Title: Exploring the relationships between International Classification of Functioning, Disability and Health (ICF) constructs of Impairment, Activity Limitation and Participation Restriction in people with osteoarthritis prior to joint replacement.

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Author's response to reviews: see over
Please find below our point-by-point reply to the reviewers and editors comments
We have indented our replies.

Reviewer 1 report

Reviewer's report:

Major compulsory revisions

This paper reports on a structural equation modeling analysis of data on individuals about to have a total joint replacement (TJR) to explore the relationships between latent variables representing impairment (I), activity limitation (A) and participation restriction (P). The title states the paper is about OA but the methods show that OA is only part (albeit the largest part) of the sample. The paper variously (and somewhat arbitrarily) presents findings for the total sample and for the OA subsample. I would suggest the authors need to decide to focus on one of these groups. Either keep the title as is, and report only on the OA sample (perhaps indicating that findings for the total group of all arthritis were very similar – but not showing the data or perhaps only in supplementary tables), or change the title to arthritis and report on the full sample.

Thank you for this suggestion, we have changed to reporting only on the OA sample. All text, tables and figures related to the total sample have been deleted or changed.

‘prior to joint replacement surgery’ needs to be added to the title.

This has been added to the title

This is a cross-sectional study. The limitations of this needs to be explicitly acknowledged, not just hinted at, as in the present version.

We have explicitly acknowledged that this was a cross sectional study and discuss this limitation in the discussion:

The authors need to be careful in their wording when it implies causality. For example, the final sentence in the abstract needs to be more carefully worded. In the discussion (para 2), I have issues with the statement ‘... ICF constructs have evidence of independence....and interventions to reduce restriction in participation are likely to be achieved by reducing activity limitations rather than directly altering impairment’. Similarly in the conclusion there is the bald statement that ‘treatment and interventions that reduce impairment only improve participation if activity limitation is improved’. While these statements are likely true, they do not fully reflect the potential (full) mediation of activity limitation between impairment and participation restriction. What this paper showed is that there were relationships between I and A and between A and P, but not between I and P. This suggests that A might mediate the relationship between I and P although longitudinal data would be needed to establish this. The wording needs some attention and the limitations of a cross-sectional analysis need to be more explicitly dealt with in
the discussion.

Thank you for these points. We have reworded statements that may have implied causality. We have also added, as suggested, that the relationship between I and P might be mediated by A although longitudinal data would be needed. We discuss the limitation of the cross-sectional design in the discussion.

Background, para 2. There has been (relatively speaking) lots written about the limitations of the ICIDH model, and this does not just relate to the reverse pathways and psychological factors (which are listed here as the only example of the omission of contextual factors, with reference to the authors own work). I suggest the authors confine the discussion to the reverse pathways only, as these important to the biomedical model. The omission of contextual factors is not relevant here (except to acknowledge this as a limitation in the discussion). I had some problems with separating out the biomedical model and focusing this paper on that. Raising the biomedical model raises old questions of the virtue of biomedical versus biopsychosocial models, and I’m not sure that this is productive. The I-A-P relationships are dominant pathways in the ICF (biopsychosocial) model and therefore worth investigating in their own right. I would suggest that the authors perhaps take this route. As indicated above a limitation of this paper (which then needs to be acknowledged) is the lack of consideration of contextual factors.

Thank you for these comments and suggestions. We have shortened the introduction as suggested by the editor and so now removed all details about the ICIDH model.

We have removed reference to a ‘biomedical’ model and biomedical pathways. Instead, as suggested, we describe the study as exploring the pathways between I, A and P, with these pathways being the’ basic/simple’ pathways (i.e. without feedback loops). We state that we have not looked in this study at contextual factors but in the discussion acknowledge their potential importance of mediating or moderating the relationships between I, A and P.

The paper spends a lot of time on the measurement model. I suggest the authors cut to the chase and present the final model with less description of the steps that were taken to arrive there. I would be content to know that after testing one and two factor models, the three factor model was the best fit. Then there were some further modifications to improve model fit (and that only suggested modifications within individual constructs were considered appropriate here). It the authors feel that readers need a blow by blow account this should go in supplementary material, not in the main paper.

We have, as suggested, present the final three factor model with the details of the comparison to other models in an Additional file 2.
I was very confused by the figures of the model – which all appear to be very similar. Figure 2 in the paper is the measurement model (and this appears from the coefficients to be the measurement model for the OA sample (or is it?). The final structural models are given in the supplementary materials. The coefficients are very similar in all models. I suggest for the paper the final SEM model is the one that is included for either OA or all arthritis (see above) – omitting Figures 3 and 4. I would be happy to take the details of the final measurement model(s) on trust – merely reporting that it was satisfactory with appropriate fit statistics (and once again, details could go in supplementary materials).

We have now only reported the measurement and structural model for the OA sample. As suggested the final SEM model is included and the other figures deleted.

Background, para 3. Reference is made to core sets for clinical conditions and ‘few studies have empirically explored the relationships between I, A and P.’ These two concepts need to be dealt with separately. The fact that few studies have looked at I, A, P relationships is irrelevant to core sets which do not distinguish between A and P. This needs to be raised here as the fact that core sets do not distinguish between A and P comes up later in the discussion. It would be nice if other studies looking at IAP relationships were mentioned (there are some).

We have separated out the two concepts (relationships of I, A and P and core sets). We discuss other studies that explore I, A and P in the background while we leave the issue of combining of A and P as in the core sets until the discussion. We have added detail about other studies that have explored I, A and P particularly within arthritic conditions.

Measures. Need more details. Need response options for the items in the measure. Table 1 needs a more informative title. At a minimum it should include the name of the measures.

We have added the response options and name of measures.

The response rate 43% is relatively low. This needs a comment in the discussion. It could be that non-responders had more severe disease; this does not seem to be the case.

We have commented on the response rate in the discussion. We have re-calculated the response rate and the responders v non-responders for the OA sample. The response rate is now 37% and the responders were younger and had better Harris hip scores. We acknowledge bias may have been introduced in the discussion.

Minor Essential Revisions
Background, para 1. Need a reference to ICIDH.
Top of page 4. Refers to ICIDH constructs – for those who don’t know ICIDH need
to say what they are (perhaps where ICIDH is mentioned in para 1)

We have since deleted reference to ICIDH

Background, para 5. This is confusing – it seems to mix up two papers in the order A-B-A. Needs clarification.

This section has now been deleted

Participants. Omit ‘on that particular joint’ (it’s redundant).

We have omitted that phrase

Results. There seem to be two versions of Table 2.

These Tables are now in Additional file 2 (as tables 1 and 2)

Labeling of figures. Supplementary figures do not have figure numbers. The SEM models are labeled ‘for all patients’ and ‘patients with confirmed OA’. More descriptive titles are needed mentioning that these were patients about to have TJR. The figures for the final models also need to have footnotes explaining what all the boxes are.

We have ensured all remaining figures are labelled appropriately. We have added ‘prior to joint replacement’ to the title and the legend explains what all the boxes are in the final SEM model (Fig 2).

Background, para 3, line 4. Who are ‘they’? – this needs to be reworded.

I was unable to find the ‘they’ referred to, however most of para 3 has been deleted

Discretionary Revisions

Figure 1: I suggest colour is not used (perhaps a broken line instead) in consideration for those who want a copy of the paper but don’t have a colour printer/copier.

We have now used a red broken line

Figures of the model. This is a suggestion to improve clarity. If the authors flipped the section of the model that relates to I (i.e. take the mirror image (in the vertical plane)) then the lines joining the circles containing I.INDEP to A.INDEP and P.INDEP would not cross over the boxes for the variables and the error terms etc. It would nicely put the I-A-P relationship in a triangle in the middle of the figure.

Thank you for the suggestion, we have amended the figure accordingly.
Reviewer 2

Reviewer's report:
The aim of the study is to explore the relationships between the ICF constructs: impairment, activity and participation in patients with knee or hip osteoarthritis or before knee or hip replacement surgery.
I have no major comment or comment on the methodology.

Discretionary Revisions
In the Aberdeen measure of impairment, only pain and stiffness items are included. Do you think items on fatigue, sleep or emotional functional could have given different results?

Thank you for this point, we agree that including these items may have given different results so we have added this point to the discussion.

It could be interesting to describe the level of impairment, activity limitation and participation restriction of your patients

We have added these details into a new table of patient characteristics (Table 2)

Could your results also mean that pain relief does not necessarily improve participation restriction; could you comment on the meaning of this “assertion”

We have added that this may be because of a mediating effect of activity on the relationship between I and P although longitudinal data would be necessary to explore this further.

The results of the study are interesting for those working on the subject but probably difficult to follow (and maybe to believe) for clinicians even if you discuss clearly practical implications for patients.

We have tried to make the paper easier to follow by putting much of the technical measurement/statistical detail into additional files
Reviewer 3

Reviewer’s report
This is an interesting article in which a limited part of possible pathways in the ICF is examined. There is a fundamental problem with the authors’ choices related to the ICF in this article. They have chosen not to mention that in a biopsychosocial understanding disability is a phenomenon constructed through the interactions between functioning and the contextual factors of the environment and the person. Rather, they avoid the topic and only present biomedical arguments for testing biomedical pathways. I find this insufficient. The introduction should present why the exclusion of contextual factors is meaningful in spite of the bio psychosocial model presented in the ICF.

Thank you for your comments.
In the background, we have tried to clarify that our aim was to explore the relationships between I, A and P. We have now deleted describing these paths as biomedical paths and have tried to be more clear in our aims by describing the pathways explored as being the simple/basic relationships in the ICF model as suggested by reviewer 1. We discuss our omission of the contextual factors in the discussion as suggested by reviewer 1. We have changed the title to reflect that the whole of the model is not explored.

1. Is the question posed by the authors well defined?
Major comments
The question posed by the authors is expressed as an aim of the study, but is somewhat incomplete.
The aim of the study should be described at the end of the introduction. Furthermore, on page 9, line 3 the authors refer to directional relationships between latent constructs that have been hypothesized. If this is part of the research question, it belongs as a hypothesis (?) in the introduction after stating the aim of the article. Did the authors expect a significant pathway from I to P?

We have clarified our aim to explore the basic pathways between I and A, A and P and I and P in the introduction (i.e. without feedback paths). We did not have prior hypotheses regarding these paths so did not state any in the paper.

In the method and result sections, they explore three two-factor models. This is not described under aims, or posed as a research question.

The comparison of the three factor model with other models was part of establishing of independent measures (i.e., to show three factor model was better than alternatives). We can see that this may have been confusing in the main paper and so have put this in additional file 2.

Was an aim of the study to explore pathways for all patients vs. patients with confirmed OA since they present the latter in the result section?
To make the paper clearer we now just report the results for the OA sample

The introduction has two main parts: the necessity to explore the biomedical pathways and the necessity to use “uncontaminated” measures to do so. The relevance of a biomedical pathway seems more valid within a hospital setting than a community setting. The authors should explain in a better way what they mean by contaminated measures of the constructs. In addition, they describe methodological flaws in other studies, and argue for the use of SEM.

We have added to the introduction more explanation to why we feel that uncontaminated measures are important when exploring relationships between I, A and P.

Page 4: The HAQ and SF-36 were linked to the ICF in 2004. (Stucki et al 2004), please add this information. In referring to the article by Fransen et al., the authors state that the low correlation between I and P may be caused by subscales containing items tapping more than one construct, and refer to their own article, ref 10, thus preparing the ground for the use of the Ab-IAP. In Table 3 in their own article (Ref 10) in which they have performed analyses of what OA instruments measures with respect to the ICF, there appears to be very little contamination of the constructs in SF-36 and HAQ except for AP in HAQ. Thus, I find it somewhat doubtful that the weak association between I and P can be explained by contamination of the measurement instruments. Furthermore, in Harris et al.’s intention was not to explore the impairment and activity dimensions as separate variables for physical and mental health. Please make sure that the facts the research questions are sufficiently based on the literature you refer to.

Thank you for this point. We have removed reference to possible contaminated measures in other studies.

I appreciate the thought of using measures that have “pure” items with respect to IAP. However, the authors should also pose arguments for why it is interesting in exploring the pathways by SEM in itself, not as a response to weaknesses other studies.

Thank you for this point, we have deleted the comments about other studies possible weaknesses as suggested.

Minor comments and Discretionary revisions:
Page 3: Spell out Myocardial Infarction (MI)

This sentence has now been deleted

Page 4 last paragraph: “The use of structural equation modeling methods would be preferable as this can evaluate models of both the measurement of the constructs and the structure of the relationships between constructs.” You might relate this to clinical aspects in the introduction as well.

Page 4, paragraph starting with: Similarly, Harris… The sentence with the
children (ref12) seems thrown in. Please rewrite/reorganize.

This sentence has been deleted

Figure 1: Explain the figure in the text. Please add this information in the figure legend as well.

The basic pathways are explained in the text and indicated in the figure legend

Page 3, second paragraph I find somewhat imprecise: Both intellectual and other psychological factors were part of the ICIDH-1980. However, appraisals and choice of coping strategies based on cognitive functioning may be considered personal factors which were not in the 1980 version.

We have deleted references to ICIDH

In the introduction references 3, 4, 8, 10, 13, 14 are articles by the authors of this current article. It should be made clearer to the reader that these are former publications from the group when you refer to them.

Thank you for pointing this out. We have removed 4 of our refs from the introduction and refer to others work.

2. Are the methods appropriate and well described?

Major comments

Did some patients without OA have hip/knee replacements since they did not have a confirmed OA diagnosis?

We now only report the 413 patients that were diagnosed with OA (previously we had also included those without OA)

Why did you select a revised (?) version of the Ab-IAP, or selected only some items from the original instrument. I assume the data collection was performed once, at the time when you developed the Ab-IAP? (The I3 item contains an activity category (d4154), an item you would consider a contamination.) Moreover, in the Ab-IAP the I concerns pain and joint stiffness, and the P concerns only social function. This should be kept in mind for the discussion of the pathways since this limits the generalizability of the pathways for the I and P factors

We revised the Ab-IAP as the measures were not statistically independent of each other, this is described in detail in Additional file 1.

Although the item I3 may appear to also contain an activity category it was classified by discriminant content validity (based on 10 expert judges) as being an I item (as in new ref 21).
We have added the limitation that only concerns pain and stiffness into the discussion.

Minor comments and Discretionary revisions:
Is the study sample the same as in ref. 17?

The study sample are a subset of diagnosed OA patients from ref 17.

Page 6, under Measures, line 9: Please use abbreviation at first time mention: Confirmatory factor analysis (CFA) or do not use abbreviation on page 9, under Results, The Measurement model.

We have abbreviated at the first mention of Confirmatory factor analysis

3. Are the data sound?
As long as the revised/derived Ab-IAP is a valid and reliable instrument, the data appears sound.

We provide evidence for the validity and reliability of the derived Ab-IAP in Additional file 1

4. Does the manuscript adhere to the relevant standards for reporting and data deposition?

Major comments
The table and figure texts should contain all the necessary information for the reader to understand their content without turning to the text. Abbreviations. Cut-off criterion for CFI and RMSEA robust in Table 2.

We have added the details suggested

Figure 1 is incomplete. An arrow indicating a biomedical pathway from Body Function/structure/Impairment to Participation (in red) is lacking. The explanation in the text should be moved to the figure text.

We have corrected the figure and the legend indicates the basic pathways.

Figure 2: The figure text should say that this shows the results of the Lagrange multiplier test. E=error variances. Circles are… Large shaded squares represent… Square boxes…. Arrows….

We have removed the Lagrange multiplier test

Figure 3: ** =p<??

Figure 3 has now been deleted

As mentioned under introduction, it is not clear whether the difference between patients with/without a confirmed OA diagnosis is an aim/research question in the
study. If not, Figure 4 should be omitted.

Figure 4 has been omitted

5. Are the discussion and conclusions well balanced and adequately supported by the data?

Major comments

The discussion starts with referring to a first stage which is not described in the article, but in a supplementary file, whereas the article mainly concerns stage two. This should be clarified or changed.

Thank you for your suggestion, we have changed the discussion to focus on stage 2

The finding that the IP path does not appear to be a significant path for people with OA is limited to the pain/stiffness impairments on social function which are what the I and P items cover.

Thank you for your comment, we have added this point to the limitations of the study

In the discussion the authors reintroduce aspects of the biopsychosocial model which they in the introduction discarded as a premise for their study testing biomedical pathways. The authors should be explicit when the contextual factors are reintroduced in the discussion. The discussion refers to surgery (procedure/environmental factor), pharmaceutical treatment/medication (environmental factor) and rehabilitation program (environmental factor) to reduce activity limitation. In addition, personal factors such as control beliefs, individual goals contribute to the disability process. Hence, the authors should be clearer about how contextual factors contribute to the disability process/participation restrictions.

We have now stated that our aim was to explore the simple relationships between I, A and P though we do discuss the potential impact of the contextual factors in the discussion as suggested by reviewer 1

There is an option in the ICF classification to denote the d-categories of activities and participation into A and P categories. (See ICF p 14.), and the study supports this option. You should state that this is an option when using the ICF.

I am unclear how to incorporate this into the paper. The d-categories are a list of the 9 domains but do not appear to donate particular domains to either A or P categories

6. Are limitations of the work clearly stated?

Major comments

No, the only limitations mentioned by the authors are activity limitations. The
limitations of studying a biomedical pathway should be discussed. The limitation of the items in the Ab-IAP should be discussed.

We have expanded the limitations of the study as suggested by all reviewers.

7. Do the authors clearly acknowledge any work upon which they are building, both published and unpublished?
Minor comments and Discretionary revisions:

The authors refer to work of others, mainly the WHO and the WHO ICF center in Munich. Eleven out of 31 references are former published articles from one or more of the authors of this present article.

Thank you for highlighting this, we have removed some of the references that refer to our work and refer more widely to other work in the area in the background (now 9/45 are from one or more of the authors).

8. Do the title and abstract accurately convey what has been found?
Minor comments and Discretionary revisions:

The authors state in the abstract and the article that biomedical pathways of the ICF are explored. I think the heading promises too much, and could rather be: “Exploring biomedical pathways between the International Classification of Functioning, Disability and Health (ICF) components of functioning in people with osteoarthritis”.

Thank you for this point, we have changed the title to reflect that our study is limited to exploring the relationships between I, A and P.

Editors Comments

My majors concerns are as following:
1- The arguments were based technical and statistical rather than clinical relevance- that is more important.

We have removed much of the technical and statistical detail and only put the essential details into additional files.

2- As Reviewers' comments, the title mentioned the target population of osteoarthritis patients. I wonder whether the only 413 osteoarthritis patients were included in the analysis. The authors should state this clearly.

We now only report the results for the 413 OA patients (previously we also reported the sample including those without an OA diagnosis). We can see that also reporting the total sample was confusing and did not add to the paper.

3- With a large amounts of factors included in the model, whether power of the study was considered, please specify.
We have included a justification for sample size/power into the methods section.

4- The characteristics and assessed factors of participants should be showed in the results sections

   We have added a new Table 2 with patient characteristics and assessed factors

5- The superiority of the new model to the conventional one should be presented in terms of clinical relevance.

   We have added more detail to the clinical relevance into the background and discussion

6- Introduction should be shortened but more focused on the rationale of the study.

   We have removed detail of the previous WHO model from the introduction and focussed on the previous work on the ICF in arthritic conditions. We have focussed more on the rationale of the study and clarified the aim.

7- Overall, the current presentation of the ms does not suit clinical readers.

   We have deleted or moved to the additional files much of the statistical and theoretical detail and focused on the clinical relevance. We hope all the changes made will now be more suitable for clinical readers

Consent

Informed consent must also be documented. Manuscripts may be rejected if the editorial office considers that the research has not been carried out within an ethical framework, e.g. if the severity of the experimental procedure is not justified by the value of the knowledge gained.

   We have added that informed consent was obtained.