Author’s response to reviews

Title: Determinants of the clinical course of musculoskeletal complaints in general practice: design of a cohort study

Authors:

Ms Johanna J.M. van der Waal (a.van_der_waal.emgo@med.vu.nl)
Ms Sandra S.D.M. Bot (s.bot.emgo@med.vu.nl)
Caroline C.B. Terwee (cb.terwee.emgo@med.vu.nl)
Dr Danielle A.W.M. van der Windt (dawm.van_der_windt.emgo@med.vu.nl)
Lex L.M. Bouter (lm.bouter.emgo@med.vu.nl)
Joost J. Dekker (jdekker@vumc.nl)

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PDF covering letter
Dear editor,

Thank you for your email of 20th December. I am very pleased that the manuscript is suitable for publication. The comments of the reviewers were valuable, and helpful in revising the manuscript. In this letter we respond to all comments, and clarify all changes made to the manuscript. Herewith I send you the revised manuscript (xx files). I am looking forward to publication of this manuscript in BioMed Central.

Kind regards,

Johanna M. van der Waal, MSc

J.M. v.d. Waal, MSc
Institute for Research in Extramural Medicine (EMGO-institute)
Van der Boechorststraat 7
1081 BT Amsterdam
The Netherlands
tel: +31 20 444 8175
fax: +31 20 444 9618
email: a.van_der_waal.emgo@med.vu.nl
web: www.emgo.nl
Response (italic) to comments on ‘Determinants of the clinical course of musculoskeletal complaints in general practice: design of a cohort study’.

Reviewer 1: Dr Isam Atroshi

The two main issues that need to be addressed are how the authors intend to categorize the large group of patients with generalized pain or multiple-site pain and how reliable and valid the chosen upper extremity measure is among this patient population.

The categorization of patients with generalized pain and a discussion about the upper extremity measure has been stated below.

Specific Comments:

1. Page 4, line 2: Postoperative thromboembolic complications after total hip replacement does not appear to be relevant for the subject of this manuscript. Also, the authors state that "most studies" had inadequate power but the studies they cited (ref 12-15) do not seem to be small sample size studies.

We agree with the reviewer. We left out the reference and the remark about inadequate power of the studies. (page 4, line 3)

2. Page 6: The expression "A number of x GPs" is not commonly used; it would be clearer to write "X GPs ..".

The sentence has been changed (page 6, line 6)

3. Page 7: According to the study methods, incomplete questionnaires returned by the patients will be completed by telephone interview. Previous studies have demonstrated that patients' responses to mailed self-completed questionnaires differ from those obtained by interview (patients commonly report better health during interview). Do the authors have any concerns about this?

Based on previous studies we expect that the number of participants for whom the questionnaire needs to be completed by telephone interview will be relatively small (<5%). We are not concerned about the influence of these subjects on the results of the study. More importantly, we think it is better to have a response by a telephone interview than no response at all.

4. Questionnaires:

a) Characteristics of the complaint need further definition of the questions.

The questions are added to Table 2:

“Where and how long do you have complaints? What do you think is the cause of your complaints? Did you visit any kind of doctor, therapist, or social worker? Did you use any medication to relieve your complaint during the past 3 months? What did your GP do concerning your complaint? Have you had the complaint before during the past year? How often did your complaint bother you during the past 3 months? Do you have any other complaints?”

b) Sociodemographics: How is work status classified? How will profession/occupation be grouped in the analysis?

Work status is classified as number of working hours (paid activities) per week (6-point rating scale). Table 2 has been adjusted.

The classification of profession/occupation will be done later, according to classifications that have been used in other studies. This will facilitate comparison across studies.

c) Sick leave: How is sick leave defined and how will it be used in the analysis. Patients might have partial sick leave, sick leave because of other disorders, several sick leave periods alternating with non-sick leave periods, etc. From which source are the sick leave data obtained?
Sick leave data are reported by the patient by means of questions. A more detailed description of the assessment of sick leave is included in Table 2: “number of days of absence and reason of absence in past 3 months because of the complaint at issue”. The question will be analyzed as an outcome measure on a 6-point rating scale.

d) The question about perceived recovery and the response choices need to be shown (not only a reference).

The sentence has been changed: “Perceived recovery is scored by the patient on a 6-point rating scale.” (page 8, line 14)
The response options have been added to Table 2: “completely recovered, much improved, improved, no change, worse, much worse”.

e) Page 8: first sentence needs to be correctly written.

The sentence has been changed into:
“The questionnaires will be sent at baseline (approximately 16 pages) and after 3, 6, 12 and 18 months (approximately 8 pages) and contain the following outcome measures:…” (page 8, lines 7-8)

5. Categories:

a) How do the authors intend to deal with patients who have generalized pain or pain in multiple locations (the authors use only 3 categories neck/upper extremity, hip/knee and foot/ankle)?

A sentence has been added to the text on page 6, lines 17-21:
“In addition, patients are asked to select one of 3 categories that best represented their complaint: neck/upper extremity, hip/knee or foot/ankle. Patients with generalized pain or pain in multiple locations are asked to indicate at which location the complaints are most severe or most troublesome, and were reason to consult their GP.”

b) What is the exact definition of a "traumatic" disorder, a "chronic" disorder and "elderly"?

The text on page 9 has been changed into:
“In each category, traumatic (according to ICPC code or cause of the complaint, indicated by the patient as 'accident') vs. non-traumatic, chronic (i.e. symptom duration at least 3 months) versus acute and elderly (65+ years) vs. non-elderly, will be compared.”

c) The upper extremity questionnaire is to my knowledge not a commonly used measure; the reference cited (ref 30) concerns validity for a specific disorder (tennis elbow?). Is it a valid measure for the variety of upper extremity disorders that the patients in this study are expected to have?

In contrast to hip or knee complaints (WOMAC) or foot problems (foot function questionnaire), an upper extremity disability scale, suitable for our study, is not available in Dutch. We considered it important to assess and analyze upper extremity function as one unit (kinetic chain). Therefore, we decided against using several joint-specific questionnaires, and derived a new scale from two existing, validated questionnaires. The face validity of our scale is satisfactory, and other clinimetric properties (internal consistency, validity and responsiveness) will be analyzed within the framework of our cohort study.
This information has been added to the manuscript on pages 8-9.

6. Considering that multiple measures are used and that many might be intercorrelated, how do the authors plan to manage this potential problem in their multivariate analysis? This can perhaps be commented on in the discussion.

Outcome measures will be analyzed separately in different multiple regression analyses. Correlations between potential determinants will be calculated with Pearson or Spearman correlation coefficients. In the case of high correlation between 2 determinants only the most predictive determinant in the univariate analyses will be included in the multiple regression models.
This information has been added to the text on page 10.
7. Because respondent burden might be a factor influencing response rate, it would be interesting to describe the length of the questionnaire (total number of questions that the patients need to answer at each occasion).

The number of pages of the questionnaires is added to the text on page 8, lines 7-8: “The questionnaires will be sent at baseline (approximately 16 pages) and after 3, 6, 12 and 18 months (approximately 8 pages) …”

8. The information that the study does not concern patients with low back pain is very important and needs to be clearly stated in the abstract (and perhaps even in the title if possible).

The information has been stated in the abstract.

Reviewer 2: Dr Vincent Hildebrandt

This paper describes the design of a cohort-study in general practice on the course of musculoskeletal complaints apart from low back pain. For the prevention of chronicity and work disability, this study can produce valuable knowledge to general practitioners and also occupational health physicians to improve their treatments. The description provided is clear and straightforward and the feasibility of a successful study seems large.

Compulsory revisions

Abstract:
The information has been stated in the abstract.

Background:
First sentence: the prevalence... please indicate which period-prevalence is meant here.

The sentence on page 3 has been changed into:
“The point prevalence among adults in the general population in the Netherlands…”

7th sentence: working population.

The cited study concerns the general population and was not limited to the working population.

Page 4: I miss a reference to the study of Ariens et al, 2000 (Scand J Work Environ Health 26,1,7-19)

The study has been added to the text on page 4, lines 10-12: “Ariëns et al reported a positive association between neck pain and the following work-related physical risk factors: neck flexion, arm force, arm posture, duration of sitting, twisting or bending of the trunk, hand-arm vibration and workplace design.”

Page 8 (sample size): each category of complaint: what is meant with category? I derive from the next sentence that there are 20 categories (2000/100)?

A sentence has been added to the text on page 8 to clarify this issue: “The expected proportion of patients in each category of complaint (according to localization of complaint) is based on the incidence of these complaints in Dutch general practice. Based on these data we expect that patients with hip complaints will comprise the smallest category (5.1%). Participation of 2000 consecutive consulting patients should be sufficient to include 100 patients with hip complaints, which enables the construction of a predictive model for hip complaints that includes 10 predictors.”

Table 2: the references given for the assessment of physical activity during leisure time do not indicate a measuring method!
Physical activity during leisure time is measured with questions derived from questionnaires used in other large surveys. As yet, no paper has been published that specifically describes the design or clinimetric properties of this scale. References no. 46 and 47 that, indeed, not specifically describe this scale, have been omitted from the revised manuscript.

Page 9: a discussion is missing of the choices made when deciding on the study-design, the determinants to address and the measuring methods to use. This would make the paper much more valuable. I'm aware of the fact that it will be difficult to limit such a discussion, but a few main issues could/should be addressed here.

In the background paragraph of our paper we describe the reasons for designing this study in a general practice setting (page 3, lines 14-21), and for selecting patients consulting for a new episode of musculoskeletal pain. The choices made about determinants were based on previous finding from our research group, as well as research carried out by others. A summary of relevant findings from previous research is described in the background paragraph (page 4).

Discretionary revisions
Page 5: since musculoskeletal symptoms are often recurrent or chronic, I wonder why each episode which was not presented within a 3 month-period) is considered as 'new'.

The reviewer is absolutely right when he states that most musculoskeletal problems are recurrent. Our study concerns patients who consulted their GP for a new episode of musculoskeletal pain. The definition of a new episode is, indeed, arbitrary. After discussing this issue with GPs and the steering committee of our study we decided on a definition of "no consultation for the complaint at issue in the preceding 3 months".

Page 7: Mailing procedure: no incentives are built in to ensure a high respons rate. Do the authors really expect that anno 2003 most patients are willing to participate in such a study without any reward?

In order to increase the response rate, participants who have not returned the questionnaire within 10 days are contacted by telephone. In addition, small incentives (coffee, tea and candies) are presented to the participants.

The text has been changed accordingly (page 7, lines 16-17).

Table 2: an open question to measure profession/occupation is time-consuming to analyze. An additional, more structured, question on the type of work could be useful. In addition, I suggest to measure - in addition to physical activity during leisure time - also physical activity during working time.

An open question will, indeed, generate a lot of work, but enables us to classify jobs adequately, or decide on classifications that have been used in other studies. This will facilitate comparison across studies. Physical load as well as physical inactivity during working hours is evaluated in the baseline questionnaire.