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The impact of training to improve patients' condition after ischemic stroke

Submission date
22/04/2022

Recruitment status
No longer recruiting

Registration date
20/05/2022

Overall study status
Completed

Last Edited
10/06/2025

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

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. New methods of physiotherapy are being used with patients after a stroke based on the natural mechanisms of reorganization of the nervous system. The aim of this study is to demonstrate the activating effect of physical effort on the nervous, muscular and vascular tissue in patients after an ischemic stroke.

Who can participate?
Patients aged 45-65 years who have had an ischemic stroke

What does the study involve?
Patients will be assigned to three groups: patients with upper limb hemiparesis treated with mirror therapy (MT), patients rehabilitated by the method of proprioceptive neuromuscular facilitation (PNF), and patients with upper limb hemiparesis practised using the traditional method (they will be treated as the control group). Each patient is treated for 6 weeks (36 days from Monday to Saturday). Each patient also participates 5 days a week in occupational therapy (30 minutes a day), in therapy with a psychologist (30 minutes a day) and with a neurologopedist (30 minutes a day). Various blood tests will be carried out at the start of the study and at 14, 28, and 42 weeks (every 2 weeks during rehabilitation in the ward and after its completion in the 6th week).

What are the possible benefits and risks of participating?
Participants may benefit from the use of modern methods of physiotherapy after stroke and the supervision of specialist personnel for 6 weeks. Risks associated with the blood sampling procedure include weakness (especially during the first blood loss), infections, vein and artery damage, nerve damage, tendon injuries, and local allergic reactions.

Where is the study run from?
Regional Specialist Hospital in Wrocław, Local Department of Neurological Rehabilitation (Wroclaw, Poland)

When is the study starting and how long is it expected to run for?
December 2020 to December 2023

Who is funding the study?
Wroclaw University of Health and Sport Sciences (Poland)

Who is the main contact?
Mr Wojciech Borowicz
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Contact information

Type(s)
Principal investigator

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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
The impact of training to improve the condition patients after ischemic stroke on the level of selected growth factors and neuronal, muscle, and vascular plasticity

Acronym
TIPS

Study objectives

The main goal of the research will be to demonstrate the activating effect of physical effort on the plasticity of nervous, muscular, and vascular tissue in patients after ischemic stroke. Tissue plasticity will be examined indirectly based on the degree of changes in the concentrations of BDNF (brain-derived neurotrophic factor) and other nerve growth factors - NGF (nerve growth factor), NT-3 (neurotrophin -3), blood vessels - VEGF (vascular endothelial growth factor), factors stimulating the proliferation of muscle satellite cells - HGF (hepatocyte growth factor) and IGF (insulin-like growth factor), released into the blood during various forms of rehabilitation training in people after ischemic stroke. For this purpose, mirror therapy, proprioceptive neuromuscular facilitation (PNF), and the traditional method will be used. The research will show whether the factors responsible for neuronal, muscular, and vascular plasticity are secreted during the rehabilitation of patients after ischemic stroke and whether their secretion correlates with ischemic changes and their extent, and with therapeutic effects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/12/2020, Institutional Review Board at Wroclaw Medical University (ul. Pasteura 1, 50-367 Wrocław, Poland; +48 71 784 17 10; bioetyka@umed.wroc.pl), ref: KB – 813/2020

Study design
Open-label non-randomized controlled interventional clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Ischemic stroke

Interventions
Patients qualified by the doctor to the study group before each unit of rehabilitation training had heart rate (HR) and blood pressure (RR) measurements. Improvement training has always been selected individually for each patient to their current physical abilities and needs. Its intensity was analyzed based on HR, measured with a sportester. At the same time, HR was current information characterizing the patient's emotional state and the level of fatigue.

Patients will be assigned to three groups:
1. Patients with upper limb hemiparesis treated with mirror therapy (MT):
Exercises performed twice a day for 30 minutes. The patient was sitting at a table with a mirror supported vertically on the side of the paresis half of the body. In such a way that the involved upper limb rested on the table behind the mirror and the healthy one in front of the mirror. The examined person tried to make symmetrical movements with both upper limbs according to the order of the researcher - moving the involved upper limb behind the mirror as best they could, starting with the easiest movements to make. The order of performing individual tasks was individually adjusted depending on the functional abilities of the examined person. The examined person was constantly watching the mirror image of the movement of the healthy hand in the mirror, which gave the impression that the involved upper limb was moving correctly. The patients were treated with kinesiotherapy (standard care rehabilitation program - active and

passive exercises of the paresis limb, active exercises to relieve the paresis limb, balance exercises, coordination exercises, breathing exercises) for 6 days a week, 1 hour a day. Each patient was treated for 6 weeks (36 days from Monday to Saturday). Each patient participated 5 days a week in occupational therapy (30 minutes a day), in therapy with a psychologist (30 minutes a day) and with a neurologopedist (30 minutes a day).

