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

Submission date
02/06/2020

Recruitment status
No longer recruiting

Registration date
10/06/2020

Overall study status
Completed

Last Edited
03/07/2020

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

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

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
1. Health-related uality of life assessed using the Stroke Specific Quality of Life scale at baseline and 6 weeks

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
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Sponsor information

Organisation
King Khalid University

ROR
https://ror.org/052kwzs30

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes