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What can we learn from patients randomly assigned a minimal wait and see approach for gluteal tendinopathy? A qualitative follow-up study.

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ABSTRACT

Objective: To elucidate patients' perspectives on, and experiences of, a wait and see approach for self-management of their gluteal tendinopathy.

Design: Descriptive qualitative design.

Setting: General community in Queensland, Australia.

Participants: Fifteen participants who had been randomly allocated to the wait and see group in a recently concluded parallel groups 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 a pamphlet containing simple advice and encouragement to stay active for the management of gluteal tendinopathy. It was delivered to the patient during one session with a physiotherapist.

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

Results: Five themes were extracted from the interview transcripts: (i) convenience and easy to follow nature of the approach; (ii) importance of having a diagnosis in the participant-screening for the clinical trial; (iii) connotation of the wording wait and see; (iv) feeling disenfranchised by being assigned to a wait and see approach; and (v) feelings regarding the effectiveness of the approach.

Conclusions: Patients who had been reassured they had gluteal tendinopathy via a clinical examination and diagnostic imaging often perceived the wait and see approach as convenient and easy to follow, yet not a real treatment. Conceivably, the wait and see approach could be delivered during a short consultation in a busy clinical practice where a clinician has limited time (e.g., general practice). In which case the clinician ought be aware of the perceived connotation that waiting and seeing is doing nothing – a solution for which may be to use an alternative term.

Key words: Qualitative Research, Lateral Hip Pain, Hip Injuries, Exercise Therapy.

Article Summary

Strengths and limitations of this study

- Four different researchers that were not involved in the previous trial carried out the interviews.
- All interviewers were trained by an experienced qualitative researcher.
- The use of semi structured interviews enabled detailed information about patients' perspectives on, and experiences of, being assigned to a wait and see approach.
- Fifteen out of 55 patients (27%) that completed the wait and see approach in the randomized 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 the management of gluteal tendinopathy,[3-5] reportedly used by 98% of physiotherapists in the United Kingdom.[6]

Clinical trials often test hypothetically effective treatments against minimal interventions like a wait and see approach or a no treatment control. A recent trial assessed two hypothetically effective interventions for gluteal tendinopathy against a wait and see approach – load management education plus exercise or ultrasound guided corticosteroid injection (the 'LEAP' trial).[4, 7] The wait and see group received a minimal intervention that consisted of general advice on tendinopathy and to stay active. This general advice was provided at a physiotherapy consult in the form of a double sided, single page pamphlet. That clinical trial showed that the wait and see group had comparable success rates to the corticosteroid group (52% versus 58% respectively) at 12 months – both of which were inferior to education plus exercise by 27% and 20%, respectively.[4, 8]

The wait and see approach was comparably low risk and less resource intensive – it involved less time and cost – compared to both the ultrasound-guided corticosteroid injection and the 14 physiotherapy sessions over 8 weeks, which required adherence to specific exercises.[4] The wait and see approach would appear a viable cheaper lower risk alternative that could be recommended – at least as the initial approach in a stepped clinical-care model with escalating levels of resource utilisation and risk.[9] Understanding the patient's experiences and perspectives on a wait and see approach may provide important insights into its clinical implementation, possibly also for other musculoskeletal conditions. The aim of this study was to qualitatively explore patients' perspectives on, and experiences of, being assigned to a wait and see intervention for the treatment of gluteal tendinopathy.

MATERIALS AND METHODS

Design

This is a follow-up study with a descriptive inductive qualitative design, using convenience sampling. We conducted semi-structured interviews designed to explore beliefs and

experiences related to following 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 [10]. Topics related to the participant's perspectives on, and experiences with, following a wait and see approach for their condition (see Appendix 1). Ethics was obtained from the University of Queensland Human Research Ethics Committee (HREC #2018001471) and all participants provided informed consent. The study adheres to the consolidated criteria for reporting qualitative research (COREQ) checklist to confirm rigour (see Appendix 2).[11]

The wait and see approach

The wait and see approach was one of three intervention arms of a randomised clinical trial of two other relatively common management approaches for gluteal tendinopathy.[7] All participants in the trial were diagnosed with gluteal tendinopathy after a clinical examination and Magnetic Resonance Imaging (MRI).[7] At baseline, 69 participants were randomly allocated in the wait and see approach. The wait and see approach consisted of one 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 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. Of these, 38 did not respond and 17 agreed to take part in the interviews. We interviewed 15 participants, as two were unable to participate due to personal reasons which meant they were unable to schedule interviews.

Procedure

Interviews occurred between 20 August and 15 September 2018. Two male and two female physiotherapists (KF, LL, JM, CP) who were undertaking a speciality Master of Physiotherapy (Sports) program 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 semi-structured interviews to ensure quality of interviews. There were no prior relationships between interviewers and interviewees. Interviewers followed a scripted introduction and a guide to questions and prompts in order to elicit the participant's perceptions about the wait and see approach (see Appendix 1). Interview duration ranged from 12-40 minutes, with only the interviewer and interviewee present. 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.

Data analysis

To identify and explore recurring patterns of perspectives on, and experiences with, the wait and see approach, we conducted an inductive thematic analysis as outlined by Braun and Clarke.[12] Data were managed in Microsoft Word and Excel. Analysis first involved data familiarisation and immersion by the four interviewers to gain an overall impression of patterns of ideas and concepts.[13] Next, initial codes were generated and discussed until a final set of codes was agreed upon 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 a wait and see approach. Two members of the research team (RM, BV) lead the original clinical trial. The authors were aware of the possible impact the perspectives of these researchers might have had on data interpretation and they made effort to include a range of perspectives.[14] None of the other authors,

including the interviewers, were involved in the original clinical trial (MP, JS, KF, LL, JM, CM).

Patient and Public Involvement

The objectives of this study were based on patient reported outcomes of a previous clinical trial. As such, participants were involved in the design, but not in the recruitment and conduct of this study.

RESULTS

Participant characteristics are presented in Table 1. The 15 participants were predominantly female (80%), with a median age of 56 (interquartile range 16) years, and an average duration of lateral hip pain of 21 (interquartile range 48) months.

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

Theme 1. 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 2. Importance of having a clinical and imaging diagnosis

Participants emphasised the importance of having been provided a diagnosis after being clinical examined and undergoing diagnostic imaging with MRI (and plain radiographs to exclude bone and joint pathology), even though this was not a part of the wait and see approach but rather of the pre-screening process. 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). The importance of diagnostic imaging may have affected how patients responded to the wait and see approach in during this clinical trial.

Theme 3. 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 "w*ait and see can be scoped down to education"* (P5).

Theme 4. Feeling disenfranchised by being assigned to a wait and see approach

Participants almost always said that they felt disenfranchised 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 5. Feelings regarding effectiveness

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 intervention (*"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).

DISCUSSION

This qualitative study obtained patients' perspectives on the wait and see approach that they were allocated to in the clinical trial on gluteal tendinopathy.[4, 7] We did this to help inform clinicians and researchers on the potential utility of this approach. Analysis of 15 interviews suggests that the wait and see approach was perceived in divergent/contrasting ways, as an intervention in itself or, conversely as doing nothing. The results suggest that the patients

consider the approach to be convenient and easy to follow. It also highlighted the importance that participants attributed to getting a diagnosis – a matter we had not considered a-priori as an item in the interview.

We included participants from a previously conducted randomized clinical trial[4] and findings are specific to that trial. The study was conducted in the context of a clinical trial so may have limited applicability to other contexts, such as, routine clinical care or in a stepped care model. Findings can still provide considerable insights into the experiences and perspectives of gluteal tendinopathy patients in regards to minimalistic interventions similar to the wait and see approach. Convenience sampling was used and thus findings are not representative of the entire gluteal tendinopathy population. Some of the researchers were actively involved in the original clinical trial, however none of the interviewers were. This study was conducted in 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 upon 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/term – wait and see. As some patients 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.[15] Future users of the wait and see approach could consider using an alternative term, one that denotes more clearly its content which is rarely solely to wait and see what happens.

A physiotherapist delivering the information about the wait and see approach to the participant did not seem to overcome the issue of it being perceived as 'nothing was being done'. This might be a function of patient beliefs that a physiotherapist delivers hands-on treatments, as suggested in a survey of 587 Australian adults (some had, and others never had a physiotherapy appointment). That survey suggested that it is extremely likely – and

important to people – that a physiotherapist provides massage in addition to physical activity and general health advice.[16] Further to this, our physiotherapists who delivered the wait and see approach did not conduct a clinical examination and specifically tailor their wait and see advice to the individual patient. A recent systematic review has revealed that patients reportedly feel a stronger bond with their therapist when their treatment is individualized and related specifically to their presentation.[17] The lack of individualization in the wait and see approach may have added to feelings of disenfranchisement or the wait and see not being perceived as a pro-active intervention.

We had not considered adding items regarding the diagnosis (as part of the clinical trial) when developing the interview guide (Appendix 1), but it was raised by our participants as being a positive experience. Our participants probably viewed a diagnosis as positive because it addressed some of their concerns. These concerns were also identified in a recent qualitative study, which reported that patients are often confused about their diagnosis, causes and meaning of their pain.[18] 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 – i.e., what is it, why do I have it and what can I do (Appendix 3). Implementation of a wait and see approach in clinic and research should consider the relevance and impact of a confirmed diagnosis or lack thereof. In addition, we are uncertain on the meaningfulness of a wait and see approach for other non-diagnosed musculoskeletal conditions like for example non-specific low back pain.

As published in the original randomised clinical trial, there was a 52% success rate at 12 months with the wait and see approach, which was comparable to the corticosteroid injection arm (58%).[4] Our interviews revealed that the wait and see approach was also convenient and easy to follow. It is tempting to hypothesize that a minimal intervention like the wait and see approach has the potential to be low-risk and cost-effective approach to encouraging patient autonomy and self-management. It could be easily implemented in busy general medical practices. The utility of this intervention will however depend on several factors. Poor expectations of recovery are known to be associated with poor outcomes for patients with musculoskeletal pain conditions.[19] Further, it has been reported that patients who have greater trochanteric pain syndrome are often pessimistic about future recovery and effectiveness of treatments -with many patients having experienced previous physiotherapy without lasting success.[18] History, patient expectations, motivation and adherence have a

substantial influence on health outcomes. These require consideration by clinicians and patients before commencing a minimalistic approach like wait and see.

Conclusion

The wait and see approach may be a clinically feasible treatment option for some patients who have a diagnosis of gluteal tendinopathy. It is perceived convenient and easy to follow by patients, and conceivably likewise by a clinician. Although perceived as easy to follow, clinical utility may be impacted by the use of the words 'wait and see' and perceptions that this approach means doing nothing. To counter this, we suggest using an alternative term to describe this approach. Future research could explore alternative terminology and the role of this wait and see approach in clinical practice.

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Author contributions

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

REFERENCES

1. Albers, I.S., et al., *Incidence and prevalence of lower extremity tendinopathy in a Dutch general practice population: a cross sectional study.* BMC Musculoskelet Disord, 2016. **17**:16. doi:10.1186/s12891-016-0885-2.
2. Segal, N.A., et al., *Greater trochanteric pain syndrome: epidemiology and associated factors.* Arch Phys Med Rehabil, 2007. **88**(8):988-92. doi:10.1016/j.apmr.2007.04.014.
3. Ganderton, C., et al., *Gluteal Loading Versus Sham Exercises to Improve Pain and Dysfunction in Postmenopausal Women with Greater Trochanteric Pain Syndrome: A Randomized Controlled Trial.* J Womens Health (Larchmt), 2018. **27**(6):815-829. doi:10.1089/jwh.2017.6729.
4. Mellor, R., et al., *Education plus exercise versus corticosteroid injection use versus a wait and see approach on global outcome and pain from gluteal tendinopathy: prospective, single blinded, randomised clinical trial.* BMJ, 2018. **361**:k1662. doi:10.1136/bmj.k1662.
5. Barratt, P.A., N. Brookes, and A. Newson, *Conservative treatments for greater trochanteric pain syndrome: a systematic review.* Br J Sports Med, 2017. **51**(2):97-104. doi:10.1136/bjsports-2015-095858.
6. Stephens, G., et al., *A survey of physiotherapy practice (2018) in the United Kingdom for patients with greater trochanteric pain syndrome.* Musculoskelet Sci Pract, 2019. **40**:10-20. doi:10.1016/j.msksp.2019.01.004.
7. Mellor, R., et al., *Exercise and load modification versus corticosteroid injection versus 'wait and see' for persistent gluteus medius/minimus tendinopathy (the LEAP trial): a protocol for a randomised clinical trial.* BMC Musculoskelet Disord, 2016. **17**:1-17. doi:10.1186/s12891-016-1043-6.
8. Coombes, B.K., L. Bisset, and B. Vicenzino, *Efficacy and safety of corticosteroid injections and other injections for management of tendinopathy: a systematic review of randomised controlled trials.* The Lancet, 2010. **376**(9754):1751-1767. doi:10.1016/s0140-6736(10)61160-9.
9. Ho, F.Y., et al., *The Efficacy and Cost-Effectiveness of Stepped Care Prevention and Treatment for Depressive and/or Anxiety Disorders: A Systematic Review and Meta-Analysis.* Sci Rep, 2016. **6**:29281. doi:10.1038/srep29281.
10. Braun, V. and V. Clarke, *Successful Qualitative Research.* . 2013, London, UK: Sage.
11. Tong, A., P. Sainsbury, and J. Craig, *Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups.* International journal for quality in health care, 2007. **19**(6):349-357.
12. Braun, V. and V. Clarke, *Using thematic analysis in psychology.* Qualitative Research in Psychology, 2006. **3**(2):77-101. doi:10.1191/1478088706qp063oa.
13. Miles, M.B., A.M. Huberman, and J. Saldana, *Qualitative data analysis*. 2013: Sage.
14. Hiller, A.J. and D.F. Vears, *Reflexivity and the clinician-researcher: managing participant misconceptions.* Qualitative Research Journal, 2016. **16**(1):13-25. doi:10.1108/qrj-11-2014-0065.
15. McPherson, K. and A. Britton, *Preferences and understnain their effects on health.* Quality in Health Care, 2001. **10**:i61-i66.
16. Kunstler, B., et al., *Australian adults expect physiotherapists to provide physical activity advice: a survey.* J Physiother, 2019. **65**(4):230-236. doi:10.1016/j.jphys.2019.08.002.
17. O'Keeffe, M., et al., *What Influences Patient-Therapist Interactions in Musculoskeletal Physical Therapy? Qualitative Systematic Review and Meta-Synthesis.* Physical Therapy, 2016. **96**(5):609-622.

18. Stephens, G., et al., *"It's just like a needle going into my hip, basically all of the time". The experiences and perceptions of patients with Greater Trochanteric Pain syndrome in the UK National Health Service.* Musculoskeletal Science and Practice, 2020. doi:10.1016/j.msksp.2020.102175.

19. Tseli, E., et al., *Predictors of multidisciplinary rehabilitation outcomes in patients with chronic musculoskeletal pain: protocol for a systematic review and meta-analysis.* Syst Rev, 2017. **6**(1):199. doi:10.1186/s13643-017-0598-0.

TABLES

Table 1. Participant characteristics

Participant number	Sex (female, male)	Age at time of study (years)	Duration of symptoms at time of study (months)
1	Female	39	21
2	Female	66	120
3	Male	60	30
4	Female	62	60
5	Female	57	60
6	Female	53	144
7	Male	48	4
8	Male	68	12
9	Female	42	18
10	Female	52	12
11	Female	66	36
12	Female	56	18
13	Female	54	12
14	Female	64	60
15	Female	47	8

Appendix 1. Guide for semi-structured interviews

GENERAL INTRODUCTION

Thank you and welcome. My name is _____ and I am currently finishing my Masters of Sports Physiotherapy and I am conducting research on behalf of the University of Queensland.

I am interested in hearing your perspectives on the W&S approach now that you have completed the LEAP trial.

Positive, negative or neutral responses are welcome. There are no right or wrong answers, and it's ok to go off track as we would like to know as much information as possible.

Please let me know if you need a break or want to stop the interview at any time. If you do not wish to answer any questions, feel free to decline and we will move on.

Finally, do I have your permission to record this interview?

EXPECTATIONS OF A WAIT AND SEE INTERVENTION

- How would you describe your thoughts when you first read and heard about the W&S intervention?
- How would you now feel if you were recommended a W&S intervention when visiting a physiotherapist or GP?
- Would you now recommend this intervention to a friend? If so/if not, why? Not sure if we need this question? Just a thought.

INFORMATION PROVIDED IN THE WAIT AND SEE INTERVENTION

- Can you tell me in your own words what kind of information was provided in the wait and see intervention?
- The results from the trial that you were a part of found that more than 50% of the participants were at least moderately to very much better one year after starting the trial. What are your thoughts on this?

ADHERANCE TO THE WAIT AND SEE INTERVENTION

- In terms of adhering to the W&S intervention, how did you find it?
- Could you describe what was easy about sticking to the W&S intervention?

- Was there anything you found challenging?
- In your own words, how effective was the W&S intervention for you?

INVOLVEMENT IN OTHER TREATMENTS

- Have you had any other treatments for your hip pain before?
- If so, how did they compare to the W&S approach?
- Did you feel like you had to seek other treatments for your hip pain? If so, why?
- Now that you have experienced the wait and see approach, would you seek out other treatment if it was recommended by a physiotherapist or GP? If so, why?
- How would you go about seeking out any other treatments after being recommended wait and see?
- How would you feel about needing to seek other treatments after being recommended a wait and see approach?

SUMMARY

Just to summarise, could you put in 3 simple bullet points what you felt were the important features of the wait and see approach for you?

Appendix 2. Consolidated criteria for reporting qualitative research (COREQ) checklist.

No. Item	Guide questions/description	Reported on Page #
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Inter viewer/facilitator	Which author/s conducted the interview or focus group?	6
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	6
3. Occupation	What was their occupation at the time of the study?	6
4. Gender	Was the researcher male or female?	6
5. Experience and training	What experience or training did the researcher have?	6
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	6
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	6, Appendix 1
8. Interviewer characteristics	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	6, Appendix 1
Domain 2: study design		
Theoretical framework		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	6
Participant selection		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	4
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	5
12. Sample size	How many participants were in the study?	5
13. Non-participation	How many people refused to participate or dropped out? Reasons?	5
Setting		

14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	6
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	6
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	7
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	5, Appendix 1
18. Repeat interviews	Were repeat inter views carried out? If yes, how many?	6
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	6
20. Field notes	Were field notes made during and/or after the inter view or focus group?	6
21. Duration	What was the duration of the inter views or focus group?	6
22. Data saturation	Was data saturation discussed?	6
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	6
Domain 3: analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	6
25. Description of the coding tree	Did authors provide a description of the coding tree?	6
26. Derivation of themes	Were themes identified in advance or derived from the data?	6
27. Software	What software, if applicable, was used to manage the data?	6
28. Participant checking	Did participants provide feedback on the findings?	6
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant #	7-9
30. Data and findings consistent	Was there consistency between the data presented and the findings?	7-9
31. Clarity of major themes	Were major themes clearly presented in the findings?	7-9
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	7-9

Appendix 3. The 'wait and see' pamphlet.

THE UNIVERSITY OF QUEENSLAND
AUSTRALIA

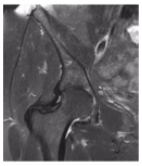
SIRPH Research Unit
School of Health & Rehabilitation Sciences

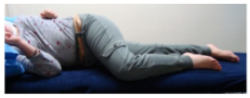
Gluteal Tendinopathy

What is it?

Gluteal tendinopathy is pain that originates at the side of the hip, over the bony prominence called the greater trochanter. The main area of pain will occur around this bone, but commonly extends down the side of the thigh, and even into the top of the lower leg, below the knee. Pain may also extend a way forward into the groin, or back into the buttock.

The condition has historically been diagnosed as 'trochanteric bursitis', however recently researchers have shown there to be problems of cells, collagen tissue and small blood vessels in the tendons of the buttock muscles - gluteus medius and minimus.





It is often worse at night lying on either side, and may be aggravated by walking, particularly uphills and stairs, standing on one leg to dress, prolonged sitting, and there is often some pain and stiffness for the first few steps after rising to stand.

Why do I have it?

Tendon health depends on the loads they bear on a regular basis, and either too much or too little loading can be problematic. For example, an athlete may overload the tendon and end up with tendon problems, whereas those who are not physically active may well suffer gradual tendon deterioration.

Either way the tendon health suffers and eventually pain is experienced when the weakened tendon is exposed to a range of possible factors, such as a rapid increase in loading that might occur with suddenly increasing training loads, or even taking up walking, particularly up hills and stairs, or with a slip or fall directly landing on the side of the hip.

Sometimes you may not be able to put your finger on a single factor as it might have occurred as a result of an accumulation of a number of small things, for example a gradual increase in weight over time and a reduction in general fitness.

What can I do?

Rest does not cure tendinopathy, but exercising to the point of feeling pain in the tendon is also not helpful, so keeping up a walking programme that does not aggravate your pain will be worthwhile.

Walk on the flat, avoid hills and keep stairs to a minimum until your pain settles. Start with 10 minutes of walking and as your pain improves gradually increase your activity levels.

Applying heat to the hip and buttock can also provide relief.

Consolidated criteria for reporting qualitative research (COREQ) checklist.

No. Item	Guide questions/description	Reported on Page #
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Inter viewer/facilitator	Which author/s conducted the interview or focus group?	6
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	6
3. Occupation	What was their occupation at the time of the study?	6
4. Gender	Was the researcher male or female?	6
5. Experience and training	What experience or training did the researcher have?	6
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	6
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	6, Appendix 1
8. Interviewer characteristics	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	6, Appendix 1
Domain 2: study design		
Theoretical framework		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	6
Participant selection		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	4
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	5
12. Sample size	How many participants were in the study?	5
13. Non-participation	How many people refused to participate or dropped out? Reasons?	5
Setting		

14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	6
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	6
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	7
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	5, Appendix 1
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Perspectives and experiences of persons who were randomly assigned to wait and see in a gluteal tendinopathy trial? A qualitative follow-up study.

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Perspectives and experiences of persons who were randomly assigned to wait and see 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 groups 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: Semi-structured 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; (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.

Key words: Qualitative Research, Lateral Hip Pain, Hip Injuries, Exercise Therapy.

Article Summary

Strengths and limitations of this study

- Four different researchers that were not involved in the previous trial carried out the interviews.
- All interviewers were trained by an experienced qualitative researcher.
- The use of semi structured interviews enabled detailed information about participant's perspectives on, and experiences of, being assigned to a wait and see approach.
- Fifteen out of 55 participants (27%) that completed the wait and see approach in the randomized 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 United Kingdom.[6]

Clinical trials may test hypothetically effective treatments against a control group, such as a placebo arm, or a no treatment arm. A recent single blinded trial assessed two hypothetically effective interventions for gluteal tendinopathy (load management education and exercise and a corticosteroid injection) using a no treatment control group, the "wait and see" approach (the 'LEAP' trial).[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] Interestingly, it also showed that the wait and see group had comparable success rates (measured by the Global Rating of Change) to the corticosteroid group (52% versus 58% respectively) at 12 months – both of which were inferior to education plus exercise by 27% and 20%, respectively.[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 (e.g., control group). This was due to screening criteria, and ensuring personal ability to receive or commit to all possible interventions. Control groups are important as comparators 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 control groups in musculoskeletal clinical trials, we were interested in gaining more insight into the experiences of participants who were allocated to a control group 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 participant's 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 semi-structured 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 Appendix 1). As such the methodology is grounded in constructivism which considers reality to be affected by people's experiences and thoughts. Ethics was obtained from the University of Queensland Human Research Ethics Committee (HREC #2018001471) and all participants provided informed consent. The study adheres to the consolidated criteria for reporting qualitative research (COREQ) checklist to confirm rigour (see Appendix 2).[10]

The wait and see approach

The wait and see approach was considered the control arm 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 Magnetic Resonance Imaging (MRI).[7] At baseline, 69 participants were randomly allocated to the wait and see approach. The wait and see approach consisted of one half 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 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 interview15 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 (KF, LL, JM, CP) who were undertaking a speciality Master of Physiotherapy (Sports) program 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 semi-structured interviews to ensure quality of interviews. There were no prior relationships between interviewers and interviewees. Interviewers followed a priori developed, semi-structured guide to questions and prompts in order to elicit the participant's perceptions about the wait and see approach (see Appendix 1). Interview duration was on average 20 (range 12-40) minutes, with only the interviewer and interviewee present. 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 upon 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 randomized clinical trial. Two members of the research team (RM, BV) lead the original clinical trial. None of the other authors, including the interviewers, were involved in the original clinical trial (MP, JS, KF, LL, JM, CM). 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 th 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. 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.

The de-identified 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 (e.g., 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

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 "w*ait and see can be scoped down to education"* (P5).

DISCUSSION

This qualitative study obtained participant's 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 randomized 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 control group consisting of a non-active treatment 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, RM), however none of the interviewers had been involved in this trial nor had MP 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 upon 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 control groups should deliberately choose the naming of their control approach to minimize discrepancies in the naming and content. It is also possible that there was divergence amongst 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 – i.e., what is it, why do I have it and what can I do (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).

At 12-month assessment in the original trial, the success rate of the wait and see group in terms of global rating of change was comparable to the group who had received the corticosteroid injection.[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, whilst 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 consult 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

Being allocated to the wait and see approach was experienced in many ways by participants – finding it convenient and easy to follow, while feeling disenfranchised 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. Our findings will benefit researchers and clinicians in designing future musculoskeletal clinical trials.

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Author contributions: MP, RM, JS, BV: conception and design of the work. KF, LL, JM, CP: acquisition of data. All authors contributed to data analysis and interpretation of the data. MP drafted the manuscript. RM, JS, BV, KF, LL, JM, 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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Data sharing statement: The de-identified interview transcripts are available from the UQ eSpace repository, doi: https://doi.org/10.14264/uql.2020.1010.

REFERENCES

1. Albers, I.S., et al., *Incidence and prevalence of lower extremity tendinopathy in a Dutch general practice population: a cross sectional study.* BMC Musculoskelet Disord, 2016. **17**:16. doi:10.1186/s12891-016-0885-2.
2. Segal, N.A., et al., *Greater trochanteric pain syndrome: epidemiology and associated factors.* Arch Phys Med Rehabil, 2007. **88**(8):988-92. doi:10.1016/j.apmr.2007.04.014.
3. Ganderton, C., et al., *Gluteal Loading Versus Sham Exercises to Improve Pain and Dysfunction in Postmenopausal Women with Greater Trochanteric Pain Syndrome: A Randomized Controlled Trial.* J Womens Health (Larchmt), 2018. **27**(6):815-829. doi:10.1089/jwh.2017.6729.
4. Mellor, R., et al., *Education plus exercise versus corticosteroid injection use versus a wait and see approach on global outcome and pain from gluteal tendinopathy: prospective, single blinded, randomised clinical trial.* BMJ, 2018. **361**:k1662. doi:10.1136/bmj.k1662.
5. Barratt, P.A., N. Brookes, and A. Newson, *Conservative treatments for greater trochanteric pain syndrome: a systematic review.* Br J Sports Med, 2017. **51**(2):97-104. doi:10.1136/bjsports-2015-095858.
6. Stephens, G., et al., *A survey of physiotherapy practice (2018) in the United Kingdom for patients with greater trochanteric pain syndrome.* Musculoskelet Sci Pract, 2019. **40**:10-20. doi:10.1016/j.msksp.2019.01.004.
7. Mellor, R., et al., *Exercise and load modification versus corticosteroid injection versus 'wait and see' for persistent gluteus medius/minimus tendinopathy (the LEAP trial): a protocol for a randomised clinical trial.* BMC Musculoskelet Disord, 2016. **17**:1-17. doi:10.1186/s12891-016-1043-6.
8. Mann, H. and B. Djulbegovic, *Choosing a control intervention for a randomised clinical trial.* 3, 2003(7):1-5.
9. Braun, V. and V. Clarke, *Successful Qualitative Research.* . 2013, London, UK: Sage.
10. Tong, A., P. Sainsbury, and J. Craig, *Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups.* International journal for quality in health care, 2007. **19**(6):349-357.
11. Braun, V. and V. Clarke, *Using thematic analysis in psychology.* Qualitative Research in Psychology, 2006. **3**(2):77-101. doi:10.1191/1478088706qp063oa.
12. Miles, M.B., A.M. Huberman, and J. Saldana, *Qualitative data analysis*. 2013: Sage.
13. McPherson, K. and A. Britton, *Preferences and understnain their effects on health.* Quality in Health Care, 2001. **10**:i61-i66.
14. Sharma, S., et al., *Clinician and patient beliefs about diagnostic imaging for low back pain: a systematic qualitative evidence synthesis.* BMJ Open, 2020. **10**(8):e037820. doi:10.1136/bmjopen-2020-037820.
15. Stephens, G., et al., *"It's just like a needle going into my hip, basically all of the time". The experiences and perceptions of patients with Greater Trochanteric Pain syndrome in the UK National Health Service.* Musculoskeletal Science and Practice, 2020. doi:10.1016/j.msksp.2020.102175.

Appendix 1. Guide for semi-structured interviews

GENERAL INTRODUCTION

Thank you and welcome. My name is _____ and I am currently finishing my Masters of Sports Physiotherapy and I am conducting research on behalf of the University of Queensland.

I am interested in hearing your perspectives on the W&S approach now that you have completed the LEAP trial.

Positive, negative or neutral responses are welcome. There are no right or wrong answers, and it's ok to go off track as we would like to know as much information as possible.

Please let me know if you need a break or want to stop the interview at any time. If you do not wish to answer any questions, feel free to decline and we will move on.

Finally, do I have your permission to record this interview?

EXPECTATIONS OF A WAIT AND SEE INTERVENTION

- How would you describe your thoughts when you first read and heard about the W&S intervention?
- How would you now feel if you were recommended a W&S intervention when visiting a physiotherapist or GP?
- Would you now recommend this intervention to a friend? If so/if not, why? Not sure if we need this question? Just a thought.

INFORMATION PROVIDED IN THE WAIT AND SEE INTERVENTION

- Can you tell me in your own words what kind of information was provided in the wait and see intervention?
- The results from the trial that you were a part of found that more than 50% of the participants were at least moderately to very much better one year after starting the trial. What are your thoughts on this?

ADHERANCE TO THE WAIT AND SEE INTERVENTION

- In terms of adhering to the W&S intervention, how did you find it?
- Could you describe what was easy about sticking to the W&S intervention?

- Was there anything you found challenging?
- In your own words, how effective was the W&S intervention for you?

INVOLVEMENT IN OTHER TREATMENTS

- Have you had any other treatments for your hip pain before?
- If so, how did they compare to the W&S approach?
- Did you feel like you had to seek other treatments for your hip pain? If so, why?
- Now that you have experienced the wait and see approach, would you seek out other treatment if it was recommended by a physiotherapist or GP? If so, why?
- How would you go about seeking out any other treatments after being recommended wait and see?
- How would you feel about needing to seek other treatments after being recommended a wait and see approach?

SUMMARY

Just to summarise, could you put in 3 simple bullet points what you felt were the important features of the wait and see approach for you?

Appendix 2. Consolidated criteria for reporting qualitative research (COREQ) checklist.

No. Item	Guide questions/description	Reported on Page #
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Inter viewer/facilitator	Which author/s conducted the interview or focus group?	6
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	6
3. Occupation	What was their occupation at the time of the study?	6
4. Gender	Was the researcher male or female?	6
5. Experience and training	What experience or training did the researcher have?	6
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	6
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	6, Appendix 1
8. Interviewer characteristics	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	6, Appendix 1
Domain 2: study design		
Theoretical framework		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	6
Participant selection		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	4
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	5
12. Sample size	How many participants were in the study?	5
13. Non-participation	How many people refused to participate or dropped out? Reasons?	5
Setting		

14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	6
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	6
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	7
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	5, Appendix 1
18. Repeat interviews	Were repeat inter views carried out? If yes, how many?	6
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	6
20. Field notes	Were field notes made during and/or after the inter view or focus group?	6
21. Duration	What was the duration of the inter views or focus group?	6
22. Data saturation	Was data saturation discussed?	6
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	6
Domain 3: analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	6
25. Description of the coding tree	Did authors provide a description of the coding tree?	6
26. Derivation of themes	Were themes identified in advance or derived from the data?	6
27. Software	What software, if applicable, was used to manage the data?	6
28. Participant checking	Did participants provide feedback on the findings?	6
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant #	7-9
30. Data and findings consistent	Was there consistency between the data presented and the findings?	7-9
31. Clarity of major themes	Were major themes clearly presented in the findings?	7-9
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	7-9

Appendix 3. The 'wait and see' pamphlet.

THE UNIVERSITY OF QUEENSLAND
AUSTRALIA

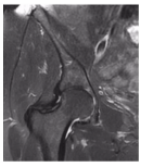
SIRPH Research Unit
School of Health & Rehabilitation Sciences

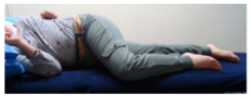
Gluteal Tendinopathy

What is it?

Gluteal tendinopathy is pain that originates at the side of the hip, over the bony prominence called the greater trochanter. The main area of pain will occur around this bone, but commonly extends down the side of the thigh, and even into the top of the lower leg, below the knee. Pain may also extend a way forward into the groin, or back into the buttock.

The condition has historically been diagnosed as 'trochanteric bursitis', however recently researchers have shown there to be problems of cells, collagen tissue and small blood vessels in the tendons of the buttock muscles - gluteus medius and minimus.





It is often worse at night lying on either side, and may be aggravated by walking, particularly uphills and stairs, standing on one leg to dress, prolonged sitting, and there is often some pain and stiffness for the first few steps after rising to stand.

Why do I have it?

Tendon health depends on the loads they bear on a regular basis, and either too much or too little loading can be problematic. For example, an athlete may overload the tendon and end up with tendon problems, whereas those who are not physically active may well suffer gradual tendon deterioration.

Either way the tendon health suffers and eventually pain is experienced when the weakened tendon is exposed to a range of possible factors, such as a rapid increase in loading that might occur with suddenly increasing training loads, or even taking up walking, particularly up hills and stairs, or with a slip or fall directly landing on the side of the hip.

Sometimes you may not be able to put your finger on a single factor as it might have occurred as a result of an accumulation of a number of small things, for example a gradual increase in weight over time and a reduction in general fitness.

What can I do?

Rest does not cure tendinopathy, but exercising to the point of feeling pain in the tendon is also not helpful, so keeping up a walking programme that does not aggravate your pain will be worthwhile.

Walk on the flat, avoid hills and keep stairs to a minimum until your pain settles. Start with 10 minutes of walking and as your pain improves gradually increase your activity levels.

Applying heat to the hip and buttock can also provide relief.

Consolidated criteria for reporting qualitative research (COREQ) checklist.

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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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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 groups 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: Semi-structured 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; (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.

Key words: Qualitative Research, Lateral Hip Pain, Hip Injuries, Exercise Therapy.

Article Summary

Strengths and limitations of this study

- Four different researchers that were not involved in the previous trial carried out the interviews.
- All interviewers were trained by an experienced qualitative researcher.
- The use of semi structured 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%) that completed the wait and see approach in the randomized 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 United Kingdom.[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 (the 'LEAP' trial).[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 (e.g., 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 semi-structured 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 Appendix 1). As such the methodology is grounded in constructivism which considers reality to be affected by people's experiences and thoughts. Ethics was obtained from the University of Queensland Human Research Ethics Committee (HREC #2018001471) and all participants provided informed consent. The study adheres to the consolidated criteria for reporting qualitative research (COREQ) checklist to confirm rigour (see 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 Magnetic Resonance Imaging (MRI).[7] At baseline, 69 participants were randomly allocated to the wait and see approach. The wait and see approach consisted of one half 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 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 interview15 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 (KF, LL, JM, CP) who were undertaking a speciality Master of Physiotherapy (Sports) program 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 semi-structured interviews to ensure quality of interviews. There were no prior relationships between interviewers and interviewees. Interviewers followed a priori developed, semi-structured guide to questions and prompts in order to elicit the participant's perceptions about the wait and see approach (see Appendix 1). Interview duration was on average 20 (range 12-40) minutes, 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 upon 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 randomized clinical trial. Two members of the research team (RM, BV) lead the original clinical trial. None of the other authors, including the interviewers, were involved in the original clinical trial (MP, JS, KF, LL, JM, CM). 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 de-identified 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 (e.g., 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

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 "w*ait 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 randomized 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, RM), however none of the interviewers had been involved in this trial nor had MP 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 upon 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 minimize discrepancies in the naming and content. It is also possible that there was divergence amongst 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 – i.e., what is it, why do I have it and what can I do (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) º– 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, whilst 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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REFERENCES

1. Albers, I.S., et al., *Incidence and prevalence of lower extremity tendinopathy in a Dutch general practice population: a cross sectional study.* BMC Musculoskelet Disord, 2016. **17**:16. doi:10.1186/s12891-016-0885-2.
2. Segal, N.A., et al., *Greater trochanteric pain syndrome: epidemiology and associated factors.* Arch Phys Med Rehabil, 2007. **88**(8):988-92. doi:10.1016/j.apmr.2007.04.014.
3. Ganderton, C., et al., *Gluteal Loading Versus Sham Exercises to Improve Pain and Dysfunction in Postmenopausal Women with Greater Trochanteric Pain Syndrome: A Randomized Controlled Trial.* J Womens Health (Larchmt), 2018. **27**(6):815-829. doi:10.1089/jwh.2017.6729.
4. Mellor, R., et al., *Education plus exercise versus corticosteroid injection use versus a wait and see approach on global outcome and pain from gluteal tendinopathy: prospective, single blinded, randomised clinical trial.* BMJ, 2018. **361**:k1662. doi:10.1136/bmj.k1662.
5. Barratt, P.A., N. Brookes, and A. Newson, *Conservative treatments for greater trochanteric pain syndrome: a systematic review.* Br J Sports Med, 2017. **51**(2):97-104. doi:10.1136/bjsports-2015-095858.
6. Stephens, G., et al., *A survey of physiotherapy practice (2018) in the United Kingdom for patients with greater trochanteric pain syndrome.* Musculoskelet Sci Pract, 2019. **40**:10-20. doi:10.1016/j.msksp.2019.01.004.
7. Mellor, R., et al., *Exercise and load modification versus corticosteroid injection versus 'wait and see' for persistent gluteus medius/minimus tendinopathy (the LEAP trial): a protocol for a randomised clinical trial.* BMC Musculoskelet Disord, 2016. **17**:1-17. doi:10.1186/s12891-016-1043-6.
8. Mann, H. and B. Djulbegovic, *Choosing a control intervention for a randomised clinical trial.* 3, 2003(7):1-5.
9. Braun, V. and V. Clarke, *Successful Qualitative Research.* . 2013, London, UK: Sage.
10. Tong, A., P. Sainsbury, and J. Craig, *Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups.* International journal for quality in health care, 2007. **19**(6):349-357.
11. Braun, V. and V. Clarke, *Using thematic analysis in psychology.* Qualitative Research in Psychology, 2006. **3**(2):77-101. doi:10.1191/1478088706qp063oa.
12. Miles, M.B., A.M. Huberman, and J. Saldana, *Qualitative data analysis*. 2013: Sage.
13. McPherson, K. and A. Britton, *Preferences and understnain their effects on health.* Quality in Health Care, 2001. **10**:i61-i66.
14. Sharma, S., et al., *Clinician and patient beliefs about diagnostic imaging for low back pain: a systematic qualitative evidence synthesis.* BMJ Open, 2020. **10**(8):e037820. doi:10.1136/bmjopen-2020-037820.
15. Stephens, G., et al., *"It's just like a needle going into my hip, basically all of the time". The experiences and perceptions of patients with Greater Trochanteric Pain syndrome in the UK National Health Service.* Musculoskeletal Science and Practice, 2020. doi:10.1016/j.msksp.2020.102175.

Appendix 1. Guide for semi-structured interviews

GENERAL INTRODUCTION

Thank you and welcome. My name is _____ and I am currently finishing my Masters of Sports Physiotherapy and I am conducting research on behalf of the University of Queensland.

I am interested in hearing your perspectives on the W&S approach now that you have completed the LEAP trial.

Positive, negative or neutral responses are welcome. There are no right or wrong answers, and it's ok to go off track as we would like to know as much information as possible.

Please let me know if you need a break or want to stop the interview at any time. If you do not wish to answer any questions, feel free to decline and we will move on.

Finally, do I have your permission to record this interview?

EXPECTATIONS OF A WAIT AND SEE INTERVENTION

- How would you describe your thoughts when you first read and heard about the W&S intervention?
- How would you now feel if you were recommended a W&S intervention when visiting a physiotherapist or GP?
- Would you now recommend this intervention to a friend? If so/if not, why? Not sure if we need this question? Just a thought.

INFORMATION PROVIDED IN THE WAIT AND SEE INTERVENTION

- Can you tell me in your own words what kind of information was provided in the wait and see intervention?
- The results from the trial that you were a part of found that more than 50% of the participants were at least moderately to very much better one year after starting the trial. What are your thoughts on this?

ADHERANCE TO THE WAIT AND SEE INTERVENTION

- In terms of adhering to the W&S intervention, how did you find it?
- Could you describe what was easy about sticking to the W&S intervention?

- Was there anything you found challenging?
- In your own words, how effective was the W&S intervention for you?

INVOLVEMENT IN OTHER TREATMENTS

- Have you had any other treatments for your hip pain before?
- If so, how did they compare to the W&S approach?
- Did you feel like you had to seek other treatments for your hip pain? If so, why?
- Now that you have experienced the wait and see approach, would you seek out other treatment if it was recommended by a physiotherapist or GP? If so, why?
- How would you go about seeking out any other treatments after being recommended wait and see?
- How would you feel about needing to seek other treatments after being recommended a wait and see approach?

SUMMARY

Just to summarise, could you put in 3 simple bullet points what you felt were the important features of the wait and see approach for you?

Appendix 2. Consolidated criteria for reporting qualitative research (COREQ) checklist.

No. Item	Guide questions/description	Reported on Page #
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Inter viewer/facilitator	Which author/s conducted the interview or focus group?	6
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	6
3. Occupation	What was their occupation at the time of the study?	6
4. Gender	Was the researcher male or female?	6
5. Experience and training	What experience or training did the researcher have?	6
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	6
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	6, Appendix 1
8. Interviewer characteristics	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	6, Appendix 1
Domain 2: study design		
Theoretical framework		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	6
Participant selection		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	4
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	5
12. Sample size	How many participants were in the study?	5
13. Non-participation	How many people refused to participate or dropped out? Reasons?	5
Setting		

14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	6
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	6
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	7
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	5, Appendix 1
18. Repeat interviews	Were repeat inter views carried out? If yes, how many?	6
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	6
20. Field notes	Were field notes made during and/or after the inter view or focus group?	6
21. Duration	What was the duration of the inter views or focus group?	6
22. Data saturation	Was data saturation discussed?	6
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	6
Domain 3: analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	6
25. Description of the coding tree	Did authors provide a description of the coding tree?	6
26. Derivation of themes	Were themes identified in advance or derived from the data?	6
27. Software	What software, if applicable, was used to manage the data?	6
28. Participant checking	Did participants provide feedback on the findings?	6
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant #	7-9
30. Data and findings consistent	Was there consistency between the data presented and the findings?	7-9
31. Clarity of major themes	Were major themes clearly presented in the findings?	7-9
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	7-9

Appendix 3. The 'wait and see' pamphlet.

THE UNIVERSITY OF QUEENSLAND
AUSTRALIA

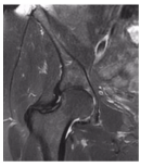
SIRPH Research Unit
School of Health & Rehabilitation Sciences

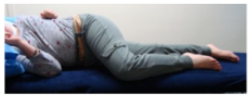
Gluteal Tendinopathy

What is it?

Gluteal tendinopathy is pain that originates at the side of the hip, over the bony prominence called the greater trochanter. The main area of pain will occur around this bone, but commonly extends down the side of the thigh, and even into the top of the lower leg, below the knee. Pain may also extend a way forward into the groin, or back into the buttock.

The condition has historically been diagnosed as 'trochanteric bursitis', however recently researchers have shown there to be problems of cells, collagen tissue and small blood vessels in the tendons of the buttock muscles - gluteus medius and minimus.





It is often worse at night lying on either side, and may be aggravated by walking, particularly uphills and stairs, standing on one leg to dress, prolonged sitting, and there is often some pain and stiffness for the first few steps after rising to stand.

Why do I have it?

Tendon health depends on the loads they bear on a regular basis, and either too much or too little loading can be problematic. For example, an athlete may overload the tendon and end up with tendon problems, whereas those who are not physically active may well suffer gradual tendon deterioration.

Either way the tendon health suffers and eventually pain is experienced when the weakened tendon is exposed to a range of possible factors, such as a rapid increase in loading that might occur with suddenly increasing training loads, or even taking up walking, particularly up hills and stairs, or with a slip or fall directly landing on the side of the hip.

Sometimes you may not be able to put your finger on a single factor as it might have occurred as a result of an accumulation of a number of small things, for example a gradual increase in weight over time and a reduction in general fitness.

What can I do?

Rest does not cure tendinopathy, but exercising to the point of feeling pain in the tendon is also not helpful, so keeping up a walking programme that does not aggravate your pain will be worthwhile.

Walk on the flat, avoid hills and keep stairs to a minimum until your pain settles. Start with 10 minutes of walking and as your pain improves gradually increase your activity levels.

Applying heat to the hip and buttock can also provide relief.

Consolidated criteria for reporting qualitative research (COREQ) checklist.

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Theoretical framework		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	6
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Domain 3: analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	6
25. Description of the coding tree	Did authors provide a description of the coding tree?	6
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