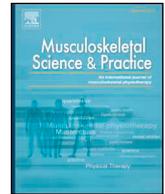




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Original article

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

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A B S T R A C T

Background: Process evaluations explore the way in which a study was conducted. 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 self-efficacy, working alliance and expectations with outcome in the management of Achilles tendinopathy.

Objectives: This study aimed to evaluate the processes conducted in the MAP study by exploring the acceptability of the study procedures from the participants' and physiotherapists' perspectives.

Design: A qualitative evaluation using semi-structured telephone interviews.

Method: All physiotherapists and participants who participated in the MAP study were invited. Data from physiotherapists (n = 6) and participants (n = 7) were transcribed and analysed using the Framework Approach.

Findings: From the physiotherapists' perspective 4 themes were identified relating to obstacles; (1) *access to participants*; (2) *recall*; (3) *visibility*; (4) *time*, and 4 themes were identified relating to facilitating success; (1) *training*; (2) *motivation*; (3) *incentives*; (4) *simplicity*. From the participants' perspective 2 themes were identified relating to obstacles; (1) *information from the physiotherapist*; (2) *follow up*, 3 themes were identified relating to facilitating success; (1) *motivation*; (2) *website*; (3) *questionnaire*, and 1 theme relating to unintended consequences of participating in the study; *positive experience*.

Conclusions: Although clinicians are enthused to be involved in research, organisational factors impact levels of engagement. Key influences to optimising the potential success of a study include the publicising of the study; optimising verbal recruitment strategies; and clarity in communication.

1. 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 (Mallows et al., 2017a,b). 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 (Fig. 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.

1.1. Ethical approval

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

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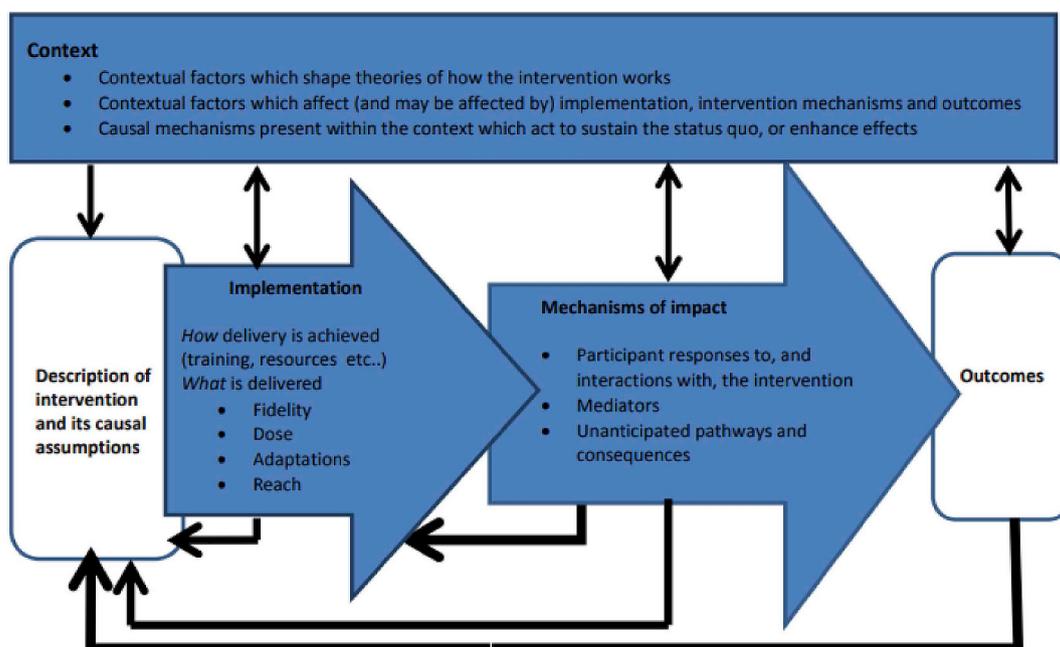


Fig. 1. Key functions of a process evaluation and relationships amongst them. Blue boxes represent components of process evaluation, which are informed by the causal assumptions of the intervention, and inform the interpretation of outcomes (Moore et al., 2015). (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

1.2. Methodological approach

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

2. Methods

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

2.1. Data collection

Whilst traditionally face to face interviews have been the preferred mode of conduct, recent research has highlighted that face to face interviews are not inherently superior to telephone interviews (Irvine et al., 2013). Consequently, to minimise burden on the interviewee (participant or physiotherapist), one-on-one interviews were conducted remotely by the lead author, a PhD candidate, via telephone. To gain maximum variation in responses, all participants who enrolled in the MAP study and all physiotherapists who had taken part in recruitment for the study, were invited to take part in this process evaluation (see Tables 1 and 2). Participants and lead physiotherapists at each recruitment site were contacted by email and sent the participant

information sheet and consent form. Lead physiotherapists were asked to share the email with all physiotherapists who had taken part in recruitment. Anyone considering volunteering then emailed the lead author. Both physiotherapists and participants were provided with the opportunity to ask questions and once any questions were answered, were invited to take part in one-to-one individual interviews at their convenience. Consent to take part in the interviews was audio recorded prior to commencing the interview. To reduce recall bias, selection and recruitment were completed within one month of the participant completing the cohort study. During the interviews the lead author took notes as needed. The lead author was unknown to participants but had provided recruitment training to the physiotherapists prior; consequently, the physiotherapists were aware of the reasons for carrying out the research and the author's interest in the research topic. Semi-

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

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

Table 2
Physiotherapists' characteristics.

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

structured interviews were directed by a topic guide and were recorded at the University of Essex using a digital voice recorder and transcribed verbatim. The lead author undertook training in conducting interviews prior to data collection and carried out practice interviews to pilot the topic guide with feedback provided by one co-author (CL).

2.2. Data analysis

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

3. Findings

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

3.1. Physiotherapists' perspectives of the study procedures

3.1.1. Key themes

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

3.1.2. Obstacles

3.1.2.1. Theme 1: access to participants. Difficulties in accessing the target population for the MAP study was often referred to in many of the interviews. Potential reasons for this varied from the serendipitous to a telephone triage system.

"The main issue seemed to be that all my Achilles tendon patients seemed to disappear." Physiotherapist 4.

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

3.1.2.2. Theme 2: recall. A common theme reported by the physiotherapists in the study related to difficulties in remembering to recruit potential participants. Some physiotherapists related this to their workload.

"In a busy clinic remembering to provide them with the information in the first place." Physiotherapist 1.

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

"But yeah, other clinicians have definitely said that they forgot, and part

of the reason for that, I guess, is if you see an Achilles tendinopathy one week and then, two or three weeks later, you see your next new patient." Physiotherapist 2.

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

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

3.1.2.3. Theme 3: visibility. Participating physiotherapists outlined a common theme of needing to improve the visibility of the study to aid with recruitment. Some felt using posters to inform patients that the study was recruiting participants would be useful. Others felt it would benefit the physiotherapists.

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

3.1.2.4. Theme 4: time. Time as an obstacle was often cited by the physiotherapists. Some felt a lack of time with the patient impacted on the success of recruitment.

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

3.1.3. Enablers

3.1.3.1. Theme 5: training. A common theme reported by the physiotherapists referred to the recruitment training which was provided for them. The training served to provide clarity on the role of the physiotherapists and installed a sense of confidence in the procedures which were described.

"I felt very confident and capable of recruiting participants after that session itself and the information given across from that." Physiotherapist 5

3.1.3.2. Theme 6: motivation. Motivation to be involved in the MAP study was commonly referred to by the physiotherapists interviewed. Some physiotherapists felt that the impact this might have on their care of patients was an important motivating factor.

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

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

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

3.1.3.3. Theme 7: incentives. Physiotherapists discussed the potential need for incentivising the MAP study. Some physiotherapists felt a reward for the efforts of the physiotherapists might be warranted, although they were not sure what that could be.

“Whether you give out 10, 20 cards to appropriate patients, then you’re not get a reward, that sounds wrong, but you’re more likely to be able to—I don’t know. It encourages clinicians to do more from that side of things.” Physiotherapist 3.

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

“And eventually, treat people that were suffering with what they’ve been suffering with. That seemed to be quite a key thing that people were interested in.” Physiotherapist 4.

3.1.3.4. Theme 8: simplicity. A common theme discussed during the interviews with the physiotherapists was the simplicity of the MAP study. Most felt this was a key issue to raise to the potential participants in order to maximise recruitment.

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

3.2. Participants’ perspectives of the study procedures

3.2.1. Key themes

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

3.2.2. Obstacles

3.2.2.1. Theme 1: information from the physiotherapist. The participants interviewed often referred to the need for more quality verbal information from the physiotherapists at the time of recruitment.

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

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

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

3.2.2.2. Theme 2: follow up. Some participants expressed confusion around the process of being invited to complete the questionnaire for a second or third time.

