

Hooper, Emma, Simkin, Zoe, Abrams, Harvey, Camacho, Elizabeth, Charalambous, Anna Pavlina, Collin, Fideline, Constantinidou, Fofi, Dawes, Piers, Elliott, Rachel, Falkingham, Sue, Frison, Eric, Hann, Mark, Helmer, Catherine, Himmelsbach, Ines, Hussain, Hannah, Marié, Sarah, Montecelo, Susana, Reeves, David, Regan, Jemma, Thodi, Chryssoula, Wolski, Lucas and Leroi, Iracema (2019) Feasibility of an intervention to support hearing and vision in dementia: the SENSE-Cog Field Trial. *Journal of the American Geriatrics Society*, 67 (7). pp. 1472-1477.

Downloaded from: <http://insight.cumbria.ac.uk/id/eprint/6180/>

***Usage of any items from the University of Cumbria's institutional repository 'Insight' must conform to the following fair usage guidelines.***

Any item and its associated metadata held in the University of Cumbria's institutional repository Insight (unless stated otherwise on the metadata record) may be copied, displayed or performed, and stored in line with the JISC fair dealing guidelines (available [here](#)) for educational and not-for-profit activities

**provided that**

- the authors, title and full bibliographic details of the item are cited clearly when any part of the work is referred to verbally or in the written form
  - a hyperlink/URL to the original Insight record of that item is included in any citations of the work
- the content is not changed in any way
- all files required for usage of the item are kept together with the main item file.

**You may not**

- sell any part of an item
- refer to any part of an item without citation
- amend any item or contextualise it in a way that will impugn the creator's reputation
- remove or alter the copyright statement on an item.

The full policy can be found [here](#).

Alternatively contact the University of Cumbria Repository Editor by emailing [insight@cumbria.ac.uk](mailto:insight@cumbria.ac.uk).

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

3  
4 Emma Hooper,<sup>1</sup> Zoe Simkin<sup>1</sup>, Harvey Abrams<sup>2</sup>, Elizabeth Camacho<sup>3</sup>, Anna Pavlina  
5 Charalambous<sup>4</sup>, Fideline Collin<sup>5</sup>, Fofi Constantinidou<sup>4</sup>, Piers Dawes<sup>6</sup>, Rachel Elliott<sup>3</sup>, Sue  
6 Falkingham<sup>7</sup>, Eric Frison<sup>5</sup>, Mark Hann<sup>8</sup>, Catherine Helmer<sup>9</sup>, Ines Himmelsbach<sup>10</sup>, Hannah  
7 Hussain<sup>3</sup>, Sarah Marié<sup>11</sup>, Susana Montecelo<sup>11</sup>, David Reeves<sup>8</sup>, Jemma Regan<sup>12</sup>, Chryssoula  
8 Thodi<sup>4</sup>, Lucas Wolski<sup>9</sup>, Iracema Leroi<sup>1,13, 14</sup>

9   <sup>1</sup> Division of Neuroscience and Experimental Psychology, University of Manchester, U.K.

10   <sup>2</sup> University of South Florida, Tampa, Florida, USA

11   <sup>3</sup> Manchester Centre for Health Economics, University of Manchester, U.K.

12   <sup>4</sup> Department of Health Sciences, School of Sciences, European University Cyprus, Nicosia,  
13   Cyprus

14   <sup>5</sup> University of Bordeaux, INSERM, EUCLID/F-CRIN Clinical Trials Platform, Bordeaux  
15   Population Health Center, France

16   <sup>6</sup> Manchester Centre for Audiology and Deafness, University of Manchester, U.K.

17   <sup>7</sup> Starkey Hearing technologies, U.K.

18   <sup>8</sup> Centre for Biostatistics, University of Manchester, U.K.

19   <sup>9</sup> University of Bordeaux, INSERM, Bordeaux Population Health Research Center, team LEHA,  
20   France

21   <sup>10</sup> Catholic University of Applied Sciences Freiburg, Freiburg, Germany

22   <sup>11</sup> Essilor International, Research & Development, Paris, France

23   <sup>12</sup> Research Associate, University of Manchester, UK

24   <sup>13</sup> Global Brain Health Institute, Trinity College Dublin, Ireland

25 <sup>14</sup> Greater Manchester Mental Health Foundation Trust, UK

26 *(Please note that the first two names are joint first authors; the final author is the senior author; all*  
27 *other authors are in alphabetical order)*

