**Reach to Grasp data**

**Key:-**

**In B1, B2 and B3 forms**

**\_t1 at the end of a short field name = baseline**

**\_t2 = 7 weeks**

**\_t3 = 3 months**

**\_t4 = 6 months**

**‘assesstime’ field – present in B4, D1 forms – is:**

**1 = baseline**

**2 = 7 weeks**

**3 = 3 months**

**4 = 6 months**

**‘ind\_X’ field indicates if the patient had data in the database for that CRF form/section e.g. if ind\_a1=1 then that patient had data entered into the database from CRF A1.**

**The main data file – “Outcomes” – contains data from CRFs A1-2, B0-5, N1, W1 and the screening log. Patient 4013 is not included in this dataset as they withdrew pre-randomisation. They are however included in a separate data file containing all of the withdrawal (CRF W1) data.**

**Randomisation system (some of these fields are also present in other datasets)**

|  |  |  |  |
| --- | --- | --- | --- |
| **CRF field name** | **Short field name***(name used in database)* | **Notes** | **Data contained in file** |
| Study ID | patientid | Number, 5 digits | Outcomes |
| Site id | siteid | 1 to 5 |
| Randomisation date | randdate |  |
| Stroke date (as help on randomisation system) | strokedate\_rand |  |
| Treatment group | treat | Usual Care or Reach to Grasp |
| ARAT score at randomisation | aratscore\_rand | 0-3; 4-28; 29-56 |
| Time from stroke to randomisation | timestroke\_rand | 3 months or under; over 3 months |

**Screening Log**

|  |  |  |  |
| --- | --- | --- | --- |
| **CRF field name***(something meaningful relating to what’s on CRF)* | **Short field name***(name used in database)* | **Field type***(text, Number, drop down with options, date etc)* | **Data contained in file(s)** |
| Study ID | patientid | Number, 5 digits | Outcomes; SL |
| Month and Year identified | iden\_month |

|  |  |
| --- | --- |
|  Dec-11 | =Dec 2011 |
| 1 | =Jan 2012 |
| 2 | =Feb 2012 |
| 3 | =Mar 2012 |
| 4 | =Apr 2012 |
| 5 | =May 2012 |
| 6 | =Jun 2012 |
| 7 | =Jul 2012 |
| 8 | =Aug 2012 |
| 9 | =Sep 2012 |
| 10 | =Oct 2012 |
| 11 | =Nov 2012 |
| 12 | =Dec 2012 |
| Jan-13 | =Jan 2013 |
| Feb-13 | =Feb 2013 |
| Mar-13 | =Mar 2013 |
| Apr-13 | =Apr 2013 |
|  |  |

 |
| Patient consent to referral to research team? | cons\_refer | Number: 1=yes, 0=no |
| Has patient consented to trial? | cons\_trial | Number: 1=yes, 0=no |
| If yes, date of consent:  | con\_date | Date |
| Date randomised | rand\_date | Date |
| Has patient consented to details being kept? | cons\_det | Number: 1=yes, 0=no |
| Gender | gend | Number: 1= Male 2= Female |
| Sitting with back against a chair, is the person able to touch their knee? | reach\_knee | Number: 1=yes, 0=no |
| Sitting with back against a chair, is the person able to lift a can off a table? | grasp\_can | Number: 1=yes, 0=no |
| Involved in other studies? | oth\_stu | Number: 1=yes, 0=no,  |
| If not participating, has patient requested not to be asked again? | not\_part\_ask | Number: 1=yes, 0=no |
| If not participating, for what reason(s)? | not\_part\_why | Max 500 characters |
| Eligible | eligible | Number: 1=yes, 0=no |
| Inclusion 1: Diagnosis of stroke | inc1\* | Number: 1=yes, 0=no |
| Inclusion 2: Discharged Home (i.e. permanent address, may include care home/sheltered accomodation) | inc2 | Number: 1=yes, 0=no |
| Inclusion 3: Remaining upper limb movement deficit defined as being unable to pick up a 6mm ball bearing from the table top, between index finger and thumb, and place it on a shelf 37cm above table | inc3 | Number: 1=yes, 0=no |
| Inclusion 4: Able to give consent to take part | inc4e | Number: 1=yes, 0=no |
| Exclusion 1: Pre-stroke pathology of stroke-affected upper limb preventing reach to grasp | exc1 | Number: 1=yes, 0=no |
| Exclusion 2: Unable to lift hand off lap when asked to place hand behind head | exc2 | Number: 1=yes, 0=no |
| Exclusion 3: Severe fixed contractures of elbow or wrist (i.e. grade 4 on the modified Ashworth scale) | exc3 | Number: 1=yes, 0=no |
| Exclusion 4: More than 12 months post-stroke (as few patients receive treatment ? 12 months) | exc4 | Number: 1=yes, 0=no |

*\*note – all inc and exc variable data are missing in the dataset*

**CRF: A1**

|  |  |  |  |
| --- | --- | --- | --- |
| **CRF field name** | **Short field name** | **Notes** | **Data contained in file** |
| Study ID | patientid | Number | Outcomes |
| Gender | gen | Number: 1=male, 2=female |
| Side affected by stroke | cve\_side | 1= Left 2= Right3 = Both |
| Handedness | lrhanded | 1=Left2= Right3 = both |
| Age at randomisation | age\_rand | Number |
| Living | livi | Number: 1=Living alone, 2=With family or friends |
| Residence | resi | 1=Sheltered accommodation, 2=with family or friends, 3=Nursing home, 4=Usual residence  |
| Date of stroke | cve\_date | date |
| Stroke type | cve\_type | 1=Infarct, 2=Haemorrhage, 3=subarachnoid haemorrhage |
| Thrombolysed | throm | Number: 1=yes, 0=no |
| Name of hospital admitted to | hospital | Max characters 100 |
| Stroke subtype | cve\_subtype | 1=total anterior, 2=partial anterior, 3=lacunar, 4=posterior circulation |
| NIHSS score on admission | nihss\_score | Number |
| Scan available | scan | Number: 1=yes, 0=no |
| Date admitted | adm\_date | date |
| Date discharged (including ESD) | dcdate | Date  |
| Early supported discharge | esd | Number: 1=yes, 0=no |
| Outpatients | outpatients | Number: 1=yes, 0=no |
| Community phsio or OT for arm including DART or ICT | physio\_ot | Number: 1=yes, 0=no |
| Botox therapy | botox | Number: 1=yes, 0=no |

**CRF: A2**

|  |  |  |  |
| --- | --- | --- | --- |
| **CRF field name** | **Short field name** | **Notes** | **Data contained in file** |
| Previous CVE or TIA | co\_morb\_stroke | Number: 1=yes, 0=no | Outcomes |
| Ischaemic heart disease  | co\_morb\_ihd | Number: 1=yes, 0=no |
| Diabetes mellitus | co\_morb\_diabetes | Number: 1=yes, 0=no |
| Peripheral vascular disease | co\_morb\_pvd | Number: 1=yes, 0=no |
| Hypertension | co\_morb\_ hypertension | Number: 1=yes, 0=no |
| Hyperlipidaemia | co\_morb\_hyperlipidaemia | Number: 1=yes, 0=no |
| Atrial fibrillation | co\_morb\_atrial | Number: 1=yes, 0=no |
| Arthritis affecting upper limb | co\_morb\_arthritis | Number: 1=yes, 0=no |
| Depression | co\_morb\_depression | Number: 1=yes, 0=no |

**CRF: B0 MOCA**

|  |  |  |  |
| --- | --- | --- | --- |
| **CRF field name** | **Short field name** | **Notes** | **Data contained in file** |
| MOCA: Alternating trail making | moca\_atm | Number | Outcomes |
| MOCA: Visuoconstructional skills (cube)  | moca\_cube | Number |
| MOCA: Visuoconstructional skills (clock)  | moca\_clock | Number |
| MOCA: Naming  | moca\_nam | Number |
| MOCA: Attention  | moca\_att | Number |
| MOCA: Abstraction | moca\_abs | Number |
| MOCA: Delayed recall  | moca\_del\_rec | Number |
| MOCA: Orientation  | moca\_ori | Number |
| MOCA: ≤ 12 years in education  | moca\_ed | Number: 1=yes, 0=no |

**CRF: B0 Assessment Details**

|  |  |  |  |
| --- | --- | --- | --- |
| **CRF field name** | **Short field name** | **Notes** | **Data contained in file** |
| **Baseline:-** |  |  | Outcomes |
| Date of baseline assessment | baseline\_date | Date  |
| Time of baseline assessment | baseline\_time | Time  |
| any AE’s | baseline\_aes | Number: 1=yes, 0=no |
| Height of table | baseline\_table\_height | Number |
| Height of chair | baseline\_chair\_height | Number |
| Arm rest on chair | baseline\_arm\_rest | Number: 1=yes, 0=no |
| Assessor | baseline\_assessor | Number: 1=Emma Heron, 2=Paul Cunningham, 3=Ailie Turton, 4=Verity Longley |
| **7 weeks:-** |  |  |
| Date of 7 week assessment | week7\_ date | Date  |
| Time of 7 week assessment | week7\_ time | Time  |
| any AE’s | week7\_aes | Number: 1=yes, 0=no |
| Other chair used | week7\_oth\_chair | Number: 1=yes, 0=no |
| Height of chair | week7\_chair\_height | Number |
| Arm rest on chair | week7\_arm\_rest | Number: 1=yes, 0=no |
| Why other chair used | week7\_why\_oth\_chair | Max 100 charcters |
| Assessor | week7\_assessor | Number: 1=Emma Heron, 2=Paul Cunningham, 3=Ailie Turton, 4=Verity Longley |
| **3 month:-** |  |  |
| Date of 3 month assessment | month3 date | Date  |
| Time of 3 month assessment | month3\_time | Time  |
| any AE’s | month3\_aes | Number: 1=yes, 0=no |
| Other chair used | month3\_oth\_chair | Number: 1=yes, 0=no |
| Height of chair | month3\_chair\_height | Number |
| Arm rest on chair | month3\_arm\_rest | Number: 1=yes, 0=no |
| Why other chair used | month3\_why\_oth\_chair | Max 100 charcters |
| Assessor | month3\_assessor | Number: 1=Emma Heron, 2=Paul Cunningham, 3=Ailie Turton, 4=Verity Longley |
| **6 month:-** |  |  |
| Date of 6 month assessment | 6 month date | Date  |
| Time of 6 month assessment | 6 month time | Time  |
| any AE’s | 6 month AE’s | Number: 1=yes, 0=no |
| Other chair used | month6\_oth\_chair | Number: 1=yes, 0=no |
| Height of chair | month6\_chair\_height | Number |
| Arm rest on chair | month6\_arm\_rest | Number: 1=yes, 0=no |
| Why other chair used | month6\_why\_oth\_chair | Max 100 charcters |
| Assessor | month6\_assessor | Number: 1=Emma Heron, 2=Paul Cunningham, 3=Ailie Turton, 4=Verity Longley |

**CRF B1: VAS – now/other**

|  |  |  |  |
| --- | --- | --- | --- |
| **CRF field name** | **Short field name** | **Notes** | **Data contained in file** |
|  How would you rate any pain you have now? | painrate | Number | Outcomes |
| How would you rate any pain you have other times? | painrateothertime | Number |

**CRF B1: ARAT**

|  |  |  |  |
| --- | --- | --- | --- |
| **CRF field name** | **Short field name** | **Notes** | **Data contained in file** |
| ARAT Grasp ‘x’ | graspx | Where ‘x’ = 1 to 6. For example, grasp1. Number. | Outcomes |
| ARAT Grasp Total | grasptotal | Number |
| ARAT Grip ’x’ | grip ’x’ | Where ‘x’ = 1 to 4. For example, grip1. Number |
| ARAT Grasp Total | griptotal | Number |
| ARAT Pinch ’x’ | pinch 1 | Where ‘x’ = 1 to 6. For example, pinch1. Number |
| ARAT Grasp Total | pinchtotal | Number |
| ARAT Gross Movement ’x’ | gross1 | Where ‘x’ = 1 to 3. For example, gross1. Number |
| ARAT Grasp Total | grosstotal | Number |
| ARAT Total | arattotal | Number |

**CRF B2: WMFT**

|  |  |  |  |
| --- | --- | --- | --- |
| **CRF field name** | **Short field name** | **Notes** | **Data contained in file** |
| WMFT ‘x’ time | wmft\_’x’\_ time | Where ‘n = 1 to 6, 8 to 13, 15 to 17. For example, wmft\_1\_time Number | Outcomes |
| WMFT ‘x’ quality | wmft \_x\_quality | Where ‘x’ = 1 to 6, 8 to 13, 15 to 17. For example, wmft\_1\_quality. Number |
| WMFT 7 Weight | wmft\_7 | Number |
| WMFT 14a Grip | wmft \_14a | Number |
| WMFT 14b Grip | wmft \_14b | Number |
| WMFT 14c Grip | wmft \_14c | Number |
| WMFT 3 Talc, duster neither | wmft \_3\_t/d/n | 1=Talcum2=Duster3=Neither |
| WMFT 14\* Talc, duster neither | wmft\_14\_t/d/n | 1=Talcum2=Duster3=Neither |
| WMFT Height of box | wmft \_box | 1=6 inches2=8 inches3=10 inches |

\*I think this is perhaps supposed to be WMFT8 not WMFT14 – (Note from Ailie Turton, the talc is only used on item 3 so this must be a mistake)

**CRF B2: MAL QoM**

|  |  |  |  |
| --- | --- | --- | --- |
| **CRF field name** | **Short field name** | **notes** | **Data contained in file** |
| MAL ‘x’ QoM | mal\_x\_qom | Where ‘x’ is MAL question number, 1 to 28. For example, mal\_1\_qom | Outcomes |

**CRF B2: MAL AoU**

|  |  |  |  |
| --- | --- | --- | --- |
| **CRF field name** | **Short field name** | **notes** | **Data contained in file** |
| MAL ‘x’ AoU | mal\_x\_aou | Where ‘x’ is MAL question number, 1 to 28. For example, mal\_1\_aou | Outcomes |

**CRF B2: VAS assessment**

|  |  |  |  |
| --- | --- | --- | --- |
| **CRF field name** | **Short field name** | **Field type** | **Data contained in file** |
| How would you rate any pain you experienced during the assessment? | vas\_assess | Number | Outcomes |

**CRF B3: SIS**

|  |  |  |  |
| --- | --- | --- | --- |
| **CRF field name** | **Short field name** | **Notes** | **Data contained in file** |
| SIS Physical ‘x’ | sis\_phys\_x | where ‘x’ is a to d. For example,. sis\_phys\_a | Outcomes |
| SIS Memory ‘x’ | sis\_mem\_ x | where ‘x’ is a to g |
| sis emotion ‘x’ | sis\_emo\_x | where ‘x’ is a to i |
| sis communication ‘x’ | sis\_comm\_ x | where ‘x’ is a to g |
| sis adl ‘x’ | sis\_adl\_x | where ‘x’ is a to j |
| sis mobility ‘x’ | sis\_mob\_x | where ‘x’ is a to i |
| sis hand function ‘x’ | sis\_hand\_x | where ‘x’ is a to e |
| sis participation ’n’ | sis\_part\_x | where ‘x’ is a to h |
| SIS Stroke Recovery | sis\_sr |  |

**CRF B4: –HSCQ – 3 and 6 months only**

|  |  |  |  |
| --- | --- | --- | --- |
| **CRF field name** | **Short field name** | **Notes** | **Data contained in file** |
| HSCQ Q1a | hscq\_q1a | Number: 1=yes, 0=no | Outcomes |
| HSCQ Q1b | hscq\_q1b | Number |
| HSCQ Q2a | hscq\_q2a | Number: 1=yes, 0=no |
| HSCQ Q2b Occasion | hscq\_q2b\_occ | Number. Database field indicating order data were entered. | Outcomes B4\_q2b |
| HSCQ Q2b reason | hscq\_q2b reason | Three separate columns, \_1 to \_3. Max 50 characters |
| HSCQ Q2b ward | hscq\_q2b ward | Three separate columns, \_1 to \_3. Max 50 characters |
| HSCQ Q2b number of nights | hscq\_q2b nights | Three separate columns, \_1 to \_3. Number |
| Outpatient visits |  |  |  |
| HSCQ Q3a | hscq\_q3a | Number: 1=yes, 0=no | Outcomes |
| HSCQ Q3b Occasion | hscq\_q3b\_occ | Number. Database field indicating order data were entered. | Outcomes B4\_q3b |
| stroke consultant: no. of one-to-one sessions  | hscq\_q3b\_stroke\_cons\_one | Number |
| stroke consultant: no. of group sessions | hscq\_q3b\_stroke\_cons\_group | Number |
| stroke nurse: no. of one-to-one sessions  | hscq\_q3b\_stroke\_nurse\_one | Number |
| stroke nurse: no. of group sessions | hscq\_q3b\_stroke\_nurse\_group | Number |
| physiotherapist: no. of one-to-one sessions  | hscq\_q3b\_physio\_one | Number |
| physiotherapist: no. of group sessions | hscq\_q3b\_physio\_group | Number |
| Occupational therapist: no. of one-to-one sessions  | hscq\_q3b\_occup\_one | Number |
| Occupational therapist: no. of group sessions | hscq\_q3b\_occup\_group | Number |
| Other: please specify | hscq\_q3b\_other\_one | text |
| Other: no. of one-to-one sessions | hscq\_q3b\_other\_one\_ spec | Number |
| Other: no. of group sessions | hscq\_q3b\_other\_group\_spec | Number |
| GP/Health centre/home visits |  |  |  |
| HSCQ Q4a | hscq\_q4a | Number: 1=yes, 0=no | Outcomes |
| HSCQ Q4b Occasion | hscq\_q4b\_occ | Number. Database field indicating order data were entered. | Outcomes B4\_q4b |
| GP/Health centre: number of one-to-one sessions with GP | hscq\_q4b\_hc\_11\_gp | Number |
| GP/Health centre: number of one-to-one sessions withPractice nurse | hscq\_q4b\_hc\_11\_pn | Number |
| GP/Health centre: number of one-to-one sessions withPhysiotherapist | hscq\_q4b\_hc\_11\_phy | Number |
| GP/Health centre: number of one-to-one sessions with occupational therapist | hscq\_q4b\_hc\_11\_occ | Number |
| GP/Health centre: number of one-to-one sessions with other | hscq\_q4b\_hc\_11\_other | Number |
| Home: number of one-to-one sessions with GP | hscq\_q4b\_home\_11\_gp | Number |
| Home: number of one-to-one sessions with practice nurse | hscq\_q4b\_home\_11\_pn | Number |
| Home: number of one-to-one sessions with physiotherapist | hscq\_q4b\_home\_11\_ phy | Number |
| Home: number of one-to-one sessions with occupational therapist | hscq\_q4b\_home\_11\_ occ | Number |
| GP/Health centre: number of one-to-one sessions with other | hscq\_q4b\_home\_11\_ other | Number |
| GP/Health centre: number of group sessions with GP | hscq\_q4b\_hc\_group\_gp | Number |
| GP/Health centre: number of group sessions withPractice nurse | hscq\_q4b\_hc\_group\_pn | Number |
| GP/Health centre: number of group sessions withPhysiotherapist | hscq\_q4b\_hc\_group\_ phy | Number |
| GP/Health centre: number of group sessions with occupational therapist | hscq\_q4b\_hc\_group\_ occ | Number |
| GP/Health centre: number of group sessions with other | hscq\_q4b\_hc\_group\_ other | Number |
| Home: number of group sessions with GP | hscq\_q4b\_home\_group\_gp | Number |
| Home: number of group sessions withPractice nurse | hscq\_q4b\_home\_group\_pn | Number |
| Home: number of group sessions withPhysiotherapist | hscq\_q4b\_home\_group\_phy | Number |
| Home: number of group sessions with occupational therapist | hscq\_q4b\_home\_group\_occ | Number |
| Home: number of group sessions with other | hscq\_q4b\_home\_group\_other | Number |
| Other: please specify | hscq\_q4b\_other | Text |
| HSCQ Q5 Received home help for personal care/household tasks | hscq\_q5b | Number: 1=yes, 0=no | Outcomes |
| HSCQ Q5 carer hours per week | hscq\_q5a  | Number |
| HSCQ Q6a | hscq\_q6a | Number: 1=yes, 0=no |
| HSCQ Q6b Occasion | hscq\_q6b\_occ | Number. Database field indicating order data were entered. | Outcomes B4\_q6b |
| HSCQ Q6b Aids | hscq\_q6b\_aids | Number.1= Wheel chair2= Zimmer frame3= Walking stick4 = electric wheel chair5 = 3 wheeled walker6= 4 wheeled walker7= kitchen trolley8= perching stool9= spreader board10= spike board11= belly clamp12= rocker knife13= stair rail14= outdoor rails15= grab rails16= perching stool17= commode18= urine bottle 19= bed lever20= splint21= orthosis22= electric bed23= hoist 24=transfer board 25= long handled shoe horn26= bath brush27= tin opener28 = stair lift29 = ramp30 = other |
| HSCQ Q6b other: please secify | hscq\_q6b\_other | text |
| HSCQ Q6b NHS | hscq\_q6b\_nhs |  |
| HSCQ Q6b Equipment number | hscq\_q6b\_num |  |

**CRF B5: Carer Strain Index – 3 and 6 months only**

|  |  |  |  |
| --- | --- | --- | --- |
| **CRF field name** | **Short field name** | **Notes** | **Data contained in file** |
| Patient’s consent to ask carer | csi\_pt\_con | Number: 1=yes, 0=no | Outcomes |
| Carer consent | csi\_carer\_con | Number: 1=yes, 0=no |
| 1. Sleep is disturbed
 | csi\_sleep | Number: 1=yes, 0=no  |
| 1. It is inconvenient
 | csi\_inconv | Number: 1=yes, 0=no  |
| 1. It is confining
 | csi\_confi | Number: 1=yes, 0=no  |
| 1. It is a physical strain
 | csi\_phys | Number: 1=yes, 0=no  |
| 1. Family adjustments
 | csi\_fam\_adj | Number: 1=yes, 0=no  |
| 1. Changes in personal plans
 | csi\_pers | Number: 1=yes, 0=no  |
| 1. Other demands on time
 | csi\_oth\_dem | Number: 1=yes, 0=no  |
| 1. Emotional adjustments
 | csi\_emo | Number: 1=yes, 0=no  |
| 1. Behaviour is upsetting
 | csi\_beh | Number: 1=yes, 0=no  |
| 1. Upsetting person has changed
 | csi\_ups | Number: 1=yes, 0=no  |
| 1. Work adjustments
 | csi\_work | Number: 1=yes, 0=no  |
| 1. Financial strain
 | csi\_fina | Number: 1=yes, 0=no  |
| 1. Completely overwhelmed
 | csi\_overw | Number: 1=yes, 0=no  |

**CRF B6: Therapy Log: 1 of 14 (repeated 14 times; 1 for each therapy contact) – Only available if treat = 1 (ie. Reach to Grasp)**

|  |  |  |  |
| --- | --- | --- | --- |
| **CRF field name** | **Short field name** | **Notes** | **Data contained in file** |
| Visit | visit | Number: 1 to 14. | B6\_TL, B6\_TL\_E |
| Visit duration | vis dura | Number | B6\_TL |
| Treatment duration | treat dura | Number |
| Consent | consent | Number: 1=yes, 0=no |
| Comments required | comment | Number: 1=yes, 0=no |
| Comments description | comm desc | Free text |
| Exercise  | ex | NLnn | B6\_TL\_E |
| Ex repetitions | ex\_reps | Number |
| Ex time (mins) | ex\_time | Number |
| Ex variation | ex\_vari | Number: 1=yes, 0=no |
| Ex description | ex\_desc | Free text |
| Ex comments description | ex\_comm\_desc | Free text |

**CRF B7: Exercise log (patients) (repeated 6 times) – Only available if treat = 1 (ie. Reach to Grasp)**

|  |  |  |  |
| --- | --- | --- | --- |
| **CRF field name** | **Short field name** | **Notes** | **Data contained in file** |
| Week beginning | Wk\_beg | Date | B7 |
| Day | Day | Number: 1 = Monday2 = Tuesday3 = Wedsnesday4 = Thurday5 = Friday6 = Saturday7 = Sunday |
|  Exercise duration (mins) | Ex\_dur | Number |
| Exercise  | Ex | Numbers and letters |
| Ex repetitions | Ex \_reps | Number |
| Comments | Ex\_comm | Max 500 characters |

**CRF B8: Usual Care Log - – Only available if group = 2 (ie. Usual Care)**

|  |  |  |  |
| --- | --- | --- | --- |
| **CRF field name** | **Short field name** | **Notes** | **Data contained in file** |
| Usual care log Duration of upper limb treatment | dura | Number | B8 |
| Usual care log Aims of treatment | aimsx | Where ‘x’ is 1 to 12:-1. Postural control 2. Musculo-skeletal range of motion 3. Oedema management 4. Alignment 5. Manipulative ability of the hand 6. Sensory ability 7. Muscle activity paretic upper limb 8. Transport ability of the arm 9. Prevent / reduce pain 10. Muscle activity non-paretic upper limb 11. Incorporate arm into balance and mobility activity 12. Awareness of secondary complications. Tick boxes. 1=yes, 0=no |
| Usual care log Gross position of patient during upper limb treatment | positionx | Where ‘x’ is 1 to 12:-1. Supine 2. Prone 3. Side-lying on unaffected side 4. Side-lying on affected side 5. 4-point kneeling 6. 2-point kneeling 7. Unsupported Sitting 8. Supported Sitting 9. Standing 10. Perch Sitting 11. Asymmetrical Sitting 12. Prone Sitting. Tick boxes. 1=yes, 0=no |
| Usual care log Setting | settingx | Where ‘x’ is 1 to 8:-1. Living Room 2. Kitchen 3. Bedroom 4. Bathroom 5. Stairs 6. Outside 7. Gym 8. Hydrotherapy/swimming pool9. Other . Tick boxes 1=yes, 0=no |
| Usual care log Setting other | settingother | Number: 1=yes, 0=no, |
| Usual care log Setting other: description | settingotherdesc | Max 50 characters |
| Usual care log Equipment used | equipm | Max 50 characters |
| Usual care log Treatment | treatx | Where ‘x’ is:-1a. Stroking 1b. Effleurage1c. Lymph drainage techniques1d. Petrissage (kneading /wringing / picking-up /  rolling)1e. Specific compression (trigger points)1f. Myofascial release1g. Frictions2a. Accessory movements2b. Passive movements2c. Active movements 3a. Mental imagery3b. Patient generated cueing3c. Therapist generated cueing3d. ‘Hands on’ to induce a desired motor response3e. Active assisted3f. Facilitated arm / hand activity from another  body part3g. Restricted use of non-paretic limb4a. Side-lying hemiplegic side4b. Side-lying non-hemiplegic side4c. Supine lying 4d. Half lying4e. Sitting in armchair4f. Forwards lean sitting4g. Sitting in wheelchair5a. Tactile stimulation5b. Proprioceptive stimulation5c. Electrical stimulation used passively for: 6a. Shoulder support6b. Elbow support6c. Wrist / hand support6d. Splinting material used: 7a. Resistance from the therapist 7a. Resistance from body weight 7b. Resistance from equipment7c. Gravity neutral repetitive movement 8a. In, or from, lying 8b. In, or from, kneeling8c. In, or from, sitting8d. In, or from, standing8e. In walking9a. To encourage self monitoring of upper limb9b. Transfers training9c. Limb handling and positioning skills9d. Written / visual / photo exercise programme10a. Acupuncture10b. Ultrasound10c. Compression10d. Other: Tick boxes 1=yes, 0=no |
| Usual care log 5c | treat5cdesc | Max 100 characters |
| Usual care log 6d | treat6ddesc | Max 100 characters |
| Usual care log 10d | treat10ddesc | Max 100 characters |
| Usual care log 11a Bilateral functional activities | treat11a | Number: 1=yes, 0=no, |
| Usual care log 11a reps with no adjunct | treat11anoadj | Number |
| Usual care log 11a - reps with adjunct | treat11aadj | Number |
| Usual care log 11b Unilateral reaching activities that are object directed | treat11b | Number: 1=yes, 0=no, |
| Usual care log 11b reps with no adjunct | treat11bnoadj | Number: |
| Usual care log 11b reps with adjunct | treat11badj  | Number |
| Usual care log 11c Unilateral reaching activities that are spatially directed | treat11c | Number: 1=yes, 0=no, |
| Usual care log 11c reps withno adjunct | treat11cnoadj | Number: |
| Usual care log 11c reps with adjunct | treat11cadj | Number |
| Usual care log 11d Dexterity exercises | treat11d | Number: 1=yes, 0=no, |
| Usual care log 11d reps with no adjunct | treat11dnoadj | Number: |
| Usual care log 11d reps with adjunct  | treat11dadj | Number |

**CRF: N1**

**TABLE: Note**

| **CRF field name** | **short field name** | **Notes** | **Data contained in file** |
| --- | --- | --- | --- |
| study id | id | Pre-filled by application | Outcomes |
| Does note relate to page in CRF? | ntf\_crf | Number: 1=Yes, 0=No |
| If yes, specify CRF | ntf\_crfpage | Text |
| Date of event | ntf\_date | Date |
| Time of event | ntf\_time | Time |
| File note | ntf\_text | Max characters 1000 |

**CRF D1: Expected adverse events**

|  |  |  |  |
| --- | --- | --- | --- |
| **CRF field name** | **short field name** | **Notes** | **Data contained in file** |
| Expected adverse events | expaex | Where ‘x’ is 1 to 5:-1. Shoulder and upper arm pain
2. Hand pain
3. Hand oedema
4. Falls

5. Equipment failure leading to injury requiring a hospital or GP visit .Tick boxes 1=yes, 0=no. | D1 |
| Date expected adverse event ‘x’ – shoulder and upper arm pain  | expaexdate | Where ‘x’ is 1 to 5 (as above)Date Dd/mm/yyyy |  |
| Expected adverse event ‘x’ – SAE? | expaexsae | Where ‘x’ is 1 to 5 (as above). Number: 0=no, 1=yes |  |

 **CRF: S0**

*Not in database*

**CRFs: S1-2**

**TABLE: SAEinitial**

| **CRF field name** | **short field name** | **Notes** | **Data contained in file** |
| --- | --- | --- | --- |
| Brief description | sae\_des | Max characters 100 | S1-4 |
| Reason - death | sae\_death | Number: 0=No, 1=Yes,  |
| Reason – life-threatening | sae\_life | Number: 0=No, 1=Yes,  |
| Reason – disability/incapacity | sae\_dis | Number: 0=No, 1=Yes,  |
| Reason – hospitalisation | sae\_hosp | Number: 0=No, 1=Yes,  |
| Reason – prolonged hospitalisation | sae\_prolong | Number: 0=No, 1=Yes,  |
| Reason - other | sae\_oth | Number: 0=No, 1=Yes,  |
| Other, specify | sae\_oth\_spec | Max characters 300 |
| Date of onset | sae\_startdate | Date |
| Time of onset | sae\_starttime | Time |
| End date | sae\_enddate | Date |
| End time | sae\_endtime | Time |
| Outcome | sae\_outcome | Number: 1=Resolved; 2=Ongoing; 3=Died, |
| Outcome details | sae\_outdetails | Max characters 500 |
| Max intensity | sae\_intense | Number: 1=Mild, 2=Moderate, 3=Severe,  |
| Full description | sae\_fulldesc | Max characters 1000 |
| Treated according to allocation | sae\_alloc | Number: 0=No, 1=Yes,  |
| Action taken | sae\_action | Max characters 1000 |
| Other information | sae\_info | Max characters 1000 |
| Patient withdrawn from treatment | sae\_withtrt | Number: 0=No, 1=Yes,  |
| If Yes, date treatment withdrawn | sae\_withtrt\_date | Date |
| Patient withdrawn from study | sae\_withd | Number: 0=No, 1=Yes,  |
| If yes, date withdrawn | sae\_withd\_date | Date |
| Randomisation code broken | sae\_rand | Number: 0=No, 1=Yes |
| If yes, details | sae\_randalloc | Number: 1=Allocation 1, 2=Allocation 2 |
| Relatedness | sae\_relate | Number: 1=Not related, 2=Unlikely to be related, 3=Possibly related, 4=Probably related, 5=Definitely related, 8=Blank on form |
| PI name | sae\_pi | Max characters 50 |
| PI signed? | sae\_pisigned | Number: 0=No, 1=Yes, |
| PI signature date | sae\_pidate | Date |
| Further information | sae\_othinfo | Max characters 1000 |

**CRF: S3**

**TABLE: SAEfup**

| **CRF field name** | **short field name** | **Notes** | **Data contained in file** |
| --- | --- | --- | --- |
| SAE onset date | sae1\_date | Date | S1-4 |
| SAE onset time | sae1\_time | Time |
| Max intensity | sae1\_intense | Number: 1=Mild, 2=Moderate, 3=Severe,  |
| Full description | sae1\_fulldesc | Max characters 1000 |
| Action taken | sae1\_action | Max characters 1000 |
| End date | sae1\_enddate | Date |
| End time | sae1\_endtime | Time |
| Outcome | sae1\_outcome | Number: 1=Resolved 2=Ongoing; 3=Died,  |
| Outcome details | sae1\_outdetails | Max characters 500 |
| Long term SAE, date of next follow-up | sae1\_spon | Date  |
| Patient withdrawn from treatment | sae1\_withtrt | Number: 0=No, 1=Yes,  |
| If Yes, date treatment withdrawn | sae1\_withtrt\_date | Date |
| Patient withdrawn from study | sae1\_withd | Number: 0=No, 1=Yes,  |
| If yes, date withdrawn | sae1\_withd\_date | Date |
| Randomisation code broken | sae1\_rand | Number: 0=No, 1=Yes |
| If yes, details | sae1\_randalloc | Number: 1=Allocation 1, 2=Allocation 2 |
| PI name | sae1\_pi | Max characters 50 |
| PI signed? | sae1\_pisigned | Number: 0=No, 1=Yes, |
| PI signature date | sae1\_pidate | Date |

**CRF: S4**

**TABLE: SAEextra**

| **CRF field name** | **short field name** | **Field type** | **Data contained in file** |
| --- | --- | --- | --- |
| Section no | sae2\_section | Max characters 10 | S1-4 |
| Further info | sae2\_info | Max characters 1000 |

**CRF: W1**

**TABLE: Withdrawal**

| **CRF field name** | **short field name** | **Notes** | **Data contained in file** |
| --- | --- | --- | --- |
| Decision for withdrawal | withd\_dec | Number: 1=patient withdrawal, 2=clinician withdrawal, 3+both clinician and patient withdrawal | Outcomes, W |
| Name of clinician | withd\_clin | Free text: max characters 30 |
| Date of withdrawal | withd\_when1 | Date |
| Was withdrawal from study | withd\_when2 | Number: 1=Before randomisation, 2=After randomisation but before intervention, 3=After intervention,  |
| Reason for withdrawal: Treatment allocation | withd\_reason |  Free text |
| Patient willing for data to be used | withd\_data | Number: 1=Yes, 0=No,  |
| If yes, patient willing for data routinely collected… | withd\_routine | Number: 1=Yes, 0=No,  |
| Is patient willing for follow-up | withd\_fup | Number: 1=Yes, 0=No,  |
| Additional information | withd\_detail | Free text: max characters 300 |

**Questionnaires**

|  |  |  |  |
| --- | --- | --- | --- |
| **CRF field name** | **short field name** | **Notes** | **Data contained in file** |
| Date of interview | rtg\_date |  | Q |
| 1. a) Do you think the number of visits during the six weeks was an acceptable or unacceptable amount? | rtg\_1a | 1=acceptable; 2=unacceptable |
| 1b) If unacceptable, how long do you think would be an acceptable amount of time for you? | rtg\_1b | Text |
| 2. a) Do you think the being asked to practice by yourself for an hour a day was an acceptable or unacceptable amount of time? | rtg\_2a | 1=acceptable; 2=unacceptable |
| 2b) If unacceptable, how long do you think would be an acceptable amount of time for you? | rtg\_2b | Text |
| 3. a) Did you find the reach tograsp training an acceptable or unacceptable physiotherapy treatment? | rtg\_3a | 1=acceptable; 2=unacceptable |
| 3b) Why? | rtg\_3b | Text |
| 4. How beneficial do you think the treatment was for you? | rtg\_4 | 1 to 10 |
| 5. What difference do you think the treatment has made to you? | rtg\_5 | Text |
| 6. Has the treatment made a difference to your ability to use the arm? | rtg\_6 | Number: 1=Yes, 0=No, |
| 7. If yes, what can you do now that you couldn't do when you joined the trial? | rtg\_7 | Text |
| 8. Was the amount of improvement in your arm or hand movement over the last six weeks worth the work you did? | rtg\_8 | Number: 1=Yes, 0=No, |
| 9. How difficult did you find the treatment? | rtg\_9 | 1 to 10 |
| 10. I'm going to show you all the exercise sheets you used. Please tell me which ones you liked and which you didn't like. |  |  |
| Week ‘x’ - Exercise | rtg\_10\_week’x’\_ex | For ’x’=1 to 6 (i.e. week number) | Q\_q10 |
| Week ‘x’- Like | rtg\_10\_week’x’\_like | For ‘x’=1 to 6 (i.e. week number). Number: 1=Yes, 0=No, |
| 11.a) What aspects of the design of the exercise sheets did you like? | rtg\_11a | Text | Q |
| 11b) Are there any changes to the design of the exercise sheets you would like to see? | rtg\_11b | Text |
| 12. Do you have any other comments about the reach to grasp training or your experience of it? | rtg\_12 | Text |
|  |  |  |
| Date of interview | out\_date |  |
| 1. We've used two tests to see how you are able to use your arm and hand. Which did you think was best for measuring changes in your arm or hand that are important to you? | out\_1a | 1= Action Research Arm Test; 2= Wolf Motor Function Test |
| 1 b) Why? | out\_1b | Text  |
| 2. As well as the hand and arm tests, we used a questionnaire that asked you to rate the amount you used your arm and the quality of the movement |  |  |
| 2a) Was the 'Amount of Use' part of the questionnaire acceptable to you as an assessment for this research project? | out\_2a | 1=acceptable; 2=unacceptable |
| 2b) Why? | out\_2b | Text |
| 2c) Was the 'Quality of Movement' part of the questionaire acceptable to you as an assessment for this research project? | out\_2c | 1=acceptable; 2=unacceptable |
| 3. Do you have any other comments about the assessments involved in this pilot study or your experience of them? | out\_3 | text |