

TITLE

Does physiotherapy change pain and function in young adults with symptoms from femoroacetabular impingement? A pilot project for a randomised controlled trial.

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ABSTRACT

Aim: Femoroacetabular impingement (FAI) is recognised as a source of hip pain but the effect of conservative treatment remains untested. The aim of this study was to pilot the methods for a substantive study comparing the effect of physiotherapy versus routine care on the symptoms of FAI.

Design: A parallel group pilot randomised controlled trial

Setting: A single NHS acute hospital trust, Devon, England.

Participants: 30 adults with symptomatic FAI were recruited. 23 (77%) completed the study

Interventions: Intervention was 3 months of specialised physiotherapy. Treatment in all cases included self-management advice and exercise. The control group received routine care.

Main outcomes: Change in pain and function measured using a Visual Analogue Scale, Non Arthritic Hip Score, Lower Extremity Functional Score (LEFS) and Hip Outcome Score (HOS).

Results: Eligibility criteria and randomisation methods were successfully identified for the main study. Recruitment rate was lower and attrition higher than anticipated and measures identified to address these issues. All participants starting physiotherapy completed their course and common themes of treatment were identified. Function improved in the physiotherapy group beyond the minimal clinically important difference on the LEFS (95% CI, median 9, IQR 24) and HOS (95% CI median 10, IQR 18). In the normal care group, there was minimal functional change. Pain improved marginally in both groups.

Conclusions: The study successfully identified methodological strengths and

weaknesses for a substantive study. The results suggest that physiotherapy can improve symptoms of FAI and further evaluation is recommended

INTRODUCTION/ BACKGROUND

The treatment of symptomatic FAI is an evolving science. Although the exact cause of pain in this condition remains unclear, nerve endings sensitive to pain and proprioception have been found in the fibrocartilaginous labrum attached to the circumference of the acetabulum. These nerve endings are more numerous in the anterior and superior portion of the labrum where the pathological changes associated with FAI are most commonly identified (1). Investigation into the pathogenesis of labral lesions has focussed on the contribution of structural abnormalities of the hip joint such as cam and pincer deformities which can cause impingement of the labrum in FAI. However these deformities are also found in asymptomatic individuals and are therefore not necessarily accompanied by pain (2, 3).

The marked increase in research into the treatment of FAI over the last 10 years has focussed on surgical correction of underlying structural abnormalities and has tended to overlook the dynamic process of impingement whereby pain is provoked on hip flexion, internal rotation and adduction. These movements, particularly when combined, place stress on the anterior labrum and if repeated habitually may cause microtrauma to the labrum even in the presence of a morphologically normal hip.

Evidence is limited on the effect of treatments which addresses movement rather than structural abnormalities (4). A systematic review of non-operative treatment for FAI (5) found five studies, of which two describe care pathways with an observational analysis of conservative management consisting of NSAIDs, physiotherapy, stretching or lifestyle modification (6, 7). Forty-four to seventy-two percent of patients improved with conservative management only, and this improvement was sustained for up to two years in one longer term study (7). This limited evidence nevertheless suggests that physiotherapy may have a previously unrecognised role to play in the management of symptomatic FAI. We therefore instigated a pilot study to inform a substantive RCT evaluating the effectiveness of physiotherapy in FAI.

METHODS

Aims and objectives

The aim of the study was to pilot the methods for a substantive randomised controlled study (RCT) comparing the effect on pain and function of a three month course of specialised, individually tailored physiotherapy versus routine care in young adults with FAI.

The objectives were to evaluate a) the recruitment process and study methods. b) a suitable primary outcome measure c) physiotherapy treatments. d) statistical analysis. e) confounding variables. f) the resources required

Design

A parallel group, pilot RCT was initiated after obtaining research ethics and Hospital Trust approval.

Setting

The Orthopaedic and Physiotherapy departments of a single NHS acute hospital trust, Devon, England.

Participants

Participants were required to fulfil all the following eligibility criteria for

inclusion in the study:

- A diagnosis of FAI made by an Orthopaedic Surgeon based on clinical findings with or without confirmatory imaging.
- Aged between 18 and 50 years
- Typical signs and symptoms of labral pathology e.g. Pain in the groin or a 'C' distribution; mechanical symptoms; pain reproduced on flexion, adduction, internal rotation (FAIR) test
- Hip pain predominating over back pain
- Willing to travel for specialist physiotherapy
- Willing to abstain from physical therapy outside the study.

Any of the following criteria excluded participation:

- Lack of consent
- Previous surgery to the hip or pelvis

- The presence of other pathology causing groin pain e.g. avascular necrosis, inflammatory arthritis; septic arthritis; iliopsoas bursitis; fracture, dislocation; tumour; hernia; Perthes disease; Radiological evidence of hip degenerative change, slipped femoral capital epiphysis (SFCE) or hip dysplasia of a degree which would preclude the option of arthroscopy
- Significant back symptoms
- Previous attendance at a pain clinic
- Inability to comply with physiotherapy protocol

Baseline/ Outcome assessment

Potential recruits were offered an information leaflet and the opportunity of discussing the study prior to choosing to participate after which informed written consent was obtained. A baseline data set of questionnaires was then completed following which participants were randomly allocated to either routine care or physiotherapy. A second set of postal questionnaires was completed after three months. The change in specific hip scores between recruitment and 3 months provided the outcome data for the study. Surgeons and therapists participating in the study were blinded to all outcome measures during the study.

Outcome measures

Baseline measurements were used to assess whether recruitment methods ensured that the intervention and control groups were equally matched.

General health was assessed by EQ5D3L (8) which is a validated measure of

general health. The University California, Los Angeles activity score (UCLA) (9) provided a ten point grading of physical activity. The Hospital Anxiety and Depression Score (HADS) (10) provided an objective measure of anxiety and depression which have been shown to be common in chronic musculoskeletal conditions (11).

No individual questionnaire has clinimetric evidence to support its use as an outcome measure in the conservative treatment of FAI, therefore a variety of valid and reliable questionnaires with evidence of sensitivity to change were used. The Non Arthritic Hip Score (NAHS) (12), the Hip Outcome Score (HOS) (13, 14) , and the Lower Extremity Functional Scale (LEFS) (15) were chosen to measure function, and the NAHS and Visual Analogue Scale (VAS) to measure pain (16). Although the NAHS and HOS were primarily designed to measure pre and post-operative change in young adult patients, the NAHS assesses subsections of pain, symptoms, function and activity and the HOS has subsections assessing activities of daily living (ADL) and sports function, therefore their use ensures a hip specific questionnaire assessing parameters equally relevant to monitor in the conservative patient.

Interventions

Control Group

Participants in the control group were allocated to routine care e.g. analgesia and continuation of any self management advice or exercises they had previously been given. They were asked to refrain from physical therapies over the trial period after which all participants were offered referral to

physiotherapy.

Intervention group

Participants in the intervention group were able to access the same routine care as the control group but in addition were referred for treatment by one of 5 senior physiotherapists with experience of treating patients with FAI.

Physiotherapy assessment was aimed at identifying movement and functional deficits following which a treatment programme was devised to address these issues and meet the objectives of the participant. Modalities could include manual therapy and exercise based rehabilitation. Electrotherapy and acupuncture were not permitted. 'One to one' treatment was delivered initially but referral to a gym based group session was permitted to progress rehabilitation. Ten appointments were funded for each participant, however frequency of attendance and discharge from treatment was at the discretion of the physiotherapist. Participant logs were maintained to identify the most commonly used treatments.

Routine Orthopaedic review and investigation continued for both groups throughout and beyond participation in the study and the resulting information was collated to assess whether the eligibility criteria had correctly identified suitable participants

Sample Size and data analysis

An initial sample size of between 30 and 40 per group was suggested for the pilot study. This was later amended to 15 per group so that the study could be

completed within the resources and time available.

Randomisation

Computer generated, block randomisation provided an allocation sequence of three blocks of ten to ensure that equal numbers were allocated to each group. A numbered, sealed envelope concealed the allocation from the investigators and minimised selection bias.

Data analysis

Statistical analysis was descriptive for the control and intervention group as hypothesis testing was not an aim of the pilot study. Continuous outcome data were tested for normality using the Shapiro Wilks test. Data was anonymised to avoid bias by the analyst.

Where the data was normally distributed, central tendency was expressed using means and dispersion using standard deviation. When not Gaussian, data was summarized using medians, interquartile ranges and ranges. Mean differences and the standard deviation of the differences were used to inform sample size calculations for a definitive trial. Confidence intervals were derived wherever possible. Categorical data were summarized as proportions and percentages as appropriate with associated confidence intervals.

RESULTS

Fig. 1. Participant flowchart

Fifty- two people with a diagnosis of FAI were approached to take part in the study. Of these, 22 (42%) were not eligible: nine cited practical difficulties preventing attendance for physiotherapy; six had exclusion criteria; five had been offered participation in an alternative research study and two expressed an initial interest but later declined. Thirty participants were therefore recruited between 19/10/2012 and 20/12/2013 and follow up was completed on 10/04/2014. The baseline profile of the participants is shown in table 1.

At baseline, both groups were similarly matched for age, general health measured by EQ5D3L, anxiety and depression measured on HADS and pain on VAS. There were a greater proportion of males in the physiotherapy group (47%) than the routine group (33%). Functional measures were higher at baseline in the routine care group with the exception of the UCLA activity score. Mean duration of symptoms exceeded 4 years in both groups but this was skewed by two participants who had been experiencing symptoms for over 20 years. The mean duration of symptoms when these participants are excluded is 38.5 months.

Retrospective analysis of medical notes revealed that with one exception, an initial clinical diagnosis of FAI was supported by XR, MRI, MRA or CT. In the remaining case the diagnosis was made on clinical examination with X-ray excluding structural change and no further imaging was performed. At three month review, there was one male participant in the routine care group in whom the initial primary diagnosis of FAI was changed to deteriorating osteoarthritis as a result of MRI findings.

In eight (27%) participants, one or more secondary contributory causes were identified by the orthopaedic surgeon: dysplasia (3), previously undiagnosed mild SUFE (1), soft tissue tightness/ weakness (5), early osteoarthritis (1).

Table 1: Baseline characteristics of participants by treatment group

Table 2: Outcome scores at baseline and 3 months

Seven of the 30 (23%) participants failed to return their three month outcome questionnaires. Four participants from the physiotherapy group failed to attend their initial physiotherapy assessment or respond to further contact. All participants who attended their first physiotherapy assessment completed the course of treatment and follow up questionnaires.

Outcome questionnaires were analysed to assess the extent and consistency of completion. Participants completed VAS, NAHS, LEFS and HOS ADL subsection. One participant in the normal care group did not complete the HOS sports subsection as an unrelated injury sustained during the study period was preventing participation in sport. Two separately analysed sections of HOS asking participants to rate their own level of ADL and sport activity were not completed by eight respondents at baseline and five at follow up and this item was excluded from analysis.

Change in hip outcome scores was analysed. Pain improved in both groups

on VAS (figure 2) (Physiotherapy group mean -0.95, SD 2.2; Routine care - 0.8 SD 1.2) and pain subsection of the NAHS. The total NAHS score (figure 3) measuring change in pain, symptoms, function, and activity improved by 10.9 points more in the physiotherapy group than in the control group. Level of function measured on LEFS (figure 4) and both subsections of HOS (figures 5 and 6) improved in the physiotherapy group beyond measurement error of 5.3 and 3 points respectively. The HOS sports subscale for the routine care group deteriorated beyond measurement error but change in all other outcome measures was minimal.

Figure 2: Change in VAS

Figure 3: Change in total NAHS score

Figure 4: Change in LEFS scores

Figure 5: Change in HOS ADL score

Figure 6: Change in HOS sport score

The range of physiotherapy treatments is shown in table 3. Participants attended for physiotherapy an average of 6.5 sessions (range 1-13). All participants were assessed and given advice on posture, activity levels, pain relief and an individual exercise programme focussing on improving pelvic and proximal femoral control. Additional modalities included stretching, spinal exercise, manual therapy, attendance at a lower limb rehabilitation class and video analysis of high level martial arts manoeuvres. One participant in the physiotherapy group had also received sports massage outside the parameters of the study. No adverse events were reported in either the

physiotherapy or routine care group.

Table 3: Physiotherapy interventions

DISCUSSION

The aim of testing the methodology for a substantive study was successfully achieved and the objectives were met.

A combination of a low recruitment and higher than anticipated attrition rate rendered the initial target of 60 participants in 12 months unattainable. Nine people cited practical issues as a barrier to participation with travel costs, family or work commitments preventing regular attendance at physiotherapy and to combat this limitation, travel expenses would be offered to ameliorate the costs for participants in the main study. A second unanticipated study drawing from the same pool of subjects also affected recruitment to this pilot and may have skewed the sample in both studies. The substantive RCT will be delayed until the second study is complete and combined with an extended period for recruitment with the intention of increasing the sample size. The reason for the high attrition rate in both groups is not known as there was no response to a questionnaire sent to participants exploring reasons for this. Three (10%) of these participants also failed to attend appointments for imaging or orthopaedic review.

The randomisation process was adequate in matching both groups at baseline. Eligibility criteria were designed to reflect the normal clinical

process involved in diagnosing FAI and with one exception, all participants had at least one finding on imaging supporting this diagnosis. Eight (27%) participants also had one or more secondary contributory causes identified by the orthopaedic surgeon, five of these cases were subsequently randomised to physiotherapy, three to normal care. Secondary structural issues with a known association to FAI were identified in four participants, three with dysplasia and one with previously unidentified mild SFCE. One participant was found to have mild degenerative change as a secondary diagnosis at initial assessment but which was a more obvious source of pain on review and in retrospect was not suitable for inclusion in the study. Five (17%) participants had notable soft tissue adaptation which is unsurprising given the chronicity of symptoms experienced by most participants. The incidence of secondary contributory factors suggests that effective management of this condition requires recognition of a number of interacting structural and neuromuscular issues and supports previous studies suggesting that the presence of subtle osseous abnormalities such as mild hip dysplasia do not predict the outcome of conservative treatment (6). For this study a pragmatic approach was taken whereby cases were included where any underlying structural change was not sufficient to preclude potential arthroscopic treatment directed at the FAI. The eligibility criteria need to acknowledge that FAI is commonly associated with secondary factors whilst limiting excessive heterogeneity and so in the substantive study eligibility criteria will stipulate a threshold of severity of OA, dysplasia and SUFE.

Data collection procedures were effective. VAS, NAHS, HOS and LEFS

questionnaires were fully completed at three months apart from one participant in the normal care group who felt that an unrelated injury rendered the questionnaires inaccurate. All four outcome measures indicated similar levels and direction of change and although none were designed specifically to measure change with conservative treatment for FAI, the study suggests that they are suitable for this purpose. Each questionnaire has different strengths and weaknesses but the NAHS is easy to administer, valid, and does not have a floor or ceiling effect (12) so would be used as the primary outcome measure for the full RCT.

Function and participation in sport improved in the physiotherapy group beyond the Minimal Clinical Important Difference and measurement error on HOS and LEFS questionnaires. In the routine care group, there was minimal change on all questionnaires apart from the HOS sports subsection where there was deterioration of 3.5 which was beyond measurement error. The change in pain was less obvious in both groups. VAS and NAHS pain subsection improved marginally in both groups at three months but no long term trend can be assumed. Increased duration of follow up in the main study would allow the longer term effects of physiotherapy to be evaluated.

All participants who attended their initial physiotherapy appointment completed treatment. Feedback from participants was good and no significant change would be made to the intervention for the main study. Attendance varied between one and 13 sessions (mean 6.5). All participants were assessed and given advice on hip posture, activity and self care and for one

participant who had received a successful steroid injection, this was all that was delivered. In all other cases, the cornerstone of treatment was an individualised rehabilitation programme focussing on improving strength and endurance of the proximal hip muscles, proprioception and movement control. These themes were consistent with previously published work (6, 7, 17-19) which provide an excellent basis for rehabilitation emphasising the importance of establishing adequate timing, strength and endurance of multifidus, transversus abdominus, gluteus medius, and maximus, the internal and external rotators and iliopsoas to establish good lumbopelvic and hip stability.

Unanticipated variables occurred and would be considered for the full RCT. One participant in each group had guided intraarticular steroid injection which would have been reflected in the pain scores. During the full study, intraarticular injection would remain as an option for short term pain relief but injection in the 3 months prior to recruitment would be an exclusion criterion so that baseline outcome data were not influenced, and the use of injection would be reported as part of the study analysis. Six (20%) participants, three in each group were on the waiting list for hip arthroscopy whilst participating in the study, and the anticipation of surgery could have a neutral, positive or negative effect on outcome data. Two patients were listed for surgery when reviewed by the surgeon after the study, both from the normal care group. No participant for the physiotherapy group was listed for surgery after the study. In the main study, participants would not be offered surgery before or during the study but would be reviewed on completion and the numbers of participants listed for surgery from each group would provide an additional

outcome measure.

The statistical analysis and resource allocation was as anticipated and would be rolled out to the mains study.

CONCLUSION

The pilot project successfully informed the methodology of a future RCT evaluating the effects of physiotherapy on symptomatic FAI. The results suggest that a three month course of specialised physiotherapy may improve function and further research is needed to evaluate the effects of conservative treatment.

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Ethical approval

Ethical approval was granted by the NRES Committee South West Exeter on

15th June 2012 (REC reference 12/SW/0136), protocol number 1210704)

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Conflict of interest statement

The authors are all employees of the Royal Devon and Exeter NHS Foundation Trust

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Figure 1: Participant flowchart

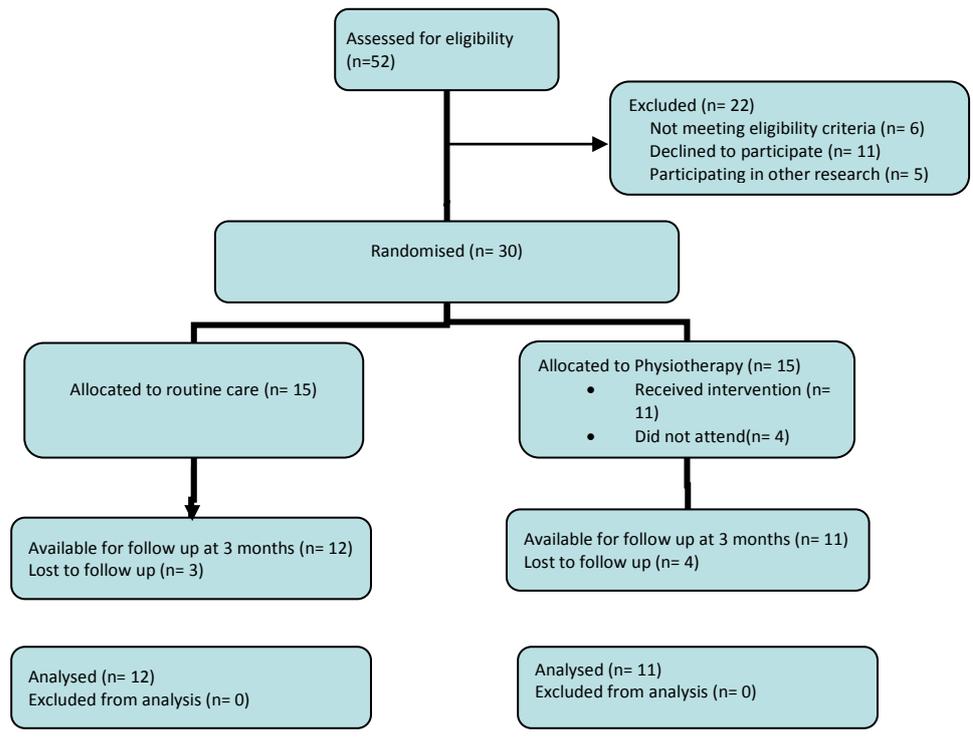


Figure 2: Change in VAS

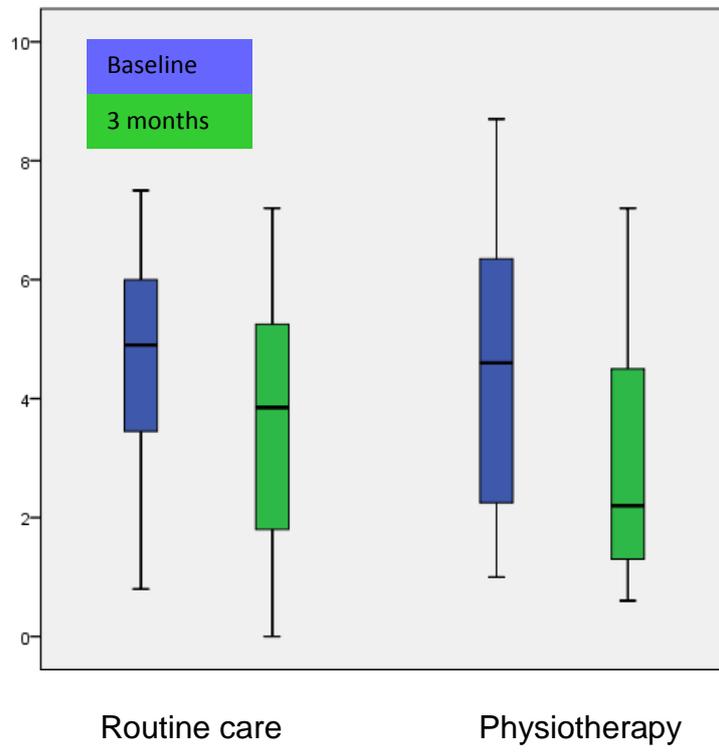


Figure 3: Change in total NAHS score

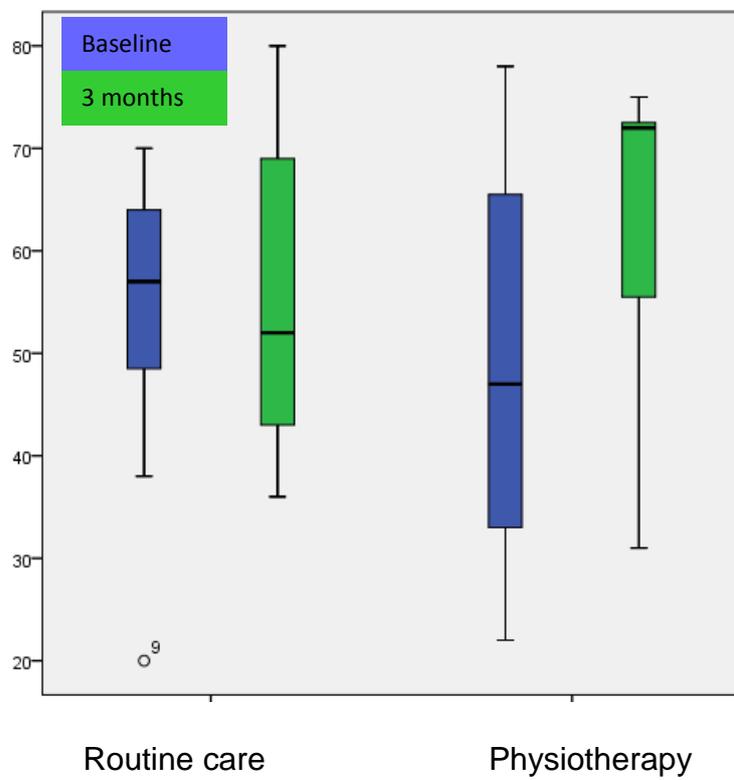


Figure 4: Change in LEFS scores

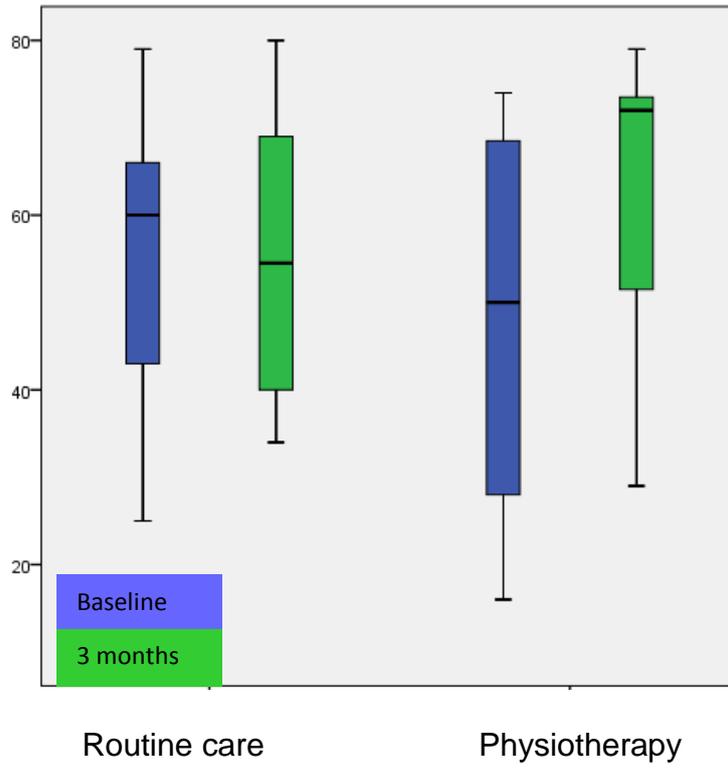


Figure 5: Change in HOS ADL score

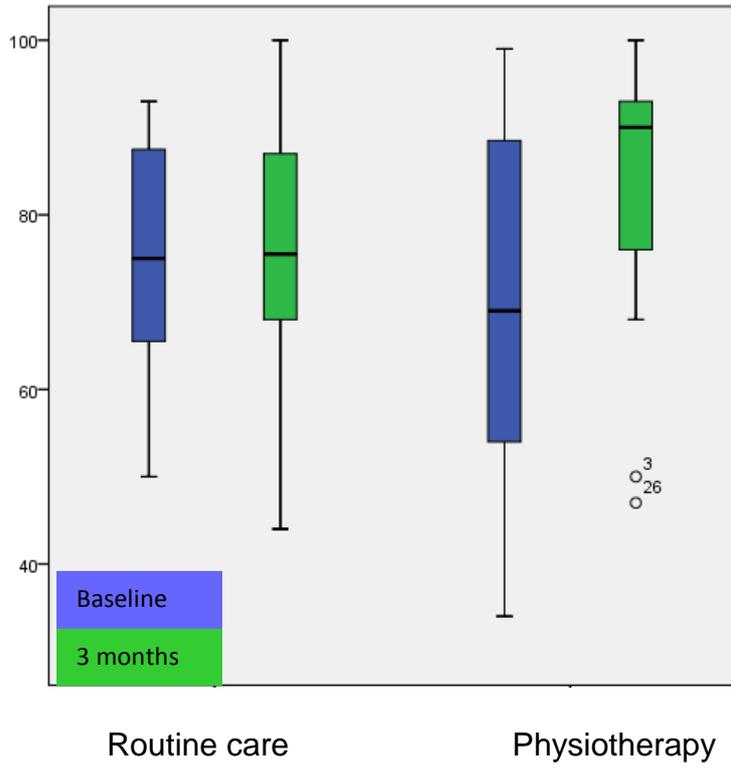


Figure 6: Change in HOS sport score

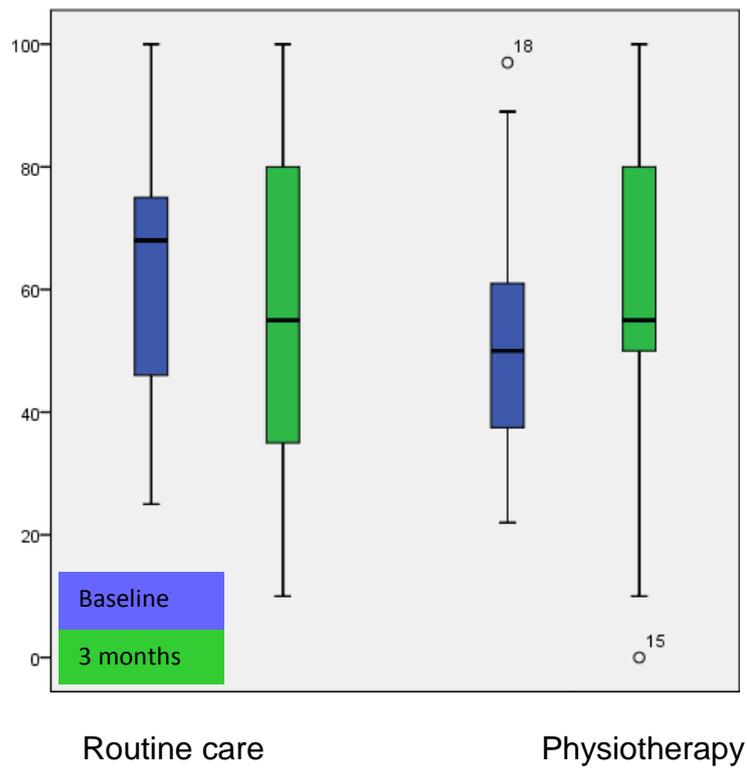


Table 1: Baseline characteristics of participants by treatment group

	Physiotherapy group N=15	Normal care group N=15
Age. Mean (range)	35.9 years (18.6-48.8)	32.6 years (18.5-50.3)
Gender- male	7 (47%)	5 (33%)
Laterality-Right	9 (60%)	8 (53%)
Duration of symptoms/ months. Mean (range)	48.7 (6-252)	56.7 (6-240)
EQ5D3L ^a	0.69 (0.24)	0.69 (0.24)
EQ5D VAS % Median (IQR)	80 (30)	80 (30)
UCLA ^b . Median (IQR)	9.0 (4)	7.0 (4)
HAD anxiety ^c . Median (IQR)	4.0 (7)	4.0 (5)
HAD depression ^c . Median (IQR)	5.0 (7)	3.0 (4)

^aScale to a maximum of 1 with a higher score indicate better quality of life.

^bScale 1-10. Increased score equates to higher level of physical activity.

^cScale 0 to 21. Higher scores indicate increased anxiety/ depression

Table 2: Outcome scores at baseline and 3 months

Outcome questionnaire	Physiotherapy			Normal care group		
	Baseline (N=15)	3 months (N=11)	Difference (95% CI)	Baseline (N=15)	3 months (N=12)	Difference (95% CI)
VAS ^a Mean (SD)	4.5 (2.5)	3.1 (2.3)	-0.95 (2.2)	4.5 (1.9)	3.7 (2.2)	-0.8 (1.2)
NAHS Pain ^b Mean (SD)	13.3 (4.3)	16.2 (4.0)	2.9 (3.1)	14.3 (3.2)	14.8 (3.9)	0.4 (2.9)
NAHS symptoms ^b Mean (SD)	10.5 (4.1)	11.9 (2.9)	1.8 (3.2)	11.3 (3.6)	11.6 (3.5)	0.42 (2.8)
NAHS Function ^b Median (IQR)	14.0 (10)	18.0 (8)	2 (7.0)	16.0 (5)	16.0 (8)	0.0 (5.8)
NAHS activity ^b Mean (SD)	12.9 (6.7)	17.7 (5.4)	5 (4.7)	13.6 (4.9)	14.36 (5.7)	0.8 (2.7)
NAHS Total ^b Mean (SD)	50.1 (19.1)	62.2 (16.1)	12.7 (11.9)	54.4 (13.3)	55.2 (15.0)	1.8 (10.6)
LEFS ^c Median (IQR)	50 (44)	72 (26)	9 (24)	60 (26)	54.5 (30)	-0.5 (10.8)
HOS ADL ^d Median (IQR)	69 (39)	90 (27)	10 (18)	75 (25)	75(21)	3 (12.3)
HOS sport ^d Mean (SD)	53.5 (21.9)	68 (21.6)	16.6 (16.4)	61.2 (21.5)	55.5 (27.7)	-3.5 (17.2)

^a Scale 0-10. Higher score equates to increased pain

^b Total scored on a scale of 0-80 points from the summation of pain (0-20 points), symptoms (0-16), function (0-20), activity (0-24)

^c Scale 0-80 points. Higher score equates to increased functional level

^d Percentage scale. Higher scores indicate higher level of ADL or sports activity

Table 3: Physiotherapy interventions

Physiotherapy Intervention	Number of participants receiving intervention (N=11)
Assessment	11
Education/ advice	11
Core stability exercise	9
Hip strengthening exercise	10
Functional exercise	10
Proprioception exercise	10
Stretches	9
Spinal exercise	6
Manual therapy	4
Gym class	3
Corrective shoe insole	1
Video analysis	1

