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Comparison of physiotherapy based on the Bobath concept and general physiotherapy for breathing muscle strength in stroke patients with hemiparesis

Submission date
27/04/2020

Recruitment status
No longer recruiting

Registration date
21/09/2020

Overall study status
Completed

Last Edited
11/03/2022

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Stroke has become one of the most predominant health problems worldwide. According to the cause of death statistics in 2013, stroke was regarded as the second leading cause of death (11.8%) in the world. Stroke can greatly decrease people's quality of life due to disability and premature death. Although hemiplegia (weakness or paralysis down one side of the body) is considered to affect limb activity only on one side, it also has the potential to paralyse the core muscles on both sides of the body. Stroke patients have been observed with partial or total weakness of the diaphragm on the affected side. The diaphragm is mainly recognised for its breathing functions. However, it also plays an essential role in the stability of the trunk. According to previous studies, the ability to stabilise the trunk in the erect position is crucial for proper breathing function. As a result, impaired ability to control the trunk muscles may cause poorer strength and endurance of the breathing muscles. The aim of this study is to compare the effects of physiotherapy based on the Bobath model of clinical practice with general physiotherapy on breathing muscle strength during forced breathing manoeuvres in hemiplegic patients.

Who can participate?
Adult stroke patients with paralysis of one side of the body, able to perform steps without assistance, without respiratory diseases

What does the study involve?
The study will measure the strength of breathing muscles using a spirometer with an attachment. The patient will sit in front of the spirometer and will be asked to perform several breathing commands (e.g. short inspiration and long exhalation or short exhalation and long inhalation) and at the same time, the electrical activity of the selected respiratory muscles will be measured. For this purpose, electrodes will be placed at specific points on the skin over the working muscles (abdominal, chest and neck areas). The timed up and go test will then be performed, which measures the time needed for the participant to move from sitting to

standing, cover a distance of 3 meters and return to the starting position in the same chair. The participant will then be randomly allocated to an experimental or control group. Physiotherapy in both groups will involve individual treatment sessions, each lasting 60 minutes, 5 days a week. The physiotherapists in charge of the intervention in the experimental group will be certified Bobath therapists, or therapists who have completed at least the basic course on this concept. However, in the latter case, they will be supervised by an accredited Bobath instructor. The physiotherapists working with the participants from the control group will have a bachelor's or master's degree in physiotherapy, but will not be trained in this concept. At the end of the therapy, the tests will be carried out again in the same way as before.

What are the possible benefits and risks of participating?
The benefit of participating in the study will be the possibility to check the efficiency of the respiratory system and participate in individual free-of-charge physiotherapy. The researchers do not expect any risks associated with the study.

Where is the study run from?
Jagiellonian University Medical College (Poland)

When is the study starting and how long is it expected to run for?
October 2018 to December 2021

Who is funding the study?
Jagiellonian University Medical College (Poland)

Who is the main contact?
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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
1

Study information

Scientific Title
Comparison of physiotherapy based on the Bobath concept and general physiotherapy for occlusion pressure and respiratory muscle activation in individuals with post-stroke hemiparesis

Acronym
HemiStrokeDiaphragm

Study objectives
Physiotherapy based on the Bobath concept model of clinical practice is more effective than general physiotherapy in terms of respiratory drive variables and electromyographic function (EMG) of selected respiratory muscles.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 31/01/2019; Bioethics Committee of the Jagiellonian University (31-531 Kraków, Poland; +48 (0)12 433 27 39; komisja_bioetyczna@cm-uj.krakow.pl), ref: 1072.6120.19.2019

Study design
Interventional parallel-group single-centre randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hemiparesis after stroke

Interventions
Post-stroke patients will be informed (via mail or personally) about the possibility of participating in the study. When they contact the study team, they will be informed about the study's principles and procedures, and asked for a written confirmation of their voluntary consent to participate in the survey. After conducting a medical examination and confirming the diagnosis, a physician will check whether the patients meet the inclusion criteria to make sure that there are no grounds for their exclusion from the study. The participants will be randomly assigned to either the experimental group or the control group. Randomisation will be performed by a researcher using the software available at https://www.randomizer.org/. The randomisation results will be known neither to the members of the research team measuring the outcomes nor to those responsible for collecting data from the participants' medical histories, questionnaire surveys and physiotherapists providing the intervention. A separate draw will be held after the recruitment of each successive patient, and hence it will not be possible to predict which group the next recruited patient will be assigned to. Next, the member of the team responsible for randomisation will contact the study team responsible for the initial measurements of the outcomes and the blinded physiotherapist to set the treatment time for the patient.

Physiotherapy in both groups will involve individual treatment sessions, each lasting 60 minutes, 5 days a week. The physiotherapists in charge of the intervention in the experimental group will be certified Bobath therapists, or therapists who have completed at least the basic course on this concept. However, in the latter case, they will be supervised by an accredited Bobath instructor. The physiotherapists working with the participants from the control group will have a bachelor's or master's degree in physiotherapy, but will not be trained in this concept.

The experimental group will receive therapy in line with the Bobath model of clinical practice. The Bobath concept is an inclusive, individualised and multidisciplinary therapeutic approach informed by contemporary movement and neuro-sciences. Emphasis is placed on a 24-hour approach to optimise movement recovery and potential for individuals with neurological pathophysiology, as well as to enhance their activity and participation. The concept provides a framework for analysing functional movement, as well as considers the influence of sensory information on the relative interaction of postural control, selective movement and cognitive /perceptual processes. The quality of movement performance is considered with respect to the integration of postural control and selective movement, the active alignment of all body segments, and the ability to receive, integrate and respond to sensory information. Active intervention, based on facilitation through therapeutic handling, voice and environment, focuses on the recovery of typical movement, minimising atypical and compensatory one.

