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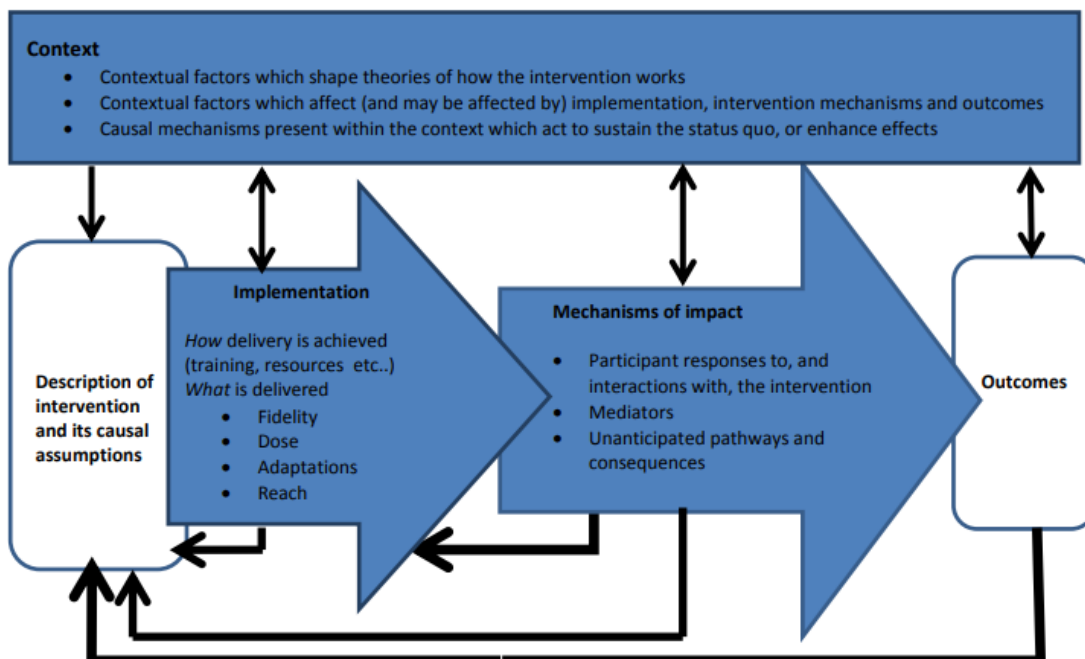
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Managing Achilles Pain (the MAP study) – a process evaluation of data collection methods

Introduction

The Managing Achilles Pain study (MAP study) had the primary aim of assessing the feasibility of the protocol for a future large longitudinal cohort study that would investigate the association and predictive relationship of contextual influences (self-efficacy, working alliance and expectations) with outcome in the management of Achilles tendinopathy (AT) (see supplementary file 1 for full protocol). In recent times, such factors have been highlighted as potentially relevant factors that would benefit from investigation in tendinopathy (A. Mallows et al., 2017; A. J. Mallows et al., 2017). The MAP study enrolled twenty-four participants with Achilles tendinopathy; participants were directed to an internet-based data collection method by their treating physiotherapist. Participants completed the same [internet-based questionnaire](#) relating to the contextual factors discussed previously, and the pain and disability relating to their AT at three data collection points over a three month period. Such a data collection method was untested, therefore, to understand more about how the data collection worked, we undertook a process evaluation. Process evaluations explore the way in which a study was conducted and can provide valuable insight into why studies work well or fail as a basis for a future large study (Day et al., 2006). The Medical Research Council (MRC) has provided a framework for process evaluation, arguing that process evaluation can have a vital role in understanding the feasibility and optimising its design and evaluation (Moore et al., 2015). The aim of the process evaluation reported here was to investigate factors affecting the implementation, context and mechanisms of impact on the data collection process described above (figure 1). These factors were considered from both the participants' and physiotherapists' perspectives. Whilst this process evaluation refers to the data collection methods of the MAP study, the data generated can provide guidance to researchers developing study protocols for similar studies.



