Author’s response to reviews

Title: A comparison of multidisciplinary team residential rehabilitation with conventional outpatient care for the treatment of non-arthritic intra-articular hip pain in UK military personnel - a protocol for a randomised controlled trial

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Version: 1 Date: 15 Sep 2016

Author’s response to reviews:

BMSD-D-16-00433 – A comparison of multidisciplinary team residential rehabilitation with conventional outpatient care for the treatment of non-arthritic intra-articular hip pain in UK military personnel – a protocol for a randomised controlled trial

Point-by-point response to reviewer comments

We have responded to each reviewer’s comments in the 2-tables below (reviewer #1 and reviewer # 2). We have accepted all of the reviewer comments and we are happy to implement the reviewer’s suggestions into our protocol; we have provided additional information where requested. Specific amendments are reflected by the highlighted text in our revised manuscript. We have also submitted these responses as an additional file as this may ease the review process.

Reviewer # 1

Reviewer Comments

1 This manuscript details the protocol for a randomized controlled trial for the treatment of prearthritic intra-articular hip pain. On further review, it becomes clear that the knowledge
gained from this protocol is really about the difference between an intensive inpatient rehabilitation compared to an outpatient rehabilitation, and may be applied to any orthopaedic condition. As such, its ability to advance the understanding of non-surgical treatment of intra-articular hip pain may be limited. Overall, the manuscript is well written and the protocol is well supported, and covers an important topic. There are a few specific areas that could be clarified, improved, or addressed.

Authors Response

We agree that the primary focus of this protocol centres on a comparison of inpatient versus outpatient treatment options for the management of intra-articular hip pain. A recent systematic review concluded there is no evidence that any surgical approach for FAI reduces the long-term risk of hip OA development and progression1. Despite an absence of study data interventions that reduce adverse mechanical forces, correct abnormal posture, manage dynamic joint stability and control pain across a compromised hip joint have obvious face validity. There is an explicit call for head-to-head randomised controlled trials to determine the optimal treatment for those with symptomatic non-arthritic hip pain and FAI1,2. We are particularly interested in exploring how the different structure, process and organisation of rehabilitation influences the clinical outcomes in UK Military personnel with non-arthritic hip pain and we acknowledge and agree with the reviewer that this may yield results of relevance to other musculoskeletal injuries. We also feel our protocol responds to recommendations for researchers to examine specific treatment options including alternative types and dosages of manual therapy and exercise strategies using randomised designs 2,3


Reviewer Comments

The issue of selection of the comparison treatments limits the enthusiasm for the protocol. The residential multidisciplinary team approach is interesting, but unique. It is not necessarily generalizable to other situations. It also makes it somewhat unclear what is being compared: an intensive inpatient treatment program compared to a limited outpatient treatment program. One of the main differences is the time spent with health care providers. As that interaction can be very important to patient outcomes, this study may not test the physical therapy intervention as much as the physical therapist interaction with the patient. Along the same lines, the inclusion of a sham treatment would strengthen the study, especially given the success of sham treatments for
Authors' Response

We acknowledge and agree that residential multidisciplinary team (MDT) rehabilitation is not a widely utilised treatment intervention in health care. However, there is evidence in the scientific literature reporting the effects of multidisciplinary in-patient rehabilitation programmes on the health status of patients with musculoskeletal disorders 4-7 and we do not necessarily consider the approach is unique. Although this research includes heterogeneous patient groups, the overall conclusion is that MDT care can effectively improve function and disease status in patients with musculoskeletal conditions. These findings are important as there is a paucity of evidence supporting the combined effectiveness of a multi-modal approach (including education, exercise, manual therapy and activity modification) for the management of non-arthritic hip pain, despite its recommendation in national clinical practice guidelines8. In contrasting the in-patient versus outpatient study options the reviewer correctly highlights the importance of the therapist:patient interaction on clinical outcomes and systematic reviews of exercise clinical trials reveal that a greater number of therapist contacts improves outcomes9. There is also evidence that the quality of the therapeutic relationship influences outcomes and a more individualised, patient-focused communication style (e.g. listening, providing encouragement, etc) enhances this relationship10. This may explain the positive benefits seen with sham interventions, whereas in an ‘active’ intervention the therapist’s focus on content delivery may reduce the time available for this element9,10. Whilst anecdotally the short intensive residential MDT approach appears effective, it has not been subject to formal evaluation and both the in-patient and outpatient treatment may contain different therapeutic elements that result in similar clinical improvements. Furthermore, there is currently no consensus or criteria surrounding which patients should be referred to which setting, and the extent to which outcomes differ between settings is unknown. Therefore, we aim to obtain an estimate of the difference in effect between two holistic rehabilitation strategies, MDT residential versus usual physiotherapy led outpatient care (the entire ‘global’ intervention according to the developed protocol), in patients with non-arthritic hip pain. We feel this research is needed to confirm if these treatment options assist in clinical decision making and influence outcomes. The reviewer also highlights the challenge presented by different follow-up and treatment time-frames. We considered this issue at length and took expert advice on how to control for time in our RCT. The follow-up time-frames are the same for both groups (3-months), and all participants will be assessed at baseline and 3-months on the same clinical outcome measures. The inclusion of post-treatment measures may help reveal if any differences occur as a consequence of the different interventions (e.g. the immediate post-treatment scores by group). This is based on the assumption that any changes from [a] baseline to [b] post-treatment to [c] 3-months are linear in direction. If the trend is non-linear there will be insufficient data points to model our outcomes over time in a manner that will enable us to compare the trajectory of patient outcomes using 3 time points. If an interim analysis reveals this is the case, we will remove the post-treatment scores from the final analysis and compare scores at baseline and 3-months. We feel this approach allows us to incorporate and evaluate the complex nature of ‘real-world’ clinical practice into the intervention research design without compromising scientific quality. Finally, to ensure a reliable evaluation of the efficacy of an intervention the reviewer states a control group receiving a sham intervention should be included.
in this RCT. We agree that given the contribution of a placebo effect to improvements following treatment of hip OA11, this study should ideally include a sham control group. However, we could not provide evidence to the institutional (MOD) research ethics committee that natural recovery was likely to occur in patients reporting functional impairments and pain at baseline. We were also unable to provide evidence from prior research reporting positive improvements of a sham treatment in young adults with non-arthritic hip pain/FAI, and in a motivated military cohort it was felt a sham treatment would not be well received and could have a negative impact on recruitment. Therefore we did not secure ethical approval to include a sham control group and will include this as a potential limitation of our study.


3 Reviewer Comments

Terminology: there are a few places where terms are used that may over-state the current level of evidence in this area. By calling the disorders "prearthritic", this implies that all of these disorders will go on to / are at high risk for developing arthritis. While this is a common assertion, there is not yet solid evidence that this is the case for all of the hips that would be
included in this study. For example, it has recently be found that there is not an increased risk of osteoarthritis with pincer FAI (Agricola, 2013). A term such as "non-arthritic" might be a better descriptor.

Authors Response

Agricola et al, 201312 does conclude that pincer type FAI was not associated with hip OA in 720 participants with symptoms of early OA. In a separate study (n=865) the same research group13 found individuals with cam-type FAI are ‘strongly predisposed to fast progression to end-stage osteoarthritis’. Cam type FAI is more commonly reported in active young men who comprise the main population at risk in the UK military and our study population is male only. We would therefore expect a greater incidence of Cam type FAI compared to the Pincer deformity (more commonly reported in women in the 30-40 year age group) in our RCT. Our description of ‘pre-arthritic’ hip pain acknowledges that early OA may lie on a spectrum of conditions that includes FAI, acetabular labral tears, chondral lesions, structural instability and (less commonly) ligamentous teres tears which may or may not develop into OA. We would also highlight that the recommended terminology surrounding FAI continues to evolve with a very recent and influential consensus statement14 recommending use of the phrases FAI syndrome, CAM morphology and Pincer morphology whilst also recommending the avoidance of commonly employed terms including asymptomatic FAI and deformity, abnormality and lesion when referring to CAM or pincer morphology. Therefore the reviewer is correct to highlight a lack of solid evidence that all hips in our study will ultimately lead to OA and we will amend our description to ‘non-arthritic’ hip pain throughout the manuscript. We have cited the work of Agricola et al at lines 95-96 on page 3.


4 Reviewer Comments

Similarly, stating that "the proximal femur abuts against the acetabular rim" in FAI (lines 90-91) misrepresents the current level of evidence. To the best of my knowledge, there is not evidence in patients with FAI that proves that the femur is making contact with the acetabular rim. This is the assertion, and is somewhat supported by models and by the location of predicted "contact" and detected damage. It is much more likely that passive tissues (such as the acetabular labrum) are actually being pinched between the femur and the acetabular rim (vs. those structures making
contact). The paper referenced for that statement does not support the statement, but instead is citing it from another paper. More accurately portraying the current state of the evidence, including the labrum as one of the involved structures, and using primary references would improve this manuscript.

Authors Response

By stating “the proximal femur abuts against the acetabular rim” we are employing an oft-cited definition of FAI that should be familiar to our target readership and we feel there is some evidence supporting the accuracy of this description. For example, assessment of cam engagement in male participants with FAI using 3-D computer tomography showed at 90˚ of flexion, the centromedial portion of the cam lesion was found to abut against the anterosuperior quadrant of the acetabular cartilage15. These results are consistent with a recent ‘cadaver’ study that found cam morphology was significantly associated with [1]MRI-observed cam intrusion into the intra-articular joint space and, [2] experimentally measured contact force on the acetabulum16. These authors state this work represents the first direct experimental evidence for cam intrusion during impingement and is consistent with empirical and simulated reports on the zone of cartilage damage in FAI17. We feel the precise aetiology of FAI remains unclear and involves a complex interaction of multiple risk factors. We do agree with the review comments surrounding the significance of the acetabular labrum in the description of FAI and we have amended our definition at lines 88-98 on page 3 accordingly to include explicit reference to the acetabular labrum.


