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1 Original Article: A Public and Patient Consultation 2 Process as an Aid to Design a Person-Centred 3 Randomised Clinical Trial

4 Abstract:

5 Background:

6 Involving patients and members of the public, together with researchers, in decisions about how
7 studies are designed and conducted can create a study that is more person-centred. The aim of this
8 consultation process was to explore ways of designing a study which takes the person into
9 consideration for the randomised clinical study entitled “Biomechanical Effects of Manual Therapy –
10 A Feasibility Study” using the novel approach of usability testing.

11 Design:

12 Patient and public volunteers were sought with experience of low back pain. Volunteers were invited
13 to participate in usability testing (a physical walkthrough) of the proposed study method. This was
14 followed by a discussion of areas where usability testing could not be used, such as recruitment
15 strategies, continuity of participant care and dissemination of results. Resulting feedback was
16 considered by the research team and alterations to the original study method were incorporated,
17 provided the research questions could be answered and were practical within the resources
18 available.

19 Results:

20 Additional recruitment strategies were proposed. Alterations to the study included reduction in
21 study time burden; completion of study paperwork in a quieter location; continuity of participant
22 care after the study; and methods of dissemination of overall study results to participants.

23 Conclusion:

24 The consultation process used the unique method of usability testing, together with a post-usability
25 discussion and resulted in alterations to the future study which may facilitate making it more
26 person-centred.

27 Patient and Public Contribution:

28 Patients and public developed the future study design but **did not** participate in manuscript
29 preparation.

30 Key Words:

31 Patient and Public Involvement, Clinical Trial, Trial Design, Research Collaboration.

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53 Background:

54 Healthcare, in recent years, has seen a paradigm shift from medical autonomy and disease-based
55 care to a more person-centred approach to care¹. The principles and concepts of person-
56 centeredness are now commonplace in national²⁻⁴ and global healthcare policies⁵. There are also
57 significant funding investments into providing tools aimed at healthcare professionals designed to
58 improve person-centred care^{6,7}, as well as independent charities working towards improving care
59 centred around the individual^{8,9}. Healthcare research is following this paradigm shift and significant
60 efforts are being made to design research which takes the person into consideration¹⁰⁻¹².

61 The term 'person-centred' in healthcare is difficult to define, largely due to it being dependent on
62 the care needs, circumstances and preferences of the individual receiving care¹³. 'Person-centred' is
63 thought to differ from the term 'patient-centred', as it focuses not only on the individual receiving
64 healthcare (as a patient), but on the person as a whole, living with their condition, in the context of
65 their work, life and family¹⁴. Care which is centred around the person has been demonstrated to be
66 effective in a healthcare setting¹⁵. Involving multidisciplinary teams, including patients, in clinical
67 decision-making as well as increased communication between patient and care provider appear to
68 be more successful¹⁵. However, the heterogeneity of the literature makes the effectiveness of this
69 approach difficult to ascertain. This is partly due to the lack of a definitive definition of person-
70 centred care which results in significantly different study designs in the literature, but also due a lack
71 of a consistently utilised outcomes measure with which to assess effectiveness¹⁵.

72 Typically, research studies have been designed by researchers with little or no input from the
73 patients or members of the public^{10,11}. Thus, studies tended to be researcher-driven or researcher-
74 centred^{10,12}. In recent years, there has been a move from researchers carrying out research "on" or
75 "to" participants, to a more inclusive research design whereby it is carried out "with" participants¹².
76 Involving patients and members of the public, together with researchers, in decisions about how
77 studies are designed and conducted can create a person-centred study, echoing the changes in
78 healthcare¹¹.

79 Participation in research studies can be burdensome on participants. Therefore, when designing a
80 study, the psychological, physical and financial burdens of participation should be recognised and
81 minimised as much as possible¹⁶. Considerations may include avoiding an overwhelming number of
82 visits to the study site, or burdensome study requirements requiring a large time commitment from
83 participants^{17,18}. The design may also acknowledge that participants have busy lives and are juggling
84 various work, life and family commitments¹⁹. Research participants have highlighted the importance
85 of good communication, for example having the researcher clearly express that their participation is

86 valued and ensuring continued care and support from researchers at the end of their participation²⁰,
87 ²¹. In developing and designing a study that is based around the participant, these important aspects
88 should be maximised.

