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The SENSE-Cog Randomised Controlled Trial (RCT): Comparing individualised sensory intervention to standard care to improve quality of life in people with dementia and their companions

Submission date
19/02/2018

Recruitment status
No longer recruiting

Registration date
19/02/2018

Overall study status
Completed

Last Edited
14/10/2024

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
To date, there is a small but convincing literature regarding the application of hearing and visual rehabilitation in older people with sensory impairment, but this does not extend to people who have concurrent cognitive impairment, particularly dementia. Dementia significantly impacts on the ability of a person to understand and benefit from rehabilitation or psychosocial approaches, particularly those therapies with a learning element, unless the approaches are significantly adapted. Likewise, the challenges of living with dementia are magnified by sensory impairment, if not corrected or supported. The main aim of this study is to combine expertise in vision rehabilitation, auditory augmentation and non-pharmacological approaches for dementia, to test a therapy for sensory optimisation in persons with dementia (PwD). This may promote mental well-being in the PwD and their companions, thereby reducing the negative impact of dementia will be evaluated.

Who can participate?
Adults aged 60 and older with dementia and their companions

What does the study involve?
Participation in this study involves having a hearing/vision assessment at the participants home and, if appropriate, receiving sensory equipment to improve their hearing and/or vision. Participants are randomly allocated to one of two groups. Those in the first group are asked to complete a series of questions about their quality of life, everyday tasks, memory function and daily activities. A Sensory Support Therapist may visit participants in their home once a week for up to 10 weeks to help to identify goals for improving their daily life. This may mean information about local activities, benefits and services, assistance with achieving and improving domestic tasks, increasing their social circle, or any other goals they would like to work on. Participants are invited to complete another set of questionnaires and take part in an informal interview to

give feedback to the researchers about their experiences of the sensory support package – what they liked about it, how they think it could be improved. Participants who have been allocated to the second group also receive a screening of their hearing and vision at home and an information sheet about how to seek support if they wish to through the usual care pathways. They also meet with the research to answer the same set of questionnaires as the at the beginning middle and end of the study.

What are the possible benefits and risks of participating?
All participants will receive a free hearing or vision screen to help identify if they need assistance. Those who are randomised to the therapy arm will also receive a comprehensive test by a qualified audiologist or optometrist in their own home and free hearing aids or glasses if required. They will be able to keep any glasses or hearing aids that they receive at the end of the study. The sensory support therapy is designed to provide benefit to the participants but the impact of this will not be known until the study is completed. This is therapeutic sensory support intervention that does not involve any drugs nor interfere with the participants' standard medical care. As such, the risk is relatively low, particularly in relation to the potential benefit that might be gained by improving hearing and vision function in people with dementia. There may be an increased risk of falls when introducing visual correction. Optometrists will take this into account and may introduce new lenses in a 'step-wise' manner, to limit this risk.

Where is the study run from?
This study is being run by the University of Manchester and takes place in hospitals in the UK, France, Cyprus, Greece and Ireland.

When is the study starting and how long is it expected to run for?
April 2017 to February 2022 (updated 16/03/2021, previously: December 2020)

Who is funding the study?
Horizon 2020 (UK)

Who is the main contact?
Ms Francine Jury (Public)
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Professor Iracema Leroi (Scientific)

Study website
http://www.sense-cog.uk

Contact information

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
36992

Study information

Scientific Title
SENSE-Cog Work Package 3.2: The SENSE-Cog trial: a 36-week randomised, controlled, parallel-group, observer-blind, multicentre superiority trial comparing individualised sensory support to standard care to improve quality of life in people with dementia and their companions

Acronym
SENSE-Cog RCT

Study objectives
The SENSE-Cog study aims to improve the quality of life of people with dementia (PWD) and their companions, by improving their hearing and vision and offering sensory support.

