Pilot and Feasibility Studies

STUDY PROTOCOL

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SENSE-Cog Residential Care: hearing and vision support for residents with dementia in long-term care in Ireland—protocol for a pilot cluster-randomised controlled trial

J. P. Connelly[1*], Erin Boland[1], Brenda Buckley[2], Niall Curley[3], Amr El Refaie[4], Miriam Galvin[1], Matthew Gibb[5], Liz Graham[6], Brendan Lennon[7], Alejandro Lopez Valdes[1], Ann-Michelle Mullally[1], Nicole Müller[4], Janice Nolan-Palmer[2], Gerald O' Nolan[1], Cíara O'Reilly[2], Valeria Raaft Rezk[1], Helen Rochford-Brennan[2], Katy Tobin[1], Helen Tormey[1], Dominic Trépel[1] and Iracema Leroi[1*]

Abstract

Background Hearing and vision loss is highly prevalent in residents with dementia (RwD) living in long-term care (LTC) facilities. Sensory loss often has a negative impact on quality of life and other dementia-related outcomes. Optimising sensory function may improve dementia-related outcomes in LTC facilities. The SENSE-Cog Residential Care pilot trial will evaluate whether a multi-faceted hearing and vision intervention for RwD and concurrent sensory loss is suitable for definitive testing in a large-scale cluster-randomised control trial (RCT) in Ireland and how this can best be achieved.

Methods This is a 6-month feasibility-pilot, multicentre, cluster RCT. Between eight and 15 LTC facilities (with an average of 5 RwD recruited per home) will be randomly assigned to receive either 'care as usual' (CAU) or a multi-component sensory intervention comprising (1) personalised resident hearing and vision support, (2) staff training in sensory health, (3) fostering a 'sensory friendly' environment, and (4) mapping sensory care provision with community-based audiologists and opticians. The intervention's feasibility, acceptability, and tolerability for residents and staff will be examined. In addition, a battery of exploratory outcome measures will be evaluated for suitability for the definitive trial and to inform the choice of primary and secondary outcome measures.

Discussion If the SENSE-Cog Residential Care pilot trial demonstrates that the sensory support intervention for residential care is feasible and tolerated in LTC facilities in Ireland, a larger definitive trial to evaluate its effectiveness in improving dementia-related outcomes will be conducted. Training materials, resources, and information will be made available to health and social care providers to enable the implementation of sensory support for RwD in routine LTC, potentially improving the quality of such care in Ireland.

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*Correspondence:
J. P. Connelly
connelj1@tcd.ie
Iracema Leroi
Iracema.Leroi@tcd.ie
Full list of author information is available at the end of the article

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Keywords Dementia, Hearing impairment, Vision impairment, Complex intervention, Cluster-randomised controlled trial, Non-pharmacological intervention, Sensory rehabilitation, Long-term care facility

Background

In Ireland, of the nearly 65,000 people living with dementia, over 30% live in long-term care (LTC) facilities [6, 7]. Of these residents with dementia (RwD), an estimated 75–90% have significant hearing loss, and estimated 40% or more have significant vision loss, which is nearly three times higher than individuals with dementia who live at home [6, 8]. Under-detection and under-management of hearing and vision loss in RwD is common [9–14].

Hearing and vision loss in dementia results in more rapid cognitive and functional decline [15], challenging behaviour (i.e. agitation, aggression, hallucinations), often requiring 'chemical restraints', and greater dependency and communication barriers [16–19]. This adds to the high rates of care worker 'burnout' in dementia care units [16] and higher costs of care. Crucially, the impact of hearing and vision loss in reducing quality of life for residents is significant [20–23]. Thus, addressing single and dual sensory loss in RwD is a potentially feasible and cost-effective way of significantly improving care standards, quality of life, and other key outcomes for RwD.

Two recent systematic reviews of interventions for people with dementia (PwD) [18, 24] found twelve hearing and five vision interventions (only one RCT), identifying an urgent need for multi-modal interventions. Sensory devices alone—especially in cases of complex auditory dysfunction, and in the absence of a comprehensive, personally tailored, hearing rehabilitation management plan, particularly in complex residential care situations—are insufficient, as several aspects of sensory function must be addressed. This assertion is supported by international guidelines on sensory health in dementia [25, 26]. To address this, the research group undertook the SENSE-Cog Trial [27, 28], which evaluated a hearing and vision rehabilitation programme for people with dementia living at home. However, since the care ecosystem of LTC facilities is markedly different to an individual's own home, this approach requires significant adaptation if it is to be applied to LTC settings.

In many LTC facilities, 'sensory unfriendly' environments with sensory under- or over-stimulation are common and may include poor or excessive lighting and noise pollution, all which influence optimal cognitive and behavioural functioning and, ultimately, quality of life [9, 29–32]. In a systematic review of 22 studies, hearing experiences of residents in care were reviewed [33]. Barriers and facilitators to optimal hearing experiences included under-detection of hearing loss, under-use of hearing aids, and the importance of the physical and social environment for effective communication. Staff training was also identified as a crucial gap. Studies outside Ireland have revealed that in LTC settings, hearing aids are often poorly maintained [13]. Support in using hearing aids, glasses, and other sensory aids is also lacking due to lack of staff awareness and lack of clear referral pathways [6, 13, 14, 34, 35].

A recent international study evaluated knowledge, attitudes, and practice (KAP) regarding sensory health of RwD in over 1000 LTC facility staff members in seven countries and found that (a) knowledge regarding the screening, diagnosis, and impact of sensory-cognitive comorbidity was low; (b) sensory loss in RwD was mostly unaddressed, with limited linked-up care pathways for sensory-cognitive health; and (c) LTC staff had a strong desire to implement better sensory care for RwD [36]. Furthermore, a systematic narrative review of hearing rehabilitation for RwD found no full-scale RCTs and a lack of definitive trials of multicomponent interventions [37]. Thus, the RCT described here will address two key gaps: (1) the insufficient provision of sensory healthcare for RwD in LTC facilities and (2) the limited evidence for how best to provide such sensory healthcare. The overarching aim of the study is to improve quality of life for residents with dementia in LTC facilities in Ireland by supporting hearing and vision function.

Research question

SENSE-Cog Residential Care aims to ascertain whether a hearing and vision (sensory) support intervention designed to enhance quality of life in residents with dementia (RwD) with concurrent sensory loss is suitable for definitive testing in a subsequent large-scale cluster RCT and how this can best be achieved.

Methods/design

This is a 6-month, feasibility-pilot, multicentre, cluster RCT. Between eight and 15 LTC facilities (with an average of 5 RwD recruited per home) will be randomly assigned to receive either 'care as usual' (CAU) or a multi-component sensory support intervention for residential care (SSI-RC) comprising (1) personalised resident hearing and vision support led by sensory champions, (2) staff training in sensory health, (3) fostering a 'sensory friendly' environment, and (4) mapping sensory care with community-based providers. A summary of the trial design is illustrated in Table 1. A cluster-randomised

Table 1 Schedule of enrolment, intervention, and assessment according to SPIRIT checklist. Abbreviations: RwD, resident with dementia; W, week

	STUDY PERIOD						
	Enrolment	Baseline	Follow-up				Final Visit
TIMEPOINT	$-t_1$	0		*Phone Call*	*Visit*	*Phone Call*	
	W 0	W 0	*W 0 - W 7*	*W 8*	*W 13 – W20*	*W 23*	*W 26*
							+/-2 weeks
ENROLMENT:							
Eligibility screen	X						
Informed consent	X						
Allocation		X					
INTERVENTIONS:							
Intervention			←			→	
Care as usual			←			→	
ASSESSMENTS:							
About the RwD							
Functional Assessment Staging of Alzheimer's Disease Tool (FAST)	X				X		X
Six Item Cognitive Impairment Test (6-CIT) [38]		X			X		X
Demographic and medical history		X					
Cumulative Illness Rating Scale-Geriatrics		X			X		X
Quality of Life for Adults with Dementia (QOL-AD) [39]		X			X		X
Dementia Quality of Life – Proxy version (DEM-QOL proxy) [40]		X			X		X
Neuropsychiatric Inventory – Nursing Home version (NPI-NH) [41]		X			X		X
Hearing Handicap Inventory for the Elderly – Proxy version (HHIE-proxy) [42]		X			X		X
Veteran's Affairs Low Vision Visual Functioning Questionnaire – Proxy version (VA-LV-VFQ - proxy) [43]		X			X		X
Perceived Health EQ-5D-5L with bolt ons - proxy [44]		X			X		X
Global Deterioration Scale (GDS) [45]		X			X		X
Engagement and Independence in Dementia Questionnaire (EID-Q) [46]		X			X		X
Serious and non-serious Adverse Events				X		X	
About the sensory champion & sensory champion training							
Demographics		X					
Knowledge, Attitudes and Practices (KAP)		X					X
Training Acceptability Rating Scale (TARS) [48]		X					
About general staff							
Demographics		X					
Knowledge, Attitudes and Practices (KAP)		X					X
Training Acceptability Rating Scale (TARS)		X					
About designated staff informant							
Demographics		X					
Nursing Home Booklet					X		X
Resident Care Note Booklet					X		X
About the dyad							
Qualitative interview (Only for the sensory intervention group)			As soon as possible after the end of the intervention				X

Note: Abbreviations: RwD = Resident with Dementia; W = week.

design was chosen because the SSI-RC is delivered at the level of the LTC facility, involving training staff and modifying the environment, thus making individual randomisation impractical due to the high risk of contamination between residents. Additionally, as LTC facilities operate as cohesive units, individual randomisation would cause greater disruption of standard care practices, burden staff, and complicate implementation of the SSI-RC [1].

Participant selection

Participants will be recruited within participating LTC facilities according to the following criteria.

LTC facility inclusion criteria:

- At least 60% of residents live with dementia
- Must be 'compliant' or 'substantially compliant' on all regulations based on Health Information and Quality Authority (HIQA) reports
- The Director of Nursing (DON) is willing and able to release staff to attend sensory health training sessions, which will be provided to all staff with direct care responsibilities (unless they specifically opt out) and to contribute to data collection
- The DON is willing to work with the research team to inform the staff, RwD and families/supporters about the study
- The DON is willing to identify potential sensory champions from existing staff
- The DON is willing to help identify potential RwD to participate in the study and provide an estimation of capacity to consent to participation

LTC facility exclusion criteria:

- Has received a 'non-compliant' status on one or more regulations on the most recent HIQA inspection report
- Has insufficient staff to provide two sensory champions to deliver the SSI-RC
- Is participating in any other research project involving service model change
- Is taking part in another research study that would interfere with the conduct or outcomes of SENSE-Cog Residential Care

Resident with dementia (RwD) inclusion criteria:

- Is aged ≥ 60 years
- Is a permanent resident of a participating LTC facility
- Has mild to moderate stage dementia as indicated by a score of 4–6 on the Functional Assessment Staging Tool (FAST) [38]; this can also be a clinically verified diagnosis or evidence of cognitive difficulties sig-

nificant enough to suggest the presence of dementia without having been formally diagnosed as having dementia, as per the protocol followed in the Attila study [39]
- If taking cognitive enhancing medication (i.e. cholinesterase inhibitors or memantine), this must be on a stable, unchanged dose for at least 4 weeks prior to screening
- Is willing to participate in the study and will accept the SSI-RC or nominated designated person expresses that they would have been willing had they had capacity
- Has capacity to give informed consent to participate in the study or has a nominated designated person to provide consent on their behalf

Resident with dementia exclusion criteria:

- Is unwilling to participate in the study
- Is unable to consent and if lacking capacity does not have a nominated designated person to consent on their behalf
- Unstable medical or psychiatric condition
- Part of any other sensory support-based intervention

Staff (sensory champions, designated staff informants) inclusion criteria:

- Is aged ≥ 18 years
- Is a current member of staff in a participating LTC facility, of at least 3 months duration, and is involved in the care of the RwD (all grades including: DONs; nurses; allied health professionals and front-line care workers)

Staff (sensory champions, designated staff informants) exclusion criteria:

- Has insufficient time allocation to participate in the education sessions of the SSI-RC

Recruitment

Recruitment of LTC facilities will include an equal balance of rural and urban, private, and public homes. All LTC facilities will be pre-screened through the Irish Health Information and Quality Authority (HIQA) quality control reports. The present study obtained data regarding the level of compliance of facilities, ascertaining their status as either compliant, substantially compliant, or not compliant through a pre-screening process. Facilities that are not-compliant on any of the regulations in their latest report are deemed ineligible exceeding 50% in their latest report are deemed ineligible. Additionally, the list of facilities will serve as a source for collecting contact details and monitoring communication attempts and the level of interest expressed by the facilities towards participation. LTC facilities will also be identified with support from collaborators, Nursing Homes Ireland (NHI), and The Alzheimer Society of Ireland (ASI) and supported by the HRB-Clinical 'Trials' Network, Dementia Trials Ireland. The DON at participating LTC facilities will assist researchers in recruiting potential sensory champions, designated staff informants, and RwD participants. A common feature of cluster-randomised trials is to recruit participants after clusters have been randomised; however, this can lead to recruitment bias whereby participants—who know what arm they are in—may opt in/out non-randomly [2]. To offset this, randomisation will take place after all baseline assessments are complete. Additionally, when recruiting, steps will be taken to clearly explain the randomisation process and the possibility of allocation to either the intervention or CAU arms.

Consent policy

This procedure will be in accordance with the Health Service Executive (HSE) National Consent Policy [40] regarding informed consent and research with individuals who lack capacity [40]. If a person lacks capacity, a representative—either a personal (family/friend) or nominated legal representative—will be asked to determine whether it is in the person's best interests to participate. When the Health Research Consent Declaration Committee (HRCDC) is convinced that the public interest in conducting health research is more important than obtaining explicit consent from the data subject, it can make a consent declaration.

Prior to obtaining written consent, the researcher will ensure that all participants are fully informed about the research and take time to answer any questions. Informed written consent will be obtained by the researcher at the participating LTC facility before any study-specific procedure for screening. All researchers will be fully trained in Good Clinical Practice (GCP) and mental capacity assessment skills. Figure 1 outlines the trial activity from screening to follow-up.

Consent process—residents with dementia

For RwD who have capacity, explicit consent will be obtained. At the initial visit, the researcher will provide an easy-read information and consent sheet—reviewing it both verbally and visually with the RwD—and observe the RwD closely to ascertain if participation is sufficiently understood. Consent will be re-confirmed at a second visit 1 week later to again ensure comprehension. If the

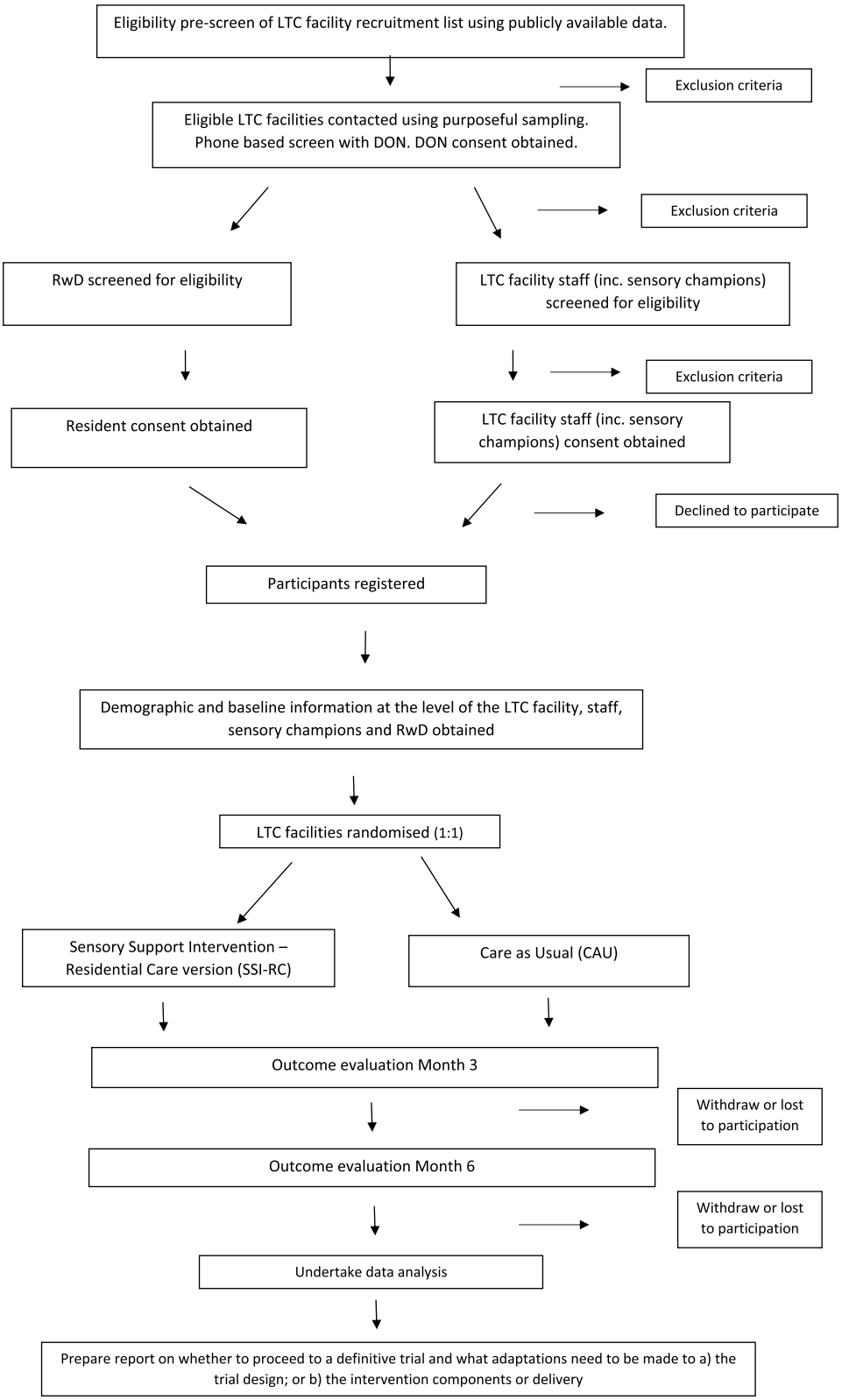

Fig. 1 Trial flow diagram. The flow of participants through the study from initial contact to study termination is outlined in a CONSORT diagram

Table 2 Clinical audiology and ophthalmology examination procedures

Audiology examination	Ophthalmological examination
• Otoscopy: an examination of the pinna (outer ear) and external auditory meatus (ear canal) using the Irish Society of Hearing Aid Audiologists (ISHAA)-recommended procedure for otoscopy (Norman et al., 2017)	• Observation of eyes and visual field testing (using confrontation test and Amsler grid for screening major visual field deficits) and intraocular pressure measures to detect any ocular pathology
• Ambient noise: background noise checks should be made before and during audiometric testing to ensure that noise levels do not exceed the recommended level of 35 dBA as stated in the ISHAA-recommended procedure (40 dBA maximum) for pure tone air conduction and bone conduction threshold audiometry with and without masking	• Current optical correction: determination of lens type and power with associated distance and near visual acuity, used as baseline visual performance
• Pure tone audiometry: air conduction and bone conduction according to ISHAA-recommended procedures for pure tone air conduction and bone conduction threshold audiometry	• Visual needs: identification of main activities with associated distance and global light sensitivity to make refraction at an appropriate distance; recommendation of any adaptive equipment to cover unmet visual needs
• Glasgow Hearing Aid Benefit Profile (GHABP)	• Visual function evaluation: ascertainment of subjective refraction (or objective when, owing to factors such as poor cooperation, subjective is not possible) with associated visual acuity, contrast sensitivity, and binocular vision

RwD lacks capacity, consent will be obtained from their designated person, in accordance with the HSE National Consent Policy [40]. The designated person will be provided with an information and consent sheet after the first visit, and the researcher will discuss the study with them at the second visit to address any questions and obtain written consent. Signed consent forms will be securely stored, and a copy provided to the designated person. For RwD who lack capacity, assent will be sought by presenting the easy-read information sheet, using verbal and visual methods. A rolling consent model will be used, ensuring continuous and repeated informed consent throughout the study.

Sample size

An objective of this study is to assess the feasibility of recruiting and retaining the required number of participants per LTC facility which would be needed in a definitive RCT. This feasibility study is not designed to determine effectiveness of the intervention and a formal power calculation is not appropriate. For the recruitment period (8 months) of this feasibility study—based on [41] and [42]—we should aim to randomise 1–2 homes per month (total 8–15 homes), with at least 12 residents per home. However, due to temporary constraints in audiology services that limit audiologist availability for this pilot trial to a maximum of 5 participants per home, a recruitment rate of 5 participants per home will be targeted. For the definitive trial, this will be scaled up to achieve the target recruitment figures. The definitive trial will be powered to detect a standardised effect size of 0.27 (equivalent to a 4-point change on the DEM-QoL and assuming a standard deviation of 13.55 points in DEM-QoL scores) [27]. Assuming, further, a correlation of 0.6 between baseline and 12-month follow-up DEM-QoL scores [56] and an attrition rate of 20% at follow-up, the trial will need to recruit 280 dyads at baseline (140 per arm) to achieve 80% power to detect the aforementioned effect size at the 2-sided 5% level of significance. The sample size requirements for a definitive RCT are thus calculated as being a minimum of 13 clusters of size 24 in each arm (total sample size of 624) or 15 clusters of size 14 (total sample size of 420) using an estimate of 0.05 for the intracluster correlation (ICC) in line with estimates from primary care trials [57, 56]. However, our study here is likely underpowered for precise estimates around other key parameters such as efficacy outcome measures [3] and thus will not be using them to inform the power calculation of the main trial. Instead, we based our sample size on a rough guide, as suggested by Teare et al. [5] which supports a guide size of 70.

Sensory support intervention for residential care (SSI-RC)

The four parts of the SSI-RC are described as follows.

Level 1: Resident with dementia (RwD)

A full hearing and vision assessment will be undertaken for participating residents by an audiologist and an optometrist or ophthalmologist, respectively, in accordance with clinically regulated, standardised procedures, in the LTC facility. Devices for the correction of sensory impairment will be prescribed, administered, and fitted for RwD participants in the LTC facility. Visioncall is the external vision care provider for the study. Chime is the external hearing care provider for the study. The sensory champion in each LTC facility will be responsible for supporting adherence and maintenance of devices (for example, cleaning and battery changing) (Table 2).

Table 3 Supplier, cost, and duration of devices used in the sensory support intervention

Device	Supplier	Cost	Duration
Hearing aid: Muse i2400 Mini Behind the ear	Starkey Hearing Technologies	Free to participant[a]	Participant keeps during and after study
Personal listening amplifier	Accredited supplier used by audiologist	Free to participant[a]	Participant keeps during and after study
Glasses lenses (including yellow filters if needed)	Visioncall Ireland	Free to participant[a]	Participant keeps during and after the study
Glasses frames (participant choice)	Visioncall Ireland	Free to participant[a]	Participant keeps during and after the study
Glasses engraving	Visioncall Ireland	Free to participant[a]	Participant keeps during and after the study

[a] HRB DIFA funding the provision of devices

The sensory champion will create a Personal Sensory Plan (PSP) for each participating RwD, which will serve as a comprehensive record of their sensory health at the time of the assessment. The PSP will cover various aspects, including the RwD's current sensory status, sensory history, and sensory needs. Additionally, it will contain the contact information of key professionals, such as audiologists, opticians, and general practitioners, who are responsible for the RwD's sensory care, as well as a schedule of appointments (Table 3).

Level 2: Staff

Every staff member who is currently working in the LTC facility in the SSI-RC arm of the study and is available will receive training in dementia and sensory health. This training will be manualised (the SSI-RC intervention manual) and designed to minimally disrupt usual care routines (facilitated in-person and virtually—depending on the preferences of the LTC facility—and lasting approximately 50 min). The research therapist will facilitate this training.

Elected staff members—'sensory champions'— in the SSI-RC arm of the study will receive further training in sensory cognitive health, sensory cognitive support, and how to carry out the sensory intervention. This training will also be manualised and carried out in an extended session lasting 2 h and delivered in-person. This training will be facilitated by the research therapist who will provide continued support throughout the intervention.

Level 3: Environment

Using a pragmatically developed tool, the sensory champion will audit the sensory environment of the RwD's personal living quarters and the broader LTC facility. The results of this audit will guide the sensory champion in implementing appropriate strategies outlined in the SSI-RC intervention manual aimed at enhancing the sensory environment. These strategies may include one-time structural changes, such as improving lighting or adding soft furnishings to improve acoustics, as well as ongoing adjustments, such as regulating the volume of televisions and radios.

Level 4: Organisational

The sensory champion will work the LTC facility manager or DON to map existing hearing and vision care provision by community-based audiologists and opticians. This will include presence and duration of each service.

Care as usual

The CAU group provides a comparison with the SSI-RC group. CAU participants will receive no intervention. Presently, little is known regarding what usual care looks like in LTC facilities for vision, hearing, or the sensory environment. In the economic evaluation conducted alongside the trial, health care use will be quantified using two bespoke health utilisation resource booklets, one focussing on the LTC facility and the other focusing on resident care notes. To further explore how patterns of healthcare use vary across different types of LTC facilities (e.g. private/public/voluntary funded, rural/urban), a Study Within a Trial (SWAT) will survey a larger sample of LTC facilities. Data from the SWAT will help us to better target the intervention and ensure appropriate power and randomisation for a definitive study.

Outcome measures

Main outcomes

Since this is not a definitive RCT, there is no specific primary outcome; however, the main outcomes of interest will be the feasibility, acceptability, and tolerability of the hearing and vision support intervention package for RwD in LTC facilities. These outcomes will inform a decision to proceed to the definitive trial, following a traffic light approach: (i) proceed to a definitive trial, (ii) review the intervention components or delivery or trial design

Table 4 Criteria for progression from a pilot feasibility study to definitive trial

Feasibility outcome	Progression criteria
Is conducting a trial of a sensory intervention for RwD feasible in Ireland	
1.1 Adequate recruitment rate	An adequate rate of recruitment in all participant groups (LTC facility, staff, sensory champion and RwD) is met within 8 months, proceed; a less than acceptable rate of recruitment is met; modify protocol, an insufficient rate of recruitment is met; do not proceed
1.2 Adequate retention rate	An adequate retention rate in all participant groups (LTC facility, staff, sensory champion and RwD) is met within 8 months, proceed; a less than acceptable retention rate is met; modify protocol, an insufficient retention rate is met; do not proceed
Can the intervention be delivered in LTC facilities in Ireland	
2.1 Feasibility	There are adequate intervention adherence rates across all participant groups (LTC facility, staff, sensory champion and RwD), proceed; less than adequate intervention adherence rates; modify protocol, insufficient intervention adherence rates; do not proceed
2.2 Barriers and facilitators	There are manageable barriers to the delivery of the intervention; proceed, there are some barriers to the delivery of the intervention; modify protocol, there are unmanageable barriers to the delivery of the intervention; do not proceed
2.3 Acceptability/tolerability	There are adequate rates of intervention acceptability and tolerability across staff, sensory champion and RwD participant groups; proceed, less than adequate rates of intervention acceptability and tolerability; modify protocol, insufficient rates of intervention acceptability and tolerability; do not proceed

elements then proceed, or (iii) do not proceed. As appropriate for a feasibility study, the main outcomes will be descriptive. Specific progression criteria for key feasibility outcomes are outlined in Table 4.

Since there are no pre-defined meanings attributed to each colour within the traffic light system [4], an overall conclusion on whether to proceed to a definitive RCT will be drawn by weighing the feasibility and acceptability outcomes indicated by the traffic light system, alongside a careful consideration of both pragmatic and methodological factors. This decision will balance the strengths and limitations revealed in the study, assessing whether modifications to the protocol could adequately address any identified challenges. Ultimately, the decision to progress will reflect a holistic evaluation of the potential for successful implementation in a larger trial, with particular attention to practical viability and methodological rigour.

Secondary (exploratory) outcomes

Outcomes will consist of an exploratory outcome set relating to RwD, facility care staff of different grades, the LTC facility sensory environment, and health economic outcomes (see Table 5). The battery of exploratory outcome measures will be evaluated for suitability for the definitive trial, particularly to inform the future choice of primary and secondary outcome measures. A proof of concept of effectiveness of the SSI-RC on resident QoL will be evaluated at three time points: baseline and post-intervention (3 and 6 months).

Demographics

Demographic information about the RwD will be captured at screening and baseline relating to age, sex, health status, nature and magnitude of sensory loss, stage of dementia, living status, current or former occupation, years in formal education, and duration of residence in the LTC facility. Demographic information about the LTC facility staff will be captured at screening and baseline relating to age, gender, ethnicity, highest level of educational qualification and occupational attainment, description of role, and duration of employment. Factors related to the LTC facility including, licensing status, inspection outcomes, resident/staff profile, type of home, external providers, type of care provision (particularly sensory-cognitive care), mortality rates, fall rates, and hospital admissions will be captured at screening and baseline. This will allow screening of eligible participants and facilitate analysis of the potential influence of demographic differences on outcome variables within and between sites.

Study procedures

Timeline

- Start of recruitment period: 2nd quarter 2023
- Duration of the recruitment period: 4 months
- Duration of participation of each participant: 6 months
- Total duration of the study: 24 months

Table 5 Battery of scales administered during baseline, week 13, and week 26 visits

Outcome	Information about	Scale
QoL of RwD	RwD	Quality of Life for Adults with Dementia (Qol-AD)
		Dementia Quality of Life – Proxy version DEM-Qol Proxy
Dementia-related functional ability	RwD	Six Item Cognitive Loss Test (6-CIT)
		Functional Assessment Staging of Alzheimer's Disease Tool (FAST)
Vision-related functional ability	RwD	Veteran's Affairs Low Vision Visual Functioning Questionnaire – Proxy version (VA-LV-VFQ—P)
Hearing-related functional ability	RwD	Hearing Handicap Inventory for the Elderly – Proxy version (HHIE-P)
Global cognitive functioning	RwD	Six Item Cognitive Impairment Test (6-CIT)
		Functional Assessment Staging of Alzheimer's Disease Tool (FAST)
		Global Deterioration Scale (GDS)
		Engagement and Independence in Dementia Questionnaire (EID-Q)
Behavioural and psychological symptoms	RwD	Neuropsychiatric Inventory – Nursing Home version (NPI-NH)
Health resource utilisation	RwD	Perceived Health EQ-5D-5L with bolt ons—proxy
	LTC facility	Nursing Home Booklet
	RwD	Resident Care Note Booklet
Perception of intervention	Intervention	Knowledge, Attitudes and Practices (KAP)
		Training Acceptability Rating Scale (TARS)

Initial screening visit

Stage of dementia will be screened using the FAST [38] and resident consent obtained. Residents will not be screened for hearing and vision at this visit.

Baseline visit

The baseline assessments will be administered by a researcher either in-person at the LTC facility or via Microsoft Teams, secured for research. During the assessment, the RwD and a designated staff informant (DSI) at each facility, who will act as a proxy for the RwD, will be asked to complete a set of assessment scales, which is expected to take approximately 2 h. If the eligibility criteria are met, the baseline assessment may be scheduled on the same day as the screening visit, but only after the screening procedures are completed and consent has been obtained. Alternatively, the baseline assessment may be divided into two sessions based on the preferences of the RwD and DSI. If the baseline assessment is divided into two sessions, the second session must be scheduled within two weeks of the first session.

Randomisation and allocation concealment

Cluster randomisation will be established at the level of the LTC facility since all staff and residents within the SSI-RC arm of a given home will be exposed to the intervention. Randomisation will be conducted by the Clinical Trials Facility (CTF) on a 1:1 basis (SSI-RC vs CAU) via a secure web-based randomisation system, considering block stratification by home type and urban/rural geography.

Unblinded researchers will be informed of the allocation to inform each LTC facility. Randomisation will only be carried out after ensuring that the home has sufficient eligible participants for the trial and after the collection of all baseline data.

Data protection and sharing

Best practice in accordance with current European Union and General Data Protection Regulation (GDPR) guidance will be followed. Trinity College Dublin is the data controllers for this study. All patient-identifiable data (PID) will be kept separately from the anonymised data entered in the case report form (CRF).

Blinding

Facility staff and researchers were not blinded to allocation due to the focus of the study being on feasibility outcomes. In a small feasibility RCT of a non-drug intervention, there are several practical and methodological reasons for not including an observer-blind outcome rater including resource constraints, the main aim of the trial being feasibility outcomes, and the relatively minor risk of introducing observer bias on outcome measurements that may have wide confidence intervals and variability inherent in small sample sizes.

Follow-up visits

At 3 months (±2 weeks) and 6 months (±2 weeks), researchers will carry out the same battery of scales used at the baseline visit with participants in person or via video conferencing technology. If the participant becomes fatigued and a second session is required, this will occur within 2 weeks of the first session.

Sensory champion compliance with intervention protocol

The sensory champion will update the participants' PSP weekly and as needed. The sensory champion will also receive ongoing support from the research therapist (trainer), who will oversee the delivery of and fidelity to the intervention across sites.

RwD adherence to the intervention

The sensory champion will document adherence to the use of sensory equipment and other intervention procedures in the RwD's PSP. Adherence to the intervention will also be described during the post-intervention semi-structured interview.

Analysis of outcomes

Statistical analysis plan (SAP)

An initial statistical analysis plan (SAP) has been devised, detailing the analysis methods, outcomes, covariates, handling of missing data, standard error estimation methods, and any sensitivity analyses. The SAP will be submitted to the trial steering committee (TSC) for review and approval before the start of statistical analyses.

Descriptive analyses

As appropriate for a feasibility study, the primary outcomes will be descriptive. Using precision estimates with 95% confidence intervals, binary and other categorical measures will be summarised using frequencies and percentages, and continuous measures using means and standard deviations, or medians and interquartile ranges for skewed distributions.

Quantitative analyses

The battery of exploratory outcome measures will be evaluated for suitability for the definitive trial, particularly to inform the choice of primary and secondary outcome measures. Missingness of data, variability (SD) of the outcomes (baseline and 3 and 6 months) and point estimates, and difference in outcomes at 6 months in each arm will be calculated overall and by arm.

Selection of outcome measures for definitive trial

Outcome measures will be selected for the definitive trial based on a number of criteria including feasibility to collect the data for the measure (i.e. missingness of data), time taken to administer the measure, real life relevance, alignment with the study aims, and sensitivity to detect a different between intervention and CAU groups.

Qualitative interview analyses

Interviews will be carried out with sensory champions and designated staff informants in the SSI-RC group. All interviews will be recorded using Microsoft Teams, transcribed verbatim and anonymised. Data from semi-structured interviews will be independently coded with inductive and deductive approaches and thematic analysis of the material [55].

Health economic analysis

An economic evaluation will be designed to be conducted alongside a future definitive randomised control trial. The feasibility of the methods will be tested in this study. It will evaluate the cost-effectiveness of sensory-cognitive interventions to improve quality of life (QoL) for residents with dementia living in LTC facilities.

Health economic analysis undertakes an initial exploration of the feasibility of a cost-effectiveness model. The cost-effectiveness of the adapted intervention will likely be a co-primary outcome in the definitive trial. Two activities will be undertaken: (1) developing the health economics analysis plan (HEAP) for cost-effectiveness analysis alongside a definitive trial and (2) testing the feasibility of the cost-effectiveness data collection forms in an Irish LTC facility context. The health economic evaluation will be conducted from the perspective of the Irish health and social care system as well as considering private and voluntary stakeholders operating LTC facilities. The cost of deploying sensory champions will be estimated and downstream cost consequences will also be measured to indicate the total cost, such that:

$$TotalCost = Cost\ of\ \text{SSI} - \text{RC} + \text{Cost Consequence}$$

To indicate whether the SSI-RC represents value for money compared to CAU, the incremental cost-effectiveness ratio (ICER) would then be estimated in a definitive study.

$$ICER = \frac{Cost_{SSI-RC} - Cost_{CAU}}{Effect_{SSI-RC} - Effect_{CAU}}$$

The goal of our analyses is to design the intervention with the highest likelihood of being clinically and cost-effective and (2) to examine sources of uncertainty for the definitive intervention study design.

Study governance

The trial steering committee (TSC) consists of an independent chair, principal investigator, site representative, hearing and vision specialists, statistician, methodologist, project coordinator, and devices suppliers. The TSC's main responsibility is to oversee all aspects of the trial and provide guidance to the trial management team (TMT), local sponsors, and other funders through its independent chair. This includes overseeing the trial's design, conduct, management, reporting, and dissemination while ensuring adherence to the highest standards of clinical research in compliance with Good Clinical Practice Guidelines (GCP) and SENSE-Cog Residential Care standard operating procedures (SOPs). To ensure all research staff are well equipped to conduct clinical trials, they will undergo GCP training, and trial-specific training will be delivered before the study commences. The TSC and TMT will work together closely to ensure seamless trial conduct.

Study safety

This trial is a low-risk non-pharmacological intervention and is therefore unlikely to cause any safety issues. Nonetheless, it is important that the highest standard of safety is maintained, and thorough safety monitoring is undertaken throughout the trial. Any serious adverse events which in the opinion of the local PI are definitely, probably, or possibly related to the intervention will be reported to TCD sponsor via a dedicated email: pharmacovigilance@tcd.ie.

The sensory champions will gather information about serious adverse reactions (SARs), i.e. serious adverse events related to the intervention, from the intervention group during their weekly visits. Only SARs will be recorded and reported to sponsor.

Information on adverse reactions related to the intervention will be collected on the adverse event log on the eCRF. These will not be reported to the sponsor.

Data management

Different tasks of data management (from study design to database closure) and the responsibilities of each person involved in the data management process and quality control are detailed in the data management plan (DMP). Data will be collected electronically at screening, baseline, and follow-up, via protected excel spreadsheets designed specifically for the trial. These will serve as electronic case report forms (eCRFs). Qualitative interviews will be video recorded. Consistency checks will be programmed to check the consistency and the completion of data in the eCRF. Monitoring is organised throughout the trial to ensure compliance to the protocol, regulations, and GCP recommendations. ClinInfo, a secure web application, will be used to build the research database. Research data will be inputted into ClinInfo with access restricted to the research team via password protected, doubly encrypted laptops.

Patient and public voice

The development of the SSI-RC was guided by principles of public involvement in research [34] and involved a cooperative approach with 'patient and public voice' (PPV) members in collaboration with the Alzheimer Society of Ireland (ASI). Three members of ASI's Dementia Research Advisory Team (DRAT) will provide advice, review, and make recommendations on all aspects of the trial, ranging from intervention development to final dissemination. Thus far, PPV members have participated in four workshops to develop the SSI-RC and reviewed the staff training programme, including study slides and materials (Personal Sensory Plan, Sensory Environment Audit), which were subsequently revised in line with their feedback. PPV input was critical in stressing the importance of including a wider array of LTC facilities, including those in rural areas, as well as both private and publicly operated facilities. Additionally, they discussed the importance of family input into the care and advocacy for care of residents, particularly if living with dementia. PPV members provided details of care staff routines, suggesting optimal times for training and data capture.

PPV members have also participated in a public event aimed at raising awareness of sensory loss in RwD where experiential components of the specialised sensory champion training were field tested.

Dissemination policy

Results will be submitted for publication in a peer-reviewed journal, and priority will be given to open-access publications. Presentations of key results will be made at local, national, and international conferences in relevant fields. Feedback on study out-comes will be offered to study participants, and the lay public by using various formats (on-line, print material, and lectures), including the SENSE-Cog website (https://www.sense-cog.com).

Sponsor

The sponsor is responsible for governance and research conduct. Details are as follows:

> Dr Ruben Eavan Keane, Trinity Research & Innovation, TCD School of Medicine, Research Office, Trinity College Dublin, Dublin 2, Ireland, email: scallina@tcd.ie

With support from Welcome Trust—HRB Clinical Research Facility (CRF), H&H Building, Level 2, St James's Hospital, James's Street, Dublin 8, D08 NHY1, Ireland, email: clinicaltrialsponsorship@tcd.ie/ info@sjhcrf.ie

Authorship eligibility guidelines and any intended use of professional writers

No professional writers are planned. Authorship will follow standard guidelines for attribution and responsibility for content and will be monitored through the TMT and then the TSC.

Plans for communicating important protocol modifications

All modifications to the study protocol, whether minor or major, will be submitted to the ethics committee for approval and communicated where appropriate to relevant parties including LTC facility management and participants. Protocol modifications will not be implemented into trial activity until ethical approval has been granted.

Interim analyses and stopping guidelines

Since this is a very-low-risk trial, there is no data monitoring and ethics committee (DMEC), and no interim analysis is planned for either safety or futility analysis.

Public access to the full protocol, participant-level data set, and statistical code

The full protocol will be communicated with primary publication of study results (and statistical code depending on the journal), and participant-level dataset (and statistical codes) will be accessible through request to the principal investigator.

Data transfer

The collection and management of data is carried out by TCD. The conditions for data transfer of all or part of the study database will be decided by the EARB and will be the subject of a written contract.

Criteria for discontinuing or modifying allocated interventions for a given trial participant

Since this is a very-low-risk RCT, discontinuation of the intervention is unlikely. However, since this is a pragmatic, tailored intervention, modification of how the intervention will be delivered will be participant specific. Decisions on how to modify the intervention will be taken by the sensory champion delivering the intervention and supported by the research therapist. If any participant withdraws consent or experiences an SAE, they will be withdrawn from the study.

Participant aftercare

This is a low-risk study with little chance of harm to participants; however, in those rare instances where participation may have triggered emotional or psychological distress in the RwD, the research team will direct next of kin and LTC facility management and staff to appropriate support services.

Discussion

The main strength of SENSE-Cog Residential Care is that it is the first feasibility pilot trial to evaluate a complex intervention for sensory correction and support for RwD living in LTC facilities in Ireland. This will enable the research team to understand the feasibility, acceptability, and tolerability of such an intervention as well as context issues and causal mechanisms.

The main limits of the trial include the cluster-randomised design, which may not completely eliminate selection bias. Additionally, there is a possibility of contamination of the intervention due to staff movement between participating LTC facilities, including both management and care staff, with the risk exacerbated by high staff turnover rates. Competing demands on the LTC facility such as maintaining existing care routines in the face of staff recruitment and retention challenges may also undermine the ability of the home to maintain fidelity to the intervention.

Furthermore, owing to the nature of the intervention, the study is not double-blinded. It is anticipated that there may be challenges to recruitment of LTC facilities due to staff shortages and the recent COVID-19 pandemic, which hit LTC facilities particularly hard.

If following trial completion, the SSI-RC is feasible in Irish LTC facilities, the aim is to carry out a larger definitive trial to examine if the intervention improves outcomes in dementia. An additional aim is to make the training materials, resources, and information available to health and social care providers to implement in routine practice. This will be a significant contribution to the therapeutic management of people with dementia and sensory impairment in LTC facilities.

Trial status

The article is based on the SENSE-Cog Residential Care protocol version 2.0, 20 April 2023. Work on the SENSE-Cog Residential Care programme began on 9 November

2021. Recruitment is projected to start June 2023. The end date for work on the trial is 28 February 2024.

Abbreviations

AD	Alzheimer's Disease
AE	Adverse Event
CAU	Care as Usual
CRF	Case Report Form
DMP	Data Management Plan
DEMQOL	Dementia Quality of Life
DSI	Designated Staff Informant
EARB	Ethical Advisory and Review Board
eCRF	Electronic Case Report Form
GCP	Good Clinical Practice
ICD-10	10th revision of the International Statistical Classification of Diseases and Related Health Problems
PI	Principal Investigator
PID	Patient-Identifiable Data
PPV	Patient and Public Voice
RwD	Resident with Dementia
QoL	Quality of Life
RCT	Randomised Controlled Trial
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SSI-RC	Sensory Support Intervention for Residential Care
SOP	Standard Operating Procedure
TMT	Trial Management Team
TSC	Trial Steering Committee

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Authors' contributions
The SENSE-Cog Residential Care Trial Development Team conceptualised and designed the field trial. IL is the programme lead and chief investigator. JPC is the research therapist and contributed to the development of the protocol and reviewed, edited, and organised the final version of the manuscript. HT was the study coordinator and assisted with protocol development and writing the first draft of the article. AMM is the current study coordinator and contributed to the development of the protocol. EB and VRR are research assistants and contributed to the development of the protocol. AER is an audiologist and assisted with protocol development. MG is a multi-disciplinary academic and assisted with protocol development. LG is a Senior Research Fellow at the Academic Unit for Ageing and Stroke Research, Bradford, UK, and assisted with protocol development. NM is a Professor of Speech and Hearing Sciences and assisted with protocol development. KT is a biostatistician and epidemiologist and provided statistical input for the study and assisted with protocol development. DT is an Assistant Professor of Economics and provided health economic input and assisted with protocol development. DT was supported by GON. All authors were involved in critical revision of the article and read and approved the final manuscript.

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Data availability
The data and materials supporting this article are available in the Open Science Framework: Sense-Cog Residential Care [https://doi.org/10.17605/OSF.IO/KDNZM].

Declarations

Ethics approval and consent to participate
The study was reviewed and approved by the Faculty of Health Sciences Research Ethics Committee at Trinity College Dublin on 09/06/2022 (Reference: 220402 Mullally).

Competing interests
The authors declare that they have no competing interests.

Author details
[1]Global Brain Health Institute, Trinity College Dublin, Dublin Dublin 2, Ireland. [2]Alzheimer Society of Ireland, Dublin, Ireland. [3]Visioncall Ireland, 21 Main Street, Derrygassan Upper, Co., Monaghan H18 DY22, Ireland. [4]Department of Speech and Hearing Sciences, University College Cork, Cork T12 XF62, Ireland. [5]St James's Hospital, Dublin Dublin 8, Ireland. [6]Academic Unit for Ageing and Stroke Research, Bradford Teaching Hospitals NHS Foundation Trust/University of Leeds, Bradford BD9 6RJ, UK. [7]Chime, The National Charity for Deafness and Hearing Loss, 35 North Frederick Street, Dublin 1, Ireland.

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