**GENERAL COMMENTS**

Concerning Helena de Sola et al: A nationwide study of the impact of chronic pain on the patient’s employment. Relationship with the family and social support.

This is a computer assisted telephone interview of 1543 adults in the general population of working age in Spain, seeking information prevalence of cncp and its consequences for sick-leave and job loss. They found 14% suffered from cncp, more than ¾ were women. Those who took sick-leave because of their pain were more women, had higher pain intensity and had higher educational levels. Almost 8 of 10 taking sick-leave were on pain-relief medication (but no information on what type of drugs), they were more often sad or anxious. 13.5% had lost their job because of cncp, again more among women, more among those with unbearable pain, 2/3 needed help with grooming etc, almost 9 of 10 felt sad and anxious. Almost 6 of 10 were not satisfied with the help from the health care system. Their families were affected by their pain, but most of the patients were satisfied with the help from their family-members. In a multivariate analysis those who were sad, those who were not satisfied with health care, but consulted doctors often and taking more medication for their pain (types of drugs not given), all these were significantly associated with losing or leaving the job.

Comments: The manuscript is fairly well written, the tables are informative. The methods used for this cross-sectional survey are appropriate for the selection of working-age adults. Focusing on sick-leave and loss of job among those with cncp in Spain is important because it documents the cost of cncp on the individual patient as well as society at large. Their results appear reasonably in agreement with similar studies in other European studies.

In the Introduction they mention (first sentence) they mention that cncp affects 19% of the population in Europe but refer to wrong citation (should be [4], not [1]. In that study the prevalence of fairly severe cncp in Spain was 12 or 13% (not 16.6%).

They list the use of pain relief medication as a risk factor for sick-leave and for losing/leaving their job. It is a pity that they do not give...
any information on what kind of pain relieving drugs these were:

Opioids, that cause so many adverse effects could well be much worse than for those who take only non-opioid medication.

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**REVIEWER**

Ben Darlow
University of Otago, New Zealand

**REVIEW RETURNED**

27-Jul-2016

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**GENERAL COMMENTS**

Thank you for asking me to review this manuscript. Chronic pain is an important health issue and associations between work loss and chronic pain are useful to explore.

In general, this manuscript has used an appropriate method to explore associations between chronic pain and work loss, however, the results are often presented in a way which infers causal links. Causal associations are not able to be demonstrated through cross-sectional surveys. It is not always clear if these causal inferences are due to inaccurate English language translation or misinterpretation of the data. I have made recommendations related to the overall manuscript and the individual sections below.

**General recommendations:**

1. English language editing would improve the readability of the manuscript
2. I recommend removing all language referring to causal relationships (e.g. the affect of x on y, or the impact of x on y, or the consequence of x, or the contribution of x to y) with language denoting associations
3. I also recommend changing ‘patients’ and ‘subjects’ to ‘people’ and ‘respondents’ as participants were not recruited in their capacity as health consumers nor were they subjected to an intervention

**Introduction**

4. In general, the introduction sets out the background and rationale for the study well. I suggest rewriting sentence 2 in paragraph 3 (lines 41 to 46) as this does not make sense
5. I suggest including reference to qualitative research which has explored the influence of familial and spousal support on employment for people with persistent pain (e.g. McCluskey S, Brooks J, King N, Burton K. The influence of ‘significant others’ on persistent back pain and work participation: a qualitative exploration of illness perceptions. BMC Musculoskelet Disord 2011;12:236; Brooks J, McCluskey S, King N, Burton K. Illness perceptions in the context of differing work participation outcomes: exploring the influence of significant others in persistent back pain. BMC Musculoskelet Disord 2013;14:48; 56. McCluskey S, Brooks J, King N, Burton K. Are the treatment expectations of ‘significant others’ psychosocial obstacles to work participation for those with persistent low back pain? Work 2014;48:391e8)

**Methods**

6. A description of the sampling frame for the telephone interviews would be helpful for examining the generalisability of the findings
7. There seems to be some confusion about the terms qualitative/quantitative on page 3, line 32, and page 6 line 33
8. I recommend including the data collection instrument used as an online appendix to present all of the items and response options. I also recommend that the psychometric properties of these items be reported, particularly the construct validity.

9. The sample size calculation (or its absence) should be reported within the methods.

Results

10. I recommend clarifying that Table 1 presents only the characteristics of the participants with chronic pain, not the entire study population. It would also be helpful in this table (and others) to report the number of respondents included in the data being reported.

11. It would be more accurate to state that 4.21% of the study population reported taking sick leave due to chronic pain in the past 12 months, indicating that between 3.2 and 5.2% of the Spanish population take sick leave due to chronic pain within a 12-month period.

12. I generally found the presentation of the results to be very confusing, particularly the presentation of proportions, for example it is stated that the proportion of females who took sick leave was greater than males, however, table 2 indicates that 39% of males with chronic pain took sick leave whereas 29% of females with chronic pain took sick leave. It would appear that chronic pain is more common in females rather than a greater proportion of females taking leave due to chronic pain.

13. Table 2 is difficult to interpret. I recommend adding the total population number for Yes and No columns. Consistent with recommendation 12, I think that it would be more meaningful to report proportions across rows rather than between rows (i.e. 19/49 (39%) of men who had chronic pain reported taking sick leave due to chronic pain and 30/49 (61%) did not).

14. I recommend adding 95% confidence intervals to all proportions and odds ratios presented in the text or within tables. This is particularly important given that these will presumably be quite wide in a number of circumstances where very few participants are included in a calculation.

15. It should be reported that 13.5% of respondents with chronic pain ‘reported’ losing or leaving their job due to chronic pain as these data rely exclusively on self-report. This number equates to 1.8% of the sample and may be used to estimate the proportion of the Spanish population who lose or leave their job (with an appropriate confidence interval). The prevalence of males with chronic pain who reported leaving or losing their job would again appear to higher than females from data reported in table 4, this contrasts with the prevalence of job loss being reported as being (non-significantly) higher in females.

Discussion

16. I recommend making changes consistent with those recommended above, particularly related to the inference of causal links. This may assist with re-writing paragraphs which do not currently seem to make sense, such as the final sentences of paragraph 1 page 15, and paragraphs 2 and 3 page 16. A great many hypotheses are presented which appear to be over-interpreting the data available.

17. I recommend considerably more discussion of this study’s limitations, particularly related to sample size. It is difficult to see how the statement that the large sample size has guaranteed sufficient statistical power can be supported given the very small
numbers included in some analyses and the wide confidence intervals presented. Other limitations which could be expanded upon include the lack of use of validated instruments for assessing key constructs, and the sampling frame employed.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Reviewer Name: Harald Breivik
Institution and Country: University of Oslo and Oslo University Hospital, Oslo, Norway
Competing Interests: None
Concerning Helena de Sola et al: A nationwide study of the impact of chronic pain on the patient’s employment. Relationship with the family and social support. This is a computer assisted telephone interview of 1543 adults in the general population of working age in Spain, seeking information prevalence of cncp and its consequences for sick-leave and job loss. They found 14% suffered from cncp, more than ¾ were women. Those who took sick-leave because of their pain were more women, had higher pain intensity and had higher educational levels. Almost 8 of 10 taking sick-leave were on pain-relief medication (but no information on what type of drugs), they were more often sad or anxious. 13.5% had lost their job because of cncp, again more among women, more among those with unbearable pain, 2/3 needed help with grooming etc, almost 9 of 10 felt sad and anxious. Almost 6 of 10 were not satisfied with the help from the health care system. Their families were affected by their pain, but most of the patients were satisfied with the help from their family-members. In a multivariate analysis those who were sad, those who were not satisfied with health care, but consulted doctors often and taking more medication for their pain (types of drugs not given), all these were significantly associated with losing or leaving the job.

Comments: The manuscript is fairly well written, the tables are informative. The methods used for this cross-sectional survey are appropriate for the selection of working-age adults. Focusing on sick-leave and loss of job among those with cncp in Spain is important because it documents the cost of cncp on the individual patient as well as society at large. Their results appear reasonably in agreement with similar studies in other European studies.

- In the Introduction they mention (first sentence) they mention that cncp affects 19% of the population in Europe but refer to wrong citation (should be [4], not [1]). In that study the prevalence of fairly severe cncp in Spain was 12 or 13% (not 16.6%).

We are grateful for this reviewer’s comments and with reference to the literature cited, this has now been revised and corrected accordingly.

- They list the use of pain relief medication as a risk factor for sick-leave and for losing/leaving their job. It is a pity that they do not give any information on what kind of pain relieving drugs these were: Opioids that cause so many adverse effects could well be much worse than for those who take only non-opioid medication.

Although it would certainly have been of interest to collect information about the medications that the patients surveyed were taking, this information was not gathered due to the nature of the survey and the data collection (telephone survey). This issue has now been mentioned and addressed as a limitation of the study.

Reviewer: 2
Reviewer Name: Ben Darlow
Institution and Country: University of Otago, New Zealand
Competing Interests: None declared
Thank you for asking me to review this manuscript. Chronic pain is an important health issue and associations between work loss and chronic pain are useful to explore. In general, this manuscript has used an appropriate method to explore associations between chronic pain and work loss, however, the results are often presented in a way which infers causal links. Causal associations are not able to be demonstrated through cross-sectional surveys. It is not always clear if these causal inferences are due to inaccurate English language translation or misinterpretation of the data. I have made recommendations related to the overall manuscript and the individual sections below.

General recommendations:

1. English language editing would improve the readability of the manuscript. Following the reviewers recommendation the paper has been revised by a native English speaker.

2. I recommend removing all language referring to causal relationships (e.g. the affect of x on y, or the impact of x on y, or the consequence of x, or the contribution of x to y) with language denoting associations. In accordance with the reviewers recommendations all the references to causal relationships in the manuscript have been modified, except the reference to “the effect of pain on the family” since the question was phrased in this manner in the questionnaire.

3. I also recommend changing ‘patients’ and ‘subjects’ to ‘people’ and ‘respondents’ as participants were not recruited in their capacity as health consumers nor were they subjected to an intervention.

These changes have been made, except when referring to data from the literature taken from studies carried out on patients where the term “patients” was used.

Introduction

4. In general, the introduction sets out the background and rationale for the study well. I suggest rewriting sentence 2 in paragraph 3 (lines 41 to 46) as this does not make sense. Sentence 2 of paragraph 3 has been rewritten in order to make it clearer to the reader.

5. I suggest including reference to qualitative research which has explored the influence of familial and spousal support on employment for people with persistent pain (e.g. McCluskey S, Brooks J, King N, Burton K. The influence of ‘significant others’ on persistent back pain and work participation: a qualitative exploration of illness perceptions. BMC Musculoskeletal Disorders 2011;12:236; Brooks J, McCluskey S, King N, Burton K. Illness perceptions in the context of differing work participation outcomes: exploring the influence of significant others in persistent back pain. BMC Musculoskeletal Disorders 2013;14:48; 56. McCluskey S, Brooks J, King N, Burton K. Are the treatment expectations of ‘significant others’ psychosocial obstacles to work participation for those with persistent low back pain? Work 2014;48:391e8).

A phrase has been added to paragraph 3 on page 4 and 5 that refers to the articles indicated by the reviewer, which have also been added to the reference list.

Methods

6. A description of the sampling frame for the telephone interviews would be helpful for examining the
generalisability of the findings

A new section has been added to the methods section on page 5 in which the sampling method used in the original study from which the data was obtained is described in detail.

7. There seems to be some confusion about the terms qualitative/quantitative on page 3, line 32, and page 6 line 33.

With regards the methods section dealing with data collection, we have now removed the term “qualitative” to avoid confusion. In addition, we have replaced the term “qualitative variable” in the first paragraph of the section “statistical analysis” with “categorical variable”, and we now use the term “continuous variable” rather than “quantitative variable”.

8. I recommend including the data collection instrument used as an online appendix to present all of the items and response options. I also recommend that the psychometric properties of these items be reported, particularly the construct validity.

As recommended, the questionnaire used in the study has been included as an appendix (original Spanish version). No information about the psychometric properties of this questionnaire has been included because the questionnaire was designed using items from the “Encuesta Española de Salud y Encuesta Española de Discapacidad”, which was carried out by the National Spanish Statistics Institute, and no validation procedure was carried out.

9. The sample size calculation (or its absence) should be reported within the methods.

According the reviewer’s suggestion, it is now stated at the end of sample section in the Methods that no sample size calculation was specifically performed for this study.

Results

10. I recommend clarifying that Table 1 presents only the characteristics of the participants with chronic pain, not the entire study population. It would also be helpful in this table (and others) to report the number of respondents included in the data being reported.

The title of Table 1 specifies that the data included in the table corresponds to that from the 213 individuals with Chronic Pain. In this table and all the others, the number of respondents for each variable (N) is now indicated.

11. It would be more accurate to state that 4.21% of the study population reported taking sick leave due to chronic pain in the past 12 months, indicating that between 3.2 and 5.2% of the Spanish population take sick leave due to chronic pain within a 12-month period.

The sentence has been rewritten to clarify the meaning of the CI 95%.

12. I generally found the presentation of the results to be very confusing, particularly the presentation of proportions, for example it is stated that the proportion of females who took sick leave was greater than males, however, table 2 indicates that 39% of males with chronic pain took sick leave whereas 29% of females with chronic pain took sick leave. It would appear that chronic pain is more common in females rather than a greater proportion of females taking leave due to chronic pain.

We are not sure we have fully understood the issue raised by the reviewer. In the text, we refer to the prevalence of sick leave due to chronic pain in males relative to the population of males that
responded to the survey (1.23%: CI 95% 0.6-1.8), and in women the prevalence relative to the population of women responders was clearly higher (2.98%: CI 95% 2.1-3.). By contrast, in Table 2 the distribution of those that took sick leave is presented in terms of sex and of the individuals that suffer chronic pain, with 65 individuals indicating that they had taken sick leave, 19 of whom were men (29.2%) and 46 were women (70.8%).

13. Table 2 is difficult to interpret. I recommend adding the total population number for Yes and No columns. Consistent with recommendation 12, I think that it would be more meaningful to report proportions across rows rather than between rows (i.e. 19/49 (39%) of men who had chronic pain reported taking sick leave due to chronic pain and 30/49 (61%) did not).

In accordance with the reviewer’s comments, we have included in Table 2 the absolute numbers (N) and the CI 95% of the data shown. However, we don’t feel it necessary to change the orientation of the data shown in the Table as we wish to emphasize the distribution of the variables in function of whether or not the individuals had to take sick leave. Nevertheless, if it were necessary we would be happy to modify the table in function of the reviewer’s recommendations.

14. I recommend adding 95% confidence intervals to all proportions and odds ratios presented in the text or within tables. This is particularly important given that these will presumably be quite wide in a number of circumstances where very few participants are included in a calculation.

The corresponding CI 95% values have been added to the ORs in the text, in accordance with the results shown in Tables 3 and 5. Tables 2 and 4 have also been modified to include the CI 95% of the data as suggested by the reviewer.

15. It should be reported that 13.5% of respondents with chronic pain ‘reported’ losing or leaving their job due to chronic pain as these data rely exclusively on self-report. This number equates to 1.8% of the sample and may be used to estimate the proportion of the Spanish population who lose or leave their job (with an appropriate confidence interval. The prevalence of males with chronic pain who reported leaving or losing their job would again appear to higher than females from data reported in table 4, this contrasts with the prevalence of job loss being reported as being (non-significantly) higher in females.

As suggested, it has been emphasized that the data related to the loss or leaving of their job is self-reported. Regarding the prevalence of leaving or losing employment, we refer to the explanation to point 12.

Discussion

16. I recommend making changes consistent with those recommended above, particularly related to the inference of causal links. This may assist with re-writing paragraphs which do not currently seem to make sense, such as the final sentences of paragraph 1 page 15, and paragraphs 2 and 3 page 16. A great many hypotheses are presented which appear to be over-interpreting the data available.

In accordance with the reviewer’s recommendation, all references to causal links have been removed from the text as indicated previously. In addition, paragraph 1 on page 15, and paragraph 2 and 3 on page 16 have been rewritten.

17. I recommend considerably more discussion of this study’s limitations, particularly related to sample size. It is difficult to see how the statement that the large sample size has guaranteed sufficient statistical power can be supported given the very small numbers included in some analyses and the wide confidence intervals presented. Other limitations which could be expanded upon include
the lack of use of validated instruments for assessing key constructs, and the sampling frame employed.

We have modified paragraph 2 on page 16 to discuss the limitation related to the sample size in more detail. Likewise, we have added information on page 16 regarding the failure to use validated tools. Given that we have included in the Methods a section on the "sampling method" where we justify that the sample is representative, we have not addressed this issue in the limitations.