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BERESFORD-DENT, J., SPRANGE, K., MOUNTAIN, G., MASON, C., WRIGHT, J., CRAIG, Claire <<http://orcid.org/0000-0002-3475-3292>> and BIRT, L.

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Published version

BERESFORD-DENT, J., SPRANGE, K., MOUNTAIN, G., MASON, C., WRIGHT, J., CRAIG, Claire and BIRT, L. (2022). Embedding patient and public involvement in dementia research: Reflections from experiences during the 'Journeying through Dementia' randomised controlled trial. *Dementia*, 21 (6), 1987-2003.

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Embedding patient and public involvement in dementia research: Reflections from experiences during the 'Journeying through Dementia' randomised controlled trial

Jules Beresford-Dent¹, Kirsty Sprange^{2*}, Gail Mountain¹, Clare Mason¹, Jessica Wright³, Claire Craig⁴, ,
Linda Birt⁶

Author affiliations

¹ Centre for Applied Dementia Research, University of Bradford, Bradford, UK

² Nottingham Clinical Trials Unit, University of Nottingham, Nottingham, UK

³ Clinical Trials Research Unit, The University of Sheffield, Sheffield, UK

⁴ Lab4Living, Sheffield Hallam University, Sheffield, UK

⁵ School of Health Sciences, The University of East Anglia

Corresponding author

Kirsty Sprange

Assistant Professor of Clinical Trials

Nottingham Clinical Trials Unit

University of Nottingham

University Park

Nottingham, NG7 2RD

Tel +44 (0)115 82 31574

Kirsty.sprange@nottingham.ac.uk

ORCID IDs:

Jules Beresford-Dent - 0000-0002-3316-2191

Claire Craig - 0000-0002-3475-3292

Gail Mountain - 0000-0002-5417-7691

Clare Mason

Jessica Wright - 0000-0002-1814-3697

Kirsty Sprange - 0000-0001-6443-7242

Linda Birt - 0000-0002-4527-4414

1 **Abstract**

2 **Background**

3 The involvement of people with a diagnosis of dementia in patient and public involvement and
4 engagement (PPIE) in research is an emerging field in the delivery of studies. Researchers need to
5 be enabled to understand and use the learning derived from various projects so that this growing
6 body of knowledge can be applied in future research.

7 **Objective**

8 Our objectives were to embed PPIE throughout a randomised controlled trial of a psychosocial
9 intervention called Journeying through Dementia. In this paper we identify and discuss the
10 approaches to involvement that worked well and those where improvements or changes were
11 indicated.

12 **Design**

13 The Guidance for Reporting Involvement of Patients and the Public Short Form (GRIPP2-SF) is used
14 to describe and critically appraise the approaches taken and the impact of PPIE involvement upon
15 study processes, the study team and those people with dementia and carers who acted as advisors
16 as well as those who were consumers of the research.

17 **Results**

18 The involvement of people with a diagnosis of dementia and carers as study advisors improved the
19 accessibility and relevance of the research for people living with dementia. It also highlighted issues
20 that researchers may have otherwise overlooked. Successful engagement of people with dementia
21 and carers in the study was associated with staff skills and scaffolding as well as participants'
22 memory and cognitive capacity. However, embedding robust and meaningful involvement
23 processes required significant time and resources.

24 **Discussion**

25 We propose that certain research processes need to be adapted to be accessible for people living
26 with cognitive impairment. Recruitment of PPIE advisors needs to reflect population diversity.;
27 thereby contributing towards greater parity of voice between people with lived experience of
28 dementia and researchers, increase the impact of PPIE in research and improve the experience for
29 those who volunteer to be PPIE advisors.

30

31 **Key words:** patient and public involvement and engagement, dementia, research

32

33

34 Background

35 Funders, such as the National Institute for Health Research (NIHR) emphasise the value of patient
36 and public involvement and engagement (PPIE) in the development, delivery and dissemination of
37 research and demand that all studies evidence this¹. Moreover, it is increasingly necessary to fully
38 describe PPIE in published research outputs using reporting tools such as the GRIPP2². Integrity,
39 quality, impact and relevance are just some of the benefits identified through involving those with
40 lived experience^{3,4}. PPIE is therefore considered integral to good research design⁵. Guidance now
41 exists on best practice to facilitate PPIE in the design and conduct of research including for people
42 living with dementia^{1,6}.

