

# THE LANCET

## Supplementary appendix

This appendix formed part of the original submission and has been peer reviewed.  
We post it as supplied by the authors.

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## Appendix 1

| Physiotherapy Advice   |  |
|------------------------|--|
| <b>Weeks 8-12</b>      | <ul style="list-style-type: none"><li>• Your physiotherapist will advise you on how to wean you off your crutches, if you are still using them, and how to improve your walking pattern.</li><li>• If your ankle is swollen they will advise you to elevate your leg and apply ice to the ankle.</li><li>• You will begin regular range of movement exercises throughout the day for the ankle (for example 3 x 10 repetitions/day) and gentle resistance exercises, using a theraband that the physiotherapist will show you.</li></ul>   |
| <b>Weeks 12-24</b>     | <ul style="list-style-type: none"><li>• You will begin specific strength training for your calf muscles. This will consist of doing exercises that are low impact and require you to complete multiple repetitions, within your capabilities. Examples include double leg heel raises progressing to single leg heel raises, as appropriate.</li><li>• Your physiotherapist will also introduce some generic strengthening and balance exercises to prepare you later on for more demanding activities, if required. Such exercises may include mini squats, cycling, balancing skills and step ups. Again all are examples of low impact exercises. This will be alongside additional low impact exercises that you may choose to undertake such as cycling, jogging, and swimming.</li><li>• At this stage your calf muscles may begin to feel stiff or tight. If this is the case the physiotherapists will show you some active calf stretching exercises that will help.</li><li>• If your ankle movements still remain reduced at this stage the physiotherapist may progress to manual mobilization of the ankle.</li></ul> |
| <b>Week 24 onwards</b> | <ul style="list-style-type: none"><li>• By 24 weeks you will have returned to completing your normal activities of daily living such as driving, walking and going up and down stairs, and you will be able to take part in low impact sports such as cycling, jogging and swimming.</li><li>• If you wish to return to higher impact sports that involve sprinting, lunging and jumping, such as football, squash or tennis, then your physiotherapist will guide you through some sport specific exercises prior to you returning fully to these sports. Once you are able to complete the sport specific exercises then the physiotherapist will advise that you can return to these sporting activities.</li></ul>   |

- 1 **Note: The above physiotherapy advice is a guide only. Your physiotherapist in consultation with**
- 2 **your doctor may decide it is in your best interests to add or remove the specific physiotherapy**
- 3 **treatments you receive within the above time frames.**

Appendix 2



## Appendix 3

### UKSTAR: UK Study of Tendo Achilles Rehabilitation

#### Rehabilitation strategy after non-surgical treatment of Achilles tendon rupture: UKSTAR, a multicentre RCT

#### Appendix: Economic Evaluation

##### 1. Overview

The objective of the health economic evaluation was to assess the comparative cost-effectiveness of the two non-surgical treatment options (plaster cast versus functional bracing) for patients with a primary (first-time) rupture of the Achilles tendon. To achieve this, a systematic comparison of the cost of resource inputs used by participants in the two arms of the trial and consequences associated with the interventions was conducted. The primary analysis adopted a National Health Service (NHS) and personal social services (PSS) perspective, in accordance with National Institute for Health and Care Excellence (NICE) recommendations [1]. A societal perspective for costs was adopted for the sensitivity analysis and this included private costs incurred by trial participants and their families, as well as productivity losses and loss of earnings as a result of work absences. The economic evaluation took the form of a cost–utility analysis, expressed in terms of incremental cost per quality adjusted life-year (QALY) gained. The time horizon covered the period from randomisation to end of follow-up at 9 months post injury. Costs and outcomes were not discounted due to the short, 9-month, time horizon adopted for this within-trial evaluation.

##### 2. Measurement of resource use and costs

Data were collected on:

- i) Resource use and costs associated with delivery of the interventions (direct intervention costs)
- ii) Broader health and social care service use during the 9 months of follow-up
- iii) Broader societal resource use and costs – this encompassed private medical costs and lost productivity costs such as lost income over the 9 months of follow-up.

All costs were expressed in pounds sterling and valued in 2017-18 prices. When appropriate, costs were inflated or deflated to 2017–18 prices using the Hospital and Community Health Services (HCHS) Pay and Price Inflation Index [2].

##### 2.1 Direct intervention costs

Direct intervention costs comprised costs associated with the application of the two interventions. This included cost of the walking boot and wedges, materials used for plaster cast, the cost associated with fitting the interventions to patients (hospital staff time), and the costs associated with any changes required to either plaster cast or functional bracing (Table A1). Information on how long it takes to deliver each intervention and type and volume of materials used was collected at each recruitment centre, through a questionnaire completed by recruitment centre staff in consultation with staff responsible for fitting the functional brace or applying the plaster cast. Unit costs for staff were obtained from the Personal Social Services Research Unit (PSSRU) Unit Costs of Health and Social Care 2018 compendium [3] and were multiplied by the median time it takes to deliver each intervention. The median time for fitting a functional brace was 10, 11 and 17.5 minutes for a plaster technician, nurse and other<sup>1</sup> staff respectively. The median time to change wedges was 5 minutes for a plaster technician and nurse and 10 minutes for ‘other’ staff. The median time for changing a plaster cast was 15 minutes for a plaster technician and 17.5 minutes for a nurse. The base case analysis assumed costs of a plaster technician. Unit costs of plaster cast materials, walking boots and wedges were obtained from the

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<sup>1</sup> Other staff category included Physiotherapists, orthotists and occupational therapists

50 2018 NHS Supply chain catalogue. The total direct intervention cost for each patient was calculated by  
 51 combining the resource inputs with their respective unit cost values.

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 53 **Table A1: Unit costs associated with direct intervention costs for plaster cast and functional bracing**

| Resource item                            | Unit cost | Unit of analysis | Source of unit cost   |
|--|-----------|------------------|---|
| <b>Direct intervention costs</b>         |           |                  |   |
| <b>Functional brace:</b>                 |           |                  |   |
| Walking boot <sup>2</sup> cost by brand: |           |                  |   |
| Samson walking boot                      | £15.00    | Per walking boot | John Radcliffe finance department;<br>NHS Supply Chain Catalogue 2018 |
| Donjoy walking boot                      | £19.24    |                  |   |
| Airstep walking boot                     | £68.66    |                  |   |
| <b>Plaster cast:</b>                     |           |                  |   |
| Plaster cast materials <sup>3</sup>      |           |                  |   |
| 2 x 7.5cm poly rolls                     | £2.83     | Per roll         | NHS Supply Chain Catalogue 2018                                       |
| 2x 10 cm poly rolls                      | £6.69     |                  |   |
| Fibreglass casting tape 5 inch x3.6m     | £11.48    | Per roll         | NHS Supply Chain Catalogue 2018                                       |
| 1m stockinette                           | £3.23     | Per roll         | NHS Supply Chain Catalogue 2018                                       |
| 2 x rolls of 5inch wool bandage          | £3.00     | Per roll         | NHS Supply Chain Catalogue 2018                                       |

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56 **2.2 Measuring broader resource use**

57 Broader resource use data were collected using follow-up questionnaires completed by trial participants at the  
 58 four follow-up assessment points: 8 weeks, 3 months, 6 months and 9 months post injury. The questionnaires  
 59 captured details of inpatient and day case admissions, outpatient and emergency care attendances,  
 60 encounters with primary or community health and social care services, medication use and walking aids  
 61 provided/self-purchased, as well adaptations to home environments. In addition, the questionnaires captured  
 62 the direct non-medical costs (including travel expenses) incurred by patients and their carers, as well as  
 63 number of days off work and gross loss of earnings attributable to the trial participant's health state or  
 64 contacts with care providers.  
 65

66 **2.3 Valuation of resource use**

67 Resource inputs were valued by attaching unit costs derived from national compendia in accordance with  
 68 NICE's Guide to the Methods of Technology Appraisal 2013 [1]. The key databases for deriving unit cost data  
 69 included the Department of Health and Social Care's Reference Costs 2016–17 schedules [4], the Personal  
 70 Social Services Research Unit (PSSRU)'s Unit Costs of Health and Social Care 2018 compendium [3], the 2018  
 71 NHS Prescription Cost Analysis database for England [5], 2018 volumes of the British National Formulary [6],  
 72 and the NHS Supply Chain Catalogue 2018 [7].  
 73 Per diem costs for hospital inpatient admissions during the follow-up period were calculated individually as a  
 74 weighted average of Healthcare Resource Group (HRG) codes of related procedures and/or clinical diagnoses.  
 75 For example, the average cost per day for an inpatient stay in a medical ward to treat a pulmonary embolus  
 76 was calculated as the sum total of weighted average HRG codes (DZ09J – DZ09Q; pulmonary embolus with or  
 77 without interventions) divided by average length of stay across elective and non-elective inpatient services.  
 78 The individual HRG codes were derived using the NHS HRG4 2017/18 Reference Cost Grouper software version

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<sup>2</sup> Unit costs for all other walking boot brands that patients received (not pre-specified in case report forms) were individually-derived from the NHS Supply Chain Catalogue