28 Figure 1. Key functions of a process evaluation and relationships amongst them. Blue boxes
29 represent components of process evaluation, which are informed by the causal assumptions of the
30 intervention, and inform the interpretation of outcomes (Moore et al., 2015).

31

32 **Ethical Approval**

33 Ethical approval was sought and granted on 14th September 2017 (IRAS project ID: 219457, REC
34 reference 17/LO/1583).

35

36 **Methodological Approach**

37 To realise the critical importance of participants' own interpretations of the issues researched, our
38 process evaluation took a 'critical realist' perspective to evaluate participant perspectives, believing
39 that the varying vantage points of different participants would yield different types of understanding
40 (Ritchie et al., 2014). This perspective was adopted to ensure data collection methods and analytical
41 strategies best met the objectives of the process evaluation (Morse and Richards, 2002; Patton,
42 2002; Ritchie and Lewis, 2003) and focused on accurately describing participants' experiences,
43 staying close to the data, and ensuring subsequent interpretations are transparent (Sandelowski,
44 2000; Thorne et al., 1997). The consolidated criteria for reporting qualitative research (COREQ)
45 checklist provided guidance during the reporting of this study (Tong et al., 2007).

46

47 **Methods**

48 We utilised the MRC framework outlined in figure 1 to meet the predetermined aim; data was
49 sought to determine factors influencing insights into factors affecting the implementation, context
50 and mechanisms of impact from the data collection procedures during the MAP study (Moore et al.,
51 2015). The process sought to discover what worked (and did not), for whom, how, why and in what
52 circumstances.

53

54 **Data collection**

55 Whilst traditionally face to face interviews have been the preferred mode of conduct, recent
56 research has highlighted that face to face interviews are not inherently superior to telephone
57 interviews (Irvine et al., 2013). Consequently, to minimise burden on the interviewee (participant or
58 physiotherapist), one-on-one interviews were conducted remotely by the lead author, a PhD
59 candidate, via telephone. To gain maximum variation in responses, all participants who enrolled in
60 the MAP study and all physiotherapists who had taken part in recruitment for the study, were
61 invited to take part in this process evaluation. Participants and lead physiotherapists at each
62 recruitment site were contacted by email and sent the participant information sheet and consent
63 form. Lead physiotherapists were asked to share the email with all physiotherapists who had taken
64 part in recruitment. Anyone considering volunteering then emailed the lead author. Both
65 physiotherapists and participants were provided with the opportunity to ask questions and once any
66 questions were answered, were invited to take part in one-to-one individual interviews at their
67 convenience. Consent to take part in the interviews was audio recorded prior to commencing the
68 interview. To reduce recall bias, selection and recruitment were completed within one month of the

69 participant completing the cohort study. During the interviews the lead author took notes as
70 needed. The lead author was unknown to participants but had provided recruitment training to the
71 physiotherapists prior; consequently, the physiotherapists were aware of the reasons for carrying
72 out the research and the author's interest in the research topic. Semi-structured interviews were
73 directed by a topic guide and were recorded at the University of Essex using a digital voice recorder
74 and transcribed verbatim. The lead author undertook training in conducting interviews prior to data
75 collection and carried out practice interviews to pilot the topic guide with feedback provided by one
76 co-author (CL).

77

78 **Data analysis**

79 The data was analysed by one author (AM) using the Framework Approach. To facilitate this, a
80 computer-assisted analysis software (CAQDS) programme was used (NVivo Version 12, QSR
81 International, Melbourne, Australia). The Framework Approach has been developed specifically for
82 applied research in which the objectives of the investigation are set *a priori* (Pope et al., 2000).
83 Framework Approach is an analytic tool that supports key steps in the data management process,
84 including the indexing and sorting tasks common across many different approaches, but adds one
85 further step; data summary and display (Ritchie et al., 2014). The framework can be used for
86 indexing, but its distinctive feature is that it forms the basis of a thematic matrix, in which every
87 participant is allocated a row and each column denotes a separate theme (Supplementary File 2).
88 The thematic matrix was then triangulated with interview notes and sent to all participants to verify
89 source interpretation.

