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Health Technology Assessment

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This report

Abstract

Moulded cast compared with K-wire fixation after manipulation of an acute dorsally displaced distal radius fracture: the DRAFFT 2 RCT

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Background: Patients with a displaced fracture of the distal radius are frequently offered surgical fixation. Manipulation of the fracture and moulded plaster casting is an alternative treatment that avoids metal implants, but evidence of its effectiveness is lacking.

Objective: To compare functional outcomes, quality-of-life outcomes, complications and resource use among patients with a dorsally displaced fracture of the distal radius treated with manipulation and surgical fixation with Kirschner wires (K-wires) and those treated with manipulation and moulded cast.

Design: Pragmatic, superiority, multicentre, randomised controlled trial with a health economic evaluation.

Setting: A total of 36 orthopaedic trauma centres in the UK NHS.

Participants: Patients (aged ≥ 16 years) treated for an acute dorsally displaced fracture of the distal radius were potentially eligible. Patients were excluded if their injury had occurred > 2 weeks previously, if the fracture was open, if it extended > 3 cm from the radiocarpal joint or if it required open reduction, or if the participant was unable to complete questionnaires.

Interventions: Participants were randomly assigned in theatre (1 : 1) to receive a moulded cast (i.e. the cast group) or surgical fixation with K-wires (i.e. the K-wire group) after fracture manipulation.

Main outcome measures: The primary outcome measure was the Patient-Rated Wrist Evaluation score at 12 months, analysed on an intention-to-treat basis. Health-related quality of life was recorded using the EuroQol-5 Dimensions, five-level version, and resource use was recorded from a health and personal social care perspective.

Results: Between January 2017 and March 2019, 500 participants (mean age 60 years, 83% women) were randomly allocated to receive a moulded cast ($n = 255$) or surgical fixation with K-wire ($n = 245$) following a manipulation of their fracture. A total of 395 (80%) participants were included in the primary analysis at 12 months. There was no difference in the Patient-Rated Wrist Evaluation score at 1 year post randomisation [cast group: $n = 200$, mean score 21.2 (standard deviation 23.1); K-wire group: $n = 195$, mean score 20.7 (standard deviation 22.3); adjusted mean difference −0.34 (95% confidence interval −4.33 to 3.66); $p = 0.87$]. A total of 33 (13%) participants in the cast group required surgical fixation for loss of fracture position in the first 6 weeks, compared with one participant in the K-wire group (odds ratio 0.02, 95% confidence interval 0.001 to 0.10). The base-case cost-effectiveness analysis showed that manipulation and surgical fixation with K-wires had a higher mean cost than manipulation and a moulded cast, despite similar mean effectiveness. The use of K-wires is unlikely to be cost-effective, and sensitivity analyses found this result to be robust.

Limitations: Because the interventions were identifiable, neither patients nor clinicians could be blind to their treatment.

Conclusions: Surgical fixation with K-wires was not found to be superior to moulded casting following manipulation of a dorsally displaced fracture of the distal radius, as measured by Patient-Rated Wrist Evaluation score. However, one in eight participants treated in a moulded cast required surgery for loss of fracture reduction in the first 6 weeks. After a successful closed reduction, clinicians may consider a moulded cast as a safe and cost-effective alternative to surgical fixation with K-wires.

Future work: Further research should focus on optimal techniques for immobilisation and manipulation of this type of fracture, including optimal analgesia, and for rehabilitation of the patient after immobilisation.

Trial registration: This trial is registered as ISRCTN11980540 and UKCRN Portfolio 208830.

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Contents

CONTENTS

List of tables

List of figures

List of abbreviations

AUC	area under the curve	ITT	intention to treat
BNF	*British National Formulary*	K-wire	Kirschner wire
CI	confidence interval	MAR	missing at random
CONSORT	Consolidated Standards of Reporting Trials	NICE	National Institute for Health and Care Excellence
CRF	case report form	NIHR	National Institute for Health Research
CRPS	complex regional pain syndrome		
DRAFFT	Distal Radius Acute Fracture Fixation Trial	NMB	net monetary benefit
		PE	pulmonary embolism
DRAFFT 2	Distal Radius Acute Fracture Fixation Trial 2	PP	per protocol
		PRWE	Patient-Rated Wrist Evaluation
DSMC	Data Safety and Monitoring Committee	PSS	Personal Social Services
		PSSRU	Personal Social Services Research Unit
DVT	deep-vein thrombosis		
EQ-5D	EuroQol-5 Dimensions	QALY	quality-adjusted life-year
EQ-5D-3L	EuroQol-5 Dimensions, three-level version	QoL	quality of life
		RCT	randomised controlled trial
EQ-5D-5L	EuroQol-5 Dimensions, five-level version	SAE	serious adverse event
		SD	standard deviation
EQ-VAS	EuroQol visual analogue scale	SE	standard error
GBP	Great British pounds	SHEAP	statistical health economics analysis plan
HRQoL	health-related quality of life		
HTA	Health Technology Assessment	TMG	Trial Management Group
ICER	incremental cost-effectiveness ratio	VAS	visual analogue scale

Plain English summary

Many patients with a wrist fracture can be treated with a simple cast or splint. However, if the broken bones have moved out of position, patients are frequently offered a manipulation of the fracture to restore the position of the broken bones. The bones may then be held in place with metal implants while they heal. A moulded plaster cast, shaped to support the bones, is an alternative treatment that avoids metal implants, but there is little research to suggest which treatment is better.

The Distal Radius Acute Fracture Fixation Trial 2 (DRAFFT 2) study compared surgical fixation with metal wires with a moulded cast for patients with a broken wrist. Half of the patients underwent surgical fixation and half were given the moulded cast. The decision about which treatment patients were given was made by chance using a computer to ensure a fair comparison. The patients in both groups described their own wrist function and quality of life in the first year after their treatment and these descriptions were compared.

A total of 500 patients took part at 36 NHS hospitals in the UK. The patients treated with a moulded cast reported very similar wrist function and quality of life to that of the patients treated with surgical fixation. However, one in eight patients treated with the moulded cast later required surgery because their broken bones had fallen back out of position.

This study showed that a moulded cast is as good as, but costs less than, surgical fixation for patients with a broken wrist in terms of wrist function. However, a small proportion of the patients treated with a moulded cast may require later surgery if the broken bones cannot be held in position by the cast alone.

Scientific summary

Background

Patients with a displaced fracture of the distal radius are frequently offered surgical fixation following a manipulation of their fracture. A moulded plaster cast is an alternative treatment that avoids metal implants, but evidence of its effectiveness is lacking.

Objectives

The primary objective of this randomised controlled trial was to compare the Patient-Rated Wrist Evaluation score in the 12 months following randomisation among patients with a dorsally displaced fracture of the distal radius who were treated with manipulation and surgical fixation with Kirschner wires (K-wires) and those treated with manipulation and a moulded cast

The secondary objectives were to compare quality-of-life outcomes, complications, resource use and cost-effectiveness between the treatments in the first 12 months after randomisation.

Methods

All adult patients presenting at the recruitment centres with an acute dorsally displaced fracture of the distal radius who would benefit from manipulation were potentially eligible to take part in the trial. These broad eligibility criteria ensure that the results of the study can be readily generalised to the wider patient population.

Prior to the manipulation, a member of the local research team collected baseline demographic information. The participants were asked to complete a questionnaire to ascertain both their current (injured) and their typical (pre-injury) status.

A randomisation sequence, stratified by recruitment centre, intra-articular extension of the fracture and age of the participant (aged < 50 or ≥ 50 years), was produced and administered independently. Each participant had their fracture manipulated in the operating theatre and was then randomly allocated to either 'manipulation and surgical fixation with K-wires' (the K-wire group) or 'manipulation and moulded casting' (the cast group). Both of these interventions are widely used in the NHS and all of the surgeons were familiar with both techniques. Post manipulation, each participant was issued with standardised written rehabilitation instructions.

Outcome

The primary outcome measure for this study was the Patient-Rated Wrist Evaluation. The Patient-Rated Wrist Evaluation is a 15-item questionnaire designed specifically for assessment of distal radial fractures and wrist injuries and comprises a range of questions in two (equally weighted) sections concerning the patient's experience of pain and function. All questions are scored on an 11-point, ordered, categorical scale ranging from 'no pain' or 'no difficulty' (0) to 'worst ever pain' or 'unable to do' (10). Five questions relate to the patient's experience of pain and 10 questions relate to function and disability; scores for the 10 function items are summed and divided by 2 and added to the total score for the five pain items to give a score out of 100 (best score = 0 and worst score = 100).

Health-related quality of life was recorded using the EuroQol-5 Dimensions, five-level version, and resource use was recorded from a health and personal social care perspective. A within-trial cost–utility analysis was computed from an NHS and Personal Social Services perspective.

A member of the local research team performed a clinical assessment and made a record of any early complications at 6 weeks, including the need for any further surgery. Outcome data were collected by the central research team using the Patient-Rated Wrist Evaluation and EuroQol-5 Dimensions, five-level version, at 3, 6 and 12 months post randomisation. These questionnaires were administered centrally. The participants were also asked to complete a health-care resource use questionnaire and to provide details of any complications or interventions related to their injury.

Results

Between January 2017 and March 2019, 500 participants (mean age 60 years, 83% women) were randomly allocated to the cast group ($n = 255$) or the K-wire group ($n = 245$) after a closed fracture manipulation. A total of 395 participants (80%) were included in the primary analysis at 12 months.

Patients' wrist function improved in the year following randomisation as measured by the Patient-Rated Wrist Evaluation score, but there was no evidence of a difference between the two treatments at 12 months [cast group: $n = 200$, mean score 21.2 (standard deviation 23.1); K-wire group: $n = 195$, mean score 20.7 (standard deviation 22.3); adjusted mean difference –0.34 (95% confidence interval –4.33 to 3.66); $p = 0.87$]. Nor was there evidence of a difference in Patient-Rated Wrist Evaluation scores at 3 or 6 months post randomisation.

Health-related quality of life, measured by the EuroQol-5 Dimensions, five-level version, also showed an improvement over time from injury until 12 months post randomisation, but there was no difference between the treatments at any time point, with a 12-month adjusted mean difference of –0.03 (95% confidence interval –0.07 to 0.02). Thirty-three participants (12.94%) in the cast group required surgery for loss of fracture reduction in the first 6 weeks post randomisation, compared with one participant (0.41%) in the K-wire group (odds ratio 0.02, 95% confidence interval 0.001 to 0.10; $p < 0.001$). The base-case cost-effectiveness analysis showed that surgical fixation with K-wires was dominated, in that it provided similar outcomes for slightly higher costs. The use of K-wires is unlikely to be cost-effective, and sensitivity analyses found this result to be robust.

Conclusions

Surgical fixation with K-wires was not found to be superior to moulded casting, as measured by Patient-Rated Wrist Evaluation score following manipulation of a dorsally displaced fracture of the distal radius. However, one in eight patients treated with the moulded cast later required surgery for loss of fracture reduction in the first 6 weeks post randomisation. If a closed reduction of the fracture can be achieved, clinicians may consider the application of a moulded cast as a safe and cost-effective alternative to surgical fixation with K-wires.

Trial registration

This trial is registered as ISRCTN11980540 and UKCRN Portfolio 208830.

Funding

Chapter 1 Introduction

Background

Fractures of the distal radius are extremely common injuries. In the developed world, 6% of women will have sustained such a fracture by the age of 80 years and 9% will have done so by the age of 90 years.[1] As the population continues to age, these figures are likely to increase. There is a bimodal distribution in terms of age. Younger patients frequently sustain complicated, high-energy injuries involving the wrist joint; however, fractures of the distal radius are also common in older patients, who are more likely to sustain low-energy fractures related to osteoporosis.[2] The optimal management of fractures of the distal radius in adults remains controversial. This study was designed to address both groups of patients, as the key management decisions pertain to all patients with a fracture of the distal radius.

In general, if the bone fragments are undisplaced, that is the bone fragments remain in anatomical alignment, fractures of the distal radius are treated non-operatively. However, if the bone fragments have moved out of their normal alignment, the treating clinician will usually recommend a 'manipulation' of the bone fragments to restore the normal anatomy. Manipulating a fracture is painful and, therefore, is carried out using local, regional or general anaesthetic.

Following the manipulation, the bone fragments can fall back out of normal alignment. Therefore, the treating clinician will apply support to the bone fragments while they heal.

This trial compared two techniques for holding the position of the bone fragments following a manipulation of a dorsally displaced fracture of the distal radius: a moulded cast and surgical fixation with Kirschner wires (K-wires).

Relevance of project

Handoll and Madhok[3] summarised the results of a series of Cochrane reviews of randomised controlled trials (RCTs) of the treatment of fractures of the distal radius and 'exposed the serious deficiency in the available evidence'. Furthermore, they were able to identify key areas for future research, including 'when and what type of surgery is indicated'.[3] In 2014, we published the results of the Distal Radius Acute Fracture Fixation Trial (DRAFFT) [National Institute for Health Research (NIHR) Health Technology Assessment 08/116/97[4]].[5] In that study, we randomly assigned 461 adult patients undergoing surgery for a dorsally displaced fracture of the distal radius to either a K-wire fixation group or a locking plate fixation group. Contrary to the existing literature, and against the increasing use of plate fixation, the DRAFFT study found that, if a closed reduction of the fracture is possible, then there is no difference in outcomes between the use of K-wires and locking plates for patients with fractures of the distal radius. K-wire fixation is less expensive and quicker to perform than locking plate fixation. This evidence led to a change in clinical practice in the UK[6] and changes to national guidelines on the management of this injury.[7]

However, there remained unanswered questions, specifically 'Is there any need to perform surgical fixation of the fracture following a closed reduction of the distal radius, or is a simple cast as effective as the insertion of metalwork?'.

In 2020, Karantana et al.[8] published the results of a Cochrane review of percutaneous wire fixation compared with plater cast use for adult patients with a dorsally displaced fracture of the distal radius. This review included a total of 11 randomised or quasi-randomised trials of manipulation and plaster

cast compared with manipulation and K-wire fixation, involving 917, mostly older, participants. Unfortunately, the authors concluded that the quality of the existing evidence was very low. All of the trials included in the review were found to be at a high risk of bias, and allocation concealment was considered adequate in only one trial. Furthermore, all trials reported outcomes incompletely, to the extent that the authors were unable to draw a conclusion with regard to the effect of the interventions on patient-reported function.[8] They did, however, find that the risk of re-displacement of the fracture in participants treated with manipulation and plaster cast was, on average, 12%, (range 3–75%). A review of the published literature[8] found no other trials addressing this question since the date of this Cochrane review search (in June 2019).

We conducted a RCT of manipulation and surgical fixation with K-wires compared with manipulation and moulded casting in the treatment of adult patients with a dorsally displaced fracture of the distal radius.

Objectives

The aim of this trial was to improve wrist function and reduce pain by determining the best treatment strategy for adult patients undergoing manipulation for a dorsally displaced fracture of the distal radius.

The primary objective was to quantify and draw inferences on observed differences in the Patient-Rated Wrist Evaluation (PRWE),[9] a validated assessment of wrist function and pain, between manipulation and surgical fixation with K-wires and manipulation followed by a moulded cast in the first year post randomisation.

The secondary objectives were to:

1. quantify and draw inferences on differences in the EuroQol-5 Dimensions, five-level version (EQ-5D-5L) [a validated assessment of health-related quality of life (HRQoL)], between surgical fixation with K-wires and moulded casting over the first year post randomisation
2. determine the complication rate, including the need for further surgery, between surgical fixation with K-wires and moulded casting during the first year post randomisation
3. investigate, using appropriate statistical and economic analysis methods, the health-care resource use and comparative cost-effectiveness of surgical fixation with K-wires and moulded casting in the first year post randomisation.

Chapter 2 Methods

The final protocol for this trial has been published and some of the content has been reproduced in this monograph.[10] Copyright © Author(s) (or their employer(s)) 2019. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by *BMJ*. This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: https://creativecommons.org/licenses/by-nc/4.0/. The text below includes minor additions and formatting changes to the original text.

See *Appendix 3*, *Table 24*, for a summary of the changes implemented with each protocol version followed during the conduct of the trial.

Trial design

The project was designed as a two-phase study. An internal pilot was to be conducted to confirm the expected rate of recruitment in a large-scale multicentre RCT. The main RCT was planned for a minimum of 24 trauma centres.

Internal pilot summary

The pilot took place at five centres over a period of 6 months. The aim of this initial phase was to determine the number of eligible and recruited patients in a small number of representative recruitment centres over 6 months.

Recruitment during the pilot phase was successful and, therefore, the project continued to the main trial without pause. Participants from the internal pilot were included in the final analysis.

Main randomised controlled trial summary

All adult patients presenting at the recruitment centres with an acute dorsally displaced fracture of the distal radius suitable for manipulation were potentially eligible to take part in the trial. The broad eligibility criteria ensured that the results of the study can be readily generalised to the wider patient population.

Prior to the manipulation, a member of the local research team, for example the research associate, collected baseline demographic data, radiographs and functional data using the PRWE and collected HRQoL data using the EQ-5D-5L. Participants were asked to complete a HRQoL questionnaire to ascertain both their current (injured) and typical (pre-injury) status.

A computer-generated randomisation sequence, stratified by recruitment centre, intra-articular extension of the fracture and age of the participant (aged < 50 or ≥ 50 years), was prepared, with the allocation provided through a secure, centralised, web-based randomisation service by the Oxford Clinical Trials Research Unit. Each participant was randomly allocated to either 'manipulation and surgical fixation with K-wires' (the K-wire group) or 'manipulation and moulded casting' (the cast group). Both of these treatments are widely used in the NHS, and all of the surgeons were familiar with both techniques. Post treatment, each participant was issued with standardised written rehabilitation instructions.

A member of the local research team performed a clinical assessment and made a record of any early complications at 6 weeks. Routine radiographs were also collected at the 6-week post-randomisation review. Functional outcome data were collected by the central trial team using the PRWE and EQ-5D-5L questionnaires at 3, 6 and 12 months post randomisation. These questionnaires were administered centrally.

The participants were also asked to fill out a health-care resource use questionnaire and provide details of any late complications or interventions related to their injury.

Participants

Patients were screened in the emergency department or trauma unit of participating trial recruitment centres. Screening logs were kept at each recruitment centre to determine the number of patients assessed for eligibility and reasons for any exclusion. In addition, the number of eligible and recruited patients and the number of patients who declined consent/withdrew were recorded.

Inclusion criteria
Patients were eligible for Distal Radius Acute Fracture Fixation Trial 2 (DRAFFT 2) if:

- they had sustained a dorsally displaced fracture of the distal radius, which was defined as a fracture within 3 cm of the radiocarpal joint
- they were over the age of 16 years and able to give informed consent
- the treating consultant surgeon believed that they would benefit from manipulation of the fracture.

Exclusion criteria
Patients were excluded from participation in DRAFFT 2 if:

- the injury was more than 2 weeks old
- the fracture extended > 3 cm from the radiocarpal joint
- the fracture was open with a Gustilo grading > 1°
- the articular surface of the fracture (specifically the radiocarpal joint) could not be reduced by indirect techniques (in a minority of fractures, the joint surface is so badly disrupted that the surgeon has to open up the fracture to restore the anatomy)
- there was evidence, such as cognitive impairment, that the patient would be unable to adhere to trial procedures or complete questionnaires.

Patients who sustained injuries to areas of the body other than the wrist that might have affected the primary outcome measure were still included in the analysis. Information with regard to additional injuries was recorded at baseline, and analysis was adjusted when necessary.

Consent
Recruitment took place in 36 NHS trusts in the UK that treat patients with distal radius fractures. Eligible patients were identified by the clinical team. A member of the local research team presented the eligible patient with the participant information sheet and provided them with a verbal explanation of the trial procedures. The patients were then given the opportunity to discuss any issues related to the trial with the local research and clinical team, as well as members of their family and friends. In general, patients who are admitted with a fracture of the distal radius have their treatment on the following day(s), so there was sufficient time for the patients to consider taking part in the trial.

Decline consent and withdrawals
Patients were able to decline to take part in the trial without prejudice. Participants could withdraw from the trial at any point. A decision to decline consent or withdraw did not affect the standard of care the patient received. Once withdrawn, the patient was advised to discuss their further care plan with their surgeon. On withdrawal of the patient, any data collected up until the time of withdrawal were retained by the research team and included in the final analysis.

Randomisation

Those patients who consented to take part in the trial had their treatment allocated using a secure, centralised, online randomisation service. The randomisation occurred after the manipulation of the fracture, when the surgeon had determined that the fracture could be adequately reduced without the need to open the fracture.

Although the great majority of these injuries were managed on planned trauma operating lists during normal working hours, the randomisation service was open 24 hours each day to facilitate the inclusion of all potentially eligible patients. Randomisation was on a 1 : 1 basis, stratified by recruitment centre, intra-articular extension of the fracture and age of the patient (< 50 or ≥ 50 years). The sequence was generated by the trial statistician based at the Centre for Statistics in Medicine in Oxford.

Stratification by recruitment centre helped to ensure that any clustering effect related to the recruitment centre itself was equally distributed in the trial treatments. Although it was possible that the surgeons at one recruitment centre were more experienced in one or other treatment than those at another centre, all of the recruiting hospitals, and indeed all hospitals throughout the NHS, use both techniques as part of their normal practice so staff and surgeons were already familiar with both forms of treatment. Although this may not eliminate any individual surgeon-specific effect at any one recruitment centre,[11] the manipulation of a fracture of the distal radius is a common procedure, so at each recruitment centre many surgeons were involved in the management of this group of patients (between 10 and 30 surgeons, including both consultants and trainees). Therefore, it was anticipated that each surgeon would operate on only a small number of patients enrolled in the trial, thus greatly reducing the risk of surgeon-specific influences affecting the outcome.

Stratification on the basis of intra-articular extension of the fracture addressed a major potential confounder, as disruption of this articular surface of the distal radiocarpal joint may predispose a patient to secondary osteoarthritis of the wrist.[12]

Evidence suggests that other associated features of fractures of the distal radius that commonly appear in the classification systems, such as involvement of the ulnar styloid process, do not actually affect the functional outcome of the injury.[13] Therefore, no other fracture variables were included in the stratification of the randomisation.

Stratification on the basis of age was used in an attempt to discriminate between younger patients with normal bone quality sustaining high-energy fractures and older patients with low-energy (fragility) fractures related to osteoporosis. Empirically, both of these groups of patients could benefit, or not, from surgical fixation. However, stratification by age could also help to identify any effect related to the quality of the patients' bone. The use of dual-energy X-ray absorptiometry is widely regarded as the gold standard for the assessment of bone density. However, this investigation was not routinely available at all recruitment centres. Therefore, we used age as a surrogate for bone density. In a large study in Norway involving 7600 participants,[14] it was demonstrated that forearm bone mineral density remains stable up until the age of 50 years. In males, bone mineral density decreases steadily after the age of 50 years, whereas in females there is an initial rapid decline between the ages of 50 and 65 years, with a further decline thereafter.[14] A study by Court-Brown et al.[15] assessed > 1000 patients with a fracture of the distal radius. The study found a clear bimodal distribution according to the age of the patient. The crossover of the two peaks of incidence was around 50 years of age. These studies provide strong evidence that patients aged > 50 years are increasingly vulnerable to fragility fractures of the distal radius. Furthermore, the study by Court-Brown et al.[15] demonstrated that in the UK approximately 60% of patients sustaining a fracture of the distal radius are aged > 50 years, whereas 40% are aged < 50 years. Therefore, we chose age under or over 50 years as the stratification criterion for this trial.

Blinding

Participants could not be blinded to their treatment allocation because the wires had to be removed, usually in the outpatient clinic at the 6-week follow-up appointment. Nor could the treating surgeons be blind to the surgical/non-surgical treatment that they were providing; however, the treating clinical team did not take part in the postoperative assessment of the patients. The central administrative team was not blind to the treatment allocation; however, the outcome data were provided independently by the participants via questionnaires.

Trial treatments

All participants underwent a closed (i.e. without making any incisions in the skin) manipulation of the fracture. The manipulation was carried out in an operating theatre under either regional or general anaesthetic. The choice of anaesthetic was left to the discretion of the treating surgeon/anaesthetist, as per their normal practice. An X-ray image intensifier machine allowed the surgeon to judge that an adequate closed reduction had been achieved during the manipulation. The decision to accept or not the reduction was left to the discretion of the treating surgeon, as per their normal practice. Only after this decision was made was the participant randomised to one treatment or the other. This trial compared two techniques for holding the position of the bone fragments following the manipulation of a dorsally displaced fracture of the distal radius.

Moulded cast

This technique involves the application of a cast that is shaped (moulded) over the skin to hold the bone fragments in position. This technique is simple and quick to perform, there is little risk of complications and the materials used are cheap. However, the cast is not applied directly to the bone fragments and, therefore, it is possible for the bone fragments to re-displace under the cast, particularly when the swelling starts to settle a few days after the surgery. The principles of applying a moulded cast are inherent in the technique, but in this pragmatic trial the type of casting material, the extent of the cast and the details of the moulding technique were left to the discretion of the treating surgeon, as per their usual technique. Relevant information about the initial technique used and any subsequent interventions, such as cast replacement or removal, was recorded.

Surgical fixation with wires

After the skin has been covered in antiseptic, sharp wires are passed through the skin over the back of the wrist and directly into the bone to hold the bone fragments in the correct position. The principles of K-wire fixation are also inherent in the technique, although there are several different options for the positioning of wires. The size and number of wires, the insertion technique and the configuration of wires were left to the discretion of the surgeon, as per their normal practice. A neutralising cast is applied at the end of the procedure, as per standard surgical practice, but this does not need to be specifically moulded as the wires themselves hold the bone in position. Relevant information on the initial technique used and any subsequent interventions, such as metalwork removal and cast replacement, was recorded.

Rehabilitation

All patients randomised, regardless of group, received the same standardised, written physiotherapy advice detailing the exercises that they needed to perform for rehabilitation following their injury. The written information was developed and tested by experienced physiotherapists/hand therapists as part of the original DRAFFT trial.[4] All patients in both groups were advised to move their shoulder, elbow and finger joints fully within the limits of their comfort. Participants were asked during the 3-, 6- and 12-month follow-ups to say if they had undergone any other investigations/interventions, including any hand therapy.

Participant care pathway

Participants were clinically reviewed at around 6 weeks, as per routine practice after this type of injury. The decision on whether or not to record details of additional rehabilitation and follow-up appointments was left to the discretion of the treating clinicians, as per their normal practice.

Primary outcome

The primary outcome measure for this study was the PRWE at 12 months post randomisation. The PRWE is a 15-item questionnaire designed specifically for the assessment of distal radial fractures and wrist injuries and comprises range of questions in two (equally weighted) sections concerning the patient's experience of pain and function. All questions are scored on an 11-point, ordered, categorical scale ranging from 'no pain' or 'no difficulty' (0) to 'worst ever pain' or 'unable to do' (10). Five questions relate to a patient's experience of pain and 10 questions relate to function and disability; scores for the 10 function items are summed and divided by 2 and added to the total score for the five pain items to give a score out of 100 (best score = 0 and worst score = 100). The PRWE was administered at baseline (at which point wrist function both pre and immediately post injury was assessed) and then again 3, 6 and 12 months post randomisation. *Table 1* shows the collection times for all of the trial outcomes. The PRWE is the most sensitive outcome measure available for patients sustaining this specific injury.[16]

Secondary outcomes

The secondary outcome measures in this trial were as follows.

Patient-Rated Wrist Evaluation score and general health-related quality of life
The PRWE score at 3 and 6 months was one secondary outcome measure, as was the area under the PRWE curve using data from all time points over the first 12 months post randomisation.

Health-related quality of life at 3, 6 and 12 months was measured using the EuroQol-5 Dimensions (EQ-5D) at 3, 6 and 12 months, and area under the curve (AUC) over the first 12 months post randomisation using all time points. The EQ-5D-5L is a validated, generalised, HRQoL questionnaire consisting of two parts. The first part, the EQ-5D-5L index, includes five domains related to daily activities, each domain being rated on a five-level scale,[17] with answers converted into multiattribute utility score.[18] This conversion was carried out, in accordance with the recommendation of the

TABLE 1 Collection time for each of the trial outcomes

Outcome measure	Time point							
	Pre injury[a]	Post injury[b]	Pre reduction	Post reduction	6 weeks	3 months	6 months	12 months
Wrist function and pain (PRWE)	✗	✗				✗	✗	✗
HRQoL (EQ-5D-5L)	✗	✗				✗	✗	✗
Radiographs			✗	✗	✗			
Resource use						✗	✗	✗
Complications (including further treatment)						✗	✗	✗

a Retrospectively.
b Before treatment.

UK National Institute for Health and Care Excellence (NICE), at the time of finalising the statistical health economics analysis plan (SHEAP).[19] The second part, the EuroQol visual analogue scale (EQ-VAS), is measure of health on a scale of 0 to 100, from the worst (0) to best health imaginable (100).

The EQ-5D-5L index ranges from –0.285 to 1, with the EQ-5D-5L crosswalk ranging from –0.594 to 1, with higher scores indicating better quality of life (QoL) and 0 being equivalent to death. EQ-VAS scores range from 0 to 100, with higher scores indicating better QoL.

Complications over the 12 months post randomisation

Further secondary outcome measures were the complications recorded included infection; damage to nerves, tendons or blood vessels; and further surgical interventions for loss of reduction/malunion after the index procedure.

Imaging outcomes

An assessment of the quality of the reduction, and the risk of subsequent loss of reduction, was made using the criteria set out by Costa et al.[4] Standard posterior–anterior and lateral radiographs were taken at baseline (pre and post reduction using the routine intraoperative fluoroscopic images from the operating theatre) and at the routine follow-up appointment 6 weeks post randomisation. These radiographs are those used for the investigation of patients with a suspected fracture of the distal radius and for the follow-up of such patients following any intervention, so there was no need to request any additional or special investigations.

Health-care resource use

Health-care resource use was monitored for the economic analysis. Unit cost data were obtained from the latest available national databases, such as the *NHS Supply Chain Catalogue,*[20] NHS Reference Cost,[21] *NHS Electronic Drug Tariff,*[22] *British National Formulary* (BNF)[23] and Personal Social Services Research Unit (PSSRU) *Unit Costs of Health and Social Care 2019.*[24] The unit cost was estimated using local sources if the unit cost could not be obtained from the national databases. The costs incurred following discharge, including NHS costs and patients' out-of-pocket expenses, were recorded in a short questionnaire that was completed by participants at 3, 6 and 12 months post randomisation. Patient self-reported information on service use has been shown to be accurate in terms of the intensity of use of different services.[25]

Data management: questionnaire completion

Patient-reported outcome data for the 3-, 6- and 12-month outcome points were collected through a questionnaire sent from the trial central office. Those participants who had provided their mobile telephone number and/or e-mail address to the research team received a text message and/or e-mail prior to the first post-out to advise them that they should expect the questionnaire. Reminder text messages and/or e-mails were sent to participants who did not return the questionnaire in a prespecified time frame. Participants who failed to respond to the questionnaire after two attempts were contacted by telephone to minimise the loss of follow-up information.

Participants were offered the option of receiving a £10 gift voucher with their 12-month questionnaire to compensate them for their time.

Adverse event management

Adverse events were listed on the appropriate case report form (CRF) for routine return to the 'DRAFFT 2' central office. Serious adverse events (SAEs) were entered onto the SAE reporting form and reported to the central study team. However, some adverse events that were foreseeable as part

of the proposed treatment were not reported on a SAE reporting form and were instead recorded on a complication form. These events included complications of anaesthesia or surgery (e.g. wound infection or damage to nerves, tendons or blood vessels), complex regional pain syndrome (CRPS), deep-vein thrombosis (DVT)/pulmonary embolism (PE) and further planned surgery for the removal of symptomatic metalwork or for the loss of fracture position/malunion. All participants experiencing SAEs were followed up as per protocol until the end of the trial.

Statistical analysis

Sample size

The DRAFFT trial,[4] which included the same patient population of patients with a fracture of the distal radius, estimated that the standard deviation (SD) of the PRWE score at 12 months post randomisation was 16 points. However, other studies of patients with a fracture of the distal radius have reported SDs for PRWE score in the range of 16–23 points.[26] Therefore, we chose a conservative estimate for the SD of 18 points. The DRAFFT results also showed an approximate normal distribution of PRWE scores at 12 months post randomisation.[5] A 6-point mean difference between groups equates to a standardised effect size of 0.33 for an assumed SD of 18 points. MacDermid et al.[16] found that the PRWE is sensitive enough to detect subtle but clinically relevant changes in wrist function of this order of magnitude in patients sustaining a fracture of the distal radius. A mean difference in PRWE scores of 6 points is slightly higher than the difference in scores that would result if all the participants in one group reported a response to any of the PRWE's constituent questions (e.g. one point less difficulty in turning a doorknob) just one point better than the other group (each point in response contributes 5 points to the overall score). We believed the target difference (i.e. 6 points) would be important to patients on both an individual and a population level and could lead to a change in clinical practice in the UK. The total number of participants required to obtain a statistical power of 90% at the two-sided 5% significance level to detect a 6-point difference between groups for the primary outcome measure was 382, that is 191 participants were required in each treatment group. Making a conservative allowance of 20% for patients 'lost to follow-up', we planned to recruit a minimum of 476 patients.

Analysis plan

Statistical significance and multiple testing

There is no multiple testing as only a single primary outcome was considered. Therefore, the significance levels used is two-sided 5%, and 95% confidence intervals (CIs) are reported.

Definition of analysis populations

Populations for analysis were defined as follows.

Intention to treat

In the intention-to treat (ITT) analysis, all available randomised participants were analysed in the groups to which they were randomly allocated. All participants with observed data at any time point were included in the analysis.

Per protocol

The per-protocol (PP) analysis included only eligible participants who received the treatment to which they were randomised and for whom data on the primary outcome were available at 12 months post randomisation. Participants who crossed over, had other types of surgery (e.g. plate fixation), did not have surgery or were randomised in error were not included in this population.

Withdrawal from treatment and/or follow-up

Some data were missing because of participant voluntary withdrawal, lack of completion of individual data items or general loss to follow-up. When possible, the reasons for missing data were ascertained and are reported.

Withdrawals/losses to follow-up together with reasons were reported by treatment, and any deaths (and their causes) were reported separately.

Baseline comparability of randomised groups

Baseline characteristics are reported by treatment group, including the stratification/minimisation factors, when applicable, and important prognostic, demographic and clinical covariates.

Numbers (with percentages) for binary and categorical variables and means (with SDs) or medians (with lower and upper quartiles) for continuous variables are presented; no tests of statistical significance or CIs for differences between randomised groups on any baseline variable were performed.

Treatment compliance

Compliance with treatment is reported by treatment group. Non-compliance was defined as failure, for any reason, to perform the original treatment to which a participant was randomised, for example if there was a need to perform an open reduction of the fracture after fracture reduction was lost after randomisation.

Reliability

To ensure consistency, validation checks were carried out on the data, including checking for duplicate records, range checking of the variables' values and validating potential outliers by comparing with CRFs and referring back to recruitment centres if necessary. Calculations and processes performed by a computer program were checked by hand calculations (when possible) for a minimum of 5% of the available data or 20 patients randomly sampled. This included checking that data had been imported correctly.

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

The reliability of the PRWE was checked through the methods described above with particular focus on the number of missing items that made up each subscale.

Analysis of primary outcome

The primary outcome measure, the role of the moulded cast compared with K-wire fixation after manipulation of the PRWE score at 12 months post randomisation, was modelled using a mixed-effects model. This model accounted for recruitment centre (random effect), baseline (post injury) values, values at other time points, articular extension of the fracture (intra- or extra-articular) and age of the patient (≥ 50 or < 50 years) (fixed effects). Treatment by time point interactions were also included in the model to allow time-specific treatment effects to be calculated. This is a different approach from that outlined in the DRAFFT 2 protocol[10] (linear regression with cluster robust option to control for recruitment centre), but it is considered in keeping with the principle outlined there (i.e. allowing for adjustment for clustering by recruitment centre as well as the other stratification variables as fixed effects). Baseline was included as a response, rather than adjusted for as a continuous covariate, to obtain time point-specific estimates to be used in the AUC analysis (see below for details on the analysis of the secondary AUC outcomes). Model fit and whether or not the model assumptions were met were assessed graphically.

Analysis of secondary outcomes

The EQ-5D-5L outcomes [index and visual analogue scale (VAS)] were measured at 3, 6 and 12 months post randomisation. A mixed-effects model, as used in the primary outcome, was used to assess this outcome, with recruitment centre as a random effect and baseline values, values at previous time points, articular extension of the fracture (intra- or extra-articular) and age of the patient (≥ 50 or < 50 years) as fixed effects. Treatment group by time point interactions were included in the model to allow time-specific treatment effects to be calculated. Comparisons were performed on an ITT basis and the results were presented as comparative summary statistics (i.e. adjusted mean difference) with 95% CIs. The distribution of the five domains was also reported separately in tabular and graphical form (see *Table 22* and *Figures 17–21*) by treatment.

The secondary outcome of complications, including those needing further surgery at 1 year post randomisation, was analysed as follows. The total number of further surgeries, including those in the cast group who received any surgery, was analysed by calculating the odds ratio and 95% CI using logistic regression. Other generic, non-surgical, complications [i.e. CRPS and DVT and PE (pooled)] were analysed using the same method. Other individual complications were summarised by treatment group, but not analysed, and reported in tabular form (see *Table 12*). As the total number of further surgeries is not a binary variable but a count, a Poisson regression adjusting for randomised treatment and randomisation variables was used for that analysis.

An AUC analysis was performed on PRWE and EQ-5D scores (both the EQ-5D-5L index and EQ-VAS). The estimates obtained in the mixed model for each time point used in the primary analysis were used to calculate the AUC. Using the estimates from the mixed model rather than raw, unadjusted estimates results in less biased estimates of the AUC when data are missing.[27] The PRWE AUC estimates were computed from the mixed model used for the primary analysis, and the standard errors (SEs) for these estimates were calculated using the delta method. The EQ-5D AUC results were produced in the same manner.

Missing data

The missing items required for definition of outcomes were investigated. Missing data were reported and summarised by treatment. An ITT analysis strategy to assess assumptions about departures from randomisation policies and handling of missing data was performed to examine the robustness of the primary analysis results. For each missing data point, the median PRWE score in the treatment group into which that patient was randomised was imputed and this 'complete' data set was analysed using the mixed-effects model used in the primary analysis. This analysis was repeated on a population that had the 60th quantile imputed for one group's missing values and on the 40th quantile for the other, then again using the 70th and 30th quantiles. The process was repeated but the treatment groups were swapped. In total, five such sensitivity analyses on PRWE scores were performed. The adjusted mean differences and 95% CIs for these analyses were plotted.

The instructions to users of the PRWE suggest a mechanism to deal with missing data: if an item is missing, then this can be replaced with the mean score of the subscale. However, no limit to the number of items that can be replaced is specified; for example, it is theoretically possible, if a value is available for only one item is on a subscale, to substitute that value for all missing values. Therefore, we explored how missing values on the PRWE subscales affected the outcome by calculating the PRWE scores obtained when two, three or four items per subscale were completed and comparing the results with the score obtained on the basis of a single item.

Sensitivity analysis

Sensitivity analysis of the primary outcome and secondary PRWE outcomes was carried out on a PP basis to examine robustness of the conclusions to different assumptions about departures from randomised policies.

An analysis was performed using a three-level model with participant within surgeon within recruitment centre to examine the potential surgeon (random) effects. This model incorporated terms that allowed for possible heterogeneity in patient's responses because there were a number of recruiting surgeons as well as recruitment centres. In addition, the fixed effects of the treatment groups, patient age and intra-articular extension also allowed for possible heterogeneity in responses.

Prespecified subgroup analysis

Subgroup analyses of the effect of the two clinical stratifying variables (age < 50 or ≥ 50 years and intra- or extra-articular extension) on the primary outcome were performed. These were undertaken for each of the stratifying variables using an extended model to formally test the interaction between each stratifying variable and the treatment factor; appropriate 95% CIs were reported for the interaction effects, in addition to *p*-values. These analyses were considered exploratory and results should be interpreted with due caution, and are reported as such in line with recommendations for subgroup analysis made elsewhere.[28] The subgroup results for the primary outcome are presented in a forest plot (see *Figure 9*).

Health economic analysis plan

A within-trial economic evaluation was conducted from the recommended NHS and Personal Social Services (PSS) perspective in the base-case (primary) analysis.[29]

Measurement of health-care resource use

Resource use in the first 6 weeks was collected on CRFs that were completed by the research team, whereas resource use during follow-up was collected through trial questionnaires given to participants at 3, 6 and 12 months post randomisation. Recall period was baseline to 3 months, 3 months to 6 months and 6 months to 12 months post randomisation. The questionnaire captured resource use information related to distal radius fracture, such as the number and duration of admissions to inpatient wards [classified as orthopaedics (wrist/arm), orthopaedics (any bones) and rehabilitation unit], number of diagnostic tests, use of outpatient services (classified as orthopaedics, physiotherapy, pathology and radiology), and use of community-based health and social care services. Participants also recorded direct medical costs (e.g. medications), direct non-medical costs (e.g. aids and adaptations, help with housework/child care and travel) and indirect costs (i.e. lost productivity) attributable to the participant's injury.

Free-text responses were reclassified to the appropriate cost category, and were removed if deemed unrelated/irrelevant to the trial by clinical experts (e.g. cardiology) or were analysed collectively as 'other' in the descriptive analysis.

Valuation of costs

The intraoperative consumable costs for both cast and K-wire fixation were obtained from the latest *NHS Supply Chain catalogue*.[30] (see *Appendix 2, Table 21*). The duration of surgery was recorded and included in the analysis as a unit cost per minute of theatre time. According to an operating theatre benchmarking study in 2013,[31] the cost of each theatre hour that included staff cost was, on average, £561. The unit cost of the initial distal radius surgery fracture fixation was assessed using the *NHS Reference Costs*[21] and the Healthcare Resource Group[32] code (HT45Z) for 'Minor Hand Procedures for Trauma' was assigned to both trial groups. Day-case costs or overnight admission costs were obtained from the latest *NHS Reference Costs*.[21] If a participant reported a length of stay longer than the trim point specified in the *NHS Reference Costs*, then the inpatient excess day cost from the *NHS Reference Costs* was used.

Direct medical costs, such as the inpatient care, outpatient care and community care, were sourced from the latest available *NHS Reference Costs*[21] and PSSRU *Unit Costs of Health and Social Care 2019*.[24] The unit cost of medication related to the distal radius fracture (e.g. analgesia) was sourced using

the latest available BNF[33] or the *NHS Electronic Drug Tariff*.[22] The cost of medication taken over the study period was computed using the cost per dose for each product and the mean quantity taken per day for the reported number of days. All medications were assumed to be in generic tablet form unless stated otherwise.

The unit cost of direct non-medical items, such as help with housework/child care and travel incurred by participant's carers, was obtained directly from the questionnaire. The unit costs of aids and adaptations were obtained from the latest *NHS Supply Chain Catalogue*. The cost of lost productivity was computed using the human capital approach from the Office for National Statistics,[34] in which the daily median wage was multiplied by the number of days that the participant had to take off work because of their injury.

The cost of health-care resource use per participant was computed by multiplying the reported frequency of health-care resource utilisation by the unit cost of each resource item and adding the direct non-medical cost, which was obtained directly from the questionnaire. The base currency of all costs was 2018/19 Great British pounds (GBP), and the unit costs were adjusted to 2018/19 prices using the NHS Cost Inflation Index, which supersedes the Hospital and Community Health Services Index.

Valuation of health outcomes

Responses to the EQ-5D-5L were converted to EuroQol-5 Dimensions, three-level version (EQ-5D-3L), utility scores using the crosswalk algorithm[18] recommended by NICE[35] and valued using the UK EQ-5D-3L time trade-off tariff.[36] Quality-adjusted life-years (QALYs) were calculated as the AUC of utility scores from baseline, 3-, 6- and 12-month data using the trapezoidal rule.[37] Estimates of mean QALYs were then adjusted using regression methods with baseline EQ-5D as the independent variable. Utilities were set to zero at the studied time point if patient had died just before that time point (e.g. if a patient died between 3 months and 6 months, then the EQ-5D score of that patient at 6 months would be zero).[38]

Data analysis

Resource use items were summarised by trial allocation group and follow-up period and differences between groups were analysed using *t*-tests for continuous variables and Pearson chi-squared (χ^2) tests for categorical variables. The means and SEs for values of each cost category were estimated by treatment allocation and follow-up period. Differences in mean costs were assessed using *t*-tests. The bootstrap 95% CI was computed based on 10,000 replications. No discounting of costs and QALYs was applied because the time horizon was 1 year. A two-sided significance level of 0.05 was used throughout.

Cost-effectiveness analysis

The cost-effectiveness of K-wires compared with a cast was assessed from the UK NHS and PSS perspective in the base-case analysis.[39] The base-case analysis adopted an ITT ('as-randomised' with imputation of missing data using multiple imputation) perspective, and an incremental cost-effectiveness ratio (ICER) was calculated as the difference in mean costs divided by the difference in mean QALYs between the treatments.

The NICE[40] cost-effectiveness threshold of £20,000 to £30,000 per additional QALY was used to determine the cost-effectiveness of K-wires compared with a cast after the manipulation of a fracture of the distal radius. An additional £15,000 per QALY cost-effectiveness threshold was also included to reflect recent trends in health-care decision-making.[41] The treatment was considered to be cost-effective if it had an ICER below the specified cost-effectiveness threshold. The net monetary benefit (NMB) of K-wires compared with a cast was computed across different cost-effectiveness thresholds. A positive incremental NMB would indicate that K-wires are cost-effective, compared with a cast, at the given cost-effectiveness threshold.

Non-parametric bootstrapping was also performed to assess the uncertainty on the ICERs. The probability that K-wires are cost-effective compared with a cast was plotted at varying levels of cost-effectiveness thresholds for an additional QALY and presented in cost-effectiveness acceptability curves. The cost-effectiveness plane was drawn based on bootstrap estimates of the differences in cost and effectiveness for the K-wire group compared with the cast group and the ellipses represented 50%, 75% and 95% confidence regions around the ICER for the K-wire group compared with the cast group. The ellipses were computed based on the methods described by Nixon *et al.*[42]

Missing data

Under the missing at random (MAR) assumption, multiple imputation analysis was used to impute missing costs and QALYs. This was carried out using chained regression equations predicting missing values from the observed covariates (observed responses of participant) and creating sets of multiple data sets containing possible values for missing observations.[43] Pooled estimates were then computed using Rubin's rules[44] to obtain an overall mean estimate of the costs or QALYs.

Mean imputation was used for missing baseline covariates whereas multiple imputation for QALYs was performed at the QALY level and costs were imputed at the total cost level (e.g. total outpatient cost) in each follow-up time point using Amelia II in R (The R Foundation for Statistical Computing, Vienna, Austria). This multiple imputation package has been shown to outperform other such packages [e.g. NORM (S-PLUS – TIBCO Spotfire, Somerville, USA or R), MICE (S-PLUS, R and Stata – StataCorp LP, College Station, TX, USA) and SPSS MI (SPSS Inc., Chicago, IL, USA)].[45] Independent variables included in the imputation model consisted of baseline covariates, such as age, sex, articular extension of fracture, PRWE score, whether or not the participant had CRPS, pre-injury EQ-5D index and VAS scores, and post-injury EQ-5D VAS score. This imputation was run 40 times in accordance with the 'rule of thumb' that suggests that the number of imputations should be similar to the percentage of incomplete cases.[46]

Subgroup and sensitivity analyses

Similarly to the statistical analysis, the economic evaluation was repeated for subgroups defined by the two clinical stratifying variables (age and articular extension of fracture). One-way sensitivity analyses, such as extending the study perspective to societal perspective by including costs of lost productivity and complete-case analysis to assess the impact of missing data on the ICERs, were conducted.

Ethics approval and monitoring

Ethics committee approval

The National Research Ethics Committee approved this study on 6 October 2016 (16/SC/0462).

Trial Management Group

The day-to-day trial management was the responsibility of the trial manager, based at Oxford Trauma/ Oxford Clinical Trials Research Unit of the University of Oxford and supported by administrative staff. The Trial Management Group (TMG) met monthly to assess overall trial progress. It was also the responsibility of the trial manager to train local research staff at each of the trial recruitment centres. The trial's statistical, health economics and programming team were closely involved in setting up data capture systems, design of databases and clinical reporting forms.

Trial Steering Committee

A Trial Steering Committee was appointed by the National Institute for Health Research (NIHR) and was responsible for overseeing, monitoring and supervising trial progress on behalf of the funder. The Trial Steering Committee consisted of three independent experts, a lay member and the chief investigator who met once per year during the recruitment period. Membership is listed in the *Acknowledgements.*

Data Safety and Monitoring Committee

The study Data Safety and Monitoring Committee (DSMC) adopted a DAta MOnitoring Committees: Lessons, Ethics, Statistics (DAMOCLES) charter, which defines its terms of reference and operation in relation to oversight of the trial. The DSMC was tasked with monitoring ethics, safety and data integrity. The trial statistician provided data and analyses requested by the DSMC so that the DSMC could review accruing data and summaries of the data presented by treatment group and assess the screening algorithm against the eligibility criteria. It also considered emerging evidence from other related trials or research and reviewed related SAEs that had been reported. The DSMC met twice during the recruitment period. Membership of the DSMC is listed in the *Acknowledgements*.

Patient and public involvement

Alongside the DRAFFT trial,[4] a series of formal qualitative interviews were performed with patients suffering from fractures of the distal radius. The views and priorities of patients taking part in the DRAFFT trial[4] were used to inform the trial treatments and processes in this study.

To ensure ongoing patient and public involvement, a patient/carer representative was actively involved in general trial management. In addition, a further independent patient representative was a member of the Trial Steering Committee.

Chapter 3 Results

Screening and randomisation

Patient screening for potential study participants was open from January 2017 to March 2019. A total of 2636 patients were screened, of whom 1441 were not eligible because they met one of the exclusion criteria. A further 495 were not included because of the clinician's treatment preference, and 196 declined to participate in the study (*Table 2* shows the reasons for declining consent and *Table 3* shows the clinicians' stated treatment preference). The Consolidated Standards of Reporting Trials (CONSORT) flow diagram shows the reasons for ineligibility (*Figure 1*).

A total of 179 patients consented to enter the study but were not randomised because the articular surface of their fracture could not be reduced by indirect techniques during manipulation under anaesthetic in the operating theatre.

A total of 504 patients were entered into the randomisation system, but four were entered in error (without consent). Therefore, this trial randomised a total of 500 participants, of whom 255 were allocated to the cast group and 245 were allocated to the K-wire group.