<sup>3</sup> Unit costs for any other plaster cast materials that sites use (not pre-specified in site-specific questionnaire) were individually-derived from the NHS Supply Chain Catalogue 2018

79 RC1718 (NHS Digital, Leeds, UK). The Department of Health and Social Care's *Reference Costs 2017–18* [4]  
80 schedule was used to assign the costs for each of the derived HRG codes.  
81 Costs for community-based health and social care services were calculated by applying unit costs extracted  
82 from national tariffs, primarily extracted from the PSSRU Unit Costs of Health and Social Care 2018  
83 compendium [3], to resource volumes. Costs of medications for individual participants were estimated based  
84 on their reported doses and frequencies, when these were available, or based on an assumed daily doses  
85 using *British National Formulary* [6] recommendations. When a dose range was reported as 'as required' or  
86 when the quantities were not recorded, we assumed a mean cost for that medication item based on the  
87 prescription cost analysis values (net ingredient cost per item). In cases where medication dosages were  
88 missing, we conservatively assumed that the patient received the same dosage as other trial participants who  
89 reported taking the same medication.  
90 The costs of walking aids and adaptations (equipment participants receive to manage their injury and make  
91 daily lives easier) were derived by combining data on number and type of items received with their unit cost  
92 values. Unit cost values were derived from the NHS supply chain catalogue [7] if equipment was provided by a  
93 health provider during the trial follow-up period. Where aids and adaptations were self-financed, the costs  
94 were provided by participants themselves.  
95 We used data on sex and employment status-specific median earnings from the UK national annual survey of  
96 hours and earnings [8] to derive the costs of time taken off work. The employment status of trial participants  
97 was derived from self-reported work status information. Broader societal costs were calculated by combining  
98 the productivity losses and income losses attributable to work absences.  
99 Summary statistics were generated for resource use variables by treatment allocation and assessment point.  
100 Between treatment-group differences in resource use and costs at each assessment point were compared  
101 using the two sample t-test. Statistical significance was assessed at the 5% significance level. Standard errors  
102 are reported for treatment group means and bootstrap 95% confidence intervals for the between-group  
103 differences in mean resource use and cost estimates.  
104

### 105 **3. Measurement of outcomes**

106 In accordance with NICE guidelines, the primary health outcome for the health economic evaluation was the  
107 quality adjusted life year (QALY) metric [1]. Health-related quality of life of trial participants was assessed at  
108 baseline (both pre and post injury), and 8 weeks, 3 months, 6 months and 9 months post injury using the  
109 EuroQoL EQ-5D-5L instrument [9]. The EQ-5D-5L instrument defines health-related quality of life in terms of  
110 five dimensions: (1) mobility, (2) self-care, (3) usual activities, (4) pain/discomfort and (5) anxiety/depression.  
111 Responses in each dimension are divided into five ordinal levels coded: (1) no problems, (2) slight problems,  
112 (3) moderate problems, (4) severe problems, and (5) extreme problems. Between-group differences in optimal  
113 versus sub-optimal level of function for each health dimension were compared at each time-point using chi-  
114 squared ( $\chi^2$ ) tests.  
115 Responses to the EQ-5D-5L instrument were converted into health utility scores using the EQ-5D-5L Crosswalk  
116 Index Value Calculator currently recommended by NICE [10], which maps the EQ-5D-5L descriptive system  
117 data onto the EQ-5D-3L valuation set. Detailed description on the mapping methodology is described  
118 elsewhere [10]. Quality-adjusted life-years (QALYs) were generated for each patient using the area under the  
119 baseline-adjusted utility curve, assuming linear interpolation between health utility measurements across  
120 assessment points.  
121 Health utility values and QALYs accrued over the 9-month follow-up period were summarised by treatment  
122 group and assessment point and presented as means and associated standard errors; between group  
123 differences were compared using the two-sample t-test, similar to the descriptive analyses of resource inputs  
124 and costs.  
125

### 126 **4. Cost-effectiveness analysis methods**

#### 127 **4.1 Missing data**

128 Missing data are a common occurrence within randomised controlled trials: participants may be lost to follow-  
129 up, questionnaires unreturned or responses to individual questionnaire items may be missing [11]. Because  
130 costs and outcomes of individuals with missing data may differ systematically to those with fully observed

131 data, it is important to handle missing data using a principled approach that is justified by, amongst other  
132 factors, the missing data mechanism. Missing costs and health utility data were imputed at each time-point  
133 using fully conditional multiple imputation by chain equations, implemented through the MICE package, under  
134 the missing at random (MAR) assumption. Appropriateness of the MAR assumption was assessed by: (i)  
135 investigating the missing data patterns (monotonic vs. non-monotonic), and (ii) comparing attributes of  
136 participants with and without missing costs and health-related quality of life data at each follow-up time-point.  
137 The multiple imputation model used baseline covariates (age, gender), costs and health utility values at each  
138 follow-up time-point to impute unobserved costs and health utility values, such that, for example, missing  
139 costs at 9 months were imputed using data on baseline covariates, costs at 8 week, 3 months and 6 months  
140 and health utility values at each follow-up time-point. The imputations were implemented separately by  
141 treatment allocation in line with best practice [11]. The imputation was run 50 times, following the rule of  
142 thumb that the number of imputations should be at least greater than the proportion of missing data [11].  
143 Bivariate regressions using a seemingly unrelated regression model (Sureg) were used to independently  
144 analyse the multiply imputed datasets so as to estimate the costs and QALYs in each treatment group over the  
145 9-month trial horizon. Joint distributions of costs and outcomes from the original data set were generated  
146 through non-parametric bootstrapping and changes in costs and QALYs were calculated for each sample. A  
147 total of 1000 bootstrap samples were drawn and means for both incremental costs and incremental QALYs  
148 (with associated 95% CIs) were calculated. Estimates from each imputed dataset were combined using Rubin's  
149 rule [12] to generate overall mean estimates of costs and QALYs and their standard errors (SE). The latter  
150 reflects the variability within and across imputations. The imputation model was validated by assessing the  
151 distributions of imputed and observed values. A mixed model with adjustment for baseline pre-injury EQ-5D  
152 health utility scores is also presented for comparison.  
153

#### 154 **4.2 Presentation of cost-effectiveness results**

155 Cost-effectiveness results are expressed in terms of the incremental cost-effectiveness ratio (ICER) and  
156 calculated as the difference between treatments in mean total costs divided by mean total QALYs. Given the  
157 pattern of results, plaster cast has been selected as the referent and functional brace as the comparator, i.e.  
158 functional brace minus plaster cast, for the estimation of ICER values. The bootstrap replicates generated by  
159 the non-parametric bootstrapping, described in the sub-section 'Missing data', were used to populate cost-  
160 effectiveness scatterplots. Cost-effectiveness acceptability curves, which showed the probability that  
161 functional brace is cost-effective relative to plaster cast across a range of cost-effectiveness thresholds, were  
162 also generated based on the proportion of bootstrap replicates with positive incremental net benefits. The net  
163 monetary benefit (NMB) of using functional brace versus plaster cast was also calculated across three pre-  
164 specified cost-effectiveness thresholds, namely £15,000 per QALY [13], £20,000 per QALY and £30,000 per  
165 QALY [1]. A positive incremental NMB indicates that the functional brace is cost-effective compared with the  
166 plaster cast at the given cost-effectiveness threshold. For the purpose of the secondary analysis that adopted  
167 the ATRS as the health outcome measure of interest, the NMB was estimated at cost-effectiveness thresholds  
168 of £100 - £500 per unit change in ATRS score. We failed to identify any external evidence on economic values  
169 for changes in ATRS score and therefore a range of arbitrary threshold values had to be selected for this  
170 analysis.  
171

#### 172 **4.3 Sensitivity and secondary outcomes analyses**

173 Several sensitivity analyses were conducted to test the robustness of the cost-effectiveness estimates. These  
174 involved re-estimating the main cost-effectiveness outcomes under the following scenarios: (1) restricting the  
175 analyses to complete cases (i.e. those with complete cost and outcome data over the 9-month follow-up  
176 period); (2) adopting a wider societal perspective that included private costs incurred by trial participants and  
177 their families, as well as economic losses placed on attributable work absences; and (3) Estimating incremental  
178 cost-effectiveness using a CACE population. In addition, as a secondary analysis, cost-effectiveness was  
179 estimated using the ATRS, rather than the QALY, as the health outcome measure of interest.  
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#### 181 **4.4 Longer-term economic modelling**

182 The study protocol also allowed for decision-analytic modelling to estimate longer-term cost-effectiveness of  
183 functional bracing or plaster cast provided the costs and health outcomes did not converge at the end of the 9-  
184 month post injury follow-up period.

