Author’s response to reviews

Title: Non-traumatic arm, neck and shoulder complaints: prevalence, course and prognosis in a Dutch university population

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Version: 4 Date: 6 December 2012

Author’s response to reviews: see over
Maastricht, 5 December 2012

Dear editor,

Thank you for giving us the opportunity to revise and resubmit our manuscript. Please find our responses to the reviewers’ comments below.

We are looking forward to your reply.
Yours sincerely, on behalf of all co-authors,

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Reviewer’s report

Title: Course and prognosis of non-traumatic arm, neck and shoulder complaints: design of a prognostic cohort study

Version: 3 Date: 22 October 2012

Reviewer: Harald S Miedema

Reviewer’s report: (The author’s reactions are underlined)

General remark:
The authors have made considerable efforts to revise the manuscript and clarify many of the points that were addressed in the first round of reviews. This results in a manuscript that is much improved. However, still there are some points of discussion. I commented on these points in the following text.
I will refer to the numbering of the previous review and the responses of the authors to them.
The authors would like to thank the reviewer sincerely for his critical review and comments.

I:
Is addressed under III.

II.
(Framework for) diagnoses: The authors underline their choice for a heterogeneous population with a focus on pain patterns and not on local, specific often single-sided diagnoses. To their opinion a traditional description and assessment in different diagnostic groups fail to reflect the diversity and complexity of pain manifestations. I agree with the authors on this point with regard to the group of non-specific disorders. But also there are many complaints in this area that have a (more) clear and characteristic pattern, are indeed most often single-sided and result in a specific diagnosis. In the study of Feleus et al in primary care (Eur Spine J 2008 17:1218–1229) the estimate of the proportion of patients having a specific diagnosis was 59%. In this study in 58% the pain was restricted to one region (single-sided), in 42% more than one region was involved. Feleus et al showed significant differences between the management of CANS when patients were diagnosed with a specific diagnosis compared to non-specific. Given these facts it is a pity that in the proposed study no information about underlying diagnoses will be generated.

We thank the reviewer for his remarks. Although the primary aims of our study focus on prognostic indicators associated with better outcomes in patients with pain at multiple sites, we agree with the reviewer that significant differences might be found between patients with a specific diagnosis and patients with non-specific diagnosis (Keijzers, Feleus et al.). As a response on your comments we decided to classify the complaints into specific and non-specific and added information to this manuscript how the classification into specific/ non-specific diagnosis will be accomplished (page 6, line22- page 7, line2).

CANS Knowledge and treatment centre: information about this centre was indeed confusing, I thought this was a second setting of the study. In the present manuscript this is clarified. However, in their comment the authors still mention that “the CANS centre is easy accessible for employees and students with CANS. Employees and students with CANS who visit this center are asked to participate in the study.” How do the authors relate this to their statement that the cohort reflects a population with CANS that reflect “usual care”? Who asks these employees and students to participate in the study? Are these participants referred to the participating primary care professionals? It seems to me that these participants do not reflect usual care, because they are identified within the special setting of the CANS Knowledge and treatment centre and are (supposedly) referred to the participating primary health care professionals thereafter. This is underlined in a later comment of the authors under III: “since the majority of patients that are recruited in the CANS centre are not treated in primary care for their complaints, we are able to explore the natural course of
CANS.” So I think in the analysis attention must be given for the different way in which these participants were included in the study. This point should be added to the “statistical analysis” section. In the present section only a separate analysis is indicated for working and non-working populations, but also in the subpopulation that originates from the consecutive inclusion of patients in the primary health care centers a substantial part will be working.

The reviewer’s comments are very helpful and have led to the decision to change the recruitment procedure of this study. We agree that recruitment through the CANS centre (which was referred to as occupational health centre in the last version of the manuscript in order to clarify its function) is not an appropriate way to recruit people for this study in which the primary aim is to gain insight in the course and prognostic factors of CANS.

The initial intention with regard to the recruitment procedure was indeed that staff of the CANS Knowledge and treatment centre (CANS centre) identifies eligible patients among employees and/or students who consult this centre. Subsequently, they would have been asked to participate in the prognostic study. In addition, students and employees could voluntary choose to be treated by one of the participating health-care professionals in order to collect process factors on treatment and investigate the association between treatment variables of usual care and outcome, which was a secondary goal of this. The reviewer is correct with regard to his remark that the procedure in which participants were referred by the staff of the CANS centre to participating health care professionals does not reflect usual care. Furthermore, since we allowed the participating primary health care professionals to include consecutive eligible patients with CANS in the study (which were not necessarily students or employees of the universities), in addition to the patients who would be referred to them by the CANS centre, the study population would be extracted from two different base populations. This should indeed be considered in the analysis, as the reviewer mentions. In order to clarify the recruitment procedure (which might still be confusing for the reader as it was described in the previous version of the manuscript) and to prevent recruitment of eligible participants out of separate base populations we decided to adapt the recruitment procedure in the design.

Based on the comments of the reviewer and the arguments mentioned above, we decided to choose only one way to include participants (and not several ways as in the previous version of the manuscript) and to change the recruitment procedure by using a survey questionnaire for the whole base population (university students and staff). This survey will be used to identify putative participants for the cohort study. For information on the procedure and survey questionnaire we added a paragraph in the manuscript in which we elucidate the survey (page 6, line 4- page 8, line 2).

Although we are aware of the extent of this change in recruitment procedure, we believe this is necessary to improve the feasibility of the present study and to prevent the reader of the manuscript for misunderstanding. Furthermore, the choice to adapt the recruitment procedure might be in favour of the number of participants that enter the study, since employees and staff with CANS can be identified more efficient and we are no longer dependant on the number of consultations at the CANS centre or health care professional to recruit participants. The selection procedure of employees by means of a survey

\[ \text{Survey Questionnaire} \]
questionnaire is an objective and relatively easy way to address many employees and students at the same time.

Even though the primary purpose of the survey is to improve the inclusion and recruitment procedure of this study, another benefit of this survey in the university population is the ability to investigate the prevalence of CANS among university employees and students. Since information on the prevalence among students is very scarce, information on these prevalence rates is very welcome. To highlight the importance of this objective the following sections were added or changed in the background:
Page 1, line 10-line 19 and line 21-22
Page 2, line 2
Page 3, line 5-7, line 9-10

Because of addition of the cross-sectional survey, we changed the tekst on the following parts in the method section:
Page 4, line 5
Page 5, line 5-15
Page 6, line 4-Page 8, line 2
Page 6, paragraph procedure of data collection is adapted to the change in recruitment procedure and one of the secondary objectives of the study.
Page 10, line 6-8

Due to this adaptation in the recruitment procedure, we decided to eliminate the objective of this study: “exploration of the association between treatment variables and outcome” out of the framework of this study design (Page 3), and replace it by the objective: “insight in the prevalence of CANS among university staff and students”.

Based on the former comments of the reviewer, we believe these choices enlighten the manuscript to a considerable degree. To clarify the flow of participant we refer the flow-chart of the study in figure 1.

Because of these adaptations we reformulated the discussion section (page 10, line 19: Page 12, line 15).
Lastly, we decided to change the title in accordance with the corrections in the manuscript (title page)

Power analysis: the authors refer to the employees and students of the various institutions as their base population. Because in the inclusion section two subpopulations are indicated, the question is why only the base population of one of the subpopulations is mentioned.

The base population consists of staff and students of two universities in the same region. The base population is considered as one source population and exists of approximately 40,0000 persons. So this number refers to the total staff and students of both universities. We specified this base population in the number of students and the number of employees to provide more insight in the composition of this population (Page 4, line 9 and 10).
The design of the study is clarified to some extent. For remarks about the population I refer to the comments under II.

It still is not clear to me whether or not the participants that originate from the CANS Knowledge and treatment centre are referred to the participating primary care therapists or other therapists, or that they are not referred at all so that the “natural course” can be studied.

We realise that several sections in the previous version of the design created confusion for the reader. As responded under II, we adapted the sections mentioned above to improve the design based on the comments of the reviewer.

The current corrections in the design give us the opportunity to follow the “natural course” of the complaints. Nevertheless, global information on treatment and information on the use of medicines will be gathered by means of the questionnaire that will be administered at baseline and at 6 months follow-up. We included questions on medicine-use and treatment-interventions in this questionnaire (Table 1).

Furthermore it is stated under “Participating health care professionals” that “the primary heath care professionals will treat according to usual care” but I am confused what the authors mean by that. These professionals received a two day training course in which they were given “instructions on the management of CANS according to the recommendations of the current practice guidelines”. To me this seems like a health care intervention, by which the normal variance of interventions that are delivered will be reduced (in the direction of the contents of the guideline). In a later comment the authors state: “the content of these instructions for management were totally based on the recommendations of the current clinical guidelines for CANS. Assuming that most therapists work already according to these guidelines, this will not influence the care they would have provided otherwise (because they receive no new information that is not available for not-participating health care professionals in the field.” If this is true, than it is irrelevant to mention the two days training course, especially since no information about the content is given. However, to my opinion, the introduction of the CANS guideline for physiotherapists in 2010 will not already have led to the situation that most therapists already work according to this guideline, and that the two days course will have changed the behaviour of the participating professionals in the direction of the guideline.

We agree with the reviewer with regard to these remarks. Although we decided to eliminate this part out of the framework of this study we want to give a short response to elucidate the initial purpose of the training: We provided the training course for the main reason to inform therapists about the research and the CANS centre, and the computer based patient record system for data collection on treatment factors. In addition we were of the opinion that discussing the current guidelines has a minimal effect on the usual care process of these therapists, especially since therapists that registered to take part in the study were mainly therapists that are interested research activities and evidence based treatment, and most of them were already familiar with the current guidelines. Although these health care professionals will not play a part in the
data collection of this study, due to the adaptations in the design (that are mentioned above), they might play a role in future study on the association of treatment factors and outcome. However, they will be left outside the framework of this study.

Furthermore, since no information about the course is given, I don’t know if maybe specific instructions have been provided in the course that are not conflicting with the guideline, but are more a sort of extension (e.g. a treatment protocol).

Computer based recording system: In re-reading the manuscript I wonder how data about treatment and referrals from other primary care professionals than the participating professionals (mainly physiotherapists and a few Mensendieck-Cesar therapists and occupational physicians), especially general practitioners, are gathered in this study. Do they all register their data in Fastguide? If not, how is this information collected?

With regard to these comments, we would like to refer to the responses above.

IV:
Definition of a new episode: on page 6 last paragraph it is now stated that “an episode is considered ‘new’ if patients have not visited their health care professional for the same complaint during the preceding 3 months. What is meant by “their”? Does this refer only to the (participating) primary care professional or to any health care professional?

By “their” is meant any health care professional.
I still think the authors should use a better definition of new episode. To what literature they are referring as they mention that “this seems to be an appropriate ‘cut-off point’ according to the literature about CANS”?

We prefer to use the same definition of a new episode of CANS as some recent studies on course and prognosis of CANS (Feleus, Bierma-Zeinstra et al. 2007; Karels, Bierma-Zeinstra et al. 2007) to facilitate comparability of the results in different settings. For this reason we changed the definition into 6 months, as reported in the studies of Feleus et al. and Karels et al., instead of 3 months (page 7, line 23). Moreover, we want to emphasize that this definition can be seen as an inclusion criteria, not as a diagnosis.

In conclusion we would like to express our sincere gratitude to the reviewer’s helpful comments, because these comments resulted into a, to our opinion, manuscript that is stronger and more readable and a study design that is more feasible. We also used the formatting checklist to ensure that the manuscript conforms to BMC manuscript format.
OBJECTIVES: To identify predictors of non-recovery in non-traumatic complaints at the arm, neck and shoulder in general practice 6 months after the first consultation.

METHODS: A prospective cohort study was set in 21 Dutch general practices. Consulters with a first or new episode of non-traumatic arm, neck or shoulder complaints and age 18 through 64 yrs entered the cohort. Complaint, patient, physical, psychosocial and work characteristics were investigated as possible predictors of non-recovery at 6 months using multiple logistic regression analyses (backward Wald).

RESULTS: At 6 months, 46% of the total population (n = 612) and 42% of the working subpopulation (n = 473) still reported complaints. Complaint characteristics (long duration of the complaint before consultation, recurrent complaint, musculoskeletal comorbidity and complaint mainly located at wrist or hand) were most predictive of non-recovery followed by psychosocial characteristics (more somatization and experiencing less social support). Having a specific diagnosis was associated with recovery. In the working subpopulation, the same variables were predictors of non-recovery. Additionally, low supervisory support was associated with non-recovery. The models correctly classified 72-75% of the patients (explained variance 0.27-0.28).

CONCLUSIONS: Besides questions on complaint characteristics, information on somatization and support can help a general practitioner to recognize patients at risk of persistent complaints.

OBJECTIVE: To investigate the clinical course and prognostic factors of complaints of arm, neck, and shoulder. STUDY DESIGN AND SETTING: A prospective cohort study in physical therapy practice. Participating physiotherapists recruited new consulters with musculoskeletal complaints of the neck and/or upper extremities. Participants filled in questionnaires at baseline, 3 months, and 6 months. The main outcome measure was the persistence of complaints over 6-month follow-up. Possible predictors like social and psychological factors, physical factors, and complaint specific factors were tested in univariate and multivariate logistic regression analyses for repeated measurements. RESULTS: Of the 624 participants at baseline 543 (87%) returned at least one follow-up questionnaire. At 6-month follow-up, 40% had persisting pain and discomfort.
Somatization, kinesiophobia, catastrophizing, and a long duration of complaints at baseline were significantly related to the persistence of complaints over 6 months in the total population. In those with paid work (77%), catastrophizing, low decision authority at work, and a long duration of complaints at baseline were significantly related to the persistence of complaints over 6 months. CONCLUSION: 40% of the participants had persisting pain and discomfort after 6 months and mainly social and psychological factors played a role in this course.


OBJECTIVES: To evaluate the differences in predictors of nonrecovery between patients with a specific diagnosis at arm, neck, and/or shoulder, vs. patients with a nonspecific diagnosis in general practice at 6 months after the first consultation. STUDY DESIGN AND SETTING: New consulters with nontraumatic arm, neck, or shoulder complaints entered the cohort. Patient, complaint, and physical, psychosocial, and work characteristics were evaluated as possible predictors. Logistic regression analyses were conducted for the specific and nonspecific groups separately. RESULTS: At 6 months, 38% (n=298) of the specific-group members and 49% (n=249) of the nonspecific-group members reported nonrecovery. Univariately, similar variables were related in both groups, although their strength sometimes differed. Multivariately, duration of complaints was predictive of nonrecovery in both groups. Other predictors in the specific group were as follows: more somatization, low social support, older age, high body mass index, and unemployment. In the nonspecific group, the predictors were as follows: musculoskeletal comorbidity, recurrent complaint, poor perceived general health, multiple-region complaints, and high level of kinesiophobia. CONCLUSION: At 6 months, nonrecovery was reported more frequently in the group of patients with a nonspecific diagnosis. The predictive value of psychosocial factors on nonrecovery is at least of equal importance in patients with a specific diagnosis compared with patients with a nonspecific diagnosis.