A corrective functional exercise program for postural thoracic kyphosis in teenagers: study protocol for a randomized, controlled clinical trial

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Abstract

Background: In this report, we describe our protocol for testing the hypothesis that a comprehensive corrective training program for teenagers could effectively treat postural thoracic kyphosis, which is a common problem in this age group.

Methods/Design: This was a prospective, single-center, randomized, controlled, open-label trial completed at the China Institute of Sport Science in Beijing, China. Eighty teenagers were enrolled and randomized into two groups (n = 40/group). The participants completed one of two training programs: 1) a comprehensive training program aimed at functional correction of posture that targeted active range of motion, proprioception, and strength of the muscles acting on the cervical, thoracic, and lumbar vertebrae (test group) or 2) a standard strength-training program (control group). The two training programs were designed to be equal in intensity and each consisted of two 20-minute sessions per week for 8 consecutive weeks. All participants underwent non-invasive testing using Spinal Mouse® while standing upright, and with their trunks in flexion and extension, before, and at 1, 2, and 4 weeks after the final training session. Outcome measures were assessed before training and 1, 2, and 4 weeks after the last training session. The primary outcome was thoracic kyphosis angle. Secondary outcomes included lumbar lordosis, sacral inclination angle, thoracic inclination angle, range of motion of the spine, posture, and the incidence of adverse events.

Discussion: Successful treatment of postural thoracic kyphosis would improve the health of affected teenagers.

Trial registration: This trial was registered in the Chinese Clinical Trial Registry (www.chictr.org.cn) (registration number: ChiCTR-INR-16008860).

Ethics: This trial has been approved by the Ethics Committee of the China Institute of Sport Science, Beijing, China and performed in accordance with the Declaration of Helsinki, formulated by the World Medical Association.

Informed consent: Training content and process was fully exposed to all the participants, and signed informed consent was obtained from each participant.

Key words: clinical trial; functional exercise; teenager; postural thoracic kyphosis; spine; thoracic kyphosis angle; range of motion of the thoracic vertebra; randomized controlled trial

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INTRODUCTION

Previous and current related studies

Sagittal spinal morphology is crucial to maintaining balanced posture (Cui et al., 2015; Erdemir et al., 2015). The "S"-shaped physiological curve of the human spine evolved with the ability to walk upright, and provides enhanced
spinal flexibility while allowing the spine to perform its biomechanical functions (Womack et al., 2011). Mechanical load and age-related bony changes in the thoracic vertebrae result in morphological changes of the thoracic vertebrae that lead to increases in the thoracic kyphosis angle (Zhou et al., 2013; Roberts et al., 2014; Liu et al., 2015).

Abnormal curvature of the spine in the sagittal plane is common in teenagers, who often suffer from postural thoracic kyphosis due to poor sitting posture. There are currently few reports describing training programs for correcting postural thoracic kyphosis in teenagers.

**Main objective**
The purpose of this trial was to determine whether a comprehensive functional training program for correcting postural thoracic kyphosis in teenagers achieved effective outcomes.

**Novelty of this study**
Previous studies have mainly addressed imaging and spinal measurements in teenagers with idiopathic scoliosis (Fan et al., 2001; Qiu et al., 2008; Zhao et al., 2011; Guo et al., 2015). Little is known about training programs for correcting postural thoracic kyphosis in teenagers.

**Methods/Design**
**Study design**
A prospective, single-center, randomized, controlled, open-label trial.

**Study setting**
This trial was conducted at the China Institute of Sport Science in Beijing, China.

**Study procedures**
(1) Participants suspected of abnormal spinal curvature in the sagittal plane were screened using Spinal Mouse®, a non-invasive testing device for measuring the curvature of the vertebral column.

(2) Eighty eligible students from Beijing No. 35 High School, the Second Affiliated Middle School of Beijing Normal University, or Beijing No. 156 High School in Beijing, China were enrolled in this study. Participants were randomized into test and control groups, each consisting of equal numbers of girls and boys.

(3) The corrective training program in the test group mainly targeted the active ranges of motion (ROMs), muscle strength, and proprioception of the cervical, thoracic, and lumbar vertebral regions. Participants in the control group performed a standard strength-training protocol. All participants performed one of the two training programs, which were of equal intensity and duration, for 20 minutes twice per week for 8 consecutive weeks.

