Feasibility of an intervention to support hearing and vision in dementia: The SENSE-Cog Field Trial

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Running head: *Feasibility of sensory support in dementia*

This paper was first presented as part of a symposium at the British Society of Gerontology Annual meeting in Manchester, 5th July 2018.

Word count:

Abstract: 300; Main text: 2333; 2 tables; 1 figure; 1 supplementary table; 28 references.

Keywords: Dementia, hearing impairment, vision impairment, feasibility, acceptability, tolerability.

Trial registration number: The trial is a psychosocial intervention with an allocated ISRCTN number 35019114 16th January 2018

Impact statement: We certify that this work is entirely novel and is the first study of hearing and vision enhancement in people living with dementia. This interdisciplinary approach makes a significant contribution to the literature and sets the stage for further full scale evaluations of hearing and vision interventions to improve outcomes for people with dementia. This is the first part of a two-part report.

Abstract

Background: People living with dementia (PwD) frequently experience hearing and vision impairment that is under-recognised and under-treated, resulting in reduced quality of life. Managing these impairments may be an important strategy to improve outcomes in PwD.

Objective: To field trial a multi-faceted 'Sensory Intervention' (SI) to enhance hearing and vision in PwD.

Design: An international single arm, open label, feasibility, acceptability and tolerability study.

Setting: Home-based, in the United Kingdom, France, and Cyprus.

Participants: Adults aged ≥ 60 with mild-moderate dementia and uncorrected or sub-optimally corrected hearing and/or vision impairment, and their study partners (n=19 dyads).

Intervention: A 'Sensory Intervention' (SI), comprising assessment of hearing and vision, fitting of corrective devices (glasses, hearing aids), and home-based support from a 'sensory support therapist' for device adherence and maintenance, communication training, referral to support services, environmental sensory modification and optimisation of social inclusion.

Measurements: Ratings of study procedure feasibility, and intervention acceptability/tolerability, ascertained through questionnaires, participant diaries, therapist logbooks and semi-structured interviews.

Results: We successfully delivered all intervention components, and these were received and enacted as intended in all those who completed the intervention. No serious adverse events were reported. Acceptability (i.e. understanding, motivation, sense of achievement) and tolerability (i.e. effort, fatigue) ratings of the intervention were within *a priori* target ranges. We met recruitment and retention (93.8%) targets in two of the three sites. Participants completed >95% of diary entries, representing minimal missing data. Delays in the logistics circuit for the assessment and delivery of hearing aids and glasses were identified, requiring modification. The need for minor modifications to some outcome measures and the inclusion criteria were identified.

Conclusion: This is the first study combining home-based hearing and vision remediation in PwD and the positive feasibility, acceptability and tolerability findings suggest that a full-scale efficacy trial, with certain modifications, is achievable.

Introduction

People with dementia (PwD) are more likely to experience vision and hearing impairment than their healthy counterparts [1,2], and such impairments, particularly in combination, may impact negatively on quality of life[3] and other outcomes[4,5], as well as imposing an additional burden on health, social and informal care [6,7]. Importantly, there is some evidence that managing vision and hearing impairments with glasses and hearing aids respectively may improve outcomes[8] but the evidence is still equivocal and represents a gap in understanding. Unfortunately, in the context of dementia, adherence to hearing aids and other devices is often low[9]. Thus, simply correcting the sensory impairment may be insufficient to have a positive impact. In contrast, an intervention targeting the wider issue of sensory impairment and adherence with corrective devices may have a role. To address this, we iteratively developed a multi-faceted 'sensory intervention' (SI) which includes assessment and management of hearing and vision deficits and additional support to aid adoption of the corrective devices into everyday life as well other components to support sensory function[3].

A first step in evaluating a complex psychosocial intervention should be a field trial of the study design, components and implementation of the intervention[10]. Thus, the primary aim of our field trial was to evaluate: (1) the feasibility of the operational aspects of an evaluation trial of the intervention; and (2) the acceptability and tolerability of the intervention. Our secondary aim was to explore a signal of clinical and cost effectiveness, which we report elsewhere (in preparation). The results of this study have informed the

design and conduct of a full-scale randomised controlled trial (RCT) in five European sites (ISRCTN 17056211)[11].

