Hearing and vision rehabilitation for people with dementia in five European countries (SENSE-Cog): a randomised controlled trial

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Summary

Background The effect of hearing and vision difficulties on the risk of developing dementia and worsening outcomes in people already living with dementia is well established. We evaluated the clinical impact of a hearing and vision rehabilitation and support programme on quality of life in people with mild-to-moderate dementia and concurrent sensory difficulties.

Methods We conducted a parallel-group, multicentre, observer-blind, superiority randomised controlled trial in seven older adult clinics in five European countries (Cyprus, France, Greece, Ireland, and the UK). People with mild-to-moderate dementia with adult-acquired hearing difficulties, vision difficulties, or both were randomly assigned (1:1) along with their care partner to an 18-week home-basedsensory support intervention (SSI) of tailored hearing and vision rehabilitation and support, or to care as usual. Randomisation was blocked (block size of four, six, or eight) and stratified by country, with allocation assigned via a remote web-based system. The SSI included: full hearing assessment, vision assessment, or both; fitting of hearing aids, glasses, or other sensory aids; and home-based support from a sensory support therapist to assist adherence and uptake of sensory aids, foster social networking, and optimise the home sensory environment. Care as usual involved no additional intervention beyond services normally available to people with dementia at the respective sites. The primary outcome was health-related quality of life (Dementia Quality of Life Instrument [DEMQoL]) score at 36 weeks, reported as an adjusted mean difference. Analyses were done according to the intention-to-treat principle. This trial is registered with the ISRCTN Registry, ISRCTN17056211.

Findings Between May 4, 2018, and May 6, 2021, 252 people with mild-to-moderate dementia were randomly assigned, of whom 251 (n=126 in the SSI group and n=125 in the care as usual group) were included in the analysis. The mean age of participants was 79·6 years (SD 5·8), and 132 (53%) were women. After a median follow-up time of 37·7 weeks (IQR 36·2–39·0), the mean DEMQoL score was 92·8 (SD 15·2) in the SSI group and 92·8 (14·0) in the care as usual group (adjusted difference 0·18, 95% CI −2·13 to 2·30, p=0·87). Among 114 adverse events reported for 56 (44%) participants in the SSI group, ten events in nine participants were related or possibly related to the intervention (medical device pain or discomfort n=6, ear pain n=1, scratch to the ear n=1, sore eye n=1, redness n=1; all of grade 1). Serious adverse events were reported for 25 (20%) participants in the SSI group and 16 (13%) in the care as usual group. Six (5%) participants in the SSI group and five (4%) in the care as usual group died. None of the serious adverse events or deaths were related to the study intervention or procedures.

Interpretation This study showed no improvement in quality in life in participants who received the intervention in the longer term. Sensory difficulties are common in people with dementia and interventions aimed at improving sensory-cognitive health should be explored further.

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Introduction

The impact of dementia on individuals, care partners and families, and society is substantial. Across Europe, informal care provided by families and friends alone represents a large proportion of the total cost of care, ranging from 40% to 75% of the total dementia care costs.[1] Of note, the mean annual cost per patient with dementia ranged from nearly €8000 (in eastern Europe and the Baltic states) to almost €75 000 (the UK and Ireland).[1] Identification of interventions to prevent dementia or improve quality of life for those with dementia has been made a priority within the UK and Europe. In this region, about 14 million people are

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See Online for appendix

Research in context

Evidence before this study

We undertook a scoping review of studies focusing on interventions for hearing or vision impairment in individuals with dementia, exploring their impact on cognitive function, rate of decline, psychiatric symptoms, hearing-related or vision-related disability, quality of life, and care partner burden (PROSPERO, CRD42016039737). We conducted electronic database searches from database inception up to May, 2016, using specific keywords, such as dementia, hearing impairment, vision impairment, intervention, and management. Additionally, manual searches of paper bibliographies and consultation with health-care professionals were conducted to identify further relevant literature. Inclusion criteria were studies involving adults older than 50 years with a progressive dementing condition, diagnosed with acquired adult-onset hearing difficulties or vision impairment. These individuals had undergone at least one hearing or vision intervention, including surgical management, assistive devices (such as hearing aids, cochlear implants, corrective refraction, talking barcode scanners, or colour helpers), environmental modifications, or behavioural training. We included peer-reviewed studies and grey literature, comprising randomised controlled trials, quasi-experimental studies, and observational studies. Our findings, summarised descriptively, indicated the inclusion of 12 reports on hearing interventions and five on vision interventions in people with dementia. The majority of these studies were assessed as low to moderate quality, with only one high-quality randomised controlled trial focusing on a hearing aid intervention. Despite these efforts, there was no consistent evidence supporting the positive impact of hearing or vision interventions on cognitive function, rate of cognitive decline, quality of life, or care partner burden. These findings underscored the necessity for well powered, controlled trials evaluating the effects of hearing and vision interventions on outcomes relevant to individuals living with dementia.

Added value of this study

To our knowledge, this is the first fully powered randomised controlled trial of hearing and vision rehabilitation in people with mild-to-moderate dementia, providing the best evidence to date on such interventions for improving dementia-related quality of life in the shorter term. Additionally, this is the first intervention addressing both hearing and vision difficulties and applying a multi-modal approach to address the multitude of factors related to the impact of ageing-related sensory difficulties in people with dementia. The findings revealed no significant improvement in quality of life in the intervention group at 36 weeks compared with the care as usual group, although some improvement in quality of life was seen at 18 weeks in the intervention group. Further evidence is needed to understand the impact on cognition, neuropsychiatric symptoms, and the role of family or the care partner.

Implications of all the available evidence

Most people with dementia experience hearing or vision difficulties (or both), which are frequently unrecognised or inadequately addressed. This study highlights the feasibility, acceptability, and potential short-term impact on quality of life of hearing and vision interventions in people with dementia, supporting the need to increase awareness and availability of sensory health interventions for this population. However, efficacy in the longer term was not seen. Such non-drug interventions should be considered in the standard care of people with dementia. Future research to ascertain which components of the intervention might or might not be effective is indicated.

living with dementia,[1] of whom at least 70% experience concurrent age-acquired hearing difficulties, vision difficulties, or both, which can have a substantial negative impact on dementia-related outcomes such as mental wellbeing and quality of life.[2,3] Although evidence is sparse, interventions that improve hearing and visual function might mitigate against cognitive and functional decline and improve quality of life for people with dementia and their care partners through several mechanisms of action, including enhanced communication and social interaction, reduced feelings of isolation, increased independence and functional ability, and reduced cognitive load.[4–6] A systematic review of hearing and vision interventions for people with dementia found no consistent evidence of positive impacts on cognitive function, decline rate, quality of life, or care partner burden.[7] Following the UK Medical Research Council framework for complex interventions,[8] we developed the SENSE-Cog sensory support intervention (SSI), a multicomponent intervention in which sensory difficulties are assessed, corrected where possible, and support is provided by trained therapists.[9] After assessing its feasibility in three EU countries,[10,11] we conducted a trial comparing the SSI to care as usual in people with mild-to-moderate dementia and sensory difficulties. We hypothesised that the SSI would promote mental wellbeing and reduce the negative impact of dementia on both individuals and care partners.

Methods

Study design and participants

The full protocol for this trial has been published previously.[12] We summarise the main points here, adhering to the CONSORT 2010 and CONSERVE 2021 statements.[13,14] Briefly, this was a two-arm, parallel-group, multicentre, observer-blind, superiority randomised controlled trial comparing the SSI to care as usual for people with mild-to-moderate dementia and sensory difficulties. The trial was conducted across seven study sites in five European countries: Cyprus (Nicosia), France (Nice), Greece (Athens), Ireland (Dublin), and the UK (Manchester, Preston, and Warrington). The intervention was

delivered by trained sensory support therapists in participants' own homes, supported by their care partners. This study was approved by national ethics review committees and research governance departments in each of the participating countries. Important changes to methods were initiated after trial commencement, and before the analysis, due to restrictions resulting from the COVID-19 pandemic. Disruptions and mitigating strategies applied to the protocol are detailed in the appendix (pp 14–18). In brief, with all study sites closed, recruitment and follow-up visits were paused, and certain elements of the intervention could not be delivered, such as in-home visits. Once restrictions were partially lifted, protocol amendments were put in place, including remote follow-up assessments and a reduced number of follow-up assessments. We undertook a standardised and partially remote delivery of the SSI for some intervention components. There were delays in hearing and vision assessments and provision of hearing aids and glasses. Additionally, all new recruitment of participants was halted until restrictions were fully lifted, from June to November, 2020, depending on the country. All protocol amendments were approved by the trial steering committee and the ethics committees at each study site.

The study used several routes for recruitment depending on country and site. The most common route was through memory assessment services run by geriatric psychiatry departments (the UK, Ireland, France, and Greece). In Cyprus, participants were identified from dementia care centres, mental health services, the Ministry of Health and private practice. Recruitment was carried out in different ways (ie, by letter, telephone call, or online national database recruitment). Participants were recruited in dyads comprising a person with dementia, as per ICD-10 criteria,[15] of mild or moderate stage (defined by a Montreal Cognitive Assessment [MoCA] score of ten or higher),[16] age 60 years or older, and living at home, and their care partner. Dementia was defined as an underlying diagnosis of Alzheimer's disease, vascular dementia, or mixed dementia. Participants with dementia were required to be on stable cognitive-enhancing medication for at least 4 weeks before screening and to have adult-acquired hearing difficulties, vision difficulties, or both. Vision difficulties were defined by binocular visual acuity of 6/9·5 or worse and greater than 6/60 in Snellen metric (or $\geq$ +0·2 logMAR [Early Treatment Diabetic Retinopathy Study (ETDRS) score 75] and < +1·0 logMAR [ETDRS score 35]) using the Peek acuity application, and a visual field of more than 10° using confrontation visual field test.[17] Hearing difficulties were defined by a bilateral hearing difficulty, indicated by failure of a pure tune hearing screening test in both ears, defined by a score of 5 or less in both ears (ie, failing to hear either the 20 dB tone at 1000 Hz or the 35 dB tone at 3000 Hz) measured with a Siemens HearCheck Screener (Siemens, Munich, Germany), and willingness to accept sensory interventions, if needed. Participants were required to have capacity to consent (or have a legal representative to consent on their behalf if lacking capacity) and, in France, to be linked to the social security system. We excluded any participants with unstable, acute, or current psychiatric or physical condition severe enough to prevent them from participating in the study, complete blindness, severe visual difficulties, or deafness (profound hearing difficulties). Those participating in any other trial, with scheduled or urgent treatment or intervention for hearing or vision difficulties (ie, cataract surgery already scheduled or treatment for macular degeneration needed), unable to read and write, or who had a clinical presentation suggestive of COVID-19 were also excluded. Care partners were required to be aged 18 years or older and an informal care partner (ie, providing care was not the person's primary paid role), with regular contact with the person with dementia (at least weekly). All participants were required to speak and understand the language of intervention delivery and to be able to read and write, and, after the COVID-19 pandemic restrictions were in place, to have access to a means of remote contact (ie, telephone or computer). Race and ethnicity data were not collected because our research questions were not focused on uncovering health disparities and inequities. Written consent was 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. For participants lacking capacity, care partners, who also signed their own consent to participate in the study, were asked to represent the wishes of the person with dementia and provide assent, taking the role of personal consultee.

This trial is registered with the ISRCTN Registry, ISRCTN17056211.

