Author's response to reviews

Title: Health-related quality of life and pain in children and adolescents - a school survey

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Author’s response to reviews:

Dear Editor,

We would like to thank you for the opportunity to respond on comments from reviewers on the manuscript entitled: Health-related quality of life and pain in children and adolescents - a school survey.

In this revision, we have taken into account the comments made by the reviewers. The reviewers raised several important points. We would like to express our sincere gratitude for relevant and precise referee comments. A point-by-point reply to reviewers’ remarks and changes made in the text are listed below. Please note that the reviewer comments copied in below. The changes made in the revised version are marked with red (uploaded in supplementary files).

We hereby hope that we have addressed the criticised points to your satisfaction, and that the manuscript now can be accepted for publication in BMC Pediatrics.

Sincerely,

On behalf of the authors

Kristin Haraldstad

BPED-D-16-00649

Health-related quality of life and pain in children and adolescents - a school survey Kristin Haraldstad; Knut-Andreas Christophersen, MSc; Solvi Helseth, PhD BMC Pediatrics
Reviewer reports:

Kotsedi Daniel Monyeki, PhD, MPH (Reviewer 1): *

Introduction is too long. I suggest that the author should focus mainly on the objective of the study:

• Response: We have changed the introduction and tried to do it more focused on the objective

  Line 27 & 57 Referencing style was done correctly. For example, referenc number 25, 26, and 36 should not appears where they are currently.

• Response: We agree and have changed the references.

METHODS

Data Analysis Line 53 (BMI was included though nowhere in the manuscript did the author wrote about the BMI. That is how weight and height were measured and the accuracy of these measurements.

• Response: We are sorry for this mistake, and have changed the wording.

DISCUSSION

Line 13 (The author should justify the confirmation of other studies with a reference.

• Response: We have confirmed this with a reference p.11

Line35 (The author should show the variation of prevalence as mentioned)

• Response: We have showed the variation of prevalence on page 11.

Luisa Barros, PhD (Reviewer 2): Thank you for the opportunity of reading the article "Health-related quality of life and pain in children and adolescents - a school survey ". This is a cross sectional study with 8-18 years old children from Norwegian schools, aiming at describing HRQoL and pain and analyze the relationships between HRQoL, pain, sex, and age. The study brings relevant data about an issue not yet much studied - pain in community samples of children and adolescents, and has the strength of using a large and mostly representative sample.

However, there are several problems in the presentation and discussion of the study that limit its relevance. The aim of the study is not completely focused and so it is difficult to understand precisely how this study adds to the existent literature.
Response: We have tried to clarify and describe more of the relevance of the study, and why this is an important study. There is a lack of studies of pain and HRQoL in children in a non-clinical, or healthy population, and several studies have used one global HRQoL score to measure HRQoL, or they have studied children with diagnosis or recruited from pain clinics, few studies have studied pain in a community sample and relation to different HRQoL dimensions. This study addresses an important gap in the literature, examining pain and HRQoL in a non-clinical, community population of children and adolescents.

In our study, we use all 10 dimensions on which makes it possible to explore different dimension of HRQoL. We believe that the multidimensionality of HRQoL measures may provide researchers and clinicians with information about the impact of a health condition, e.g. pain, on different aspects of quality of life.

The introduction is poor, mostly descriptive and not directly connected with the aims and variables studied. If focus mostly pain prevalence, (which is OK), determinants and consequences, with several references to variables not studied (socioeconomic status, BMY, smoking) on pain in children and adolescents. However, the connection with HRQoL is poorly explored. The sentence "Health-related quality of life (HRQoL) is a way to assess children’s subjective perspectives on pain experience and the impact it has on their lives" is not correct. The authors used a general HRQoL, so participants are assessing their quality of life globally and not only related to pain. The diminished HRQoL of some youth may be due to many other factors. The only sentence explaining the anticipated relation between pain and HRQoL is "Therefore, the measurement of health-related quality of life may be important and relevant in relation to pain", which is clearly insufficient.

Response: Thank you for useful comments. We agree that this might be more clear. We have revised the introduction, and we have made it more connected with the aims and variables studied. According to the use of a generic HRQoL measure, generic questionnaires can measure all dimensions of HRQoL and can therefore be applied in healthy populations as well as in clinical populations. The advantage of using a generic questionnaire is that they provide a comprehensive overview of HRQoL, however a generic questionnaire may not be that sensitive to impact of changes in clinical conditions or treatment.

It is important to understand what is the relevance of studying HRQoL and what are the hypothesized processes connecting pain with HRQoL in community samples. An hypothesis would help to understand this rational.

Response: We have included more information on the relevance of studying HRQoL and pain in a non-clinical population. There is a lack of studies of pain and HRQoL in a non-clinical population, an issue not yet much studied. We have tried to make the rationale for the study clearer p.5.

Methods are overall correct, but some information is repeated in more than one section of the study (elimination of HRQoL questionnaire missing more than 1 item per subscale) or between text and tables (sociodemographics).
• Response. We have removed information repeated in more than one section.

On the other hand, information is missing: The measure of pain, central to this study is not enough described. It seems the authors only used 3 or 4 of the 13 questions. Why? What were these questions? What is the rational for using the mean of frequency, intensity and duration? Has this been done before? What evidence of validity is there? If one of the objectives was to describe pain, why not use the full questionnaire, so that the different types of pain could be characterized?

• Response: We agree that the Lübeck pain questionnaire need to be explained, and especially the method of reporting only a sample of the full questionnaire with computed results. We would not use the entire questionnaire because it was important for us to do the regression analyses for all ten dimensions of KIDSCREEN-52, and therefore had to construct one pain variable. Otherwise, we would have lost much information about the association of pain and the 10 different dimensions of KIDSCREEN-52. Few studies in pain and HRQOL include multiple HRQoL dimensions such as those in KIDSCREEN-52. Constructing the pain variable makes it possible to explore which HRQOL dimensions are most affected by pain.

The LPQ consists of single items, and single items have been shown to be valid and reliable measures of pain. The pain variable was created as the average of the three indicators frequency, duration and intensity. Each indicator was measured on a scale from 0 to 6, where 0 indicates that the students suffer little and 6 that they suffer a lot of pain.

The LPQ questionnaire was designed for epidemiological purposes and has been used in several European studies for which it was considered an appropriate instrument. It has been shown that children and adolescents are capable of understanding and completing the LPQ and that the feasibility, content, and face validity of the LPQ is satisfactory (Haugland et al 2001). Cronbach’s alpha for this pain questions was .92 which is good.

Moreover, previous studies have shown that children and adolescents are able to report subjective health complaints and pain experiences reliably.

Data Analysis:

There is also a mysterious reference to class (socioeconomic class? school class?). There is a reference for not so good psychometric values in the HRQoL is this section, but this is not any further discussed. The sentence" Internal consistency reliability for multi-item scales was estimated using Cronbach's alpha with 0.70” needs some clarification.

• Response: We are sorry for the unclear reference to class; school class is correct and this is changed in the manuscript p. 9

• Response: We have changed the sentence about internal consistency reliability to: Cronbach’s alpha with a value ≥ 0.70 considered satisfactory for group comparisons [24].
Results: I don't understand the sentence: pain prevalence across the 10 domains of KIDSCREEN-52. What is pain prevalence across HRQoL domains? Are you talking about differences in pain prevalence?

• Response: We agree that this might be unclear, and we have changed the wording to: Table 2 presents the HRQoL and pain prevalence in all 10 domains of the KIDSCREEN-52, p.10

There is a reference to absence from school, but this measure is not described in the instrument section.

• Response: We used one question from LPQ about absence from school to describe how many children had been absent from school due to pain (self-reported). This is now included in the Methods section. In our study, we used four questions from the LPQ questionnaire: one question about absence from school because of pain (“Have you been absent from school because of pain?”) and three of the pain-related questions to construct a pain variable.

In Table 3, *unique contribution refers to what? There is no * in Table 3

• Response: We are sorry for this, we have included * in the table showing the unique contribution of sex, age, interaction, see table 3.

Discussion: Again, this section is very broad and lacks some deeper discussion of the specific results, namely the specific HRQOL domains that have poorer results, or are more affected by age, sex or pain. How can you interpret the fact that the interaction between age and sex increasing the explained variance (in what sense?).

• Response: We have revised the discussion section, and we have tried to discuss the results more in depth, and also the specific domains that have poorer results. Regarding the results showing that the interaction between sex and age increase the explained variance in the scales physical, mood, self-perception, and autonomy. This indicates that the effect of age is different for boys and girls, girls are more impaired than boys.

The added variance in HRQoL from pain is small. This should be more specifically discussed because the results are significant but of small magnitude. How can the authors explain this? Is this consistent with other similar studies.

• Response:

We agree that this need to be more discussed. Even though pain was significantly associated with lower HRQoL in all KIDSCREEN-52 subcales, our analysis shows that adding pain into the model resulted in small changes in the explained variance, which mean that pain was not found to be a strong explanatory factor for variations in HRQoL. These results are in line with some other studies, e.g. the study from Tsao (2007), however the participants in this study were recruited from pain clinics.
The specific description of what is assessed by each HRQoL subscale does not belong in the discussion, rather it should appear in the methods. And it does not substitute a more theoretically driven discussion of these specific results.

- Response: We have removed the description of what is assessed by each HRQoL subscale, and we have revised the discussion part, tried to discuss more depth, and we have also discussed the specific domains that have poorer results focusing more on the results.

The discussion about absenteeism is somehow puzzling because, although this theme was mentioned in the introduction, this was not announced in the objective of the study or in the methods section and only a very general result is presented (children have been absent from school for how many days? Was there any control of the reason for this absence?).

- Response: We agree that the discussion about absenteeism may be “puzzling” and we have revised the discussion and do not emphasize the absenteeism discussion as much as in earlier version. However, for children and adolescents, school and friends are important areas where they can socialize and learn. Absenteeism is worrying, and in our study, 30% of the girl’s reports being absent from school due to pain (“Have you been absent from school because of pain?”). This is self-reported data, and we have no more control of the reason for this absence, and we do not know for how many days. However, we are focusing less on this in the discussion, and we do not focus on it in the conclusion.

The limitations are well described but should appear in a different paragraph and made clear that they are describing limitations. Clinical implications should be more grounded on the specific results of this study and not so global.

- Response: We have made a new paragraph called limitations, and we have tried to make the clinical implications more grounded in the specific results.

Luciane Costa, DDS, MS, PhD (Reviewer 3): This study is very well designed, the topic is relevant, but there are some problems of clarity and consistency that should be solved.

My major concern regarding this manuscript is about "novelty". Apparently, the authors have published a few papers as a result of the same investigation. They cite two, but there are others, e.g.: Haraldstad K, Christophersen KA, Eide H, Nativg GK, Helseth S. Predictors of health-related quality of life in a sample of children and adolescents: a school survey. J Clin Nurs. 2011 Nov;20(21-22):3048-56. So, I encourage the authors to highlight, in the manuscript, their advances in the knowledge with their already published studies and the present one. Are there redundant data? Is it justified another publication by the same group of authors originated from this sample and data? It seems that the authors had collected other variables that could be analyzed in the regression models in the same manuscript.

- Response: Our research group have been working with children and adolescent’s health, and especially in relation to HRQoL and pain problems, and we have published some papers from the study. However, the data in this study have not been published before. We believe that
we have important results that addresses gap in the literature, and that this study adds new knowledge to this field.

We could have included more variables in the regression model, but because we wanted to focus on HRQoL and pain in this study, and explore the association between pain and HRQOL more in depth, we did not include other variables in the regression model.

The ABSTRACT needs more information on data values found in the Results. Please do not bring new results in the Conclusions. Besides, try not to repeat results in the Conclusions.

• Response: We agree and have changed the abstract, and we do not have new results and tried not to repeat the results in the conclusion.

INTRODUCTION: The relevance of the topic is very well presented in the Introduction. However, the originality of this study is superficially described. Please explain the limitations of the studies ref. # 5, 19-21 (page 4, lines 31-34) that the present investigation intends to address. What is/are the specific gap/s in the literature that this study aims to fill in?

• Response: We agree that the originality of the study could be more described. This study addresses an important gap in the literature, and we have included more information about the specific gaps in the literature that our study aims to fill in in the introduction p.4.

4- METHODS:

4.1- Describe the relevant dates, including periods of recruitment and data collection.

• Response: we have included more information about including periods in the methods section.

4.2- Give the exclusion criteria.

• Response: we have added information about exclusion criteria on p.6.

4.3- Page 7, lines 19-21: Give more specific information on what pain questions were used.

Response: We have included more information about the pain questions on page 7.

4.5- Was the data normally distributed?

• Response: We have included a new table, table 1b to show descriptive statistics for KIDSCREEN 52, pain, sex and age. As shown in table 1b, nine of the ten dimensions had skewness and kurtosis between ±1, most of them between ±1. This indicate that these variables are approximately normally distributed. However, the bullying dimension (no 10) had skewness -2.43 and kurtosis 7.41, so the standard error for this dimension may be somewhat impaired.
4.6- Please be more specific about when Pearson correlations were used.

- Response: Pearson’s product moment correlation was used to examine the bivariate relationships between each of the 10 dimensions of KIDSCREEN-52 scales and the independent variables sex, age and pain respectively.

5- RESULTS:

5.1- The first paragraph should report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, and analyzed. Give reasons for non-participation at each stage. Therefore, the information brought in the Methods (Page 5, lines 41-56) should be transferred to the Results.

- Response: we agree and have transferred this information to the Results section.

5.2- Page 8, lines 32-33: Was the nationality assessed according to the father only or both parents?

- Response: Nationality was assessed according to the father only due to Statistics Norway’s recommendations, however we have removed this from the table.

5.3- Page 8, lines 49-52: A better description of the pain variable data would give more soundness to the Results.

- Response: We agree that the pain variable should be better described, and have included more information about it on page 7.

5-4- Table 2: correct the typo "Totalt". Report the statistical tests used as a table footnote.

- Response: We are sorry that the statistical tests were not included, we have added following information: pa age differences within sex (f-test); pb sex differences (t-test); pc age differences (f-test).

We have changed the word “totalt” to total.

6- DISCUSSION:

6.1- Page 10, lines 17-20: "21% reported pain lasting more than 3 months”. I did not see this result in the appropriate section.

- Response: We have removed this information from the discussion.

6.2- Page 11, lines 12-17: I am afraid that authors should be more cautious with the following statement: "The results of our study indicates that living with pain has negative physical, mental,
and social consequences for the children, and that pain is a symptom of a multidimensional health problem". Do this study design and results support that report?

- Response: We agree that we should be more cautious, and we have changed the wording in the discussion p. 11 and 12.

6.3- Please describe this study limitations.

- Response: We have described the study limitations on p. 13 and 14.

7- CONCLUSIONS:

7.2- Why is absenteeism mentioned? I did not see any results on it. Please rewrite the Conclusions to keep it coherent with the aims of the study and the results found, preventing to have conclusions not supported by the results.

- Response: We have removed absenteeism from the conclusion section, and we have tried to make the conclusion more coherent with the aims of the study.