2. Patients rehabilitated by the method of proprioceptive neuromuscular facilitation (PNF):
The physiotherapy program was selected individually to the patient's abilities. The duration of the PNF therapy was 1 hour a day. The following main principles of PNF were used: therapist body mechanics, contact: manual, verbal and visual, optimal resistance, irradiation, approximation, and PNF techniques: rhythmic initiation of movement, combination of isotonic contractions, dynamic continuous maneuver, feedback stabilization, restoration of movement. PNF patterns were used: for work on the trunk: posterior depression of the scapula, front elevation of the scapula, front elevation of the pelvis, posterior pelvic depression, combinations of scapula and pelvis patterns (shortening of the elongation of the trunk with rotation), chopping - bilateral, asymmetric bend of the upper limbs with neck flexion, bilateral flexion patterns of the lower limbs with flexion of the knee joints, scooting - walking on the buttocks, rocking - moving the pelvis forwards and backwards. For work on the upper limb: flexion - abduction - external rotation, extension - abduction - internal rotation. For work on the lower limb: directly affected side: flexion - abduction - internal rotation with knee flexion, to the transfer phase flexion - adduction - external rotation, to the stance phase: extension - abduction - internal rotation.
The patients were treated with kinesiotherapy (standard care rehabilitation program - active and passive exercises of the paresis limb, active exercises to relieve the paresis limb, balance exercises, coordination exercises, breathing exercises) for 6 days a week, 1 hour a day. Each patient was treated for 6 weeks (36 days from Monday to Saturday). Each patient participated 5 days a week in occupational therapy (30 minutes a day), in therapy with a psychologist (30 minutes a day) and with a neurologopedist (30 minutes a day).

3. Patients with upper limb hemiparesis - practiced using the traditional method, treated as the control group (K):
The patients were treated with kinesiotherapy (standard care rehabilitation program - active and passive exercises of the paresis limb, active exercises to relieve the paresis limb, balance exercises, coordination exercises, breathing exercises) for 6 days a week, 1 hour a day. Each patient was treated for 6 weeks (36 days from Monday to Saturday). Each patient participated 5 days a week in occupational therapy (30 minutes a day), in therapy with a psychologist (30 minutes a day) and with a neurologopedist (30 minutes a day).

Intervention Type
Behavioural

Primary outcome(s)
The concentrations of BDNF, IGF-1, HGF, NT-3, NGF, VEGF, serotonin, lactate, dopamine, and cortisol from the blood serum at baseline, 14, 28, and 42 weeks (every 2 weeks during rehabilitation in the ward and after its completion, in the 6th week). Each patient will have blood drawn four times.

Key secondary outcome(s))
1. Everyday activities assessed using the Barthel Scale at baseline, 14, 28, and 42 weeks
2. Ability to perform complex everyday activities assessed using the Instrumental Activities of Daily Living Scale (IADL Scale) at baseline, 14, 28, and 42 weeks

3. Hand dexterity assessed using the Frenchay hand test (Frenchay Arm Test) at baseline, 14, 28, and 42 weeks
4. Degree of depression assessed using the Anxiety and Depression Scale (HADS Scale) at baseline, 14, 28, and 42 weeks

Completion date
01/12/2023

Eligibility

Key inclusion criteria
1. Consent to participate in the trial
2. 45-65-year-old patients who suffered an ischemic stroke
3. In the regeneration and compensation period after a stroke
4. Patients admitted for early post-stroke rehabilitation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
45 years

Upper age limit
65 years

Sex
All

Key exclusion criteria
1. Complete lack of movement of the upper limb
2. Very fit upper limb
3. Time from stroke longer than 30 days
4. Complete lack of cooperation on the part of the patient (global aphasia, lack of patient consent)
5. Complete stiffening of the shoulder joint

Date of first enrolment
01/01/2021

Date of final enrolment
01/09/2023

Locations

Countries of recruitment
Poland

Study participating centre
Regional Specialist Hospital in Wrocław
Local Department of Neurological Rehabilitation
Poświecka 8 Street
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51-128

Sponsor information

Organisation
Wroclaw University of Health and Sport Sciences

Funder(s)

Funder type
University/education

Funder Name
Wroclaw University of Health and Sport Sciences

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from Mr Wojciech Borowicz (wojtekborowka@interia.pl) on reasonable request. Raw data (taking into account the anonymity of patients) will become available from the end of the study for 5 years. The research results will be passed on to other researchers in order to compare these results with the results of their own research.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		29/01/2023	10/06/2025	Yes	No
Results article		30/05/2023	10/06/2025	Yes	No

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