STUDY PROTOCOL

Social Behavioral Template

Application Evaluation of Baduanjin with Resistance Training Program for Elderly Patients with Osteoporosis and Lumbar Disc Herniation

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Confidentiality Statement: Participant confidentiality and privacy are strictly held in confidence by the participating investigators, their staff, and sponsors. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence, except where required by U.S. law (e.g., knowledge of abuse of a child or elderly person). The study will not obtain a certificate of confidentiality since none of the collected data will be sensitive enough to warrant one.

Synopsis

Purpose

Osteoporosis (OP) is a systemic degenerative bone disease characterized by bone mass reduction, bone density loss, bone microarchitecture destruction, bone fragility, and increases facture susceptibility. OP is particularly prevalent among elderly women. Patients with OP are also prone to developing complications such as lumbar disc herniation (LDH), as OP can alter vertebral morphology and affect the spinal curvature and mechanical properties of the spine. Many patients do not experience noticeable symptoms until a fracture occurs. Numerous studies have shown that aerobic and resistance exercise can improve symptom of LDH and OP. The Baduanjin (BDJ) exercise is a widely accepted aerobic exercise among the elderly in China. Resistance training can also strengthen elderly muscle ability. However, BDJ exercise combing with resistance elastic bands for elderly patients with LDH and OP have the potential to improve physical function and quality of life in people with LDH and OP, but its efficacy has not been evaluated in China. Evaluating the effect of BDJ with resistance training on the physical status of elderly patients with LDH and OP, are urgently needed to achieve better quality of life. Therefore, **the purpose of this study** is to assess implementation outcomes (feasibility, acceptability) and the effect of BDJ with resistance training for elderly patients with LDH and OP in China. We will examine the following associated factors and outcomes, including demographic characteristics, the quality of life, physical activity, self-efficacy of exercise, exercise benefits and barriers and complications after surgery. This study will also provide new insights on aerobic exercise for elderly patients with LDH and OP to achieve health and healthcare equity for elderly patients.

Objectives

AIM 1: To assess implementation outcomes such as feasibility, acceptability of BDJ with resistance training for elderly patients with LDH and OP in China.

AIM 2: To conduct a randomized control trial (RCT) with 2 parallel groups (BDJ treatment and conventional treatment) and assess its effect of BDJ with resistance training on the following outcomes among elderly patients with LDH and OP: the quality of life, physical activity, self-efficacy of exercise, exercise benefits and barriers and complications after surgery.
Study Population Patients with LDH and OP who will be treated and undergo surgery will be recruited as potential participants from two spinal wards at the Second Xiangya Hospital of Central South University (Class A hospital) in Changsha city, Hunan province.
Number of Participants A total of 110 participants with LDH and OP will be enrolled in this study and randomly assigned to either control or experimental group (n=55 each group).
Study Design This is a RCT to achieve the specific aims in this study. First, we will recruit patients with LDH and OP from the outpatients at the Second Xiangya hospitals. Eligibility will be assessed based on inclusion and exclusion criteria to identify potential participants. We will send emails to potential participants to invite them to contact us if they are interested in the study. Researchers will conduct the screening participates by phone, explaining the study procedures and methods. On the first day of admission in the hospital, participants will sign informed consent and complete a baseline survey. Second, researchers will use a computer-generated random number sequence to randomly assign participants to one of two group based on admission date: control group and experimental group. A total of 55 participants will be assigned randomly to the control group receiving conventional treatment. Patients in the control group will continue with their original treatment, medication, and diet habits. Post-spinal surgery, two nurses trained by this study protocol will teach participants

standard guidance for lumbar and back exercises, which includes exercise suggestions and health education.

Another 55 participants will be assigned to the experimental group participating in BDJ with resistance training. Both control and experimental groups will be treated by the same medical and nursing team. We will implement a BDJ exercise combined with resistance training in the experimental group. Two nurses will provide training to ensure that participants can perform the movements skillfully and coherently.

For the experimental group, (1) Individual sessions: for one day before surgery and one day before discharge, participants will receive two individual sessions for 30 minutes-session, where they can learn proper exercise techniques and safety. (2) Post-surgery Period (Week 1): Participants will pause the BDJ with resistance training to receive standard rehabilitation and nursing care in the hospital on first 5 days of Week 1 post-surgery. If participants meet the discharge criteria on day 6-7 of Week 1 Post-Surgery, they will be arranged for discharge. (3) Week 2 Post-Surgery: During the second week after surgery, participants will be monitored and manage any potential complications. No formal BDJ with resistance training session will be conducted during this week. (4) Group Session Ⅰ (Weeks 3–4 Post-Surgery): Participants will continue the online Group Session Ⅰ (WeChat) for 30 minutes-session, three times a week, a total of 2 weeks. Each group will include 10 participants. (5) Group Session Ⅱ (Weeks 5–12 Post-Surgery): Participants will continue online Group Session Ⅱ (WeChat) for 30 minutes-session, once a month, a total of 8 weeks. These sessions will be designed to provide ongoing support, adjustments to exercise regimens and feedback. (6) Independent Exercise (Week 13-24 Post-Surgery): Participants will be required to perform the exercise independently at home. They will be encouraged to follow the exercise plan and maintain a daily training diary to record their activities for 12 weeks.

We will conduct outcome assessment and data collection through face-to-face consultations at baseline and Week 1, followed by phone calls at Week 12 and

Week 24. We will use Demographic Scale, Oswestry disability index (ODI), Five Times Sit-to-Stand Test (FTSS), International Physical Activity Questionnaire (IPAQ), the Self-Efficacy for Exercise Scale (SEE), and Exercise Benefits and Barriers Scale (EBBS) to explore the demographic characteristics, the quality of life, muscle strength, physical activity level, exercise self-efficacy and exercise benefits and barriers of elderly patients with LDH and OP.

Study Duration

The duration of the study for each participant will be 6 months. The study will be conducted for 2 years.

Outcome Variables

(1) Implementation Outcome Variables

All the implementation outcomes will be assessed at week 24.

Acceptability: Acceptability is measured by the Acceptability of Intervention Measure (AIM), a standardized tool used to evaluate how acceptable an intervention. The AIM consists of 12 items that cover different dimensions of acceptability using 5-Likert scale (from “Completely Disagree” to “Completely Agree”).

Feasibility: Feasibility is measured including: (1) recruitment, (2) enrollment rate (refusal rate), (3) adherence to the study protocol (attendance at the session) and participants will be instructed to record an exercise diary. The adherence rate will be calculated using the formula: adherence rate (%) = (Number of completed entries / Total number of exercise entries) ×100, and (4) retention (and attrition reasons).

(2) Effectiveness Outcome Variable

Primary outcome: Quality of life measured by Oswestry disability index (ODI), muscle strength by Five Times Sit-to-Stand Test (FTSS) and physical activity level by the International Physical Activity Questionnaire (IPAQ).

Secondary outcomes: Exercise self-efficacy by the Self-Efficacy for Exercise Scale (SEE), exercise benefit by the Exercise Benefits and Barriers Scale (EBBS) and complication after surgery.

Locations/Facilities

This study will be conducted in two spinal wards in a Class A hospital in Hunan (the Second Xiangya Hospitals of Central South University in Changsha city, Hunan province, China).

Abbreviations

Abbreviation	Explanation
LDH	Lumber disc herniation
OP	Osteoporosis
BDJ	Baduanjin
IPAQ	International Physical Activity Questionnaire
EBBS	Exercise Benefits and Barriers Scale
SEE	The Self-Efficacy for Exercise Scale
ODI	Oswestry Disability Index
FTSST	Five Times Sit-to-Stand Test
RCT	Randomized Control Trial
AIM	Acceptability of Intervention Measure
NSAIDs	Nonsteroidal Anti-Inflammatory Drugs
VAS	Visual analogue scale
BMD	Bone mass density
BMI	Body mass index
RNs	Registered nurses
CONSORT	Consolidated Standards of Reporting Trials

IPAQ-LC	International Physical Activity Questionnaire-Chinese version
AE	Adverse event
IRB	Institutional Review Board
PI	Principal Investigator
HIPAA	Health Insurance Portability and Accountability Act
DSMB	Data and Safety Monitoring Board
UPIRSOs	Unanticipated Problems Involving Risks to Subjects or Others
RNI	Report of New Information
UP	Unanticipated problems

Glossary of Terms

Glossary	**Explanation**

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Protocol Revision History

Version Date	Summary of Substantial Changes

1 Background

1.1 Background

Osteoporosis (OP) is a common clinical bone disease characterized by systemic damage and structural destruction of bone tissue, resulting in an increased fragility of bone[1]. There were some risk factors for OP, such as gender, age, weight, smoking, alcohol consumption, physical inactivity, and dietary calcium deficiency[2]. With the growing aging population in the world, the prevalence of OP is increasing, and OP is a global public health problem[3,4]. The global prevalence of OP in the elderly population is as high as 21.7%, with prevalence in Asia, America, and Europe at 24.3%, 11.5%, and 17.7%, respectively, with the highest in Asia[5]. Besides, chronic use of glucocorticoids, lifestyle condition, habits and major depression are also other contributing factors of OP. In addition, women are at a higher risk of OP, especially after menopause when bone loss accelerates due to a lack of estrogen[6]. Women between the aged of 18-49 who smoke, have fair skin, or have a family history of OP are at higher risk than others[7,8]. According to a recent multicenter survey, China, one of the most populous countries in the world, has an age-standardized prevalence of OP at 6.46% for men and 29.13% for women aged 50 years and older, respectively[9]. Thus, the prevalence of OP in China is notably high, making it a serious chronic disease that affects millions of individuals, especially elderly women.

OP is an important risk factor for fractures[10]. Approximately 2.33 million osteoporotic fractures occurred in 2010 in China, estimating this number could be double by 2035[11]. Financial pressure of treating fractures due to OP places a huge burden on our healthcare systems[12]. According to the Chinese Health Yearbook in 2022 reports, total health expenditure in China had risen from $1129.5 billion in 2014 to $2120.5 billion in 2021[13]. The annual costs of osteoporotic hip fractures in China were estimated at approximately $2.05 billion in 2006, rising to $27.48 billion by 2020 and $581.97 billion by 2050, largely due to the increasing aging of China's population, respectively[14]. Therefore, the growing aging population and high incidence of osteoporosis fractures in China are significant public health problems that require more public attention and urgent intervention.

In addition, patients with OP are more likely to suffer from lumbar disc herniation (LDH)[15]. The lumbar disc is the most important load-bearing structure in the human body, and any structural changes can adversely affect the mechanical properties of the spine, accelerate spinal degeneration[16]. Studies have shown that patients with OP may experience prolonged symptoms and more severe implications of LDH. As bone mineral density decreases, the structural integrity of the spine is compromised, leading to increased vulnerability to injury and prolonged recovery times[17]. As OP progresses, changes in bone microstructure are most pronounced in the spine, particularly in the lumbar vertebrae. These changes can lead to alterations in vertebral body morphology and spinal mechanical properties. These pathological changes often cause severe low back pain[18]. Spinal surgery is an effective treatment to relieve low back pain and stable the lumbar spine. However, the presence of OP can complicate treatment strategies, as clinicians must consider patients' bone status when planning interventions such as surgery or physical therapy[19]. Patients with LDH and OP not only causes changes in vertebral shape, but also have an increased risk of vertebral fractures in adjacent vertebrae, resulting in a higher prevalence of complications, even leading to failure of spinal surgery[20]. Therefore, it is very important to focus on increasing awareness of prevention and improving the quality of life for patients with LDH and OP. This involves developing strategies to decrease the risk of vertebral fractures of due to LDH and OP and exploring effective management programs for elderly patients with OP and LDH.

