented an Amsler grid which shows a grid pattern with a dot in the centre. They will be asked to look at the grid, holding it about 30cm from their face, and focus on the centre dot; each eye is tested separately. Wavy, broken, or distorted lines may be indicative of age-related macular degeneration and require a follow-up appointment with an optometrist. | 2 mins |
|  |  | Visual field-testing using confrontation41 | Confrontation field testing provides a gross assessment of the patient’s visual field using a comparison of the subject’s visual field with the examiner’s field using the examiner’s fingers. The examiner would position in front of the participant, facing her/him with their face level with that of her/his, at a distance of about a meter. The examiners and the participant’s fields are compared monocularly in all quadrants. Any defect will be identified by the absence of participant’s response to the target and will be followed up with an optometrist for detailed visual fields testing. | 2 – 5 mins |
|  | Global cognitive functioning | Montreal Cognitive Assessment (MoCA) (hearing or vision version as appropriate)5, 42 | MoCA: **30 items** assessing multiple cognitive domains. In the MOCA-H, the items that are presented in spoken format are substituted with suitably adapted written items. Likewise, in the MOCA-V, the items that are presented in written format are substituted with adapted verbal items. All versions are scored out of 30. A cut-off score of 24 signifies mild cognitive functioning. | 10 mins |
|  |  | Functional Assessment Staging Tool (FAST)22 | The FAST scale is a functional scale designed to evaluate patients with dementia. The FAST stages dementia from levels 1 to 7, with level 1 representing a normal adult and 7 representing severe dementia. The FAST scale has good reliability and validity.43 | 10 min |
|  |  |  | **Total** | **54 mins** |

Table 4. Description of Primary and Secondary Outcome Measures for Part 1 (Baseline) and Part 2 (Intervention effectiveness 3 months and 6 months).

| Variable | Instrument | Description | Estimated time |
| --- | --- | --- | --- |
| Primary outcome |  |  |  |
| Health-related quality of life | Health Utilities Index Mark 3 (HUI3)34 | **40-item** questionnaire interviewer administered (self-report and proxy) that is a multi-attribute utility instrument used to measures health-related quality of life over a 1-week period. It evaluates the attributes of vision, hearing, speech, ambulation, dexterity, emotion, cognition, and pain.34 | 10 mins |
|  | Quality of Life – Aged Care Consumer (QOL-ACC) instrument.44 | **6-item** questionnaire that incorporates dimensions important and preferred by older people in aged care services. It evaluates mobility, pain, emotional wellbeing, independence, social connections and activities. | 2 mins |
| Secondary outcomes |  |  |  |
| Social care-related quality of life | Adult Social Care Outcomes Toolkit (SCT4) 45, 46 | **9-item** self-reported questionnaire that is a multi-attribute utility instrument that captures aspects of social care-related quality of life. The self-reported version has good convergent validity and has good test-retest reliability (intraclass correlation coefficients of 0.87 and 0.85, respectively).45, 46 The SCT4 is appropriate to measure social care outcomes in community settings. | 5 mins |
| Functional ability |  |  |  |
| Instrumental Activities of Daily Living Scale47 | **8-item** questionnaire that assesses independent living skills. It has good validity47 and is useful for screening community-dwelling residents for dementia.48 | 5 mins |
| Visual function | National Eye Institute Visual Function Questionnaire 2549 | 25-item self-reported measure of vision-related function on the domains of general health, general vision, near activities, distance activities, driving, peripheral vision, colour vision, ocular pain, and vision-related role difficulty, dependency, social function and mental health. It has good reliability, validity, and robut psychometric properties49 | 10 mins |
| Hearing function | Revised Hearing Handicap Inventory for the Elderly Screening version50 | **10-item** self-report measure that asks about the emotional impacts of hearing loss. Psychometric testing revealed that a cutoff score of ≥6 detected hearing impairment with 70.3% sensitivity and 78.8% specificity.50 | 5 mins |
| Cognitive function | Montreal Cognitive Assessment51 (Hearing and Vision Impairment versions) | **30-item** test of eight cognitive domains: visuospatial/executive, naming, memory, attention,  language, abstraction, delayed recall, and orientation. The MoCA has good sensitivity and specificity for detection of dementia and mild cognitive impairment.52, 53 The sensitive and reliable MoCA-H will be used for people with hearing impairment.42 | 10 mins |
| Mental well-being | Geriatric Anxiety Inventory (GAI) Short Form 54 | **5-item** self-reported questionnaire that assesses anxiety in older adults. It is a reliable, valid and easy-to-use instrument.54 | 5 mins |
|  | Geriatric Depression Scale SF (GDS-5)55 | **5-item** self-reported questionnaire that assesses depressive symptoms in elderly people. The GDS-5 is a valid screening tool with good sensitivity (97%) and specificity (85%).55 | 5 mins |
| Dementia symptoms | Neuropsychiatric Inventory Questionnaire (NPI\_Q)56 | **12-item** self-administered questionnaire completed by informants about a person for whom they care. It provides a brief assessment of neuropsychiatric symptoms experienced by the patient by exploring 12 domains. The initial response to each domain question are Yes (present) or No (absent). If Yes, the informant then rates both severity of symptoms (3-point scale) and the associated impact of the symptoms on the carer (6-point scale). The NPI-Q has adequate test-retest reliability and convergent validity.56 | 5 min |
| Quality & quantity of Social Interactions | Questions from UK Biobank | **3-items** self-reported questionnaire that assesses social interaction | 3 mins |
|  |  | **Total time** | **70 mins** |

**Outcome measures for Family Members or Informal Caregivers**

Table 5. Outcome Measures and Data Collection Instruments for Family Members or Informal Caregivers

|  |  |  |  |
| --- | --- | --- | --- |
| Variable | Instrument | Description | Estimated time |
| Baseline description | | | |
| Demographic and health status | Age  Sex  Ethnicity  Education  Frequency of contact with resident | Purposefully developed questionnaire | 5 min |
| Intervention effectiveness (baseline, 3-and 6-months post intervention) | | | |
| Primary outcome |  |  |  |
| Health Resources Used | Resource Utilisation in Dementia (RUD) Lite.33 | The RUD-lite is a standardised instrument that measures data on formal and informal care resource use that uses the caregiver as the informant. The RUD-lite has two variant questionnaires, one for baseline (**24-items**) and one for follow-up (25-items) that are interviewer administered. The RUD instrument accurately estimates the amount of informal care provided by caregivers to dementia patients.33 | 10 mins |
| Health-related Quality of Life | EQ-5D-5L57 | **5-item** self-report questionnaire describing five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems and extreme problems. It also has a visual analogue scale to report overall quality of life. | 2 mins |
| Secondary Outcomes |  |  |  |
| Mental well-being | Geriatric Anxiety Inventory (GAI) Short Form54 | **5-item** self-reported questionnaire that assesses anxiety in older adults. It is a reliable, valid and easy-to-use instrument.54 It is validated for use in young and middle-aged adults.58 | 5 mins |
|  | Geriatric Depression Scale SF (GDS-5)55 | **5-item** self-reported questionnaire that assesses depressive symptoms in elderly people. The GDS-5 is a valid screening tool with good sensitivity (97%) and specificity (85%).55 It is validated for use in young and middle-aged adults.59 | 5 mins |
| Cognitive function | Montreal Cognitive Assessment51 (Hearing and Vision Impairment versions) | **30-item** test of eight cognitive domains: visuospatial/executive, naming, memory, attention,  language, abstraction, delayed recall, and orientation. The MoCA has good sensitivity and specificity for detection of dementia and mild cognitive impairment.52, 53 The sensitive and reliable MoCA-H will be used for people with hearing impairment.42 | 10 mins |
| Quality of Relationship | Relationship Satisfaction Scale60 | **7-item** self-reported questionnaire about communication and openness, resolving conflicts and arguments and the degree of affection and caring. Respondents answer each item using a 7-point scale ranging from 0 (very dissatisfied) to 6 (very satisfied). Higher scores indicate greater satisfaction with relationship. | 5 mins |
|  | Family Caregiving Role Scale61 | **16-item** self-reported questionnaire that assesses feelings related to care provision across three sub-scales: (1) satisfaction with the caring role, (2) resentment and (3) anger. Respondents answer each item using a 5-point Likert scale from 1 (strongly disagree) to 5 (strongly agree). A mean score are calculated for each subscale with higher scores indicating greater satisfaction with caring role and greater feelings of resentment and anger. The subscales had good internal consistency being 0.661, 0.804, 0.729 for satisfaction, resentment and anger, respectively.62 | 5 mins |
| Third-party hearing loss-related quality of life | Significant Other Scale for Hearing Disability (SOS-HEAR)63 | **27-item** scale that measures third-party hearing loss-related QoL in spouses of people with hearing loss. Measures the effects of hearing impairment on the significant other in the following domains: Changes to communication; Communication burden; Relationship changes; Going out and socializing; Emotional reactions to adaptations; Concern for partner. | 10 mins |
|  |  | **Total** | **52 mins** |

