Reviewer’s report

Title: Physiotherapist as primary assessor for patients with suspected knee osteoarthritis in primary care—A randomised controlled pragmatic study

Version: 0 Date: 21 Apr 2019

Reviewer: Ana Paula Ribeiro

Reviewer's report:

General comments on the paper:

Scientific article is very important for knee osteoarthritis area, especially orthopedic. The authors bring important contributions to understanding of the differences in health-related quality of life (HrQoL), pain and physical function for patients with KOA when initially assessed by a physiotherapist or a physician. However, several points should be rewritten with greater scientific support that best justifies the relevance of the clinical study. The authors need to clarify and explain with more detail on the rationale of the study for better understanding and specification of the research problem. Just below follows some points to clarify the text content. The introduction needs be worked in several ways. The information is short and not very explanatory with the scientific literature. The methodology needs to be rewritten at some points with information important for a better understanding of what was done in this study. The result needs to be rewritten. The discussion needs to be reviewed in several paragraphs. The conclusion must be rewritten.

TITLE

Author: Physiotherapist as primary assessor for patients with suspected knee osteoarthritis—A randomised controlled pragmatic study.

SESSION ABSTRACT

Background: Add in the abstract

Author: "In Swedish primary care, either a physician or a physiotherapist initially assesses patients with suspected knee osteoarthritis (KOA). However, it is unclear if the treatment results differs between these assessments in patient reported outcomes."
Reviewer: Please, restructure the first sentence. Could the authors detail and clarify what is not clear? The clinical treatment or physical therapy? Or the assessments made before and after treatment?

Objective:

Author: "The purpose of this study was to examine the differences in health-related quality of life (HrQoL), pain and physical function for patients with KOA when initially assessed by a physiotherapist or a physician."

Reviewer: The aim of the study is to understand the profile of patients who are cared for in primary care. If so, the background should be directed to evaluate the characteristics of the patient.

Materials and Methods:

Author: "An assessor-blinded randomised controlled trial. Patients seeking primary care with suspected KOA were randomized to either a physiotherapist or physician for primary assessment, diagnosing, and treatment. Inclusion criteria: knee pain and > 38 years of age. Exclusion criteria: knee pain due to trauma, other systemic, somatic, mental or rheumatic diseases, pregnancy, or previous diagnosis as source of current knee pain. Measurements were made before randomization and at 3, 6, and 12 months. Primary outcome was HrQoL (EQ5D-3L index and EQ5D-3L VAS); secondary outcomes were pain intensity (VAS) and physical function (the 30-second chair stand test). Mixed effect model analyses compared repeated measures of HrQoL between groups."

Reviewer: Authors should remove the inclusion and exclusion criteria from this summary session. Specify the method of randomization and duration time and acronyms used. Make clear the assessed physical function, as well as the process of research evaluation and statistical analysis.

Results:

Author: "Patients were randomised to either a physiotherapist (n=35) or physician (n=34) for primary assessment. All patients were included in the analysis. HrQoL was significantly different over time (EQ-5D-3L index, p<0.001; EQ-5D-3L VAS, p=0.005). There were no statistically significant differences between a physiotherapist and a physician as primary assessor (EQ-5D-3L index, p=0.176; EQ-5D-3L VAS, p=0.493). No adverse events or side effects were reported."
Reviewer: The results are confusing and not very explanatory of the observations found in the study. I suggest to rewrite this session with more detail the observed results of the analyzes performed.

Conclusion: There were no significant differences between a physiotherapist or physician initiating the healthcare process. Both assessments resulted in higher long term HrQoL for patients with suspected KOA. Physiotherapists could be considered a first option as primary assessor for patients with suspected KOA. However, more research is needed to determine whether this management is more cost efficient.

Reviewer: Description of the results. Please, restructure and rewrite with more detail.

Keywords: Direct access, healthcare process, health related quality of life, pain, physical function.

Reviewer: Please, excluded the words: Direct access, healthcare process, health related quality of life. Add: health, osteoarthritis, knee, life, pain.

SESSION INTRODUCTION

Author: "Osteoarthritis (OA) is one of the most common joint diseases and a major cause of chronic musculoskeletal pain and disability in working and older adults [1, 2]. In Sweden, 14% of those over 45 are estimated having knee OA (KOA) [3]. Common OA symptoms such as pain and physical disability directly affect patients' social interactions, mental functioning, and sleep quality [4], and patients with KOA report among the lowest health-related quality of life (HrQoL) compared with patients suffering other chronic diseases [5]. This patient group has a twofold risk for sick leave, and the diagnosis entails a 40-50% higher risk for disability pension. KOA accounts for 2% of all sick days in Sweden [2]."

Reviewer: Please, describe what are the physical disabilities observed in the literature and add more citations regarding the changes.

Author: "At the same time, patients with OA seem reluctant to seek professional help, partly because they do not want to burden physicians with their problems [10]. Previous studies of back and neck pain have shown that the most common expectation when consulting a clinician (physiotherapist (PT) or physician) is not recovery, but having their diagnosis confirmed [11, 12]. Early access to a PT has previously been shown safe and effective for patients with musculoskeletal disorders [13, 14]. A pilot study showed that most patients assessed by a rehabilitation professional first (PT, occupational therapist, psychologist or counsellor) did not need to see a physician later [15]. PTs as primary assessors reduce referrals, sick leave, and
prescriptions of analgesics for most musculoskeletal conditions [16], by providing an early consultation by health professionals other than a physician competent in diagnosing and treating patients with OA. However, whether all patients with suspected KOA should be referred to a PT as primary assessor needs further study."

Reviewer: Describe more details about the reluctance of patients when they do not want to overload the doctors, since in column dysfunctions they seek this professional to confirm the diagnosis. The authors must specify the importance of the physiotherapist for primary care in the initial degree of knee osteoarthritis and its advantages for a preventive rehabilitation to improve symptomatological aspects and progressive physical limitations.

Author: "…The question of whether a physician is still needed for treatment in the early phase of OA remains. Recommended pharmacological treatments [20] have shown only short-term effects, thus conservative dosages due to safety risks were recommended. Core treatment of OA should be individually customized and include patient education, an exercise regimen, weight loss if overweight or obese, reduction of adverse mechanical factors, and consideration of walking aids [20, 21]. Advice on exercise and pain relief comprises the bulk of the PT assessment, in comparison with other medical staff members [22-24], providing a key role in the acute and long-term management of OA".

Reviewer: It is necessary to better detail what are the education points, mechanical factors and exercise regime and physical activity that should be performed by the physiotherapist in the primary care of the initial degree of knee OA.

Author: "Common PT management in Sweden includes patient education and supervised exercise following a nationwide program called "Better management of patients with OA" (BOA) [25]. Participation in the Swedish BOA results in improvements in HrQoL, pain, and self-efficacy [26]. Management of future expected increases in OA consultations by early referrals of patients with suspected OA to a PT could save time for primary care physicians and lead to fewer healthcare visits for the patients. An early contact to a PT would also aid in assuring correct management through information about the disease and long-term guided strength training, physical performance and fitness. Today, in Swedish primary care, either a physician or a PT can initially assess patients with suspected KOA. However, it is unclear if there are any differences between these managements that are reflected in HrQoL, pain and physical function. The question remains whether task shifting to PTs as the only primary assessor is at least as effective as consulting a physician first for patients with KOA. We hypothesise that all patients with suspected KOA could be assessed initially by a PT, and then be referred to a physician if required."

Reviewer: The authors' question remains on the evaluations of the physician and physiotherapist on the symptomatic and physical changes of patients with Knee OA or in relation to the clinical
and rehabilitative treatment at an early stage of the disease. This is confusing and needs to be clarified. Add the purpose of the study and list the hypotheses of the authors.

SESSION METHODS

Author: This is a multicentre, assessor-blinded, randomised controlled trial comparing primary assessment, diagnosis, and treatment either by a PT or physician. The study comprised a healthcare process initiated either by PT or physician assessment. Measurements were taken before randomisation (baseline) and at 3-, 6- and 12-month follow-ups. The participant flow is illustrated in Figure 1. The Regional Ethical Review Board in Gothenburg approved the study (reference number: 979-12). The study was retrospectively registered at clinicaltrial.gov, ID: NCT03715764.

Reviewer: Specify the primary assessment, diagnosis and treatment directed by both professionals (physician and physiotherapist).

Author: "...Inclusion criteria were: age ≥38 years, knee pain most days of the past month, morning stiffness ≤30 minutes, and crepitus during active motion [27]. Exclusion criteria were knee pain due to trauma (i.e. not insidious debut), other diseases that could affect outcome measures (rheumatic or systemic diseases, severe somatic or mental diseases (e.g. depression), pregnancy, or if already diagnosed or assessed by another healthcare provider due to current knee pain. The patient had to know enough Swedish to understand test instructions and complete self-administered questionnaires. The screening procedure was modified after 20 patients to intensify patient."

Reviewer: In the inclusion criteria were considered overweight and obese patients?

Already in the exclusion criteria was considered independent gait or with bracing? Did the authors consider the level of pain?

Author: Using a computer-generated list of random numbers, participants were randomly assigned to initial assessment, diagnosis and treatment by either a PT or physician. A project coordinator was included from among healthcare providers in the study, but was neither involved in the screening procedures nor data collection. The project coordinator managed the sequence generation, allocation concealment, enrolment and assignments of participants, and kept the concealed randomisation scheme and sequentially numbered, sealed envelopes in a locked cupboard (in the same building as enrolment), available only to the project coordinator. The project coordinator revealed allocation to the participant and healthcare providers shortly after baseline measurement. Participants and healthcare providers in both groups were aware of the allocated group, whereas the data collector (CH), data analyst (CH) and statistician were blinded.
to allocation until completion of all outcome assessments. CH was not involved in assessing, diagnosing, or treating patients with KOA while the study was in progress.

Reviewer: How many professionals participated in the randomization process. Who and how many evaluated or treated at different centers and clinics for recruiting patients with OA knee?

Author: Patients were allocated to either a PT or physician for initial assessment, diagnosis and treatment. Treatment by a PT could involve individual or group treatment including patient education and physical training, according to the BOA program [25]. BOA consisted of individual assessment, patient education (3 sessions), and six weeks of physical training. Physician treatment could include prescriptions, referrals to x-ray examination, a PT, or another healthcare provider. Consultations with other healthcare providers were registered between baseline and the 12-month follow-up.

Reviewer: The intervention performed by the physiotherapist should be detailed. How the medical treatment was performed, since this patient was also referred to a physiotherapist. This can have a big influence on the results. How the authors addressed this issue.

Author: Physical function was measured using the 30-second Chair Stand Test (30CST) [35]. The score was the total number of stands executed correctly from sitting on a chair within 30 seconds (more than halfway up at the end of 30 seconds was considered a full stand). Incorrectly executed stands (incomplete stands, or not seated between the stands) were not counted.

Reviewer: Have the authors performed no specific evaluation for knee function with OA?

SESSION STATISTICAL ANALYSIS

Author: Independent variables in the model were checked for noncollinearity using Spearman's rank correlation coefficient \( r \leq 0.7 \), boxplot overlap, and cross tables (for >80% observations in diagonal and cells >5 observations). The mixed effect model analysis consisted of two models, Model 1 and Model 2. Model 1 (unadjusted): Variables: Group, Time and Group*Time (Group intervention interacted with time). Model 2 (final model with confounder adjustment): Model 1 and adjusted for confounders according to the criteria described below confounders. The independent variables considered possible confounders were age, sex, body mass index (BMI), and educational level, pain intensity and physical function. Possible confounders were added one at a time to Model 1, and checked stepwise and carried forward to the final model if \( p < 0.20 \). Variables in the models were considered statistically significant if \( p < 0.05 \). Data was analysed statistically in the Statistical Package for Social Science for Windows 22.0 [36]. Data was applied with intention-to-treat where patients received the randomized allocated intervention, i.e. the first assessment either by a PT or physician.
Reviewer: What was the correlation considered to enter the regression analysis? And what were the predictive variables in each model performed until reaching the final regression model?

SESSION RESULTS

Author: There were no missing data in the current study. Descriptive statistics for the studied clinical and radiographic measures are displayed in Table (2). FPI-6 demonstrated high intra-rater reliability [ICC= 0.97] with 95% confidence interval (95% CI) of 0.96-0.98, while, CA To establish if HrQoL differed between the effects of being assessed by a PT or a physician for suspected KOA, 69 patients were randomised to either a PT or physician as primary assessor. Most of the patients, 79%, participated in the six-month follow up and 64% completed the one-year follow-up. Demographic data and clinical characteristics are presented in Table 1. The mixed effect model showed that HrQoL was significantly different over time (variable "Time": EQ-5D-3L index, p<0.001; EQ-5D-3L VAS, p=0.005). There was no statistical significance for HrQoL if the primary assessor was a PT or physician (variable "Time*Group" EQ-5D-3L index, p=0.176; EQ-5D-3L VAS, p=0.493). See Table 2 for EQ-5D-3L index results and Table 3 for EQ-5D-3L VAS results. The final model of the EQ-5D-3L index was adjusted for the confounder's sex, education level, pain intensity and physical function. The final model of EQ-5D-3L VAS was adjusted for the confounder's sex, pain intensity and physical function. Additional analyses were made for the first three months only, where the final model showed no significant differences between groups (p=0.417) or when comparing the groups interacted with time (p=0.242). See Additional File 1a and 1b. The model means for the EQ-5D-3L index increased for both groups. The physician group had a larger increase from baseline to the 12-month follow-up (PT = +0.084, physician =+0.181). For the EQ-5D-3L VAS, the total increase from baseline to 12-month follow-up in model means were similar between groups (PT = +9, physician = +8). The changes in model means are illustrated in Figures 2 and 3 for adjusted models.

Reviewer: The results are very confusing and difficult to understand. All tables should be redone presented important variables considered in the different regression models until arriving at the final model and not only presentation of p-values. Retake the tables for a better understanding of the findings observed in the study.

SESSION DISCUSSION

Author: "When examining the differences in being assessed initially by a PT or a physician for patients with KOA, both groups improved in HrQoL, pain and physical function. Analysing the HrQoL results over time, patients being assessed by a PT did not differ in HrQoL from patients
being assessed by a physician. These findings imply that PTs can be the first assessor when patients with suspected KOA seek primary care for the first time."

Reviewer: This paragraph is most appropriate in the results session. I suggest adding it in this session.

Author: "In this study, we found no statistically significant differences in HrQoL between groups over time. However, Figure 2 indicates a difference in the EQ-5D-3L index between groups in model means at the three-month follow-up. Yet, analysing the first three months separately did not change the results. There were still no statistically significant differences in HrQoL. Even though the physician group had a 0.097 larger increase in model means for the EQ-5D-3L index one year after assessment, this does not exceed the minimal clinical difference of 0.121. Altogether, the results indicate no statistically significant or clinical differences between PT or physician assessment. The reason for the large improvement in HrQoL for the physician group over the first three months could be related to the baseline mean value for the EQ-5D-3L index, which was much lower for the physician group when compared with the PT group. Patients allocated to a PT as primary assessor were somewhat older and had a slightly higher BMI at baseline. These patients also had longer pain duration, but graded lower pain intensity and had better physical function, which could also explain why patients in the PT group rated a higher HrQoL. A larger sample size and/or use of a questionnaire with more levels such as EQ-5D-5L [44], could probably provide a better distribution of the EQ-5D index values at baseline."

Reviewer: The authors should better discuss the issue of patient differences for both health care professionals (physiotherapist and physician).

Author: "One reason for the low patient flow could have been organisational, which involved both primary care centres and rehabilitation clinics during the study time. The recruitment process was closed when no new participant was recruited for an entire year. Ongoing reorganisation was probably given priority at the clinics instead of recruiting study participants. When calculating power using existing values from collected data such as the mean standard deviation for the EQ-5D-3L-index (SD=0.17) and 35 patients in each group, minimal clinical improvement still set to 0.121 [28, 33], with a two-sided 5% significance level, the power is 85%. A sample size estimation calculation using the Mann-Whitney U test (due to skewed distributions) resulted in a sample size of 58 patients per group with a significance level of 5% and 80% power. Calculated on 35 patients per group, with the same significance level, the power for this study's sample size was 58%."

Reviewer: This paragraph does not discuss the findings of the study. I suggest to limit the study.

Further discussion is needed with the regression analyzes obtained.

Author: "The dropout rate was 40% for the PT group and 32% for the physician group at the 12-month follow-up. The benefits of an analysis with mixed effect models is that participants with
missing data can be used in the analysis as long as the missing data is missing-at-random. The missing value analysis for this study showed that the gender distribution, age range for the dropouts, and the reason for missing at follow-ups were similar in both groups (see Figure 1). Mixed effect models handle the imbalanced data in available observations. A strength of this study is using mixed effect models, which is specifically designed for analysing data characterised by repeated measurements on the same individual [47]. The mixed effect models gave us a result showing how the primary assessment for patients with KOA affected their HrQoL over time with consideration to possible confounders, which we cannot obtain from analyses with traditional statistical methods such as the Mann-Whitney U test”.

Reviewer: This sample loss was significant. As the authors considered this sample loss based on the results found. This paragraph does not discuss the findings of the study. Again, I suggest to limit the study. Further discussion is needed with the regression analyzes obtained (pain and physical function).

Author: "It might be possible that the patients in the physician group were positively affected by the fact that they met the physician, which they expected from the beginning. Patients expect investigations such as x-rays or magnetic resonance imaging (MRI) to provide evidence for their experienced problem. Lack of these investigations could be experienced as a possible barrier for being understood and helped [47]. In this study, it could have led to higher satisfaction in the physician group due to received expected examinations and treatments, which could have affected the results with a higher HrQoL and less pain because of decreased anxiety for their problems. It would have been interesting if the patients did not know what profession the primary assessor had to rule out a potential placebo effect. Unfortunately, this was not possible in this primary care setting because most primary care centres and rehabilitation centres have different locations.”

Reviewer: Would this explanation also be for pain and physical function? What is the discussion for these variables?

Author: "With this study, we showed that PTs and physicians did not differ as primary assessors for patients with suspected KOA, regarding HrQoL, pain intensity, or physical function up to one year after patients consulted primary care. These results support previous findings showing that PTs could be used as primary assessor for patients with musculoskeletal disorders. Our results imply a task-shift in primary care, which would probably enhance the access for patients with KOA to a better OA management including core treatment of patient education and exercise."

Reviewer: To rewrite this discussion. No discussion was made regarding pain and physical function. improve and add to this discussion.
SESSION CONCLUSION

Author: In this study, we found that there were no significant differences in results regardless of whether the healthcare process was initiated by a PT or physician. Both assessments resulted in higher HrQoL in the long run for patients with suspected KOA. We suggest that PTs should be considered to be the first option as primary assessor for patients with suspected KOA. However, more research is needed to clarify if this management is more cost efficient.

Reviewer: Reformulate according to the analysis of the results.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Unable to assess

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I am able to assess the statistics

Quality of written English
Please indicate the quality of language in the manuscript:

Needs some language corrections before being published

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