Author’s response to reviews

Title: QUALITY OF LIFE AND WELL-BEING FROM THE PERSPECTIVE OF PATIENTS ON OPIOID AGONIST MAINTENANCE TREATMENT: STUDY PROTOCOL FOR A SYSTEMATIC REVIEW AND THE DEVELOPMENT OF A PATIENT-CENTRED QUESTIONNAIRE

Authors:

Ivan Sola (ISola@santpau.cat)
Joan Trujols (jtrujols@santpau.cat)
Elisa Ribalta (eribalta@santpau.cat)
Saul Alcaraz (salcaraz@santpau.cat)
Gemma Robleda (grobleda@santpau.cat)
Clara Selva (clara.selva@uab.cat)
José Pérez de los Cobos (jperezc@santpau.cat)

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[THE RESPONSE TO REVIEWERS HAS BEEN ALSO INCLUDED AS A SUPPLEMENTARY MATERIAL]

SYSR-D-19-00078
QUALITY OF LIFE AND WELL-BEING FROM THE PERSPECTIVE OF PATIENTS ON OPIOID AGONIST MAINTENANCE TREATMENT: STUDY PROTOCOL FOR A SYSTEMATIC REVIEW AND THE DEVELOPMENT OF A PATIENT-CENTRED QUESTIONNAIRE
Systematic Reviews
Response to peer review comments

Editor's comments: Your manuscript "QUALITY OF LIFE AND WELL-BEING FROM THE PERSPECTIVE OF PATIENTS ON OPIOID AGONIST MAINTENANCE TREATMENT: STUDY PROTOCOL FOR A SYSTEMATIC REVIEW AND THE DEVELOPMENT OF A PATIENT-CENTRED QUESTIONNAIRE" (SYSR-D-19-00078) has been assessed by our reviewers. Although it is of interest, we are unable to consider it for publication in its current form. The reviewers have raised a number of points which we believe would improve the manuscript and may allow a revised version to be published in Systematic Reviews.
REPLY TO EDITOR:

We are completely grateful for the comments received by the reviewers, which have provided and expert and profitable insight to the manuscript and its readability. The comments have prompted some discussion that has finally encouraged us to submit a revised version of the manuscript for your consideration. The table that follows displays the main amendments made to the manuscript according the comments received. The new version of the manuscript displays the main changes made highlighted in yellow to improve readability.

We are still convinced that the scope and framework of our protocol fits completely with that of “Systematic Reviews” and at present we cannot figure a better place to see that manuscript published.

We remain at your entire disposal to discuss anything you may consider necessary to the manuscript.

With kind regards,

Ivan Solà
Joan Trujols
On behalf of the study researchers

Reply to reviewer #1

Comment #1 Line 87 - I would not suggest referencing like this. Suggest updating
ACTION / COMMENT
A new –and recent– reference has been included in the revised version of the manuscript (the added parts have been highlighted for quick identification).
Current version / Revised text
Line 88 to 94.- In this respect, De Maeyer and collaborators explored the nature and dimensions of this construct […]. Similarly, a new QOL instrument developed with significant input from OAMT patients did not include items on physical health [18].

Comment #2 Line 130 - are these your protocols? You refer to them as if they are you protocols, but these look like actual guidelines to me - please clarify
ACTION / COMMENT We amended the sentence to make clear that our study protocol was developed according accepted guidance.
Current version / Revised text
Line 133 to 134.- We have prepared protocols to conduct the two reviews, according standardised guidance [24, 25].

Comment #3 The link to your PROSPERO does not work - where is your registration?
ACTION / COMMENT The original manuscript already included the PROSPERO registration ID both in the abstract and methods, but we have included a link to the database registration into the abstract, and could be included through the editorial process if it is considered necessary.
Comment #4 Line 170 - what software?
ACTION / COMMENT We did not plan to use software to analyse the data from qualitative studies. Although the use of software can be considered in some steps as an efficient solution, there are not mandatory for conducting such analyses. As a matter of fact, some authors [1, 2, 3] have argued that the use of software can be driven by unrealistic expectations (mistakenly considering them as a methodology rather than a tool).
2 St John W, Johnson P. J Nurs Scholarsh. 2000;32(4):393-7
3 Cypress BS Dimens Crit Care Nurs. 2019;38(4):213-220

Comment #5 I do not see the inclusion criteria for this scoping review?
ACTION / COMMENT Although we described common steps for the planned reviews (search methods, study selection) we have tried to be more clear in those aspects in which the scoping review was different from the synthesis of qualitative research. Specifically, for inclusion criteria we renamed the sub heading in which we defined eligibility and described clearly the types of studies deemed relevant for the scoping review.

Comment #6 What is the justification for not doing a full scoping review?
ACTION / COMMENT What we think we interpret from the words of the reviewer is that he / she is asking why we decided to conduct a scoping review instead of a systematic review. Our initial intention ‘only’ was to characterize the available PROMs [assessing quality of life / wellbeing in OAMT users] in terms of their content validity, relevance, comprehensiveness and comprehensibility, and describe the degree to which these instruments incorporate the patient’s perspective. In consequence a complete systematic review (i.e., evaluating all the psychometric properties) of such PROMs was not planned. This approach fit better with the indications for scoping reviews, as some authors have discussed (Munn Z. BMC Med Res Methodol. 2018 Nov 19;18(1):143).

Comment #7 There seems to be a dominance/focus on the development of the survey. Systematic Reviews concerns itself predominantly with SLRs and I think the methods and rigor to this review needs more thought/comment.
ACTION / COMMENT We partly and gently disagree with the reviewer’s comment. Of course we state that our study aims to develop and validate an instrument to measure how patients in OAMT experience and perceive their quality of life and well-being. However one of the main strengths of our proposal is that we will inform the instrument’s items according the
results from qualitative research synthesis and the scoping review will delimit the paucity of efforts made to develop instruments from the users’ perspective. In consequence our protocol (and the manuscript) dedicates a substantial part of the text to describe the methodology to develop such reviews. We are convinced that this approach fits with the aim of the journal.

Comment #8 Have you considered possibly taking out the protocol for part 2? If not, please ensure you give particular attention to clearly defining your SLR methods.

ACTION / COMMENT We respectfully consider that the planned scoping review is relevant and necessary to highlight— even further if possible— the pertinence and relevance of a scale such as the one planned to develop by means of study 3. As a matter of fact, similar scoping reviews [e.g., 1, 2] have been conducted in other research areas. In any case, we have further clarified (please see comments above) the scoping review methods.


Reply to reviewer #2

Comment #1, line 130: "We have prepared protocols to conduct the two reviews [24, 25].” It reads like these protocols were published as references 24 and 25. Yet, these references refer to guides/guidance. I would consider rewording.

ACTION / COMMENT We amended the sentence to make clear that our study protocol was developed according accepted guidance.

Current version / Revised text
Line 133 to 134.- We have prepared protocols to conduct the two reviews, according standardised guidance [24, 25].

Comment #2, line 269 - 283: There is something going wrong with the references here. Many are referring to reference 58, sometimes double. So please could you correct these references, probably from 58 till 65.

ACTION / COMMENT We have amended the numbers to the references, and the current version should link numbers and references properly.

Comment #3: PROM and COSMIN. Part of developing a PROM is to assess the reliability with a test-retest procedure. There is no mention of it in this protocol. When you are not planning to do this procedure, whilst referring to COSMIN, please explain why and include this as a limitation.

Furthermore, responsiveness is one of the COSMIN items. I am aware that the target group does not undergo an intervention, so that might not be feasible. To be more complete, I would describe the lack of this COSMIN-item. This could be a limitation, and as such described, when the tool is intended to be used to measure changes over time. Yet, it need not be a limitation per se, as PROMs can also be used to assess the current state of a person. In that case I would describe this briefly in the protocol.

ACTION / COMMENT Throughout the manuscript, the only reference to the COSMIN initiative is made regarding scoping review. It should be noted that, strictly speaking, the COSMIN initiative has not developed a guideline for developing a PROM. According the COSMIN website the “initiative developed a consensus-based taxonomy including definitions of the nine
measurement properties, and consensus-based standards for assessing the quality of studies on measurement properties. In order to enable evidence-based selection of the most suitable outcome measurement instrument COSMIN also developed a methodology for conducting systematic reviews of patient-reported outcome measures (PROMs)” (own remarks). Besides, our study 3 was already aimed to assess, among other, the most important measurement properties (i.e., content validity and internal structure) according to COSMIN (please see https://www.cosmin.nl/tools/cosmin-taxonomy-measurement-properties/ for the order of importance of measurement properties). In addition, it is not common to assess all measurement properties in an initial validation study since the evaluation of each measurement property requires, as the reviewer correctly points out, different design requirements. Either way and in order to acknowledge both the limitations suggested and the permanently ongoing process of instrument validation (psychometric characteristics are not properties per se but, rather, are properties of an instrument when used for a specific purpose with a specific sample), we have slightly modified the beginning of the manuscript’s last paragraph. Line 365 to 367.- At the end we will be able to develop and initially validate an instrument with the capacity to genuinely grasp the perspective from patients on OAMT regarding their perception of well-being and QoL.