43
44 However, it has been noted that undertaking meaningful PPIE can be challenging for both
45 researchers and volunteers⁷, for example those with lived experience may question researcher
46 preferences or decisions⁸. The power imbalance that can exist within healthcare and research
47 contexts can result in service users being rendered unable to influence research design,
48 implementation and outcome⁹. Therefore approaches to public involvement need to be relevant,
49 accessible and support meaningful engagement¹⁰. When working with people living with dementia
50 this may involve managing individual expectations of cognitive capacity, including those of the
51 researcher¹¹, whilst also empowering and valuing the voice of lived experience¹². Alzheimer Europe's
52 position on PPIE is one of inclusivity, and encouraging engagement such as identifying research
53 priorities, interpretation of research findings and dissemination¹³. Identifying and applying methods
54 of PPIE that are acceptable and understandable to people living with dementia, both those living
55 with a diagnosis of dementia and their family carers, is therefore vital to improve the depth, delivery
56 and utility of dementia research¹⁰.

57
58 Journeying through Dementia (JtD) is a psychosocial intervention designed for those diagnosed with
59 mild dementia. It aims to equip individuals with the knowledge, skills and understanding to be able
60 to self-manage and maintain independence and meaningful participation, thereby improving
61 mastery, wellbeing and life satisfaction¹⁴. PPIE was embedded throughout the entire JtD research
62 programme from inception and design of the intervention¹⁵, through to feasibility testing¹⁶ and the
63 definitive randomised controlled trial (RCT) involving 480 people with a diagnosis of dementia and
64 350 supporters¹⁴. This paper describes our experience of PPIE in the JtD randomised controlled trial.
65 Through reporting our experiences, we aim to highlight when and how PPIE strengthened our
66 research and also the challenges we encountered whilst endeavouring to deliver meaningful
67 approaches towards PPIE.

68

69 Methods

70 The GRIPP2 short form (SF) format for reporting involvement of patients and the public is used to
71 report and critically reflect upon the PPIE processes and outcomes².

72

73 Establishing and facilitating PPIE in the trial

74 Our approach to PPIE, was informed by NIHR INVOLVE guidelines¹, the Dementia Engagement and
75 Empowerment (DEEP) project⁶, the work of the Scottish Dementia Working Group¹⁷, and the
76 experiences of study team members. Our aims were to:

- 77 • Create opportunities for meaningful involvement of people living with dementia and family
78 carers in the design and delivery of the study and in the dissemination of results.
- 79 • Increase the relevance and accessibility of the research to people living with dementia and
80 other members of the public.
- 81 • Create relevant, accessible and useful outputs from the study for people affected by
82 dementia.

83 To support the aims of PPIE engagement in the trial the research team agreed and upheld a number
84 of 'guiding principles' to inform the planning and execution of involvement activities, see **Box 1**.

85 **Box 1: Guiding principles for PPIE involvement in the JtD trial**

- All PPIE advisors compensated for their time in line with NIHR INVOLVE guidance¹⁸.
- A 'you said, we did' approach regarding how advice was used and taken forward.
- Use of best practice accessibility guidance⁶ e.g. avoidance of jargon, acronyms and academic language.
- Meeting venues selected in consultation with PPIE to ensure accessibility e.g. layout, transport, low noise levels. Provision of wayfinding advice to venues e.g. maps and instructions. Taxis provided if required while at the same time being mindful of offering support rather than becoming paternalistic¹⁹.
- Inclusion of regular breaks during meetings as well as time and space to engage and respond to materials or discussion topics.
- Venue preparation to ensure a dementia friendly layout, provide additional signage and 'meet and greet' to help direct people.
- Use of aid memoirs in all encounters with PPIE advisors e.g. flipcharts posted up in meeting rooms to remind members of the aims of the study and of the specific meeting, provision of verbal or written updates on study progress.
- For all PPIE meetings content limited to one item per meeting e.g. input to documentation, dissemination activity.
- For Trial Steering Committee meetings, papers sent in hard copy well ahead of the meeting with highlighted sections for specific consideration.

86

87 For any study it is essential that appropriate funding is allocated to PPIE activity for reimbursement
88 or payment of time as well as for associated costs such as travel or equipment¹⁸. At the outset a
89 budget was identified for PPIE for the JtD trial although this needed to be increased over time as
90 additional activities were identified.

91

92 Applying an appropriate level of expertise towards PPIE engagement is also known to be essential. A
93 researcher, with previous experience of facilitating engagement of people living with dementia in
94 research, was responsible for identifying PPIE activities and co-ordinating involvement.

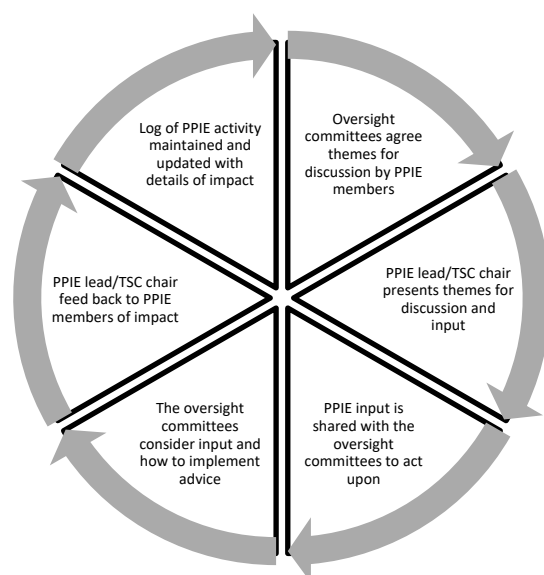
95

96 All PPIE activities, records of discussions, the advice given to researchers and how it was
97 subsequently used was recorded on a PPIE activity log²⁰. This approach allowed us to continually
98 review the impact of advice of PPIE upon the overall trial and provide transparency and
99 accountability.

100

101 PPIE in trial oversight and operationalisation

102 The involvement of people living with dementia was rooted strategically and operationally in JtD trial
103 governance and processes. It was embedded in trial oversight through PPIE membership of our
104 Study Advisory Group and of the independent Trial Steering Committee (TSC) as well as being
105 included as a standing agenda item for the Trial Management Group (TMG). As it is important to
106 provide a bridge between PPIE and researchers²⁰, a cycle of identifying activities, discussion,
107 reporting and taking action was established between the TSC and TMG oversight committees and
108 PPIE advisors as illustrated in figure one, see figure 1.



109

110 **Figure 1: PPIE cycle of discussion, implementation, and feedback**

111

112 PPIE Recruitment

113 Recruitment of volunteers for membership of the TSC proved challenging. One person living with
114 dementia, who was already active in research and known to the Trial Steering Committee members
115 through existing research networks, was approached to join the Committee ahead of the inaugural
116 meeting and remained a member throughout the four-year trial, attending every meeting. Although
117 the initial intention had been to involve two PPIE members to provide cover and co-support, and
118 spread the workload, we failed to identify a second PPI member. This may have been due to the four
119 year time commitment, or perceptions of the necessary the confidence and skills for this more
120 formal role.

121

122 We decided to recruit a PPIE advisory group to provide advice and guidance to the TMG throughout,
123 thereby ensuring that our approach remained relevant and accessible to people living with dementia
124 from recruitment to dissemination. Recruitment to the PPIE study advisory group was through the
125 existing University of Bradford 'Experts by Experience' cohort of people with a diagnosis of dementia
126 and carers who volunteer to be involved in research and education²¹. We recruited individuals who
127 were new to the cohort as well as long-standing members who may have had previous involvement
128 in research. Consequently, some PPIE members had a deeper understanding of research than others.
129 Initially the PPIE lead, and a second member of the research team conducted individual
130 consultations with potential volunteers to explain the trial and what their involvement in the
131 advisory group would entail. They emphasised to each potential volunteer that they could engage in
132 as much or as little as they chose and that involvement in just one event would be valuable.
133 Although interest in joining the group was high, with 10 applicants for the first meeting in July 2017,
134 attendance was initially poor (three people) due to a clash with another meeting held by a local
135 dementia support group. However, the advisory group continued to meet between July 2017 and
136 October 2019 and numbers increased to 12. Several people with dementia attended with a spouse
137 or another family member but others attended alone. Some changes in membership took place due
138 to a change in commitments, through illness, and progression of dementia. The group were
139 predominantly white and therefore did not reflect diversity and the experience of dementia by other
140 ethnicities or social groups¹⁰.

141

142 Supporting PPIE involvement

143 *Trial Steering Committee*

144 The role of any TSC is to provide study supervision, monitor conduct and progress and ensure that
145 the safety and well-being of study participants are upheld²². The TSC for the JtD trial met twice
146 yearly and involved members from clinical, academic and PPIE backgrounds.