1.2 Current Practice

Currently, clinical treatment of patients with LDH and OP mainly use bone resorption inhibitor drugs (e.g., Alendronate, Denosumab and Calcitonin) and bone formation promoter drugs (e.g., Vitamin D, Calcium and Teriparatide), but there are some inevitable adverse reactions, including nausea, abdominal pain, esophageal irritation, hypercalcemia, pain, swelling or redness at the injection site, and potential for osteosarcoma[21]. In addition, analgesics such as acetaminophen or nonsteroidal anti-inflammatory drugs (NSAIDs) are used to relieve the low back pain, but the effectiveness of these medications can vary from individuals which may pose risks, including gastrointestinal problems (ulcers, bleeding or gastritis), impairing kidney

function, increasing risk of cardiovascular event[22]. Although pharmacological strategies for OP have been shown to be highly effective, only a small part of patients can adhere to receive pharmacological treatments because of the cost and side effects[23]. Many patients have a difficulty to follow prescribed medication regimens consistently, which can impact the effectiveness of treatment and prevention. In China, in the medicine treatment of patients with OP, only 28.7% of women and 11.9% of men received anti-osteoporotic drugs[24]. In addition, only 50% patients of vertebral fracture were still under any medication after 1 year and one third of them persisted to the treatment for 2 year or more. The reasons for poor compliance include ignorance of the disease, reluctance to take medicine, intolerance or side effects of medication and too many medicines for comorbidities[25]. Thus, poor medication adherence for patients with LDH and OP can lead to worsen the risk of secondary fracture.

Moreover, most of LDH and OP patients who have surgical indications benefited from discectomies (surgical removal of the herniated disc pressing on a spinal root) to relieve the low back pain[26]. However, OP can lead to the deterioration of biomechanical characteristics in the adjacent segment disc after surgery, this variation can also result in an increase in the incidence of adjacent segment disease[27]. Some researchers have reported that elderly patients have a worse postoperative outcome after LDH surgery than younger and middle-aged patients[28]. Furthermore, in spinal surgery, patients with LDH and OP may experience several complications, including adjacent segment fractures, screw loosening, and proximal junctional kyphosis[29]. Thus, considering for the limited uptake of current treatments and potential side effects, it is critical to explore an alternative therapy for patients with LDH and OP, to minimize risks associated with pharmacological and surgical treatments and improve patients' physical function and the quality of life.

Exercise plays an important role in the management of OP and LDH, which can benefit to enhance bone mass and reduce the risk of fracture[20]. Exercise is recommended as a non-pharmacological and complementary treatment for OP by WHO guidelines on physical activity and sedentary behavior[30]. It is a crucial and effective management strategy that enhance physical function and mental health in the elderly while significantly improving bone health[31]. The Chinese guideline for the

treatment of OP pointed out that exercise could improve body agility, strength, posture, and balance and effectively reduce the risk of falls and fracture[32]. Chinese traditional exercises such as Qigong, Taiji and Martial arts are aerobic exercise, derived from several theories, which pay attention to the unity of mind, breath regulation of guiding techniques[33]. Chinese traditional exercise is a synthesis of various exercise forms that have gradually evolved and been passed through generation, in which these exercises hold significant roles for prevention and treatment of diseases.

Baduanjin (BDJ), a branch of traditional Qigong exercises that is divided into eight movements on specific body parts and meridians and is a low-to-medium intensity aerobic exercise. It is gaining popularity in China for its health benefits[34]. BDJ exercise has been known as an effective form of Chinese traditional exercise that emphasizes health and well-being [35]. There is abundant evidence that BDJ exercise can improve overall health by enhancing cognitive function, regulating blood lipids and blood pressure and mitigating various health risks [36,37]. It is particularly suitable for the elderly, as it is a safe and easy aerobic exercise that strengthens lower limb muscles, improve balance and helps prevent falls and fractures [38]. Additionally, many studies have demonstrated that BDJ exercise can effectively relieve pain associated with various spinal diseases[39]. Although exercise is known to improve overall physical activity and quality of life in older adults, but there is still limited empirical evidence and few research exploring the effect of BDJ exercise as a form of non-pharmacological intervention for elderly patients with LDH and OP.

In addition, clinical guidelines suggest a combination of aerobic exercise resistance training, and balance, as a critical non-drug treatments for OP[40]. Resistant and weight-bearing exercise can increase muscle mass and temporarily increase bone mineral density (BMD)[41]. For example, resistance training with elastic bands is mainly used to improve muscle mass, gait, walking ability in the elderly. A study has shown that progressive resistance training with elastic band in twelve weeks can effectively improve women's physical fitness and bone density, and significantly increase muscle mass and life quality[42]. Also, resistance training with elastic bands significantly increased muscle mass compared to nutrition supply, especially for patients with chronic diseases[43]. Many studies have suggested that single treatment may be

limited in treating diseases or addressing symptoms and recommended combination therapy[44]. Therefore, in this study, we will conduct a RCT to evaluate implementation outcomes and the preliminary efficacy of BDJ combined with resistance training in patients with LDH and OP, which provides a reference for clinical practice and scientific research.

2 Rationale/Significance

2.1 Rationale and Study Significance

(1) Dilemmas in treatment of LDH and OP. OP is a chronic condition that requires long term management plan, but poor patient compliance makes OP management much more challenging. Research indicates that only a small part of patients can adhere to the drugs therapy due to the high cost of anti-osteoporosis drugs and long duration of therapy[45]. In China, nearly 30% of patients with vertebral fractures have never received basic calcium and/or vitamin D supplementation, and only 28% of patients have been prescribed pharmacological treatment for OP[25]. This indicates that current medication treatments for OP are still insufficient. Compared to treatments in developed countries, the awareness of anti-osteoporotic medication in China is low, and patient compliance is weak. Additionally, pharmacological therapy for OP also has various adverse effects that often lead to non-compliance. Many elderly patients may have nausea, abdominal pain, esophageal irritation, hypercalcemia, pain or other adverse effects[21]. Furthermore, patients with LDH and OP may experience more complications after surgery compared to younger and middle-aged individuals. Osteoporosis can lead to poor bone quality, increasing the likelihood of complications such as inadequate healing, implant failure, and adjacent segment disease. Consequently, surgical interventions may not yield the expected outcomes, leaving patients with persistent pain and disability. Nowadays, it is a significant challenge for patients with LDH and OP to endure the long duration of drugs therapy and higher complications after surgery.

Exercise as an alternative therapy can often address physical problem while also decreasing the side effects of drug treatment, especially in older populations[46]. Therefore, it is necessary to find a potential alternative therapy or non-drug treatment with fewer side effects and more flexibility, which is very significant and valuable.

(2) Addressing gaps in research. China is one of the largest aging population in the world, the age-standardized prevalence of OP in China is 6.46% for men and 29.13% for women aged 50 years and older[9]. The incidence of OP in LDH patients was up to 14.3%, with an increasing trend[47]. Research has identified overlapping risk factors for both LDH and OP, indicating that OP can change spinal structure, leading to intervertebral disc degeneration and an increased risk of LDH[48]. Some research focuses on examining the effect of BDJ exercise for diabetes[49], cardiac function[50] and cognitive function[37] for the elderly patients. However, there is limited data on the effects of BDJ combined with resistance training for patients with LDH and OP. Thus, it is essential to examine the impact of resistant BDJ exercise for elderly patients with LDH and OP to enhance physical function and improve quality of life.

(3) Chinese traditional exercises. Chinese traditional exercises originated more than 1000 years ago. Chinese traditional exercises are widely accepted by clinicians, patients, and family members. Some exercises have various forms that are safe and easy to learn, attract strong interest and have less side effects[38]. BDJ exercise involves eight distinct postures, and each one has beneficial effects on different parts of the body or particular organs[51]. BDJ exercise is a health-promoting exercise recommended by the Chinese Health Qigong Association[52]. Therefore, it is important to examine the effect BDJ combined with resistance training using elastic bands. This exercise represents a fusion between traditional Chinese exercise and modern treatments for spinal diseases. It is critical to explore the potential connection between BDJ exercise and bone health, as it combines cultural heritage with contemporary health needs.

Study Significance

The study has several innovative aspects and strengths:

(1) Addressing a growing aging health concern: By investigating the physical status and the efficacy of BDJ with resistance training, this study aims to provide an effective and non-pharmacological intervention which can address current aging health problems.

(2) Integration of Chinese tradition exercise and modern training: By combining the BDJ exercise with resistance training of elastic bands, this study aims to maximize the benefits of both exercises and demonstrate their relevance in disease prevention. This combination therapy is a strong symbol of the fusion between cultural heritage and contemporary health needs.

(3) Promoting bone health and physical activity of elderly patients: Comparing changes in physical activity, quality of life and exercise benefit and barrier before and after the intervention, this study aims to demonstrate that BDJ with resistance training can supplement the limitations of pharmacological therapy for LDH and OP, therefore improving bone health and quality of life for elderly patients.

2.2 Risks

The potential risk for this study is minimal. Data collection at the baseline visit (30 minutes) and at each subsequent time point (30 minutes) will involve minimal inconvenience.

(1) All participants will be clearly informed about study procedures. All participants will be clearly informed about the study procedures. They will be instructed to contact their healthcare providers for any health concerns. It is not anticipated that any of the survey instruments or collection of actigraphy data will cause any adverse effects.

(2) Participation in this trial is entirely voluntary. Participants have the right to refuse to participate or to withdraw from the trial at any time, without facing any discrimination or retaliation. This decision will not affect their medical treatment or other rights. A participant will be withdrawn if for any reason it would be clinically indicated for the bad for the participant as determined by either the primary doctors or the study team. In the unlikely event of persistent uncontrolled severe chronic illness such as ulcerative colitis, gastrointestinal bleeding, pancreatitis, lung cancer, pneumonia, acute respiratory distress syndrome or psychosis, depression, anxiety or

substance abuse, identified by diagnosis and interview, we will consult with the participant's primary doctors to determine appropriate action such as altering or stopping intervention process. Once a participant withdraws from the trial, no further data will be collected, thereby respecting their decision to exit the study.

(3) Confidentiality. We will ensure and clearly explain to participants that we will make every effort to maintain confidentiality and will not inadvertently reveal any information. We will not only restrict the number of project personnel who have access to identifying information but also ensure adequate training of project personnel in confidentiality protection.

2.3 Anticipated Benefits

(1) Potential benefit of this study to research participants. The risk/benefit ratio is judged to be favorable. Participants will have several benefits, including regular assessments of physical activity function and quality of life, acquiring resistance BDJ exercise skills. Additionally, self-management skills for LDH and OP, including lifestyle, nutrition supplement, sleeping and exercise therapy, may improve through the intervention. Researchers will benefit from the study findings, acquiring valuable results to inform future prevention for LDH and OP. Researchers will also have opportunity to implement Chinese traditional exercise for the elderly to improve physical function. In sum, the low risk of this study appears to be far outweighed by the greater, more-compelling potential benefits.

(2) Importance of Knowledge to be gained. This study aims to enhance awareness of the prevention and treatment of OP and LDH. Specifically, it will evaluate the effect of BDJ with resistance training on elderly patients with LDH and OP, focusing on physical activity function, quality of life, muscle strength and the self-efficacy of exercise. Importantly, the findings from this study will contribute to providing sustainable implementation strategies for clinical researchers and evidence of how Chinese traditional exercise therapy influences intervention implementation and which approaches can solve dilemmas in the prevention and treatment of LDH and OP.

3 Study Purpose and Objectives

3.1 Purpose

The purpose of this study is to conduct a RCT and evaluate implementation outcomes (acceptability and feasibility) and the effects of BDJ with resistance training program on elderly patients with LDH and OP (physical activity, quality of life, muscle strength). Our long-term goal is to raise awareness of exercise benefits within population through educational workshops, interactive sessions and educational brochures, and ultimately enhancing physical activity and rehabilitation care.

3.2 Hypothesis

By conducting a BDJ with resistance training program among patients with LDH and OP, we hypothesize that:

(1) Enhanced muscle strength: Participants in the experimental group will experience a significant increase in muscle strength, particularly in the lower body and back muscles, compared to a control group.

(2) Improved physical function: Participants in the experimental group will enhance physical function, including flexibility and stability, compared to a control group.

(3) Increased the quality of life: Participants in the experimental group will improve the quality of life compared to a control group.

(4) Decreased complication rates after surgery: Participants in the experimental group will have a lower incidence of complications related to both OP and LDH during the rehabilitation process compared to a control group.

3.3 Objectives

We have specific aims of this study as follows:

AIM 1: To assess implementation outcomes such as feasibility, acceptability and benefit and barriers to the BDJ with resistance training program for elderly patients with LDH and OP in China.

AIM 2: To conduct a RCT with 2 parallel groups (BDJ with resistance training and conventional treatment) and assess the effect of BDJ with resistance training on the following outcomes among elderly patients with LDH and OP: the quality of life, muscle strength, physical activity level, exercise self-efficacy and exercise benefits and barriers and complications after surgery.

4 Study Design

This is a 2-parallel-group RCT trial. A total of 110 participants will be randomly assigned to the experimental and control group (1:1), with 55 participants in each group by using a random number generator based on admission time. Both groups will receive care from the same medical and nursing teams to minimize variability in treatment.