185 **5. Results of economic analysis**

186 Table A2 shows the degree of missing health economic data by treatment allocation and follow-up time point.  
 187 The missing data pattern is non-monotonic, as individuals with missing data at one follow-up time point may  
 188 return to the trial subsequently. For example, there are more missing EQ-5D data at 6 months than at 9  
 189 months post injury. A similar pattern can be observed for economic costs. It is worth noting that the lower  
 190 number of participants with complete data for the entire duration of follow-up (baseline to 9 months post-  
 191 injury) was due to a strict application of the term missing i.e. we considered a participant as having incomplete  
 192 data if, for example, they responded positively to visiting a GP surgery at 3 months but did not specify number  
 193 of consultations, despite all other resource use items being completed. However, for the cost-effectiveness  
 194 analysis, imputation was not done at the aggregate level such that most of the data used for the analysis was  
 195 based on actual participant responses.

196  
 197 **Table A2: Number and proportion of individuals with missing health economic data by treatment allocation**

| Variable | Description  | Treatment group, missing values, n (%) |                            | Total, missing values, n (%) |
|----------|--|--|----------------------------|------------------------------|
|          |  | Plaster cast (n=266)                   | Functional brace (n = 274) |                              |
| eq5db    | EQ-5D index score pre injury                                 | 2 (0.75)                               | 2 (0.73)                   | 4 (0.74)                     |
| eq5d0    | EQ-5D index score post injury                                | 2 (0.75)                               | 1 (0.36)                   | 3 (0.56)                     |
| eq5d1    | EQ-5D at 8 weeks   | 32 (12.06)                             | 33 (12.04)                 | 65 (12.04)                   |
| eq5d2    | EQ-5D at 3 months  | 37 (13.91)                             | 29 (10.58)                 | 66 (12.22)                   |
| eq5d3    | EQ-5D at 6 months  | 42 (15.79)                             | 37 (13.5)                  | 79 (14.63)                   |
| eq5d4    | EQ-5D at 9 months  | 22 (26)                                | 15 (5.47)                  | 37 (8.27)                    |
| QALY     | QALYs generated from EQ-5D utility scores                    | 76 (28.57)                             | 74 (27.01)                 | 149 (27.78)                  |
| c0       | Total resource use between baseline and 8 weeks post injury  | 66 (24.8)                              | 59 (21.53)                 | 125 (23.15)                  |
| c1       | Total resource use between 8 weeks and 3 months post injury  | 59 (22.18)                             | 47 (17.15)                 | 106 (19.63)                  |
| c2       | Total resource use between 3 and 6 months post injury        | 56 (21.05)                             | 48 (8.89)                  | 104 (19.26)                  |
| c3       | Total resource use between 6 and 9 months post injury        | 31 (11.65)                             | 18 (6.57)                  | 49 (9.07)                    |
| c4       | Total resource use between baseline and 9 months post injury | 132 (49.62)                            | 116 (42.34)                | 248 (45.93)                  |

198 QALY: quality adjusted life-year  
 199

200 **5.1 Health and social care resource use**

201 In terms of specific resource use for plaster cast versus functional brace for all participants at the 8 week  
 202 follow-up, notable differences were observed for: proportion prescribed anticoagulant as VTE prophylaxis  
 203 treatment (0.72 vs 0.59; p=0.003), mean number of NHS outpatient orthopaedic visits (2.63 vs 1.80; p<0.001),  
 204 mean number of NHS outpatient physiotherapy visits (0.23 vs 0.46; p=0.003), mean number of GP surgery  
 205 visits (0.10 vs 0.19; p=0.028), and mean number of grab rail installations (0.05 vs 0; p=0.019). For all other  
 206 resource use items, there were no noticeable differences between the trial groups.

207 Between 8 week and 3 months post injury, for all participants there were differences in resource use for  
 208 plaster cast versus functional brace observed for: proportion of participants prescribed analgesics (0.11 vs  
 209 0.05; p=0.015) and proportion of participants prescribed other medications (0.02 vs 0; p=0.038). For all other  
 210 resource use items, there were no noticeable differences between the trial groups.

211 There were no significant differences in resource use for the Plaster Cast versus Functional Brace trial groups  
 212 at 6 months and 9 months post injury. Table A3 provides details on use of health care resources by follow-up  
 213 time-point and treatment group.

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**Table A3: Use of health and social care resources related to two non-surgical treatment options for patients with a primary (first-time) rupture of the Achilles tendon by each follow-up period and treatment group (complete cases)**

|  | Plaster Cast<br>(N=266)  | Functional brace<br>(N=274) | Mean difference (Bootstrapped<br>95% CI) |
|--|--|-----------------------------|--|
| <b>8-week follow-up</b>                |  |                             |  |
| <b>Inpatient Care</b>                  | <b>Mean length of stay in days (SE)</b>  |                             |  |
| Hospital stay                          | 0.035 (0.018)  | 0.071 (0.032)               | -0.036 (-0.110 to 0.028)                 |
|  |  |                             |  |
|  | <b>Proportion of participants prescribed<br/>anticoagulant as VTE prophylaxis treatment<br/>(SE)</b> |                             |  |
| <b>Anticoagulant treatment</b>         | 0.716 (0.028)  | 0.594 (0.030)               | 0.122 (0.032 to 0.200)                   |
|  |  |                             |  |
| <b>Outpatient care</b>                 | <b>Mean no. of visits (SE)</b>   |                             |  |
| Orthopaedics                           | 2.627 (0.107)  | 1.800 (0.097)               | 0.827 (0.574 to 1.119)                   |
| Pathology                              | 0.041 (0.014)  | 0.068 (0.023)               | -0.027 (-0.084 to 0.025)                 |
| Radiology                              | 0.150 (0.023)  | 0.146 (0.029)               | 0.004 (-0.070 to 0.074)                  |
| Physiotherapy NHS                      | 0.228 (0.042)  | 0.460 (0.064)               | -0.232 (-0.397 to -0.095)                |
| Physiotherapy Private                  | 0.091 (0.037)  | 0.184 (0.160)               | -0.093 (-0.575 to 0.117)                 |
| Emergency Department (Injury –related) | 0.104 (0.023)  | 0.096 (0.021)               | 0.008 (-0.051 to 0.070)                  |
| Emergency Department (other reasons)   | 0.029 (0.012)  | 0.016 (0.008)               | 0.013 (-0.012 to 0.044)                  |
| Other                                  | 0.111 (0.037)  | 0.168 (0.045)               | -0.058 (-0.162 to 0.062)                 |
|  |  |                             |  |
| <b>Community health care</b>           | <b>Mean no. of contacts (SE)</b>   |                             |  |
| GP Visits (surgery)                    | 0.100 (0.024)  | 0.188 (0.032)               | -0.088 (-0.176 to -0.012)                |
| GP (home visits)                       | 0.008 (0.006)  | 0 (0)                       | 0.008 (0 to 0.024)                       |
| GP (telephone contacts)                | 0.084 (0.025)  | 0.108 (0.031)               | -0.024 (-0.103 to 0.049)                 |
| Practice nurse contacts                | 0.008 (0.006)  | 0.008 (0.006)               | 0 (-0.015 to 0.018)                      |
| District nurse contacts                | 0.151 (0.146)  | 0 (0)                       | 0.151 (0 to 0.553)                       |
| Community physiotherapy contacts       | 0.021 (0.013)  | 0.040 (0.020)               | -0.019 (-0.074 to 0.020)                 |
| Calls to NHS direct                    | 0.017 (0.010)  | 0.008 (0.008)               | 0.009 (-0.012 to 0.039)                  |
| Calls for an ambulance or paramedic    | 0.004 (0.004)  | 0 (0)                       | 0.004 (0 to 0.017)                       |
| Occupational therapy contacts          | 0.013 (0.009)  | 0.008 (0.006)               | 0.005 (-0.012 to 0.034)                  |
| Other                                  | 0.216 (0.146)  | 0.034 (0.015)               | 0.183 (-0.010 to 0.580)                  |
|  |  |                             |  |
| <b>Medicines</b>                       | <b>Proportion of participants prescribed each<br/>class of drug (SE)</b>                             |                             |  |
| Analgesics                             | 0.388 (0.055)  | 0.330 (0.050)               | 0.058 (-0.083 to 0.213)                  |
| Anti-inflammatories                    | 0.042 (0.013)  | 0.076 (0.017)               | -0.034 (-0.081 to 0.004)                 |
| Anti-coagulant                         | 0.151 (0.023)  | 0.112 (0.020)               | 0.039 (-0.026 to 0.093)                  |
| Other                                  | 0.017 (0.008)  | 0.048 (0.014)               | -0.031 (-0.064 to -0.001)                |
|  |  |                             |  |
| <b>Aids and adaptations</b>            | <b>Mean count (SE)</b>   |                             |  |
| Crutches                               | 1.290 (0.059)  | 1.124 (0.062)               | 0.166 (0.012 to 0.341)                   |

