Author’s response to reviews

Title: Neuropsychiatric symptoms in patients with dementia in primary care: a study protocol

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Author’s response to reviews: see over
To the editorial office
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Dear members of the BMC editorial team,

We would like to thank you for the valuable third review of our manuscript "Neuropsychiatric symptoms in patients with dementia in primary care: a study protocol". Please find our itemized, point-to-point response to the comments of the reviewers below.

Yours sincerely,
Also on behalf of the co-authors,

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Referee 1:

1. My main concern is still relating to the overall aims and hypothesis of the paper. In the abstract the aim is purely to investigate the course of NPS and caregiver distress. In the body of the paper there are two aims – the one just described as well as a second aim to detect the determinants of the course of NPS and caregiver distress. However, the hypothesis suggests that specialized services will impact on NPS and caregiver distress over time. In the method you then describe how ‘CONCERN’ will be implemented in 14 out of 18 participating clinics. If you are introducing an intervention, isn’t the study really an evaluation of the CONCERN program and more of an intervention study than a pure observational study? Whilst not a randomised controlled trial, it involves an invention that is expected to influence outcomes and these will be compared to patients from four ‘control’ clinics that do not implement CONCERN.

Author’s reaction:

In this study we aim to investigate the course of NPS in patients with dementia and informal caregiver distress in primary care. Eighteen general practices were selected based on their willingness to participate in this study. CONCERN is provided in 14 of these general practices. Not all dementia patients and their informal caregivers in these 14 practices will participate in CONCERN. It is possible that patients and informal caregivers who will not participate in CONCERN are supported by case managers of other care organizations or health care services. This is also the case in the 4 general practices were CONCERN is not at all provided. CONCERN should be considered as a collaborative health care service that is developed in the reality of care as usual. Therefore this is a prospective observational cohort study and not an intervention study.

We agree with referee that the aims and hypotheses are not consistently displayed throughout the manuscript and maybe caused confusion in the reviewer.

Changes made to the text:

“We also aim to detect determinants of both the course of NPS in patients with dementia and informal caregiver distress in primary care.” (page 2).

We removed the paragraph Study hypotheses “We hypothesize that patients with dementia and their informal caregivers who receive more extensive types of care, such as specialized
care for elderly people in general practices, multicomponent collaborative care and single component dementia case management (CM) display a different course of NPS and informal caregiver distress than patients with dementia and their informal caregivers who receive care as usual. Other determinants might be NPS at baseline, cognition, use of health care services (home care: nursing and domestic; use of day care services).” (page 7)

2. I also think that given the study is about an intervention that aims to reduce NPS, there should be more background about existing research that has aimed to reduce NPS in community dwelling populations. There has been a number of studies that have aimed to do this, mainly through education with caregivers.

Author’s reaction:
As stated before this study is a prospective (exploratory) observational cohort study. Therefore, there is no need to give more background about existing research that has aimed to reduce NPS in community dwelling populations.

3. Acronyms should be spelt out in full the first time they are presented.

Author’s reaction:
In line with the request of the referee, we spelt out acronyms in full the first time they are presented.

Changes made to the text:
“REAL.FR (Réseau sur la Maladie d’Alzheimer Français)” (page 5).
“MAASBED (MAAstricht Study of BEhaviour in Dementia)” (page 4).
“LASER-AD (London And the South East Region – Alzheimer’s Disease)” (page 5).

4. I am curious as to how this study would not require ethical review given the involvement of patients and caregivers completing assessments. Can you add a statement as to why it did not require ethical review?

Author’s reaction:
Our study investigates daily practice in care for community dwelling people with dementia. Most of the data are collected by interviewing the informal caregivers. The people with dementia spend only a small amount of time completing their assessment (15-20 minutes for 2 questionnaires). Therefore, the Dutch Medical Research Involving Human Subjects Act (WMO) does not apply to this study and no formal ethical scrutiny was required and undertaken. This is also stated in a letter from the local Medical ethics committee which is submitted along with the manuscript.
5. Quality of written English: Needs some language corrections before being published

**Author’s reaction:**

This study protocol was edited for proper English language, grammar, punctuation, spelling and overall style by two of the native English speaking editors at American Journal Experts.