

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

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ABSTRACT

Introduction Quality of life and other key outcomes may be improved by optimising hearing and vision function in people living with dementia. To date, there is limited research assessing the efficacy of interventions aimed at improving hearing and vision in people with dementia. Here, we outline a protocol to field test a newly developed home-based intervention, designed to optimise sensory functioning in people with dementia in three European sites. The results of this study will inform the design and conduct of a full-scale randomised controlled trial (RCT) in five European sites.

Methods and analysis In this multisite, single arm, open label, feasibility study, participants with dementia (n=24) will be assessed for hearing and vision impairments and be prescribed a hearing aid and/or glasses. Each participant will have a study partner ('dyads'). A subset of dyads will receive 'sensory support' from a 'sensory support therapist', comprising home visits over 12 weeks. The therapist will offer the following intervention: adherence support for corrective devices; adaptations to the home environment to facilitate sensory function; communication training; and referral to community-based support services. The primary outcomes will be process measures assessing the feasibility, tolerability and acceptability of: (1) the intervention components; (2) the method of implementation of the intervention and (3) the study procedures, including outcome assessment measures. Quantitative data will be collected at baseline and follow-up. Qualitative data using semistructured interviews will be collected postintervention and weekly, using participant diaries. Finally, we will explore a model of cost-effectiveness to apply in the subsequent full-scale trial. This feasibility study is a necessary step in the development of a complex, individualised, psychosocial intervention. The data gathered will allow logistical and theoretical processes to be refined in preparation for a full-scale RCT.

Ethics and dissemination Ethical approval was obtained in all three participating countries. Results of the field trial will be submitted for publication in a peer-reviewed journal.

INTRODUCTION

In Europe, there are approximately 10.5 million people living with dementia.¹ Furthermore, over two-thirds of older

Strengths and limitations of this study

- This study is limited by being adaptable to the pragmatic realities of a multicountry project while maintaining scientific integrity. For example, in terms of understanding different health organisations and ethics processes, monitoring accurate translation of questionnaire scales, permissions and copyright.
- This study is led by experienced research leaders across the fields of psychiatry, psychology, optometry and audiology.
- This study has an integrative, iterative approach to the research programme; testing the feasibility and operational aspects of the sensory intervention aims to enable a more robust, subsequent randomised controlled trial.

Europeans experience age-acquired sight or hearing loss.² Presbycusis is one of the most common age-related conditions³ and the rate of self-reported hearing difficulties increases in the older adult population with the onset of dementia.⁴ For the general population aged 75 years and above, one in four people experience sight loss and for those people aged 85 years and above this rises to one in three people.⁵ Sight loss in dementia is more prevalent than in healthy older adult populations.⁶ Despite the prevalence of sensory impairment in dementia, hearing and vision loss is often not diagnosed and not treated.⁷

The comorbidity of sensory impairment and dementia has been associated with an increased mortality rate in the elderly,⁸ and hearing and vision deficits are independent risk factors for increased cognitive impairment, lower quality of life, anxiety and depression in people with dementia.^{9–14} The higher prevalence of depression and disorientation may lead to isolation from family, loss of social activities and hobbies and marginalisation within the community, as the person is less able to use visual and auditory cues to orientate themselves and communicate.^{15–17} Caregiver burnout is compounded



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by communication barriers and a greater dependency of self-care for activities of daily living.¹⁸

There is a small existing literature regarding the application of hearing and vision rehabilitation in older people with sensory impairments,^{19–21} but this does not comprehensively extend to people who have concurrent cognitive impairment, particularly dementia.²² Despite this, there is some preliminary evidence that sensory remediation in dementia can be effective in the following ways: alleviating personal and social difficulties²³; decreasing the impact of behavioural and psychological symptoms of dementia²⁴; improving cognition with hearing aid use^{25 26} and reducing social isolation.²⁷ Nonetheless, to be effective, treatment should be introduced at an early stage in the condition²⁸ and should be tailored to suit the specific care needs of the individual.²⁹ For example, optometric assessments may need to be adapted for older people with dementia to account for the impact of impaired decision-making and the fluctuation in cognitive ability and mental capacity.³⁰

Psychosocial therapies offer a potential solution for improving quality of life for people with dementia and concurrent sensory impairment. Here, we outline a protocol to field test the feasibility and tolerability of a newly developed home-based, individualised intervention, with psychosocial aspects, designed to support hearing and vision functioning in people with dementia. The results of this field trial will inform the design and conduct of a full-scale randomised controlled trial (RCT) across several European sites evaluating the efficacy of this ‘sensory support intervention’ (SSI) on quality of life and other outcomes in people with dementia. This study is part of a wider programme: the ‘SENSE-Cog project’.