90

91 **Findings**

92 Data from seven participants and six physiotherapists were analysed. Three participants declined to
93 be interviewed without stating a reason, and no response was received from fourteen participants.
94 It is unknown how many physiotherapists participated and therefore how many did not respond.
95 Interviews lasted up to 30 minutes.

96

Participant	Age range*	Gender
1	30-39 years	Male
2	60-69 years	Female
3	40-49 years	Male
4	50-59 years	Male
5	40-49 years	Female
6	40-49 years	Male
7	60-69 years	Female

97 Table 1. Participants' characteristics. *Only age range was collected from participants

98

Physiotherapist	Years Qualified	Years of speciality in MSK	Gender	Private or NHS provider
1	7	6	Male	NHS
2	4	3	Male	Private
3	4	4	Male	NHS
4	18	16	Male	Private
5	15	12	Female	NHS
6	3	3	Male	NHS

99 Table 2. Physiotherapists' characteristics

100 **Physiotherapists' perspectives of the study procedures**

101 **Key themes**

102 To meet the aim of the process evaluation, two main themes were sought from the data after
103 transcription; obstacles and enablers. From these two themes a further eight subthemes were
104 identified; (1) access to participants; (2) recall; (3) visibility; (4) time; (5) training; (6) motivation; (7)
105 incentives; (8) simplicity.

106

107 **Obstacles**

108 Theme 1: Access to participants

109 Difficulties in accessing the target population for the MAP study was often referred to in many of the
110 interviews. Potential reasons for this varied from the serendipitous to a telephone triage system.

111 *"The main issue seemed to be that all my Achilles tendon patients seemed to disappear."*

112 Physiotherapist 4.

113 *"I think because whether those patients get better on the phone or not, it definitely means that less
114 of Achilles pain comes through to eventually see in a clinic."* Physiotherapist 3.

115

116 Theme 2: Recall

117 A common theme reported by the physiotherapists in the study related to difficulties in
118 remembering to recruit potential participants. Some physiotherapists related this to their workload.

119 *"In a busy clinic remembering to provide them with the information in the first place."*

120 Physiotherapist 1.

121

122 Other physiotherapists felt that the infrequency of seeing people with Achilles tendinopathy was a
123 contributing factor.

124 *“But yeah, other clinicians have definitely said that they forgot, and part of the reason for that, I*
125 *guess, is if you see an Achilles tendinopathy one week and then, two or three weeks later, you see*
126 *your next new patient.”* Physiotherapist 2.

127

128 Although training was provided, and a staff meeting was attended one month later to discuss any
129 recruitment queries followed by monthly email reminders sent to the Lead Physiotherapist at each
130 site, physiotherapists were keen to be contacted directly to be reminded of recruitment.

131 *“You might receive six or seven or eight emails from the manager, and there might be potential to*
132 *only skim-read that, whereas if there was an email from a different source that you don't normally*
133 *see in your email box, that might prompt you to pay more attention.”* Physiotherapist 1.

134

135 Theme 3: Visibility

136 Participating physiotherapists outlined a common theme of needing to improve the visibility of the
137 study to aid with recruitment. Some felt using posters to inform patients that the study was
138 recruiting participants would be useful. Others felt it would benefit the physiotherapists.

139 *“If the information's there for them, the patient, they might actually start that conversation off, kind*
140 *of like what you just said, rather than the other way around.”* Physiotherapist 2.

141

142 Theme 4: Time

143 Time as an obstacle was often cited by the physiotherapists. Some felt a lack of time with the patient
144 impacted on the success of recruitment.

145 *“If you got half an hour to get a patient in, treat them, manage them, and document, and then you*
146 *starting thinking there are other things on top sometimes. So that is then pushed to the less of a*
147 *priority and such.”* Physiotherapist 1.

148

149 **Enablers**

150 Theme 5: Training

151 A common them reported by the physiotherapists referred to the recruitment training which was
152 provided for them. The training served to provide clarity on the role of the physiotherapists and
153 installed a sense of confidence in the procedures which were described.