89 It is important to understand the potential participant population¹¹. One of the ways to achieve this
90 is to involve the people from that population and invite them to provide their input in building the
91 study design and protocol ^{17, 19}. There is some discussion in the literature regarding methodology for
92 involving patients and members of the public in research^{22, 23}. INVOLVE ²⁴ suggest patient and public
93 involvement may include a consultation, a collaboration or user-led research. A consultation involves
94 patients and the public to consult on either an aspect of the study or throughout the research study;
95 collaboration involves the patients and the public as members of the research team; and user-led
96 allows people with the lived experience of the condition to take the lead in study direction and
97 design ²⁵. Involvement needs to be flexible to the needs of research studies and research methods,
98 rather than a ridged token addition to a pre-designed study²².

99 Literature suggests that simulations have been used to give patients and members of the public a
100 chance to experience the research study method²⁶. This is not always possible, particularly if the aim
101 is to contribute to the design of a future study, where the study design has not been finalised.
102 Equally, there may be ethical considerations if the study involves potentially invasive investigations
103 or treatment. For this reason, an alternative method of patient and public consultation may need to
104 be considered, such as usability testing. Usability testing is extensively used in computer
105 engineering fields. It was introduced by Lewis²⁷ and later refined by Ericsson and Simon²⁸. The aim is
106 to gain an understanding of users and identify the main problems associated with using a system²⁹.
107 During the consultation, volunteers are encouraged to keep talking and focus on how they
108 experience the system in their own words, with minimal intervention from the researcher³⁰. This
109 differs from other usability tests, such as cognitive walkthroughs which are usually carried out by an
110 analyst or engineer (fellow expert in the field), and not the end stage user. There is a paucity of
111 literature relating to the use of a usability testing as an aid to designing clinical studies, as such this is
112 a novel approach to a patient and public involvement consultation.

113 This patient and public involvement process utilised a targeted consultation process and involved
114 patients and the public in one aspect of the study design²⁵, to assist in creating a more person-
115 centred study for the randomised clinical trial (RCT) entitled: Biomechanical Effects of Manual
116 Therapy – A Feasibility Study. Both collaboration and user-led involvement were considered for the
117 RCT, however as the study forms part of a PhD it was not possible to include a paid lay person on the

118 research team. Equally, by utilising a targeted consultation process, a large group of volunteers
119 could be recruited for maximum feedback on one aspect of the study design.

120 The resulting RCT will look at biomechanical changes associated with acute low back pain. As such,
121 patients currently having treatment for low back pain and members of the public who have had
122 experience of low back pain were invited to participate in usability testing of the proposed study
123 method. This was followed by a post-usability test discussion for areas of the method where
124 usability testing could not be utilised.

125 Method:

126 Ethics:

127 This Patient and Public Involvement was a consultation process, and not considered research by the
128 NHS³¹. Following completion of the HRA NHS Review decision tool³² and under the advice of local
129 ethics, ethical approval was not required.

130 Recruitment:

131 Adult public and patient volunteers were sought with current or prior experience of low back pain.
132 Volunteers were recruited via the university public and patient partnership, as well as an
133 advertisement displayed in the reception of the university's private teaching clinic. Involvement was
134 voluntary, and volunteers were not paid for their time. All interested volunteers were sent an email
135 containing details of the consultation process including:

- 136 • The role of the volunteer in the consultation process. Volunteers were being recruited to
137 assist in the design of a research study to make it as participant friendly as possible. Their
138 experience of low back pain allowed volunteers to view the study design from the
139 participant's standpoint, which placed them in a unique position to provide valuable
140 feedback.
- 141 • What to expect on the day of the consultation process.
- 142 • Date and time the consultation processes were taking place. Two dates and time slots were
143 available.

144 An additional date was arranged with two volunteers as they were unavailable for the proposed
145 dates. No more than five volunteers per time slot, this was largely dictated by the need to minimise
146 disruption in a busy clinic during opening hours. A total of nine interested volunteers responded to
147 the advertising, all volunteers who responded were recruited and took part in the consultation
148 process.

149 Consultation Process:

150 Volunteers agreed to: voice recording of the consultation process; future contact for the purposes of
151 discussion clarification; and named acknowledgement in future publications if they wished. The
152 process followed that set out in Figure 1.

153 The aims and objectives of the future study, and how it would contribute to existing knowledge
154 related to low back pain were outlined to the volunteers. This provided background information to
155 enable a better understanding of the study. An outline of the proposed study method (Table 1) was
156 handed out to support discussion between the researcher and volunteers.

157

158 Table 1: Outline summary of the future study method. The study is a two-arm randomised clinical
159 study investigating the biomechanical effects of manual therapy.

Timeline:	Study Stage:	Details of study stage:	
	Recruitment	Recruitment carried out in private university teaching clinic; Patient identified; Patient eligibility established at the New Patient Examination.	
Day 1	Baseline Measurements:	Participant consented into study; Back pain questionnaires; Pre-fluoroscopy form (pregnancy statement); fluoroscopy (moving video x-rays)	
Day 2 to day 13	Intervention:	Both groups receive a home management booklet.	
		Group 1: Five manual therapy appointments within two weeks	Group 2: No treatment appointments
Day 14	Follow-up Measurements:	Back pain questionnaires; Pre-fluoroscopy form (pregnancy statement); fluoroscopy	
	Study completion:	Signposting for treatment once study is complete; Dissemination of results of study	

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161

162 The consultation process was carried out in two parts, all volunteers took part in both parts.

163 Usability testing:

164 Volunteers were walked through the physical environment of the clinic and what would be expected
165 of study participants in each of the study locations was described (Figure 2). Walking the volunteers
166 through the physical environment linked the study expectations to the physical space in which it
167 would take place. Stopping and exploring each room provided insight into the reaction of future
168 participants to the study experience. Volunteers were encouraged to 'think aloud' in each room and
169 respond to the activity description. They were also given a clip board, paper, and a pen to make
170 additional notes.

171 Post-usability Test Discussion:

172 Following the usability testing, a discussion took place in a quiet environment. The researcher-led
173 discussion focused on areas of the study not addressed during the usability testing. The discussion
174 was based on a semi-structured focus group format to ensure all volunteer groups discussed similar
175 topics.

176 The topics for discussion were:

- 177 • Recruitment strategies.
- 178 • Participants willingness to be randomised.
- 179 • Treatment schedules for both arms of the randomised clinical study.
- 180 • Continuity of patient care once the research study is complete.
- 181 • Dissemination of study results to participants.

182 Discussions lasted a maximum of thirty minutes. Any additional notes taken by the volunteers
183 during the usability testing were collected. At the close, volunteers were thanked for their
184 assistance.

185 Feedback:

186 Feedback was collated by the researcher who carried out the consultation process and compiled into
187 one document (Microsoft® Word for Microsoft 365, USA). All researchers discussed the feedback
188 from the consultation process and decided which areas of the study required alterations; if any
189 alterations may impact the research questions; and if the alterations to the study were practical and
190 achievable for the clinic layout and resources. Agreed alterations were made to the future study
191 method to create a study which took the individual participants into consideration.

192 Results:

193 Three consultation processes took place, with a total of nine volunteers. There were five volunteers
194 in the first while the second and third comprised of two volunteers each. One male and eight
195 females took part in the process, with an age range of 24 – 76 years of age. **The ethnic group of all**
196 **volunteers was white (British).**

197 Usability testing recommendations:

198 Clinic Reception: It was felt that the waiting room was very busy and noisy and as such other places
199 for the filling out of forms and questionnaires were discussed. A treatment room was thought to be
200 more comfortable for the participant, where it is quiet. Volunteers also felt it was awkward to
201 complete questionnaires and forms while sitting in a chair with a clipboard. As the participants will
202 be suffering from back pain, volunteers felt they may need a little space to move around if needed.

203 The radiology waiting area: The radiology waiting area is smaller, less noisy, and more private. This
204 was considered by one volunteer group as an area where the consent process, questionnaires and
205 pre-fluoroscopy forms could be completed. The remaining two groups felt that a treatment room
206 would be the best option.

207 The radiology room: The volunteers enjoyed the fluoroscopy demonstration and felt that both the
208 researchers present made them feel comfortable. The volunteers acknowledged that the room
209 contained lots of “*scary looking complicated equipment*”, but the personal interaction with the
210 researchers, and demonstration of the equipment made the process of a fluoroscopy less
211 intimidating.

212 The treatment room: As most of the volunteers have had treatment at the university teaching clinic
213 before, it was acknowledged that all rooms are essentially the same. It would be preferable to get a
214 treatment room close to the radiology suite for ease of getting to and from the fluoroscope.

215 Post-usability Test Discussion:

216 Recruitment: Volunteers were interested in discussing additional recruitment strategies:

- 217
- Volunteers discussed the option of recruitment via general practitioner (GP) surgeries as a
218 viable option.
 - Private practice recruitment was discussed, it was felt that the clinicians may feel that paying
219 patients are being taken away from them and as such the volunteers felt this may not be a
220 viable option.
- 221

- 222 • Recruitment via hospitals was discussed, the researcher outlined that these patients may
223 not fulfil the inclusion/ exclusion criteria of the future study.

224 Regarding the approach to potential participants for the study by the researcher, volunteers
225 discussed that potential participants may like time to consider whether to take part in the study or
226 may want someone else present in the room. The researcher informed volunteers that potential
227 participants were given 24 hours to decide whether to take part in the study or not.

228 Randomisation: The researcher led a discussion on what randomisation is, and the two groups of the
229 clinical study. The researcher had concerns regarding willingness of participants to be randomised.
230 The volunteers felt that the information sheet provided to potential future study participants was
231 well written and explained the randomisation process and what would happen to the participant in
232 each group. As such, if potential participants did not want to be randomised, they will not join the
233 study.

234 Appointment schedules for both groups: An in-depth discussion was had by the volunteers regarding
235 the non-manual therapy group. This group will receive a fluoroscopy at the first and last research
236 visit, and a Home Management Booklet. One volunteer group discussed that the participants in this
237 group may feel as if they are left on their own to cope and as such have a higher risk of drop out. As
238 a result of the discussion, an additional appointment halfway through the research will be made
239 with participants in the non-manual therapy group (See Table 2). While another volunteer group
240 seemed to pick up on my wording when explaining the two groups and gave feedback that I could be
241 more encouraging and positive when discussing this study arm. Home management (advice and
242 reassurance) is a recognised form of treatment for low back pain, but potentially participants may
243 not view the booklet as that, and it may need to be discussed and explained to the participants. The
244 researcher should try to use wording that evokes participant empowerment (Volunteer Quotes:
245 *“You can control the progress of your back pain”; “you can control your own back pain”*).

246 Regarding the manual therapy group, this group’s participation includes a first research visit which
247 includes fluoroscopy (study day 1); followed by five manual therapy appointments (study day 2 –
248 13); followed by the last research appointment which includes fluoroscopy (study day 14). One
249 volunteer group suggested that when thinking about driving to and from appointments and research
250 load on participants, this was a lot of appointments in two weeks. Could they be cut down? This was
251 discussed at length between researchers and it was concluded that the first manual therapy
252 treatment would take place at the first research visit (study day 1); followed by three manual
253 therapy appointments (study day 2 – 13) and the fifth manual therapy treatment would take place at

254 the last research visit (study day 14), thus reducing the appointment total from seven to five
 255 appointments (See table 2).

256

257 Table 2: Outline of original proposed appointment schedule and the alterations made following the
 258 consultation process for both research groups.

	Group 1: Manual Therapy		Group 2: Non-manual Therapy	
Timeline (days)	Appointment schedule before PPI	Appointment schedule after PPI	Appointment schedule before PPI	Appointment schedule after PPI
1	Both groups receive a Home Management Booklet			
	Baseline Measurements (fluoroscopy and questionnaires)	Baseline Measurements (fluoroscopy and questionnaires) and first manual therapy appointment	Baseline Measurements (fluoroscopy and questionnaires)	Baseline Measurements (fluoroscopy and questionnaires)
2 – 13	Five manual therapy appointments	Three manual therapy appointments	No appointments	Appointment halfway through the study.
14	Follow-up measurements (fluoroscopy and questionnaires)	Final manual therapy appointment and follow-up measurements (fluoroscopy and questionnaires)	Follow-up measurements (fluoroscopy and questionnaires)	Follow-up measurements (fluoroscopy and questionnaires)

259

260 Continuity of care: Upon completion of the study, participants will be signposted back to the original
 261 clinician who completed the New Patient Appointment. The volunteers thought this was an excellent
 262 idea, it allows continuity of care for participants. Clinicians will also have access to all research
 263 documentation related to the participant, such as treatment notes, fluoroscopy images and
 264 completed questionnaires.

265 Dissemination of results: Volunteers thought it was important to provide participants with a
266 summary of the study results as they had a vested interest in the outcome of the study.

267 Discussion:

268 All volunteers provided feedback during the consultation process and were willing to enter
269 discussions on trial improvements. As a result of the discussions that took place during the
270 consultation process, several changes will be included in the design of the future trial including
271 recruitment; location for questionnaire completion; the consent process; randomisation; the
272 appointment schedule burden; continued support of participants; continuity of care; and
273 dissemination of results.

274 Recruitment:

275 The current feasibility study proposes single site recruitment at a university teaching clinic. However,
276 a future fully powered randomised control trial would need to recruit from a larger pool of
277 volunteers to meet the required sample size. During the post-usability test discussion, volunteers
278 provided valuable thoughts on additional potential participant identification and recruitment sites.
279 Recruitment from GP practices in the area, private practices (musculoskeletal health care providers)
280 and hospitals were discussed. Each of these options would require further investigation as to the
281 feasibility of using these additional Participant Identifying Centres, and a Participant Identifying
282 Centre Agreement would need to be completed³³. While this is not an obstacle, it will require further
283 resources and it is recommended that this should be considered at the proposal stage and not as an
284 amendment or addition to an existing project³⁴.

285 Recruitment at the university teaching clinic will take place at the New Patient Appointment. While
286 the New Patient Appointment will be carried out by a student intern (final year chiropractic student),
287 if the patient appears eligible for the study the researcher will then approach them. As means of
288 introduction, they will give a brief outline of the study, and hand out an information sheet. Involving
289 the researcher in recruitment aids development of a trusting relationship with the researcher and
290 opens lines of communication from the outset. All of this is thought to aid person-centred
291 recruitment^{20, 21}. It will also allow potential participants to ask questions related to the study from a
292 researcher who is better versed in the study method. This facilitates open dialog between the
293 researcher and the potential participant when discussing the option of joining the study²¹. Shared
294 decision making allows the researcher and potential participant to converse about the best course of
295 care for the individual, which may or may not be the research study³⁵. As the decision to take part in
296 any research study should not be taken lightly, the volunteers in this PPI process felt that potential

297 participants may want to be given the opportunity to have an additional person in the room with
298 them. This is mirrored in the literature where it is suggested that researchers should encourage
299 potential participants to speak to their family members to aid the decision making process³⁴.

300 Volunteers felt that potential participants should not have to decide at the New Patient
301 Appointment as to whether they would like to join the study. This had been considered during the
302 study design by the researchers as it is suggested in the HRA guidance for consent and participant
303 information³⁴. All potential participants will be asked for permission to be contacted telephonically
304 by the researcher after 24 hours. There is no fixed guidance on the amount of time a potential
305 participant should be given³⁴, however the study has an inclusion criteria of patients suffering from
306 acute non-specific low back pain. Due to potential participants being in acute pain, it was thought
307 that 24 hours would be sufficient time for the participant to consider taking part in the study while
308 balanced with receiving care in a timeous manner. While the researcher will contact the potential
309 participant in 24 hours, they may request further time to decide whether they would like to take
310 part in the study.

