Author's response to reviews

Title: A comparison of isometric, isotonic concentric and isotonic eccentric exercises in the physiotherapy management of subacromial pain syndrome/rotator cuff tendinopathy: study protocol for a pilot randomised controlled trial.

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Author’s response to reviews:

Cindy Gray, PhD
Editorial Manager
Pilot and Feasibility Studies

10th June 2017

Dear Dr Gray,

Re:

PAFS-D-17-00006

Comparison of isotonic (concentric and eccentric) and isometric exercises in the treatment of patients diagnosed with rotator cuff tendinopathy/subacromial pain syndrome: feasibility study protocol for a randomised controlled trial.

Thank you for your email regarding the above manuscript and for your invitation to revise and resubmit to BMC Pilot and Feasibility Studies having addressed the reviewer’s comments.

We would like to thank the reviewers for their thorough examination of the manuscript and believe that in addressing their comments the manuscript is improved. A detailed response to each comment is outlined below. A tracked version of the main document has also been uploaded along with the other re-submission documents.

Responses to comments from Reviewer 1, Reviewer 2 and Chief Editor
REVIEWER 1

Abstract

A well-written abstract that contains the needed information to inform the reader about the intended pilot study, the main goals being (a) determining the feasibility of a future trial and (b) treatment effects.

The following are suggestions to improve the Abstract:

Comment 1

* Line 38: the authors state the study is to determine "feasibility" but it is unclear what "feasibility" is or how it is define. A sentence here on indeed how feasibility is measured/determined would be useful to inform the reader;

Response:

Thank you for this comment. The following text has been added in the background and aims section to further inform the reader:

“Various key parameters including ease of recruitment, suitability of the assessment algorithm, adherence to the exercise intervention including home based exercises, compliance with log-book completion, retention rates and, nature of adverse events will determine whether this study design can feasibly be undertaken as a full-scale RCT.”

Line 114-117.

Comment 2

* Line 41: the authors indicate that this pilot study will determine the "treatment effects". Pilot studies are not fully powered to determine treatment outcomes or effects, and inferential statistics should be used with great caution. I understand that the authors wish to explore possible outcomes, but should clearly understand the limitation of pilot studies and that one cannot draw definitive conclusions from pilot study outcomes. Rather state that the analysis will offer insights into possible outcomes and guide the design of future studies. A very useful reference to read related to this is:


Response:

Thank you for this comment and for providing these very informative references. The authors agree that this feasibility study is not powered to determine treatment effects. The text has been changed to reflect this:

“The secondary aim is to explore potential trends or treatment effects of the exercise intervention. The analysis may offer insights as to whether the isometric group achieves faster gains in pain, strength and therefore function compared to either of the other isotonic groups”.

Line 40-43.

Comment 3

* Line 44: the sample size of 36 is indicted. I assume that this sample size was estimated using some list of criteria, or was it arbitrary? Note that performing inferential statistics in a total sample size of 36 (12 per group over 3 groups) very unlikely to offer meaningful results, so the authors should consider outcomes with great caution and should not be the focus of this pilot study;

Response:

Thank you for this comment and for allowing us the opportunity to justify our sample size.

The power calculation for a full scale RCT was undertaken, based on a published trial:


in which an exercise intervention comparing a specific rotator cuff exercise strategy to control exercises was undertaken in a similar cohort of patients. The authors estimated that they needed 82 patients to detect a mean 10 point difference between two groups The standardised mean difference for an outcome measure that is common to both studies (visual analogue scale for night pain) was used to calculate the sample size for our study, with our calculations indicating a minimum of 30 patients would be required in each group for a full-scale RCT.

As our protocol is for a feasibility study, 30% of the estimation for the full RCT was considered to be appropriate. This 30% approximation was based on a trial that was previously published in BMC:


In order to assess the suitability of the various components of our study it is considered that an overall sample size of 36 participants will provide an opportunity to: estimate the
rate/proportion of eligible patients who are willing to participate from the recruiting sites; evaluate the number of participants who drop out and their reasons why, test out the assessment algorithm and, observe the ability of the participants to comply with their allocated intervention.