154 *“I felt very confident and capable of recruiting participants after that session itself and the*
155 *information given across from that.”* Physiotherapist 5

156

157 Theme 6: Motivation

158 Motivation to be involved in the MAP study was commonly referred to by the physiotherapists
159 interviewed. Some physiotherapists felt that the impact this might have on their care of patients was
160 an important motivating factor.

161 *"I think the study was very much with the patient's interest at the forefront."* Physiotherapist 4.

162 Physiotherapists were also motivated by the opportunity to be involved in a research project.

163 *"It's always interesting to get involved with any research or the data collection side of things that*
164 *may turn up for our department. And it's important, I think, from a physio side of things to engage*
165 *with that."* Physiotherapist 4.

166

167 Theme 7: Incentives

168 Physiotherapists discussed the potential need for incentivising the MAP study. Some
169 physiotherapists felt a reward for the efforts of the physiotherapists might be warranted, although
170 they were not sure what that could be.

171 *"Whether you give out 10, 20 cards to appropriate patients, then you're-- not get a reward, that*
172 *sounds wrong, but you're more likely to be able to-- I don't know. It encourages clinicians to do more*
173 *from that side of things."* Physiotherapist 3.

174

175 Questions were also raised with regard how participants felt incentivised. Some physiotherapists felt
176 the answer laid in the opportunity to help others who are experiencing what they are.

177 *"And eventually, treat people that were suffering with what they've been suffering with. That*
178 *seemed to be quite a key thing that people were interested in."* Physiotherapist 4.

179

180 Theme 8: Simplicity

181 A common theme discussed during the interviews with the physiotherapists was the simplicity of the
182 MAP study. Most felt this was a key issue to raise to the potential participants in order to maximise
183 recruitment.

184 *"If someone has to go through something that takes them half an hour, then they're going to,*
185 *generally speaking, not really want to fill that out or complete it. So if they know it's going to be fairly*
186 *quick and easy to do, then most people will try to engage."* Physiotherapist 5.

187

188 **Participants' perspectives of the study procedures**

189 **Key themes**

190 To meet the aim of the process evaluation, three main themes were sought from the data after
191 transcription; consequences, obstacles and enablers. From these three themes a further six
192 subthemes were identified; (1) information from the physiotherapist; (2) follow up; (3) motivation;
193 (4) website; (5) questionnaire; (6) positive experience.

194

195 **Obstacles**

196 Theme 1: Information from the physiotherapist

197 The participants interviewed often referred to the need for more quality verbal information from the
198 physiotherapists at the time of recruitment.

199 *"If I hadn't been quite so spontaneously happy to do it, I might have benefitted with a little bit more*
200 *explanation as to what they were trying to get out of it."* Participant 1.

201

202 Most participants viewed the postcard as a positive tool, enhancing engagement in the study.

203 *"Eager though, I was to do it when my physiotherapist told me about it. It's one of those things that I*
204 *probably would have forgotten about had I not had the postcard and thought, "Oh, I was going to do*
205 *that. I need to do that."* Participant 4.

206

207 Theme 2: Follow up

208 Some participants expressed confusion around the process of being invited to complete the
209 questionnaire for a second or third time.

210 *"I think the problem lies with the amount of rubbish we all receive over email. And I'm sure you're*
211 *exactly the same as the rest of us. Sometimes more important things do get lost amongst the dross*
212 *really, there's just so much of it."* Participant 3.

213

214 Participants offered ways of improving communication, including the suggestion of adding a text
215 message reminder and ensuring communications were clearly headed as to which number survey
216 the correspondence was referring to.

217 *"Heading them up and making it clear at the start that there were going to be three and heading*
218 *them up two and three, I think that would be very helpful."* Participant 5.

219 *"I don't think for future people taking part it would be that much of an extra step to give their phone*
220 *number for this service as well."* Participant 2.

221

222 **Enablers**

223 Theme 3: Motivation

224 Almost all the participants outlined their motivation for involving themselves in the MAP study.
225 Motivation appeared to be largely altruistic in nature.

226 *"Advancing research on such issues is beneficial for everyone, isn't it? So it's something one should*
227 *do rather than not."* Participant 2.

228

229 Theme 4: Website

230 A positive experience from using the website was expressed from most of the participants. This
231 ranged from providing information which was missed by the recruiting physiotherapist to the ease of
232 navigating the webpage.

233 *“Once I got to the website page, it gave me all the information I needed.”* Participant 3.
234 *“I don't recall being frustrated by anything. I'm easily frustrated on the Internet.”* Participant 4.

235

236 Theme 5: Questionnaire

237 A positive engagement with the questionnaire was often cited by the participants. Particular
238 reference was made to the simplicity and short duration of the questionnaire.

239 *“We've all had questionnaires of customer feedback where they ask you to write so much detail, you
240 give up because it's too painful. So it wasn't like that, which is really good.”* Participant 3.

241

242 **Consequences**

243 Theme 6: Positive experience

244 Many participants stated that their involvement in the MAP study resulted in a positive experience;
245 it made them reconsider their condition and treatment and how they engaged with their
246 physiotherapist.

247 *“It made me take it a bit more seriously really and feel a bit more as though, I wasn't on my own.
248 There were other people obviously who were going through the same kind of problem. So maybe it
249 validated it a bit more, I think, for me, which was good.”* Participant 7.

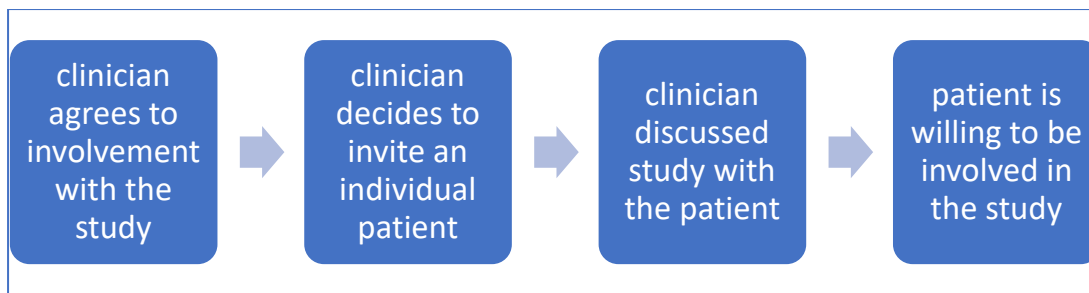
250

251 **Discussion**

252 The purpose of this process evaluation was to explore the MAP study procedures from the
253 participants' and physiotherapists' perspectives respectively. From the physiotherapists' perspective
254 four themes were identified which related to obstacles; (1) *access to participants*; (2) *recall*; (3)
255 *visibility*; (4) *time*, and four themes were identified which related to facilitating success; (1) *training*;
256 (2) *motivation*; (3) *incentives*; (4) *simplicity*. From the participants' perspective two themes were
257 identified which related to obstacles; (1) *information from the physiotherapist*; (2) *follow up*, three
258 themes were identified which related to facilitating success; (1) *motivation*; (2) *website*; (3)
259 *questionnaire*, and one theme which related to unintended consequences of participating in the
260 study; *positive experience*.

261 The NHS Constitution for England pledges to inform all patients about opportunities for involvement
262 with suitable research studies (Department of Health, 2015). In this context healthcare professionals
263 play a vital role in clinical research, linking researchers and patients. A variety of challenges may exist
264 in recruiting participants from specialist healthcare services, such as physiotherapy, into cohort
265 studies and little formal research has investigated these challenges (Zucchelli et al., 2018). Frayne et
266 al (Figure 2) have conceptualised a process by which a patient may be referred to a research study
267 when the initial invitation to participate is delivered by a healthcare professional in the clinical
268 setting (rather than being invited by a healthcare provider who has responsibilities and involvement
269 in the whole trial) (Frayne et al., 2001).