28 \* **Corresponding author:**

29 Iracema Leroi

30 Global Brain Health Institute

31 Room 0.60, Lloyd Building

32 Trinity College Dublin

33 Dublin 2, Ireland

34 +353 (0) 1 896 8500

35 Email: [iracema.leroi@manchester.ac.uk](mailto:iracema.leroi@manchester.ac.uk)

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, 5<sup>th</sup> 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 16<sup>th</sup> 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  $\geq 60$  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<sup>1,2</sup>, and such impairments, particularly in combination, may  
89 impact negatively on quality of life<sup>3</sup> and other outcomes<sup>4,5</sup>, as well as imposing an additional  
90 burden on health, social and informal care<sup>6,7</sup>. Importantly, there is some evidence that  
91 managing vision and hearing impairments with glasses and hearing aids respectively may  
92 improve outcomes<sup>8</sup> 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 low<sup>9</sup>. 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 function<sup>3</sup>.

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 intervention<sup>10</sup>. 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)<sup>11</sup>.

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 UK<sup>12</sup>. Detailed inclusion  
121 and exclusion criteria have been described elsewhere<sup>13</sup>. 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)<sup>14</sup>. 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 International<sup>15</sup>, and/or hearing aids ('behind

141 the ear' Muse Mini i2400), provided by Starkey Hearing Technologies<sup>16</sup>, 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 elsewhere<sup>13</sup> 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 screener<sup>17</sup>, Peek

153 Acuity app<sup>18</sup>, and MoCA<sup>19</sup>, 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 studies<sup>20</sup>. 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 elsewhere<sup>13</sup>, 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 intended<sup>21</sup>, 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 intervention<sup>22</sup> 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 analysis<sup>23</sup>, 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  $\geq 12$ ) 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  $\geq 10$ .  
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 trials<sup>24</sup>. 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)<sup>11</sup>, 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

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



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

317

### 318 **Sponsor's role**

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

321

### 322 **References**

- 323 1. Bowen M, Edgar DF, Hancock B, et al. The Prevalence of Visual Impairment in People  
324 with Dementia (the PROVIDe study): a cross-sectional study of people aged 60–89  
325 years with dementia and qualitative exploration of individual, carer and professional  
326 perspectives. *Heal Serv Deliv Res.* 2016;4(21):1-200. doi:10.3310/hsdr04210
- 327 2. Lin FR, Metter EJ, O'Brien RJ, Resnick SM, Zonderman AB, Ferrucci L. Hearing loss and  
328 incident dementia. *Arch Neurol.* 2011;68(2):214-220.
- 329 3. Leroi I, Pye A, Armitage CJ, et al. Research protocol for a complex intervention to  
330 support hearing and vision function to improve the lives of people with dementia.  
331 *Pilot Feasibility Stud.* 2017;3(1):1-16. doi:10.1186/s40814-017-0176-1
- 332 4. Guthrie DM, Davidson JGS, Williams N, et al. Combined impairments in vision, hearing  
333 and cognition are associated with greater levels of functional and communication

- 334 difficulties than cognitive impairment alone: Analysis of interRAI data for home care  
335 and long-term care residents in Ontario. *PLoS One*. 2018;13(2):e0192971.  
336 doi:10.1371/journal.pone.0192971
- 337 5. Lawrence V, Murray J, Ffytche D, Banerjee S. The experiences and needs of people  
338 with dementia and serious visual impairment: a qualitative study. *Int*  
339 *Psychogeriatrics*. 2009;21(3):511-518. doi:10.1017/S1041610209008424
- 340 6. Nyman SR, Innes A, Heward M. Social care and support needs of community-dwelling  
341 people with dementia and concurrent visual impairment. *Aging Ment Health*.  
342 2017;21(9):961-967. doi:10.1080/13607863.2016.1186151
- 343 7. Ke KM, Montgomery A-M, Stevenson M, O'Neill C, Chakravarthy U. Formal and  
344 informal care utilisation amongst elderly persons with visual impairment. *Br J*  
345 *Ophthalmol*. 2007;91(10):1279-1281. doi:10.1136/bjo.2006.113142
- 346 8. Dawes P, Wolski L, Himmelsbach I, Regan J, Leroi I. Interventions for hearing and  
347 vision impairment to improve outcomes for people with dementia: A scoping review.  
348 *Int Psychogeriatrics*. 2018:1-19. doi:10.1017/S1041610218000728
- 349 9. Hartley D, Rochtchina E, Newall P, Golding M, Mitchell P. Use of hearing AIDS and  
350 assistive listening devices in an older Australian population. *J Am Acad Audiol*.  
351 2010;21(10):642. doi:10.3766/jaaa.21.10.4
- 352 10. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and  
353 evaluating complex interventions: the new Medical Research Council guidance. *Br*  
354 *Med J*. 2008;337:a1655. doi:10.1136/bmj.a1655

- 355 11. Regan J, Frison E, Collin F, et al. Individualised sensory intervention to improve quality  
356 of life in people with dementia and their companions (SENSE-Cog trial): study  
357 protocol for a randomised controlled trial. *Trials*. 2019;20:80(1):1-15.  
358 doi:10.1186/s13063-018-2973-0
- 359 12. Join Dementia Research. [www.joindementiaresearch.nihr.ac.uk](http://www.joindementiaresearch.nihr.ac.uk).
- 360 13. Regan J, Dawes P, Pye A, et al. Improving hearing and vision in dementia: Protocol for  
361 a field trial of a new intervention. *BMJ Open*. 2017;7(11):1-12. doi:10.1136/bmjopen-  
362 2017-018744
- 363 14. Department of Health. *Mental Capacity Act*. London; 2005.
- 364 15. Essilor International. <https://www.essilor.com/en/>.
- 365 16. Starkey Hearing Technologies. <https://www.starkey.com/>.
- 366 17. Sivantos Siemens Hearcheck. [https://www.bestsound-  
367 technology.co.uk/nhs/equipment/hear-check/](https://www.bestsound-technology.co.uk/nhs/equipment/hear-check/).
- 368 18. Peek Vision. <https://www.peekvision.org/>.
- 369 19. Nasreddine ZS, Phillips NA, Bédirian V, et al. The Montreal Cognitive Assessment,  
370 MoCA: a brief screening tool for mild cognitive impairment. *J Am Geriatr Soc*.  
371 2005;53(4):695-699.
- 372 20. Charlesworth G, Burnell K, Hoe J, Orrell M, Russell I. Acceptance checklist for clinical  
373 effectiveness pilot trials: a systematic approach. *BMC Med Res Methodol*.  
374 2013;13(78):1-7. doi:10.1186/1471-2288-13-78

- 375 21. Burgio L, Corcoran M, Lichstein KL, et al. Judging outcomes in psychosocial  
376 interventions for dementia caregivers: The problem of treatment implementation.  
377 *Gerontologist*. 2001;41(4):481-489. doi:10.1093/geront/41.4.481
- 378 22. Sekhon M, Cartwright M, Francis JJ. Acceptability of healthcare interventions: An  
379 overview of reviews and development of a theoretical framework. *BMC Health Serv*  
380 *Res*. 2017;17(1):1-13. doi:10.1186/s12913-017-2031-8
- 381 23. Hsieh H-F, Shannon SE. Three approaches to qualitative content analysis. *Qual Health*  
382 *Res*. 2005;15(9):1277-1288.
- 383 24. Hawe P, Shiell A, Riley T. Complex interventions: how “out of control” can a  
384 randomised controlled trial be? *Br Med J*. 2004;328(June):1561-1563.
- 385 25. Chen G, Gully S, Eden D. Validation of a New General Self-Efficacy Scale. *Organ Res*  
386 *Methods*. 2001;4(1):62-83. doi:10.1177/109442810141004
- 387 26. Yesavage JA. Geriatric depression scale. *Psychopharmacol Bull*. 1988;24(4):709-711.
- 388 27. Burns DD. *Ten Days to Self-Esteem: The Leader's Manual*. Quill/HarperCollins  
389 Publishers; 1993.
- 390 28. Zigmond A, Snaith R. The Hospital Anxiety and Depression Scale. *Acta Psychiatr*  
391 *Scand*. 1983;67:361-370.