|  | <b>Plaster Cast<br/>(N=266)</b>         | <b>Functional brace<br/>(N=274)</b> | <b>Mean difference (Bootstrapped<br/>95% CI)</b> |
|--|---|-------------------------------------|--|
| Stick                                  | 0.017 (0.010)                           | 0.024 (0.010)                       | -0.007 (-0.033 to 0.024)                         |
| Zimmer frame                           | 0.054 (0.018)                           | 0.028 (0.010)                       | 0.026 (-0.014 to 0.068)                          |
| Grab Rail                              | 0.046 (0.020)                           | 0 (0)                               | 0.046 (0.013 to 0.090)                           |
| Dressing aids                          | 0.008 (0.008)                           | 0.008 (0.006)                       | 0 (-0.016 to 0.024)                              |
| Long-handle shoe horn                  | 0.004 (0.004)                           | 0 (0)                               | 0.004 (0 to 0.016)                               |
| Other                                  | 0.387 (0.045)                           | 0.220 (0.043)                       | 0.166 (0.040 to 0.277)                           |
|  |   |                                     |  |
| <b>Personal social services</b>        | <b>No. of contacts (SE)</b>             |                                     |  |
| Frozen meals on wheels                 | 0                                       | 0                                   | -  |
| Hot meals on wheels                    | 0                                       | 0                                   | -  |
| Laundry services                       | 0.029 (0.029)                           | 0 (0)                               | 0.029 (0 to 0.095)                               |
| Social worker contacts                 | 0                                       | 0                                   | -  |
| Care worker/home help                  | 0.668 (0.542)                           | 0 (0)                               | 0.668 (0 to 2.165)                               |
| Other                                  | 0                                       | 0                                   | -  |
|  |   |                                     |  |
| <b>Productivity losses</b>             | <b>Mean days off work (SE)</b>          |                                     |  |
| Days off work                          | 21.227 (1.682)                          | 20.786 (1.637)                      | 0.441 (-3.947 to 5.176)                          |
|  |   |                                     |  |
| <b>Three-month follow-up</b>           |   |                                     |  |
| <b>Inpatient Care</b>                  | <b>Mean length of stay in days (SE)</b> |                                     |  |
| Hospital stay                          | 0.009 (0.009)                           | 0 (0)                               | 0.009 (0 to 0.034)                               |
|  |   |                                     |  |
| <b>Outpatient care</b>                 | <b>Mean no. of visits (SE)</b>          |                                     |  |
| Orthopaedics                           | 0.428 (0.055)                           | 0.318 (0.045)                       | 0.110 (-0.035 to 0.256)                          |
| Pathology                              | 0.017 (0.011)                           | 0.024 (0.014)                       | -0.007 (-0.044 to 0.026)                         |
| Radiology                              | 0.057 (0.020)                           | 0.045 (0.017)                       | 0.012 (-0.038 to 0.062)                          |
| Physiotherapy NHS                      | 0.978 (0.070)                           | 0.959 (0.067)                       | 0.019 (-0.175 to 0.180)                          |
| Physiotherapy Private                  | 0.271 (0.073)                           | 0.180 (0.045)                       | 0.091 (-0.069 to 0.279)                          |
| Emergency Department (Injury –related) | 0.061 (0.022)                           | 0.033 (0.011)                       | 0.028 (-0.013 to 0.085)                          |
| Emergency Department (other reasons)   | 0.009 (0.006)                           | 0.004 (0.004)                       | 0.005 (-0.008 to 0.023)                          |
| Other                                  | 0.057 (0.018)                           | 0.050 (0.024)                       | 0.007 (-0.057 to 0.062)                          |
|  |   |                                     |  |
| <b>Community health care</b>           | <b>Mean no. of contacts (SE)</b>        |                                     |  |
| GP Visits (surgery)                    | 0.088 (0.022)                           | 0.107 (0.029)                       | -0.019 (-0.099 to 0.057)                         |
| GP (home visits)                       | 0 (0)                                   | (0)                                 | -  |
| GP (telephone contacts)                | 0.044 (0.017)                           | 0.029 (0.013)                       | 0.015 (-0.026 to 0.057)                          |
| Practice nurse contacts                | 0.004 (0.004)                           | 0.008 (0.008)                       | -0.004 (-0.026 to 0.009)                         |
| District nurse contacts                | 0.004 (0.004)                           | 0.004 (0.004)                       | 0 (-0.011 to 0.013)                              |
| Community physiotherapy contacts       | 0.253 (0.065)                           | 0.201 (0.044)                       | 0.052 (-0.085 to 0.223)                          |
| Calls to NHS direct                    | 0.004 (0.004)                           | 0.004 (0.004)                       | 0 (-0.009 to 0.013)                              |
| Calls for an ambulance or paramedic    | 0.013 (0.010)                           | 0.004 (0.004)                       | 0.009 (-0.008 to 0.036)                          |
| Occupational therapy contacts          | 0.022 (0.014)                           | 0.049 (0.027)                       | -0.027 (-0.096 to 0.022)                         |
| Other                                  | 0.061 (0.032)                           | 0.021 (0.012)                       | 0.041 (-0.017 to 0.122)                          |
|  |   |                                     |  |

|  | Plaster Cast<br>(N=266)  | Functional brace<br>(N=274) | Mean difference (Bootstrapped<br>95% CI) |
|--|--|-----------------------------|--|
| <b>Medicines</b>                       | <b>Proportion of participants prescribed each class of drug (SE)</b> |                             |  |
| Analgesics                             | 0.109 (0.021)  | 0.049 (0.014)               | 0.060 (0.014 to 0.111)                   |
| Anti-inflammatories                    | 0.008 (0.006)  | 0.008 (0.006)               | 0.001 (-0.015 to 0.019)                  |
| Anti-coagulant                         | 0.022 (0.010)  | 0.016 (0.008)               | 0.005 (-0.019 to 0.031)                  |
| Other                                  | 0.017 (0.009)  | 0 (0)                       | 0.017 (0.004 to 0.039)                   |
|  |  |                             |  |
| <b>Aids and adaptations</b>            | <b>Mean count (SE)</b>   |                             |  |
| Crutches                               | 0.118 (0.030)  | 0.106 (0.029)               | 0.012 (-0.071 to 0.100)                  |
| Stick                                  | 0.070 (0.020)  | 0.033 (0.014)               | 0.037 (-0.009 to 0.086)                  |
| Zimmer frame                           | 0 (0)  | 0.004 (0.004)               | 0.004 (-0.016 to 0)                      |
| Grab Rail                              | 0.022 (0.013)  | 0 (0)                       | 0.022 (0 to 0.055)                       |
| Dressing aids                          | 0.031 (0.020)  | 0 (0)                       | 0.031 (0.004 to 0.083)                   |
| Long-handle shoe horn                  | 0.013 (0.008)  | 0 (0)                       | 0.013 (0 to 0.032)                       |
| Other                                  | 0.227 (0.064)  | 0.155 (0.038)               | 0.072 (-0.056 to 0.244)                  |
|  |  |                             |  |
| <b>Personal social services (PSS)</b>  | <b>No. of contacts (SE)</b>  |                             |  |
| Frozen meals on wheels                 | 0 (0)  | 0 (0)                       | -  |
| Hot meals on wheels                    | 0 (0)  | 0 (0)                       | -  |
| Laundry services                       | 0 (0)  | 0.008 (0.008)               | -0.008 (-0.033 to 0)                     |
| Social worker contacts                 | 0 (0)  | 0 (0)                       | -  |
| Care worker/home help                  | 0 (0)  | 0 (0)                       | -  |
| Other                                  | 0.009 (0.009)  | 0 (0)                       | 0.009 (0 to 0.029)                       |
|  |  |                             |  |
| <b>Productivity losses</b>             | <b>No. of days off work</b>  |                             |  |
| Days off work                          | 4.511 (0.820)  | 5.44 (0.880)                | -0.930 (-3.342 to 1.494)                 |
|  |  |                             |  |
|  |  |                             |  |
| <b>Six-month follow-up</b>             |  |                             |  |
| <b>Subsequent Inpatient Care</b>       | <b>Mean length of stay in days (SE)</b>                              |                             |  |
| Hospital stay                          | 0 (0)  | 0 (0)                       | -  |
|  |  |                             |  |
| <b>Outpatient care</b>                 | <b>Mean no. of visits (SE)</b>                                       |                             |  |
| Orthopaedics                           | 0.224 (0.043)  | 0.289 (0.059)               | -0.065 (-0.230 to 0.071)                 |
| Pathology                              | 0.018 (0.011)  | 0.030 (0.015)               | -0.012 (-0.048 to 0.024)                 |
| Radiology                              | 0.044 (0.015)  | 0.033 (0.012)               | 0.011 (-0.027 to 0.050)                  |
| Physiotherapy NHS                      | 1.946 (0.257)  | 1.915 (0.182)               | 0.031 (-0.550 to 0.674)                  |
| Physiotherapy Private                  | 0.417 (0.103)  | 0.366 (0.091)               | 0.051 (-0.218 to 0.316)                  |
| Emergency Department (Injury –related) | 0.013 (0.008)  | 0.026 (0.010)               | -0.012 (-0.039 to 0.014)                 |
| Emergency Department (other reasons)   | 0.013 (0.008)  | 0.017 (0.008)               | -0.004 (-0.026 to 0.018)                 |
| Other                                  | 0.093 (0.031)  | 0.067 (0.031)               | 0.026 (-0.065 to 0.103)                  |
|  |  |                             |  |
| <b>Community health care</b>           | <b>Mean no. of contacts (SE)</b>                                     |                             |  |

|                                     | <b>Plaster Cast<br/>(N=266)</b>  | <b>Functional brace<br/>(N=274)</b> | <b>Mean difference (Bootstrapped<br/>95% CI)</b> |
|-------------------------------------|--|-------------------------------------|--|
| GP Visits (surgery)                 | 0.094 (0.037)  | 0.060 (0.018)                       | 0.035 (-0.034 to 0.122)                          |
| GP (home visits)                    | 0 (0)  | 0.009 (0.009)                       | -0.009 (-0.028 to 0)                             |
| GP (telephone contacts)             | 0.018 (0.011)  | 0.021 (0.015)                       | -0.003 (-0.046 to 0.031)                         |
| Practice nurse contacts             | 0 (0)  | 0.004 (0.004)                       | -0.004 (-0.017 to 0)                             |
| District nurse contacts             | 0 (0)  | 0 (0)                               | -  |
| Community physiotherapy contacts    | 0.605 (0.187)  | 0.557 (0.101)                       | 0.048 (-0.311 to 0.547)                          |
| Calls to NHS direct                 | 0 (0)  | 0 (0)                               | -  |
| Calls for an ambulance or paramedic | 0 (0)  | 0 (0)                               | -  |
| Occupational therapy contacts       | 0.067 (0.033)  | 0.043 (0.023)                       | 0.025 (-0.054 to 0.115)                          |
| Other                               | 0.058 (0.043)  | 0.106 (0.077)                       | -0.048 (-0.264 to 0.085)                         |
|                                     |  |                                     |  |
| <b>Medicines</b>                    | <b>Proportion of participants prescribed each<br/>class of drug (SE)</b> |                                     |  |
| Analgesics                          | 0.103 (0.020)  | 0.064 (0.016)                       | 0.040 (-0.008 to 0.090)                          |
| Anti-inflammatories                 | 0.009 (0.006)  | 0.021 (0.009)                       | -0.012 (-0.036 to 0.009)                         |
| Anti-coagulant                      | 0.004 (0.004)  | 0.013 (0.007)                       | -0.008 (-0.025 to 0.009)                         |
| Other                               | 0.009 (0.006)  | 0.008 (0.006)                       | 0 (-0.013 to 0.019)                              |
|                                     |  |                                     |  |
| <b>Aids and adaptations</b>         | <b>Mean count (SE)</b>   |                                     |  |
| Crutches                            | 0.054 (0.021)  | 0.051 (0.020)                       | 0.003 (-0.051 to 0.066)                          |
| Stick                               | 0.031 (0.012)  | 0.030 (0.015)                       | 0.002 (-0.041 to 0.035)                          |
| Zimmer frame                        | 0.009 (0.009)  | 0.013 (0.007)                       | -0.004 (-0.022)                                  |
| Grab Rail                           | 0.018 (0.011)  | 0.008 (0.008)                       | 0.009 (-0.013 to 0.038)                          |
| Dressing aids                       | 0 (0)  | 0 (0)                               | -  |
| Long-handle shoe horn               | 0.018 (0.009)  | 0.008 (0.006)                       | 0.009 (-0.009 to 0.032)                          |
| Other                               | 0.144 (0.047)  | 0.091 (0.030)                       | 0.054 (-0.031 to 0.188)                          |
|                                     |  |                                     |  |
| <b>Personal social services</b>     | <b>No. of contacts (SE)</b>  |                                     |  |
| Frozen meals on wheels              | 0 (0)  | 0 (0)                               | -  |
| Hot meals on wheels                 | 0 (0)  | 0 (0)                               | -  |
| Laundry services                    | 0 (0)  | 0 (0)                               | -  |
| Social worker contacts              | 0 (0)  | 0 (0)                               | -  |
| Care worker/home help               | 0.036 (0.036)  | 0 (0)                               | 0.036 (0 to 0.138)                               |
| Other                               | 0 (0)  | 0 (0)                               | -  |
|                                     |  |                                     |  |
| <b>Productivity losses</b>          | <b>No. of days off work</b>  |                                     |  |
| Days off work                       | 1.894 (0.743)  | 4.301 (1.172)                       | -2.407 (-5.642 to -0.110)                        |
|                                     |  |                                     |  |
|                                     |  |                                     |  |
| <b>Nine-month follow-up</b>         | <b>Mean length of stay in days (SE)</b>                                  |                                     |  |
| Hospital stay                       | 0 (0)  | 0 (0)                               | -  |
|                                     |  |                                     |  |

|  | <b>Plaster Cast<br/>(N=266)</b>  | <b>Functional brace<br/>(N=274)</b> | <b>Mean difference (Bootstrapped<br/>95% CI)</b> |
|--|--|-------------------------------------|--|
| <b>Outpatient care</b>                 |  |                                     |  |
|  | <b>Mean no. of visits (SE)</b>   |                                     |  |
| Orthopaedics                           | 0.090 (0.024)  | 0.077 (0.030)                       | 0.013 (-0.060 to 0.081)                          |
| Pathology                              | 0.016 (0.008)  | 0.073 (0.027)                       | -0.057 (-0.120 to -0.012)                        |
| Radiology                              | 0.029 (0.011)  | 0.012 (0.009)                       | 0.017 (-0.005 to 0.047)                          |
| Physiotherapy NHS                      | 0.709 (0.108)  | 0.857 (0.147)                       | -0.148 (-0.540 to 0.178)                         |
| Physiotherapy Private                  | 0.234 (0.073)  | 0.174 (0.058)                       | 0.060 (-0.103 to 0.260)                          |
| Emergency Department (injury –related) | 0.004 (0.004)  | 0.008 (0.005)                       | -0.004 (-0.016 to 0.012)                         |
| Emergency Department (other reasons)   | 0.020 (0.011)  | 0.030 (0.014)                       | -0.010 (-0.051 to 0.019)                         |
| Other                                  | 0.140 (0.058)  | 0.089 (0.045)                       | 0.051 (-0.090 to 0.206)                          |
| <b>Community health care</b>           |  |                                     |  |
|  | <b>Mean no. of contacts (SE)</b>   |                                     |  |
| GP Visits (surgery)                    | 0.058 (0.024)  | 0.046 (0.017)                       | 0.011 (-0.046 to 0.072)                          |
| GP (home visits)                       | 0 (0)  | 0 (0)                               | -  |
| GP (telephone contacts)                | 0.008 (0.006)  | 0.004 (0.004)                       | 0.004 (-0.007 to 0.021)                          |
| Practice nurse contacts                | 0 (0)  | 0.004 (0.004)                       | -0.004 (-0.016 to 0)                             |
| District nurse contacts                | 0 (0)  | 0 (0)                               | -  |
| Community physiotherapy contacts       | 0.169 (0.052)  | 0.255 (0.066)                       | -0.085 (-0.258 to 0.071)                         |
| Calls to NHS direct                    | 0 (0)  | 0 (0)                               | -  |
| Calls for an ambulance or paramedic    | 0 (0)  | 0 (0)                               | -  |
| Occupational therapy contacts          | 0.074 (0.038)  | 0.031 (0.017)                       | 0.043 (-0.033 to 0.128)                          |
| Other                                  | 0.136 (0.070)  | 0.131 (0.100)                       | 0.005 (-0.307 to 0.214)                          |
| <b>Medicines</b>                       |  |                                     |  |
|  | <b>Proportion of participants prescribed each<br/>class of drug (SE)</b> |                                     |  |
| Analgesics                             | 0.037 (0.012)  | 0.031 (0.011)                       | 0.006 (-0.027 to 0.037)                          |
| Anti-inflammatories                    | 0.012 (0.007)  | 0 (0)                               | 0.012 (0 to 0.029)                               |
| Anti-coagulant                         | 0.004 (0.004)  | 0 (0)                               | 0.004 (0 to 0.016)                               |
| Other                                  | 0.004 (0.004)  | 0.004 (0.004)                       | 0 (-0.008 to 0.016)                              |
| <b>Aids and adaptations</b>            |  |                                     |  |
|  | <b>Mean count (SE)</b>   |                                     |  |
| Crutches                               | 0 (0)  | 0.008 (0.008)                       | -0.008 (-0.029 to 0)                             |
| Stick                                  | 0.012 (0.009)  | 0.004 (0.004)                       | 0.009 (-0.008 to 0.036)                          |
| Zimmer frame                           | 0 (0)  | 0 (0)                               | -  |
| Grab Rail                              | 0.008 (0.008)  | 0 (0)                               | 0.008 (0 to 0.031)                               |
| Dressing aids                          | 0 (0)  | 0 (0)                               | -  |
| Long-handle shoe horn                  | 0.004 (0.004)  | 0 (0)                               | 0.004 (0 to 0.017)                               |
| Other                                  | 0.062 (0.025)  | 0.093 (0.026)                       | -0.031 (-0.097 to 0.046)                         |
| <b>Personal social services</b>        |  |                                     |  |
|  | <b>No. of contacts (SE)</b>  |                                     |  |
| Frozen meals on wheels                 | 0.045 (0.045)  | 0 (0)                               | 0.045 (0 to 0.182)                               |
| Hot meals on wheels                    | 0 (0)  | 0 (0)                               | -  |
| Laundry services                       | 0.045 (0.045)  | 0 (0)                               | 0.045 (0 to 0.182)                               |

|                            | Plaster Cast<br>(N=266)     | Functional brace<br>(N=274) | Mean difference (Bootstrapped<br>95% CI) |
|----------------------------|-----------------------------|-----------------------------|--|
| Social worker contacts     | 0 (0)                       | 0 (0)                       | -  |
| Care worker/home help      | 0.008 (0.008)               | 0 (0)                       | 0.008 (0 to 0.037)                       |
| Other                      | 0 (0)                       | 0 (0)                       | -  |
|                            |                             |                             |  |
|                            |                             |                             |  |
| <b>Productivity losses</b> | <b>No. of days off work</b> |                             |  |
| Days off work              | 0.340 (0.340)               | 1.952 (0.758)               | -1.613 (-3.357 to 0.019)                 |

222 GP: general practitioner

223 **5.2 Economic Costs**

224 Table A4 summarises the total NHS and PSS costs associated with resource use during the trial period among  
225 complete cases, by cost category and follow-up period. The mean direct intervention costs were £35.71 for the  
226 Plaster Cast group compared with £108.64 for the Functional Brace group; the mean difference of £72.93 was  
227 statistically significant at the 5% level. The mean total NHS and PSS costs were significantly lower in the  
228 Functional Brace group between randomisation and 8-week post injury and between 8 weeks and 3 months  
229 post injury with mean between-group cost differences of £107.73 and £92.95, respectively. The mean total  
230 NHS and PSS cost throughout the entire follow-up period was £1182.64 for the Plaster Cast group and  
231 £1018.26 for the Functional Brace group; the mean between-group cost difference of £164.39 was not  
232 statistically significant at the 5% level.

233

234

235

236 **Table A4: NHS and personal social services costs for cases with complete resource use data by trial**  
237 **allocation, study period and cost category (£, 2017-18 prices)**

| Cost category by period  | Treatment group,<br>mean (SE) Cost |                       | Mean<br>difference | p-value <sup>a</sup> | Bootstrap 95%<br>CI <sup>b</sup> |
|--|------------------------------------|-----------------------|--------------------|----------------------|----------------------------------|
|  | Plaster Cast                       | Functional Brace      |                    |                      |                                  |
| <b>Baseline to 8 weeks post injury – direct intervention costs<sup>c</sup> (total, n = 497: Plaster Cast group; n = 241; Functional Brace group, n =256)</b> |                                    |                       |                    |                      |                                  |
| Total direct intervention costs  | 35.71 (0.492)                      | 108.64 (3.114)        | -72.93             | <0.0001              | (-79.22 to -66.64)               |
| <b>Baseline to 8 weeks post injury – NHS PSS resource use (total, n = 432: Plaster cast group; n = 210; Functional brace group, n =222)</b>                  |                                    |                       |                    |                      |                                  |
| Inpatient care   | 55.8 (28.382)                      | 39.3 (22.163)         | 16.51              | 0.65                 | (-53.48 to 86.49)                |
| Outpatient care  | 370.2 (15.114)                     | 282.6 (15.078)        | 87.59              | <0.0001              | (45.97 to 129.21)                |
| Community care   | 9.66 (2.521)                       | 28.94 (14.493)        | -19.28             | 0.19                 | (-47.64 to 9.07)                 |
| Medications  | 151.35 (9.334)                     | 106.45 (8.701)        | 44.9               | <0.0001              | (20.34 to 69)                    |
| Aids and adaptations   | 9.51 (0.842)                       | 7.32 (0.568)          | 2.19               | 0.032                | (0.20 to 4.19)                   |
| Personal Social Services   | 0.15 (0.151)                       | 0 (0)                 | 0.15               | 0.32                 | (-0.14 to 0.45)                  |
| Total NHS and PSS cost   | 596.67 (36.596)                    | 464.61 (32.946)       | 132.06             | 0.0080               | (33.35 to 230.78 )               |
| <b>Total Costs throughout first 8 weeks (including direct intervention costs)<sup>d</sup></b>  | <b>647.88 (37.99)</b>              | <b>540.15 (26.10)</b> | <b>107.73</b>      | <b>0.02</b>          | <b>(16.15 to 199.31)</b>         |
| <b>8 weeks – 3months post injury (total, n = 434: Plaster Cast group; n = 207; Functional Brace group, n =227)</b>   |                                    |                       |                    |                      |                                  |
| Inpatient care   | 61.69 (27.278)                     | 4.74 (4.74)           | 56.95              | 0.041                | (4.33 to 109.57)                 |
| Outpatient care  | 118.74 (9.948)                     | 98.76 (7.608)         | 19.98              | 0.11                 | (-5.07 to 45.03)                 |
| Community care   | 31.96 (15.86)                      | 19.89 (4.77)          | 12.07              | 0.34                 | (-20.69 to 44.83)                |
| Medications  | 5.95 (3.359)                       | 2.86 (2.133)          | 3.1                | 0.44                 | (-4.56 to 10.75)                 |
| Aids and adaptations   | 1.65 (0.359)                       | 0.75 (0.261)          | 0.9                | 0.044                | (0.014 to 1.78)                  |

| Cost category by period  | Treatment group, mean (SE) Cost |                         | Mean difference | p-value <sup>a</sup> | Bootstrap 95% CI <sup>b</sup> |
|--|---------------------------------|-------------------------|-----------------|----------------------|-------------------------------|
|  | Plaster Cast                    | Functional Brace        |                 |                      |                               |
| PSS  | 0 (0)                           | 0.04 (0.04)             | -0.04           | 0.32                 | (-0.12 to 0.039)              |
| <b>Total NHS and PSS cost</b>  | <b>220.00 (36.662)</b>          | <b>127.04 (12.333)</b>  | <b>92.95</b>    | <b>0.017</b>         | <b>(14.80 to 171.11)</b>      |
| <b>3 – 6 months post injury (total , n = 436: Plaster Cast group; n = 210; Functional Brace group, n =226)</b> |                                 |                         |                 |                      |                               |
| Inpatient care   | 21.08 (16.736)                  | 43.94 (22.392)          | -22.86          | 0.41                 | (-80.61 to 34.90)             |
| Outpatient care  | 128.56 (11.731)                 | 142.56 (13.215)         | -14             | 0.43                 | (-47.66 to 19.67)             |
| Community care   | 33.56 (2.617)                   | 27.75 (5.679)           | 5.812           | 0.38                 | (-19.98 to 31.60)             |
| Medications  | 0 (0)                           | 1.51 (1.015)            | -1.51           | 0.14                 | (-3.56 to 0.54)               |
| Aids and adaptations   | 1.02 (0.472)                    | 1.03 (0.534)            | -0.01           | 0.99                 | (-1.38 to 1.36)               |
| PSS  | 0.49 (0.491)                    | 0 (0)                   | 0.49            | 0.32                 | (-0.42 to 1.40)               |
| <b>Total NHS and PSS cost</b>  | <b>184.70 (26.350)</b>          | <b>216.78 (29.988)</b>  | <b>-32.07</b>   | <b>0.42</b>          | <b>(-108.74 to 44.58)</b>     |
| <b>6 – 9 months post injury (total , n = 491: Plaster Cast group; n = 235; Functional Brace group, n =256)</b> |                                 |                         |                 |                      |                               |
| Inpatient care   | 5.94 (4.771)                    | 45.45 (45.45)           | -39.51          | 0.39                 | (-133.06 to 54.05)            |
| Outpatient care  | 76.44 (22.253)                  | 65.98 (9.884)           | 10.46           | 0.67                 | (-39.34 to 60.26)             |
| Community care   | 14.03 (4.022)                   | 17.302 (7.197)          | -3.27           | 0.69                 | (-19.78 to 13.24)             |
| Medications  | 0.33 (0.228)                    | 0.13 (0.058)            | 0.2             | 0.40                 | (-0.26 to 0.66)               |
| Aids and adaptations   | 0.36 (0.217)                    | 0.08 (0.052)            | 0.28            | 0.21                 | (-0.15 to 0.71)               |
| PSS  | 0.11 (0.11)                     | 0 (0)                   | 0.11            | 0.32                 | (-0.10 to 0.32)               |
| <b>Total NHS and PSS cost</b>  | <b>97.21 (23.666)</b>           | <b>128.94 (46.80)</b>   | <b>-31.73</b>   | <b>0.54</b>          | <b>(-127.40 to 63.94)</b>     |
| <b>0 – 9 months post injury (total , n = 292: Plaster Cast group; n = 134; Functional Brace group, n =158)</b> |                                 |                         |                 |                      |                               |
| Total direct intervention costs  | 35.96 (0.646)                   | 106.46 (4.08)           | -70.5           |                      | (-78.30 to -62.69)            |
| Inpatient care   | 162.29 (85.042)                 | 45.43 (24.373)          | 116.86          | 0.19                 | (-62.66 to 296.38)            |
| Outpatient care  | 722.78 (39.326)                 | 653.42 (40.288)         | 69.36           | 0.22                 | (-38.61 to 177.33)            |
| Community care   | 103.22 (33.32)                  | 91.18 (22.809)          | 12.04           | 0.77                 | (-67.72 to 91.80)             |
| Medications  | 146.41 (11.364)                 | 112.61 (10.884)         | 33.8            | 0.033                | (-2.66 to 64.94)              |
| Aids and adaptations   | 11.75 (1.331)                   | 9.16 (1.127)            | 2.59            | 0.14                 | (-0.71 to 5.88)               |
| PSS  | 0.24 (0.236)                    | 0 (0)                   | 0.24            | 0.32                 | (-0.22 to 0.70)               |
| <b>Total NHS and PSS costs throughout first 9 months</b>   | <b>1182.64 (114.696)</b>        | <b>1018.26 (58.143)</b> | <b>164.39</b>   | <b>0.20</b>          | <b>(-95.75 to 424.52)</b>     |

238

<sup>a</sup> p-value calculated using the student's t-test, two-tail unequal variance

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<sup>b</sup> Non-parametric bootstrap estimation using 1000 replications

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<sup>c</sup> Time horizon for calculating total direct intervention costs was 8 weeks in order to capture costs associated with any changes required to either plaster cast or functional bracing (e.g. plaster cast changes)

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<sup>d</sup> Total costs throughout first 8 weeks calculated based on total sample size of 415: Plaster cast, n=200;

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Functional brace, n=215) i.e. cases with complete intervention and resource use costs at 8 weeks.

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PSS: Personal social services

**5.3 Health outcomes**

Table A5 summarised the EQ-5D Utility and EQ-5D VAS estimates and the estimated difference between the two treatment groups for each study period. The mean EQ-5D utility score was significantly lower at 8 weeks post injury in the Functional Brace group (0.588 versus 0.655; p<0.0001) amongst complete cases. However, there were no statistically significant differences in EQ-5D utility scores between the treatment groups at any other follow-up time-point. There were no statistically significant differences in the Visual Analogue Scale scores between the comparator groups.

**Table A5: EQ-5D Utility and EQ-5D VAS mixed effects model results at 8, 3, 6 and 9 months post injury (modified ITT population) by trial allocation and study period**

|                      | Plaster Cast (n = 266)          |     | Functional Brace (n = 274)      |     | Between - Group Difference (95% CI) |                       |         |
|----------------------|---------------------------------|-----|---------------------------------|-----|-------------------------------------|-----------------------|---------|
|                      | Mean (SD)                       | n   | Mean (SD)                       | n   | Unadjusted                          | Adjusted <sup>b</sup> | p-value |
| <b>EQ-5D Utility</b> |                                 |     |                                 |     |                                     |                       |         |
| Baseline post injury | 0.242 (0.02, .47) <sup>a</sup>  | 264 | 0.282 (0.03, 0.52) <sup>a</sup> | 273 | 0.042 (0.01, 0.08)                  | 0.041 (0.01, 0.07)    | 0.017   |
| 8 week               | 0.588 (0.23)                    | 234 | 0.655 (0.18)                    | 241 | 0.066 (0.03, 0.1)                   | 0.069 (0.03, 0.1)     | 0.00051 |
| 3 month              | 0.638 (0.22)                    | 229 | 0.669 (0.19)                    | 245 | 0.031 (-0.01, 0.07)                 | 0.035 (0, 0.07)       | 0.056   |
| 6 month              | 0.766 (0.15)                    | 224 | 0.757 (0.18)                    | 237 | -0.009 (-0.05, 0.03)                | -0.002 (-0.04, 0.03)  | 0.916   |
| 9 month              | 0.829 (0.72, 0.91) <sup>a</sup> | 244 | 0.795 (0.72, 0.88) <sup>a</sup> | 259 | -0.010 (-0.05, 0.03)                | -0.009 (-0.04, 0.03)  | 0.623   |
| <b>EQ-5D VAS</b>     |                                 |     |                                 |     |                                     |                       |         |
| Baseline post injury | 90.0 (80, 95) <sup>a</sup>      | 263 | 90.0 (80, 95) <sup>a</sup>      | 273 | 0.77 (-2.18, 3.72)                  | 1.28 (-1.4, 3.97)     | 0.349   |
| 8 week               | 75.0 (60, 85) <sup>a</sup>      | 234 | 75.0 (65, 85) <sup>a</sup>      | 240 | 1.08 (-2.05, 4.2)                   | 1.61 (-1.21, 4.43)    | 0.264   |
| 3 month              | 80.0 (65, 85) <sup>a</sup>      | 229 | 80.0 (65, 90) <sup>a</sup>      | 245 | 1.29 (-1.84, 4.42)                  | 1.66 (-1.16, 4.48)    | 0.249   |
| 6 month              | 81.5 (70, 90) <sup>a</sup>      | 224 | 80.0 (70, 90) <sup>a</sup>      | 236 | 0.49 (-2.69, 3.66)                  | 1.08 (-1.77, 3.93)    | 0.458   |
| 9 month              | 86.0 (80, 92) <sup>a</sup>      | 242 | 85.0 (75, 91) <sup>a</sup>      | 259 | -0.76 (-3.8, 2.28)                  | -0.56 (-3.32, 2.2)    | 0.693   |

<sup>a</sup> Median (Interquartile Range); <sup>b</sup> Analysis adjusted for site, age, gender and EQ-5D baseline pre-injury with repeated observations within participant  
 VAS: Visual Analogue Scale; CI: Confidence Interval; SD: standard deviation

**5.4 Cost-effectiveness results**

The cost-effectiveness results are presented in Table A65 with Plaster Cast selected as the referent and Functional Brace as the comparator, i.e. functional brace minus plaster cast, for the estimation of ICER values. The analytic time horizon covers the entire 9-month post-injury follow-up period of the trial. The joint distribution of costs and outcomes for the base-case analysis is graphically represented in Figure A1.

**5.4.1 Base case analysis**

Patients in the Functional Brace group experienced a non-statistically significant increase in QALYs in the base case (0.015 QALYs, 95% CI: -0.0013 to 0.030) over the 9-month follow-up period. Mean NHS and PSS costs were also lower in the Functional Brace group [mean cost difference: -£103 (95% CI: -289 to 84)]. The ICER for the base-case analysis indicates that functional bracing is the dominant procedure as average costs for this intervention were lower whilst average benefits were greater than those for plaster cast. Assuming cost-effectiveness thresholds of £15000 per QALY, £20000 per QALY and £30000 per QALY, respectively, the probability of cost-effectiveness for functional bracing ranged from 0.96 to 0.97, whilst the NMB associated with functional bracing was positive (Table A56; Figure A2).

**5.4.2 Sensitivity analyses**

Comparing mean costs and QALY estimates using different analytical scenarios (complete case, societal perspective and CACE population) revealed that the cost-effectiveness results generally supported the base case finding, with the exception of the sensitivity analysis that adopted a societal perspective. For the societal



279 perspective, mean costs were higher in the Functional Brace group (£248, 95% CI: -476 to 972). However, the  
280 QALY results followed the same pattern as that for the base case analysis and indicated that participants in the  
281 Functional Brace group experienced a non-statistically significant increase in QALYs over the 9-month follow-  
282 up period (0.015 QALYs, 95%CI: -0.0042 to 0.031). The probability of cost-effectiveness of functional brace  
283 declined to a range of 0.50 to 0.69 at cost-effectiveness thresholds of £15000 per QALY, £20000 per QALY and  
284 £30000 per QALY. The results of the mixed effects model followed a similar pattern to that of the base case  
285 (imputed) model: Patients in the Functional Brace group experienced a non-statistically significant increase in  
286 QALYs (0.014 QALYs, 95% CI: -0.0018 to 0.031) over the 9-month follow-up period. Mean NHS and PSS costs  
287 were also lower in the Functional Brace group [mean cost difference: -£135 (95% CI: -342 to 71)].  
288

#### 289 **5.4.3 Long-term economic modelling**

290 The protocol allowed for decision-analytic modelling to estimate the longer-term cost-effectiveness of  
291 functional bracing or plaster cast. However, we note that cost and health utility values started to converge  
292 from the 3-month follow-up time-point and converged at subsequent time points, even though functional  
293 brace was cost-effective over the entire follow-up period. It was therefore concluded that longer-term  
294 extrapolation of cost-effectiveness of functional is highly unlikely to be meaningful. Furthermore, we did not  
295 identify external studies that compared differences in economic costs, functional outcomes or health-related  
296 quality of life beyond 9 months post injury in non-surgical patients treated with a plaster cast or functional  
297 brace. This lack of data needed to parameterize a model further challenged any efforts to conduct longer-term  
298 decision modelling.

