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Kinematic Motion Analyses of Upper Extremity After Intensive Training with Spring-assisted Dynamic Hand Orthosis in Patient with Stroke

Submission date 11/10/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 19/10/2010	**Overall study status** Completed	
Last Edited 19/10/2010	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2009-44

Study information

Scientific Title
Effects of Spring Assisted Dynamic Hand Orthosis Training on Functions and Movement Smoothness of the Hemiparetic Upper Extremity: A randomised controlled trial

Acronym
SADHO

Study objectives
The purpose of this experiment was to evaluate the effectiveness of training using a spring assisted dynamic hand orthosis on smoothness of movement, clinical assessment score, and grip strength of the affected limb in hemiparetic patients. To determine resultant velocity and jerkiness score for movement smoothness, the Box and Block Test (BBT), Action Research Arm Test (ARAT), and Fugl-Meyer Assessment (FMA) for functions of the hemiparetic upper extremity were conducted.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yonsei University, College of Medicine approved on the 25th of March 2010 (ref: 2009-44)

Study design
Randomised comparative interventional pretest-posttest control group design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Hemiparesis due to Stroke

Interventions
Patients will undergo training activities while each wore a spring assisted dynamic hand orthosis. Training will be guided by a physiotherapist for 1 hour per day per week for 4 weeks.

Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
3 clinical assessments and the measurement of grip strength. Fugl-Meyer Assessment and grip strength and Action Research Arm Test and Box and Block Test.
All outcomes were measured at baseline and after 4 weeks of training.

Secondary outcome measures
Spatiotemporal parameters were collected using a 3-D motion analysis system and workstation software pre- and post-test (VICON MX system, Oxford Metrics, U.K.). Data collection was conducted at the Motion Analysis Research Laboratory in the Yonsei University.
All outcomes were measured at baseline and after 4 weeks of training.

Overall study start date
23/12/2009

Completion date
15/03/2010

Eligibility

Key inclusion criteria
1. 18 years or older
2. Unilateral hemiparesis more than 6 months post-stroke duration
3. No current or previous orthopedic or surgical histories affecting the hemiparetic upper extremity
4. Mini-Mental State Examination (MMSE) Korean version - score ≥ 23 (to ensure that they fully understood the study procedure)
5. Patients should have at least some active voluntary movement of the upper extremity (i.e., 10 degrees of shoulder flexion/abduction, 10 degrees of elbow flexion/extension, and 30 degrees of interphalangeal proximal joints / 20 degrees of interphalangeal distal joints of volitional finger flexion when the hand is positioned in wrist and finger extension)
6. No flaccidity of the affected limb
7. No severe contracture or spasticity of the affected wrist or hand

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
10

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
23/12/2009

Date of final enrolment
15/03/2010

Locations

Countries of recruitment
Korea, South

Study participating centre
Department of Physical Therapy
Gyeongsangbuk-do
Korea, South
760-709

Sponsor information

Organisation
Yonsei University College of Medicine (South Korea)

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Sponsor type
Not defined

ROR
https://ror.org/01wjejq96

Funder(s)

Funder type
Other

Funder Name
Investigator funded (South Korea) - Dissertation project

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration