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: Post-intervention 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

**ASSESSMENT 2 (POST INTERVENTION) CONFIRM 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:**  |

**ASSESSMENT 2 (POST INTERVENTION) PARTICIPANT WITHDRAWAL**

|  |
| --- |
| Yes No❑ [1] ❑ [0] |
| State reason |

**ASSESSMENT 2 (POST INTERVENTION) continued verbal CONSENT**

|  |
| --- |
| Yes No❑ [1] ❑ [0] |
| If no, state reason |

|  |
| --- |
| **ASSESSMENT 2 (POST INTERVENTION) EVALUATION QUESTIONNAIRE** |
| **Please answer the following questions and add your comments, if appropriate:**

|  |
| --- |
| 1. Did you help your partner/relative to do any of his/her exercise programme? Yes [0]⃝ No[1] ⃝
 |
| If you answered ‘Yes’, please go straight to Question 2.If you answered ‘No’, could you please let us know why that was?Enter your comments here:(Thanks for your feedback – there is no need to answer further questions) |

**Section 1:** Evaluation of the augmented exercise programme:

|  |  |  |
| --- | --- | --- |
| **Question number** | **Question**  | **Please circle one answer**  |
|  | It was easy for me to help my partner/relative to do the exercises. | Strongly disagree [0] | Moderately disagree [1] | Neither agree or disagree [2] | Moderately agree [3] | Strongly agree [4] |
|  | The exercises were clear and understandable. | Strongly disagree [0] | Moderately disagree [1] | Neither agree or disagree [2] | Moderately agree [3] | Strongly agree [4] |
|  | I would be happy to use this website to help my relative/partner exercising again in the future. | Strongly disagree [0] | Moderately disagree [1] | Neither agree or disagree [2] | Moderately agree [3] | Strongly agree [4] |

**Section 2**: Evaluation of the website:

|  |  |  |
| --- | --- | --- |
| **Question number** | **Question**  | **Please circle one answer**  |
|  | Learning to use the website for my partner/relative’s exercises was easy for me. | Strongly disagree [0] | Moderately disagree [1] | Neither agree or disagree [2] | Moderately agree [3] | Strongly agree [4] |

**Section 3: please answer the following questions and add your comments, if appropriate:**

|  |
| --- |
| 1. How often did you help your partner/relative to do his/her exercise programme?
 |
| Once per week [0] ⃝ Twice per week [1] ⃝ 3-5 times per week [2] ⃝ Other [3], please specify:…………What did you help him/her with? |
| 1. Did you ask staff to help your partner/relative doing his/her exercise programme? Yes [0] ⃝ No [1] ⃝ If yes, please answer the following questions:
 |
| How often? Once per week [0] ⃝ Twice per week [1] ⃝ 3-5 times per week [2] ⃝ Other [3], please specify:…………Who did you ask? Nursing staff [0] ⃝ Physiotherapy staff [1]⃝ Other [2], please specify:…………What did you need the staff to help your partner/relative with? |

|  |
| --- |
| 1. How difficult/easy was helping your partner/relative to exercise using the website without supervision?

Easy [0] ⃝ Neither easy nor difficult [1] ⃝ Difficult [2] ⃝ |
| Please provide details. For example, did you worry about helping your partner/relative to exercise properly or knowing how many exercises your partner/relative needed to do?Please tell us about things that went well? What was difficult (if anything)?  |

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