ISRCTN17138124 https://doi.org/10.1186/ISRCTN17138124

Treadmill in stroke rehabilitation

Submission date
14/02/2022

Recruitment status
No longer recruiting

Registration date
03/03/2022

Overall study status
Completed

Last Edited
03/03/2022

Condition category
Other

[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.
Strokes are a global burden. People of all ages suffer from strokes, including relatively young and professionally active people. Post-stroke rehabilitation is multi-directional and long-lasting. There is still a need to search for new methods of rehabilitation of post-stroke therapy that will ensure effective and quick recovery of patients. Thanks to the development of medicine, physiotherapy and biomedical engineering, modern technologies are created and used in the process of post-stroke rehabilitation. However, there is a need for research confirming the effectiveness of therapy with the use of these technologies, as well as the need to improve the methodology of conducting therapy with the use of these devices.
These novel technologies include i.a. stationary gait rehabilitation robots, exoskeletons, treadmills equipped with virtual reality and feedback or treadmills with other various modifications, e.g. systems that unbalance the patient while walking.
The general aim of the study is to obtain knowledge on whether exercise using modern technologies such as the use of a treadmill equipped with virtual reality, biofeedback and balance perturbation systems can contribute to the improvement in stroke rehabilitation.

Who can participate?
Chronic post-stroke survivors over 18 years of age

What does the study involve?
50 patients, who will be randomly assigned to one of the 2 following groups:
1) The experimental group (EG), in which 25 patients will receive treadmill training with controlled body balance perturbations (Balance Tutor; MediTouch, Israel), 6 days a week (Monday to Saturday) for 30 minutes a day, for 3 weeks.
2) The control group (CG), in which 25 patients will receive traditional ground gait training for 30 minutes a day for 3 weeks, 6 days a week (Monday to Saturday).
In addition, all patients in both groups will be subjected to typical post-stroke rehabilitation for 2.5 hours a day, 6 days a week (Monday-Saturday), based on the principles of best clinical practices. The aim of the exercises will be to normalize muscle tone and improve movement patterns.

What are the possible benefits and risks of participating?
It is presumed that the treatment will contribute to the improvement of static and dynamic body balance, quality of gait, postural control and quality of life of stroke patients.
The exercises will be conducted and supervised by physiotherapists. During the exercises, patients will be provided with protection against falls and injuries. The methodology of individual exercises will be planned on the basis of scientific publications in which modern technologies were used safely in post-stroke rehabilitation. Therefore, no adverse events except fatigue is expected in patients. Possible side effects will be noted and, if necessary, the studies will be modified and discontinued, with appropriate notification to the Bioethics Committee.

Where is the study run from?
1. Academy of Physical Education in Katowice (Poland)
2. The Medical and Rehabilitation Center ''Solanki'' in Inowroclaw (Poland).

When is the study starting and how long is it expected to run for?
July 2020 to June 2022

Who is funding the study?
The Medical and Rehabilitation Center ''Solanki'' in Inowroclaw (Poland).
European Regional Development Fund for the Kuyavian-Pomeranian Voivodeship, Poland (No. RPKK.01.02.01-04-0016/18).

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
Nil known

Study information

Scientific Title
The effectiveness of the treadmill exercises with controlled balance perturbances in the rehabilitaion of patients with chronic stroke. Randomized clinical trial.

Study objectives
1. The perturbance balance training (PBT) carried out with the use of the treadmill Balance Tutor; MediTouch, Izrael will improve quality of gait of stroke patients.
2.The perturbance balance training (PBT) carried out with the use of the treadmill Balance Tutor; MediTouch, Izrael) will improve static and dynamic body balance of stroke patients.
3. The perturbance balance training (PBT) carried out with the use of the treadmill Balance Tutor; MediTouch, Izrael will improve quality of life of stroke patients.
4.The perturbance balance training (PBT) carried out with the use of the treadmill Balance Tutor; MediTouch, Izrael will improve activities of daily living (ADL).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/07/2020, Bioethics Commission for Scientific Research at The Jerzy Kukuczka Academy of Physical Education in Katowice (Mikołowska 72a Street, 40-065 Katowice, Poland; +48 032 2075152; komisjabioetyczna@awf.katowice.pl), ref: 5/2020

Study design
Single-center interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Treadmill perturbance balance training in modern rehabilitation of patients after stroke

Interventions
Chronic post-stroke patients, treated in the same Medical and Rehabilitation Center ''Solanki'' in Inowroclaw (Poland) will participate in the study.

After the medical examination and meeting the inclusion criteria, 50 patients will be randomly assigned to the experimental (25 patients) and control (25 patients) groups.
Treadmill training with controlled body balance perturbations (Balance Tutor; MediTouch, Israel) will be administered to patients in the experimental group (EG).

Training with body balance perturbations on the treadmill will be performed 6 days a week (Monday to Saturday) for 30 minutes a day, for 3 weeks.Patients in the control group (CG) will receive traditional ground gait training for 30 minutes a day for 3 weeks, 6 days a week (Monday to Saturday).
In addition, all patients in both groups will be subjected to typical post-stroke rehabilitation for 2.5 hours a day, 6 days a week (Monday-Saturday), based on the principles of best clinical practices.
The aim of the exercises will be to normalize muscle tone and improve movement patterns.

Intervention Type
Behavioural

Primary outcome(s)
1.Gait assessed by 10 Metre Walk Test (10MWT), at baseline and after the 3-week rehabilitation period.
2.Gait assessed by treadmill walking test (Zebris FDM-T; Rehawalk, MaxxusDaum h/p Cosmos Force), at baseline and after the 3-week rehabilitation period.
3.Spatial and temporal gait parameters assessed using the 3D MyoMotion device (Noraxon, USA), at baseline and after the 3-week rehabilitation period.

Key secondary outcome(s))
1. Static and dynamic body balance assessed by Berg Balance Scale (BBS), at baseline and after the 3-week rehabilitation period.
2. Dynamic body balance assessed by Time Up and Go Test (TUG), at baseline and after the 3-week rehabilitation period.
3. Dynamic body balance assessed by Functional Reach Test (FRT) , at baseline and after the 3-week rehabilitation period.
4. Static body balance assessed by stabilometric platform (Zebris FDM-T; Rehawalk, MaxxusDaum h/p Cosmos Force) at baseline and after the 3-week rehabilitation period.
5. Quality of life assessed with Stroke Impact Scale (SIS - 59), at baseline and after the 3-week rehabilitation period.
6. ADL assessed with Barthel Scale at baseline and after the 3-week rehabilitation period.

Completion date
30/06/2022

Eligibility

Key inclusion criteria
1. Women and men over 18 years of age;
2. First history of ischemic or hemorrhagic brain;
3. The period min. 4 months from the onset of stroke;
4. The patient's consent to participate in the study;
5. Ability to understand and follow the therapist's instructions;
7. Ability to walk independently on a distance of 10 m (allowed to use supporting tools such as a cane, crutch or walker);
8. Walking speed at least 0.4 km/h (enabling walking on a treadmill)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Contraindications to exercises in the study;
2. Subarachnoid hemorrhage;
3. Neurological diseases other than stroke affecting body balance and gait quality;

Date of first enrolment
28/03/2022

Date of final enrolment
03/06/2022

Locations

Countries of recruitment
Poland

Study participating centre
The Jerzy Kukuczka Academy of Physical Education in Katowice
Mikolowska 72a Street
Katowice
Poland
40-065

Study participating centre
The Medical and Rehabilitation Center "Solanki"
Sienkiewicza 50 Ave
Inowroclaw
Poland
88-100

Sponsor information

Organisation
Akademii Wychowania Fizycznego im. Jerzego Kukuczki w Katowicach

ROR
https://ror.org/05wtrdx73

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The Medical and Rehabilitation Center ''Solanki'' in Inowroclaw, Poland

Funder Name
European Regional Development Fund for the Kuyavian-Pomeranian Voivodeship, Poland No. RPKK.01.02.01-04-0016/18.

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be 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	Participant information sheet	11/11/2025	11/11/2025	No	Yes