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

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

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

“I don’t think for future people taking part it would be that much of an extra step to give their phone number for this service as well.” Participant 2.

3.2.3. Enablers

3.2.3.1. Theme 3: motivation. Almost all the participants outlined their motivation for involving themselves in the MAP study. Motivation appeared to be largely altruistic in nature.

“Advancing research on such issues is beneficial for everyone, isn’t it? So it’s something one should do rather than not.” Participant 2.

3.2.3.2. Theme 4: website. A positive experience from using the website was expressed from most of the participants. This ranged from providing information which was missed by the recruiting physiotherapist to the ease of navigating the webpage.

“Once I got to the website page, it gave me all the information I needed.” Participant 3.

“I don’t recall being frustrated by anything. I’m easily frustrated on the Internet.” Participant 4.

3.2.3.3. Theme 5: questionnaire. A positive engagement with the questionnaire was often cited by the participants. Particular reference was made to the simplicity and short duration of the questionnaire.

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

3.2.4. Consequences

3.2.4.1. Theme 6: positive experience. Many participants stated that their involvement in the MAP study resulted in a positive experience; it made them reconsider their condition and treatment and how they engaged with their physiotherapist.

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

4. Discussion

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

The NHS Constitution for England pledges to inform all patients about opportunities for involvement with suitable research studies (Department of Health, 2015). In this context healthcare professionals play a vital role in clinical research, linking researchers and patients. A variety of challenges may exist in recruiting participants from specialist healthcare services, such as physiotherapy, into cohort studies and little formal research has investigated these challenges (Zucchelli et al., 2018). Frayne et al. (Fig. 2) have conceptualised a process by which a

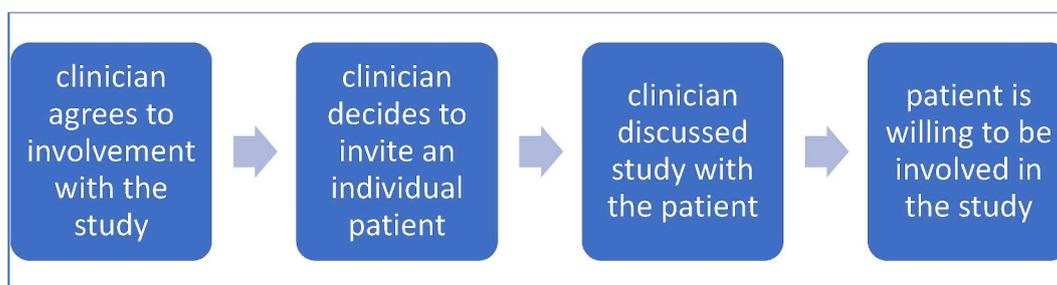


Fig. 2. Process of a patient being referred to a research study by a clinician (adapted from Frayne et al. (Frayne et al., 2001)).

patient may be referred to a research study when the initial invitation to participate is delivered by a healthcare professional in the clinical setting (rather than being invited by a healthcare provider who has responsibilities and involvement in the whole trial) (Frayne et al., 2001).

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

4.1. Involvement with the study

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

4.2. Inviting a patient

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

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

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

4.3. Discussing the study

Reporting lack of time as an obstacle to recruiting participants would appear significant. This was also reflected by the participants expressing they were given minimal verbal information by the physiotherapists during the invitation process. Limited time for recruitment resulting in clinicians not prioritising research activities has been seen in previous studies (Borschmann et al., 2014; Zucchelli et al., 2018). Resources are critical and lack of resources have been seen to negatively influence recruitment at all stages (Fenlon et al., 2013). The absence of dedicated resources, such as clinical time, not only constrains the capacity of clinicians to undertake research activity but can also undermine their belief in the research and lose a sense that their roles are respected (Borschmann et al., 2014). Consequently, research resources must be seen to make a difference. Here, effective communication is considered central to promote respect, reciprocity and maximise recruitment (Borschmann et al., 2014; Fenlon et al., 2013). Ensuring that the right information reaches the right people in a timely manner, and that clinicians are provided with progress reports and study findings, is essential (Borschmann et al., 2014). Improved communication from the

researcher directly to the physiotherapists involved in recruiting was a finding from this study. To address this, future studies should consider providing progress reports and developing a newsletter which includes 'frequently asked questions' and tips from research sites that have good recruitment rates (Fenlon et al., 2013).

4.4. Willingness to be involved

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

4.4.1. Strengths and limitations

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

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

5. Conclusion

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

Conflicts of interest

None declared.

Ethical approval

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

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.msksp.2019.04.008>.

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