A randomised controlled trial of hearing and vision support in dementia: Protocol for a process evaluation in the SENSE-Cog Trial

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Abstract

Background: Optimising hearing and vision function may be important in improving a range of outcomes for people living with dementia (PwD) and their companions. The SENSE-Cog cross-national randomised controlled trial (RCT) is evaluating the effectiveness of a sensory intervention (SI) to improve quality of life for PwD with concurrent hearing and/or vision impairment, in five European countries. To ascertain how or why the intervention will, or will not, achieve its outcomes, we have designed a process evaluation to explore potential discrepancies between expected and observed outcomes. This will also help us to understand how context may influence the outcomes. Here we describe the protocol for this process evaluation, which is embedded within the RCT.

Methods and analysis: We will use a mixed method approach with a theoretical framework derived from the UK Medical Research Council’s’ guidance on process evaluations. It will include the following: (1) evaluating how key aspects of the intervention will be delivered, which will be important to scale the intervention in real world populations; (2) characterising the contextual issues, which may shape the delivery and the impact of the intervention in different countries; and (3) investigating possible causal mechanisms through analyses of potential moderators and mediators. To avoid bias, we will analyse the process data before the analysis of the main effectiveness outcomes.

Discussion: This evaluation will provide insight into how the complex SENSE-Cog SI will be tailored, enacted and received, across the different European contexts, all of which have unique health and social care economies. The findings will provide insight into the causal mechanisms effecting change, and will determine whether we
should implement the intervention, if effective, on a wider scale for PwD and concurrent sensory impairment.

Trial registration number: ISRCTN17056211. Registered on 19 February 2018. http://www.isrctn.com/ISRCTN17056211

Background

There is growing evidence that people with dementia (PwD) with age-related hearing and vision impairment experience worse outcomes compared to PwD with optimal sensory function. These outcomes include increased disorientation, difficulties self-locating using visual or auditory cues, higher levels of distress leading to agitation and aggression, and increased prevalence of hallucinations, delusions and depression (Fortunato et al., 2016; Rutherford et al., 2018; Lawrence et al., 2008). Sensory impairment itself can worsen cognitive decline, as well as exacerbate the social isolation that is often associated with dementia (Maharani et al., 2019). Individuals may withdraw from social activities and hobbies, and become marginalised (McKeefry et al., 2010; Elliott et al., 2009; Lupsakko et al., 2002; McDonnell et al., 2009). Furthermore, burnout and physical exhaustion in care partners can be amplified by communication barriers (Lawrence et al., 2008), and greater dependency of the PwD. Thus, we designed the SENSE-Cog randomised controlled trial (RCT) to answer the research question, ‘Can a home-based, tailored ‘sensory intervention’ (SI) improve quality of life in PwD with comorbid hearing and/or visual impairment?’

The multi-component SI that the SENSE-Cog Trial will evaluate comprises assessment, treatment, and support of hearing and vision impairment in PwD. We developed the SI iteratively over 24 months. This involved: (1) a scoping review of
the literature (Dawes et al., 2018); (2) an in-depth qualitative exploration of the support care needs of PwD with sensory impairment in three European countries (Leroi et al., 2017b); (3) an international survey (n=653); and (4) an interdisciplinary Expert Reference Group (n=17) (Leroi et al., 2019a; Leroi et al., 2017a). The findings were synthesized into a draft SI that was then field tested in the UK, France and Cyprus (Regan et al., 2017; Hooper et al., 2019; Leroi et al., 2019b), prior to development of the protocol for the full multi-site RCT (Regan et al., 2019), the SENSE-Cog Trial.

The SENSE-Cog Trial is a 36-week parallel-group, observer-blind, multicentre, superiority RCT comparing the individualised SI to usual care in PwD with hearing and/or visual impairment and their companion (the participant ‘dyad’). Briefly, it involves 354 randomized dyads (1:1; 177 per arm) in five European sites: Athens (Greece), Dublin (Ireland), Manchester (UK), Nice (France), and Nicosia (Cyprus).

The primary outcome of the trial is quality of life in the PwD. Secondary outcomes include neuropsychiatric symptoms, measures of mental wellbeing, sensory and cognitive functional ability, relationships, and health resource utilisation. Companion outcomes and health economic measures are also being assessed. Here we describe the protocol for a process evaluation of the RCT as per the UK Medical Research Council (MRC) recommendations (Moore et al., 2015).