Randomisation and masking

After providing consent and undergoing baseline assessment, participants were randomly assigned (1:1) to the SSI or care as usual according to a randomisation list with permuted blocks of varying size (four, six, or eight) stratified by country, generated centrally by a masked biostatistician at the University of Manchester (Manchester, UK). Randomisation of participants was conducted through the trial electronic case report form by the site sensory support therapist. Masking of participants, carers, or the sensory support therapist was not possible. Each centre had both masked and unmasked researchers involved with different aspects of the study, with standardised procedures put in place to maintain masking.[12] After each visit, masked researchers rated their perception of which group the participant dyad had been assigned to.

For the **Peek acuity application** see https://peekvision.org

Procedures

We have previously described the development, rationale, and components of the SSI according to TiDIER standards.[10–12] Briefly, the SSI is a complex, multicomponent intervention comprised of three core parts, delivered over a

period of up to 18 weeks: (1) assessment of sensory difficulties by audiologists (including the Glasgow Hearing Aid Benefit Profile), vision health specialists, or both; (2) correction of sensory difficulties with devices such as hearing aids, pocket talkers, and glasses; and (3) ongoing support from a sensory support therapist. The sensory support therapist offered sub-components of the intervention, which included: adherence advice and training or support in maintenance of sensory devices, communication training with care partners, enhancing social networks, and referrals to additional health and social care support agencies if needed. The structure of the intervention was guided by goals co-established by the participant dyad and support therapist around hearing and vision health and agreed strategies to achieve the goals. Each dyad received a maximum of ten home visits by the sensory support therapist, typically on a weekly basis. The sensory support therapist is not currently a recognised professional role at either the national level (in national qualification frameworks) or at EU level (European Skills, Competences, and Occupations classification). Thus, we applied a pragmatic approach to identify a core set of skills and attributes for the role, ensuring that health professionals from different backgrounds (eg, clinical psychology, social work, audiology or vision rehabilitation, and occupational therapy) would be eligible for the role.

Care as usual involved no additional intervention. After the initial study screening for hearing and vision difficulties, participants were informed of any suspected hearing or visual difficulties (or both), and information sheets provided on where they could access local health and social care services normally available to people with dementia and their care partners in their respective sites. The study team did not interfere with care as usual but documented it in the study case report form.

An overview of the data collected at baseline and during 18 weeks and 36 weeks of follow-up is provided in the protocol.[12] Details of the exact nature of the intervention components received by participants in the SSI group will be outlined in a future publication.

Outcomes

The primary outcome was the 36-week Dementia Quality of Life Instrument (DEMQoL) score of participants with dementia.[18] The DEMQoL is a 28-item interviewer-administered patient-reported outcome measure answered by the person with dementia (scored 28 to 112; higher scores indicate better quality of life). It addresses four domains: daily activities, memory, negative emotions, and positive emotions, although the focus of our primary analysis was the overall scale score. Secondary outcomes for the participants with dementia were the 18-week DEMQoL score, and the following measures undertaken at week 18 and week 36: DEMQoL-Proxy,[18] functional independence using the Bristol Activities of Daily Living (BADL) scale,[19] visual function using the Veterans Affairs Low Vision-Visual Functioning Questionnaire (VALV-VFQ; including an adapted version for care partners),[20] and hearing function using the Hearing Handicap Inventory for the Elderly (HHIE) and HHIE spousal rating.[21,22] Additionally, at week 18 and week 36, global cognitive functioning in participants with dementia was assessed using the MoCA (only before the COVID-19-related protocol amendments),[16] neuropsychiatric symptoms were assessed using the 12-item Neuropsychiatric Inventory,[23] and relationship with the care partner was assessed using the Relationship Satisfaction Scale.[24] Adherence to sensory aids was assessed through participant dyad diaries and research therapist log books, using a five-point Likert scale of device use: never wearing; wearing infrequently (<1 h per day); wearing moderately (1 to <4 h per day); wearing frequently (4–8 h per day); wearing fully (>8 h per day). Hearing aid use and adherence were established by dyad self-report and semi-structured questions during the sensory support therapist visits. As exploratory outcomes, barriers and facilitators were assessed using qualitative, semi-structured interviews of dyads who experienced the SSI (at least two completed visits of the intervention with the sensory support therapist) in a subset of participants; however, these results are reported elsewhere.[25] Time spent with the sensory support therapist per visit and the number of visits per participant were also recorded in sensory support therapist logbooks. Adverse events were recorded and their relationship with the intervention assessed at each study contact, including specific telephone calls at 8 weeks and 26 weeks. The cost to deliver the intervention was calculated and included resources required for: training sensory support therapists, assessment of sensory impairment (to tailor devices), provision of sensory augmentation device or devices, and sensory support therapist time supporting dyads. Finally, 20 participant dyads (n=40) in each of the five European sites were interviewed using a semi-structured questionnaire about the impact of the intervention on quality of life for people with mild-to-moderate dementia. Interviews were analysed using qualitative content analysis and a grounded theory approach. Results of this analysis will be published elsewhere.

Statistical analysis

The trial was originally powered to detect a four-point change on the DEMQoL, which, coupled with an SD of 15 points,[18] yielded a standardised effect size of 0·267, equivalent to the smallest change considered clinically meaningful and in line with other outcomes in dementia trials.[26] Assuming a correlation of 0·6 between baseline and 36-week follow-up DEMQoL scores and an attrition rate of 20% at follow-up (a conservative estimate based on the rates observed by Wenborn and colleagues),[27] the trial would have needed to recruit 354 dyads at baseline (177 per group) to achieve 80% power to detect the target effect size at the two-sided 5% level of significance.

Due to the disruption in trial activity resulting from the COVID-19 pandemic restrictions, we revised the sample size calculation using pooled baseline DEMQoL data from the 132 participants randomly assigned up to that point.