(4) Non-invasive assessment using Spinal Mouse® was carried out prior to training, and 1, 2, and 4 weeks after the final training session to determine the thoracic kyphosis angle, lumbar lordosis, sacral inclination angle, thoracic inclination angle, ROMs at different spinal segments, and spinal morphology. The incidence of adverse events was also recorded. **Figure 1** shows a flow chart of the study procedures.
Inclusion criteria
Participants of both genders were required to meet all of the following conditions to be included in this study:
• Thoracic kyphosis angle > 40° as determined by assessment with Spinal Mouse® (Livanelioglu et al., 2016)
• Current high school students, 16–19 years old
• Both genders

Exclusion criteria
Potential participants were excluded from the trial if they had:
• A history of spinal fracture or related spinal surgery
• Pelvic-related injury or spinal disease, such as cauda equina syndrome, lumbar disc herniation, spinal stenosis, congenital scoliosis, etc.
• Sports-related shoulder injury
• Structural kyphosis with remarkable structural abnormality
• Abnormal kyphosis combined with thoracic deformity
• Scoliosis, positive for Adam’s forward bending test (Côté and Cassidy, 1998)
• Engaged in professional sports training for amateur sports
• Other related spinal diseases that made them unsuitable for sports training

Baseline analysis
Baseline data, including demographic data (age, sex, and body mass index) and general disease history (current, previous, and genetic history), were collected from the participants prior to randomization (Table 1).

Table 1: Baseline analysis

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<th>Demographic data</th>
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Sample size
A search of the literature revealed no gold standard for assessing the effectiveness of training interventions on thoracic kyphosis angle. Based on our previous experience, we assumed that the thoracic kyphosis angle would be reduced by 40% after training in the test group and by 10% in the control group. Considering \( \alpha = 0.05 \) (two-sided), \( \beta = 0.1 \), and power = 90%, the necessary sample size was calculated to be \( n = 40 \) per group. With a predicted dropout rate of 20%, the required sample size was \( n = 48 \) per group. After application of the inclusion and exclusion criteria, our final group size was \( n = 40 \) per group.

Recruitment
High school students were recruited through an advertisement on the school bulletin board, and interested potential participants contacted the project manager. After providing their written informed consent, potential participants who met the requirements of the inclusion and exclusion criteria were enrolled in the study.

Randomization
One day prior to the training, the project manager used a random number table generated by Office Microsoft Excel 2007 (Microsoft, WA, USA) to number the 80 participants in successive order. The participants were then equally randomized into two groups using the Rand function.

Blinding
This was an open-label trial. All participants and trainers were informed of their grouping information and training program.

Interventions
(1) The corrective training program (test group) was designed to reestablish normal curvature of the spine by restoring normal spinal biomechanical function. This comprehensive functional training program involved posture adjustment and respiratory control, cervical muscle strength training, thoracic extension and rotation, upward rotation of the shoulder blades, cat-like stretching, chest muscle stretching, pelvis control training, and core muscle strength training. The aim of this program was to improve ROM, proprioception, and strength of the muscles acting on the cervical, thoracic, and lumbar vertebrae, thereby achieving functional correction of spinal and pelvic alignment.
(2) The standard strength-training program (control group) was designed based on China’s recommended guidelines for physical training. It consisted of two 20-minute sessions of push-ups, sit-ups, pull-ups, and standing leaps per week.
(3) The duration of training was 8 weeks for both groups. All participants underwent non-invasive testing using Spinal Mouse® before and 1, 2, and 4 weeks after the final training session.
(4) The Spinal Mouse® assessments were performed after the participants had removed their shoes (especially high-heeled shoes) and shirts to expose their C₇–S₃ segments (gluteal cleft). The anatomical landmarks associated with each vertebra (superior and inferior ends, spinous process, etc.) were identified and labeled with a marker to confirm
Standing with trunk anteflexion: Participants were asked to relax and stand as they normally would, with their hands hanging naturally at their sides, eyes looking straight ahead, and feet shoulder-width apart and evenly weighted. The trainer reminded the participants to maintain this position three times. Using the Spinal Mouse® receiver, spine morphology was assessed relative to the position of the spinous processes. Thoracic kyphosis angle, lumbar lordosis angle, and sacral inclination angle were measured.

Standing with trunk extension: Participants were asked to stand with both legs straight in a position of trunk anteflexion with their head and hands hanging naturally and their feet shoulder-width apart. Using the Spinal Mouse® receiver, the spinal morphology was assessed relative to the position of the spinous processes. The ROMs of the different spinal segments in different postures were measured.

Standing with trunk anteflexion: Participants were asked to stand with both legs straight in a position of trunk anteflexion with their head and hands hanging naturally and their feet shoulder-width apart. Eyes looking straight ahead, and their feet shoulder-width apart and evenly weighted. After extending the trunk as much as possible (arching backwards), the ROMs of different spinal segments in different postures were assessed relative to the position of the spinous processes using the Spinal Mouse® receiver.

The Matthiass test, which is a method to assess whether a participant can maintain correct posture under outside pressure (Betsch et al., 2010): Each participant was asked to stand with their feet shoulder-width apart and eyes looking straight ahead. The trainer’s command the participant raised their straight arms upwards to a shoulder flexion angle of 90°. The trainer then evaluated their posture while the participant stood in the arms-raised position. Thirty seconds later, the posture was retested in the same position.

Data collection: In accordance with principles of Cobb angle measurement, the Spinal Mouse® software system was used to measure the thoracic (T₁–T₁₂) kyphosis angle, lumbar (L₁–L₅) lordosis angle, sacral inclination angle, and ROMs of the different spinal segments.

