Author’s response to reviews

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

Authors:

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Author’s response to reviews:

Response letter – BMSD-D19-00370

Dear Dr Carly McKay, Dr Ana Paula Ribeiro and Dr Donald Manlapaz,

We sincerely thank you for reading and suggesting important revisions to our manuscript. We have carefully read the comments and have restructured and rewritten the manuscript.

In this letter we provide responses to each reviewer/editorial point that has been raised, using italic font. This letter also include some revised versions copied from the manuscript, where the changes in the manuscript are indicated by highlighting the text with yellow background.

We hope that this revision meets your anticipations. Please notify us if you want further changes in the manuscript.

Best regards,

Chan-Mei Ho

RPT, PhD-student
Carina A Thorstensson
RPT, PhD

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Editor Comments:

Regarding the major areas that needed revision:

1. The introduction to the paper needs to better highlight the role of the Physiotherapist in providing patient care. A clearer statement of the study objectives would help in this regard.

2. More methodological detail is needed, particularly around the contents of the intervention(s) provided to patients, and a stronger rationale for your choice of outcome measures is warranted given Reviewer 2's comments about OARSI guidelines.

3. In the results and discussion, more attention needs to be paid to the secondary outcomes of pain and physical function. You have included these in the study objectives, so it is striking that they do not feature in the discussion at all. Reviewer 1 has provided extensive feedback on the discussion but you may wish to focus less on their suggestions to restructure the paper and focus more on limiting the discussion to interpretation of the results across all included outcomes.

Response 1-3: Thank you for addressing these matters. The introduction is now revised and include more descriptions on what physiotherapists (PT) do and why PTs should be the first choice of primary assessor based on how recommended initial assessments and treatments for patients with osteoarthritis (OA) are in line with how PTs manage this patient group in primary care today. We have now stated the purpose to clarify that this study focuses on the effects on the healthcare process by using different primary assessors. The interventions are not standardized since we wanted to explore how PT assessment and physician assessment differs in a clinical primary care setting, using the pragmatic study design. Therefore the management could vary since the assessment and treatments were based on patients’ symptoms. We have explained further what could be involved when seeing a PT or a physician for their knee OA (KOA) in this study. The OARSI recommendations were published in 2013, and were not available when we were planning the study in 2012. More details about selected outcome measures is described further down this document, i.e. point 17 and 32 in response letter. Pain intensity and physical function were used as adjusting variables in the analysis. We have now revised the purpose to clarify that we wanted to examine the differences of health-related quality of life (HrQoL) when
adjusting for pain intensity and physical function. The discussion section have been revised to focus more on results discussion.

Reviewer 1, Ana Paula Ribeiro, Ph.D.:

Response: Thank you for spending time and effort to allow further improvement of our manuscript.

Comments:

SESSION ABSTRACT

4:1 Background

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?

Response: We are grateful for your thoughtful comments and questions. Please see our response below at point 4:2.

4:2 Objectives

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.

Response 4:1 and 4:2: We wanted to explore the effects in patient reported outcomes between healthcare processes that were initiated by PT assessment compared to when initiated by a physician assessment. We have now restructured the background and objectives in the abstract to clarify this.
After revision: “In Swedish primary care, the healthcare process for patients with knee osteoarthritis (KOA) could be initiated with physician assessment or physiotherapy assessment. However, it is unclear how the different assessments affects the healthcare processes and patient reported outcomes over time. The purpose of this study was to examine the differences in health-related quality of life (HrQoL), adjusted for pain and physical function, for patients with KOA when the healthcare process is initiated with physiotherapy assessment compared to physician assessment in primary care.

5. 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.

Response: We have taken this comment into consideration and the acronyms are now revised throughout the abstract. More information about the measurements, outcomes and statistical analysis is added. The inclusion and exclusion criteria are removed accordingly.

After revision: “An assessor-blinded randomised controlled trial. Using a computer-generated list of random numbers, patients seeking primary care during 2013-2017 with suspected KOA were randomised to either a physiotherapist or physician for primary assessment and treatment. Data was collected before randomisation and at follow ups 3, 6, and 12 months. Primary outcome was HrQoL using EuroQol 5 dimensions 3 levels questionnaire, index (EQ-5D-3L index) and visual analogue scale (VAS) (EQ5D-3L VAS); pain intensity was measured with VAS (0-100 mm) and physical function measured with the 30-second chair stand test. Mixed
effect model analyses compared repeated measures of HrQoL between groups. The significance level was \( p<0.05 \) and data was applied with intention-to-treat.

6. 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 after 12 months (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.

Response: Thank you for this comment. The results section are now rewritten.

Revised at Abstract - Results section, line 46-50, page 2.

After revision: "Patients were randomised to either a physiotherapist (n=35) or physician (n=34) for primary assessment. All 69 patients were included in the analyses. There were no significant differences in HrQoL for patients assessed by a physiotherapist or a physician as primary assessor (EQ-5D-3L index, \( p=0.18 \); EQ-5D-3L VAS, \( p=0.49 \)). We found that HrQoL changed significantly 12 months after baseline assessment for all patients regardless assessor (EQ-5D-3L index, \( p<0.001 \); EQ-5D-3L VAS, \( p=0.0049 \)). No adverse events or side effects were reported."

7. Conclusion

Author: There were no significant differences between a physiotherapist or physician initiating the healthcare process. Both assessments resulted in significant 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.

Response: Thank you for the comment. The conclusion is now revised.

Revised at Abstract - Conclusion section, line 52-56, page 2-3.
After revision: “There were no differences in HrQoL, when adjusted for pain and physical function, for patients with KOA when the healthcare process was initiated with physiotherapy assessment compared to physician assessment in primary care. Both assessments resulted in significant higher HrQoL at the 12 months follow up. The results implies that physiotherapists and physicians in primary care are equally qualified as primary assessors.”

8. Keywords

Author: 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.

Response: The keywords are now revised accordingly to MeSH-terms focusing on terms describing healthcare process, management and treatment outcome together with the terms “Osteoarthritis” and “Knee”.

Revised at Abstract - Keywords section, line 58-59, page 3.

After revision: Delivery of health care, disease management, treatment outcome, quality of life, osteoarthritis, knee.

SESSION INTRODUCTION

9. 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.

Response: We appreciate your feedback. OA symptoms and description of the risk for comorbidities have been added to this paragraph.

Revised at Introduction section, line 83-92, page 4.
Common OA symptoms are pain, morning stiffness, reduced range of motion, joint instability, swelling, muscle weakness and fatigue [4]. This directly affects … all sick days in Sweden [2]. Patients with OA are less active and have more comorbidities than the overall population [7]. OA causes activity limitations, especially in walking [8]. Walking disability is related to greater risk of mortality [9], which is largely explained by lack of physical activity [10-12].

10. 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.

Response: Thank you for this suggestion. We have now described in more detail why patients are reluctant to seek professional help. We have also described why it is important to seek a PT in time for patients with OA. E.g. PTs can individualize an exercise regime to improve muscle strength or avoid muscle weakness, and to maintain or start with physical activities – which is essential to minimize the risk of worsening of OA symptoms and prevent other diseases such as cardiovascular diseases.

Reluctance to seek help: Revised at Introduction section, line 108-112, page 5.

After revision: “…but having their diagnosis confirmed [21, 22], which is similar to what has been seen in patients with OA [23]. At the same time, patients with OA seem reluctant to seek professional help, partly because they wait until their problems affect their lifestyle or safety (e.g. risk of falling) [23, 24]. Later in the healthcare process, patients with OA feel unsure when to see their physician, they believe that physicians were more for initial diagnosis rather than following treatment [25-27]. “
PT role: Revised at Introduction section, line 118-134, page 5-6.

After revision: “…both physicians and PTs can act as primary assessors. European League Against Rheumatism (EULAR) guidelines does not recommend any particular healthcare provider for the initial assessment since evidence studying effectiveness of various forms of assessment is lacking. The recommendation is that the initial assessment should use a biopsychosocial approach including physical status, activities of daily living, participation in work, leisure or education, mood and health education needs, health beliefs and motivation to self-manage [31]. Core treatment of …

…walking aids [31, 32]. Muscle strengthening exercises and maintaining physical activities, gives patients with OA a better chance to maintain their level of physical function [33]. It is recommended that physical activity interventions should be delivered by healthcare providers competent in treating this patient group [34]. Advice on exercise…

…consisting patient education and supervised exercise to increase patients’ efficacy to self-manage the disease and increase their level of physical activity [38]. Participation in the…”

11. 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.

Response: We agree that the role of PTs can be described in more detail to motivate why it is important to see a PT first. The revised paragraph includes recommended OA management/treatment description as well as why PTs are most qualified to manage this patient group.

Revised at Introduction section, line 118-134, page 5-6.

After revision: Please see point 10, about the PT role.
12. 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.

Response: Thank you for pointing this out. This paragraph is now revised by adding a purpose to clarify that we want to evaluate differences in HrQoL when the healthcare process is initiated by different primary assessors in primary care.

Revised at Introduction section, line 141-147, page 6.

After revision: “Today, in Swedish primary care, patients can access a PT without referral. Thus, patients with suspected knee OA can have a first assessment by either a physician or a PT. However, it is unclear if there are any differences between these managements that are reflected in HrQoL, pain and physical function. The purpose of this study was to examine the differences in HrQoL, adjusted for pain and physical function, for patients with KOA when the healthcare process is initiated with PT assessment compared to physician assessment in primary care.”

SESSION METHODS

13. 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).

Response: We agree that the primary assessment, diagnosis and treatment can be more specific. To avoid redundancy, we decided to revise the paragraph later in the Methods section – Interventions where you have addressed this matter as well.

Revised at Methods section, line 206-215, page 8-9. (Please, see the revised version at point 16)

14. 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?

Response: The inclusion and exclusion criteria were considered to include participants with OA (using clinical diagnostic criteria by American College of Rheumatology, Altman et al) and exclude patients with OA that had any other severe diseases that could affect patient reported outcomes too much. With the pragmatic design of the study, we wanted to study the patient group as it is in a clinical setting. This means that all patients with suspected KOA regardless their level of disabilities were eligible for this study.

15. 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?

Response: A more detailed description is now included according to your suggestions.

Revised at Methods section, line 188-190, page 8.

After revision: “…to initial assessment, diagnosis and treatment by either a PT or physician. Each primary care centre (n=6) consisted of 6-11 physicians and the rehabilitation centres in primary care (n=3) had 3-10 PTs. One project coordinator was included from among healthcare providers in the study, but was neither involved in the screening procedures nor data collection. “

16. 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.

Response: Thank you for this comment. We wanted to examine the actual clinical setting and explore if the initial assessment had any effect on the following healthcare process in the long run, which is why we chose the pragmatic trial design. The assessments and individual treatments were according to Swedish national guidelines by the National Board of Health and Welfare. The standardization using these guidelines are now explained in the manuscript. A paragraph about the possible effect of referral to PT on the results have been added to the discussion section.

Revised at Methods section, line 206-215, page 8.

After revision: Patients were allocated to either a PT or physician for initial assessment, diagnosis and treatment. The assessments or treatments by either PT or physician were
conducted in accordance with Swedish treatment guidelines [43] and could vary depending on the patients’ symptoms. PT treatment could involve individual or group treatment. Individual treatment could include exercise regimen (PT led or home exercising), education, pain relief or walking aids. Group treatment included patient education and individualized exercise regimen, according to the BOA program [38]. BOA consisted … healthcare provider. With the purpose to examine daily clinical setting, patients could see the other healthcare provider at anytime after the first assessment if needed.”

Revised at Discussion section, line 370-379, page 15.

After revision: “Both groups improved in HrQoL 12 months after assessment. PT treatment in this study (i.e. the BOA program) were individualized, comprising patient education and exercise regime with the purpose to increase patients’ ability to self-manage. This program has been developed in accordance to national and international guidelines [31, 32]. Participation in the BOA program decrease pain, and increase HrQoL and self-efficacy [39]. Exercise therapy, with or without being combined with other treatments, is an effective intervention to improve HrQoL in patients with KOA [60, 61]. It is possible that most patients in the present study got PT treatment, either by randomisation to PT as primary assessor or they were referred to PT by a physician. This could explain why the improvements in HrQoL were seen in both groups.

17. 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?

Response: We chose the 30-seconds Chair Stand Test since it is a valid and reliable performance test to evaluate physical function in patients with KOA. The function that is tested is sit-to-stand activity, but it is also a test of lower body strength and dynamic balance. The test is one of the minimum core sets of recommended performance tests by OARSI.

SESSION STATISTICAL ANALYSIS

18. Author: Independent variables in the model were checked for noncollinearity using Spearman's rank correlation coefficient (r ≤ 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?

Response: Thank you for this comment. The criteria used for an independent variable (possible confounder) to enter Model 2, a Mixed effect model analysis (or also called General Linear Mixed Model), were p<0.20. The paragraph is now reformulated in the description of the different steps in the mixed effect model analysis.

Revised at Methods – Statistical analysis, line 250-260, page 10.

After revision: Independent variables in the model were checked for collinearity using Spearman’s rank correlation coefficient (r ≤ 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 (interaction between Group intervention and time). Model 2 (final model with confounder adjustment): Based on Model 1, with confounder adjustment according to the criteria described below. Variables considered to be 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 carried forward to the final model if p<0.20. Variables in the final models were considered statistically significant if p<0.05.

SESSION RESULTS

19. Author: 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.

Response: We apologize for the lack of clarity. We have rewritten the results section and the tables have been revised to point out the different steps to the final model. Revised at Results section, line 271-283, page 11.

After revision: "Demographic data and clinical characteristics are presented in Table 1. All 69 patients were included in the mixed effect model analyses. We found that HrQoL changed significantly 12 months after assessment for all patients regardless assessor (variable "Time": EQ-5D-3L index, p<0.001; EQ-5D-3L VAS, p=0.0049). There were no significant differences in HrQoL between PTs and physicians as primary assessors (variable "Time*Group": EQ-5D-3L index, p=0.18; EQ-5D-3L VAS, p=0.49). See Table 2... Additional analyses were made for the first three months only, where the final model showed no significant change in HrQoL for both groups (variable "Time": EQ-5D-3L index, p=0.42; EQ-5D-3L VAS, p=0.99) or significant difference between PTs and physicians as primary assessors (variable "Time*Group": EQ-5D-3L index p=0.24; EQ-5D-3L VAS, p=0.55). See Additional File 1a and 1b."

SESSION DISCUSSION

20. 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.
Response: Thank you for your suggestion. We have now shorten the summary of the results. Revised at Discussion section, line 344-345, page 14.

After revision: “The findings of this study imply that PTs can be the first assessor when patients with suspected KOA seek primary care for the first time. Our results are similar to previous findings showing that PTs are…”

21. 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).

Response: Thank you for your comment. Because of the pragmatic study design, patient characteristics have a larger variation within group. A larger sample size would probably decrease the differences between the groups seen at baseline. We have now added this explanation to the paragraph.

Revised at Discussion section, line 365-366, page 14.

After revision: “…PT group rated a higher HrQoL. The pragmatic study design might contribute to a larger variation in patient characteristics within group [58]. A larger sample…”

22. 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.

Response: Thank you for pointing this out. We have now removed parts of this paragraph from the discussion section and added more result discussion instead. Discussion about the chosen regression analysis mixed effect models is described further down in the discussion section at line 419-429, page 16-17.

23. 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).

Response: We have added more results discussion in this section. At the same time, we want to address some of the limitations of the study, and explain how we managed the matter of large sample loss. Discussion about the chosen regression analysis mixed effect models is described further down in the discussion section at line 419-429, page 16-17.
24. 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?

Response: We believe that this could explain the improved function as well and have added it to the text. Revised at Discussion section, line 389, page 15.

After revision: “…which could have affected the results with a higher HrQoL, less pain and improved physical function because of decreased anxiety for their problems.”

25. 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.

Response: The entire Discussion section has been rewritten and restructured with more focus on result discussion. We have also added paragraphs about how pain and function are affected by different treatments, and how improvements in pain and function results in better HrQoL.

Revised at Discussion section, line 370-379, page 15. (Please see revised version at point 16)
SESSION CONCLUSION

26. 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.

Response: We agree that this section needs a revision and it is now reformulated.

Revised at Conclusion section, line 449-453, page 17-18.

After revision: “In this study, we found no differences in HrQoL, when adjusted for pain and physical function, for patients with KOA when the healthcare process was initiated with PT assessment compared to physician assessment in primary care. Both assessments resulted in significant higher HrQoL at the 12 months follow up. The results implies that PTs and physicians in primary care are equally qualified as primary assessors.”

Reviewer 2, Donald Manlapaz, PhD:

Response: We are grateful for your time and effort to allow further improvement of our manuscript.

Comments

27. Reviewer: It is good that the pragmatic study was registered.

Response: Thank you for this comment!


Response: We agree that this sentence needed to be rewritten. This sentence are now removed after restructuring the introduction section.

29. Reviewer: *Page 6: I was wondering why 38 years old and above. The authors need to justify this inclusion criteria aside from to increase the number of participants.
Response: Thank you for addressing this. We have revised the paragraph describing the inclusion criteria by adding the clinical guideline by American College of Rheumatology in the text. Since the inclusion criteria were used when recruiting new participants by phone, we chose the clinical classification tree algorithm presented by Altman et al, which did not include any criteria that needed a physical examination. Following criteria for KOA: knee pain, crepitus, mornings stiffness less than 30 minutes and >38 years gives an 89% sensitivity and 88% specificity.

Revised at Methods section, line 167-168, page 7.

After revision: "…Inclusion criteria according to American College of Rheumatologys (ACR) clinical criteria, which were: age ≥38 years, knee pain most days of the past month, morning stiffness ≤30 minutes, and crepitus during active motion [40].

30. Reviewer: Page 6 line 154: double parenthesis "))"

Response: We have now rewritten this sentence.

Revised at Methods section, line 171-172, page 7.

After revision: “…other diseases that could affect outcome measures (rheumatic or systemic diseases, severe somatic or mental diseases such as depression), pregnancy, or if already diagnosed or assessed by another healthcare provider due to current knee pain.”

31. Reviewer: Page 7: Sample size section. I suggest having a sample size subheading. You may transfer the paragraph from Data Analysis

Response: Thank you for this suggestion, we have now transferred the paragraph as suggested.

Revised at Methods section, line 181-184, page 7.

32. Reviewer: **Page 8. **The Osteoarthritis Research Society International (OARSI) recommends a set of outcome measures for Physical Performance Measure (PPM) like Timed Up and Go Test, Stairs, and 30 seconds sit to stand. Please justify why only one outcome measure?

Response: We agree that the OARSI recommendations of a set of performance tests should be used when evaluating patients with OA. When we were planning the study in 2012, to the best of our knowledge, no recommendations about which specific performance-based tests of physical function were available. The OARSI recommendations were e-published in May 2013, which were the same time as we started to recruit patients to the study. We chose the 30 seconds chair
stand test since it is a valid and reliable performance test to evaluate physical function in patients with KOA.


Response: We have now transferred this paragraph. It is now under the subheading Sample size, directly after the “Participant” paragraph.

Revised at Methods section, line 181-184, page 7.

34. Reviewer: Page 9 Line 229-230: was?

Response: Thank you for noticing this. We have now revised the sentence. Revised at Methods section, line 255-256, page 10.

After revision: Model 2 (final model with confounder adjustment): Based on Model 1, with confounder adjustment according to the criteria described below.

35. Reviewer: The last two paragraphs of the discussion were stated well.

Response: We appreciate this comment!