Methods

Study design and participants

This was an international single-arm, open-label field study of a newly developed 'sensory intervention' to improve the hearing and/or vision of PwD in three sites: Bordeaux, France (Site B), Manchester, UK (Site M) and Nicosia, Cyprus (Site N). The study received favourable ethical opinion at each site. All participants provided written informed consent prior to their inclusion. The planned sample size was n=24 dyads (PwD and study partner), with 8 dyads per site. All dyads received the *basic* version of the SI, with a sub-set of 4 receiving a 12-week *extended* version. We recruited participants from memory assessment clinics, and dementia research registries such as Join Dementia Research in the UK[12]. Detailed inclusion and exclusion criteria have been described elsewhere[13]. Briefly, these included people over the age of 60, living at home with a formal diagnosis of mild-moderate stage dementia (Alzheimer disease, vascular dementia or 'mixed' Alzheimer and vascular dementia) and with capacity to consent (as per the UK's Mental Capacity Act, 2005)[14]. All had a clinically significant uncorrected or partially corrected (e.g. outdated prescription for sensory aids) hearing and/or vision problem, ascertained using a brief objective screening procedure. The inclusion threshold for hearing was >35 dB HL over 1-3 kHz and above in the better ear, and for vision was binocular corrected visual acuity of ≤ 6/9, 5 Snellen metric or ≥+0,2LogMAR and a visual field of >/=10º. We did not include people with congenital hearing and/or vision impairments. Study partners were informal carers in regular contact with the PwD.

[Insert Table 1 here]

We have detailed participants' demographic and clinical characteristics in Table 1. Briefly, all PwD were above age 62 years and all study partners were above age 42. Of the PwD, 42% (n=8) had hearing impairment only; 58% (n=11) had both vision and hearing impairment; and none had vision impairment alone. There was an equal proportion of PwD due to Alzheimer disease and vascular dementia; and one individual had 'mixed' dementia.

Description of the intervention

The basic SI comprised: a clinical vision and/or hearing assessment with prescription and fitting of corrective lenses, provided by Essilor International [15], and/or hearing aids ('behind the ear' Muse Mini i2400), provided by Starkey Hearing Technologies[16], and information about device maintenance. The extended SI comprised additional components, delivered by a Sensory Support Therapist (SST) in the participant's own home: (1) individualised adherence support; (2) communication training; (3) functional assessment and goal-setting; (4) referral to health and social care services; (5) supplementary sensory aids to enhance the home environment; and (6) fostering social inclusion. The SST was an occupational therapist skilled in dementia who received additional training in hearing and vision rehabilitation.

Study procedures

The detailed study protocol and schedule of events are described elsewhere[13] and shown in Figure 1 in abbreviated form. Briefly, after informed consent, we screened PwD for hearing, vision and cognitive impairment using the Sivantos Siemens HearCheck screener[17], Peek Acuity app[18], and MoCA [19], followed by a baseline assessment and the intervention. The

basic SI was delivered over 4 weeks at all three sites to enable us to evaluate feasibility of study procedures. At Site M, the extended SI, delivered over 12 weeks in participants' homes, enabled us to evaluate further study procedures, feasibility of the intervention delivery, and its acceptability and tolerability.

[add Figure 1 here]

Evaluation framework

We based our evaluation on a modified version of the ACCEPTANCE framework for feasibility studies[20]. Data were captured at baseline and within one week of the last intervention visit. At each visit for the extended SI, PwD and study partners completed diaries with in-house Likert-type scales (rating each aspect of acceptability and tolerability on a scale of 1=strongly disagree to 5= strongly agree) and space for free text, and the SST completed a log book and field notes. We conducted semi-structured interviews with a sub-sample of dyads at sites M and N who received either the basic (n=8 dyads) or extended (n=2 dyads) SI. The focus of the interviews was on participants' perception, experiences and acceptance of the SI.

Feasibility of trial procedures: These included our recruitment strategy, suitability of eligibility criteria, execution of the 'logistics circuit' for assessment and supply of hearing aids and glasses, feasibility of the participant diaries, data collection methods, suitability of the battery of effectiveness measures, and retention.

