



Preliminary Findings From the SENSE-Cog Project

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<http://www.sense-cog.eu/>

Disclosures




I have no financial or non-financial interests to disclose related to this presentation

Starkey Hearing Technologies is providing hearing aids for this project but I receive no compensation from Starkey



What is the SENSE-Cog Project?

SENSE-Cog aims to investigate the combined impacts of **sensory** and **cognitive** problems on patients, and to develop new tools and at-home support that could improve quality of life and help optimize health and social care budgets and resource allocation across Europe

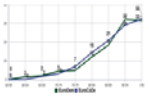
The Project Rationale

Mental, cognitive, vision and hearing health problems in elderly people are among the top 10 public health challenges in Europe

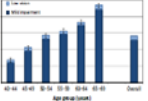
The European Commission, as part its Horizon 2020 program, funded the 'SENSE-Cog Project' to better understand the interrelationship between sensory impairments and cognitive and mental health functioning

The project is designed to identify novel screening and detection methods for diagnostic and therapeutic purposes and to translate this knowledge into clinical applications

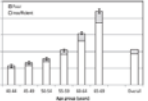
Hearing and vision impairment in dementia represents an unmet need



Dementia

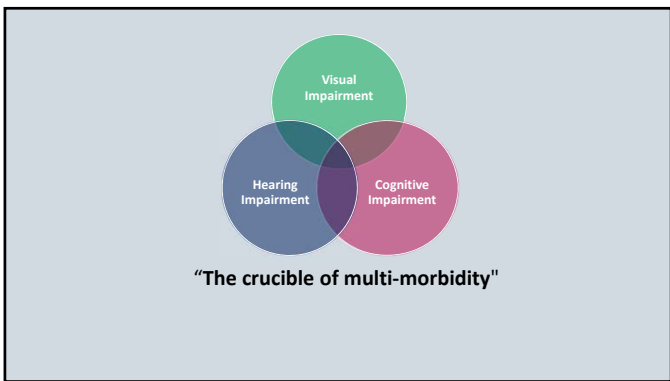


Vision impairment



Hearing impairment

- >33% of Europeans at age 90 have dementia
- 70% of Europeans >age 65 have sight or hearing loss
- Cognitive & sensory problems are under-treated



The Project

Project leads at the University of Manchester:

- Iracema Leroi, M.D., Ph.D., Clinical Senior Lecturer/ Honorary Consultant in Psychiatry
- Piers Dawes, Ph.D., Lecturer in Audiology

Funding




- 6.5 m € from Horizon 2020 (EU research program)

Start date

- 1 January 2016

Duration

- 5 Years

The Project Team



Universities and Hospitals

- UK, Greece, Cyprus, France, The Netherlands, Norway, Germany, Ireland

Subject Matter Experts (biostatistics, epidemiology)

- Germany, UK

Industry (devices)

- France, USA

City-government and “patient-public voice” members


Total: 17 participants in the project + connected teams and institutions



Participant No.	Participant organisation name	Country
01 - Coordinator	University of Manchester (UNIMAN) Iracema Leroi	United Kingdom
02 - University	European University Cyprus (EUC) Christosoulis Theodoros	Cyprus
03 - University	Manchester Metropolitan University (MMU) Abelton Yifan	United Kingdom
04 - University	University of Athens (UA) Andreas Flogas	Greece
05 - University	University of Nice, Sophia Antipolis (UNS) Philippe Robert	France
06 - University	University College Dublin	Dublin
07 - University	Erasmus University Medical Center Rotterdam (EUMC) Caroline Klaver	The Netherlands
08 - University	University of Tromsø (UiT) Thomas von Hanno	Norway
09 - University	Catholic University of Freiburg (CUF) Ines Heilmann	Germany
10 - SME	Dementia Pal Ltd (DEMPAL) Janice Pool	United Kingdom
11 - SME	WACO Technologies Ltd (WACO) Kate McLeish	United Kingdom
12 - Industry	Starkey Hearing Technology (STARKEY) Helen Morgan	USA
13 - NPO	HörTech gGmbH (HTCH) Michael Bachmann	Germany
14 - Industry	RSO Optique Essentielle Estabot, RSO Optique Essentielle Estabot (ESSE-EST) Anne Catherine Schuster	France
15 - SME	Gewerkschaft für Arbeitsgemeinschaften immanuel mbH & Co. KG (GAWCO) Bernd Fuchs	Germany
16 - Hospital	Centre Hospitalier Universitaire de Nice (CHUN) Renaud David	France
17 - University	University of Cyprus (UCY) Frah Constantinidou	Cyprus





The Project Aims



Aim I: understand the links among hearing, vision, cognitive and emotional systems


Aim II: improve the early detection and diagnosis of sensory, cognitive and emotional problems

Aim III: determine the effectiveness of a newly developed vision and hearing support intervention

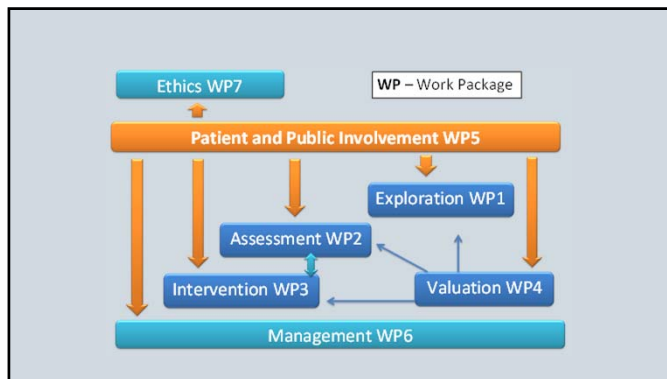
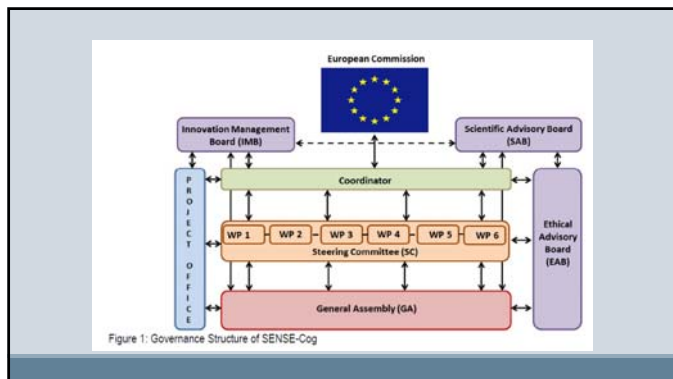



Aim IV: provide new information about the economic impact of sensory impairment on mental well-being and quality of life

Aim V: raise awareness and communicate the message that sensory health (hearing and vision) is a key feature of mental well-being



Project Structure



The Work Packages

Project aims will be each be supported by 6 dedicated Work Packages (WP) with specific objectives organized around SENSE-Cog's overall approach to promote mental well-being in elderly Europeans

- WP1: Exploration
- WP2: Assessment
- WP3: Intervention
- WP4: Valuation
- WP5: Participation, communication and dissemination
- WP6: Management, governance and ethics

WP1: Exploration

Objectives: explore the links among mental health, cognitive, hearing, and vision systems in various large cohorts of elderly Europeans to identify healthy and poor trajectories in cognitive and mental health, and thereby foster prevention and early diagnosis of cognitive and emotional problems by analyzing longitudinal data to:


- find the associations among mental health and cognitive status and sensory impairment, thereby identifying predictive risk profiles for good and poor mental health outcomes

- develop and apply advanced statistical modelling techniques, thereby understanding the contribution of sensory impairments on longitudinal trends and distal outcomes (i.e. institutionalization) that affect mental well-being
- identify and unravel the specific impact of gender, and sociodemographic factors on mental well-being



WP2: Assessment

Objectives:

- To *scope, review and critique* the most appropriate methods sensory and cognitive-emotional health screening in elderly people in different EU settings, including care pathways
- To *adapt and validate* existing cognitive assessment tools appropriate for people with sensory impairment AND sensory assessment tools for people with cognitive impairment
- To *adapt and validate* cognitive and sensory assessment tools for people from 'vulnerable communities' with language, cultural or educational barriers