‘Complex interventions’, such as the SENSE-Cog SI, are defined as those comprising multiple components interacting to produce change (Moore et al., 2015; Craig et al. 2008).

The range of outcomes, and the degree of tailoring or flexibility required for each individual participant, is significant, thus adding to the complexity (Leroi et al., 2017a). While RCTs are the soundest means of inferring causality of an intervention, they cannot ascertain how or why an
intervention may or may not achieve the outcomes (Barratt et al. 2016). Thus, we have embedded a detailed process evaluation within the RCT to clarify this (Moore et al., 2015). This evaluation, together with the outcomes of the RCT, will enable policy makers, funders, and practitioners to determine whether the intervention is effective or not, and whether it should implemented on a wider scale. This is particularly relevant for the cross-national SENSE-Cog Trial, which is taking place in five European contexts. It will fill a significant evidence gap in the management of hearing and vision impairment in PwD.

The specific aims of this process evaluation are to: (1) explore the delivery, or the process through which the SI will be offered, including barriers and facilitators; (2) evaluate contextual issues and clarify factors that may affect the SI delivery, mechanisms, and outcomes (Howarth et al., 2016); and (3) investigate possible causal mechanisms, using analyses of potential moderators and mediators.

Methods

The protocol for our process evaluation follows a systematic approach for the design and conduct of the evaluation (Moore et al., 2015).

Planning the process evaluation

Working with intervention developers and implementers

A process evaluation requires a degree of independence to appraise the intervention team’s delivery of the trial (Moore et al., 2015). Thus, we delegated oversight of the evaluation to an expert not involved in the day-to-day conduct of the RCT but on the wider SENSE-Cog team (CA). Regular process evaluation reports will be made at Trial Steering Committee meetings (see Regan et al., 2019), and
specific meetings with the study chief investigator (IL), the methodologist (EF) and the process lead (CA).

**Overlap of the process and outcomes, and cost-effectiveness evaluations**

Due to the complexity of the study, we have embedded the process evaluation within the daily conduct of the outcomes and cost-effectiveness evaluations. Thus, data for all three purposes are being collected concurrently, and some measures may be used for both process and outcomes’ evaluations. During team training, emphasized the multi-purposing of data and the need to maintain ‘researcher equipoise’.

**Description of the intervention**

We have previously detailed the SI components and implementation (Leroi et al., 2017). In summary, the SI, which is delivered as 10-session programme by a trained ‘sensory support therapist’ (SST) and audiologists/optometrists, is outlined in Figure 1. It involves several components, notably: (1) Identifying and correcting any vision or hearing impairment; (2) supporting adherence with the hearing and/or vision devices, through advice and training in correct use and care; (3) enhancing communication between the PwD and their companion; (4) demonstrating environmental aids and sensory devices; and (5) accessing relevant support services and social networks. The non-intervention group receives ‘care as usual’ (CAU) accesses the services and interventions normally available to PwD and their companions in their respective countries and sites.

**Causal assumptions about how change will be produced**
To understand fully the impact of the intervention on the outcomes, and to
generalise the findings in the pan-European context of SENSE-Cog, an exploration of
causal mechanisms and unanticipated pathways is needed (Craig et al., 2008). We
will do this by extracting pre-specified mediating variables and qualitative data
(from a sub-sample of 30 participant dyads), and evaluating adverse events and
unexpected consequences of the intervention. We will also undertake semi-
structured interviews with the SSTs at each of the five study sites.

The principal aim of the intervention is to improve quality of life and functional
ability by improving sensory function through devices and behavioural change.

Dementia-related quality of life comprises the domains of daily activities (activities
of daily living and self-care), physical health and wellbeing, cognitive functioning
and social relationships (Mulhern et al., 2013). To influence these domains, we
have adopted the COM-B component of the Behaviour Change Wheel (Michie et al.,
2011) as our framework for how the intervention might work. According to this
model, behavioural change (‘B’) results from: capability (‘C’), the individual’s
psychological and physical capacity to engage in the activity concerned; opportunity
(‘O’), the external factors that support behavioural change; and motivation (‘M’),
the conscious and sub-conscious processes that direct decision making (Michie et
al., 2011). In Table 1 and Figure 1, using a logic model, we outline how each COM-B
element aligns with specific components of the SI, and how these might
hypothetically lead to improvements in quality of life, our primary outcome.

