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Stationary robot in stroke rehabilitation

Submission date
18/02/2022

Recruitment status
No longer recruiting

Registration date
14/03/2022

Overall study status
Completed

Last Edited
14/03/2022

Condition category
Circulatory System

[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.
In recent years, attempts have been made to implement modern technologies in post-stroke rehabilitation, including rehabilitation robots. It is assumed that robots enable precise repetition of movements, which enables the training of movement patterns, including gait. However, there are still few scientific studies, the results of which would allow for unequivocal determination of the effectiveness of robotic rehabilitation in training movement patterns in patients at different times from the onset of stroke and with dysfunctions of varying severity. The results of these studies would also enable the development of a methodology for robotic post-stroke rehabilitation.
The aim of the study is to obtain knowledge on the effectiveness of rehabilitation carried out with the use of a stationary robot in patients with subacute stroke (minimum 1 month after stroke).

Who can participate?
Sub-acute stroke survivors over 18 years of age

What does the study involve?
The study will include sub-acute stroke patients treated in the same Medical and Rehabilitation Center ''Solanki'' in Inowroclaw (Poland). Participants will be randomly divided into four groups. In the first experimental group, participants will perform gait exercises on a stationary robot once a day for 6 days a week (Monday to Saturday) for 3 weeks. In the second experimental group, participants will perform gait exercises on a stationary robot once a day for 3 days a week (Monday, Wednesday, Friday) for 3 weeks. In the first control group, participants will perform traditional ground gait exercises once a day for 6 days a week (Monday to Saturday) for 3 weeks. In the second control group, participants will perform traditional ground gait exercises once a day for 3 days a week (Monday, Wednesday, Friday) for 3 weeks. The duration of all exercises will be from 20 to 45 minutes, depending on the patient's ability. In addition, patients in all groups

will undergo 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 hoped 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 are 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?
1. The Medical and Rehabilitation Center ''Solanki'' in Inowroclaw (Poland)
2. 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

Protocol serial number
5/2020

Study information

Scientific Title
The effectiveness of a stationary robot in the rehabilitation of sub-acute stroke patients: a pilot randomized clinical trial

Study objectives
1. Training performed 6 times a week with the use of the stationary robot (GEOSYSTEM TM, RehaTechnology, Germany) will improve the quality of gait of post-acute stroke patients.
2. Training performed 6 times a week with the use of the stationary robot (GEOSYSTEM TM, RehaTechnology, Germany) will improve static and dynamic body balance of post-acute stroke patients.
3. Training performed 6 times a week with the use of the stationary robot (GEOSYSTEM TM, RehaTechnology, Germany) will improve the quality of life of post-acute stroke patients.
4. Training performed 6 times a week with the use of the stationary robot (GEOSYSTEM TM, RehaTechnology, Germany) will improve activities of daily living (ADL) of post-acute stroke patients.
5. Training performed 3 times a week with the use of the stationary robot (GEOSYSTEM TM, RehaTechnology, Germany) will improve the quality of gait of post-acute stroke patients.
6. Training performed 3 times a week with the use of the stationary robot (GEOSYSTEM TM, RehaTechnology, Germany) will improve static and dynamic body balance of post-acute stroke patients.
7. Training performed 3 times a week with the use of the stationary robot (GEOSYSTEM TM, RehaTechnology, Germany) will improve the quality of life of post-acute stroke patients.
8. Training performed 3 times a week with the use of the stationary robot (GEOSYSTEM TM, RehaTechnology, Germany) will improve activities of daily living (ADL) of post-acute stroke patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/07/2020, the Bioethics Commission for Scientific Research at The Jerzy Kukuczka Academy of Physical Education in Katowice (Mikołowska 72a Street, 40-065 Katowice, Poland; +48 (0)32 2075152; komisjabioetyczna@awf.katowice.pl), ref: 5/2020

Study design
Single-center interventional pilot randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
After the medical examination and meeting the inclusion criteria, patients will be randomly assigned by the attending physician to participate in the study to one of the following groups. Patients will be randomly assigned to groups based on the group symbol in an opaque and sealed envelope. Randomization will take place after the medical examination and meeting the inclusion criteria by the attending physician.
1. In the first experimental group patients will receive rehabilitation with the use of a stationary robot G-EOSYSTEM TM (RehaTechnology, Germany) once a day, 6 days a week (Monday - Saturday) for 20 - 45 minutes a day depending on the condition of the patient.
2. In the second experimental group patients will receive rehabilitation with the use of a stationary robot G-EOSYSTEM TM (RehaTechnology, Germany) once a day, 3 days a week (Monday, Wednesday, Friday) for 20 - 45 minutes a day depending on the condition of the patient.
3. In the first control group patients will receive overground gait training once a day, 6 days a week (Monday - Saturday) for 20 - 45 minutes a day depending on the condition of the patient.
4. In the second control group patients will receive overground gait training once a day, 3 days a week (Monday, Wednesday, Friday) for 20 - 45 minutes a day depending on the condition of the patient.

The overall treatment duration in all groups will be 3 weeks. In addition, patients in all 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
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
G-EOSYSTEM TM (RehaTechnology, Germany)

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. 1 month after stroke
4. The patient's consent to participate in the study
5. Ability to understand and follow the therapist's instructions
6. Ability to walk independently on a distance of 10 meters (it is allowed to use supporting tools, such as a walking stick, a ball or a walking frame)

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 quality of the gait
5. Body structure, articular stiffness and other dysfunctions that are contraindicators to therapy in a stationary gait rehabilitation robot (mainly: body weight over 95 kg, body height below 150 cm and over 199 cm, difference in the length of the lower limbs over 1.5 cm, spasticity over the 3rd degree in Ashworth scale, wounds on the body at fixation sites on stationary rehabilitation robot)

Date of first enrolment
20/03/2022

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
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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 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