- To *assemble* and *field test* a 'toolkit' of the adapted, validated tools for professional use in EU clinical settings
- To *develop, validate* and *field test* a composite computerized *e-screen* to simultaneously detect sensory, cognitive and emotional health in community settings
- To foster the *implementation* of the toolkit and *e-screen* in EU professional and community settings

WP3: Intervention

Objectives: To promote mental well-being in elderly Europeans by improving quality of life and other outcomes with hearing and vision impairments we will:



- scope, develop and field test an *intervention* to support hearing and vision function in PwD
- evaluate the *impact of the sensory support intervention* on mental well-being in PwD and their caregivers by means of a randomized controlled trial (RCT)
- explore the *experience of living with dementia and sensory impairment* and the impact of sensory support in PwD and their caregivers, using qualitative methods
- produce and disseminate a *training manual for hearing, vision and dementia therapists* to deliver 'sensory support' to PwD

WP4: Valuation

Objectives: To promote mental well-being in elderly Europeans with co-morbid mental health, cognitive and sensory impairments by providing health economic evidence to support improved services, we will:



- determine the *health economic resource use* and *associated cost* of the interaction between mental and cognitive health aspects and sensory impairment in the existing EU population databases from WP 1
- ascertain the *cost effectiveness of an intervention* to support sensory function in people with dementia (PwD) (from the RCT in WP 3)



WP5: Participation, Communication & Dissemination

Objectives: To promote mental well-being in elderly Europeans through engagement of the public AND the full and meaningful inclusion of patients, participants and caregivers in every aspect of our research efforts, we will:

- develop a trans-EU network of patients, study participants & caregivers ('Patient & Public Voice'; PPV)
- train our EU PPV network in the principles of research and how to provide meaningful input into the entire SENSE-Cog project


- evaluate the effectiveness and impact of the training on: (i) our EU PPV network's research understanding and level of inclusion in the WPs; and (ii) the level of acceptance and engagement of PPV input by our researchers
- develop a cross-disciplinary, trans-EU network of 3rd sector agencies to promote and disseminate SENSE-Cog findings beyond the academic community
- disseminate research output from SENSE-Cog with active public engagement

WP6: Management, Governance & Ethics

Objectives: To promote mental well-being in elderly Europeans by delivering a project of exceptional scientific and ethical standards on time and to target, we will:


- ensure the correct overall management of the project so as to strengthen and support the consortium members in achieving the objectives, completing the milestones on time and delivering the deliverables



- verify that the consortium's contractual duties are carried out by advising and guiding the participants to comply with the EU regulations and their contractual and legal requirements and to abide by the "good practice" of resources management as presented in the Financial Guidelines
- establish an effective communication infrastructure and foster integration within the consortium
- ensure compliance with the highest ethical standards for research

The Sense-Cog Field Trial

FEASIBILITY, TOLERABILITY AND ACCEPTABILITY OF A NEW INTERVENTION



Field testing the draft intervention

Open label, small scale feasibility study using

- rating scales • hearing aids & glasses lenses • therapist support
- participant diaries • qualitative interviews

Site	Participants	Basic / Extended Intervention
Nicosia	n=4 Hearing & vision n=0 Hearing only n=4 Vision only	n=8 Basic Intervention
Bordeaux	n=3 Hearing only n=5 Not recruited	n=3 Basic Intervention
Manchester	n=3 Hearing & vision n=5 Hearing only n=0 Vision only	n=4 Basic Intervention n=4 Extended Intervention

