Case Report Form

**Augmented Upper Limb Physiotherapy for Acute Stroke Survivors undergoing Inpatient Stroke Rehabilitation; a feasibility study**

Chief Investigator: Dr Eileen Cowey

Principle Investigator: Abdullah Alhusayni

REC ref: 18/WS/0101

Study Sponsor: NHS Glasgow & Clyde & University of Glasgow

Name of Site: Hairmyres Hospital

CRF version: 1, Date: 06.09.18

Time point: Screening & Baseline assessment

Participants: Carer

Patient Initials: Participant ID:

Researcher(s):

**CRF Completion Instructions**

**General**

The CRF should be completed during the scheduled visit. Complete the CRF using a **black ballpoint pen** and ensure thatall entries are complete and legible.

Avoid the use of abbreviations and acronyms.

Do not use participant identifiers anywhere on the CRF, such as name, hospital number etc., in order to maintain the confidentiality of the participant. Ensure that the header information (i.e. participant initials and ID number) is completed consistently throughout the CRF.

Each CRF page should be initialled and dated by the person completing the form. This must be legible on each page and **CRFs should only be completed by individuals delegated to complete CRFs on the Site Delegation log. Assessments should be completed at 0 and 12 weeks ± 2 weeks.**

Ensure that all fields are completed on each page:

* + If a test was Not Done record **ND** in the relevant box(es)
  + Where information is Not Known write **NK** in relevant box(es)
  + Where information is not applicable write **NA** in the relevant box(es)

**Corrections to entries**

If an error is made, draw a single line through the item, then write the correct entry on an appropriate blank space near the original data point on the CRF and initial and date the change.

**Do NOT**

* Obscure the original entry by scribbling it out
* Try to correct/ modify the original entry
* Use Tippex or correction fluid

If a participant prematurely withdraws from the trial a single line must be drawn across each uncompleted page to correspond with the last visit of the participant. The protocol deviation/violation/serious breach log should be used to record comments relating to each CRF visit that cannot be captured on the page itself. This includes reason for delayed or missed protocol visits or trial assessments, unscheduled visits etc.

**Adverse Events (AEs) and Serious Adverse Events (SAEs)**

AEs and SAEs should be emailed **within 24 hours** of the site being aware of the event using the trial specific SAE report form to **Mr Abdullah Alhusayni**, **Dr Eileen Cowey, Dr Aleksandra Dybus and Dr Lorna Paul**

**Storage**

CRF documents for each time point should kept separately and stored on site in a locked, secure area when not in use where confidentiality can be maintained. Ensure that they are stored separately to any other documents that might reveal the identity of the participant.

**Equipment**

1- 2 chairs 2- Table

**First meeting (SCREENING) PATIENT CONTACT DETAILS**

* **Once completed remove this page from CRF, enter contact details into ‘Contacts Database’**

**and store in ‘Participant Contacts File’**

|  |
| --- |
| **Participant Name:** |
| **Phone Number:**  **Mobile Number:**  **Email address:** |

|  |  |  |  |
| --- | --- | --- | --- |
| **(SCREENING) Inclusion/EXCLUSION Criteria** | | | |
| **The following criteria MUST be answered YES for participant to be included in the trial (except where NA is appropriate):** | | **Yes** | **No** |
| 1. | Over 18 years old |  |  |
| 2. | Able to support the patient in the augmented programme (intervention group) |  |  |
| 3. | Able to understand and speak English language |  |  |

|  |  |
| --- | --- |
| **Informed Consent:** | |
| **Date participant** **signed written consent form:** | **\_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_**  (DD / MM / YYYY) |
| **Name of person taking informed consent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | |

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**VISIT 1 (BASELINE ASSESSMENT) demographic data**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Age:** ……………………… |  | |  | |  |
| **Gender:**  Male (0)  Female (1)  Other: …………….. (3) | | | | | |
| **Relationship to stroke survivor:**………….. | | | | | |
| **Ethnicity**: ………….. | | | | | |
| **Occupation**: ………….. | | | | | |
| **How long ago did you start using computers in years/months? ………………………** | | | | | |
| **How often do you use computers?** | Daily  (0) | | Occasionally  (1) | | Never  (2) |
| **Educational level (tick all that apply)** | Primary school  (0) | | Secondary school  (1) | | College  (2) |
| University (Undergraduate) (3) | | University (Postgraduate)  (4) | | Other: …………….. (5) |
| **General health status:** | Excellent  (0) | Fair  (1) | | Poor  (2) | Other: ………………(3) |