Theoretical basis for a new intervention

The new intervention being field trialled here, the ‘SENSE-Cog SSI’, is based on the premise that improving sensory deficits through corrective devices alone may not be sufficient to improve outcomes for people with dementia. Instead, the SSI aims to offer a period of sustained support delivered by a sensory support therapist (SST) to participants, to assist them to achieve positive, lasting changes in behaviour, as a result of optimised sensory rectification. This support is as follows: continuous training in use of glasses and hearing aids; promoting a ‘sensory friendly’ home environment; delivering communication techniques and assisting with access to community support services. It is anticipated these SSI components will lead to a change in behaviour by improving uptake of glasses and hearing aids through daily wear and second, improving the persons quality of life (measured by DemQol and DemQol Proxy),³¹ for example, by participating in activities which may have been previously hindered or avoided, as a result of sensory impairment. Encouraging a change in behaviour can be challenging and evidence has shown that many attempted behaviour changes may not be sustained, unless key underlying elements are addressed.³² In this

study, the underlying elements are existing attitudes and knowledge about participants’ own sensory impairment and towards sensory equipment, contributing to subsequent behaviours such as avoiding social situations or impaired communication. Consequently, we have developed our SSI using an evidenced-based model of behavioural change, the COM-B model,³³ as the theoretical framework. Each component of the SSI aligns with each domain of the COM-B model, as outlined in [table 1](#): ‘capability’ (C); ‘opportunity’ (O) and ‘motivation’ and aims to promote a sustained behavioural change (B) in the appropriate usage of sensory equipment and living well with dementia and sensory impairment (see [table 1](#)).

RESEARCH QUESTION

Overall research question

Is a newly developed, individualised, 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 AND ANALYSIS

Research design

This is a 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.

Study procedures

We will recruit 24 participant dyads, each comprising a PwD and their study partner, across three clinical sites (eight dyads per site) in Manchester, UK; Bordeaux, France and Nicosia, Cyprus. Following a full hearing and vision assessment, each participant will receive a hearing aid and/or glasses, if required, alongside either basic support of sensory equipment in an ‘abbreviated’ intervention (components 1 and 2) over three to four visits across 3–4 weeks or ‘extended’ support (n=4 participants in Manchester). The extended intervention will be delivered to participants by a research therapist, the SST. The research therapist has experience in delivering supportive interventions to people with long-term conditions and will receive additional training in hearing and vision rehabilitation. Starkey Hearing Technologies will provide an operations manual for the provision of

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' (33 p4) In dementia, these aspects may increasingly become impaired, particularly with the development of apathy 58 59 |
| SSI component (c) | 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

hearing devices and advice on care specific to the device. They will also provide training to the SST on the correct maintenance and cleaning of the hearing aid. The abbreviated version of the intervention will allow testing of the 'logistics' circuit' for the supply of the corrective devices (hearing aids and glasses), the scheduling of the hearing and vision assessments, the timing of the baseline and end-point outcome evaluations, the operations of the recruitment and retention strategy and the tolerability of the study protocol and procedures. Additionally, at the Manchester site, the extended intervention (components 3 to 7) will enable us to evaluate each component of the intervention and the fidelity of delivery of the intervention by the SST. After each visit, the PwD, study partners and the SST will complete a diary to capture experiences, acceptance, tolerability and adherence to procedures. A subset of participants (n=15) will undertake a semi-structured interview postintervention to ascertain perceptions and experiences of the intervention. The schedule of study procedures is outlined in table 2.

