# SCOPING REVIEW AND CLINICAL RESEARCH ON CONSERVATIVE INTERVENTIONS TO ADOLESCENT IDIOPATHIC SCOLIOSIS

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# Scoping Review and Clinical Research on Conservative Interventions to Adolescent Idiopathic Scoliosis

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**A thesis submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy**

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**CERTIFICATE OF ORIGINALITY**

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## ABSTRACT OF THESIS

Adolescent idiopathic scoliosis (AIS) is a complex three-dimensional deformity of spinal and trunk. Untreated idiopathic scoliosis tends to progress during the growth period. Due to limited knowledge about its etiology and pathogenesis, there is no specific and effective treatment to prevent or reduce spinal deformity. The choice of conservative treatment is usually based on the habits of clinicians or patients' preferences rather than reasonable basis. In order to provide scientific evidence for conservative managements of AIS, this research conducted a scoping review of the effects of various conservative interventions based on evidence-based methods firstly. The results showed that exercise combined with orthosis as well as traditional Chinese medicine had good application prospects in the treatment of AIS. However, there is lack of evidence from high quality research to support their application. Therefore, we further conducted clinical controlled studies to identify the feasibility and validity of these two approaches. The thesis includes the following three parts:

**Part I: Conservative interventions in the management of adolescent idiopathic scoliosis: a scoping review**

Objective: To provide scientific evidence for clinical application of conservative treatments in the management of AIS, through systematically reviewing the related literatures based on evidence-based methods. Method: The studies were searched in the MEDLINE, EMBASE, CENTRAL, CINAHL, PEDro and CNKI databases by two independent reviewers. Results: Fifteen studies met the final inclusion criteria, because of the high heterogeneity among included studies, the statistical pooling was refrained. The results were analyzed based on the quality and the outcome of the studies, which showed that:1) Orthosis was more effective than other conservative treatments in reducing spinal deformity; 2) Scoliosis specific exercises showed benefits in patients with mild scoliosis, the effectiveness of the combination of scoliosis specific exercise with orthosis was lack of scientific evidence from randomized controlled studies. 3)

Traditional Chinese medicine could correct spinal deformities and balance the muscles on both sides of the spinal curvature, which provided a new strategy for conservative management of patients with AIS; 4) In addition to spinal deformity, more attention should be paid to the impacts of conservative treatments on patients' appearance, mental health, cardiopulmonary function as well as the quality of life. Conclusion: Low methodological weaknesses existed in the current research related to conservative treatments for AIS. High quality studies with well-designed and long follow-up were needed to evaluate the effectiveness of different conservative treatments for AIS.

**Part II: The effectiveness of scoliosis specific exercise combined with orthosis on patients with adolescent idiopathic scoliosis: a randomized controlled trial study**

Objective: To investigate the effectiveness of the integration of orthotic intervention (OI) and scoliosis specific exercise (SSE) in the treatment of adolescent idiopathic scoliosis. Method: It was a prospective randomized controlled study. Patients who fulfilled the selection criteria were randomly assigned to the OE group or the OI group. All the subjects were prescribed with a rigid thoracolumbosacral orthosis (TLSO). An additional SSE program was provided to the subjects in the OE group. Cobb angle, back muscle endurance, cardiopulmonary function and quality of life of the subjects were measured at baseline, 6-month and 12-month follow-up visits. Results: After 12-month intervention, the patients in OE group showed better spinal deformity reduction than those in the OI group. The back muscle endurance, pulmonary function as well as quality of life decreased in the patients wearing orthosis only, whereas some reductions happened in the patients receiving orthosis combined with exercise. Between-group statistical significances were detected at both 6-month and 12-month follow-ups among Cobb angle, back muscle endurance time, mental health and total score of quality of life as well as all parameters of cardiopulmonary function except for $FEV_1$/FVC and $O_2$/pulse, while between-group differences among ATR and pain score of quality of life were found at 12-month follow-up only. Conclusion: Orthotic intervention combined with SSE could further increase the Cobb angle correction compared with orthotic

intervention only. Additional SSE could improve the deteriorated respiratory parameters and back muscle endurance of patients treated with orthosis. Compared with orthosis only, patients showed better quality of life when applying SSE during orthotic intervention, especially in terms of pain and mental health.

**Part III: The effectiveness of acupuncture combined with tuina on patients with adolescent idiopathic scoliosis: a quasi-experimental study**

Objective: To investigate the effectiveness of acupuncture combined with tuina in the treatment of patients with adolescent idiopathic scoliosis. Method: It was a quasi-experimental study. Patients who fulfilled the selection criteria were included and divided into the experimental group (the TCM group) and the control group. Patients in the experimental group received traditional Chinese medicine intervention (acupuncture combined with tuina), those in the control group received meaningful observation without further intervention. Cobb angle, back muscle endurance, spinal flexibility and quality of life of subjects were measured at baseline and 6-month follow-up visit. Results: Forty-five patients completed the treatment schedule with data available for evaluation. No serious adverse events occurred during the study. After 6-month intervention, patients in the TCM group showed significant reduction in Cobb angle correction, while those in the control group presented significant deterioration. The results of back muscle endurance and spinal flexibility in the TCM group were found to be significantly better than that in the control group. In terms of quality of life, the pain score and self-image score of the patients in the TCM group were significantly better than that in the control group at the 6-month assessment. Conclusion: TCM intervention could not only reduce the spinal deformity but also enhance the back muscles strength and the spinal flexibility of AIS patients with mild curvature. In terms of raising the quality of life, TCM relieved patients' pain and increased their self-image. As an effective and safe intervention in the treatment of adolescent idiopathic scoliosis, acupuncture combined with tuina is worth popularizing and applying in Chinese clinical practice

## LIST OF PUBLICATIONS

### *Peer-reviewed journal papers (published)*

**GAO C.F**, ZHENG Y, FAN C.J, YANG Y, HE C.Q, WONG M.S. Could the Clinical Effectiveness Be Improved Under the Integration of Orthotic Intervention and Scoliosis-Specific Exercise in Managing Adolescent Idiopathic Scoliosis? : A Randomized Controlled Trial Study. American Journal of Physical Medicine & Rehabilitation, 2019, 98.

**GAO C.F**, CHEN G.H, YANG H, HUA Z, XU P, WONG M.S, HE C.Q. Relative effectiveness of different forms of exercises for treatment of chronic low back pain: protocol for a systematic review incorporating Bayesian network meta-analysis. BMJ Open. 2019 Jun 18;9(6).

SHI X.J[#], **GAO C.F[#]**, WANG L, CHU X, SHI Q.L, YANG H, LI T.S. Botulinum toxin type A ameliorates adjuvant-arthritis pain by inhibiting microglial activation-mediated neuroinflammation and intracellular molecular signaling. Toxicon. 2020 Apr 30; 178:33-40.

### *Peer-reviewed journal papers (submitted)*

**GAO C.F**, ZHENG Y, HE C.Q, WONG M.S. Conservative Interventions in the Management of Adolescent Idiopathic Scoliosis: a Systematic Review. Submitted to Spinal Journal. ***Under review***.

**GAO C.F**, HE C.Q, WONG M.S. The effectiveness of acupuncture combined with tuina on patients with adolescent idiopathic scoliosis: a quasi-experimental study. Submitted to American Journal of Physical Medicine & Rehabilitation. ***Under review***.

## *Peer-reviewed conference papers*

**GAO C.F**, ZHENG Y, WONG M.S. The Combined Effect of Orthotic Intervention and Scoliosis Specific Exercise to the Patients with Adolescent Idiopathic Scoliosis (AIS). In: Asian Prosthetic and Orthotic Scientific Meeting 2018 in Bangkok, Thailand, 7th-9th November 2018.

**GAO C.F**, HE C.Q, WONG M.S. Whether acupuncture can facilitate orthotic intervention to adolescent idiopathic scoliosis? A preliminary report. In: International Society of Prosthetic and Orthotic World Congress 2019, Kobe, Hyogo, Japan, 5th-8th October 2019.

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## LIST OF ABBREVIATIONS

| | |
|---|---|
| ACCP | American college of chest physicians |
| AE | Aerobic exercise |
| AEMG | Average electromyogram |
| AIS | Adolescent idiopathic scoliosis |
| AT | Anaerobic threshold |
| ATS | American thoracic society |
| BMI | Body mass index |
| BST | Biering-sorenson test |
| CI | Confidence interval |
| CS | Core stabilization exercise |
| $FEV_1$ | Forced expiratory volume in the first second |
| FFDT | Fingertip-to-floor distance test |
| FVC | Forced vital capacity |
| MCID | Minimal clinically important difference |
| PedsQoL | Pediatric quality of life |
| SAQ | Spinal appearance questionnaire |
| QoL | Quality of life |
| RCT | Randomized controlled trials |
| SD | Standard deviation |
| SEAS | Scientific exercises approach to scoliosis |
| SOSORT | International society on scoliosis orthopedic and rehabilitation treatment |
| SRS | Scoliosis research society |
| SRS-22 | Scoliosis research society-22 questionnaire |
| SSE | Scoliosis specific exercise |
| TCM | Traditional Chinese medicine |
| TLSO | Thoracolumbosacral orthosis |
| $VCO_2$ | Volume of carbon dioxide elimination |

| | |
|---|---|
| VC | Vital capacity |
| VE | Minute ventilation |
| $VO_{2max}$ | Maximal oxygen uptake |
| WBV | Whole body vibration |

# CHAPTER 1 INTRODUCTION

## 1. Background

Adolescent idiopathic scoliosis (AIS) is a complex three-dimensional deformity of spinal and trunk, which predominantly afflicts adolescents[1]. The prevalence of AIS is about 2-3% of children between 10 and 16 years of age, the scoliosis in girls tends to progress more often than boy[2]. About 10% of adolescents diagnosed with scoliosis have curve progression requiring medical intervention. Untreated idiopathic scoliosis tends to progress during the growth period, which may lead to back pain, cardiopulmonary dysfunction, limited participation as well as psychological issues[3-5]. Medical intervention is required when a patient's cobb angle exceeds 20°. However, due to limited knowledge about its etiology and pathogenesis, there is no specific and effective treatment to prevent or reduce spinal deformity. Currently, the interventions for patients with AIS mainly include conservative treatment and surgical treatment. Surgical correction is applied to a few patients with spinal curvature over 45° accompanied by severe rotation deformity[6], while the most adolescents with idiopathic scoliosis receive conservative treatments, including various types of orthoses, exercise and traditional Chinese medicine (TCM) etc.[7-9]. Orthoses are the most commonly interventions in clinical practice, but their effectiveness is still controversial[10,11]. It has been reported that wearing orthoses does not seem to change the natural course of idiopathic scoliosis or reduce the surgical rate[12]. Monticone[13] reported that scoliosis specific exercise (SSE) could significantly reduce spinal deformity, but only mild AIS patients (cobb angle 10-25°) were included in his study. The therapeutic effect of SSE on moderate or severe AIS remains unclear. Chinese scholars have reported the positive effects of traditional Chinese medicine, such as acupuncture, moxibustion and tuina (massage) on the reduction of spinal deformity, but the lack of scientific research design has affected the reliability of the results[9,14], therefore the treatment effect of TCM on

AIS remains to be further confirmed. In summary, the optimal conservative treatment of AIS remains unclear.

The choice of conservative treatment is usually based on the habits of clinicians or patients' preferences rather than reasonable basis. In order to provide scientific evidence for conservative managements of AIS, in Chapter 2, we conducted a scoping review to investigate the effects of various conservative interventions in the management of AIS based on evidence-based methods. The results of review study showed that exercise combined with orthosis as well as traditional Chinese medicine had good application prospects in the treatment of AIS. However, there is lack of evidence from high quality research to support their application. Therefore, in Chapter 3 and Chapter 4 we further conducted clinical controlled studies to identify the feasibility and validity of these two approaches. The results of current research will provide evidence-based rationales for the choice of type of conservative treatments, and also provide scientific evidence for the clinical application of exercise combined with orthosis and traditional Chinese medicine in the treatment of AIS. Finally, Chapter 5 summarized the major findings of current study and recommendations for future research.

## 2. Research objectives

**Part I: Conservative interventions in the management of adolescent idiopathic scoliosis: a scoping review**

1) To provide evidence-based evidence for clinical application of conservative treatments in the management of AIS, through systematically reviewing the curve correction effect of all sorts of conservative interventions and comprehensive evaluation of their influence on patients' appearance, mental health, cardiopulmonary function and the quality of life.

**Part II: The effectiveness of scoliosis specific exercise combined with orthosis on**

**patients with adolescent idiopathic scoliosis: a randomized controlled trial study**

1) To investigate whether the integration of scoliosis specific exercise and orthotic intervention would achieve better correction of spinal deformity than orthosis alone in the management of patients with AIS.
2) To investigate whether performing scoliosis specific exercise during orthotic intervention would reduce the negative effects of orthosis on back muscle endurance and cardiopulmonary function of patients with AIS.
3) To investigate the influence of scoliosis specific exercise combined with orthotic intervention on the quality of life of AIS patients

**Part III: The effectiveness of acupuncture combined with tuina on patients with adolescent idiopathic scoliosis: a quasi-experimental study**

1) To investigate the effects of traditional Chinese medicine (acupuncture combined with tuina) on reducing spinal deformities muscle function, spinal flexibility as well as quality of life of patients with AIS

# CHAPTER 2 CONSERVATIVE INTERVENTIONS IN THE MANAGEMENT OF ADOLESCENT IDIOPATHIC SCOLIOSIS: A SCOPING REVIEW

## 2.1 Introduction

Adolescent idiopathic scoliosis (AIS) is a structural abnormality of the spine, common in adolescent, which usually presents as a lateral curvature of the spine on the coronal plane, with or without sagittal or horizontal changes[1]. The incidence of AIS in adolescents aged 10-17 years old is 2-3%, and girls have a higher incidence than boys[2]. About 10% of AIS patients occurred curve progression, and without timely treatment, spinal deformity will be further aggravated, which will have a negative impact on the appearance, mental health and quality of life of teenager[3-5].

Medical intervention is required when a patient's cobb angle exceeds 20°. The interventions mainly include conservative treatment and surgical treatment. Surgical correction is applied to a few patients with spinal curvature over 45° accompanied by severe rotation deformity[6]. The most adolescents with idiopathic scoliosis receive conservative treatments, including various types of orthoses, exercise and traditional Chinese medicine (TCM) etc.[7-9]. Because the etiology of AIS is still unclear, there is still no specific and effective treatment to prevent or reduce spinal deformity. Orthoses are the most common interventions in clinical practice, but their effectiveness is still controversial[10,11]. It has been reported that wearing orthoses does not seem to change the natural course of idiopathic scoliosis or reduce the surgical rate[12]. Monticone[13] reported that scoliosis specific exercise (SSE) could significantly reducee spinal deformity, but only mild AIS patients (cobb angle 10-25°) were included in his study. The therapeutic effect of SSE on moderate or severe AIS remains unclear. Chinese scholars have reported the positive effects of traditional Chinese medicine, such as acupuncture, moxibustion and tuina (massage) on the reduction of spinal deformity, but the lack of scientific research design has affected the reliability of the results[9,14], therefore the treatment effect of TCM on AIS remains to be further confirmed. In summary, the optimal conservative treatment of AIS remains unclear.

Previous research on the conservative treatment for AIS paid more attention to the spinal deformity itself, but ignored the impact of deformed appearance on children's psychology, social development and quality of life etc., In addition, the treatment for AIS usually lasts for many years, and the possible effects of intervention (such as long-term wearing of orthoses) on patients' psychological, cardiopulmonary function and quality of life should not be ignored[15-17]. As a result, the Scoliosis Research Society (SRS) and the International Society on Scoliosis Orthopedic and Rehabilitation Treatment (SOSORT) reached a consensus on the research on the conservative treatment of scoliosis and suggested that in addition to the effect of different interventions on the correction of spinal deformity, the possible influence of interventions on patients' appearance, mental health, cardiopulmonary function and quality of life should be evaluated to better reflect the influence of different conservative treatments on the survival state of AIS patients[18].

This research aimed to provide evidence-based evidence for clinical application of conservative treatments in the management of AIS, through systematically reviewing the curve correction effect of all sorts of conservative interventions and comprehensive evaluation of their influence on patients' appearance, mental health, cardiopulmonary function and the quality of life.

## 2.2 Materials and methods

### 2.2.1 Search strategy

A comprehensive search was undertaken to identify all relevant studies in the following electronic databases: MEDLINE (via PubMed), EMBASE, Cochrane Central Register of Controlled Trials(CENTRAL), Cumulative Index to Nursing and Allied Health Literature (CINAHL), Physiotherapy Evidence Database (PED) and China National Knowledge Infrastructure (CNKI). The time was limited from inception of the database to December 2021, and the database would be researched regularly before the results were reported in order to include the latest literature. The following keywords and word combinations were used to identify the study population and intervention: "orthosis", “braces”, “orthotic devices”, “exercise”, “exercise movement techniques”, “exercise therapy”, “exertion”, “human activities”, “musculoskeletal manipulations”, “physical therapy techniques”, “chiropractic therapy”, “acupuncture”, “massage”, “tuina”, “traditional Chinese medicine,” “scoliosis,” “idiopathic scoliosis,” “spinal curvatures,” “adolescent idiopathic scoliosis” The specific search strategies of MEDLINE and EMBASE were shown in **Appendix I**. The search strategies of other databases were adjusted accordingly. The reference lists in these identified studies were also reviewed to identify potentially relevant studies. The literature search was carried out independently by two reviewers, and if there was a disagreement, a consensus was obtained through negotiation.

### 2.2.2 Eligibility criteria

#### 2.2.2.1 Type of participants

Patients who suffered from adolescent idiopathic scoliosis needed to meet the following conditions: under the age of 18; cobb angle10-45 °; bone immature (Risser sign 0-4). Patients with congenital or other causes of secondary scoliosis were excluded.

#### 2.2.2.2 Type of interventions

All of the following conservative interventions would be included either alone or in combination: 1) various types of orthoses; 2) various types of exercise; 3) other conservative interventions, including but not limited to manipulation, chiropractic, electrical stimulation, traditional Chinese medicine, acupuncture, massage, tuina, etc.

#### 2.2.2.3 Type of outcome measures

##### 2.2.2.3.1 Progression of scoliosis

1) Cobb angle in degrees; 2) Angle of trunk rotation (ATR) in degree; 3) Treatment effective rate: the proportion of patients with curvature reduction ≥5° or stable at ±5°; 4) Treatment failure rate: the proportion of patients requiring surgical correction, etc.

#### 2.2.2.3.2 Appearance problems

1) Spinal Appearance Questionnaire (SAQ)[19]; 2) Clinical shoulder balance (CSB)[20] etc.

#### 2.2.2.3.3 Quality of life

1) SRS-22,23 scale[21]; 2) SF-36 scale[22]; 3) PedsQoL scale[23], etc.

#### 2.2.2.3.4 Pain

1) VAS score; 2) the application of drugs, etc.

#### 2.2.2.3.5 lung function

1) Static lung function; 2) Cardiopulmonary exercise test (CPET), etc.

#### 2.2.2.3.6 Psychological problems

1) Psychological part of SRS-22,23 scale; 2) The psychological part of SF-36 scale; 3) The psychological part of PedsQoL scale, etc.

#### 2.2.2.3.7 Muscle function

1) Muscle strength; 2) Muscle endurance; 3) EMG, etc.

### 2.2.2.4 Type of studies

Only randomized controlled trials(RCT) concerning conservative treatment for AIS were included.

### 2.2.3 Literature quality assessment

RevMan 5.3 software was used to assess the bias risk of the included studies, which was based on the Cochrane Bias Methods Group's criteria for randomized controlled trials[24]. The quality of the included studies was scored according to the Delphi list. Delphi checklists were commonly used to evaluate the quality of RCT and CCT studies[25]. This criteria list had high reliability and validity and was often used for systematic reviews on musculoskeletal disorders[26]. The Delphi list contained 9 items, all items had three options: "Yes," "No," or "Unclear." A score of 1 point was given to each item assessed with a "Yes" answer. Equal weights were applied, resulting in a maximum score of 9 points for the overall methodological quality score. The higher the score was, the higher quality of the study would be. The literature quality was evaluated by two reviewers at the same time. In case of disagreement, consensus was obtained through negotiation.

**2.2.4 Data extraction and analysis**

The two reviewers carefully read the full text of the final included literature, extracted relevant information of each article by using the data extraction form, and summarized the characteristics and outcome measurements of included studies. The two reviewers extracted the data independently, and then checked with each other to ensure the accuracy of the data.

Relative risk (RR) and 95% Confidence interval (CI) were calculated for binary variables, and standardized mean difference (SMD) and 95% CI were calculated for continuous variables. Results of clinically homogeneous studies, defined as studies with similar populations, interventions, and observational measures, were statistically pooled. If the included studies cannot be combined due to high clinical heterogeneity or lack of data, we evaluated the results using a rating system with levels of evidence[27]. The level of evidence can be divided into five levels according to the quality and the outcomes of the studies. 1) strong evidence: consistent findings multiple (2 or more) high-quality RCTs; 2) moderate evidence: consistent findings among 1 high-quality RCT and multiple (2 or more) low-quality RCTs or CCTs; 3) limited evidence: 1 low-quality RCT or CCT; 4) conflicting evidence: inconsistent findings among multiple RCTs or CCTs; 5) no evidence: no RCTs or CCTs found. When more than 75% of the studies reported the same conclusion, the findings were considered as consistent. We used 2 different ways of defining “high quality” studies: 1) presenting a concealed randomization procedure and adequate blinding or (2) a positive score on 5 or more Delphi items (50% of the maximum attainable score).

## 2.3 Results

A total of 445 relevant articles were found in the preliminary search. After careful reading of titles and abstracts, 261 of records after duplicates removed, a total of 52 articles were further screened by reading the full text. Finally, 20 randomized controlled clinical studies that met the inclusion criteria were included. The flow chart of literature retrieval and screening was shown in **Figure 2-1**.

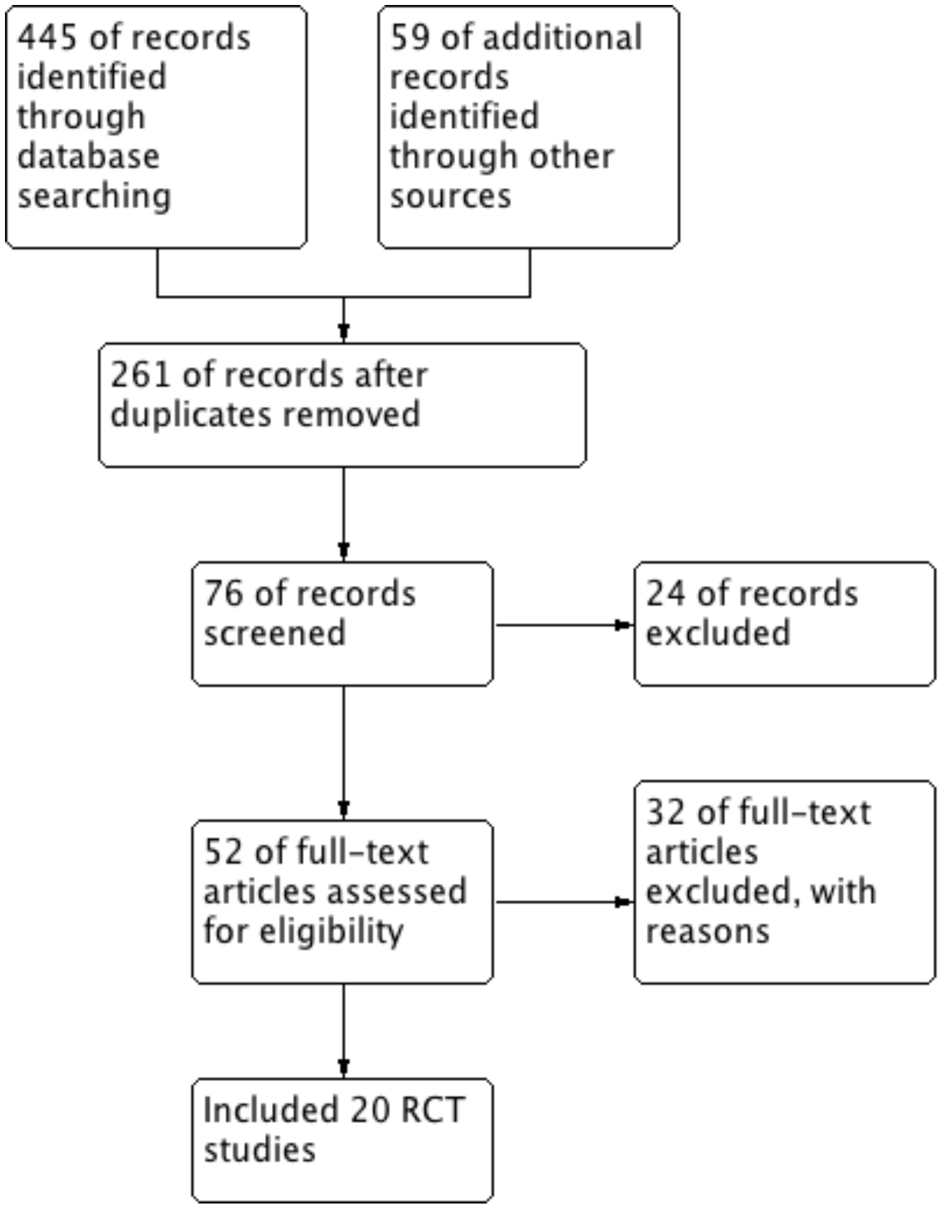


**Figure 2-1 The flow chart of Literature retrieval and screening**

### 2.3.1 Characteristics of the included studies

Finally, 20 RCTs[13,23,28-45] were included, publication date from 1994 to 2021, patients aged from 6 to 18 years old, sample size ranged from 25 to 132, and total number of participants was 1166. In addition to conservative treatment measures like various types of orthoses commonly used in clinical practice (such as Milwaukee, TLSO, Spinecor, 3D-printed orthosis, Pressure-adjustable orthosis etc.) and various types of scoliosis specific exercise (such as SEAS, active self-correction task oriented exercise, Schroth, forward head correction, direction sensitive exercise, etc.) and traditional exercise, electrical stimulation, traditional Chinese medicine (TCM), Whole body vibration (WBV), Core stabilization exercise (CS), Aerobic exercise (AE), etc. were also involved. Among them, 18 articles[13,23,28,30-42,44,45] evaluated the angle of scoliosis, and 9 articles[13,23,34,37,40,42-45] reported the quality of life. Only a few articles reported the appearance, lung function and muscle function of the patients', with 4[23,34,37,45],3[29,35,38] and 3[37,38,43], respectively. The characteristics of the included studies were summarized in **Table 2-1.**

**Table 2-1 Summary of characteristics of included studies**

| Study | Participants | Interventions | Outcomes | Main conclusion |
|---|---|---|---|---|
| **Sayyad (1994)[32]** | N=30;<br>Age=6-16y;<br>Cobb angle: 15-45°;<br>Average Cobb angle: 23.42 ±8.24° | I: Electrical stimulation +TE:<br>n=8;<br>Average age=10.75±1.67y; Average Cobb angle =24.92±8.48°<br>II: Milwaukee brace +TE:<br>n=8;<br>Average age=12.13±1.55y; Average Cobb angle=25.65±7.95°<br>III: Traditional exercise(TE):<br>n=10;<br>Average age=11.80±1.62y; Average Cobb angle=20.37° ±7.67° | 1)Cobb angle | Statistically significant decreases in spinal curvature angle were achieved through each of three methods of management in 12 weeks. The amount of change was modest, about 3° to 4°, with the greatest reduction in Brace group. However, no one regimen was found to be significantly superior to the others. |
| **Alayat (2017)[28]** | N=50;<br>Age=10-17y;<br>Cobb angle: 10-20° | I: SSE (Direction sensitive exercise):<br>n=25;<br>Average age=14.1±1.6y;<br>Average Cobb angle=13.20° ±4.1°<br>II: TE:<br>n=25;<br>Average age=14.4±1.7y;<br>Average Cobb angle=12.68 ± 3.7° | 1)Cobb angle | SSE (Direction sensitive exercise therapy) was more effective than traditional exercises in decreasing Cobb angle in patients with AIS. |
| **Schwieger (2016)[23]** | N=132;<br>Age =10-15y;<br>Cobb angle: 20-40° | I: Brace:<br>n=64;<br>Average Cobb angle=29.7° ±4.7°<br>II: Observation:<br>n=68;<br>Average Cobb angle=29.3±5.7° | 1) Cobb angle；<br>2) PedsQoL；<br>3) SAQ； | This study did not support findings from previous research indicating that wearing a brace had a negative impact on or was negatively impacted by body image or QOL. |
| **Wei (2016)[38]** | N=120;<br>Age ≥10y;<br>Cobb angle: 20-40° | I: TCM:<br>n=58;<br>Average Cobb angle= 30.4±3.7°;<br>Average age=9.1±0.4y;<br>II: Brace: | 1) Cobb angle；<br>2) Static lung function: VC ， FEV1/FVC, etc.<br>3)Electromyograph | TCM combined therapy can prevent the progression of scoliosis. The AEMG ratio was a promising index that could replace radiography in the evaluation of treatment effect and progression |

| | | | | |
|---|---|---|---|---|
| | | n=49;<br>Average Cobb angle= 31.5±3.2°<br>Average age= 8.9±0.6y; | y(EMG)：AEMG ratio | in scoliosis. |
| **Coillard (2014)[30]** | N=68;<br>Age ≥10y;<br>Cobb angle: 15-30° | I: Dynamic spinecor brace;<br>n=36;<br>Average Cobb angle= 20±4.1°;<br>Average age=12±2y;<br>II: Observation;<br>n=32;<br>Average Cobb angle=22±4.94°;<br>Average age= 12±2y; | 1) percentage of patients who have 5° or less curve progression and the percentage of patients who have 6° or more progression at 3 and 5 years post-randomization (skeletal maturity) for each group<br>2) percentage of patients with curve exceeding 45° at maturity. | The results 5 years after the treatment suggested that the spinecor brace reduced the probability of the progression of early idiopathic scoliosis comparing with its natural history. Moreover, the positive outcome appeared to be maintained in the long term. |
| **Monticone (2014)[13]** | N=110;<br>Age ≥10y;<br>Cobb angle: 10-25° | I: SSE (Active self-correction task-oriented spinal exercises); n=55; Average Cobb angle= 19.3±3.9°; Average age =12.5±1.1y;<br>II: TE; n=55; Average Cobb angle=19.2±2.5°; Average age = 12.4±1.1y; | 1) Cobb angle;<br>2) ATR;<br>3) Quality of life: SRS-22 | SSE (Active self-correction task-oriented spinal exercises) was superior to traditional exercises in reducing spinal deformities and enhancing the HRQL in patients with mild AIS. The effects lasted for at least 1 year after the intervention ended. |
| **Kumar (2017)[35]** | N=36;<br>Age =10-15y;<br>Cobb angle<20° | I: SSE (Task oriented exercises):<br>n=18;<br>Average Cobb angle=12.61±1.81°;<br>Average age=12.17±1.72y;<br>II: TE:<br>n=18;<br>Average Cobb angle=12.72±1.40°;<br>Average age=11.56±1.46y; | 1) Cobb angle;<br>2) Static lung function：FVC, FEV1, FEV1/FVC,VC | SSE (Task oriented exercises) benefited patients with AIS which had a significant improvement of their pulmonary functions and Cobb angle. |

| | | | | |
|---|---|---|---|---|
| **Langensiepen (2017)[36]** | N=41;<br>Age =10-17y;<br>Average Cobb angle: 29.7 ±8.7° | I: WBV (whole body vibration) +SSE:<br>n=20;<br>Average Cobb angle= 30.1±9.0°;<br>Average age =13.6±1.6y;<br>II: SSE:<br>n=18;<br>Average Cobb angle=29.7±8.7°;<br>Average age=14.0±0.9y; | 1) Cobb angle;<br>2) Treatment effective rate: the ratio of scoliosis reduction ≥5° or stable ratio of ±5° | Home-based SSE combined with WBV for six months counteracted the progression of scoliosis in girls with AIS; the results were more obvious before the onset of the menarche. |
| **Schreiber (2015)[37]** | N=50;<br>Age =10-18y;<br>Average Cobb angle: 28.5 ±8.8°<br>Average age: 13.4 ±1.6y | I: SSE (Schroth)+Brace/ Observation:<br>n=25;<br>Cobb angle=29.1° (25.4° to 32.8°)；Age=13.5 (12.7 to 14.2y)<br>II: Brace/ Observation:<br>n=25;<br>Cobb angle=27.9° (24.3° to 31.5°);<br>Age=13.3y (12.7 to 13.9); | 1) Cobb angle；<br>2) Quality of life: SRS-22；<br>3) SAQ；<br>4) Muscular endurance: BST | Supervised SSE provided added benefit to the standard of care by improving SRS-22r pain, self-image scores and BME. Given the high prevalence of ceiling effects on SRS-22r and SAQ questionnaires' domains, we hypothesized that in the AIS population receiving conservative treatments, different QOL questionnaires with adequate responsiveness were needed. |
| **Gür (2016)[34]** | N=25;<br>Age =10-16y; | I:CS (Core stabilization exercise) +Brace:<br>n=12;<br>Average Cobb angle=29±8.35°;<br>Average age=14.2±1.8y;<br>II: Brace:<br>n=13;<br>Average Cobb angle=34.33±9.2°;<br>Average age=14.0±1.6y | 1) Cobb angle；<br>2) ATR；<br>3) SAQ；<br>4) Quality of life: SRS－22 | Core stabilization training in addition to traditional exercises (including exercise and bracing) was more effective than traditional exercises alone in the correction of vertebral rotation and reduction of pain in adolescent idiopathic scoliosis. |
| **Zheng (2017)[40]** | N=60;<br>Age =10-18y;<br>Cobb angle: 10-25° | I: SSE (SEAS):<br>n=29;<br>Average Cobb angle=27.0±3.6°;<br>Average age=12.4±0.9y<br>II: Brace (TLSO):<br>n=24;<br>Average Cobb angle=28.0±3.6°;<br>Average age=12.3±0.8y | 1) Cobb angle；<br>2) ATR;<br>3) Quality of life: SRS-22 | Both interventions of bracing and exercise showed significant treatment effectiveness on the patients with AIS. Bracing was superior to capture corrections in parameters of spinal curvature and body symmetry, while the QoL, especially in aspect of the functional and psychological status, was significantly better in the exercise |

| | | | | |
|---|---|---|---|---|
| | | | | group. |
| **Athanasopoulos (1999)** [29] | N=40; | I: Aerobic training + Brace:<br>n=20;<br>Average Cobb angle=27.4±1.9°;<br>Average age=13.5±0.16y<br>II: Brace:<br>n=20;<br>Average Cobb angle=29.5±1.8°;<br>Average age=13.6±0.18y | 1) Static lung function: VC, FVC, FEV1, FEV1/FVC；<br>2)Exercise cardiopulmonary function: aerobic exercise capacity | Aerobic training can significantly improve the FVC of patients wearing Brace, while other indicators reflecting static lung function had no significant changes. Aerobic exercise increased the aerobic capacity of a patient wearing Brace by about 50%. |
| **Diab (2016)**[31] | N=76;<br>Age =10-18y;<br>Cobb angle: 10-30°;<br>Average age: 13.4 ±1y | I: SSE (Forward head correction exercise:<br>n=36;<br>Average Cobb angle=16.8±2.3°;<br>Average age=13.2±1.2y<br>II: TE:<br>n=33;<br>Average Cobb angle=15.1±1.8°;<br>Average age=14.5±1.3y | 1) Cobb angle;<br>2) ATR | SSE combined with conventional rehabilitation improved three-dimensional scoliotic posture and functional status in patients with adolescent idiopathic scoliosis. |
| **Guo (2014)**[33] | N=38;<br>Age =10-14y;<br>Cobb angle: 20-30° | I: Brace; n=18; Average Cobb angle= 24.0±2.8°;<br>Average age =12.6±0.8y<br>II: Spinecor; n=18; Average Cobb angle= 24.1±2.9°;<br>Average age =12.3±0.9y | 1) Treatment effective rate: the ratio of scoliosis reduction ≥5° or stable ratio of ±5° | Curve progression rate was found to be significantly higher in the SpineCor group when compared with the rigid brace group. Changing to rigid bracing could control further curve progression for majority of patients who previously failed with SpineCor bracing. For both SpineCor and rigid brace treatments, 30–40 % of patients who were originally successfully treated by bracing would exhibit further curve progression beyond skeletal maturity. The post-maturity progression rate was found to be 1.5° per year in the current study, which was relatively greater than those reported before. |

| | | | | |
|---|---|---|---|---|
| **Weinstein (2013)[39]** | N=116;<br>Age =10-15y;<br>Cobb angle: 20-40°;<br>Average age: 12.7 ±1.1y | I: Brace:<br>n=51;<br>Average Cobb angle=31.3±6.7°;<br>Average age=12.7±1.2y<br>II: Observation:<br>n=65;<br>Average Cobb angle=29.4±4.7;<br>Average age=12.6±1.1y | 1) Treatment success rate: It is defined as the percentage of patients whose spinal curvature has not progressed to 50° or more when bone matures. | Bracing significantly decreased the progression of high-risk curves to the threshold for surgery in patients with adolescent idiopathic scoliosis. The benefit increased with longer hours of brace wear. |
| **Lin (2020)[45]** | N=24;<br>Age =10-14y;<br>Cobb angle: 20-40°; | I: Pressure-adjustable orthosis (PO):<br>n=12;<br>Average Cobb angle=26.2±4.7°;<br>Average age=12.4±1.2y<br>II: Conventional orthosis (CO):<br>n=12;<br>Average Cobb angle=27.4±5.6;<br>Average age=12.6±0.9y | 1) Cobb angle；<br>2) SAQ;<br>3) Quality of life: SRS-22, BrQ | This study showed that the automated PO could enhance wearing quality when compared with the CO, thus offering a better biomechanical corrective effect in the study period without adverse effect on the patients' wearing quantity and QoL. |
| **Abdel-aziem (2021)[41]** | N=52;<br>Age =10-18y;<br>Cobb angle: 10-25°; | I: Hipptherapyd + SSE(Schroth):<br>n=29;<br>Average Cobb angle=18.59±2.66°;<br>Average age=14.74±1.79y<br>II: SSE(Schroth):<br>n=25;<br>Average Cobb angle=19.32±2.69;<br>Average age=15.04±1.81y | 1) Cobb angle;<br>2) Dynamic postural stability | In adolescence idiopathic scoliosis, hippotherapy training combined with Schroth exercises improves posture asymmetry and balancing ability more effectively than Schroth exercises alone |
| **Lin (2021)[44]** | N=30;<br>Age =10-14y;<br>Cobb angle: 20-40°; | I: 3D-printed orthosis:<br>n=15;<br>Average Cobb angle=31.8±5.8°;<br>Average age=12.4±0.8y<br>II: Conventional orthosis:<br>n=15;<br>Average Cobb angle=29.3±4.0;<br>Average age=12.0±1.0y | 1) Cobb angle；<br>2) TAPS;<br>3) Quality of life: SRS-22 | The 3D-priented orthosis could provide comparable clinical effects as compared with the conventional orthosis, while patients with 3D orthosis showed similar compliance and QoL compared to those with conventional orthosis. |

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|---|---|---|---|---|
| **Lau (2021)[43]** | N=40;<br>Age =11-14y;<br>Cobb angle: 15-40°; | I: Home-based exercise:<br>n=20;<br>Average Cobb angle=20.6±5.0°;<br>Average age=12.8±0.9y<br>II: Observation:<br>n=20;<br>Average Cobb angle=23.4±6.7;<br>Average age=13.2±1.1y | 1) Bone mineral density and content;<br>2) Muscle endurance;<br>3) Physical activity;<br>4) Quality of life: SRS-22r | The present results provided some evidence to support the positive benefits of home-based exercise for bone health and muscle function in AIS girls. |
| **Kocaman (2021)[42]** | N=28;<br>Age =10-18y;<br>Cobb angle: 10-26°; | I: SSE (Schroth):<br>n=14;<br>Average Cobb angle=17.64±4.01°(T), 15.80±3.42°(L);<br>Average age=14.07±2.37y<br>II: CS:<br>n=20;<br>Average Cobb: 17.29±3.45°(T), 15.17±4.02°(L);<br>Average age=14.21±2.19y | 1) Cobb angle；<br>2) ATR;<br>3) Quality of life: SRS-22 | Schroth exercises are more effective than core stabilization exercises in the correction of scoliosis and related problems in mild adolescent idiopathic scoliosis, and core stabilization exercises are more effective than Schroth exercises in the improvement of peripheral muscle strength. |

**AIS: Adolescent idiopathic scoliosis, TE: traditional exercise, SSE：Scoliosis specific exercise, PedsQoL: Pediatric quality of life, SAQ: Spinal appearance questionnaire, TCM: Traditional Chinese medicine, VC: Vital capacity, $FEV_1$: Forced expiratory volume in the first second, FVC: Forced vital capacity, AEMG ratio: Average EMG ratio, ATR: Angle of trunk rotation, TAPS: Trunk Appearance Perception Scale, SRS-22: Scoliosis research society-22 questionnaire, BrQ: Brace Questionnaire; WBV: Whole body vibration, BST: Biering-sorenson test, CS: Core stabilization exercise, SEAS: Scientific exercises approach to scoliosis, TLSO: Thoracolumbosacral orthosis, AT: Aerobic training.**

### 2.3.2 Literature quality scores

The randomized allocation method was described in all the included studies. Eight studies[13,28,30,31,35-37,40] reported the allocation concealment method. Due to the particularity of the intervention methods, only four studies[13,28,34,35] blinded the patients. However, in 8 articles[13,29,32,34,36,37,39,40], evaluators were blinded. 11 articles[13,23,28,29,31,32,34-37,39] reported complete data, while 12 articles[13,23,28,30,32-39] could not interpret the existence of selective reporting bias. The detailed risk assessment results of the included studies were shown in **Figure 2-2, Figure 2-3**. The quality of the included studies was rated using the Delphi checklist, and the overall quality was acceptable (average score was 5.2). A total of 12 articles[13,28,30,31,34-37,39-41,45] scored ≥5 points and were rated as "high quality" according to the previous standards. The detailed Delphi list score were shown in **Table 2-2**.

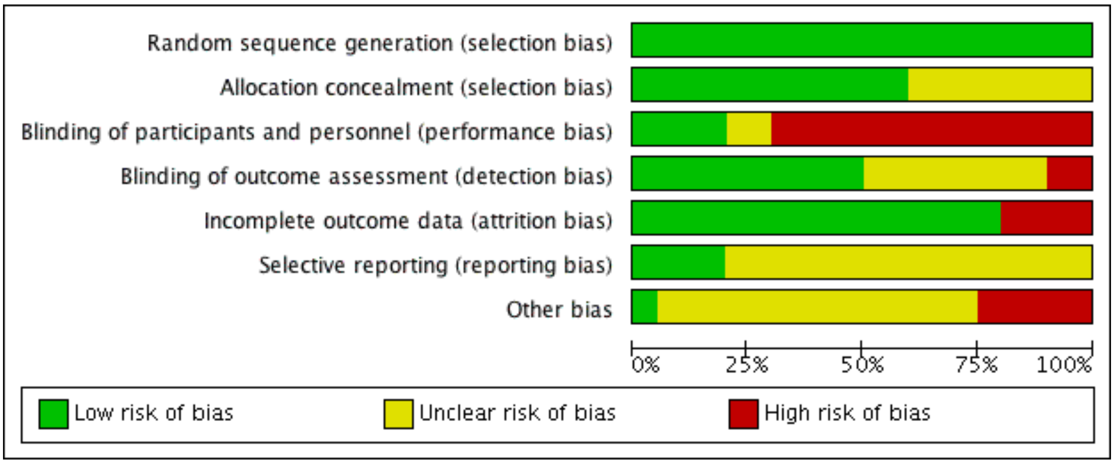



**Figure 2-2 "Risk of bias" summary of the included studies**

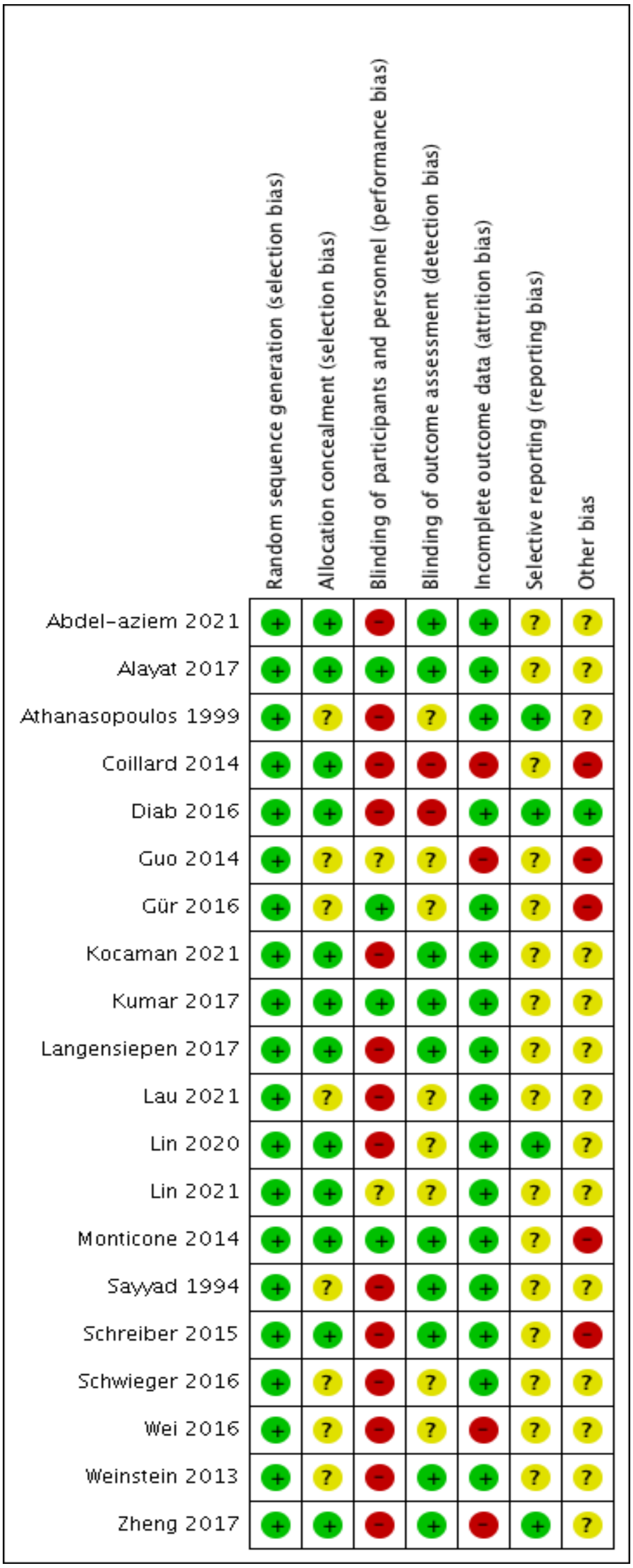



**Figure 2-3 “Risk of bias” summary of the included studies**

**Table 2-2 Delphi list score of the included studies**

| Study | Randomization | Concealed allocation | Baseline similarity | Eligibility criteria | Patient masked | Care provider masked | Outcome assessor masked | Data presentation | Intention-to-treat analysis | Total scores |
|---|---|---|---|---|---|---|---|---|---|---|
| **Sayyad (2009)[32]** | yes | unclear | unclear | yes | no | no | yes | yes | no | 4 |
| **Alayat (2017)[28]** | yes | yes | yes | yes | no | no | yes | yes | unclear | 6 |
| **Schwieger (2016)[37]** | unclear | unclear | yes | yes | no | no | unclear | yes | unclear | 3 |
| **Wei (2016)[38]** | yes | unclear | unclear | yes | no | no | unclear | yes | no | 3 |
| **Coillard (2014)[30]** | yes | yes | yes | yes | no | no | no | yes | yes | 6 |
| **Monticone (2014)[13]** | yes | yes | yes | yes | yes | no | yes | yes | unclear | 7 |
| **Kumar (2017)[35]** | yes | yes | yes | yes | yes | no | yes | yes | unclear | 7 |
| **Langensiepen (2017)[36]** | yes | yes | yes | yes | no | no | yes | yes | no | 6 |
| **Schreiber (2015)[37]** | yes | yes | yes | yes | no | no | yes | yes | yes | 7 |
| **Gür (2016)[34]** | yes | unclear | yes | yes | yes | no | unclear | yes | unclear | 5 |
| **Zheng (2017)[40]** | yes | yes | yes | yes | no | no | yes | yes | no | 6 |
| **Athanasopoulos (1999)[29]** | yes | unclear | yes | unclear | no | no | unclear | yes | unclear | 3 |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Diab (2016)[31]** | yes | yes | yes | yes | no | no | unclear | yes | unclear | 5 |
| **Guo (2014)[33]** | yes | unclear | yes | yes | no | no | unclear | yes | no | 4 |
| **Weinstein (2013)[39]** | yes | unclear | yes | yes | no | no | yes | yes | yes | 6 |
| **Lin (2020)[45]** | yes | yes | yes | yes | no | no | yes | yes | yes | 7 |
| **Abdel-aziem (2021)[41]** | yes | unclear | yes | yes | no | no | yes | yes | unclear | 5 |
| **Lin (2021)[44]** | yes | unclear | yes | yes | no | no | unclear | yes | unclear | 4 |
| **Lau (2021)[43]** | yes | unclear | yes | yes | no | no | unclear | yes | unclear | 4 |
| **Kocaman (2021)[42]** | yes | unclear | yes | yes | no | no | unclear | yes | unclear | 4 |

The included studies were not considered clinically comparable with regard to interventions, study populations, and treatment duration. Because of this heterogeneity, we refrained from statistical pooling, the results were reported qualitatively.

### 2.3.3 Comparison of the effects of different interventions on the Cobb angle of AIS patients

Many studies have reported the effects of orthoses and scoliosis specific exercise (SSE) on the Cobb angle correction. Of the 8 studies involving SSE, 5 studies[13,28,31,35,42] compared SSE with traditional exercise (TE). Despite differences in exercise regimens across the four studies, SSE was superior to TE in reducing patients' Cobb angle. 1 study[40] compared orthosis and SSE, and found that the correction effect of orthosis on Cobb angle was better than SSE. In addition, compared with traditional Chinese medicine (TCM) and observation, the correction effect of orthosis was also better[38]. However, another study[32] has compared the effects of orthosis, electrical stimulation and TE, and found no significant difference between the effects of orthosis and the other two interventions. In another study[34], core stabilization exercise (CS) was performed when wearing orthosis, and no additional Cobb angle correction was found compared with orthosis only. See **Table 2-3** for detailed comparison.

### 2.3.4 Comparison of the effects of different interventions on Angle of trunk rotation (ATR) of AIS patients

A total of 5 studies reported the effects of different interventions on ATR in patients with AIS, as shown in **Table 2-4**. The effect of SSE in reducing ATR of patients was better than that of orthosis (1 study)[40] and TE (3 studies)[13,31,42]. Another study[34] reported that CS, as an additional treatment for orthosis, was more effective than orthosis alone in reducing patients' ATR.

### 2.3.5 Comparison of the effects different interventions on preventing curve progression

A total of 3 studies have reported the effects of different interventions on preventing curve progression of patients with AIS, as shown in **Table 2-5**. Among them, two studies[30,33] compared Spinecor with observation, and the results all suggested that the effectiveness of Spinecor in preventing the progression of scoliosis was significantly better than observation. Another study[36] compared the combination of WBV and SSE with SSE alone, and found that there was no significant difference in preventing curve progression between two interventions.

