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SENSE-Cog Field Trial: Dementia and Sensory Impairment

Submission date
01/12/2017

Recruitment status
No longer recruiting

Registration date
16/01/2018

Overall study status
Completed

Last Edited
24/02/2023

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Under-treated hearing and vision loss in the elderly costs the EU billions per year. The impact is significantly compounded by the presence of these impairments in people with dementia. To date, there have been almost no interventions to support vision and hearing impairment in people with dementia. The aim of the project is to develop, test and refine a newly developed 'sensory support' intervention for people with dementia and concurrent sensory impairment living at home. This will be undertaken using a mixed-methods approach, involving the integration of new information with existing evidence, experience and expertise.

Who can participate?
Adults aged 60 and older who have dementia and a family member or close friend.

What does the study involve?
Participants with dementia receive a sensory support intervention consisting of assessing their hearing/vision impairment, correcting hearing/vision impairment by receiving hearing aids /glasses where required and12 home visits by a sensory support therapist to assist participants with adapting to sensory equipment, promoting sensory conducive home environment, improving communication, and setting and obtaining goals. The person with dementia and sensory impairment and study partners are assessed before and after the sensory support for their quality of life, mental wellbeing, relationship satisfaction, activities of daily living, self-efficacy and cognition.

What are the possible benefits and risks of participating?
Direct benefits are free state of the art hearing aids and glasses, home based clinical assessment, support in own home for 12 weeks with a qualified therapists. Risks are minimal but may involve risk of falls with change in glasses. Steps to minimise this risk include therapist support and introduction of new lenses in a step-wise manner.

Where is the study run from?
University of Manchester (UK)

When is the study starting and how long is it expected to run for?
January 2016 to December 2017

Who is funding the study?
EU funder Horizon 2020 (EU)

Who is the main contact?
Dr Jemma Regan
jemma.regan@manchester.ac.uk

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

Contact information

Type(s)
Scientific

Contact name
Dr Jemma Regan

Contact details
Division of Neuroscience and Experimental Psychology
School of Biological Sciences
Faculty of Biology, Medicine and Health
University of Manchester
3.309 3rd Floor Jean McFarlane Building
Oxford Road
Manchester
United Kingdom
M13 9PL
+44 161 306 7957
jemma.regan@manchester.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.0

Study information

Scientific Title
SENSE-Cog Work Package 3.1 Field Trial Intervention Study: Testing the feasibility of a Sensory Support Intervention for people with dementia and sensory impairment

Study objectives
Can a new complex non-pharmacological individualised 'sensory support' intervention be developed to support people with dementia and concurrent sensory impairment living at home?

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West - Preston Research Ethics Committee, 30/09/2016, ref: 212501

Study design
This is an open-label feasibility study in people with dementia and sensory impairments and their study partners (8 dyads in each of three clinical sites); there is no control group.

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home

Study type(s)
Quality of life

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Dementia and hearing/vision impairment

Interventions
The SENSE-Cog sensory support intervention (SSI) is a home-based individualised approach for PwD and sensory impairment and their study partners aimed at improving quality of life, reducing functional disability and increasing social connectedness. PwD and their study partners will work with a sensory support worker (SSW) in various domains over 12 weekly sessions (the number of sessions may vary from participant to participant but the maximum number of visits will be 12 at a rate of 1 per week) to:
(1) Identify and correct any vision or hearing impairment (Component 1)
(2) Support the impairment correction with on-going advice and training in correct use and care of provided devices (Component 2);
(3) Communication training for the participant and their study partner (Component 3);
(4) Perform a home-based functional assessment with participants to identify skill areas in which they lack and wish to improve – this in turn leads to individualised goal setting with participants (Component 4);
(5) Participants are referred on to other services as appropriate which are beyond the remit of the SENSE-Cog study (e.g. psychological services, sensory support service)(Component 5);
(6) Signposting to environmental aids / devices in keeping with identified goals of participants – these are not provided to participants as part of the research study (Component 6).

(7) Signposting to social engagement activities / support groups / special interest groups as appropriate for participant identified goals (Component 7).

