



Feasibility of an Intervention to Support Hearing and Vision in Dementia

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

3
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36

37 **Running head:** *Feasibility of sensory support in dementia*

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

40

41 **Word count:**

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

43 **Keywords:** Dementia, hearing impairment, vision impairment, feasibility, acceptability,
44 tolerability.

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

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

52 **Abstract**

53 **Background:** People living with dementia (PwD) frequently experience hearing and vision
54 impairment that is under-recognised and under-treated, resulting in reduced quality of life.

55 Managing these impairments may be an important strategy to improve outcomes in PwD.

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

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

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

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

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

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

72

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

82

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

86 Introduction

87 People with dementia (PwD) are more likely to experience vision and hearing impairment
88 than their healthy counterparts^{1,2}, and such impairments, particularly in combination, may
89 impact negatively on quality of life³ and other outcomes^{4,5}, as well as imposing an additional
90 burden on health, social and informal care^{6,7}. Importantly, there is some evidence that
91 managing vision and hearing impairments with glasses and hearing aids respectively may
92 improve outcomes⁸ but the evidence is still equivocal and represents a gap in
93 understanding. Unfortunately, in the context of dementia, adherence to hearing aids and
94 other devices is often low⁹. Thus, simply correcting the sensory impairment may be
95 insufficient to have a positive impact. In contrast, an intervention targeting the wider issue
96 of sensory impairment and adherence with corrective devices may have a role. To address
97 this, we iteratively developed a multi-faceted 'sensory intervention' (SI) which includes
98 assessment and management of hearing and vision deficits and additional support to aid
99 adoption of the corrective devices into everyday life as well other components to support
100 sensory function³.

101

102 A first step in evaluating a complex psychosocial intervention should be a field trial of the
103 study design, components and implementation of the intervention¹⁰. Thus, the primary aim
104 of our field trial was to evaluate: (1) the feasibility of the operational aspects of an
105 evaluation trial of the intervention; and (2) the acceptability and tolerability of the
106 intervention. Our secondary aim was to explore a signal of clinical and cost effectiveness,
107 which we report elsewhere (in preparation). The results of this study have informed the

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

110

111 **Methods**

112 *Study design and participants*

113 This was an international single-arm, open-label field study of a newly developed ‘sensory
114 intervention’ to improve the hearing and/or vision of PwD in three sites: Bordeaux, France
115 (Site B), Manchester, UK (Site M) and Nicosia, Cyprus (Site N). The study received favourable
116 ethical opinion at each site. All participants provided written informed consent prior to their
117 inclusion. The planned sample size was n=24 dyads (PwD and study partner), with 8 dyads
118 per site. All dyads received the *basic* version of the SI, with a sub-set of 4 receiving a 12-
119 week *extended* version. We recruited participants from memory assessment clinics, and
120 dementia research registries such as Join Dementia Research in the UK¹². Detailed inclusion
121 and exclusion criteria have been described elsewhere¹³. Briefly, these included people over
122 the age of 60, living at home with a formal diagnosis of mild-moderate stage dementia
123 (Alzheimer disease, vascular dementia or ‘mixed’ Alzheimer and vascular dementia) and
124 with capacity to consent (as per the UK’s Mental Capacity Act, 2005)¹⁴. All had a clinically
125 significant uncorrected or partially corrected (e.g. outdated prescription for sensory aids)
126 hearing and/or vision problem, ascertained using a brief objective screening procedure. The
127 inclusion threshold for hearing was >35 dB HL over 1-3 kHz and above in the better ear, and
128 for vision was binocular corrected visual acuity of $\leq 6/9$, 5 Snellen metric or $\geq +0,2$ LogMAR
129 and a visual field of $\geq 10^\circ$. We did not include people with congenital hearing and/or vision
130 impairments. Study partners were informal carers in regular contact with the PwD.

131

132

[Insert Table 1 here]

133 We have detailed participants' demographic and clinical characteristics in Table 1. Briefly, all

134 PwD were above age 62 years and all study partners were above age 42. Of the PwD, 42%

135 (n=8) had hearing impairment only; 58% (n=11) had both vision and hearing impairment;

136 and none had vision impairment alone. There was an equal proportion of PwD due to

137 Alzheimer disease and vascular dementia; and one individual had 'mixed' dementia.

138 *Description of the intervention*

139 The basic SI comprised: a clinical vision and/or hearing assessment with prescription and

140 fitting of corrective lenses, provided by Essilor International¹⁵, and/or hearing aids ('behind

141 the ear' Muse Mini i2400), provided by Starkey Hearing Technologies¹⁶, and information

142 about device maintenance. The extended SI comprised additional components, delivered by

143 a Sensory Support Therapist (SST) in the participant's own home: (1) individualised

144 adherence support; (2) communication training; (3) functional assessment and goal-setting;

145 (4) referral to health and social care services; (5) supplementary sensory aids to enhance the

146 home environment; and (6) fostering social inclusion. The SST was an occupational therapist

147 skilled in dementia who received additional training in hearing and vision rehabilitation.

148

149 *Study procedures*

150 The detailed study protocol and schedule of events are described elsewhere¹³ and shown in

151 Figure 1 in abbreviated form. Briefly, after informed consent, we screened PwD for hearing,

152 vision and cognitive impairment using the Sivantos Siemens HearCheck screener¹⁷, Peek

153 Acuity app¹⁸, and MoCA¹⁹, followed by a baseline assessment and the intervention. The

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

158 *[add Figure 1 here]*

159 *Evaluation framework*

160 We based our evaluation on a modified version of the ACCEPTANCE framework for
161 feasibility studies²⁰. Data were captured at baseline and within one week of the last
162 intervention visit. At each visit for the extended SI, PwD and study partners completed
163 diaries with in-house Likert-type scales (rating each aspect of acceptability and tolerability
164 on a scale of 1=strongly disagree to 5= strongly agree) and space for free text, and the SST
165 completed a log book and field notes. We conducted semi-structured interviews with a sub-
166 sample of dyads at sites M and N who received either the basic (n=8 dyads) or extended
167 (n=2 dyads) SI. The focus of the interviews was on participants' perception, experiences and
168 acceptance of the SI.

169

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

174 Described in detail elsewhere¹³, effectiveness measures for the PwD were: quality of life,
175 mental wellbeing, neuropsychiatric symptoms, functional ability (dementia-, hearing- and
176 vision-related), and relationship satisfaction. Effectiveness measures for the study partner

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

180 Feasibility of the intervention components and implementation: To determine whether the
181 intervention was delivered, received and enacted as intended²¹, we obtained SST visit
182 completion rates, visit duration and SST logbook feedback.

183

184 Acceptability of the intervention: The appropriateness of the delivery and receipt of the
185 intervention²² was determined by: percentage dropouts due to non-acceptability and rate of
186 serious adverse events. The 'acceptability' criterion for the extended SI was 100% of
187 participants scoring within the *a priori* target ranges on a five point Likert-type scale: $\geq 3/5$
188 for '*understanding*', '*interest*', '*emotional response*', '*motivation*' and '*sense of*
189 *achievement*'.

190

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

195

196 **Data analysis**

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

200 analysis²³, a reliable method of analysing of qualitative data using ‘coding units’, to the non-
201 quantitative data from the semi-structured interviews, participant dyad diaries, researcher
202 field notes and SST logbooks.

203 **Results**

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

206 *Feasibility of the trial procedures*

207 (a) Recruitment and retention

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

217

218 (b) Suitability of eligibility criteria

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

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

225

226 (c) Execution of the service and device logistics circuit

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

234

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

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

242 *Feasibility of the intervention components and implementation*

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

252

253 *Acceptability and tolerability of the intervention*

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

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

268 *[Insert Table 2 here]*

269 **Discussion**

270 This is the first reported study of a hearing and vision intervention in PwD, demonstrating
271 that such an intervention is feasible as a home-based therapy, with slight modifications, in
272 two of the three study sites. We ascertained that the intervention itself is acceptable to and
273 tolerated by PwD and their study partners. We identified the need for modifications to the
274 study design for a full clinical trial, including: tightening the logistics circuit, widening the
275 recruitment pool, replacing the under-recruiting site, changing certain effectiveness
276 measures and altering the inclusion criteria for level of cognitive impairment to MoCA ≥ 10 .
277 Since most of the outcome measures are informant-rated or proxy-rated, it will be possible
278 to capture accurate data for this group of participants. Diary feedback on participant
279 fatigue, effort and motivation and other parameters allowed fine-tuning of the intervention,
280 and underscored the need for careful tailoring to individualised requirements, an approach
281 consistent with the conduct of pragmatic trials²⁴. We have incorporated all modifications
282 into a final protocol for a full RCT. We have addressed the recruitment and retention
283 problems at Site B by replacing it with a new site in Dublin, which has a dedicated dementia
284 service a proven record of successful recruitment to non-pharmacologic RCTs. Furthermore,
285 using the experience of this feasibility study, we have selected a further two European
286 dementia services (Athens and Nice) with similarly strong research experience to participate
287 in the full SENSE-Cog RCT (ISRCTN 17056211)¹¹, making five sites in total. The experience in
288 this study enabled us to develop robust site selection criteria for the additional sites. Finally,

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

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

294 **Acknowledgements**

295 **Conflict of interest**

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

298

299 **Authors' contributions**

300

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

309

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317

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321

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392

393 **Legends**

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

395

396

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

399

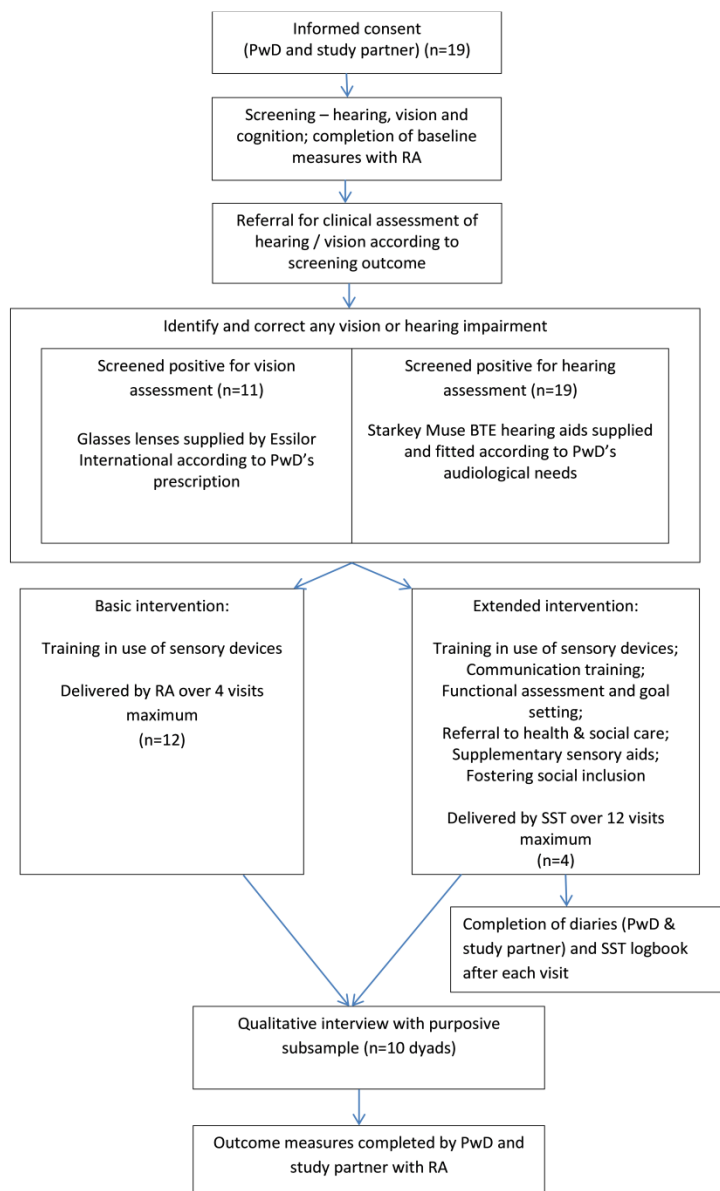
Variable	Category	Participants with Dementia	Study partner Participants
N		19	19
Age (Years)	Median (IQR)	76 (11)	67 (13)
	Range	63 to 88	43 to 82
Gender	Female	7 (36.8%)	16 (84.2%)
	Male	12 (63.2%)	3 (15.8%)
Duration of Cognitive Impairment (Months)	Median (IQR)	60 (54)	NA
	Range	6 to 120	
Level of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

400 **SD: standard deviation; IQR: interquartile range**

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



405 **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)

406 Key: ^{PwD} PwD rating of response; ^{SP} Study partner rating of PwD's response; ^{SST} SST rating of
 407 PwD's response.

408 * Rated by participants on a 5-point Likert-type scale: 1=strongly disagree; 2=disagree;
 409 3=neutral; 4=agree; 5=strongly agree (reverse rating for 'effort' and 'fatigue').

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

Parameter and <i>a priori</i> 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.	<p>items^a.</p> <p>Minimal or no concerns were noted on battery duration and level of difficulty, other than all 3 sites reporting problems with:</p> <p>PwD understanding the General Self Efficacy Scale²⁵ items^b;</p> <p>The Geriatric Depression Scale²⁶ was not appropriate for younger study partners^a;</p> <p>PwD self-report of hearing and vision impairment was not valid^a.</p> <p>The Relationship Satisfaction Scale²⁷ was difficult to administer in presence of the study partner^b</p>	<p>Caregiver reports of hearing and vision impairment introduced alongside PwD's self-report.</p> <p>Relationship Satisfaction Scale²⁷ administration procedure amended.</p>
Device logistics circuit:	Broadly feasible; areas for improvement identified.	<p>All prescribed hearing aids and glasses were received by participants^a.</p> <p>Delays in assessment for and receipt of corrective devices impacted on overall study timelines^a.</p>	<p>Logistics circuit tightened through training and identification of dedicated clinicians.</p> <p>Timeframe for SI delivery extended.</p>
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	<p>Logistics circuit tightened up.</p> <p>Window for vision /</p>

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

of achievement Score ≥ 3 on SP and SST scales for interest and emotional response			
<i>Tolerability of the intervention by participants:</i>			
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 <i>a priori</i> range for tolerability.	SST to monitor diary responses and tailor the SI to the PwD's needs.

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

415 ^a Quantitative data; ^b SST logbook; ^c Participant dyad diaries

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