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Effects of hot pack and ice pack intervention and electrical intervention on sensation and movement ability of the arm and hand in individuals with acute stroke

Submission date
13/05/2022

Recruitment status
No longer recruiting

Registration date
25/05/2022

Overall study status
Completed

Last Edited
03/07/2025

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
Over 85% of the post-stroke population will experience impaired upper-limb functionality. The functional recovery in the upper limbs for post-stroke is more difficult than that in the lower limbs. Furthermore, the coordination of both sides of upper extremity is needed to accomplish most of the daily activities, such as face washing, tooth brushing, eating, and getting dressed. Therefore, helping patients with stroke recover the use of their affected upper limbs seems to be very essential. Hence, the purpose of this clinical trial is to investigate the effects of electrical stimulation and the hot pack and ice pack stimulation on the sensory and motor recovery in upper extremity for individuals with stroke in acute stage.

Who can participate?
Acute stroke patients with hemiplegia (paralysis on one side of the body) in Taiwan

What does the study involve?
Participants were allocated into the electrical stimulation group, thermal stimulation group and conventional physical therapy group. Participants in each group underwent a 5-day intervention. The intervention for the electrical stimulation group includes electrodes attached to the forearm, and, participants might feel itchy during the electrical stimulation protocol. Participants will undergo a total 10 intervention sessions, 2 sessions in a day for 5 days. Participants in the thermal stimulation group will receive a 30-minute heat and cold stimulation, 2 sessions per day for 5 days. Participants will be requested to sit with both hands flat on the table. During the session, the therapist encouraged the participants to move away their limb from the hot pack or ice pack through active movements.

What are the possible benefits and risks of participating?
The possible benefits are motor function recovery. The possible risks include scald and allergy to the ice pack.

Where is the study run from?
E-Da Hospital (Taiwan)

When is the study starting and how long is it expected to run for?
December 2014 to January 2016

Who is funding the study?
This work was supported by the Chi-Mei KMU Joint Project (106CM-KMU-12), Ministry of Science and Technology in Taiwan (MOST 109-2221-E-037-003-) and the NSYSU-KMU Joint Research Project (#NSYSUKMU 105-P009).

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Contact information

Type(s)
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
EMRP-103-113

Study information

Scientific Title
Comparison of the effects of thermal stimulation and transcutaneous electrical nerve stimulation on upper extremity sensory and motor function in individuals with acute stroke: a randomized controlled pilot study

Study objectives
The sensory stimulation might improve the sensory and motor function for individuals with acute stage stroke.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/01/2015, Institutional review board of E-Da hospital (No.1, Yida Road, Jiaosu Village, Yanchao District, Kaohsiung City, Taiwan (R.O.C) 82445; +886 7-6151100 ext. 5110; ed107339@edah.org.tw), ref: EMRP-103-113

Study design
Single center interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
intervention for individuals with acute stroke

Interventions
Participants in this study will be allocated into thermal stimulation group, transcutenous electrical nerve stimulation group, and the control group by sealed envelope.

For thermal stimulation (TS) group, the following equipment and intervention protocol were used. The hot and cold stimulation devices used were a Firstek heating circulator water bath (B300, Firstek Corp, Taiwan) and a Firstek cooling circulator water bath (B401L, Firstek Corp, Taiwan), respectively. Each was connected to a temperature therapy pad (TP22E, Gaymer Corp, USA). Water temperature was adjusted or maintained at a constant as necessary by using the operation panel, and hot or cold water was then circulated to the therapy pads. The therapy pads (38 × 55 cm) were made of soft materials that allowed the forearm to be covered completely. The participants received hot and cold stimulation in 30-min sessions administered twice daily (once in the morning and afternoon, respectively) over 5 days, totaling 10 sessions. In accordance with the procedure used in one study, participants receiving TS were instructed to sit with both hands flat on the table. Heat stimulation was applied to their healthy arm for no more than 15 s. A thermometer was placed on the stimulated body part to prevent frostbite or burns. For the hot and cold stimulation, the temperatures were set at 51°C and 4°C, respectively. The

therapy pad was wrapped around the palm and wrist of the affected limb. During the session, the therapist encouraged the participants to pull their limb from the therapy pad through active movements. They were instructed to remove their healthy hand when they began feeling discomfort or when a score of seven had been reached on a standard 10-point visual analog scale (administered by the therapist), and the time from the beginning of the session to this point was recorded. The same procedure was repeated with the participants' affected hand. If no adverse skin reactions occurred, heat was applied on their affected arm 10 consecutive times, separated by 3 min of rest. Cold therapy involved the same procedure and was applied alternately with heat therapy. With both heat and cold therapy, stimulation was applied for 15 s, followed by at least 30 min of rest. Heat and cold were applied 20 times in each session (in order: 10 cycles of heat therapy, 10 cycles of cold therapy, 10 cycles of heat therapy, 10 cycles of cold therapy). During each session, the therapist constantly the skin surface temperature on the tested limb to prevent frostbite or burns. Moreover, the participants' blood pressure, heart rates, and breathing before and after the intervention were monitored, and the rest periods were extended as necessary.

For transcutenous electrical nerve stimulation (TENS) group, the following equipment and intervention protocol were conducted. A portable transcutaneous electrical nerve stimulator (TRIO-310) was used. Patches were adhered to the back of the forearm and the side of the palm. The skin was cleaned with alcohol before and after each session for disinfection and to reduce the possibility of increased electrical resistance. Wounds were avoided during the intervention. The TENS settings were as follows: pulse width 200 μs, output frequency 100 Hz, and output time 30 min. The output frequency was selected mainly for the purpose of stimulating the Aβ fibers, which produce sensations of light touch and pressure[19]. The current strength was adjusted as the maximum that the participant could withstand. As with the TS, TENS was applied in 30-min sessions administered twice daily (once in the morning and afternoon, respectively) over 5 days, totaling 10 sessions. Moreover, the therapist monitored the participants during each session and measured their blood pressure, heart rates, and breathing before and after the intervention, adjusting the rest periods as necessary and taking care to prevent electrical burns.

Participants in the control group received regularly scheduled rehabilitation therapy (1 h each of physical and occupational therapy). The physical therapy included therapeutic exercise, facilitation training, and functional training. Occupational therapy involved hand function training and training on activities of daily living.

Intervention Type
Mixed

Primary outcome measure
Measured at baseline (before intervention) and after 5 days (after completing intervention):
1. Motor recovery is measured using Fugl-meyer upper extremity scale assessment
2. Motor function recovery is measured by Brunnstrom stage assessment
3. Sensory is measured by minimal current perception

Secondary outcome measures
Measured at baseline (before intervention) and after 5 days (after completing intervention):
The spasticity of upper limb is measured by Modified ashworth scale assessment

Overall study start date
05/12/2014

Completion date
27/01/2016

Eligibility

Key inclusion criteria
1. Aged 20 years or older
2. Have a stroke for the first time
3. Have been examined by a physician, and were approved to receive rehabilitation treatment
4. Hospitalized during the acute phase
5. Hemiparesis
6. Do not have obvious cognitive impairments
7. Can independently maintain a sitting posture for at least 30 min

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
30

Total final enrolment
27

Key exclusion criteria
1. Have skin conditions or injuries (e.g., wounds) on upper limbs or have other contraindications for electrotherapy or TS (e.g., a malignant tumor)
2. Have a language disorder (e.g., aphasia) and is therefore unable to communicate or comply with instructions
3. Have other orthopedic conditions (e.g., severe arthritis) or nerve damage (e.g., peripheral nerve injury) affecting movement in their upper limbs
4. Have diabetes or complete sensory impairment not caused by stroke (e.g., peripheral vascular disease or neuropathy)
5. Have developed neurological disorders during the experiment period or other conditions that may affect the study results
6. Have uncontrolled hypertension, unstable angina, a history of myocardial infarction or epilepsy (excepting febrile seizures) in the past 3 months, or a pacemaker
7. Have participated in other rehabilitation trials or drug trials
8. Unable to cooperate with the researchers because of cognitive or personal reasons or refused to provide written informed consent

Date of first enrolment
28/01/2015

Date of final enrolment

15/01/2016

Locations

Countries of recruitment
Taiwan

Study participating centre
E-Da hospital
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82445

Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/03gk81f96

Funder(s)

Funder type
Government

Funder Name
Ministry of Science and Technology, Taiwan

Alternative Name(s)
Ministry of Science and Technology, R.O.C. (Taiwan), Ministry of Science and Technology of Taiwan, MOST

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Taiwan

Funder Name
Chi-Mei Medical Center and Kaohsiung Medical Unversity

Funder Name
National Sun Yat-sen University and Kaohsiung Medical University

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/07/2022

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		28/06/2024	03/07/2025	Yes	No