Recruitment

The first randomisation took place on 31 January 2017 and the final randomisation was on 28 March 2019, and the final 12-month follow-up was received on 18 May 2020.

TABLE 2 Reasons for patients declining consent to the study

Reasons	Number of participants
Patient does not want to take part in research	143
Patient does not want to complete questionnaires	9
No reason given	32
Total	184

TABLE 3 Clinicians' stated treatment preference

Treatment preference	Number of participants
Conservative	31
Surgical fixation with K-wires	120
Surgical fixation with plate	183
Other	7
Unknown	154
Total	495
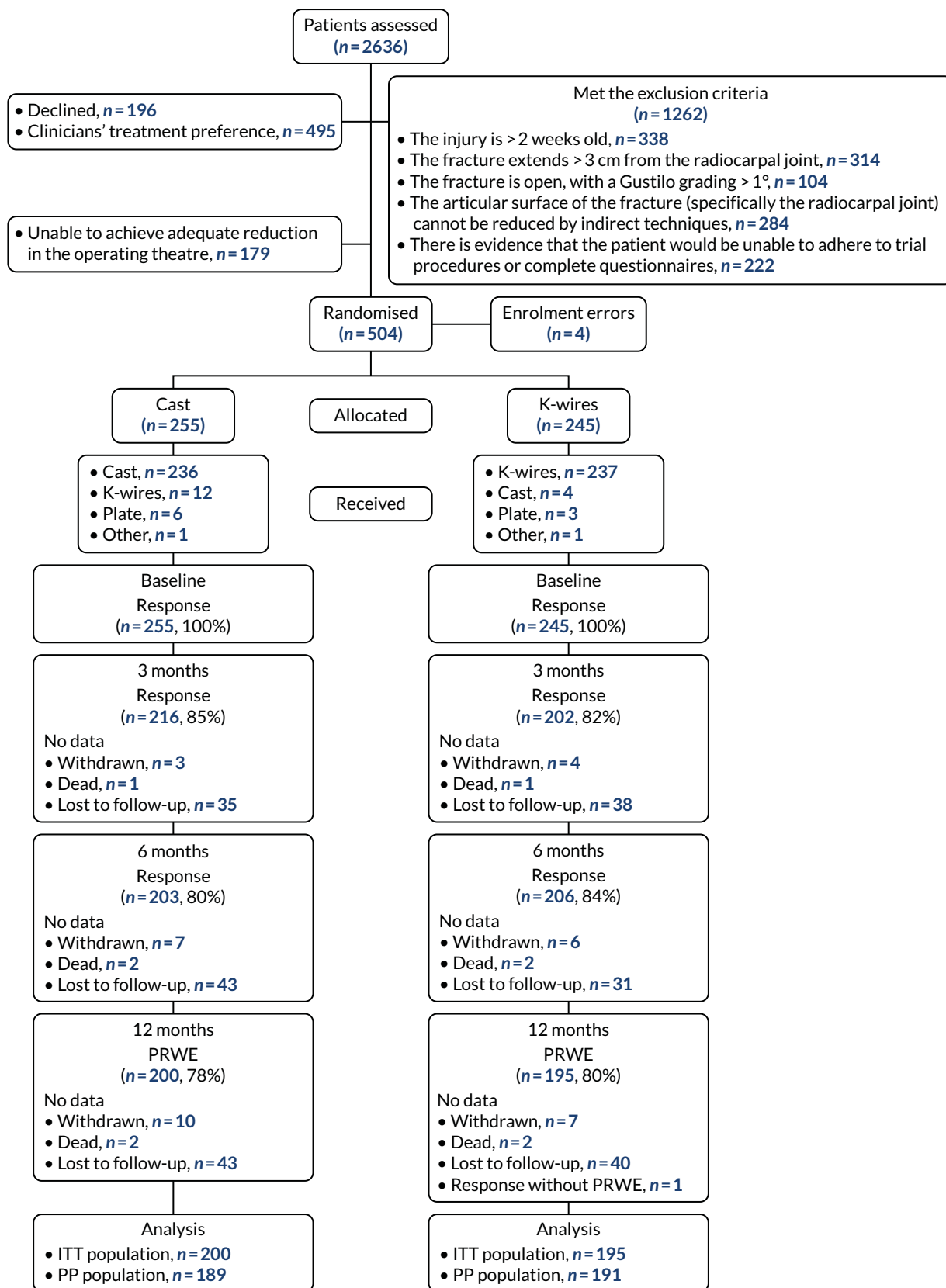
FIGURE 1 The CONSORT flow diagram.

Baseline characteristics

Baseline participant characteristics

The randomisation was stratified by recruitment centre, articular extension (extra- or intra-articular) and age (< 50 or ≥ 50 years). *Table 4* shows the allocation of the participants to the treatment groups for each stratification variable. Pinderfields Hospital and Addenbrooke's Hospital were open to recruitment but did not randomise any participants and so were omitted from this table.

Table 5 shows the baseline continuous variables as means and SDs by treatment group. The mean age in the cast group was 59.6 (SD 17.2) years and in the K-wire group was 60.7 (SD 16.0) years. Baseline pre- and post-injury patient-reported outcomes (i.e. PRWE, EQ-5D-5L index and EQ-VAS scores) are also reported in *Table 5* and were similar across the treatment groups. *Table 6* shows the categorical baseline variables (presented as number of participants with percentages) of sex, treated wrist and grade of surgeon performing the procedure. Two-hundred and twelve (83.1%) participants in the cast group and 205 (83.7%) participants in the K-wire group were female.

Treatment information

Information on treatments is presented in *Figure 2* and *Table 7*. *Figure 2* is a box plot of procedure duration for each group and shows that fixation with K-wire took longer than moulded casting. *Table 7* shows other details about the treatments performed. The majority of treatments (87.1% and 82.4% in the cast and K-wire group, respectively) were performed by experienced surgeons who had performed over 20 procedures for both cast and K-wire interventions. A total of 361 surgeons performed the treatments as part of the trial. The median number of treatments per surgeon was 1, with a range of 1–11.

Treatment compliance

There was > 92% compliance for both treatments with 236 (92.5%) of those randomly allocated a moulded cast receiving one and 237 (96.7%) receiving their allocated K-wire (*Table 8*). More participants randomised to the cast group crossed over to receive K-wire than participants randomised to the K-wire group who crossed over to receive a cast. A small number from both groups (the cast group, $n = 4$; the K-wire group, $n = 3$) received a plate. The 'other' in the K-wire group received an external fixation (after a fasciotomy for compartment syndrome and decompression of carpal tunnel) and the 'other' treatment received for the participant allocated to the cast treatment could not be confirmed.

Deaths and withdrawals

Overall, there were 17 withdrawals (cast group, $n = 10$; K-wire group, $n = 7$) and four deaths (cast group, $n = 2$; K-wire group, $n = 2$). In most cases, the reason for withdrawals was not wanting to complete questionnaires (nine in total: cast group, $n = 6$; K-wire group, $n = 3$) or participant decision (four in total: cast group, $n = 2$; K-wire group, $n = 2$). Seventeen participants withdrew from the study; however, five of them agreed for medical routine data to still be collected for the trial by the local research team. There were four deaths, two of unknown cause, one was due to stroke and the other due to suspected graft-versus-host disease.

Primary outcome

Analysis of primary outcome: Patient-Rated Wrist Evaluation score at 12 months post randomisation

The PRWE score was assessed at baseline (pre and post injury), and at 3, 6 and 12 months post injury. The mean PRWE score and SD for each treatment group at each time point (excluding pre-injury baseline as this did not contribute to the analysis model) are provided in *Table 9* and were based on all available data at each time point. The adjusted mean differences in PRWE score were obtained from a linear mixed-effects regression model adjusting for the stratification factors age and articular extension and observations within participants within recruitment centres as random effects.

TABLE 4 Stratification variables by treatment group

	Treatment group, n (%)	
Stratification variable	Cast (N = 255)	K-wire (N = 245)
Recruitment centre		
Basingstoke and North Hampshire Hospital	5 (2.0)	8 (3.3)
Blackpool Victoria Hospital	2 (0.8)	3 (1.2)
Cumberland Infirmary	4 (1.6)	5 (2.0)
Eastbourne District General Hospital	10 (3.9)	8 (3.3)
Ipswich Hospital	1 (0.4)	2 (0.8)
James Cook University Hospital	16 (6.3)	15 (6.1)
John Radcliffe Hospital	12 (4.7)	13 (5.3)
Leicester General Hospital	10 (3.9)	9 (3.7)
Luton & Dunstable Hospital	7 (2.7)	8 (3.3)
Manchester Royal Infirmary	5 (2.0)	5 (2.0)
Musgrove Park Hospital	2 (0.8)	3 (1.2)
North Tyneside General Hospital	5 (2.0)	6 (2.4)
Northampton General Hospital	12 (4.7)	8 (3.3)
Peterborough City Hospital	6 (2.4)	6 (2.4)
Poole Hospital	4 (1.6)	7 (2.9)
Royal Berkshire Hospital	4 (1.6)	5 (2.0)
Royal Blackburn Hospital	9 (3.5)	10 (4.1)
Royal Cornwall Hospital	7 (2.7)	7 (2.9)
Royal Derby Hospital	7 (2.7)	5 (2.0)
Royal Hampshire County Hospital	1 (0.4)	2 (0.8)
Royal Stoke University Hospital	10 (3.9)	7 (2.9)
Royal Victoria Infirmary	13 (5.1)	14 (5.7)
Salisbury District Hospital	12 (4.7)	9 (3.7)
Sandwell General Hospital	7 (2.7)	10 (4.1)
Southampton General Hospital	6 (2.4)	3 (1.2)
Southmead Hospital	19 (7.5)	21 (8.6)
St. George's University of London	3 (1.2)	2 (0.8)
Tunbridge Wells Hospital	5 (2.0)	3 (1.2)
University Hospital (Coventry)	21 (8.2)	21 (8.6)
University Hospital Llandough	10 (3.9)	7 (2.9)
University Hospital of North Tees	5 (2.0)	3 (1.2)
Whiston Hospital	3 (1.2)	2 (0.8)
Wrightington Hospital	3 (1.2)	3 (1.2)
Wythenshawe Hospital	9 (3.5)	5 (2.0)
Age (years)		
< 50	62 (24.3)	51 (20.8)
≥ 50	193 (75.7)	194 (79.2)
Articular extension of the fracture		
Extra-articular extension	184 (72.2)	176 (71.8)
Intra-articular extension	71 (27.8)	69 (28.2)
Total	255 (51.0)	245 (49.0)

TABLE 5 Continuous baseline variables by treatment group

| | Treatment group | | | | |
| | Cast (N = 255) | | | K-wire (N = 245) | |
Variable	n	Mean (SD)		n	Mean (SD)
Age (years)	255	59.6 (17.2)		245	60.7 (16.0)
Baseline pre injury (retrospective)					
PRWE score (points)	254	3.1 (10.3)		245	4.5 (14.0)
EQ-5D-5L index score	254	0.9 (0.2)		244	0.9 (0.1)
EQ-VAS score, 0–100	254	84.6 (15.3)		243	86.4 (13.9)
Baseline post Injury					
PRWE score (points)	253	84.3 (13.3)		243	81.9 (14.5)
EQ-5D-5L index score	252	0.3 (0.3)		241	0.4 (0.3)
EQ-VAS score, 0–100	253	63.9 (22.8)		242	64.2 (23.1)

TABLE 6 Categorical baseline variables by treatment group

| | Treatment group, n (%) | |
Variable	Cast (N = 255)	K-wire (N = 245)
Sex		
Female	212 (83.1)	205 (83.7)
Male	43 (16.9)	40 (16.3)
Treated wrist		
Left	147 (57.6)	146 (59.6)
Right	108 (42.4)	98 (40.0)
Not documented	0 (0.0)	1 (0.4)
Surgeon's grade		
Consultant	139 (54.5)	104 (42.4)
Other	11 (4.3)	21 (8.6)
Specialist trainee	73 (28.6)	91 (37.1)
Staff grade/associate/specialist	32 (12.5)	28 (11.4)
Not documented	0 (0.0)	1 (0.4)

Baseline (post injury) was included as a response, rather than adjusted for as continuous covariate fixed effect, to obtain time point-specific estimates for baseline to be used in the AUC analysis. The number of observations for each treatment group is the number of participants who supplied PRWE data at that time point. The analysis was performed on the prespecified ITT population defined in *Chapter 2, Definition of analysis populations*. The adjusted analysis was prespecified as the primary trial results.
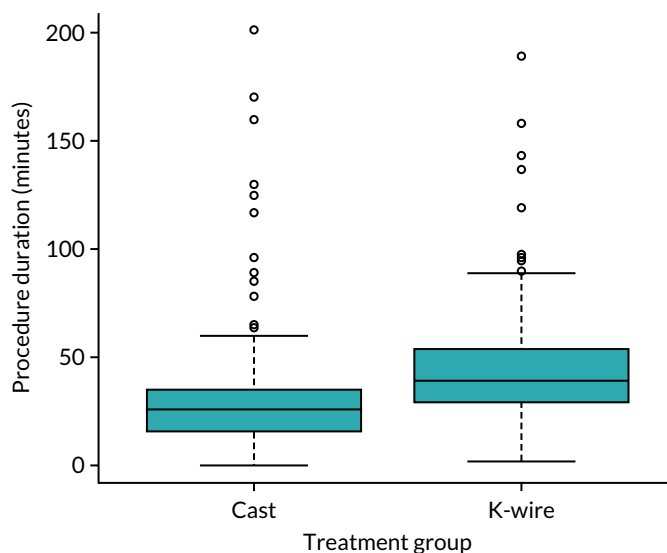
FIGURE 2 Box plot of procedure duration time by treatment group.

TABLE 7 Treatment details by treatment group

	Treatment group, n (%)	
Treatment details	Cast (N = 255)	K-wire (N = 245)
Perioperative antibiotic cover used		
Yes	48 (19.0)	181 (74.8)
No	204 (81.0)	61 (25.2)
Number of prior patients with a displaced distal radius fracture treated by surgeon		
0	1 (0.4)	5 (2.0)
< 5	4 (1.6)	13 (5.3)
5–10	11 (4.3)	7 (2.9)
11–20	17 (6.7)	18 (7.4)
> 20	222 (87.1)	201 (82.4)
K-wire information		
Number of wires used		
1	0 (0.0)	5 (2.0)
2	4 (1.6)	154 (63.1)
3	7 (2.7)	74 (30.3)
> 3	1 (0.4)	3 (1.2)
N/A	243 (95.3)	8 (3.3)
Wire size (mm)		
1.1	0 (0.0)	1 (0.4)
1.6	9 (3.5)	172 (72.6)
Other	3 (1.2)	56 (23.6)
N/A	243 (95.3)	8 (3.4)

Health Technology Assessment 2022 Vol. 26 No. 11

TABLE 7 Treatment details by treatment group (*continued*)

Treatment details	Treatment group, *n* (%)	
	Cast (*N* = 255)	K-wire (*N* = 245)
Pinning technique used		
Interfragmentary	6 (2.4)	91 (38.2)
Kapanji	4 (1.6)	93 (39.1)
Mixed technique	2 (0.8)	46 (19.3)
N/A	243 (95.3)	8 (3.4)
Cast information[a]		
Thumb included		
Yes	59 (23.2)	
No	176 (69.3)	
N/A	19 (7.5)	
Material used		
Fibreglass	13 (5.1)	
Plaster of Paris	222 (87.1)	
Other	1 (0.4)	
N/A	19 (7.5)	
Coverage		
Backslab	19 (7.5)	
Full cast	214 (84.9)	
N/A	19 (7.5)	

N/A, not applicable.
a All participants in the K-wire group had a neutralising cast.

TABLE 8 Treatment allocation

Treatment received	Treatment group allocated, *n* (%)		Total, *n* (%)
	Cast	K-wire	
Cast	236 (92.5)	4 (1.6)	240 (48.0)
K-wire	12 (4.7)	237 (96.7)	249 (49.8)
Plate	6 (2.4)	3 (1.2)	9 (1.8)
Other	1 (0.4)	1 (0.4)	2 (0.4)
Total	255 (51.0)	245 (49.0)	500 (100.0)

The adjusted results in *Table 9* show no significant treatment effect at any of the time points or in the AUC analysis. The primary outcome (i.e. PRWE score at 1 year) shows a between-group difference of −0.34 (95% CI −4.33 to 3.66; $p = 0.87$). *Figure 3* shows the means and SDs at each time point used in the analysis model (baseline post injury and 3, 6 and 12 months post randomisation). *Figure 4* shows the density plot of the 12-month PRWE score for both the cast and the K-wire groups.

TABLE 9 Patient-reported wrist evaluation scores (primary outcome)

| Time point | Treatment group | | | | Mean difference | | |
| | Cast | | K-wire | | | | |
	n	Mean (SD)	n	Mean (SD)	Unadjusted	Adjusted (95% CI)	p-value
Baseline (post injury)	253	84.3 (13.30)	243	81.91 (14.52)	−2.39		
3 months	213	42.08 (23.85)	201	41.56 (24.77)	−0.51	−0.45 (−4.37 to 3.47)	0.82
6 months	202	28.35 (23.35)	206	27.56 (22.33)	−0.79	−0.32 (−4.26 to 3.62)	0.87
12 months (primary outcome)	200	21.16 (23.09)	195	20.69 (22.33)	−0.47	−0.34 (−4.33 to 3.66)	0.87
AUC over 12 months		38.19[a]		37.60[a]		−0.60 (−4.41 to 3.21)	0.88

a Model estimate.
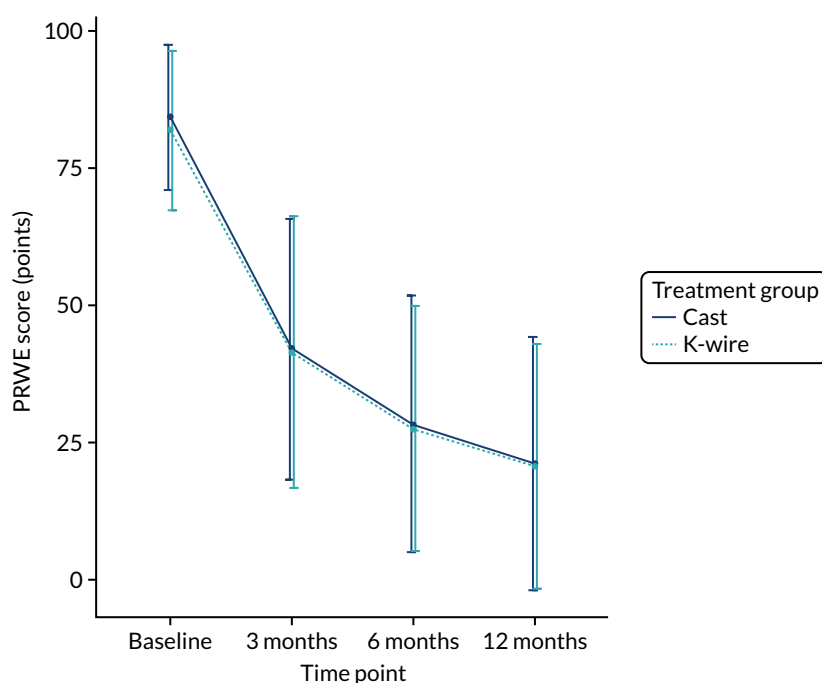
FIGURE 3 Change in PRWE score by treatment group over time.

Graphical model checks were performed as part of the analysis and indicated no issues with the model fit as well as no evidence of the underlying assumptions not being met. These checks are available on the project webpage (www.journalslibrary.nihr.ac.uk/programmes/hta/152701/#/; accessed October 2021) .

Secondary outcomes

EuroQol-5 Dimensions, five-level version, index
The secondary outcomes (i.e. EQ-5D-5L index at 3, 6 and 12 months post randomisation, as well as the EQ-5D-5L index AUC) are presented in *Table 10*. A mixed-effects model, as used in the primary outcome, was used to assess these outcomes. The means and SDs are presented, as well as adjusted mean differences, 95% CIs and p-values derived from the model. A graphical summary of the EQ-5D-5L index means and SDs for each time point by treatment group is shown in *Figure 5*. The EQ-5D-5L index showed

(a)

(b)
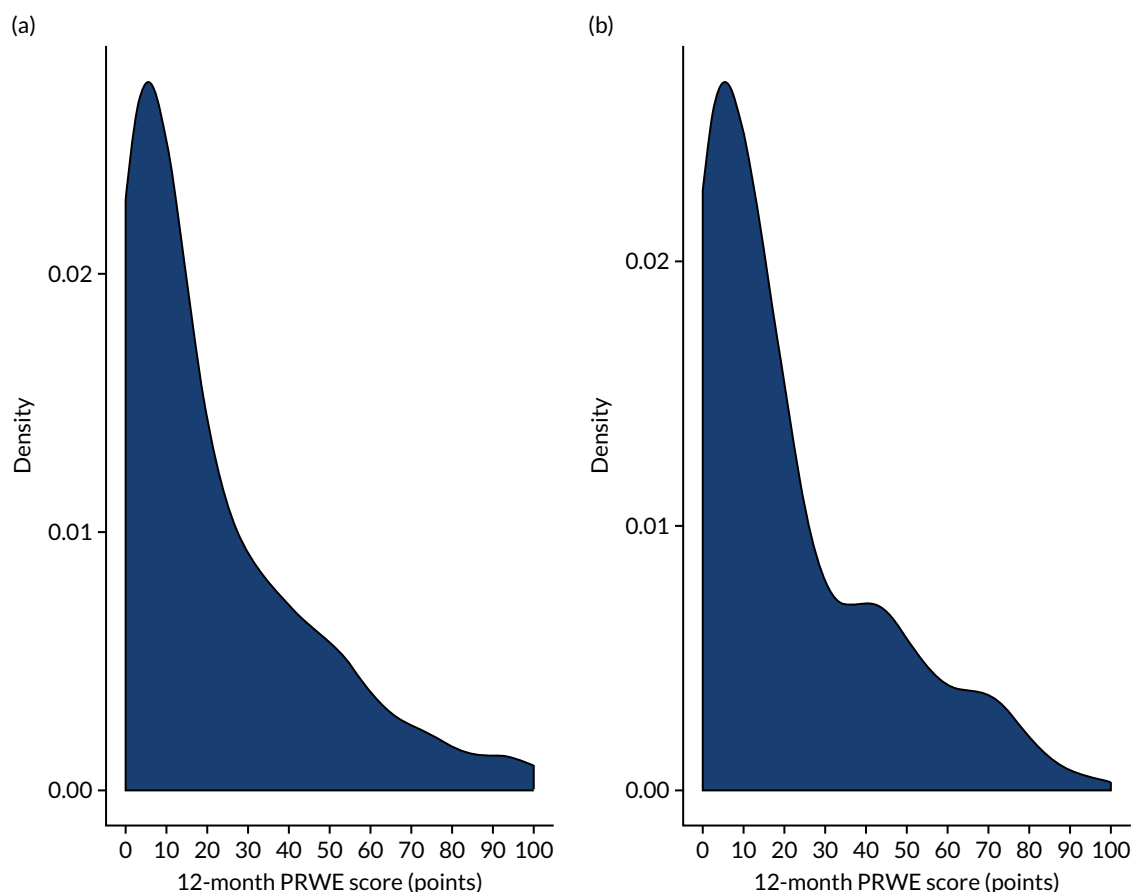
FIGURE 4 Histograms of PRWE score at 12 months post randomisation by treatment group. (a) Cast group and
(b) K-wire group.

TABLE 10 The EQ-5D-5L index results

| Time point | Treatment group | | | | Mean difference | | |
| | Cast | | K-wire | | | | |
	n	Mean (SD)	*n*	Mean (SD)	Unadjusted	Adjusted (95% CI)	*p*-value
Baseline (post injury)	252	0.35 (0.28)	241	0.37 (0.26)	0.02		
3 months	217	0.68 (0.21)	203	0.67 (0.20)	–0.01	–0.02 (–0.06 to 0.02)	0.37
6 months	204	0.75 (0.21)	207	0.75 (0.18)	0.00	0.00 (–0.04 to 0.04)	0.96
12 months	199	0.81 (0.20)	197	0.78 (0.21)	–0.02	–0.03 (–0.07 to 0.02)	0.26
AUC over 12 months		0.69[a]		0.68[a]		–0.01 (–0.05 to 0.03)	0.82

a Model estimate.

improvement over time from injury until 12 months post randomisation, but there was no significant
treatment effect at any time point or AUC analysis with a 12-month adjusted mean difference of –0.03
(95% CI –0.07 to 0.02). The distribution of the five domains is presented in *Appendix 2, Figures 17–21*.

EuroQol-5 Dimensions visual analogue scale
The secondary outcome EQ-VAS, a QoL score running from 0 to 100 with higher values indicating
better QoL, at 3, 6 and 12 months post randomisation, and the EQ-VAS AUC scores are presented in
Table 11. A linear mixed-effects model, as used in the primary outcome, was used to assess these outcomes.
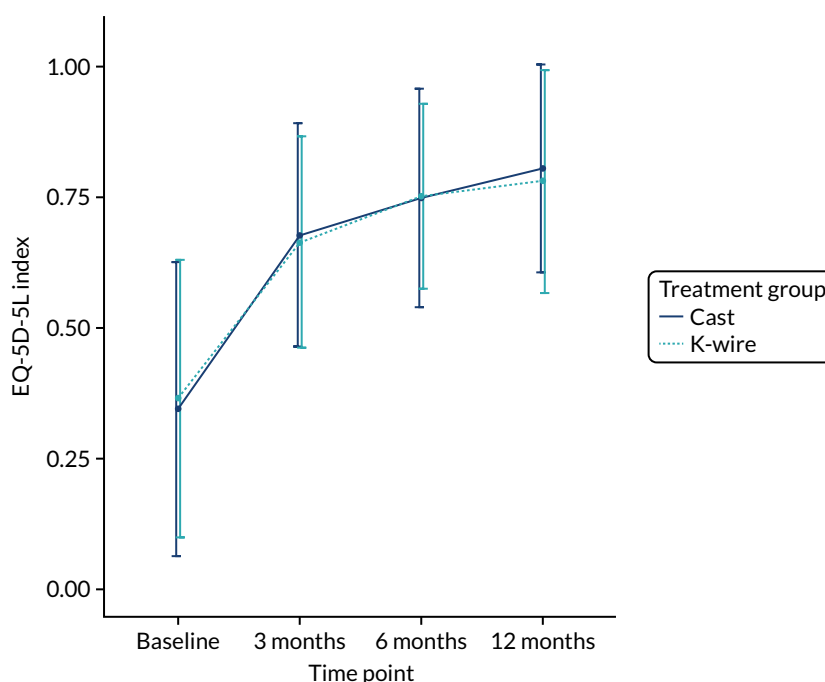
FIGURE 5 Change in EQ-5D-5L index by treatment group over time.

TABLE 11 The EQ-5D VAS results

| Time point | Treatment group | | | | Mean difference | | |
| | Cast | | K-wire | | | | |
	n	Mean (SD)	n	Mean (SD)	Unadjusted	Adjusted (95% CI)	p-value
Baseline (post injury)	253	63.87 (22.76)	242	64.19 (23.14)	0.32		
3 months	216	77.08 (18.25)	201	75.55 (18.51)	−1.53	−1.73 (−5.44 to 1.98)	0.36
6 months	202	79.29 (20.02)	204	81.09 (16.37)	1.80	1.87 (−1.88 to 5.61)	0.33
12 months	199	81.11 (18.06)	195	80.42 (18.00)	−0.69	−0.51 (−4.30 to 3.29)	0.79
AUC over 12 months		76.81[a]		76.98[a]		0.16 (−3.59 to 3.92)	0.97

a Model estimate.

The means and SDs are given along with adjusted mean differences, 95% CIs and *p*-values derived from the model. A plot of the EQ-5D VAS means and SDs on all available data for each time point by treatment group is given in *Figure 6*. The EQ-5D VAS showed improvement over time but there was no significant treatment effect at any time point or AUC analysis with a 12-month adjusted mean difference of −0.51 (95% CI −4.30 to 3.29; *p* = 0.79). This result is supported by *Figure 6*, indicating no raw mean difference at any time.

Complications

Complications, including the need for further surgery, CRPS and DVT/PE were analysed by calculating the odds ratio and 95% CI using logistic regression. The total number of further surgeries was analysed using a Poisson regression adjusting for randomised treatment and randomisation variables as that is a count variable, not binary. Other individual complications were summarised by treatment group, but not analysed, and reported in *Table 12*. The logistic regression and Poisson models adjusted for randomised treatment and the variables used in the stratification process (age group, extension of the fracture, and recruitment centre).
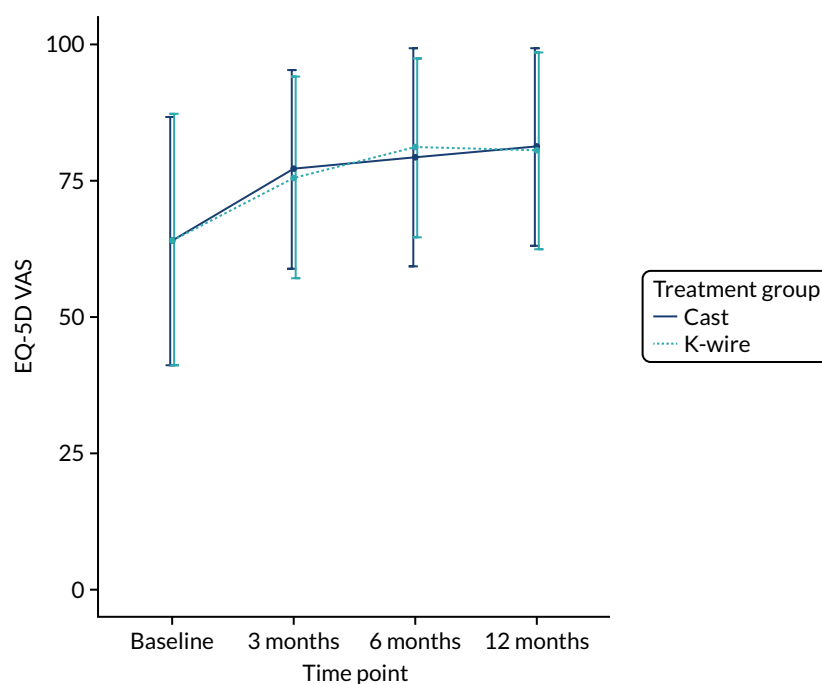
FIGURE 6 Change in EQ-5D VAS by treatment group over time.

TABLE 12 Treatment-specific complications within 6 weeks post randomisation

Complication	Treatment group, *n* (%)	
	Cast	K-wire
Cast-specific complications (6 weeks)		
Cast discomfort	65 (25.5)	32 (13.0)
Cast changed	72 (28.2)	105 (42.9)
Pressure sores	11 (4.3)	3 (1.2)
K-wire-specific complications (6 weeks)		
Neurological injury	0 (0.00)	7 (2.9)
Vascular injury	0 (0.00)	0 (0.00)
Tendon injury	0 (0.00)	4 (1.6)
Redness around wound	0 (0.00)	20 (8.2)
Leaking from pin site	0 (0.00)	16 (6.5)
If leaking, purulent drainage	0 (0.00)	4 (1.6)
If leaking, confirmation of infection	0 (0.00)	4 (1.6)

At 6 weeks post randomisation, there was evidence that K-wire fixation reduced the need for further surgery because of loss of fracture reduction (*Table 13*). There were 33 occurrences of loss of fracture reduction in the cast group, compared with one occurrence in the K-wire group (odds ratio 0.02, 95% CI 0.001 to 0.10). The majority of the participants who had further surgery because of a loss of reduction were those whose original fracture was extra-articular (70%) and were aged > 50 years (76%). There were only two additional surgeries in the first 6 weeks post randomisation that were not due to loss of reduction.

TABLE 13 Further surgery in the first 6 weeks post randomisation

Details of further surgery	Treatment group, n (%)		Odds ratio (95% CI)	p-value
	Cast	K-wire		
Reasons for further surgery				
Loss of reduction	33 (12.94)	1 (0.41)	0.02 (0.001 to 0.10)	< 0.001
Other reason for surgery	1 (0.39)	1 (0.41)		
Fracture type in those with loss of reduction				
Extra-articular	22 (8.63)	1 (0.41)		
Intra-articular	11 (4.31)	0 (0.00)		
Age (years) of those with loss of reduction				
< 50	9 (3.53)	0 (0.00)		
≥ 50	24 (9.41)	1 (0.41)		
Treatment received in further surgery				
Cast	1 (0.39)	0 (0.00)		
K-wire	11 (4.31)	1 (0.41)		
Plate	22 (8.63)	1 (0.41)		

During the 6-week to 12-month follow-up period there were six additional surgeries in the cast group, compared with three in the K-wire group. None of these surgeries was due to loss of reduction. The reasons for the additional surgeries included a second fall, carpal tunnel, tendon transfer and stiffness. The number of other generic complications during the first year post randomisation was similar in both treatment groups (cast group, $n = 28$; K-wire group, $n = 22$). These complications included osteoarthritis in the thumb, cellulitis around the pin site, stiffness, swelling, loss of radial height, numbness, sensitivity, a scapholunate injury and pain. No statistically significant result was found when testing for associations between the treatment groups and these complications (*Table 14*).

TABLE 14 Overall further surgery and complications during the first 12 months post randomisation

Details of further surgery	Treatment group, n (%)		Odds ratio (95% CI)	p-value
	Cast group	K-wire group		
Total number of further surgeries	40 (15.69)	5 (2.04)	0.13 (0.04 to 0.23)	< 0.001
Number of participants who had further surgery	37 (14.51)	5 (2.04)	0.08 (0.02 to 0.20)	< 0.001
Time point of further surgery				
6 weeks	34 (13.33)	2 (0.82)		
3 months	1 (0.39)	1 (0.41)		
6 months	1 (0.39)	2 (0.82)		
12 months	4 (1.57)	0 (0.00)		
Generic complications				
CRPS	5 (1.96)	7 (2.86)	1.45 (0.43 to 5.28)	0.55
Other complications	28 (10.98)	22 (8.98)	0.74 (0.39 to 1.39)	0.35

The PRWE score at 12 months post randomisation among those in the cast group who had further surgery because of loss of reduction [mean 20.79 points (SD 20.95 points)] was very similar to that in the cast treatment group as a whole [mean 21.16 points (SD 23.09 points)] (*Table 15*).

Missing data

The primary analysis was performed using a complete-case analysis, which assumed the data were MAR (i.e. the unobserved data were from the same conditional distribution as the observed data.) This seemed to be a plausible assumption for this trial as the number of patients lost to follow-up was low and there were roughly equal numbers of missing data across both treatment groups. However, two sensitivity analyses on missing data were performed.

The first sensitivity analysis used imputation of quantiles. For each missing data point, the median value of the treatment group was imputed and analysed using the same mixed model as in the primary analysis. The analysis was repeated on a population that had the 60th quantile imputed for one group's missing values and the 40th quantile for the other, then again using the 70th and 30th quantiles. The process was repeated but the treatment groups were swapped. In total, five sensitivity analyses were performed and the results were displayed graphically (see *Figure 7*).

Figure 7 shows how the estimates of the adjusted mean difference changed depending on the values imputed. This sensitivity analysis showed that there would need to be a large violation of the MAR assumption in the main analysis to render the results invalid and such a departure seems unlikely.

In the primary analysis it was assumed that one item present per subscale was not defined as missing; in the second sensitivity analysis, the effect of requiring at least two, three, four and all items present in a subscale to not be called missing; was examined. *Figure 8* showed that there was no difference in the estimated treatment effect at 12 months post randomisation for different ways of handling missing data in the PRWE subscales.

Sensitivity analysis

Two sensitivity analyses were specified in the SHEAP:[19] a PP analysis on PRWE outcomes to examine different assumptions about departures from randomised policies and a three-level model with participant within surgeon within recruitment centre to examine potential surgeon (random) effects. This model incorporated terms that allowed for possible heterogeneity in patients' responses as a result of there being multiple recruiting surgeons as well as recruitment centres.

TABLE 15 The PRWE scores (points) for the cast group as a whole compared with those who had a loss of reduction in the cast group

Time point	Total cast group		Loss of reduction in the cast group	
	n	Mean (SD)	*n*	Mean (SD)
Baseline (post injury)	253	84.3 (13.30)	33	86.52 (9.51)
3 months	213	42.08 (23.85)	32	45.46 (22.46)
6 months	202	28.35 (23.35)	30	29.17 (22.61)
12 months	200	21.16 (23.09)	28	20.79 (20.95)
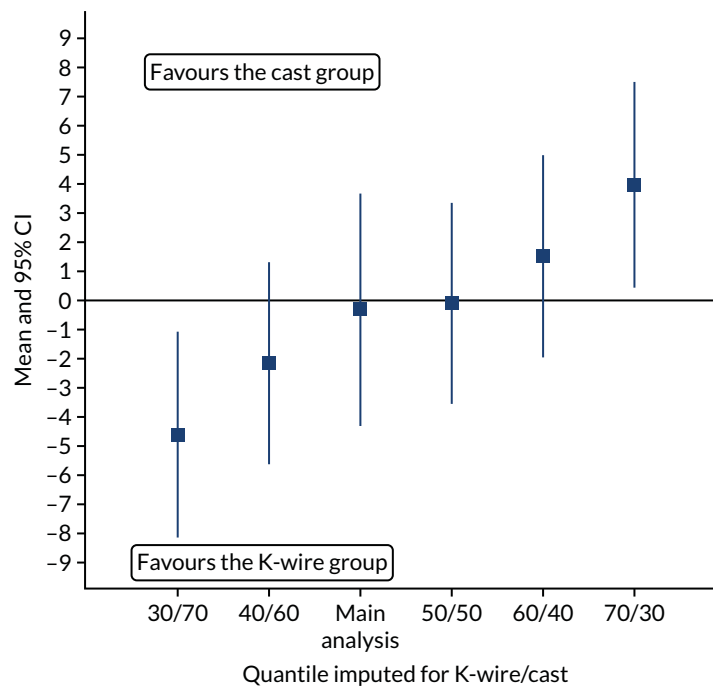
FIGURE 7 The 12-month PRWE scores (points) for imputed quantiles.
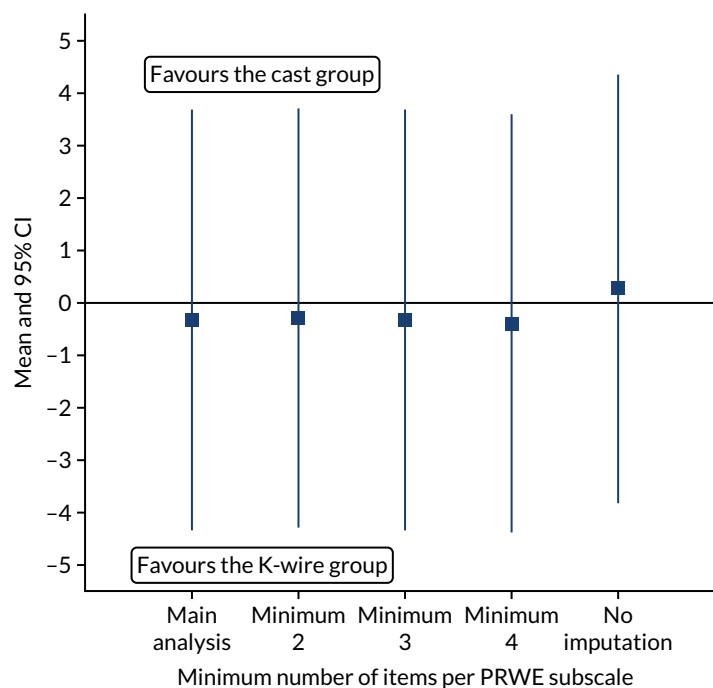
FIGURE 8 The 12-month PRWE scores (points) for different minimum number of items required in the PRWE subscales.

Per protocol

This sensitivity analysis used the same mixed model as in the primary analysis, adjusting for person within recruitment centre as random effects and age and articular extension as fixed effects. Baseline and the other time points were included, with treatment by time point interactions also included to allow time-specific treatment effects to be calculated. The results are presented in *Table 16*. These results support the result from the main analysis that there was no treatment effect at any of the time points on the PRWE (12-month PRWE adjusted mean difference of –0.80 points, 95% CI –5.11 to 3.52 points; $p = 0.72$).

TABLE 16 The PRWE PP population results

Time point	Cast n	Cast Mean score (SD) (points)	K-wire n	K-wire Mean score (SD) (points)	Mean score difference (points) Unadjusted	Mean score difference (points) Adjusted (95% CI)	*p*-value
Baseline (post injury)	188	83.94 (13.62)	189	81.51 (13.67)	−2.43		
3 months	179	42.11 (23.78)	176	40.23 (24.75)	−1.88	−2.12 (−6.51 to 2.27)	0.34
6 months	178	28.52 (23.16)	186	27.53 (22.51)	−0.99	−1.03 (−5.39 to 3.32)	0.64
12 months	189	21.73 (23.38)	191	20.85 (22.42)	−0.88	−0.80 (−5.11 to 3.52)	0.72
AUC over 12 months		38.07[a]		36.67[a]		−1.39 (−6.12 to 3.34)	0.77

a Model estimate.

Multilevel analysis

An analysis using a three-level model with participant within surgeon within recruitment centre to examine potential surgeon (random) effects was fitted, and the results are shown in the *Table 17*. This model incorporated terms that allowed for possible heterogeneity in patients' responses as a result of there being a number of recruiting surgeons as well as recruitment centres, in addition to the fixed effects of the treatment groups, patient age, articular extension and baseline PRWE score. This was different from the primary analysis model, which did not incorporate baseline PRWE score as a covariate as was needed for AUC analysis. As there was no AUC analysis from this model, baseline is included as a covariate, but interaction terms for other time points (3 and 6 months) were retained.

Table 17 shows that the direction of the treatment effect on the 12-month PRWE score was the opposite of that in the main analysis (i.e. of opposite sign) and suggests that there is an adjusted mean difference of 0.65 points favouring cast treatment (95% CI −3.70 to 4.99 points). There was still no statistically significant result for any time point, which reinforced the overall interpretation of the clinical trial results.

Subgroup analysis

There were two predefined subgroups analyses for DRAFFT 2 based on the two clinical stratifying variables (i.e. age and articular extension). These were performed using an extended model to formally test the interaction between each stratifying variable and the treatment factor. The interaction test

TABLE 17 The PRWE three-level (patient within surgeon within recruitment centre) results

Time point	Cast n	Cast Mean score (SD) (points)	K-wire n	K-wire Mean score (SD) (points)	Mean score difference (points) Unadjusted	Mean score difference (points) Adjusted (95% CI)	*p*-value
Baseline (post injury)	253	84.3 (13.30)	243	81.91 (14.52)	−2.39		
3 months	213	42.08 (23.85)	201	41.56 (24.77)	−0.51	0.55 (−3.70 to 4.79)	0.80
6 months	202	28.35 (23.35)	206	27.56 (22.33)	−0.79	0.85 (−3.41 to 5.12)	0.70
12 months	200	21.16 (23.09)	195	20.69 (22.33)	−0.47	0.65 (−3.70 to 4.99)	0.77

results are reported in *Figure 9* as adjusted mean differences and 95% CIs. Two models were fitted: one fitting an interaction term with age and one fitting an interaction term with articular extension. A linear mixed model adjusting for baseline PRWE score, age and articular extension as fixed effects and participant within recruitment centre was used as a base model to perform these analyses; time point (3 and 6 months) interactions with treatment effect were fitted. It is important to note that subgroup analyses are exploratory and hypothesis generating, so results from *Figure 9* should be interpreted with caution. No significant difference between any of the predefined subgroups in treatment effect on the 12-month PRWE score was found.

Adverse events

Most adverse events were reported as complications in *Chapter 2, Secondary outcomes*.

There were 10 other SAEs (cast group, *n* = 5; K-wire group, *n* = 5); all were classified as 'unexpected' and all but one were classified as 'not related'. The other SAE, which was classified as 'unlikely to be related', was a patient readmitted with discitis and primary hyperparathyroidism. Other SAEs included a fall leading to hip fracture, chest pain, removal of a cataract and admission to a psychiatric hospital.
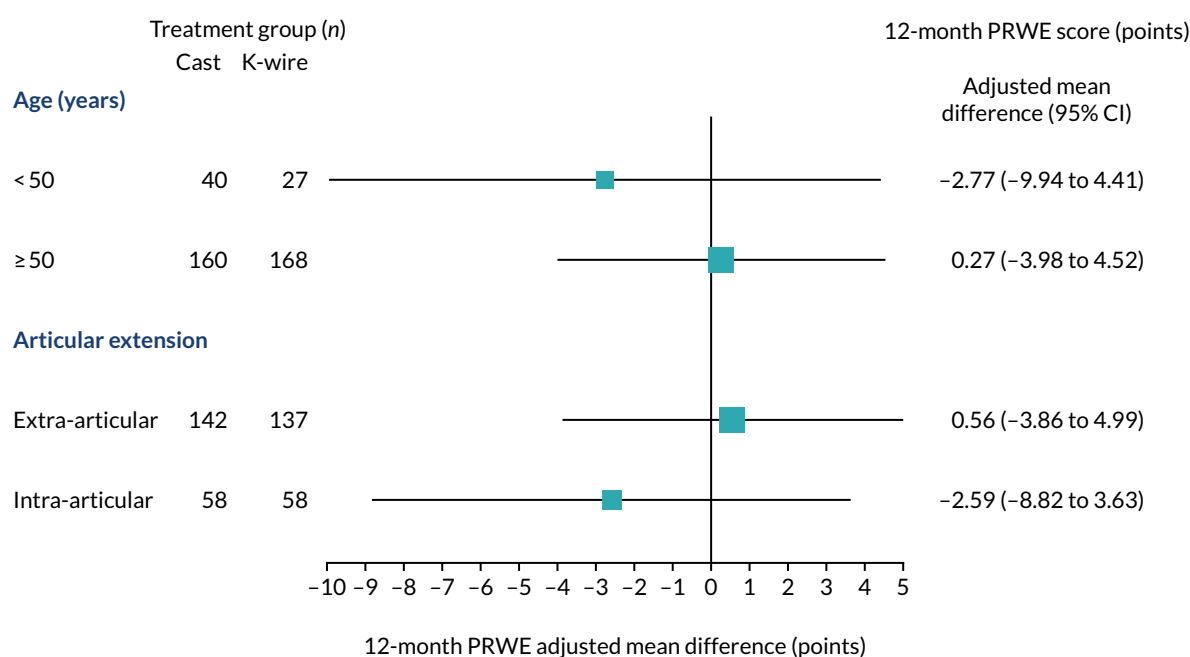
FIGURE 9 Forest plot of predefined clinical subgroups' 12-month PRWE score.

Chapter 4 Health economic evaluation

Completion rate

A complete set of EQ-5D and health-care resource use values (from the NHS and PSS perspective) from baseline to 12 months post randomisation was collected from 290 out of 500 participants (58.0%). Completion rates of all the health-care resource items by treatment group for each time point are shown in *Table 18* and the response rate of each domain of the EQ-5D-5L is presented in *Appendix 2, Table 22*.

TABLE 18 The number (%) of patients with complete data on health-care resource use, by treatment group and follow-up time points between baseline and 12 months (NHS and PSS perspective)

Health-care resource use type	Treatment group, *n* (%)	
	Cast (*N* = 255)	K-wire (*N* = 245)
Data available on health-care resource use only	147 (57.6)	151 (61.6)
Data available on health-care resource use and quality of life	143 (56.1)	147 (60.0)
3 months	*216 (84.7)*	*202 (82.4)*
Subsequent inpatient care	214 (83.9)	202 (82.4)
Outpatient care	214 (83.9)	202 (82.4)
Community care	215 (84.3)	202 (82.4)
Medications	216 (84.7)	201 (82.0)
PSS	216 (84.7)	202 (82.4)
Aids and adaptations	216 (84.7)	200 (81.6)
Time off work	136 (53.3)	126 (51.4)
Additional costs[a]	213 (83.5)	202 (82.4)
6 months	*203 (79.6)*	*206 (84.1)*
Subsequent inpatient care	203 (79.6)	206 (84.1)
Outpatient care	203 (79.6)	206 (84.1)
Community care	202 (79.2)	206 (84.1)
Medications	198 (77.6)	203 (82.9)
PSS	203 (79.6)	205 (83.7)
Aids and adaptations	202 (79.2)	205 (83.7)
Time off work	203 (79.6)	203 (82.9)
Additional costs[a]	202 (79.2)	205 (83.7)
12 months	*200 (78.4)*	*196 (80.0)*
Subsequent inpatient care	199 (78.0)	195 (79.6)
Outpatient care	199 (78.0)	196 (80.0)
Community care	199 (78.0)	195 (79.6)
Medications	199 (78.0)	195 (79.6)
PSS	199 (78.0)	196 (80.0)
Aids and adaptations	199 (78.0)	195 (79.6)
Time off work	197 (77.3)	196 (80.0)
Additional costs[a]	197 (77.3)	195 (79.6)

a Additional costs refer to additional (private) cost items incurred by participants or their next of kin (e.g. travel expenditure, child care and help with housework).

Our data are non-monotonic; that is, participants who did not complete the 3-month questionnaire could have completed the 6- or 12-month questionnaire.

Health-care resource use

The observed health-care resource use recorded by participants is presented *Appendix 2, Table 23*, by treatment group per follow-up time point. There were no significant differences in health-care resource utilisation rates between the treatment groups.

Health-care costs

The mean costs of the key resource inputs associated with the trial are summarised in *Table 19*. The mean unadjusted costs (SE) by treatment groups and follow-up time points, in 2018/19 prices (GBP) (available case). There were no significant differences in the mean cost between treatment groups except

TABLE 19 The mean unadjusted costs (SE) by treatment groups and follow-up time points, in 2018/19 prices (GBP) (available case)

Health-care resource use type	Treatment group, mean unadjusted costs (SE) (£)		Mean difference (£)	Bootstrapped 95% CI (£)	*p*-value[a]
	Cast	K-wire			
Baseline to 12 months					
Initial treatment cost[b]	1363.69 (15.76)	1520.86 (16.52)	157.18	111.78 to 202.96	< 0.001
Treatment of complications[c]	105.15 (18.10)	11.59 (6.28)	−93.56	−131.73 to −57.63	< 0.001
Subsequent inpatient care	24.08 (10.80)	5.58 (5.58)	−18.50	−42.92 to 3.99	0.129
Outpatient care	272.79 (27.72)	267.92 (24.11)	−4.87	−77.47 to 66.40	0.895
Community care	38.56 (6.49)	43.13 (6.49)	4.58	−13.68 to 22.49	0.618
Medications	2.75 (0.75)	0.98 (0.25)	−1.76	−3.43 to −0.37	0.027
PSS	20.51 (15.89)	12.16 (10.79)	−8.36	−49.04 to 26.6	0.664
Aids and adaptations	8.28 (1.06)	7.92 (1.65)	−0.36	−4.05 to 3.79	0.854
Total cost, NHS and PSS	1835.40 (46.96)	1870.15 (38.04)	34.75	−82.51 to 153.21	0.566
Medications, out of pocket	0.78 (0.15)	0.77 (0.19)	−0.01	−0.46 to 0.50	0.982
Time off work	807.70 (158.89)	943.89 (197.48)	136.19	−358.39 to 635.40	0.591
Additional costs	22.65 (4.31)	43.96 (10.25)	21.30	1.25 to 44.50	0.056
Total cost, societal	2666.52 (169.03)	2858.77 (211.42)	192.24	−333.73 to 729.72	0.478
Breakdown: baseline to discharge					
Initial treatment cost[b]	1363.69 (15.76)	1520.86 (16.52)	157.18	111.78 to 202.96	< 0.001
Treatment of complications[c]	105.15 (18.10)	11.59 (6.28)	−93.56	−131.73 to −57.63	< 0.001
Total cost, NHS and PSS	1468.43 (24.18)	1532.45 (17.73)	64.02	4.50 to 123.22	0.033
Breakdown: discharge to 3 months					
Subsequent inpatient care	11.45 (8.13)	0.00 (0.00)	−11.45	−29.26 to 0.00	0.160
Outpatient care	155.63 (14.10)	162.38 (14.45)	6.74	−32.00 to 46.28	0.739
Community care	25.36 (5.38)	23.62 (4.01)	−1.74	−15.57 to 11.00	0.796

TABLE 19 The mean unadjusted costs (SE) by treatment groups and follow-up time points, in 2018/19 prices (GBP) (available case) (*continued*)

Health-care resource use type	Treatment group, mean unadjusted costs (SE) (£)		Mean difference (£)	Bootstrapped 95% CI (£)	*p*-value[a]
	Cast	K-wire			
Medications	1.89 (0.70)	0.86 (0.24)	−1.04	−2.65 to 0.23	0.166
PSS	24.19 (18.75)	14.80 (13.15)	−9.39	−57.91 to 32.99	0.682
Aids and adaptations	5.26 (0.69)	5.46 (1.61)	0.20	−2.67 to 4.09	0.909
Total cost, NHS and PSS	187.86 (22.77)	170.64 (18.19)	−17.22	−76.39 to 38.88	0.555
Medications, out of pocket	0.77 (0.16)	0.77 (0.17)	0.00	−0.46 to 0.45	0.999
Time off work	1060.71 (210.84)	1104.92 (214.37)	44.21	−547.71 to 627.81	0.883
Additional costs	19.03 (3.58)	42.09 (10.49)	23.06	3.94 to 46.95	0.039
Total cost, societal	770.17 (120.86)	765.34 (119.28)	−4.83	−342.56 to 326.69	0.977
Breakdown: 3–6 months					
Subsequent inpatient care	0.00 (0.00)	6.61 (6.61)	6.61	0.00 to 19.83	0.318
Outpatient care	102.73 (14.24)	100.70 (13.41)	−2.03	−40.23 to 36.35	0.918
Community care	15.42 (4.23)	17.45 (3.72)	2.03	−9.33 to 12.57	0.718
Medications	0.42 (0.16)	0.18 (0.06)	−0.24	−0.61 to 0.07	0.165
PSS	0.02 (0.02)	0.00 (0.00)	−0.02	−0.07 to 0.00	0.318
Aids and adaptations	2.67 (0.75)	2.12 (0.70)	−0.54	−2.55 to 1.50	0.598
Total cost, NHS and PSS	97.13 (13.13)	107.19 (14.90)	10.06	−27.44 to 50.11	0.613
Medications, out of pocket	0.30 (0.13)	0.26 (0.17)	−0.04	−0.42 to 0.41	0.866
Time off work	1236.75 (428.96)	2046.50 (671.53)	809.75	−652.09 to 2376.41	0.316
Additional costs	5.59 (2.75)	5.60 (2.17)	0.01	−7.22 to 6.35	0.998
Total cost, societal	218.15 (47.94)	312.51 (79.44)	94.36	−79.97 to 290.85	0.310
Breakdown: 6–12 months					
Subsequent inpatient care	18.31 (10.66)	0.00 (0.00)	−18.31	−41.31 to 0.00	0.087
Outpatient care	74.83 (18.18)	59.77 (9.75)	−15.07	−57.27 to 23.13	0.466
Community care	7.70 (2.21)	12.35 (4.87)	4.65	−4.85 to 15.86	0.385
Medications	1.16 (0.59)	0.21 (0.12)	−0.95	−2.28 to 0.04	0.114
PSS	0.00 (0.00)	0.02 (0.02)	0.02	0.00 to 0.05	0.319
Aids and adaptations	2.13 (0.67)	2.06 (0.79)	−0.08	−2.05 to 2.07	0.942
Total cost, NHS and PSS	81.98 (18.37)	59.87 (10.16)	−22.11	−64.66 to 17.02	0.293
Medications, out of pocket	0.00 (0.00)	0.07 (0.06)	0.06	−0.01 to 0.19	0.318
Time off work	2134.93 (1228.59)	3471.31 (1228.91)	1336.37	−2066.78 to 4526.59	0.449
Additional costs	2.83 (1.64)	5.44 (2.96)	2.61	−3.27 to 10.02	0.442
Total cost, societal	209.78 (80.14)	248.47 (83.23)	38.69	−193.97 to 261.49	0.738

a Computed using *t*-tests.
b Initial treatment cost is the sum of the cost of the cast or K-wires, surgeon and admission stay.
c Treatment of complications cost is the sum of cost of further surgery, cast change and complication of further surgery.

for the following: the mean initial treatment cost was higher in the K-wire group [£1520.86 (SE £16.52)] than in the cast group [£1363.69 (SE £15.76); *t*-test, *p* < 0.001], but the mean cost of treatment of complications between baseline and 12 months post randomisation was lower in the K-wire group [£11.59 (SE £6.28)] than in the cast group [£105.15 (SE £18.10); *t*-test, *p* < 0.001]. In terms of medications from baseline to 12 months post randomisation, those randomised to the cast group incurred a higher mean cost [£2.75 (SE £0.75)] than those in the K-wire group [£0.98 (SE £0.25); *t*-test, *p* = 0.027]. The mean additional cost, which refers to additional (private) cost items incurred by participants and their next of kin (e.g. travel expenditure, child care and help with housework), between baseline and 3 months post randomisation was higher in the K-wire group [£42.09 (SE £10.49)] than in the cast group [£19.03 (SE £3.58); *t*-test, *p* = 0.039].

Health utilities

The summary statistics of the EQ-5D utility scores for all observed cases across all time points by treatment groups are presented in *Tables 10* and *11*. There was no evidence of a difference in the EQ-5D utility between treatment groups at any time point and the mean QALY gain in the cast group [0.706 (SE 0.013)] was also not statistically significant from that in the K-wire group [0.707 (SE 0.011); *t*-test, *p* = 0.955].

Cost-effectiveness results

The incremental cost-effectiveness analysis results for the K-wire group compared with the cast group in the base-case analysis and in each of the sensitivity and subgroup analyses are shown in *Table 20*. The probability that manipulation with K-wire fixation is cost-effective at cost-effectiveness thresholds of £15,000, £20,000 and £30,000 per QALY gained is also presented. The NMB, cost-effectiveness acceptability curve and cost-effectiveness plane with the confidence ellipse for the base-case analysis and in each of the sensitivity and subgroup analyses are presented in *Figures 10–16*.

The base-case analysis showed that manipulation with K-wire fixation was dominated [higher cost (£29.65, 95% CI –£94.85 to £154.15)] and almost as effective (–0.007, 95% CI –0.03 to 0.016) when compared with the cast group from the NHS and PSS perspective. In addition, the probability of manipulation with K-wire fixation being cost-effective was < 0.5 at the assumed cost-effectiveness thresholds of £15,000, £20,000 and £30,000 per QALY, whereas the NMB was negative. Therefore, the base-case analysis indicated that manipulation with K-wire fixation is unlikely to be cost-effective relative to the use of a cast among the studied population.

Both sensitivity analyses (societal perspective and complete-case) showed similar results that supported the base-case finding that manipulation with K-wire fixation was dominated. The probability of manipulation with K-wire fixation being cost-effective relative to the use of a cast among the studied population was < 0.5 in both sensitivity analyses, and the NMB was negative.

The subgroup analyses showed similar results to the base-case finding in that manipulation with K-wire fixation was found to be unlikely to be cost-effective relative to manipulation followed by a cast in the studied population (probability < 0.5 and negative NMB) using the prespecified cost-effectiveness thresholds. In the intra-articular extension group, the ICER was £22,801 per QALY (a point estimate), which suggests that manipulation with K-wire fixation would not be cost-effective relative to the use of a cast at a cost-effectiveness threshold of £15,000 per QALY or £20,000 per QALY. In the intra-articular extension group, the ICER was £22,801 per QALY (a point estimate), which suggests that manipulation with K-wire fixation would likely not be cost-effective (probability of being cost-effective at 0.55) relative to the use of a cast at a cost-effectiveness threshold of £15,000 or £20,000 per QALY.

TABLE 20 Incremental cost-effectiveness analysis of manipulation followed by a moulded cast compared with manipulation with K-wire fixation

Analysis	Incremental cost (£) (bootstrapped 95% CI)	Incremental QALYs (bootstrapped 95% CI)	ICER (£/QALY)	Probability K-wire is cost-effective at specified cost-effectiveness threshold		
				£15,000	£20,000	£30,000
Base-case						
NHS and PSS perspective: imputed costs and QALYs, covariate adjusted	29.65 (−94.85 to 154.15)	−0.007 (−0.03 to 0.016)	−4296.24 (dominated; north-west quadrant)	0.24	0.24	0.25
Sensitivity						
1. Societal perspective: imputed costs and QALYs, covariate adjusted	399.44 (−147.73 to 946.6)	−0.007 (−0.03 to 0.016)	−57,870.32 (dominated; north-west quadrant)	0.06	0.07	0.09
2. NHS and PSS perspective: complete-case costs and QALYs, covariate adjusted	59.57 (−91.96 to 211.09)	−0.006 (−0.037 to 0.026)	−10,674.63 (dominated; north-west quadrant)	0.28	0.30	0.32
Subgroup						
1. NHS and PSS perspective: imputed costs and QALYs, covariate adjusted						
i. < 50 years	49.02 (−222.92 to 320.97)	−0.012 (−0.055 to 0.031)	−4106.06 (dominated; north-west quadrant)	0.26	0.26	0.27
ii. ≥ 50 years	21.58 (−119.61 to 162.78)	−0.005 (−0.032 to 0.022)	−4188.54 (dominated; north-west quadrant)	0.32	0.33	0.34
2. NHS and PSS perspective: imputed costs and QALYs, covariate adjusted						
i. Extra-articular extension	94.85 (−41.14 to 230.84)	−0.007 (−0.034 to 0.019)	−12,896.62 (dominated; north-west quadrant)	0.17	0.19	0.22
ii. Intra-articular extension	−148.54 (−427.29 to 130.22)	−0.007 (−0.055 to 0.042)	22,801.42 (south-west quadrant)	0.55	0.51	0.48

(a)

(b)

(c)

FIGURE 10 Base-case analysis of K-wire vs. cast. (a) NMB; (b) cost-effectiveness acceptability curve; and (c) confidence ellipse on the cost-effectiveness plane.

(a)

(b)

(c)
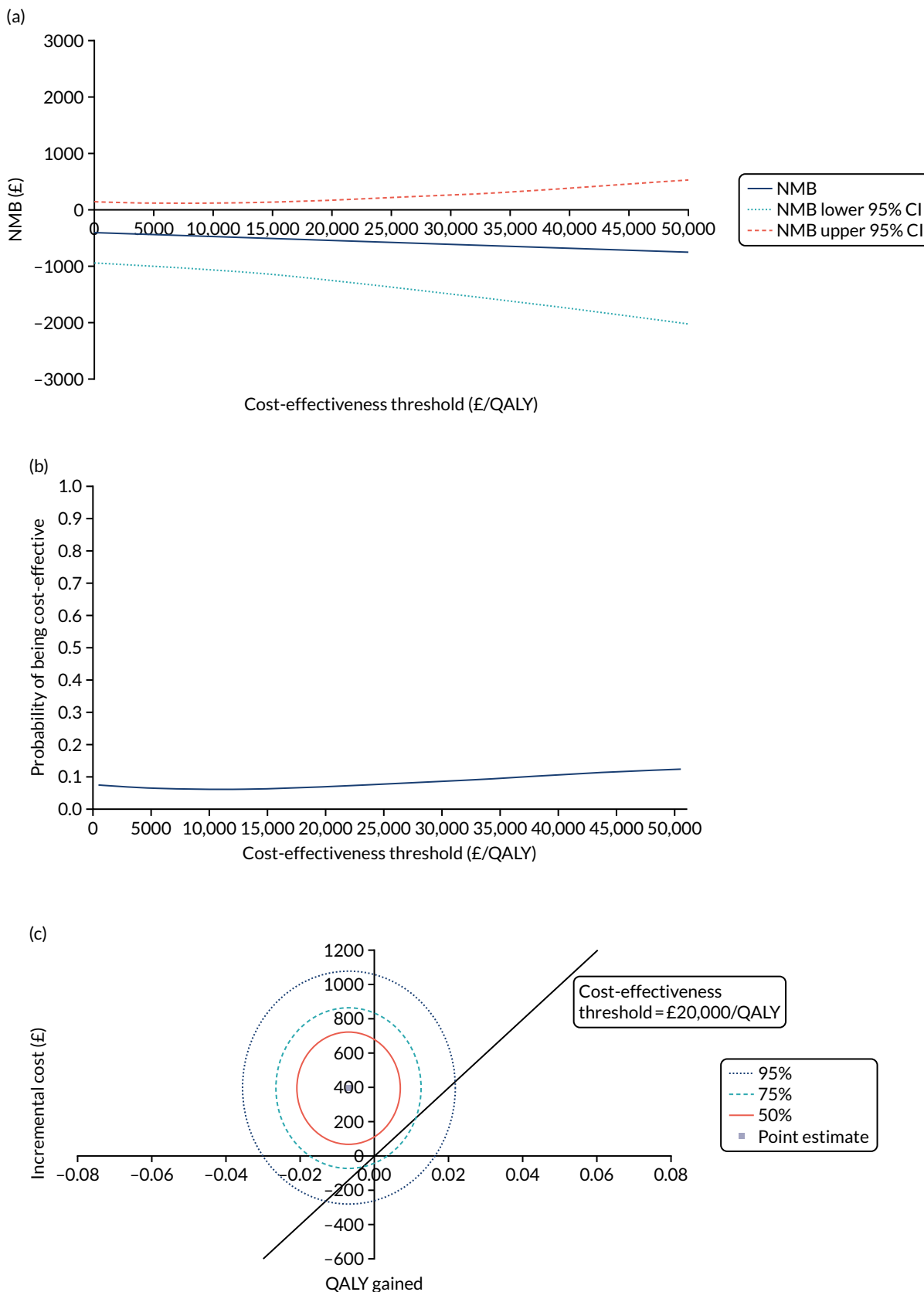
FIGURE 11 Sensitivity analysis (societal perspective) of K-wire vs. cast. (a) NMB; (b) cost-effectiveness acceptability curve; and (c) confidence ellipse on the cost-effectiveness plane.
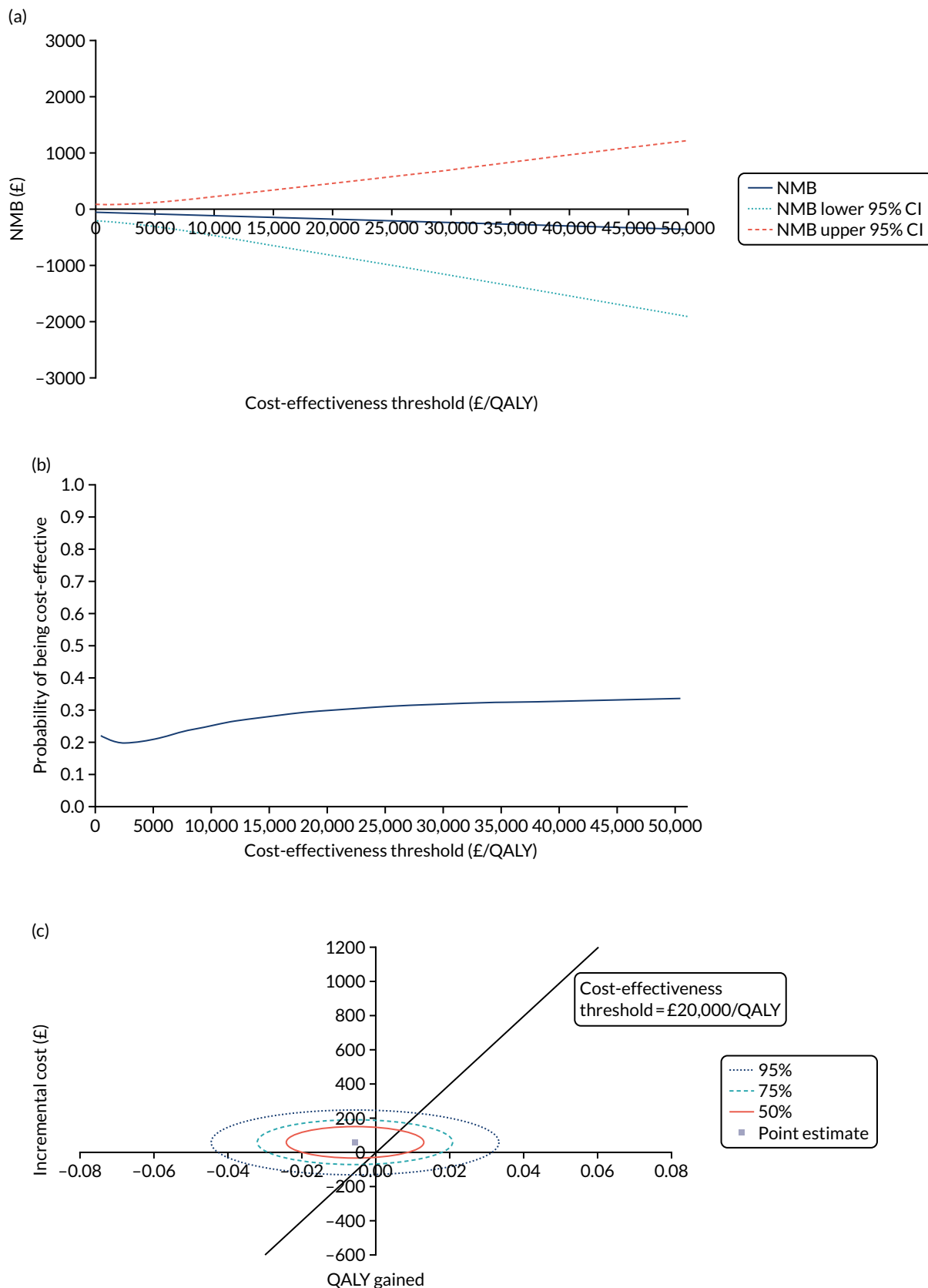
FIGURE 12 Sensitivity analysis (complete-case analysis) of K-wire vs. cast. (a) NMB; (b) cost-effectiveness acceptability curve; and (c) confidence ellipse on the cost-effectiveness plane.

Health Technology Assessment 2022 Vol. 26 No. 11

(a)

(b)

(c)
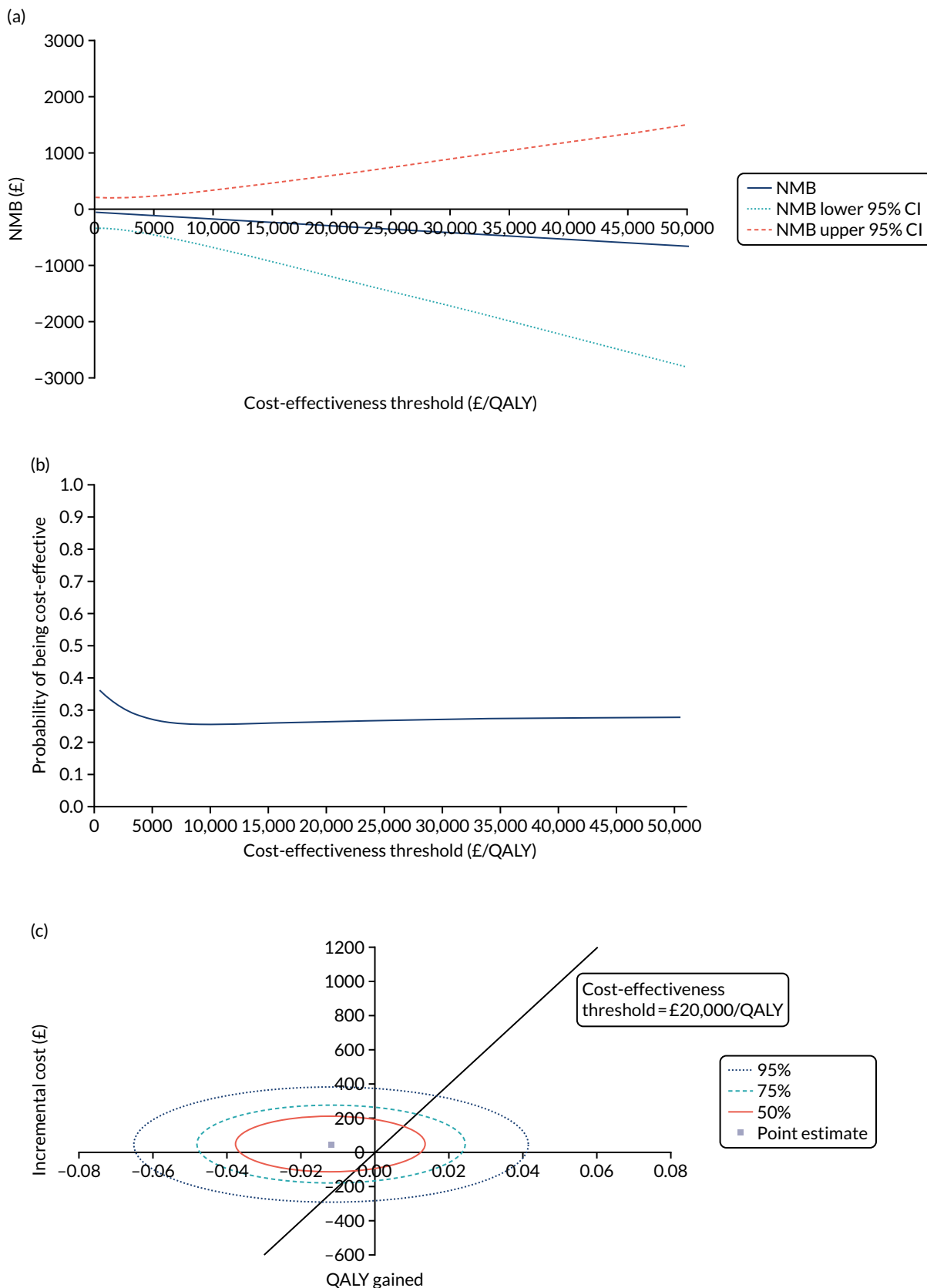
FIGURE 13 Subgroup analysis (aged < 50 years) of K-wire vs. cast. (a) NMB; (b) cost-effectiveness acceptability curve; and (c) confidence ellipse on the cost-effectiveness plane.

(a)

(b)

(c)
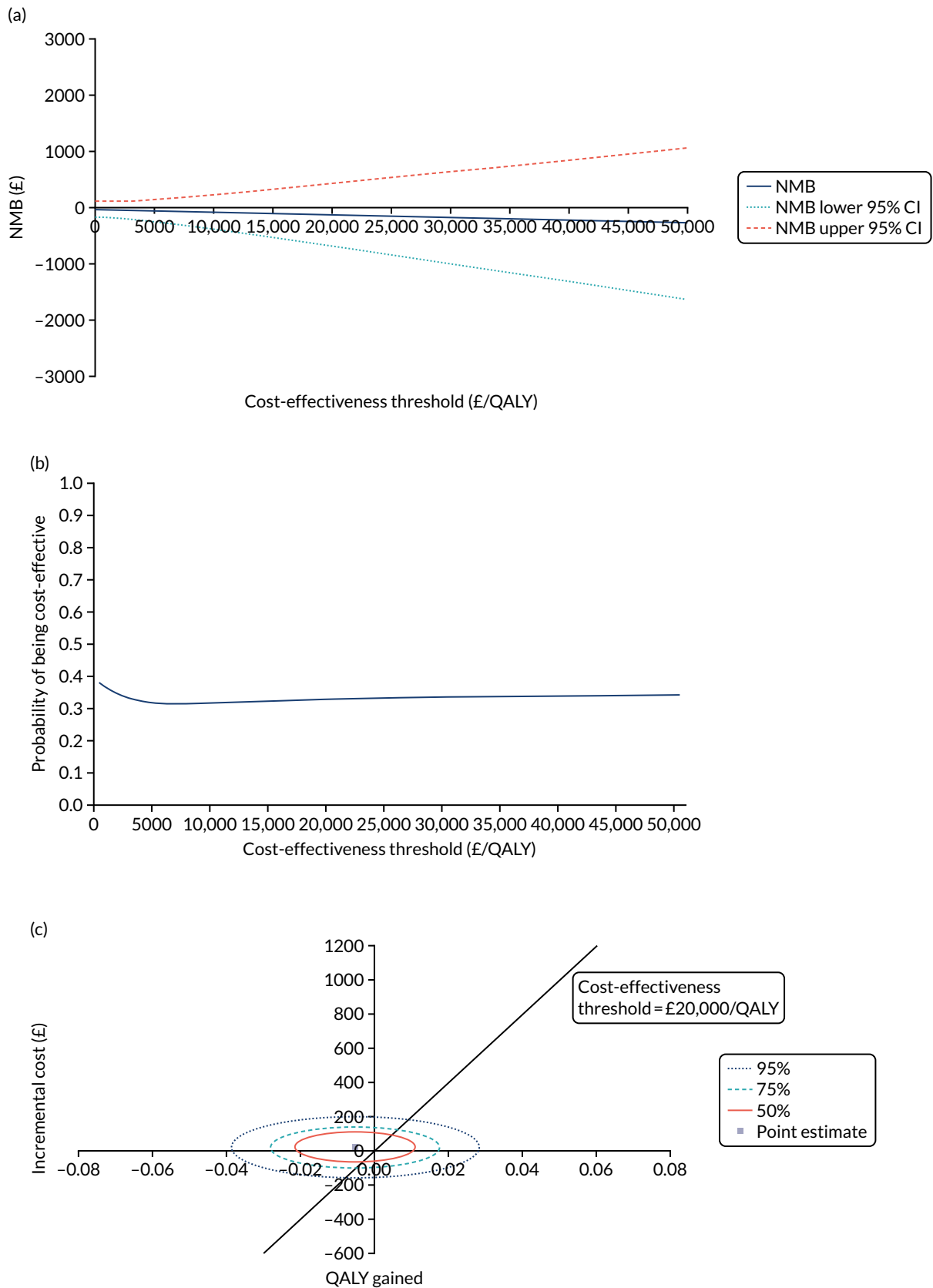
FIGURE 14 Subgroup analysis (aged ≥ 50 years) of K-wire vs. cast. (a) NMB; (b) cost-effectiveness acceptability curve; and (c) confidence ellipse on the cost-effectiveness plane.

(a)

(b)

(c)
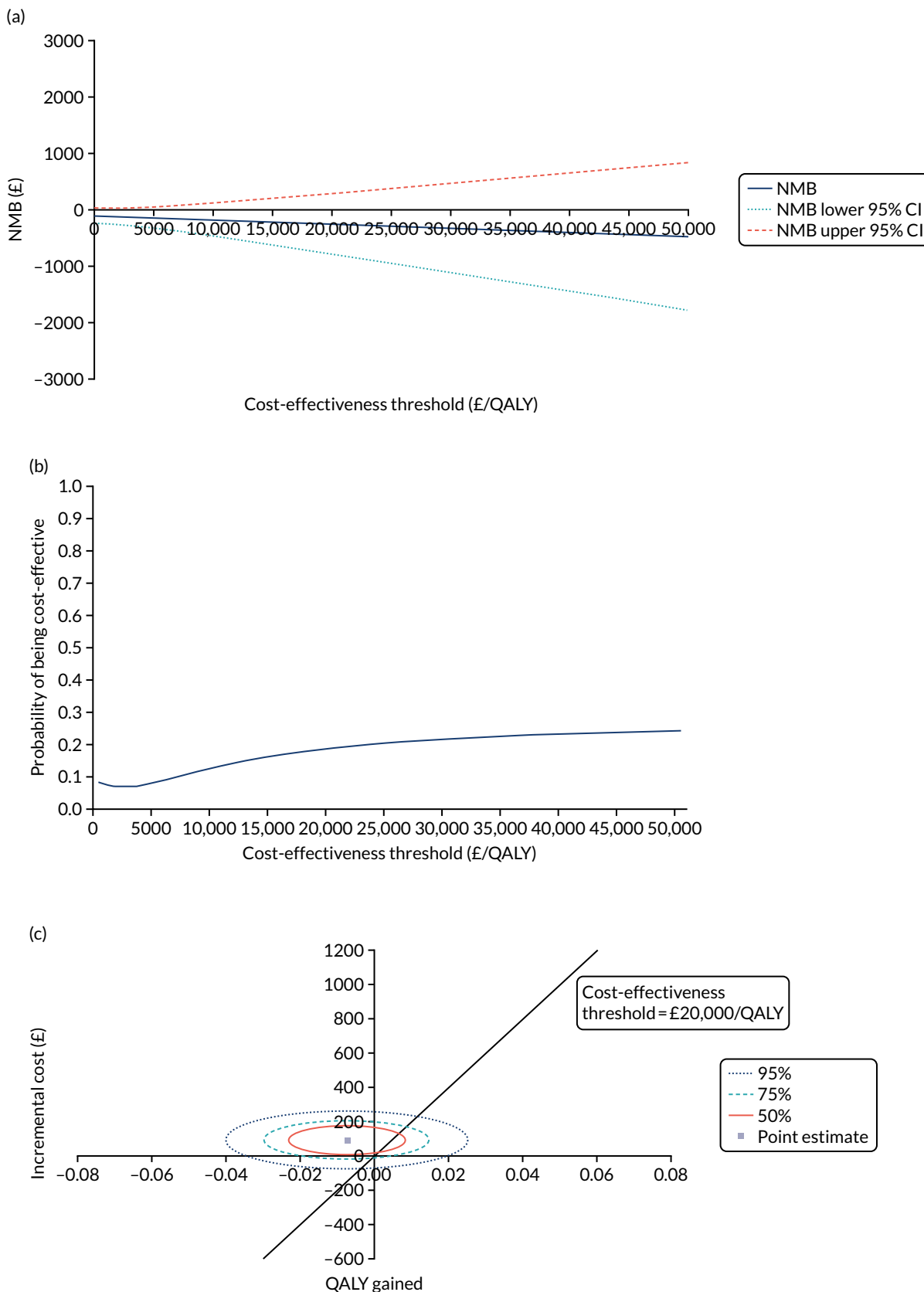
FIGURE 15 Subgroup analysis (extra-articular extension) of K-wire vs. cast. (a) NMB; (b) cost-effectiveness acceptability curve; and (c) confidence ellipse on the cost-effectiveness plane.
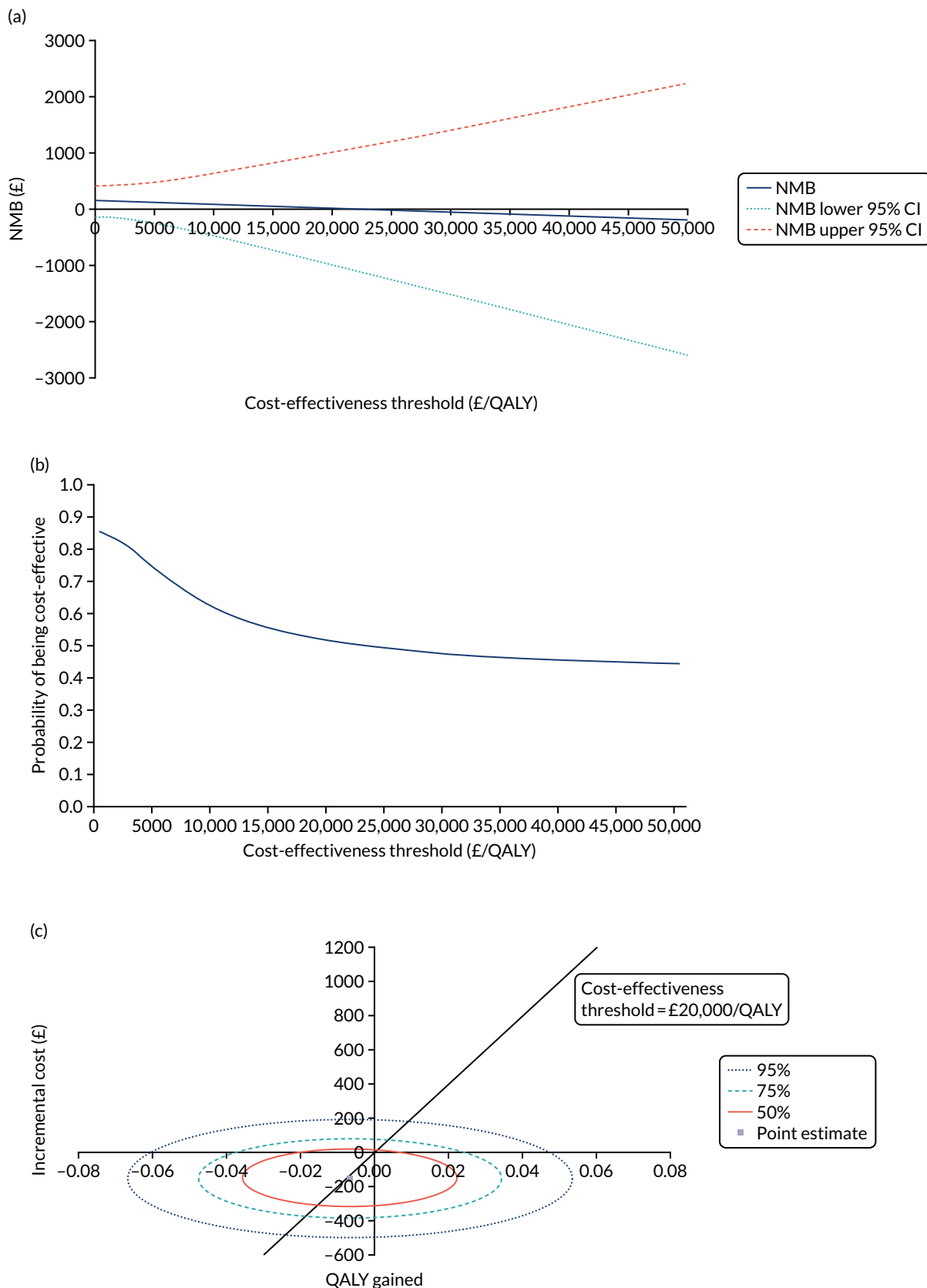
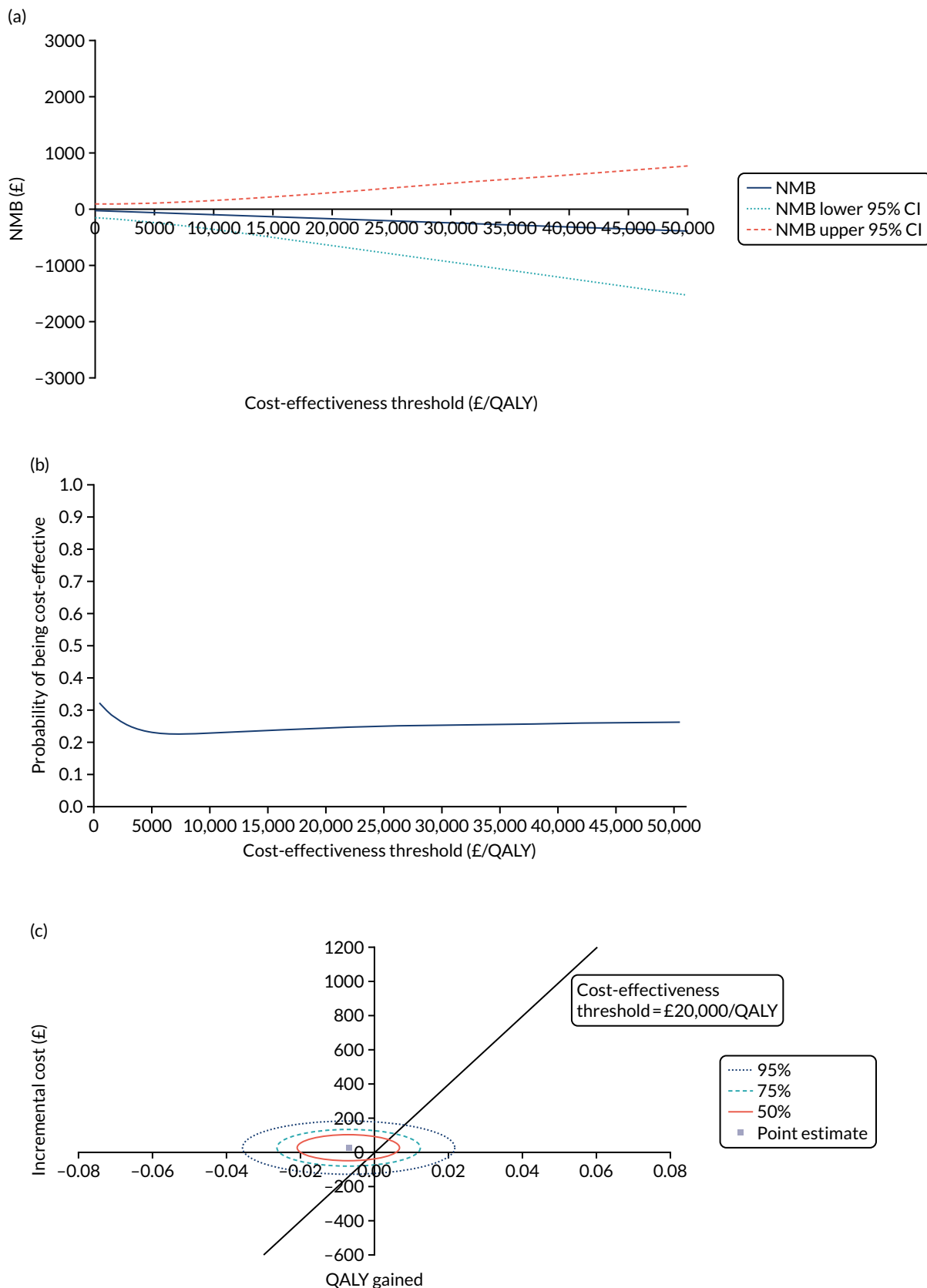FIGURE 16 Subgroup analysis (intra-articular extension) of K-wire vs. cast. (a) NMB; (b) cost-effectiveness acceptability curve; and (c) confidence ellipse on the cost-effectiveness plane.

Chapter 5 Discussion

Recruitment

Between January 2017 and March 2019, a total of 2636 patients with a dorsally displaced fracture of the distal radius were screened in the recruitment centres. A total of 1441 patients met one or more of the exclusion criteria. Somewhat surprisingly, 338 of these patients were excluded because the injury was > 2 weeks old. Although some patients with an injury to the distal radius do try to manage this themselves without visiting the hospital, this is not very common in the case of a displaced fracture as, in such cases, there is often a visible deformity. It seems more likely that this exclusion criterion was met by patients whose fracture was initially managed non-operatively, but in whom fracture displacement or re-displacement subsequently occurred or was managed > 2 weeks after the index injury. It is common practice in many NHS hospitals for patients to undergo manipulation of a displaced distal radius fracture in the emergency department or a minor injuries unit and to then be followed up with repeat radiographs in the orthopaedic fracture clinic. Re-displacement can then occur in the second or third week. This in itself does raise questions about the optimal initial management of these injuries (see *Chapter 6, Future research recommendations*). A total of 104 patients were excluded because their fracture was open with a Gustilo grading > 1°. As the outcome in such cases is usually dictated more by the associated soft-tissue injury than by the underlying fracture, it is appropriate that these patients were excluded. A total of 222 patients were excluded because they were deemed to be unable to adhere to the trial procedures or complete questionnaires. This proportion is similar to that found in the first DRAFFT trial,[4] and is in keeping with the fact that distal radius fractures are common in patients with cognitive impairment. A total of 284 patients were excluded during screening because the treating surgeon felt that the fracture would require open reduction and hence could not be treated with either of the two trial treatments. Again, this is in keeping with the fact that a proportion of patients with intra-articular fractures have an obvious step or gap in the radiocarpal joint surface that cannot be reduced by a closed manipulation of the fracture.

The great majority of patients who met the eligibility criteria and who were approached for their informed consent were happy to take part in the trial, but 196 patients declined, most commonly because they 'did not want to take part in research'.

In addition to the 196 patients who declined to consent, 495 potentially eligible patients were not approached for consent into the trial because the treating clinician had a strong preference for a particular treatment. In 151 cases, the surgeon preferred one of the two treatments under investigation (cast group, *n* = 31; K-wire group, *n* = 120). Although the exclusion of these patients does affect the external validity of the trial, this is a relatively small number compared with the 500 patients who were included in the trial. The remaining patients (*n* = 344) were not offered the opportunity to enter the trial because the consulting surgeon had a preferred 'other' treatment. In 154 cases, this other treatment was not specified in the screening data. For the other 190 patients, some surgeons recommended external fixation, but the most commonly recommended treatment was plate fixation.

There is likely to have been some overlap in this group with the exclusion criterion 'the articular surface of the fracture cannot be reduced by indirect means', but we do not have radiographical data to confirm this. However, despite the results of the DRAFFT trial (which found no evidence that plate fixation was superior to K-wire fixation if a dorsally displaced fracture of the distal radius could be reduced without opening the fracture),[4] and the subsequent national guidelines,[47] some surgeons still routinely offer plate fixation to all patients for whom they are recommending surgical fixation for a distal radius fracture.[48] Excluding this group of patients may also have affected the generalisability of

the trial but, again, this is a relatively small number compared with the 500 participants who were offered the chance to take part and consented to do so.

In the DRAFFT trial,[4] patients were randomised to their treatment group before their surgery. This was in keeping with common practice at the time but did lead to some potentially eligible patients being excluded preoperatively if the surgeon was not confident that a closed reduction of the fracture could be achieved during surgery. Therefore, to prevent unnecessary exclusions, and facilitated by the increased availability of real-time online randomisation via operating theatre computers, DRAFFT 2 was designed such that randomisation was planned to take place after a closed reduction of the fracture had been achieved in the operating theatre, but before any fixation was performed. Patients who gave their informed consent before the reduction was attempted were advised that, if their surgeon felt that the manipulation of the fracture was unsatisfactory and that the fracture could not be reduced without opening the skin, they would not be randomised into the trial but the surgeon would proceed with open reduction and fixation, as per routine clinical practice. A total of 179 patients who consented to enter the trial were subsequently excluded before randomisation because the surgeon was unable to achieve or maintain a closed reduction intraoperatively. This is lower than the proportion of patients in the DRAFFT trial[4] who were excluded preoperatively because the surgeon was uncertain that a closed reduction of the fracture could be achieved (40% of potentially eligible patients in the DRAFFT trial[4] were excluded on this criterion), indicating that the use of real-time randomisation following the manipulation of the fracture did help to improve the external validity of the trial. This is worthy of note in the design of future studies.

Participants and treatment groups

Five hundred participants were randomised into the trial. The larger centres screened more eligible patients, but recruitment of participants was distributed across all of the recruitment centres apart from two that did not recruit any participants. The recruitment centres represent the range of major trauma centres, trauma units and local emergency hospitals that routinely treat patients with distal radius fracture in the NHS. Therefore, we can be confident that the participants were representative of the UK population with distal radius fractures.

A total of 255 participants were allocated to the cast group and 245 were allocated to the K-wire group. We anticipated some crossover of participants immediately after randomisation but, in fact, only 27 participants did not receive their allocated treatment. Twelve participants in the cast group crossed over to the K-wire group and four participants in the K-wire group crossed over to the cast group. The remaining participants underwent plate fixation ($n = 10$) or other surgery ($n = 2$). As part of the statistical analysis plan, we included a secondary PP analysis of the PRWE outcomes to supplement the primary ITT analysis, but, given the relatively small number of participants who did not receive their allocated treatment, we were reassured that non-compliance was unlikely to affect the integrity of the trial findings.

The baseline characteristics of the two groups were well balanced in terms of both participant demographics and pre-injury patient-reported wrist function and HRQoL. Fracture characteristics were also well balanced, with 72% of participants in both treatment groups having extra-articular fractures. This distribution was expected, as intra-articular fractures are those more likely to require open reduction and hence be excluded from the trial as per the eligibility criteria.

In both groups, the treatments were most commonly performed by an orthopaedic consultant (48%) or a specialist trainee under supervision (33%), which reflects routine clinical practice in the UK. As with all surgical interventions, the experience of the surgeon may affect the outcome of the surgery beyond the choice of treatment. Therefore, we were pleased to note that there was reasonable balance of senior surgeons (consultants or staff and associate specialists) across the groups. If anything, the proportion of procedures performed by senior surgeons was higher in the cast group (67%) than in the K-wire

group (54%), which is interesting given that the K-wire fixation treatment may be considered the more 'technically demanding' of the two. However, both treatments are used routinely throughout the NHS. and the surgeons in both groups were very experienced in performing both treatments: over 80% of the 361 surgeons involved in the trial reported that they had performed > 20 procedures of each type before the trial started. In the group undergoing surgical fixation with K-wires, two or three 1.6-mm wires was the most common option, with surgeons using an equal mix of interfragmentary and Kapanji insertion techniques, which reflects routine clinical practice in the UK. In the cast group, the great majority of participants were treated with a plaster of Paris cast moulded around the full circumference of the wrist and forearm in the manner of a 'close-contact' cast. This again reflects routine practice, as plaster of Paris can be moulded to maintain fracture reduction more easily than the alternative cast material, fibreglass.

As anticipated, the number of patients who withdrew or were lost to follow-up increased slightly during the 1 year following randomisation. In the sample size calculation, we estimated the loss to follow-up to be 20% and, indeed, follow-up was 79% in the cast group and 80% in the K-wire group at the 12 months post randomisation point. In total, 499 out of 500 participants provided data to inform the primary analysis (as data from earlier time points were used in this analysis). As the trial also exceeded the minimum recruitment target of 460 participants (500 participants being randomised), we can be confident that the trial fulfilled the assumptions made in the sample size calculation.

Results

Primary outcome
This trial found no evidence that manipulation and surgical fixation with K-wires was superior to manipulation followed by a moulded cast in the management of acute dorsally displaced distal radius fractures. The CIs excluded our target difference of 6 points. There was no evidence of a difference between the treatments at 3 or 6 months, or in the AUC for the PRWE score over the 12 months post randomisation. There was no evidence of a difference in the secondary PP analysis of the PRWE score or in the pre-planned sensitivity analysis to examine surgeon within recruitment centre effects. Nor was there any evidence of a difference in the pre-planned subgroup analyses for patients above and below 50 years of age and for patients with extra-articular compared with intra-articular fractures.

These data provide strong evidence that, if a closed reduction of the fracture can be achieved, surgical fixation with K-wires does not provide superior wrist function to moulded casting for patients with a dorsally displaced fracture of the distal radius.

Secondary outcomes
The trial also found no evidence that manipulation and surgical fixation with K-wires was superior to manipulation and a moulded cast in the management of acute dorsally displaced distal radius fractures in terms of HRQoL. There was no evidence of a difference between the treatments at 3 or 6 months, or in the AUC for the EQ-5D index score in the 12 months post randomisation. Nor was there any evidence of a difference in the EQ-5D VAS scores at any time point. These data provide corroborating evidence to support the analysis of the primary outcome measure.

In terms of complications, the overall number of complications was small in both treatment groups. In the 12 months post randomisation, one DVT was reported in each group and there were five diagnoses of CRPS in the cast group and seven in the K-wire group. These findings are in keeping with the low rate of complications reported in the literature and the complication profile reported in the DRAFFT trial.[4]

However, there was a statistically significant and clinically important difference in the number of further interventions performed for loss of fracture reduction in the 6 weeks following the index manipulation of the fracture: 33 (13%) participants in the cast group compared with one participant (< 1%) in the

K-wire group required a further intervention. This finding is not unexpected, as the purpose of surgical fixation is to secure the reduction of the fracture by holding the bones in position using metalwork, in this case by passing metal wires across the fracture to hold the bone fragments in their anatomical position while they heal. By contrast, a moulded cast provides only indirect support to the bones following their manipulation. As soft-tissue swelling settles after the injury, the cast becomes looser and the reduction of the bone fragments may be lost. These data provide important information for clinicians advising patients about their treatment options following this common injury. If treated in a moulded cast, 13% of patients (one in eight) will require a further intervention for loss of fracture reduction in the first 6 weeks. This is in keeping with a recent Cochrane review, which found a 12% 're-displacement' rate among patients treated with a plaster cast after manipulation.[8]

To investigate the outcome of those patients who required a further intervention for loss of fracture reduction compared with those in the cast group as a whole, we performed an unplanned secondary analysis of the PRWE outcomes in these participants. The mean PRWE score in those participants requiring further intervention following their cast treatment ($n = 33$) was 21 (SD 21) points at 12 months post randomisation, which is the same as in the cast group as a whole [mean 2 (SD 23 points)]. Although these data are reassuring, in that participants did not seem to suffer longer-term deficits in wrist function despite requiring a further intervention to treat their fracture, this review was unplanned and should be interpreted with caution.

Health economic evaluation

The economic evaluation in this trial indicates that manipulation and K-wire fixation is dominated by manipulation followed by a moulded cast (i.e. K-wire fixation is more costly but no more effective). Therefore, K-wire fixation is unlikely to be cost-effective among adult patients who have sustained an acute dorsally displaced fracture of the distal radius.

This finding was consistent across the pre-planned sensitivity analyses and subgroup analyses except in the intra-articular extension subgroup, in which the probability that K-wire would be cost-effective relative to a cast was slightly above 0.5 when a cost-effectiveness threshold of £15,000 per QALY or £20,000 per QALY was applied. This appears to be driven by the difference in the mean cost of treatment of complications, complications being more common in the subgroup with intra-articular extension. The mean cost of treatment of complications in the cast group [£147.03 (SE £47.62)] was higher than that in the K-wire group [£2.95 (SE £0.50)] in the intra-articular extension subgroup analysis.

The initial treatment cost was higher in the K-wire group than in the cast group because of the cost of the K-wires, the cost of the theatre consumables and the longer time in the operating theatre. However, the cost of treatment of complications was higher in the cast group. This was because those in the cast group reported more further surgeries than those in the K-wire group between baseline and 6 weeks after discharge, specifically the loss of fracture reduction leading to further surgical intervention.

The mean cost of medications from baseline to 12 months post randomisation was higher in the cast group than in the K-wire group, and this was attributable to two participants taking risedronate (one for 30 days and one for 42 days), which has a higher unit cost than other medications. It is unlikely that the use of risedronate is associated with the choice of treatment in the trial, but both participants happened to be randomised to the cast group. If a t-test was performed without these two observations, the mean cost of the medication in the cast group would drop from £2.75 (SE £0.75) to £1.94 (SE £0.48) and there would not be a statistically significant difference in the mean cost of medications between the K-wire and cast groups (t-test, $p = 0.074$). Likewise, additional (non-NHS) costs were statistically significantly different between the K-wire and cast groups because one participant incurred an exceptionally high travel and help with housework cost between discharge and 3 months. If a t-test was performed without this single observation, there would not be a statistically significant difference in the mean additional costs between the K-wire and cast groups.

Of note, the analysis presented here differs from the published SHEAP[19] in two ways. First, it differs in the measurement of the cost of the initial treatment. As the duration of the operation was significantly different between the two groups [31.2 minutes (SE 1.7 minutes) in the cast group compared with 44.2 minutes (SE 1.7 minutes) in the K-wire group; *t*-test, $p < 0.001$], we used the cost associated with the time that each patient spent in the operating theatre, instead of using only the cost of surgical staff, to obtain more comprehensive estimate of the overall cost of the treatment. It has been shown that staff costs account for only 65% of operating theatre time.[31] To avoid double-counting the cost of the surgeon's time, the cost of surgical staff was not computed. Of note, the Healthcare Resource Group code includes a standard cost for operating theatre time, thus overestimating the cost of surgery, but, because this code is assigned to patients undergoing both treatments, this would not lead to any difference between groups. Second, we added a cost-effectiveness threshold of £15,000 per QALY in our analysis to reflect current trends in health-care decision-making.

Limitations

Recruiting patients to clinical trials in the context of urgent surgery is difficult. A concern before this trial started was that patients and/or surgeons would not be willing to take part. In fact, only 196 patients declined to take part in the study. A bigger issue was equipoise in the surgical community. A total of 495 potentially eligible patients were not offered the chance to take part in the trial because the treating surgeon had a clinical preference for a particular treatment; 120 patients were offered manipulation and K-wire fixation, 31 manipulation and cast and 344 other treatments or unspecified. Although these numbers are low in relation to the total of 2636 patients who were screened as part of the study, they do have an impact on the external validity of the trial.

A further anticipated limitation was crossover of participants from the allocated treatment. However, only 27 of the 500 participants did not receive their allocated treatment. The secondary PP analysis, that is the analysis that included only those participants who received their allocated treatment, confirmed the results of the primary ITT analysis, finding no evidence of a difference between the two treatment groups.

There was also some loss to follow-up in the trial, but this was in keeping with the loss to follow-up of 20% used in the sample size calculation, which indicated that a minimum of 460 participants should be recruited. As the trial recruited 500 participants, we can be confident that DRAFFT 2 fulfilled the assumptions made in the sample size calculation.

The final major limitation of the trial was that neither the treating clinicians nor the participants could be blind to the treatments. This is, of course, inevitable in the case of surgical interventions, as the wires are clearly visible to the patient and surgeon when removed. Assessment bias was minimised by the fact that the surgeons providing the interventions played no part in the assessment of the participants' outcomes.

Chapter 6 Conclusions

Surgical fixation with K-wires was not found to be superior to moulded casting in terms of wrist function following manipulation of an acute dorsally displaced fracture of the distal radius. If a closed reduction of the fracture can be achieved, clinicians may consider the application of a moulded cast as a safe and cost-effective alternative to surgical fixation.

Future research recommendations

With regard to fractures of the distal radius, further health technology assessments are recommended to investigate the following:

- What is the optimal technique for immobilisation of a dorsally displaced distal radius fracture that does not require manipulation to achieve reduction?
- What are the optimal techniques for immobilisation of a dorsally displaced distal radius fracture following the first manipulation of the fracture?
- What is the optimal technique for providing pain relief to patients who require a reduction of a dorsally displaced distal radius fracture?
- What is the optimal regime for rehabilitation of the patient after immobilisation of their wrist for a fracture of the distal radius?

Furthermore, further research to explore patient treatment preferences could inform all future research in this area.

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Basingstoke and North Hampshire Hospital – Hampshire Hospitals NHS Foundation Trust.

Blackpool Victoria Hospital – Blackpool Teaching Hospitals NHS Foundation Trust.

Cumberland Infirmary – North Cumbria University Hospitals NHS Trust.

Eastbourne District General Hospital – East Sussex Healthcare NHS Trust.

Ipswich Hospital – East Suffolk and North Essex NHS Foundation Trust.

James Cook University Hospital – South Tees NHS Hospital Trust.

John Radcliffe Hospital – Oxford University Hospitals NHS Foundation Trust.

Leicester General Hospital – University Hospitals of Leicester NHS Trust.

Luton & Dunstable Hospital – Luton & Dunstable University Hospital NHS Foundation Trust.

Manchester Royal Infirmary – Manchester University NHS Foundation Trust.

Musgrove Park Hospital – Somerset NHS Foundation Trust.

North Tyneside General Hospital – Northumbria Healthcare NHS Foundation Trust.

Northampton General Hospital – Northampton General Hospital NHS Trust.

Peterborough City Hospital – North West Anglia NHS Foundation Trust.

Pinderfields Hospital – Mid Yorkshire Hospitals NHS Trust.

Poole Hospital – Poole Hospital NHS Foundation Trust.

Royal Berkshire Hospital – Royal Berkshire NHS Foundation Trust.

Royal Blackburn Hospital – East Lancashire Hospitals NHS Trust.

Royal Cornwall Hospital – Royal Cornwall Hospitals NHS Trust.

Royal Derby Hospital – University Hospitals of Derby and Burton NHS Trust.

Royal Hampshire County Hospital – Hampshire Hospitals NHS Foundation Trust.

Royal Stoke University Hospital – University Hospitals of North Midlands NHS Trust.

Royal Victoria Infirmary – Newcastle upon Tyne NHS Trust.

Salisbury District Hospital – Salisbury NHS Foundation Trust.

Sandwell General Hospital – Sandwell and West Birmingham Hospitals NHS Trust.

Southampton General Hospital – University Hospital Southampton NHS Foundation Trust.

Southmead Hospital – North Bristol NHS Trust.

St. George's University of London – St George's University Hospitals NHS Foundation Trust.

Tunbridge Wells Hospital – Maidstone and Tunbridge Wells NHS Trust.

University Hospital (Coventry) – University Hospitals Coventry and Warwickshire NHS Trust.

University Hospital Llandough – Cardiff and Vale University Health Board.

University Hospital of North Tees – North Tees and Hartlepool NHS Foundation Trust.

Whiston Hospital – St Helens and Knowsley Teaching Hospitals NHS Trust.

Wrightington Hospital – Wrightington, Wigan and Leigh NHS Foundation Trust.

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Data-sharing statement

All data requests should be submitted to the corresponding author for consideration. Access to available anonymised data may be granted following review.

Patient data

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety, and plan NHS services. Patient data should be kept safe and secure, to protect everyone's privacy, and it's important that there are safeguards to make sure that it is stored and used responsibly. Everyone should be able to find out about how patient data are used. #datasaveslives You can find out more about the background to this citation here: https://understandingpatientdata.org.uk/data-citation.

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Appendix 1　The DRAFFT 2 Collaborators

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Appendix 2 Health economics supplementary data

TABLE 21 Summary of unit cost (in 2018/19 GBP)

Resource item	Unit type	Unit cost (£)	Source
DRAFFT 2 cost			
Fixation surgery			
K-wires	Each	2.96	*NHS Supply Chain Catalogue*[20]
Reinforced gown XL	Each	1.76	*NHS Supply Chain Catalogue*[20]
Surgical visor masks	Each	0.48	*NHS Supply Chain Catalogue*[20]
Theatre masks	Each	0.09	*NHS Supply Chain Catalogue*[20]
Biogel gloves	Each	1.90	*NHS Supply Chain Catalogue*[20]
Image intensifier cover	Each	4.26	*NHS Supply Chain Catalogue*[20]
Laceration pack	Each	13.55[a]	DRAFFT[4]
Sterilisation of drill	Each	10.23[a]	DRAFFT[4]
Sterile dressing gauze	Each	0.24	*NHS Supply Chain Catalogue*[20]
Full cast	Each	3.21	*NHS Supply Chain Catalogue*[20]
Non-sterile gloves	Each	0.58	*NHS Supply Chain Catalogue*[20]
Surface wipes	Each	0.05	*NHS Supply Chain Catalogue*[20]
Black bag	Each	0.03	*NHS Supply Chain Catalogue*[20]
Yellow bag	Each	0.09	*NHS Supply Chain Catalogue*[20]
Polythene bag for extras	Each	0.02	*NHS Supply Chain Catalogue*[20]
Incontinence pad	Each	0.11	*NHS Supply Chain Catalogue*[20]
Hospital stay			
Intensive care unit	Per day	834.00	*NHS Reference Costs* 2018/19[21]
Acute trauma ward	Per day	353.99[a]	*NHS Reference Costs* 2017/18[49]
Rehabilitation ward	Per day	443.00	*NHS Reference Costs* 2018/19[21]
Treatment after index surgery			
Ulna shortening	LOS of 6 days	5662.79	*NHS Reference Costs* 2018/19[21]
Revision to plate and screw/removal of metalwork/washout of joint	LOS of 6 days	4144.66	*NHS Reference Costs* 2018/19[21]
Debridement	LOS of 2 days	1209.00	*NHS Reference Costs* 2018/19[21]
Injection	LOS of 1 day	190.00	*NHS Reference Costs* 2018/19[21]
Carpal tunnel decompression/surgery to tendon/manipulation/wire fixation	LOS of 4 days	5471.73	*NHS Reference Costs* 2018/19[21]

TABLE 21 Summary of unit cost (in 2018/19 GBP) (*continued*)

Resource item	Unit type	Unit cost (£)	Source
Inpatient care			
Orthopaedics: wrist/arm	LOS of 2 days	1043.00	*NHS Reference Costs* 2018/19[21]
Orthopaedics: other bones	LOS of 4 days	5776.00	*NHS Reference Costs* 2018/19[21]
Orthopaedics: other bones	Per excess bed-day	373.43[a]	*NHS Reference Costs* 2017/18[49]
Other non-surgery	Per day	353.99[a]	*NHS Reference Costs* 2017/18[49]
Day case	LOS of 1 day	1094.00	*NHS Reference Costs* 2018/19[21]
Rehabilitation ward	Per day	443.00	*NHS Reference Costs* 2018/19[21]
Outpatient care			
Orthopaedics/fracture clinic	Per visit	120.00	*NHS Reference Costs* 2018/19[21]
Physiotherapist (NHS)	Per hour	38.88[a]	*Unit Costs of Health and Social Care 2015*[50]
Physiotherapist (private)	Per hour	75.00	The Physiotherapy Centre 2020[51]
Pathology (blood tests)	Per test	2.79	*NHS Reference Costs* 2018/19[21]
Radiology	Per test	30.59	*NHS Reference Costs* 2018/19[21]
Emergency department: wrist	Per visit	168.00	*NHS Reference Costs* 2018/19[21]
Emergency department: others	Per visit	168.00	*NHS Reference Costs* 2018/19[21]
Others:			
Bone health assessment	Per visit	71.00	*NHS Reference Costs* 2018/19[21]
Falls clinic	Per visit	83.21[a]	*Unit Costs of Health and Social Care 2018*[52]
Injection	Per visit	204.00	*NHS Reference Costs* 2018/19[21]
Neurophysiologist	Per visit	425.00	*NHS Reference Costs* 2018/19[21]
Occupational health advisor	Per hour	90.00	UMS Occupational Health Department 2020[53]
Occupational therapist	Per visit	83.00	*NHS Reference Costs* 2018/19[21]
Psychologist	Per visit	183.00	*NHS Reference Costs* 2018/19[21]
Rheumatologist	Per visit	147.00	*NHS Reference Costs* 2018/19[21]
Primary and community care			
General practitioner (surgery visit)	Per minute	4.30	*Unit Costs of Health and Social Care 2019*[24]
General practitioner (home visit)	Per minute	5.32[a]	*Unit Costs of Health and Social Care 2010*[54]
General practitioner (telephone contact)	7.1 minutes	27.62[a]	*Unit Costs of Health and Social Care 2015*[50]
Practice nurse (surgery visit)	Per hour	42.00	*Unit Costs of Health and Social Care 2019*[24]
Practice nurse (home visit)	Per hour	45.02[a]	*Unit Costs of Health and Social Care 2010*[54]
Practice nurse (telephone contact)	Per hour	36.83[a]	*Unit Costs of Health and Social Care 2010*[54]

TABLE 21 Summary of unit cost (in 2018/19 GBP) (*continued*)

Resource item	Unit type	Unit cost (£)	Source
District nurse (surgery visit)	Per hour	51.16[a]	*Unit Costs of Health and Social Care 2015*[50]
District nurse (home visit)	Per hour	93.10[a]	*Unit Costs of Health and Social Care 2010*[54]
Physiotherapist (surgery visit)	Per hour	36.83[a]	*Unit Costs of Health and Social Care 2014*[55]
Physiotherapist (home visit)	Per hour	36.83[a]	*Unit Costs of Health and Social Care 2014*[55]
Occupational therapist (surgery visit)	Per hour	48.00	*Unit Costs of Health and Social Care 2019*[24]
Occupational therapist (home visit)	Per visit	47.06[a]	*Unit Costs of Health and Social Care 2010*[54]
Other			
Radiology	Per hour	37.00	*Unit Costs of Health and Social Care 2019*[24]
Aids and adaptations			
Wrist support (e.g. brace/splint)	Each	4.54	*NHS Supply Chain Catalogue*[20]
Grab rail	Each	48.00	*Unit Costs of Health and Social Care 2019*[24]
Dressing aids	Each	6.78	*NHS Supply Chain Catalogue*[20]
Long-handled aids (e.g. shoe horn, reacher)	Each	4.25	*NHS Supply Chain Catalogue*[20]
Bathing aids	Each	3.92	*NHS Supply Chain Catalogue*[20]
Kitchen aids (e.g. jar/tin openers)	Each	5.86	*NHS Supply Chain Catalogue*[20]
Other			
Computer aids (e.g. ergonomic keyboard)	Each	8.18	*NHS Supply Chain Catalogue*[20]
Exercise aids (e.g. exercise band, putty)	Each	30.08	*NHS Supply Chain Catalogue*[20]
PSS			
Frozen Meals on Wheels	Per meal	3.17	Meals on Wheels 2020[56]
Hot Meals on Wheels	Per meal	6.75[a]	*Unit Costs of Health and Social Care 2014*[55]
Laundry services	Per load	4.90	North Yorkshire County Council 2020[57]
Calls to NHS 111	Per call	14.32[a]	*Financial Times* 2017[58]
Social worker	Per hour	51.00	*Unit Costs of Health and Social Care 2019*[24]
Care worker/help at home	Per hour	28.00	*Unit Costs of Health and Social Care 2019*[24]
Lost productivity			
Median wage	Per week	585.00	Office for National Statistics[34]

TABLE 21 Summary of unit cost (in 2018/19 GBP) (*continued*)

Resource item	Unit type	Unit cost (£)	Source
Medications *Analgesic*			
Algesal cream 50 g	Each	1.49	*NHS Electronic Drug Tariff*[22]
Aspirin 75 mg	Pack of 28	1.47	BNF[23]
Co-codamol 8 mg/500 mg	Pack of 100	3.17	*NHS Electronic Drug Tariff*[22]
Co-codamol 30 mg/500 mg	Pack of 100	4.60	*NHS Electronic Drug Tariff*[22]
Codeine 15 mg	Pack of 28	1.04	*NHS Electronic Drug Tariff*[22]
Codeine 30 mg	Pack of 28	1.21	*NHS Electronic Drug Tariff*[22]
Codeine 60 mg	Pack of 28	1.79	*NHS Electronic Drug Tariff*[22]
Co-dydramol 10 mg/500 mg	Pack of 30	0.95	*NHS Electronic Drug Tariff*[22]
Diclofenac 50 mg	Pack of 28	7.41	*NHS Electronic Drug Tariff*[22]
Dihydrocodeine 30 mg	Pack of 28	1.19	*NHS Electronic Drug Tariff*[22]
Gabapentin 100 mg	Pack of 100	1.98	*NHS Electronic Drug Tariff*[22]
Gabapentin 300 mg	Pack of 100	3.04	*NHS Electronic Drug Tariff*[22]
Gabapentin 600 mg	Pack of 100	7.93	*NHS Electronic Drug Tariff*[22]
Lidocaine 5%	Pack of 30	72.40	*NHS Electronic Drug Tariff*[22]
Ibuprofen 200 mg	Pack of 24	1.09	*NHS Electronic Drug Tariff*[22]
Ibuprofen 400 mg	Pack of 24	1.05	*NHS Electronic Drug Tariff*[22]
Ibuprofen 600 mg	Pack of 84	4.08	*NHS Electronic Drug Tariff*[22]
Morphine 5 mg	Pack of 60	3.29	*NHS Electronic Drug Tariff*[22]
Morphine 10 mg	Pack of 60	5.20	*NHS Electronic Drug Tariff*[22]
Morphine 15 mg	Pack of 60	9.10	*NHS Electronic Drug Tariff*[22]
Morphine 20 mg	Pack of 56	10.61	*NHS Electronic Drug Tariff*[22]
Morphine 30 mg	Pack of 60	12.47	*NHS Electronic Drug Tariff*[22]
Morphine 60 mg	Pack of 60	24.32	*NHS Electronic Drug Tariff*[22]
Naproxen 250 mg	Pack of 28	3.29	*NHS Electronic Drug Tariff*[22]
Naproxen 500 mg	Pack of 28	3.02	*NHS Electronic Drug Tariff*[22]
Nefopam 30 mg	Pack of 90	5.66	*NHS Electronic Drug Tariff*[22]
Oxycodone 5 mg	Pack of 28	12.52	*NHS Electronic Drug Tariff*[22]
Oxycodone 10 mg	Pack of 56	25.04	*NHS Electronic Drug Tariff*[22]
Oxycodone 15 mg	Pack of 56	38.12	*NHS Electronic Drug Tariff*[22]
Paracetamol 500 mg	Pack of 100	2.19	*NHS Electronic Drug Tariff*[22]
Solpadeine 12.8 mg/500 mg	Pack of 30	4.91	*NHS Electronic Drug Tariff*[22]
Tramadol 50 mg	Pack of 60	4.60	*NHS Electronic Drug Tariff*[22]
Tramadol 100 mg	Pack of 60	14.47	*NHS Electronic Drug Tariff*[22]
Tramadol 150 mg	Pack of 60	21.71	*NHS Electronic Drug Tariff*[22]
Flucloxacillin 250 mg	Pack of 28	1.67	*NHS Electronic Drug Tariff*[22]
Flucloxacillin 500 mg	Pack of 28	2.68	*NHS Electronic Drug Tariff*[22]

TABLE 21 Summary of unit cost (in 2018/19 GBP) (*continued*)

Resource item	Unit type	Unit cost (£)	Source
Pregabalin 75 mg	Pack of 56	2.47	*NHS Electronic Drug Tariff*[22]
Pregabalin 150 mg	Pack of 56	3.09	*NHS Electronic Drug Tariff*[22]
Pregabalin 300 mg	Pack of 56	5.28	*NHS Electronic Drug Tariff*[22]
Clopidogrel 75 mg	Pack of 28	1.49	*NHS Electronic Drug Tariff*[22]
Heparinoid 0.30%	Each	3.99	*NHS Electronic Drug Tariff*[22]
Other bone protection medication			
Alendronate 10 mg	Pack of 28	2.63	*NHS Electronic Drug Tariff*[22]
Bisphosphonate			
Risedronate 35 mg	Pack of 4	11.34	*NHS Electronic Drug Tariff*[22]
Supplement and vitamin			
Adcal 1.5 g	Pack of 100	8.70	*NHS Electronic Drug Tariff*[22]
Calcichew 800 units/2.5 g	Pack of 30	6.75	*NHS Electronic Drug Tariff*[22]
Calcium and colecalciferol 400 units/1.5 g	Pack of 60	2.95	*NHS Electronic Drug Tariff*[22]
Vitamin D 800 units/1.25 g	Pack of 30	4.21	*NHS Electronic Drug Tariff*[22]
Vitamin D 20,000 units	Pack of 30	29.00	*NHS Electronic Drug Tariff*[22]
Vitamin D 50,000 units	Pack of 3	4.95	*NHS Electronic Drug Tariff*[22]

LOS, length of stay; UMS, University of East Anglia Medical Services; XL, extra large.
a   Unit cost has been inflated to 2018/19 prices.

TABLE 22 Response rate (%) of EQ-5D-5L by follow-up time points and treatment groups

|		Time point									
		Pre injury		Post injury		3 months		6 months		12 months	
Domain	Levels	Cast (n = 255)	K-wire (n = 245)	Cast (n = 255)	K-wire (n = 245)	Cast (n = 216)	K-wire (n = 202)	Cast (n = 203)	K-wire (n = 206)	Cast (n = 200)	K-wire (n = 196)
Mobility	1	229 (89.8)	219 (89.4)	199 (78.0)	185 (75.5)	181 (83.8)	167 (82.7)	172 (84.7)	168 (81.6)	168 (84.0)	161 (82.1)
	2	11 (4.3)	12 (4.9)	22 (8.6)	30 (12.2)	12 (5.6)	18 (8.9)	13 (6.4)	21 (10.2)	14 (7.0)	18 (9.2)
	3	9 (3.5)	9 (3.7)	20 (7.8)	17 (6.9)	16 (7.4)	13 (6.4)	9 (4.4)	15 (7.3)	13 (6.5)	11 (5.6)
	4	5 (2.0)	4 (1.6)	7 (2.7)	2 (0.8)	7 (3.2)	4 (2.0)	8 (3.9)	1 (0.5)	3 (1.5)	6 (3.1)
	5	0 (0.0)	0 (0.0)	5 (2.0)	9 (3.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Self-care	1	241 (94.5)	241 (98.4)	7 (2.7)	11 (4.5)	108 (50.0)	96 (47.5)	135 (66.5)	141 (68.4)	160 (80.0)	150 (76.5)
	2	8 (3.1)	2 (0.8)	59 (23.1)	59 (24.1)	75 (34.7)	70 (34.7)	52 (25.6)	51 (24.8)	25 (12.5)	32 (16.3)
	3	3 (1.2)	2 (0.8)	92 (36.1)	101 (41.2)	30 (13.9)	27 (13.4)	13 (6.4)	12 (5.8)	14 (7.0)	11 (5.6)
	4	1 (0.4)	0 (0.0)	58 (22.7)	40 (16.3)	2 (0.9)	8 (4.0)	2 (1.0)	1 (0.5)	0 (0.0)	2 (1.0)
	5	1 (0.4)	0 (0.0)	37 (14.5)	31 (12.7)	1 (0.5)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Usual activities	1	231 (90.6)	233 (95.1)	5 (2.0)	7 (2.9)	52 (24.1)	42 (20.8)	92 (45.3)	88 (42.7)	111 (55.5)	101 (51.5)
	2	13 (5.1)	5 (2.0)	24 (9.4)	18 (7.3)	87 (40.3)	76 (37.6)	75 (36.9)	80 (38.8)	64 (32.0)	61 (31.1)
	3	5 (2.0)	5 (2.0)	70 (27.5)	74 (30.2)	63 (29.2)	66 (32.7)	31 (15.3)	32 (15.5)	22 (11.0)	27 (13.8)
	4	3 (1.2)	2 (0.8)	47 (18.4)	53 (21.6)	6 (2.8)	12 (5.9)	3 (1.5)	5 (2.4)	2 (1.0)	7 (3.6)
	5	2 (0.8)	0 (0.0)	107 (42.0)	91 (37.1)	8 (3.7)	6 (3.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
Pain	1	200 (78.4)	194 (79.2)	5 (2.0)	5 (2.0)	28 (13.0)	15 (7.4)	44 (21.7)	42 (20.4)	88 (44.0)	71 (36.2)
	2	32 (12.5)	34 (13.9)	45 (17.6)	44 (18.0)	98 (45.4)	103 (51.0)	109 (53.7)	115 (55.8)	70 (35.0)	90 (45.9)
	3	18 (7.1)	15 (6.1)	107 (42.0)	111 (45.3)	81 (37.5)	64 (31.7)	40 (19.7)	43 (20.9)	32 (16.0)	24 (12.2)
	4	4 (1.6)	2 (0.8)	64 (25.1)	59 (24.1)	7 (3.2)	18 (8.9)	7 (3.4)	4 (1.9)	8 (4.0)	10 (5.1)
	5	0 (0.0)	0 (0.0)	31 (12.2)	24 (9.8)	2 (0.9)	2 (1.0)	2 (1.0)	1 (0.5)	1 (0.5)	1 (0.5)
Anxiety/ depression	1	198 (77.6)	193 (78.8)	131 (51.4)	122 (49.8)	127 (58.8)	130 (64.4)	140 (69.0)	147 (71.4)	144 (72.0)	141 (71.9)
	2	28 (11.0)	31 (12.7)	55 (21.6)	70 (28.6)	54 (25.0)	42 (20.8)	36 (17.7)	38 (18.4)	31 (15.5)	34 (17.3)
	3	21 (8.2)	17 (6.9)	39 (15.3)	34 (13.9)	22 (10.2)	25 (12.4)	21 (10.3)	14 (6.8)	19 (9.5)	14 (7.1)
	4	6 (2.4)	4 (1.6)	21 (8.2)	5 (2.0)	8 (3.7)	4 (2.0)	2 (1.0)	5 (2.4)	4 (2.0)	5 (2.6)
	5	1 (0.4)	0 (0.0)	6 (2.4)	11 (4.5)	5 (2.3)	1 (0.5)	3 (1.5)	1 (0.5)	0 (0.0)	2 (1.0)
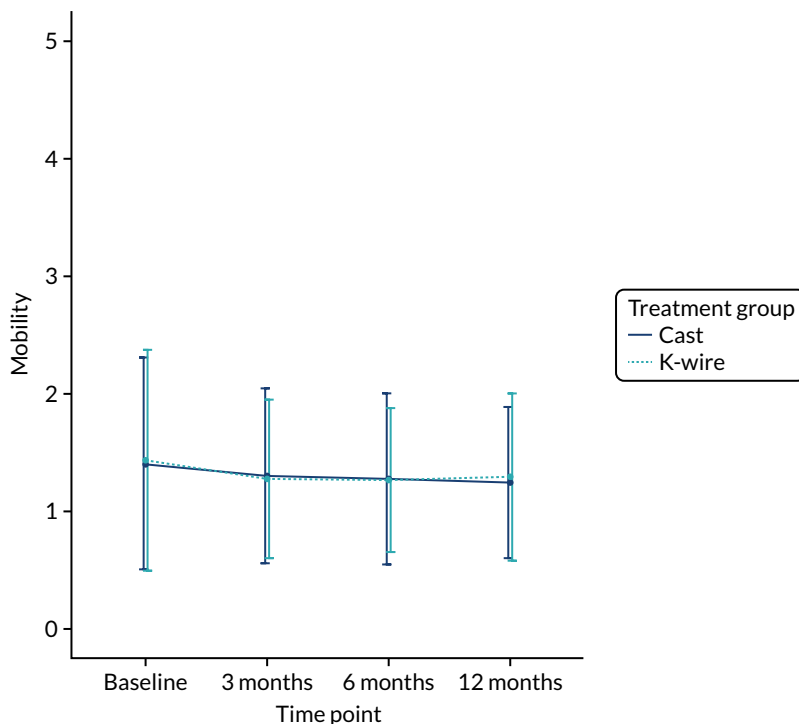
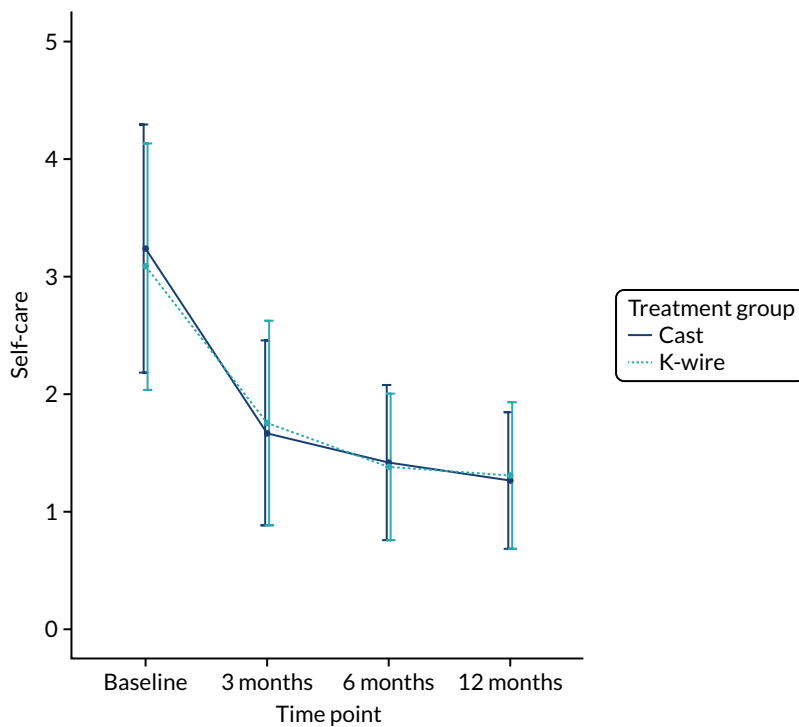FIGURE 17 Change in EQ-5D-5L mobility domain by treatment group over time.

FIGURE 18 Change in EQ-5D-5L self-care domain by treatment group over time.
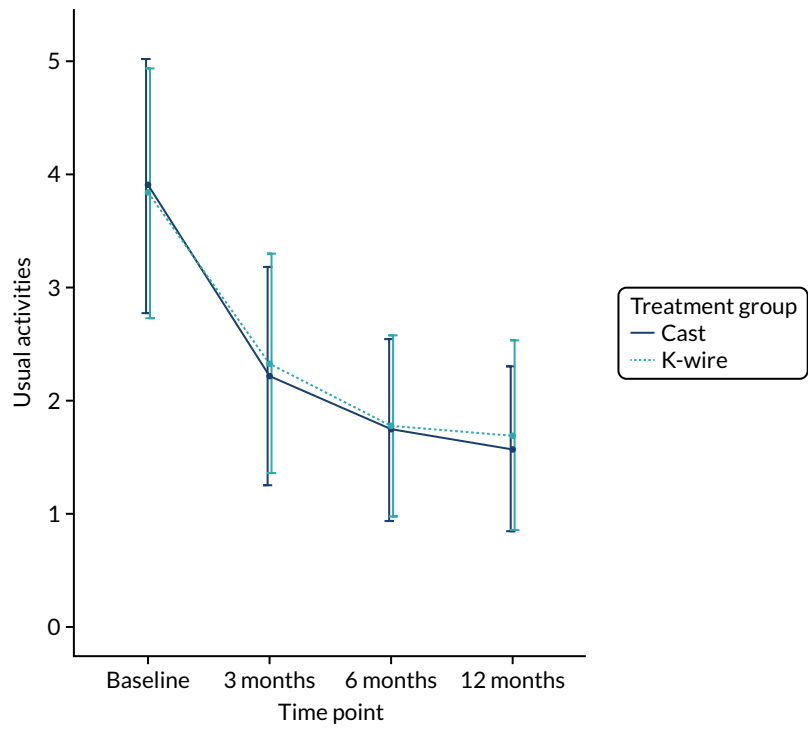
FIGURE 19 Change in EQ-5D-5L usual activities domain by treatment group over time.
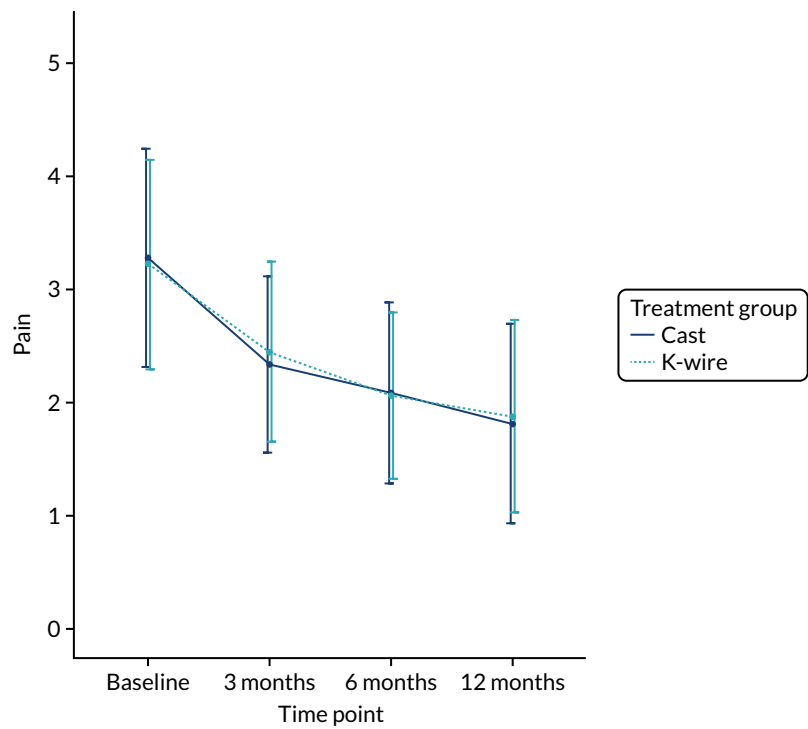
FIGURE 20 Change in EQ-5D-5L pain domain by treatment group over time.
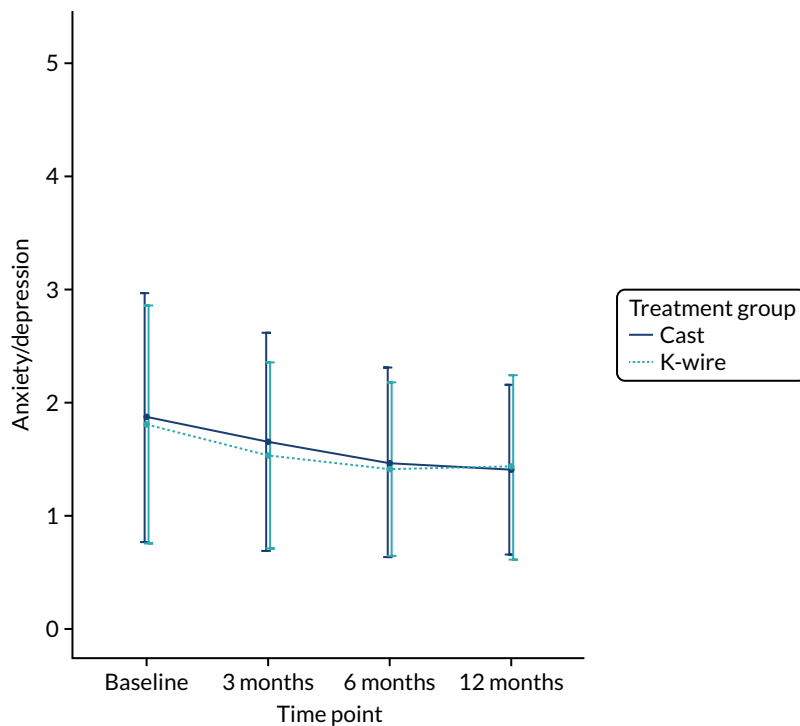
FIGURE 21 Change in EQ-5D-5L anxiety/depression domain by treatment group over time.

TABLE 23 Health-care resource utilisation (numbers of items per participant) by treatment groups and follow-up time points (available case)

Health-care resource type	Treatment group		Bootstrapped 95% CI	*p*-value
	Cast	K-wire		
Discharge to 3 months				
Subsequent inpatient care, mean number of days (SE)	0.005 (0.005)	0 (0)	−0.014 to 0	0.318
Outpatient care, mean number of visits (SE)				
Orthopaedics/fracture	0.678 (0.091)	0.752 (0.096)	−0.184 to 0.333	0.571
Physiotherapist: NHS	0.028 (0.015)	0.079 (0.024)	−0.002 to 0.106	0.067
Physiotherapist: private	0.140 (0.038)	0.153 (0.036)	−0.090 to 0.116	0.800
Pathology: blood tests	1.336 (0.127)	1.248 (0.124)	−0.444 to 0.251	0.617
Radiology	0.140 (0.062)	0.233 (0.073)	−0.098 to 0.282	0.335
Emergency department: wrist	0.009 (0.007)	0.005 (0.005)	−0.019 to 0.010	0.594
Emergency department: others	0.028 (0.016)	0.005 (0.005)	−0.061 to 0.005	0.172
Others	0.014 (0.008)	0.005 (0.005)	−0.028 to 0.010	0.336
Community care, mean duration in minutes[a] (SE)				
General practitioner: surgery visit	1.540 (0.345)	2.839 (0.617)	−0.046 to 2.763	0.067
General practitioner: home visit	0 (0)	0 (0)	–	–
General practitioner: telephone contact	0.376 (0.206)	0.542 (0.255)	−0.452 to 0.839	0.612

TABLE 23 Health-care resource utilisation (numbers of items per participant) by treatment groups and follow-up time points (available case) (continued)

Health-care resource type	Treatment group		Bootstrapped 95% CI	p-value
	Cast	K-wire		
Practice nurse: surgery visit	0.558 (0.441)	0.995 (0.514)	−0.888 to 1.801	0.519
Practice nurse: home visit	0.419 (0.419)	0 (0)	−1.256 to 0	0.318
Practice nurse: telephone contact	0.047 (0.047)	0.050 (0.050)	−0.14 to 0.149	0.965
District nurse: surgery visit	4.000 (3.908)	0 (0)	−11.907 to 0	0.307
District nurse: home visit	0 (0)	0 (0)	–	–
Physiotherapist: surgery visit	11.611 (2.962)	10.149 (3.207)	−9.842 to 7.120	0.738
Physiotherapist: home visit	1.612 (1.121)	2.040 (1.278)	−2.876 to 3.881	0.802
Occupational therapist: surgery visit	4.116 (3.055)	0.746 (0.498)	−10.388 to 0.925	0.277
Occupational therapist: home visit	0.977 (0.977)	0.199 (0.199)	−2.930 to 0.398	0.436
Others	0 (0)	0 (0)	–	–
Medications, proportion of participants[b]				
Analgesic	0.398 (–)	0.396 (–)	–	0.904
Antibiotic	0 (–)	0 (–)	–	–
Bisphosphonate	0.009 (–)	0 (–)	–	0.169
Other bone protection medication	0.014 (–)	0.040 (–)	–	0.094
Supplement and vitamin	0.046 (–)	0.050 (–)	–	0.873
Aids and adaptations, mean number (SE)				
Wrist support (e.g. brace/splint)	0.414 (0.045)	0.420 (0.038)	−0.11 to 0.119	0.919
Grab rail	0.023 (0.012)	0.020 (0.012)	−0.037 to 0.031	0.855
Dressing aids	0.079 (0.058)	0.030 (0.030)	−0.19 to 0.06	0.453
Long-handled aids (e.g. shoe horn, reacher)	0.023 (0.010)	0.025 (0.011)	−0.027 to 0.031	0.902
Bathing aids	0.074 (0.021)	0.055 (0.016)	−0.073 to 0.032	0.468
Kitchen aids (e.g. jar/tin openers)	0.042 (0.018)	0.040 (0.016)	−0.049 to 0.042	0.944
Others	0.014 (0.008)	0.010 (0.007)	−0.023 to 0.016	0.704
PSS, mean number (SE)				
Frozen Meals on Wheels	0 (0)	0 (0)	–	–
Hot Meals on Wheels	0.005 (0.005)	0 (0)	−0.014 to 0	0.318
Laundry services	0 (0)	0 (0)	–	–
Calls to NHS 111	0 (0)	0 (0)	–	–
PSS				
Social worker, mean duration in minutes[a] (SE)	0 (0)	0 (0)	–	–
Care worker/help at home, mean duration in minutes[a] (SE)	53.958 (40.927)	31.650 (28.113)	−129.008 to 70.087	0.653
Time off work, mean number of days (SE)	47.704 (4.824)	48.644 (5.199)	−12.908 to 14.430	0.895
Additional costs, proportion of participants[b]	0.241 (–)	0.243 (–)	–	0.971

TABLE 23 Health-care resource utilisation (numbers of items per participant) by treatment groups and follow-up time points (available case) (*continued*)

Health-care resource type	Treatment group		Bootstrapped 95% CI	*p*-value
	Cast	K-wire		
3 months to 6 months				
Subsequent inpatient care, mean number of days (SE)	0 (0)	0 (0)	–	–
Outpatient care, mean number of visits (SE)				
Orthopaedics/fracture	0.187 (0.058)	0.180 (0.043)	–0.155 to 0.129	0.916
Physiotherapist: NHS	0.034 (0.019)	0.049 (0.021)	–0.044 to 0.073	0.624
Physiotherapist: private	0.153 (0.029)	0.112 (0.027)	–0.119 to 0.037	0.299
Pathology: blood tests	1.128 (0.172)	1.277 (0.204)	–0.363 to 0.684	0.578
Radiology	0.182 (0.063)	0.214 (0.111)	–0.190 to 0.313	0.806
Emergency department: wrist	0.020 (0.016)	0.005 (0.005)	–0.049 to 0.010	0.363
Emergency department: others	0.025 (0.013)	0.034 (0.014)	–0.030 to 0.048	0.630
Others	0.059 (0.026)	0.029 (0.014)	–0.094 to 0.019	0.302
Community care, mean duration in minutes[a] (SE)				
General practitioner: surgery visit	1.154 (0.362)	2.488 (0.626)	–0.029 to 2.825	0.066
General practitioner: home visit	0 (0)	0 (0)	–	–
General practitioner: telephone contact	0.040 (0.031)	0.340 (0.196)	–0.025 to 0.736	0.133
Practice nurse: surgery visit	0.025 (0.025)	0 (0)	–0.074 to 0	0.319
Practice nurse: home visit	0 (0)	0 (0)	–	–
Practice nurse: telephone contact	0.020 (0.020)	0 (0)	–0.059 to 0	0.319
District nurse: surgery visit	0.000 (0.000)	0.388 (0.388)	0.000 to 1.165	0.318
District nurse: home visit	0 (0)	0 (0)	–	–
Physiotherapist: surgery visit	8.375 (2.765)	7.146 (2.460)	–8.677 to 5.873	0.740
Physiotherapist: home visit	2.970 (2.970)	1.165 (0.899)	–8.717 to 2.621	0.561
Occupational therapist: surgery visit	3.582 (3.582)	0 (0)	–10.746 to 0	0.319
Occupational therapist: home visit	0 (0)	0 (0)	–	–
Others	0.074 (0.074)	0 (0)	–0.223 to 0	0.319
Medications, proportion of participants[b]				
Analgesic	0.123 (–)	0.146 (–)	–	0.964
Antibiotic	0 (–)	0 (–)	–	–
Bisphosphonate	0.005 (–)	0 (–)	–	0.271
Other bone protection medication	0.015 (–)	0.015 (–)	–	0.820
Supplement and vitamin	0.034 (–)	0.029 (–)	–	0.506
Aids and adaptations, mean number (SE)				
Wrist support: (e.g. brace/splint)	0.104 (0.034)	0.117 (0.028)	–0.076 to 0.097	0.766
Grab rail	0.020 (0.012)	0.005 (0.005)	–0.045 to 0.005	0.253
Dressing aids	0.030 (0.030)	0.020 (0.012)	–0.084 to 0.039	0.750

continued

TABLE 23 Health-care resource utilisation (numbers of items per participant) by treatment groups and follow-up time points (available case) (*continued*)

Health-care resource type	Treatment group		Bootstrapped 95% CI	*p*-value
	Cast	K-wire		
Long-handled aids (e.g. shoe horn, reacher)	0 (0)	0.015 (0.008)	0 to 0.034	0.083
Bathing aids	0.010 (0.010)	0.029 (0.015)	−0.015 to 0.058	0.289
Kitchen aids (e.g. jar/tin openers)	0.015 (0.011)	0.034 (0.014)	−0.015 to 0.054	0.293
Others	0.030 (0.014)	0.010 (0.007)	−0.055 to 0.010	0.196
PSS, mean number (SE)				
Frozen Meals on Wheels	0 (0)	0 (0)	–	–
Hot Meals on Wheels	0 (0)	0 (0)	–	–
Laundry services	0.005 (0.005)	0 (0)	−0.015 to 0	0.319
Calls to NHS 111	0 (0)	0 (0)	–	–
PSS				
Social worker, mean duration in minutes[a] (SE)	0 (0)	0 (0)	–	–
Care worker/help at home, mean duration in minutes[a] (SE)	0 (0)	0 (0)	–	–
Time off work, mean number of days (SE)	21.864 (7.242)	26.652 (6.916)	−14.629 to 23.288	0.635
Additional costs, proportion of participants[b]	0.064 (–)	0.092 (–)	–	0.288
6 months to 12 months				
Subsequent inpatient care, mean number of days (SE)	0 (0)	0 (0)	–	–
Outpatient care, mean number of visits (SE)				
Orthopaedics/fracture	0.176 (0.047)	0.163 (0.044)	−0.139 to 0.119	0.845
Physiotherapist: NHS	0.060 (0.023)	0.097 (0.029)	−0.035 to 0.113	0.329
Physiotherapist: private	0.116 (0.035)	0.122 (0.034)	−0.089 to 0.103	0.889
Pathology: blood tests	0.437 (0.132)	0.474 (0.146)	−0.332 to 0.427	0.850
Radiology	0.176 (0.070)	0.071 (0.039)	−0.271 to 0.041	0.192
Emergency department: wrist	0.055 (0.036)	0.010 (0.007)	−0.126 to 0.015	0.227
Emergency department: others	0.055 (0.037)	0.036 (0.013)	−0.110 to 0.041	0.621
Others	0 (0)	0.026 (0.014)	0.005 to 0.057	0.059
Community care, mean duration in minutes[a] (SE)				
General practitioner: surgery visit	1.396 (0.676)	1.042 (0.443)	−2.116 to 1.112	0.661
General practitioner: home visit	0.503 (0.362)	0.000 (0.000)	−1.307 to 0.000	0.166
General practitioner: telephone contact	0 (0)	0 (0)	–	–
Practice nurse: surgery visit	0 (0)	4.639 (4.639)	0 to 13.918	0.319
Practice nurse: home visit	0 (0)	0 (0)	–	–
Practice nurse: telephone contact	0.025 (0.025)	0 (0)	−0.075 to 0	0.319
District nurse: surgery visit	0 (0)	0 (0)	–	–
District nurse: home visit	0 (0)	0 (0)	–	–

TABLE 23 Health-care resource utilisation (numbers of items per participant) by treatment groups and follow-up time points (available case) (*continued*)

| Health-care resource type | Treatment group | | Bootstrapped 95% CI | *p*-value |
	Cast	K-wire		
Physiotherapist: surgery visit	4.924 (2.353)	9.359 (5.515)	–5.311 to 17.652	0.460
Physiotherapist: home visit	0 (0)	0 (0)	–	–
Occupational therapist: surgery visit	0.303 (0.303)	0 (0)	–0.909 to 0	0.319
Occupational therapist: home visit	0 (0)	0.256 (0.184)	0 to 0.667	0.166
Others	0 (0)	0 (0)	–	–
Medications, proportion of participants[b]				
Analgesic	0.080 (–)	0.082 (–)	–	0.768
Antibiotic	0 (–)	0 (–)	–	–
Bisphosphonate	0.005 (–)	0.000 (–)	–	0.323
Other bone protection medication	0.020 (–)	0.015 (–)	–	0.731
Supplement and vitamin	0.025 (–)	0.015 (–)	–	0.477
Aids and adaptations, mean number (SE)				
Wrist support (e.g. brace/splint)	0.101 (0.033)	0.092 (0.027)	–0.094 to 0.073	0.848
Grab rail	0.015 (0.011)	0.010 (0.010)	–0.035 to 0.026	0.751
Dressing aids	0.010 (0.010)	0.005 (0.005)	–0.030 to 0.015	0.665
Long-handled aids (e.g. shoe horn, reacher)	0.015 (0.011)	0.021 (0.010)	–0.025 to 0.031	0.720
Bathing aids	0.015 (0.011)	0.010 (0.007)	–0.035 to 0.021	0.718
Kitchen aids (e.g. jar/tin openers)	0.030 (0.014)	0.056 (0.028)	–0.030 to 0.093	0.407
Others	0.015 (0.015)	0 (0)	–0.045 to 0	0.319
PSS, mean number (SE)				
Frozen Meals on Wheels	0.000 (0.000)	0.005 (0.005)	0.000 to 0.015	0.319
Hot Meals on Wheels	0 (0)	0 (0)	–	–
Laundry services	0 (0)	0 (0)	–	–
Calls to NHS 111	0 (0)	0 (0)	–	–
PSS				
Social worker, mean duration in minutes[a] (SE)	0 (0)	0 (0)	–	–
Care worker/help at home, mean duration in minutes[a] (SE)	0 (0)	0 (0)	–	–
Time off work, mean number of days (SE)	45.385 (20.833)	63.636 (21.170)	–38.196 to 73.924	0.545
Additional costs, proportion of participants[b]	0.030 –	0.046 –	–	0.418

a Mean duration (minutes) = number of visits × average duration per visit (minutes).
b *p*-values were computed using *t*-tests, except for the ones indicated here that were computed using chi-squared tests.

Appendix 3 Changes to protocol

All protocol versions can be found on the project web page: www.journalslibrary.nihr.ac.uk/programmes/hta/152701/#/documentation (accessed 8 September 2020). *Table 24* shows the summary of changes implemented with each protocol version.

TABLE 24 Protocol versions and summary of changes from the previous version

Version and date	Summary of changes
1.0: 9 August 2016	None. This was the first version approved by IRAS and given to recruiting centres
2.0: 25 June 2019	Inclusion of e-mail/SMS messages, extension of the trial duration and update on committee members
3.0: 27 September 2019	Inclusion of intention to send patient incentive gift vouchers

IRAS, Integrated Research Application System; SMS, short message service.