Clinicians' perspectives on planned interventions tested in the Otago MASTER feasibility trial: an implementation-based process evaluation study

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ABSTRACT

OBJECTIVES This study reports a process evaluation of the Otago MASTER (MANagement of Subacromial disorders of The shoulder) feasibility trial. This mixed-methods process evaluation study was conducted parallel to the Otago MASTER feasibility trial. Our aims were to investigate: (1) supervised treatment fidelity of the interventions and (2) clinicians' perceptions of the trial interventions through a focus group.

DESIGN Nested process evaluation study using a mixed-methods approach.

SETTING Outpatient clinic.

Participants Five clinicians (two men, three women) aged 47–67 years, with clinical experience of 18–43 years and a minimum of postgraduate certificate training, were involved with the delivery of interventions within the feasibility trial. We assessed treatment fidelity for supervised exercises through audit of clinicians' records and compared those with the planned protocol. Clinicians took part in a focus group that lasted for approximately 1 hour. The focus group was transcribed verbatim and group discussion was analysed thematically using an iterative approach.

RESULTS The fidelity score for the tailored exercise and manual therapy intervention was 80.3% (SD: 7.7%) and for the standardised exercise intervention, 82.9% (SD: 5.9%). Clinicians' perspectives about the trial and planned intervention were summarised by one main theme 'conflict experienced by individual clinical practice and the intervention protocol', which was supported by three subthemes: (1) programme strengths and weaknesses; (2) design-related and administrative barriers; and (3) training-related barriers.

CONCLUSION This mixed-methods study assessed supervised treatment fidelity of interventions and clinicians' perceptions on planned interventions tested in the Otago MASTER feasibility trial. Overall, treatment fidelity was acceptable for both intervention arms; however, we observed low fidelity for certain domains within the tailored exercise and manual therapy intervention. Our focus group identified several barriers clinicians faced while delivering the planned interventions. Those findings are of relevance for planning the definite trial and for researchers conducting feasibility trials.

TRIAL registration number ANZCTR: 12617001405303.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ We performed a detailed audit of clinicians' notes during the trial.
⇒ We conducted an implementation-based process evaluation study at a feasibility stage, which adds significant value to the planning of the future full trial.
⇒ We adopted an active monitoring of implementation of the trial and were able to correct any deviation of the protocol during the trial.
⇒ We conducted one focus group with clinicians and that increases the possibility of a false consensus due to some participants dominating the discussion.

INTRODUCTION

This paper expands the analysis that was conducted and reported in the MANagement of Subacromial disorders of The shoulder (MASTER) feasibility trial. The Otago MASTER trial recruited 28 participants and allocated them into one of the following interventions: tailored exercise and manual therapy or standardised exercise interventions. A total of five clinicians delivered the interventions. Both interventions consisted of 16 sessions, delivered as two sessions per week over 8 weeks. Each session lasted for approximately 45 min. Outcome measures were taken at baseline, 4, 8 and 12 weeks. One important characteristic of interventions planned for the MASTER trial was the high dose of interventions.

Physiotherapy interventions (eg, exercise, manual therapy, advice and education) are considered as the first line of treatment with patients who have shoulder pain. There is limited evidence supporting exercise therapy as an effective intervention for improving pain and function in patients with shoulder pain. Trials with low risk of bias showed no difference between progressive exercise and best practice advice, or between exercise...
and manual therapy when compared with detuned ultrasound.\textsuperscript{5} One common characteristic between those two trials\textsuperscript{4 5} is the relatively low prescribed dose of exercise therapy interventions, with a significant reliance on patients performing home-based exercises. Currently, there is a debate on the ideal or minimum dose of exercise therapy for this group of patients as well as which type of exercise shoulder be prescribed for patients with shoulder pain.\textsuperscript{6}

Clinical trials are considered the gold standard for determining whether an intervention is effective for improving clinical outcomes. However, outcome evaluation studies provide little information about ‘why’ an intervention may have worked or not.\textsuperscript{7 8} Process evaluation studies examine how an intervention was implemented during the trial, by assessing the contextual factors within which the intervention was delivered, and by assessing the mechanisms of impact of that intervention.\textsuperscript{8} Process evaluation studies inform ‘which, how and why’ complex interventions are effective (or not) and provide valuable information for clinicians, researchers and policymakers.\textsuperscript{8}

The Otago MASTER feasibility trial had several explanatory design characteristics (eg, a planned intervention, limited flexibility for adapting it, single-centred trial)\textsuperscript{9} and those may impact on the implementation of planned interventions within the trial. Ideally, process evaluation studies should be assessed in parallel to outcome evaluations at all stages of clinical trials, including feasibility and pilot studies.\textsuperscript{8} This study reports a process evaluation of the Otago MASTER feasibility trial. This mixed-methods, process evaluation study aimed to investigate: (1) supervised treatment fidelity of the interventions and (2) clinicians’ perceptions of the trial interventions through a focus group.

**METHODS**

**Design**

This is a nested process evaluation study using mixed-methods, triangulation design,\textsuperscript{10} with purposive sampling conducted parallel to the Otago MASTER feasibility trial. We adopted the triangulation design to ensure we obtained complementary data regarding the implementation of interventions within the trial.\textsuperscript{10} Details of the trial (registration number: ANZCTR: 12617001405303) have been published elsewhere.\textsuperscript{11} This paper reports results and findings from the nested process evaluation study.

**Patient and public involvement**

Patients or members of the public were not involved in the design or conduct of this study.

**Participants**

Participants were recruited by email. Five clinicians (two men, three women) aged 47–67 years, with clinical experience of 18–43 years and a minimum of postgraduate certificate training, were involved with the delivery of interventions within the feasibility trial and took part in the focus group. All clinicians delivering the interventions within the feasibility trial agreed to take part in this study.

**Supervised treatment fidelity**

We assessed treatment fidelity for supervised exercises. To assess treatment fidelity, we audited and categorised the clinicians’ records on a weekly basis and compared those with the planned protocol. The audit was performed by the trial coordinator to ensure consistency throughout the trial. We adopted an active monitoring of treatment fidelity during the trial\textsuperscript{8} and met with clinicians to clarify doubts about the protocol or we sent messages to clinicians to remind them to follow the protocol. The decision on whether to meet or send message was based on how complex the deviation from the protocol was. If perceived as complex by the trial coordinator, the trial coordinator met with the clinician. If simple, the trial coordinator communicated by email or by posting a message on a participant’s folder.

Treatment fidelity was analysed by identifying key domains within the planned intervention protocol. We evaluated whether each domain was delivered according to the planned protocol. Given that each intervention arm had different active elements in it, we assessed treatment fidelity for each intervention arm separately. Details on domains for each intervention arm are presented in tables 1 and 2.

When assessing supervised treatment fidelity, we used a dichotomous scoring system: yes (1 point) or no (0 point). We calculated the overall treatment fidelity score and its SD for each intervention (ie, tailored exercise and manual therapy and standardised exercise) separately. We considered the number of sessions attended by participants. This was calculated for each participant across all their treatment sessions and then averaged across all participants within each intervention arm. Not applicable items were accounted for by adjusting the denominator (ie, the item was not considered when calculating the total number of items). Treatment fidelity scores were expressed as a percentage of the total possible score, given the total number of sessions attended by the participant.

To gain a better understanding of treatment fidelity, we also calculated the treatment fidelity score for domains within each intervention arm. That allowed us to identify whether certain aspects of the protocol were more commonly changed or adapted by clinicians. For the purposes of this study, we used the following criteria for interpreting fidelity scores: (1) excellent fidelity: greater than 90%; (2) acceptable fidelity: between 89% and 75%; (3) low fidelity <74%.

**Clinicians’ perceptions on planned interventions**

A qualitative descriptive approach\textsuperscript{12 13} was used to explore clinician perspective about the planned intervention. Clinicians were recruited from the MASTER feasibility trial through email by the trial coordinator. All provided signed consent to participate. A focus group was organised at a mutually suitable time with...
Table 1  Treatment fidelity: intervention domains for tailored exercise and manual therapy delivered with supervision of a clinician, as per Otago MASTER feasibility trial protocol

<table>
<thead>
<tr>
<th>Domain</th>
<th>Criteria</th>
<th>Score allocation</th>
<th>Total possible score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exercise</td>
<td>Eight exercises based on the initial assessment correctly included. MWM included if physical assessment showed improvement when MWM was applied. MWM was counted as one of the eight possible exercises.</td>
<td>1 point for each exercise that was correctly prescribed.</td>
<td>8</td>
</tr>
<tr>
<td>Exercise dose</td>
<td>Isometric exercises should be performed as 2 sets, 10 repetitions, with 10 s hold each repetition. Dynamic strengthening exercises should be performed as 2 sets, 10 repetitions. MWM should be performed as 3 sets, 10 repetitions, 30 s rest between each set.</td>
<td>1 point allocated if exercise sets and repetitions were correct.</td>
<td>8</td>
</tr>
<tr>
<td>Exercise intensity</td>
<td>Initially, the motor control exercise should be performed with a low intensity. This could progress to moderate and after high intensity. Strength exercise intensity was defined as follows: low intensity (3–4 RPE), moderate intensity (5–6 RPE), high intensity (7–8 RPE).</td>
<td>1 point allocated if intensity of exercise was correct</td>
<td>8</td>
</tr>
<tr>
<td>Exercise variation</td>
<td>Clinicians could vary five exercises of the previously prescribed exercises. Performed with the correct number of sets and repetitions. Performed with the correct intensity.</td>
<td>1 point allocated if variation of exercise was correctly prescribed. Not always applicable.</td>
<td>Max 5*</td>
</tr>
<tr>
<td>Exercise progression</td>
<td>Clinicians could increase either sets and repetitions or exercise intensity if participants could perform exercise in two consecutive sessions. Progression of isometric exercises followed in two stages: (1) 3 sets, 10 repetitions, 10 s hold each repetition; (2) 3 sets, 10 repetitions, 20 s hold each repetition. Progression of dynamic strengthening exercise followed in two stages: (1) 3 sets, 10 repetitions; (2) 3 sets, 20 repetitions. Progression of intensity to (1) moderate intensity (5–6 RPE); (2) high intensity (7–8 RPE).</td>
<td>1 point allocated if progression of exercise was correctly prescribed. Not always applicable.</td>
<td>Max 8*</td>
</tr>
<tr>
<td>MT technique included</td>
<td>Three optional MT technique, if required, one for cervical spine, one for thoracic spine or one for shoulder based on physical assessment findings. MT could be passive joint mobilisations for cervical spine, thoracic spine or shoulder. MT could be HVT for cervical spine or thoracic spine. Clinician decided which technique to perform. Only one technique per joint was allowed.</td>
<td>1 point allocated if the MT technique was included as per protocol. Not always applicable.</td>
<td>Max 3*</td>
</tr>
<tr>
<td>MT dose</td>
<td>If pain was dominant in the physical assessment: 3 sets, 30 s duration, grade −III or −IV. If stiffness was dominant in the physical assessment: 3 sets, 30 s duration, grade +III or +IV. HVT should be performed once a session, if required per physical assessment. No points were given if level or dose was not recorded.</td>
<td>1 point allocated if the dose of MT technique was included as per protocol. Not always applicable.</td>
<td>Max 3*</td>
</tr>
</tbody>
</table>

*Not always applicable.
HVT, high-velocity manipulation technique; MASTER, MANagement of Subacromial disorders of The shoulder; Max, maximum; MT, manual therapy; MWM, mobilisation with movement; RPE, 10-point Rate of Perceived Exertion Scale.

one researcher not involved with the trial undertaking the interview. The focus group was conducted in a room within the School of Physiotherapy building. Table 3 provides the focus group questions. The interview was not piloted nor repeated. Five clinicians (two men, three women) aged 47–67 years, with 18–43 years of clinical experience and a minimum of post-graduate certificate training were involved with the delivery of interventions within the feasibility trial and took part in a focus group. These five clinicians were
Table 2  Treatment fidelity: detailed description of intervention domains for the standardised exercise intervention delivered with supervision of a clinician, as per Otago MASTER feasibility trial protocol11

<table>
<thead>
<tr>
<th>Domain</th>
<th>Criteria</th>
<th>Score allocation</th>
<th>Total possible score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exercise</td>
<td>Eight strengthening exercises correctly included. Three stretching exercises: one for the cervical spine, one for the thoracic spine and one for the shoulder correctly included.</td>
<td>1 point allocated for each exercise that was correctly prescribed.</td>
<td>11</td>
</tr>
<tr>
<td>Exercise dose</td>
<td>Strengthening exercise should be performed as 2 sets, 10 repetitions. Stretching exercise either 2 sets, 10 s hold; or 2 sets, 20 s hold.</td>
<td>1 point allocated if exercise sets and repetitions were correct.</td>
<td>11</td>
</tr>
<tr>
<td>Exercise intensity</td>
<td>Initially, the strengthening exercises should be performed with a low intensity (3–4 RPE). These could progress to moderate and after high intensity. Strengthening exercise intensity was defined as follows: low intensity (3–4 RPE), moderate intensity (5–6 RPE), high intensity (7–8 RPE).</td>
<td>1 point allocated if intensity of exercise was correct.</td>
<td>8 (This item was applicable to the 8 strengthening exercises and not applicable to stretching exercises)</td>
</tr>
<tr>
<td>Exercise variation</td>
<td>Clinicians were allowed to vary five strengthening exercises to the previous prescribed exercises. Performed with the correct number of sets and repetitions. Performed with the correct intensity.</td>
<td>1 point allocated if variation of exercise was correctly prescribed. Not always applicable.</td>
<td>Max 5*</td>
</tr>
<tr>
<td>Exercise progression</td>
<td>Progression of strengthening exercises followed in three stages: (1) 3 sets, 10 repetitions; (2) 3 sets, 20 repetitions; (3) clinician can either increase the intensity to moderate or replace the exercise. Progression of intensity to (1) moderate intensity (5–6 RPE); (2) high intensity (7–8 RPE).</td>
<td>1 point allocated if progression of exercise was correctly prescribed. Not always applicable.</td>
<td>Max 8*</td>
</tr>
</tbody>
</table>

*Not always applicable.

MASTER, MAnagement of Subacromial disorders of The shoulder; Max, maximum; RPE, 10-point Rate of Perceived Exertion Scale.

RESULTS

Supervised treatment fidelity

The overall average scores of supervised treatment fidelity per domain in the tailored exercise and manual therapy intervention and the standardised exercise intervention are presented in table 4, respectively. The fidelity scores were acceptable for both intervention arms (tailored exercise and manual therapy intervention: 80.3%, SD: data saturation of qualities of the resulting groupings noted.15 16 Groups were reviewed and subthemes and themes identified and named, summarising the experiences of the clinicians about delivering the intervention.

While we did not return transcripts to participants for feedback, rigour of the study has been enhanced through rapport developed during interviews and the clinician’s willingness to discuss the topic of interest (credibility), summarisation of clinician demographics and inclusion of direct quotes to support the themes (confirmability), purposeful sampling and provision of clear outline of the study’s processes (transferability).12 The Consolidated Criteria for Reporting Qualitative Research guided reporting of this study.17

responsible for delivering 100% of interventions in the trial. The focus group lasted approximately 1 hour and was audio taped with permission of the group. The focus group was transcribed verbatim. A male research officer (DJ), with 15 years of experience with clinical research, who was known to clinicians and not involved with the data analyses, and experienced with qualitative research, conducted the focus group. No information about the researchers’ bias and assumptions in the research topic was provided to clinicians.

Clinicians were aware of the research question of the feasibility trial and the rationale for conducting such study.

Data obtained from the focus group discussion were analysed thematically using an iterative and inductive approach.14 One of the team members (AW), with experience in qualitative analysis, worked together with another team member (DCR) to analyse the data. DCR is the principal investigator with clinical experience on shoulder rehabilitation and clinical research. Both analysts were involved with all steps of data analyses.

Transcripts were read independently, and codes, representing what clinicians said (quotes) that answered the research question, were jotted in the margins. Codes and their linked quotes were then collated, and read and reread, refined, discussed, and combined, with
Within the tailored exercise and manual therapy intervention, the supervised treatment fidelity scores per domain ranged from low (38.5%, SD: 32.9%) to excellent (98.2%, SD: 2.8%); within the standardised exercise intervention, supervised treatment fidelity scores per domain ranged from acceptable (77.1%, SD: 29.2%) to excellent (96.6%, SD: 6.4%). In the tailored exercise and manual therapy intervention, the two domains with the lowest scores were ‘manual therapy dose’ (38.5%, SD: 32.9%) and ‘exercise intensity’ (59.3%, SD: 22.03%); in the standardised exercise intervention, the two domains with lowest scores were ‘exercise intensity’ (77.1%, SD: 16.6%) and ‘exercise variation’ (77.1%, SD: 29.2%).

Clinicians’ perspectives about the planned interventions within the Otago MASTER trial

Clinicians’ perspectives about the trial and planned intervention were summarised by one main theme ‘conflict experienced between individual clinical practice and the intervention protocol’, which was supported by three subthemes: (1) programme strengths and weaknesses; (2) design-related and administrative barriers; and (3) training-related barriers. A summary of themes and subthemes is presented in online supplemental appendix 1.

### Table 3  Focus group topic guide

<table>
<thead>
<tr>
<th>Topic</th>
<th>Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>About the study</td>
<td>1. What were your expectations and initial views on the study?</td>
</tr>
<tr>
<td></td>
<td>2. In your opinion, what are the strengths of the tailored exercise and manual therapy intervention?</td>
</tr>
<tr>
<td></td>
<td>3. In your opinion, what are the strengths of the standardised exercise intervention?</td>
</tr>
<tr>
<td></td>
<td>4. In your opinion, what are the weaknesses of the tailored exercise and manual therapy intervention?</td>
</tr>
<tr>
<td></td>
<td>5. In your opinion, what are the weaknesses of the standardised exercise intervention?</td>
</tr>
<tr>
<td></td>
<td>6. How does the care you were providing for the standardised intervention compare with your usual practice?</td>
</tr>
<tr>
<td></td>
<td>7. How does the care you were providing for the tailored intervention compare with your usual practice?</td>
</tr>
<tr>
<td></td>
<td>8. How would you say the preparation/training beforehand went? Could it have been facilitated any other way for you to better deliver the planned interventions?</td>
</tr>
<tr>
<td></td>
<td>9. How did you find the strategies that we used (i.e., verbal feedback, short meetings and written notes as part of fidelity assessment) to help you follow the planned interventions?</td>
</tr>
<tr>
<td></td>
<td>10. What are your thoughts about the forms and resources used in the study (e.g., assessment forms, exercise forms, patient logbook, RPE)?</td>
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<tr>
<td></td>
<td>11. What are your thoughts about the criteria for progressing with exercises?</td>
</tr>
<tr>
<td></td>
<td>12. What are your thoughts about the duration and frequency of the sessions?</td>
</tr>
<tr>
<td>About a future fully powered RCT and future clinical practice</td>
<td>1. In your opinion, what were the barriers for you as a clinician to take part in the study?</td>
</tr>
<tr>
<td></td>
<td>2. In your opinion, what were the facilitators for you as a clinician to take part in the study?</td>
</tr>
<tr>
<td></td>
<td>3. In your opinion, are there resources that would be useful for minimising barriers for you to deliver the interventions planned as part of the study?</td>
</tr>
<tr>
<td></td>
<td>4. What sorts of resources would be useful for minimising barriers for you to deliver the interventions planned as part of the study?</td>
</tr>
<tr>
<td></td>
<td>5. In your opinion, what changes should be made to the tailored intervention? Why?</td>
</tr>
<tr>
<td></td>
<td>6. In your opinion, what changes should be made to the standardised exercise intervention? Why?</td>
</tr>
<tr>
<td></td>
<td>7. In your opinion, are there any other changes that might need to be made in terms of training, resources or design of intervention?</td>
</tr>
<tr>
<td></td>
<td>8. Do you have any other issues, concerns or suggestions regarding the study, resources or the design of interventions?</td>
</tr>
</tbody>
</table>

RCT, randomised controlled trial; RPE, 10-point Rate of Perceived Exertion Scale.

### Table 4  Supervised treatment fidelity scores (%) per domain for each intervention arm (mean and SD)

<table>
<thead>
<tr>
<th>Group</th>
<th>Exercise</th>
<th>Exercise dose</th>
<th>Exercise intensity</th>
<th>Exercise variation</th>
<th>Exercise progression</th>
<th>MT included</th>
<th>MT dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tailored exercise and manual therapy</td>
<td>98.2 (2.8)</td>
<td>80.8 (11.8)</td>
<td>59.3 (22.0)</td>
<td>93.7 (7.4)</td>
<td>85.2 (24.1)</td>
<td>73 (27.5)</td>
<td>MT included</td>
</tr>
<tr>
<td>Standardised exercise</td>
<td>96.6 (6.4)</td>
<td>84.9 (8.2)</td>
<td>77.1 (16.6)</td>
<td>77.1 (29.2)</td>
<td>90.8 (9.7)</td>
<td>N.A.</td>
<td>MT dose: N.A., not applicable.</td>
</tr>
</tbody>
</table>

MT, manual therapy; N.A., not applicable.
Programme strengths and weaknesses

Clinicians thought exercises included on intervention arms were good but had different perceptions for each intervention arm in the trial. In the tailored exercise and manual therapy intervention, they perceived certain exercises as good and appropriate for patients, and the inclusion of manual therapy techniques as well as perceived by some clinicians.

I would actually probably use a bunch of those exercises clinically with my patients ‘cause I think they were reasonably good. The difference would be as we’ve said is the progression probably wouldn’t be occurring that quickly…. But I think there were some good exercises available in the tailored group. (Clinician 3)

Well, I quite like that you could actually do some manipulation and you can do some MWMs [Movement with Mobilization] so that was good, whereas the other one [standard programme] was just total exercise. (Clinician 4)

However, they had mixed perceptions about the standardised exercise group. Some considered that the standardised exercise intervention had better progression and diversity of exercises, thought the design of interventions was good and that the protocol was easier to follow when compared with the tailored group.

Yeah, the exercises [in the standardised exercise intervention] were quite easy to follow and progress, … they were very, and good balanced exercises… [The Standard group is easy, had a chat, had some laughs. They [patients] hit it off, the other one was, yeah definitely a lot harder to negotiate [i.e., to follow the protocol]. (Clinician 2)

I think you guys did a pretty good job on that, and I think just change that three lots of 20 and you’re pretty much, you’re almost there, or if not there. (Clinician 1—about the standardised exercise intervention)

One clinician thought the standardised programme was boring when compared with the tailored intervention.

Overall, it’s a simple basic programme but the problem was we all got a bit bored including the patient. (Clinician 2—about the standardised intervention)

Some clinicians thought the tailored intervention was not appropriate, with exercises that focused excessively on scapular muscle control or that the tailoring did not reflect clinical practice.

Too much scapular stuff [exercises], no extra, they’re generally exercises that we wouldn’t necessarily use. (Clinician 2—about the tailored intervention)

Tailored group is not completely up to what you would do in a clinic to say this is tailored. (Clinician 5—about the tailored intervention)

Participants considered that both intervention arms would form a good intervention programme if merged, with one arm focusing on the earlier stages and the other on the later stages of rehabilitation.

… It seems like you’re working one half of the rehab process with a patient, with one group and then the other half of the next group so if you brought the two together, yep I think you’ve got a pretty good package. (Clinician 1)

There were perceived weaknesses with the trial design. Clinicians experienced a conflict between what the trial protocol required and what they did in their own individual clinical practice. All participants suggested the protocol limited their clinical reasoning and their ability to individualise treatment.

I’m sorry but it didn’t use any of our skill or judgement. It used our ability to follow a set of prescriptive instructions and you don’t need to be at high level to do that, so it was quite boring. For a fourth year or new grad, then they’ll probably be a bit more motivated to do it. (Clinician 1)

Clinicians also considered the criteria for exercise prescription (volume and progression) to be a barrier.

[standardised programme] Oh the progression from three sets of ten to three sets of 20, it’s double the volume so that was a big oversight. (Clinician 1)

Yes I think it got hard quite quickly for some patients, progressing them to that amount that quickly. (Clinician 3)

Exercise intensity and mandated timed rest periods were not deemed appropriate with the long rest periods frustrating clinicians.

I think the intensity of the exercise the majority of the time wasn’t enough to justify an extended period of time for rest. (Clinician 1)

[The rest periods] quickly dropped off just because it got a bit tedious [for us both]. The patient’s sort of standing around [and saying] “oh can I do the next one yet?” “Is it time yet?” So, what you find yourself doing was actually progressing quickly through the set without following, sorry to say, the protocol precisely around the timing and the rest periods. (Clinician 3)

The number of exercises prescribed within a session (for both intervention arms) was a barrier, as the number of exercises did not reflect clinicians’ clinical practice or because they considered those exercises and their variations to be very similar.

We would never in a treatment give patients that many exercises to do as part of our management. There were just too many. (Clinician 4)

There’s anything between six to ten different exercises which were essentially the same exercises, but
they are labelled with a different number and in a different place [in the trial manual for clinicians].

(Clinician 2)

One clinician stated that one of their participants was unable to tolerate that volume of exercises and questioned why the trial was set up differently to what was offered in usual clinical practice.

For those who are struggling with their exercises, we would usually start with two sets of ten. [In this trial] in their home programme, they’re starting with three sets of ten! I had a couple of patients who couldn’t actually tolerate three sets of ten in their home programmes. So why would you have it different [from usual clinical practice]? (Clinician 2)

**Design-related and administrative barriers**

Clinicians considered the screening process was not correctly identifying the right participants for the trial and deemed the initial assessment of patients in the first session as an administrative barrier.

There were patients in the trial that didn’t really have shoulder injury pain. I had one who had a slap lesion and he should never have been in the trial. (Clinician 4)

There were quite a few [with] postural-related shoulder pain that were here [enrolled] or thoracic [that should not have been]. (Clinician 2)

The number of clinical assessments performed in the first day was deemed inappropriate.

I felt like there was a lot of tests, well not a lot, but some of the tests I probably wouldn’t use clinically. (Clinician 2)

Additionally, they argued that in usual clinical practice, a reassessment of a patient within a session is undertaken to ensure treatment achieves the expected clinical outcomes. This is usually done to confirm whether the patient symptoms improved immediately after the intervention. This is something that we did not include in our protocol.

Other than doing the simple pain scale, there wasn’t actually any reassessment of the patient. (Clinician 3)

...[you prescribe an exercise] and it comes back to retesting [to re-assess the patient and confirm they improved], the likes of being as simple as retesting a comparable sign after they’ve done an exercise. (Clinician 2)

Following feedback from clinicians prior to the start of the trial, and to reduce barriers for clinicians, the research team had adapted the protocol booklets to make those easier to follow.

... what happened was we had this, the 1, 2, 3 book and it went serially but in the beginning, [clinician’s name] suggested it’s easier if you group them exercises and so we had a different version [which made it easier for us to follow the protocol]. (Clinician 5)

Despite that, following the protocol was considered an administrative barrier for some clinicians who thought it was difficult to follow the trial protocol booklet.

I didn’t like how it [the book] was all out of order. I was forever flicking pages to find the [right] number of the jolly exercise. (Clinician 3)

In the end, I stopped using the book. I relied on memory; I committed the programme to memory because I couldn’t negotiate my way through the book. (Clinician 1)

Finally, clinicians felt there were too many forms to fill in.

The other thing is the filling in of the forms every single time. You had to re-write the exercise, you had to re-write the number of reps, you had to re-write that. (Clinician 2)

**Training-related barriers**

Clinicians reported that more practical hands-on training would have been beneficial. They suggested multiple dry runs of the protocol were needed because it took time to become familiar with the trial protocol and expectations.

Yeah, I think the practical application of the assessment probably needed to be done a bit more. Practiced [a lot more]. ... It’s hard because until you start doing it, you don’t realise what’s actually happening and what’s not there or there. ... So I think as it went on, I think we just all became increasingly frustrated because it wasn’t what we thought it was going to be and then it was just too late by then because we were in the middle of it. (Clinician 3)

But I think what it is was all on paper and we’re all like it all looks good on paper but when we actually got our hands dirty, it was like oh, geez what was that again? (Clinician 2)

**DISCUSSION**

This mixed-methods study assessed supervised treatment fidelity of interventions and clinicians’ perceptions on planned interventions (tailored and standardised) tested in the Otago MASTER feasibility trial. Overall, supervised treatment fidelity was low for some domains and our focus group identified several barriers clinicians faced while delivering the planned interventions. Our findings identified deviations from the protocol and barriers faced by clinicians when delivering the intervention. The protocol deviations and barriers are likely connected and, when planning the full trial, we will need to incorporate changes to the design of the trial to improve supervised treatment fidelity.
Supervised treatment fidelity

Overall, clinicians delivered interventions following most of the planned protocol. This is in part because the research team adopted an active monitoring of supervised treatment fidelity during the trial. During that process, the research team reminded clinicians of the protocol if a deviation from it was identified. If deviation was considered minor, the trial coordinator communicated with the relevant clinician by using two strategies: (1) attaching a written reminder to the participants’ folder and (2) sending a direct email to the clinician. If the deviation from the protocol was major, then the trial coordinator would meet with the clinician to clarify and explain the planned protocol.

Findings from supervised treatment fidelity are likely explained by barriers faced by clinicians when delivering the intervention. For example, the overall fidelity score for the standardised exercise intervention was higher than the tailored exercise and manual therapy intervention. The standardised exercise intervention adopted a ‘one-size-fits-all’ approach, while the tailored exercise and manual therapy group had interventions matching findings from clinical examination.

The criteria adopted within the tailored exercise and manual therapy intervention aimed to provide a framework for clinical reasoning for the purpose of this trial. However, it would seem from the results that those criteria did not necessarily reflect the clinicians’ usual way of reasoning and treating shoulder subacromial pain. There are different models of clinical reasoning, and this is a complex cognitive process that may be difficult to implement using a prescriptive approach. In addition, expert clinicians use hypothetico-deductive and a pattern recognition model in their practice. Hence, it is reasonable to expect them to face difficulties with following a structured method for assessing and managing patients with shoulder pain.

The low supervised treatment fidelity scores for ‘manual therapy dose’ and ‘exercise intensity’ domains within the tailored exercise and manual therapy group may be explained, in part, by the design, whereby the clinicians needed to follow specific criteria for implementing the tailored intervention. For example, exercises were prescribed only if there was evidence of muscle weakness during the examination, and additionally, there were set criteria for progressing exercises. Shoulder mobilisation was only to be applied if clinicians identified limited passive accessory mobility during examination. These criteria were adopted to replicate and standardise clinical reasoning; however, they imposed changes in the way clinicians practised.

Programme strengths and weaknesses

One key finding from our study was the conflict between clinicians’ individual practice and the intervention protocol. During training sessions, the research team explained the rationale for the study, consulted with clinicians and adapted part of the intervention planned based on feedback from clinicians. This was done to ensure clinicians were on board and understood the goals of the study. In addition, we only started the trial once clinicians agreed they felt comfortable with the protocol. Despite that, clinicians were uncomfortable with some aspects of the design of the trial and the way interventions were expected to be delivered.

Other studies have discussed and reported the challenges faced by clinicians when having to change their practice and follow a specific protocol or clinical practice guidelines. It is common for clinicians to perceive trials take away their professional autonomy, something we have identified in our study. Other studies have reported the inability to individualise treatment as a perceived barrier by clinicians. This message came through very strongly in our study.

Clinicians questioned some design characteristics of our feasibility trial. Previous studies highlighted the importance of providing training and education in research methods and trial design to clinicians involved in a trial. This is something we did not do when planning the feasibility trial and when training clinicians. In addition, it is recommended that researchers need to invest time to ‘sell’ the research project to improve clinicians’ engagement, understanding of the trial and the protocol requirements. We designed the feasibility trial prior to consulting with clinicians and amended some of its characteristics based on clinicians’ feedback. Not having the clinicians involved with the feasibility trial from inception potentially contributed to the concerns raised by the clinicians in the focus group.

Similar challenges may be encountered during large-scale implementation within healthcare services. To minimise such challenges, it is recommended that clinicians are involved from the inception of a study. It is possible that barriers reported by this sample of clinicians may have been accentuated by the extensive clinical experience these clinicians had. Over many years, clinicians develop and refine their own way of practice, to an extent that recent graduates may not have, and it may be challenging to change such practice.

Design-related and administrative barriers

Clinicians reported several design-related and administrative barriers (e.g., screening process, number of clinical assessments, numerous forms, reassessment of patients needed, booklet needs reorganisation). Clinicians considered the screening process needed revision. Clinicians’ disagreement with eligibility criteria has been raised by other studies as well. Within our study, this barrier is probably caused by a mismatch between evidence and clinical practice. Two clinicians reported treating participants whose diagnosis, they considered, was not shoulder subacromial pain. The challenge is that most clinical tests or imaging cannot confirm an anatomical structure as the cause of symptoms. Our screening process followed
the British Elbow and Shoulder Society (BESS) guidelines and has been adopted by other trials, in which the diagnosis of shoulder subacromial pain is based on exclusion of other shoulder disorders and symptoms characteristics. However, these criteria described by the BESS are not necessarily adopted by all clinicians. These findings highlight the importance of training and liaising with the clinicians throughout the trial to clarify uncertainties and rationale for study protocol.

Clinicians considered there were numerous assessments and forms to be completed. Administrative burden is a common barrier for clinicians taking part in clinical trials. Given this was an explanatory feasibility trial, we attempted to have detailed records of interventions delivered. This was done so we could monitor supervised treatment fidelity and amend any deviation from the protocol. The negative impact of this requirement was burnout of clinicians, who got frustrated with administrative requirements for the trial. To reduce burden on clinicians, when planning the definite trial, the research team should consider what are the key active elements of the intervention and focus on recording only those. That should reduce part of the administrative barriers.

**Training-related barriers**

All clinicians received training prior to getting involved with the trial. During the training sessions, clinicians confirmed to the research team they understood the plan and were ready to deliver the programme. During the trial, the research team offered ‘refresher sessions’ to clinicians, separate from other meetings for reminding clinicians about protocol deviations. The refresher sessions were offered particularly to those clinicians who were frequently deviating from the planned protocol. Those clinicians were identified on a weekly basis, by audits of clinicians’ notes.

Clinicians considered more training was required to deliver planned interventions. The training barrier identified was mainly related to clinicians’ ability to follow the protocol, rather than the practical techniques that were used. In our study, this barrier was caused by a misinterpretation by the principal investigator, who considered that experienced clinicians would not require practical training in addition to theoretical training sessions, given their extensive clinical experience. For that reason, we considered that practical training was not required in addition to going over the protocol ‘on paper’. In addition to that, clinicians in our feasibility trial verbally confirmed to have understood the protocol and agreed they were ready to start with the study. We did not assess clinicians’ competency for delivering the interventions. This finding indicates it would have been advantageous to have simulated interventions prior to starting the trial, to allow clinicians to practise the required steps within the protocols used. Other studies have found health practitioners need further training if they are required to change their clinical practice, when involved in a trial or when implementing a new programme of care. These findings suggest that even very experienced clinicians may need to actively practise an intervention prior to delivering it within a trial. This is particularly important for explanatory trials, where planned interventions may not reflect current practices.

**Limitations and strengths**

The limitation of this study was that we included only one focus group; we believe the participants freely spoke and were forthcoming with their opinions with regard to the interventions planned and delivered within the feasibility trial. One limitation of focus groups is the possibility of a false consensus. This tends to happen when one or few participants dominate the discussion, while others avoid informing, they disagree with what is being said. We did have few participants who tended to dominate the discussion. The moderator was an experienced researcher, who has been involved on numerous focus groups who tried to encourage contributions from all participants during data collection.

The strengths of this study were: (1) we performed a detailed audit of clinicians’ notes during the trial; (2) we conducted an implementation-based process evaluation study at a feasibility stage, which adds significant value to the planning of the future full trial; (3) we adopted an active monitoring of implementation of the trial; hence, we were able to correct any deviation of the protocol during the trial. That approach minimised protocol deviations. We plan to use an active monitoring of implementation when conducting the full trial. Another strength is that one of the researchers (AW) conducting the data analyses is not a physiotherapist and was not involved with the planning, design and implementation of the feasibility trial: this allowed us to have a robust process and discussion when analysing and interpreting the data, which we believe increases the credibility of our findings.

**Implications for future research**

This mixed-methods study identified programme strengths and weaknesses of planned interventions as well as barriers faced by clinicians when delivering interventions within a feasibility trial. These findings will inform the design of the definite trial. It is possible that barriers faced by clinicians in our study are like those experienced by clinicians delivering other trials with a similar mechanistic design. Researchers and trialists should bear in mind the balance between accurate recording, detailed prescription of interventions and overburden of clinicians.

**CONCLUSION**

Overall, supervised treatment fidelity of interventions was acceptable, with certain aspects of interventions presenting low supervised treatment fidelity. Clinicians’ perspectives about the trial can be summarised by one theme, that is, ‘conflict experienced between individual clinical practice and the intervention protocol’, which was supported by three subthemes: (1) programme strengths and weaknesses; (2) design-related and administrative...
barriers; and (3) training-related barriers. Findings from this study will inform the design of the definitive trial. Trialists and researchers need to adopt a collaborative and pragmatic approach when planning and designing trials to optimise planned interventions and minimise barriers when implementing the trial.

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Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

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Data availability statement Data are available upon reasonable request. We stored participants’ data on a secure local server and used unique identification number on follow-up questionnaires. To protect participants’ privacy, all identifying information will be stored separately and deleted following the conclusion of the trial. We will not share or report identifying information. The datasets generated during the study will be available from the corresponding author on reasonable request.

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