311 Consent and Baseline Measurements:

312 Once a study participant decides to take part, a baseline measurement appointment will be
313 scheduled. During this appointment, the information sheet will be discussed and written informed
314 consent will be completed in accordance with the HRA guidance³⁴. While the content of the
315 information sheet; the consent form; and the questionnaires were subject to a separate stakeholder
316 consultation process³⁶, the location for the consent process and completing questionnaires was
317 discussed. A treatment room was thought to be best option for this activity due to the room being
318 quieter and more private. It is vital that a future study participant understands fully what the study is
319 for; what their involvement will be; the risks involved with taking part; and alternative treatment
320 options, before signing an informed consent³⁴. It is suggested that an information sheet and consent
321 form, together with a meeting with a research team member for an extended discussion can
322 improve understanding of the study³⁷. It would be difficult to have a private discussion in a busy
323 waiting room, and as such the suggestion of using a treatment room would be the best option. A
324 treatment room would also give the participant the option of a chair and desk to complete the
325 consent and study baseline questionnaires, as well as room to stand and walk around if needed. The
326 volunteers felt that completing paperwork using a clipboard in a busy waiting area would be
327 uncomfortable, and the option of sitting at a desk with a comfortable chair would be welcomed by
328 participants. As participants will be in acute low back pain, it was felt the option of walking around
329 during the appointment would also be welcomed. As majority of the volunteers had or have had

330 episodes of acute low back pain, their experience provided invaluable feedback for the creation of
331 an environment which takes participant comfort into consideration.

332 During the baseline measurement appointment, study participants will have a fluoroscopy
333 investigation of their low back. The radiology suite does have a number of “*scary looking*
334 *complicated*” machines, as a clinician and researcher working with these machines daily, one forgets
335 how intimidating they can appear³⁶. For the usability testing the fluoroscopy was demonstrated and
336 explained. The volunteers felt that this put them at ease with the equipment and as such
337 recommended a brief explanation of the equipment for the study participants. This contributes
338 towards fully informed consent, whereby it is vital that study participants understand what their
339 involvement entails and potential risks³⁸. As such the brief demonstration will not only contribute to
340 putting the study participants at ease, but ensure they fully understand the investigation they are
341 about to take part, supporting the notion that research should be carried out ‘with’ the participant
342 and not ‘to’ the participant¹².

343 Randomisation:

344 Following baseline measurements, the study participants will be randomised onto one of two
345 groups. While the researcher had reservations about participants willingness to be randomised, the
346 volunteers did not. Volunteers felt that all participants were given adequate detail in the study
347 information sheet as to what the two groups involved. Participants not willing to be randomised
348 would not take part in the study. The future study is a feasibility study and as such, willingness to be
349 randomised will be explored as part of the study and the proposed randomisation process may be
350 refined or altered following the outcome. Potential study participants who do not wish to take part
351 will be asked whether they are willing to give a reason as to why. Information may give further
352 insight into participants willingness to be randomised.

353 Appointment Schedule:

354 The volunteers were open to discussing the appointment schedules for both groups of the study.
355 They felt that the non-manual therapy group had a chance of ‘drop out’ as this group was only seen
356 by the researchers for their investigations. The volunteers suggested an additional appointment
357 halfway through the study would be helpful to allow the study participants to make contact with the
358 researcher and gain reassurance and advice if needed. Ongoing communication fosters a positive
359 relationship and can be reassuring to study participants^{20, 21}, as such the appointment schedule for
360 this group was altered for the study. Equally, the language used by the researcher may lead to
361 potential drop out in the non-manual therapy group. This highlighted the need to be more cognisant

362 of wording used to describe the trial arms. It is suggested that participants who have a more positive
363 interaction are more likely to view the study more positively²⁰.

364 Regarding the manual therapy group, the volunteers felt that the research burden on the study
365 participants was large as there could potentially be seven appointments in two weeks. The literature
366 mirrors the concern of patients regarding overwhelming numbers of appointments or large research
367 burdens on patients^{16, 17}. Five treatments in two weeks is recommended by treatment guidelines,
368 however as a result of the feedback from the volunteers it was decided that the first treatment
369 would be carried out in the same appointment after the first fluoroscopy, and the last treatment
370 would be carried out in the same appointment before the last fluoroscopy, as such the study
371 participants would only have five research appointments in total, rather than the original seven.
372 Although this would make the first and last appointments longer, participants who may be traveling
373 a distance for the trial would ultimately save time as well as travel costs.

