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 Time of the assessment:

Participants: Stroke Survivor

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- Action Research Arm Test Kit 3- Goniometer 4- Bed 5- Table

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

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

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

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

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| **ASSESSMENT 2 (POST INTERVENTION) adverse and serious conditions** |
| since we last met, have you had any of the following condition * Falls
* Musculoskeletal injury
* Shoulder pain and subluxation
* Any other symptom or injury

Serious adverse events are not anticipated but would include any of the following that could be attributed to the intervention* Incidence of life threatening illness
* Require extra care at hospital for any reason
* Any occurrence that results in significant impairment or disability
* Any medical event that could be describe as significant by the Principal Investigator
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| **ASSESSMENT 2 (POST INTERVENTION) the Action Research Arm Test score** |
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| InstructionsThere are four subtests: Grasp, Grip, Pinch, Gross Movement. Items in each are ordered so that:• if the subject passes the first, no more need to be administered and he scores top marks for that subtest;• if the subject fails the first and fails the second, he scores zero, and again no more tests need to beperformed in that subtest;• otherwise he needs to complete all tasks within the subtest

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| **Scoring (taken from Carroll, 1965, p.484):** |
| 0 | Can perform no part of test |
| 1 | Performs test partially |
| 2 | Completes test, but takes abnormally long time or has great difficulty |
| 3 | Performs test normally |

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| --- | --- |
| **Activity** | **Score** |
| **Grasp** | **Left** | **Right** |
| 1. Block, wood, 10 cm cube (If score = 3, total = 18 and to Grip) Pick up a 10 cm block  |  |  |
| 2. Block, wood, 2.5 cm cube (If score = 0, total = 0 and go to Grip)Pick up 2.5 cm block |  |  |
| 3. Block, wood, 5 cm cube  |  |  |
| 4. Block, wood, 7.5 cm cube |  |  |
| 5. Ball (Cricket), 7.5 cm diameter  |  |  |
| 6. Stone 10 x 2.5 x 1 cm  |  |  |
| **SUBTOTAL** Grasp  |  /18 | /18 |

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| --- | --- |
| **Activity** | **Score** |
| **Grip** | **Left** | **Right** |
| 1. Pour water from glass to glass (If score = 3, total = 12, and go to Pinch)  |  |  |
| 2. Tube 2.25 cm (If score = 0, total = 0 and go to Pinch)  |  |  |
| 3. Tube 1 x 16 cm  |  |  |
| 4. Washer (3.5 cm diameter) over bolt  |  |  |
| **SUBTOTAL** Grip |  /12 |  /12 |

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| **Activity** | **Score** |
| **Pinch** | **Left** | **Right** |
| 1. Ball bearing, 6 mm, 3rd finger and thumb (If score = 3, total = 18 and go to Grossmt)  |  |  |
| 2. Marble, 1.5 cm, index finger and thumb (If score = 0, total = 0 and go to Grossmt)  |  |  |
| 3. Ball bearing 2nd finger and thumb |  |  |
| 4. Ball bearing 1st finger and thumb |  |  |
| 5. Marble 3rd finger and thumb |  |  |
| 6. Marble 2nd finger and thumb |  |  |
| **SUBTOTAL** Pinch |  /18 |  /18 |

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| **Activity** | **Score** |
| **Gross Movement** | **Left** | **Right** |
| 1. Place hand behind head (If score = 3, total = 9 and finish) |  |  |
| 2. (If score = 0, total = 0 and finish) |  |  |
| 3. Place hand on top of head |  |  |
| 4. Hand to mouth |  |  |
| **SUBTOTAL** Gross movement |  /9 |  /9 |

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| Action Research Arm Test (ARAT) score  | **Left /57** | **Right /57** |

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| **ASSESSMENT 2 (POST INTERVENTION) Trunk Impairment Scale** |
| **Instructions** |
| * The starting position for each item is the same. The patient is sitting on the edge of a bed or treatment= table without back and arm support. The thighs make full contact with the bed or table, the feet are hip width apart and placed flat on the floor. The knee angle is 908. The arms rest on the legs. If hypertonia is present the position of the hemiplegic arm is taken as the starting position. The head and trunk are in a midline position.
* If the patient scores 0 on the first item, the total score for the TIS is 0.
* Each item of the test can be performed three times. The highest score counts. No practice session is allowed.
* The patient can be corrected between the attempts.
* The tests are verbally explained to the patient and can be demonstrated if needed.
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| **Static sitting balance** |
| **ITEM** | **STATEMENT** | **SCORE** |
| **Item 1** | Patient falls or cannot maintain starting position for 10 seconds without arm support | [ ]  (0) |
| Patient can maintain starting position for 10 seconds**If score 0, then TIS total score 0** | [ ]  (2) |
| **Item 2**, starting position:Therapist crosses the unaffected leg over the hemiplegic leg | Patient falls or cannot maintain sitting position for 10 seconds without arm support | [ ]  (0) |
| Patient can maintain sitting position for 10 seconds | [ ]  (2) |
| **Item 3**, starting position:Patient crosses the unaffected leg over the hemiplegic leg | Patient falls | [ ]  (0) |
| Patient cannot cross the legs without arm support on bed or table | [ ]  (1) |
| Patient crosses the legs but displaces the trunk more than 10 cm backwards or assists crossing with the hand | [ ]  (2) |
| Patient crosses the legs without trunk displacement or assistance | [ ]  (3) |
| **Total static sitting balance : /7** |

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| **Dynamic sitting balance** |
| **ITEM** | **STATEMENT** | **SCORE** |
| **Item 1**, starting position:Patient is instructed to touch the bed or table with the hemiplegic elbow (by shortening the hemiplegic side and lengthening the unaffected side) and return to the starting position | Patient falls, needs support from an upper extremity or the elbow does not touch the bed or table | [ ]  (0) |
| Patient moves actively without help, elbow touches bed or table**If score 0, then items 2 and 3 score 0** | [ ]  (1) |
| **Item 2**, repeat item 1 | Patient demonstrates no or opposite shortening/lengthening | [ ]  (0) |
| Patient demonstrates appropriate shortening/lengthening **If score0, then item 3 scores 0** | [ ]  (1) |
| **Item 3**, repeat item 1 | Patient compensates. Possible compensations are: (1) use of upper extremity, (2) contralateral hip abduction, (3) hip flexion (if elbow touches bed or table further then proximal half of femur), (4) knee flexion, (5) sliding of the feet | [ ]  (0) |
| Patient moves without compensation | [ ]  (1) |
| **Item 4**, starting position:Patient is instructed to touch the bed or table with the unaffectedelbow (by shortening the unaffected side and lengthening thehemiplegic side) and return to the starting position | Patient falls, needs support from an upper extremity or the elbow does not touch the bed or table | [ ]  (0) |
| Patient moves actively without help, elbow touches bed or table**If score 0, then items 5 and 6 score 0** | [ ]  (1) |
| **Item 5,** repeat item 4 | Patient demonstrates no or opposite shortening/lengthening | [ ]  (0) |
| Patient demonstrates appropriate shortening/lengthening **If score 0, then item 6 scores 0** | [ ]  (1) |
| **Item 6,** repeat item 4 | Patient compensates. Possible compensations are: (1) use of upper extremity, (2) contralateral hip abduction, (3) hip flexion (if elbow touches bed or table further then proximal half of femur), (4) knee flexion, (5) sliding of the feet | [ ]  (0) |
| Patient moves without compensation | [ ]  (1) |
| **Item 7,** starting position:Patient is instructed to lift pelvis from bed or table at the hemiplegic side (by shortening the hemiplegic side and lengthening the unaffected side) and return to the starting position | Patient demonstrates no or opposite shortening/lengthening | [ ]  (0) |
| Patient demonstrates appropriate shortening/lengthening **If score 0, then item 8 scores 0** | [ ]  (1) |
| **Item 8,** repeat item 7 | Patient compensates. Possible compensations are: (1) use of upper extremity, (2) pushing off with the ipsilateral foot (heel loses contact with the floor) | [ ]  (0) |
| Patient moves without compensation | [ ]  (1) |
| **Item 9,** starting position:Patient is instructed to lift pelvis from bed or table at the unaffected side (by shortening the unaffected side and lengthening the hemiplegic side) and return to the starting position | Patient demonstrates no or opposite shortening/lengthening | [ ]  (0) |
| Patient demonstrates appropriate shortening/lengthening **If score 0, then item 10 scores 0** | [ ]  (1) |
| **Item 10,** repeat item 9 | Patient compensates. Possible compensations are: (1) use of upper extremities, (2) pushing off with the ipsilateral foot (heel loses contact with the floor) | [ ]  (0) |
| Patient moves without compensation | [ ]  (1) |
| **Total** **dynamic sitting balance: /10** |

