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Effects of pressure garment in managing arm function among stroke patients

Submission date
03/06/2019

Recruitment status
No longer recruiting

Registration date
06/06/2019

Overall study status
Completed

Last Edited
21/05/2020

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
After a stroke (a serious life-threatening medical condition that occurs when the blood supply to part of the brain is cut off), damage to the brain can block messages between muscles and the brain causing arm and leg muscles to cramp or spasm (spasticity). This post-stroke condition makes daily activities such as bathing, eating and dressing more difficult. Spasticity can cause long periods of strong contractions in major muscle groups, causing painful muscle spasms. The aim of this study is to test the effect of a new tight-fitting pressure garment worn on the affected arm/hand on spasticity over a six-week occupational therapy program.

Who can participate?
Aged 21 years old and above, between one month and 12 months post-stroke.

What does the study involve?
All participants will take part in a conventional occupational therapy program for two hours every week. Half of the participants will wear a custom fitted pressure garment on the affected arm for six hours a day for six weeks.

What are the possible benefits and risks of participating?
There may or may not be any benefits of participating in the study. Information obtained from this study will help improve the treatment or management of other participants with the same disease or condition.
Potential risks of participating in this study:
a) Upper extremity becomes discoloured (white/ blue) or skin allergy.
b) Pain and loss of sensation in the affected hand.
c) The pressure garment is too tight and painful.
The participants are allowed to remove pressure garment if these symptoms occur and inform the therapist immediately.

Where is the study run from?
Tengku Ampuan Rahimah Hospital, Malaysia

When is the study starting and how long is it expected to run for?
June 2016 to June 2017

Who is funding the study?
Investigator funded

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
NMRR-16-423-29688

Study information

Scientific Title
The effectiveness of pressure garment in the management of spasticity and upper extremity function among stroke patients

Acronym
PGUE

Study objectives
The participants in the intervention group were gained greater improvement in all three outcomes as compared to those in the control group after 6 weeks of pressure garment (PG) intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/06/2016, Medical Research and Ethics Committee, Ministry of Health Malaysia (Blok A, Kompleks Institut Kesihatan Negara [NIH], No.1 Jalan Setia Murni U13/52, Seksyen U13 Bandar Setia Alam, 40170, Shah Alam, Malaysia; 03-22874032; nmrr@moh.gov.my) ref: NMRR-16-423-29688

Primary study design
Interventional

Study design
Interventional open-label single centre randomised controlled trial

Study type(s)
Treatment

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

Interventions
Forty-six envelopes with number 1 to 46 were randomly chosen by one of the therapists who was blinded to the study protocol, i.e. therapist who was not treating patients with neurological conditions and also not involved in the numbering and envelope preparations. Participants who received odd numbers were allocated in the intervention group and those received even numbers were allocated in the control group. Both the intervention group and the control group participated in a conventional occupational therapy program for 2 hours every week. Twenty-three participants in the intervention group were given custom fitted pressure garment (PG) at the affected upper extremity (UE). PG was custom fabricated using Lycra material by the researcher of this study. The pattern of the affected hand and the circumference of the mid-forearm of each participant in the intervention group was measured to ensure the fabricated PG fits exactly well on the forearm and hand. Participants in the intervention group were required to wear the PG for 6 hours a day for 6 weeks continuously. The necessary adjustment was made on the PG to maintain its tight fit.

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
All participants were assessed pre-intervention and 6 weeks post-intervention:
1. Spasticity as measured by the Modified Modified Ashworth Scale (MMAS)
2. Hand function as measured by the Jebsen Taylor Hand Function Test for the actual performance
3. Disabilities of Arm, Shoulder and Hand (DASH) Outcome Measure for the self-report measurement

Key secondary outcome(s)

none

Completion date
01/06/2017

Eligibility

Key inclusion criteria
1. Patient aged 21 years old and above
2. Between one month and 12 months post-stroke (ischemic or hemorrhagic adult stroke)
3. Absence of severe cognitive problems with Mini Mental State Examination (MMSE) score of at least 24
4. Modified Ashworth Scale of 1, 2 or 3 when wrist and hand perform flexion and extension movements

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
46

Key exclusion criteria
1. Behavior disturbances or serious chronic diseases that can interfere with the ability to give informed consent or cooperation in the study.
2. History of UE injuries, e.g. fracture, tendon injuries in the affected side.

Date of first enrolment
10/06/2016

Date of final enrolment
01/06/2017

Locations

Countries of recruitment
Malaysia

Study participating centre

Tengku Ampuan Rahimah Hospital
Jalan Langat
Klang
Malaysia
41200

Sponsor information

Organisation
Universiti Kebangsaan Malaysia

ROR
https://ror.org/01590nj79

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to data protection regulations.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2020	21/05/2020	Yes	No
Participant information sheet		06/06/2019	07/06/2019	No	Yes