374 Continuity of care

375 Once a participant has completed the study, they will be signposted back to their original clinic
376 intern (final year chiropractic student); thus, they would not have to start again with someone new.
377 The unique experience of the volunteers of having been treated within the university teaching clinic
378 highlighted the importance of continuity of care for the future study participants, which is consistent
379 with the literature²⁰.

380 Dissemination of results

381 The volunteers felt that if participants had given their time to be a part of the study, they should be
382 informed of the study outcome, which is supported in the literature²⁰. As such, changes were made
383 to the study consent form to include an additional optional tick box *"I am interested in the overall
384 results of the research. I would like the overall results emailed to me upon completion of the
385 research. I agree to my email address being used for this purpose."*

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388 Interestingly, during the usability testing, volunteers were focused on the physical rooms, although
389 they were introduced to the receptionists and fluoroscope operators. There was very little feedback
390 relating to the people who the future participants will be in contact with. One of the keys to
391 developing a person-centred study is communication and reassurance²⁰. While much of this will
392 come from the researcher, the whole healthcare team is instrumental in providing this.

393 This usability test and discussion resulted in changes to the original study method with the aim of
394 producing a more person-centred study design. The method of this consultation process was unique
395 in a healthcare study development setting. Many patient and public involvement processes
396 encourage payment of volunteers for ongoing research collaboration, or expenses reimbursed for a
397 'one off' involvement³⁹. During recruitment for this consultation process volunteers were informed
398 that no payment would be provided, which is generally considered poor practice⁴⁰. However, a
399 reward may be offered which is not necessarily financial and as such volunteers were provided with
400 refreshments during the consultation process and asked whether they would like to be
401 acknowledged in any resulting publications⁴⁰. Future studies should consider building in a public and
402 patient involvement process into the proposal and budget calculations of a study. The method is
403 most likely more time consuming than a cognitive walkthrough, which would use fellow experts in
404 the field such as fellow clinicians or researchers. However, the benefits of using a participant
405 representative population outweigh the time burden for researchers. There is a growing need for a
406 wider range of voices to be heard in study development and research, such as Black, Asian and
407 minority ethnic populations (BAME)⁴¹. This consultation process advertised for, and welcomed, all
408 adults from any ethnic group. However, responses were only obtained from one ethnic group, which
409 is generally considered a weakness as not all voices are represented. For this reason, future public
410 involvement processes should aim to include under-represented groups.

411 The original study method had already been viewed by the team of researchers; the volunteers were
412 able to view the study through the eyes of a participant. This resulted in recommendations and
413 changes to the study the research team had not considered. As such, this consultation process was
414 invaluable in helping to create a more person-centred study. It should be reiterated that the future
415 study is a feasibility study and as such the alterations suggested by the volunteers can be
416 implemented, reflected upon and possibly refined before the final study protocol is established.

417 Limitations:

418 The age range of the volunteers (24 – 76 years of age) is slightly older than the age range of the
419 future study which is 18 – 65 years of age. Gender representation within the consultation group was
420 skewed as only one of the volunteers was male, the remaining volunteers were female. It is
421 proposed that a gender gap in research participation, especially when voluntary (unpaid), is
422 influenced by gender roles, responsibilities and gender specific decision-making processes⁴². Females
423 are significantly more likely to volunteer for research based on general altruistic considerations⁴².
424 The significant gender gap evident in this consultation process was not thought to influence the
425 outcome of the process.

426 Volunteers were not paid for their time, and, while all volunteers from any ethnic group were
427 welcome, only one ethnic group was represented in the consultation process. The extent to which
428 either of these factors influenced the outcome of the process is unknown.

429 Conclusion:

430 The consultation process used the unique method of usability testing, together with a post-usability
431 discussion to aid the design of a more person-centred study. The process resulted in alterations to
432 the future study, including participant recruitment, location of study paperwork completion, study
433 appointment schedule, continuity of care, and informing the participants of the study outcome. It is
434 hoped that these alterations may facilitate making the future study as person-centred as possible.

435

436 References:

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