

The main analyses were conducted on an intention to treat basis including all sites in the groups they were assigned to at randomisation, using two-sided statistical tests at the 5% significance level. Analyses were conducted using STATA version 13. The minimisation factors, and trial outcomes are summarised descriptively overall and by trial arm. The site-level outcomes of time in days from first contact to: (i) submission of R&D application; (ii) receipt of R&D approval; (iii) final set up meeting prior to starting recruitment; and (iv) first randomised participant, were compared between the trial arms using a Cox proportional hazards model. Sites that withdrew their interest in the trial before reaching these events were right censored at their date of withdrawal. The minimisation factors used in the randomisation were not included in the model owing to the small number of observations. Group differences in the form of a hazard ratio (HR) are presented with a 95% confidence interval (CI) and p-value. Site-level recruitment outcomes were compared via Mann–Whitney U tests, due to their non-normal distributions. Return of hospital forms and participant questionnaires, and time to return, were analysed at the participant-level, using logistic and Cox regression as appropriate. The models adjusted for main trial allocation of the participant (surgical fixation or plaster cast) and questionnaire, and accounted for clustering by centre using robust standard errors (logistic) or a shared frailty (Cox). Time to return was censored at the date on which the data for this substudy was extracted (follow-up data collection for the main trial will continue until June 2017). Odds ratios (OR) and HRs are presented with a 95% CI and p-value.

To account for non-compliance with the allocated regimen, we repeated analyses on a per-protocol basis, removing those sites that crossed-over to the other allocation.