5 Reviewer Comments

Line 180: "An outpatient group will undergo a reduced dose of fixed clinic appointments…” It is unclear why a reduced dose is used here. That would seem to bias the comparison (MDT vs. a reduced does of IP). This should be clarified.

Authors Response

We agree with the reviewer that use of the phrase ‘reduced dose’ to describe the outpatient intervention is potentially misleading and ‘clumsy’ terminology as it predicts in advance that superior gains may result from the residential MDT intervention in the absence of any supporting evidence. We have amended this extract to provide a more objective, brief description of the
residential MDT versus individualised, outpatient ‘usual’ care treatment groups. Lines 183-184 pages 5-6.

6 Reviewer Comments

Lines 225-231: The section is confusing as written because the purpose of the MIAC is to "establish patient's eligibility", but it sounds as if "potential participants meeting the eligibility criteria" are contacted prior to the MIAC. I assume that there are criteria that can be determined before the MIAC (screening criteria) and then criteria that require assessment to determine eligibility. This section should be written more clearly to reflect what is being used to determine potential candidates vs. eligible patients.

Authors Response

We have amended and clarified this section. We will recruit patients from multiple primary care medical centres across the entire UK military community. The only screening criteria during the initial consultation with the local unit medical officer is that patients must have had hip/groin pain for at least 3-months. Patients meeting this screening criteria are then referred to the DMRC MIAC where eligibility for inclusion in the study will be assessed by a specialist consultant and physiotherapist in accordance with the study criteria. This procedure will ensure a consistent and standardised interpretation of the inclusion criteria (non-arthritic hip pain) by rehabilitation medicine specialists, thereby removing any potential for inter-individual variation in assessment arising from multiple non-specialist staff at different units. Lines 227-237 page 7.

7 Reviewer Comments

Line 249: "minimum 3-sessions per week" It is unclear if this is referring to the home-based exercise program or to the treatment sessions. This should be clarified. It should, if possible, be supported by literature that 3 sessions / week for the home exercise program is considered sufficient. Typically, I think of a home exercise program as a daily program.

Authors Response

The “minimum 3-sessions per week” refers to the home-based exercise programme. Evidence to inform decisions regarding prescription of a home exercise component of treatment for non-arthritic hip pain is currently lacking. A relatively recent systematic review3 concluded the experimental evidence examining non-operative treatment for FAI is limited to 5-articles (non-randomised controlled trials), none of which provided details of the dosage and/or prescription for a home-based programme. However, a more recent pilot RCT examining non-operative management of FAI found physical therapy interventions, including home-based exercise 2-3 times per week, led to clinically important improvements in patients with FAI2. A further recent RCT investigating exercise therapy in hip OA reported a twelve week exercise programme, including home exercise 2-times per week, reduced pain and improved physical function in the intervention group (n=65)18. The reviewer is correct to highlight that daily home exercise programmes are commonly employed, however, we recommend restricting the home-based exercise programme to 3-times per week based upon the limited available evidence from clinical
trials in non-arthritic hip pain / OA, and a compromise between addressing the clinical goals whilst optimising adherence19. We will tailor the home-based programme to the individual needs of the patient, and utilise self-monitoring by means of an exercise diary. These measures were recommended as likely to improve adherence at the MOVE consensus conference20. This recommendation, based on level 1B evidence, pertains to general exercise as no studies specifically investigating exercise adherence in non-arthritic hip pain care are available. Lines 262-267 page 8.


8 Reviewer Comments

Lines 353-362: Typically, muscle "strengthening" programs require higher load (vs. the low load exercise stated here). Low load exercises are typically used for neuromuscular re-education. It is unclear if true strengthening will result from low load exercises, and especially in a short time frame. The use of "three sets of 8-10 repetitions" should also be supported by literature.

Authors Response

We consider strengthening a vital component of this rehabilitation protocol and feel this review comment reflects an ongoing challenge in designing optimal treatment programmes that facilitate neurological and muscular adaptations whilst concurrently accommodating biological healing, recovery and the safety of the patient. Despite an abundance of information on the implementation of strength and conditioning principles with healthy participants, investigation regarding the application of these principles in rehabilitation programmes is lacking21. We would also highlight that decisions of when to add an external stimulus, increase resistance or reduce stability in the progression of strength in non-arthritic hip pain rehabilitation programmes are not well understood. Consequently, due to poor agreement in the literature, loading is often a subjective estimate based on a therapist’s assessment of an appropriate resistance tailored to the individual needs of the patient. Therefore, the use of the term ‘strength exercises’ in our protocol reflects a common use in the rehabilitation literature describing exercises that apply an external resistance to a target muscle/muscle group. These exercises will be performed statically and dynamically and will initially focus on low-load exercise commencing in non-weight bearing positions and progressing to functional positions. Loads will be adjusted based on the participant’s functional performance, findings on repeat assessments and pain response to weight-bearing. Our justification for the initial dosage of 3x8-12 repetitions† also takes account of the following considerations:
[a] Pain provoked by exercise has been shown to reduce adherence to exercise in rehabilitation programmes22,23. We believe it is important to establish and stabilise pain within a given range-of-motion during the early stages of rehabilitation. Therefore we have chosen a relatively conservative initial dosage that should allow a short period of adaptation whilst controlling for pain, thereby promoting exercise adherence.

