Appendix 1: Data checks and reliability

To ensure consistency, validation checks on the data will be carried out including checking for duplicate records, range checking of variables' values and validating potential outliers by comparing with CRFs and referring back to sites if necessary. Calculations and processes performed by a computer program will be checked by hand calculations (where possible) for a minimum of 5% of the available data or 20 patients randomly sampled. This will include whether data has been imported correctly. Clarification will be sought by the trial office in the case of discrepancies.

For each variable, missing value codes will be checked for consistency and the proportion of missing values per variable will be presented. Patterns of missing data will be explored.

The reliability of the PRWE will be checked through the methods described above with particular focus on the number of missing components that make up each subscale.

Appendix 2: Additional analysis

Two Bayesian reanalyses and one Bayesian trial redesign utilising the DRAFFT2 trial primary outcome data (Patient Reported Wrist Evaluation at 12 months) are planned.

1. Re-analysis of the trial data in a Bayesian framework using a non-informative prior.
2. Re-analysis of the trial data in a Bayesian framework using an informative prior for the K-wire arm (derived from the original DRAFFT study data).
3. Re-design of the trial. We will re-randomise (random draws from the trial data with replacement) using an unequal allocation ratio, more in the cast arm, with a reduced sample size. The informative prior for the K-wire arm will be used to re-analyse this data.

The results of these analyses will be interpreted independently and comparatively to the main analysis results. A Bayesian framework allows statements about the probability of one treatment being superior to the other, the two arms being clinically equivalent, and there being a clinically relevant difference. These probabilities will be quantified for each analysis. These exploratory Bayesian analyses may be reported separately to the main trial results.

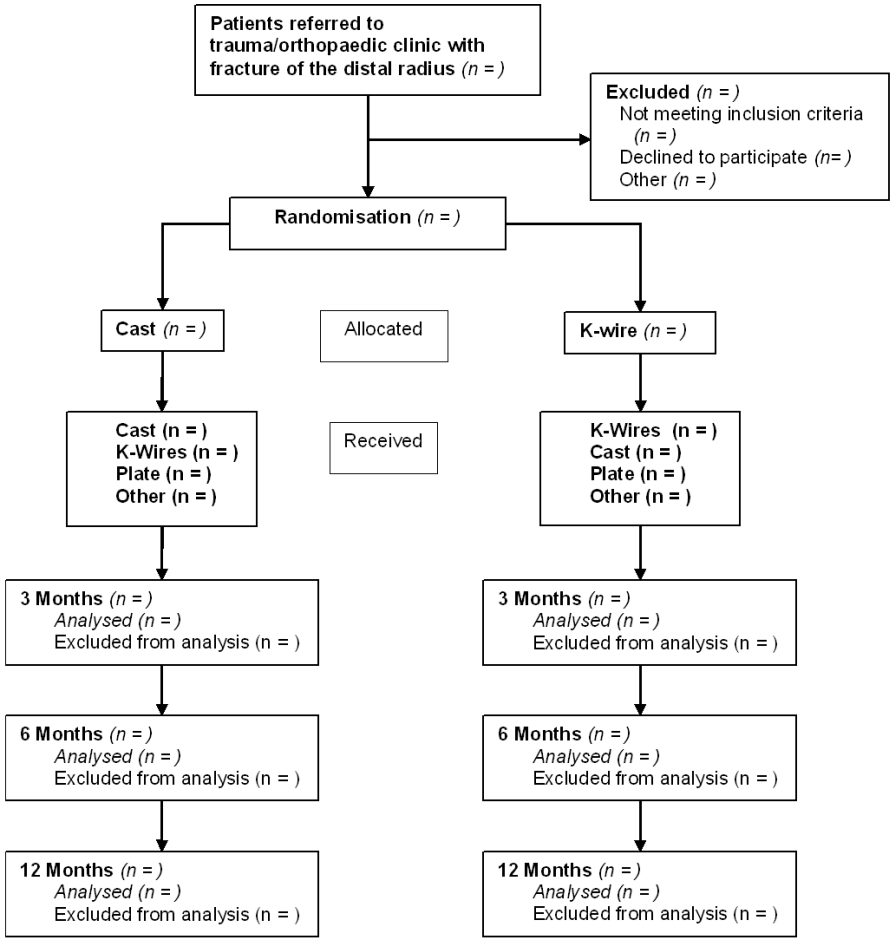

Fig. 1
CONSORT Diagram