Briefly, for capability, the sensory aids (i.e. hearing aids, glasses, and sensory
environment modification in the home) and SST adherence support will improve
hearing and vision (physical capability), which will enhance sensory-cognitive
function, overall functional ability, and reduce neuropsychiatric symptoms (Wong et al., 2014; Maharani et al., 2018; Ghiringhelli & Lorio, 2013; Martini et al., 2015; Dawes et al., 2015). The SST will train communication skills and improve knowledge of dementia and sensory impairment (psychological capability). This will increase opportunity by decreasing dependency on companions, enhancing social interactions and reducing loneliness. Adherence support for PwD with sensory devices will enhance hearing (Nieman et al., 2016), vision (Acton et al., 2016), or both (Leroi et al, 2019b). Furthermore, social opportunities will be enhanced through signposting outside the home, thus addressing social isolation, improving social relationships, and providing respite for companions. Regarding motivation, higher sensory-cognitive function and improved neuropsychiatric symptoms will improve self-efficacy, self-esteem, and mental wellbeing (Kreeger et al., 1995; Rogers et al., 2010). However, motivation may be reduced in dementia, particularly if apathy is present. Thus, the SI will address this through goal setting. We will measure apathy to take account of motivation as a potential moderator, or even mediator, of the intervention’s impact. Greater independence and communication ability in the PwD will reduce companions’ burden and stress, which will also impact positively the overall wellbeing. Attitudes and knowledge training will support change maintenance and relationship quality (Ogden & Hills, 2008).

[*Please insert Table 1 here*]

[*Please insert Figure 1 here*]

Identification of key uncertainties, and developing a framework for the process evaluation
In Table 2, we identified key uncertainties to address for each SI. We will use a mixed method approach to capture the data for the evaluation. This will involve a variety of instruments, as outlined in Table 3.

[*Please insert Table 2 here*]

[*Please insert Table 3 here*]

**Exploration of delivery**

To ascertain whether the SI is delivered (i.e. ‘how’) and enacted (i.e. ‘what’) as intended (Moore et al., 2015), we will examine the fidelity and dose (i.e. duration, number and frequency of SI visits) of the delivered intervention. Due to potential burden on participants, we have chosen not to include an external evaluation of fidelity (i.e. independent observer during sessions). Instead, we will rely on the proxy measure of ‘fidelity’ as determined by rigour of SST training and supervision, use of therapist manual, and SST logbook recordings of sessions. We will document the nature of the support offered by the intervention, including the type of corrective devices, the environmental changes to support sensory function, the number and types of referral or signposts to extra-trial services. These data will be captured in through participant diaries (the PwD and their companion), and the SST logbook.

Specifically, the *PwD diaries* will contain Likert style ratings (Likert, 1932) of acceptability and tolerability of SI visits, including measures of helpfulness, effort, fatigue, understanding and motivation; and how acceptable the corrective sensory devices are. The *companions’ diaries* will capture data relating to how the PwD engages with the visit, how the PwD is adapting to their sensory aids, and how confident the companion feels in supporting the PwD in using the aids. The SST
logbooks will contain details of each visit, the components of the SI delivered, participant response to the intervention and skill in managing their aids. Additionally, the SST logbooks will detail how the SI is specifically tailored to the dyad.

We will assess reach through the representativeness of the sites, the recruitment process (refusal rate, attrition rate) and the representativeness of the study population according to the target population (Liu et al., 2016).

**Evaluation of contextual issues**

The SENSE-Cog RCT will take place in several different countries and involve three languages (English, French and Greek). Thus, contextual issues, which are external to the intervention itself, need to be carefully considered. These include differences in language, culture, access to services, and the health and social care economy. Context may influence the SST’s ability to foster change in the participant dyad’s circumstances. For example, for social isolation, the SST may recommend attendance at a local lunch club; however, if transportation is not suitable for individuals with sensory and cognitive impairment, the opportunity to take up the offer will be hampered. Likewise, communication training with companions may be differently received in diverse cultural and linguistic contexts. Thus, the same intervention may have divergent outcomes according to the setting in which it is delivered (Moore et al., 2015). The dyadic relationship (between the PwD and their companion) should also be considered because the level of support and quality of relationship may vary among dyads. To capture contextual data, we will collect information from the demographic and outcome measures, the participant dyad
diaries, the SST logbook, and in-depth qualitative interviews of a sub-sample of participant dyads (n=30 dyads across the sites), as detailed in the SENSE-Cog Trial protocol (Regan et al., 2019).

**Sampling and timing of data collection**

We will collect characteristics of each participant dyad, including gender, age and support structure at the screening visit, and at baseline, week 18 and week 36 (Table 3 & Table 4). Following each SI visit (for the active arm), participant diaries and SST logbooks will be completed. The sub-sample qualitative interviews will take place within two weeks following the SI (details described in Regan et al., 2019). Training logs for the SSTs were collected prior to study start. SST supervision logs and fidelity checks of the SST logbooks are being collected throughout the trial. SST interviews will be held within two weeks after the last intervention visit of the last randomised dyad in each site.

[*Please insert Table 4 here*]

**Analysis**

To avoid biased interpretation, as recommended by the MRC’s guidance, we will analyse and explore process data arising from the qualitative interviews and contextual factors before trial outcomes are known (Moore et al., 2015). We will use the process data to generate specific hypotheses (pre-trial explanation before trial outcomes are revealed) regarding factors that moderate and/or mediate the effect of the SI on outcomes, notably quality of life. This will minimise the risk of “fishing”
for relationships and falsely significant findings due to multiple testing. Moderator analyses will be undertaken, with appropriate caution, to investigate any influence of the baseline characteristics of the dyads (e.g. age, gender, type of sensory impairment, level of cognitive impairment, type of companion), and country/site effect on the strength and/or direction of the relationship between the SI and the outcomes. We will undertake mediation analyses to assess the degree to which the impact of the SI on the stated outcomes is a direct effect, or is indirect via the hypothesised mediating factors. We will conduct the moderator/mediator analysis only after the final RCT analysis has been completed and the dataset has been un-blinded. We will do this regardless of whether the SI has a significant direct impact on the primary outcome. We will apply a regression framework, using newer methods and statistical models (Hayes and Rockwood, 2017, Fairchild et al., 2009) that improve on traditional approaches (e.g. Baron & Kenny, 1986). These models can become complex, particularly when controlling for multiple covariates. Thus, depending upon the number and complexity of the hypotheses to be tested, we will assess whether it will be better to analyse each factor separately, or to combine sets of moderators and/or mediators into a ‘conditional process analysis’ (Hayes and Rockwood, 2017). We will conduct separate analyses for those variables available in both trial arms, and those available in the intervention group only (e.g. related to the SI). The latter analyses will help to identify process measures that are part of the SI and may moderate its efficacy (for e.g., number of SST visits, SST experience, and fidelity), using appropriate techniques (Dunn et al., 2015). 

Discussion
The process evaluation of the SENSE-Cog RCT will appraise several important aspects of the delivery of the intervention, the context of delivery, and the hypothesised causative mechanisms. These issues are key to interpreting the effectiveness outcomes of the trial and, if outcomes are positive, to assist in understanding implications for scale-up in clinical settings. The SI will have multiple interacting components: assessing and correcting hearing and vision impairment (hearing aids and / or glasses lenses), training in the use of the devices, enhancing communication within the dyad, optimising the home sensory environment, and supporting engagement in health and wellbeing opportunities in the community, including social integration and external support services.

A key challenge in delivering the SENSE-Cog SI is to maintain standardisation and rigour when implementing such a complex intervention across five different European sites. The SENSE-Cog SI is ambitious in its vision in addressing three co-morbidities simultaneously: cognitive impairment, hearing loss and vision loss and to assess the impact of a psychosocial intervention on managing these impairments.

We will aim to capture the cultural, social and economic nuances of the respective European study sites whilst deriving results that can be applied in a pan-European context. To ensure that we capture the cultural differences from the qualitative interviews, we will keep translation to a minimum, as recommended by Haak et al. (2013).

The theoretical model with causal relationships will be informed by the mediation analyses. The elicited data will also enable us to ‘test’ the theoretical model of the COM-B by addressing the key uncertainties listed in Table 1. This will be the first opportunity to evaluate empirically the COM-B model in a RCT setting, as demonstrated in Figure 1.
**Strengths and limitations of the study**

A strength of our study protocol includes the use of a mixed method approach, including both qualitative and quantitative measures, to carefully explore the ‘how and why’ of the intervention. Another strength of our approach includes the sound theoretical framework on which the intervention was developed, and the iterative manner in which it was modified and field-tested (Leroi et al., 2017a; Leroi et al., 2019b) before arriving at the final version of the intervention, ready for full scale effectiveness testing. A limitation (although also a potential strength) is the significant degree of variability in the study sites due to the different EU contexts in which the programme takes place, as well as the variability of the intervention offered to each participant dyad, resulting from the tailored approach.