[b] Very few studies have evaluated the effects of neuromuscular exercises targeting hip control in combination with progressive strengthening exercises in patients with non-arthritic hip pain3. Combined neuromuscular and strength training may induce patient specific adaptations in non-arthritic hip pain rehabilitation. We do not think strength and ‘functional’ exercises can be separated completely due to the overlap between exercise type. Many ‘functional’ exercises include strengthening components and can induce fatigue in untrained or de-conditioned patients. Therefore, some of our functional/neuromuscular exercises could be classified as ‘strength’ exercises for some patients and this factor was considered when establishing the initial dosage.

[c] In the absence of evidence to inform decisions regarding integration of strength training in rehabilitation, it is recommended that a rehabilitating patient should be considered similar to an untrained individual when establishing exercise dosage24. The current guidelines for untrained individuals recommends strength training at an intensity of 60%-80% of 1 repetition maximum (1RM), a volume of 4 sets, and a frequency of 2 to 3 times per week25. We feel determining the 1RM is contraindicated in patients with non-arthritic hip pain and this model is based solely on research using healthy participants21,24,25. Therefore we recommend 3 sets of 8-12 repetitions for strengthening exercises, 3 times per-week initially. In order to measure exercise intensity, we will use the modified Rating of Perceived exertion (RPE) scale. The patient should be working at an intensity they rate as 5-to-8 on the 11-point RPE scale26. Resistance and difficulty of the exercise can be progressed and individually adjusted for each patient by the supervising physiotherapist to ensure strength gains are achieved. We feel this approach acknowledges the most recent recommendations for strength training whilst (with respect to loading) accommodating the safety and adherence considerations discussed in para’s a and b above. By allowing the supervising therapist to adjust the intensity in response to the RPE rating it also ensures a form of progression is applied that is individually tailored from a standardised menu of exercises, thereby reflecting ‘real-world’ clinical practice within the constraints of our RCT protocol. The full menu of recommended exercises is contained in the additional file.

[d] This repetition range has been recommended and/or used for strengthening exercises in recent RCT protocols / studies for non-arthritic hip pain2,27,28 or hip OA studies11,18,29. None provided references to sources of experimental evidence supporting selection of this exercise dosage, however, in two studies2,18 improvements in pain and function were reported following this programme.

With the limited available knowledge it is difficult for us to include rules, formulas and principles for a physiological adaptation to strength training and justify such recommendations. We acknowledge this as a limitation of the intervention protocol but do not feel this is unique to our study proposal. We feel our pragmatic rationale has a sound basis and can be defended. We will rely on the experienced physiotherapist to assess the patient and select the most appropriate strength exercise and progressions from the available options, thereby giving each intervention
an optimal chance of proving effective for the study participants. Lines 365-374 and 384-401 page 11.

† this repetition-range is amended in our revised manuscript to reflect the choices available to the supervising therapist.


Reviewer Comments
Lines 365-368: It would make more sense to order the stretching to match the direction. As written, the stretching of the hip flexors will help maintain hip flexion (not extension)

Authors Response

Agreed. We have re-written / re-ordered this section. Lines 404-407 page 12.

10 Reviewer Comments

Lines 488-494: More information about how the participant is asked about pain is required for the VAS measurement. Is the participant asked about current pain? Average pain? Worst pain in the last 24 hours? And does it matter where the pain is? All of this will improve the understanding of the VAS measurement.

Authors Response

We will ask the patient to rate their worst hip/groin pain they have experienced over the past 24-hours using a 100mm horizontal VAS anchored by the terms ‘no pain’ and ‘worst pain possible’. The supervising physiotherapist will also enquire if the sensation of pain is [a] sharp or [b] a dull ache and if pain is made worse by movement. The reported strengths of the VAS pain rating is its rapid completion by respondent, ease of scoring, and is conceptually simple30. Whilst we acknowledge other pain responses in non-arthritis hip pain sufferers including an increase with prolonged activity, change in posture (lying, driving sitting etc), and localised versus diffuse pain, we will intentionally keep the VAS simple to understand and easy to administer by only concentrating on localised hip and groin pain. However, we will also examine the pain, symptoms and physical-function sub-scales on the HAGOS patient reported outcome measure to gain a broader insight on the inter-action between pain and function over the course of the preceding week in our participants. Lines 533-537 page 15.


11 Reviewer Comments

Lines 547-550: Positions of the hip during the HROM test would be important to specify. For example, is the medial rotation performed in hip flexion or neutral? In sitting or prone? Etc. It would also be helpful to explain how the motion of the femur is separated from the motion of the pelvis during these tests to get a true "hip" measurement.

Authors Response

The testing positions to assess HROM are as follows:

Hip Internal Rotation: The patient is positioned sitting with the hip at 90° of flexion with the lower-legs resting over the end of the assessment couch. The hip measured is placed in 0° of
abduction, and the contralateral hip in approximately 30° of abduction to provide a firm base and comfort. The reference knee is flexed to 90°, and the leg is passively moved to produce the desired hip rotation. The seated position assists to stabilise the pelvis and the pelvis is closely monitored to avoid unwanted pelvic motion. The motion is stopped when the examiner detects a firm end-feel or when pelvic movement is necessary for additional movement of the limb.

Hip Flexion: The patient is positioned in the back-lying (supine) position with the hip in 0° of abduction, adduction and rotation. With the knee flexed, the hip is passively flexed while the lumbar spine is monitored to avoid posterior pelvic tilt. The motion is stopped when the clinician reaches a firm end-feel or when pelvic movement is necessary for additional movement of the limb. The examining physiotherapist will also assess joint play with particular attention to evidence of insufficient posterior glide.

Hip Abduction: The patient is positioned in back-lying with the hip in 0° of flexion and rotation. With the knee extended, the hip is passively abducted. Manual stabilisation is provided at the pelvis to prevent lateral pelvic tilt or pelvic rotation. The motion is stopped when the examiner reaches a firm end-feel or when pelvic movement is necessary for additional movement of the limb.

The examiner will enquire if concordant pain and/or symptoms are produced during HROM tests. To our knowledge there are no known studies reporting the measurement properties of hip range of motion in individuals with non-arthritic hip disorders. Our procedures represent techniques commonly recommended and described in clinical practice guidelines and the non-arthritic hip pain / FAI literature. Additional File Appendix 10.


12 Reviewer Comments

Line 558-574: It would be helpful to state specifically if this is a make test or a break test. It is also unclear why only the affected side is being tested.

Authors Response

In accordance with the description of Thorborg et al32 we will utilise an isometric ‘make-test’. We chose this test as isometric loading induces less stress on the musculoskeletal system than eccentric loading (‘break-test’), which is a key consideration when testing individuals with a physical injury. We will utilise a long lever arm during the six individual tests wherever possible to ensure the tester’s strength exceeds the isometric force applied by the participant. We have clarified this issue at lines 614-620 page 17 and provided an additional section in our supplementary file illustrating the test positions. We will test both sides. The statement indicating only the affected side would be tested is an error.


13 Reviewer Comments

Table 1: "Anterior hip impingement test": as this is done different by different people, it would be important to clearly describe the position in which this is done (some test this in 90 degrees of hip flexion, some test in more hip flexion).

Authors Response

The patient is positioned in the back-lying position. The hip is passively flexed to 90˚ and then internally rotated and adducted as far as possible or to the first point of reported pain. The patient is asked what effect the motion has on symptoms. The test is considered positive if the patient reports the production of anterior hip pain34. Appendix 10, additional file.


14 Reviewer Comments

Table 1: "Resisted straight leg-raise": the same issue exists with this with some authors resisting with the hip in neutral, and others with the leg actively held (following passive positioning) in 30 degrees of hip flexion.

Authors Response

The test is performed with the patient in back-lying with the hip in neutral and knee in full extension. The patient is asked to raise the leg while the examiner applies a counter-resistance to the anterior thigh just proximal to the knee. This test is felt to load the joint anterosuperiorly and reproduce anterior groin pain when an intra-articular lesion is present35. We do not passively raise the leg to 30˚ before applying the external resistance as this can apply unwanted strain to the lumbrosacral region36. Appendix 10, additional file.


Table 1: Is history of stress fracture an exclusion criteria?

Authors Response

Yes. For clarification we have inserted “Hip fracture and/or history of stress fracture” in our exclusion criteria at table 1.

16 Reviewer Comments

Table 2: Individual occupational therapy: it seems that there may be variation in the roles of occupational (and physical) therapist across different systems as many of these treatments would fall under physical therapy where I practice.

Authors Response

It is true that there is some overlap and close collaboration in the different roles of the occupational therapist and physiotherapist in the delivery of the residential intervention that makes them amenable to an ‘interdisciplinary’ team approach. Therapy staff recognise the existence of role overlap as inevitable within our collaborative residential setting and we believe this is to the benefit of the patient. However, whilst we encourage and promote overlap between disciplines working towards a shared treatment goal, duplication is actively discouraged and there is sufficient diversity for these services to be recognised as different. To foster an effective MDT in our study, role clarity and treatment boundaries are well established in accordance with governing body definitions and standards of clinical practice, and the UK Director of Defence Rehabilitation (DDR) best practice care pathway37.


17 Reviewer Comments

Figures: these pictures seem distorted. It might just be the reviewing version, but would be helpful to accurately represent the movements without stretching / shrinking in individual directions.

Authors Response

We have reviewed our images as submitted and they appear in proportion in accordance with the original version. The reviewer correctly highlights however that it is possible they have been distorted during the submission process and we will act upon guidance and direction during editing (subject to editorial decisions) if this problem persists.
Reviewer Comments

1 The addition of an economic comparison between the residential and outpatient groups would enhance the study. I would imaging the decision to critically look at inpatient rehab programs is one related to the cost of the programs. If the hypothesis is true, and the inpatient program produces superior outcomes to the outpatient program, the addition of cost-efficiency data would increase the chance of inpatient programs being continued at the completion of the study, and the findings of the study being implemented into clinical practice. In addition, a contractual obligation between the study team and the funders of the inpatient and outpatient programs (I assume the MOD), to continue to fund the superior program once the study is complete, will also ensure that the superior program is translated effectively into clinical practice.

Authors Response

We agree with the reviewer that an economic comparison of residential and outpatient rehabilitation would enhance the study and we proposed an economic evaluation of care be undertaken as part of this RCT. This recommendation was made to address the dearth of economic analysis studies assessing the cost-effectiveness of a residential MDT model of care1. However, a broader economic analysis of UK defence rehabilitation has been proposed with a comprehensive ‘health economic analysis plan’ finalised that will commence in Autumn 2016. The service at DMRC Headley Court will be included in this analysis, and the study funding body (Arthritis Research UK) have cautioned against nesting an economic analysis of our study participants in this wider cost-effectiveness project due to the potential of a Hawthorne / Observer Effect producing biased data (personal communication, Prof Nigel Arden). For these reasons, we will not undertake an economic comparison of care in our RCT.


2 Reviewer Comments

Page 3, line 88-94: there are a number of publications by Agricola that support the premise that FAI leads to increased risk of OA and THA and these should be described and cited in this paragraph.

Authors Response

We noted that another reviewer of our manuscript cited Agricola (2013)2 reporting there is not an increased risk of OA with pincer type FAI. We have highlighted that this same research team found individuals with CAM-type FAI are “strongly pre-disposed to fast-progression to end-stage osteoarthritis”3, and that CAM-type FAI is more commonly seen in active young men comprising the main population at risk in our study. We have now cited Agricola et al at lines 95-96 on page 3 of the revised manuscript.


3 Reviewer Comments

Page 5, line 169-170: please describe the treatment outcomes in more detail (e.g.: pain, function, quality of life).

Authors Response

We have provided a full description of our study outcomes and measurement instruments at pages 14-18 and at appendix 10 in our online additional file (strength measures).

4 Reviewer Comments

Page 6, line 193: please add "superiority" to the study design as this is a superiority, parallel design RCT.

Authors Response

We have added “superiority” to the description of the study design at line 196 on page 6.

5 Reviewer Comments

Page 10, line 359: please justify why 3 sets of 8-10 were chosen in terms of the physiological effects of dosage of exercise.

Authors Response

This observation was raised by a separate reviewer and we have reproduced our response to this review comment:

We consider strengthening a vital component of this rehabilitation protocol and feel this review comment reflects an on-going challenge in designing optimal treatment programmes that facilitate neurological and muscular adaptations whilst concurrently accommodating biological healing, recovery and the safety of the patient. Despite an abundance of information on the implementation of strength and conditioning principles with healthy participants, investigation regarding the application of these principles in rehabilitation programmes is lacking4. We would also highlight that decisions of when to add an external stimulus, increase resistance or reduce stability in the progression of strength in non-arthritic hip pain rehabilitation programmes are not
well understood. Consequently, due to poor agreement in the literature, loading is often a subjective estimate based on a therapist’s assessment of an appropriate resistance tailored to the individual needs of the patient. Therefore, the use of the term ‘strength exercises’ in our protocol reflects a common use in the rehabilitation literature describing exercises that apply an external resistance to a target muscle/muscle group. These exercises will be performed statically and dynamically and will initially focus on low-load exercise commencing in non-weight bearing positions and progressing to functional positions. Loads will be adjusted based on the participant’s functional performance, findings on repeat assessments and pain response to weight-bearing. Our justification for the initial dosage of 3x8-12 repetitions† also takes account of the following considerations:

[a] Pain provoked by exercise has been shown to reduce adherence to exercise in rehabilitation programmes5,6. We believe it is important to establish and stabilise pain within a given range-of-motion during the early stages of rehabilitation. Therefore we have chosen a relatively conservative initial dosage that should allow a short period of adaptation whilst controlling for pain, thereby promoting exercise adherence.

[b] Very few studies have evaluated the effects of neuromuscular exercises targeting hip control in combination with progressive strengthening exercises in patients with non-arthritis hip pain7. Combined neuromuscular and strength training may induce patient specific adaptations in non-arthritis hip pain rehabilitation. We do not think strength and ‘functional’ exercises can be separated completely due to the overlap between exercise type. Many ‘functional’ exercises include strengthening components and can induce fatigue in untrained or de-conditioned patients. Therefore, some of our functional/neuromuscular exercises could be classified as ‘strength’ exercises for some patients and this factor was considered when establishing the initial dosage.

[c] In the absence of evidence to inform decisions regarding integration of strength training in rehabilitation, it is recommended that a rehabilitating patient should be considered similar to an untrained individual when establishing exercise dosage8. The current guidelines for untrained individuals recommends strength training at an intensity of 60%-80% of 1 repetition maximum (1RM), a volume of 4 sets, and a frequency of 2 to 3 times per week9. We feel determining the 1RM is contraindicated in patients with non-arthritis hip pain and this model is based solely on research using healthy participants4,8,9. Therefore we recommend 3 sets of 8-12 repetitions for strengthening exercises, 3 times per-week initially. In order to measure exercise intensity, we will use the modified Rating of Perceived exertion (RPE) scale. The patient should be working at an intensity they rate as 5-to-8 on the 11-point RPE scale10. Resistance and difficulty of the exercise can be progressed and individually adjusted for each patient by the supervising physiotherapist to ensure strength gains are achieved. We feel this approach acknowledges the most recent recommendations for strength training whilst (with respect to loading) accommodating the safety and adherence considerations discussed in para’s a and b above. By allowing the supervising therapist to adjust the intensity in response to the RPE rating it also ensures a form of progression is applied that is individually tailored from a standardised menu of exercises, thereby reflecting ‘real-world’ clinical practice within the constraints of our RCT protocol. The full menu of recommended exercises is contained in the additional file.
This repetition range has been recommended and/or used for strengthening exercises in recent RCT protocols / studies for non-arthritic hip pain11,12,13 or hip OA studies14,15,16. None provided references to sources of experimental evidence supporting selection of this exercise dosage, however, in two studies11,15 improvements in pain and function were reported following this programme.

With the limited available knowledge it is difficult for us to include rules, formulas and principles for a physiological adaptation to strength training and justify such recommendations. We acknowledge this as a limitation of the intervention protocol but do not feel this is unique to our study proposal. We feel our pragmatic rationale has a sound basis and can be defended. We will rely on the experienced physiotherapist to assess the patient and select the most appropriate strength exercise and progressions from the available options, thereby giving each intervention an optimal chance of proving effective for the study participants. Lines 365-374 and 384-401 page 11.


6 Reviewer Comments

Page 10, line 354: please justify why only the gluteals and deep hip rotators are being strengthened. There is considerable evidence that hip muscles are globally weak with FAI, and I would suggest that other muscle groups should also be targeted for optimal effects.

Authors Response

We agree with the reviewer that a global strengthening programme that focuses on all core muscle groups acting on the hip is recommended. We highlighted the gluteal and deep hip rotators to emphasise their particular importance in regaining functional control in patients with structural instability. To be clear, we will implement a comprehensive strengthening programme to optimise neuromuscular control, strength and stability of the hip. This includes exercises targeting gluteus medius, gluteus maximus, iliopsoas, quadratus femoris, obturator internus, inferior and superior gemelli, adductor brevis and pectineus. We will also include core strengthening based on studies of hip muscle activity during the performance of core exercises, and its recommendation in clinical guidelines for the management of non-arthritic hip pain. We also include functional, weight-bearing hip muscle strengthening including some proprioception exercises to optimise neuromuscular control, stability and strength of the hip in patient specific (military) activities. We have amended the section at lines 365-374 on pages 10-11 to clarify this global hip strength programme.

17. Eneski K, Harris-Hayes M, White DM, Cibulka MT. Non-arthritic hip pain: clinical practice guidelines linked to the international classification of functioning, disability, and health from the


7 Reviewer Comments

Page 15, line 551: why was an aggregate ROM score chosen, rather than individual ROM measures? Differences between the groups may be lost/watered down by this approach, given that people with FAI have restriction in flexion range (related to symptoms) and IR range (related to structure). Please justify the decision to aggregate the range score.

Authors Response

We did not make it clear at this section that we will collect and analyse individual and aggregate HROM measures in our study. We have amended this section. Lines 595-597 page 17.

8 Reviewer Comments

Page 16, line 558: will the muscle strength measures be reported as peak torque normalized for body weight? This should be the case to ensure that individual differences in leg length and body weight are accounted for. I would also recommend adding figures of how all ROM and strength tests will be measured, to ensure the study is reproducible.

Authors Response

We acknowledge the potential benefits of reporting strength measures as peak torque normalised for body-weight. For several reasons, we chose (in accordance with the description of Thorborg et al21) to utilise an isometric ‘make-test’ and report scores in Newtons (N). We chose this test as isometric loading induces less stress on the musculoskeletal system than eccentric loading (‘break-test’), which is a key consideration when testing individuals with a physical injury22. We will utilise a long lever arm during the six individual tests wherever possible to ensure the tester's strength exceeds the isometric force applied by the participant. We have clarified this issue at lines 614-620 page 17 and provided an additional section at appendix 10 in the online supplementary file illustrating the test positions. We will test both sides. The statement indicating only the affected side would be tested is an error.


9 Reviewer Comments

Discussion: some of the limitations of the study should be listed here, the main one is the lack of blinding in this study. I understand that the study design does not allow blinding but this should still be listed as a possible source of bias.

Authors Response

We have added what could be considered some of the limitations of the study on p.21. This includes reference to a lack of blinding, short follow-up period and limited generalisability. Lines 805-814 pages 22-23.

10 Reviewer Comments

Table 1: please add more detail about how the clinical diagnosis of FAI will be determined

Authors Response

We have added more detail on how the clinical diagnosis of non-arthritic hip pain/FAI will be established as a footnote to table 1. In addition to the inclusion/exclusion criteria specified we have added that the consultant diagnostic criteria will include [1] anterior or lateral hip pain for a minimum of 3-months; [2] history of pain worsening with activity, pivoting, hip flexion or weight bearing; [3] pain associated mechanical symptoms including popping, clicking or locking; [4] pain at rest; [5] physical examination findings or reproduction of pain in the groin or lateral hip with the anterior hip impingement test (combined flexion, internal rotation and adduction); [6] physical examination findings that exclude the spine and other lower-limb disorders as a potential source of pain and dysfunction; [7] patient may report sensations of instability during functional movements (e.g. squatting); [8] Standard AP radiograph of hip and pelvis. These clinical indicators are employed as part of the current UK defence rehabilitation clinical guidelines for the management of hip pain, and cited in clinical trials from the scientific literature 23,24, and non-arthritic hip pain clinical practice guidelines17. Table 1 footnote, page 34.


11 Reviewer Comments
Table 1: why were the log roll test and resisted straight leg raise chosen? These tests have poor sensitivity and specificity in diagnosing FAI and will neither rule people in or out as having the condition (see the work of Mike Reiman et al)

Authors Response

There is currently no universally accepted consensus on the diagnostic criteria to confirm or reject a specific condition, and we agree with the reviewer that the log roll test and straight leg raise will not provide a differential diagnosis of FAI. The pathology of central interest in our study is intra-articular non-arthritic hip pain which includes, but is not solely focussed on, FAI. Therefore, the aim of our examination is primarily to confirm the hip as the source of the patient’s symptoms and to exclude alternative diagnosis including referred pain. We included the log roll test to assess ligamentous laxity at the joint. This test, though not sensitive, is regarded as a specific test for hip joint injuries, may be suggestive of a labral tear in the presence of clicking, and is recommended for the management of non-arthritic hip pain in clinical practice guidelines. There is evidence that, by loading the joint anterosuperiorly, the resisted straight-leg raise test will reproduce anterior groin pain when an intra-articular lesion is present. The meta analysis and systematic reviews of Reiman et al highlighted by the reviewer concluded (a) there is limited evidence to support the use of hip physical examinations (HPE) tests as stand-alone clinical tests for the diagnosis of hip related pathology and; (b) clinicians should not rely on a single HPE test when diagnosing other hip joint pathologies. These authors also highlight that clustering tests does appear to provide more promising findings and the process of clustering to produce a “preponderance of evidence” of the existence of a hip specific diagnosis more closely approximates an “actual clinical examination”. Therefore, in agreement with Reiman et al, we have chosen several tests not on the basis of their diagnostic accuracy, but as a screening for intra-articular hip pathology. According to Byrd (2007) this form of clinical assessment is 98% reliable in localising intra-articular hip pathology, but poor at defining its precise nature. Reiman et al did report that the Thomas Test of hip flexor length showed the highest sensitivity (0.89) and specificity (0.92) and has value as both a screen and diagnostic test of a labral tear. Whilst this recommendation is only based on one study, we will include this test in our study. Appendix 10 additional file.


Reviewer Comments

Table 2: in its current form, the intervention is not reproducible. It would be beneficial to add further detail on specific exercises, and how and why they would be progressed, to ensure that a reader could reproduce the program. Some figures would help this.

Authors Response

Table 2 is intentionally designed to provide a general overview of the framework of the residential intervention and we agree with the reviewer that our intervention protocols cannot be reproduced from the information in this table. Our additional file provides a comprehensive overview of the core components and optional techniques and exercises available to the supervising therapist including over 100 images. The semi-structured nature of both interventions, including constraints and choices on the number and options for manual therapy techniques and exercises from which the supervising physiotherapist may choose, will reduce treatment variation and allow our interventions to be reported and replicated. However, this is a complex multi-modal intervention that recognises treatment is problem-based, individualised to each patient and needs to incorporate patient preferences in the treatment planning. Therefore, it is not possible to describe every exercise in detail, or precisely how and when each technique will be delivered and progressed for every patient as we cannot report in advance therapist choices and decisions. However, we believe we have reported the study protocol in sufficient detail in our intervention guide to allow the reader to draw opinions on the key components of treatment, and reproduce the treatment choices available to the therapist and patient. Please refer to the additional file.