Study sample³⁴

Participants with dementia: inclusion criteria

To be included in the study, each person with dementia must meet the following inclusion criteria:

- ▶ Age 60 years or older;
- ▶ Has a formal, clinical diagnosis of dementia of the following subtypes: Alzheimer's disease (AD), as per National Institute of Neurological and Communicative Disorders and Stroke and the Alzheimer's

Disease and Related Disorders Association (NINCDS-ADRDA) criteria³⁵; vascular dementia (VaD) or mixed AD/VaD;

- ▶ Montreal Cognitive Assessment (MoCA)³⁵ score of 12 or above;
- ▶ Adult acquired hearing and/or vision impairment;
- ▶ Hearing threshold >35 dB HL over 1–3 kHz and/or vision score of present binocular corrected visual acuity of ≤6/9, 5 Snellen metric or +0.2 LogMAR (75 Early Treatment Diabetic Retinopathy Study (ETDRS) Score) and/or visual field of 10–20°;
- ▶ Speaks and understands the language of the intervention delivery;
- ▶ Is willing to accept sensory support;
- ▶ Is living in an ordinary community dwelling (including sheltered and very sheltered accommodation);
- ▶ Has a study partner willing to participate in the study (a family member or close friend who is either co-resident or in regular contact (at least three times per week));
- ▶ Has mental capacity sufficient to give informed consent to participate.

Participants with dementia: exclusion criteria

If the person with dementia has one or more of the following, they will be excluded from participation in the study:

- ▶ Congenital hearing or vision impairment;

Table 2 SENSE-Cog SSI field trial schedule of events and assessments

| Visit number | SSI* | | | | | | | | | | | Follow-up | | | | | |
|------------------------------------|------|----|---|---|-----|-----|---|---|---|---|---|-----------|---|----|----|----|----|
| | -2 | -1 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | | 9 | 10 | 11 | 12 | 13 |
| Visit week | / | / | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | |
| Identification | X | | | | | | | | | | | | | | | | |
| Information | X | | | | | | | | | | | | | | | | |
| Recruitment | | X | | | | | | | | | | | | | | | |
| Informed consent | | X | | | | | | | | | | | | | | | |
| Screening: HearCheck | | X | | | | | | | | | | | | | | | |
| Screening: PEEK Acuity (Worldwide) | | X | | | | | | | | | | | | | | | |
| Screening: visual field | | X | | | | | | | | | | | | | | | |
| Screening: MoCA | | X | | | | | | | | | | | | | | | |
| LV-VFQ-20 | | X | | | A | (A) | | | | | | | | | | | X |
| HHIE-S | | X | | | A | (A) | | | | | | | | | | | X |
| DEM-QOL | | X | | | A | (A) | | | | | | | | | | | X |
| DEM-QOL-P | | X | | | A | (A) | | | | | | | | | | | X |
| NPI | | X | | | A | (A) | | | | | | | | | | | X |
| GSE | | X | | | A | (A) | | | | | | | | | | | X |
| EQ-5D-5L | | X | | | A | (A) | | | | | | | | | | | X |
| EQ-5D-5L-P | | X | | | A | (A) | | | | | | | | | | | X |
| PHQ-15 | | X | | | A | (A) | | | | | | | | | | | X |
| SF-12 | | X | | | A | (A) | | | | | | | | | | | X |
| SF-12-P | | X | | | A | (A) | | | | | | | | | | | X |
| GDS-15 | | X | | | A | (A) | | | | | | | | | | | X |
| FCRS | | X | | | A | (A) | | | | | | | | | | | X |
| BADLS | | X | | | A | (A) | | | | | | | | | | | X |
| RSS | | X | | | A | (A) | | | | | | | | | | | X |
| RUD-Lite baseline | | X | | | | | | | | | | | | | | | |
| RUD-Lite follow-up | | | | | A | (A) | | | | | | | | | | | X |
| Ophthalmological assessment† | | | | X | | | | | | | | | | | | | |
| Audiological assessment† | | | | X | | | | | | | | | | | | | |
| Glasses fitting | | | | X | (X) | | | | | | | | | | | | |
| Hearing aid fitting‡ | | | | X | (X) | | | | | | | | | | | | |
| SST diary | | | | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| PwD diary | | | | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| SP diary | | | | X | X | X | X | X | X | X | X | X | X | X | X | X | X |

Continued

Table 2 Continued

| Visit number | Baseline | | | | | | | | | | SSI* | | | | | | | | | | Follow-up |
|--|----------|----|---|---|---|---|---|---|---|---|------|---|----|----|----|----|----|--|--|--|-----------|
| | / | / | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | | | | |
| Visit week | -2 | -1 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | | | | |
| Sensory devices training | | | | | | X | X | X | X | X | X | X | X | X | X | X | X | | | | |
| Functionality/usability of sensory devices | | | | X | X | X | X | X | X | X | X | X | X | X | X | X | X | | | | |
| Communication training | | | | X | X | X | X | X | X | X | X | X | X | X | X | X | X | | | | |
| Goal setting | | | | X | X | X | X | X | X | X | X | X | X | X | X | X | X | | | | |
| Goal review | | | | | | | | X | X | X | X | X | X | X | X | X | X | | | | |
| Goal outcome | | | | | | | | | X | X | X | X | X | X | X | X | X | | | | |
| Referral to clinical/social services | | | | | | | | | | X | X | X | X | X | X | X | X | | | | |
| Provision of supplementary devices | | | | | | | | X | X | X | X | X | X | X | X | X | X | | | | |
| Develop hobbies, interests | | | | | | | | | | X | X | X | X | X | X | X | X | | | | |
| Semistructured interview | | | | | | | | | | A | A | A | A | A | A | A | A | | | | |
| Revisit and recap (F2F or phone) | | | | | | | | | | | X | X | X | X | X | X | X | | | | |

Key. X this date; (X) on this date; A—may take place/follow on at this date for abbreviated intervention participants only; (A)—may take place/follow on at this date for abbreviated intervention participants.

*This details the process for the full intervention. The 'abbreviated' intervention will complete at week 3 with follow up assessments and follow-up interviews at week 4/5. The order of the SSI is flexible, depending on time to receive sensory equipment and participant's needs.⁶⁰

†Ophthalmological and audiological assessments will be conducted based on positive screening results. Not all participants will receive full clinical hearing and vision screening, if not required. Hearing aids and glasses are prescribed if deemed necessary by clinical assessment. Not all participants may require both hearing aid and glasses.

‡There may be a longer duration than 1 week between prescribing a hearing aid and receipt of hearing aid, depending if instant fit or moulded fit. The SST will undertake SSI visits during this time on weekly basis.

§Revisit and recap: these additional weeks of intervention allow for the SST to revisit and recap any of the previous components in more depth and to work on goal-setting and achievement activities with the person with dementia and study partner.

BADLS, Bristol Activities of Daily Living Scale⁴⁷; DEM-QOL, Dementia Quality of Life³¹; DEMQOL-P, Dementia Quality of Life Proxy³¹; EQ-5D-5L-P, EuroQol 5 Dimensions 5 Levels Proxy⁵⁵; EQ-5D-5L, EuroQol 5 Dimensions 5 Levels⁵⁵; F2F, face to face; FCRS, Family Caregiving Role Scale⁶¹; GDS-15, Geriatric Depression Scale (15-item)⁶²; GSE, Generalised Self-Efficacy Scale Chen⁶³; HHIE-S, Hearing Handicap Inventory for the Elderly Screening Tool⁶⁴; LV-VFQ-20, Low Vision Visual Functioning Questionnaire—20-item⁶⁴; MoCA, Montreal Cognitive Assessment³⁶; NPI, Neuropsychiatric Inventory Cummings⁶⁵; PHQ-15, The Patient Health Questionnaire (15 item)⁶⁰; PwD, person with dementia; RSS, Relationship Satisfaction Scale Burns⁶⁵; RUD-Lite, Resource Utilisation in Dementia⁵⁷; SF-12-P, 12-Item Short Form Survey Proxy⁵⁵; SP, study partner; SSI, sensory support intervention; SST, Sensory Support Therapist.

- ▶ Unstable, acute and current psychiatric or physical condition severe enough to prevent them from undertaking the study procedures;
- ▶ Has a less common form of dementia (eg, Parkinson's disease dementia, dementia with Lewy bodies, frontotemporal dementia);
- ▶ Is currently participating in any other medication or non-medication related trial;
- ▶ Has urgent treatment scheduled for hearing or vision (eg, cataract operation, treatment for macular degeneration needed).