Randomization will be performed using a random number generator based on the order of participant enrollment (admission date). As participants are enrolled, their admission date will be recorded, and they will be randomly assigned to group with separated rooms. The randomization process ensures that participants are assigned to the experimental and control groups without bias, avoiding interaction and the risk of treatment contamination of the study. Baseline characteristics of participants in both groups will be assessed to confirm the comparability of the groups and to ensure that the baseline characteristics of participants have no statistical significance between the two groups (as shown in Figure 1).

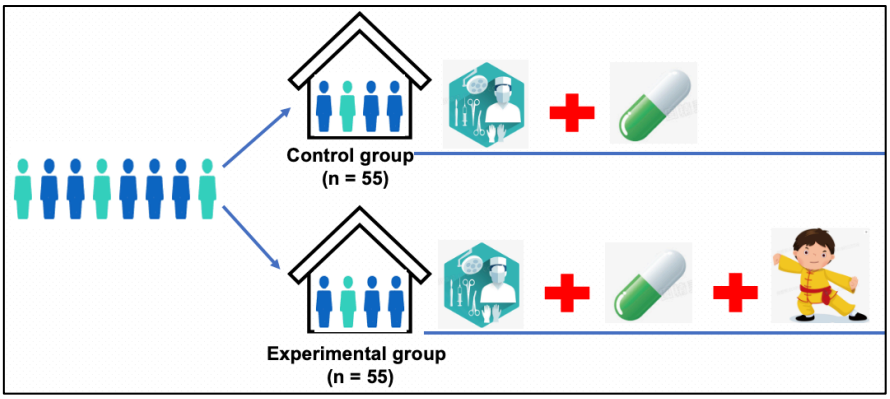


Figure 1 Randomization and intervention

The control group (n=55) will receive conventional treatment, which consists of usual medical care and nursing support. This includes comprehensive post-operative care, educational handouts including guidelines for lumbar and back exercises, and three interactive Q&A sessions over a 24-week period following surgery.

Another 55 participants will be assigned to the experimental group in BDJ with resistance training. Participants in the experimental group will receive intervention of BDJ with resistance training, in addition to the conventional treatment.

For the experimental group, we will implement a BDJ with resistance training in addition to the conventional treatment for elderly patients with LDH and OP. Participants will receive the same conventional treatment as the control group. The BDJ with resistance training will include as follows:

(1) **Individual Session (Pre-surgery and Pre-discharge):**

Timing: One day before surgery and one day before discharge.

Content: Participants will attend two individual sessions (one day before surgery and one day before discharge) for 30 minutes each. Each session will focus on teaching participants about proper exercise techniques and key training points.

Instructors: Two registered nurses (RNs) will serve as the primary instructors, guiding participants to do the necessary exercises and safety precautions.

Aim: The goal of individual sessions is to prepare participants for the rehabilitation by ensuring they understand the exercises and are familiar with exercise movements.

(2) Post-surgery Period (Week 1)

First 5 days of Week 1 Post-Surgery: Participants will pause the BDJ with resistance training to receive standard rehabilitation and nursing care in the hospital.

Day 6 and Day 7 of Week 1 Post-Surgery: These days will allow participants additional rest and gradual exercises under supervision, focusing on the rehabilitation and monitoring of any complications. If participants meet the discharge criteria, they will be arranged for discharge. An individual session will be conducted one day before discharge.

(3) Week 2 Post-Surgery

During the second week after surgery, participants will be monitored and manage any potential complications. No formal BDJ with resistance training session will be conducted during this week to allow for recovery.

(4) Group Session I (Weeks 3–4 Post-Surgery)

Timing: Week 3-4 after surgery.

Content: Participants will continue the online Group Session Ⅰ(WeChat) for 30 minutes-session, three times a week, a total of 2 weeks. Each group will include 10 participants.

Instructors: Two RNs will lead the group session online through video demonstrations and offer real-time instruction.

Aim: The aim is to introduce participants to group-based exercises, build confidence in their ability to exercise at home, and offer continuous support as they recover.

(5) Group Session Ⅱ (Weeks 5–12 Post-Surgery)

Timing: Week 5-12 after surgery.

Content: Participants will continue online Group Session Ⅱ(WeChat) for 30 minutes-session, once a month, a total of 8 weeks. These sessions will be designed to provide ongoing support, adjustments to exercise regimens and feedback. In addition to watch exercise video, participants will receive pre-recorded exercise videos and electronic materials. These resources will be available to participants to support home-based exercises.

Instructors: Two RNs will lead the group session online through video demonstrations and offer real-time instruction.

Aim: To ensure that participants continue their BDJ with resistance training, while providing them with elastic bands and knowledge to maintain their exercises independently.

(5) Independent Exercise (Week 13-24 Post-Surgery)

Participants will be required to perform the exercise independently at home. They will be encouraged to follow the exercise plan and maintain a daily training diary to record their activities. Nurses will provide twice a month follow-up to monitor the participants' exercise progress. Participants will follow this independent exercise plan for a total of 12 weeks.

We will conduct outcome assessment and data collection through face-to-face consultations at baseline and Week 1, followed by phone calls at Week 12 and Week 24. We will use Demographic Scale, Oswestry disability index (ODI), Five Times Sit-to-Stand Test (FTSS), International Physical Activity Questionnaire (IPAQ), the Self-Efficacy for Exercise Scale (SEE), and Exercise Benefits and Barriers Scale (EBBS) to explore the demographic characteristics, the quality of life, muscle strength, physical activity level, exercise self-efficacy and exercise benefits and barriers of elderly patients with LDH and OP (shown in Figure 2). We will follow the Consolidated Standards of Reporting Trials (CONSORT) guidelines.

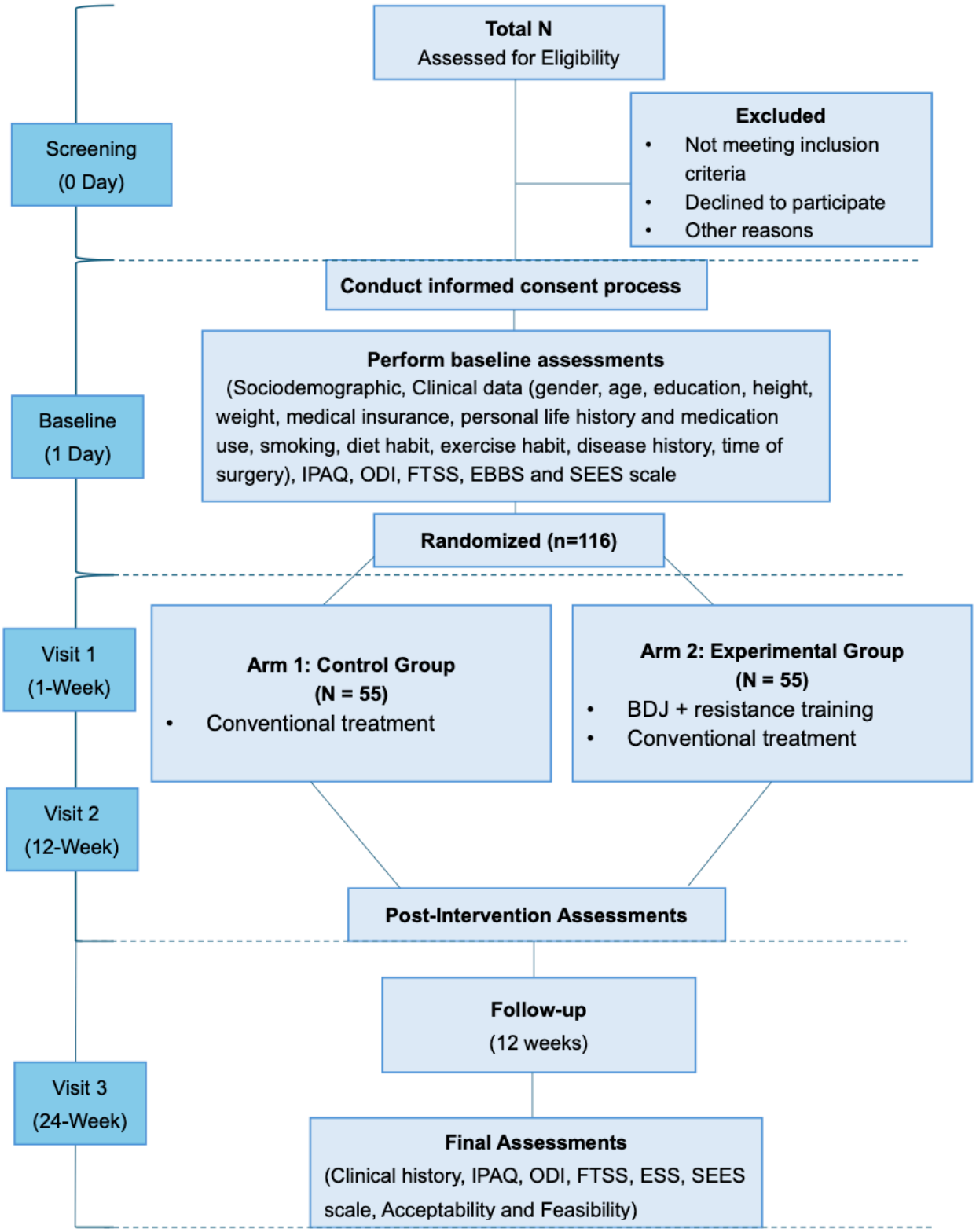


Figure 2 Flow diagram of this study by a 2-group parallel RCT

4.1 Study Duration

The duration of the study for each participant will be 6 months. The study will be conducted for 2 years.

4.2 Outcome Variables/Endpoints

Outcome variables include sociodemographic information, clinical characteristics, complications, the following primary and secondary outcomes (See Table 1). All questionnaires used to assess physical activity status are validated, widely utilized, and have available Chinese versions.

Table 1 Measures and the Frequency of Data Collection

Outcome variables (Reliability)	Data Collection			
	0 w	1w	12w	24w
Sociodemographic (Gender, Age, Education, Height, Weight, Medical insurance, Personal life history) and medical history	√			
Clinical data (smoking, diet habit, exercise habit, disease history, time of surgery)	√			√
Physical activity: International Physical Activity Questionnaire (7-item) (a=0.88) **(Primary Outcome)**	√	√	√	√
Quality of Life: Oswestry Disability Index (ODI) (10-item) (a=0.78) **(Primary Outcome)**	√	√	√	√
Muscle Strengths: Five Times Sit-to-Stand Test (FTSS) **(Primary Outcome)**	√	√	√	√
Exercise benefit and barriers: Exercise Benefits and Barriers Scale(43-item) (a=0.88) **(Secondary Outcome)**	√	√	√	√
Exercise self -efficacy: The Self-Efficacy for Exercise Scale(10-item) (a=0.93) **(Secondary Outcome)**	√	√	√	√
Complication of surgery **(Secondary Outcome)**		√		
Acceptability				√
Feasibility (refusal rate, adherence and retention)				√

4.2.1 Baseline and clinical characteristics

We will collect sociodemographic information and clinical data, including gender, age, education, height, weight, medical insurance, and medication use. Weight will be measured with participants in light clothing and without shoes, using a calibrated scale. Height will be measured with a stadiometer, ensuring the participant stands upright

with heels together and eyes facing forward. Body mass index (BMI) will be calculated by an individual's weight in kilograms by the square of height in meters[53].

4.2.2 Implementation outcome variables

All the implementation outcome (acceptability, feasibility) at week 24.

Acceptability: Acceptability is measured by the Acceptability of Intervention Measure (AIM), a standardized tool used to evaluate how acceptable an intervention. The AIM consists of 12 items that cover different dimensions of acceptability using 5-Likert scale (from "Completely Disagree" to "Completely Agree")[54]. We will collect the acceptability data from participants and interventionists conducted by registered nurses (RNs), ensuring a comprehensive understanding of acceptability across different perspective.

Feasibility: Feasibility is measured including: (1) recruitment/ enrollment (refusal rate), (2) attendance rate at the sessions, (3) adherence to the study protocol which participants will be instructed to record exercise diary for 24 weeks and (4) retention rate (and attrition reasons).

4.2.3 Primary Outcome Variables/Endpoints

Primary outcomes are physical activity level, quality of life and muscle strength, which will be measured by the following questionnaires at week 0, 1, 12, 24.

(1) Physical Activity level: will be measured by the International Physical Activity Questionnaire-Chinese version (IPAQ-LC). The IPAQ-LC is a widely used tool for assessing physical activity levels in various populations. This scale requires the participants to complete 31 questions in four activity domains (transportation, work, household and leisure time), and includes sections on walking, moderate, vigorous and sedentary behaviors (sitting and lying awake)[55]. The exercises recorded must last at least 10 minutes each time. The Cronbach's alpha of this scale was 0.88[56].

(2) Quality of Life: will be measured by the Oswestry Disability Index (ODI). The ODI is the most widely accepted scales for assessing quality of life and the severity of disability caused by back pain. It assesses the impact of back pain on various daily activities and provides valuable insights into patients' functional status and quality of life. The ODI is a questionnaire containing 10 items covering disability caused by low

back pain, consisting of pain intensity, self-care, lifting, walking, sitting, standing, sleeping, sex life, social life and traveling. Each item is assessed on a six-level ordinal scale with “0” describing “no limitation” and “5” describing “extreme limitation or an inability to function”, with higher values representing a greater extent of disability. The Cronbach’s alpha of this scale was 0.89[57].

(3) Muscle strength: will be measured by the Five Times Sit-to-Stand Test (FTSST)**.** FTSST is used to assess one’s muscle strength. The researchers need to record the total time spent. At last, the test will be performed three times, and the final average is taken. Each patient was given 2 minutes intervals for rest. The Cronbach alpha 0.99, and the reliability was 0.97[58].

4.2.4 Secondary Outcome Variables/Endpoints

Secondary outcomes are exercise self-efficacy and exercise benefits and barriers which will be measured at week 0, 1, 12 and 24, and complication after surgery at week 1.

Exercise self-efficacy: will be measured by the Self-Efficacy for Exercise Scale (SEE). This scale is designed to test people’s confidence to continue exercising in the face of barriers to exercise. It consists of 9 items, with scores ranging from 0 to 10 representing the confidence level of the participants. A score of 0 indicates “no confidence”, while a score of 10 indicates “very confident”. Higher scores reflect a greater level of exercise self-efficacy. The Cronbach alpha for this scale is 0.93[59].

Exercise benefits and barriers: will be measured by the Exercise Benefits and Barriers Scale (EBBS)**.** This scale assesses the perceived benefits and barriers to exercise among patients. The EBBS consists of 43 items that evaluate the perceived benefits of exercise and factors that hinder participation. It includes two dimensions: exercise benefits and exercise barriers. A 4-point Likert scale is used (1 = “strongly disagree”, 4 = “strongly agree”). The total score ranges from 43 to 172, with higher scores indicating more positive perceptions of exercise benefits and fewer perceived barriers. The Cronbach alphas for the overall scale and the two subscales are 0.86, 0.95, and 0.86, respectively[60].

Complication after surgery: will be recorded by RNs. This includes lung infections, inadequate healing, implant failure, and adjacent segment pain. The data will be collected by clinical chart reviews and patient interviews. The incidence of complication after surgery will be calculated by the number of new complications / total number of participants in each group.

5 Study Participants

5.1 Study Population

Patients with LDH and OP who will be treated and undergo surgery will be recruited from two spinal wards at the Second Xiangya Hospital of Central South University (Class A hospital) in Changsha city, Hunan province, China.

5.2 Number of Participants

Based on the formula N = 2*[(Zα+Zβ)*σ/δ]^2, with a power of 1−β = 0.90 and a significance level of α = 0.05, chosen to minimize the risk of Type II errors and ensure the detection of meaningful effects, along with pre-test data indicating a standard deviation σ=12.405 and the effect size of δ=8.64, 44 participants will be needed in each group. Accounting for a 20% attrition rate, 55 participants will be required in each group, a total of 110 participants with LDH and OP will be needed in this study.

5.3 Eligibility Criteria

To be eligible to participate in this study, potential participants must meet of all the “inclusion criteria” and none of the “exclusion criteria” (Table 2).

Table 2 Inclusion and Exclusion Criteria in enrollment

Inclusion criteria	Exclusion criteria
① Patients diagnosed with LDH and OP based on the clinical diagnostic criteria. ② Age of female patients ≥ 45 years，age of male patients ≥ 50 years. ③ Visual analogue scale (VAS) ≥ 3 points. ④ Surgical operation will be performed during the 7-day admission period. ⑤ Mandarin speakers.	①Severe primary diseases: ulcerative colitis, gastrointestinal bleeding, pancreatitis, lung cancer, pneumonia, acute respiratory distress syndrome or psychosis, depression, anxiety or substance abuse, identified by diagnosis and interview. ② Current engagement in regular physical activity routines over the past 3 months: aerobic exercises for at least 30 minutes, at least 3 times per week. ③Taken drugs within 3 months before enrollment: bisphosphonates, glucocorticoids, calcitonin, anticonvulsant drugs, heparin, etc.

5.4 Recruitment Procedures

(1) Patients of LDH and OP will be recruited from two spinal wards at the Second Xiangya Hospital, the largest Class A hospital in Changsha city, Hunan province, China. The spinal department currently has 95 regular beds and admits an average of 140 spinal patients each month, providing a substantial number of potential spinal surgery patients. 20 potential participants will be admitted in a month.

(2) **Identifying Potential Participants:** We will collaborate with doctors at the outpatient Spinal Clinic at the Second Xiangya Hospital to identify patients who meet the study's inclusion and exclusion criteria (Table 2) through chart reviews.

(3) **Contacting Potential Participants:** Once potential participants are identified, we will send invitation emails to inform them about the study and invite them to reach out if they are interested in participating. The email will include details of the study, its objectives, and the potential benefits or risks of participation.

(4) **Screening Participants by Phone:** After certifying the potential participants, we will conduct screening participants by phone with the interested participants, we will screen the potential participants using eligibility criteria such

as age, VAS score, and BMD level. They will know study procedures, requirements and methods. If they agree to participate, we will confirm their eligibility and explain the next steps.

(5) **Informed Consent and Baseline Survey:** On the admission day in the hospital, participants will fully understand about the study procedures involved, potential risks and their right to withdraw at any time. All participants will provide written informed consent upon enrollment. They will also complete a baseline survey to collect relevant data before the study.

5.5 Consent/Assent Procedures/HIPAA Authorization

- Research staff trained in the study protocols and human subject research will present the consent form to each participant during a face-to-face interview on upon enrollment. Consent forms describing the study intervention, study procedures, and risks are given to the participant.
- A trained research assistant or the site PI will explain the research study to the participant and answer any questions that may arise. This conversation will take place in a private room.
- Participants will have the opportunity to carefully review the written consent form and ask questions prior to signing. The participants should have the opportunity to discuss the study with their family or surrogates or think about it prior to agreeing to participate.
- Participants must be informed that participation is voluntary and that they may withdraw from the study at any time, without prejudice. A copy of the informed consent document will be given to the participants for their records.

6 Study Methods/Procedures

6.1 Study Procedures

The study is designed to assess the effect of BDJ with resistance training with elderly patients with LDH and OP. Table 3 present the data collection timeline.

(1) Randomization process in two groups

1) Random assignment to groups

Randomization will be performed using a random number generator based on the order of participant enrollment (admission date). As participants are enrolled, their admission date will be recorded, and they will be randomly assigned to group with separated rooms. The randomization process ensures that participants are assigned to the experimental and control groups without bias, avoiding interaction and the risk of treatment contamination of the study. Baseline characteristics of participants in both groups will be assessed to confirm the comparability of the groups and to ensure that the baseline characteristics of participants have no statistical significance between the two groups. The research and data collection schedule are as follows in Table 3.

Table 3 Research and Data Collection Schedule

Study Activity and Assessment	Screening（Day 0）	Baseline (Day 1)	Surgery (5 days rest)	Visit 1: Week 1	Visit 2: Week 12	Visit 3: Week 24
Review Eligibility	X					
Consent Signed	X					
Demographics		X				
Clinical history		X				X
Outcome Evaluation						
International Physical Activity Questionnaire (IPAQ)		X		X	X	X
Oswestry Disability Index (ODI)		X		X	X	X
Lower extremity muscle strength (FTSS)		X		X	X	X
Exercise Benefits and Barriers Scale (EBB)		X		X	X	X
The Self-Efficacy for Exercise Scale (SEE)		X		X	X	X
Randomization		X				
Control & Experimental Interventions		X		X	X	
Adverse Event Reporting		X				
Complication of surgery				X		

2) Baseline Assessment

Baseline assessment will be done on the first day of admission. This assessment will evaluate demographic characteristics and health status, including gender, age, education level, marital status, place of residence, monthly income, and medical insurance status on the first day of admission. Medical data will be collected the history of disease, personal medical history, medication use and BMI. The outcomes screening tools (summarized in Table 4) include the International Physical Activity Questionnaire (IPAQ)[56], Oswestry Disability Index (ODI), Five Times Sit-to-Stand Test (FTSST), Exercise Benefits and Barriers Scale (EBBS) [61]and The Self-Efficacy for Exercise Scale (SEES)[59]. These questionnaires will take 30 minutes to complete.

***Table 4* Questionnaires Summary**

Domain	Screening Test	Comments	Interpretation of score
Physical Activity	Physical Activity Questionnaire (IPAQ) (see Appendix 1)	The questionnaire is designed to be used by adults aged 18~65 years. The short version (7 items) provided information on the time spent walking, in vigorous and moderate intensity activity and in sedentary activity. The reliability and validity were 0.88 and 0.33.	To calculate a total activity score, the reported activity is assigned a Metabolic Equivalents (MET) value based on its intensity. (1) Low Activity Level: <600 MET minutes/ a week; (2) Moderate Activity Level: 600~3000 MET minutes/ a week; (3) > 3000 MET minutes/ a week.
Quality of life	Oswestry Disability Index (ODI) (see Appendix 2)	A 10-items measures the quality of life of spinal patients, consisting of pain intensity, self-care, lifting, walking, sitting, standing, sleeping, sex life, social life and traveling. Each item is assessed on a six-level ordinal scale with "0" describing "no limitation" and "5" describing "extreme limitation or an inability to function", with higher values representing a greater extent of disability. The Cronbach's alpha of this scale was 0.89.	The total score is converted to a percentage to determine the severity of disability. Scores are interpreted as follows: 0-20% (minimal disability), 21-40% (moderate disability), 41-60% (severe disability), 61-80% (crippled), and 81-100% (bed-bound or exaggerating symptoms).
Muscle strength	Five Times Sit-to-Stand Test (FTSST)	5 times sit-to-stand test assess one's muscle strength. The researchers need to record the total time spent. At last, the test will be performed three times, and the final average is taken. Each patient was given 2 minutes intervals for rest. The Cronbach alpha 0.99, and the reliability was 0.97.	The time taken is recorded. Healthy adults complete the test in ≤ 10 seconds; times ≥15 seconds indicate increased fall risk and mobility impairments.

Exercise benefits/ barriers	Exercise Benefits and Barriers Scale (EBBS) (see Appendix 3)	A 43-item measures patients' perceptions of exercise benefits and barriers. Using a 4-point Likert scale, "1" point represents "strongly disagree", "4" point represents "strongly agree". The Cronbach's a of the total scale and the two subscales are 0.86, 0.95 and 0.86.	The more positive the benefits of exercise, the fewer barriers are reported, resulting in a higher score on the scale. Higher scores indicate stronger beliefs in the positive aspects of exercise or more perceived obstacles to engaging in physical activity.
Self-efficacy	Self-Efficacy for Exercise Scale (SEES) (see Appendix 4)	A 10-item measures patients' exercise self-efficacy. The scale is a self-report measure. The scale instructs respondents to indicate on the 4-point rating scale (1= not at all true, 2 = rarely true, 3 = moderately true, 4= always true) how confident they are regarding carrying out regular physical activities and exercise. The Cronbach's a of the scale is 0.93.	The scores for all items are summed to produce a total self-efficacy score. Higher scores indicate greater self-efficacy for exercise. Low score indicates lacking confidence in one's ability.

(2) Intervention Implementation for two groups

The control group will not receive the specific treatment and serve a baseline to observe outcomes without intervention. The experimental group will receive the intervention. By comparing the results of the two groups, we aim to verify the hypothesis. The timeline of intervention and follow-up is shown in Figure 3.

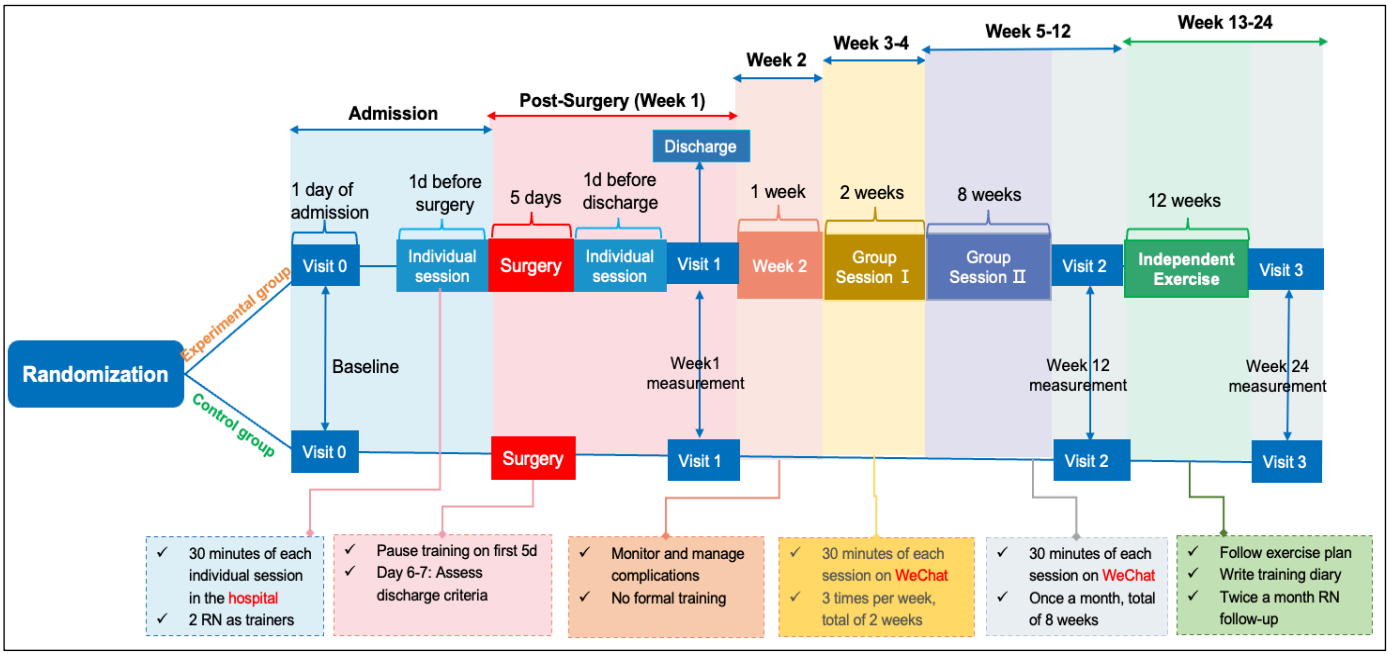


Figure 3 Timeline of intervention and follow-up

Control Group Treatment

Patients in the control group will continue with their conventional treatment as follows:

After spinal surgery, patients will receive comprehensive post-operative care, which will include nursing care and monitoring complications. They will also receive educational handouts that include guidelines for lumbar and back exercises to improve recovery and promote spinal health. In addition, participants will receive three interactive Q&A sessions before their discharge (pre-operation, post-operation and on the day of discharge), including pain management strategies, lifestyle modifications and the importance of adherence. During these sessions, patients can discuss their concerns and ask questions about their recovery.

We will conduct data collection through face-to-face consultations at baseline and Week 1, followed by phone calls at Week 12 and Week 24.

Experimental Group (as shown in Figure 4)

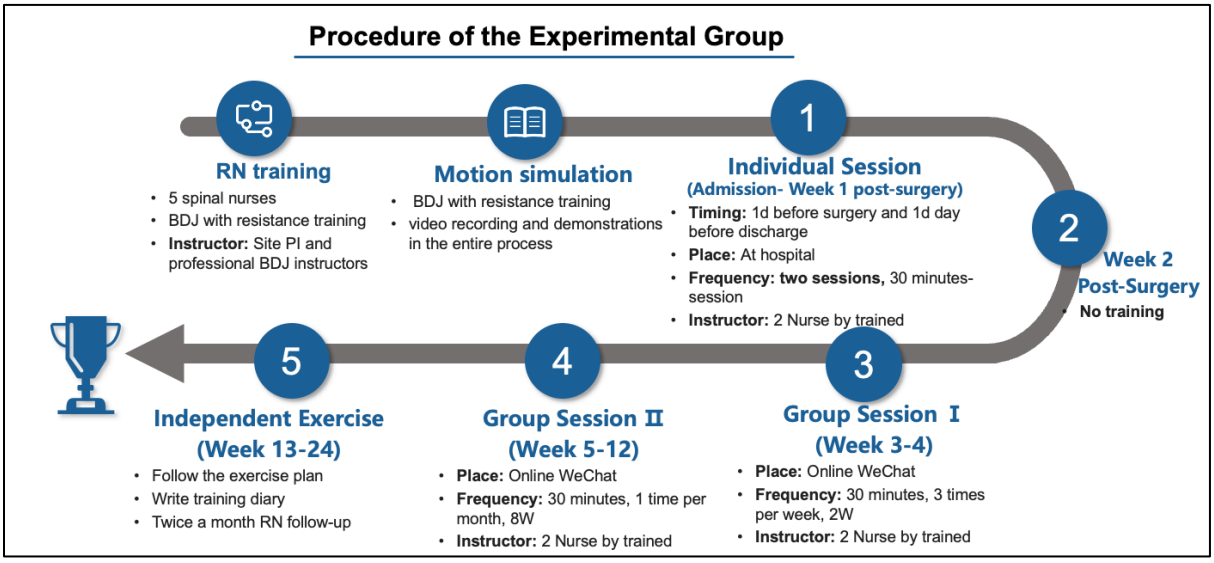


Figure 4 Procedure of the experimental group in this study

1) RN training: Five spinal nurses will receive training and must successfully pass a test to qualify for providing the BDJ intervention. The site PI and a professional BDJ instructor will serve as the main trainers, providing specialized guidance throughout the training program. A video of BDJ with resistance training will be used

during the training process. Five nurses will undergo comprehensive training including BDJ with resistance training and education. Following the training, nurses will participate in practical assessments to demonstrate their skill and knowledge. After this, the qualified nurses will be assigned to guide participants in performing exercises and to provide educational guidance.

2) Motion simulation of BDJ with resistance training

The researcher will act as the subject for motion simulation, which will be centered around BDJ exercise. This simulation will be framed around three core principles: body exercise, mental regulation, and breath control. Specifically, the motion design will combine BDJ with resistance training using an elastic band. Additionally, the training will focus on the specific muscle training of the upper and lower limbs. During the simulation process, researchers will use video recording and demonstrations in the entire process. After the simulation, feedback will be collected to inform improvements. Finally, the study team will review the simulation process and video, engage in discussions, and make final revisions (as shown in Figure 3).

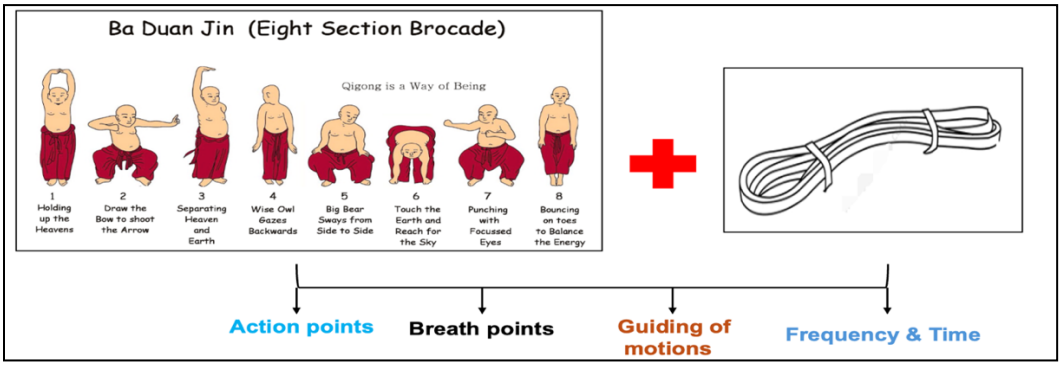


Figure 3 Eight movements of BDJ with resistance training program

3) Implementation of the intervention

Except the conventional treatment, the experimental group will receive BDJ with resistance training for individual session and group session. Two trained nurses will conduct the sessions in group to foster team support and motivation among participants, the timeline of intervention and follow-up are as shown in Figure 4.

(1) **Individual Session (Pre-surgery and Pre-discharge):**

Timing: One day before surgery and one day before discharge.

Content: Participants will attend two individual sessions (one day before surgery and one day before discharge) for 30 minutes each. Each session will focus on teaching participants about proper exercise techniques and key training points. These sessions will involve direct supervision by trained instructors to ensure that participants can understand correctly and perform the exercise. In training content, participant will do exercise about three parts: Warm-up (5 minutes), BDJ exercise (20 minutes) and resistance training (5minutes) in Table 5.

Table 5 training content and specific details

Training Content	Specific Details
Warm-Up	Gentle stretching and breathing exercises (5 minutes)
BDJ exercise	Learning and practicing all BDJ movements, focusing on proper posture and breathing (20 minutes)
Resistance training	Integrating resistance exercises using elastic bands to enhance core strength and overall muscle stability (5 minutes)

Instructors: Two registered nurses (RNs) will serve as the primary instructors, guiding participants to do the necessary exercises and safety precautions.

Aim: The aim of individual sessions is to prepare participants for the rehabilitation by ensuring they understand the exercises and are familiar with exercise movements.

(2) Post-surgery Period (Week 1)

First 5 days of Week 1 Post-Surgery: Participants will pause the BDJ with resistance training to receive standard rehabilitation and nursing care in the hospital.

Day 6 and Day 7 of Week 1 Post-Surgery: These days will allow participants additional rest and gradual exercises under supervision, focusing on the rehabilitation and monitoring of any complications. If participants meet the discharge criteria, they will be arranged for discharge. An individual session will be conducted one day before discharge.

(3) Week 2 Post-Surgery

During the second week after surgery, participants will be monitored and manage any potential complications. No formal BDJ with resistance training session will be conducted during this week to allow for recovery.

(4) Group Session I (Weeks 3–4 Post-Surgery)

Timing: Week 3-4 after surgery.

Content: Participants will continue the online Group Session Ⅰ (WeChat) for 30 minutes-session, three times a week, a total of 2 weeks. Each group will include 10 participants.

Instructors: Two RNs will lead the group session online through video demonstrations and offer real-time instruction.

Aim: The aim is to introduce participants to group-based exercises, build confidence in their ability to exercise at home, and offer continuous support as they recover.

(5) Group Session Ⅱ (Weeks 5–12 Post-Surgery)

Timing: Week 5-12 after surgery.

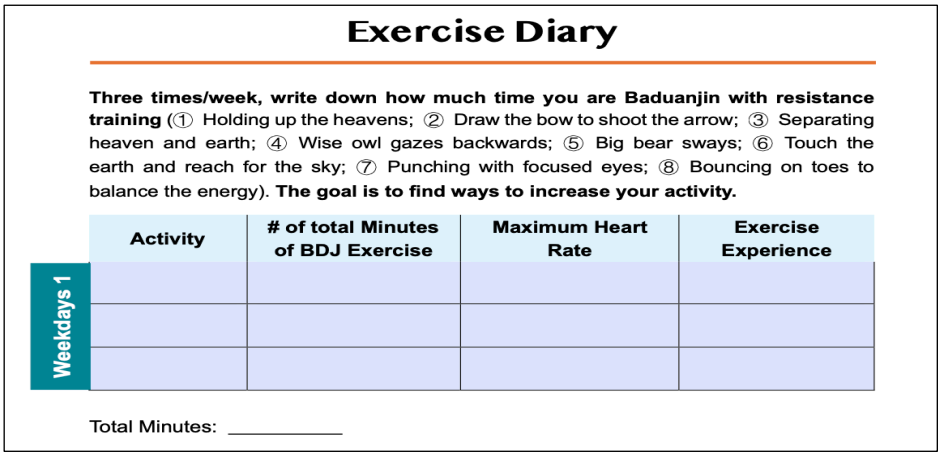
Content: Participants will continue online Group Session Ⅱ (WeChat) for 30 minutes-session, once a month, a total of 8 weeks. These sessions will be designed to provide ongoing support, adjustments to exercise regimens and feedback. In addition to watch exercise video, participants will receive pre-recorded exercise videos and electronic materials. These resources will be available to participants to support home-based exercises.

