**Research Study Protocol**

# Study Protocol Title

Effects of Online Exercise Intervention on Physical and Mental Conditions in Young Adults with Chronic Neck Pain

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# List of Abbreviations:

Visual Analog Scale (VAS)

Neck Disability Index (NDI)

Hospital Anxiety and Depression Scale (HADS)

Work Limitations Questionnaire (WLQ)

the Modified Brügger’s Exercise (MBE)

the Modified Proprioceptive Neuromuscular Facilitation Diagonal Flexion Exercise (MPNFDFE)

Repetitions Maximum (RM)

Rating of Perceived Exertion (RPE)

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# Research Synopsis

## Study Title

Effects of Online Exercise Intervention on Physical and Mental Conditions in Young Adults with Chronic Neck Pain

## Study Population

The target participants were adults with self-reported non-specific neck pain for more than three months. They were recruited through posters and social media in the campus of the Beijing Sport University.

## Study Design

The present study was an assessor blinded randomized controlled trial conducted according to the Declaration of Helsinki (World Medical Association, 2013). The Institutional Review Board of the Beijing Sport University approved the study (reference number: 2023006H).

## Sample Size

With an anticipated dropout rate of 15%, a total of 39 participants was required.

## Study Duration

Totally 8 weeks, including 1-week baseline testing, 6-week intervention and 1-week post intervention testing.

## Study Intervention Description

Participants in both groups completed the same exercise program three times a week for six weeks with either face-to-face or online mode of delivery by physiotherapists.

## Primary Objective

The primary objective is to study the effectiveness of online and conventional exercise therapy on pain level and function in adults with chronic neck pain. There were three primary outcomes, including average and maximum neck pain using visual analog scale (VAS), and Neck Disability Index (NDI).

## Secondary Objectives

The secondary objectives are investigating the effectiveness of online and conventional exercise therapy on mental condition and working efficacy in adults with chronic neck pain. There were two secondary outcomes: anxiety and depression measured with the Hospital Anxiety and Depression Scale (HADS) and work efficiency assessed with the Work Limitations Questionnaire (WLQ).

# Background and Significance:

Neck pain is one of the most common musculoskeletal disorders causing significant burden in public health worldwide (Safiri et al., 2020). In China, neck pain also influences large population, the age standardized point prevalence of neck pain was 4532.6 per 100000 persons, which was higher than the global age standardized point prevalence of 3551.1 per 100000 persons in 2017 (Safiri et al., 2020; Wu et al., 2021). The China Mental Health Survey reported that the prevalence of chronic back or neck pain among people with any mental disorders was more than twice that of those without mental disorder (Xu et al., 2020). It is believed that psychological factors such as stress, distress, anxiety, mood and emotions, cognitive function and pain-related behaviors are important factors related to chronic neck pain (Kazeminasab et al., 2022). Additionally, because of COVID-19 pandemic, people's physical activity has been greatly reduced and the prevalence of anxiety and depression all over the world is prone to increase. In 2020, the pandemic will lead to an increase of 27.6% in cases of severe depression and 25.6% in cases of anxiety disorders worldwide (Santomauro et al. 2021). In this way, people with chronic neck pain may have a higher risk to develop mental disorder.

Most chronic neck pain is non-specific with no identifiable pathoanatomical cause (Beltran-Alacreu et al., 2018). Many therapies have been used to treat patients with chronic non-specific neck pain but exercise therapy is considered as the integral component of interventions (Blanpied et al., 2017). It has also been proved that exercise can reduce the symptoms of depression, anxiety and pain in patients with neck pain (Nazari et al., 2018). However, due to the lack of time, money and rehabilitation resources, many people cannot receive high quality conventional rehabilitation. Since the start of COVID-19 pandemic in 2020, it became more difficult to deliver the conventional form of exercise therapy to those patients with chronic neck pain by the physiotherapists. In response to this crisis, telerehabilitation, as a new service mode of delivering rehabilitation, has become popular for physiotherapists to treat various musculoskeletal, neurological and cardiopulmonary disorders (Havran and Bidelspach, 2021). Telerehabilitation not only alleviates the time cost and economic cost of patients, but also reduces the pressure on the medical system (De Biase et al., 2020). In addition, online rehabilitation can maximize the use of high-quality rehabilitation resources, and neck pain patients in remote areas can also receive the cutting-edge and effective interventions at home. Recent review on systematic reviews of telerehabilitation in physiotherapy provides preliminary evidence that “telerehabilitation in physical therapy could be comparable with in-person rehabilitation or better than no rehabilitation for conditions such as osteoarthritis, low-back pain, hip and knee replacement, and multiple sclerosis and also in the context of cardiac and pulmonary rehabilitation” (Seron et al., 2021). However, the efficacy of telerehabilitation for patients with chronic non-specific neck pain is still unknown. A Cochrane review protocol on telerehabilitation for neck pain has been published but the review results are not available yet (Fandim et al., 2021).

# Objectives:

People with chronic neck pain suffer from persistent pain with impaired physical function and mental health. The proportion of mental issues among them is much higher than healthy population. The purposes of this study were to compare the efficacy of online exercise therapy with conventional exercise therapy on pain, function, psychological status and work efficiency of young adults with chronic neck pain.

Objective outcome assessments were taken at baseline prior to randomization and after the 6-week intervention period. Additional assessments of the WLQ were done after two weeks and four weeks of intervention.

## Primary Objective

The primary objective is to investigate the effectiveness of online and conventional exercise therapy on pain and function in adults with chronic neck pain. One primary outcome was the average and maximum neck pain measured by VAS. Another outcome was the neck dysfunction measured by the NDI.

## Secondary Objectives

The secondary objective is to investigate the effectiveness of online and conventional exercise therapy on mental condition and working efficacy in adults with chronic neck pain. There were two secondary outcomes: anxiety and depression measured with HADS, and work efficiency assessed with WLQ.

# Study design/methodology:

Randomized clinical trial with 39 adults with self-reported chronic neck pain recruited. They were randomly assigned into two groups. The experimental group received online exercise therapy and the control group received conventional exercise therapy.

Participants in both groups completed the same exercise program three times a week for six weeks with either face-to-face or online mode of delivery by physiotherapists. The degree of pain was assessed by the improvement in average and maximum VAS. Neck function and work limitations were assessed by NDI and WLQ respectively. HADS and its subscales were used to evaluate anxiety and depressive symptoms. Participants were assessed at baseline and at 6 weeks while the changes in WLQ were assessed biweekly. To ensure the effectiveness of online exercise therapy, therapists delivered the online exercise 3 times a week for 6 weeks, with videoconferencing once a week and posting of exercise record on WeChat app twice a week.

# Study Population:

The target participants were adults with self-reported non-specific neck pain for more than three months. They were recruited through posters and social media in the campus of the Beijing Sport University.

## Inclusion /Exclusion Criteria

The inclusion criteria were: (1) adults between 18 and 50 years of age with neck pain (from occiput to 7th cervical vertebra) for at least 3 months; (2) a score of ≥ 4/50 on the NDI. The participants with the following were excluded: (1) adults with a history of previous neck surgery, cervical radiculopathy, acute neck injury or fracture; (2) persons who had more than two hours of moderate intensity exercise or more than four hours of low intensity exercise in a week; and (3) persons who had received any form of physiotherapy treatment in the last 6 months.

# Interventions:

Participants in both groups completed the same exercise program three times a week for six weeks with either face-to-face or online mode of delivery by physiotherapists.

At baseline, the suitable elastic bands (Thera-band®) for performing the exercises were selected by testing the 15 repetitions maximum (15RM) of the Modified Brügger’s Exercise (MBE) and the Modified Proprioceptive Neuromuscular Facilitation Diagonal Flexion Exercise (MPNFDFE) for the participants of both the experimental group and control group. The details of the MBE and MPNFDFE were described in supplementary file 1.

Participants randomized to the control group performed the following exercises three times a week for six weeks in a group of 3-5 participants in the laboratory of the Sport Medicine and Rehabilitation School of the Beijing Sport University:

A. Warm-up exercises

B. Cranio-cervical flexion exercises

C. Strength-endurance exercises

D. Scapular stabilization exercises

E. Stretching exercises

The details of the exercises were described in supplementary file 2.

Participants allocated to the experimental group performed the same set of exercise three times a week for six weeks in their home, with the following arrangements:

The participants had weekly online exercise meetings with the physiotherapist in a group of 3-5 participants using the TENCENT Meeting. Then the participants performed the remaining two sessions of exercises themselves weekly. If they had encountered any problems, they could consult the physiotherapist during the online session or texting to the physiotherapist using the WeChat app. All the participants of the experimental group received a package of exercise pamphlet and a video disc containing 17-minute exercise demonstrations by the physiotherapist.

# Study Schedule:



# Adverse Event Reporting:

In this study, the tests and interventions may include physical activities, which may irritate neck pain. Physical activities have little risk of heart attack and other life-threatening conditions. During the test and trial, if there are adverse reactions such as acute aggravation of neck pain, the test or intervention will be stopped immediately, and emergency treatment will be conducted. If there is any emergency, the principal investigator(s) will provide basic life support including chest compressions and ventilation until emergency medical staff are on hand. Participants can consult the clinicians if they are experiencing any side effects from taking part in the study and should also inform the principal investigator.

# Statistical Analysis Plan:

Continuous data were expressed as means and standard deviations. Categorical data were shown as frequencies or percentages. All statistical analyses were conducted using the IBM SPSS Statistics for Windows, Version 24.0 (Armonk, NY: IBM Corp). The normality of continuous data was checked with the Shapiro-Wilk test. The change scores of the primary and secondary outcome variables from baseline to end of intervention between the two groups were compared using independent sample t test. Within-group comparisons were done using paired sample t test. The level of significance of all statistical tests was set with two-tailed at 0.05. Per-protocol analysis was used.

The sample size for the study was calculated to be 32 using the G\*Power 3.1.9.2 (Universitat Kiel, Germany), with an estimated effect size of group difference of 0.9 in primary outcomes and a level of significance of 0.05, statistical power of 80% with two-tailed independent sample t test. The estimated effect size was based on previous studies of home exercise on patients with neck pain (Zronek et al., 2016). With an anticipated dropout rate of 15%, a total of 39 participants was required.

# Informed Consent Process:

Before participating in the study, physiotherapists will explain this study to all participants to ensure they are clear about this study. Participants can drop out at any time during this study. Then they will complete the informed consent form. All the participants are recruited from Beijing Sport University, China, and they are all native Chinese speakers, so the informed consent form is in Chinese (simplified). All participants should meet the inclusion criteria, and anyone meets the exclusion criteria will be excluded.

## Privacy and confidentiality:

Subject’s names will be kept on a password protected database, and they will be linked only with a study identification number for this research. There are no patient identifiers. All data will be entered into a computer that is password protected. Data will be stored in a locked office of the investigators and usually maintained for a minimum of three years after the completion of the study.

# Risk/Benefit:

## Risk to participants:

This is a relatively safe study which has rare risk. Since it is a training for neck muscles, it has possibility of muscle strain and worse neck condition. It has little risk of heart attack and other life-threatening conditions.

**Benefits to Participants**

This study provides a good exercise plan for the participants which improves their neck functions and decreases their neck pain.

# Study Timeline:

Stage 1, screening, enrollment, ----2 weeks

Stage 2, treatment phase, ----6 weeks

Stage 3, data collection and data analysis, -----4weeks

Stage 4, presentation and publication, ----1 year

# Data Safety Monitoring:

All data about participants that is collected during the course of the research will be kept strictly confidential. The data collected with be de-identified before being analysed, and identified data including medical history will be confidential and stored separately. However, confidentiality of participants’ data is subject to legal limitations (e.g. subpoena, freedom of information claim, or mandatory reporting in some professions). All data will be kept in locked filing cabinets as well as password protected electronic files. Data will be securely stored for at least three years and may be kept indefinitely.

# Conflict of Interest:

No potential conflict of interest.

# Publication and Presentation Plans:

Results of this study was used for the graduation thesis and presentation for masters’ degree.

Plan to publish 1 SCI paper.

# References:

Beltran-Alacreu, H., López-de-Uralde-Villanueva, I., Calvo-Lobo, C., Fernández-Carnero, J., and La Touche, R. (2018). Clinical features of patients with chronic non-specific neck pain per disability level: a novel observational study. *Rev Assoc Med Bras* 64(8)**,** 700-709. doi: 10.1590/1806-9282.65.2.291.

Blanpied, P., Gross, A., Elliott, J., Devaney, L., Clewley, D., Walton, D., et al. (2017). Neck pain: revision 2017. *J Orthop Sports Phys Ther* 47(7)**,** A1-A83. doi: 10.2519/jospt.2017.0302.

