

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

2023.08.06

1. Study Protocol Title

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

2. Table of Contents:

1. Study Protocol Title.....	2
2. Table of Contents:	3
3. List of Abbreviations:.....	5
4. Principal Investigator, Research Team, and Study Site:	5
5. Research Synopsis	5
Study Title.....	5
Study Population	5
Study Design	5
Sample Size.....	5
Study Duration	5
Totally 8 weeks, including 1-week baseline testing, 6-week intervention and 1-week post intervention testing.....	6
Study Intervention Description	6
Primary Objective	6
Secondary Objectives.....	6
6. Background and Significance:.....	6
7. Objectives:.....	7
Primary Objective	7
Secondary Objectives.....	8
8. Study design/methodology:	8
9. Study Population:	8
Inclusion /Exclusion Criteria.....	8
10. Interventions:.....	9
11. Study Schedule:.....	10
.....	10
12. Adverse Event Reporting:	10
13. Statistical Analysis Plan:	11
14. Informed Consent Process:.....	11
Privacy and confidentiality:	11
15. Risk/Benefit:.....	12
Risk to participants:.....	12
16. Study Timeline:	12

17.	Data Safety Monitoring:	12
18.	Conflict of Interest:.....	12
19.	Publication and Presentation Plans:	12
	References:.....	14

3. 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 (MPNFD FE)

4. Principal Investigator, Research Team, and Study Site:

Principal investigator:

Co-Investigators:

Research team and contact Information:

Study site: Rehabilitation Medicine Centre, School of Sports Medicine and Rehabilitation, Beijing Sport University

5. 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).

6. 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 Bidelsbach, 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).

7. 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 Work Limitations Questionnaire 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 visual analog scale (VAS). Another outcome was the neck dysfunction measured by the Neck Disability Index (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 the Hospital Anxiety and Depression Scale (HADS), and work efficiency assessed with the Work Limitations Questionnaire (WLQ).

8. 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 visual analogue scale (VAS). Neck function and work limitations were assessed by the Neck Disability Index (NDI) and Work Limitations Questionnaire (WLQ) respectively. The Hospital Anxiety and Depression Scale (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.

9. 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 $\geq 4/50$ on the Neck Disability Index. Those 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.

10. 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

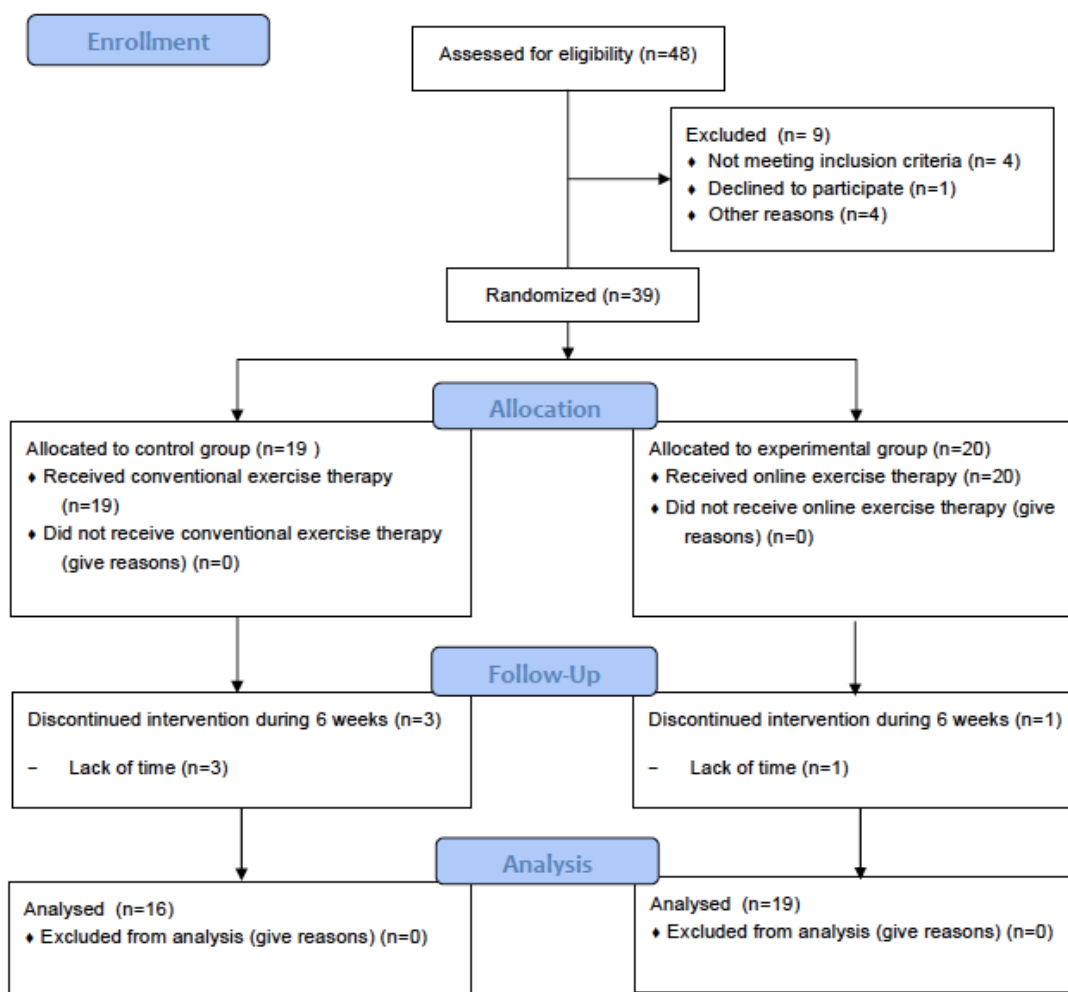
The details of the exercises were described in supplementary file 2.

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.

11. Study Schedule:

CONSORT 2010 Flow Diagram



12. Adverse Event Reporting:

In this study, the tests and interventions may include physical activities, which may irritate neck pain and 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. Participant can consult the general practitioners if they

are experiencing any side effects from taking part in the study and should also inform the Principal Investigator.

13. 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.

14. 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.

15. 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.

16. 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

17. Data Safety Monitoring:

All data about participants that is collected during the course of the research will be kept strictly confidential. The data collected will 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.

18. Conflict of Interest:

No potential conflict of interest.

19. Publication and Presentation Plans:

List any meetings or conferences where you will be presenting the data and the results of your

study.

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.
- Bjelland, I., Dahl, A.A., Haug, T.T., and Neckelmann, D. (2002). The validity of the Hospital Anxiety and Depression Scale: An updated literature review. *J Psychosom Res* 52(2), 69-77. doi: 10.1007/s00221-003-1814-9.
- 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>
- Falla, D., Jull, G., and Hodges, P.W. (2004). Feedforward activity of the cervical flexor muscles during voluntary arm movements is delayed in chronic neck pain. *Exp Brain Res* 157(1), 43-48. doi: 10.1007/s00221-003-1814-9.
- Falla, D., Jull, G., Russell, T., Vicenzino, B., and Hodges, P. (2007). Effect of Neck Exercise on Sitting Posture in Patients With Chronic Neck Pain. *Phys Therapy* 87(4), 408-417. doi:10.2522/ptj.20060009.
- 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.
- Gialanella, B., Comini, L., Olivares, A., Gelmini, E., Ubertini, E., and Grioni, G. (2020). Pain, disability and adherence to home exercises in patients with chronic neck pain: long term effects of phone surveillance. A randomized controlled study. *Eur J Phys Rehabil Med* 56(1), 104-111. doi: 10.23736/S1973-9087.19.05686-7.
- Havran, M., and Bidelsbach, 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.
- Huang, X., Meyers, K., Liu, X., Li, X., Zhang, T., Xia, W., et al. (2018). The double burdens of mental health among AIDS patients with fully successful immune restoration: a cross-sectional study of anxiety and depression in China. *Front Psychiatry* 9, 384. doi: 10.3389/fpsy.2018.00384.
- Jorritsma, W., Dijkstra, P.U., Vries, G., Geertzen, J., and Reneman, M.F. (2012). Detecting relevant changes and responsiveness of Neck Pain and Disability Scale and Neck Disability Index. *Eur Spine J* 21(12), 2550-2557. doi: 10.1007/s00586-012-2407-8.
- 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.
- Lerner D, Amick III, B., Rogers, W., Malspeis, S., Bungay, K., and Cynn, D. (2001). The Work Limitations Questionnaire. *Med Care* 39(1), 72-85. doi: 10.1097/00005650-200101000-00009.

- Leung, C.M., Ho, S., Kan, C.S., Hung, C.H., and Chen, C.N. (1993). Evaluation of the Chinese version of the Hospital Anxiety and Depression Scale. A cross-cultural perspective. *Int J Psychosom* 40(1-4), 29-34. doi : 10.1111/j.1365-2702.2008.02736.x
- 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](https://doi.org/10.1016/S0140-6736(21)02143-7)
- Stewart, W.F., Ricci, J.A., and Leotta, C. (2004). Health-related lost productive time (LPT): recall interval and bias in LPT estimates. *J Occup Environ Med* 46(6 Suppl), S12-22. doi: 10.1097/01.jom.0000126685.59954.55.
- Vernon, H. and Mior, S. (1991). The Neck Disability Index: a study of reliability and validity. *J Manipulative Physiol Ther* 14(7), 409-415. doi:10.1300/J094v04n04_09
- Wang, W., Chair, S.Y., Thompson, D.R., and Twinn, S.F. (2009). A psychometric evaluation of the Chinese version of the Hospital Anxiety and Depression Scale in patients with coronary heart disease. *J Clin Nurs* 18(13), 1908-1915. doi: 10.1111/j.1365-2702.2008.02736.x.
- 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.
- Zigmond, A.S., and Snaith, R.P. (1983). The Hospital Anxiety and Depression Scale. *Acta Psychiatr Scand* 67(6), 361-370. doi: 10.1111/j.1600-0447.1983.tb09716.