Study partner: inclusion criteria

To be included in the study, the study partner must meet the following inclusion criteria:

- ▶ Age 18 years or older;
- ▶ Speaks and understands language of intervention delivery;
- ▶ Able to read and write;
- ▶ Not employed as a professional carer for the PwD, (except Nicosia, which may include professional, live-in carers);
- ▶ Is a family member or a close friend who is either coresident or in regular contact (minimum of three times per week).

Study partner: exclusion criteria

If the person with study partner has the following, they will be excluded from participation in the study:

- ▶ Has an unstable, acute and current psychiatric or physical condition severe enough to prevent them from participating.

Screening methods

Cognition will be screened by administering the MoCA.³⁶ Hearing will be screened with a simple handheld screening device, 'HearCheck'.³⁷ Vision will be screened using the 'PEEK Acuity App'³⁸ alongside the confrontation visual field test: 'can you see my hands?'.³⁹

Recruitment

Recruitment will occur over a 3-month period, beginning Spring 2017. In all three sites, participants will be recruited from local memory clinics and dementia research registries. Ethically approved participant information sheets (PIS) will be provided to inform potentially eligible participants about the study. At least 24 hours will be given for the potential participants to read and understand the PIS, prior to being offered a screening appointment. Informed, written consent will be obtained prior to participation and following an assessment of capacity to consent to the study.

The intervention

The SSI to be field tested was developed in accordance with the UK's Medical Research Council's (MRC) guidelines on the development and testing of complex interventions.⁴⁰ This involved a multistage programme which generated data that were synthesised to develop the current version of the

intervention. Details of this development programme are reported elsewhere⁴¹ and involved the following: (1) scoping the gaps in understanding, awareness and service provision for the hearing and/or vision impairment care needs of people with dementia, using a systematic literature review⁴² and an expert reference group; (2) investigating the support care needs through a literature search, stakeholder survey, focus groups, semistructured interviews and an expert reference group, leading to a prototype sensory support package; (3) refining the prototype through additional input from stakeholders using focus groups and semistructured interviews. Input from lay members (the 'patient and public voice') is a cornerstone of the work and informed the development process at each step.⁴³

Components of the intervention

The complete intervention comprises seven components. For this field trial, an abbreviated version of the intervention (the abbreviated intervention comprising only components 1 to 2) will be administered in the study sites in Nicosia and Bordeaux. In the Manchester site, the full intervention (the extended) will be administered.

Abbreviated intervention

Following screening, participants at all three sites will be administered the following intervention components:

Component 1: identify and correct any vision or hearing impairment

Vision and hearing assessments will be undertaken by an audiologist, optometrist or ophthalmologist, according to standardised procedures (see [table 3](#)).

Should medical management of cataracts or macular degeneration be necessary following this visual assessment, participants will be deemed ineligible for the study and referred for medical or surgical management as per standard care. Essilor International⁴⁴ will provide the lenses for the study. Starkey Hearing Technologies⁴⁵ (based in Stockport, UK) will provide the hearing aids. These will be the 'behind the ear' fitting Muse Mini BTE i2400.

Component 2: continuous training in the correct use of sensory devices

The SST will work with participants to ensure adherence and correct usage of the prescribed hearing aids and glasses. For example, advice will be given on cleaning and storing devices correctly and changing batteries as required (based on a checklist provided by Essilor Limited and Starkey Hearing Technologies).

Extended intervention

Following components 1 and 2, each participant in the Manchester site will be contacted by the research therapist, the SST, to undertake the remaining components of the intervention over a 12-week period, with a maximum of 12 weekly, one 2-hour sessions in the participants' home (see [table 2](#)). Each intervention step will be tailored to meet the participant's individual needs, which will be

Table 3 Audiological and ophthalmological examination procedures

| Audiology examination | Ophthalmological examination |
|---|---|
| Medical and social history | Current optical correction |
| Otoscope | Habitual vision/habitual Visual Acuity (both LogMAR and Snellen equivalent) |
| Ambient noise evaluation | Medical and vision history |
| Pure tone audiometry | Intraocular pressures |
| Uncomfortable loudness levels examination | Ocular motor balance assessment |
| Glasgow Hearing Aid Benefit Profile ⁶⁷ | Ocular health assessment using direct ophthalmoscopy |
| | Fundus |
| | Subjective prescription findings |
| | Objective prescription findings using retinoscopy |
| | Visual field testing |

considered from multiple perspectives (environment, existing knowledge and skills and access to services). The remaining five components (components 3 to 7) may be delivered in a flexible order.

Component 3: communication training

Communication difficulties are a barrier to living well with dementia and sensory impairment.⁴⁶ Based on findings from our focus group with occupational therapists from across Europe (step 2 of our development programme), communication difficulties between a person with dementia and sensory impairment and their spouse was a prominent theme. The SST will work with dyads on improving communication, using adapted, evidence-based materials.

Component 4: home-based functional assessment and goal setting

During baseline assessments, the PwD will complete the Bristol Activities of Daily Living Scale,⁴⁷ a home-based functional assessment of activities of daily living. Combined with the results of the hearing and/or vision assessment, this will form the basis for setting personalised goals by the participant and their study partner, supported by the SST. Goal setting is a highly successful strategy for use in this population.⁴⁸ Goals will be revisited by the SST on a weekly basis. The Bangor Goal Setting Inventory, which reviews goal attainment at 25%, 50%, 75% and 100% increments,^{49 50} will be the tool used by the SST to assist the participant dyad with goal setting and monitoring achievement of goals.

Component 5: referral to health and social services

Based on the functional assessment and goals set in component 6, the SST may refer participants to health or social care services in the community. This may include psychological services, geriatric psychiatry services, falls' clinics or other services, as indicated by the assessments and goal-setting exercises. This will be particularly important for participants who may be socially isolated and not in contact with supporting agencies.

Component 6: provision of supplementary sensory devices to enhance the home environment

Participants with visual impairment will be offered a lamp (The Daylight Company Twist Portable Lamp in White D33700) to assist with low vision in the home setting. Glasses' straps and hearing aid clips will be provided, if required. Participants will be signposted to beneficial devices to support vision and hearing function in the home, which may correspond with their goal setting.

Component 7: fostering social inclusion through hobbies/interests/social groups

People with dementia and sensory impairment may become isolated from family and the wider community.⁵¹ Thus, it is important to link dyads to community groups and resources, based on their hobbies and interests. Information about support for hobbies and interests will be sourced from local charities and healthcare providers.

Component 8: recap and revisit

The remaining weeks allow the SST to revisit and recap previous components, based on the participant's individual needs and goal-attainment.

Outcome measures

Primary outcome measures

A set of process measures will be undertaken to assess the primary outcomes of the study: are the intervention components, method of implementation and study processes are feasible, acceptable and tolerated? This includes an assessment of the following: recruitment; retention; screening procedure; inclusion/exclusion criteria; assessment of impairment; the role of support offered by the SST; delivery and fitting of devices and the functional assessment procedure. We will also include measures of behavioural change, as per the COM-B approach (capability, opportunity and motivation) regarding the use of hearing aids and glasses, captured by the diaries and semistructured interviews (see table 4).

Table 4 SENSE-Cog sensory support intervention field study primary outcomes measures and methods to capture outcomes

| Field study outcome | Method to capture outcome |
|---|---|
| PwD effort | In-house rating scale in PwD and SP diaries; semistructured interview with both dyad members |
| PwD fatigue | |
| PwD motivation | |
| PwD engagement | |
| PwD understanding | |
| Frequency/duration of SSI sessions | SST diary |
| SSI feasibility | Completion rates/missing data at baseline and follow-up |
| Is SSI delivered as intended? | SST diary checklist after each visit |
| Is SSI received as intended? | Records of contact between SST and recipient. This will include information on: number and duration of contact, sessions; method; referrals and protocol deviations. PwD and SP will have their knowledge of the SSI components checked by the SST |
| Is SSI enacted as intended? | SST, PwD, SP diaries; semistructured interview |
| Reach | Proportion of referred patients who enter the study |
| Recruitment | Number of patients approached versus number recruited |
| Retention | Number of participants withdrawing and reasons |
| Screening | Number of patients screened 'suitable' versus 'unsuitable' |
| Inclusion/exclusion criteria | Feedback from CRN/other recruiters about ease of screening criteria |
| Assessment of impairment and corrective device delivery and fitting | SST, PwD, SP diaries; feedback from research team and industry partners |
| Functional assessments | SST, PwD, SP diaries; analysis of frequency of missing data |
| 'Logistics circuit' of hearing/vision assessments and devices | SST, PwD, SP diaries; feedback from research team and industry partners |
| SST training | SST diary will identify areas of training for the role |
| SST visits | SST, PwD, SP diaries; semistructured interview |
| Glasses usage | |
| Hearing aid usage | |
| Receptivity to sensory equipment | |
| Helpfulness of SSI | |
| Motivation to continue with SSI activities | |

CRN, Clinical Research Network; PwD, people with dementia; SP, study partner; SSI, sensory support intervention; SST, sensory support therapist.

Secondary outcome measures

The secondary outcome is to gain an initial impression of treatment efficacy and ascertain the utility of different ratings scales. We will examine preintervention (baseline) and postintervention (follow-up) measures using a battery of rating scales of the following dementia-related outcomes, completed by the PwD and study partner: quality of life; behaviour/mood; general mental well-being; functional ability; mental health; social connectedness; burden and stress due to the caregiver role and caregiver/patient relationship. It is important to include economic evaluation during field testing to ascertain utility for the subsequent RCT⁵² and we will assess the use of the quality of life and healthcare resource instruments. For full details of scales corresponding to field study outcome, see [table 5](#).

Data analysis

Qualitative analysis

The qualitative analyses of the semistructured interviews and diaries will highlight aspects of perceived efficacy. Data from the diaries and verbatim data from the interviews will be analysed using summative content analysis.⁵³ The findings will be analysed into codes and descriptive evidence to support the coding framework. A subsection of interview sessions (n=15) will be audiotaped, transcribed verbatim and analysed using MaxQda qualitative software⁵⁴ by colleagues at University of Freiburg, Germany. The diary material will be analysed by the University of Manchester. Based on summative content analysis, we will formulate criterion from the theoretical background and the research question. This criterion will be as follows: the perception of the intervention material; adherence

Table 5 SENSE-Cog SSI field study secondary outcomes measures and methods to capture outcomes

| Tool to capture outcome | |
|---------------------------|--|
| PwD outcome | |
| Quality of life | Dementia Quality of Life ³¹ ; EuroQol 5 Dimensions 5 Levels ⁵⁵ ; 12-Item Short Form Survey ⁵⁶ |
| Cognition | Neuropsychiatric Inventory ⁶⁵ |
| General mental well-being | Generalised Self-Efficacy Scale ⁶³ |
| Function | Bristol Activities of Daily Living Scale ⁴⁷ |
| Cognition | Montreal Cognitive Assessment ³⁶ |
| SP outcome | |
| Quality of Life | Dementia Quality of Life Proxy ³¹ ; EuroQol 5 Dimensions 5 Levels Proxy ⁵⁵ ; 12-Item Short Form Survey Proxy ⁵⁶ |
| Mental health | Geriatric Depression Scale 15 ⁶² |
| Burden and stress | Family Caregiving Role Scale ⁶¹ |
| Healthcare resource use | Resource Utilisation in Dementia Lite ⁵⁷ |
| PwD and SP Outcome | |
| Relationship | Relationship Satisfaction Scale ⁶⁶ |
| Initial SSI efficacy | Dementia Quality of Life ³¹ and Dementia Quality of Life Proxy ³¹ |

PwD, person with dementia; SP, study partner; SSI, sensory support intervention

to the glasses; hearing aids and sensory support, documented in terms of behavioural change. We will deduce the categories in an iterative manner, based on data from the semistructured interviews and diaries. Within a feedback loop, the identified categories will be revised and refined in to the main themes and checked against the data for reliability.

Quantitative analysis

For this feasibility study, we did not perform a formal power calculation. Data will be entered into the Statistical Package for the Social Sciences V.20.0.0.2 (SPSS) and recoded so all items have a consistent valance. Any missing data will be recorded, along with any protocol violations. To explore participants' impression of change across various outcome parameters (eg, quality of life, cognition, behaviour, social connectedness, mental well-being, study partner indices), we will examine the difference (ie, change) between baseline (preintervention) and follow-up (postintervention) subjective rating scales of 'perceived efficacy' to explore the feasibility, tolerability and face validity of the measures for the subsequent RCT. The distributions of the secondary outcome measures, both preintervention and postintervention, will be summarised using appropriate measures of central tendency (mean or median) and variability (SD or IQR). Due to the small sample, we will use a large p value, 0.2, as an indication of effect only. The score distributions, both preintervention and postintervention, will be examined for degree of variability and ceiling and floor effects.

Economic analysis

We will summarise the statistics of EuroQoL 5 Dimensions (EQ-5D),⁵⁵ 12-Item Short Form Survey (SF-12)⁵⁶ and Resource Utilisation in Dementia (RUD)-Lite.⁵⁷ EQ-5D⁵⁵

and EQ-5D Proxy⁵⁵ version will allow health utility data to estimate quality-adjusted life years (QALYs). Costs will be calculated based on the number of healthcare resources used, collected using RUD-Lite and the reference costs estimated from published reports, for example, Personal Social Services Research Unit unit costs, administrative datasets and/or experts' opinion. We will conduct exploratory modelling work using preintervention and postintervention health economics data to ensure it is possible to use these data in a cost-effectiveness model. SF-12-based and Dementia Quality of Life-derived health utility data will be implemented as alternative ways to calculate QALYs.

Ethics and dissemination

The study has received favourable ethical approval for Manchester on 30th September 2016 from the NW Preston REC IRAS ID 212501, REC reference 16/NW/0685 and the Health Research Authority on 29th November 2016. For Nicosia, the study was reviewed by the Cyprus National Bioethics Committee on the 27th September 2016 and bioethical approval was granted. For Bordeaux the ethical opinion from the Comité de Protection des Personnes Sud-ouest et Outremer III was given on 25th May 2016.

Manuscripts with the results of this field trial will be submitted for publication in peer-reviewed journals. We will post results on the SENSE-Cog website (www.sense-cog.eu/) and on the SENSE-Cog Twitter account (@sense_cog). Feedback will be sent to the RCT Trial Development Team and disseminated at public engagement events.

DISCUSSION

This field trial is the next logical step in a multipart process, developing a new, complex intervention. The field trial was

designed to refine and test the feasibility, tolerability and acceptability of a draft intervention to support hearing and vision functioning in PwD living at home across Europe. Data from this field trial will highlight weaknesses and strengths in the components and implementation of the intervention, as well as the study procedures and conduct in preparation for a five-site, full-scale RCT beginning Autumn 2017. This field trial will also evaluate the efficacy of a new job role designed specifically for the SENSE-Cog research, the SST; allow refinement of the SST training, SST job description and step-by-step user manuals across sites prior to the RCT. While the RCT will test the efficacy of the SSI and impact on quality of life for people with dementia and study partners, trialling of these operational aspects 'in the field' prior to the RCT is imperative to ensure these can be optimally implemented in a larger scale, complex, multisite, cross-disciplinary study.

The outcome of the subsequent RCT aims to expound the benefits of a domiciliary approach for hearing and vision assessments and sustained support for people with dementia. This sensory support package is derived from existing local resources, driven by person-centred goals and could potentially lessen the economic impact on EU clinical services, by offering a home-based, individualised alternative to a pharmacological model of care for dementia and sensory loss.

Study timeline

The overall programme started on 1st January 2016. The Expert Reference was held in Athens, Greece in April 2016. Applications for ethical approval were submitted and favourable approval received in August and September 2016. This study will begin recruiting in Spring 2017 and will be completed by September 2017. The RCT to follow this development programme is scheduled to begin in November 2017.

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Contributors IL and PD are the programme leads and conceptualised and designed the field trial. JR is study coordinator and had primary responsibility for writing the paper. ZS and AP are research assistants and FY provided health economic input. MR and DR provided statistical input for the study. CA is a health psychologist and provided input on the theoretical framework. IH is leading the qualitative methods and analysis. All authors were involved in critical revision of the article.

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