De Biase, S., Cook, L., Skelton, D. A., Witham, M., and Ten Hove, R. (2020). The COVID-19 rehabilitation pandemic. *Age and ageing*, 49(5), 696–700. https://doi.org/10.1093/ageing/afaa118

Fandim, J., Costa, L., Yamato, T., Almeida, L., Maher, C., Dear, B., et al. (2021). Telerehabilitation for neck pain. *Cochrane Database of Systematic Reviews* (3). doi: 10.1002/14651858.CD014428.

Havran, M., and Bidelspach, D. (2021). Virtual physical therapy and telerehabilitation. *Phys Med Rehabil Clin N Am* 32(2)**,** 419-428. doi: 10.1016/j.pmr.2020.12.005.

Kazeminasab, S., Nejadghaderi, S., Amiri, P., Pourfathi, H., Araj-Khodaei, M., Sullman, M., et al. (2022). Neck pain: global epidemiology, trends and risk factors. *BMC Musculoskelet Disord* 23(1)**,** 26. doi: 10.1186/s12891-021-04957-4.

Nazari, G., Bobos, P., Billis, E., and MacDermid, J.C. (2018). Cervical flexor muscle training reduces pain, anxiety, and depression levels in patients with chronic neck pain by a clinically important amount: A prospective cohort study. *Physiother Res Int* 23(3), e1712. doi: 10.1002/pri.1712.

Safiri, S., Kolahi, A., Hoy, D., Buchbinder, R., Mansournia, M., Bettampadi, D., et al. (2020). Global, regional, and national burden of neck pain in the general population, 1990-2017: systematic analysis of the Global Burden of Disease Study 2017. *BMJ* 368**,** m791. doi: 10.1136/bmj.m791.

Seron, P., Oliveros, M., Gutierrez-Arias, R., Fuentes-Aspe, R., Torres-Castro, R., Merino-Osorio, C., et al. (2021). Effectiveness of telerehabilitation in physical therapy: a rapid overview. *Phys Ther* 101(6)**,** pzab053. doi: 10.1093/ptj/pzab053.

Santomauro, D. F., Herrera, A. M. M., Shadid, J., Zheng, P., Ashbaugh, C., Pigott, D. M. et al. (2021). Global Prevalence and Burden of Depressive and Anxiety Disorders in 204 Countries and Territories in 2020 Due to the COVID-19 Pandemic. *The Lancet*, 398, 1700-1712. https://doi.org/10.1016/S0140-6736(21)02143-7

World Medical Association (2013). World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. *JAMA* 310(20)**,** 2191-2194. doi: 10.1001/jama.2013.281053.

Wu, A., Dong, W., Zeng, X., Xu, X., Xu, T., Zhang, K., et al. (2021). Neck pain is the leading cause of disability burden in China: findings from the Global Burden of Disease Study 2017. *Ann Transl Med* 9(9)**,** 777. doi: 10.21037/atm-20-6868.

Xu, Y., Wang, Y., Chen, J., He, Y., Zeng, Q., Huang, Y., et al. (2020). The comorbidity of mental and physical disorders with self-reported chronic back or neck pain: results from the China Mental Health Survey. *J Affect Disord* 260**,** 334-341. doi: 10.1016/j.jad.2019.08.089.

Zronek, M., Sanker, H., Newcomb, J.,&Donaldson, M. (2016). The influence of home exercise programs for patients with non-specific or specific neck pain: a systematic review of the literature. *J Man Manip Ther*, 24(2), 62-73. doi: 10.1179/2042618613Y.0000000047

# Supplementary file 1. The assessment of 15 repetitions maximum of exercises of Modified Brügger’s Exercise and Modified Proprioceptive Neuromuscular Facilitation Diagonal Flexion Exercise

A. Modified Brügger’s Exercise (MBE)

The subject was seated in a starting position for shoulder adduction (90° flexion of the elbows; supination of the forearms). The Thera-band® was wrapped around the subjects’ hands and kept tight. The subjects performed scapular retraction and external rotation of shoulder joint. Afterwards, the subjects straightened the elbows and abducted shoulders, and then gradually recovered to the starting position.

B. Modified Proprioceptive Neuromuscular Facilitation Diagonal Flexion Exercise (MPNFDFE)

The subject was seated in a starting position with their hands grasping the Thera-band® and placing on their legs, shoulders in internal rotation, scapulars in protraction, forearms in pronation, and fingers in flexion. Then they performed one sided scapular retraction, shoulder flexion, abduction and external rotation. At the meantime, they did a trunk rotation. After that they slowly returned to the starting position and did the other side.

The most appropriate training intensity for the subjects was: the participant could complete 15 times, with a rating of perceived exertion (RPE) of 15 points (hard/heavy) on the 15-grade Borg RPE scale as shown in Figure S1, and does not cause neck pain.



**Figure S1.** the Borg RPE 6–20 scale with Chinese verbal descriptors

# Supplementary file 2. Exercise program

**A. Warm up exercises**

In the warm-up phase, the participant should slowly perform neck flexion, extension and lateral flexion to the end of the range of motion, with 10 times in each direction. Then he or she would perform circumduction of shoulder joint for 10 times.

**B. Cranio-cervical flexion exercises**

Training volume: 190 seconds in total, hold in each movement for 10 seconds, rest for 10 seconds, and with repetitions of 10 times.

There were 7 movements in total (from A to G), four of which were performed in each training session. In the first two weeks, the movements (A), (B), (D) and (E) were performed, in the third and fourth weeks, the movements (A), (C), (E) and (F) were performed, and in the fifth and sixth weeks, the movements (C), (E), (F) and (G) were performed.

(A) Chin retraction in supine position

(B) Chin retraction in sitting position

(C) Chin retraction in sitting position and turning head left and right consecutively

(D) Four kneeling position with chin retraction

(E) Chin retraction against the wall in standing position

(F) Chin retraction in standing position with turning head left and then right consecutively

(G) Chin retraction against the towel behind neck in supine position

**C. Strength-endurance exercises**

Training volume: hold in each side for 10 seconds (left, right and back), with repetitions of 10 times for each.

(1) Lateral neck muscles: the participant sat with chin retraction, then complete one side isometric lateral flexion against manual resistance for 10 seconds. Then this was repeated in another side alternatively.

(2) Back neck muscles: the participant sat with chin retraction. The Thera-band® was placed at the back of the head and held in both hands. Then an isometric backward head extension against the resistance of the Thera-band® was performed for 10 seconds. The holding distance of the band from the hands should be adjusted to achieve suitable resistance during the exercise.

**D. Scapular stabilization exercises**

Training volume：15 repetitions of the resistance of 15RM initially determined were performed for each movement. There was rest of one minute between each movement. If the participant could perform the exercise without difficulty, then he or she could increase the resistance of Thera-band® accordingly.

There were 6 movements in total, with three of which being performed in each training. Each movement was performed for 1 set in the first four weeks, and 2 sets in the last two weeks. In the first two weeks, the movements (1), (2) and (3) were performed, and in the third and fourth weeks, the movements (4), (5) and (6) were performed. In the last two weeks, the movements (4), (5) and (6) were performed in two sets.

(1) Side-lying shoulder external rotation:

- in side lying with arms close to the trunk

- both hands holding the Thera-band® with the elbow flexed to 90°

- external rotation of the shoulder to full ROM

(2) Prone T exercise

- in a prone position with shoulder 90° abduction, like a letter "T"

- lifting the hands toward the ceiling, bringing both shoulder blades together

- head and neck in neutral position

(3) Y-to-I exercise

- in a prone position with shoulder 120° abduction, like a letter "Y"

- shoulder blades retraction with the hands lifting toward head, forming a letter "I"

(4) Unilateral row

- in standing position, one arm holding the resistance band, then with the shoulder blades retraction slowly to drive the upper arm to perform shoulder extension and elbow flexion, completing a rowing movement

- the action was maintained 2 seconds at the end range of retraction, then the action was slowly released with shoulder and arm returning to the starting position

(5) Reversed flies

- the resistance band holding in both hands in standing position

- then straight arm shoulder horizontal abduction was performed against the resistance with shoulder blades retraction

- the action was maintained 2 seconds at the end range of retraction, then the action was slowly released with shoulder and arm returning to the starting position

(6) Lateral pulldown

- the resistance band secured stably above the head

- the resistance band was pull down with both hands with elbow extended

- the shoulder blades retraction with shoulder adduction and extension

- the action was maintained 2 seconds at the end range of retraction, then the action was slowly released with shoulder and arm returning to the starting position

**E. Stretching exercises**

The sternocleidomastoid, levator scapulae, pectorals minor and pectorals major were stretched, 30 seconds for one muscle.