Reviewer's report

**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)

**Version:** 1  **Date:** 28 March 2011

**Reviewer:** Ching-Chuan Jiang

**Reviewer's report:**

The aim of paper is to describe the design and methods of a RCT assessing the cost-effectiveness of ultrasound imaging to improve management of primary care patients with non-chronic shoulder pain.

According to the study design, patients with SP were randomly assigned to the intervention or control group. Patients in the intervention group will receive tailored therapies based on the US results, while those in the control group will be treated following the DCGP guideline for SP.

There are some major concerns for the study design:

A 2-step tailored treatment will be applied to the patients in the intervention group. Step 1 treatment for patients with (1) tendinopathy and partial-thickness tear, (2) calcific tendinitis and subacromial-subdeltoid bursitis, and (3) full-thickness tear were: (1) physical therapy, (2) subacromial corticosteroid injection, and (3) referral to an orthopedic surgeon. In the meanwhile, the DCGP guideline for patient in the control group will be treated by a stepwise approach including a wait-and-see policy with advice and analgesia for another 2 weeks; in persisting cases corticosteroid injections and referral to a physiotherapist are advised, depending on the level of pain; referral to a hospital specialist is advised if conservative treatment fails. In fact I don’t really see a significant difference between the choices of treatment between the intervention and the control groups except that there will be (1) early referral to the orthopedic 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.

Another major concern is about the sample size calculation in this study. 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. Also, 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.

Since the reading of musculoskeletal US is highly operator dependent, it is best that one single operator performs all the US examination. If that is not possible, the authors should describe the clinical experience of the radiologists in musculoskeletal US.
**Level of interest:** An article of limited interest

**Quality of written English:** Acceptable

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**
I declare that I have no competing interests.