Response to: 'Correspondence on 'Non-surgical and surgical treatments for rotator cuff disease: a pragmatic randomised clinical trial with 2year follow-up after initial rehabilitation" by Randelli *et al* 

We warmly thank Randelli and coworkers for their interest in our work.<sup>1</sup> Our randomised, pragmatic, controlled trial compared surgical and non-surgical treatments for rotator cuff disease (RCD) with or without full-thickness tendon tears after unsuccessful initial rehabilitation.<sup>2</sup>

Randelli and coworkers commented that the power of our study lies in the fact that potential eligible patients underwent a systematic, adequately performed 3-month rehabilitation, after which only patients who remained symptomatic were randomised; we agree. Symptoms alleviated in 102 of the 417 shoulders with chronic RCD (mean duration of symptoms 9 months before recruitment) during the 3 month, pragmatic nonoperative treatment. This indicates that conservative management should be carried out in all patients with chronic RCD before considering surgical treatment for fullthickness rotator cuff tear.

Randelli and coworkers criticised us for not reporting baseline characteristics of the prespecified subgroups (RCD with and without full-thickness tendon rupture). They also noted that while 25% of shoulders were not treated per protocol, the number of those with a full-thickness rupture was unreported. Randelli and coworkers find interpreting our results based on the intentionto-treat principle difficult. We deliberately chose this approach for the following reasons. RCD and its surgical treatment are common.<sup>3 4</sup> Our primary aim was to answer a question frequently asked by many GPs, rheumatologists and orthopaedic surgeons: How should I treat a patient with RCD? At the time our trial was registered (2008), these two types of RCD were considered clinically different conditions by many physicians, although it is not possible to reliably distinguish these two forms of RCD by clinical examination. The initial nonsurgical treatment of RCD with or without a full-thickness lesion is largely identical. Due to stratification, the numbers of non-full-thickness and full-thickness lesions are equal. We applied the intention-to-treat principle in all primary analyses. We, therefore, consider it logical to report the baseline characteristics of the whole study population, one of which was the presence of full-thickness tendon lesion.

Randelli and coworkers emphasised that a longer follow-up is needed to further clarify the relative superiority of nonsurgical and surgical RCD treatments; we totally agree on this. Our 5-year follow-up results will be reported later.

Fine characterisation of tendon lesions and surgical techniques were called for. Due to our pragmatic approach, MRI arthrographies were performed using different MRI machines, hence the scanning protocols varied slightly. Thus, we did not aim to perform a detailed evaluation of rotator cuff tear sizes. We believe that the presence of a full-thickness tear (yes/no) and its operability (fatty infiltration, tendon retraction) are more important than tear size when considering treatment options in clinical practice. Furthermore, dividing tears into different (arbitrary) size groups would have reduced the power of the study. According to the previous literature, differences in outcome between open and arthroscopic rotator cuff procedures have not been demonstrated.<sup>5 6</sup> In our study, we observed no obvious difference. Also, the subgroups were too small for detailed analyses. Moreover, this was not a question registered in our trial protocol.

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## **Correspondence response**

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