Instructors: Two RNs will lead the group session online through video demonstrations and offer real-time instruction.

Aim: To ensure that participants continue their BDJ with resistance training, while providing them with elastic bands and knowledge to maintain their exercises independently.

(6) **Independent Exercise (Week 13-24 Post-Surgery)**

Participants will be required to perform the exercise independently at home. They will be encouraged to follow the exercise plan and maintain a daily training diary to record their activities (as shown in Figure 4). Nurses will provide twice a month follow-up to monitor the participants' exercise progress. Participants will follow this independent exercise plan for a total of 12 weeks.



Exercise Diary

Three times/week, write down how much time you are Baduanjin with resistance training (① Holding up the heavens; ② Draw the bow to shoot the arrow; ③ Separating heaven and earth; ④ Wise owl gazes backwards; ⑤ Big bear sways; ⑥ Touch the earth and reach for the sky; ⑦ Punching with focused eyes; ⑧ Bouncing on toes to balance the energy). **The goal is to find ways to increase your activity.**

	Activity	# of total Minutes of BDJ Exercise	Maximum Heart Rate	Exercise Experience
Weekdays 1				

Total Minutes: _____

Figure 4 Exercise Diary

6.1.1 Data Collection

Upon admission, the following data will be collected from participants: Sociodemographic data will be collected at Week 0, and clinical data will be assessed at week 0 and week 24. All the implementation outcome variables (acceptability, feasibility) will be assessed at Week 24. Acceptability will be measured by the Acceptability of Intervention Measure (AIM), a standardized tool used to evaluate how acceptable an intervention. Feasibility will be measured including: (1) recruitment/ enrollment (refusal rate), (2) attendance rate at the sessions, (3) adherence to the study protocol which participants will be required to record Exercise diary for 24 weeks and (4) retention rate (and attrition reasons).

The primary outcomes are physical activity level, quality of life and muscle strength, which will be measured by the following questionnaires at Week 0, 1, 12, 24 (IPAQ, ODI, FTSS).

The secondary outcome variables are the Self-Efficacy of Exercise (SEE), Exercise Benefits and Barriers Scale (EBBS), which will measured at Week 0, 1, 12 and 24, complication after surgery will be measured at week 1 (as shown in Table 6).

Table 6 Measures and the Frequency of Data Collection

Outcome variables (Reliability)	Data Collection			
	0 w	1w	12w	24w
Sociodemographic (Gender, Age, Education, Height, Weight, Medical insurance, Personal life history) and medical history	√			
Clinical data (smoking, diet habit, exercise habit, disease history, time of surgery)	√			√
Physical activity: International Physical Activity Questionnaire (7-item) (a=0.88) **(Primary Outcome)**	√	√	√	√
Quality of Life: Oswestry Disability Index (ODI) (10-item) (a=0.78) **(Primary Outcome)**	√	√	√	√
Muscle Strengths: Five Times Sit-to-Stand Test (FTSS) **(Primary Outcome)**	√	√	√	√
Exercise benefit and barriers: Exercise Benefits and Barriers Scale(43-item) (a=0.88) **(Secondary Outcome)**	√	√	√	√
Exercise self -efficacy: The Self-Efficacy for Exercise Scale(10-item) (a=0.93) **(Secondary Outcome)**	√	√	√	√
Complication of surgery **(Secondary Outcome)**		√		
Acceptability				√
Feasibility (refusal rate, adherence and retention)				√

6.2 Assignment

Patients with LDH and OP will be selected from the spinal wards in the Spinal Surgery Department of the Second Xiangya Hospital of Central South University. Researchers will use a computer-generated random number sequence to randomly assign participants to one of two groups based on admission time, creating an unpredictable sequence for assigning participants to two groups. 55 participants will be assigned to the control group, where they will receive conventional treatment. These patients will continue with their usual treatment, medication, and dietary habits. Another 55 participants will be randomly assigned to the experimental group, which

will receive BDJ with resistance training. Both the control and experimental groups will be treated by the same medical and nursing teams, ensuring that the baseline characteristics of participants show no statistical significance between the two groups.

6.3 Adverse Events Definition and Reporting

Adverse event (AE) refers to any untoward medical occurrence associated with the use of an intervention in humans, regardless of whether considered intervention related. An AE or suspected adverse reaction is considered "serious" if, in the view of either the investigator or sponsor, it leads to any of the following outcomes: death, a life-threatening adverse event, inpatient hospitalization or prolongation of an existing hospitalization, persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect.

The Investigator Manual protocol for reporting AEs to the Institutional Review Board (IRB) is given below:

Yale IRBs require Reportable Events (which are events that are serious or life-threatening and unanticipated (or anticipated but occurring with a greater frequency than expected) and possibly, probably, or related to study procedures or Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs) that may require a temporary or permanent interruption of study activities to be reported to both the IRB and any appropriate funding and regulatory agencies.

The following events may represent UPIRSOs that should be promptly reported:

- Adverse device effects that are unanticipated.
- Adverse events or injuries that are serious, unexpected, and related.
- Breaches of confidentiality involving risks.
- Monitoring reports by the PI and study physician altering the risk/benefit profile by identifying increased risks.
- New information indicating an unexpected increase in risks or decrease in potential benefits(e.g., literature/scientific reports or other published findings).
- Protocol deviations, violations, or other accidental or unintentional changes to the protocol orprocedures involving risks or with the potential to recur.
- Unapproved changes made to the research to eliminate an apparent

immediate hazard to a subject.

- Other problem or finding (e.g., loss of study data or forms) that an investigator or research staff member believes could influence the safe conduct of the research. Also, see the section 8.7.

6.4 Reaction Management

Reaction management involves a comprehensive approach to identifying, assessing, and responding to AE associated with the intervention of this study. This process begins with continuous monitoring of participants for any signs of AEs during the study and ensuring that both participants and staff are aware of the procedures for prompt reporting. Each reported AE is carefully evaluated for its severity and potential causal relationship with the intervention. In the event of serious AEs, immediate response protocols are enacted, including notifying medical personnel and providing necessary care. It is essential to report timely serious AEs to regulatory authorities and communicate with all stakeholders ensuring transparency and accountability. In addition, it is necessary to have some ongoing training for researchers and regular reviews of the protocol, which will help to decrease risks and enhance participants safety in this study.

6.5 Withdrawal Procedures

Participants will be free to withdraw at any time:

- Upon withdrawal, no further information will be collected.
- Researchers may still use information collected prior to withdrawal.
- Participants withdrawing will be asked to return all supplies
- Participants withdrawing may request copies of their data up to the point of withdrawal
- Participants guilty of harassment or disruption at group sessions will be removed from all further activities.
- Researchers may withdraw participants from the study if they have not followed instructions, or the researchers otherwise believe it is not in their best interest to continue.

6.6 Locations/ Facilities

This study will be conducted in two spinal wards in a Class A hospital in Hunan (the Second Xiangya Hospitals of Central South University in Changsha city, Hunan province, China).

7 Statistical Design

7.1 Sample Size Considerations

Based on the formula N = 2*[(Zα+Zβ)*σ/δ]^2, with a power of 1−β = 0.90 and a significance level of α = 0.05, chosen to minimize the risk of Type II errors and ensure the detection of meaningful effects, along with pre-test data indicating a standard deviation σ=12.405 and the effect size of δ=8.64, 44 participants will be needed in each group. Accounting for a 20% attrition rate, 55 participants will be required in each group, a total of 110 participants with LDH and OP will be needed in this study.

7.2 Planned Analyses

Demographic data (including gender, age, education, height, weight, medical insurance, personal life history) along with descriptive characteristics for other proposed variables (medical history, smoking, dietary habits, exercise habits, disease history, and time of surgery) will be tabulated. Continuous data will be presented as mean ± standard deviation (x ± s), and categorical variables will be presented as frequencies (%). The Kruskal-Walli's test, Chi-square test, and Fisher's exact test will be used to evaluate differences in baseline characteristics among participants with LDH and OP in two groups. The significance of the Oswestry Disability Index (ODI), Five Times Sit-to-Stand Test (FTSST), International Physical Activity Questionnaire (IPAQ), Exercise Benefits and Barriers Scale (EBB), and Self-Efficacy for Exercise Scale (SEE) will be evaluated using independent sample t-tests. A p-value of < 0.05 will be considered statistically significant.

7.3 Data Coding

All data will be coded by anonymous participant ID numbers. Names of the participants will be removed from data and a code assigned. Each participant's identifying information will be separated from the study data. A single copy of contact and personal information needed to track and communicate with participants will be kept by researcher Tieying Qiu in a locked and secure location separate from all study data. All identifying information will be destroyed at the earliest possible time following completion of the study. All data will be analyzed by groups, with no potential for individual participants to be identified. Any publications arising from the study will not contain personal information. All study personnel will undergo Human Research Compliance training, which among other topics educates staff about confidentiality matters. All protocols approved by Yale IRB's will be required to meet the standards of HIPAA.

7.4 Data Analysis Tools

All the statistical analyses were conducted using SPSS software (ver. 29.0; IBM Corp, Armonk, NY, USA) or R software to facilitate comprehensive evaluation of the collected data.

7.5 Data Monitoring

A Data and Safety Monitoring Board (DSMB) will oversee the progress of the study, evaluate the data collected, and ensure the safety of all participants. The PI will have primary responsibility for the ongoing monitoring of AEs and will submit reports in accordance with Section 6.3 and the IRB guidelines. The research team will review all AEs and provide recommendations as necessary. The PI will assess study progress every two months, which will include metrics on recruitment (number of participants approached, number eligible, number enrolled, and reasons for ineligibility or non-enrollment), retention (percentage of participants completing baseline and follow-up assessments and reasons for dropouts), and adherence (exercise duration and attendance at group sessions).

7.6 Handling of Missing Data

Participants with missing outcomes at baseline will be excluded from the analysis of that outcome. For participants who miss the response window for follow-up time points after the baseline data is collected, the reasons will be recorded. If the participant does not terminate the study, they will still be contacted for the next follow-up. If the participant fails to follow up, the reasons will be recorded in detail.

8 Data/Specimen Handling and Record Keeping

8.1 Subject Data Confidentiality

Participant confidentiality and privacy will be strictly maintained by the investigators, their staff, and sponsors. Therefore, the study protocol, documentation, data, and all other information generated will be kept confidential. All research activities will be conducted in as private a setting as possible. Representatives of the IRB, regulatory agencies or the study sponsor/funding agency may inspect all documents and records required to be maintained by the investigator for participants in this study. The study site will permit access to these records.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be transmitted to and stored at SPSS. This will not include the participant's contact or identifying information. Only study investigators and staff will have access to the data. Other researchers may request the use of the data collected in this study. At the discretion of the PI and other investigators, data may be shared with outside researchers for research, analysis, and statistical reporting purposes. In such cases, only anonymous information will be provided. No identifying information will ever be sent to researchers using the data in this way.

At the conclusion of the study, all records will be securely maintained within the Second Xiangya Hospital of Central South University network for as long as required by the reviewing IRB, institutional policies, regulatory guidelines, or sponsor/funding agency requirements.

8.2 Data Quality Assurance

During a participant’s hospitalization, researchers will proactively engage with the patient and their relatives to understand their condition and establish a positive rapport. Before the investigation, researchers must fully inform participants about the purpose, methods, and potential benefits of the study and obtain informed consent. All

assessments will be conducted when the participant's physical and emotional condition is stable.

The PI will be responsible for data quality and management. All data will be monitored monthly. This monitoring will include audits to ensure completeness. The PI will also audit intervention in experimental group, adhering to an internal standard procedure manual. Well-trained research team members will conduct standardized interventions and administer questionnaires during each survey. A schedule for data collection will be established. The participant will follow up according to this schedule.

8.3 Data or Specimen Storage/Security

All data will be stored in a password-protected computer file in the Second Xiangya Hospital of Central South University, and paper records will be stored in a locked filing cabinet.

8.4 Study Records

Study records will be maintained by the site PI Tieying Qiu on a secure box folder. These include all IRB documents, an internal standard operating procedure manual, AE forms and confidential data sources (list in section 8.1).