Research Questions

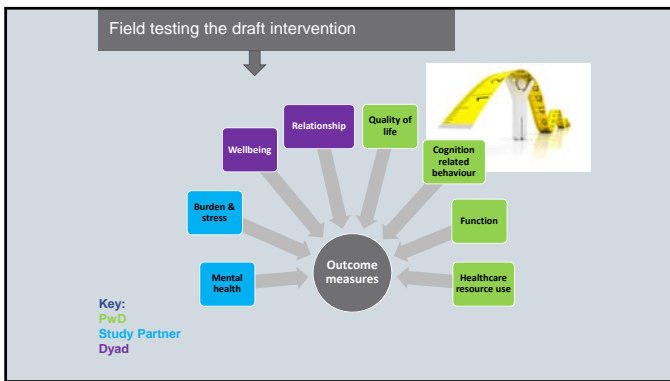


Overall Research Question:

- Is a newly developed, individualized, sensory support intervention for people with dementia and concurrent sensory impairment suitable for full-scale efficacy testing in a subsequent RCT in different European sites?

Specific research questions for the feasibility study



- What is the optimal manner to implement an SSI in the participant group?
- What is the acceptability and tolerability of the SSI by participants?
- What specific local contextual issues should be considered in delivering a full trial across multiple different EU sites?
- Is it possible to use the health economics data in a cost effectiveness model?

Methods

Research Design


- Single-arm, open-label field study with no control group, to assess the feasibility, acceptability and tolerability of a new sensory support intervention for people with dementia (PwD) and concurrent hearing and/or vision impairment

Participants

Participants with Dementia (PwD)

- 60 years and older
- Formal clinical diagnosis of dementia
- MoCA score of 12 and above
- Adult acquired hearing or vision impairment
- Living in ordinary community dwelling
- Has study partner willing to participate
- Has mental capacity sufficient to provide informed consent



Participants

Study Partner (SP)


- 18 years or older
- Able to read and write
- Not employed as professional caregiver to PwD
- Family member or close friend who is either a co-resident or in regular contact



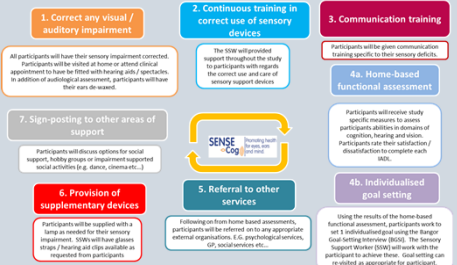
The Sensory Support Therapist (SST)

Prior experience delivering supportive interventions to people with long-term condition (audiologist, psychologist, nurse, optometrist)

- Received additional training in hearing and vision rehabilitation as well as on the protocol
- Assists the PwD and SP to achieve positive, lasting changes in behavior, as a result of optimized sensory rectification



Intervention Procedures: Sensory Support Intervention (SSI)



- Correct any visual / auditory impairment**
All participants will have their sensory impairment corrected. Participants will be referred at home or attend clinical appointment to have fitted with hearing aids / spectacles. In addition to audiological assessment, participants will have their ears de-waxed.
- Continuous training in correct use of sensory devices**
The SST will provide support throughout the study to participants with regards to the correct use and care of sensory support devices.
- Communication training**
Participants will given communication training specific to their sensory deficits.
- Home-based functional assessment**
Participants will receive study specific measures to assess participants' abilities in domains of cognition, hearing and vision. Participants will then satisfaction / dissatisfaction to complete each item.
- Sign-posting to other areas of support**
Participants will receive options for social support, hobby groups or impairment supported social activities (e.g. dance, cinema etc...)
- Referral to other services**
Following on from home based assessments, participants will be referred on to any appropriate external organisations, i.e. psychological services, GP, social services etc...
- Provision of supplementary devices**
Participants will be supplied with a lamp as needed for their sensory requirements. They will have glasses, straps / hearing aid clips available on request from participants.
- Individualised goal setting**
Using the results of the home-based functional assessment, participants work to set 3 individualised goals using the Bangor Goal Setting Interview (BSGI). The Sensory Support Worker (SSW) will work with the participant to achieve these. Goal setting can be revised as appropriate for participant.


Table 2: SENSE Cog 700 lists the variables of counts and assessments

	Baseline										SP										Assess	
Variable	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	
Valid number	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Valid words	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Countdown	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Countdown	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
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Countdown	0	1	2	3	4																	


Interview quotes - caregivers

- "My son said ... oh I've noticed a difference with me dad since he's worn those hearing aids"
- "That's a huge thing that he now manages to do that [change hearing aid battery] himself..."
- "Which is something very important, to feel comfortable and friendly with the person that visits you to do the research"
- "It took a lot of persuasion and encouragement to wear them"


Follow-up interview quotes: PwD



- PwD effort/fatigue:**
 - "Visit from the audiologist was 'tedious rather than tiring'"
- PwD motivation/engagement:**
 - "I used to look forward to them"
 - "We used to have a really open chat...and it was very useful."
- Helpfulness of SSI:**
 - "I got the ability to listen to people all the day rather than just gradually fading away after lunchtime...it's just made a huge difference."




Follow up interview quotes: SP




- SST training:**
 - "The thing for me was about the general environment that was a revelation it really was"
- Audiology visits:**
 - "The technology was good, what was hard was getting an appointment...we had a few false starts."
- Helpfulness of SSI:**
 - "I wasn't prepared for a dramatic change and it really was, after a week..."
 - "...not possible to talk to him after about 6:00 without getting your head bitten off and suddenly that all changed and it was really like switching on a light....I had (PwD) back"


Follow-up interview quotes: SP



- SST visits:**
 - "made easy by the fact that they come to the house...that makes a huge difference"
 - "it's very clear how much SSW's input got PwD much more happy and confident using the hearing aids."
- Receptivity to sensory equipment:**
 - "the first new thing (hearing aid usage) he's learnt to do in a very long time."





Qualitative interview themes



- Positives:**
 - Home visits were good
 - Achieved goals
 - Improved communication
 - Professional and friendly staff
- Improvements:**
 - Clearer hearing aid information needed
 - Uncertainty about follow-up procedures

Field trial outcomes

Feasible scales and diaries completion	Successful recruitment at 2 sites	MoCA inclusion score	RCT sites
SI delivery & components	Successful devices delivery	Outcome measures	Timeline deviations
Signal of effectiveness	High acceptability	PwD tolerability	Quantification of device adherence

Follow-up interviews themes


Session duration good	<i>Clearer hearing aid information needed</i>	Improved communication
Achieved goals	<i>Uncertainty about follow up processes</i>	Professional and friendly staff



RCT SSI Refinements

Delays in sensory equipment means SST visits can begin sooner	Reduce waiting times for audiology/optometry assessments
Ensure SST visits are no longer than two hours to minimise fatigue	Improve therapist/participant diaries to capture behavioural change


SST refinement




RCT Researcher Refinements

Replace GDS with HADS for non-geriatric spouses	Remove GSE as causes distress/complex
Include proxy reports for hearing aids/glasses skills and knowledge to improve SST delivery	Placing RSS in companion self-report booklet from researcher administered to minimise discomfort

Researcher refinement



Field testing the draft intervention




We have developed and refined a complex, novel 'Sensory Intervention' ready to be researched in a full scale, multi-site RCT.

Conclusion

It is feasible to conduct this research in a full scale, multi-site RCT, accounting for identified changes:

- measurement scales
- hearing and vision supply logistics
- development of the researcher and therapist practice manuals to ensure consistency of research delivery across sites




BMJ Open Improving hearing and vision in dementia: protocol for a field trial of a new intervention

Journal: *BMJ Open* | Published: 2018


Authors: *James Rogers, Peter Davies, Anne Pao, Christopher J Ambridge, Mark Lewis, Anne Horsburgh, David Reeves, Zhe Sun, Fan Yang, Suzanne Lewis*

Abstract: Hearing and vision impairment are among the most common and disabling comorbidities of dementia. This paper describes the protocol for a randomised controlled trial (RCT) to evaluate the effectiveness of a complex, novel 'Sensory Intervention' (SSI) designed to improve hearing and vision in people with dementia. The SSI is a multi-component intervention that includes hearing aids, glasses, and a self-report booklet. The trial will be conducted in a multi-site RCT design across three sites in the UK. The primary outcome is the proportion of participants who are able to use the SSI at the end of the study. Secondary outcomes include changes in hearing and vision, quality of life, and caregiver burden. The trial is currently recruiting participants and is expected to complete in 2020.


The SENSE-Cog RCT

36 week single blind randomised controlled superiority trial of 'Sensory Support Intervention' vs typical care

- Primary outcome: QoL (DemQoL) in PwD + HI/VI
- Secondary outcomes: function, cognition, behaviour, relationship satisfaction, caregiver outcomes and cost effectiveness
- n=354 dyads (n=177 in the active arm)




SENSE-Cog RCT: Sites




56

WP2: Assessment



Objectives:

- To *scope, review and critique* the most appropriate methods sensory and cognitive-emotional health screening in elderly people in different EU settings, including care pathways



REVIEW

Screening tools for the identification of dementia for adults with age-related acquired hearing or vision impairment: a scoping review

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Abstract: Cognitive screening tests frequently rely on items being correctly heard or seen. We aimed to identify, describe, and evaluate the adaptation, validity, and availability of cognitive screening and assessment tools for dementia which have been developed or adapted for adults with acquired hearing and/or vision impairment.


Method: Electronic databases were searched using various terms: "hearing disability" OR "vision disability" AND "cognitive assessment", supplemented by exploring reference lists of included papers and no conclusions with health professionals in selected additional sources.

Results: 1,511 papers were identified, of which 13 met inclusion criteria. Four papers related to tests adapted for hearing impairment, 11 papers related to tests adapted for vision impairment. Frequently selected tests were the Mini-Mental State Examination (MMSE) and the Montreal Cognitive Assessment (MoCA). Adaptations for vision impairment involved adding non-visual items or substituting visual items of usual tests. No study reported validity of the test in relation to detection of dementia in people with hearing/vision impairment. Some studies had a negative impact on the psychometric properties of the test.


Conclusion: While attempts have been made to adapt cognitive tests for people with acquired hearing and/or vision impairment, the primary limitation of these adaptations is that their validity is uncertain, detecting dementia among those with acquired hearing or vision impairment is not to be established. It is likely that the sensitivity and specificity of the adapted versions are poorer than the original, especially if the adaptation involved some deletion. Our review would involve some substitution in an alternative sensory modality followed by re-validation of the adapted test.

Keywords: cognitive screening, hearing impairment, prognosis, vision impairment, cognitive tests, dementia

WP1: Exploration



Objectives: explore the links among mental health, cognitive, hearing, and vision systems in various large cohorts of elderly Europeans to identify healthy and poor trajectories in cognitive and mental health, and thereby foster prevention and early diagnosis of cognitive and emotional problems by analyzing longitudinal data



CLINICAL INVESTIGATION

Longitudinal Relationship Between Hearing Aid Use and Cognitive Function in Older Americans

Jan Malvar, PhD^{1,2}, Peter Davies, PhD³, James Ramirez, PhD⁴, Grahk Tanphiphak, PhD^{5,6}, and Paul Robinson, PhD⁷, on behalf of the HEAR-ING RCT group

Abstract: HEAR-ING is the largest hearing aid use trial ever conducted in older adults. HEAR-ING is a randomized controlled trial comparing hearing aid use to no hearing aid use in older adults with hearing impairment. The primary outcome is cognitive function at 12 months. Secondary outcomes include hearing aid use, quality of life, and health-related quality of life. The trial is currently recruiting participants across the United States. The trial is currently recruiting participants across the United States. The trial is currently recruiting participants across the United States.

Visual and hearing impairments are associated with cognitive decline in older people

Aspi Moshayir,^{1,2} Pam Dawitt,³ Jessi Natchoo,² Gocce Terasakouch,² Nita Phrashton¹, on behalf of the SENSE-Cog WP1 group