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| **Co-ordination** |
| **ITEM** | **STATEMENT** | **SCORE** |
| **Item 1,** starting position:Patient is instructed to rotate upper trunk 6 times (every shoulder should be moved forward 3 times), first side that moves must be hemiplegic side, head should be fixated in starting position | Hemiplegic side is not moved three times | [ ]  (0) |
| Rotation is asymmetrical | [ ]  (1) |
| Rotation is symmetrical **If score 0, then item 2 scores 0** | [ ]  (2) |
| **Item 2,** repeat item 1 within 6 seconds | Rotation is asymmetrical | [ ]  (0) |
| Rotation is symmetrical | [ ]  (1) |
| **Item 3,** starting position:Patient is instructed to rotate lower trunk 6 times (every kneeshould be moved forward 3 times), first side that moves must behemiplegic side, upper trunk should be fixated in starting position | Hemiplegic side is not moved three times | [ ]  (0) |
| Rotation is asymmetrical | [ ]  (1) |
| Rotation is symmetrical**If score 0, then item 4 scores 0** | [ ]  (2) |
| **Item 4,** repeat item 3 within 6 seconds | Rotation is asymmetrical | [ ]  (0) |
| Rotation is symmetrical | [ ]  (1) |
| **Total co-ordination: /6** |

**Total Trunk Impairment Scale (TIS): /23** |

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| ASSESSMENT 2 (POST INTERVENTION) Modified Ashworth Scale |
| **General Information (derived Bohannon and Smith, 1987):*** Place the patient in a supine position
* If testing a muscle that primarily flexes a joint, place the joint in a maximally flexed position and move to a position of maximal extension over one second (count "one thousand one”)
* If testing a muscle that primarily extends a joint, place the joint in a maximally extended position and move to a position of maximal flexion over one second (count "one thousand one”)
* Score based on the classification below
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| **Scoring (taken from Bohannon and Smith, 1987):** |
| 0 | No increase in muscle tone |
| 1 | Slight increase in muscle tone, manifested by a catch and release or by minimal resistance at the end of the range of motion when the affected part(s) is moved in flexion or extension |
| 1+ | Slight increase in muscle tone, manifested by a catch, followed by minimal resistance throughout the remainder (less than half) of the ROM |
| 2 | More marked increase in muscle tone through most of the ROM, but affected part(s) easily moved |
| 3 | Considerable increase in muscle tone, passive movement difficult |
| 4 | Affected part(s) rigid in flexion or extension- |

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| **Patient Instructions:**The patient should be instructed to relax. |
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| **Muscle Tested** | **Left/right** | **Score** |
| Arm adductor muscle group |  |  |
| Elbow flexor muscle group |  |  |
| Wrist flexor muscle group |  |  |
| Finger flexor muscle group |  |  |

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| ASSESSMENT 2 (POST INTERVENTION) **TARDIEU SCALE** |
| **Instructions** |
| * This scale quantifies muscle spasticity by assessing the response of the muscle to stretch applied at specified velocities.
* Grading is always performed at the same time of day, in a constant position of the body for a given limb. For each muscle group, reaction to stretch is rated at a specified stretch velocity with 2 parameters x and y.
 |
| **Velocity to stretch (V)** |
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| **V1**  | As slow as possible |
| **V2**  | Speed of the limb segment falling |
| **V3**  | As fast as possible (> natural drop) |
| V1 is used to measure the passive range of angle,Motion. (PROM). Only V2 and V3 are used to rate spasticity |

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| **Quality of muscle reaction (X)** |
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| 0 | No resistance throughout passive movement |
| 1 | Slight resistance throughout, with no clear catch at a precise angle |
| 2 | Clear catch at a precise angle, followed by release |
| 3 | Fatigable clonus (<10secs) occurring at a precise angle |
| 4 | Unfatigable clonus (>10secs) occurring at a precise angle |
| 5 | Joint Immobile |

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| **Angle of muscle reaction (Y)** |
| Measure relative to the position of minimal stretch of the muscle (corresponding at angle)

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| **R1**  | Angle of catch seen at Velocity V2 or V3 |
| **R2** | Full range of motion achievedwhen muscle is at rest andtested at V1 velocity |

* A large difference between R1 & R2 values in the outer to middle range of normal m. length indicates a large dynamic component
* A small difference in the R1 & R2 measurement in the middle to inner range indicates predominantly fixed contracture
 |
| **Testing Positions** |
|  **Upper Limb**To be tested in a sitting position, elbow flexed by 90° at the recommended joint positions and velocities.

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| --- | --- | --- | --- |
| Shoulder | Horizontal Adductors | V3 |  |
| Elbow | Flexors | V2 | Shoulder adducted |
| Extensors | V3 | Shoulder adducted |
| Wrist | Flexors | V3 |  |
| Extensors | V3 |
|  | Fingers |  | Angle PII of digit III- MCP |

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| **Muscle Teste** | **Left/right** | **Starting position°**  | **V**  | **X**  | **R1** | **R2** | ° |
| Arm adductor muscle group |  |  |  |  |  |  |  |
| Elbow flexor muscle group |  |  |  |  |  |  |  |
| Wrist flexor muscle group |  |  |  |  |  |  |  |
| Finger flexor muscle group |  |  |  |  |  |  |  |

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| **ASSESSMENT 2 (POST INTERVENTION) EVALUATION QUESTIONNAIRE** |
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| 1. Did you do any of the exercises in your 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:

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| --- | --- | --- |
| **Question number** | **Question**  | **Please circle one answer**  |
|  | I feel I benefited from the exercise programme. | 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] |
|  | The exercise programme did not increase my fatigue (tiredness). | Strongly disagree [0] | Moderately disagree [1] | Neither agree or disagree [2] | Moderately agree [3] | Strongly agree [4] |
|  | It was easy to contact the physios to make changes to my exercise programme. | Strongly disagree [0] | Moderately disagree [1] | Neither agree or disagree [2] | Moderately agree [3] | Strongly agree [4] |
|  | I was happy with the length of time it took for the study assessments. | Strongly disagree [0] | Moderately disagree [1] | Neither agree or disagree [2] | Moderately agree [3] | Strongly agree [4] |
|  | I would be happy to do exercises using this website 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

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| --- | --- | --- |
| **Question number** | **Question**  | **Please circle one answer**  |
|  | Doing my exercises through the website gave me the chance to choose when to exercise. | Strongly disagree [0] | Moderately disagree [1] | Neither agree or disagree [2] | Moderately agree [3] | Strongly agree [4] |
|  | Doing my exercises through the website gave me the feeling of being independent in exercising. | Strongly disagree [0] | Moderately disagree [1] | Neither agree or disagree [2] | Moderately agree [3] | Strongly agree [4] |
|  | Learning to use the website for my 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:

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| 1. On average, how many times each week did you do your exercise?
 |
| Once per week [0] ⃝ Twice per week [1] ⃝ 3-5 times per week [2] ⃝ Other [3], please specify:………… |
| 1. On average, how long did you spend doing the exercises each exercise session?
 |
| Less than 30 minutes [0] ⃝ Up to 1 hour [1] ⃝ 1-2 hours [2] ⃝ Other [3], please specify:……………… |

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| 1. Did your partner/relative help you do your 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:…………**What did you need your partner/relative to help you with?** |
| 1. Did you ask staff to help you do your 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 you with?** |

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| 1. How difficult/easy was exercising using the website without supervision? Easy [0]⃝ Neither easy nor difficult [1]⃝ Difficult [2] ⃝
 |
| **Please provide details. For example, did you worry about not exercising properly or knowing how many exercises you needed to do?** **Please tell us about things that went well? What was difficult (if anything)?**  |
| 1. **Only for participants who have problems with speech, memory and thinking (aphasia)**

Was the website aphasia version helpful?  |
|  Certainly yes [0] ⃝ To a large extent [1] ⃝ To some extent [2] ⃝ No [3] ⃝ I didn’t use it [4] ⃝ |
| 1. Did you discuss your exercises with other patients? Yes [0] ⃝ No [1] ⃝
 |
| 1. Did other patients ask you about your exercises? Yes [0] ⃝ No [1] ⃝
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| ASSESSMENT 2 (POST INTERVENTION) Record of upper limb exercises |
| **Please circle or tick the appropriate option:**During the participant hospitalisation period, did the participant get upper limb exercises during his/her normal physio?* **Yes [0] ⃝ No [1] ⃝**
 |
| **If yes,** please complete the following table by circling or ticking the appropriate option, and filling the blanks:

|  |  |  |
| --- | --- | --- |
| **Type of exercise** | **Please circle or tick all the appropriate options** | **Duration** |
| Flexibility exercises | ⃝ | …………….. |
| Strengthening exercises | ⃝ | …………….. |
| Functional exercises | ⃝ | …………….. |
| Other, please indicate: ……………………………………………….............. | ⃝ | …………….. |

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