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)

Authors:

Ramon PG Ottenheijm (ramon.ottenheijm@hag.unimaas.nl)
Manuela A Joore (m.joore@mumc.nl)
Geert HIM Walenkamp (g.h.walenkamp@home.nl)
René E Weijers (r.weijers@mumc.nl)
Bjorn Winkens (bjorn.winkens@maastrichtuniversity.nl)
Jochen WL Cals (j.cals@maastrichtuniversity.nl)
Rob A de Bie (ra.debie@maastrichtuniversity.nl)
Geert-Jan Dinant (geertjan.dinant@maastrichtuniversity.nl)

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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”. We want to thank the reviewers for their comments.

Below we explain how we have addressed the comments. These comments did not require any changes in the document. Therefore, no revision has been submitted.

We are looking forward to your response.

Yours sincerely,

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

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

Reviewer 1

Comment:
I am satisfied with the revised protocol.

Reviewer 2

Minor essential revisions

Comment 1:
The sample size of 226 is the total of both study groups. I am assuming the randomization will be accomplished so group sample sizes are about equal (if not explain in methods).

Reply:
That is indeed the case. As outlined in the “Randomisation and allocation” paragraph on page 11, patients will be randomly assigned by central block randomization (blocks of 4) to the intervention or control group after stratification for age (≥ 50 years).

Revision:
No revision required.

Discretionary revisions

Comment 2:
I wonder if patients requiring shoulder surgery would be analyzed as a separate subgroup?

Reply:
We expect that only a small percentage of patients will undergo surgery. However, these patients might not be recovered after 1 year follow-up, and can be responsible for a large percentage of the total costs. If this seems to be the case, we will report this.

Comment 3:
If this makes sense, are there any plans to measure the contralateral shoulder (possible covariate data)

Reply:
Normally, no ultrasounds are made of the contralateral (asymptomatic) shoulder. As we are interested in this care as usual, we chose not to make these images.
Comment 4:
Would patients with a history of shoulder surgery be excluded (surgery could possibly have fewer options)? It seems the recruitment will be patients with a first life-time shoulder event (not sure).

Reply:
Yes indeed, patients with shoulder surgery are excluded and only patients with non-chronic shoulder pain are included (see paragraph “Study population” on page 9)

Reviewer 3

Minor essential revisions

Comment 1:
Data analysis: pp 15, 2nd para, 3rd sentence: what systems will be put in place to avoid study protocol violations as these are undesirable in a clinical trial?

Reply:
To avoid study protocol violations, all participating GPs are trained in an instruction workshop prior to start of the study (see paragraph “Setting” on page 9). Also, during the recruitment phase, all GPs will be visited on a regular base to discuss study progress.

Revision:
No revision required.