## Process Evaluation Outcomes

**Implementation Outcomes**

A combination of proxy measures, logbook data, surveys and semi-structured will be used to explore implementation.

***Feasibility*** is the extent to which an intervention is successfully conducted within a given setting.31 ***Appropriateness*** is the extent to which the intervention is compatible and relevant to people delivering or receiving the intervention.31 Feasibility and appropriateness will be assessed via person with dementia and care partner diaries and SSW log books which will contain the validated Feasibility of Intervention Measure (FIM) and Intervention Appropriateness Measure (IAM) surveys that are rated on a 5-point Likert scale (Completely agree to completely disagree) (Appendix J).64

***Fidelity*** is the degree to which an intervention is delivered as intended.31 Proxy measures will be used to determine fidelity: visit completion rates, visit durations, the support offered including type of corrective devices, the environmental changes to support sensory function made, and the number and types of referrals to extra-services or social opportunities, and feedback. This data will be collected via the SSW logbook. (Appendix J).

***Acceptability*** is degree to which people delivering or receiving the intervention believe it is agreeable, palatable or satisfactory.31 Acceptability will be explored at the end of each study visit with all participants via a survey in the home care recipients’ logbook (Appendix J), and during semi-structured interviews with a sub-sample of participants and with sensory support worker that will take place during and after the intervention. Exploration of acceptability will be guided by the seven constructs of the Theoretical Framework of Acceptability for Healthcare Interventions (TFA).65 The TFA is an established framework for assessing the acceptability of interventions where acceptability is conceived to be a multifaceted comprised of seven constructs: affective attitude, burden, ethicality, opportunity costs, perceived effectiveness, and self-efficacy.65 The generic TFA questionnaire was used for the logbook surveys.66

**Context**

Context is the set of circumstances that surround an intervention that encompasses intervening variables such as the physical, social, cultural and political environments that interact with and influence an intervention’s implementation.67 Context will be explored during semi-structured interviews with a sub-sample of participants and with sensory support worker that will take place during and after the intervention. Exploration of context will be guided by the Context and Implementation of Complex Interventions (CICI) Framework that assists in the structural analysis of implementation context at (e.g., individual), meso (e.g., community or organisation) and macro levels (e.g., regional, national).67 In addition, contextual data will be collected in the SSW logbook reflections and through debrief sessions (Appendix J).

**Causal Mechanisms**

Causal mechanisms are the mediators and moderators that attempt to explain why and how behaviour change occurs.68 Mediators and moderators will be explored during semi-structured interviews with a sub-sample of participants and with sensory support worker that will take place during and after the intervention. Exploration of the causal mechanisms will be guided by the Behaviour Change Wheel and COM-B model.30

# Results, Outcomes and Future Plans

* ***Plans for return of results of research to participants:*** All participants who indicate they would like to receive a verbal and/or written summary of findings at the completion of the study will be forwarded a copy of the results.
* ***Plans for dissemination and publication of project outcomes:*** The results from this study will be presented at both national and international conferences, disseminated to lay and scientific audiences using social media outlets and the project website (https://sense-cog.eu/), and submitted to peer-reviewed journals for publication.
* ***Other potential uses of the data at the end of the project:*** Nil
* ***Project closure processes:*** The project will be considered complete once all findings have been published and/or there are no plans for continued use with the data. After this date, all data will be archived and stored as per The University of Queensland archiving procedures.
* ***Plans for sharing and/or future use of data and/or follow-up research:*** There are currently no plans for sharing/future use of the data. However, deidentified data will be stored in an online data repository and made available for re-use if requested.

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