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| 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 |

|  |  |
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| **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 week assessment 12 month assessment

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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 | | | | | |
|  | | | | | |

**Assessment**

Date: \_\_ \_\_/\_\_ \_\_ \_\_/\_\_ \_\_ \_\_ \_\_ Assessor Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Demographic and Background Information**

Date of Birth: \_\_ \_\_/\_\_ \_\_ \_\_/\_\_ \_\_ \_\_ \_\_ Gender: Male Female

Dominant hand: Right Left Both

Height - ­­­­­­­­­­­­­ (cms) Weight - (kgs)

1. **Relevant medical history:**

Diagnosis of primary osteoporosis: Yes Yes No 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 - \_\_ \_\_/\_\_ \_\_ \_\_/\_\_ \_\_ \_\_ \_\_

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 Left |  |
| Elbow Right Left |  |
| Wrist Right Left |  |
| Hip Right Left |  |
| Knee Right Left |  |
| Ankle Right Left |  |
| Others |  |

Other previous fractures

|  |  |
| --- | --- |
| Fracture 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 |  |

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

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

**Falls history in past year**

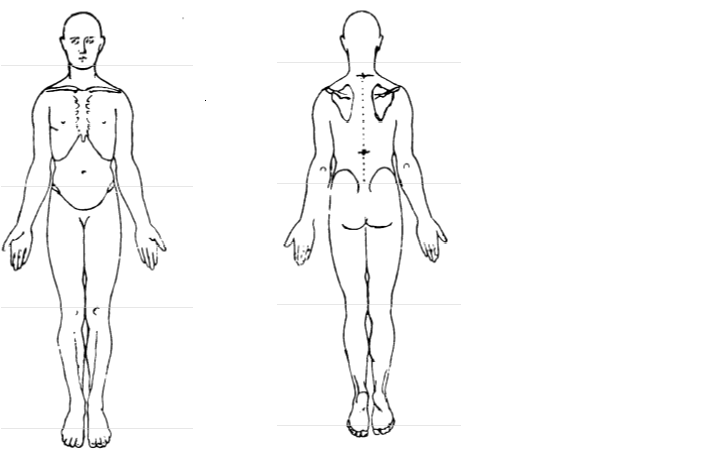
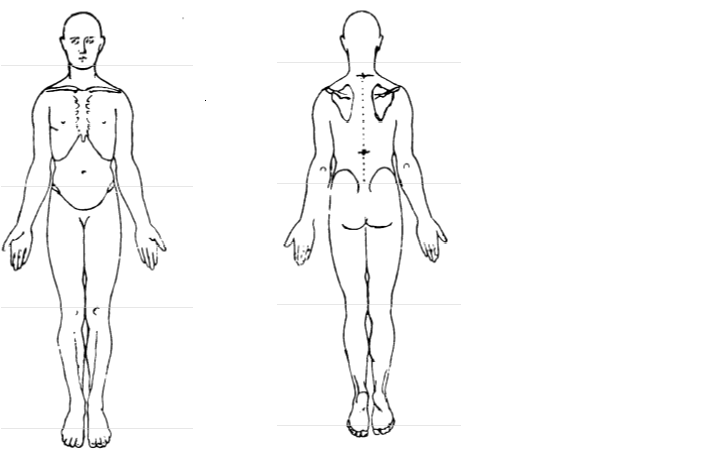
Number of falls -

**Falls History in General**

Frequent (≥ once a week) occasionally (≤ once a month) rarely (≤ once a year)

**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 = **//////**

** **

R

L

L

R

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.

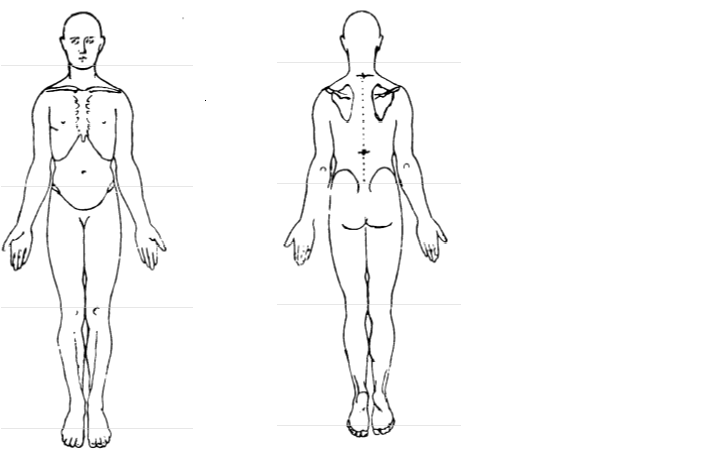
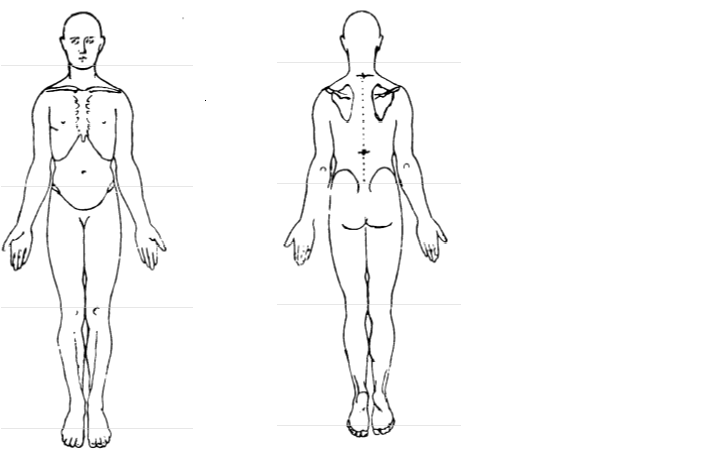
|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **0** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** |

No pain Worst pain

Imaginable

**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 = **//////**

** ­­­­­­­**

L

R

L

R

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

**C. Outcome Measures**

**1. Functional Reach Test**

|  |  |  |
| --- | --- | --- |
|  | **Trial 1** | **Trial 2** |
| **Distance (cms)** | **.** | **.** |

**2. Timed Loaded Standing**

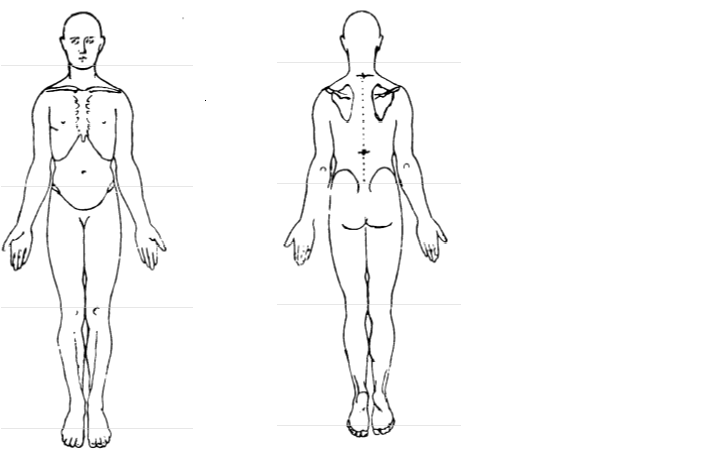
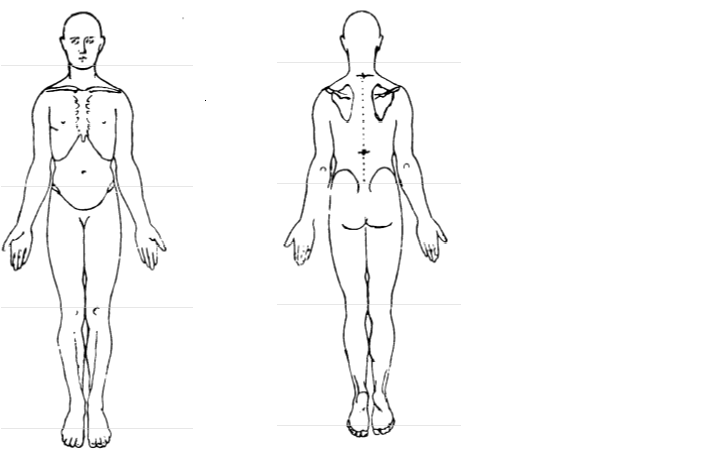
Weight used (kg): Total time (seconds):

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 = +

** ­­­­ **

L

R

L

R

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

**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) |
| **1st** |  |  |  |  |
| **2nd** |  |  |  |  |
| **3rd** |  |  |  |  |

C7

H

L1

Length

Height

L1

L2

**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.**  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; number of seconds held  0. Not attempted | **a) Side-by-side** | **b) Semi-tandem** | | **c) Tandem** |
| 2  1 – state  time sec  0 | 2  1 – state    time sec  0 | | 2  1 – state    time sec  0 |
| **Gait Testing**  2.44 metres | **Walk 1.**  **Time: sec** | | **Walk 2**  **Time: sec** | |

**5. Six minute walk test**

|  |  |  |
| --- | --- | --- |
| **Distance completed** | m 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** |  |
| **Legs** |  |

**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: \_\_ \_\_/\_\_ \_\_ \_\_/\_\_ \_\_ \_\_ \_\_

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 | 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 | 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: \_\_\_ \_\_\_ / \_\_\_ \_\_\_ / \_\_\_ \_\_\_ \_\_\_ \_\_\_  *(DD/MM/YYYY)* |

|  |
| --- |
| Date Of Last Assessment: \_\_\_ \_\_\_ / \_\_\_ \_\_\_ / \_\_\_ \_\_\_ \_\_\_ \_\_\_  *(DD/MM/YYYY)* |

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| --- |
| **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**

1. Participant has agreed to receive postal questionnaires at 6 and 9 months

**YES NO**

1. Participant is willing to be contacted for assessment visits and may come in for the assessments only
2. **YES NO**