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SENSE-Cog Residential CARE: hearing and vision support for residents with dementia

Submission date
28/01/2022

Recruitment status
No longer recruiting

Registration date
23/02/2022

Overall study status
Completed

Last Edited
17/06/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Of the 55,000 people with dementia in Ireland, nearly 17,000 live in long-term care (LTC) facilities. Over 90% of these residents have significant hearing and vision problems that are frequently undetected or under-corrected. Poor sensory function can worsen quality of life for residents with dementia (RwD) by making communication more difficult and increasing confusion and challenging behaviour.
The study aims to ascertain the feasibility of delivery, acceptability and tolerability of a sensory support intervention in Irish LTC facilities. To explore whether the sensory support intervention may be effective in improving quality of life and other outcomes for RwD and facility staff. To explore what Care as Usual looks like in LTC facilities, and lastly, to evaluate cost-effectiveness parameters of the intervention. The findings from this study will inform progression to a definitive trial and contribute to emerging evidence of LTC facility research methodology.

Who can participate?
The study aims to recruit approximately ten LTC facilities across Ireland. Within each LTC facility, we will recruit residents living with dementia to participate in this study. We will also recruit two staff members, who we will call sensory champions. These staff members will undergo staff training in sensory-cognitive healthcare.

What does the study involve?
The ten LTC facilities that participate in the study will be split up into two groups. This will be a random process. Five will be allocated to the intervention group and five will be allocated to the care as usual (CAU) group. Those in the CAU group will receive care as usual within their LTC facility setting. Those in the intervention group will receive the intervention on site, at the LTC facility, by trained Sensory Champions (care home staff) selected from each LTC facility. The sensory support intervention involves personalised resident sensory support, staff training, developing a ‘sensory friendly’ environment and ensuring optimal care pathways to hearing /vision providers.
In order to see if the intervention has any effect, we will look at aspects such as resident quality of life, functional ability, behaviour and cognition, culture of care and the sensory environment. A researcher who does not know whether the nursing home has received the intervention or not, will administer tests looking at these elements at baseline, 3, and 6 months. We will also

examine if the intervention is feasible by looking at areas such as acceptability to staff, engagement and retention. The total duration of the intervention will be 12 weeks. Exploration of barriers and facilitators to intervention and trial delivery will inform future trial design.

What are the possible benefits and risks of participating?
There is reason to believe that staff in the intervention group will benefit professionally from the sensory cognitive health training provided. There is also reason to believe that RwD participants in the Intervention group will benefit directly from the activity, gaining further sensory support through participation. The intervention and evaluation will not pose any great risk onto the care homes, or individuals (staff and RwD) who consent to participant in this study.

Where is the study run from?
The research team is based at St James's Hospital, Dublin, Ireland. Testing will be carried out off-site at participating nursing homes (locations yet to be determined).

When is the study starting and how long is it expected to run for?
November 2021 to August 2024

Who is funding the study?
The Health Research Board (HRB), Dublin, Ireland

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
212073

Study information

Scientific Title
SENSE-Cog Residential CARE: A feasibility study of hearing and vision support to improve quality of life in care home residents with dementia

Acronym
SENSE-Cog Residential CARE

Study objectives
The study aims to ascertain feasibility of delivery, acceptability, and tolerability of a Sensory Support Intervention for hearing and vision function, for residents with dementia in care homes in Ireland.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 09/04/2025, Faculty of Health Sciences Research Ethics Committee (Faculty of Health Sciences, Chemistry Building, Trinity College Dublin, Dublin, Dublin 2, Ireland; +353 (0)1 896 4193; ethicscommittee@tcd.ie), ref: 240101
2. Approval 09/04/2024, Faculty of Health Sciences Research Ethics Committee (Faculty of Health Sciences, Chemistry Building, Trinity College Dublin, The University of Dublin, Dublin 2, Ireland; +353 1 896 4193; ethicscommittee@tcd.ie), ref: 220402

Study design
Feasibility-pilot cluster randomized controlled parallel-group observer-blind multicentre trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Sensory support for hearing and vision impairment in residents with dementia living in the care home setting

Interventions
There will be two study arms involving up to 10 nursing homes across Ireland, randomly allocated (1:1) to receive a complex intervention, the Sensory Support Intervention for care homes (SSI-C), or to continue Care as Usual (CAU). Randomisation will be conducted by the Clinical Trials' Facility at St James Hospital via secure web-based randomisation system.
Those in the CAU group will receive care as usual within their care home setting.
Those in the SSI-C group will receive the intervention by Sensory Champions (care home staff) selected from each care home. The SSI-C will involve personalised resident sensory support, staff training, developing a 'sensory friendly' environment and ensuring optimal care pathways to hearing/vision providers.
The total duration of treatment will be 12 weeks.
Assessments will be undertaken by a blinded researcher with all study arms at baseline, 3- and 6-month follow-up.

Intervention Type
Behavioural

Primary outcome(s)
1. Feasibility to conduct the SSI-C in Irish care homes is measured using, the rate of recruitment of care homes, and retention rate of randomised homes and participants.
2. Feasibility of the intervention is measured using percentage staff agreeing to participate, staff reporting sufficient time to undertake the intervention, barriers, and facilitators of the intervention.
3. Acceptability/tolerability of the intervention is measured using Staff attendance, Residents' adverse event (AE) rate related to the intervention and Staff perceptions of the training component using qualitative interviews and the Training Acceptability Rating Scale (TARS), pre-post training.

Key secondary outcome(s))
1. Exploratory Outcome Set for Residents (EOS-R) measured using key dementia- and sensory-related outcomes including measures of quality of life at three time points: baseline and post-intervention (3- and 6-months).
2. Battery of Care home staff measures including sensory-cognitive health knowledge and change in staff practice, care home culture measured using self-report questionnaires and qualitative interviews at three time points: baseline and post-intervention (3- and 6-months).
3. Battery of Care Environment measures including sensory aspects such as the physical environment (light, temperature, and noise) using Screening Surveys and standardised assessment protocols at three time points: baseline and post-intervention (3- and 6-months).

Completion date
20/08/2024

Eligibility

Key inclusion criteria

Current inclusion criteria as of 16/06/2025:
LTC Facility:
1. At least 60% of residents live with dementia
2. Must be ‘compliant' or 'substantially compliant' on all regulations based on Health Information and Quality Authority (HIQA) reports
3. The Director of Nursing (DON) is willing and able to release staff to attend sensory health training sessions and contribute to data collection
4. The DON is willing to work with the research team to inform staff, RwD, and families /supporters about the study
5. The DON is willing to identify potential sensory champions from existing staff
6. The DON is willing to help identify potential RwD to participate in the study and provide an estimation of capacity to consent to participation

Resident with Dementia (RwD):
1. Is aged ≥ 60 years
2. Is a permanent resident of a participating LTCF
3. Has mild to moderate stage dementia (FAST score 4-6) or significant cognitive difficulties suggesting dementia
4. If taking cognitive-enhancing medication, the dose must be stable for at least 4 weeks prior to screening
5. Is willing to participate or has a nominated legal representative who consents on their behalf
6. Has the capacity to give informed consent or has a nominated Legal Representative to provide consent

Staff (Sensory Champions, General Staff):
1. Is aged ≥ 18 years
2. Is a current member of staff in a participating LTCF for at least 3 months and involved in the care of RwD (including DONs, nurses, allied health professionals, and front-line care workers)

Previous inclusion criteria:
1. Care Home has at least 60% of residents with dementia.
2. Care Home must be ‘compliant’ or ‘substantially compliant’ based on HIQA reports.
3. Staff Is aged ≥18 years.
4. Staff Is a current member of staff in a participating care home and is involved in the care of the RwD (all grades including: Director of Nursing; nurses; allied health professionals and front-line care workers).
5. Resident with Dementia (RwD) Is aged ≥60 years.
6. RwD Is a permanent resident of a participating care home.
7. RwD Has received a clinical diagnosis of dementia or has evidence of dementia as per care home staff
8. RwD Has mild to moderate stage of dementia as indicated by a score of 1 or 2 on the Clinical Dementia Rating global score (CDR)
9. RwD if taking cognitive enhancing medication (i.e., cholinesterase inhibitors or memantine), this must on a stable, unchanged dose for at least 4 weeks prior to screening.
10. RwD is willing to participate in the study and will accept the SSI-C.
11. RwD has mental capacity to give informed consent to participate in the study or has a nominated consultee (a primary care worker, named at the study start) to provide consent on their behalf.

Participant type(s)

Patient, Health professional, Resident

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Sex
All

Total final enrolment
27

Key exclusion criteria
Current exclusion criteria as of 16/06/2025:
LTC Facility:
1. Has received a 'non-compliant' status on one or more regulation on the most recent HIQA inspection report
2. Has insufficient staff to provide two sensory champions to deliver the SSI-RC
3. Is participating in any other research project involving service model change
4. Is taking part in another research study that would interfere with the conduct or outcomes of SENSE-Cog Residential Care

Resident with Dementia:
1. Is unwilling to participate in the study.
2. Lacks capacity to consent and does not have a nominated Legal Representative to consent on their behalf
3. Has an unstable medical or psychiatric condition
4. Part of any other sensory support-based intervention

Staff (Sensory Champions, General Staff):
1. Has insufficient time allocation to participate in the education sessions of the SSI-RC

Previous exclusion criteria:
1. Care Home has received a ‘non-compliant’ status on HIQA quality standards at their last inspection
2. Care Home has insufficient staff to provide two Sensory Champions to deliver the SSI-C
3. Care Home is participating in any other research project involving service model change
4. Staff have insufficient time allocation to participate in the education sessions of the SSI-C
5. Staff intending to change jobs in the next 6 months
6. Resident with Dementia (RwD) is unwilling to participate
7. RwD has an unstable medical or psychiatric condition

Date of first enrolment
09/04/2024

Date of final enrolment

09/06/2024

Locations

Countries of recruitment
Ireland

Study participating centre
Mercer's Institute for Successful Ageing (MISA) St. James's Hospital
31 James's Walk
Rialto
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D08 E191

Sponsor information

Organisation
Trinity College Dublin

ROR
https://ror.org/02tyrky19

Organisation
Welcome Trust - HRB Clinical Research Facility (CRF)

Funder(s)

Funder type
Government

Funder Name
Health Research Board

Alternative Name(s)
Health Research Board, Ireland, An Bord Taighde Sláinte, HRB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Ireland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available in accordance with our participant consent agreements. Participant-level data will only shared between the core research team.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		12/02/2025	13/02/2025	Yes	No
Basic results		16/06/2025	17/06/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes