Author's response to reviews

Title: The Maastricht Ultrasound Shoulder pain trial (MUST): Ultrasound imaging as a diagnostic triage tool to improve management of patients with non-chronic shoulder pain in primary care: study protocol (NTR2403)

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Author's response to reviews: see over
Dear doctor Shipley,

We would like to thank you for giving us the opportunity to revise our manuscript “The Maastricht Ultrasound Shoulder pain trial (MUST): Ultrasound imaging as a diagnostic triage tool to improve management of patients with non-chronic shoulder pain in primary care: study protocol (NTR2403)”. We want to thank the reviewer for his comments, which we have incorporated in the revised version of our paper. The changes are highlighted in the revised manuscript. Below we explain how we have addressed the comments.

We appreciate a further review by a statistician, yet we would like to stress that the remark of the current reviewer regarding the sample size calculation for the economic evaluation is not relevant. We are aware of the possibility of calculating a sample size based on not only the clinical endpoint (patient recovery), but also on costs. However, it is nowadays generally accepted that rules of inference are arbitrary and irrelevant to the resource allocation decisions which economic evaluations inform. Resource allocation decisions should be based only on the mean net benefits irrespective of whether differences are statistically significant. Also, we would like to emphasize that two of the authors are experts on this topic; B. Winkens is a statistician, and M. Joore is a health technology assessment expert.

In the Acknowledgement section we forgot to thank radiologist dr. Jong. Therefore we added his name.

On behalf of all authors I submit the revised manuscript for your consideration for publication.

We are looking forward to your response.

Yours sincerely,

Ramon P.G. Ottenheijm
Response to reviewers’ comments:

We would like to thank the reviewer for reviewing our paper and the helpful comments.

Comment:
In fact I don’t really see a significant difference between the choices of treatment in the intervention and control groups except that there will be (1) early referral to the orthopaedic surgeon for full-thickness tear in the intervention group, and (2) a 2 more weeks wait-and-see period in the control group for all cases.

Reply:
It is correct that the treatment options for the intervention and control group do not differ. However, the significant difference between the treatment regimes in the intervention and control groups is that patients in the intervention group receive tailored treatment according to their patho-anatomical disease state. This in contrast with patients in the control group, who are treated according to the Shoulder guideline of the Dutch College General Practitioners, and receive treatment based on complaints. In this cost-effectiveness study we compare diagnosis – treatment combinations, and not only treatments. It is our hypothesis that these tailored treatment regimes, applying evidence based treatment without delay, have a positive effect on patient recovery and costs. Moreover, the prevention of unnecessary interventions can contribute to this effect.

Revision:
As this is an important comment, we elaborate on this topic in an additional paragraph in the Discussion section (page 17).

Comment:
The author calculated the sample size needed to “to detect the difference of 20% (recovery rate) between the study groups after 52 weeks”. However, the definition of recovery rate was not clearly stated.

Reply:
Through this comment, we realize that the definition of recovery rate, which was defined in the paragraph entitled “Outcome assessment”, was placed after the paragraph entitled “Sample size”. The primary outcome will be patient-perceived recovery using the Global Perceived Effect questionnaire (GPE); a one-item score concerning recovery following treatment, measured on a seven-point ordinal scale. Patients are considered to be recovered when they report to be much improved or fully recovered.

Revision:
We changed the sequence of paragraphs into Design, Setting, Study population, Interventions, Randomisation and allocation, Outcome assessment, Sample size, and Data analysis. Additionally, the primary outcome (GPE), is added to the Sample size paragraph (page 14).
Comment:
The sample size calculation for the economic evaluation was not given in the protocol, which was an important endpoint for this study. This needs to be reviewed by a statistician.

Reply:
We are aware of the possibility of calculating a sample size based on not only the clinical endpoint (patient recovery) but also on costs. However, it is nowadays generally accepted that rules of inference are arbitrary and irrelevant to the resource allocation decisions which economic evaluations inform. Resource allocation decisions should be based only on the mean net benefits irrespective of whether differences are statistically significant (see: K. Claxton. J Health Econ. The irrelevance of inference: a decision-making approach to the stochastic evaluation of health care technologies.1999 Jun;18(3):341-64).

Comment:
Since the reading of musculoskeletal ultrasound is highly operator dependent, it is best that one single operator performs all the US examinations. If that is not possible, the author should describe the clinical experience of the radiologists in musculoskeletal ultrasound.

Reply:
We agree with the reviewer that the accuracy of musculoskeletal ultrasound is operator dependent. We discussed the advantages and disadvantages of single versus multiple operators. For two reasons we did not choose for a single operator. First, due to our design (the ultrasound has to be made within two weeks after patient inclusion, and the inclusion period runs for two years), the radiology departments were not able to guarantee a single operator. Second, a single operator would limit the external validity, as in The Netherlands it is common that within a radiology department, more radiologists are experienced in musculoskeletal ultrasound. Therefore, all ultrasounds in our study are only made by experienced radiologists in musculoskeletal ultrasound. For study purposes, these radiologists use a standardized protocol (Table 1), which was developed by the project group and radiology departments.

Revision:
We have revised the manuscript by adding the clinical experience in musculoskeletal ultrasound (page 10). Also, we added a paragraph on this topic to the Discussion section (page 17).