With this pooled SD of 13·55 points, a revised sample size of 290 participant dyads was required.

Outcomes were analysed according to the intention-to-treat principle. DEMQoL scores were assumed to be continuous and multivariable linear regression was conducted to estimate and test the mean difference between groups. Prespecified covariates were baseline DEMQoL score, age, and sex of the participant with dementia, nature of sensory difficulties, and country. Analyses were additionally adjusted for care partner sex and dementia type, because a baseline imbalance between groups was observed (predefined in the statistical analysis plan as a >10% difference in any single category). Country was treated as a fixed effect because there were only five countries. Because distribution of responses to patient-reported outcomes is often found to be non-normal (negatively skewed), we used a non-parametric bootstrapped estimate of the standard error to generate 95% CIs (using 1000 replications).

Guidance from the developers of the DEMQoL suggests that if no more than half of the 28 items are missing, an overall score can be computed by imputing the mean score observed in the sample on an item-by-item basis. However, as suggested by previous work,[28] we replaced missing item scores with the mean across the DEMQoL items answered by each specific participant, because these are more likely to be correlated with each other than with responses from other participants. Thus, for a given participant, if no more than half of the 28 items were missing, imputation was made at the item level to compute a DEMQoL total score; if more than half of the 28 items were missing, the DEMQoL total score was treated as missing. Then, assuming missingness at random, DEMQoL total scores were handled using multiple imputation by chained equations (MICE), with generation of 25 imputed datasets and pooling of results using Rubin's rule.[29]

Additional adjustment for the remote conduct of the 36-week follow-up visit and a complete case analysis were conducted as sensitivity analyses. We determined intervention adherence to the allocated treatment in each trial group, defined as attendance to at least the minimal version of the SSI—ie, correction of visual or auditory difficulties (or both), training in the use of sensory devices, a functional assessment, individualised goal setting and communication training for the intervention group, and not having received any component of the SSI, except for glasses, a hearing aid, or both, via usual care, in the care as usual group. A per-protocol analysis was conducted on the subset of participants who adhered to their allocated intervention and with available 36-week DEMQoL score. A prespecified subgroup analysis by country was also conducted, including an interaction term between trial group and country, and computing a mean treatment effect and 95% CI for each country.

Secondary outcomes were analysed using a similar analytical strategy and appropriate regression models controlling for baseline scores and a common set of covariates (age and sex of the participant with dementia, sex of the care partner, sensory difficulties, country, and dementia type). The distribution of BADL scores was highly positively skewed, so scores were dichotomised (0–14 representing lower dependence *vs* 15–60 representing higher dependence),[19] and analysed using logistic regression. For the same reason, HHIE scores were categorised (0–16 for no or minimal difficulties; 18–42 for mild to moderate difficulties; 44–100 for severe difficulties),[21] and analysed using ordinal logistic regression. MICE was used to handle missing data on secondary outcomes, except for VALV-VFQ, for which regression models were not fitted due to the large amount of missing data.

The intervention cost was estimated based on a price year of 2020 and an exchange rate of £0·86 to €1·00. This was the most recent annual average exchange rate available at the time of the analysis. Further details about the methods used to calculate the intervention cost are reported elsewhere (appendix pp 6–7).

All inferential analyses were conducted using Stata statistical software (versions 14 and 15). Statistical tests were performed with a two-sided type I error rate of 5%.

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

Between May 4, 2018, and May 6, 2021, 299 people were deemed eligible for inclusion at initial screening, with 252 randomly assigned (127 to the SSI and 125 to care as usual; figure 1). One participant in the SSI group was excluded from all analyses by the trial steering committee, who were masked to intervention allocation, because they had arranged to have cataract surgery before being randomly assigned. 53 participants prematurely terminated the study. The primary intention-to-treat analysis was conducted on 251 participants. The overall week 36 DEMQoL completion rate of 76% was similar in both groups. Moreover, 35 (36%) of 96 dyads in the intervention group and 37 (39%) of 96 dyads in the care as usual group received the week 36 follow-up remotely, due to COVID-19 restrictions. The median time from randomisation to final follow-up was similar in the two groups: 37·8 weeks (IQR 36·6–39·4) for the SSI and 37·3 weeks (36·0–39·0) for care as usual. The mean age of the participants with dementia was 79·6 years (SD 5·8; range 60–93). Care partners were, on average, 15 years younger (mean 64·6 years, SD 13·3; range 30–97). There were slightly more female participants with dementia (n=132, 53%) compared with men, and most care partners were female (n=182, 73%). Most participants with dementia had hearing difficulties, either alone (n=150, 60%) or in combination with visual difficulties (n=92, 37%). The majority (n=182, 73%) of participants with dementia lived with either their life partner or another family member, although 59 (23%) lived alone. The characteristics of participants with dementia were similar in the two groups,

