Study Protocol

The effectiveness of kyphosis-specific exercise on reducing the angle of kyphosis among Chinese older adults with thoracic hyperkyphosis — a randomized control trial

IRB ID: [2019] IEC (P001)

Data: 2019/10/9

1. Investigators

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2. Aims of the project

The primary aim of the proposed randomized control trial is to investigate the effect of a kyphosis-specific exercise intervention on reducing the angle of kyphosis in Chinese older adults with thoracic hyperkyphosis. The secondary aim of this trial is to evaluate the effect of the kyphosis-specific exercise intervention on improving the self-image, pain, and physical performance in Chinese older adults with thoracic hyperkyphosis.

3. Study sites

Participants will be recruited from the community centers in Wuhan, China.

4. Planned sample size

It is planned to recruit 156 participants, and 20 participants for pilot.

5. Measurements

The participants meeting the inclusion criteria will be arranged to finish spine measurements, physical performance tests, and questionnaires (Appendix 1).

6.1 Spine measurements (Primary outcome)

The angle of kyphosis will be measured by manual inclinometer in the proposed study. There are two reasons we do not use X-ray, the gold standard. First, the study will be conducted in community centres without access to the X-ray facilities. Second, the participants will accomplish the angle of kyphosis measurement in two postures in three time points within 12 weeks. Manual measurements can protect the participants from exposing to unnecessary radiation.

Manual inclinometer is have previously demonstrated excellent levels of inter-rater (ICC=0.90), and intra-rater reliability (ICC=0.92) (Barrett, McCreesh, & Lewis, 2013), and satisfied concurrent validity (r=0.86) (Barrett, Lenehan, O'Sullivan, Lewis, & McCreesh, 2018).

The angle of kyphosis will be measured in two conditions, once in participants standing relaxed, once in participants stand as straight as possible. The measurement procedure is as follow: 1) the researcher explaining measuring instructions; 2) participants exposing upper body in two standing posture; 3) identifying and marking the spinous processes of C7, T1, T2, T12, and L1 in two postures; 4) using manual inclinometers measure the angle in two postures. The measurements will also be performed three times in succession.

6.2 Physical performance assessments (Secondary outcomes)

The physical performance assessments include two balance tests, One-leg Standing Test and Timed Up & Go Test; two cardiopulmonary function tests, the Thoracic Expansion test and the Six Minutes Walking Test; and a gait assessment, the Farsi Version of Functional Gait Assessment. All have been reported having satisfying validity and reliability (Kamrani, Seyed Hojjat Zamani Sani, Rezaie, & Aghdasi, 2010; Michikawa, Nishiwaki, Takebayashi, & Toyama, 2009; Wrisley, Marchetti, Kuharsky, & Whitney, 2004; Hu, Nan Liu, & Zhou, 2014).

6.3 Questionnaires (Secondary outcomes)

Participants will also be given a set of questionnaires asking social-

demographic information and health-related information. Social-demographic information includes age, gender, marital status, and education level. The health-related information asks spine surgery history, illnesses, daily life posture, daily exercises level (via the International Physical Activity Questionnaire-Short Form) (Deng, Macfarlane, Thomas, Lao, Jiang, & Cheng, 2008). The self-image and pain will be measured via Scoliosis Patient Questionnaire - version 22 which has been found suiting for the evaluation of thoracic hyperkyphosis patients (Petcharaporn, Pawelek, Bastrom, Lonner, & Newton, 2007) and having a validated Chinese version (Cheung et al., 2007). The height and weight of participants will also be recorded in the questionnaire after measurement.

6. Estimated duration and commencement date

Proposed starting date:	19/08/2019
Proposed study completion date:	01/03/2021
Expected final report date:	01/09/2021

7. Scientific/historical background

Thoracic hyperkyphosis refers to an exaggerated curvature between the first thoracic vertebra body (T1) and the 12th thoracic vertebra body (T12) (Katzman, Wanek, Shepherd, & Sellmeyer, 2010) has a high prevalence among older adults. Studies reported that the prevalence of the thoracic hyperkyphosis in elderly ranged from 20% to 40% among community-dwelling subjects aged ≥ 60 years (Hinman, 2004; Kado, Huang, Karlamangla, Barrett-Connor, & Greendale, 2004; Takahashi et al., 2005). The cross-sectional study conducted by the Principal Investigator found thoracic hyperkyphosis have a high prevalence (72%) in Chinese community-dwelling older adults.

Thoracic kyphosis has been found having negative effects on health. An increased angle of thoracic kyphosis was related to decreased self-image diminished physical function, impairment of respiratory function, increased

chronic upper back pain, decreased balance, decreased quality of life, and decreased gait performance (Petcharaporn et al., 2007; Huang, Barrett, Greendale, & Kado, 2006; Kado, 2017; Kado, Huang, Barrett, & Greendale, 2005; Sangtarash, Manshadi, & Sadeghi, 2015).

Treatment options of thoracic hyperkyphosis included surgery (Katzman, Wanek, Shepherd, & Sellmeyer, 2010), peptides injection (Liu, Wu, & Li, 2004), menopausal hormone therapy (Woods et al., 2018), bracing (Zaina et al., 2009), traditional Chinese medicine therapies (Shen, 2011). Exercise, a noninvasive and less pain treatment method, has also been conducted for relieving thoracic hyper-kyphosis abnormality (Seidi, Rajabi, Ebrahimi, Alizadeh, & Minoonejad, 2014; Senthil, Sudhakar, Radhakrishnan, & Jeyakumar, 2017).

The previous studies reported that different types of exercise such as strength training, pilates, yoga, and corrective exercise were effective in reducing the thoracic hyperkyphosis (Greendale, Huang, Karlamangla, Seeger, & Crawford, 2009; Katzman et al., 2010). Investigator conducted a systematic review in order to explore the most effective exercise intervention for thoracic hyperkyphosis correction.

According to the systematic review, the most popular kyphosis-specific exercise protocol was designed by Katzman and team. There were two versions of the protocol, one published in 2007 (Katzman, Sellmeyer, Stewart, Wanek, & Hamel, 2007), another published in 2016 (Katzman et al., 2016). One third of 12 selected studies used this protocol, and two of them reported the largest decrease of the angle of kyphosis.

Both of the two studies with largest angle change reported more than 5° angle decrease. One was pre-post cohort study conducted by Katzman and team (2007) reported from baseline to post-intervention, the angle of kyphosis decreased 6°±3° ($p<0.001$) in relaxed standing posture, and 5°±3° ($p<0.001$) decrease in best standing posture. Another one was RCT conducted by Bahrekazemi and colleagues (2017) used the protocol published in 2016. They found the intervention group having a 6.5° mean angle reduction within group ($p<0.05$), and a 6.8° mean angle

reduction between groups ($p<0.05$).

Another two studies also found a statistically significant change of the kyphotic angle. One RCT reported that within the intervention group, the angle of kyphosis decreased by 3.3° (95% CI −4.9, −1.7), compared to a decrease of 0.3° (95% CI −1.9, 1.2) among controls (Katzman, Vittinghoff, et al., 2017). Another reported participants in the intervention group had a 3.8° (95% CI: −5.3 to −2.3) decrease in the angle of kyphosis while the control group had an insignificant change (1°, 95% CI: −0.5 to 2.4), between-group difference was 4.8° ($p< 0.001$) (Katzman, Parimi, et al., 2017).

However, the 12 systematic review selected studies either excluded older adults have and exercise habit or lack of information about participants' daily activity level. Thus there is a lack of information about the effectiveness of kyphosis-specific exercise intervention on reducing the angle of kyphosis in older adults having exercise habit. The cross-sectional study conducted by the Principal Investigator found that older adults in Wuhan, China were active in daily life that more than 92.5% of the participants with thoracic hyperkyphpsis reported moderate or high exercise intensity.

Currently, multimedia education has been successfully employed in healthcare fields (Batuyong, Birks, & Beischer, 2012). For example, exercise video has been used to help patients mastering the pelvic floor muscle exercise (Crowe, Harbison, Wootten, Pillay, & Morrison, 2018), preventing shoulder problems (Park, & Song, 2017), and enhance exercise adherence of patients with osteoarthritis of the knee (Tohyama, Chiba, Tadano, Ikoma, & Yasuda, 2010).

Video is a promising method for giving exercise intervention to elderly. Because the video can provide accurate visual guidance on how to perform the exercises and, in addition, music and verbal instruction can be motivational during the exercises (Vestergaard, Kronborg, & Puggaard, 2013). Using video as intervention can also overcome the limitations on finance and transportation when the elderly wants professional exercise guidance.

All the kyphosis-specific exercise interventions in reviewed studies by the

Principal investigator were delivered by professional trainer or physical therapist in the form of face-to-face exercise class. No evidence shows whether the kyphosis-specific exercise intervention be given in the form of video also have effects on reducing the angle of kyphosis or enhancing the overall physical performance in older adults with thoracic hyperkyphosis.

So, it is valuable to conduct the proposed study providing kyphosis-specific exercise in the form of video and face to face exercise class as intervention to Chinese older adults with thoracic hyperkyphosis. The proposed study can test the effects of such kyphosis-specific exercise intervention on the angle of kyphosis, physical performance, pain, and self-image among Chinese older adults with thoracic hyperkyphosis.

8. Research question and hypotheses

9.1 research questions

1) what are the effects of kyphosis-specific exercise intervention (video and exercise class) on the angle of kyphosis in Chinese elderly with thoracic hyperkyphosis, as compared with control?

2) what are the effects of kyphosis-specific exercise intervention (video and exercise class) on pain, self-image, and physical performance, including gait performance, balance, and cardiopulmonary functions in Chinese elderly with thoracic hyperkyphosis?

9.2 Hypothesis

1) older adults receive kyphosis-specific exercise intervention (video and exercise class) have reduced the angle of kyphosis;

2) older adults receive kyphosis-specific exercise intervention (video and exercise class) have decreased pain, better self-image, and improved the overall physical performance.

9. Study design

10.1 Study type

The proposed study is a single blinded randomized control trial. The participants and kyphosis-specific exercise intervention instructor are not able to be blinded, while the people conducted assessments will be blinded for group allocation.

10.2 Method of selection of subjects

The target population will be elderly living in Wuhan, Mainland China. The older adults participated in the previous cross-sectional study conducted by the principle investigator will be first invited.

Inclusion criteria for subjects to be screened are:

1) Chinese;
2) Aged 60 years and above;
3) No cognitive impairment or communication problems;
4) The angle of thoracic kyphosis > 40° measured by Manual Inclinometer;
5) Able to decrease the angle of kyphosis of 5° while standing.

Exclusion criteria for subjects to be screened include:

1) Having central or peripheral neuropathy (this may affect balance);
2) Taking drugs that affect the nervous system or affect balance and strength;
3) Having untreated severe heart and lung disease (this may affect cardiopulmonary function);
4) Having a history of spinal fracture (this may increase the risk of injury);
5) Having surgery in spinal, shoulder, and pelvis in the past year or having plan to do so in the coming six month (this may increase the risk of injury);
6) Having scoliosis ≥ 10°;
7) Having done any specific therapeutic exercise for posture in the past year or having plan to do so in the coming six month (may affect the study result).

10.3 Intervention design

The intervention of the proposed study contains two parts. One is the kyphosis-specific exercise class given by certified physical trainer. Another is the home practice following kyphosis-specific exercise video. The intervention arrangement is:

- Group learning and practice: a 1-hour kyphosis-specific exercise training session will be provided two times in the first week,
- Weekly follow-up: a 1-hour kyphosis-specific exercise will be conducted with reinforcement of learning and remedial teaching by a certified physical trainer once a week for five consecutive months after the group learning and practice,
- Self-practice: participant will following the kyphosis-specific exercise video doing self-practice every day for the whole intervention period lasting 6 weeks.

The kyphosis-specific exercise class will be led by a licensed physical trainer and a trained assistant. The participant to instructor (assistant) ratio will no less than 5:1. The content of kyphosis-specific exercise video is the same as exercise class.

The kyphosis-specific exercise protocol is based on Kaztman's studies published in 2007 and 2016 (Katzman, Sellmeyer, Stewart, Wanek, & Hamel, 2007; Katzman et al., 2016). The target group of these two studies were different. Participants included in 2007 were older and have more severe thoracic hyperkyphosis. In 2007 women aged 65 and above with a thoracic of 50° and greater were included while in 2016 older adults in both genders aged 60 and above with a thoracic of 40° and greater were recruited. As the sample of the proposed study is similar to 2016 protocol, the proposed study mainly follow the protocol published in 2016.

The choices for the specific exercise were slightly different between the protocol in 2007 and 2016, but no information of revision was given. More exercises were included in 2016 protocol than that in 2007, but overhead arm wall slid and calf stretching were only mentioned in 2007 protocol. As the 2016 protocol

already include full leg stretching exercise supine straight-leg raise, the calf stretching will not be included in the proposed study. Overhead arm wall slid has been found effectively improving scapular alignment (Kim & Lim, 2016) which is associated with spine alignment (Helgadottir, Kristjansson, Mottram, Karduna & Jonsson, 2011).The comprehensive intervention protocol is presented in Appendix 2.

10.4 Number of subjects to be recruited

According to the systematic review, the effect size of four studies used Katzman's kyphosis-specific exercise protocol ranged from 0.44 to 2.45 (Bahrekazemi, et al., 2017; Katzman, Vittinghoff, et al., 2017; Katzman, Parimi, et al., 2017; Katzman, Sellmeyer, Stewart, Wanek, & Hamel, 2007). We expect the proposed RCT can attain similar effect size, hence for a more conservative estimate, effect size 0.44 (which was equivalent to intervention group had the angle of kyphosis 3.0°, 95% CI 0.56°-3° less than the controls) was taken into sample size calculation. Assuming the level of significance at 0.05 and power as 0.8, the calculated sample size will be in each group. The proposed study will recruit at least 78 participants in each group taking a drop-out rate of 20%. In the pilot study, 20 eligible participants will be recruited.

10.5 Procedures

The participants are to be selected from the communities located in different regions in Wuhan by convenient sampling. The participants joined the cross-sectional study conducted by principal investigator in 2018 will be first invited. The staff working in community centers will also send notice to the residents' online chat room. Every potential participant will have a trained research assistant responsible for explaining the RCT details with the information sheet (Appendix 3) and re-assuring the respondents that data collected in the study will be kept strictly confidential, and then seeking permission for conducting the screening. The potential participants will be screened according to inclusion and exclusion

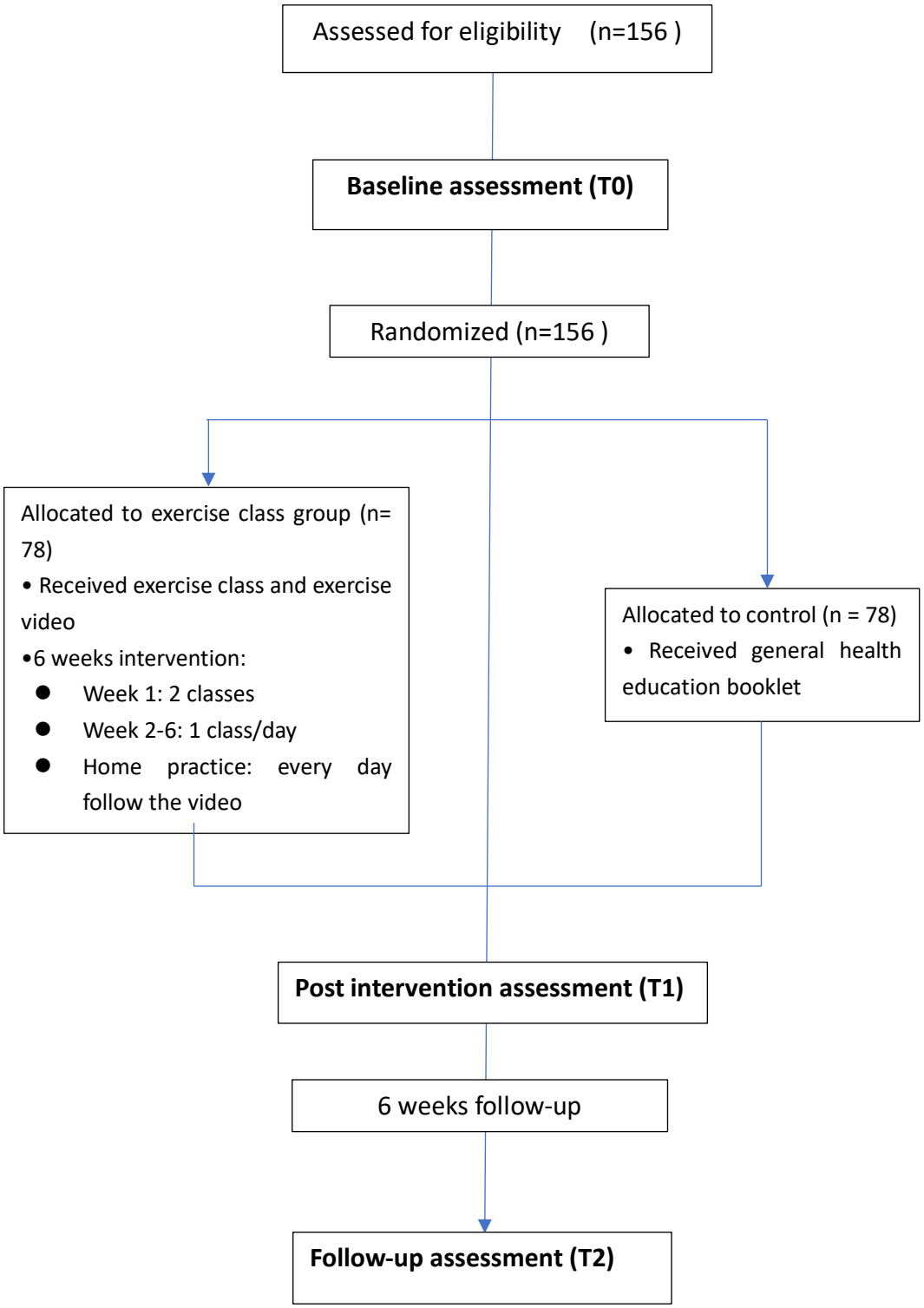
criteria (Appendix 4). The eligible participants will sign the written consent (Appendix 5) and accomplish the baseline questionnaire and assessments (T0). After that the participant will be randomly divided into intervention group or control group.