Abstract: Introduction: Sight, hearing, and vision impairments among older people may contribute to the risk of cognitive decline and potential cognitive impairment. Objective: This study aims to determine whether single and dual sensory impairments (hearing and/or vision) are independently associated with cognitive decline among older adults with no cognitive impairment according to their impairment pattern. **Method and results:** We used data from visits 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100, 101, 102, 103, 104, 105, 106, 107, 108, 109, 110, 111, 112, 113, 114, 115, 116, 117, 118, 119, 120, 121, 122, 123, 124, 125, 126, 127, 128, 129, 130, 131, 132, 133, 134, 135, 136, 137, 138, 139, 140, 141, 142, 143, 144, 145, 146, 147, 148, 149, 150, 151, 152, 153, 154, 155, 156, 157, 158, 159, 160, 161, 162, 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963, 964, 965, 966, 967, 968, 969, 970, 971, 972, 973, 974, 975, 976, 977, 978, 979, 980, 981, 982, 983, 984, 985, 986, 987, 988, 989, 990, 991, 992, 993, 994, 995, 996, 997, 998, 999, 1000.



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The sensory support worker (SSW) participants will be recruited from a range of relevant professional backgrounds, e.g. occupational therapy, audiology, vision support or psychology or dementia community nursing. They will have an interest in supporting people with concurrent impairments and will be willing to be trained as a 'sensory support worker' for the purposes of the field test. We will strive to balance the sample by professional background across the three sites. A job description and person specification will be agreed by consensus input by relevant professionals, users and caregivers in the workshops and focus groups in the preceding steps.

Sensory support worker training: Full training will be given to SSWs in the role with 2 training days to familiarise them with the protocol. They will also have access to a SSW manual and a lead SSW who will be in contact with them regularly to provide mentoring, feedback and troubleshooting

A training session will be held at each site in order to ensure that each SSW participant is familiar with:

- Clinical and social aspects of the three domains of impairment (cognition, hearing and vision);
- The 'assessment of needs' protocol;
- The baseline assessment of level of impairment in each domain (cognitive, functional, behavioural, visual and hearing);
- The contents and administration of the draft SENSE-Cog Sensory Support Intervention package, which will include the toolkit of measures, educator/advice materials, sign-posting etc.

We will assess the support workers' knowledge and skills in the following way:

- a) Administering a pre- and post-training 'knowledge and skills questionnaire'
- b) Engaging in regular scheduled feedback with the senior support worker, as well as a monthly cross-site feedback session with all the support workers for problem solving and sharing of solutions.
- c) By ensuring the fidelity of the intervention delivery, receipt and enactment as described in Table 1 above through a checklist to be completed during / after each study visit.

The SSW will work with participants and their study partners on improving communication - we will utilise communication tips for people with hearing, vision and cognitive impairment based on guidance from "Action on Hearing Loss", "Deaf Action", information given by audiologists at the Manchester Royal Infirmary, Vision Australia and Henshaw's.

<http://www.actiononhearingloss.org.uk/live-well/living-with-hearing-loss/>

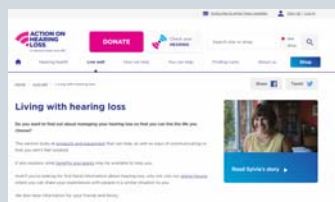


Table 1 The capability, opportunity, motivation – behavioural model and the corresponding components of the sensory support intervention leading to anticipated behavioural change

COM-B domain	Capability (C)	Opportunity (O)	Motivation (M)
Meaning	The individual's psychological and physical capacity to engage in the activity concerned	External factors which impact on the individual's ability to 'live well' with dementia. For this study, we focus on living well with dementia and sensory impairment	'Brain processes that energise and direct behaviour, as well as goals and conscious decision-making' (14). In dementia, these aspects may increasingly become impaired, particularly with the development of apathy (15)
SSI component (s)	c1: correct visual/auditory impairment; c2: training in correct use of hearing aid/glasses; c3: communication training; c4a: Home-based functional assessment	c5: referral to health and social care services; c6: provision of supplementary sensory devices	c4b: individualised goal setting; c7: referral to social/hobby/interest activities
Anticipated Behavioural Change (B): improved adherence to sensory equipment and improved quality of life			
Glasses and hearing aid correct and regular usage Participation in activities/hobbies/groups previously hindered by sensory impairment Attainment of goals previously hindered by sensory impairment Improved communication with spouse and in different environments			