147

148 To ensure that our PPIE member was fully informed a significant amount of time was taken by the
149 TSC Chair and/or Trial Manager prior to each meeting to talk through any associated paperwork or
150 preparatory materials. During meetings, the PPIE member sat adjacent to the Chair to facilitate
151 communications. The responsibilities of the Chair were to ensure that the PPIE member understood
152 all discussions throughout, including limiting the use of acronyms and overly technical language by
153 all members and providing time for the PPIE member to consider and respond to an agenda item or
154 question. With these adjustments in place The PPIE member was able to provide unique insights
155 from the perspective of someone living with dementia and made significant contributions in key
156 areas and documented her experiences of being involved in the trial as an adviser in her blog ‘Which
157 me am I today?’ <https://whichmeamitoday.wordpress.com/>. The following quotes illustrates their
158 contribution and participation in the TSC.

159

160 *“Many of the [meeting] papers were way beyond me but [name] had put a friendly post-it on*
161 *each one telling me what each paper was about – wonderful idea. Definitely worth a brownie*
162 *point.”* TSC PPIE member

163

164 *“I raised the question of the reality of relying on our [participants with dementia] answers in*
165 *follow-ups. And that raised a whole issue of current practices. I said that even if it shows how*
166 *the current practices need to be revisited, that’s a good outcome. I said revisits 8 months*
167 *after an event and asking us to recollect is a tad adventurous. We don’t like to feel*
168 *embarrassed at not remembering so may make things up so we don’t look stupid.....or we*
169 *simply give an answer that comes to mind today.”* TSC PPIE member

170

171 *Advisory group*

172 The operational management of the trial was overseen by the Trial Management Group (TMG) who
173 agreed that embedding high quality PPIE into protocol development and trial processes throughout
174 was a priority. The PPIE lead for the trial (CM) and coordinator of the PPIE advisory group was a
175 member of the TMG and PPIE was a standing-item on every TMG agenda.

176 Activities where the TMG requested specific input from PPIE advisors included:

- 177 1. the design of participant newsletters which were originally designed in newspaper column
178 format but were changed to a cross page format which our advisory group reported as being
179 easier for people living with dementia to read.
- 180 2. the content of a study proforma completed by facilitators and sent to study participants,
181 summarising the group or individual sessions as part of the intervention. With consultation
182 identified that the content needed to be personalised by adding the participants name and
183 that the overall language used should be simplified using less research terminology.
- 184 3. the content, deliverability and impact of burden of our qualitative interview schedule.
185 Advisor feedback proposed that the language and wording should be more concrete for
186 study participants to engage with and that to scaffold recall during the interview researchers
187 should use prompts about what had taken place during intervention sessions. Consequently,
188 the researchers asked shorter more direct questions for clarity and understanding; and
189 referred to activities the participant took part in to prompt recall.

190

191 To ensure that the PPIE advisory group felt supported and integrated into the study team we
192 employed several methods. Firstly, we used our guiding principles to support set-up and
193 engagement of the group, see Box 1. One to one discussion was offered and taken up by some
194 individuals instead of participation in a group or to aid their decision to join the group. When an
195 advisory group had been assembled, we asked members about their preferences for involvement
196 including how they would like to be communicated with throughout the study, the length and
197 duration of meetings and meeting venues. All members did subsequently take part in the group but
198 some people with dementia needed support from their carer to achieve this. In addition, brief verbal
199 and written reminders were provided at every advisory group meeting to reiterate the purpose of
200 the study and what taking part entailed. A welcoming and informal structure was maintained to
201 encourage active participation. At the start and end of each meeting time was scheduled for
202 refreshments, creating opportunities for PPIE advisors to enjoy a group atmosphere, and share more
203 personal experiences and coping strategies whilst at the same time advising the study. Members
204 expressed that participating had made them feel useful and saw their contribution as helping other
205 people living with dementia, one carer said:

206 *"[Person with dementia] and I enjoyed the meeting....to discuss*
207 *Journeying through Dementia. We both like to feel that we can contribute in some small way*
208 *to make life as easy as possible for people with dementia". Family carer 2*

209

210 To promote inclusivity, support group dynamics and maintain active interest in the study all
211 members were invited to be involved in every activity. On most occasions all members attended,
212 reflecting the overall interest the study generated and the possible benefits people were deriving
213 from taking part. For larger groups however, it was challenging to ensure that the voices of all
214 members were heard. PPIE advisors with a diagnosis of dementia could need additional time to
215 process discussions and respond accordingly. This could lead to another person (often their carer),
216 speaking before them or on their behalf. We therefore used techniques such as turn-taking and
217 signalling using purpose made cards or simply a 'hands-up' gesture to try and avoid this.

218

219 Dementia friendly, accessible venues in familiar city centre locations were identified by the group in
220 preference to university campus settings which were deemed too busy and confusing. Use of
221 community venues proved positive and some advisory group members reported that they had
222 engaged in an activity in or near such venues following meetings such as shopping or going for lunch.
223 Whether this was simply opportunistic or attending the advisory group resulted in greater
224 confidence to do more activity is unclear.

225

226 *Trial delivery and data collection*

227 Our PPIE group advisors' and TSC PPIE member's views and ideas on participant retention during the
228 lifetime of the study were invaluable. For the trial we were collecting outcome data for up to 12
229 months after recruitment from all participants whether they had attended the intervention or been
230 randomised to treatment as usual. Recommendations that were actioned included:

- 231 • emphasising the value of contributions from all participants whether they received the
232 intervention or not in the participant newsletter.
- 233 • booking follow-up researcher visits in advance as part of their first visit with a participant.
234 This would mean that all follow-up visits would be in the diary and a confirmation would just
235 be needed nearer the time of the follow-up.
- 236 • sending a reminder card (rather than letter or sheet) before attending follow-up
237 appointments. PPIE members proposed that a card would be brighter and more visually
238 appealing to participants thereby reducing the anxiety that a formal letter may provoke.
- 239 • including a photo of, and a personal message from, the researcher doing the follow-up.
- 240 • communicating with carers about the importance of the person with dementia's
241 participation in the study.

242

243 *Data analysis*

244 Advisory group members used their personal experiences of living with dementia to assist the
245 researchers to understand and interpret our qualitative data. Their contributions informed
246 the final analysis of interview data as described in Sprange et al (2021)²³.

247

248 Advisory group members were approached to participate in two half day validation workshops to
249 discuss and reflect upon researcher interpretations of anonymised data from qualitative interviews
250 conducted with participants and their carers²³. We had to obtain consent from each participant at
251 the outset and identified appropriate researcher resource to do this in a relaxed manner. However
252 late arrivals to the workshop questioned how this is best achieved.

253

254 Selected quotations from the interview data representative of the themes identified in the
255 framework were presented as raw data, i.e. without coding or categorisation²³. These were
256 presented for discussion one at a time alongside some descriptive and contextual detail to aid
257 understanding. For example, the voice being heard i.e. participant or carer and what the person was
258 talking about i.e. an element of the intervention or the facilitators etc. Consideration was given to
259 how to present each quote to the group in a dementia friendly format to aid understanding⁶. This
260 included use of large font size, colour of paper, amount of text per quotation and printing one copy
261 per person. By using ongoing validation observation techniques such as listening and reflecting to
262 gauge understanding and interest in the activity during the workshops the researchers were able to
263 support participation.

264

265 The levels of impairment experienced by participants were varied which made pitching the task
266 correctly and maintaining the engagement of everyone a challenge for researchers. During our first
267 workshop the level of direction provided by researchers was therefore relatively high. As this was a
268 novel approach to PPIE in dementia research there was some concern expressed by the researchers
269 of not wanting to overwhelm the group. Therefore, different approaches were needed to engage
270 and support those with more severe memory issues e.g. giving adequate time for the group to read
271 and re-read quotation as well as presenting quotation in both written and verbal formats (facilitator
272 read aloud the quotation). The facilitator also started with an open-ended question such as “what do
273 you think this person is saying/feeling?”, but this may have been followed up with a more structured
274 question to aid contribution for example focussing on an interesting word or phrase in the quotation
275 to initiate discussion. For those more cognitively able and carers who took part there was
276 enthusiasm and great interest in the research and being part of the interpretation of findings. Those

277 less cognitively able appeared to enjoy the social occasion but it was less clear whether they had
278 been able to engage with all the materials.

