A single-arm, non-randomized investigation into the short-term effects and follow up of a 4-week lower limb exercise programme on kinesiophobia in individuals with knee osteoarthritis

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http://dx.doi.org/10.1002/pri.1831

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Concept and design. Molyneux, Herrington, Riley, Jones.

Analysis and interpretation of data. Molyneux, Herrington, Jones.

Critical revision of the article for important intellectual content. Molyneux, Herrington, Jones.

Final approval of the article. Molyneux, Herrington, Jones.

FUNDING. None.

DECLARATIONS OF INTEREST. **None.**

KEY WORDS:

Osteoarthritis, Knee

Exercise

Pain

Word Count: 2893

Abstract

Objective

To investigate the short-term effects and follow-up of a 4-weeks lower limb exercise programme on kinesiophobia in individuals with knee osteoarthritis.

Design

Participants diagnosed with knee OA clinically against the American College of Rheumatology criteria (ACR) were recruited. Participants completed a 4 weeks lower limb exercise programme. Each participant completed two questionnaires, the Tampa kinesiophobia scale (TSK) and the knee injury and osteoarthritis outcome score (KOOS). Each measurement was completed at the baseline assessment, at session 4 of the programme, at session 8 of the programme, and 6-weeks after the exercise programme. Perceived levels of exertion (RPE) were measured after each exercise session using the modified Borg scale.

Results

Fifty-four participants took part in the study. Kinesiophobia decreased from the baseline assessment to 6-weeks after the exercise programme. KOOS pain, symptoms, sports and

recreation, quality of life and activities of daily living score increased, therefore showed improvement. Correlational analysis highlighted a moderate negative correlation between the KOOS pain and kinesiophobia at baseline and 6- weeks after the exercise programme (0.44, 0.48 respectively).

Conclusions

Understanding baseline kinesiophobia scores could provide an important resource for health professionals who manage individuals with knee osteoarthritis to improve the quality of care due to the correlation with pain changes and may improve exercise related outcomes for a longer duration.

CONTRIBUTION OF THE PAPER

-Kinesiophobia is prevalent in individuals diagnosed with knee osteoarthritis.

-Kinesiophobia decreased in 75% of individuals with knee osteoarthritis after a 4-weeksexercise programme.

-Correlation between pain and kinesiophobia at baseline and 6-weeks after an exercise programme.

-An understanding of an individual's kinesiophobia level before an exercise programme is important for future prognosis of changes in pain.

CLINICAL TRIAL NUMBER

NCT02734342

Introduction

Osteoarthritis (OA) is one of the leading causes of pain and musculoskeletal disability (1) and represents a typical chronic musculoskeletal condition (2). The management of knee osteoarthritis can be categorized into pharmacological, surgical, and conservative management. Usage of pharmacological treatments such as paracetamol and intra-articular injections provide a reduction in pain (1). However, both have complications e.g. renal toxicity, septic arthritis, and joint degradation (3). Surgical interventions may be required, such as arthroscopic resection, osteotomies, and joint replacements, but come with risks such as infection, deep vein thrombosis and revision surgery (4). Non-pharmacological core interventions recommended via the NICE guidelines (1) include local muscle strengthening, general aerobic exercises, and education for their effectiveness in reducing pain and increasing function.

Increasing muscle strength can significantly reduce knee OA symptoms, pain and therefore improve the quality of life and activities of daily living. Exercise has been recommended as a core treatment for knee osteoarthritis (1). Despite positive evidence regarding exercise (7) individuals with knee OA avoid exercise to prevent pain (12) and are not achieving the recommended level of exercise (13). Psychological factors such as kinesiophobia are as important as the physical characteristics in driving this behaviour (14). Kinesiophobia is a psychological impairment that results from a feeling of vulnerability to a painful injury or re-injury and therefore prevents individuals completing an activity (15). Kinesiophobia is prevalent in individuals with knee OA with greater pain and functional limitations being reported in individuals with increased kinesiophobia (16, 17). Therapeutic exercise has the potential to improve knee instability and psychological factors (23, 35).

There is little research exploring kinesiophobia in knee OA with only one recent study investigating the effects of dynamic balance and exercise in forty individuals diagnosed with medial knee OA (28). Kinesiophobia was measured as a secondary outcome using the brief fear of movement scale questionnaire with positive effects after completing a 10-weeks partially supervised exercise programme. The study undertaken is the first study to measure the short-term effects of kinesiophobia using the Tampa Scale of Kinesiophobia throughout a 4 weeks exercise programme at baseline, session 4, session 8 and 6-weeks after the exercise programme in individuals with knee OA. The Tampa Scale of Kinesiophobia (TSK) is a brief, reliable and a valid measure to link fear of movement with knee OA (26). We hypothesized that a short-term exercise programme reduces kinesiophobia in individuals diagnosed with knee OA.

Participants and Methods

The study is a level one prospective clinical trial (clinical trial number NCT02734342) whereby ethical approval was obtained from the South West Research Ethics Committee (16/SW/0036).

Participants

Individuals referred to physiotherapy were invited to participate who had a clinical diagnosis of knee OA using the American College of Rheumatology guidelines, which are 95% sensitive and 69% specific for the diagnosis of osteoarthritis (18). Individuals aged 45 and above were invited into the study, as per national guidelines (1) with specific sign and symptoms to include stiffness for less than thirty minutes; crepitus; bony tenderness; bony enlargement and no palpable joint warmth, individuals must elicit three of the six to be included in the study. Individuals who had a radiographic diagnosis were also included in the study, as x-rays are gold standard in the diagnosis of OA with a greater specificity (18).

Reasons for exclusion from the study included previous lower limb joint injection within three months; previous bilateral hip or knee joint replacement; any severe cognitive, cardio-respiratory, musculoskeletal or neurological diagnosis that prevents participants from exercising. Individuals with a body mass index (BMI) over 40 had a choice of being involved in the study or be referred to the NHS weight management service, as per service specification. Other minor health related issues were assessed prior to the commencement of the study to ensure safe practice. All participants provided written informed consent.

Intervention

Procedures

Participants were asked to attend eight exercise sessions within a group class environment that lasted for 1 hour per session. Participants attended each class, twice per week for four weeks. Four-weeks was chosen due to time and workload constraints within the physiotherapy department. Clinical guidelines suggest two to three exercise sessions per week are required to attain a positive response in symptoms (20). During the hour, all participants completed a 5-minute warm up and then commenced the 14-station exercise programme, which were specifically orientated to strengthen the lower limb and improve aerobic capacity. Exercises included cycling, treadmill walking, cross trainer, step machine, wall squats with a swiss ball, mini- squats with an elastic band, trampette, step-ups, heel raises, hip extension over a plinth, crab walking with an elastic band, monster walking with an elastic band, balancing on a tilt board and single leg stands. Participants recorded the number of repetitions, and progression of exercises was patient led based on pain and perceived exertion. Each exercise was timed for two minutes with approximately one minute in between each exercise. After seven exercises, a 5-minute hydration break occurred. After each exercise class, a cool down was completed, with the participant completing the Borg

scale for patient specific maximal exertion. Participants were advised to have a recovery day to prevent overloading (21). The group class operated from the physiotherapy department gymnasium and was supervised by a specialist physiotherapist, who received three hours training by the principal investigator, which consisted of reviewing each exercise station, outcome measurements, and documentation. Both the principal investigator and specialist physiotherapist offered telephone support to any of the participants during department open times. Participants also received text message reminders the day before each exercise class to increase attendance, which is cost effective (22). Other forms of interventions during the study were not permitted such as the provision of injections or orthotics.

All individuals completed the Knee Injury and Osteoarthritis Outcome Score (KOOS) and the Tampa Scale of Kinesiophobia (TSK) at the baseline assessment. TSK Scores range from 17-68 points, with high kinesiophobia being classified with a score above 37 (15). Although no evidence has been reported in relation to the minimal clinical detectable change for the TSK in knee OA, a 4.6-point change in kinesiophobia was found using the brief fear of movement with medial knee OA (28), with a 5.6-point change for generalised chronic pain (26) and 9.2 point for low back pain (38). Furthermore, a minimal clinical detectable change of 13.4 points has been suggested for the KOOS pain scale in knee OA (29-30).

The questionnaires were repeated at session 4 and session 8 of the exercise programme. At the end of the allocated sessions, all participants were issued with a six-week follow up assessment and referred to a local leisure centre for further exercise. Perceived level of exertion was measured after each exercise programme using the modified Borg scale.

Statistical Analysis

Statistical analysis was performed using Statistical Package for Social Sciences (SPSS version 24.0) with the significance level set at $p< 0.05$. Data were reviewed for normality

prior to data analysis with the Kolmogorov-Smirnov tests being completed. The KOOS data were normally distributed; therefore, a repeated measure of analysis of variance (ANOVA) was completed to investigate the mean variability within the participants' scores. Normal distribution was not found in the TSK; therefore, a Friedman test was completed with a post hoc Wilcoxon sign ranks test. A Spearman's correlation coefficient was completed to analyse the TSK and KOOS.

Results

Ninety- five individuals diagnosed with knee OA were invited into the study. Thirty-one individuals did not consent to the exercise programme and were re-appointed with another physiotherapist. Ten individuals completed the 60-minute assessment and then e-mailed/telephoned directly after to decline participation. Therefore, Fifty- four individuals with knee OA participated in the study, 27 males and 27 females with a mean age of 63.35 (SD 8.1) years; mean height 1.64 (SD 0.34) metres; mean mass 78.37 (SD 21.22) kilograms; mean body mass index 27.12 (SD 4.08). Seventeen participants (31.5%) were diagnosed with grade 2 Kellgren and Lawrence scale (KL); 19 participants (35.2%) diagnosed with grade 3 KL; 12 participants (22.2%) diagnosed with grade 4 KL, all with medial compartment OA, and six participants (11.1%) diagnosed without x-ray but with specific clinical symptoms using the American College of Rheumatology criteria (ACR).

Insert Table 1 here

Table 2 shows the median points scored after completing the TSK at baseline, session 4, session 8 and 6-weeks after the exercise programme. Participants' baseline scores recorded a median of 37 (IQR 9.25), at session 4, median score 33.5 (IQR 11), at session 8, median score 32 (IQR 8.5) and 6-weeks post-exercise programme, median score 33 (IQR 12). Therefore, an overall median change score of four was recorded from baseline to 6-weeks post-exercise programme. Secondary analysis using the Wilcoxon signed ranks test data indicated a non-significant change from baseline to session 4 (p= 0.052), however from baseline to session 8 (p= 0.002) and baseline to 6-weeks post-exercise programme (p= 0.001) there was a statistically significant change. Over half of the participants' recorded high levels of kinesiophobia at baseline (52% scored 37 and over). Fourteen participants' remained high after 6-weeks post-exercise programme, 12 scored highly at baseline and remained high throughout the exercise programme. Two participants scored low at baseline, but had a re-occurrence of their symptoms at the 6-week follow-up. Those participants whose kinesiophobia remained high, the pain levels minimally reduced (baseline 46.69, 6-weeks post-exercise programme 45.88).

Insert Table 2 here

Table 3 shows the KOOS mean scores at baseline, session 4, session 8 and 6-weeks after the exercise programme. Participant's baseline KOOS pain score recorded a mean of 41.06 (SD 17.46) at session 4, mean score 47.79 (SD 14.83) at session 8, mean score 51.18 (SD 21.82) and 6-weeks post-exercise programme, mean score 56.53 (SD 22.21). A non-significant change from baseline to session 4 (p= 0.06) occurred, however from baseline to session 8 (p=0.009) and baseline to 6-week post- exercise programme (p= 0.001) the change was statistically significant. Participant's baseline KOOS symptoms score recorded a mean of 41.67 (SD 18.78) at session 4, mean score 49.34 (SD 14.09) at session 8, mean score 49.03 (SD 20.29) and 6-weeks post-exercise programme, mean score 56.48 (SD 19.19). With