8.5 Access to Source

All data and study records (including regulatory documents, protocols, consent forms, case report forms, subject medical records, surveys, etc.) will be restricted to only members of the research team. Research staff making any changes will document the reason for the change and sign their initials. Source documents will be maintained in a neat and legible manner. When making changes or corrections, the initial entry will be crossed out with a single line, initialed, and dated.

8.6 Retention of Records

Identifiers and consent forms will be securely retained in a locked folder at the Second Xiangya Hospital of Central South University for 3 years. Following the completion of data collection and anonymous data will be retained indefinitely.

8.7 Data and Safety Monitoring Plan

(1) Data monitoring is detailed in section 7.5 and pasted below for reference:

A Data and Safety Monitoring Board (DSMB) will oversee the progress of the study, evaluate the data collected, and ensure the safety of all participants. The PI will have primary responsibility for the ongoing monitoring of AEs and will submit reports in accordance with Section 6.3 and the Institutional Review Board (IRB) guidelines. The research team will review all AEs and provide recommendations as necessary. The PI will assess study progress every two months, which will include metrics on recruitment (number of participants approached, number eligible, number enrolled, and reasons for ineligibility or non-enrollment), retention (percentage of participants completing baseline and follow-up assessments and reasons for dropouts), and adherence (exercise duration and attendance at group sessions).

(2) Safety monitoring is detailed in section 6.3 and pasted below for reference:

Adverse event (AE) refers to any untoward medical occurrence associated with the use of an intervention in humans, regardless of whether considered intervention related. An AE or suspected adverse reaction is considered "serious" if, in the view of either the investigator or sponsor, it leads to any of the following outcomes: death, a life-threatening adverse event, inpatient hospitalization or prolongation of an existing hospitalization, persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect.

The Investigator Manual protocol for reporting AEs to the IRB is given below:

Yale IRBs require Reportable Events (which are events that are serious or life-threatening and unanticipated (or anticipated but occurring with a greater frequency than expected) and possibly,probably, or related to study procedures or Unanticipated Problems Involving Risks to Subjects or Others that may require a temporary or

permanent interruption of study activities to be reported to both the IRB and any appropriate funding and regulatory agencies.

The following events may represent UPIRSOs that should be promptly reported:

- Adverse device effects that are unanticipated.
- Adverse events or injuries that are serious, unexpected, *and* related.
- Breaches of confidentiality involving risks.
- Monitoring reports by the PI and study physician altering the risk/benefit profile by identification of increased risks*.
- New information indicating an unexpected increase in risks or decrease in potential benefits(e.g., literature/scientific reports or other published findings).
- Protocol deviations, violations, or other accidental or unintentional changes to the protocol orprocedures involving risks or with the potential to recur.
- Unapproved changes made to the research to eliminate an apparent immediate hazard to a subject.
- Other problem or finding (e.g., loss of study data or forms) that an investigator or research staffmember believes could influence the safe conduct of the research.

9 Study Considerations

9.1 Institutional Review Board (IRB) Review

The protocol will be submitted to the IRB for review and approval. Approval of the protocol must be obtained before initiating any research activity. Any change to the protocol will require an approved IRB amendment before implementation. The IRB will have final determination whether informed consent and HIPAA authorization are required. Study closure will be submitted to the IRB after all research activities have been completed. Other study events (e.g., data breaches, protocol deviations) will be submitted per Yale policies.

9.2 Research Personnel Training

The site PI will oversee the training of all research assistants on screening, recruitment, retention of participants, intervention delivery, data collection, and human

subject/HIPPA training. Researcher Tieying Qiu will train and supervise RNs responsible for delivering the intervention of the BDJ with resistance training. All research team members will receive a minimum of 10 hours of training on study procedures, including research protocol, questionnaires, intervention methods and follow-up processes.

9.3 Study Monitoring

Safety monitoring will be handled by PI and Safety Monitoring Committee (Section 8.7). Data quality monitoring will be handled by the PI (section 8.2).

9.4 Unanticipated Problems and Protocol Deviations

Researchers have the responsibility to identify and report deviations within 5 working days of identification of the protocol deviation. All deviations must be addressed in study source documents, reported to the study sponsor, and the reviewing IRB per their policies. If the study team becomes aware of an unanticipated problem (e.g., data breach, protocol deviation), the event will be reported to the IRB by a Report of New Information (RNI).

Unanticipated problems (UP) involving risks to participants or others include, in general, any incident, experience, or outcome that meets all the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied.
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research).
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

9.5 Study Discontinuation

The decision to discontinue the study will be made by the PI in consultation with the research team and relevant stakeholders, including the IRB and study sponsors. In the event of discontinuation, all participants will be promptly informed of the decision, and appropriate measures will be taken to ensure their safety and well-being. A formal report will be submitted to the IRB detailing the reasons for discontinuation and any implications for ongoing research.

9.6 Study Completion

The expected completion date is on December 31, 2026. The IRB will be notified by submission of a closure request. The sponsor will be notified in the final progress report.

9.7 Conflict of Interest Management Plan

There is no conflict of interest in this research.

9.8 Funding Source

Yale-China Association.

9.9 Publication Plan

The PI holds primary responsibility for publishing the study results. We plan to present our results at the national and international meeting, including the Chinese Nursing Association Annual Meeting and the International Council of Nursing. Additionally, we will share the data at the Yale-China Annual Meeting. We aim to publish one or two manuscripts based on the outcomes of this research.

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10 Appendices

Appendix #	Title	Section	Topic
Appendix 1	International Physical Activity Questionnaire (IPAQ)-English/Chinese		
Appendix 2	Oswestry Disability Index (ODI)-English/Chinese		
Appendix 3	Exercise Benefits and Barriers Scale (EBBS)-English/Chinese		
Appendix 4	The Self-Efficacy for Exercise Scale (SEE)- English/Chinese		

Appendix 1: International Physical Activity Questionnaire (IPAQ)-English version

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the **last 7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think *only* about those physical activities that you did for at least 10 minutes at a time.

1. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling?

   _____ **days per week**

   ☐ No vigorous physical activities → ***Skip to question 3***

2. How much time did you usually spend doing **vigorous** physical activities on one of those days?

   _____ **hours per day**

   _____ **minutes per day**

   ☐ Don't know/Not sure

Think about all the **moderate** activities that you did in the **last 7 days**. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

3. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

   _____ **days per week**

   ☐ No moderate physical activities → ***Skip to question 5***

4. How much time did you usually spend doing **moderate** physical activities on one of those days?

_____ **hours per day**

_____ **minutes per day**

☐ Don't know/Not sure

Think about the time you spent **walking** in the **last 7 days**. This includes at work and at home, walking to travel from place to place, and any other walking that you have done solely for recreation, sport, exercise, or leisure.

5. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time?

_____ **days per week**

☐ No walking → ***Skip to question 7***

6. How much time did you usually spend **walking** on one of those days?

_____ **hours per day**

_____ **minutes per day**

☐ Don't know/Not sure

The last question is about the time you spent **sitting** on weekdays during the **last 7 days**. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

7. During the **last 7 days**, how much time did you spend **sitting** on a **week day**?

_____ **hours per day**

_____ **minutes per day**

☐ Don't know/Not sure

This is the end of the questionnaire, thank you for participating.

Appendix 1: International Physical Activity Questionnaire (IPAQ)

-Chinese version

IPAQ 国际体力活动量表

1、 最近 7 天内，您有几天做了剧烈的体育活动，像足提重物、挖掘、有氧运动或足快速骑车？

每周_____天

☐ 无相关体育活动 →跳到问题 3

2、 在这其中一天您通常会花多少时间在剧烈的体育活动上？

每天_____小时_____分钟

☐ 不知道或不确定

3、 最近 7 天内，您有几天做了适度的体育活动，像是提轻的物品、以平常的速度骑车或打双人网球？请不要包括走路。

每周_____天

☐ 无适度体育活动 →跳到问题 5

4、 在这其中一天您通常会花多少时间在适度的体育活动上？

每天_____小时_____分钟

☐ 不知道或不确定

5、 最近 7 天内，您有几天足步行，H 一次步行至少 10 分钟？

每周_____天

☐ 没有步行 →跳到问题 7

6、 在这其中一天您通常花多少时间在步行上？

每天_____小时_____分钟

☐ 不知道或不确定

7、 最近七天内，工作日您有多久时间是坐着的？

每天_____小时_____分钟

☐ 不知道或不确定

IPAQ 短卷共 7 道问题，其中 6 道询问个体的体力活动情况。问题 结构与长卷相同，仅保留活动强度的部分。短卷仅 简单地分步行、中等强度和高强度询问不同强度活 动的 1 周频率和每天累计时间

IPAQ 短卷中步行的 MET 赋值为 3.3，中等强度活动的赋 值为 4.0，高强度活动的赋值为 8.0。

Appendix 2: Oswestry Disability Index (ODI)- English version

Oswestry Disability Index (ODI)

Patient Name: _____

Date: _____

1. Pain Intensity

☐ I have no pain at the moment	+0
☐ The pain is very mild at the moment	+1
☐ The pain is moderate at the moment	+2
☐ The pain is fairly severe at the moment	+3
☐ The pain is very severe at the moment	+4
☐ The pain is the worst imaginable at the moment	+5

2. Personal Care (Washing, Dressing, etc.)

☐ I can look after myself normally without causing extra pain	+0
☐ I can look after myself normally but it causes extra pain	+1
☐ It is painful to look after myself and I am slow and careful	+2
☐ I need some help but can manage most of my personal care	+3
☐ I need help every day in most aspects of self-care	+4
☐ I do not get dressed, I wash with difficulty and stay in bed	+5

3. Lifting

☐ I can lift heavy weights without extra pain	+0
☐ I can lift heavy weights but it gives extra pain	+1
☐ Pain prevents me lifting heavy weights off the floor, but I can manage if they are conveniently placed, for example on a table	+2
☐ Pain prevents me from lifting heavy weights but I can manage light to medium weights if they are conveniently positioned	+3
☐ I can only lift very light weights	+4
☐ I cannot lift or carry anything at all	+5

4. Walking

☐ Pain does not prevent me walking any distance	+0
☐ Pain prevents me from walking more than 1 mile	+1
☐ Pain prevents me from walking more than ½ mile	+2
☐ Pain prevents me from walking more than 100 yards	+3
☐ I can only walk using a stick or crutches	+4
☐ I am in bed most of the time	+5

5. Sitting

☐ I can sit in any chair as long as I like	+0
☐ I can only sit in my favorite chair as long as I like	+1
☐ Pain prevents me sitting more than 1 hour	+2
☐ Pain prevents me from sitting more than 30 minutes	+3
☐ Pain prevents me from sitting more than 10 minutes	+4
☐ Pain prevents me from sitting at all	+5

6. Standing

☐ I can stand as long as I want without extra pain	+0
☐ I can stand as long as I want but it gives me extra pain	+1
☐ Pain prevents from standing for more than 1 hour	+2
☐ Pain prevents me from standing for more than 30 minutes	+3
☐ Pain prevents me from standing for more than 10 minutes	+4
☐ Pain prevents me from standing at all	+5

7. Sleeping

☐ My sleep is never disturbed by pain	+0
☐ My sleep is occasionally disturbed by pain	+1
☐ Because of pain I have less than 6 hours sleep	+2
☐ Because of pain I have less than 4 hours sleep	+3
☐ Because of pain I have less than 2 hours sleep	+4
☐ Pain prevents me from sleeping at all	+5

8. Sex life (if applicable)

☐ My sex life is normal and causes no extra pain	+0
☐ My sex life is normal but causes some extra pain	+1
☐ My sex life is nearly normal but is very painful	+2
☐ My sex life is severely restricted by pain	+3
☐ My sex life is nearly absent because of pain	+4
☐ Pain prevents any sex life at all	+5

9. Social life

☐ My social life is normal and gives me no extra pain	+0
☐ My social life is normal but increases the degree of pain	+1
☐ Pain has no significant effect on my social life apart from limiting my more energetic interests, for example sport	+2
☐ Pain has restricted my social life and I do not go out as often	+3
☐ Pain has restricted my social life to my home	+4
☐ I have no social life because of pain	+5

10. Travelling

☐ I can travel anywhere without pain	+0
☐ I can travel anywhere but it gives me extra pain	+1
☐ Pain is bad but I manage journeys over two hours	+2
☐ Pain restricts me to journeys of less than 1 hour	+3
☐ Pain restricts me to short necessary journeys under 30 minutes	+4
☐ Pain prevents me from travelling except to receive treatment	+5

