Author's response to reviews

Title: Passive movement therapy in patients with moderate to severe paratonia; study protocol of a randomised clinical trial (ISRCTN43069940)

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Author's response to reviews: see over
Dear Dr. Norton,

Please find enclosed our revised manuscript entitled *Passive movement therapy in patients with moderate to severe paratonia; study protocol of a randomised clinical trial (ISRCTN43069940)*, which we would like to submit for publication in BMC geriatrics.

We thank the reviewer for his insightful and valuable comments and we were able to meet most of them in this revised version. In this cover letter we will address subsequently the major compulsory revisions, language corrections and some minor changes.

As suggested by the reviewer we recalculated the sample size for this trial by using the observed proportion of natural decline of 10% (control group) and a decline of 30% (PMT group). With an alpha of 0.05 and a beta of 0.20 sample size is calculated at 62 participants per group. In our original protocol we proposed a drop out percentage of 25%, yet our pilot study and data from the first 22 participants indicate that the drop out percentage is less than 10%. Therefore, in our new sample-size calculation we propose a drop out percentage of 10% resulting in group sizes of 69 each.

We also adjusted our analytical strategy to accommodate the ordinal dependent variable, the modified Ashworth scale. At the end of page 8 and the beginning of page 9 this new strategy is clarified:

**Analysis**

*All data will be analysed with SPSS 15.0. The Modified Ashworth scale, an ordinal 5-point scale, will be measured at 3 times, at baseline (T0) after 2 weeks (T1) and after 4 weeks (T2). Our premise in this study is that PMT causes an accelerated worsening of paratonia over 4 weeks time. Success of the intervention is defined as a significant (p < 0.05) difference between the proportion of change on the modified Ashworth scale in the two groups. To determine any development or change over time of The Modified Ashworth score in the two groups the Stuart-Maxwell statistic will be used. The difference in proportion of change between the two groups will be calculated and tested for significance [20]. However controlling for relevant confounders e.g. age, sex, severity and type of dementia is not possible with this analysis. Therefore a multiple logistic regression analysis will be performed on the dichotomised outcome measure, “declined” and “stable/improved”, of the difference on T0 and T2 on The Modified Ashworth score. Missing data will be assumed to be missing at random. The Last Observation Carried Forward method will be used in those cases with no last measurement (T2) yet with valid data from the second assessment (T1). Analyses will be carried out according to the intention to treat principle.*


Consequently this has been changed in the abstract into: "Success of the intervention is defined as a significant increase of decline on the modified Ashworth scale. The 'proportion of change' in two and four weeks time on this scale will be analysed. Also a multiple logistic regression analysis using declined/not declined criteria as dependent variable with correction for relevant confounders (eg stage of dementia, medication, co-morbidity) will be used."

Next to some minor language changes we corrected the English language of several sentences.

On page 3, line 6 we changed: “Thus, negatively impacting on the quality of life and imposing practical difficulties for carers and nurses to wash and dress patients with paratonia.” Into: “Thus, paratonie has a negative impact on the quality of life and can result in problems with washing and dressing.”

Also on page 3, line 26 we changed: “The use of PMT in patients with paratonia is therefore controversial: they are not able to actively use regained mobility, often show signs of discomfort during the treatment and they are prone to injury” into: “Given the fact that these frail patients, who often show signs of discomfort during the treatment, are prone to injury and are not able to actively use regained mobility PMT is controversial.”

On page 5, line 2-3 we changed: “After computerised and concealed block randomisation (block size of four) patients are included in one of two groups.” Into: “Patients are included in one of two groups after computerised and concealed block randomisation (block size of four).”

On page 5, line 5-7 we changed: “Some of the participants have especially designed clothing that enables easier dressing of patients by the nurses while the patient is lying in bed or sitting in a wheelchair.” Into: “Some of the participants wear especially designed clothing that enables the nurses to dress patients more easy while the patient is lying in bed or sitting in a wheelchair.”

On page 6, line 3-12 we changed: “Severity of paratonia will be assessed by assessors blinded to treatment allocation, with the modified Ashworth scale, at baseline one day prior to treatment start, one day after treatment 6 (after 2 weeks) and one day after treatment 12 (after 4 weeks) between 8a.m. and 10a.m. before washing and dressing by nursing staff. The Modified Ashworth scale is the primary outcome measure.” Into: “The Modified Ashworth scale is the primary outcome measure and tested with an acceptable reliability to assess the severity of paratonia (intrarater reliability; Kendall’s Tb 0.62-0.80 and interrater reliability; Kendall’s Tb 0.72-0.77) [14]. It is a 5 point scale ranging from 0 to 4, in which 0 = no resistance to passive movement, 1= slight resistance during passive movement, 2= more marked resistance to passive movement, 3 = considerable resistance to passive movement, 4= severe resistance, passive movement is impossible. Severity of paratonia will be assessed by assessors blinded to treatment allocation at baseline one day prior to treatment start, one day after treatment 6 (after 2 weeks) and one day after treatment 12 (after 4 weeks) between 8a.m. and 10a.m. before washing and dressing by nursing staff.”

On page 9, line 11-15 we changed: “For this reason we designed this RCT in a very pragmatic way, close to daily practice with ethical aspects limiting the time frame within bounds of 4 weeks per participant and using assessment tools that are valid and reliable but above all with a minimal burden for the frail participants.” Into: "For this reason we designed this RCT in a very pragmatic way, close to daily practice bounded by ethical aspects limiting the time frame of 4 weeks per participant and using assessment tools that are valid and reliable but above all with a minimal burden for the frail participants."

Additionally we corrected one of the proposed protocols which had been changed in the time lapse between initial submission and revision. On page 4, line 26 as a part of the exclusion criteria the following sentence was in the original manuscript: “…….. patients who receive typical antipsychotics or high doses of a-typical antipsychotics (for Risperdone, max. dose of 4mg, Olanzapine, max dose of 10mg or Quetiapine, max dose of 100mg are accepted).” . This has been changed into all antipsychotics.

Yours sincerely,

Hans Hobbelen

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