**Reporting and dissemination**

We will report the results of the process evaluation described here using a combination of reporting guidance, including CONSORT (Moher et al., 2010), and COREQ (for the qualitative outcomes; Tong et al., 2007), as well as statistical methods for mediators and moderators (Lang and Secic, 2006). We will submit the findings to an open-access journal, as per the requirements of the funder. As recommended by others (Liu et al., 2016), we have described our protocol in advance to foster transparency in reporting, and to help the development and evaluation of complex psychosocial interventions for PwD, an emerging area of health services research. Finally, we will link our outputs related to the SENSE-Cog Trial through the SENSE-Cog programme’s website (www.sense-cog.eu).

**Ethics approval and consent to participate**
In Manchester, the study received final approval (Version 3.0) by the NW Haydock ethics committee on 22 January 2018 and obtained sponsor approval on 8 March 2019. In Nicosia, the study received favourable opinion on 27 September 2016 from the Cyprus National Bioethics Committee. In Athens, the Local Ethical Committee of Health Sciences and Scientific Committee of the Eginition Hospital of the National and Kapodistrian University of Athens ethics committee granted a favourable opinion on 24 January 2018. In Dublin, the Saint James Hospital/AMNCH Research Ethics Committee gave approval on the 25 October 2018. In Nice, the “Comité de Protection des personnes Sud Est I” gave a favourable opinion on 12 July 2018. Written consent is collected from the participants eligible for the study, using procedures in accordance with the national guidance regarding informed consent and clinical research (for individuals with or without capacity to consent) in each of the participating countries (detailed in Regan et al., 2019). All researchers have been fully trained in Good Clinical Practice (GCP) and mental capacity assessment skills and follow national guidance in their respective countries, such as the Mental Capacity Act (2005) in the UK. If a person lacks capacity, a nominated consultee will be asked to deem whether it is in the PwD’s best interests to participate.

**Trial status**

This process evaluation is based on the SENSE-Cog RCT protocol version 4.0 of 16 November 2018. The overall SENSE-Cog research programme started in January 2016 and the SENSE-Cog RCT (Work Package 3.2) started recruitment in summer 2018. Recruitment is expected to end in December 2020. The first qualitative interviews with participants took place in November 2018. The process evaluation will start in following the last W36 assessment of the first randomized participant dyad.
List of Abbreviations

**AE** = adverse events

**COM-B** = capability, opportunity, motivation - behavioural change wheel

**MRC** = medical research council

**PwD** = people with dementia

**RCT** = randomized controlled trial

**SI** = sensory intervention

**SST** = sensory support therapist

Declarations

**Ethics approval and consent to participate**

This study has been reviewed by the local ethics committees in the UK, Cyprus, France, Greece and Republic of Ireland. Ethical approvals were granted by the North West – Haydock Research Ethics Committee (Ref: 17/NW/0702; UK) on 21 December 2017. By the Cyprus National Bioethics Committee (Ref: EEBK/EP/2016/29) on 19 January 2017. By the Comité de Protection des Personnes Sud-Est I (Ref: 2018-A00667-48) on 03 April 2018. By the Local Ethical Committee of Health Sciences and Scientific Committee of the Egnition Hospital of the National and Kapodistrian University of Athens (Ref: OZ5E4648N2-FT4) on 24 January 2018. By the St. James University Hospital and Tallaght University Hospital, joint Research and Ethics Committee (Ref: 2018-10 List 35 (2)) on 25 October 2018. Signed informed consent will be obtained from all participants in the study. Participation in this study is voluntary, and participants can withdraw from the study at any time.

**Consent for publication**
Not applicable

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Availability of data and materials

Data generated or analysed during this study will be included in the article reporting the results that will be shared through scientific articles and international conferences.

Authors' contributions

IL, EF, FC, MH, DR, EH and ZS and LW were responsible for the overall development of an ethically sound protocol. IL, EF, MH, LW, EH, ZS and CA led the design of the
process evaluation. All authors contributed to the drafting, critical revision and final approval of the manuscript.

**Competing interests**

The authors declare no conflict of interest.

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**Tables**

Due to technical limitations, tables 1 - 4 are only available as a download in the supplemental files section.

**Figures**
Figure 1 How the elements of the ‘COM-B Behaviour Change’ model and components of the sensory intervention link together

Supplementary Files

This is a list of supplementary files associated with the primary manuscript. Click to download.

Table 2.pdf
Table 1.pdf
SPIRIT_Fillable-checklist-Apr_2019.pdf
Table 4.pdf
Table 3.pdf