Scoring Instructions:

Raw Score:

Summation of Points

Raw Score: _____ Points

Percentage Score: Raw Score/# Completed Questions * 5

Percentage Score: _____%

Appendix 2: Oswestry Disability Index (ODI)- Chinese version

Oswestry Disability Index (歐氏失能量表) Chinese Version of the Oswestry Disability Index Version 2.1

第一部份：疼痛程度
☐ 我現在不痛。
☐ 我現在的疼痛非常輕微。
☐ 我現在的疼痛中等程度。
☐ 我現在的疼痛相當嚴重。
☐ 我現在的疼痛非常嚴重。
☐ 我現在的疼痛已無法形容。

第二部份：自我照顧（例如洗澡、穿衣服等）
☐ 我可以自我照顧，不會更痛。
☐ 我可以自我照顧，但覺得很痛。
☐ 自我照顧時很痛，我的動作需小心緩慢進行。
☐ 大部分自我照顧都可以自己來，但需要一些協助。
☐ 每天的自我照顧大部分都需要協助。
☐ 我無法自己穿衣服，洗澡有困難，我都躺在床上。

第三部份：抬舉物品
☐ 我可以舉起重物，不會更痛。
☐ 我可以舉起重物，但會更痛。
☐ 疼痛讓我無法從地面舉起重物，但如果放在方便的位置，我就可以。（例如：放在桌上）
☐ 疼痛讓我無法舉起重物，但如果放在方便的位置，我就可以舉起輕到中等重的東西。
☐ 我只能舉起很輕的東西。
☐ 我完全無法舉起或攜提任何東西。

第四部份：走路
☐ 我不受疼痛阻礙，可以走任何距離。
☐ 疼痛使我無法走超過 1.6 公里。（大約 4 圈大操場）
☐ 疼痛使我無法走超過 400 公尺。（大約 1 圈大操場）
☐ 疼痛使我無法走超過 100 公尺。
☐ 我只有依靠枴杖才能走。
☐ 我大部分時間都臥床，無法走到廁所。

第五部份：坐
☐ 我可以坐任何椅子，想坐多久都可以。
☐ 我只能坐特定椅子，想坐多久都可以。
☐ 疼痛使我無法坐超過 1 小時。
☐ 疼痛使我無法坐超過半小時。
☐ 疼痛使我無法坐超過 10 分鐘。
☐ 疼痛使我無法坐著。

第六部份：站
☐ 我要站多久都可以，不會更痛。
☐ 我要站多久都可以，但會更痛。
☐ 疼痛使我無法站超過 1 小時。
☐ 疼痛使我無法站超過半小時。
☐ 疼痛使我無法站超過 10 分鐘。
☐ 疼痛使我無法站著。

第七部份：睡眠
☐ 我的睡眠從未受到疼痛干擾。
☐ 我的睡眠偶而受到疼痛干擾。
☐ 因為疼痛，睡眠時間少於 6 小時。
☐ 因為疼痛，睡眠時間少於 4 小時。
☐ 因為疼痛，睡眠時間少於 2 小時。
☐ 疼痛使我無法入睡。

第八部份：性生活 （如果有的話）
☐ 我的性生活正常而且不會增加背痛。
☐ 我的性生活正常但會增加背痛。
☐ 我的性生活幾乎正常但背部非常疼痛。
☐ 因為背痛，我的性生活受到嚴重限制。
☐ 因為背痛，我幾乎沒有性生活。
☐ 因為背痛，我完全沒有性生活。

第九部份：社交生活
☐ 我的社交生活正常而且不會更痛。
☐ 我的社交生活正常但會增加疼痛的程度。
☐ 除了無法從事激烈運動外，身體疼痛對我的社交生活並無明顯影響。
☐ 疼痛限制了我的社交生活，使我不常出門。
☐ 疼痛使我的社交生活侷限在家裡。
☐ 因為疼痛，我沒有社交生活。

第十部份：旅遊
☐ 我可以到處旅遊不會疼痛。
☐ 我可以到處旅遊但會更痛。
☐ 我可以旅遊超過 2 個小時，但疼痛令人不適。
☐ 疼痛限制我只能從事少於 1 個小時的旅程。
☐ 疼痛限制我只能從事少於 30 分鐘必要的外出活動。
☐ 除了接受治療，疼痛讓我無法外出活動。

Appendix 3: Exercise Benefits and Barriers Scale (EBBS)-English version

EXERCISE BENEFITS/BARRIERS SCALE

DIRECTIONS: Below are statements that relate to ideas about exercise. Please indicate the degree to which you agree or disagree with the statements by circling SA for strongly agree, A for agree, D for disagree, or SD for strongly disagree.

		Strongly Agree	Agree	Disagree	Strongly Disagree
1.	I enjoy exercise.	SA	A	D	SD
2.	Exercise decreases feelings of stress and tension for me.	SA	A	D	SD
3.	Exercise improves my mental health.	SA	A	D	SD
4.	Exercising takes too much of my time.	SA	A	D	SD
5.	I will prevent heart attacks by exercising.	SA	A	D	SD
6.	Exercise tires me.	SA	A	D	SD
7.	Exercise increases my muscle strength.	SA	A	D	SD
8.	Exercise gives me a sense of personal accomplishment.	SA	A	D	SD
9.	Places for me to exercise are too far away.	SA	A	D	SD
10.	Exercising makes me feel relaxed.	SA	A	D	SD
11.	Exercising lets me have contact with friends and persons I enjoy.	SA	A	D	SD
12.	I am too embarrassed to exercise.	SA	A	D	SD
13.	Exercising will keep me from having high blood pressure.	SA	A	D	SD
14.	It costs too much to exercise.	SA	A	D	SD
15.	Exercising increases my level of physical fitness.	SA	A	D	SD
16.	Exercise facilities do not have convenient schedules for me.	SA	A	D	SD
17.	My muscle tone is improved with exercise.	SA	A	D	SD
18.	Exercising improves functioning of my cardiovascular system.	SA	A	D	SD
19.	I am fatigued by exercise.	SA	A	D	SD
20.	I have improved feelings of well being from exercise.	SA	A	D	SD
21.	My spouse (or significant other) does not encourage exercising.	SA	A	D	SD

(Continued on reverse side)

		Strongly Agree	Agree	Disagree	Strongly Disagree
22.	Exercise increases my stamina.	SA	A	D	SD
23.	Exercise improves my flexibility.	SA	A	D	SD
24.	Exercise takes too much time from family relationships.	SA	A	D	SD
25.	My disposition is improved with exercise.	SA	A	D	SD
26.	Exercising helps me sleep better at night.	SA	A	D	SD
27.	I will live longer if I exercise.	SA	A	D	SD
28.	I think people in exercise clothes look funny.	SA	A	D	SD
29.	Exercise helps me decrease fatigue.	SA	A	D	SD
30.	Exercising is a good way for me to meet new people.	SA	A	D	SD
31.	My physical endurance is improved by exercising.	SA	A	D	SD
32.	Exercising improves my self-concept.	SA	A	D	SD
33.	My family members do not encourage me to exercise.	SA	A	D	SD
34.	Exercising increases my mental alertness.	SA	A	D	SD
35.	Exercise allows me to carry out normal activities without becoming tired.	SA	A	D	SD
36.	Exercise improves the quality of my work.	SA	A	D	SD
37.	Exercise takes too much time from my family responsibilities.	SA	A	D	SD
38.	Exercise is good entertainment for me.	SA	A	D	SD
39.	Exercising increases my acceptance by others.	SA	A	D	SD
40.	Exercise is hard work for me.	SA	A	D	SD
41.	Exercise improves overall body functioning for me.	SA	A	D	SD
42.	There are too few places for me to exercise.	SA	A	D	SD
43.	Exercise improves the way my body looks.	SA	A	D	SD

The instrument may be scored and used in its entirety or as two separate scales. The instrument has a four-response, forced-choice Likert-type format with responses ranging from 4 (strongly agree) to 1 (strongly disagree). Barrier Scale items are reverse scored. Items on the Barrier Scale are numbers 4, 6, 9, 12, 14, 16, 19, 21, 24, 28, 33, 37, 40 and 42.

Appendix 3: Exercise Benefits and Barriers Scale (EBBS) -Chinese version

运动益处/障碍量表（Exercise Benefits and Barriers Scale，EBBS）

下是关于你的运动巧尚和认知的一些描迷， 请根据你的认可程度进行选择。

	非常不认同	不认同	认同	非常认同
1）我很享受运动				
2）运动降低了我的压力和紧张的感受				
3）运动提高了我的心理或精神健康水平				
4）运动锻炼耗费了我大量的时间				
5）我将通过运动预防心脏方面的疾病				
6）运动使我感觉很累				
7）运动增强了我的肌肉力量				
8）运动使我获得了个人成就感				
9）运动场所或地点通常距离我太远				
10）运动使我感觉放松				
11）运动使我认识到了我喜欢的朋友或伙伴				
12）参与运动让我感到害羞或尴尬				
13）运动将有助于我预防高血压				
14）我在运动锻炼方面耗费了太多费用				
15）运动增强了我的体能水平				
16）运动器材/设备往往都不太方便使用				
17）运动让我的肌肉变得更加结实				
18）运动提高了我的心血管系统功能				
19）运动让我感觉疲乏				
20）运动提升了我的精神状态				
21）我的朋友/伙伴不鼓励我参与运动				
22）运动增强了我的体力				
23）运动增强了我的灵活性				
24）运动占用了我太多本应与家人相处（在一起）的时间				
25）运动使我的脾气（性格）有所改善				
26）运动提升了我的睡眠质量				
27）运动将有助于我缓解疲劳				
28）我觉得穿运动装的人感觉很好笑				
29）运动有助于我缓解疲劳				
30）运动对于我来说，是一种认识新朋友的好方法				
31）运动提高了我的耐力				
32）运动提升了我的自我意识（自我概念）				
33）我的家人不鼓励我进行运动锻炼				
34）运动使我的头脑更加清醒				
35）保持运动使我参与一些常规的活动时，不再感到疲惫				
36）运动提升了我的学习效率				
37）运动占用了我太多本应在家的时间				
38）对于我来说，运动是一种很好的娱乐方式				
39）运动锻炼让我更收到朋友的欢迎				
40）对于我来说，运动是件很辛苦的事情				
41）运动整体性提升了我的身体机能				
42）我能找到的可以运动的地方很少				
43）运动改善了我的体型				

Appendix 4: The Self-Efficacy for Exercise Scale (SEE)- English version

Self-efficacy For Exercise (SEE) Scale

How confident are you right now that you could exercise three times per week for 20 minutes if:

	Not Confident										Very Confident
1. The weather was bothering you	0	1	2	3	4	5	6	7	8	9	10
2. You were bored by the program or activity	0	1	2	3	4	5	6	7	8	9	10
3. You felt pain when exercising	0	1	2	3	4	5	6	7	8	9	10
4. You had to exercise alone	0	1	2	3	4	5	6	7	8	9	10
5. You did not enjoy it	0	1	2	3	4	5	6	7	8	9	10
6. You were too busy with other activities	0	1	2	3	4	5	6	7	8	9	10
7. You felt tired	0	1	2	3	4	5	6	7	8	9	10
8. You felt stressed	0	1	2	3	4	5	6	7	8	9	10
9. You felt depressed	0	1	2	3	4	5	6	7	8	9	10

Total score is calculated by summing the responses to each question. This scale has a range of total scores from 0-90. A higher score indicates higher self-efficacy for exercise.

Appendix 4: The Self-Efficacy for Exercise Scale (SEE)- Chinese version

运动/锻炼自我效能感量表(Chinese self-efficacy for exercise scale, SEE-C)

如果有以下情况，你有多少信心可以进行运动:

0 没什么信心，10 非常有信心

	没什么信心 → 非常有信心									
	1	2	3	4	5	6	7	8	9	10
1. 如果天气使您感到困扰的时候										
2. 如果您对该运动没有兴趣的时候										
3. 如果运动时会感到疼痛的时候										
4. 如果您一个人运动、没有人作伴的时候										
5. 如果您觉得没有感受到运动的乐趣的时候										
6. 如果您忙于其他事情的时候										
7. 如果您觉得疲惫的时候										
8. 如果您觉得有压力的时候										
9. 如果您觉得心情忧郁的时候										