279

280 Whether to provide participant training for this activity was debated amongst the research team.
281 Some considered that training would be helpful to guide and support engagement in the activity¹⁹,
282 whereas others felt that memory and retention of training prior to the activity may be challenging
283 and therefore could cause frustration or distress. We chose not to undertake a separate training
284 session prior to the workshops but instead we took time at the start of each session (after consent
285 was taken) to summarise the study and the activity. We included a practice example which we
286 worked through together in which the researcher could prompt the group on items we were looking
287 for feedback such as language used or tone of the quotation. In addition we also provided visual aids
288 in the form of flip charts bullet pointing the key facts of the trial to scaffold memory⁶.

289

290 To support engagement we provided props such as 'I want to speak please' cards⁶ as a
291 communication aid to indicate when a person wanted to speak. However, we found in our
292 experience that these cards were not used. Potential reasons were that firstly, the group were not
293 used to using these props and therefore it was no habit to do so, and secondly this was a very close
294 knit and well-established group where carers as well as the more cognitively able members already
295 felt comfortable speaking with each other and enabling each other to participate. This was less
296 evident for those members with more severe dementia.

297

298 *Dissemination activity*

299 Advisory group members were consulted on the format and content of both hard copy and online
300 versions of a lay summary of study results. These documents were intended for a wide readership
301 including people living with dementia who had taken part in the trial, members of the public and
302 health and social care professionals. PPIE feedback led to the inclusion of information about
303 organisations that can support people living with dementia and information about how the results
304 might be used to inform healthcare and future research. The group also helped us design and
305 produce a satisfaction questionnaire to obtain feedback regarding the presentation and
306 comprehensibility of the summary findings. This was considered important if are findings were to be
307 accessible and relevant to people living with dementia and those who care for them as well as for
308 the lay public, clinicians and academics.

309

310 Our final trial dissemination event for all comers was held in a central public venue with invitees
311 including researchers who had been associated with the study, people living with dementia,
312 members of the public and health and social care professionals. Advisory group members suggested
313 the need for a speaker protocol to encourage presenters to make their session accessible for people
314 living with dementia including means by which those attending might interact with speakers. As a
315 consequence, all speakers were provided with a protocol and large cards were made available at the
316 venue that stated “I don’t understand”, “I want to ask a question” and “Please speak more slowly”
317 which delegates did use.

318

319 PPIE advisors also recommended that study team members wore brightly coloured sashes that
320 identified them as ‘helpers’ and suggested they should be situated at the main public transport hubs
321 where people attending the event might arrive and at the venue entrance. A member of the
322 advisory group, a former carer also volunteered to co-host the event reception desk with a member
323 of the study team. At a previous meeting, advisory group members had been invited to speak about
324 their experiences of being involved in research, but none accepted. Two advisory group members
325 with a diagnosis of dementia were involved in making a video to demonstrate the intervention as
326 part of a study dissemination film ([https://www.bradford.ac.uk/dementia/research/journeying-
327 through-dementia/](https://www.bradford.ac.uk/dementia/research/journeying-through-dementia/)) which was viewed at the event.

328

329 Discussion

330 We achieved involvement in all stages of this large randomised controlled trial at a time when this
331 level of engagement of people with a dementia diagnosis was not established practice. Importantly
332 the voice of people living with dementia and their carers was heard first-hand and acted upon, which
333 is acknowledged as being essential⁴. However, we also found that meaningful involvement could be
334 challenging at times and our aspirations could not always be met, particularly given that PPIE
335 described here was for a trial with necessary study processes.

336

337 During both PPIE recruitment and involvement activities we found that the informed consent
338 process could easily disempower people, including those with the capacity to consent. The process
339 was time consuming and burdensome for some people with a diagnosis of dementia who found it
340 confusing to have to agree to numerous statements. It is important that people living with dementia
341 feel empowered to make decisions for themselves when consenting²⁴. We therefore suggest that
342 using a simplified consent form, co-produced with people living with dementia, would minimise
343 unnecessary participant burden whilst complying with research governance requirements. At the

344 outset of this trial, researchers aspired to create and test methods of video consent for potential
345 trials participants, but it was quickly realised that this could not be achieved within the resource
346 constraints of the study.

347

348 Having reliable methods in place to encourage and capture the impact of involvement activities was
349 greatly facilitated by having a designated PPIE lead and researchers within the study team who were
350 both knowledgeable and supportive of PPIE. Our experiences underscore the need for researchers to
351 have expertise in working with people living with dementia or that the requisite training and support
352 is provided so that they always take a sensitive and considered approach, enabling involvement in an
353 informed and nuanced manner¹³. The more we undertake research involving people living with
354 dementia as PPIE advisors or co-researchers the more we learn to pave the way for models of
355 successful participation in research¹⁹.