Described in detail elsewhere[13], effectiveness measures for the PwD were: quality of life, mental wellbeing, neuropsychiatric symptoms, functional ability (dementia-, hearing- and vision-related), and relationship satisfaction. Effectiveness measures for the study partner

were: wellbeing, mental health, caregiving-related burden and stress, and relationship satisfaction. Health care resource use questionnaires were included. Since this was an open-label study, we did not evaluate randomisation and blinding procedures.

Feasibility of the intervention components and implementation: To determine whether the intervention was delivered, received and enacted as intended[21], we obtained SST visit completion rates, visit duration and SST logbook feedback.

Acceptability of the intervention: The appropriateness of the delivery and receipt of the intervention[22] was determined by: percentage dropouts due to non-acceptability and rate of serious adverse events. The 'acceptability' criterion for the extended SI was 100% of participants scoring within the *a priori* target ranges on a five point Likert-type scale: ≥ 3/5 for '*understanding*', '*interest'*, *'emotional response',* '*motivation*' and '*sense of achievement*'.

Tolerability of the intervention: This was operationalised by percentage dropouts due to intolerance of the intervention and diary ratings of '*effort'* and *'fatigue'* for the extended SI. The criterion for 'tolerability' was 75% of participants scoring the intervention with the *a priori* target ranges: ≥ 3/5 for '*effort*' and '*fatigue*'.

Data analysis

We used descriptive statistics for the quantitative analysis since the study was not formally powered to detect specific post-intervention effect sizes. The small sample size increases the likelihood of a Type II error when using inferential statistics. We applied content

analysis[23], a reliable method of analysing of qualitative data using 'coding units', to the non-quantitative data from the semi-structured interviews, participant dyad diaries, researcher field notes and SST logbooks.

Results

Details of the feasibility of trial procedures and acceptability and tolerability of the intervention are outlined in Supplementary Table S1.

Feasibility of the trial procedures

(a) Recruitment and retention

Recruitment was successful in Sites M and N, but slower in Site N (2.6 dyads per month for 3 months and 1.3 dyads per month for 6 months, respectively) and did not reach target in Site B, which recruited 3 dyads. This resulted in a total sample size of 19 dyads from an intended sample of 24 dyads. The retention rate at Site M was 87.5% (one participant dyad withdrew due to study-related burden) and at Site N was 100%. All three dyads at Site B did not complete the study. Non-completion and failure to recruit at Site B was due to the lack of a pathway between the study site and the necessary referral sources and lack of infrastructure to support the logistics circuit. Screening and baseline visits were conducted according to protocol in all sites.

(b) Suitability of eligibility criteria

Investigators at all sites perceived that the cognitive score cut-off threshold (MoCA ≥12) was too high and would potentially exclude PwD who could meaningfully participate.

Additionally, of the 19 PwD who screened positive for hearing impairment, the assessing audiologist did not prescribe hearing aids for five of the participants due to mildness of impairment. None of these PwD received the extended intervention. All other inclusion/exclusion criteria were considered appropriate by investigators.

(c) Execution of the service and device logistics circuit

Referrals to vison and/or audiology assessments post-baseline visit were successful although we experienced some delays and variation across study sites, with delivery of glasses ranging from 7-9 weeks and hearing aids 3-20 weeks post-baseline. Delays in the logistics circuit impacted on the study timeline, with post-intervention assessments being conducted 7-25 weeks post-baseline. Reasons for delay were clearly identified, including difficulties in arranging study visits, inadequate communication among assessing clinicians and the study team, and delays in delivery of devices from suppliers.

(d) Usability of study materials and suitability of effectiveness battery

Diary use by dyads was feasible and acceptable, with a 95% completion rate of entries for PwD and 97% for the study partners. The battery of effectiveness measures was feasible and well-tolerated, except for the self-efficacy and self-reported hearing and vision impairment scales, which were difficult for the PwD to report on due to deteriorating insight. Missing data on effectiveness scales for study completers was minimal (<10%) and within the *a priori* acceptability threshold (see Supplementary Table S1).

