Author’s response to reviews

Title: Belt restraint reduction in nursing homes: Design of a quasi-experimental study

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Author’s response to reviews: see over
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Dear editor,

We would like to thank you for considering our manuscript entitled “Belt restraint reduction in nursing homes: Design of a quasi-experimental study” for publication in BMC Geriatrics. Moreover, we would like to thank you for your useful comments, which have helped us to improve our manuscript. All revisions suggested have been addressed by alterations to the manuscript. We hereby re-submit the revised manuscript. A point-by-point response to your comments is set out below.

We hope that the current manuscript is acceptable for publication in BMC Geriatrics and we look forward to your final decision.

Yours sincerely, on behalf of the co-authors

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Author’s reply to Editor’s comments:

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For your information, the comments are presented in italics.
New or added text from the revised manuscript is presented as underlined citations.

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(1) Structure your abstract according to the following guidelines: This should not exceed 350 words and should be structured into separate sections headed Background, Methods/Design, Discussion (if appropriate). Please do not use abbreviations or references in the abstract. Trial Registration, if your study protocol is a protocol of a controlled health care intervention, please list the trial registry, along with the unique identifying number, e.g. Trial registration: Current Controlled Trials ISRCTN73824458. Please note that there should be no space between the letters and numbers of your trial registration number.

We structured the abstract according to your guidelines, not exceeding 350 words, using separate sections headed Background, Methods/Design, and Discussion. We placed the trial identification number NTR2140 from the Dutch Trialregister at the bottom of our abstract.

(2) Remove the trial registration number from the title of your manuscript and place this at the bottom of your abstract as mentioned above.

We removed the trial identification number NTR2140 from the title and placed it at the bottom of our abstract.
(3) Include a power calculation within your manuscript, used to determine the sample size of your study.

We have rewritten a few parts of the Design and Sample section of our manuscript and included a power calculation into the methods section.

**Design and sample**

Effects of EXBELT will be studied in a quasi-experimental longitudinal study design. Alongside the effect evaluation, a process evaluation will be carried out in order to further develop EXBELT. Figure 1 shows the design of the study presented. After contacting seven Dutch nursing home associations (networks of nursing homes) in order to assess whether they would be interested to participate in our study, four nursing home associations, located in three regions in the Netherlands (Zuid-Limburg, Midden Limburg/ Zuid-Oost Brabant en Zuid-Holland) contacted the EXBELT research group to participate in the current study. To participate, the prevalence of belt use on psychogeriatric nursing home wards had to be at least 10%. Wards are excluded if the unit is dedicated to residents with Korsakoff’s, if far-reaching reorganizations and/or constructional renovations will be implemented, and if participating in other studies and/or projects aimed at the reduction of restrain use. The total study sample comprises four nursing home associations, 13 nursing homes with a total of 26 psychogeriatric wards. The 26 wards were assigned to either the intervention or control group. Assignment to either to intervention or control groups was carried out by the research team. Since no randomization took place, allocation was based on avoidance of contamination bias. Overlap of nursing home staff between the intervention and control wards was averted. In addition, based on the geographical location of the participating wards, wards from each of the four nursing associations that were situated closely together were allocated to the same group. The wards allocated to the control group will receive care as usual, while the wards allocated to the intervention group will receive the EXBELT program.
**Sample size considerations**

Sample size calculations are based on the primary outcome measure for residents: proportion of residents using a belt. We expect a reduction of 50% in belt use in the intervention group and no changes in use in the control group. Based on a significance level $\alpha$ of 0.05 (two sided) and a power of 60%, 216 residents are needed in each group in the analyses. Taken into account an informed consent rate of 80% and a drop-out rate of 25%, 720 psychogeriatric nursing home residents have to be selected at the start of the study.