Further, since exercise has been well documented as a first line treatment in patients with this disorder, the authors do not feel that the small sample size breaches ethical conduct. All participants will be receiving a structured semi-individualised program, delivered by experienced clinicians. We anticipate that none of the groups will be disadvantaged compared to the standard care that such patients currently receive.

The text has been amended to clarify our sample size selection:

“Based on a previous study investigating the use of exercise in subacromial pain syndrome with an effect size of 0.66 and maintaining a power of 0.80, calculations indicate a minimum of 30 patients would be required in each group for a full-scale RCT. To determine the feasibility for a full-scale RCT, a sample of 36 across the three groups (12 per group) has been chosen. This is approximately 30% of the calculation for a full-scale RCT (Kemp et al, 2016), with an allowance for drop outs. It is anticipated that this sample-size will provide the opportunity to observe suitability of the assessment algorithm, compliance with the exercise intervention, including any adverse responses, and enable preliminary evaluation of outcome trends, while saving the costs associated with a full-scale trial”.

Line 134-142

As per our response to comment 2 above, the authors agree that the primary focus of this study is to determine feasibility and that any inferential statistics should be treated with caution.

Line 40-43

Comment 4

* Line 51: the authors state the outcome measures being used. It would be useful for the authors to divide the outcome measures into primary outcome measures and secondary outcome measures, based on the clinical importance or clinical relevance of each outcome measure. This pilot study would then focus on using the primary outcome measures to inform the design of a future study and the data from these primary outcome measures could be used to estimate or calculate the sample size needed for a future definitive study (based on calculated effect size). I am assuming that sample size estimates will be discussed in the body of the paper;

Response:

Thank you for this comment. As this is a feasibility study, the authors consider that the primary outcome is whether the study in its current form is feasible to undertake in terms of ease of recruitment, suitability of the assessment algorithm, ability of the participants to comply with both stages of the exercise intervention, compliance with completing questionnaires, ease with which the assessment and treatment components are fitted into clinic schedules etc. The
secondary outcomes have been listed in order of clinical relevance, as the reviewer suggests, and are being used to inform the design of the future study as well as to make some preliminary observations of clinical outcomes.

Comment 5

* Line 56: Key words. Limit to 5 key words. Also, I did a key words search using Mesh Heading on PubMed, but the key words provided do not seem to match with Mesh Headings. It is best practice to choose keywords that are also mesh Heading or some type in the main databases. For example, the term "subacromial pain syndrome" may be replaced with a Mesh Term that is the same thing (from PubMed) -

*Shoulder Impingement Syndromes

*Rotator Cuff Impingement Syndrome

*Rotator Cuff Impingement

*Impingement, Rotator Cuff

*Impingements, Rotator Cuff

*Rotator Cuff Impingements

*Coracohumeral Impingement Syndrome

*Impingement, Posterosuperior Glenoid

*Impingements, Posterosuperior Glenoid

*Posterosuperior Glenoid Impingements

Response:

Thank you for this comment. The key words have been changed to reflect MeSH terms.

“Key words: Shoulder pain, shoulder impingement syndromes, rotator cuff, rehabilitation.”

Line 57

Comment 6

Background & Aims
The authors offer a convincing literature review in support of the pilot trial, and common sense tells us that isometric exercises would be useful in patients where their shoulder pain would prohibit full range-of-motion exercises;

Line 96: I can't help but feel that high-load isometric exercises may lead to tearing of relevant rotator cuff muscles. How would this risk be reduced or mitigated? A brief sentence here would informative;

Response:

Thank you for allowing us to clarify this point. Although in the abstract the authors refer to a previous study published by Rio, E., et al., Isometric exercise induces analgesia and reduces inhibition in patellar tendinopathy. Br J Sports Med, 2015. 49(19): p. 1277-83 that investigates the use of high load isometric contractions in patella tendinopathy, in this present rotator cuff study, the isometric exercises being undertaken are not high-load and are not described as such. The isometric contraction is undertaken using a rigid band and held for up to 10 seconds. Repetitions are progressed in accordance with patient ability and symptom response.

Indeed, isometric exercises are increasingly supported in the treatment of tendinopathy in different body regions and although only a small pilot study, recent findings from Parle PJ, Riddiford-Harland DL, Howitt CD, et al. Br J Sports Med 2017; 51:208–209 suggest that isometric exercises for rotator cuff tendinopathy may positively influence pain and tendon thickness. In this study, as in ours, high-load isometrics were not used.

Comment 7

Line 108 and line 111: the authors again use the terms "feasibility" and "treatment effects. What is mean by "feasibility" and what are the criteria to determine feasibility? This is critically important to elucidate at this point in the paper. There are many aspects that would either make a study "feasible" or "unfeasible" e.g. resources, access to patients, staffing, and funding is probably the most important. These aspects of feasibility need to be offered and described in this paper;

Response:

Thank you for this comment. The following text has been added to further inform the reader regarding the determinants of feasibility being considered:

“The primary aim of this study is to establish the feasibility of running a large full-scale RCT that compares the effects of isometric, isotonic concentric and isotonic eccentric rotator cuff contractions when used as part of a structured semi-individualised exercise-based physiotherapy...
rehabilitation program in patients diagnosed with subacromial pain syndrome/rotator cuff tendinopathy. Various key parameters including ease of recruitment, suitability of the assessment algorithm, evaluation of the randomisation process, adherence to the exercise intervention, compliance with log-book completion, retention rates and, nature of adverse events will determine whether this study design can feasibly be undertaken as a full-scale RCT”.

Line 111-117

Comment 8

* Line 115 and line 119: the author's state hypotheses, which implies that this pilot study intends to perform hypothesis testing using inferential statistics. I am not opposed to a degree of statistical testing in pilot studies with a view to offer insights into outcomes, but formal inferential statistics to determine outcomes should be avoided, as explained by Lancaster et al. (reference earlier). The sample size and poor Power of this pilot study would exclude the ability to offer meaningful and valid outcomes. This paper should be tempered by focusing the aims at feasibility and less so at hypothesis testing/treatment outcomes;

Response:

Thank you for this comment. The authors agree that including hypotheses is inappropriate for a feasibility study. The text has now been amended to focus the aims more on determining the feasibility of the study and reference to hypotheses testing removed.

Comment 9

* The last section of the Background, lines 108 to 120, should be re-written with the view to provide the Aims and Objectives:

  o Primary Aim….

  o Secondary Aim…

  o To achieve these aims the objectives are to: Objective 1…. Objective 2…. And so on

* I note that there is no aim to examine, explore or evaluate the research design and process e.g. evaluation of the randomisation process, flow of patients, staff acceptance of the research design and process, and so forth. These elements are critical to the feasibility and design of a definitive study, particularly a RCT, and should thus receive attention in the write-up of a pilot study or a pilot study protocol;

Response:

Thank you for this comment. As per our response to comments 7 and 8 above, the text has been amended to more fully reflect the aims of the study including evaluation of the research design and processes.
Methodology

* The description of the study is good and registered with ANZCTR

Comment 10

* Line 138: the authors offer a rationale that a minimum of 30 subjects per group would be required for a definitive, fully powered RCT. Although this estimate is based on a published trial, the sample seems very low and, in my view, unlikely to offer robust data for a full-scale RCT as suggested. Calculated samples sizes for musculoskeletal disorder RCT are usually underestimated and a sample size per group of around 120 is more likely to offer valid and reliable data in a definitive clinical trial. The minimum sample per group in a decent pilot trial is generally considered to be 30 /group, so the authors need to think carefully about the sample size per group chosen for their study (at 12 per group). Julious et al (2005) offers justification for a sample size per group as low as 12, but this is within the context of highly controlled laboratory or pharmaceutical settings, and does not account for the variance found in real-life clinical practice (Julious, Steven A.

"Sample size of 12 per group rule of thumb for a pilot study." Pharm Stat 4, no. 4 (2005): 287-291). If the authors are going to stick to their stated sample size then a stronger argument is needed to support the sample size, particularly since a great deal of the inferences will be drawn from hypothesis test and outcomes. Amorin-Woods et al. (2016) paper offers a good approach to pilot study design (Lyndon G. Amorin-Woods, Lee Nedkoff, Gregory F. Parkin-Smith, and Colleen Fisher. "The Design of a Practice-based Study of Attendees at Chiropractic Offices in Western Australia." (2015).

Response:

Thank you for this comment. Please see our response to comment 3 above for the justification of the sample size chosen for this study.

* The authors provide a good set of inclusion and exclusion criteria;

Comment 11

* Line 156: an exclusion criteria is GHL and/or AC joint moderate-severe degeneration, which is quite sensible, but I do think that all participants would need a recent x-ray (if they do not have one) to determine the extent of degeneration. This would ensure consistency and reliability ion the recruitment process;

Response:
The authors agree that a recent x-ray to exclude OA of the GHJ/ACJ is appropriate. Generally the patients present with an x-ray report or images. Since we do not wish to expose our patients unnecessarily to radiation, if they have shoulder pain and have not undergone a shoulder x-ray within the previous 12 months, recommendation will be made that they discuss this with their GP. In the absence of an x-ray within the previous 12 months, they will be excluded from the study. The text has therefore been amended to:

“To determine the severity of OA, a shoulder x-ray within 12 months is required for inclusion in the study”.

Line 1670-171

Comment 12

* Line 164: the authors indicate that inclusion/exclusion would be primarily based on clinical decision-making. Of course, clinical decision-making is essential in reaching any diagnosis, but for a study to be replicated and the process to be reliable, it is better to have a clear decision-making process. In this regard, a decision-making algorithm that guide diagnosis and inclusion would be useful for this pilot trial. This tried algorithm could then be used as reliable method of decision-making in a future definitive study. Such an algorithm would be appreciated by participating practitioners/clinicians;

Response:

The authors agree that a clear decision-making algorithm would be useful to guide diagnosis and inclusion. Subsequent to the initial manuscript submission, a study manual including a decision-making algorithm was developed for use by the assessing physiotherapists. The inclusion/exclusion criteria section has been modified in accordance with the assessment algorithm. A shortened version of this algorithm has now been developed and uploaded for this feasibility study publication. The authors believe that the manuscript is improved with the inclusion of this algorithm. Thank you.

See Figure 2. Assessment algorithm.

Comment 13

* The description of patients and recruitment is good. Any particular active recruitment or advertising planned?

Response:

Thank you for this comment. The authors agree that more information regarding recruitment would be helpful and the text has been amended accordingly:
“Participants will be recruited from a physiotherapy-led shoulder screening clinic at a large public hospital and two private physiotherapy clinics, all within metropolitan Melbourne, using internal flyers and social media to promote participation”.

Line 130-132

Comment 14

* Line 198: the authors offer the criteria for feasibility in this section, which appear sensible - (a) ease of recruitment (b) adherence to treatment, (c) non-compliance/drop-out, and (d) adverse events. These are entirely appropriate, but there is very little justification or expansion on these feasibility criteria in the paper. The authors should offer some benchmark or threshold levels for each criterion, which in turn would inform the authors/reader if a future study is indeed feasible. For example, what does "ease of recruiting mean" - 1 recruit per day? 10 per fortnight? To what degree do the participants need to be non-adherent before they are excluded? What adverse events would exclude them from the study, or is this about serious adverse events? The devil is in the detail here, which I turn will inform the authors if a future definitive trial is feasible, more so than the treatment outcomes themselves;

Response:

Thank you for this comment. The authors agree that this criteria for feasibility information is important to include. The text has been amended as follows:

“Participant compliance will be obtained by recording the number of physiotherapy sessions attended (out of a maximum number of 5). They will be provided with a daily log-book to record the number of home exercise sessions completed as well as adherence to the home exercise program. Adverse events and the use of co-intervention will also be recorded in the log-book along with further questioning by the assessor at trial completion (6 months). All adverse events will be documented by the treating physiotherapist and the project coordinator informed (RK).