Intervention Type
Behavioural

Primary outcome measure
1. PwD effort in-house rating scale in PwD and SP diaries after follow up at 12 weeks
2. PwD fatigue dyad members assessed by in-house rating scale in PwD and SP diaries and semistructured interview after follow up at 12 weeks
3. PwD motivation assessed by in-house rating scale in PwD and SP diaries and semistructured interview after follow up at 12 weeks
4. PwD engagement assessed by in-house rating scale in PwD and SP diaries and semistructured interview after follow up at 12 weeks
5. PwD understanding assessed by in-house rating scale in PwD and SP diaries and semistructured interview after follow up at 12 weeks
6. Frequency/duration of SSI sessions assessed by In-house rating scale in PwD and SP diaries and semistructured interview after follow up at 12 weeks
7. SSI feasibility is assessed by completion rates/missing data at baseline and follow-up
8. SSI delivered as intendef is assessed by SST diary checklist after each visit and at follow-up
9. SSI received as intended is assessed by Records of contact between SST and recipient. This will include information on: number and duration of contact, sessions, method, referrals and protocol deviations assessed at each visit. PwD and SP will have their knowledge of the SSI components checked by the SST at each visit
10. SSI enacted as intended is assessed by SST, PwD, SP diaries and semistructured interview at each visit and follow up
11. Reach assessed by proportion of referred patients who enter the study at baseline
12. Recruitment assessed by number of patients approached versus number recruited at baseline
13. Retention assessed by number of participants withdrawing and reasons throughout and at follow up
14. Screening assessed by number of patients screened ‘suitable’ versus ‘unsuitable’ at baseline
15. Assessment of impairment and corrective device delivery and fitting, assessed by SST, PwD, SP diaries; feedback from research team and industry partners at follow up
16. Functional assessments assessed by SST, PwD, SP diaries; analysis of frequency of missing data at follow up
17. ‘Logistics circuit’ of hearing/vision assessments and devices, assessed by SST, PwD, SP diaries; feedback from research team and industry partners at follow up
18. SST training assessed by SST diary will identify areas of training for the role at follow up
19. SST visits SST, Glasses usage, Hearing aid usage, Receptivity to sensory equipment, Helpfulness of SSI, Motivation to continue with SSI activities assessed by PwD, SP diaries; semistructured interview at follow up

Secondary outcome measures
Initial impression of efficacy measured by the following scales all at baseline and follow up:

PwD outcome:
1. Quality of life measured by Dementia Quality of Life, EuroQol 5 Dimensions 5 Levels, 12-Item Short Form Survey
2. Cognition measured by Neuropsychiatric Inventory

3. General mental well-being measured by Generalised Self-Efficacy Scale
4. Function measured by Bristol Activities of Daily Living Scale
5. Cognition measured by Montreal Cognitive Assessment

Study Partner outcome
1. Quality of Life measured by Dementia Quality of Life Proxy, EuroQol 5 Dimensions 5 Levels Proxy, 12-Item Short Form
Survey Proxy
2. Mental health measured by Geriatric Depression Scale
3. Burden and stress measured by Family Caregiving Role Scale
4. Healthcare resource use measured by Resource Utilisation in Dementia Lite

PwD and Study Partner Outcome
1. Relationship measured by Relationship Satisfaction Scale
2. Initial SSI efficacy measured by Dementia Quality of Life and Dementia Quality of Life Proxy

Overall study start date
01/01/2016

Completion date
31/12/2017

Eligibility

Key inclusion criteria
Participants with dementia:
1. Age 60 years or older
2. 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 (NINCDSADRDA) criteria35; vascular dementia (VaD) or mixed AD/VaD
3. Montreal Cognitive Assessment (MoCA)35 score of 12 or above
4. Adult acquired hearing and/or vision impairment
5. 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°
6. Speaks and understands the language of the intervention delivery
7. Is willing to accept sensory support
8. Is living in an ordinary community dwelling (including sheltered and very sheltered accommodation)
9. Has a study partner willing to participate in the study (a family member or close friend who is either coresident
or in regular contact (at least three times per week)
10. Has mental capacity sufficient to give informed consent to participate

Study partner:
1. Age 18 years or older
2. Speaks and understands language of intervention delivery
3. Able to read and write
4. Not employed as a professional carer for the PwD, (except Nicosia, which may include professional, live-in carers)

5. Is a family member or a close friend who is either coresident or in regular contact (minimum of three times per week)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
48 (24 people with dementia/24 companions)

Total final enrolment
38

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

Study partner:
Has an unstable, acute and current psychiatric or physical condition severe enough to prevent them from participating.

Date of first enrolment
01/01/2017

Date of final enrolment
30/09/2017

Locations

Countries of recruitment
Cyprus

England

France

United Kingdom

Study participating centre
University of Manchester
Manchester
United Kingdom
M13 9PL

Study participating centre
INSERM Université Victor Ségalen
France
-

Study participating centre
Center for Applied Neuroscience, University of Cyprus
Cyprus
-

Sponsor information

Organisation
University of Manchester

Sponsor details
3.309 3rd Floor Jean McFarlane Building
Oxford Road
Manchester
England
United Kingdom
M13 9PL

Sponsor type
University/education

Website
http://www.manchester.ac.uk/

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
Horizon 2020 Framework Programme

Alternative Name(s)
EU Framework Programme for Research and Innovation H2020, Horizon 2020, Rahmenprogramm Horizont 2020, Programa Marco Horizonte 2020, Programme-cadre Horizon 2020, Programma quadro Orizzonte 2020, Program ramowy Horyzont 2020, Horizont 2020, Horizonte 2020, Orizzonte 2020, Horyzont 2020, Horizon 2020 Framework Programme (H2020), H2020

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal. The protocol is published in BMJ Open.

Intention to publish date
01/03/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Professor Iracema Leroi, Iracema.leroi@manchester.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	28/11/2017		Yes	No
Participant information sheet		17/01/2017	01/04/2019	No	Yes
Participant information sheet	version v3.0	17/01/2017	01/04/2019	No	Yes
Results article	results	01/07/2019	24/01/2020	Yes	No

Results article	03/12/2019	24/02/2023	Yes	No