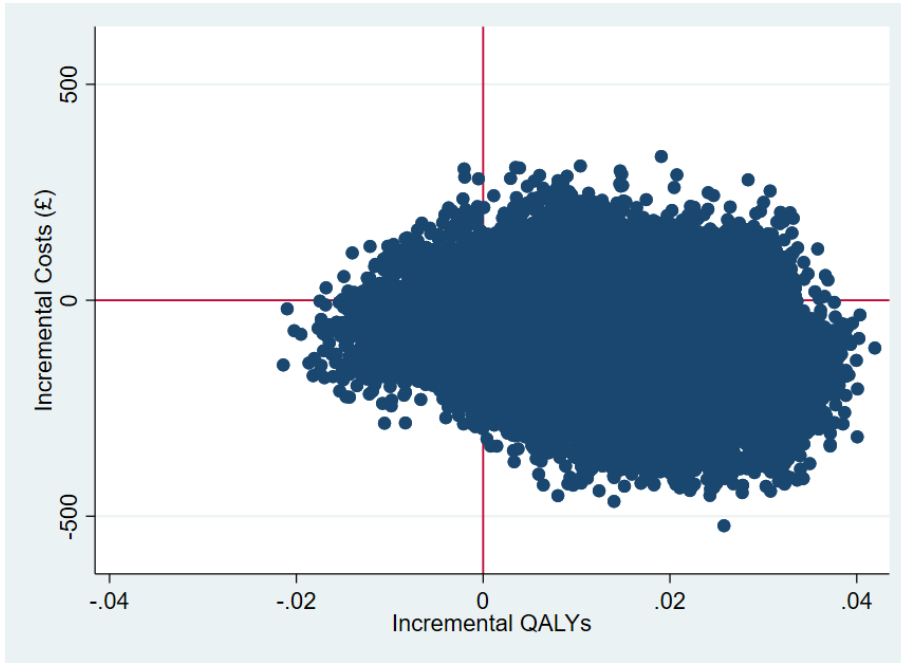
**Table A65: Cost-effectiveness, cost/QALY (£, 2017): functional brace compared to plaster cast**

| Scenario   | Treatment group, mean (SE) Cost |                  | Incremental cost (95% CI)  | Treatment group, mean (SE) QALY |                 | Incremental QALYs (95% CI) | ICER*    | Probability of cost-effectiveness |                |                | Net monetary benefits                   |   |   |
|--|---------------------------------|------------------|----------------------------|---------------------------------|-----------------|----------------------------|----------|-----------------------------------|----------------|----------------|---|---|---|
|  | Functional Brace                | Plaster Cast     |                            | Functional Brace                | Plaster Cast    |                            |          | p <sup>1</sup>                    | p <sup>2</sup> | p <sup>3</sup> | NMB <sup>1</sup> (95% CI <sup>6</sup> ) | NMB <sup>2</sup> (95% CI <sup>6</sup> ) | NMB <sup>3</sup> (95% CI <sup>6</sup> ) |
| <b>Base case analysis</b>  |                                 |                  |                            |                                 |                 |                            |          |                                   |                |                |   |   |   |
| Imputed attributable costs and QALYs, covariate adjusted                         | 1078.16 (83.42)                 | 1180.72 (89.63)  | -102.56 (-289.28 to 84.16) | 0.506 (0.0064)                  | 0.492 (0.0066)  | 0.015 (-0.0013 to 0.030)   | Dominant | 0.963                             | 0.965          | 0.966          | 312.28 (-31.26 to 655)                  | 383.82 (-32.67 to 793.80)               | 526.90 (-42.50 to 1076.87)              |
| <b>Sensitivity analyses</b>  |                                 |                  |                            |                                 |                 |                            |          |                                   |                |                |   |   |   |
| Complete case attributable costs and QALYs, covariate adjusted                   | 948.77 (53.91)                  | 1117.28 (110.66) | -168.51 (-458.01 to 32.88) | 0.513 (0.00642)                 | 0.497 (0.0064)  | 0.017 (-0.0035 to 0.037)   | Dominant | 0.976                             | 0.976          | 0.972          | 443.54 (19.83 to 933.22)                | 527.26 (9.11 to 1094.07)                | 694.70 (-17.56 to 1406.23)              |
| Societal perspective   | 4362.15 (348.71)                | 4114.54 (292.18) | 247.61 (-476.44 to 971.66) | 0.506 (0.0063)                  | 0.502 (0.007)   | 0.015 (-0.0042 to 0.031)   | 16510    | 0.501                             | 0.576          | 0.688          | -29.65 (-991.50 to 874.93)              | 44.36 (-964.19 to 991.46)               | 192.39 (-926.97 to 1244.53)             |
| CACE <sup>4</sup> population   | 1038.6 (62.89)                  | 1169.44 (78.48)  | -130.84 (-335.38 to 90.36) | 0.510 (0.00609)                 | 0.488 (0.00688) | 0.022 (0.0051 to 0.038)    | Dominant | 0.992                             | 0.993          | 0.994          | 44.52 (89.86 to 852.63)                 | 57.36 (127.50 to 1030.39)               | 818.02 (199.26 to 1434.03)              |
| Secondary cost-effectiveness analysis using ATRS <sup>4</sup> as outcome measure | 1057.22 (71.91)                 | 1149.44 (79.25)  | -92.21 (-273.86 to 89.44)  | 45.09 (0.72)                    | 44.30 (0.73)    | 0.78 (-1.12 to 2.69)       | Dominant | 0.875                             | 0.839          | 0.822          | 174.03 (-117.37 to 463.44)              | 328.84 (-306 to 970.91)                 | 406.25 (-403.75 to 1218.76)             |

300 \*ICER: Incremental cost-effectiveness ratio. Given the pattern of results, Plaster Cast has been selected as the referent and Functional Brace as the comparator, i.e. functional brace minus  
301 plaster cast, for the estimation of ICER values. Dominance indicates average costs were less and average benefit greater for functional brace vs. plaster cast  
302 P<sup>1</sup>, P<sup>2</sup>, P<sup>3</sup>: probability cost-effective if cost-effectiveness threshold set at £15,000/QALY, £20,000/QALY or £30,000/QALY, respectively with the exception of the sensitivity analysis using ATRS  
303 as the health outcome measure of interest. In the latter case P<sup>1</sup>, P<sup>2</sup>, P<sup>3</sup> refer to probability of cost-effectiveness if cost-effectiveness threshold arbitrarily set at £100; £300 and £500 per unit  
304 gain in ATRS score

305 NMB<sup>1</sup>, NMB<sup>2</sup>,NMB<sup>3</sup>: net monetary benefit if cost-effectiveness threshold set at £15,000/QALY, £20,000/QALY or £30,000/QALY, respectively with the exception of the sensitivity analysis  
306 using ATRS as the health outcome measure of interest. In the latter case NMB<sup>1</sup>, NMB<sup>2</sup>,NMB<sup>3</sup> refer to net monetary benefit if cost-effectiveness threshold arbitrarily set at £100; £300 and  
307 £500 per unit gain in ATRS score  
308 <sup>4</sup>CACE Complier Average Causal Effect  
309 <sup>5</sup> ATRS (Achilles Tendon Rupture Score) range from 0 to 100 with higher scores indicating better outcome  
310 <sup>6</sup>CI: confidence interval  
311 QALY: quality adjusted life-year  
312  
313

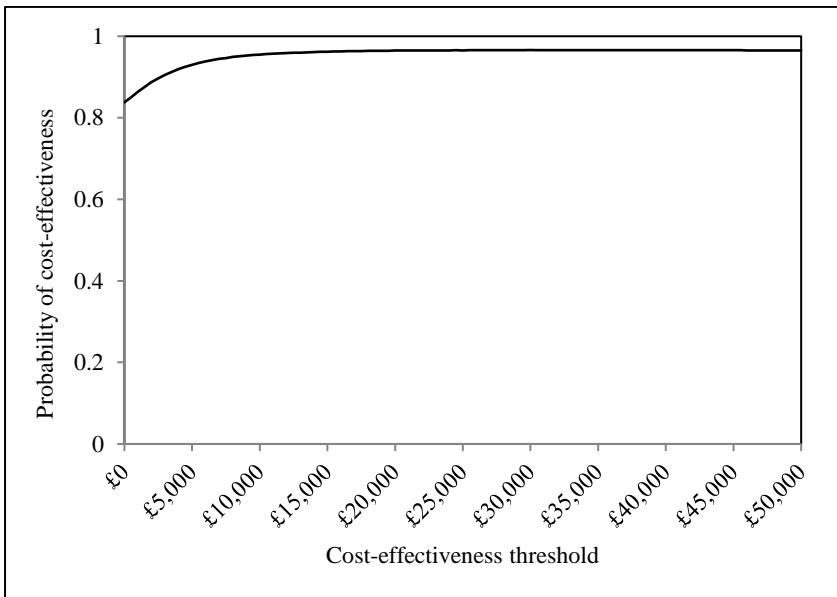
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316 **Figure A1: Cost-effectiveness scatterplot at 9 months for base case analysis (NHS and personal social service**  
317 **perspective, imputed- additionally controlled for pre-injury utility, intention-to-treat analysis)**

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320 **Figure A2: Cost-effectiveness acceptability curve at 9 months for base case analysis (NHS and personal social**  
321 **service perspective, imputed- additionally controlled for pre-injury utility, intention-to-treat analysis)**

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