PEDro scores were based on information in the paper

I would like to thank Kucera and Barna for their correspondence regarding our systematic review (Bleakley et al 2008). They provide clarification on aspects of the treatment intervention used in their high quality randomised controlled trial (RCT) (Kucera 2004), and challenge the PEDro scores that we attributed to the following items: allocation concealment, baseline comparability, and blinding.

Whilst it is possible to implement allocation concealment in every RCT (Schulz et al 1995), without detailed reporting we cannot assume that it is carried out successfully. Although Kucera et al (2004) state that subjects were provided with a randomisation number, there were no further details on the generation and implementation of the random allocation sequence (eg opaque sealed envelopes, or ‘third party’ assignment). Therefore, from the manuscript alone, we could not rule out the possibility of selection bias.

The fourth item on the PEDro scale assesses baseline comparability, and has the lowest inter-rater reliability (Maher et al 2003). Raters score this item based on the between-group comparability, using key prognostic indicators (in this case for ankle sprain recovery) measured prior to intervention. As a minimum, studies must include at least one measure of injury severity and one (different) key outcome. I appreciate that the rater's definition of 'comparable' may be open to subjectivity, and indeed may relate to his/her experience of the injury or condition (Maher et al 2003). Kucera's study showed clearly that there were no baseline differences in pain and function between the two intervention groups, however we did not feel that there was enough additional information on injury severity and prognostics.

The authors should be commended on the measures they employed to potentially certify participant blinding (ie by ensuring that the intervention medications used in their study were identical in appearance and composition).

However, aside from this, few other details were provided in this important area. Describing trials as 'single blind', 'double blind', or 'triple blind' can mean different things to different people, and when they are used without accompanying clarification readers should remain sceptical about the effect on bias reduction (Schulz et al 2002). Kucera and colleagues (2004) described their RCT as 'double blind'; however, from the manuscript alone, it is difficult to determine if this refers to participants, administrators, outcome assessors, or indeed the data analysts.

Assessing the methodological quality of RCTs is an important and challenging process when conducting a systematic review. We opted to use the PEDro scoring scale based on its acceptable inter-rater reliability (Maher et al 2003), and the discriminative and face validity of its 11 items. In conjunction with the CONSORT guidelines for RCT reporting (Begg et al 1996), the PEDro scale requires that studies provide adequate detail on the most important aspects of study methodology, with scoring based on standardised written criteria. In their correspondence, Kucera and Barna have clarified key details of the methods used in their interesting RCT (Kucera et al 2004), which further highlight the quality of the research. Notwithstanding this, the PEDro scores we attribute must be based on the original manuscript, and cannot be changed in light of this additional information.

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References