**Table 2-3 Comparison of the effects of different interventions on the Cobb angle of AIS patients**

| Study | Interventions | Before treatment (°) Mean(SD) | | After treatment (°) Mean(SD) | | Differences between before and after treatment (°) Mean(SD) | | Comparative effect values among interventions SMD(95%CI) | Outcomes |
|---|---|---|---|---|---|---|---|---|---|
| Sayyad (1994) | I: Electrical simulation +TE; n=8 | 24.92 | 8.48 | 21.16 | 6.71 | 3.76 | 7.48 | I vs. II: -0.04(-1.02,0.94); II vs. III: 0.15(-0.79,1.08); I vs. III: 0.11(-0.82,1.04) | Electrical stimulation, Brace, and TE had no difference in the correction of Cobb angle. |
| | II: Brace +TE; n=8 | 25.65 | 7.95 | 21.60 | 6.08 | 4.05 | 7.20 | | |
| | III: TE; n=10 | 20.37 | 7.67 | 17.44 | 7.05 | 2.93 | 7.38 | | |
| Alayat (2017) | I: SSE; n=25 | 13.2 | 4.1 | 5.2 | 2.7 | 8 | 3.61 | I vs. II: 0.84(0.26,1.42); | SSE was superior to TE in reducing the patients' Cobb angle. |
| | II: TE; n=25 | 12.6 | 3.7 | 7.6 | 3.1 | 5 | 3.44 | | |
| Schwieger (2016) | I: Brace; n=64 | 29.7 | 4.7 | 31.9 | 10.3 | -2.2 | 8.93 | I vs. II: 0.83(0.47,1.19); | Brace was superior to observation in correcting the patient's Cobb angle. |
| | II: Observation; n=68 | 29.3 | 5.7 | 38.3 | 8.3 | -9 | 7.35 | | |
| Wei (2016) | I: TCM; n=58 | 30.4 | 3.8 | 12.0 | 2.5 | 18.4 | 3.35 | I vs. II: -1.69(-2.14, -1.25); | Brace was superior to TCM in correcting the patient's Cobb angle. |
| | II: Brace; n=49 | 31.6 | 3.1 | 7.9 | 0.8 | 23.7 | 2.79 | | |
| Monticone (2014) | I: SSE; n=55 | 19.3 | 3.9 | 14.0 | 2.4 | 5.3 | 3.41 | I vs. II: 2.37(1.88, 2.86); | SSE was superior to TE in correcting the patients' Cobb angle. |
| | II: TE; n=55 | 19.2 | 2.5 | 20.9 | 2.2 | -1.7 | 2.36 | | |
| Kumar (2017) | I: SSE; n=18 | 12.61 | 1.81 | 6.83 | 1.72 | 5.78 | 1.77 | I vs. II: 2.02(1.20, 2.84); | SSE was superior to TE in correcting the patients' Cobb angle. |
| | II: TE; n=18 | 12.72 | 1.40 | 9.67 | 1.32 | 3.05 | 1.36 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Langensiepen (2017) | I: WBV+SSE; n=20 | 30.1 | 9.0 | 27.8 | 10.5 | 2.30 | 9.84 | I vs. II: 0.28(-0.36, 0.92); | WBV+SSE were not superior to SSE alone in correcting patients' Cobb angle. |
| | II: SSE; n=18 | 29.65 | 8.7 | 30.01 | 9.0 | -0.36 | 8.85 | | |
| Gür (2016) | I: CS+ Brace; n=12 | 29 | 8.35 | 23.63 | 10.39 | 5.37 | 9.54 | I vs. II: 0.36(-0.43, 1.15); | CS+Brace were not superior to Brace alone in correcting patients' Cobb angle. |
| | II: Brace; n=13 | 34.33 | 9.9 | 32.63 | 10.2 | 1.70 | 10.05 | | |
| Zheng (2017) | I: SSE; n=29 | 27.03 | 3.57 | 24.79 | 4.36 | 2.24 | 4.02 | I vs. II: -0.86(-1.43, -0.29); | Brace was superior to SSE in correcting the patient's Cobb angle. |
| | II: Brace; n=24 | 28.00 | 3.60 | 22.13 | 4.78 | 5.87 | 4.31 | | |
| Diab (2016) | I: SSE; n=36 | 16.8 | 2.3 | 14.7 | 2.4 | 2.10 | 2.35 | I vs. II: 1.19(0.67, 1.70); | SSE was superior to TE in correcting patients' Cobb angle. |
| | II: TE; n=33 | 15.1 | 1.8 | 15.5 | 1.7 | -0.40 | 1.75 | | |
| Lin (2020) | I: PO; n=11 | 26.2 | 4.7 | 22.3 | 5.3 | 3.9 | 5.03 | I vs. II: 0.50(-0.33, 1.33) | PO was superior to CO in correcting patients' Cobb angle. |
| | II: CO; n=12 | 27.4 | 5.6 | 26.9 | 8.8 | 0.5 | 7.71 | | |
| Abdel-aziem (2021) | I: Hippotherapy+SSE; n=27 | 24.09 | 5.50 | 18.41 | 5.42 | 5.68 | 5.46 | I vs. II: 0.55(0.00, 1.11) | Hippotherapy+SSE was superior to SSE alone in correcting patients' Cobb angle. |
| | II: SSE; n=25 | 25.06 | 5.24 | 22.32 | 4.73 | 2.74 | 5.00 | | |
| Lin (2021) | I: 3O; n=11 | 31.7 | 6.0 | 29.6 | 7.0 | 2.10 | 6.56 | I vs. II: -0.20(-1.04, 0.64) | No significant difference was observed between the two groups in cobb angle correction. |
| | II: CO; n=11 | 29.8 | 4.4 | 26.3 | 7.9 | 3.5 | 6.86 | | |
| Kocaman (2021) | I: SSE; n=14 | 17.64 | 4.01 | 9.71 | 3.47 | 7.93 | 3.77 | I vs. II: 0.99(0.20, 1.78) | SSE was superior to CS in correcting patients' Cobb angle. |
| | II: CS; n=14 | 17.29 | 3.45 | 13.57 | 5.03 | 3.72 | 4.46 | | |

**AIS: Adolescent idiopathic scoliosis, SD: Standard deviation, SMD: Standardized mean difference, CI: Confidence interval, TE: traditional exercise, SSE:**

**Scoliosis specific exercise, TCM: Traditional Chinese medicine, WBV: Whole body vibration, CS: Core stabilization exercise, PO: Pressure-adjustable orthosis, CO: Conventional orthosis, 3O: 3D-printed orthosis**

**If the 95%CI of SMD contained 0, it was equivalent to P>0.05, indicating that there was no significant difference between the two interventions. On the contrary, if both the upper and lower limits of 95%CI were greater than 0 or less than 0, it was equivalent to P<0.05, indicating that there was a significant difference between the two interventions.**

**Table 2-4 Comparison of the effects of different interventions on Angle of trunk rotation (ATR) in patients with AIS**

| Study | Interventions | Before treatment (°) Mean(SD) | | After treatment (°) Mean(SD) | | Differences between before and after treatment (°) Mean(SD) | | Comparative effect values among interventions SMD(95%CI) | Outcomes |
|---|---|---|---|---|---|---|---|---|---|
| Monticone (2014) | I: SSE; n=55 | 7.1 | 1.4 | 3.6 | 1.1 | 3.5 | 1.28 | I vs. II: 2.5(2.01, 3.02); | SSE was superior to TE in reducing ATR of patients. |
| | II: TE; n=55 | 6.9 | 1.3 | 6.6 | 1.2 | 0.30 | 1.25 | | |
| Gür (2016) | I: CS+ Brace; n=12 | 7.67 | 3 | 3.78 | 3.23 | 3.89 | 2.09 | I vs. II: 2.5(2.01, 3.02); | CS+Brace was superior to Brace in reducing ATR of patients. |
| | II: Brace; n=13 | 10.27 | 6.43 | 8.18 | 4.77 | 2.09 | 2.02 | | |
| Zheng (2017) | I: SSE; n=29 | 8.62 | 2.24 | 7.31 | 1.44 | 1.31 | 1.97 | I vs. II: -0.39(-0.94, 0.15); | There was no significant difference between SSE and Brace in reducing ATR of patients. |
| | II: Brace; n=24 | 9.58 | 2.17 | 7.50 | 1.02 | 2.08 | 1.88 | | |
| Diab (2016) | I: SSE; n=36 | 7.4 | 1.2 | 6.2 | 1.5 | 1.20 | 1.37 | I vs. II: 0.83(0.34, 1.33); | SSE was superior to TE in reducing ATR of patients. |
| | II: TE; n=33 | 6.7 | 0.9 | 6.5 | 1.0 | 0.20 | 0.95 | | |
| Kocaman (2021) | I: SSE; n=14 | 8.71 | 2.37 | 3.64 | 1.91 | 5.07 | 2.18 | I vs. II: 0.94(0.15, 1.73); | SSE was superior to CS in reducing ATR of patients. |
| | II: CS; n=14 | 8.43 | 2.50 | 5.79 | 3.02 | 2.64 | 2.80 | | |

**AIS: Adolescent idiopathic scoliosis, SD: Standard deviation, SMD: Standardized mean difference, CI: Confidence interval, TE: traditional exercise, SSE: Scoliosis specific exercise, CS: Core stabilization exercise**

**If the 95%CI of SMD contained 0, it was equivalent to P>0.05, indicating that there was no significant difference between the two interventions. On the contrary, if both the upper and lower limits of 95%CI were greater than 0 or less than 0, it was equivalent to P<0.05, indicating that there was a significant difference between the two interventions.**

**Table 2-5 Comparison of the effects different interventions on preventing curve progression**

| Study | Interventions | Effective rate of treatment (%) | Comparative effect values among interventions RR(95%CI) | Outcomes |
|---|---|---|---|---|
| Coillard (2014) | I: Spinecor; n=32 | 65.63 | I vs. II: 0.38(0.21,0.71); | The effective rate of Spinecor in controlling the progression of scoliosis was significantly higher than observation. |
| | II: observation; n=36 | 25.00 | | |
| Langensiepen (2017) | I: WBV+SSE; n=20 | 95.00 | I vs. II: 0.94(0.77,1.13); | The effective rate of WBV+SSE in controlling the progression of scoliosis was not significantly different from that of SSE alone. |
| | II: SSE; n=18 | 89.00 | | |
| Guo (2014) | I: Spinecor; n=20 | 65.00 | I vs. II: 0.69(0.49,0.97); | The effective rate of Brace in controlling the progression of scoliosis was significantly higher than that of Spinecor. |
| | II: Brace; n=18 | 94.40 | | |

**AIS: Adolescent idiopathic scoliosis, SD: Standard deviation, RR: Relative risk, CI: Confidence interval, SSE: Scoliosis specific exercise, WBV: Whole body vibration**

**Treatment effective rate was defined as the number of patients with the Cobb angle reduction ≥5° or stable at ±5° after treatment/ the total number of patients receiving treatment; If the 95%CI of RR contained 1, it was equivalent to P>0.05, indicating that there was no significant difference between the two interventions. On the contrary, if the upper and lower limits of 95%CI were both greater than 1 or less than 1, it was equivalent to P<0.05, indicating that there was a significant difference between the two interventions.**

### 2.3.6 Comparison of the effects of different interventions on the appearance of AIS patients

A total of 4 studies have reported the effect of orthosis on the appearance of patients, and have drawn different conclusions. One of these studies[23] found that the impact of orthosis on the appearance of patients was not significantly different from observation. The other two studies have reported that the appearance score of patients with orthoses decreased significantly after wearing orthosis. Among them, one study[37] found that the combination of SSE on the appearance of patients who receiving SSE during orthosis was significantly better than that of orthosis alone, while another study[34] reported that there was no significant difference on the effect of the appearance of patients between the joint application of CS and orthosis and the orthosis alone. See **Table 2-6** for details.

### 2.3.7 Comparison of the effects of different interventions on AIS patients' quality of life

Eight studies reported the effects of different interventions on patients' quality of life. One of these studies[40] found that patients undergoing SSE had a better quality of life than those wearing orthoses. However, two other studies have found that[34,37], after adding SSE or CS, the quality of life of patients wearing orthoses does not significantly improve. Another study[23] reported that the impact of orthoses on the quality of life of patients had no significant difference when compared with observation. See **Table 2-7** for details.

### 2.3.8 Comparison of the effects of different interventions on cardiopulmonary function in patients with AIS

A total of three studies reported the effects of different interventions on patients' lung function. Among them, one study[38] compared the influence of traditional Chinese medicine and orthosis on the lung function of patients, and found that the static lung function of patients decreased when orthoses were prescribed, while TCM can significantly improve the static lung function of patients. In another study[29], Aerobic exercise (AE) was applied to patients receiving orthosis treatment, and it was found that the influence of the combination of AE and orthosis on patients' static lung function was not significantly different from that of orthosis alone, but the aerobic capacity which reflecting the dynamic cardiopulmonary function of patients was significantly better than that of patients receiving orthosis alone. Another study[13] compared SSE and TE, and found that patients in the SSE group had significantly better static lung function than those in the TE group.

### 2.3.9 Comparison of effects of different interventions on back muscle function in patients with AIS

One study[37] added SSE as an add-on means to the standard conservative treatment of AIS (including orthosis or meaningful observation), so that patients can obtain more significant improvement of back muscle endurance. Another study[38] measured and compared the average electromyogram (AEMG) of the muscle on the concave and convex sides of the spine of AIS patients receiving TCM or orthotic treatment. It was found that the average EMG ratio (AEMG ratio) of patients in the TCM group was closer to 1, while the AEMG ratio of patients in the orthosis group was much greater than 1.

**Table 2-6 Comparison of the effects of different interventions on the appearance of AIS patients**

| Study | Interventions | Before treatment Mean(SD) | | After treatment Mean(SD) | | Differences between before and after treatment Mean(SD) | | Comparative effect values among interventions SMD(95%CI) | Outcomes |
|---|---|---|---|---|---|---|---|---|---|
| Schwieger (2016) | I: Brace; n=64 | 17.6 | 4.8 | 17.6 | 5.0 | 0 | 4.90 | I vs. II: -0.34(-0.64,0.05); | There was no significant difference between Brace and observation in improving the appearance of patients. |
| | II: Observation; n=68 | 18.1 | 4.2 | 19.7 | 6.5 | -1.60 | 5.71 | | |
| Schreiber (2015) | I: SSE+Brace/Observation; n=25 | 2.71 | 0.9 | 2.84 | 0.95 | -0.13 | 0.19 | I vs. II: -1.71(-2.36, -1.05); | SSE+Brace/Observation was superior to Brace/Observation alone in improving the appearance of patients. |
| | II: Brace/Observation; n=25 | 2.64 | 0.9 | 2.44 | 0.95 | 0.20 | 0.19 | | |
| Gür (2016) | I: CS+ Brace; n=12 | 3.03 | 0.49 | 3.53 | 0.45 | -0.50 | 0.45 | I vs. II: 0.27(-0.52, 1.06); | There was no significant difference between CS+Brace and Brace alone in improving the appearance of patients. |
| | II: Brace; n=13 | 2.83 | 0.6 | 3.45 | 0.62 | -0.62 | 0.42 | | |
| Lin (2020) | I: PO; n=11 | 41.2 | 13.0 | 50.3 | 5.8 | -9.10 | 11.28 | I vs. II: -0.82(-1.60, -0.05); | PO was superior to CO in improving the appearance of patients. |
| | II: CO; n=12 | 46.6 | 9.5 | 47.3 | 5.8 | -0.70 | 8.29 | | |

**AIS: Adolescent idiopathic scoliosis, SD: Standard deviation, RR: Relative risk, CI: Confidence interval, SSE: Scoliosis specific exercise, CS: Core stabilization exercise, PO: Pressure-adjustable orthosis, CO: Conventional orthosis**

**If the 95%CI of SMD contained 0, it was equivalent to P>0.05, indicating that there was no significant difference between the two interventions. On the contrary, if both the upper and lower limits of 95%CI were greater than 0 or less than 0, it was equivalent to P<0.05, indicating that there was a significant difference between the two interventions.**

**Table 2-7 Comparison of effects of different interventions on AIS patients' quality of life**

| Study | Interventions | Before treatment Mean(SD) | | After treatment Mean(SD) | | Differences between before and after treatment Mean(SD) | | Effect size among interventions SMD(95%CI) | Outcomes |
|---|---|---|---|---|---|---|---|---|---|
| Schwieger (2016) | I: Brace; n=64 | 82.2 | 14.6 | 82.3 | 15.1 | -0.1 | 14.86 | I vs. II: -0.25(-0.60,0.09); | There was no significant difference between Brace and observation in improving patients' quality of life. |
| | II: Observation; n=68 | 83.4 | 12.6 | 79.8 | 15.4 | 3.6 | 14.21 | | |
| Schreiber (2015) | I: SSE+Brace/Observation; n=25 | 4.25 | 0.35 | 4.29 | 0.35 | -0.04 | 0.35 | I vs. II: -0.03(-0.58,0.53); | There was no significant difference between SSE+Brace/Observation and Brace/observation in improving patients' quality of life. |
| | II: Brace/ Observation; n=25 | 4.15 | 0.35 | 4.18 | 0.35 | -0.03 | 0.35 | | |
| Gür (2016) | I: CS+ Brace; n=12 | 3.98 | 0.5 | 4.26 | 0.36 | -0.28 | 0.45 | I vs. II: -0.61(-1.42,0.20) | There was no significant difference between CS+Brace and Brace alone in improving patients' quality of life. |
| | II: Brace; n=13 | 3.98 | 0.48 | 3.96 | 0.46 | 0.02 | 0.47 | | |
| Zheng (2017) | I: SSE; n=29 | 92.59 | 2.13 | 102.17 | 1.87 | -9.58 | 2.01 | I vs. II: -1.15(-1.73, -0.56) | SSE was superior to Brace in improving patients' quality of life. |
| | II: Brace; n=24 | 92.67 | 4.05 | 99.00 | 2.32 | -6.33 | 3.52 | | |
| Lin (2020) | I: PO; n=11 | 4.3 | 0.2 | 4.1 | 0.2 | 0.20 | 0.20 | I vs. II: 0.33(-0.50, 1.15) | There was no significant difference between PO and CO in improving patients' quality of life. |
| | II: CO; n=12 | 4.3 | 0.4 | 4.2 | 0.3 | 0.10 | 0.36 | | |
| Lin (2021) | I: 3O; n=15 | 4.5 | 0.2 | 4.1 | 0.6 | 0.40 | 0.53 | I vs. II: 0.7(-0.04, 1.44) | There was no significant difference between 3O and CO in improving patients' quality of life. |
| | II: CO; n=15 | 4.3 | 0.2 | 4.2 | 0.3 | 0.10 | 0.26 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Lau (2021) | I: SSE; n=13 | 4.40 | 0.25 | 4.31 | 0.23 | 0.09 | 0.24 | I vs. II: 0.08(-0.65, 0.81) | There was no significant difference between SSE and observation in improving patients' quality of life. |
| | II: Observation; n=16 | 4.27 | 0.40 | 4.21 | 0.45 | 0.06 | 0.43 | | |
| Kocaman (2021) | I: SSE; n=14 | 3.49 | 0.13 | 4.56 | 0.13 | -1.07 | 0.13 | I vs. II: -1.39(-2.23, -0.55) | SSE was superior to CS in improving patients' quality of life. |
| | II: CS; n=14 | 3.48 | 0.24 | 4.30 | 0.17 | -0.82 | 0.21 | | |

**AIS: Adolescent idiopathic scoliosis, SD: Standard deviation, RR: Relative risk, CI: Confidence interval, SSE: Scoliosis specific exercise, CS: Core stabilization exercise, PO: Pressure-adjustable orthosis, CO: Conventional orthosis, 3O: 3D-printed orthosis**

**If the 95%CI of SMD contained 0, it was equivalent to P>0.05, indicating that there was no significant difference between the two interventions. On the contrary, if both the upper and lower limits of 95%CI were greater than 0 or less than 0, it was equivalent to P<0.05, indicating that there was a significant difference between the two interventions.**

## 2.4 Discussion

This study reviewed and compared the effects of various conservative treatments for AIS on patients' spinal deformity, appearance, cardiopulmonary function, quality of life and muscle function, etc., The results were analyzed based on the quality and the outcome of the included studies, which were discussed in terms of different interventions.

### 2.4.1 Orthoses

A total of 20 randomized controlled studies were included in this scoping review, 10 of them involved comparison of the efficacy of orthoses. It can be seen that orthoses were still the most studied and widely prescribed conservative treatment for patients with AIS in the world. Since 1945, when Blount et al.[46] first applied Milwaukee orthoses instead of plaster as a corrective device for further treatment after spinal fusion, the efficacy of spinal orthoses in the treatment of scoliosis has been controversial until the last 40 years. It was only in recent years that Weinstein et al.[39] published a landmark high-quality RCT study. The study confirmed that wearing orthosis significantly reduced the progression of high-risk curves to the threshold for surgery, compared to observations that represented the natural progression of scoliosis. Similar results were also reported in one of this review included studies[23]. However, due to the short observation period, this study only compared the effect of orthosis and observation on patients' Cobb angle, and reported that the orthotic group obtained greater Cobb angle correction.

There were various types of orthoses, commonly include Cheneau, Charleston, Milwaukee, Spinecor, etc., which were different in material, production method, the time of wearing and mechanism of action[47-50]. The clinician prescribed the appropriate orthosis according to the patient's scoliosis type, compliance and other conditions. It should be clear, however, that not all orthoses were equally effective in reducing spinal curvature. There was still a lack of high quality research on the comparison of the efficacy of different orthoses. Only one RCT study[33] was included in this review comparing the treatment effects of different types of orthotic devices, and it was found that the progression rate of scoliosis after wearing Spinecor was significantly higher than that of rigid brace. Moreover, the progression of scoliosis could be effectively controlled after changing to rigid brace for patients with progression of more than 5° after wearing Spinecor. But with a Delphi quality score of only 4, the reliability of the evidence has been questioned.

Two of the included studies compared orthoses with other interventions. Sayyad et al.[32] compared the effects of electrical stimulation, orthoses and traditional exercise (TE)on patients' spinal deformity, and found that all the three could effectively reduce patients' Cobb angle, but the difference among the three was not statistically significant. The small sample size (8 people per group) and short observation time (12 weeks) in this study may have a negative impact on the reliability of the study conclusions. Another high-quality study[40] (Delphi score 6) compared the effect of 12 months of orthoses treatment with SSE on spinal deformities of patients with AIS and found that the orthoses group achieved higher Cobb angle correction. However, the corrected Cobb angle absolute value of patients in both groups was less than 5°, not reaching the Minimal clinically important difference (MCID), which would reduce the validity of the conclusion to some extent[47]. It was suggested that long follow-up until children skeletal maturation were needed for future studies, and using the effective rate of treatment or the incidence of surgery as outcome measures when comparing the effectiveness of different interventions in the treatment of AIS.

Recent studies paid more attention to the effects of orthoses on patients' spinal deformity, which reflected that clinicians' treatment concept for AIS still regarded avoiding or at least limiting the progression of scoliosis during the period of growth puberty in adolescent as the primary target, but ignored the possible negative influences happened in the course of treatment such as appearance, psychology, cardiopulmonary function, and the quality of life issues. Among the studies included in this review, 2 studies reported the effects of orthoses on patients' appearance, 4 studies reported their effects on patients' quality of life, and only 3 studies reported their effects on patients' lung function. In terms of appearance, both studies found that wearing brace did not decrease patients' appearance, and that some patients' appearance scores even increased after wearing brace. The present study suggested that the improvement in the patient's appearance score was associated with the reduction in spinal deformity after receiving orthotic intervention. The assessment of AIS patients' quality of life involved multiple aspects. For example, SRS-22 questionnaire that commonly used for scoliosis patients contained five aspects including pain, function, appearance, treatment satisfaction and mental health. Zheng et al.[40] used the SRS-22 questionnaire to evaluate the quality of life of adolescent with idiopathic scoliosis who received orthotic intervention, and found that the overall quality of life score, function score and treatment satisfaction score of patients were significantly improved, but the score of mental health was significantly decreased. The result can be explained as severe psychological burden was often associated with patients when orthoses were prescribed. especially for adolescents, whose sensitivity to orthoses was even greater than that of spinal deformity itself[51]. The effect of orthotic intervention on patients’ cardiopulmonary function has received less attention, but should not be ignored. The study that Wei et al.[38] conducted found that $FEV_1$ and FVC, the main indicators reflecting patients' lung function, decreased to varying degrees after orthoses were prescribed, which may be related to the restriction of thoracic activity and respiratory movement caused by orthoses[17]. Although there were no obvious symptoms of abnormal breathing occurred at the initial stage, the above abnormalities may be further aggravated with long-term orthotic intervention, and even lead to adverse consequences such as decreased lung elastic recoil and weakness of respiratory muscles[52]. To sum up, with concern for the correction of spinal deformity, we also need to pay more attention to the psychological, appearance, lung function and other influences that may occur in the process of orthotic intervention.

### 2.4.2 Scoliosis specific exercise (SSE)

SSEs differed from general physiotherapy, which included a series of individualized exercise programs with a therapeutic aim of reducing spinal deformities or controlling the progression of scoliosis[53]. At present, there is no general agreement relating to the effectiveness of SSE in the treatment of adolescent idiopathic scoliosis. A systematic review in 2008 indicated that SSE was effective in the treatment of adolescent idiopathic scoliosis[54]. But another Cochrane systematic review published in 2012 concluded that there was insufficient evidence to support the use of SSE in the treatment of AIS[55]. The reasons for the different conclusions may be related to different types of SSE methods were performed in the two systematic reviews, and the heterogeneity among different SSEs affected the final results. According to the latest the International Society on Scoliosis Orthopedic and Rehabilitation Treatment (SOSORT) guideline[56], SSE was mainly applied in the following three situations: 1) as a primary intervention performed in patients with mild AIS (Cobb angle 10-25°); 2) as an add-on treatment to improve the therapeutic effect of orthoses, meanwhile, prevent or treat possible pulmonary dysfunction, lumbar and back pain, and improve patients' appearance through postural correction[56,57]. 3) to reduce back pain, abnormal breathing and other problems that may occur in adult patients with scoliosis[58]. However, these recommendations were mainly based on observational studies or experts' opinions, and no relevant RCT studies have been retrieved in this review. Therefore, high quality RCT studies should be carried out in the future to further confirm the effectiveness of the integration of SSE and orthotic intervention in the treatment of AIS.

When compared with other interventions, SSEs could not take the place of orthoses in the correction of spinal deformity, especially for AIS patients with moderate or severe curvatures (Cobb angle greater than 25°). Zheng et al.[40] compared the treatment effects of SSE with rigid brace in patients with moderate AIS and found that patients in the orthosis group had a better correction in parameters of spinal deformity and body symmetry, but SSE was significantly better than orthosis in improving patients' quality of life, especially in terms of functional and mental health status. In addition, four of the included studies compared the therapeutic effects of SSE with traditional exercise. Although diverse exercise methods were performed in different study, all studies reported that SSEs were superior to traditional exercise in Cobb angle correction. Traditional exercise was usually performed to reduce spinal flexibility, muscle strength and endurance, rather than specifically designed to reduce spinal deformities. It has been suggested that traditional exercise is ineffective for AIS treatment[55].

### 2.4.3 Traditional Chinese medicine (TCM)

One study included in this review investigated the effects of TCM and orthoses in the treatment of adolescent idiopathic scoliosis, both of which can significantly reduce patients' spinal deformity[38]. Although the degrees of Cobb angle correction were much lower than orthosis, TCM can significantly improve lung function of AIS patients. The study also measured and compared the average electromyography (AEMG) values of the muscles on both sides of the spinal curvature, and found that AEMG ratio of concave/convex side was closer to 1 in the TCM group after treatment. This could be explained as the correction of TCM on spinal curvature may through balancing paraspinal muscle activity. TCM can not only correct spinal deformities, but also improve the lung function and balance of the muscles on both sides of the spinal curvature, which provided a new strategy for conservative management of patients with AIS. Traditional Chinese medicine, mainly including acupuncture and tuina (massage), was widely performed in the treatment of lumbar and back diseases, especially in the mainland China. In the retrieval of literatures, we also found some studies about the treatment of adolescent idiopathic scoliosis with traditional Chinese medicine methods such as acupuncture and tuina (massage). However, as most of them were observational studies and the study design often had certain defects, high quality RCT studies were required to further confirm the therapeutic effect of TCM on AIS[9].

### 2.4.4 Other intervention measures

There was no sufficient evidence to support the effectiveness of electrical stimulation in the treatment of adolescent idiopathic scoliosis[59]. Chiropractic therapy and traditional exercise were also considered to have no significant effect on AIS[60].

**2.4.5 Limitations**

This review had the following limitations: 1) There was great clinically heterogeneity among the included studies, statistical pooling was not undertaken, and some of the studies with low power and methodological quality. Therefore, it was impossible to draw firm conclusions regarding the effectiveness of conservative treatments for patients with AIS. 2) Most of the included studies did not report the patient compliance, as we all known compliance had an important impact on the results of the study. 3) The sample size of the included studies was low in general, which affected the reliability of the results to certain extent.

## 2.5 Conclusion

(1) Regardless of its types, orthosis was more effective than other conservative treatments in reducing spinal deformity, although more high-quality studies were required to consolidate this conclusion.

(2) Scoliosis specific exercises showed benefits in patients with mild scoliosis, the effectiveness of the combination of scoliosis specific exercise with orthosis was lack of scientific evidence from randomized controlled studies.

(3) Traditional Chinese medicine could correct spinal deformities and balance the muscles on both sides of the spinal curvature, which provided a new strategy for conservative management of patients with AIS.

(4) In addition to spinal deformity, more attention should be paid to the impacts of conservative treatments on patients’ appearance, mental health, cardiopulmonary function as well as the quality of life of patients with AIS.

(5) Methodological weaknesses existed in the current studies relating conservative treatments for AIS. High quality studies with well-designed and long follow-up were required to evaluate the effectiveness of different conservative treatments for AIS.

# CHAPTER 3 THE EFFECTIVENESS OF SCOLIOSIS SPECIFIC EXERCISE COMBINED WITH ORTHOSIS ON PATIENTS WITH ADOLESCENT IDIOPATHIC SCOLIOSIS: A RANDOMIZED CONTROLLED TRIAL STUDY

## 3.1 Introduction

Adolescent idiopathic scoliosis (AIS) is a complex three-dimensional deformity of the spine and trunk that occur in adolescents with unknown etiology[61]. As defined by the Scoliosis Research Society (SRS), Scoliosis can be diagnosed in a standing posterior-anterior radiograph with a Cobb angle of greater than 10 degrees. It has been reported that the incidence of AIS in the general population is about 0.9%-12%, with a higher incidence in girls than boys[62]. If spinal deformity is not intervened in time, it tends to further deteriorate, leading to back pain, cardiopulmonary dysfunction, limited participation in activities and mental health problems in adolescents[63-66].

Due to the etiology and pathogenesis of AIS are still unclear, there are no specific and effective interventions in preventing or reversing the progression of spinal curvature. The intervention decision is made mostly based on the severity of spinal deformity and the risk of progression, mainly including conservative treatment and surgical treatment. Surgical correction is usually recommended for a small number of adolescents in growth period with Cobb angle greater than 45 degrees, while most patients with AIS receive conservative treatment with the goal to prevent and slow down the progression of scoliosis[67].

When patients with spinal deformities greater than 25° and still have significant growth potential, orthotic intervention is recommended. Wearing orthoses as an important conservative intervention in the treatment of adolescent idiopathic scoliosis has a history of more than 50 years. Based on the three-point force principle, orthoses can produce external forces acting on the apical vertebrae and the top and the lower ends of deformed spine to control the progression of scoliosis, which works mainly through reducing asymmetric load of the vertebral body and improving neuromuscular control of paraspinal muscles[62,68]. There are various types of orthoses applied to patients with

AIS, which are different from diverse materials, casting methods, the time of wearing and mechanism of action[47,48,50,69,70]. It should be clear that different types of orthoses have different therapeutic effects in the management of AIS.

Thoracic lumbosacral orthosis (TLSO) is one of the most frequently prescribed orthoses for adolescent with idiopathic scoliosis, although its therapeutic efficacy has been debated. Until recently, a randomized controlled trials (RCT) study published in the New England Journal, reported that wearing TLSO significantly reduced the progression of high-risk curves to the threshold of surgery compared with observation without special intervention[47]. The study reported the effective rate of TLSO was 72%, suggesting that still a proportion of patients required surgical correction even wearing orthoses. On the other hand, in order to ensure the therapeutic effects, the orthosis was generally suggested to wear throughout the day (>23h/d) for 2-3 years until the bone maturity of the patients, which may inevitably lead to some adverse effects: the long-term orthotic intervention may limit the trunk activity resulting in the decreased strength of back muscles, and its rigidity may also restrict the thoracic movement leading to cardiopulmonary dysfunction, skin damage and low back pain, etc.[71,72].

Scoliosis specific exercise (SSE), as another conservative treatment for AIS, is mostly applied in Germany, Italy and other European countries[73]. In contrast to general physical exercise, SSE includes a series of individually adapted postural correction trainings that are tailored specifically to reduce spinal deformity. The exercises work mechanically by instructing patients how to self-correct abnormal postures in daily activities to restore their spine upright[74]. Currently, there are a variety of SSEs used in the management of patients with AIS, such as Schroth, Scientific Exercises Approach to Scoliosis (SEAS), Lyon etc.[74-76]. An increasing number of studies have reported that SSE is effective in controlling the progression of spinal deformity[54,77,78]. In addition, some experts and scholars have demonstrated that the positive outcomes of SSE on improving the pulmonary function and back muscle function of the patients receiving orthotic intervention[54,79]. SSE was therefore recommended by the International

Society on Scoliosis Orthopedic and Rehabilitation Treatment (SOSORT) guidelines as an add-on treatment for patients under orthotic intervention (OI), not only to enhance the effectiveness of OI but also to prevent or treat the adverse effects caused by long-term OI[67]. However, these recommendations were mostly based on observational studies or experts' opinions. To date there have been no RCT studies that have provided high-level of evidence supporting the clinical application of SSE combined with orthotic intervention. Therefore, we conducted a randomized controlled trial study to investigate: 1) whether the integration of SSE and OI would achieve better correction of spinal deformity than orthosis alone in the management of patients with AIS. 2) whether SSE during OI would reduce the negative effects of OI on back muscle endurance and cardiopulmonary function of patients with AIS.

According to the latest SOSORT guidelines, the basic goals of conservative treatment for adolescent idiopathic scoliosis were as follows: to stop or possibly even reduce curve progression at puberty; to prevent or treat respiratory dysfunction; to prevent or treat spinal pain syndromes; to improve aesthetics via postural correction[80-82]. Previous studies have pay more attention to the effectiveness of conservative treatments in correcting spinal deformity, but their effectiveness on patient-centered outcomes (i.e. aesthetics, pain, disability and quality of life) have rarely been evaluated and reported. Therefore, this study also 3) to investigate the influence of SSE combined with OI on the quality of life of AIS patients.

## 3.2 Materials and Methods

### 3.2.1 Study design

This was a prospective randomized controlled trial study comparing the effectiveness of the integration of SSE and orthotic intervention versus orthosis alone in the management of patients with AIS, which was confirmed to all consolidated standards of reporting trials guidelines and reported the required information accordingly.

### 3.2.2 Subjects

The patients who fulfilled the subject selection criteria of the Scoliosis Research Society for orthotic intervention[83] were enrolled from Wuxi Rehabilitation Hospital from March 2017 to December 2018. This randomized controlled trial study was approved by the Chinese Clinical Trial Registry (Granted Number ChiCTR1800014730) and approved by its Ethics Committee prior to the commencement of patient recruitment. The clinician introduced the purpose and study plan to the subjects and their guardians in detail. After the eligible subjects agreed to participate, their guardians signed the information sheets and consent forms (**See Appendix II-V**).

### 3.2.3 Inclusion and exclusion criteria

#### 3.2.3.1 Inclusion criteria

1) Age: above 10 years of age;

2) Cobb Angle: 25°-40°;

3) Risser grade: 0,1 or 2;

4) Female with premenarchal or less than 1-year postmenarchal.

#### 3.2.3.2 Exclusion criteria

1) Congenital scoliosis or secondary scoliosis due to other diseases;

2) Contraindications to exercise (such as cardiopulmonary disease, systemic infections, uncontrolled metabolic diseases, psychological diseases and neuromuscular diseases, etc.);

3) Received other treatments prior to initial diagnosis.

### 3.2.4 Sample size calculation

Sample size was calculated with G-Power software using a priori power analysis, with power set at 0.80, type 1 error rate $\alpha$=0.05, and an effect size *d* value of 0.8, on the basis of Cobb angle correction of OI referred from the previous literature[40]. The estimated sample size would be 21 participants per groups. Based on previous OI research experience, a total of 50 patients need to be recruited, with 25 subjects per groups for allowing 20% loss in follow-up visits.

### 3.2.5 Randomization and blinding assessment

Subjects were randomly allocated to the orthosis combined with exercise (OE) group or the orthotic intervention only (OI) group in the ratio of 1:1. The randomization sequence was generated using a computer program. The allocation information was sealed in the envelopes and given to special person in charge. Once a patient consented to participate in, an individual administrator opened the envelopes in sequence and then informed the doctor with the allocated treatment regimen. Due to the particularity of the intervention, the patients, the orthotists and physical therapists who performing the intervention were not blinded. However, the investigators who performed evaluation and analyzed data were blinded.

### 3.2.6 Interventions

#### 3.2.6.1 Intervention for the OI group

At the first visit, patients assigned to the OI group were prescribed with a rigid thoracolumbosacral orthosis (TLSO) (**Figure 3-1A**, **Figure 3-1B**). The rehabilitation physician and the orthotist worked together to assess each patient, and an orthosis was fabricated for the patient individually. In order to ensure optimum correction and wearing comfort, the patients were invited to the hospital for orthosis checking and modification at the first month of intervention and then every three months. (**Figure 3-2**) The orthosis was adjusted according to the correction of spinal curvatures or replaced if needed. Subjects were requested to wear orthosis 23 hours per day and 1 hour for personal hygiene and basic exercise activities. For compliance monitoring, log sheets were provided to the subjects and their parents for recording their wearing time in daily basis. In addition, interview for compliance was launched when the subjects came to hospital for follow-up visits.

**Figure 3-1A Front view of patient prescribed with an orthosis**

**Figure 3-1B Back view of patient prescribed with an orthosis**

#### 3.2.6.1.1 Evaluation of the effectiveness of orthosis

The orthotist evaluated the effectiveness of orthotic intervention through examining: the correction of Cobb angle on the X-ray before and after wearing the orthosis; the correction of spinal rotation angle by X-ray before and after wearing the orthosis; the improvement of flat back before and after wearing the orthosis; the relation between the height of the pressure pad and the top vertebra of spinal curvature, whether the pressure on the spinous process was balanced; and whether there was a deviation of the 7th thoracic vertebra when the patients in a standing position.

**Figure 3-2 Evaluation and adjustment of the orthosis by an orthotist**

### 3.2.6.2 Intervention for the OE group

In addition to wearing orthoses, scoliosis specific exercise was also required for patients in the OE group. The exercise protocol adopted in this study based on Scientific Exercise Approach to Scoliosis (SEAS)[75,84-86], which was an evidence-based individualized physiotherapy whose core guiding principle was "active self-correction". Before performing exercise, subjects in the OE group were systematically evaluated by the rehabilitation physicians and physical therapists, then the specific exercises were prescribed according to patients' individual conditions. The main contents of SEAS program included: active self-correction exercise (coronal plane, sagittal plane and horizontal plane), muscle endurance exercise, balance exercise, respiratory exercise, aerobic exercise, etc. The detailed SEAS protocol used in the current study was shown in **Appendix VI**. The specific implementation of SEAS was divided into three parts: 1) Patients attended a single session of 1.5 hours once a month at the hospital. Therapists specialized in SEAS assessed patients periodically, adjusted the exercise content, and guided the core postural correction strategies in active self-correction, spinal stabilization exercise and daily activities; 2) According to the content of the above course, patients were required to complete a daily 10-15 minutes home exercise session, which was the self-postural correction exercise in daily activities; 3) In addition, patients needed to undergo 40 minutes clinical treatment per week , that is, postural correction and other exercise contents should be completed under the guidance of physical therapists.

### 3.2.7 Assessments

#### 3.2.7.1 Measurement of Cobb angle

The severity of spinal deformity in coronal plane was assessed by measuring the Cobb angle on the patient's anteroposterior or posteroanterior X-ray radiograph. When measuring the spinal curvature, the apical vertebra (apical vertebra is the vertebra most deviated laterally from the vertical axis that passes through the patient's sacrum) was first identified. This was the most likely displaced and rotated vertebra with the least tilted endplate. The end vertebrae were then identified through the curve above and below. The end vertebrae were the most superior and inferior vertebra which were least displaced and rotated and had the maximally tilted endplate. A line was drawn along the upper endplate of the upper end vertebra and a second line was drawn along the lower endplate of the lower end vertebra. The angle between these two lines or lines drawn perpendicularly to them was measured as the Cobb angle. (**Figure 3-3**)

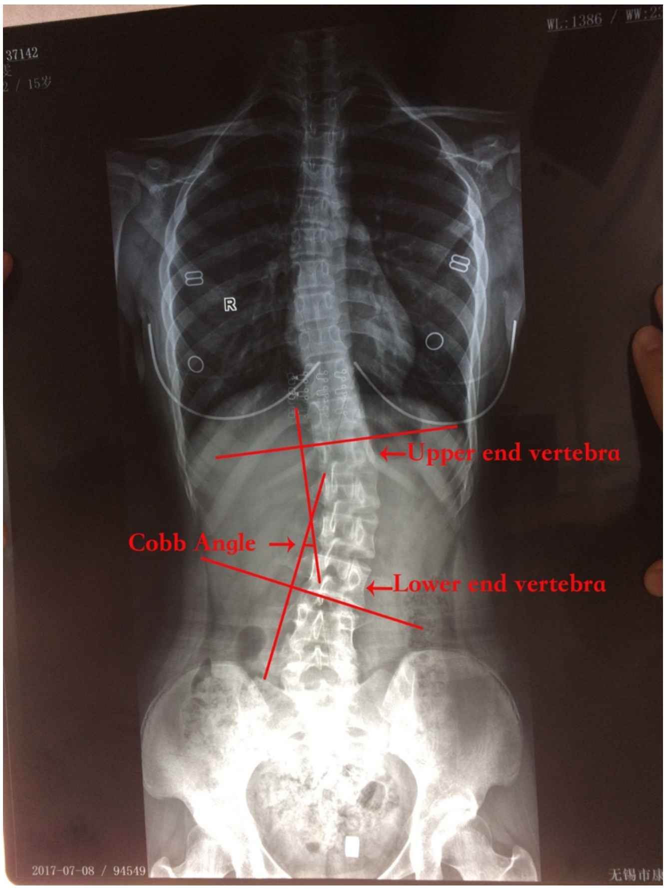



**Figure 3-3 Measurement of Cobb angle**

#### 3.2.7.2 Measurement of angle of trunk rotation (ATR)

The angle of trunk rotation was measured using a scoliometer. The patient was required to take off his\her clothes to expose the back, close the feet, unbend knees, bend forward and two arms hang down after unbending. The evaluators stood behind the patients carefully observe the back in order to find out the most protruding part located in the unequal height on both sides of the back, and put the scoliometer vertically on the site to let zero calibration align with spinous process, and then the angle of trunk rotation was measured. (**Figure 3-4**)

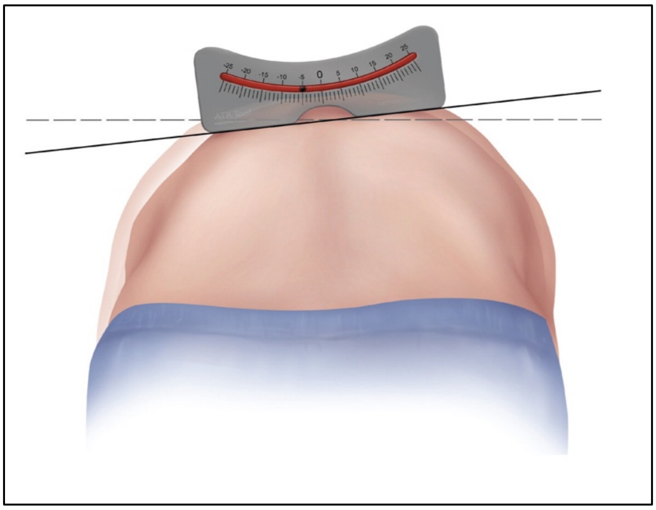


**Figure 3-4 Measurement of Angle of trunk rotation**

### 3.2.7.3 Assessment of back muscle endurance

Back muscle endurance was assessed with the Biering-Sorensen test (BST). The detailed method as follows: The patients laid on the examining table in the prone position with the upper edge of the iliac crest in alignment with the edge of the table. The lower body was fixed with three straps, which were located around the pelvis level, the knee level, and the ankle level, respectively. The patients were asked to hold on the upper body in a horizontal position with hands crossed over the chest. (**Figure 3-5**) The time the patients could hold the horizontal position was recorded. Longer hold time would indicate better back muscle function.

**Figure 3-5 Assessment of back muscle endurance by Biering-Sorenson test**

#### 3.2.7.4 Assessment of cardiopulmonary function

The cardiopulmonary function of the patients was evaluated using the MasterScreen™ CP system (Yeager, Germany). The patients were requested to remove the orthoses and heavy clothing for at least two hours before the cardiopulmonary function test, and the test room was required to keep quiet, appropriate humidity and temperature. Before the test, the relative parameters of the instrument were debugged and calibrated to ensure the reliability and validity of test results. The cardiopulmonary function assessments of the patients included two parts: the static pulmonary function and the dynamic cardiopulmonary function.

##### 3.2.7.4.1 Assessment of static pulmonary function

Before the test, the patients were introduced the detailed test process to help them master the right method of breathing. During the test, the patients should remain in a sitting position with feet on the ground, chest straight and not leaning against the back of the chair (**Figure 3-6**). The test method and process were carried out in strict accordance with the description of pulmonary volume examination in the Chinese Guidelines for Pulmonary Function Examination[87]. The main outcome measurements included forced expiratory volume in the first second ($FEV_1$), forced vital capacity (FVC), and $FEV_1$/FVC %

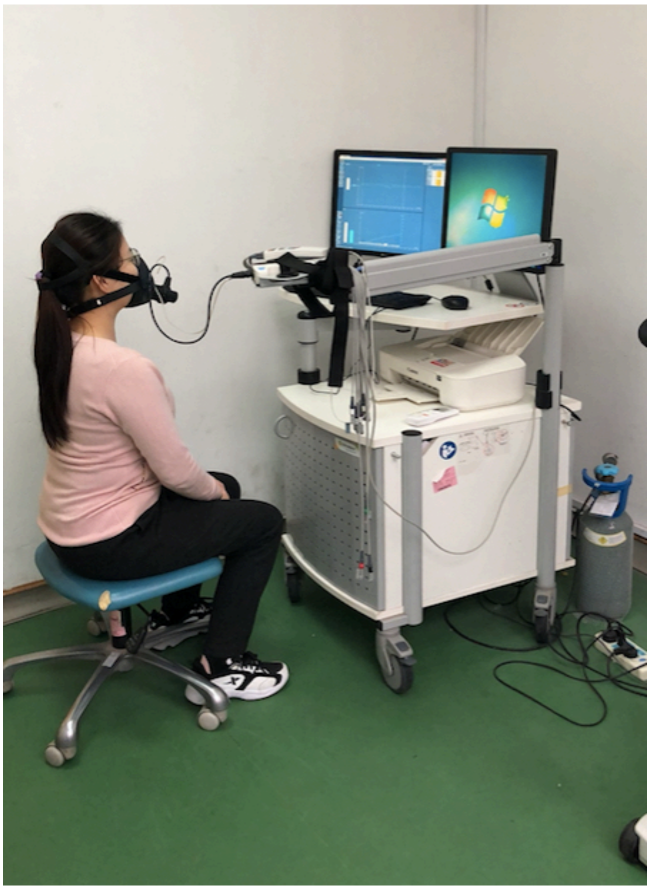


**Figure 3-6 Assessment of static pulmonary function**

**3.2.7.4.2 Assessment of dynamic cardiopulmonary function**

The dynamic cardiopulmonary function of the patients was assessed through the cardiopulmonary exercise testing (CPET) using bicycle ergometer (**Figure 3-7**). The test protocol was conducted according to guidelines on CPET from the American Thoracic Society (ATS) and American College of Chest Physicians (ACCP)[88]. After completing the 3-minute zero-load warm-up period, the load of the bicycle increased at a rate of 10,15 or 20W/ min (adjusting according to actual condition of the patients), and the patients needed to keep the bicycle speed stable at 55-60 RPM during this stage. When the patients reached a predetermined heart rate or presented intolerable symptoms, the load gradually decreased until the end of the test. During the whole process, the patients' vital signs such as electrocardiogram activity and blood pressure fluctuation were monitored. Maximal oxygen uptake ($VO_{2max}$), ventilatory equivalent of $CO_2$ ($VE/VCO_2$) and oxygen absorption per heartbeat ($O_2$/pulse) were measured.

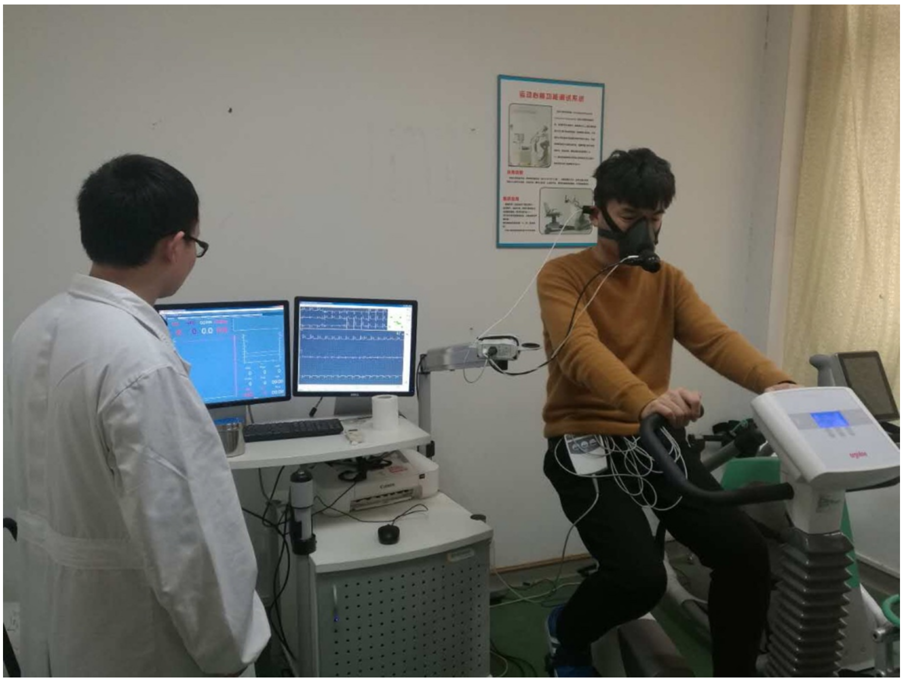


**Figure 3-7 Assessment of exercise cardiopulmonary function**

#### 3.2.7.5 Assessment of health-related quality of life (QoL)

This study used the simplified Chinese version of Scoliosis Research Society-22 questionnaire (SRS-22 questionnaire) to evaluate the health-related quality of life (QoL) of patients with AIS[89]. The SRS-22 questionnaire was consisted of 22 questions evaluating five dimensions: function, pain, self-image, mental health and satisfaction. Each question was scored from 1 (worst) to 5 (best). The score for each dimension was the average of the scores for all questions in that dimension. (see **Appendix VII&VIII**)

#### 3.2.7.6 Assessment time points

All patients were evaluated at baseline, after 6 months intervention and after 12 months intervention.

### 3.2.8 Treatment compliance recording

The parents were required to supervise children to wear the orthosis in accordance with the required time, truthfully record the children's actual time of orthosis wearing, and reported to the doctor at the follow-up visits. A treatment log was established to record the actual exercise time of patients in the hospital and at home. Compliance was calculated as actual exercise training time/prescribed exercise training time (%) or actual orthosis wearing time/prescribed orthosis wearing time (%).

### 3.2.9 Statistical analysis

According to Shapiro-Wilks test results, the age, height, weight, BMI and Cobb angle of the patients showed normal distribution. Therefore, independent sample *t* test was used to compare the above demographic characteristics of the patients. The main outcome measurements in current study were all continuous variables and showed normal distribution, therefore, the independent sample *t* test was used for inter-group comparison. Intragroup comparisons were carried out with one-way repeated analysis of variance across three time points. Post hoc tests were conducted with Bonferroni method. The Statistical significance was set at $p<0.05$. All the statistical analyses were conducted using the SPSS 22.0 software (IBM Corporation, USA)

## 3.3 Results

### 3.3.1 Patients participating in the study

There were 86 patients with AIS visited the hospital during the study, 20 of whom refused to participate in the study, 16 of whom did not meet the inclusion criteria and were excluded, and finally a total of 50 patients were enrolled. Patients were randomly assigned to either the orthotic intervention (OI group, n=25) or the orthosis combined with exercise (OE group, n=25). Throughout the whole study, 3 patients in the OI group were lost to follow-up (2 preferred other intervention, and 1 withdrew for unknown reason), and 2 patients in the OE group were lost to follow-up (1 transferred to another location, and 1 withdrew for unknown reason). Finally, a total of 45 patients (22 in the OI group and 23 in the OE group) completed the study, and their data were collected for statistical analysis. Treatment compliance of patients was 62.3±8.5% in the OI group versus 60.8±7.9% in the OE group. The flow chart of this study was shown in **Figure 3-8**.