The control group will undergo individual, general physiotherapy (methods, such as general fitness gymnastics and instrumental exercises, adapted to the level of patient's disability) for the same period of time as the experimental group.

The study will involve functional assessment of the participants, which will consist of the Fugl-Meyer Assessment (FMA) for upper (UE) and lower extremity (LE) motor functions (only before intervention), the Timed Up & Go test (TUG) (before and after intervention) and assessment by a physiotherapist before the intervention.
In the next step, participants will have the respiratory drive, maximal inspiratory and expiratory pressures measured, with simultaneous recording of the EMG of the auxiliary respiratory

muscles. The electromyography will be carried out using electrodes placed on the skin over the working muscles, i.e. the scalene muscles (SC), the sternocleidomastoid muscles (SCM), and the abdominal external oblique muscles (AEO). Prior to electrode placement, the surface of the participants' skin must be shaved, scrubbed/abraded and cleansed with an alcohol wipe to reduce skin impedance. The location of the sEMG electrodes is determined by identification of the muscle bellies on the left and right side of the body. All of the electrodes are positioned over the skin transversely to the palpated muscle fibers. Prior to EMG recording, the participant will be verbally and visually instructed about the direction of each isometric contraction to assess maximal voluntary contraction (MVC). Each muscle will be tested individually, giving a total of 6 tests per participant. In order to normalise the EMG signals, three series of MVCs against stable manual resistance will be performed, with a 10-second interval between each contraction.

The values of all dependent variables of the respiratory system assessment: PImax (maximal inspiratory pressure); PEmax (maximal expiratory pressure); P0.1max (mouth occlusion pressure registered after 0.1 sec. at forced breathing) and P0.1 (mouth occlusion pressure after 0.1 sec. at tidal, calm breathing) will be measured by the Jaeger MasterScope spirometer with a special attachment.

The starting position will be standardised by seating the participants on a modified table with their knees bent at 90 degrees. During all the recordings, the patients will be sitting without any back support and will have to maintain the natural sitting posture. The distance between the knee joint and the end of the table will be estimated by determining half the length between the greater trochanter and the distal femoral condyle. The measurements will be made with a flexible tape measure.

At the end of the therapy, the measurements of the respiratory muscles drive, and the maximal inspiratory and expiratory pressures with simultaneous EMG assessment will be repeated, in the same way as at the beginning of the study.

Intervention Type
Behavioural

Primary outcome(s)
Respiratory muscle strength expressed by respiratory drive variables given in units of pressure: kilopascals [kPa], measured using spirometry at the beginning of the first therapy and after the fifth. Respiratory drive variables include:
1. Occlusion pressure: P0.1 (inspiratory occlusion pressure for the first 100 ms of inspiration during calm breathing)
2. PImax (maximal inspiratory pressure)
3. PEmax (maximal expiratory pressure)
4. P0.1max (inspiratory occlusion pressure for the first 100 ms of forced breathing)

Key secondary outcome(s))
1. Electromyographic activity (EMG) of the auxiliary respiratory muscles (mm. scaleni, m. obliques externus, m. sternocleidomastoideus) at frequency in the range from 7 to 500 Hz. The EMG measures will be obtained during all breathing manoeuvres listed in the primary outcomes measure and expressed as a percentage of the values achieved during their maximal voluntary contractions (MVCs) measurements. EMG is examined at the beginning of the first therapy and

after the fifth, at the same time as respiratory muscle strength
2. Functional status measured with the Timed Up & Go test (TUG) at the beginning of the first therapy and after the fifth

Completion date
31/12/2022

Eligibility

Key inclusion criteria
1. Independent locomotion (with or without aids)
2. Time from stroke onset not less than 6 months
3. Ability to establish logical verbal or non-verbal contact
4. Facial muscle efficiency, to maintain the mouthpiece of the measuring device

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Lack of independent locomotion
2. Time from onset less than 6 months
3. No possibility of establishing logical verbal or non-verbal contact
4. Other neurological diseases
5. Contraindications for physiotherapy, e.g. unstable coronary artery disease, resting heart rate above 100 thighs/min and less than 50, blood pressure above 160/95 or below 90/50, fever or hyperpyretic state

Date of first enrolment
01/09/2019

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
Poland

Study participating centre

The University Hospital in Kraków
Skawińska 8
Kraków
Poland
31-006 Kraków

Sponsor information

Organisation
Jagiellonian University

ROR
https://ror.org/03bqmcz70

Funder(s)

Funder type
University/education

Funder Name
Uniwersytet Jagielloński Collegium Medicum

Alternative Name(s)
Jagiellonian University Medical College

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Poland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Agnieszka Śliwka (agnieszka.sliwka@uj.edu.pl) and Wioleta Plewa (wioleta.plewa@gmail.com). All participants in the survey sign "Information on the processing of personal data" in accordance with the Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of

personal data and on the free movement of such data and on the repeal of Directive 95/46/EC - known as the "RODO Jagiellonian University". In addition, the participant also gives informed consent to the use of his results for scientific purposes, without providing personal data that would enable him to be identified. Therefore, the results obtained in the course of the survey may be made available to research institutions without personal data only if they provide comprehensive and appropriate documentation on the purpose and use of these results.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes