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Perspectives and experiences of people who were randomly assigned to wait-and-see approach in a gluteal tendinopathy trial: a qualitative follow-up study

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ABSTRACT

Objective To explore participants' perspectives on, and experiences of, being assigned to a wait-and-see arm of a gluteal tendinopathy trial.

Design Descriptive qualitative.

Setting General community in Brisbane and Melbourne, Australia.

Participants Fifteen participants who had been randomly allocated to the wait-and-see group in a recent parallel group superiority clinical trial. That trial compared the wait-and-see approach to a physiotherapist-led education plus exercise approach, and an ultrasound-guided corticosteroid injection. The wait-and-see approach involved one physiotherapy session in which participants received reassurance, general advice and encouragement to stay active for the management of gluteal tendinopathy.

Data collection and analysis Semistructured interviews were conducted by four interviewers in person or over the internet, audio recorded and transcribed verbatim. Transcripts were coded and data analysed using an inductive thematic approach.

Results Five themes were extracted from the interview transcripts: (1) Feeling disenfranchised by being assigned to a wait-and-see approach; (2) the importance of having a clinical and imaging diagnosis during screening for inclusion into the clinical trial; (3) feelings regarding the effectiveness of the approach; (4) the convenient and easy to follow nature of the wait-and-see approach and (5) the connotation of wait-and-see not always being perceived as an intervention.

Conclusions Participants found the wait-and-see approach convenient and easy to follow, yet almost always felt disenfranchised that nothing was being done. Participants highlighted the importance of a definite clinical and imaging diagnosis.

Trial registration number ACTRN12612001126808; Post-results.

Strengths and limitations of this study

- Four different researchers who were not involved in the previous trial carried out the interviews.
- All interviewers were trained by an experienced qualitative researcher.
- The use of semistructured interviews enabled detailed information about participants' perspectives on and experiences of, being assigned to a wait-and-see approach.
- Fifteen out of 55 participants (27%) who completed the wait-and-see approach in the randomised clinical trial agreed to be interviewed for this study.

INTRODUCTION

Gluteal tendinopathy is one of the most common lower limb tendinopathies presenting to general practice,[1] affecting approximately 10%–25% of the population.[2] Load management through exercise and education is currently regarded as best practice for conservative management of gluteal tendinopathy,[3–5] reportedly used by 98% of physiotherapists in the UK.[6]

Clinical trials may test hypothetically effective treatments against a comparator group, such as a placebo arm, or a no treatment arm. A recent single-blinded trial assessed two active interventions for gluteal tendinopathy (load management education and exercise and a corticosteroid injection) using a no-treatment comparator group, the 'wait-and-see' approach (trial number ACTRN12612001126808).[4 7] The wait-and-see group attended one physiotherapy appointment where they received reassurance about their condition, general advice and encouragement to stay active. This general advice was provided in the form of a double sided, single page pamphlet. Outcomes of the clinical trial revealed that the education plus exercise group and corticosteroid injection group were superior to the wait-and-see group at 8 weeks.[4] At 12 months, the corticosteroid treatment group was not superior to the

wait-and-see group (58% and 52% reporting moderately to very much better on the primary outcome of Global Rating of Change scale)—both were inferior to education and exercise group (79%).[4]

Eligible participants in this trial knew before randomisation that they had a 33.3% chance of being allocated a wait-and-see group where they would not receive any active treatment (eg, comparator group). This was due to screening criteria, and ensuring personal ability to receive or commit to all possible interventions. Comparator groups are important for quality clinical trials,[8] but in contrast to pharmaceutical trials where placebo tablets, for example, allow for complete double blinding of participants and researchers, some musculoskeletal intervention trials make it impossible to blind participants to which arm they have been allocated to, and to what the other possible treatment arms comprised. Due to the importance of comparator groups in musculoskeletal clinical trials, we were interested in gaining more insight into the experiences of participants who were allocated to a no-treatment comparator like the wait-and-see arm of a trial in which it was not possible, due to the nature of the eligibility criteria of the trial, to be blinded to the other interventions.[4] The aim of this study was to qualitatively explore participants' perspectives on, and experiences of, being assigned to a wait-and-see arm of a gluteal tendinopathy trial.

MATERIALS AND METHODS

We conducted a qualitative study to answer the question 'how do participants experience, and what are their perspectives on, being assigned to a wait-and-see arm of a gluteal tendinopathy trail?'

Design

This is a follow-up qualitative study with a descriptive inductive design, in a group of participants from a previous trial. Purposeful sampling was used to recruit participants that completed the trial. We conducted semistructured interviews designed to explore beliefs and experiences of participants who had been assigned to a wait-and-see approach in a parallel groups' superiority clinical trial. Participants were interviewed on a single occasion, and interviews were guided by questions in a flexible conversation that allowed new ideas to be developed as they were introduced.[9] Topics related to the participant's perspectives on, and experiences with, following a wait-and-see approach for their condition (see online supplemental appendix 1). As such the methodology is grounded in constructivism which considers reality to be affected by people's experiences and thoughts. All participants provided informed consent. The study adheres to the Consolidated criteria for Reporting Qualitative research checklist to confirm rigour (see online supplemental appendix 2).[10]

The wait-and-see approach

The wait-and-see approach was the comparator in a randomised clinical trial that also included two other common management approaches for gluteal tendinopathy.[7] All participants in the trial had been diagnosed with gluteal tendinopathy after a clinical examination and MRI.[7] At baseline, 69 participants were randomly allocated to the wait-and-see approach. The wait-and-see approach consisted of 1.5-hour session with a physiotherapist where the participant received a double-sided single page pamphlet and reassurance that the condition is likely to resolve over time. The pamphlet included general advice regarding tendon care and advice to remain active within pain limits (see online supplemental appendix 3).[7]

Participants

All 69 participants who had been allocated to the wait-and-see approach of the clinical trial in Brisbane or Melbourne were invited, via email, to participate in this study. We were able to contact 55 of the 69 participants via email. Of these, 38 did not respond and 17 agreed to take part in the interviews. We were able to interview 15 participants, as two were unable to participate due to inability to schedule interviews for personal reasons.

Procedure

Interviews occurred between 20 August and 15 September 2018. Two male and two female physiotherapists (KJF, LL, JM and CP) who were undertaking a specialty Master of Physiotherapy (Sports) programme conducted the interviews face to face where possible, or by telephone or video call. They were trained by an experienced qualitative researcher (JS) in conducting semistructured interviews to ensure quality of interviews. There were no prior relationships between interviewers and interviewees. Interviewers followed a priori developed, semistructured guide to questions and prompts in order to elicit the participant's perceptions about the wait-and-see approach (see online supplemental appendix 1). Interview duration was on average 20 (range 12–40) min, with only the interviewer and interviewee present. Seven participants were interviewed via telephone, one via video and seven participants face to face in a sound-controlled room at The University of Queensland. Field notes were taken by all interviewers about interactions between interviewer and interviewee and the physical environment. Interviews were audio recorded and transcribed verbatim by the researcher who conducted the interview. Participants did not comment on transcripts or initial findings. Recruitment, data collection and analysis proceeded concurrently until data saturation was reached. That is, the point at which no new themes were identified from the interviews.

Data analysis

To identify and explore recurring patterns of perspectives on, and experiences of the wait-and-see approach, we conducted an inductive thematic analysis as outlined by Braun and Clarke.[11] Data were managed in Microsoft Word and Excel. Analysis first involved data familiarisation and immersion in the entire dataset by the four interviewers to gain an overall impression of patterns of ideas

and concepts.[12] Next, initial codes were generated and discussed until a final set of codes was agreed on by these researchers and were then reviewed by the other researchers in the team. Ideas and patterns were grouped into themes through an evolving process that involved rereading transcripts and codes, discussions between researchers and modifying themes to ensure the themes were grounded in the data. Themes captured important beliefs or experiences relating to the wait-and-see approach and were noted across a number of transcripts.

The research team consisted of clinicians and researchers with experience working with people with lateral hip pain and knowledge of the wait-and-see arm that was part of the randomised clinical trial. Two members of the research team (RM and BV) lead the original clinical trial. None of the other authors, including the interviewers, were involved in the original clinical trial (MLP, JS, KJF, LL, JM and CP). All interviewers were physiotherapists conducting their Masters in Sports Physiotherapy at the time of the interviews.

Patient and public involvement

The objectives of this study were based on patient reported outcomes of a previous clinical trial. As such, participants were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

RESULTS

The 15 participants were predominantly female (80%), with a mean age of 56 (SD 9) years and a median duration of lateral hip pain of 21 (range 8–144) months. All participants were in paid employment at the time of the study, 27% (n=4) listed their occupation as tradesperson or clerical worker and 73% (n=11) as manager or professional.

The deidentified interview transcripts are available from the UQ eSpace repository, doi: https://doi.org/10.14264/uql.2020.1010. Thematic analysis identified five themes related to the research question: (1) feeling disenfranchised by being assigned to a wait-and-see approach; (2) the importance of having a clinical and imaging diagnosis during screening for inclusion into the clinical trial; (3) feelings regarding the effectiveness of the approach; (4) the convenient and easy to follow nature of the wait-and-see approach; (5) the connotation of wait-and-see not always being perceived as an intervention. Numbers are used to distinguish participants (eg, P1, P2… …P15).

Theme 1: feeling disenfranchised by being assigned to a wait-and-see approach

Participants almost always felt disappointed or frustrated by being allocated to a wait-and-see approach at the start of the clinical trial, rather than education plus exercise or injection treatments. Participants 'would rather feel like something was being done, rather than sort of, sitting back and feeling like nothing was being done' (P9) and were 'hoping I would be in a more proactive group' (P3). This disenfranchisement resulted in emotions like frustration and disappointment, for example 'I was on the wait and see. I felt a bit um, the power or control had been taken away from me about doing something about it. […] I remember… I was frustrated' (P13) and 'Uh, well I was disappointed I didn't get treatment of some kind, but I think anyone going through the hoops and coming into a randomized controlled trial hopes they'll get into the arm that's looking at treatment you know" (P6). Some participants commented that they stuck to the intervention, because it was part of a research study: 'I was sceptical about it… but I knew… that's what we agreed upon, so that's why I stuck with it' (P7). Participant 8 mentioned that 'I only accepted the wait and see because it was part of a trial, not on the results. If you go into a trial, you accept what you're given'.

Theme 2: importance of having a clinical and imaging diagnosis

Participants emphasised the importance of having been provided a definitive diagnosis after being clinical examined and undergoing diagnostic imaging with MRI (and plain radiographs to exclude bone and joint pathology), as part of the screening process for eligibility for participation in the clinical trial. The interview guide did not include items on the diagnosis specifically, but a majority of participants recalled and reported that the MRI report was important to them and mentioned that 'I got an accurate diagnosis of what was causing it' (P2), and 'I was quite glad that I got the… MRI of the hip… I felt that was something that I gained from doing it…because I was then able to show it to my local doctor…and I suppose that helps to rule out certain conditions' (P14). Participants often emphasized the relief felt, like 'It was really quite a relief to see, that, yes, there is something wrong with it and I'm not just, making it up almost' (P1).

Theme 3: feelings regarding effectiveness of the approach

Participants remarked on the challenge of the wait-and-see approach being a slow process and not a quick fix. It was generally perceived that the information provided was useful and that it was a good approach, for example 'I think it's a good approach to do first of all rather than go straight in and fix it' (P10) and 'the aids they gave me in terms of information, they were very useful' (P13). Some participants reported wait-and-see to be an effective approach ('I basically took the whole thing on board, and did what I was told, and my hip pain went away' (P2)), while others did not ('Not very effective…I mean, put it this way, it was… clearly not working at all' (P7)). Participants occasionally highlighted modifications in their daily routine and/or usual activities while on the wait-and-see approach, for example 'I did get into some walking regimes and walking certainly helped' (P8), and 'cycling used to aggravate it a bit. So I guess my lifestyle has changed' (P5).

Theme 4: convenient and easy to follow

Participants almost always highlighted the convenience of the wait-and-see approach. A common comment was that participants reported it was convenient for those with a busy lifestyle. For example, this was discussed as being because 'I

didn't have to make lots of appointments' (P9), and 'It was in writing that I was to go about doing the things that I had always been doing' (P11). The minimal effort required to adhere to the wait-and-see approach was often mentioned as 'I tend to lead a fairly busy life so fitting one more thing in was just going to be… …impossibly problematic' (P10) and 'Work around making an appointment to see a physio… you know, for 15mins, half an hour, it's a hassle' (P13).

Theme 5: connotation of waiting and seeing

Participants reflected on the connotation of the term wait and see as it not being a treatment approach, as education only, as activity modification only, or literally waiting and seeing. A common comment was that the wait-and-see approach was not perceived as an intervention, but as '…a necessary component to have a control in an experiment' (P14). Participants often commented on the requirement to literally wait and see, for example 'You just do what was required to do…that was do nothing' (P8), "It wasn't really a program…. Just wait and see… it wasn't like going to a physio' (P1), or 'you are just waiting to see if there's any changes, so there's nothing actually really happening, but in other ways it's kind of good as well, because it does give it the opportunity to heal itself' (P9). Other participants understood the approach as 'Maybe we should [call it] 'monitored walking' or whatever' (P2) or 'wait and see can be scoped down to education' (P5).

DISCUSSION

This qualitative study obtained participants' perspectives on the wait-and-see approach that they were allocated to in the clinical trial on gluteal tendinopathy.[4 7] Identified themes suggest that assignation to the wait-and-see approach was perceived in divergent/contrasting ways. It appeared that participants were generally somewhat disappointed (disenfranchised) by the allocation to this group, where 'nothing was being done', as it is possible that they had hoped to receive an intervention for their condition as part of their involvement in the trial. However, a theme emerged which highlighted the importance that participants attributed to getting a definitive diagnosis of their condition. The results also suggest that the participants, once they had accepted that they had been allocated to this study arm, considered the approach to be convenient and easy to follow, allowing adherence to their study arm without interfering with their normal lifestyle.

We interviewed participants from a previously conducted randomised clinical trial[4] and findings are specific to that trial. The study was conducted in the context of a clinical trial and included 22% of the original participant pool that was assigned to the wait-and-see approach (n=15/69). This limits applicability to other contexts, but findings can still provide considerable insights for researchers that are developing musculoskeletal trials with a no-treatment comparator group like the wait-and-see approach. As outlined in the Methods section, some of the researchers were actively involved in the original clinical trial (BV nd RM), however none of the interviewers had been involved in this trial nor had MLP or JS. Knowledge about the trial may have influenced data interpretation, although data triangulation and the perspectives of the external researchers should have ensured consistency and coherence of the analysis and reporting. This study was conducted in Brisbane and Melbourne, Australia and findings may not be transferable to other countries and their cultures. The majority of participants were women (reflective of the gluteal tendinopathy population) and this may have limited transferability to men who might have a different conceptualisation of the wait-and-see approach. Interviews were conducted face to face, via telephone and video calls, and therefore we were not always able to note non-verbal communication. The depth of the data resulting from the interviews is likely impacted on by the nature of any prompting statements by the interviewers.