Ethics approval required

Old ethics approval format

Ethics approval(s)
North West -Haydock Research Ethics Committee, 12/02/2018, ref: 17/NW/0702

Study design
36week randomised controlled parallelgroup observerblind multicentre superiority trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Dementia

Interventions
Participants are randomised on a 1-to 1 allocation to either the sensory intervention or care as usual group. This is done following completion of baseline assessment. Randomisation is stratified by centre, using permuted blocks of varying sizes. The block sizes are be disclosed to ensure allocation concealment. Full details of the randomisation scheme are included in a separate document with restricted access, kept by the independent statistician.

The Sensory Intervention (SI) is comprised of three parts, delivered over a period of up to 18 weeks:
1. Assessment of sensory impairment
2. Correction of sensory impairment
3. Maximum of ten Sensory Support Therapist home visits, typically on a weekly basis. A qualitative semi-structured interview areoffered to dyads who experienced the SI, at the end of the SI

The components of part three of the intervention are introduced one at a time on a weekly schedule in a flexible manner (over 10 weekly sessions maximum) to account for the extent to which a participant dyad requires a particular component, and their rate of progress with each component. Each dyad completes all the primary components of the SI, and whichever supportive and review components are agreed with the SST to meet their needs (see figure 2). These are accomplished through one visit from the SST per week, on average (some deviation will be allowed to account for personal circumstances, such as hospitalisation i.e. needing to do a catch-up visit for having a missed a week). In many cases, the work on one component overlaps with the initiation of another component, and will complement each other. Some components

may require more time from the SST than others, e.g. one participant may need minimal assistance with fitting of glasses or hearing aid, while others may need repeated visit to get the correct fit and to be able to use the device. Another example is that a participant may have adequate knowledge about their concurrent conditions and providing information leaflets for their use would be sufficient, whereas another participant may require several sessions of discussions and explanations about their conditions.

'Care as usual' (CAU) group: Participants in this group receive no additional intervention, but access the services and interventions normally available to people with dementia and their companions in their respective sites. Differences in availability of services among sites are captured by recording health and social care resource utilisation (RUD-lite) from W0 to W36. This includes the receipt of hearing and vision impairment treatment and support services outside of the trial.

Intervention Type
Other

Primary outcome measure
Quality of life in PwD with hearing and or visual impairment is measured using the self-rated DEMQOL at 36 weeks

Secondary outcome measures
For the person with dementia:
1. Quality of life is measured using
1.1. DEMQOL proxy at 18 weeks and 36 weeks
1.2. DEMQOL self-rated in PwD at 18 weeks
2. Functional ability (activities of daily living) are measured at 18 weeks
2.1. Dementia-related functional ability is measured using Bristol Activities of Daily Living (BADL)
2.2. Vision-related functional ability is measured using Veterans Affairs Low Vision –Visual Functioning Questionnaire (LV-VFQ-12) (self-report and proxy)
2.3. Hearing-related functional ability is measured using Hearing Handicap Inventory for the Elderly -Spouse (HHIE-S) (self-report and proxy)
2.4. Global cognitive functioning is measured using MOntreal Cognitive Assessment (MOCA)
3. Mental well-being is measured at 18 weeks:
3.1. Behaviour and psychological symptoms of dementia is measured using Neuro Psychiatric Inventory (NPI)-12
3.2. Relationships with companions are measured using Relationship Satisfaction Scale (RSS)

For the companion:
1. Mental wellbeing and quality of life are measured using General Health Questionnaire (QHS) -12 at weeks 18 and 36
2. General mental and emotional health is measured using 12 item Short Form Survey (SF12) at weeks 18 and 36
3. Depression and anxiety are measured using Hospital Anxiety and Depression Scale (HADS) at weeks 18 and 36
4. Caregiving experience (relationships with the PwD) are measured using Family Caregiving Role (FCR) and Relationship Satisfaction Scale weeks 18 and 36

Overall study start date
03/04/2017

Completion date
28/02/2022

Eligibility

Key inclusion criteria
Person with Dementia:
1. Aged ≥ 60 years
2. Has received a clinical diagnosis of dementia as per NINCDS-ADRDA or ICD-10 criteria, of the following type: Alzheimer's disease (AD), vascular dementia, or mixed AD and vascular dementia
3. Has mild to moderate stage of dementia as indicated by a Montreal Cognitive Assessment scale score ≥10 (MOCA; Nasreddine et al., 2005)
4. 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
5. Has adult acquired hearing and/or vision impairment, defined by at least one of:
5.1. Vision impairment: defined by the presence of:
5.1.1. Binocular visual acuity ≤ 6/9.5 and >6/60 in Snellen metric (or ≥ +0.2 logMAR [75 EDTRS Score] and < +1.0 logMAR [35 EDTRS Score]) using the PEEK tool
5.1.2. Visual field > 10° using confrontation visual field tests
5.2. Hearing impairment: defined by symmetrical, mild to moderate, sloping high frequency sensorineural hearing loss of at least 40 dB at 2-6 kHz, with a score of 1 to 5 in each ear, using the HearCheck device
6. Living in an ordinary community dwelling (including sheltered and very sheltered accommodation)
7. Willing to accept SI
8. Has a companion who fulfils the criteria below and is willing to participate in the study
9. Has mental capacity to give informed consent to participate in the study or has a nominated consultee to provide consent on their behalf
10. Speaks and understands language of intervention delivery, as determined by the investigator;
11. Affiliated to a social security system (for France)

Companion:
1. Aged ≥ 18 years
2. Informal caregiver (where providing care is not the person's primary paid role), such as a significant other of the PwD (e.g. a family member or close friend), who is either co-resident or in regular contact (on at least a weekly basis)
3. Willing to participate in the study
4. Speaks and understands language of intervention delivery, as determined by the investigator
5. Affiliated to a social security system (for France)

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
Planned Sample Size: 708; UK Sample Size: 142

Key exclusion criteria
Person with dementia:
1. Has an unstable, acute or current psychiatric or physical condition severe enough to prevent them from participating in the study, as determined by the investigator
2. Has complete blindness or severe visual impairment (category 2 & more on ICD-10 Version: 2016) or deafness (profound hearing loss) to prevent them from following study procedures
3. Is currently participating in any other trial of a potentially cognitive enhancing intervention, excluding marketed cognitive enhancing medication
4. Has scheduled or urgent treatment or intervention for hearing or vision impairment (i.e. cataract operation already scheduled, treatment for macular degeneration needed)
5. Is unable to read and write

Companion:
1. Has an unstable, acute or current psychiatric or physical condition severe enough to prevent them from participating in the study, as determined by the investigator
2. Is unable to read and write

Note: The companion cannot participate if the person with dementia is ineligible or unwilling to participate.

Date of first enrolment
01/03/2018

Date of final enrolment
30/04/2021

Locations

Countries of recruitment
Cyprus

England

France

Greece

Ireland

United Kingdom

Study participating centre
University of Manchester
Greater Manchester Mental Health NHS Foundation Trust,
Division of Neuroscience and Experimental Psychology
Jean McFarlane Building, 3rd Floor, Oxford Road

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Study participating centre
University of Athens
1st Department of Psychiatry
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Study participating centre
St. James's Hospital
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Study participating centre
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Study participating centre
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Sponsor type
University/education

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ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
European Commission

Alternative Name(s)
European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, Ευρωπαϊκής Επιτροπής, Европейската комисия, Evropské komise, Commission européenne, Choimisiúin Eorpaigh, Europskoj komisiji, Commissione europea, La Commissione europea, Eiropas Komisiju, Europos Komisijos, Európai Bizottságról, Europese Commissie, Komisja Europejska, Comissão Europeia, Comisia Europeană, Európskej komisii, Evropski komisiji, Euroopan komission, Europeiska kommissionen, EC, EU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
Planned publication of the results of the SENSE-Cog RCT in a high impact peer reviewed journals by December 2021. The protocol will be available as a publication shortly.

Intention to publish date
30/06/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from:
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IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	25/01/2019		Yes	No
Protocol article	process evaluation protocol	24/02/2020	26/02/2020	Yes	No
Abstract results	LP42	29/11/2022	22/03/2023	No	No
HRA research summary			26/07/2023	No	No
Results article		17/09/2024	14/10/2024	Yes	No