Line 205-210

And:

“In order to meet the target sample size, it is planned that the recruitment coordinator will achieve a telephone screening percentage of 75% and the assessors at each site will achieve a clinical assessment screening percentage of 50%; screening will continue until the target population is reached (12 participants per site (Chan 2013). Making a diagnosis of subacromial pain syndrome/rotator cuff tendinopathy is complex and an assessment algorithm has been designed in order to ensure the appropriate participants are included in this study. Part of the feasibility of this study relates to the assessment algorithm and its influence on recruitment rates. Calculating the time it takes to recruit will facilitate planning for the full-scale RCT.

For completeness of data collection and improved statistical analysis, we seek to maximize study retention and adherence. In accordance with the Pedro Scale criterion, we plan for a retention
rate of at least 85%. By keeping the intervention period relatively short to reduce the patient burden as well as by contacting participants to remind them of their treatment and assessment appointments, we anticipate this will be achievable. In studies that have investigated exercise interventions in participants with Subacromial pain syndrome/rotator cuff tendinopathy, adherence to intervention protocols has been reported as 80% and over (Blume 2015, Holmgren 2012, Bennell 2010). We consider this will be achievable in our study with the exercise check-review during week 9, specifically designed to ensure ongoing compliance.

All groups in our study will undertake an exercise-based intervention only and we therefore do not anticipate any serious adverse events. Increased short term pain during and following performance of exercises has been reported in other exercise based studies (Bennell 2010). As all of our participants will undergo a structured semi-individualised exercise program, with progression governed by symptoms and stage of tendon pathology, we anticipate minimal reporting of these kinds of minor adverse events.”

Line 213-234

Comment 15

* The secondary outcomes are well written and clear. There is a major focus on clinical outcomes, but I am still sceptical due to the sample size of 12 per group, which is small. Is this pilot study an "external" or an "internal" pilot study? If it is planned as an internal pilot study, the study may be able to just continue on and recruit a few more patients per group, say up to 20 per group, as part of the pilot component;

Response:

Thank you for this comment. The authors consider that the primary outcome of this study is to ascertain the feasibility of undertaking a full scale RCT with regard to several key parameters as described earlier in our response to comment 7, including ease of recruitment, use of the assessment algorithm, and compliance with treatment/drop-out rates.

* The treatment intervention are described clearly and this section is good, since it spells out clearly what is to happen at each treatment/intervention session. The number of supervised sessions and home-exercise sessions are reasonable and are sufficient to produce a possible treatment effect;

Comment 16

* Line 290: the authors indicate that manual therapies may be included in treatment, but not always. Manual therapies, such as joint mobilisation, soft-tissue work/stretching, trigger point therapy and joint manipulation, may all have a therapeutic effect and thus confound the outcomes and negatively influence decision-making as to whether the isometric exercise specifically and discretely is having any meaningful effect. I would exclude any kind of manual therapy in the study as part of treatment - if manual therapy is included in some way, it changes the whole focus of the study and the study aims, so should not be included;
Response:

This study is structured, semi-individualised and primarily exercise based. In patients presenting clinically with subacromial pain syndrome/rotator cuff tendinopathy, some manual therapy is often provided in order to facilitate progression to the next stage of treatment. This is particularly the case when muscle imbalances for example prohibit a patient achieving an optimal scapular position. In this case, manual therapy could include soft tissue release to the pec minor or lev scapulae in order that a participant be able to achieve the optimal scapular position and therefore progress to scapular shrugs.

The study explicitly states that all manual therapy should be kept to a minimum and documented. Further, the physiotherapy treatment is essentially only provided over 4 sessions; the home exercises are therefore being undertaken at a much greater frequency than manual treatment over the course of the intervention.

The text has been amended to reflect usual clinical considerations:

“To standardise treatment as much as possible, and since this study is primarily focussed on exercise intervention, manual therapy techniques will not be used routinely. As per usual clinical care in management of patients with this shoulder disorder, for individual participants who are unable to progress beyond an exercise stage without manual therapy to facilitate, this will be undertaken but kept to a minimum and recorded”.

Comment 17

* Line 305: the level of significance is stated as p<0.5. Is this correct? Usually, the level of significance is <0.05 and the way it is written is "level of significance of p<0.05" or "α=0.05. A p-value of <0.5 is very high and may not be very meaningful - that said even p=0.1 is sometimes reasonable;

Response:

Thank you for this comment and for highlighting this typographical mistake. It has now been corrected throughout the text.

Comment 18

* Line 305: there is not much detail here regarding the anticipated statistical analysis. Please elaborate more on aspects such as: what type of data is expected, who will the data be organised and tabulated, who will do the statistical analysis, why is the proposed analysis and statistics chosen, how will the results be interpreted, will there be consensus agreement related to the results/outcomes?

Response:
Thank you for this comment. The text has been amended to inform the reader of the statistical analysis:

“All analyses will be conducted on intention-to-treat principles with missing data replaced by the last-score-carried-forward technique. Analyses of variance (ANOVA) with repeated measures will be used to analyse trends in between-group changes in secondary outcome scores at baseline, and after six and twelve weeks of the exercise intervention. Continuous variables (SPADI, WORC, 11-point NRS, dynamometer and, GRCS) will be summarised using means and standard deviations, or medians and interquartile range, while categorical variables (gender) will be summarised using frequencies and proportions (and 95% confidence intervals).”

Line 359-365

Comment 19

* I note there is no mention of sample size calculations or estimated in the methods section for a definitive study. This is a critical component to a pilot study and the methods that are anticipated to be used to calculate the sample size of a future definitive study should be provided. A great deal is published on sample size estimated/calculations, but at least a brief description and anticipated calculations should be offered in this paper.

Response:

Thank you for this comment. Please see our response to comment 3 above which details the sample size justification used in this feasibility study.

Line 134-142

Reviewer 2

Comment 20

Randomisation method: Can the authors add detail about the practical way that randomisation and allocation concealment will be performed in this trial?

Response:

An offsite computer generated randomisation schedule will be generated by an independent statistician and that individual will contact the treating clinician to notify them which group the participant falls into. The text has been amended to clarify this point:

“Once consented, participants will be randomly allocated using an off-site randomiser and computer generated allocation sequence to one of three groups: (i) isotonic concentric exercises; (ii) isotonic eccentric exercises; (iii) isometric exercises. The treating clinician will be informed by the off-site randomiser via telephone of the group each participant is randomised to just prior to commencement of the treatment intervention.”
Outcome measures: Please provide more information about how each outcome measure will be quantified and summarised, e.g. categorical variables will be summarised using frequencies and proportions (and 95% CIs for these proportions), and continuous measures will be summarised using means and standard deviations, or medians and IQRs/range.

Response:

Thank you for this comment. As per our response to comment 18 above, the text has been amended to further inform the reader:

Sample size calculation: Can the authors provide means and SDs on which the effect size (of 0.66) is estimated (for the main trial), rather than stating an effect size without any justification? It may be that this effect size is unrealistic, in which case the main trial would be underpowered at 30 per group. A sample size of 12 per group for the pilot study is very small - and I am concerned that the justification of only 30 per group for the main trial is not a valid basis on which to justify such a small pilot study.

Response:

Thank you for this comment. Please see our response to comment 3 above, which provides the justification for the sample size chosen for this feasibility study.

I am concerned about the wording of the second objective of the trial, namely that the trial aims to determine treatment effects in the three groups. The authors need to recognise that treatment effect sizes based on only 12 patients may suggest trends but without any degree of accuracy.

When the authors refer to statistical significance, I assume that they mean "p<0.05" rather than "p<0.5"? However, I would stress that analysis should focus on confidence interval (CIs) estimation, rather than hypothesis tests or regression analysis - I would advise that the authors state this explicitly.
Thank you for this comment. There was a typographical mistake and significance would be set at $p<0.05$.

Further to this, yes the authors agree that treatment effect sizes based on a small sample size can only suggest trends. Please also refer to our response to comment 3 above along with the following amended text:

“As this is a feasibility study, it is not fully powered to determine treatment effects, and any inferential statistics will be used cautiously. Nevertheless, the analysis of between-group changes in secondary outcomes at each of the follow up time-points may offer insights into possible trends and guide the design of the future full-scale RCT. Similarly, baseline between-group participant characteristics and any associated influence on outcomes may also be observed.

Line 355-359

Comment 24

Comparison of between-group changes in secondary outcomes at each of the follow up time-points will be used to determine treatment efficacy." Authors should clarify that they will compare descriptive statistics rather than carrying out hypothesis tests.

Response:

Thank you for this comment. The notion of hypotheses testing has now been removed from the manuscript text.

Associate editor further comments to be addressed:

Comment 25

It is important to make it clear throughout the manuscript that effectiveness cannot be assessment in this small-scale study

Response:

Thank you for this comment. Yes the authors agree. The text has been amended throughout and as per our response to comment 24 to reflect this important point.

Comment 26

Can the assessor be blinded? – i.e. the assessor should be different from the physiotherapist delivering the intervention

Response:
There is an assessor and two treating physiotherapists at each site. The assessor will undertake the telephone screening, clinical assessment (algorithm) and all outcomes measures at baseline, week 6 and week 12 and will be blinded to treatment allocation. The treating physiotherapists will deliver the intervention. They will also undertake pre and post treatment strength and pain assessments during treatment sessions 2 and 3 when the rotator cuff intervention is delivered.

The text has been amended to clarify this at the outset: “This protocol describes a feasibility study for a randomised, assessor- and participant–blind, controlled trial conforming to the SPIRIT 2013 recommendations for clinical trial protocols.”

Line 124-125

and

“Eligibility will be confirmed through a clinical assessment undertaken by a blinded assessing physiotherapist at each site.”

Line 182-183

and

“While the treating physiotherapist cannot be blinded to treatment allocation, in order to minimise bias, the assessor is blinded, patients will not be told which intervention group they have been randomised to, all data will be de-identified and, data analysis will be performed by an independent analyst with group allocation undisclosed.

The intervention will be carried out by designated, experienced physiotherapists at each site, with the treatment sessions delivered by a physiotherapist who is not involved in any stage of the assessment process.”

Line 192-200

Comment 27

Is the intervention individual or group based?

Response:

The intervention is individual – all participants attend semi-structured individualized treatment sessions. The text has been amended to clarify this:

“The physiotherapy intervention will involve two treatment phases. In Phase 1, participants will attend on four consecutive weekly occasions for one-on-one treatment sessions with the physiotherapist.”

Line 295-296
Comment 28

Is the research design for an RCT being tested as well as the intervention? If so, then is it a pilot trial rather than a feasibility trial?

Response:

The authors understanding of a feasibility study is that it is used to gauge whether a study can be done and therefore it evaluates how the components of a study work together. In this study this includes an evaluation of the following parameters: ease of recruiting participants (number and rate); ease of using the assessment algorithm; ease with which participants complete the questionnaires; participant compliance with the exercise intervention including phase 1 (individual treatment sessions) and phase 2 (progressive exercise sheet); participant adherence to the intervention (home-exercise program and daily log-book recording); non-completion (dropout number and rate) and; adverse events (number and type).

Comment 29

How can analysis be conducted with group allocation undisclosed?

Response:

Groups will be coded and analysis will be undertaken by a statistician who will not be made aware of what exercise program is used in each of the three groups.

Thank you again for your thorough review of our manuscript. We believe it has been improved with the alterations and additional text.

We hope that our amendments, in response to the reviewer comments meet with your approval.

We look forward to hearing from you in due course.

Yours sincerely,

Rita Kinsella.