356

357 PPIE advisory group members were recruited from existing PPIE cohorts and networks. Whilst this
358 approach perhaps led to a more relaxed exchange of ideas between researchers and PPIE advisors, it
359 created limitations in terms of diversity. Almost all our PPIE advisors were White British. Also, some
360 members were living with more advanced stages of dementia which did not reflect the population of
361 study participants. As the membership of the PPIE advisory group evolved, people living in earlier
362 stages of dementia, including some who lived alone joined the group. How to ensure the
363 involvement of the range of people who represent any one group remains a challenge²⁵ and in
364 common with overall recruitment to dementia studies, achieving diversity is difficult²⁶. We
365 recommend that to reflect the study population, early liaison, during the design phase of research,
366 with representatives from relevant community organisations might gain support, both for
367 participant recruitment and for recruitment of PPIE representatives This may in turn increase
368 interest in research from underrepresented groups.

369

370 It may require time for participants living with dementia to feel participation in research is
371 meaningful⁵. Feeling useful and being able to help others is important to people living with
372 dementia²⁷ but it is important to consider what might be other motivations and needs of people
373 acting as PPIE advisors to research. We found that members who had recently received their
374 diagnosis sought personal support and specific advice from the group and from researchers
375 regarding their recent diagnosis and what this meant for their future. Those supporting PPIE
376 therefore need to understand the boundaries between research, clinical advice and personal
377 support and be prepared to respond by signposting individuals to appropriate services. Family

378 members can feel the need to protect people living with dementia, which can lead to a form of
379 gatekeeping, taking decisions on behalf of the person with dementia¹¹. During this study we found
380 that some carers spoke on behalf of their spouse on occasion. Researchers were aware of the need
381 to listen to the voice of the person with dementia¹³ and study team members explored ways of
382 achieving this for example 'turn taking' and using smaller discussion groups. It has also been
383 observed that offering guidance to carers on how to enable the people they support to be involved
384 in PPIE activities may be beneficial and make the carer feel valued¹³.

385

386 Involvement in the TSC for this study did not meet agreed best practice²² in that only one person
387 with a diagnosis of dementia was recruited to the committee. The arrangement was considered to
388 work well due to the skills and previous experience of the PPIE representative but having two
389 members to take account of absence and meet needs for peer support is recommended. Being a TSC
390 PPIE member creates different demands for the PPIE advisory group member due to the time lag
391 between meetings and the necessary independence of the TSC which aids objectivity but also
392 creates distance from the study. This can affect ability of all PPIE members to retain knowledge and
393 understanding of the trial, but particularly if the person is living with memory issues. Therefore,
394 approaches to scaffold memory and recall are helpful and should be provided as we identified during
395 this study.

396

397 In accord with best practice²⁸⁻³⁰, providing opportunities to share experiences and coping strategies
398 whilst at the same time advising on the study proved important. Additionally, we found that hosting
399 advisory group meetings in a community setting could provide social opportunities that might not
400 have occurred otherwise. Most of our PPIE advisors were, or had recently been, involved in other
401 research studies which perhaps created an understanding of research, and familiarity with other
402 PPIE advisors, that was helpful to enable them to participate.

403

404 Our experiences have confirmed that PPIE approaches and processes need to be established early on
405 to have greatest effect upon the design and implementation of a study. The time taken to establish
406 the advisory group meant that some decisions which would have benefited from PPIE input were
407 initially taken in the absence of consultation, e.g. the format and presentation of newsletters sent to
408 study participants which was subsequently changed following recommendations from the advisory
409 group.

410

411 Questions remain about how to achieve maximum involvement in research outputs such as
412 presentations and publications. The optimum time to engage people living with cognitive
413 impairment in recording their experiences and input needs careful consideration. However, when
414 working with people living with cognitive impairment (as some of our PPIE advisors were) the
415 convention of writing most outputs at the end of a study can limit the participation of PPIE advisors
416 as it relies on recall. Indeed, in the preparation of this paper for publication we left writing up
417 towards the end of the trial and the PPIE advisor approached to contribute felt they could not recall
418 their involvement sufficiently to directly contribute, thus creating disparity between the voice of the
419 researchers and the voice of people living with dementia. We therefore propose assisting PPIE
420 advisors to record their experiences at the time might result in authentic publication.

421

422 Involving people living with dementia in the analysis of data can improve the quality of research, and
423 if done well can be a satisfying experience for PPIE advisors⁵. The importance of providing PPIE
424 members with appropriate training and support for this and for other aspects of the role is
425 indisputable but questions remain about how this can be achieved to best effect when involving
426 people living with dementia¹⁹. More specifically; for people with a diagnosis of dementia when does
427 PPIE involvement become too much of a challenge¹¹ and who decides; and secondly how can needs
428 for training and support be most effectively met³¹.

429 Conclusion

430 We posit that we could improve engagement of people living with dementia in research through
431 increasing diversity and adjusting research processes to be more accessible. This in turn would
432 create parity of voice between people with lived experience and researchers and increase the
433 impact of meaningful PPIE in research whilst improving the experience for PPIE advisors. Many
434 aspects of our approach to involving people living with dementia were effective in that members of
435 the advisory group reported their involvement as enjoyable, sociable and satisfying. Regular review
436 of the purpose and approach to PPIE on any study is necessary and can improve the experience for
437 PPIE members.

438

439 Declarations

440 Acknowledgements

441 All of our patient and public involvement and engagement partners. The sponsor Nicholas Bell,
442 Sheffield Health and Social Care NHS Foundation Trust. Stephen Walters, Ellen Lee, Amanda Loban,
443 Emily Turton, Esme Moniz-Cook, Tom Dening, Tracey Young, Peter Bowie, Daniel Blackburn and

444 Jasper Palmier-Claus of the Trial Management Group (TMG). Kathryn Ludwin and Michelle Drury of
445 the CTRU. Catherine Hewitt (Chair), University of York, Wendy Mitchell, PPIE Representative,
446 Jennifer Wenborn, University College London of the Trial Steering Committee (TSC) and Mona
447 Kanaan (Chair) University of York, Jane Burgess, North East London NHS Foundation Trust and Emily
448 Robinson, Kings College London of the Data Monitoring and Ethics Committee (DMEC) whom all
449 advised on and critically reviewed the trial protocol.

450

451 The sponsor Nicholas Bell, Sheffield Health and Social Care NHS Foundation Trust. Stephen Walters,
452 Ellen Lee, Amanda Loban, Emily Turton, Esme Moniz-Cook, Tom Denning, Tracey Young, Peter Bowie,
453 Daniel Blackburn and Jasper Palmier-Claus of the Trial Management Group (TMG). Kathryn Ludwin
454 and Michelle Drury of the CTRU. Catherine Hewitt (Chair), University of York, Wendy Mitchell, PPI
455 Representative, Jennifer Wenborn, University College London of the Trial Steering Committee (TSC)
456 and Mona Kanaan (Chair) University of York, Jane Burgess, North East London NHS Foundation Trust
457 and Emily Robinson, Kings College London of the Data Monitoring and Ethics Committee (DMEC)
458 whom all advised on and critically reviewed the trial protocol..

459

460 [Funding](#)

461 This work was funded by the NIHR Health Technology Assessment Programme (project number
462 14/140/80). The views expressed are those of the author(s) and not necessarily those of the NHS,
463 the NIHR or the Department of Health.

464

465 [Author contributions](#)

466 CM led PPIE recruitment and co-ordination supported by GM, JW, CC and JBD. LB provided advice
467 and guidance on PPIE involvement in qualitative analysis. WM was the TSC PPIE Member. KS and JBD
468 lead the qualitative analysis workshops. GM, KS and JBD developed the manuscript. All authors
469 reviewed and approved the final manuscript.

470

471 [Ethical approval and consent to participate](#)

472 Ethical approval was obtained in July 2016 (ref no. 16/YH/0238) from the United Kingdom National
473 Health Service Research Ethics. United Kingdom Health Research Authority approval was given (IRAS
474 reference 199383) in August 2016.

475

476 We obtained written informed consent for the participants who took part in the qualitative analysis
477 workshops via a Consent Form. This information is held as part of the archived record of the trial.
478 Only anonymised nonidentifiable data are used in this report as per written consent.

479

480 [Availability of data and material](#)

481 The datasets generated and analysed for this study will be available upon request from the
482 corresponding author.

483

484 [Competing interests](#)

485 Clare Craig is the author of the Journeying through Dementia manual. All other authors declare no
486 competing interests.

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