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Human Study Approval

Date: 2018.05.02

Title: Effects of Cervical Stabilization Exercise in Violinists with Chronic Neck Pain
Protocol No/ IRB No: -- / A-ER-107-073
Period of Project: From 2018.05.01 to 2018.12.31
Period of Approval: From 2018.05.01 to 2018.12.31
Content/Version:
1. Protocol: Version: 2, Date: 2018.04.18
2. Informed Consent Form: Version: 2, Date: 2018.04.18
3. Questionnaire (Neck Disability Index): Version: 1, Date: 2018.03.13

Institute: National Cheng Kung University
Investigator: Associate Prof. Yi-Jui Tsai (Department of Physical Therapy)
Co-Investigator: Assistant Prof. Yi-Liang Kuo

Approved Number of Participants: TW 25 Persons. If the number of participants enrolled exceeds the approved number, please submit an application for amendment and approval.

The Institutional Review Board of National Cheng Kung University Hospital (NCKUH) is organized and operated according to the laws and regulations of ICH-GCP and of Central Competent Authorities.

This project is reviewed and approved by NCKUH IRB in 2018.05.01. The period of approval is granted until 2018.12.31.

Regarding multi-period project, please submit the Interim Report before 2018.11.30. If the approval of the interim report is not granted on its expiry date, except safeguarding the health of the participants, the research is suspended.

Regarding completed project, the Final Report shall be submitted within three months of its approved expiry date. Except for the health of the participants, all the procedures of the project shall be terminated on its approved stated deadline.

If PI does not submit the Interim/Final Report on time, he/she will be recorded in the overdue list and received the suspension/ termination notice from NCKUH IRB. The overdue list will be reported to the IRB. After the resolution of the board meeting, NCKUH IRB will suspend all the new projects applied by PI until the Interim/Final Report is submitted.

Please submit the Interim/Final Report in written form and send to NCKUH IRB office. The lastest application forms can be downloaded in its website (http：// www.ncku.edu.tw/ ~nckuhirb)

Any changes or amendments to the project (including the project period), please submit an amendment application to NCKUH IRB within its approved period. Any changes or amendments in any other way will not be accepted. Before the approval of the amendment application, the project is carried out according to its previously approved plan.

For some reasons projects granted approval by NCKUH IRB couldn't be implemented, PI shall apply for suspension/termination.

During or after the project is completed, please report any unfavorable occurrence in a human study particant according to GCP.

Yours sincerely,
Thy-Sheng Lin M.D.
Chairman Thy-Sheng Lin

Institutional Review Board
National Cheng Kung University Hospital

Effects of Cervical Stabilization Exercise in Violinists with Chronic Neck Pain

I. Background

Many people start to learn a musical instrument at an early age because substantial time is required to become skilled. Playing the violin requires constant elevation of the left shoulder and lateral flexion and rotation of the cervical spine to firmly support the instrument against the chin. Prolonged exposure to an asymmetric posture and increased muscle activity in the neck‐shoulder region may lead to neck pain. Playing-related musculoskeletal symptoms is very common. Seventy-four percent of adolescent string instrumentalists in Australia experienced musculoskeletal symptoms, and approximately sixty-eight percent of Dutch university students reported chronic musculoskeletal pain and symptoms that interfered with their ability to play the instrument at the usual level during the past year. Neck pain is associated with reduced strength and endurance of cervical muscles, in particular the deep cervical flexors. The deep cervical flexors (longus capitis and colli) play a vital role in adjusting cervical curve and maintaining segmental stability. The aim of this study is to investigate the effects of cervical stabilization exercise on neck pain, neck disability, and physical impairments in university violin players with chronic nonspecific neck pain.

II. Methods

Participants

Violin players aged 18-25 years will be recruited from university symphony orchestras. The inclusion criteria are: duration of playing the instrument longer than 5 years; practicing the violin more than 5 hours per week; constant or frequently occurring neck pain for more than 3 months. The participants will be excluded if they had previous surgery in the neck and shoulder regions, currently participate in a structured exercises program, currently receive treatment for neck and shoulder pain, have neurological symptoms of the upper extremities, and other diseases that might prevent full participation in the study, such as cancer and rheumatic arthritis.

Study design and procedure

This study has a single-group pretest-posttest design with 3 measurements. The period between the 2 pretests at week 0 and 4 served as the baseline period. During the baseline period, the participants will not receive any intervention and be instructed to maintain their usual activity. Participants start a 6-week exercise program at week 5. The period between the second pretest at week 4 and the posttest at week 10 served as the intervention period.

Measurement

All the participants will complete the following measurements:

(1) Basic information
Includes age, gender, height, mass, duration of playing violin, average weekly hour of playing, health status and history of neck pain.

(2) Neck Disability Index (NDI)
NDI is a reliable, valid and responsive questionnaire used to assess the self-rated disability of patients with neck pain. The index is composed of 10 items including pain, personal care, lifting, reading, headaches, concentration, work, driving, sleeping and recreation. A higher percentage score of NDI indicates greater disability associated with neck pain.

(3) Cervical joint position sense
Cervical joint position sense will be assessed by the cervcal joint reposition error. The participants will be instructed to memorize the neutral head position, perform maximal cervical movement, and then relocate the head to the starting position blindfolded. The greater the distance between the starting and returning positions, the poor the cervical joint position sense.

(4) Cervical range of motion (ROM)
Cervical range of motion will be measured using a validated cervical range-of-motion device (Performance Attainment Associates, Lindstrom, MN, USA). Participants will be instructed to move their heads from their own natural neutral position into maximal flexion, extension, left lateral flexion, right lateral flexion, left rotation, and right rotation positions.

(5) Spinal Posture and Scapular Position Test)

Upper body posture will be measured using the photographic method. Postural angles (frontal head tilt, frontal shoulder, scapular rotation and upper thoracic) will be analyzed and measured from the images using the ImageJ software.

(6) Cervical muscle endurance
Cervical muscle endurance will be measured using a stopwatch for the successful time holding the tested position. The longer the holding time, the better the muscle endurance.

(7) Craniocervical Flexion Test (CCFT)
The craniocervical flexion test is a clinical test for assessing the neuromuscular control of deep cervical flexors. A pressure biofeedback unit (Stabilizer, Chattanooga Group, USA) will be used to measure the pressure change during head nodding in a hook-lying position.

Intervention

The participants will follow instructional videos and perform the exercise program at home, 20 minutes a day, 3 days a week for 6 weeks. The exercise program will be progressed by increasing the repetition of exercise first and then by increasing the intensity. The exercise program will include axial elongation exercise, craniocervical flexion exercise, cervical extension exercise, and cervico-scapulothoracic strengthening exercises

Statistical analysis

Descriptive statistics were summarized as means and standard deviations for normally distributed data and medians and interquartile ranges for skew data. A one-way repeated-measures analysis of variance (ANOVA) was used to identify any statistically significant differences among three time points for each dependent variable.

III. Expected outcome

The results of this study will help clinicians in management of nonspecific neck pain for violinists. The cervical stabilization exercise program used in this study can empower the violinists for self-care, and improve their quality of life.