

CASE REPORT FORM

Physiotherapy Rehabilitation for Osteoporotic Vertebral Fracture Study - PROVe study

Study Reference numbers
Ethics Ref: 12/SC/0411
Project ID: 1078633
Study Sponsor – University of Oxford

STUDY SITE: Nuffield Orthopaedic Centre

PRINCIPAL INVESTIGATOR: Karen Barker

PARTICIPANT INITIALS:

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PARTICIPANT ID:

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I am confident that the information supplied in this case record form is complete and accurate data. I confirm that the study was conducted in accordance with the protocol and any protocol amendments and that written informed consent was obtained prior to the study.

Investigator's Signature: _____

Date of signature:

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Please check only one box

Baseline assessment

16 week assessment

12 month assessment

Participant Initials: Study Number: Results - DEXA T-score lumbar spine . Fracture Sites (Check box(es)) – Lower lumbar (L3, L4, L5) Mid-Lumbar (L1, L2), Lower Thoracic (T6 -T12) Upper Thoracic (T1-T5)Number of total spinal fractures - Number of previous non-spinal fractures in **past year** -

Fracture Location			Fracture Date (DD/MMM/YYYY)
Shoulder	Right <input type="checkbox"/>	Left <input type="checkbox"/>	
Elbow	Right <input type="checkbox"/>	Left <input type="checkbox"/>	
Wrist	Right <input type="checkbox"/>	Left <input type="checkbox"/>	
Hip	Right <input type="checkbox"/>	Left <input type="checkbox"/>	
Knee	Right <input type="checkbox"/>	Left <input type="checkbox"/>	
Ankle	Right <input type="checkbox"/>	Left <input type="checkbox"/>	
Others	<input type="checkbox"/>	<input type="checkbox"/>	

Other previous fractures

Fracture Location			Fracture Date (DD/MMM/YYYY)
Shoulder	Right <input type="checkbox"/>	Left <input type="checkbox"/>	
Elbow	Right <input type="checkbox"/>	Left <input type="checkbox"/>	
Wrist	Right <input type="checkbox"/>	Left <input type="checkbox"/>	
Hip	Right <input type="checkbox"/>	Left <input type="checkbox"/>	
Knee	Right <input type="checkbox"/>	Left <input type="checkbox"/>	
Ankle	Right <input type="checkbox"/>	Left <input type="checkbox"/>	
Others	<input type="checkbox"/>	<input type="checkbox"/>	

Participant Initials:

Study Number:

Current mobility: (Circle only one from each relevant level of function)

Walking distance	Stairs	Aid Use
Unlimited	Normal (reciprocal)	None
500m-1km	One step at a time	Stick outdoors
100-500m	Down with rail	Stick always
<100m	Up & down with rail	2 sticks
Housebound	Unable down	2 Crutches
Unable	Unable	Walking frame wheeled walker

Falls history in past year

Number of falls -

Falls History in General

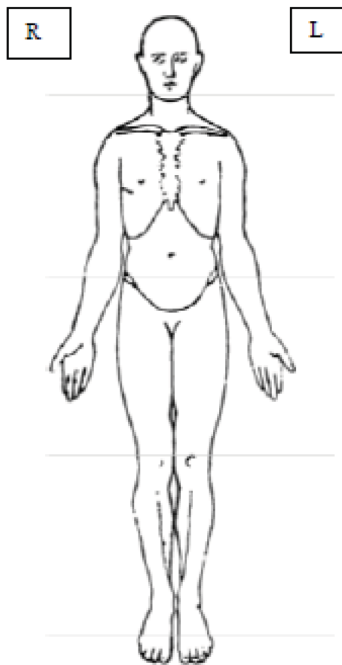
Frequent (\geq once a week) occasionally (\leq once a month) rarely (\leq once a year)

Participant Initials:

Study Number:

BODY CHART – past two weeks

Researcher please check the box(es) at the bottom of the chart to show any areas where the participant has experienced pain in the past **two weeks**. P = /////



Have you experienced any back pain in the last two weeks? (Please tick)

Yes

No

Pain Site Lower lumbar (L3, L4, L5), Mid-Lumbar (L1, L2), Lower Thoracic (T6 -T12) Upper Thoracic (T1-T5)

Mark on the scale below the severity of any back pain in the last two weeks.

0	1	2	3	4	5	6	7	8	9	10
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No pain

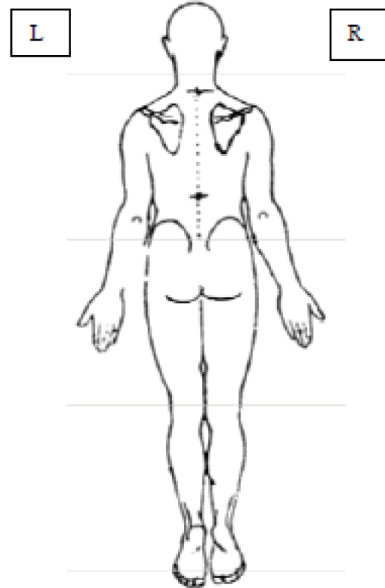
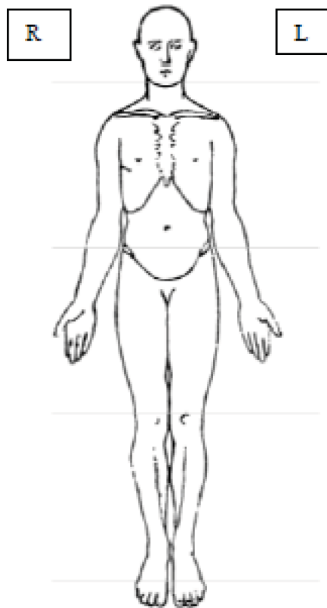
Worst pain Imaginable

Participant Initials:

Study Number:

BODY CHART – Today

Researcher please check the box(es) at the bottom of the chart to show any areas where the participant has experienced pain today. P = /////



Do you have any back pain today? (Please tick)

Yes

No

Pain Site Lower lumbar (L3, L4, L5), Mid-Lumbar (L1, L2), Lower Thoracic (T6 -T12) Upper Thoracic (T1-T5)

Mark on the scale below the severity of any back pain is today.

0	1	2	3	4	5	6	7	8	9	10
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No pain

Worst pain imaginable

Participant Initials:

Study Number:

C. Outcome Measures

1. Functional Reach Test

	Trial 1	Trial 2
Distance (cms)	<input type="text"/> <input type="text"/> · <input type="text"/>	<input type="text"/> <input type="text"/> · <input type="text"/>

2. Timed Loaded Standing

Weight used (kg):

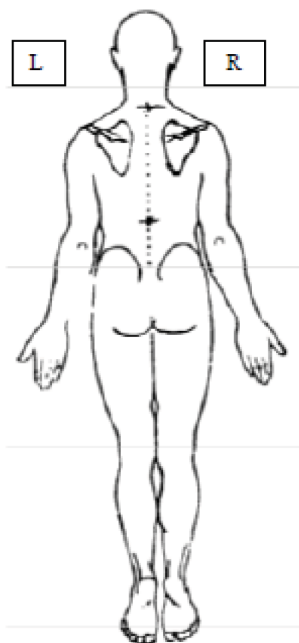
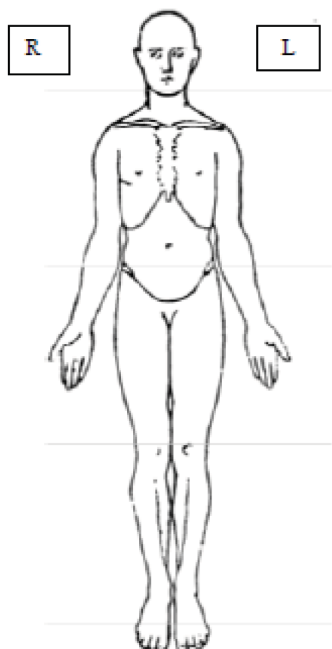
Total time (seconds):

Use 1 kg. Only if participant is unable to use 1 use 0.5 kg.

Stopped by: participant physiotherapist

Reason for stopping: pain fatigue

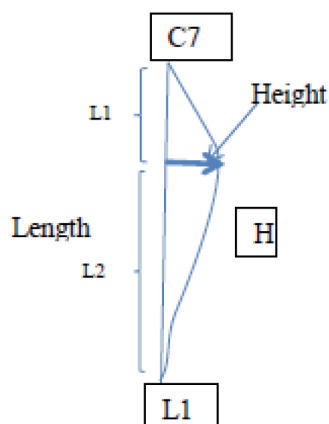
Location of any pain or fatigue on body diagram: Pain = ///// Fatigue = +



Pain Site Lower lumbar (L3, L4, L5), Mid-Lumbar (L1, L2), Lower Thoracic (T6 -T12) Upper Thoracic (T1-T5)

Participant Initials: Study Number: **3. Flexicurve (mm) - use the graph paper to obtain readings**

	Total Curve Length (C7 – L1)	Curve Height (H) (Perpendicular line from apex to base)	Curve length 1 (L1) (C7 to where height intersects base)	Curve length (L2) (L1 to where height intersects base)
1 st				
2 nd				
3 rd				

**4. Short Physical Performance Battery**

Lower Limb Strength Repeated chair stands with arms folded. Stop at 5 stands or after 1 minute	Number of stands completed: 1 2 3 4 5 (Circle)		
	Time: <input type="text"/> <input type="text"/> sec (if 5 stands completed)		
Balance Testing. Please circle level achieved. Must achieve level 2 (hold 10sec) to advance from a) to b) to c). 2. Held for 10 sec 1. Held for <10 sec;	a) Side-by-side	b) Semi-tandem	c) Tandem
	2	2	2
	1 – state time <input type="text"/> <input type="text"/> sec	1 – state time <input type="text"/> <input type="text"/> sec	1 – state time <input type="text"/> <input type="text"/> sec
	0	0	0

Participant Initials: Study Number:

number of seconds held 0. Not attempted			
Gait Testing 2.44 metres	Walk 1. Time: <input type="text"/> <input type="text"/> sec	Walk 2 Time: <input type="text"/> <input type="text"/> sec	

5. Six minute walk test

Distance completed	<input type="text"/> <input type="text"/> m <input type="text"/> <input type="text"/> cm	
Track Length		
Number of stops or rests (if any)		
Duration of stop		
Self-report rating of exertion CR10-RPE scale (0-10)	Before 6 minute walk	After 6 minute walk
	Breathing <input type="text"/>	<input type="text"/>
	Legs <input type="text"/>	<input type="text"/>

Checklist (check appropriate box)

- Comorbidity questionnaire (General Health Questions) completed incomplete
- PASE Questionnaire completed incomplete
- Qualeffo 41 completed incomplete
- ED-5DL completed incomplete
- Participant health diary & Falls calendar collected at 16 wks and 12 mths

Assessor signature: _____

Assessor printed name: _____

Date: ___/___/___

Participant Initials: Study Number: **Adverse Events:**

Has the patient experienced any Adverse Events since signing the Informed Consent?

Yes

No

If an adverse event has occurred please use DATIX (incident reporting system) to log and describe event and note below

Adverse Event 1	Details
Date of event: ___ / ___ / _____	Diagnosis if known or signs and symptoms:
Logged on DATIX Yes No <input type="checkbox"/> <input type="checkbox"/>	Severity 1 = Mild 2 = Moderate 3 = Severe
Action Taken	
Outcome 1 = Resolved 2 = Recovered with sequelae 3 = Continuing	
Withdrawn from study due to SAE? 1 = No 2 = Yes, happy for existing data to be used 3 = Yes, data destroyed	

Adverse Event 2	Details
Date of event: ___ / ___ / _____	Diagnosis if known or signs and symptoms:
Logged on DATIX Yes No <input type="checkbox"/> <input type="checkbox"/>	Severity 1 = Mild 2 = Moderate 3 = Severe
Action Taken	
Outcome 1 = Resolved 2 = Recovered with sequelae 3 = Continuing	
Withdrawn from study due to SAE? 1 = No 2 = Yes, happy for existing data to be used 3 = Yes, data destroyed	

Add more pages if there are more than 2 adverse events.

Participant Initials:

Study Number:

OFF STUDY FORM

Date Off Study: ____/____/_____
(DD/MM/YYYY)

Date Of Last Assessment: ____/____/_____
(DD/MM/YYYY)

Reason Off Study (Please mark only the primary reason. **Reasons other than Completed Study require explanation next to the response**)

- AE/SAE (complete AE CRF & SAE form, if applicable) _____
- Lost to follow-up _____
- Non-compliant participant _____
- Medical contraindication _____
- Withdraw consent _____
- Death (complete SAE form) _____
- Other _____

Please circle as appropriate

1. Participant has permitted use of already collected data for the final data analysis
YES **NO**
2. Participant has agreed to receive postal questionnaires at 6 and 9 months
YES **NO**
3. Participant is willing to be contacted for assessment visits and may come in for the assessments only
4. YES **NO**

Patient Initials _ _ _

Study ID _ _ _ _ _ Date _ _ / _ _ / _ _ _ _ _

GENERAL HEALTH QUESTIONS

The following questions are related to your general health

Please **circle** the response that applies to you

1. Have you ever had a heart attack?	YES/NO
2. Have you ever been treated for heart failure? (You may have been short of breath and the doctor may have told you that you had fluid in your lungs or that your heart was not pumping well.)	YES/NO
3. Have you had an operation to unclog or bypass the arteries in your legs?	YES/NO
4. Have you had a stroke, cerebrovascular accident (CVA), blood clot or bleeding in the brain or transient ischemic attack (TIA)?	YES/NO
5. Do you have asthma?	YES/NO
If yes , do you take medicines for your asthma? a. no b. yes, only with flare-ups of my asthma c. Yes, I take medicines regularly, even when I'm not having a flare up	A/B/C
6. Do you have emphysema, chronic bronchitis, or chronic obstructive lung disease?	YES/NO
If yes , do you take medicine for your lung disease? a. no b. yes, only with flare-ups of my lung disease c. Yes, I take medicines regularly, even when I'm not having a flare up	A/B/C
7. Do you have stomach ulcers, or peptic ulcer disease?	YES/NO
If yes , has this condition been diagnosed by endoscopy (where a doctor looks into your stomach through a scope) or an upper GI or barium swallow study (where you swallow chalky dye and then x-rays are taken)?	YES/NO