Feasibility of the intervention components and implementation

We achieved 100% adherence to the study protocol for the basic SI at Sites M and N for study completers. At Site B, study procedures were not completed due to problems with the study team, thus we could not evaluate feasibility at this site. At Site M, 100% of components of the extended SI were delivered, received and enacted as intended, over a range of 7-12 sessions (median 9), and a median session duration of 95 minutes (range 45-135). This included certain iterative changes to the intervention recorded in the SST logbook. This number of sessions, together with the need to schedule vision and hearing assessments and wait for delivery of sensory aids, required 20 weeks for full intervention package to be delivered.

Acceptability and tolerability of the intervention

At Sites M and N there were no withdrawals due to lack of acceptability of the basic or extended SI. At site M, one dyad withdrew due poor tolerability of the extended SI (Table 2, participant 4). All adverse events were classified as 'mild', including poor fit or discomfort from corrective devices. This included expressions of concern about the potential to lose or damage the corrective device, resulting in anxiety of a mild level. No serious adverse events were experienced. For the extended SI, Likert-style mean acceptability ratings of '*understanding*', '*motivation*', '*emotional response', 'interest'* and '*sense of achievement'* all fell within the target range, as did tolerability ratings of '*effort*' and '*fatigue*' (Supplementary Table S1 and Table 2). Themes emerging from the post-intervention semi-structured interviews were: (1) good acceptability of session duration; (2) home-based delivery was acceptable, convenient and desirable; (3) additional SST support was 'extremely helpful' in encouraging the introduction of the corrective devices and optimising activity engagement;

and (4) study evaluation procedures were burdensome for some dyads because it was challenging for the PwD to distinguish between their different impairments.

[Insert Table 2 here]

Discussion

This is the first reported study of a hearing and vision intervention in PwD, demonstrating that such an intervention is feasible as a home-based therapy, with slight modifications, in two of the three study sites. We ascertained that the intervention itself is acceptable to and tolerated by PwD and their study partners. We identified the need for modifications to the study design for a full clinical trial, including: tightening the logistics circuit, widening the recruitment pool, replacing the under-recruiting site, changing certain effectiveness measures and altering the inclusion criteria for level of cognitive impairment to MoCA ≥10. Since most of the outcome measures are informant-rated or proxy-rated, it will be possible to capture accurate data for this group of participants. Diary feedback on participant fatigue, effort and motivation and other parameters allowed fine-tuning of the intervention, and underscored the need for careful tailoring to individualised requirements, an approach consistent with the conduct of pragmatic trials[24]. We have incorporated all modifications into a final protocol for a full RCT. We have addressed the recruitment and retention problems at Site B by replacing it with a new site in Dublin, which has a dedicated dementia service a proven record of successful recruitment to non-pharmacologic RCTs. Furthermore, using the experience of this feasibility study, we have selected a further two European dementia services (Athens and Nice) with similarly strong research experience to participate in the full SENSE-Cog RCT (ISRCTN 17056211)[11], making five sites in total. The experience in this study enabled us to develop robust site selection criteria for the additional sites. Finally,

a limitation of this study was the extended SI was only delivered in one of the field trial sites, but this gave us rich data from which to develop the final extended SI for the RCT.

In summary, this is the first study combining hearing and vision remediation in PwD and the positive feasibility, acceptability and tolerability findings suggest that a full-scale efficacy trial with certain modifications is achievable.

Acknowledgements

Conflict of interest

HA and SF are employed by Starkey Hearing Technologies, SMa and SMo are employed by Essilor International. There are no other conflicts of interest.

Authors' contributions

IL and PD are the programme leads and conceptualised and designed the field trial. EH is the Senior Sensory Support Therapist. ZS and APC are research assistants. JR was study coordinator for the field trial. RE and EC provided health economic input. MH and DR provided statistical input for the study. IH and LW led the qualitative analysis. CH and FoC oversaw study delivery in their sites. FiC and EF were involved in the study design and interpretation of study results. CT, HA, SF, SMa and SMo provided professional input to the design and conduct of the trial. EH, ZS and IL took primary responsibility for writing the paper; all authors were involved in critical revision of the article.

We thank Christine Dickinson, University of Manchester for assisting with the design of the study. We thank our industry collaborators at The Outside Clinic, Starkey Hearing

Technologies, Essilor International, Siemens Hearing Aids, Sivantos Limited (HearCheck) and PEEK Vision Limited (PEEK Acuity). We thank the Greater Manchester NIHR Clinical Research Network and Greater Manchester Mental Health Trust (GMMH) for supporting the study. We thank the Research User Group for input on the design and development of the intervention and participants and their families for taking part in the study.

Sponsor's role

This work was supported by the European Union's Horizon 2020 research and innovation programme under grant agreement No 668648.

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Legends

Figure 1: Flowchart of study procedures (submitted separately as a TIF file)

Table 1 Description of the baseline demographic and clinical variables in participants with dementia and their study partners

Variable	Category	Participants with Dementia	Study partner Participants
N		19	19
Age (Years)	Median (IQR) Range	76 (11) 63 to 88	67 (13) 43 to 82
Gender	Female Male	7 (36.8%) 12 (63.2%)	16 (84.2%) 3 (15.8%)
Duration of Cognitive Impairment (Months)	Median (IQR) Range	60 (54) 6 to 120	NA
Level of Cognitive Impairment (MoCA Total Score)	Mean (SD) Range	17.3 (3.7) 12 to 23	NA
Dementia Sub-Type	Alzheimer's Vascular Mixed	9 (47.4%) 9 (47.4%) 1 (5.3%)	NA
Sensory Impairment	Hearing only Vision only Hearing & Vision	8 (42.1%) 0 11 (57.9%)	NA
Relationship to PwD	Spouse/ Partner Son/ Daughter Other Relative	NA	13 (68.4%) 5 (26.3%) 1 (5.3%)
Hours per Week spent with PwD	Median (IQR) Range	NA	100 (115) 3 to 168

SD: standard deviation; IQR: interquartile range

403 **Figure 1: Flowchart of study procedures**

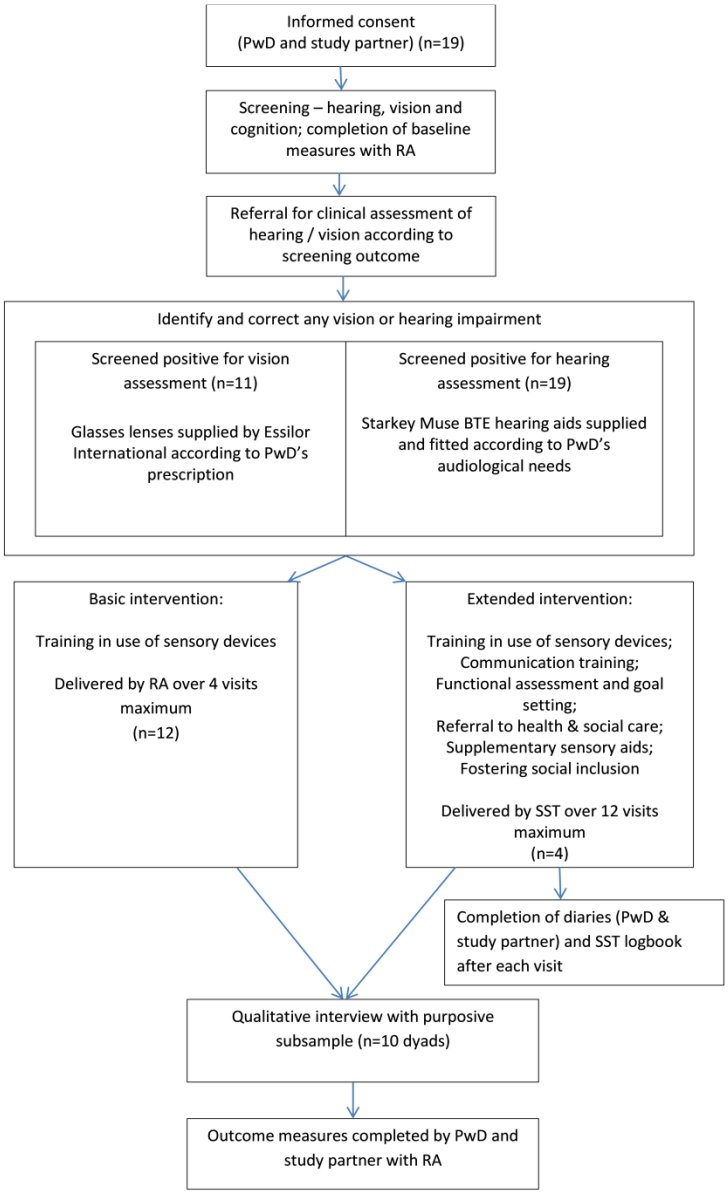

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Table 2 Acceptability and tolerability of the extended Sensory Intervention*

		Ratings of SI visits by PwD, study partner and SST: Mean score (range)			
		Participant 1	Participant 2	Participant 3	Participant 4
Acceptability	Understanding [PwD]	4.7 (4-5)	4.6 (4-5)	3.1 (2-4)	3.3 (2-5)
	Motivation [PwD]	4.6 (4-5)	4.9 (4-5)	3.9 (3-5)	3.3 (2-4)
	Motivation [SP]	4.4 (4-5)	5 (5-5)	3.3 (2-4)	3.8 (3-4)
	Motivation [SST]	4 (4-4)	4.8 (4-5)	3.3 (2-4)	4.5 (4-5)
	Sense of achievement [SP]	4.4 (4-5)	4.7 (4-5)	3 (2-5)	3.5 (3-4)
	Sense of achievement [SST]	3.8 (3-4)	4.6 (4-5)	3.1 (2-4)	4 (3-5)
	Interest [SP]	4.7 (4-5)	5 (5-5)	3.6 (3-4)	3.8 (3-4)
	Interest [SST]	4 (4-4)	4.8 (4-5)	3.8 (2-4)	4.8 (4-5)
	Emotional response [SP]	4.1 (4-5)	4.4 (4-5)	3.1 (2-4)	3.3 (3-4)
Tolerability	Effort [PwD]	4.7 (4-5)	4.5 (4-5)	3.1 (2-5)	2.3 (1-4)
	Fatigue [PwD]	5 (5-5)	3.2 (2-5)	3.4 (1-4)	1.5 (1-2)

Key: [PwD] PwD rating of response; [SP] Study partner rating of PwD's response; [SST] SST rating of PwD's response.

* Rated by participants on a 5-point Likert-type scale: 1=strongly disagree; 2=disagree; 3=neutral; 4=agree; 5=strongly agree (reverse rating for 'effort' and 'fatigue').

Supplementary Table S1: Feasibility of trial procedures and intervention feasibility, acceptability and tolerability

Parameter and *a priori* evaluation criteria (if applicable)	Findings	Evidence to support finding	Changes implemented for RCT
Feasibility of study procedures			
Eligibility criteria: ≥75% screened meet study criteria	Criteria are acceptable except: (1) cognitive score cut-offs may be set too high and exclude PwD who may be appropriate; (2) HearCheck screening cut-off may not be stringent enough.	100% of those screened met inclusion criteria[a]. 5 participants who screened positive on hearing impairment using the HearCheck were deemed not clinically suitable for hearing aids on full assessment[a]. There was an imbalance of sensory diagnostic groupings across the sites[a].	Inclusion criteria adjusted to MoCA ≥10. Remaining components of the SI will continue for any PwD not prescribed sensory aids following clinical assessment.
Recruitment: Total target number Rate	Successful at 2 of 3 sites. Slower than required for a larger trial.	100% at Site M and N; 38% at Site B[a]. Rate was 2.7 dyads per month at Site M and 1.3 dyads per month at Site N[a]. Incomplete recruitment at Site B.	Site B replaced with an alternative. Recruitment pool widened.
Retention: ≥60% completed all study procedures	Successful in 2 of 3 sites.	93.8% completed the study in Sites M and N; 0% completed in Site B[a].	Site B replaced with an alternative.
Screening & baseline process:	Appropriate due to the length of assessment battery.	9 dyads had one visit; 10 had two visits[a].	No changes indicated.
Outcome battery administration and suitability: ≥10% missing data suggests scale is not acceptable	Outcome rating scales are generally acceptable. Some scales were not suitable for the study population and require	<10% missing data from outcome rating scales at baseline and follow-up[a]. Missing items within given scales included gender-specific physiological	General Self Efficacy Scale[25] dropped. Geriatric Depression Scale[26] replaced with the Hospital Anxiety and Depression Scale[28].

	revision.	items[a]. Minimal or no concerns were noted on battery duration and level of difficulty, other than all 3 sites reporting problems with: PwD understanding the General Self Efficacy Scale[25] items[b]; The Geriatric Depression Scale[26] was not appropriate for younger study partners[a]; PwD self-report of hearing and vision impairment was not valid[a]. The Relationship Satisfaction Scale[27] was difficult to administer in presence of the study partner[b]	Caregiver reports of hearing and vision impairment introduced alongside PwD's self-report. Relationship Satisfaction Scale[27] administration procedure amended.
Device logistics circuit:	Broadly feasible; areas for improvement identified.	All prescribed hearing aids and glasses were received by participants[a]. Delays in assessment for and receipt of corrective devices impacted on overall study timelines[a].	Logistics circuit tightened through training and identification of dedicated clinicians. Timeframe for SI delivery extended.
Participant diary: ≥80% completion	Diary activity was feasible for both PwD and study partner.	95% of diary entries completed by both members of the dyad[c].	No changes indicated.
Feasibility of the Sensory Intervention (SI) components and implementation: Basic SI: Basic intervention (Sites M, N and B) Extended SI: Extended intervention (Site M)			
Basic SI: Was the basic SI delivered, received and enacted as intended?	It is feasible, although timeline deviations were evident.	100% of participants received a vision and / or hearing assessment and prescription of	Logistics circuit tightened up. Window for vision /

		corrective devices (if indicated) within 20 weeks of baseline[a]. 100% of participants completed measures of device skills and knowledge (hearing aids / glasses)[a].	hearing assessment specified as 1-8 weeks from randomisation.
Extended SI: Completion of extended SI within 12 weeks	It is feasible to complete the SI within 12 visits. The timeline of 12 weeks was not feasible due to logistics circuit delays and participant / SST availability. Successful delivery of each component is possible. It is viable to introduce the SI components in a flexible manner to account for delays in receiving hearing aids / glasses.	SI was completed over a mean of 9 visits (range 7-12)[b]. Time from baseline to follow-up was mean 18 weeks (range 17-20)[a]. 100% of participants completed functional assessment and set study-related goals[b]; of those that continued the SI to completion, 100% of components were addressed[b]. Elements of the extended SI were successfully introduced prior to device delivery[b].	Timeframe extended from 12 weeks to 18 weeks for SI delivery.
Acceptability of the intervention:			
Basic SI: Was the Sensory Intervention appropriate?	The basic intervention is acceptable	100% of participants were willing to receive their prescribed aids[a]. No participant withdrawals due to lack of acceptability[a].	No changes indicated.
Extended SI: 100% of: Score ≥ 3 on PwD scales for understanding and motivation Score ≥ 3 on SP and SST scales for motivation and sense	The intervention is broadly acceptable. PwD may not demonstrate anticipated levels of sense of achievement; however there were no withdrawals due to lack of acceptability.	100% of mean scores are within range for PwD[c]. 100% of mean scores are within range for SP and SST[b,c].	No changes indicated.

of achievement Score ≥ 3 on SP and SST scales for interest and emotional response			
Tolerability of the intervention by participants:			
Basic SI:	The basic intervention is tolerable	100% of participants were able to complete their vision and / or hearing assessment[a]. The basic intervention was completed over maximum 3 visits[a].	No changes indicated.
Extended SI: 75% of: Score ≥ 3 on PwD scale for effort and fatigue	The intervention is broadly tolerable but the SST needs to be mindful that lower tolerability ratings could indicate withdrawal risk.	One participant withdrew after 4 SI visits due to perceived burden (Participant 4). This is reflected in their effort and fatigue scores[c]. 75% of scores were ≥3. This is within the *a priori* range for tolerability.	SST to monitor diary responses and tailor the SI to the PwD's needs.

Key PwD = Person with dementia; SP= Study Partner; SST= Sensory Support Therapist

[a] Quantitative data; [b] SST logbook; [c] Participant dyad diaries