Different views existed about what the wait-and-see approach entailed—some regarded it as a simple guide that helped, while others indicated it was doing no treatment. As all participants were given the same content, this difference in perceptions may have resulted from divergent interpretations of the label—wait-and-see. As some participants suggested, labelling it something other than wait-and-see may have lessened these differences. This finding is consistent with evidence that knowledge of a particular intervention has the potential to significantly contribute to the health outcomes of the patient.[13] Future musculoskeletal clinical trials that include no-treatment comparator groups should deliberately choose the naming of their comparator approach to minimise discrepancies in the naming and content. It is also possible that there was divergence among clinical trial physiotherapists on the content of the wait-and-see approach and not only among participants. Therefore, future research should also look into possible divergence among those providing care in addition to those receiving care.

A strong positive theme regarding receiving a definitive clinical and confirmatory MRI diagnosis is notable. Our participants probably viewed a diagnosis as positive because of the thorough assessment including pathological findings from the MRI. The confirmation that their pain may be explained by something pathologically, and that something is 'wrong' likely have contributed to a feeling of relief. This aligns with outcomes from a qualitative systematic review in low back pain that reported that patients believed pathological findings on diagnostic imaging provide evidence that pain is real.[14] Getting a clinical and imaging diagnosis is likely to have affected their experience of being in the trial, even though the participants were not allocated to an active treatment arm. This is supported by findings of a recent trial that reported patients are often confused about their diagnosis, causes and meaning of their pain.[15] Being enrolled in our trial would have taken away some of this confusion with the thorough clinical and imaging diagnosis. Further, the diagnosis may have underpinned and provided a level of authenticity to the information provided in the pamphlet and by the physiotherapist—explaining gluteal

tendinopathy in simple terms—that is, what is it, why do I have it and what can I do (online supplemental appendix 3). The relevance and impact of a confirmed diagnosis or lack thereof should be considered when giving general advice on a condition, reassurance and encouragement to stay active (as was done in the wait-and-see approach).

In the trial, similar numbers of participants in the corticosteroid and wait-and-see groups reported being moderately to very much better (58% and 52%, respectively on the Global Rating of Change scale)—which were less than the 78% of the education plus exercise group.[4] During participation in the trial, no adverse trial related events had occurred, and participants did not have to change their lifestyles, or drastically inconvenience themselves. Hence, a possible relief was suggested by some that participation in this arm of the trial would allow them to adhere to their trial requirements/commitments without inconvenience, while still resulting in similar outcomes to one of the intervention groups. Possibly future clinical trials could assess if a minimal approach like the wait-and-see that consists of one consultation to cover assurance about their condition, general advice and encouragement to stay active, could be a low-risk and cost-effective approach for a subgroup of people to encourage patient autonomy and self-management. Subsequently, it could be investigated if minimal approaches could be implemented in busy general medical practices with short consultations or telehealth practices.

CONCLUSION

Participants found the wait-and-see approach convenient and easy to follow, while experiencing feelings of disenfranchisement that nothing was being done. Participants were reassured by information provided in the wait-and-see approach as well as a diagnosis of gluteal tendinopathy confirmed by a clinical examination and diagnostic imaging. Future trials could consider renaming what have been traditionally called 'wait-and-see' approaches into terms that are more content specific and reflect the minimal approach better. Our findings will benefit researchers and clinicians in designing future musculoskeletal clinical trials.

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Contributors MLP, RM, JS and BV: conception and design of the work. KJF, LL, JM and CP: acquisition of data. All authors contributed to data analysis and interpretation of the data. MLP drafted the manuscript. RM, JS, BV, KJF, LL, JM and CP: Revision of the manuscript for important intellectual content. All authors have approved the final version of the manuscript to be published.

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Competing interests None declared.

Patient consent for publication Not required.

Ethics approval Ethics was obtained from the University of Queensland Human Research Ethics Committee (HREC #2018001471).

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement All data relevant to the study are included in the article or uploaded as online supplemental information. The deidentified interview transcripts are available from the UQ eSpace repository, doi: https://doi.org/10.14264/uql.2020.1010.

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