

PRESTO TRIAL: 2 WEEK TREATMENT CONFIRMATION FORM

Participant ID Number:

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Date of visit:

		/			/				
day			month			year			

Tick here if patient did not attend visit

☐

This form is for the Research Nurse/Associate and Surgeon to complete at the 2 Week follow up assessment appointment.

If patient was initially recruited via consultee process have they provided informed consent?

*Yes ☐

No ☐

*If 'Yes', date of consent:

		/			/				
day			month			year			

1. Regardless of which treatment the patient was randomised to, please tick any of the following that the patient received for their spine injury since the Eligibility Assessment:

Surgery 1*	<input type="checkbox"/>	If so, date of surgery	<table style="display: inline-table; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="padding: 0 5px;">/</td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="padding: 0 5px;">/</td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> </tr> </table>			/			/				
		/			/								
Surgery 2*	<input type="checkbox"/>	If so, date of surgery	<table style="display: inline-table; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="padding: 0 5px;">/</td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="padding: 0 5px;">/</td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> </tr> </table>			/			/				
		/			/								
Orthotic Brace (off the shelf)	<input type="checkbox"/>	If so, date commenced	<table style="display: inline-table; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="padding: 0 5px;">/</td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="padding: 0 5px;">/</td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> </tr> </table>			/			/				
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		Stop date	<table style="display: inline-table; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="padding: 0 5px;">/</td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="padding: 0 5px;">/</td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> </tr> </table>			/			/				
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Orthotic Brace (customised)	<input type="checkbox"/>	If so, date commenced	<table style="display: inline-table; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="padding: 0 5px;">/</td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="padding: 0 5px;">/</td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> </tr> </table>			/			/				
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		/			/								
Other:	<input type="checkbox"/>	If so, date commenced	<table style="display: inline-table; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="padding: 0 5px;">/</td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="padding: 0 5px;">/</td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> </tr> </table>			/			/				
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Specify:		Stop date	<table style="display: inline-table; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="padding: 0 5px;">/</td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="padding: 0 5px;">/</td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> </tr> </table>			/			/				
		/			/								

*Please ensure that a surgery form is completed for each surgery listed

2. If the patient did not receive the treatment they were randomised to, please record the date of, and reason for, the decision to cross-over to the alternative treatment.

Date:

day	month

 /

day	month

 /

day	month	day	month

Reason for cross-over: ☐ Patient Choice

☐ Surgeon Choice

Reason:

3. For patients randomised to conservative treatment option, is fracture stabilised? Yes ☐ *No ☐

*If 'No', please indicate action to be taken (specify if none):

4. For patients randomised to conservative treatment option, please list any specific instructions regarding treatment compliance given at this clinic visit?

☐ Brace worn for 24 hours/day (except washing)

☐ Brace worn during day only

☐ Bed rest with activity allowed

☐ Other (specify):



Pragmatic Randomised Evaluation of Stable Thoracolumbar fracture treatment Outcomes (PRESTO)
A multi-centre randomised controlled trial funded by NHS R&D Health Technology Assessment Programme
(International Standardised Randomised Controlled Trial Number 12094890)

5. Physiotherapy received in hospital from physiotherapist/spinal CNS/Orthotist since randomisation

Date of 1st Physiotherapy session: / /
day month year

Number of sessions: Average duration of sessions: mins

Advice and education given (*please tick all that apply*):

☐ Bracing ☐ Mobilisation ☐ Precautions ☐ Exercises

Date of mobilisation at the advice of the Physio: / /
day month year

Walking aids given? Yes ☐ No ☐ Specify:

Any lasting complications?

☐ Pain ☐ Stiffness ☐ Reduced function ☐ None ☐ Other (specify):

Date of discharge from Physiotherapy: / / ☐ Tick if not yet discharged
day month year

6. Imaging received since treatment date (*please tick all that apply*):

Date: (dd/mm/yyyy)	x-ray (standing)	x-ray (sitting)	x-ray (supine)	CT scan (standing)	CT scan (sitting)	CT scan (supine)	MRI (supine)
<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Kyphotic angle measurement (COBB) degrees

Date of imaging used in measurement: / /
day month year

Kyphotic angle measured: ☐ Supine ☐ Sitting ☐ Standing

Via which imaging type:

7. Date of discharge from hospital:

/ / ☐ Tick if not yet discharged Length of hospital stay days
day month year

Where was patient discharged to?

☐ Own home ☐ Relative's home ☐ Residential home ☐ Nursing home

☐ Other (specify):

Completed by (signature/date):

/ /
day month year

Thank you for completing this form which the designated person should now return to York Trials Unit in the freepost envelope provided.