significant changes occurring from baseline to session 4 (p= 0.001), from baseline to session 8 (p=0.05) and baseline to 6-week post-exercise programme (p= 0.001). Participant's baseline KOOS activities of daily living score recorded a mean of 46.9 (SD 21.62) at session 4, mean score 54.33 (SD 18.04) at session 8, mean score 57.44 (SD 25.31) and 6-weeks post-exercise programme, mean score 61.39 (SD 20.97). There was a non-significant change from baseline to session 4 (p= 0.09) was recorded, however from baseline to session 8 (p=0.038) and baseline to 6-week post- exercise programme (p= 0.01) the change was statistically significant. Participant's baseline KOOS sport and recreation score recorded a mean of 21.39 (SD 29.71) at session 4, mean score 29.07 (SD 21.06), at session 8, mean score 32.41 (SD 26.22) and 6-weeks post-exercise programme, mean score 32.94 (SD 27.13). There was a non-significant change from baseline to session 4 (p= 0.25), however from baseline to session 8 (p=0.010) and baseline to 6-week post-exercise programme (p= 0.029) the change was statistically significant. Participant's baseline KOOS quality of life score recorded a mean of 24.15 (SD 19.39) at session 4, mean score 37.06 (SD 17.74) at session 8, mean score 40.33 (SD 24.21) and 6-weeks post -exercise programme, mean score 43.08 (SD 23.47). A significant change occurred from baseline to session 4 (p= 0.001), baseline to session 8 (p= 0.0001) and baseline to 6 week post-exercise programme (p= 0.001). Mean scores throughout the 8-session exercise programme ranged from 13.22 to 14.07. Baseline scores for the participants perceived exertion was 13.5, with the greatest increases at session 4 (13.98) and session 5 (14.07), then the score levels decreased to 13.29 at session 8. Correlational analysis suggests that the KOOS pain and TSK have a moderate negative correlation at baseline (coefficient -0.48) and at 6-weeks after the exercise programme (coefficient -0.44). Mean scores for the Borg scale ranged from 13.22 to 14.07 throughout the programme.

Insert Table 3 here

Discussion

The study aimed to understand whether kinesiophobia was altered following an 8 session physiotherapy intervention. To the authors' knowledge, this is the first study to demonstrate that an 8-session exercise programme in the national health service setting reduces kinesiophobia, pain, and symptoms, increases quality of life, sporting and recreation activities. Kinesiophobia has a negative influence on the outcome of rehabilitation with a high level of kinesiophobia presenting poorer rehabilitation outcomes (34) with an increased level of disability and a reduction in strength being reported (37). Kinesiophobia interferes with descending pain-inhibitory systems and facilitates neuroplastic changes in the spinal cord during painful stimulation, which ends with pain sensitisation (38). Consequently, this pain sensitisation causes functional decline that in turn causes depression and disturbed sleep that can increase psychological distress (19). Over half of the participants' recorded high levels of kinesiophobia at baseline (23), therefore assessing for kinesiophobia during an initial assessment is important to allow the therapist and patient to collaborate a physical activity programme with specific goals that will reduce the fear of movement sooner and potentially reduce the chronic processes that can be related to kinesiophobia.

Previous research into kinesiophobia using the TSK for functional disability reported an average score of 24.5 with osteoarthritis (39), which is much lower than our study. However, a mean reduction of 4.6 points in kinesiophobia was found using the brief fear of movement scale after an exercise programme in individuals with medial knee OA (28), which aligns with our findings. Furthermore, the difference in this study is lower than the average score for other musculoskeletal conditions, which is 42 (24). Higher levels of kinesiophobia have been reported at baseline in individuals with chronic low back pain, which reduced after 6 months of physical activity (25). Although no evidence has been reported in relation to the minimal clinical detectable change for kinesiophobia in knee OA, the median change of 4 during this study does not appear to meet the minimal clinical detectable change of 5.6 for generalised

chronic pain (26) or even 9.2 for low back pain (27). Correlational analysis between the TSK and KOOS pain highlighted a moderate negative correlation at baseline and 6-weeks post programme, therefore, the reduction in pain might be potentially related to the reduction in kinesiophobia, but it is unlikely this is the only reason and future study should attempt to investigate this in detail. Identifying individuals who have high TSK at the start of the exercise programme may help to stratify different strategies to increase physical activity levels, reduce chronic behaviour patterning, and improve the rehabilitation process. Similarly, pain coping strategies and exercise programmes have been positively associated in individuals with knee OA (17, 35), however not cost effective (17).

At the 6-week review compared to baseline, the KOOS pain subscale significantly improved. However, between baseline and session 4 no significant improvement was found, this could be related to the individuals starting an exercise programme or even commencing exercises that they had never completed before and after the first few sessions developing pain due to working the muscles. From session 4 onwards, the exercise programme provided the individuals with reduced pain. With a mean change of 15.47, which is clinically significant (29, 30). Further KOOS subscale scores highlighted statistically significant scores reducing symptoms, increasing quality of life, increasing sport and recreation and increasing activities of daily living. However, between baseline and session 4 no significant improvement was found in the individual's activities of daily living, with the exercise programme reducing the individuals' activities, which could be down to pain and reduced function (32).Perceived exertion was recorded whilst using the Borg scale, with scores ranging from 13.22 to 14.07, which can significantly influence knee OA (33). Moderate activity has been linked with improved function and reduced pain for up to 6-months (34).

The main limitation of this study relates to the multiple factors that are associated with kinesiophobia, as it is considered a psychological behavioural factor with sociological, lack of confidence and previous experience being as important as the physical characteristics. We have assumed that the exercise programme had a positive impact on kinesiophobia; however, the interaction with the physiotherapist could have influenced the results and reduced kinesiophobia. Therefore, a control group is an essential part of research to minimize the effects of the intervention; future studies should include a control group with a matched alternative therapy. Understanding individual exercise behaviours and habits should be established as part of the routine examination and treatment for chronic musculoskeletal conditions especially in relation to physical activity.

In conclusion, our findings demonstrate that kinesiophobia and pain reduces after completing an exercise programme in participants with knee OA. During the exercise programme, as kinesiophobia reduced, so did the participant's pain, therefore an understanding an individual's kinesiophobia level before an exercise programme is important for future prognosis of changes in pain, as individuals who interpret pain as none threatening confront the situation, maintain daily activities, and are more likely to recover quicker and are less likely to experience problems.

ETHICAL APPROVAL

The study is a level one prospective clinical trial (clinical trial number NCT02734342) whereby ethical approval was obtained from the South West Research Ethics Committee (16/SW/0036).

Table 1: Descriptive characteristics. Data presented as mean (SD) unless otherwise indicated.

Characteristics	**N=54**
Age (years)	63.35 (SD 8.1)
	Range: 47-79
Gender	Male: 27
	Female: 27
Weight (kg)	78.37 (SD 21.22)
	Range: 57.15 – 120.6
Height (m)	1.64 (SD 0.34)
	Range: 1.49- 1.91
Body Mass Index (BMI)	27.12 (SD 4.08)

Table 2: Friedman Test. Median change (IQR), percentage difference between sessions, p-values, and changes in kinesiophobia using the TSK (* Significant value)

	TSK	P-value from baseline	% of change betweem session
Baseline Score	37 (9.25)		
Session 4 Score	33.5 (11)	0.052	-9.46%
Session 8 Score	32 (8.5)	0.002*	-4.48%
6-week post Score	33 (12)	0.002*	+3.13%
Total change	4		-10.81%

Table 3: Repeated Analysis of Variance. Mean (SD) changes in the KOOS questionnaire at baseline, session 4, session 8, and 6-week post exercise programme (* Significant value) .

KOOS Subscale	Baseline score	Session 4 score	Session 8 score	6-week post score	Total change from baseline	P-value from baseline
Pain	41.06 (17.46)	47.79 (14.83)	51.18 (21.82)	56.53 (22.21)	15.47	0.001*
Symptoms	41.67 (18.78)	49.34 (14.09)	49.03 (20.29)	56.48 (19.19)	14.81	0.001*
Activities of daily living	46.9 (21.62)	54.83 (18.04)	57.44 (25.31)	61.39 (20.97)	14.49	0.002*
Sport/Recreation	21.89 (29.71)	29.07 (29.07)	32.41 (26.22)	32.94 (27.13)	11.55	0.011*
Quality of life	24.15 (19.39)	37.06 (17.74)	40.33 (24.21)	43.08 (23.47)	18.93	0.001*

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