# Physiotherapy exercises to improve trunk control in people who have suffered a stroke

Submission date 02/06/2020	<b>Recruitment status</b> No longer recruiting	[X] Prospectively registered [] Protocol
Registration date 10/06/2020	<b>Overall study status</b> Completed	<ul> <li>Statistical analysis plan</li> <li>Results</li> </ul>
Last Edited 03/07/2020	<b>Condition category</b> Nervous System Diseases	<ul><li>Individual participant data</li><li>Record updated in last year</li></ul>

#### Plain English summary of protocol

#### Background and study aims

A stroke is a serious life-threatening medical condition that happens when the blood supply to part of the brain is cut off. This can cause paralysis (being unable to move) other problems with movement in part of the body. Often one side of the body is affected and this can lead to problems with balance and coordination.

The trunk has a vital role in holding the body upright and providing a stable foundation for the arms and legs to move. Previous research has shown that strength and control of trunk movement is linked to better recovery of movement after a stroke. Trunk control can be improved by physiotherapy. This study aims to compare two new physiotherapy methods with conventional physiotherapy.

Who can participate?

Men and women aged 40-60 years who have had their first stroke 3-6 months previously.

#### What does the study involve?

The participants will be randomly allocated to one of three groups. All participants will receive 6 weeks of physiotherapy, with 5 sessions each week. The type of physiotherapy they receive will depend on their group. Before and after the physiotherapy course, the participants will have their trunk control, arm and leg function, general mobility and quality of life assessed by a healthcare profession who is not involved in the study.

What are the possible benefits and risks of participating?

All participants are expected to benefit from the physiotherapy in terms of their strength, mobility and endurance. There is a risk that they might find the physiotherapy uncomfortable or tiring. Any problems will be assessed and managed immediately by expert medical professionals

Where is the study run from? King Khalid University (Saudi Arabia)

When is the study starting and how long is it expected to run for? January 2020 to June 2021 Who is funding the study? Investigator initiated and funded

Who is the main contact? Kumar Gular, kmeny@kku.edu.sa

## **Contact information**

**Type(s)** Scientific

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## Additional identifiers

**EudraCT/CTIS number** Nil known

**IRAS number** 

**ClinicalTrials.gov number** Nil known

**Secondary identifying numbers** Nil known

# Study information

#### Scientific Title

Comparison of Bobath/NDT and proprioceptive neuromuscular facilitation techniques on trunk control in a late subacute stroke population: A randomized controlled trial

#### Study objectives

1. There is no significant difference between NDT, PNF, and control group in improving trunk control, function, balance, and quality of life

2. There is no association of trunk control with upper extremity functions and quality of life

Ethics approval required

Old ethics approval format

**Ethics approval(s)** Approved 26/02/2020, King Khalid University Research Ethics Committee (Guraiger, Abha 622217, Saudi Arabia; +966 17 2418667; ecm@kku.edu.sa), ref: ECM#2020-174, HAPO-06-B-001

**Study design** Convenience sampling three-group randomized controlled trial

**Primary study design** Interventional

Secondary study design Randomised controlled trial

**Study setting(s)** Other

**Study type(s)** Treatment

**Participant information sheet** See additional files

#### Health condition(s) or problem(s) studied

Neuromuscular rehabilitation during late subacute stroke

#### Interventions

Subjects will be randomly allocated into three groups by block randomization method. Each block will be having nine subjects with six blocks. Pretesting will be done by an independent evaluator who is not involved with the subject treatment for all the primary and secondary outcome measures. After the evaluation, the subjects will be provided treatment as per their group protocol.

#### Group 1: Bobath/NDT group

In this group, the total intervention will be for 1 h. It includes 30 min of NDT/Bobath based trunkbased exercises based on functional limitation and capability of the individual patient. The therapist will strictly follow the fundamental principles of the Bobath/NDT method in encouraging active participation of the patient, focusing on functional movements, repetitions, and isometric contractions in inner-range positions if the movement is difficult. Assistance followed by resistance

- Stretching and functional strengthening of latissimus dorsi muscle.
- Functional strengthening of abdominal and oblique abdominal muscles (supine lying, side-lying, and sitting)

• Placing exercises in order to facilitate trunk rotations and counter-rotations (right and left) of

the hips with the trunk extended (supine lying, side-lying and sitting)

- Training of lumbar spine stabilizers
- Functional reach of the shoulder, anterior, right, and left sides

Group2: Proprioceptive Neuromuscular Facilitation (PNF) group

In this group, the total intervention will be for 1 h. It includes 30 min trunk-targeted PNF. The PNF exercises were based on functional limitations and the capability of individual patients. The therapist will strictly follow the fundamental principles of the PNF method like manual contact, body position and body mechanics, verbal commands, vision, traction/approximation, stretch, timing, and repetitions. Trunk chopping and lifting patterns, bilateral lower limb/upper limb patterns, combined scapular, and pelvic patterns will be used to facilitate trunk. These exercises will be done in different positions like supine, side-lying, prone, sitting, and standing based on patient capabilities. Techniques of PNF are incorporated based on patient requirement but stabilizing reversals/rhythmic stabilization are mandatory techniques.

#### Group 3: Conventional Physical Therapy group

In this group, the total intervention will be for 90 min. Muscle elongation exercises for tight muscles, strengthening exercises for weak muscles, mat activities like bridging, rolling and sitting, weight-bearing and shifting in sitting and standing, range of motion exercises, and gait training activities.

#### Intervention Type

Other

#### Primary outcome measure

 Trunk performance assessed using the Trunk Impairment Scale at baseline and 6 weeks
 Upper limb and lower limb motor function assessed using the Fugl-Meyer Assessment of Motor Recovery after stroke (FMA) at baseline and 6 weeks
 Mobility assessed using the TUG (Timed Up and Go) test at baseline and 6 weeks

#### Secondary outcome measures

1. Health-related uality of life assessed using the Stroke Specific Quality of Life scale at baseline and 6 weeks

Overall study start date 25/01/2020

Completion date 25/06/2021

# Eligibility

#### Key inclusion criteria

- 1. First-time stroke
- 2. Late sub-acute stroke (3-6 months)
- 3. Aged 40-60 years
- 4. Subjects able to follow commands
- 5. Subjects scoring less than 21 in trunk impairment scale
- 6. Otherwise apparently healthy

Participant type(s)

#### Patient

**Age group** Adult

**Sex** Both

**Target number of participants** 54

**Key exclusion criteria** Does not meet inclusion criteria

Date of first enrolment 01/07/2020

Date of final enrolment 30/07/2021

### Locations

**Countries of recruitment** Saudi Arabia

Study participating centre King Khalid University King Khalid physiotherapy clinic Department of medical rehabilitation Guraiger Abha Saudi Arabia 62529

## Sponsor information

**Organisation** King Khalid University

**Sponsor details** Guraiger Abhā Saudi Arabia 62217 +966 531138703 ecm@kku.edu.sa

**Sponsor type** University/education

Website http://www.kku.edu.sa/

ROR https://ror.org/052kwzs30

## Funder(s)

**Funder type** Other

**Funder Name** Investigator initiated and funded

## **Results and Publications**

#### Publication and dissemination plan

We intend to publish a pilot study and a review on the effects of various techniques on trunk control and functions before disseminating and publishing the results of clinical trial.

#### Intention to publish date

30/07/2021

#### Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

**IPD sharing plan summary** Data sharing statement to be made available at a later date

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		08/06/2020	03/07/2020	No	Yes