

**Protocol Title: Increasing intensity of practice in Stroke rehabilitation: The  
effect of different instructions**

**Short Title: Increasing practice intensity in Stroke rehabilitation**

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<b>1. LAY DESCRIPTION</b>	
.....	<b>3</b>
<b>2. BACKGROUND.....</b>	
.....	<b>3</b>
<b>3. AIMS / OBJECTIVES</b>	
.....	<b>4</b>
<b>4. PARTICIPATING</b>	
<b>SITES.....</b>	<b>4</b>
<b>5. RESEARCH PLAN / STUDY</b>	
.....	<b>5</b>
<b>6. ETHICAL</b>	
<b>CONSIDERATIONS.....</b>	<b>9</b>
<b>7. OUTCOMES AND SIGNIFICANCE</b>	
.....	<b>12</b>
<b>8. APPENDIX.....</b>	
.....	<b>13</b>
<b>9. REFERENCES</b>	
.....	<b>14</b>

## **1. LAY DESCRIPTION**

It is well documented that Stroke survivors need to perform hundreds of repetitions in rehabilitation to regain functional recovery. In this study we want to establish the most effective instructions for increasing repetitions.

## **2. BACKGROUND**

To optimise outcomes after Stroke large amounts of practice are required (1). In fact, hundreds of repetitions per day may be essential for neural changes to occur (2). However, patients in rehabilitation units spend the majority of their day inactive and only a small part of their day engaged in active practice (3). Even during therapy sessions patients may achieve very few practice repetitions (4).

Therapy intensity may be increased through the delivery of instructions for example, Stroke survivors respond to instructions that encourage speed (5, 6), thus they may have the capacity to do more repetitions in a certain time period. Additionally, instructions that focus on the external environment require less cognitive demand than those that focus on body movements, and result in more repetitions being performed (7-9).

However, there is very limited research on the way that instructions impact the number of repetitions that are performed by Stroke survivors in rehabilitation. This research will examine the types of instructions that result in the fastest rate of

repetitions. This will be helpful to inform therapists of the best instruction to use to increase the intensity of practice during Stroke rehabilitation.

### **3. AIM / OBJECTIVES**

The broad aim of this study is to determine strategies to increase the number of repetitions performed during therapy sessions. This study aims to quantify the effect of different types of instructions on the amount of time it takes to complete a set of repetitions.

The research question is:

What are the most effective instructions to increase repetitions performed by Stroke survivors in rehabilitation?

### **4. PARTICIPATING SITES**

Bankstown-Lidcombe Hospital

## **5. RESEARCH PLAN / STUDY DESIGN**

### *Type of study:*

This will be a randomized cross-over study.

### *Data collection:*

The Stroke survivor will do their usual exercises in Bankstown-Lidcombe rehabilitation gym. The researcher will observe the participant perform twenty five repetitions of one exercise under no instruction. This will be timed to form a baseline. Following this, the researcher will use one of three different types of instructions to direct their practice of the same exercise. The participant will receive a different instruction each day across three days. The order of these three types of instructions will be randomised giving six possible orders. Each patient will be randomly assigned to one of the six orders..

The types of instructions that will be used will be (using standing up as an example); an instruction with an endpoint such as “can you stand up and sit down 25 times”, an instruction with a time component such as “can you stand up and sit down 25 times as fast as you can”, and an instruction with motivation such as “can you stand up and sit down 25 times as fast as you can, aim for your personal best!!”.

The order of the instructions will be randomised across the three days allowing for each of the three instructions to be used. The time taken to perform the twenty five repetitions under each instruction will be recorded.

A new baseline will be measured each day to account for recovery over the three days. Data will be collected at a similar time each day to reduce the risk of fatigue affecting rate of repetitions.

*Source of participants:*

The participants for this study will be Stroke survivors admitted to Bankstown Stroke unit who meet the inclusion criteria.

*Sample size*

There are three different instructions that are being tested. The order of instructions will be randomized. There are six different orders that the instruction can be presented. Therefore, the participants will be randomised to one of six groups. Six groups of three participants will be recruited to account for any affect that the order of instructions has on the rate that the repetitions are performed. Therefore, a total of approximately eighteen participants will be recruited for this study.

*Inclusion criteria:*

- Stroke is diagnosed by clinical presentation, CT or MRI scan results
- All Stroke types are eligible (haemorrhagic or ischaemic)
- The admission period is likely to be more than one week
- The participant can perform 50 repetitions of either stand ups, tilt table or sit and reach without physical assistance

*Exclusion criteria:*

- The patients do not require physiotherapy intervention during their admission
- Not medically stable to perform exercise
- Are unable to follow one-stage commands
- English is not sufficient to understand instructions

*Justify exclusion criteria:*

Stroke patients who are not requiring physiotherapy intervention in the form of repetitive exercise are not included as this is required for intensity of practice to be measured.

If the patient is not medically stable, performing exercise may be of risk to the participant.

The participant must be able to follow one-stage commands to understand the instruction that is being delivered to them and for different instructions to have an affect of the rate of repetitions.

The participant must have English competency to the level of understanding the instructions delivered to them. This enables them to respond to the different instructions, resulting in a different rate of repetitions for each.

### *Recruitment of participants*

During the period of data collection, Tessa Hillig will meet with all potential participants who meet the inclusion criteria. She will present them with participant information and consent form and return in two days, allowing them time to read over the information presented to them and discuss it with family.

### *Duration of study*

The data collection will last for 6 months – from 1/7/17 to 1/12/17

### *Data analysis*

For each instruction, the recorded time for twenty five repetitions will be converted to a rate of repetitions/minute. The time taken to perform the twenty five repetitions under instruction will be compared with baseline to calculate an percentage increase in rate of repetitions.

A repeated measures ANOVA will be used to ascertain the effect of the different types of instructions on the percentage increase in rate of repetitions.



## **6. ETHICAL CONSIDERATIONS**

### *Recruitment and selection of participants:*

The participants for this study will be Stroke survivors admitted to the Stroke unit at Bankstown Lidcombe Hospital who meet the inclusion criteria.

### *Informed consent:*

Tessa Hillig will meet with patients that meet inclusion criteria and their family if appropriate and explain the research project. Potential participants and/or carers will be individually given a participant information letter. Contact details to discuss this further will be included as well as the opportunity to discuss the project at the time of being given the participant information letter. Patients will be told that Tessa will come back in two days to allow time to read the information letter, discuss the information with family members and decide whether they are interested in participating. Questions will be encouraged at both meetings.

Consent will be recorded on consent forms.

Participants who are able to give their consent will also be given the choice of what they would like to happen should they lose the capacity to consent during the research data collection period. This shall be recorded in the consent form.

Mini-Mental State Examination (MMSE) score in the medical record will be used to determine the cognitive capacity of the potential participant to consent. A MMSE score less than 21 suggests that the individual is unable to provide consent themselves

and their Person Responsible will be asked to decided if they will be included in the study or not. A MMSE great than 21 signifies that an individual is capable to providing their own consent.

*Confidentiality and privacy:*

Upon recruitment, the participant will be de-identified and given a unique identification number. Data will be stored on an Excel spreadsheet on a password protected computer in a locked office. Only the research team will have access to this data.

*Data storage and record retention:*

The data will be collected on paper in the Bankstown-Lidcombe rehabilitation gym and then transferred on to an Excel spreadsheet on a password protected computer in the Physiotherapy Rehabilitation office. The paper will be shredded after it is transferred onto the computer.

The Physiotherapy Rehabilitation office is a locked office and all the computers are password protected. The data analysis will be done on a computer in this office. The data will be stored on a computer in this office for five years. At the conclusion of five years the data will erased from the computer by Simone Dorsch.

*Risks:*

The risks in this intervention are no greater than the usual demands of exercise. To manage the risks of exercise, there will always be one researcher and one other physiotherapist present when the participants are performing their exercise. They will be closely observed to ensure they are not experiencing discomfort whilst exercising. The participant will also be informed that they should stop exercising if they experience pain, or discomfort.

Furthermore, participants will be excluded from the study if they are medically unstable, as determined by the medical team.

The instructions delivered to the participants are not different to what would commonly be used in clinical practice. Therefore, the participants are very unlikely to exert themselves beyond what they would in normal rehabilitation.

**Vulnerable group**

Stroke survivors may fall into the vulnerable category, as defined as ‘people with a cognitive impairment, an intellectual disability or mental illness’ (10). Individuals with a cognitive impairment will still be included in the study. Consent from these individuals will be sought from that person if they have the capacity to consent or from their Person Responsible. The ability to consent will be determined by the potential participants Mini-Mental State Examination results. If their score is 21 or higher, the individual has the capacity to consent for themselves. If their score is

below 21, it is deemed that they do not have the capacity to consent and their Person Responsible will provide consent on the participants behalf.

## **7. OUTCOMES AND SIGNIFICANCE**

Evidence suggests that large amounts of repetitious practice are necessary for functional improvement after Stroke. However, this is not being achieved in rehabilitation sessions in Stroke units across the globe. The potential benefit of this study is to establish if instructions have an affect on the number of repetitions performed in rehabilitation. This information will assist therapists to deliver the most suitable instruction to Stroke survivors to ensure that the fastest rate of repetitions are being performed during rehabilitation. This may allow for greater repetitions to be performed over a session.

This study will contribute to the research on intensity of practice in Stroke rehabilitation and provide insight into the affect of instructions, an area where research is currently very limited.

Participants will not receive any direct benefit as a result of their participation, other than establishing which instruction results in the fastest rate of repetitions. Family members and therapists can use this information for the duration of their Stroke rehabilitation.

**8. APPENDIX: Mini Mental State Examination (11)**


**MINI MENTAL STATE EXAMINATION (MMSE)**

Name:

Date:

Hospital Number:

*Score 1 point for each correct response within each question or activity*

<b>ORIENTATION</b> Year Season Month Date Time Country Town District Hospital Ward/Floor	...../5 ...../5
<b>REGISTRATION</b> Examiner names three objects (e.g. apple, table, penny) and asks the patient to repeat (1 point for each correct. THEN the patient learns the three names repeating until correct)	...../3
<b>ATTENTION AND CALCULATION</b> Subtract 7 from 100, then repeat form result. Continue five times: 100, 93, 86, 79, 65	...../5
<b>RECALL</b> Ask for names of the three objects learned earlier	...../3
<b>LANGUAGE</b> Name two objects (e.g. pen, watch). Repeat “No ifs, ands, or buts”. Give a three-stage command. Score 1 for each stage. (e.g. “Place index finger of right hand on your nose and then on your left ear”). Ask the patient to read and obey a written command on a piece of paper. The written instruction is: “Close your eyes”. Ask the patient to write a sentence. Score 1 if is possible and has a subject and a verb.	...../2 ...../1 ...../3 ...../1 ...../1
<b>COPYING</b> Ask the patient to copy a pair of intersecting pentagons. 	...../1
<b>TOTAL</b>	...../30

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