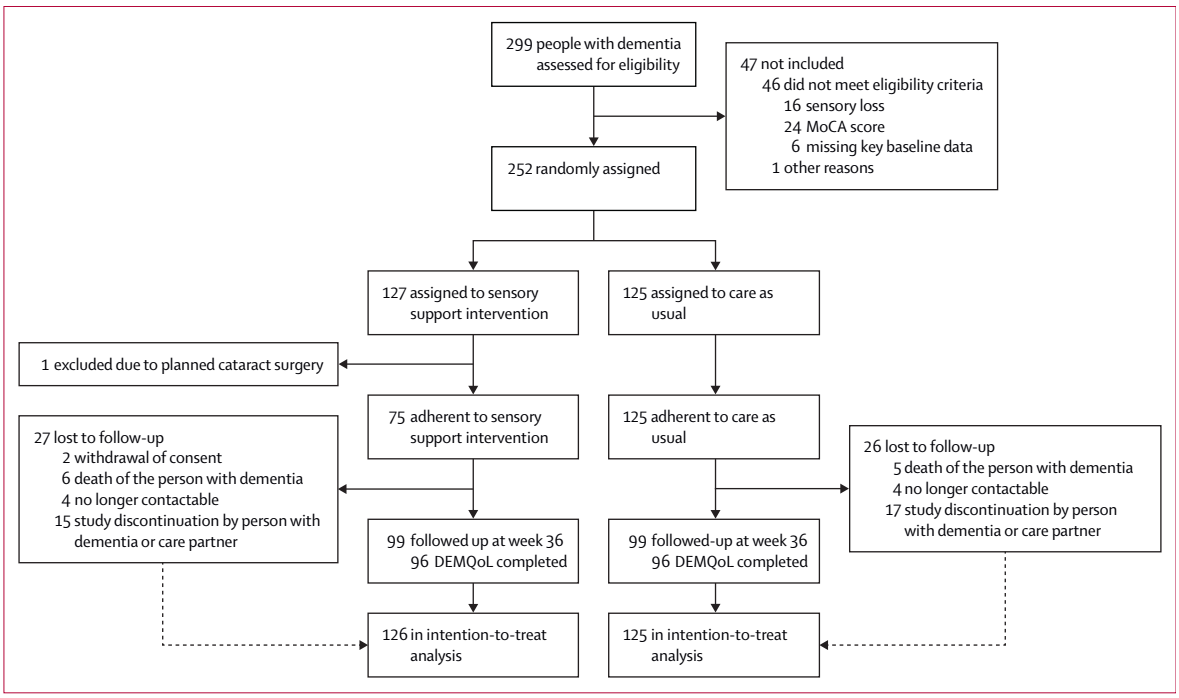

Figure 1: **Trial profile**
DEMQoL=Dementia Quality of Life Instrument. MoCA=Montreal Cognitive Assessment.

except for sex and dementia type. The sex of care partners was also unbalanced between groups (table 1).

Before COVID-19 restrictions were introduced, the SSI was delivered weekly in participants' homes, over a median duration of 14·5 weeks (IQR 12·3–16·6). 75 (60%) participants allocated to the SSI adhered to the COVID-19-amended intervention, and the proportion of participants who completed each SSI component varied from 65% to 94% (appendix p 9). Participants received a mean of 6·3 visits from the sensory support therapist (median eight, IQR 7–10), totalling a mean of 444 min spent with the sensory support therapist (median 475, 330–585); appendix p 13). Of the 126 participants assessed for hearing difficulties as indicated by screening, 101 (80%) were prescribed hearing aids, with acceptable adherence, as ascertained by average five-point Likert scale score of 3·85 (higher is more adherent). Of the 54 participants who received a vision assessment as indicated by screening results, 43 (80%) were given a new prescription for glasses. 90 (71%) completed training in use of sensory devices (appendix p 9). No participants allocated to care as usual followed any aspect of the SSI, nor did they receive new hearing aids or glasses during the study period. Baseline Glasgow Hearing Aid Benefit Profile responses indicated significant hearing-related functional challenges (defined as great difficulty or cannot manage for a given situation) for up to 25% of 108 respondents, particularly in group settings or with background noise. After hearing aid administration, at week 36, 56–63% of 93 respondents reported substantial improvement in these areas. Moreover, more than 60% expressed high satisfaction with their hearing aids (appendix p 11).

At week 18, the allocation was correctly guessed by masked researchers for 58 (56%) of 104 participants in the SSI group and 80 (77%) of 104 in the care as usual group. At week 36, the proportions were 56 (57%) of 99 and 68 (69%) of 98, respectively. Among participants whose intervention allocation was correctly guessed (across both groups combined), levels of rater certainty at week 18 were: 21 (15%) of 138 completely certain, 43 (31%) somewhat certain, and 74 (54%) not at all certain. At week 36, they were 15 (12%) of 124 completely certain, 57 (46%) somewhat certain, and 52 (42%) not at all certain.

Self-reported dementia quality of life for the participants with dementia did not change substantially over the study period in both groups (figure 2, appendix p 9). No significant difference between groups in 36-week DEMQoL was observed (92·8 [SD 15·2] in the SSI group and 92·8 [14·0] in the care as usual group; mean adjusted difference 0·18, 95% CI –2·13 to 2·30, p=0·87; table 2). All sensitivity analyses provided consistent results (table 2). No between-group difference on the 36-week DEMQoL-Proxy, rated by the care partner, was observed (table 3). The 95% CI of the difference in 18-week DEMQOL score was marginally compatible with a better quality of life in the SSI group compared with the care as usual group (2·62, 0·29 to 4·80, with the upper bound of the 95% CI exceeding the pre-specified minimally important clinical difference of 4 points). No clinically significant between-group differences were supported at 36 weeks for dementia-related

	Sensory support intervention (n=126)	Care as usual (n=125)
Age, years	79·7 (5·6)	79·4 (6·1)
Sex		
Female	60 (48%)	72 (58%)
Male	66 (52%)	53 (42%)
Sensory difficulties		
Visual only	2 (2%)	7 (6%)
Hearing only	71 (56%)	79 (63%)
Vision and hearing	53 (42%)	39 (31%)
Duration of use of vision aids, years	22 (10–40)	30 (10–45)
Duration of use of hearing aids, years	5 (4–10)	3·5 (2·5–8)
Country		
Greece	29 (23%)	28 (22%)
Ireland	14 (11%)	16 (13%)
UK	44 (35%)	44 (35%)
France	17 (13%)	17 (14%)
Cyprus	22 (17%)	20 (16%)
Time since dementia diagnosis, years		
<1	35 (28%)	32 (26%)
1 to <2	42 (33%)	48 (38%)
2 to 3	31 (25%)	34 (27%)
>3	16 (13%)	9 (7%)
Missing	2	2
MoCA score	16·7 (4·2)	16·6 (3·7)
Dementia diagnostic subtype		
Alzheimer's disease	87 (69%)	76 (61%)
Vascular dementia	22 (17%)	18 (14%)
Mixed	17 (13%)	31 (25%)
Living status		
With partner	80 (63%)	77 (62%)
With family	15 (12%)	10 (8%)
Alone	26 (21%)	33 (26%)
Other	5 (4%)	5 (4%)
DEMQoL score	92·0 (14·6)	92·4 (13·4)
Age of care partner, years	64·2 (13·8)	65·0 (12·9)
Sex of care partner		
Female	98 (78%)	84 (67%)
Male	28 (22%)	41 (33%)

Data are mean (SD), n (%), or median (IQR). Percentages might not add to 100% due to rounding. MoCA=Montreal Cognitive Assessment. DEMQoL=Dementia Quality of Life Instrument.

Table 1: **Baseline characteristics of the participants with dementia in the intention-to-treat population**

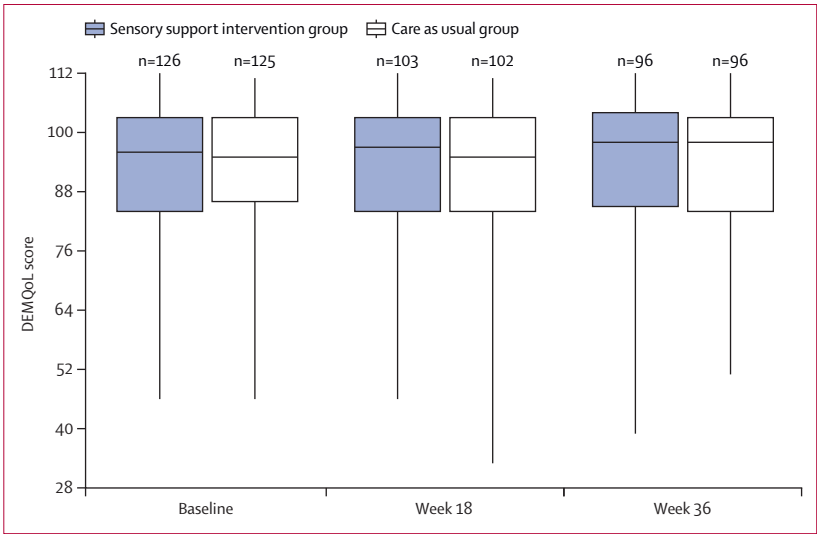

Figure 2: **DEMQoL score as reported by participants with dementia**
Shaded boxes show the median and IQR, with whiskers showing the range. DEMQoL=Dementia Quality of Life Instrument.

	n	Adjusted mean difference* in 36-week DEMQoL score between groups (95% CI)†	p value
Primary analysis	251	0·18 (–2·13 to 2·30)	0·87
Sensitivity analyses			
Adjusted for remote *vs* face-to-face follow-up	251	0·21 (–2·03 to 2·40)	0·85
Complete case analysis	192	–0·25 (–3·26 to 2·59)	0·87
Per-protocol analysis	171	0·13 (–3·34 to 3·39)	0·94
Subgroup analysis by country‡			
Greece	46	1·64 (–3·57 to 6·85)	..
Ireland	20	2·74 (–3·18 to 8·66)	..
UK	70	–1·02 (–5·33 to 3·29)	..
France	25	–3·18 (–11·7 to 5·30)	..
Cyprus	31	–0·83 (–10·9 to 9·20)	..

DEMQoL=Dementia Quality of Life Instrument. *Adjusted for baseline DEMQoL score, age, sex of the participant with dementia and care partner, sensory difficulties, country, and dementia type. †A positive value indicates that the mean 36-week DEMQoL score is higher in the sensory support intervention group than the care as usual group. ‡Estimated on complete cases from a regression model with an interaction term between country and trial group.

Table 2: **Primary outcome**

functional ability, hearing-related and vision-related functional ability, neuropsychiatric symptoms, or relationship satisfaction (table 3, appendix p 12). The following secondary outcomes at 18 weeks were not analysed due to limited perceived utility, based on analysis of the 36-week outcomes: DEMQoL-Proxy, BADL, VALV-VFQ, and HHIE (spousal and non-spousal). Additionally, the 36-week HHIE (non-spousal) outcome was not analysed because the validity of self-report on this scale at this timepoint in participants was questionable.

The mean total intervention cost per patient across countries was €662 (SD 281; appendix p 13). People who had both hearing and visual difficulties underwent assessment of both impairments and were provided sensory aids for both and so their costs were higher than people with a single impairment. One of the drivers of the intervention cost was the amount of time spent by sensory support therapists with the dyads.

Six (5%) of 126 participants in the SSI group and five (4%) of 125 in the care as usual group died; none of the deaths were related to the study intervention or study procedures. In the SSI group, 114 adverse events in 56 (44%) participants were reported, of which 31 were serious adverse events in 25 (20%) participants with dementia. Five adverse

	Sensory support intervention group		Care as usual group		Parameter	Adjusted estimate (95% CI); p value*
	n	Mean (SD), n (%), or median (IQR)	n	Mean (SD), n (%), or median (IQR)		
18-week DEMQoL	103	93·1 (14·5)	102	91·8 (14·6)	Difference	2·62 (0·29 to 4·80); 0·02
36-week DEMQoL-Proxy	100	97·0 (13·8)	100	96·9 (14·3)	Difference	–0·52 (–2·91 to 1·86); 0·67
Higher dependence on BADL score†	92	40 (43%)	97	30 (31%)	OR	1·33 (0·80 to 2·50); 0·32
HHIE spousal rating‡	96	..	94	..	..	..
No or minimal difficulties	..	61 (64%)	..	61 (65%)	..	..
Mild or moderate difficulties	..	28 (29%)	..	19 (20%)	..	..
Significant difficulties	..	7 (7%)	..	14 (15%)	..	..
Odds of greater impairment§	..	..	..	..	OR	1·32 (0·69 to 2·56); 0·44
RSS score for person with dementia¶	91	30 (26–30)	93	30 (28–30)	Difference	–0·14 (–0·93 to 0·18); 0·63
NPI-12 rated by care partner¶	97	10·9 (3–19)	98	8 (1–19)	Difference	0·32 (–1·87 to 2·51); 0·77
VALV-VFQ spousal rating‖	42	2·8 (2·2–3·2)	29	2·5 (1·3–3·4)	..	..

DEMQoL=Dementia Quality of Life Instrument. BADL=Bristol Activity of Daily Living scale. OR=odds ratio. HHIE=Hearing Handicap Inventory for the Elderly. RSS=Relationship Satisfaction Scale. NPI-12=12-item Neuropsychiatric Inventory. VALV-VFQ=Veterans Affairs Low Vision-Visual Functioning Questionnaire. *Adjusted for baseline outcome score, age of the participant with dementia, sex of the participant with dementia and their care partner, sensory difficulties, country, and dementia type; all models are fitted following multiple imputation and CI estimates are bootstrapped percentile type using 1000 replications. †Higher dependence was represented by a BADL score of 15–60. ‡HHIE categories: 0–16 represents no or minimal hearing difficulties; 18–42 represents mild or moderate difficulties; 44–100 represents significant difficulties, defined as great difficulty or cannot manage. §Estimates are obtained from ordinal logistic regression. ¶Estimates are obtained from quantile (median) regression (data are not normally distributed). ‖Regression models were not fitted to this outcome due to the large amounts of missing data.

Table 3: **Secondary outcomes**

events were related to the intervention, and five were possibly related (medical device pain or discomfort n=6, ear pain n=1, scratch to the ear n=1, sore eye n=1, redness n=1; all of grade 1). All serious adverse events were unrelated to the SSI. In the care as usual group, 48 adverse events were reported by 32 (26%) participants with dementia and 16 serious adverse events were reported by 16 (13%) participants with dementia.

Discussion

To the best of our knowledge, this is the first large-scale randomised controlled trial of a tailored, home-based sensory support and rehabilitation intervention for people with dementia. Despite the high prevalence of concurrent hearing and vision difficulties in people with dementia, there has been a paucity of large-scale, well designed trials investigating the impact of sensory support and rehabilitation in dementia.[7,30] In the current study, at 18 weeks after randomisation, which was about 6 weeks after the end of the intervention, study data were compatible with a better quality of life in the SSI group compared with the care as usual group; however, the findings suggested no sustained effect at 36 weeks post randomisation, which represented the primary outcome of the trial. These findings support, in part, our initial field trial outcomes,[11] which showed an improvement in quality of life following the intervention, albeit in an open-label study. Finally, no significant impact of the SSI on functional, hearing, or visual abilities, neuropsychiatric symptoms, or relationship satisfaction was observed compared with care as usual. These findings are consistent with some of the studies described in our scoping review of hearing and vision interventions in dementia,[30] which found no consistent evidence for a positive impact of hearing or vision interventions on cognitive function, rate of cognitive decline, quality of life, or care partner burden. However, comparisons should be made with caution due to the quality of previous studies mostly being low to moderate, with small sample sizes and methodological limitations.

Supporting sensory health in the context of ageing-related declining cognition is increasingly seen as a critical approach. Indeed, epidemiological evidence is increasingly convincing regarding the potential prevention of cognitive decline through hearing rehabilitation.[31] The ACHIEVE study from 2023 examined the efficacy of auditory rehabilitation versus standard care in older individuals with cognitive vulnerability, focusing on primary prevention.[32] Although the primary analysis found no significant impact on cognitive trajectory over a 3-year period, a predetermined subgroup analysis suggested that auditory intervention could potentially mitigate cognitive deterioration in older cohorts at high risk of cognitive decline. In our study, our focus was on tertiary, rather than primary or secondary prevention, specifically to address the large proportion of people living with established dementia whose hearing and vision health needs are unaddressed. For this population, unlike those in the preclinical or prodromal stages of a neurodegenerative disorder, the potential for slowing of progression is lower. Hence, the focus on quality of life and living well with dementia is paramount, supporting our choice of quality of life as our main outcome. This approach is crucial because, with the advent of disease-modifying therapies for Alzheimer's disease,[33] the focus of dementia research is increasingly on prevention and efforts to slow progression, at the potential expense of efforts to support quality of life for the

55 million people worldwide who already have established dementia. Thus, investigating accessible, low-technology, non-pharmacological solutions, such as sensory support and rehabilitation, needs to be prioritised.

Although our finding of an improvement in quality of life at 18 weeks, which is near the delivery of the intervention, is positive, it could fall below the threshold for a clinically meaningful change.[18] There are a few possible reasons for the lack of efficacy seen at 36 weeks post randomisation. First, we did not include a booster session with the SSI after the final home visit at 12 weeks. Adherence with sensory devices such as hearing aids is challenging in people with dementia,[7] and successful hearing aid use requires social reinforcement, positive interactions with the environment, proficiency handling hearing aids, and assurance of device fit and comfort. Moreover, consistent with our findings, non-drug interventions that focus on quality of life as an outcome in dementia have been shown to be more effective in the short term compared with the longer term for several reasons, including an initial engagement and novelty effect, which wears off over time, adaptation and habituation to the intervention, progression of dementia, care partner fatigue and perceived burden in sustaining the intervention, and the challenge of maintaining continuity and consistency of a new intervention or change in behaviour.[34,35] Nevertheless, although supported by previous results,[11] we cannot totally exclude that this improvement observed at 18 weeks is a chance finding due to multiple hypothesis testing on secondary outcomes, and interpretation must remain cautious.

Second, although the SSI addressed several aspects of sensory-cognitive care, the support might not have been sustained for long enough and was probably affected by disruptions to the delivery of at-home support resulting from the COVID-19 pandemic lockdown. Consequently, the SSI delivered was altered as compared with the SSI designed. We will report on these factors in more detail elsewhere. Of note, over the 36 weeks of the study, there was no appreciable change in quality of life for participants with dementia, despite many having participated during the COVID-19 pandemic. This finding is consistent with a UK study of 261 people with newly diagnosed dementia who were found to have maintained their quality of life during the pandemic and even had an increase towards the end of the period. This finding contrasted with carers who reported a general deterioration in their quality of life over the same period.[36]

Finally, another possible reason for our findings is the high variability of intervention delivery across sites in five different European countries, as well as between phases of the study, namely before and during the COVID-19 pandemic. Only 10% of study participants were included and followed up before the COVID-19 pandemic, which prevented any quantitative analysis of the interaction between the SSI and this context. Future, in-depth process evaluation of the SSI might help to qualitatively assess these aspects. Detailed descriptions of factors related to hearing aid adherence in the trial are outlined elsewhere.[25,37] These theory-driven analyses of correlates of hearing aid use and qualitative reports from people with dementia and care partners revealed a range of factors that might influence hearing aid use in the context of dementia. In multivariable analysis, variables significantly associated with hearing aid use were: greater self-perceived hearing difficulties, lower hearing acuity, higher cognitive ability, and country of residence.

Although the complexity of this study might have made the findings harder to interpret, it also represents a strength. To date, few studies of pragmatic, non-pharmacological interventions for dementia have been conducted across regions with differing languages, cultures, and health systems. Hence, the learnings from both a trial operational perspective as well as an intervention delivery perspective have been informative. In our intervention development programme, we found that people with dementia and concurrent hearing or vision difficulties (or both) had significant unmet healthcare needs, some of which could be addressed by a carefully constructed support intervention.[3,38] Moreover, those with higher needs had the highest intervention costs, related to increased time spent with the sensory support therapist. We purposefully adopted a flexible intervention to allow for complexity of the participant group, and to be able to tailor the intervention to the individual needs of participants. Finally, we allowed for the possibility of rapid implementation in clinical settings should the outcome have been positive.

Baseline imbalance that was observed in important characteristics was accounted for in the primary analysis; therefore, a residual imbalance on unobserved prognostic factors would need to be major to account for the observed findings. Although the trial was open label, the lack of accessing any additional form of sensory rehabilitation by participants in the care as usual group suggested that these participants were not in favour of any sensory care-seeking behaviour simply by virtue of being in the trial. We experienced a high proportion (23%) of missing data at 36 weeks, balanced between groups. We chose to impute those missing data under a missing-at-random assumption to estimate the mean difference in DEMQoL change that would have been observed without any death or loss to follow up. The low proportion (<5%) of death observed in this population supports this strategy. Of note, patient-reported and carer-reported quality of life was assessed without masking to the study intervention. We consider a positive effect on quality of life of being assigned to the care as usual group to be unlikely, and thus expect any bias to be in favour of the SSI, with participants possibly feeling obliged to assess their quality of life more favourably if they had benefited from the SSI. Similarly, a hypothesised differential measurement error for self-reported quality of life, in which better hearing and vision would increase the rating by themselves, should be in favour of the SSI. The level of correctly guessed allocation was higher in the care as usual group, but with a high uncertainty from the rater in both groups. Thus, it seems unlikely that this would account for our findings on secondary outcomes. Finally, we can exclude any differential impact of remote follow-up assessment, balanced between groups, on

outcomes measurement. Therefore, systematic biases seem unlikely to explain the study results.

SENSE-Cog is the largest randomised controlled trial to date evaluating the efficacy of a combined hearing and vision rehabilitation intervention for people with dementia living at home. Hearing and vision support and rehabilitation in people with dementia and sensory difficulties living at home did not benefit quality of life at 36 weeks, but might show benefits in the shorter term. Sensory difficulties are common in people with dementia and interventions aimed at improving sensory-cognitive health should be explored further.

Contributors

All authors have contributed to drafting or reviewing the manuscript and approving the final version. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted. IL (chief investigator) conceived and designed the study and had overall responsibility for the study design and delivery. EF was the study methodologist and MH and DR led the statistical analysis. AH and EH supported development, training, and implementation of the intervention. CJA provided the theoretical framework for the study. Euclid Clinical Trials Unit (EF, JL, and CS) was responsible for study coordination, trial logistics and data management. EMC, LP, and RAE were responsible for the economic analysis. AMP, SPK, BAL, DR, CT, FC, MW, and RD were study site leads. APC, JPC, WKY, and EK coordinated the study at their respective sites and led recruitment. PD provided expert audiology advice. IL and EF accessed and verified the data. All authors had full access to the data and had final responsibility for the decision to submit for publication.

Declaration of interests

IL declares membership of advisory boards for Biogen, NovoNordisk, and Eisai; honorarium for a lecture and support for attending meetings or travel from Biogen; and membership of the Board of Directors for Lewy Body Ireland (unpaid, charity). CJA and PD were supported by the National Institute for Health and Care Research (NIHR) Manchester Biomedical Research Centre under grant BRC-1215-20007. All other authors declare no competing interests.

Data sharing

De-identified individual participant data that underlie the results reported in this Article (text, tables, figures, and appendix), the study protocol, and the statistical analysis plan will be available following publication to researchers who provide a methodologically sound proposal to achieve aims in the approved proposal, by contacting the corresponding author.

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