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

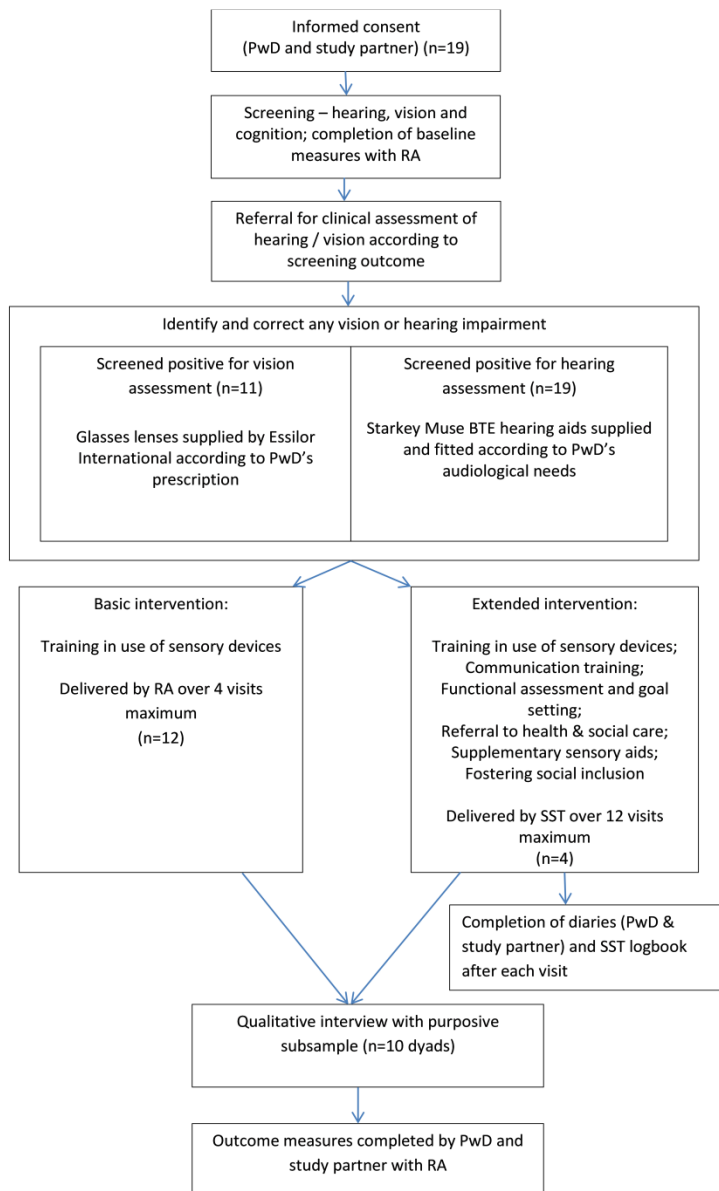
Variable	Category	Participants with Dementia	Study partner Participants
N		19	19
Age (Years)	Median (IQR)	76 (11)	67 (13)
	Range	63 to 88	43 to 82
Gender	Female	7 (36.8%)	16 (84.2%)
	Male	12 (63.2%)	3 (15.8%)
Duration of Cognitive Impairment (Months)	Median (IQR)	60 (54)	NA
	Range	6 to 120	
Level of 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**

401

402

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
<b>Acceptability</b>	Understanding <sup>PwD</sup>	4.7 (4-5)	4.6 (4-5)	3.1 (2-4)	3.3 (2-5)
	Motivation <sup>PwD</sup>	4.6 (4-5)	4.9 (4-5)	3.9 (3-5)	3.3 (2-4)
	Motivation <sup>SP</sup>	4.4 (4-5)	5 (5-5)	3.3 (2-4)	3.8 (3-4)
	Motivation <sup>SST</sup>	4 (4-4)	4.8 (4-5)	3.3 (2-4)	4.5 (4-5)
	Sense of achievement <sup>SP</sup>	4.4 (4-5)	4.7 (4-5)	3 (2-5)	3.5 (3-4)
	Sense of achievement <sup>SST</sup>	3.8 (3-4)	4.6 (4-5)	3.1 (2-4)	4 (3-5)
	Interest <sup>SP</sup>	4.7 (4-5)	5 (5-5)	3.6 (3-4)	3.8 (3-4)
	Interest <sup>SST</sup>	4 (4-4)	4.8 (4-5)	3.8 (2-4)	4.8 (4-5)
	Emotional response <sup>SP</sup>	4.1 (4-5)	4.4 (4-5)	3.1 (2-4)	3.3 (3-4)
<b>Tolerability</b>	Effort <sup>PwD</sup>	4.7 (4-5)	4.5 (4-5)	3.1 (2-5)	2.3 (1-4)
	Fatigue <sup>PwD</sup>	5 (5-5)	3.2 (2-5)	3.4 (1-4)	1.5 (1-2)

406 Key: <sup>PwD</sup> PwD rating of response; <sup>SP</sup> Study partner rating of PwD's response; <sup>SST</sup> 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').

410

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
<b>Feasibility of study procedures</b>			
<b>Eligibility criteria:</b> ≥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 <sup>a</sup> .  5 participants who screened positive on hearing impairment using the HearCheck were deemed not clinically suitable for hearing aids on full assessment <sup>a</sup> .  There was an imbalance of sensory diagnostic groupings across the sites <sup>a</sup> .	Inclusion criteria adjusted to MoCA ≥10.  Remaining components of the SI will continue for any PwD not prescribed sensory aids following clinical assessment.
<b>Recruitment:</b> 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 <sup>a</sup> .  Rate was 2.7 dyads per month at Site M and 1.3 dyads per month at Site N <sup>a</sup> . Incomplete recruitment at Site B.	Site B replaced with an alternative.  Recruitment pool widened.
<b>Retention:</b> ≥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 <sup>a</sup> .	Site B replaced with an alternative.
<b>Screening &amp; baseline process:</b>	Appropriate due to the length of assessment battery.	9 dyads had one visit; 10 had two visits <sup>a</sup> .	No changes indicated.
<b>Outcome battery administration and suitability:</b> ≥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 <sup>a</sup> . Missing items within given scales included gender-specific physiological	General Self Efficacy Scale <sup>25</sup> dropped.  Geriatric Depression Scale <sup>26</sup> replaced with the Hospital Anxiety and Depression Scale <sup>28</sup> .



	revision.	<p>items<sup>a</sup>.</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 Scale<sup>25</sup> items<sup>b</sup>;</p> <p>The Geriatric Depression Scale<sup>26</sup> was not appropriate for younger study partners<sup>a</sup>;</p> <p>PwD self-report of hearing and vision impairment was not valid<sup>a</sup>.</p> <p>The Relationship Satisfaction Scale<sup>27</sup> was difficult to administer in presence of the study partner<sup>b</sup></p>	<p>Caregiver reports of hearing and vision impairment introduced alongside PwD's self-report.</p> <p>Relationship Satisfaction Scale<sup>27</sup> administration procedure amended.</p>
<b>Device logistics circuit:</b>	Broadly feasible; areas for improvement identified.	<p>All prescribed hearing aids and glasses were received by participants<sup>a</sup>.</p> <p>Delays in assessment for and receipt of corrective devices impacted on overall study timelines<sup>a</sup>.</p>	<p>Logistics circuit tightened through training and identification of dedicated clinicians.</p> <p>Timeframe for SI delivery extended.</p>
<b>Participant diary:</b> ≥80% completion	Diary activity was feasible for both PwD and study partner.	95% of diary entries completed by both members of the dyad <sup>c</sup> .	No changes indicated.
<b>Feasibility of the Sensory Intervention (SI) components and implementation:</b> Basic SI: Basic intervention (Sites M, N and B) Extended SI: Extended intervention (Site M)			
<b>Basic SI:</b> 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>

		corrective devices (if indicated) within 20 weeks of baseline <sup>a</sup> .  100% of participants completed measures of device skills and knowledge (hearing aids / glasses) <sup>a</sup> .	hearing assessment specified as 1-8 weeks from randomisation.
<b>Extended SI:</b> 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) <sup>b</sup> .  Time from baseline to follow-up was mean 18 weeks (range 17-20) <sup>a</sup> .  100% of participants completed functional assessment and set study-related goals <sup>b</sup> ; of those that continued the SI to completion, 100% of components were addressed <sup>b</sup> .  Elements of the extended SI were successfully introduced prior to device delivery <sup>b</sup> .	Timeframe extended from 12 weeks to 18 weeks for SI delivery.
<b>Acceptability of the intervention:</b>			
Basic SI: Was the Sensory Intervention appropriate?	The basic intervention is acceptable	100% of participants were willing to receive their prescribed aids <sup>a</sup> .  No participant withdrawals due to lack of acceptability <sup>a</sup> .	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 <sup>c</sup> .  100% of mean scores are within range for SP and SST <sup>b,c</sup> .	No changes indicated.

of achievement  Score $\geq 3$ on SP and SST scales for interest and emotional response			
<b>Tolerability of the intervention by participants:</b>			
Basic SI:	The basic intervention is tolerable	100% of participants were able to complete their vision and / or hearing assessment <sup>a</sup> .  The basic intervention was completed over maximum 3 visits <sup>a</sup> .	No changes indicated.
Extended SI: 75% of: Score $\geq 3$ 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 <sup>c</sup> .  75% of scores were $\geq 3$ . 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.

413

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

415 <sup>a</sup> Quantitative data; <sup>b</sup> SST logbook; <sup>c</sup> Participant dyad diaries

416

417

418