

#### 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:						
PARTICIPANT ID:						
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:						
d d m m	m y y y y					
Please check only one box						
Baseline assessment 16 we	eek assessment 12 month assessment					

PROVE measures: Case report form: March 2013 REC Number: 12/SC/0411 ISRCTN Number: 49117867

INFORMED CONSENT
Please note: written informed consent must be given before any study specific procedures take place.
Has the person freely given written informed consent? Yes No
Date consent form signed://
Original consent in study master file, copy given to participant Yes No
<u>Assessment</u>
Date:/ Assessor Name
A. <u>Demographic and Background Information</u>
Date of Birth:// Gender: Male Female
Dominant hand: Right Left Both
Height - (cms) Weight - (kgs)
B. Relevant medical history:
Diagnosis of primary osteoporosis: Yes No
Time since diagnosis MMM/YYYY/
Radiology (from medical notes - Check spinal fractures: note date, location and number of spinal fractures)
Did you have a DEXA scan? Yes No
Most recent DEXA scan date - MMM/YYYY/

Study Number:

Participant Initials:

Participant Initials:	Study Numb	er:						
Results - DEXA T-score lumbar spine								
Lower Thor	acic (T6 -T12) Upp	per Thoracic (T1-T5)						
Number of total spin	al fractures -							
Number of previous	non-spinal fractures in past year	ar						
Fra	cture Location	Fracture Date (DD/MMM/YYYY)						
Shoulder	Right Left							
Elbow	Right Left							
Wrist	Right Left							
Hip	Right Left							
Knee	Right Left							
Ankle	Right Left							
Others								
Other previous fracti	ures							
	cture Location	Fracture Date (DD/MMM/YYYY)						
Shoulder	Right Left							
Elbow	Right Left							
Wrist	Right Left							
Hip	Right Left							
Knee	Right Left							
Ankle	Right Left							
Others								

ISRCTN Number: 49117867

Walking distance	Stairs	Aid Use
Jnlimited	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
Jnable	Unable	Walking frame wheeled walker
alls history in past y	<u>rear</u>	

Study Number:

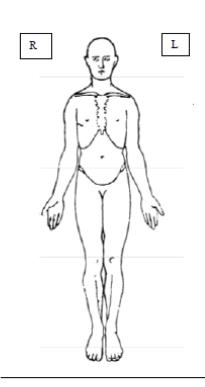
Participant Initials:

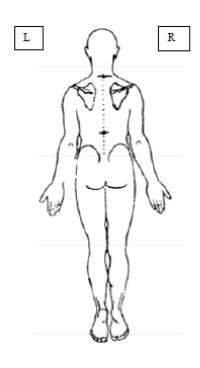
year)

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 = IIIIII





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

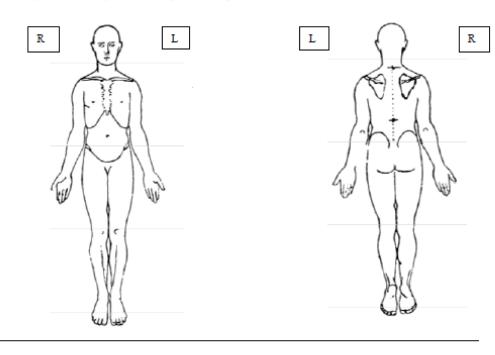
No pain

Worst pain Imaginable

Participant Initials:		Study Number:		ı		
ranticipant initiais.				Study Number.		ı

#### **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 = IIIIII



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

No pain Worst pain imaginable

Participant Initials:	Study Number:		

## C. Outcome Measures

## 1. Functional Reach Test

	Trial 1	Trial 2		
Distance (cms)				

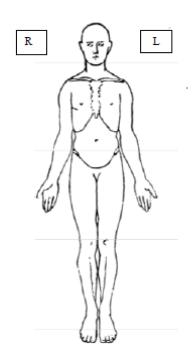
2	Time	d L	oad	ed	Stan	dinc
-	1 111115		vuu	EM.	Juli	MILITY

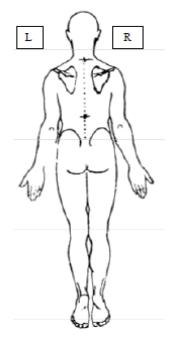
Weight used (kg):			Total time (seconds):			
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Use 1 kg. Only if participant is unable to use 1 use 0.5 kg.

Stopped by:	participant		physiotherapist	
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Location of any pain or fatigue on body diagram: Pain = ///// Fatigue = +



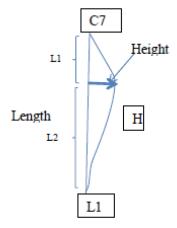


Pain Site	Lower lumbar (L3, L4, L5),	Mid-Lumbar (L1, L2),	Lower Thoracio
(T6 -T12)	Upper Thoracic (T1-T5)		

Participant Initials:		Study Number:			
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## 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 <sup>st</sup>				
2 <sup>nd</sup>				
3rd				



## 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: sec (if 5 stands completed)				
Balance Testing.	a) Side-by-side	b) Semi-tandem	c) Tandem		
Please circle level achieved.	2	2	2		
Must achieve level 2 (hold 10sec) to advance from a) to b) to c).	1 – state sec	1 – state sec	1 – state sec		
2. Held for 10 sec 1.Held for <10 sec;	0	0	0		

Participant Initials:		Study Number:				
· · · · · · · · · · · · · · · · · · ·						
number of seconds held 0. Not attempted						
Gait Testing 2.44 metres	Walk 1	1. Walk		sec		
5. Six minute walk tes	<u>st</u>					
Distance completed		m		cm		
Track Length						
Number of stops or rests	(if any)					
Duration of stop						
Self-report rating of exert	ion	Before 6 minute walk		After 6 minute walk		
CR10-RPE scale (0-10)		Breathing				
		Legs				
	-					
		ecklist (check appro	•	_		
	aire (G	General Health Questions	_	completed incomplete		
PASE Questionnaire			completed incomplete			
Qualeffo 41			completed incomplete			
ED-5DL				completed incomplete		
Participant health diary	& Fal	ls 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 Eve	ents 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	Severity 1 = Mild 2 = Moderate 3 = Severe			
Action Taken	o- Jevele			
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	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.

OFF STUDY FORM
Date Off Study://
Date Of Last Assessment://
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
<ol> <li>Participant has permitted use of already collected data for the final data analysis YES NO</li> </ol>
<ol> <li>Participant has agreed to receive postal questionnaires at 6 and 9 months YES NO</li> </ol>
Participant is willing to be contacted for assessment visits and may come in for the assessments only

Study Number:

Participant Initials:

NO

4. YES

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

Patient Initials				
Study ID	Date _	/	/	

Do you have diabetes (high blood sugar)?	YES/NO
If yes, is your diabetes treated by	A/B/C
a. modifying my diet	
c. medications taken by mouth	
d. insulin injections	
has the diabetes caused any of the following problems	
a. problems with your kidneys	A/B
b. problems with your eyes, treated by an ophthalmologist	
O. D	1/50710
Do you have rheumatoid arthritis?	YES/NO
If yes do you take medications for it regularly?	YES/NO
Do you have Lupus (systemic lupus erythematosus)?	YES/NO
Do you have Polymyalgia rheumatica?	YES/NO
10. Do you have any of the following conditions:	
i) Alzheimer's disease or any other form of dementia	YES/NO
ii) Cirrhosis, or serious liver damage	YES/NO
iii) Leukemia or polycythemia vera	YES/NO
iv) Lymphoma	YES/NO
v) Cancer, other than skin cancer, leukaemia or lymphoma?	YES/NO
<u>If yes</u>	
has this been present for more than 5 years?	
Has the cancer spread, or metastasized to other parts of your	YES/NO
body?	YES/NO
vi) AIDs	YES/NO
Do you have any other joint problems?	YES/NO
<u>If yes</u> , please provide details	