270



271

272 Figure 2. Process of a patient being referred to a research study by a clinician (adapted from Frayne
 273 et al (Frayne et al., 2001).)

274 In order to contextualise the findings from this process evaluation with previous research and
 275 consider implications for future studies, the discussion is framed by the conceptual process outlined
 276 in figure 2.

277

278 Involvement with the study

279 Motivation to be involved in research was a theme identified from participants and physiotherapists
 280 alike. From the participants’ perspectives, the motivation was largely altruistic in nature; the chance
 281 to ‘give back’, and from the physiotherapists’ perspectives the drive was the opportunity to be
 282 involved in research which was considered to directly influence patient care. Motivation as a driving
 283 factor for recruitment wasn’t considered in the training provided. Although the training was
 284 considered by the physiotherapists as facilitatory for recruitment, the training focused on how to
 285 recruit (Realpe et al., 2016) rather than serving to motivate recruitment. Nevertheless, this focus did
 286 have benefits; the physiotherapists understood what they were required to do, were happy to
 287 answer questions from patients and felt confident in carrying out the recruitment. Cvijovic et al
 288 (Cvijovic et al., 2010) highlighted that pharmacists were reluctant to invite patients when they felt
 289 this could prompt questions they could not answer. However, valuing the research has been seen as
 290 a key driver of engagement of recruiting healthcare providers previously (Borschmann et al., 2014)
 291 and as such, training would benefit from tailoring to ensure the physiotherapists not only
 292 understood what to do and how to do it, but also developed attitudes towards the research which
 293 were as positive as possible. For example, future training could emphasise the positive experience
 294 (and absence of negative experience) which the participants have described from being involved in
 295 the study. Whilst, the provision of such training has been shown to modify some aspects of recruiters’
 296 behaviour, this may still result in clinicians not sufficiently restructuring their recruitment consultations
 297 (Brown et al., 2007). As such, a process of monitoring and further visits, where necessary, from the
 298 researcher to the recruitment sites to ensure recruiters are clear how participation in research varies
 299 from clinical practice might be a useful strategy (Chen et al., 2003). At this stage, the focus might turn
 300 to communication skills facilitated by role play scenarios to highlight common obstacles to recruitment
 301 (Hietanen et al., 2007).

302

303 Inviting a patient

304 Pragmatic issues rather than ‘gate keeping’ concerns (Howard et al., 2009; Newington and Metcalfe,
 305 2014) largely influenced whether a patient was invited to be involved, in the study or not. Two main
 306 pragmatic issues were identified; remembering to recruit participants and the visibility of the study.
 307 Reasons for not remembering to invite a participant ranged from other work pressures to the
 308 infrequency of seeing people with Achilles tendinopathy. French et al (French and Stavropoulou,

309 2016) identified the clinical work setting as an influence on recruitment; an organisation which has
310 developed a positive research culture is an important facilitator to inviting patients to participate. It
311 was unknown what the research culture was like at each recruitment site prior to commencing
312 recruitment. Fenlon et al (Fenlon et al., 2013) utilised a careful pre-screening and selection of
313 participating centres. Although the nature of pre-screening sites and the decisions to work with sites
314 varies according to the given study, it is a useful way to initiate relationships and potentially identify
315 sites at risk of low recruitment (Fenlon et al., 2013). Recognising this complexity, formal methods of
316 evaluation have been developed that identify problems with recruitment and informed consent and
317 develop action plans to address them while recruitment is underway (Donovan et al., 2016).
318 Increasingly such methods, evaluating processes, need to be integrated in to the pilot phases of
319 research work to maximise the chance of success.

320 To address the second pragmatic issue relating to the visibility of the study, physiotherapists
321 suggested recruitment for the study might be enhanced if the study was visualised in some way,
322 such as posters in the waiting room and staff room to act as a reminder to staff and to encourage
323 questions from potential participants. This would incur only a small increase in cost, and also provide
324 a further opportunity to share the positive experience which participants can have from being
325 involved in research (National Institute for Health Research Clinical Research Network, n.d.). A
326 positive experience from this study was found from the use of the postcard to invite patients to
327 become participants; the design resonated with participants and it served as a tangible reminder to
328 take part. Contrastingly, the use of a follow up via email was sub-optimal. Using email and text
329 message reminders to encourage questionnaire completion amongst participants appears to be a
330 viable strategy; following two email reminders, a text message reminder appeared to be more
331 effective than another email reminder in a study also utilising an online questionnaire (Toledano et
332 al., 2015).

333

334 Discussing the study

335 Reporting lack of time as an obstacle to recruiting participants would appear significant. This was
336 also reflected by the participants expressing they were given minimal verbal information by the
337 physiotherapists during the invitation process. Limited time for recruitment resulting in clinicians not
338 prioritising research activities has been seen in previous studies (Borschmann et al., 2014; Zucchelli
339 et al., 2018). Resources are critical and lack of resources have been seen to negatively influence
340 recruitment at all stages (Fenlon et al., 2013). The absence of dedicated resources, such as clinical
341 time, not only constrains the capacity of clinicians to undertake research activity but can also
342 undermine their belief in the research and lose a sense that their roles are respected (Borschmann
343 et al., 2014). Consequently, research resources must be seen to make a difference. Here, effective
344 communication is considered central to promote respect, reciprocity and maximise recruitment
345 (Borschmann et al., 2014; Fenlon et al., 2013). Ensuring that the right information reaches the right
346 people in a timely manner, and that clinicians are provided with progress reports and study findings,
347 is essential (Borschmann et al., 2014). Improved communication from the researcher directly to the
348 physiotherapists involved in recruiting was a finding from this study. To address this, future studies
349 should consider providing progress reports and developing a newsletter which includes 'frequently
350 asked questions' and tips from research sites that have good recruitment rates (Fenlon et al., 2013).

351

352 Willingness to be involved

353 The minimal burden of the study design appeared to be key to both physiotherapists' and
354 participants' willingness to be involved in the study. As previously discussed, time is a precious
355 commodity to physiotherapists. The simplicity of the MAP study was referred to as an enabler to
356 engaging physiotherapists and that this simplicity needed to be highlighted more effectively in the
357 training to provide reassurance on the minimal impact of time to the physiotherapists. Participants
358 described a positive engagement with the website; it appeared to enhance patients' willingness to
359 participate by being easy to navigate and ensuring it gave them all the information they required. In
360 addition, the short duration of the questionnaire appeared a significant factor for participants to be
361 willing to be involved. Previous research shows participants appear to start abandoning
362 questionnaires after around 9 minutes, regardless of whether they are told the survey would take 8-
363 10 minutes or 20 minutes (Crawford and Couper Mark J Lamias, 2001).

364

365 **Strengths and Limitations**

366 This study included physiotherapists from all but one recruitment site and this ensured that the
367 views expressed were a fair representation of those sites involved. However, the self-selecting
368 nature of recruitment may have resulted in 'volunteer bias'; for example, physiotherapists largely
369 expressed an interest in research, meaning perceptions of physiotherapists who felt negatively or
370 ambivalent towards research were not obtained. Nevertheless, those taking part offered both
371 positive and negative comments towards the MAP study. In addition, 5 of the 6 physiotherapists
372 who volunteered were male which, depending on the gender balance at each site, suggests female
373 physiotherapists views were underrepresented.

374 Participants who dropped out, but had agreed to be contacted for interview, were invited for
375 interview but no responses were received. Again, this may have resulted in 'volunteer bias' and
376 therefore alternative views were not captured.

377

378 **Conclusion**

379 This process evaluation has highlighted some important factors for researchers to consider when
380 planning future research studies. Although clinicians are enthused to be involved in research,
381 organisational factors, such as time, appear to be key drivers of levels of engagement. Publicising the
382 study to all involved; optimising verbal recruitment strategies between the physiotherapists and
383 potential participants; and ensuring clarity in communication to recruiting physiotherapists and the
384 participants all appear key to optimising the potential success of a study.

385

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