Additional file 2. Criteria used for judgments of GRADE.

Effect sizes were back-transformed from standard mean differences to the 100 mm visual analogue scale. Outcomes were rated down one level for limitations if greater than 25% of the participants included in the outcome came from studies considered to have a high risk of bias. Studies were rated down one level for inconsistency if there was significant heterogeneity (i.e. $I^2$ greater than 40%) [1]. Outcomes were rated down for indirectness if there were significant differences between the populations, interventions or outcomes measured across studies [2]. Outcomes were rated down for imprecision if the confidence intervals represented different conclusions and/or the total participants included for the outcome was less than 100. This sample size was calculated using the minimal important difference of 12 points on the 100 point Foot Health Status Questionnaire pain subscale,[3] and a standard deviation of 21 derived from previous research [4,5]. This provides 80% power to detect a moderate standard mean difference of 0.5 [6]. Publication bias was assessed using funnel plots for analyses with greater than 10 studies or if there was obvious industry involvement [1]. Outcomes for each comparison were classified into four categories: (i) high (we are very confident that the true effect lies close to the estimate of effect), (ii) moderate (we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect but there is a possibility that it is substantially different), (iii) low (our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of effect), and (iv) very low (we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect) [7].
References