Block randomization method will be used (Kang, Ragan, & Park, 2008). The investigator will randomly select block sizes such as two, four, or six, to make randomization sequences for 156 participants. Then randomization sequences will be printed and placed in a sequentially numbered opaque sealed envelope. After older adult sign consent and finishing the baseline questionnaire and assessments, the researcher will open the envelop according to the numbered sequence for the grouping allocation.

The intervention group will receive kyphosis-specific exercise class, kyphosis-specific exercise video and a log book (sample page is shown in Appendix 6). Before every exercise class, the researcher will send them time and location as reminders. Class attendance is recorded every time. The participants are asked to record the time of home kyphosis-specific exercise practice and other daily exercises. They can also write down questions about kyphosis-specific exercise in the log book. The investigator will check the log book and respond to the questions once a week. The Control group will receive a booklet introducing general health education material, and a log book recording the time of daily exercises (sample page is shown in Appendix 7).

After the end of 6 weeks intervention, all participants will be invited to finish the postintervention assessment (T1). The flowchart of the proposed RCT is presented in Figure 1.

Figure 1 The flowchart of proposed RCT



10. Methods of statistical analysis

The data will be analyzed according to intention to treat. Descriptive statistics will be used to explore the characteristics of the elderly.

The primary outcome is the change in the angle of kyphosis. The secondary outcomes are the score change of pain and self-image, the change in score of the Farsi version of Functional Gait Assessment, change in time of the Timed Up and Go Test and the One Leg Standing Test, change in walking distance of the Six Minutes Walking Test, and change in length of the Chest Expansion test.

T-test and Chi-square test will be used to determine any baseline differences among two intervention groups and one control group in terms of baseline socio-demographics, regular exercise type and intensity, illness condition, and the angle of kyphosis.

Linear mixed effect model will be conducted to explore the between-group and within-group differences in the outcomes across the time, while controlling socio-demographics, illness condition, BMI, type and intensity of regular exercise. SPSS version 23.0 was used to analyze data collected, the significance level will be 0.05.

11. Describe any unusual or discomforting procedures to be used

Exposing the upper body in spine measurement may be embarrassing for some participants. In order to protect their privacy, the participant will be invited to a private room with air-conditioned, one at a time. The principal investigator and well-trained researcher helpers will perform the measurement. And the participants can stop measuring whenever they want to. For the measurement of physical fitness, participants may be tired. They can take a rest whenever they need.

In kyphosis-specific exercise class, the instructor participants ratio will be no less than 1:5 to endure the participants' safety. During exercise class, the participants can rest whenever they think is necessary. The first aid equipment will

be prepared. In the video exercise group orientation, the investigator will give exercise safety instruction.

Most of the exercises including in the kyphosis-specific exercise video are taking supine or prone posture, in order to prevent fall during exercise. In every follow up kyphosis-specific exercise classes, the certified physical trainer will reinforce safety instructions and exercise skills. The participants will be encouraged to contact the investigator whenever they have questions. No serious adverse event was reported by the previous studies letting older adults following exercise video doing home exercise.

12. Are there any hazards associated with the investigation?

No known potential hazards will be introduced to participants.

13. Direct access to source data/documents

The principal investigator is responsible for processing and storing the raw data during and after the completion of the study. Three copies of the raw data will be stored as encrypted files on the principal investigator's computer, external hard drive, and reliable networked cloud.

14. Consent

In order to respect the principles of human dignity, when approaching the participants, the researcher will explain the purpose and steps of the study based on the information sheet (Appendix 3). The researcher will also emphasize that joining the study will be entirely voluntary and every participant has the right to withdraw or refuse to give information at any time during the study without incurring any penalties. Eligible participants will sign a consent form (Appendix 5).

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