Author's response to reviews

Title: Back Complaints in the Elders (BACE); design of cohort studies in primary care: an international consortium

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Dear editor,

We thank you and the reviewer for the constructive comments on our manuscript ‘Back Complaints in the Elders (BACE); design of cohort studies in primary care: an international consortium’. Our reply on all comments of the reviewer are presented below. We adjusted the manuscript according these comments, using track-changes.

**Major compulsory Revisions**

**Comment 1:**
Introduction: the potential differences between younger and older age subjects will not be studied, hence, this part of the rationale should be phrased more carefully.

*Reply:*
The part of the introduction about the difference between younger and older aged patients is written to emphasize the importance of the study objectives. We rephrased this in the manuscript: “It is important to assess the course of back complaints in older adults, because…”.

**Comment 2:**
The term 'developing chronic back complaints' may create confusion, since this study is about the transition for acute back complaints to chronic back complaints. Thus, it is about aggravation whereas developing may also include onset.

*Reply:*
We adjusted the manuscript: “To identify possible prognostic factors for the transition from acute back complaints to chronic back complaints in older people”.

**Comment 3:**
The secondary aim of "To determine the level of functional disability, quality of life and loss of productivity associated with back pain in older people" must be rephrased, since the cohort does not include subjects without back complaints. It will only be possible to study prognostic factors for these endpoints.

*Reply:*
We rephrased this secondary objective: “To determine the level of functional disability, quality of life and productivity loss in older people with back pain”.
Comment 4:
A clear definition of chronicity is not provided and essential for this study. How does the definition applied relate to the follow-up period of at least 12 months and the timing of the questionnaires with regard to duration of back complaints. In addition, how does chronicity relate to recurrence?

Reply:
We defined chronic back complaints as ‘back complaints lasting more than 3 months’ (the text is highlighted under the subheading statistical analyses. We defined recurrence as ‘a return of back pain lasting at least 24 h with a pain intensity of >2 on an 11-point NRS (>20 mm on a 100 mm VAS) following a period of at least 30 days pain free’ (the text is highlighted under the subheading outcome measures).

Comment 5:
Treatment received should be part of the prognostic factors, please provide information. Also, the aim to establish the influence of national systems on the prognosis is not addressed in the data collection.

Reply:
Treatment received is indeed a possible prognostic factor and is now addressed in the data collection. Also, we addressed the national system characteristics that will be collected in the cohort study: “We will also measure characteristics of the national health system of the different countries joining the BACE consortium (e.g. insurance form, present guidelines, availability off direct access to medical facilities), to analyse if they influence prognoses.”

Comment 6:
Since the development of a prognostic model is one of the goals of the study, simple logistic regression analysis will not be sufficient. How will authors achieve:
- development of a model with regard to overfitting and shrinkage?
- test the development model in other populations in ordre to validate the predictive power?
[or alternatively, the aim should be strictly limited to insight into prognostic factors]

Reply:
The aim of the study is to provide insight into prognostic factors and not the development of a prognostic model.

Comment 7:
The discussion is not really a discussion. Important issues to address are:
- generalisibility of the prognostic model in different countries (how does one want to achieve this? is there information from literature to guide?)
- comparability of the prognostic factors among older people with published models for younger people
- cross-cultural appreciation of back complaints as part of the influence of national systems.
Reply:
Because the aim of the study is to identify the prognostic factors, instead of developing a prognostic model, we did not include the first two issues to the discussion. We added the third issue into the discussion section.

Minor essential revisions

Comment 1:
The inclusion criterion of not having visited a GP in the past 6 months does not completely select only acute episodes. One would think that subjects with chronic back episodes during e.g. the last 2 years should be excluded as well.

Reply:
The inclusion criteria could not be changed any more. The BACE-D study has already started recruiting patients. The duration of the current back complaints is one of the questions of the baseline questionnaire (as mentioned in Table 3 of the manuscript). This information can be useful to identify patients who have longer lasting back complaints at baseline. We will use this variable as a possible prognostic factor.

Comment 2:
Blinding of participants for the clinical examination is required, please provide details.

Reply:
The participant is blinded for the outcome of the physical examination. We added the following sentences in the methods section: “The patients will be blinded for the outcomes of the physical examination. If the information gathered during the physical information is important for the health of the patient, the GP will be informed (e.g. low bone quality or high C-reactive protein level).

Comment 3:
It does not make sense to include falling in older people in this international study, since it is limited to only one national cohort.

Reply:
The objectives regarding falling in older people are limited to the BACE-B and BACE-A studies. We rephrased this in the manuscript.

Comment 4:
Why are different follow-up periods used? My guess would be that a one-year follow-up may be too short depending on the definition of chronicity. Perhaps it should be stated that the core of the project is 1-yr follow-up, but that some national cohorts will have longer follow-up periods.
Reply:
The core of the project is one-year follow-up. The extended follow-up of 5 years is, for now, only executed in the Dutch BACE study, to study the 5-year course of the patients. The one-year follow-up should be long enough to give good insight to the course of back complaints.


We hope that you find our revised manuscript suitable for publication.

We look forward to hear from you.

Yours sincerely,

On behalf of the co-authors,

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