Outcome measures
Primary outcome
- Thoracic kyphosis angle prior to training, and 1, 2, and 4 weeks after the final training session. An increased thoracic kyphosis angle indicates more serious postural thoracic kyphosis.
- Thoracic inclination angle prior to training, and 1, 2, and 4 weeks after the final training session. An increased thoracic inclination angle indicates an increased probability of forward bending of the spine.
- Lumbar lordosis angle prior to training, and 1, 2, and 4 weeks after the final training session. A larger lumbar lordosis angle indicates limited mobility of the thoracic vertebrae.
- Sacral inclination angle prior to training, and 1, 2, and 4 weeks after the final training session. An increased sacral inclination angle indicates limited mobility of the sacral vertebrae.
- ROMs of the thoracic, lumbar, and sacral vertebrae prior to training, and 1, 2, and 4 weeks after the final training session. Decreased ROMs of any of the spinal segments indicates limited mobility of that segment.
- Spinal posture prior to training, and 1, 2, and 4 weeks after the final training session, as assessed by the Matthiass test. This tests whether a participant can maintain correct posture under outside pressure.
- Incidence of adverse events 1, 2, and 4 weeks after the final training session. The schedule of the trial procedure is shown in Table 2.

Adverse events
During the trial, we recorded adverse events such as thoracic shifting, lumbar shifting, chest and back muscle damage, non-specific lumbar back pain, dizziness, nausea, and vomiting. If severe adverse events occurred, information including the date of occurrence and treatment were recorded and reported to the project manager and the institutional review board within 24–48 hours.

Data collection, management, analysis, and open access
Data collection
Clinical data, including demographic data, disease diagnosis, accompanying diseases, and adverse events, were collected and summarized using standardized case report forms. These data were processed using Office Microsoft Excel 2007 (Microsoft) and SPSS 19.0 software (IBM Corporation, Armonk, NY, USA).

Data management
After database confirmation, only the project manager was able to access the database. The locked data were unable to be altered and were preserved by the China Institute of Sport Science.
**Data analysis**

All data were statistically analyzed by professional statisticians who were responsible for completing an outcome analysis report that was submitted to the project manager. An independent data monitoring committee was responsible for data monitoring and management throughout the entire trial to ensure scientific accuracy, stringency, authenticity, and integrity.

**Open data**

Published data will be released within 6 months of completing the trial at http://www.medresman.org.

**Statistical analysis**

All data were statistically analyzed by statisticians using SPSS 19.0 software (IBM Corporation) in accordance with the intention-to-treat principle. Normally distributed measurement data were expressed as means, standard deviations, minimums, and maximums, while non-normally distributed data were expressed as lower quartiles, medians, and upper quartiles. A two-way repeated analysis of variance was used for intergroup comparison of thoracic kyphosis angle, inclination angle, and ROMs. The Pearson $\chi^2$ test was used to compare the incidence of adverse events between the two groups. The statistical significance level was $\alpha = 0.05$.

**Auditing**

Trial progress was reported to the ethics committee of the China Institute of Sport Science every month and the trial status was updated in the registration database after each report.

**Confidentiality**

Valuable trial data were transcribed, dated, and uploaded to a dedicated computer by two staff members. These data were scheduled, checked, locked by an investigator, and were not altered after locking. Unauthorized persons were unable to access the database. Data recorded on paper regarding this trial protocol were preserved by the China Institute of Sport Science, China.

**Trial Status**

Data processing at the time of submission.

**Discussion**

**Significance of this study**

In this study, we explored the feasibility of a corrective functional training protocol for the correction of postural...
thoracic kyphosis in teenagers. It is our hope to promote healthy spinal development in teenagers.

Advantages and limitations of this study
Advantages of this study include that it is a prospective, single-center, randomized, controlled, open-label trial. It is also the first study to investigate the use of interventional training to correct the abnormal sagittal spinal curvature in teenagers. The comprehensive corrective training program used in this study was designed to treat the spine as a whole, with the hope of improving the postural thoracic kyphosis of the participants.

Limitations include the need for further studies to determine the long-term efficacy of this corrective functional training program.

Contributions to future studies
We hope that the results of this study will provide valuable information about the short-term effects of a corrective functional training program on abnormal sagittal curvature of the thoracic spine in teenagers.

Declaration of patient consent
The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) gave his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Conflicts of interest
None declared.

Author contributions
QF conceived and designed the study protocol and wrote the manuscript. YZ was responsible for trial organization and arrangement. MW and YFZ were responsible for guiding and revising the trail execution and paper writing. FBHW was responsible for statistical analysis. All authors approved the final version of this manuscript.

Plagiarism check
This paper was screened twice using CrossCheck to verify originality before publication.

Peer review
This paper was double-blinded and stringently reviewed by international expert reviewers.

REFERENCES