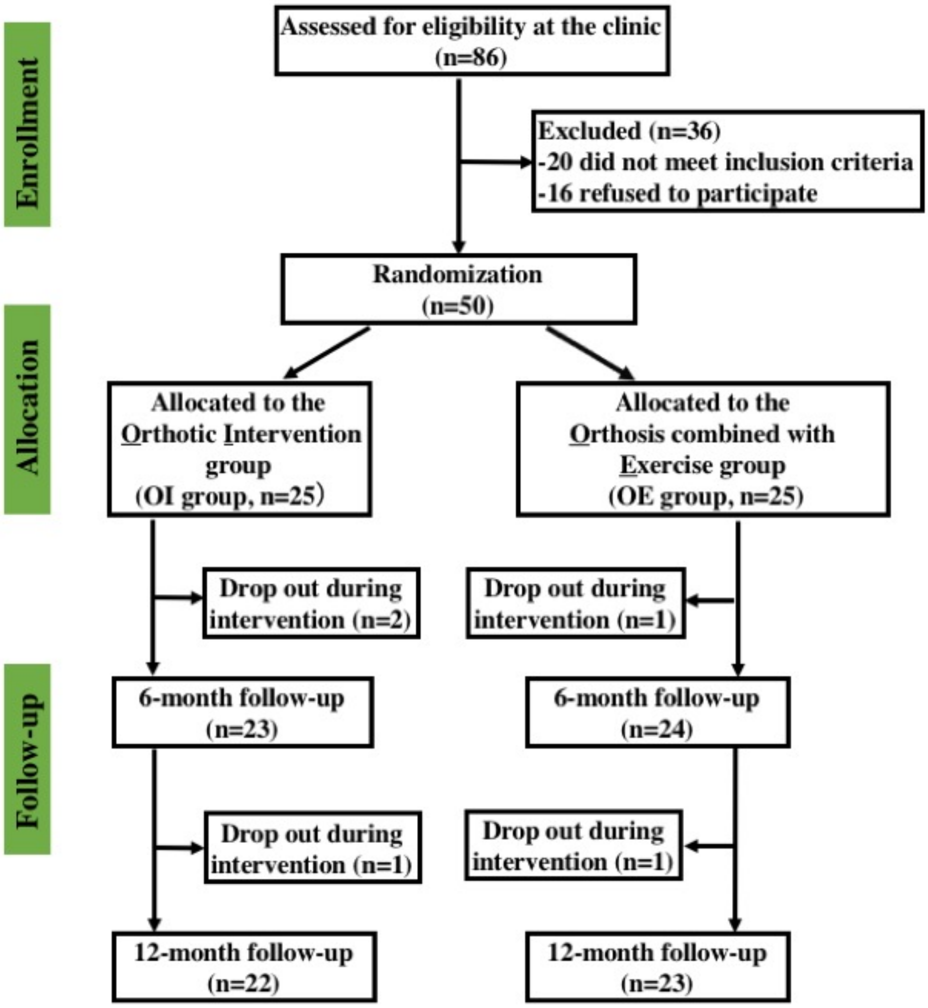



**Figure 3-8 The flowchart of patients participating in this study**

### 3.3.2 Intergroup comparison of demographic characteristics and baseline data

Demographic characteristics and baseline data of the two groups were shown in **Table 3-1**. The mean age, Cobb angle and ATR of patients in the OE group were slightly higher than those in the OI group, while the mean height, weight and BMI were slightly lower than those in the OI group, but the differences between the two groups were not statistically significant.

**Table 3-1 Comparison of demographic characteristics and baseline date of the two groups**

| | OI Group (n=22,18F/4M) (Mean ± SD) | OE Group (n=23,18F/5M) (Mean ± SD) | t | p |
|---|---|---|---|---|
| **Age (year)** | 12.1±1.3 | 12.2±1.3 | -0.204 | 0.840 |
| **Height (cm)** | 161.5±8.1 | 160.2±7.7 | 0.582 | 0.563 |
| **Weight (kg)** | 49.2±8.0 | 47.1±7.9 | 0.901 | 0.372 |
| **BMI (kg/m$^2$)** | 18.7±1.7 | 18.2±1.9 | 0.939 | 0.353 |
| **Cobb angle (°)** | 28.6±3.9 | 29.1±4.3 | -0.402 | 0.690 |
| **ATR (°)** | 8.9±2.1 | 9.4±2.3 | -0.563 | 0.268 |

**F: female; M: male; BMI: body mass index; ATR: angle of trunk rotation; OI Group: the orthotic intervention group; OE Group: the orthosis combined with exercise group**

### 3.3.3 Intragroup comparison of spinal deformity, back muscle endurance, cardiopulmonary function and quality of life of the two groups at different time points

The intragroup comparison results of spinal deformity, back muscle endurance, cardiopulmonary function and quality of life of patients in the OI group at different time points were shown in **Table 3-2**.

Comparison of spinal deformity: The Cobb angle of the patients in the OI group measured at the 12-month follow-up was significantly lower than that at the 6-month follow-up (p=0.030) and at baseline (p<0.001), whereas intragroup comparison of ATR did not differ significantly across all three time points.

Comparison of back muscle endurance: The back muscle endurance of patients in the OI group measured at the 6-month follow-up and at baseline was lower than that measured at the 12-month follow-up, and the differences were both statistically significant (p=0.002; p<0.001, respectively).

Comparison of static pulmonary function: In term of $FEV_1$, the OI group demonstrated significant decrease from the baseline to the 6-month follow-up (p=0.002), although a significant improvement was recorded between the 6-month and the 12-month follow-ups (p=0.009), the average values of $FEV_1$ measured at the 12-month follow-up were still significantly lower than that measured at baseline (p=0.020). The FVC levels measured at the 6-month follow-up and at the 12-month follow-up were significantly lower than that measured at baseline (p=0.008; p=0.010, respectively). Whereas $FEV_1$/FVC% did not differ significantly across the three follow-ups.

Comparison of dynamic cardiopulmonary function: The $VO_{2max}$ measured at the 12-month follow-up in the OI group was significantly lower than that measured at the 6-month follow-up (p=0.035) and that measured at baseline (p=0.009). Regarding VE/$VCO_2$, statistical improvement was only detected in the comparison of the 12-month measurement versus the baseline measurement (p=0.044), whereas intragroup comparison of $O_2$/pulse did not differ significantly across all three time points.

Comparison of quality of life: The scores of function and pain measured at the 12-month visit in the OI group were significantly lower than that measured at the baseline (p=0.017; p=0.002 respectively), meanwhile the 6-month self-image score was also significantly lower than the baseline level (p=0.038), and the score of self-satisfaction measured at the 12-month follow-up showed significant improvement compared with that measured at the baseline (p=0.030). Whereas, both the mental health score and the total score did not differ significantly across all three time points.

The intragroup comparison results of spinal deformity, back muscle endurance, cardiopulmonary function and quality of life of patients in the OE group at different time points were shown in **Table 3-3**.

Comparison of spinal deformity: The Cobb angle of patients in the OE group demonstrated significant decrease from the baseline to the 6-month follow-up (p=0.004) as well as from the 6-month to the 12-month follow-up (p=0.018). The ATR measured at the 12-month follow-up was significantly lower than that measured at the 6-month follow-up ($p=0.007$) and at baseline ($p<0.001$).

Comparison of back muscle endurance: The back muscle endurance of patients in the OE group significantly improved among all the comparisons of three visits (all $p<0.001$).

Comparison of static pulmonary function: The $FEV_1$ of patients in the OE group significantly increased among all the comparisons of three visits (all $p<0.001$), meanwhile FVC measured at the 12-month follow-up was significantly higher than that measured at baseline ($p<0.001$) and the 6-month follow-up ($p<0.001$), and $FEV_1/FVC\%$ measured at the 6-month and the 12-month follow-ups showed remarkable improvement in contrast to that measured at baseline ($p=0.013$; $p=0.003$ respectively).

Comparison of dynamic cardiopulmonary function: The $VO_{2max}$ of patients in the OE group showed significant improvement among all the comparisons of three visits (all $p<0.001$), and the $VE/VCO_2$ measured at the 12-month follow-up was significantly lower than that measured at baseline ($p=0.043$). Whereas intragroup comparison of $O_2$/pulse did not differ significantly across all three time points.

Comparison of quality of life: In the OE group, the functional score of patients measured at the 6-month and the 12-month follow-ups was significantly higher than that measured at baseline ($p=0.009$; $p<0.001$ respectively), and the pain score measured at the 12-month follow-up was significantly higher than that measured at the 6-month follow-up ($p=0.007$) and at baseline ($p<0.001$). The self-image score measured at 6-month follow-up was significantly higher than that measured at baseline ($p=0.041$). The mental health score measured at the 12-month follow-up was significantly higher than that measured at the 6-month follow-up ($p=0.016$) and at baseline ($p<0.001$), meanwhile treatment satisfaction score measured at the 6-month and the 12-month follow-ups was significantly higher than that measured at baseline ($p=0.002$; $p<0.001$ respectively), and the total score measured at the 12-month follow-up was significantly higher than that measured at the 6-month follow-up ($p=0.023$) and at baseline ($p=0.004$).

**Table 3-2 Intragroup comparison of spinal deformity, back muscle endurance, cardiopulmonary function and quality of life of patients in the OI group**

| | Baseline | | 6-month | | 12-month | | p | | |
|---|---|---|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | Mean | SD | 6-month vs. baseline | 12-month vs. 6-month | 12-month vs. baseline |
| **Cobb angle (°)** | 28.64 | 3.91 | 26.59 | 3.57 | 22.31 | 4.71 | 0.116 | 0.030 | <0.001 |
| **ATR (°)** | 8.92 | 2.09 | 8.61 | 1.26 | 8.33 | 1.94 | 0.252 | 0.359 | 0.417 |
| **BST (s)** | 121.98 | 24.28 | 119.62 | 23.00 | 115.79 | 21.71 | 0.101 | 0.002 | <0.001 |
| **Static pulmonary function** | | | | | | | | | |
| $FEV_1$ (L) | 2.49 | 0.65 | 2.36 | 0.65 | 2.43 | 0.66 | 0.002 | 0.009 | 0.020 |
| FVC (L) | 2.95 | 0.69 | 2.85 | 0.72 | 2.88 | 0.72 | 0.008 | 0.845 | 0.010 |
| $FEV_1$/FVC (%) | 84.05 | 4.89 | 82.41 | 4.45 | 83.93 | 4.12 | 0.110 | 1 | 0.140 |
| **Dynamic cardiopulmonary function** | | | | | | | | | |
| $VO_{2max}$ (ml/kg/minute) | 37.88 | 5.12 | 35.64 | 4.27 | 32.76 | 4.06 | 0.264 | 0.035 | 0.009 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| VE/$VCO_2$ (%) | 36.80 | 7.23 | 38.46 | 8.12 | 40.24 | 8.55 | 0.489 | 0.632 | 0.044 |
| $O_2$/pulse (ml/beat) | 6.78 | 2.04 | 6.53 | 2.26 | 6.65 | 1.89 | 0.696 | 0.583 | 0.337 |
| **SRS-22** | | | | | | | | | |
| Function (0-5) | 4.47 | 0.23 | 4.56 | 0.11 | 4.70 | 0.14 | 0.286 | 0.544 | 0.017 |
| Pain (0-5) | 4.18 | 0.22 | 4.09 | 0.17 | 3.85 | 0.21 | 0.334 | 0.592 | 0.002 |
| Self-image (0-5) | 3.46 | 0.35 | 3.31 | 0.44 | 3.39 | 0.33 | 0.038 | 0.619 | 0.770 |
| Mental health (0-5) | 4.22 | 0.18 | 4.05 | 0.16 | 4.27 | 0.34 | 0.423 | 0.769 | 0.234 |
| Treatment satisfaction (0-5) | 4.35 | 0.20 | 4.47 | 0.26 | 4.67 | 0.17 | 0.886 | 0.383 | 0.030 |
| Total score (0-5) | 4.14 | 0.26 | 4.10 | 0.27 | 4.18 | 0.28 | 0.672 | 0.841 | 0.983 |

**ATR: Angle of trunk rotation; BST: Biering-Sorenson test; $FEV_1$: Forced expiratory volume in the first second; FVC: Forced vital capacity; $FEV_1$/FVC: Forced expiratory volume in the first second/ Forced vital capacity; $VO_{2max}$: Maximal oxygen uptake; VE/$VCO_2$: Ventilatory equivalent of $CO_2$; $O_2$/pulse: the oxygen absorption per heartbeat; SRS-22: Scoliosis Research Society-22 questionnaire**

**Table 3-3 Intragroup comparison of spinal deformity, back muscle endurance, cardiopulmonary function and quality of life of patients in the OE group**

| | Baseline | | 6-month | | 12-month | | *p* | | |
|---|---|---|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | Mean | SD | 6-month vs. baseline | 12-month vs. 6-month | 12-month vs. baseline |
| **Cobb angle (°)** | 29.13 | 4.32 | 24.26 | 1.96 | 20.08 | 2.36 | 0.004 | 0.018 | <0.001 |
| **ATR (°)** | 9.40 | 2.28 | 8.13 | 2.53 | 6.25 | 1.46 | 0.123 | 0.007 | <0.001 |
| **BST (s)** | 127.78 | 23.43 | 140.18 | 25.36 | 146.85 | 26.20 | <0.001 | <0.001 | <0.001 |
| **Static pulmonary function** | | | | | | | | | |
| $FEV_1$ (L) | 2.67 | 0.74 | 2.74 | 0.78 | 2.93 | 0.76 | 0.007 | <0.001 | <0.001 |
| FVC (L) | 3.12 | 0.77 | 3.16 | 0.82 | 3.36 | 0.83 | 0.143 | <0.001 | <0.001 |
| $FEV_1$/FVC (%) | 84.96 | 4.41 | 86.17 | 4.26 | 87.22 | 3.66 | 0.013 | 0.253 | 0.003 |
| **Exercise pulmonary function** | | | | | | | | | |
| $VO_{2max}$ (ml/kg/minute) | 36.84 | 4.86 | 40.83 | 8.19 | 45.10 | 9.47 | 0.004 | <0.001 | <0.001 |
| VE/$VCO_2$ (%) | 37.41 | 7.02 | 36.25 | 5.25 | 34.11 | 4.88 | 0.745 | 0.562 | 0.043 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| $O_2$/pulse (ml/beat) | 6.26 | 1.88 | 6.41 | 2.10 | 6.44 | 2.17 | 0.171 | 1 | 0.220 |
| **SRS-22** | | | | | | | | | |
| Function (0-5) | 4.53 | 0.17 | 4.76 | 0.16 | 4.88 | 0.11 | 0.009 | 0.150 | <0.001 |
| Pain (0-5) | 4.13 | 0.15 | 4.21 | 0.14 | 4.56 | 0.22 | 0.671 | 0.007 | <0.001 |
| Self-image (0-5) | 3.38 | 0.37 | 3.20 | 0.18 | 3.32 | 0.29 | 0.041 | 0.534 | 0.771 |
| Mental health (0-5) | 4.17 | 0.14 | 4.08 | 0.31 | 4.51 | 0.17 | 0.379 | 0.016 | <0.001 |
| Treatment satisfaction (0-5) | 4.40 | 0.19 | 4.71 | 0.13 | 4.83 | 0.10 | 0.002 | 0.335 | <0.001 |
| Total score (0-5) | 4.12 | 0.20 | 4.23 | 0.20 | 4.42 | 0.24 | 0.085 | 0.023 | 0.004 |

**ATR: Angle of trunk rotation; BST: Biering-Sorenson test; $FEV_1$: Forced expiratory volume in the first second; FVC: Forced vital capacity; $FEV_1$/FVC: Forced expiratory volume in the first second/ Forced vital capacity; $VO_{2max}$: Maximal oxygen uptake; VE/$VCO_2$: Ventilatory equivalent of $CO_2$; $O_2$/pulse: the oxygen absorption per heartbeat; SRS-22: Scoliosis Research Society-22 questionnaire**

### 3.3.4 Intergroup comparison of spinal deformity, back muscle endurance, cardiopulmonary function and quality of life between the two groups at different time points

The intergroup comparison results of Cobb angle, angle of trunk rotation (ATR) and back muscle endurance of patients at different time points were shown in **Figure 3-9**. As compared to the OI group, the OE group achieved significant smaller Cobb angle at both the 6-month ($p<0.05$) and the 12-month ($p<0.01$) follow-ups, whereas statistically significant difference of ATR was only detected at the 12-month follow-up ($p<0.05$). For the back muscle endurance, the OE group had significant longer hold time than the OI group at both the 6-month ($p<0.01$) and the 12-month ($p<0.001$) follow-ups.

The intergroup comparison results of cardiopulmonary function at different time points were shown in **Figure 3-10**. The $FEV_1$ and FVC of patients in the OE group measured at the 12-month follow-up were significantly lower than that of patients in the OI group ($p<0.05$; $p<0.05$ respectively), whereas $FEV_1$/FVC measured at the 6-month and the 12-month follow-ups in the OE group was significantly higher than that in the OI group ($p<0.01$; $p<0.01$ respectively). The $\mathbf{VO_{2max}}$ value in the OE group was significantly higher than that in the OI group at both the 6-month and the 12-month ($p<0.01$; $p<0.01$ respectively), while statistically significant difference of $VE/VCO_2$ was only detected at the 12-month follow-up ($p<0.01$), but not presented at the 6-month follow-up ($p=0.465$). There was no statistical difference in $O_2$/pulse between the two groups during all three follow-up periods (baseline, 6-month and 12-month).

The intergroup comparison results of quality of life at different time points were shown in **Figure 3-11**. The self-image score did not differ significantly between the two group at all three visits. As compared to the OI group, the OE group achieved significant higher functional score at the 6-month follow-up ($p<0.01$), and significant higher pain score at the 12-month follow-up ($p<0.001$). The score of mental health in the OE group was significant higher than that in the OI group at both the 6-month follow-up ($p<0.05$) and the 12-month follow-up ($p<0.01$), whereas statistically significant between-group differences of the score of treatment satisfaction was only detected at the 6-month follow-up ($p<0.05$). The total score of SRS-22 questionnaire measured at the 6-month and at the 12-month follow-ups in the OE group was significantly higher than that in the OI group ($p<0.05$; $p<0.01$ respectively).

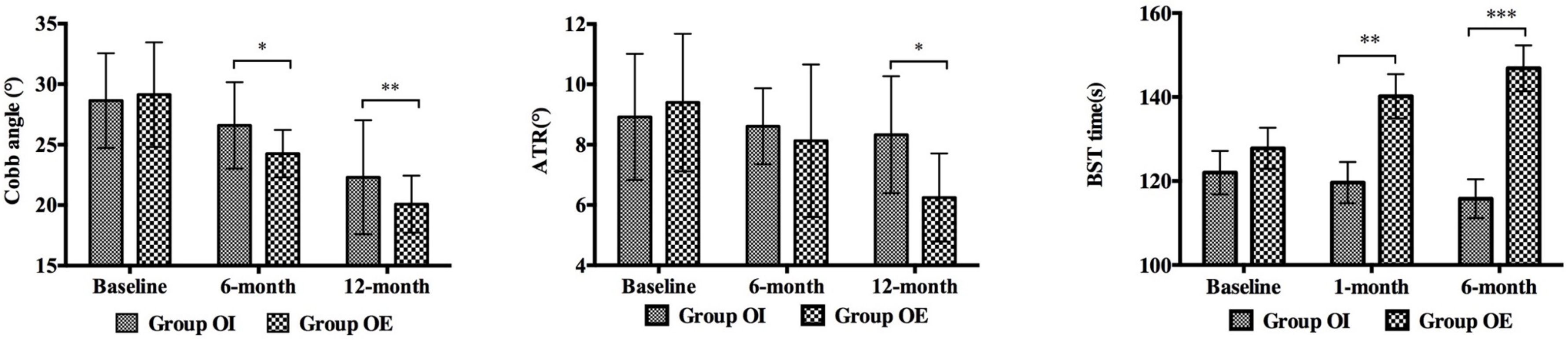



**Figure 3-9 Intergroup comparison of Cobb angle, ATR and back muscle endurance between the two groups**

**ATR: angle of trunk rotation; BST time: Biering-Sorenson test time; Group OI: the orthotic intervention group; Group OE: the orthosis combined with exercise group; *: p<0.05；**: p<0.01；***: p<0.001**

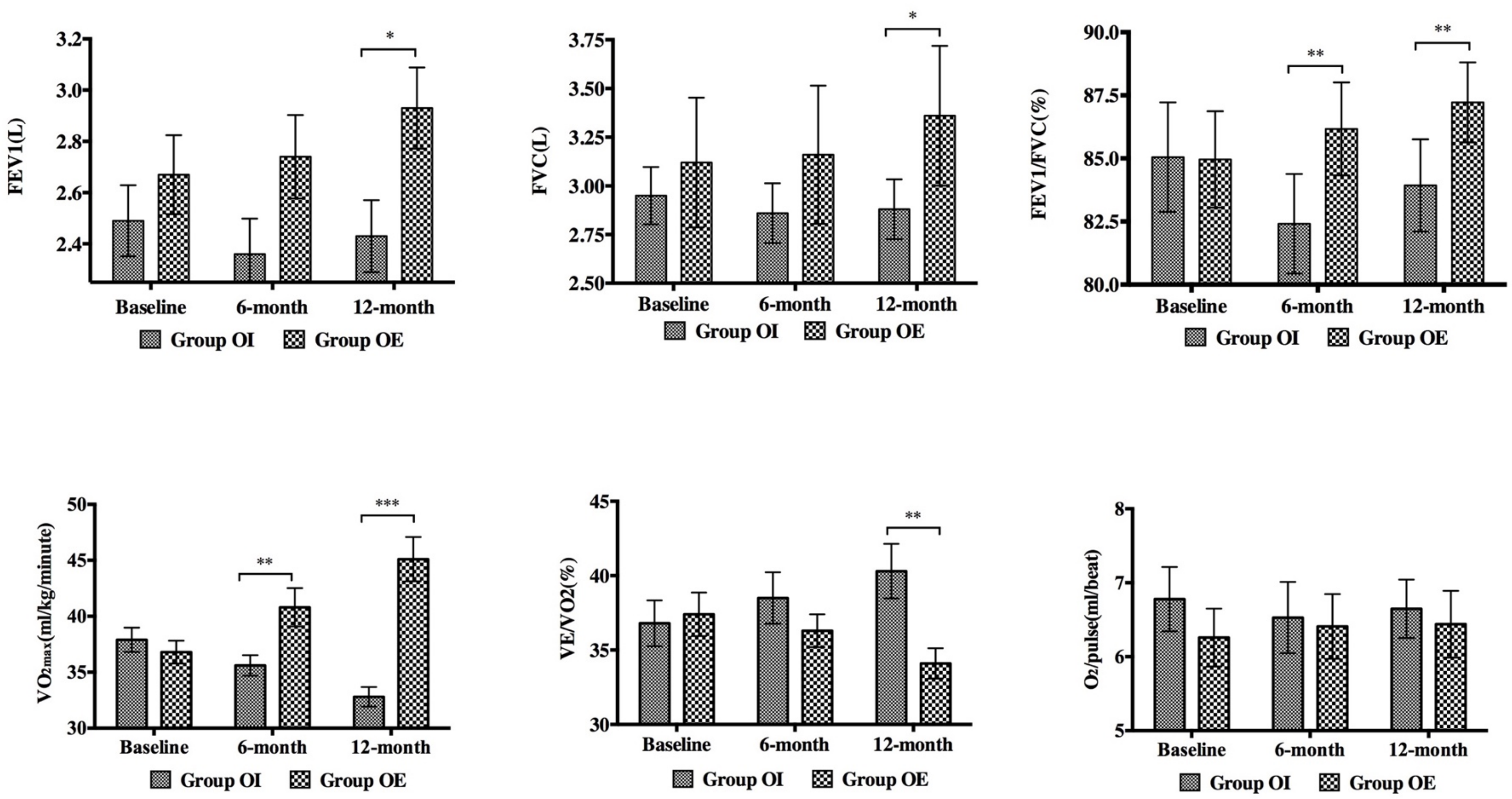



**Figure 3-10 Intergroup comparison of static pulmonary function and dynamic cardiopulmonary function between the two groups**

**$FEV_1$: Forced expiratory volume in the first second; FVC: Forced vital capacity; $FEV_1$/FVC: Forced expiratory volume in the first second/Forced vital capacity; $VO_{2max}$: Maximal oxygen uptake; VE/$VCO_2$: Ventilatory equivalent of $CO_2$; $O_2$/pulse: the oxygen absorption per heartbeat; Group OI: the orthotic intervention group; Group OE: the orthosis combined with exercise group； *: p<0.05； **: p<0.01； ***: p<0.001**

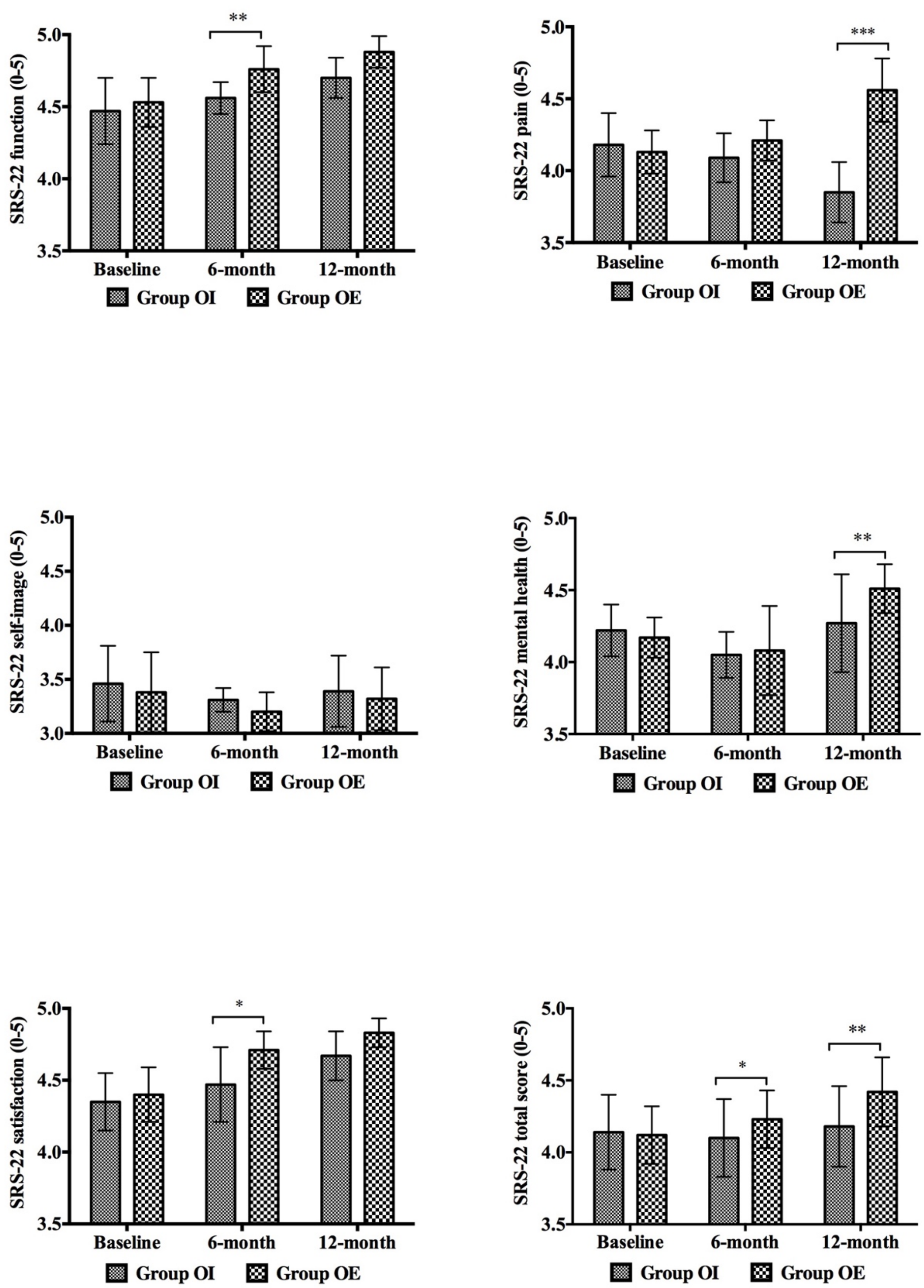



**Figure 3-11 Intergroup comparison of SRS-22 scores between the two groups**

**SRS-22: Scoliosis Research Society-22 questionnaire; Group OI: the orthotic intervention group; Group OE: the orthosis combined with exercise group; *: p<0.05; **: p<0.01; ***: p<0.001`**

## 3.4 Discussion

Due to the pathogenesis of adolescent idiopathic scoliosis (AIS) was still unclear, there was lack of specific and effective intervention aiming at the pathogenic factor of AIS. Various interventions being used to control the progression of spinal deformity, with the therapeutic purposes of avoiding spinal curvature progress to 50°. When scoliosis was greater than 50°, adolescents were at high risk of further progression even in the adulthood. Therefore, surgical correction was needed eventually. Orthosis was the most widely used conservative treatment for AIS worldwide, but its failure rate had been reported to be 25-28%[90,91], which meant that some patients still need to undergo surgical correction after several years' orthoses wearing. On the other hand, to ensure the efficacy of orthosis, patients were usually advised to wear orthoses almost throughout the day until bone matures. Long-term orthotic intervention might limit the trunk movement and thoracic activity, which can lead to many side effects such as the decreased back muscle strength and cardiopulmonary function and so on. Scoliosis specific exercise, as another common conservative treatment for AIS, was easier to be accepted by children. Differing from orthotic intervention, SSE allowed patients to move without restrictions; thus, less adverse effects were reported, and its role in reducing spinal deformity had been reported in several studies. In addition, there have been an increasing number of studies that reported the positive outcomes of SSE on improving back muscle strength[37] and cardiopulmonary function of adolescents with idiopathic scoliosis[92]. SSE was therefore recommended by the SOSORT guidelines as an add-on treatment for patients under orthotic intervention, with purpose not only to improve the effectiveness of orthosis but also to prevent or treat the possible adverse effects of long-term orthoses wearing. However, these recommendations were mostly based on expert opinions or observational studies, and there was still a lack of high level of evidence-based medicine to support the effectiveness of the combined application of orthoses with SSE. In current study, a prospective randomized controlled trial was conducted to explore the effectiveness of the integration of orthotic intervention and SSE on patients with AIS, in order to provide a higher level of evidential basis for the clinical application of orthosis combined with SSE for AIS. Our study found that orthotic intervention combined with SSE could further increase the Cobb angle correction compared with orthotic intervention only. Additional SSE could improve the deteriorated respiratory parameters and back muscle endurance of patients treated with orthosis. Compared with orthosis only, patients showed better quality of life when applying SSE during orthotic intervention, especially in terms of pain and mental health.

In the management of patients with AIS, the effectiveness of spinal deformity correction was one of the major considerations for clinicians to prescribe intervention. After 12 months intervention, the Cobb angle of patients in both groups showed significant reduction, while the correction of Cobb angle of patients in the OE group was significantly higher than that of patients in the OI group (9.05° vs 6.33°, $p<0.05$), indicating that the combined application of exercise and orthosis could better reduce scoliosis than orthotic intervention only. Our results substantiated the findings of a previous cohort study, which showed that exercise combined with orthosis increased the proportion of patients with Cobb angle reduction of 6° or greater by 6% compared with that of OI only[93]. Although the SSE programs performed in the two studies were different, they follow the similar principles and shared common goals to help orthoses take effects. It was generally believed that the working principle of orthosis was through three-point force system, which generated external forces to “passively” or “statically” correct spinal deformity, while exercise acted as a “dynamic” tool to increase the "static" correction force generated by orthoses[94]. A series of specifically designed training included in the SSE program, such as kyphotization and rotation training, were performed during orthosis wearing, which allowed additional forces to be acted on the soft tissues and through them to increase the pressure that orthoses exerted on the spine. In addition, mobilizing training was taught to the patients aiming at improving the mobility and flexibility of the spine, allowing the orthoses to achieve a better corrective result[85,92]. The angle of trunk rotation(ATR) was also measured in current study, and the results showed that the ATR of patients in the OI group had no obvious changes before and after treatment. However, the ATR in the OE group decreased after treatment, which was significantly lower than that in the OI group. The ATR reflected the appearance of scoliotic patients to some extent, but depending on the results of our study, we could not draw the conclusion that exercise combined with orthosis improved the appearance of AIS patients. More reliable and objective outcome measurements were needed for future studies.

In recent years, many studies have reported the positive role of various of orthoses in controlling the progression of spinal deformity and reducing the risk of surgery. The Boston brace (a commonly used TLSO) is an individually fitted orthosis with corrective pads placed on the convexity of the curve and relief points, which prevents progression through applying three-point pressure to the spinal curvature[95]. SpineCor is a flexible orthosis that provides dynamic de-rotation straps rather than rigid thermoplastic shell, and it seems more acceptable to patients because of its fabric material; however, its failure rate was found significantly higher than that of the rigid brace[96]. Charleston brace is designed to be worn during sleeping hours with the patient arranged in the supine bending position. Katz et al.[97] retrospectively compared 319 patients with AIS treated either a Charleston brace or a Boston brace, 83% of Charleston brace patients had curve progression of greater than 5 degrees, whereas only 43% of Boston brace patients progressed. Each type of spinal orthosis has its characteristics and target population, and none was distinctly superior to the others with regard to curve progression, psychological impact, or need for surgery. The commonly used TLSO was prescribed in the current study. In order to achieve better therapeutic outcomes, patients were usually required to wear the orthosis throughout the day(>23h/d) for 3-4years until skeletal maturity. Since orthoses limited the movement of the spine, long-term wearing may inevitably bring about the immobilization of trunk and disuse of back core muscle[98]25. However, less attention has been paid to back muscle function of patients with AIS, and little was known about the influence of OI on the back muscles function. Danielsson et al.[99] evaluated the back muscle function of AIS patients who were prescribed with orthosis and found reduced muscle endurance of both lumbar flexors and extensors even 20 years after the end of orthotic intervention when compared with the age- and sex-matched normal population. The results of current study were consistent with their findings, patients treated with orthoses showed a significant decrease in back muscle endurance at the 12-month follow-up. Therefore, back muscle weakness caused by orthosis wearing should not be ignored, as back muscle was essential to maintain spine alignment and stabilize the body posture. More than that, the combination of back muscle weakness and asymmetry of trunk muscle has been considered to serve an important role in the occurrence and development of scoliosis[100]. Schreiber et al.[37] were the first to report the effects of SSE on back muscle function of adolescents with idiopathic scoliosis. However, their study could not identify the effects of exercise combined with orthosis on patients' back muscle endurance, because observation was also included in the standard treatment. Only orthosis-treated patients were enrolled in current study, and patients treated with orthosis combined with SSE showed better back muscle endurance than those who received orthosis only at the 12month follow-up. These findings suggested that SSE is effective in improving back muscle function of patients undergoing orthotic intervention. SSE applied in the OE group were based on an active self-correction technique, with the purpose of using the intrinsic muscles of the spine as much as possible. The deep core muscles (such as transversus abdominis and multifidus) could be activated and trained to achieve the goal of improving the negative effects of orthoses on back muscles.

Potential respiratory alteration caused by orthotic intervention is another concern for clinicians and patients, although it remains controversial. Sevastikoglou[101] observed 26 AIS patients treated with Milwaukee orthoses and found orthotic intervention had no distinct influence on patients' vital capacity (VC). However, Noble-Jamieson et al.[102] reported that forced vital capacity (FVC) decreased by 22% for 16 AIS patients treated with orthosis. There are multiple possible reasons leading to discrepant results between studies, such as different types of orthoses, inconsistent orthosis wearing times or inclusion of different population. Our results supported the latter, which showed a significant decrease in $FEV_1$ and FVC (the important indicators reflecting static pulmonary function of the patients) after 6 months of orthotic treatment. The reasons for the decrease in static pulmonary function caused by orthotic intervention were considered as follows: 1) the orthosis limited the movement of lower ribs during inhalation; and 2) the increased intra-abdominal pressure caused by OI could restrict the relaxation activity of the lung[17]. Unlike the previous studies, our study discovered a trend of improvement on the parameters of pulmonary function form 6-month to 12-month evaluation. This might be explained by the physical adaption to the restriction of OI, and reduced pulmonary function could recover through some respiratory compensatory mechanisms[103]. However, we observed that $FEV_1$ and FVC of patients in the OI group measured at the 12-month follow-up were still significantly lower than that measured at baseline, indicating that 12-month OI still negatively affected the static pulmonary function of patients with AIS. Although most patients were asymptomatic in the early stage, the impairment of pulmonary function could be further aggravated with orthosis wearing time prolonging, leading to loss of lung elastic recoil, weakness of respiratory muscle obstruction of the airway[52]. Therefore, early specific intervention was needed for patients under orthotic treatment to prevent further deterioration of pulmonary function. In current study, through performing a specific breathing training, patients in the OE group presented a significant better static pulmonary function than patients treat with orthosis only at the 12-month follow-up. Current studies suggested mechanism of specific breathing training influencing patients' pulmonary function were as follows: firstly, through loosening of the thoracic spine, it enabled patients to obtain a more upright posture, making it easier for the thoracic cage and ribs to dilate[104]; secondly, it increased the strength of respiratory muscles and improved the respiration range[105].

Despite the abnormal static pulmonary function reported above, the patients treated with orthoses usually did not experience any respiratory disorder during resting state. However, in our clinical observation, these children often complained difficulties for upstairs and downstairs and bad exercise performance, which revealed the decline of dynamic cardiopulmonary function. Cardiopulmonary exercise capability reflected the ability of the body to engage in physical exercise, which was the basis for completing physical movements. The effect of orthotic intervention on dynamic cardiopulmonary function of adolescent with IS has been less investigated, and the reasons for damaged dynamic cardiopulmonary function have remained unclear. A recent study conducted by Muller et al.[98] found that although orthotic intervention did not affect patients' daily steps, their total steps were significantly lower than that of an age-matched general population. Therefore, the reduction of physical activity was considered as one of the reasons for the decline of patients' cardiopulmonary exercise capacity. Some scholars believed that this was related to the reduction of muscle oxidation and metabolic capacity due to the rigidity and stiffness of the orthoses limiting the activities of relevant muscle groups[106]. Current study evaluated three major indicators of dynamic cardiopulmonary function during exercise: $VO_{2max}$, $VE/VCO_2$, and $O_2$/pulse through cardiopulmonary exercise testing (CPET). It was found that $VO_{2max}$ measured at 12-month follow-up in the OI group was significantly lower than that measured at baseline. $VO_{2max}$ is an important indicator of aerobic exercise ability, which representing the volume of oxygen a person can consume in one minute exercising at maximum exertion. For adolescents in period of growth and development stage, having a certain level of aerobic exercise ability is the basis of performing daily physical activities. Aerobic exercise capacity in low levels can reduce their potentials in other areas, which can eventually have a negative impact on their old age[107]. We also found that $VE/VCO_2$, another indicator of dynamic cardiopulmonary function in the OI group, tended to increase gradually during the orthotic intervention, and the assessment results at the 12-month follow-up were significantly higher than that measured at baseline. $VE/VCO_2$ refers to quotient between minute ventilation and expelled volume of CO2, which is a measure of ventilatory equivalents for carbon dioxide. $VE/VCO_2$ value in the OI group increased with wearing time, indicating that the degree of inadequate ventilation was gradually aggravating and the dynamic cardiopulmonary function was gradually decreasing. DiRocco et al.[108] suggested that the decreased $VE/VCO_2$ was associated with the decrease of $VO_{2max}$ during exercise. In addition, the limitation of breathing movement caused by orthotic intervention has also been considered as an important reason for the decreased $VE/VCO_2$. With regard to $O_2$/pulse, there was no significant change in the OI group, which suggested that orthotic treatment might have little effect on cardiovascular function. Bas et al.[92] reported in their study that the $VO_{2max}$ of AIS patients increased by 17% after 6 weeks of aerobic training, indicating that aerobic training could significantly improve the cardiopulmonary function of AIS patients during exercise. In this study, in addition to traditional aerobic training, thoracic loosening training and respiratory muscle training specifically designed for scoliosis were also performed in the OE group, so as to improve the cardiopulmonary function of patients during exercise from the perspective of improving ventilation. When applying SSE during orthotic intervention, $VO_{2max}$ and $VE/VCO_2$ of the patients in the OE group measured at 12-month follow-up were significantly higher than that of patients in the OI group. Therefore, the influence of orthoses on the dynamic cardiopulmonary function of patients should not be ignored. Assessing the cardiopulmonary function of patients during exercise is helpful for early detection of possible decreased dynamic cardiopulmonary function. In order to reduce the negative effects of orthotic intervention on the dynamic cardiopulmonary function of patients with AIS, aerobic training should be advocated for patients under orthotic treatment.

When applying orthoses to correct spinal deformities, an increasing number of patients began to concern about the influence of orthoses on their quality of life, especially on their mental health, self-image and function, which were directly related to adolescents' physical and mental health in their growth and development stage. In this study, patients' quality of life was followed up with the SRS-22 questionnaire. The results at 12-month follow-up showed that the mental health, pain and total scores of patients in the OE group were significantly higher than those in the OI group. However, there were no significant differences in function, self-image and satisfaction subscales between the two groups. On the whole, patients' quality of life in the OE group was better than that in the OI group. In the first 6 months, the mental health scores of patients in both groups decreased with different degrees, which could be interpreted as the psychological pressure originated from the resistance to orthoses at the early stage of orthotic intervention. Compared with the impact of spinal deformities, adolescents were more sensitive to the changes of their appearance after wearing orthoses[109,110]. Studies have pointed out that about 1/3 of patients might suffer from anxiety, depression, even poor social interaction after receiving orthotic treatment[111]. It was interesting to find that the mental health scores of patients in both groups increased in the last six months, which was thought to be linked to patients' adaptation to orthoses and the reduction of spinal deformity[112]. In terms of pain subscale, patients in the OI group showed gradual reduce as the time went on. The pain scores measured at 12-month was significantly higher than that measured at baseline. Previous studies have reported that the incidence of low back pain in patients with AIS is significantly higher than that in the matched normal population[113], with the reason of the asymmetry of the load on both sides of the vertebral body and the degeneration of intervertebral discs and joint ligaments[34]. These factors could be aggravated by long-term use of orthoses that limited the activity of muscles and ligaments. As a result, the score of pain were decreased in the OI group. Exercise can improve back muscle strength, and increase the control of the spine to balance the load on both sides. After SSE were added, the pain score of patients in the OE group improved significantly. As to satisfaction, the comparison between the two groups was significantly different only at the 6-month assessment, which was considered to be related to patients' acceptance of therapeutic effect at the beginning of treatment. (patients in the OE group had a higher Cobb angle correction at the 6-month follow-up compared with OI group). Only patients with moderate scoliosis (Cobb angle of 25°-40°) were included in this study, most of them usually had a high level of function before receiving conservative treatments[114]. It should be noted that the SRS-22 questionnaire is specifically used to evaluate the impact of surgery on patients with AIS, and the ceiling effect may occur when it was used to evaluate the patients receiving conservative treatment[37,115]. There was no significant difference in function assessment between the two groups, which may have something to do with the ceiling effect that limited the evaluation of function improvement when using the SRS-22 questionnaire.

**Study innovations and limitations**

**The innovative aspects of this study were listed as below:** 1) As the first RCT study to explore the therapeutic effect of the combination of SSE with orthosis on patients with AIS, the results of this study provided a higher-level evidence-based medicine for the clinical application of exercise during orthotic intervention. 2) According to the recommendations of SRS and SOSORT consensus on scoliosis treatment, this study evaluated the secondary predictive outcomes such as Cobb angle and ATR, which reflected the severity of patients' spinal deformity, as well as the primary patient-centered outcomes such as cardiopulmonary function, quality of life. 3) While assessing patients' static pulmonary function, this study also applied the cardiopulmonary exercise testing to evaluate and follow up patients' dynamic cardiopulmonary function, which comprehensively reflected the influence of different interventions on the cardiopulmonary function of AIS patients.

**This study also has the following limitations:** 1) Due to the relatively short follow-up time, this study only evaluated the effect of interventions on spinal deformity which was presented in terms of the pretreatment and posttreatment changes in Cobb angle. The number of patients who reduced by greater than 5 degrees (success rate) or progressed by greater than 5 degrees (failure rate) would be more persuasive to reflect the effectiveness of an intervention in the long-term follow-up. The long-term follow-up study is still ongoing, and we will report the results in the future. 2) Due to ethical issues, no blank controlled group was set in current study, and the natural course of disease may have impacts on the results of the study. 3) In this study, the treatment compliance of patients was recorded and evaluated through writing a treatment diary, lack of objectivity of this method may affect the accuracy of the results. More objective evaluation means (like video recording or implantation of sensors) are recommended to be adopted in the future studies.

## 3.5 Conclusion

In the current study, SSE combined with orthosis could further increase the Cobb angle correction compared with orthotic intervention only. Additional SSE could improve the deteriorated respiratory parameters and back muscle endurance of patients treated with orthosis. Compared with orthosis only, patients showed better quality of life when applying SSE during orthotic intervention, especially in terms of pain and mental health. Taken together, SSEs were suggested to patients with AIS during the period of orthoses wearing. However, a long-term study with more subjects is deserved for confirmation of the current findings.

# CHAPTER 4 THE EFFECTIVENESS OF ACUPUNCTURE COMBINED WITH TUINA ON PATIENTS WITH ADOLESCENT IDIOPATHIC SCOLIOSIS: A QUASI-EXPERIMENTAL STUDY

## 4.1 Introduction

Adolescent idiopathic scoliosis (AIS) is a kind of non-congenital deformity of spine that occurs in children's puberty period[67]. If left untreated, spinal deformity could further aggravated. Severe trunk deformity will affect the appearance and motor function of the patients, while the thoracic deformity will compress patients' chest organs and lead to abnormal cardiopulmonary function. In addition, abnormal physical appearance can cause inferiority, depression and social psychological disorders in children, which is not conducive to the development of adolescents' mental health[116-118]. Therefore, to correct or delay spinal deformity as early as possible is particularly important to the physical and mental health of adolescents.

Orthotic intervention and scoliosis specific exercise (SSE) are the most commonly used conservative treatments for children with mild or moderate curve, whereas both of them have some shortcomings in clinical application. Orthoses are usually recommended for patients with curvature 25-40°[119]. To ensure the correction effect, patients are suggested to wear orthoses at least 23 hours a day until skeletal maturity[120]. Long-term orthotic intervention inevitably leads to some adverse effects, such as pressure sores, reduced back muscle strength and cardiopulmonary endurance[121]. SSE consists of individualized exercise programs that are tailored specifically to reduce spinal deformities[75,122]. However, there is no general agreement relating to the effectiveness of SSEs in the treatment of adolescent idiopathic scoliosis, owing to the lack of high level of evidence. In addition, some problems may arise during the process of SSEs activities[77,123]. Firstly, the regimen of SSE typically involves intensive and complex training, which is not easy to be accepted and acquired by teenagers. Moreover, SSE is typically conducted one-on-one or in small groups, lack of therapists specialist in SSE scarcely meets the requirements of huge population of AIS patients in China.

To seek a new intervention which can effectively reduce spinal deformity with less treatment-related side effects and adjusts to Chinese circumstance is an important research direction of conservative treatment for patients with AIS. Traditional Chinese medicine, which has a broad basis of clinical practice in the treatment of low back diseases, can be regarded as an alternative choice. Traditional Chinese medicine classifies scoliosis into the categories of "arthralgia" and "muscle and bone disease".

Due to the stagnation of Yang Qi, the imbalance between the yin and yang of the meridians around the spine causes the strength of the paraspinal muscles to decrease and the spine cannot be kept upright, which eventually leads to scoliosis[124]. Acupuncture is a therapeutic method for the prevention and treatment of diseases through stimulating external acupoints on the body surface on the basis of meridian theory and syndrome differentiation of traditional Chinese medicine (TCM). Through acupuncturing the relevant acupoints such as Bladder Meridian and Governor Meridian to dredge meridians and increase Yang Qi, the effect of balancing Yin and Yang can be achieved[125]. Tuina is a form of TCM manipulative therapy often used in conjunction with acupuncture. The practitioner may brush, roll, press, knead, and rub the areas of scoliotic deformity to attempt to restore muscle elasticity and release contracture muscles in an effort to bring bilateral paravertebral muscles into balance, and ultimately achieve the purpose of the correction of scoliosis[126]. At present, many studies have applied the above TCM theory in the management of patients with AIS, and achieved positive therapeutic results in clinical practice[9,127,128]. However, these studies are mostly observational studies without setting control groups, and the study design is often unscientific, which reduces the reliability of evidence. Therefore, the objective of current study was to explore the therapeutic effects of traditional Chinese medicine (acupuncture combined with tuina) in correcting spinal deformities through conducting a clinical controlled trial, in order to provide scientific evidence for its clinical application. In addition, according to the latest SOSORT guideline, this study also evaluated patient-centered outcomes such as muscle function, spinal flexibility and quality of life, in order to comprehensively reflect the therapeutic effect of TCM in the management of patients with adolescent idiopathic scoliosis.

## 4.2 Material and methods

### 4.2.1 Study design

This was a quasi-experimental study because random assignment cannot be performed for the allocation of participants into the intervention or control groups. The end-point for the analysis of the outcomes was 6 months after the baseline assessment.

### 4.2.2 Subjects

The patients who were eligible for the following criteria were enrolled from Wuxi Rehabilitation Hospital Scoliosis Center from June 2018 to December 2019. This study was pre-registered in the Chinese Clinical Trial Registry (Granted Number ChiCTR1800014730) and approved by its ethics committee prior to the commencement of patient recruitment. The clinician introduced the purpose and study plan to the subjects and their guardians in detail. After the eligible subjects agreed to participate, their guardians signed the inform sheets and consent forms (**See Appendix II-V**).

### 4.2.3 Inclusion and exclusion criteria

#### 4.2.3.1 Inclusion criteria

1) Age: 10-18 years;

2) Cobb Angle: 10°-25°;

3) Risser grade: 0-2;

Because the effectiveness of TCM (acupuncture combined with tuina) in the management of AIS remained uncertain, only patients with mild curves (Cobb angle less than 25°) were enrolled in current study from the perspective of medical ethics. If a positive result could be confirmed through this preliminary study, patients with moderate or severe scoliosis will be included in the future studies to further verify its efficacy.

#### 4.2.3.2 Exclusion criteria

1) Congenital scoliosis or secondary scoliosis due to other diseases;

2) with thrombocytopenia or other bleeding illness.

3) with skin damage or infection in the chest, waist or back.

4) Received other treatments prior to initial diagnosis;

### 4.2.4 Sample size calculation

Sample size was calculated with G-Power software using a priori power analysis, with a type 1 error rate α=0.05 to achieve an 80% power yielding an effect size of d=0.85, which was on the basis of Cobb angle correction of TCM treatment referred from a previous study[129]. The estimated sample size would be 18 participants per groups. Based on previous research experience, a total of 50 patients need to be recruited, with 25 subjects per groups for allowing 30% loss in follow-up visits.

### 4.2.5 Grouping and blinding assessment

In order to achieve maximum participation, the enrolled patients were assigned to the intervention group or the control group according to their personal willingness. Patients in the intervention group received acupuncture combined with tuina treatment, while patients in the control group only received "meaningful observation" without special intervention. Due to the particularity of the intervention methods, the patients and the acupuncturists who implemented the intervention were not blinded to the study group, while the researchers who performed outcomes measurement and data analyses were not blinded regarding the study groups.

### 4.2.6 Treatment protocol

#### 4.2.6.1 Treatment protocol for the intervention group

##### 4.2.6.1.1 Tuina therapy

The patients were asked to lie prone on the treatment bed, the tuina therapist used the hypothenar kneading and pressing along the Bladder Meridian of Foot-taiyan from top to bottom, fully relaxing the back fascia and muscles (**Figure 4-1**). In the convex side of scoliotic spine, flicking-plucking manipulation was performed to relax the spastic muscles, while kneading-pressing manipulation was applied in the concave side to restore the elasticity of the muscles, then pressed back Shu points of the Bladder Meridian, Huatuojiaji points, and acupoints of the Governor with thumb from top to bottom[130]. Moreover, pulling manipulation was selected according to the pattern of scoliotic curve: The patient lied on the table in lateral position, with hip flexion on the side of the lower limb flexion, the next side of the lower limb is naturally straight. The therapist stood opposite the patient, with one hand fixing the patient's shoulder and the other fixing the hip, applying pulling manipulation to correct the scoliotic spine (**Figure 4-2**). The whole process was about 25 minutes.

**Figure 4-1 Manipulative treatment to fully relax the back fascia and muscles**

**Figure 4-2 Pulling manipulation to correct the scoliotic spine**

#### 4.2.6.1.2 Acupuncture therapy

##### 4.2.6.1.2.1 Acupoints selecting

1) Main acupoints: Jiaji points of the scoliotic curve level, Dachangshu points, Weizhong points, Ashi points

2) Auxiliary acupoints: selected according to patients' TCM syndrome differentiation. Blood-stasis type with Geshu points, cold-dampness type with Yaoyangguan points, and kidney-deficiency type with Shenshu points[131].

##### 4.2.6.1.2.2 Acupoints positioning

The selected acupoints were located with reference to the national standard of the people's Republic of China "Nomenclature and location of acupuncture points" (GB/T12346-2006) issued in 2006[132], as shown in **Figure 4-3**.

The specific positioning methods are as follows,

**Jiaji points (EX-B2):** In the spinal region, the inferior sides of the spinous process from the first thoracic vertebra to the fifth lumbar vertebra, 0.5 inch beside the posterior midline.

**Dachangshu points (BL25):** In the spinal region, under the spinous process of the fourth lumbar vertebra, 1.5 inch beside the posterior midline.

**Weizhong points (BL40):** In the posterior knee region, the midpoint of popliteal crease.

**Geshu points (BL17):** In the spinal region, under the spinous process of the seventh lumbar vertebra, 1.5 inch beside the posterior midline.

**Yaoyangguan points (GV3):** In the spinal region, under the spinous process of the seventh lumbar vertebra, on the posterior midline.

**Shenshu points (BL23):** In the spinal region, under the spinous process of the seocnd lumbar vertebra, 1.5 inch beside the posterior midline.

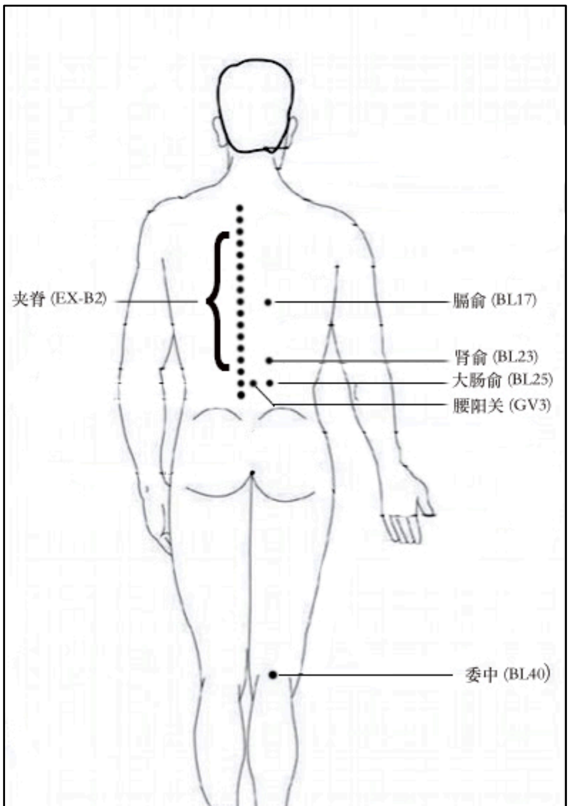



**Figure 4-3 Location of acupoints used in current study**

#### 4.2.6.1.2.3 Acupuncture operation

The patient lied prone on the treatment bed in a comfortable position. After routinely disinfecting the skin around the selected acupoints with 75% alcohol, acupuncturists inserted the acupuncture needle with suitable length quickly. The depth of needle insertion was adjusted based on different acupoints and different somatotypes of patients. According to the deficiency and excess of the disease, lifting, thrusting and rotating techniques were carried out. De qi sensation was provoked by manual stimulation at the beginning of each session, then the needles were retaining for 30 minutes. Acupuncture was carried out by the same skilled and experienced acupuncturist throughout the study.

#### 4.2.6.1.2.4 Needling instrument

"Hwato" brand disposable acupuncture needles were used (Suzhou Medical Devices Company Limited), with specification parameters: 0.30mm×40mm (1.5in), 0.30mm×75mm (3in)

#### 4.2.6.1.2.5 Case report of acupuncture therapy

A 15-year-old female patient with Cobb angle 22° (L1-L4), X-ray file was shown in the **Figure 4-4A**. After TCM syndrome differentiation, the patient was diagnosed as the kidney-deficiency type, hence the following acupoints were selected. Main acupoints: Jiaji points on the convex side of L1-L4 vertebral segment (**Figure 4-4B 1-4**), Dachuangshu point on the concave side of scoliotic spine (**Figure 4-4B 5**), and Weizhong points on both sides (**Figure 4-4C 7,8**). Auxiliary acupoints: Shenshu point (**Figure 4-4B 6**)


**Figure 4-4A Patient's X-ray film**


**Figure 4-4B Location of the acuponts on the back of patient**


**Figure 4-4C Location of the acupoints on the legs of patient**

#### 4.2.6.1.3 Intervention period

The patient first received tuina therapy, then acupuncture was performed after a 5-minute rest. The whole process lasted about 1 hour. 2 times per week, 3 weeks were regarded as one treatment course. After one week's rest, the next course will be carried out.

### 4.2.6.2 Treatment protocol for the control group

Except meaningful observation, that is, the patients were followed up every 3 months to monitor the progress of spinal curvature, no special interventions were performed in the control group[133].

## 4.2.7 Outcome measures

### 4.2.7.1 Baseline data collection

All patients' demographic characteristics, such as age, sex, height, weight, body mass index, menstruation and type of scoliosis, were collected.

#### 4.2.7.2 Radiological examination

##### 4.2.7.2.1 Cobb angle measurement

The Cobb angle method was used to assess patients' spinal deformity, which had been described in **Chapter 3.**

##### 4.2.7.2.2 Risser sign

The skeletal maturity of the patients was graded through Risser sign in standing radiograph. The Risser sign is an assessment of the ossification stage of a patient's upper pelvic bone, known as the iliac crest, to determine how much more spinal growth is expected. This can be important for the evaluation of patients with scoliosis. A patient with a score that indicates much more spinal development is on the way may need more aggressive interventions to prevent curvature. The doctor can assign a score of one through five to a patient. A low score indicates lower maturity, which means the spine still has more room to grow, and there is an increased risk of additional curvature in a patient with scoliosis. Higher scores indicate more maturity and less of a risk of curvature because the patient's spine is almost, or completely, developed. A one indicates 25% ossification, a two 50%, a three 75%, and a four 100%, while a five means that patient's ossification is complete and the fusing process is also done[134].

#### 4.2.7.3 Assessment of back muscle endurance

Back muscle endurance was assessed with the Biering-Sorensen test (BST), which had been described in **Chapter 3.**

#### 4.2.7.4 Assessment of spinal flexibility

Fingertip-to-floor distance test (FFDT) was used to evaluate the spinal flexibility of the patients, which was performed with the patient standing erect, feet together. The patient was asked to bend forward as far as possible, while maintaining the knees, arms, and fingers fully extended. The vertical distance between the tip of the middle finger and the floor was measured before and after 6 months intervention with a straight rule (**Figure 4-5**).


**Figure 4-5 Fingertip-to-floor distance test**

#### 4.2.7.5 Assessment of health-related quality of life (QoL)

The simplified Chinese version of Scoliosis Research Society-22 questionnaire (SRS-22 questionnaire)[89] was used to evaluate patients' quality of life, which had been described in **Chapter 3.**

### 4.2.8 Assessment time points

All patients were evaluated before and after 6 months intervention.

### 4.2.9 Statistical analysis

According to Shapiro-Wilks test results, the age, height, weight, BMI, Risser sign, Cobb angle, back muscle endurance, spinal flexibility and SRS-22 scores of the patients showed normal distribution. Therefore, independent sample *t* test was used to compare the above demographic characteristics and baseline data of the patients. The Cobb angle, back muscle endurance, spinal flexibility and the domains of the SRS-22 questionnaire in current study were all continuous variables and showed normal distribution, therefore, the independent sample *t* test was used for inter-group comparison of the difference before and after intervention of the above variables, and the paired t test was used to compare the mean scores for the above variables at baseline and the final assessment. Chi-square test was performed to compare the stability, reduction and progress of spinal deformity between the two groups. The statistical significance was set at $p<0.05$. All the statistical analyses were conducted using the SPSS 22.0 software (IBM Corporation, USA)

## 4.3 Results

### 4.3.1 Patients participating in the study

There were 166 patients with AIS visited the hospital during the study, 930 of whom refused to participate in the study, 23 of whom did not meet the inclusion criteria and were excluded, and finally a total of 50 patients were enrolled. Patients were assigned to either the intervention group (OI group, n=25) or the control group (OE group, n=25). Throughout the whole study, 4 patients in the intervention group were lost to follow-up (3 cannot tolerate the pain caused by acupuncture, and 1 withdrew for unknown reasons), and 1 patients in the control group were lost to follow-up (1 transferred to another location). Finally, a total of 45 patients (21 in the intervention group and 24 in the control group) completed the study, and their data were collected for statistical analysis. The flow chart of this study was shown in **Figure 4-6**.

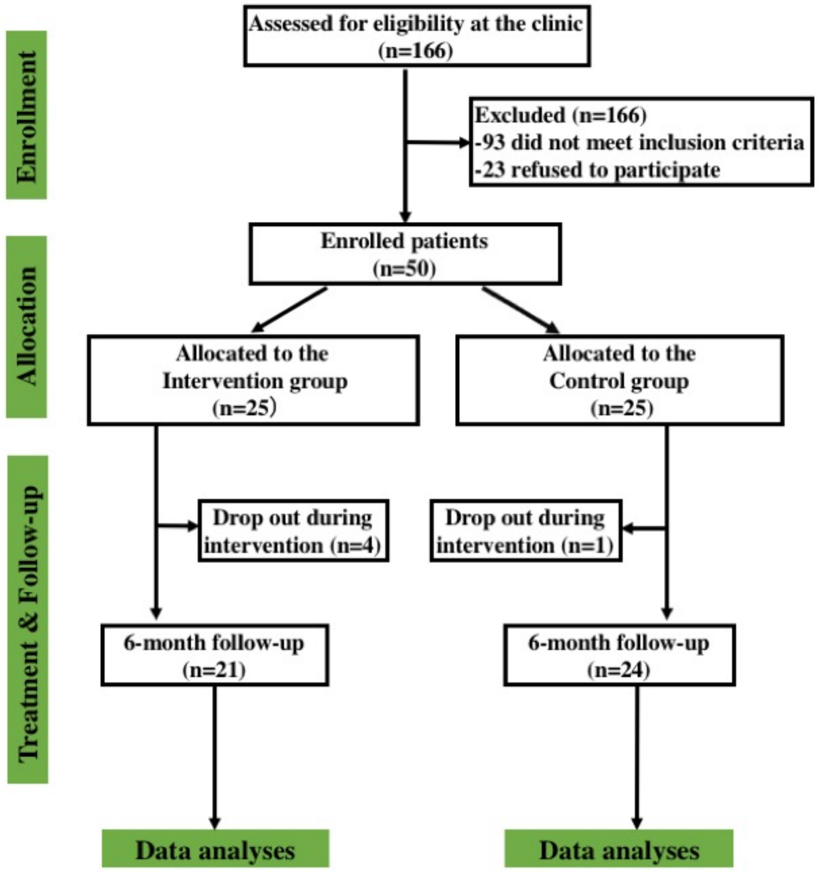



**Figure 4-6 The flowchart of patients participating in this study**

### 4.3.2 Intergroup comparison of demographic characteristics and baseline data

Demographic characteristics and baseline data of the two groups were shown in **Table 4-1**. Despite the non-randomized method performed in current study, no significant differences were found between the two groups. The curve pattern of the two groups classified by Ponseti method[135] was demonstrated in **Figure 4-7**.

**Table 4-1 Comparison of demographic characteristics and baseline date of the two groups**

| | Intervention Group (n=21,17F/4M) (Mean ± SD) | Control Group (n=24,19F/5M) (Mean ± SD) | p |
|---|---|---|---|
| Age (year) | 11.9±1.3 | 11.8±1.3 | 0.853 |
| Height (cm) | 161.9±7.9 | 160.1±7.2 | 0.677 |
| Weight (kg) | 48.9±8.1 | 47.4±7.8 | 0.528 |
| BMI (kg/m$^2$) | 18.5±1.8 | 18.2±2.0 | 0.554 |
| Riiser sign | 1.0±0.7 | 1.1±0.7 | 0.710 |
| Cobb angle (°) | 17.3±3.5 | 17.8±3.8 | 0.648 |
| BST (s) | 127.8±23.2 | 122.4±24.4 | 0.453 |
| FDDT(cm) | 31.1±4.7 | 30.7±5.9 | 0.123 |
| SRS-22 | | | |
| Function (0-5) | 4.5±0.5 | 4.4.0±0.6 | 0.994 |
| Pain (0-5) | 3.9±0.4 | 4.0±0.5 | 0.285 |
| Self-image (0-5) | 3.3±0.7 | 3.2±0.5 | 0.857 |
| Mental health (0-5) | 4.6±0.6 | 4.7±0.7 | 0.570 |
| Treatment satisfaction (0-5) | 4.3±0.6 | 4.0±0.7 | 0.441 |

F: female; M: male; BMI: body mass index; BST: Biering-Sorenson test; FDDT: Fingertip-to-floor distance test; SRS-22: Scoliosis Research Society-22 questionnaire

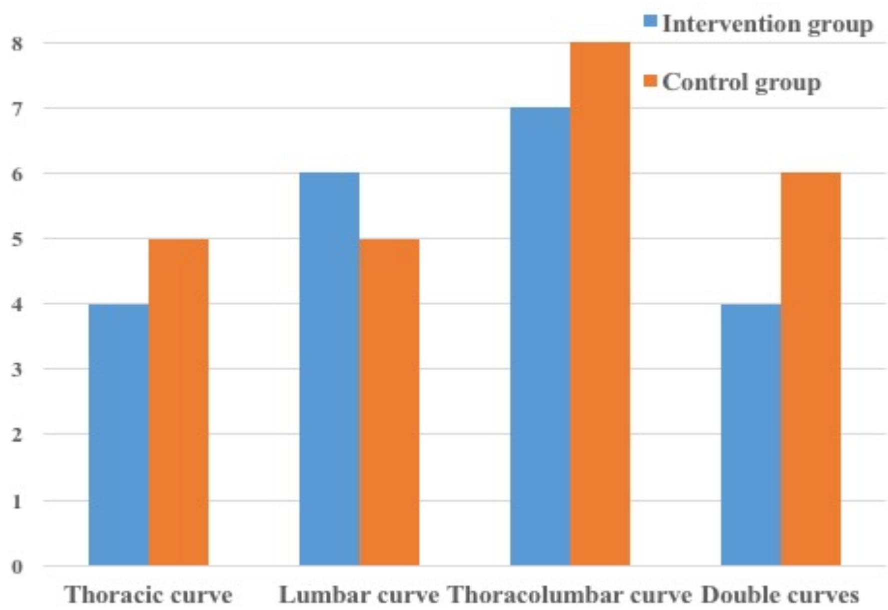



**Figure 4-7 Comparison of the curve pattern of the patients in the two groups**

**Table 4-2 Comparison of Cobb angle, BST, FDDT and SRS-22 between the two groups before and after treatment**

| | Baseline (Mean ± SD) | | 6-month intervention (Mean ± SD) | | Difference before and after intervention (Mean ± SD) | |
|---|---|---|---|---|---|---|
| | Intervention group | Control group | Intervention group | Control group | Intervention group | Control group |
| Cobb angle (°) | 17.3±3.5 | 17.8±3.8 | 12.2±4.3[a] | 20.1±3.4[a] | -5.1±4.6[b] | 2.3±3.2 |
| BST (s) | 127.8±23.2 | 122.4±24.4 | 140.9±24.9[a] | 120.7±23.8 | 13.1±5.2[b] | -1.7±4.3 |
| FDDT (cm) | 31.1±4.7 | 30.7±5.9 | 24.5±4.5[a] | 31.2±5.0 | -6.6±2.7[b] | 0.5±3.1 |
| SRS-22 | | | | | | |
| Function (0-5) | 4.5±0.5 | 4.4±0.6 | 4.6±0.6 | 4.2±0.3 | 0.1±0.43 | -0.2±0.35 |
| Pain (0-5) | 3.9±0.4 | 4.0±0.5 | 4.7±0.7[a] | 3.8±0.4 | 0.8±0.30[b] | -0.2±0.51 |
| Self-image (0-5) | 3.3±0.7 | 3.2±0.5 | 4.2±0.6[a] | 3.0±0.3 | 0.9±0.17[b] | -0.2±0.45 |
| Mental health (0-5) | 4.6±0.6 | 4.7±0.7 | 4.7±0.4 | 4.8±0.4 | 0.1±0.33 | 0.1±0.39 |
| Treatment satisfaction (0-5) | 4.3±0.6 | 4.0±0.7 | 4.5±0.4 | 4.3±0.3 | 0.2±0.44 | 0.3±0.57 |

**BST: Biering-Sorenson test; FDDT: Fingertip-to-floor distance test; SRS-22: Scoliosis Research Society-22 questionnaire；**

**a: $p<0.05$, Intra-group comparison showed significant difference before and after intervention.**

**b: $p<0.05$, Inter-group comparison of the difference before and after intervention showed significant difference.**

### 4.3.3 Comparison of main outcome measurements before and after 6-month intervention (as shown in the Table 4-2)

#### 4.3.3.1 Cobb angle

There was no significant difference in Cobb angle between the two groups before intervention ($p=0.648$), indicating that the degree of spinal deformity of the two groups was comparable at the baseline assessment. After 6 months intervention, there was significant difference in Cobb angle between the two groups ($p<0.001$). Specifically, the Cobb angle of the patients treated with acupuncture combined with tuina showed significant decrease after intervention ($p<0.001$), while the patients in the control group showed significant increase ($p<0.001$), which meant that acupuncture combined with tuina could effectively reduce the spinal deformity of the patients with AIS, while the degree of scoliosis in the control group was further worsened.

#### 4.3.3.2 Back muscle endurance

There was no significant difference in low back muscle endurance between the two groups before intervention ($p=0.453$), indicating that the low back muscle function of the two groups was comparable at the baseline assessment. After 6 months intervention, there was significant difference in the back muscle endurance between the two groups ($p=0.008$). The BST time of patients in the intervention group was significantly longer than that measured at baseline ($p<0.001$), while in the control group, there was no significant difference in BST time between the 6-month assessment and the baseline assessment ($p=0.130$). It meant that acupuncture combined with tuina could effectively improve the back muscle endurance of patients with AIS.

#### 4.3.3.3 Spinal flexibility

There was no significant difference in spinal flexibility between the two groups before intervention ($p=0.123$), indicating that the spinal flexibility of the two groups was comparable at the baseline assessment. After 6 months intervention, there was significant difference in spinal flexibility between the two groups ($p<0.001$). The FDDT distance of patients in the intervention group was significantly longer than that measured at baseline ($p<0.001$), while in the control group, there was no significant difference in BST time between the 6-month assessment and the baseline assessment ($p=0.482$). It meant that acupuncture combined with tuina could effectively improve the spinal flexibility of patients with AIS.

#### 4.3.3.4 Quality of life

There was no significant difference in all the five dimensions of SRS-22 scale between the two groups before intervention, indicating that the quality of life of the two groups was comparable at the baseline measurement. After 6 months intervention, there were significant differences in pain score and self-image score between the two groups (pain: $p<0.001$; self-image: $p=0.02$). The pain score and self-image score in the intervention group was significantly higher than that measured at baseline (all $p<0.001$), while in the control group, there was no significant difference in pain score and self-image score between the 6-month assessment and the baseline assessment (all $p>0.05$). In terms of function, mental health and treatment satisfaction scores, there was no significant difference between the two groups in the baseline period as well as after 6 months intervention (all $p>0.05$). It meant that acupuncture combined with tuina significantly improve the pain and self-image score of patients with AIS.

#### 4.3.3.5 The changes of spinal deformity of the two groups before and after intervention.

The change of spinal deformity of the two groups before and after intervention was shown in **Figure 4-8**. In the intervention group, there were 14(66.7%) patients reduced (Cobb angle decreased>5°), 1(4.8%) patient progressed (Cobb angle increased>5°) and 6(28.6%) patients remained stable. (Cobb angle increased or decreased≤5°); While in the control group, there were 0 patient reduced, 7(29.2%) patients progressed and 17(70.8%) patients remained stable. After 6-month intervention, intergroup comparison showed that the reduction rate and stable rate of the intervention group were significantly higher than that of the control group ($p<0.001$, $p=0.005$, respectively), while progress rate was significantly lower than that of the control group ($p=0.033$).

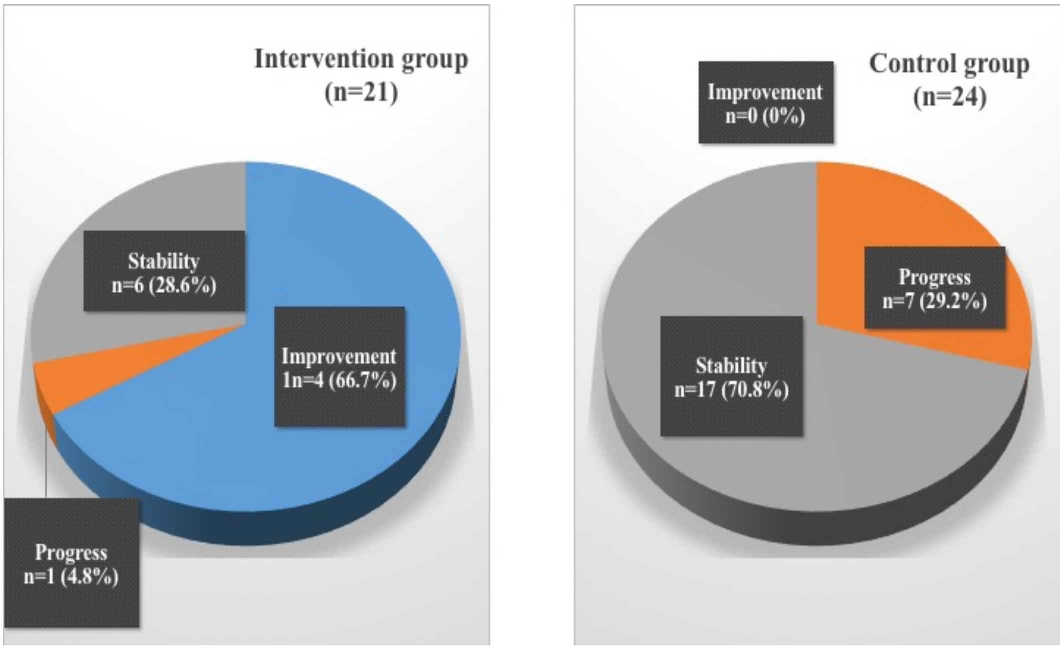



**Figure 4-8 The changes of spinal deformity of the two groups before and after intervention**

### 4.3.4 Adverse events recording and handling

There were no accidents such as broken needles, bent needles, or pneumothorax happened during acupuncture intervention. One patient had fainting during acupuncture and was asked to lie down immediately, and the symptoms were then relieved. After psychological counseling, the patient did not faint again, completed the entire intervention process. Two other patients complained of mild soreness on the convex side of the spine during tuina intervention. After the massage therapist reduced the intensity of the manipulation, the patient no longer experienced pain and discomfort and completed the entire intervention process.

## 4.4 Discussion

The main purpose of current study was to explore the therapeutic effect of traditional Chinese medicine (acupuncture combined with tuina) on patients with adolescent idiopathic scoliosis, so as to provide an effective and safe conservative treatment method for adolescent idiopathic scoliosis, especially suitable for patient in china. Our results indicated that 6 months of TCM intervention could not reduce the spinal deformity but also enhance the back muscles strength and the spinal flexibility of AIS patients with mild curvature. In terms of raising the quality of life, TCM relieved patients' pain and increased their self-image.

For AIS patients with mild to moderate curvatures (Cobb angle 10-40°), conservative treatments are usually suggested to prevent and slow down the progression of spinal deformities. The physician recommended appropriate treatments to the patients according to the severity of their spinal deformity and treatment compliance. Meaningful observation, scoliosis-specific exercise, and orthotic intervention are the widely accepted intervention methods used today.

For patients with Cobb angle 25-40°, orthoses were prescribed to correct scoliotic spine. While for patients with a curvature of 10-25°, the negative effects of orthotic intervention tended to outweigh its benefits on spinal deformities correction. As a result, these patients usually received "meaningful observation" or scoliosis-specific exercise. There were a variety of SSE programs applied in the management of AIS patients, yet their therapeutic effects on prevent curve progression remained controversial. What's more, most of SSEs were proposed by foreign scoliosis clinics, and the theory and practical operation were relative complicated, which was not easy to be popularized, especially in china where have large AIS populations. On the other hand, only observation without interventions was often inadequate, as the spinal deformities could develop and the patients might miss effective early intervention. In this study, 7 patients in the observation group (29.2%) appeared curve progression (Cobb angle increased>5°) at the 6-month follow-up. Traditional Chinese medicine had hundreds of years history in the treatment of low back diseases. In recent years, some domestic researches have applied a variety of traditional Chinese medicine theories and methods to correct patients' spinal deformities, which achieved better curative effect. Qian et al.[136] observed 180 mild AIS patients who received tuina therapy. The results showed that 114 patients with Cobb angle decreased to less than 5° and 40 patients reduced (Cobb angle decreased>5°), the total corrective rate was 85%. Wang et al.[137] reported that 5-weeks tuina therapy could significantly decreased the Cobb angle of the patients with AIS, and the total curve corrective rate was significantly higher than that of the control group treated with traction. According to theory of traditional Chinese medicine, the key points of tuina in the management of AIS was to fully restore the tension balance of muscles and fasciae on both sides of scoliotic spine[138]. In this study, different intensity tuina manipulations were performed to activate the muscles and fasciae around spine in order to improve the contracture of soft tissues on the concave side and to reduce the tissue tension on the convex side. Through the pulling manipulation, the therapist applied the body as a lever to produce drawing force on the concave side of deformed spine, with the aim to alleviate the tension caused by soft tissue contracture. It should be noted that tuina therapy exerted therapeutic effects mainly through balancing the tension on both sides of the curvature while applying external force to passively correct spinal deformities, which could bring a good effect in the short term. However, patients with AIS were usually with a longer course, and the long-term therapeutic effect could not be guaranteed by tuina therapy alone. In this study, acupuncture therapy was added, aiming to stimulate the paravertebral muscles (such as erector spinae, spinal muscles, etc.) through needling the corresponding points to restore the balance of strength, so as to improve the ability of active maintaining the spine upright[139]. Its action mechanism may be related to acupuncture stimulation improving motor neuron excitability, increasing motor unit voltage and promoting muscle fiber contraction[140,141]. The combination of acupuncture and tuina can improve the bowstring effect while balancing and increasing the strength of low back muscles, active and passive work together to reduce spinal deformities.

The latest SOSORT guidelines pointed out that in the management of AIS patients, attention should be paid not only to the correction of spinal deformities, but also to the impact of interventions on patients' quality of life. In current study, SRS-22 questionnaire was used to evaluate patients’ quality of life. The results showed that the pain score of the patients treated with acupuncture combined with tuina was significantly higher than that of the control group. Acupuncture has been widely used to reduce pain symptoms caused by low back diseases, although the exact mechanism is still unclear[142,143]. Current studies considered that the possible mechanisms of acupuncture in relieving the pain symptoms of patients with AIS could be in the following ways, (1) Inhibiting inflammation: It was suggested that the appearance of pain in patients with scoliosis may be related to aseptic inflammatory stimulation produced by soft tissue contracture. Acupuncture can relieve pain through reducing inflammatory exudation and decreasing vascular permeability; (2) Improving local microvascular circulation: Microvascular circulation was usually regulated by vasoactive substances and sympathetic nerves, acupuncture can act simultaneously on these two processes, through stimulating axonal reflex to promote the release of various inflammatory cytokines[144,145]; (3) Inhibition of pain signals input: animal experiments have found that acupuncture at Jiaji points around the paravertebral muscles can inhibit the pulsed electrical signals in the posterior horn of the spinal cord[146], which in turn restrained the afferent of pain signal, this may be related to the inhibition of c_fos gene expression of neurons in the dorsal horn of spinal cord[147]. In addition to the improvement of pain score, the self-image score of the patients in the intervention group also improved significantly after treatment, which was considered to be related to the better correction of spinal deformities in this group compared with the control group.

#### 4.4.1 Study significances and innovations

Adolescent idiopathic scoliosis (AIS) is a complex three-dimensional deformity of the spine and trunk that occur in adolescents with unknown etiology. If untreated in time, it tends to further deteriorate, which seriously affect the physical and mental health of the teenagers. For patients with mild AIS, in addition to "meaningful observation", scoliosis specific exercise is usually recommended. However, most of these SSEs involves intensive and complex training, and the patients' treatment compliance is poor, which leads to its therapeutic effects remain controversial. Based on China’s national conditions, this study summarized the clinical practice of traditional Chinese medicine in the treatment of adolescent idiopathic scoliosis, early applied acupuncture and tuina to patients with mild AIS. Our results showed that acupuncture combined with tuina was effective in correcting spinal deformity. This method has high feasibility and good patient compliance, which provided a new choice for the treatment of AIS. When applying acupuncture to AIS patients, this study conducted TCM syndrome differentiation on patients, selected appropriate Shu points for compatibility according to different syndrome types of patients, and improved the effect of acupuncture therapy through individualized acupoints selection.

#### 4.4.2 Study limitations

Firstly, as a novel conservative intervention for patients with adolescent idiopathic scoliosis, TCM intervention is not well accepted by patients at the moment. Therefore, this study adopted a quasi-experimental research design, that is, patients were allocated to the intervention group or the control group according to their preferences. Although increasing patients’ compliance, this study design reduced the reliability of research conclusions. However, the baseline data of the patients in the two groups were comparable, which to some extent reduced the bias caused by non-random grouping. Follow-up studies still need to carry out more RCTs to provide high-level evidence supporting for the effectiveness of traditional Chinese medicine in the management of AIS. Secondly, only patients with mild curves were included in this study, and the therapeutic effect of TCM intervention on moderate and severe spinal deformities remains an important extension of this research. Thirdly, the outcome measurements were relatively less due to limited equipment in the clinic, more quantitative outcomes are needed for the future study. Finally, the relatively short follow-up period could be considered as one of the disadvantages of current study. Although correction of Cobb angle after 6-month intervention is statistically significant, a long-term clinical significance is needed to be further investigated.

## 4.5 Conclusion

TCM intervention could not only reduce the spinal deformity but also enhance the back muscles strength and the spinal flexibility of AIS patients with mild curvature. In terms of raising the quality of life, TCM relieved patients' pain and increased their self-image. As an effective and safe intervention in the treatment of adolescent idiopathic scoliosis, acupuncture combined with tuina is worth popularizing and applying in clinical practice.

# CHAPTER 5 CONCLUSIONS

This PhD project mainly include three parts, part I was a scoping review, which was conducted in order to provide evidence-based evidence for clinical application conservative treatments in the management of AIS. Based on the findings of this review, In Part II, a RCT study were performed to investigate the effectiveness of the integration of orthotic intervention and scoliosis specific exercise in the treatment of adolescent idiopathic scoliosis; and in Part III, a quasi-experimental study was conducted to explore the effectiveness of TCM (acupuncture combined with tuina) in the treatment of patients with adolescent idiopathic scoliosis.

**Major findings of current study and recommendations for future research**

1) Regardless of its types, orthosis was more effective than other conservative treatments in reducing spinal deformity, although more high-quality studies were required to consolidate this conclusion.

2) Scoliosis specific exercises showed benefits in patients with mild scoliosis, the effectiveness of the combination of scoliosis specific exercise with orthosis was lack of scientific evidence from randomized controlled studies.

3) Traditional Chinese medicine could correct spinal deformities and balance the muscles on both sides of the spinal curvature, which provided a new strategy for conservative management of patients with AIS.

4) In addition to spinal deformity, more attention should be paid to the impacts of conservative treatments on patients' appearance, mental health, cardiopulmonary function as well as the quality of life of patients with AIS.

5) Methodological weaknesses existed in the current studies relating conservative treatments for AIS. High quality studies with well-designed and long follow-up were required to evaluate the effectiveness of different conservative treatments for AIS.

6) SSE combined with orthosis could further increase the Cobb angle correction compared with orthotic intervention only. Additional SSE could improve the deteriorated respiratory parameters and back muscle endurance of patients treated with orthosis. Compared with orthosis only, patients showed better quality of life when applying SSE during orthotic intervention, especially in terms of pain and mental health. Taken together, SSEs are suggested to patients with AIS during the period of orthoses wearing. However, a long-term study with more subjects is deserved for confirmation of the current findings.

7) TCM intervention could not only reduce the spinal deformity but also enhance the back muscles strength and the spinal flexibility of AIS patients with mild curvature. In terms of raising the quality of life, TCM relieved patients' pain and increased their self-image. As an effective and safe intervention in the treatment of adolescent idiopathic scoliosis, acupuncture combined with tuina is worth popularizing and applying in clinical practice.

# APPENDICES

## APPENDIX I: SEARCH STRATEGIES OF MEDLINE AND EMBASE DATABASES

***Search Strategies for MEDLINE Database:***

1. exp Spinal Diseases/

2. Scoliosis/

3. scoliosis.mp.

4. or/1-3

5. exp Rehabilitation/

6. rehabilit$.tw.

7. rehabilitation.fs.

8. exp Physical Therapy Modalities/

9. Physical Therapy Speciality.mp.

10. physiotherapy.tw.

11. physical therapy.tw.

12. exp Exercise/

13. exercise$.tw.

14. Exercise Movement Techniques/

15. exp Exercise Therapy/

16. exp Musculoskeletal Manipulations/

17. Immobilization/

18. Braces/

19. exp Orthotic Devices/

20. Orthopedic Equipment/

21. exp Acupuncture/

22. expTraditional chinese medicine/

23. (non-surg$ or nonsurg$ or non-operat$ or nonoperat$ or conserv$).tw.

24. (immobilis$ or immobiliz$ or therap$ or taping or tape$ or tuina or electrotherapy$).tw.

25. or/5-24

26. 4 and 25

27. limit 26 to adolescent <13 to 18 years>

28. Adolescent/

29. adolescen$.mp.

30. 28 or 29

31. 26 and 30

32. 27 or 31

33. randomized controlled trial.pt.

34. controlled clinical trial.pt.

35. randomi#ed.ti,ab.

36. randomly.ti,ab.

37. trial.ti,ab.

38. groups.ti,ab.

39. or/32-38

40. (Animals not (Humans and Animals)).sh.

41. 39 not 40

42. 31 not 40

43. 41 or 42

44. 32 and 43

***Search Strategies for EMBASE Database:***

#1. 'spine'/exp

#2. 'spine disease'/exp

#3. 'scoliosis'/exp

#4. 'idiopathic scoliosis'/exp

#5. #1 OR #2 OR #3 OR #4

#6. 'rehabilitation'/exp

#7. rehabilitat$:ti,ab

#8. 'physiotherapy'/exp

#9. 'physiotherapist'/exp

#10. 'physical therapy':ti,ab

#11. 'exercise'/exp

#12. 'kinesiotherapy'/exp

#13. 'manipulative medicine'/exp

#14. 'immobilization'/exp

#15. 'brace'/exp

#16. brace$:ti,ab

#17. 'traditional chinese medicine'/exp

#18. nonsurg$:ti,ab OR nonoperat$:ti,ab OR conserv$:ti,ab

#19. immobilis$:ti,ab OR immobiliz$:ti,ab OR therap$:ti,ab OR taping:ti,ab OR tape$:ti,ab OR electrotherap$:ti,ab OR acupuncture:ti,ab OR tuina:ti,ab

#20. #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19

#21. #5 AND #20

#22. #21 AND [adolescent]/lim

#23. 'adolescent'/exp

#24. adolescen$:ti,ab

#25. #23 OR #24

#26. #21 AND #25

#27. 'controlled study'/exp

#28. 'randomized controlled trial'/exp

#29. 'double blind procedure'/exp

#30. 'multicenter study'/exp

#31. 'placebo'/exp

#39. #27 OR #28 OR #29 OR #30 OR #31

#40. #39 AND 'human'/de

#41. #26 AND #40

## APPENDIX II: INFORMATION SHEET

### Information Sheet for the RCT Study

**Study Title:**

***The Effectiveness of Scoliosis Specific Exercise Combined with Orthosis on Patients with Adolescent Idiopathic Scoliosis: a Randomized Controlled Trial Study***

You are invited to participate in a study conducted by Dr. Man-sang WONG, Associate Professor of the Department of Biomedical Engineering, The Hong Kong Polytechnic University. Mr. GAO CHENGFEI who is a PhD student of Dr. Man-sang WONG, will be the assistance in this study.

The aim of this study is to investigate the effectiveness of the integration of orthotic intervention (OI) and scoliosis specific exercise (SSE) in the treatment of adolescent idiopathic scoliosis. Participants who are eligible for the included criteria will be randomly assigned into the OE group (combined orthotic and exercise intervention) or the OI group (orthotic intervention only). All participants will be prescribed with a rigid TLSO, an additional SSE program will be provided to the participants in the OE group. Cobb angle, back muscle endurance and cardiopulmonary function of the participants will be measured at baseline, 6-month and 12-month follow-up visits. This is the first RCT study to explore the therapeutic effect of the combination of SSE with orthosis on patients with AIS, the results will provide a higher-level evidence-based medicine for the clinical application of exercise during orthotic intervention.

All information related to you will remain confidential and will be identifiable by codes only known to the researcher. Subjects are at minimum risk with this study. Minimal risk means that the risks of harm anticipated in the proposed research are not greater considering probability and magnitude, than those ordinarily encountered in daily life. You have every right to withdraw from the study before or during the intervention without penalty of any kind.

If you have any complaints about the conduct of this research study, please do not hesitate to contact Miss. Ivy CHAU, Secretary of the Human Subjects Ethics Sub-Committee of The Hong Kong Polytechnic University in person or in writing (c/o Room M1303, Human Resources Office of the Hong Kong Polytechnic University). If you would like more information about this study, please contact Dr. Man-sang WONG at 2766-7680.

Thank you for your interest in participating in this study.

Principal Investigator: Dr. Man-sang WONG

## Information Sheet for the quasi-Experimental Study

**Study Title:**

***The Effectiveness of Acupuncture Combined with Tuina on Patients with Adolescent Idiopathic Scoliosis: a quasi-Experimental Study***

You are invited to participate in a study conducted by Dr. Man-sang WONG, Associate Professor of the Department of Biomedical Engineering, The Hong Kong Polytechnic University. Mr. CHENGFEI GAO who is a PhD student of Dr. Man-sang WONG, will be the assistance in this study.

The aim of this study is to investigate the effectiveness of acupuncture combined with tuina in the treatment of patients with adolescent idiopathic scoliosis. Participants who are eligible for the included criteria will be divided into the experimental group (the TCM group) or the control group. Participant in the experimental group will receive traditional Chinese medicine intervention (acupuncture combined with tuina), those in the control group will receive meaningful observation without further intervention. Cobb angle, back muscle endurance, spinal flexibility and quality of life of subjects will be measured at baseline and 6-month follow-up visit.

This is the first quasi-experimental study to explore the therapeutic effect of traditional Chinese medicine on patients with AIS, the results will provide an effective and safe conservative treatment method for adolescent idiopathic scoliosis, especially suitable for patients in china.

All information related to you will remain confidential and will be identifiable by codes only known to the researcher. Subjects are at minimum risk with this study. Minimal risk means that the risks of harm anticipated in the proposed research are not greater considering probability and magnitude, than those ordinarily encountered in daily life. You have every right to withdraw from the study before or during the intervention without penalty of any kind.

If you have any complaints about the conduct of this research study, please do not hesitate to contact Miss. Ivy CHAU, Secretary of the Human Subjects Ethics Sub-Committee of The Hong Kong Polytechnic University in person or in writing (c/o Room M1303, Human Resources Office of the Hong Kong Polytechnic University).

If you would like more information about this study, please contact Dr. Man-sang WONG at 2766-7680.

Thank you for your interest in participating in this study.

Principal Investigator: Dr. Man-sang WONG

**APPENDIX III: INFORMATION SHEET (CHINESE VERSION)**

## 項目名稱：

## *運動訓練配合矯形器治療青少年特發性脊柱側凸的臨床研究*

誠邀閣下參加由香港理工大學生物醫學工程學院 黃文生 副教授負責執行的研究項目。此項目將由 黃文生 副教授的博士研究生 高呈飞 來協助執行。

此研究的目標是探究運動訓練配合器對青少年特發性脊柱側凸的治療效果。符合納入條件的受試者將被隨機分配到矯形器聯合運動訓練組（OE 組）或僅矯形器治療組（OI 組）。所有受試者均需配戴 TLSO 矯形器，而 OI 組受試者還進行額外的運動訓練。分別在基線期、6 個月及 12 個月對所有受試者的 Cobb 角、後背部肌肉耐力、心肺功能及生活質量進行評估。本研究是第一項探索運動訓練聯合矯形器對青少年特發性脊柱側凸治療效果的隨機對照研究，研究結果將為運動訓練聯合矯形器的臨床應用提供高等級證據支持。

凡有關閣下的資料均會保密,一切資料的編碼只有研究人員知道。

閣下享有充分的權利在研究開始之前或之後決定退出這項研究，而不會受到任何對閣下不正常的待遇或責任追究。

如果閣下有任何對這項研究的不滿，請隨時親自或寫信聯絡香港理工大學人事倫

理委員會秘書 周艾維 （地址：香港理工大學人力資源辦公室 M1303 室轉交）。

如果閣下想獲得更多有關這項研究的資料， 請與 黃文生 副教授聯絡，辦公室

電話：2766-7680.

謝謝閣下參與這項研究。

首席調查員：黃文生 副教授

**項目名稱:**

***針灸聯合推拿治療青少年特發性脊柱側凸的臨床研究***

誠邀閣下參加由香港理工大學生物醫學工程學院 黃文生 副教授負責執行的研究項目。此項目將由 黃文生 副教授的博士研究生 高呈飞 來協助執行。

此研究的目標是探索針灸聯合推拿對青少年特發性脊柱側凸的治療效果。符合納入標準的受試者按照個人意願被分配到實驗組（接受針灸聯合推拿治療）或對照組（僅進行“有意義”的觀察，而無特殊干預）。分別在基線期及干預 6 個月後對受試者的 Cobb 角、腰背肌肉耐力、脊柱靈活性及生活質量進行評估。本研究是第一項探索傳統中醫（針灸聯合推拿）對青少年特發性脊柱側凸治療效果的准實驗研究。研究結果青少年特發性脊柱側凸患者提供一種新的有效且安全的保守治療方法，尤其適用於中國的患者。

凡有關閣下的資料均會保密,一切資料的編碼只有研究人員知道。

閣下享有充分的權利在研究開始之前或之後決定退出這項研究, 而不會受到任何對閣下不正常的待遇或責任追究。

如果閣下有任何對這項研究的不滿，請隨時親自或寫信聯絡香港理工大學-人事倫理委員會秘書 周艾維 （地址: 香港理工大學人力資源辦公室 M1303 室轉交)。

如果閣下想獲得更多有關這項研究的資料， 請與 黃文生 副教授聯絡，辦公室

電話：2766-7680.

謝謝閣下參與這項研究。

首席調查員: 黃文生 副教授

## APPENDIX IV: CONSENT FORM

**Consent to Participate in Research**

**Study Title:**

***Scoping Review and Clinical Research on Conservation Interventions to Adolescent Idiopathic Scoliosis***

I ____________ hereby consent to participate in the captioned research conducted by Dr. Man-sang WONG (Associate Professor of the Department of Biomedical Engineering, The Hong Kong Polytechnic University), and assisted-conducted by Mr. CHENGFEI GAO.

I understand that the information obtained from this research may be used in future research and published. However, my right to privacy will be retained, i.e. my personal details will not be revealed.

The procedure as set out in the attached information sheet has been fully explained. I understand the benefit and risks involved. My participation in the project is voluntary.

I acknowledge that I have the right to question any part of the procedure and can withdraw at any time without penalty of any kind.

If you would like more information about this study, please contact Dr. Man-sang WONG at 2766-7680.

Name of participant: ________________________________________

Signature of participant: _____________________________________

Date: ____________________________________________________

Name of researcher: _________________________________________

Signature of researcher: ____________________________________

Date: ___________________________________________________

**APPENDIX V: CONSENT FORM (CHINESE VERSION)**

參與研究同意書

**項目名稱:**

***青少年特發性脊柱側凸保守治療的系統評價與臨床研究***

本人 ____________特此同意參加由香港理工大學生物醫學工程學院 黃文生 副教授負責執行及加以說明的研究項目, 並且該項目將由 黃文生 副教授的博士研究生 高呈飞 來協助執行。

我理解此研究所獲得的資料可用於未來的研究和學術交流。然而我有權保護自己的隱私，我的個人資料將不能被洩漏。

我對所附資料的有關步驟已經得到充分的解釋。我是自願參加與這項研究。

我理解我有權在研究過程中提出問題, 并可在任何時候決定退出研究而不會受到任何不正常的待遇或責任追究。

如果閣下想獲得更多有關這項研究的資料， 請與 黃文生 副教授聯絡，辦公室電話：2766-7680.

參加者姓名：___________________________________________

參加者簽名：___________________________________________

日期：___________________________________________________

研究人員姓名：_________________________________________

研究人員簽名：_________________________________________

日期：____________________________________________________

導師姓名：_____________________________________________

導師簽名：________________________________________

日期：____________________________________________

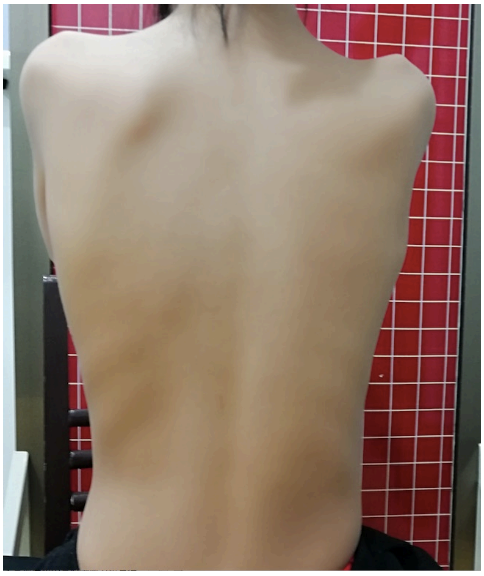
## APPENDIX VI: SCOLIOSIS SPECIFIC EXERCISE PROTOCOL

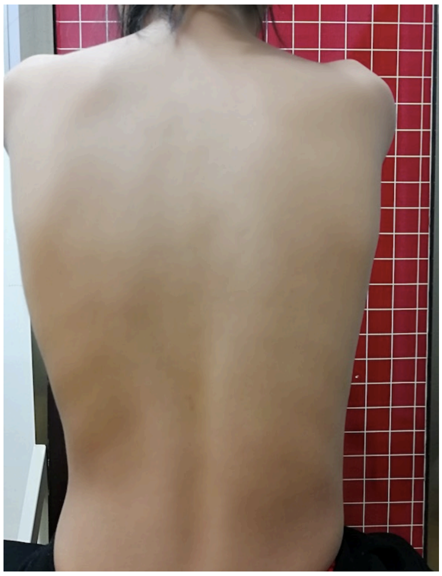
### i. *Active self-correction on the frontal plane*

The aim of Active self-correction on the frontal plane is to restore the neutral position of the scoliotic spine. The physician places his finger on the spinous process correspondent to the apex of thoracic curve, while the children are asked to move the vertebrae shift to the concave side, then the apical vertebrae can move to the midline. Similarly, the physician places his finger on the spinous process correspondent to the apex of lumbar curve, while the children are asked to move the vertebrae shift to the concave side, then the apical vertebrae can move to the midline. To avoid imbalance, the counter-support of the physician's hand on the hemithorax and hemipelvis opposed to the convexity side of spinal curvature. Through repetitive practice, the adolescents can remember the required position of the spinous processes and apical vertebrae, in order to achieve the goal that the children could practice these exercise training at home with no guidance required.

### ii. *Active self-correction on the sagittal plane*

The aim of active self-correction on the sagittal plane is to restore the physiological curvature of thoracic kyphosis and lumbar kyphosis. The detailed steps are as follows: A mirror was set on the side of the body, then a vertical stick is used to help the patient to feel the 4 physiological curvatures of the spine, and then the patient is required to move backward of the thoracic vertebra and tilt forward of the pelvis, in order to restore patient's physiological curvature to the maximum extent. Once the patients master this training, the vertical stick and mirror can be removed. Finally, the training of active self-correction on frontal and sagittal active self-correction can be performed at the same time.





### iii. *Active self-correction on the horizontal plane*

According to previous study, when the spine is corrected in the coronal and sagittal planes at the same time, the deformity on the horizontal plane can be corrected automatically. Therefore, joint active self-correction training on the coronal and sagittal planes can achieve the effect of active self-correction on the horizontal plane.

### *iv. Muscular endurance strengthening in the correct posture*

The aim of this exercise is to strengthen the endurance of para-spinal muscle, abdominal muscles, shoulder muscles, back muscles and lower limbs muscles through isometric contraction training. During active self-correction training, 1/3 to 2/3 muscle contraction can resist the maximum load, thus strengthening the endurance of the corresponding muscles.

### *v. Balance training*

The balance training is to strengthen the axial balance of the back through a variety of static and dynamic balance training. This part of the training is also required to be carried out during active self-correction, which adjusts the training intensity and difficulty according to the condition of the patients.

### *vi. Breathing training*

The therapist loosens the patient's thoracic spine and rib cage, which helps the patient obtain an upright posture and increases the expansion of the thoracic cage and rib cage. At the same time, the therapists instruct the patient to perform the respiratory muscles strength training to increase the patient's breathing strength.

### *vii. Aerobic exercise training*

The patient performs aerobic exercise training on a treadmill, with no load at the beginning, and adjusts the pace and slope based on individual conditions. Necessary protection should be given to the patients during the training process.

## APPENDIX VII: SCOLIOSIS RESEARCH SOCIETY-22 QUESTIONNAIRE

**SRS-22 Questionnaire**

**Patient Name: ______ ______ ______ Date of Birth: ____ ____ ____**
**Today's Date: ____ ____ ____ Age: ____ ____**
**Medical Record #: ___________________**

**INSTRUCTIONS: WE ARE CAREFULLY EVALUATING THE CONDITION OF YOUR BACK AND IT IS IMPORTANT THAT YOU ANSWER EACH OF THESE QUESTIONS YOURSELF. PLEASE CIRCLE THE ONE BEST ANSWER TO EACH QUESTION.**

***1. Which one of the following best describes the amount of pain you have experienced during the past 6 months?***

None

Mild

Moderate

Moderate to severe

Severe

***2. Which one of the following best describes the amount of pain you have experienced over the last month?***

None

Mild

Moderate

Moderate to severe

Severe

***3. During the past 6 months have you been a very nervous person?***

None of the time

A little of the time

Some of the time

Most of the time

All of the time

***4. If you had to spend the rest of your life with your back shape as it is right now, how would you feel about it?***

Very happy

Somewhat happy

Neither happy nor unhappy

Somewhat unhappy

Very unhappy

***5. What is your current level of activity?***

Bedridden

Primarily no activity

Light labor and light sports

Moderate labor and moderate sports

Full activities without restriction

***6. How do you look in clothes?***

Very good

Good

Fair

Bad

Very bad

***7. In the past 6 months have you felt so down in the dumps that nothing could cheer you up?***

Very often

Often

Sometimes

Rarely

Never

***8. Do you experience back pain when at rest?***

Very often

Often

Sometimes

Rarely

Never

***9. What is your current level of work/school activity?***

100% normal

75% normal

50% normal

25% normal

0% normal

***10. Which of the following best describes the appearance of your trunk; defined as the human body except for the head and extremities?***

Very good

Good

Fair

Poor

Very Poor

***11. Which one of the following best describes your pain medication use for back pain?***

None

Non-narcotics weekly or less (e.g., aspirin, Tylenol, Ibuprofen)

Non-narcotics daily

Narcotics weekly or less (e.g. Tylenol III, Lorcet, Percocet)

Narcotics daily

***12. Does your back limit your ability to do things around the house?***

Never

Rarely

Sometimes

Often

Very Often

***13. Have you felt calm and peaceful during the past 6 months?***

All of the time

Most of the time

Some of the time

A little of the time

None of the time

***14. Do you feel that your back condition affects your personal relationships?***

None

Slightly

Mildly

Moderately

Severely

***15. Are you and/or your family experiencing financial difficulties because of your back?***

Severely

Moderately

Mildly

Slightly

None

***16. In the past 6 months have you felt down hearted and blue?***

Never

Rarely

Sometimes

Often

Very often

***17. In the last 3 months have you taken any days off of work, including household work, or school because of back pain?***

0 days

1 day

2 days

3 days

4 or more days

***18. Does your back condition limit your going out with friends/family?***

Never

Rarely

Sometimes

Often

Very often

***19. Do you feel attractive with your current back condition?***

Yes, very

Yes, somewhat

Neither attractive nor unattractive

No, not very much

No, not at all

***20. Have you been a happy person during the past 6 months?***

None of the time

A little of the time

Some of the time

Most of the time

All of the time

***21. Are you satisfied with the results of your back management?***

Very satisfied

Satisfied

Neither satisfied nor unsatisfied

Unsatisfied

Very unsatisfied

***22. Would you have the same management again if you had the same condition?***

Definitely yes

Probably yes

Not sure

Probably not

Definitely not

***Thank you for completing this questionnaire. Please comment if you wish.***

**APPENDIX VIII: SCOLIOSIS RESEARCH SOCIETY-22 QUESTIONNAIRE (CHINESE VERSION)**

*SRS-22 問卷*

姓 名 :____________________________ 出 生 日 期 :_________ _________ _________

日期:_________ _________ _________ 性別: 男 / 女

電話:____________________________ 年齡:_________ + _________

病歷記錄#:_________________________

指示: 我們正在小心評估你背部的情況，因此問卷上的每一條問題必須由你親自回答。

請在每一條問題所提供的選擇中，小心圈出你認為最正確的一個答案。

*一. 以下哪一項最能夠準確描述你在過去六個月所感受到痛楚的程度?*

無痛楚

輕微

中等

中等至嚴重

嚴重

*二. 以下哪一項最能夠準確描述你在過去一個月所感受到痛楚的程度?*

無痛楚

輕微

中等

中等至嚴重

嚴重

*三. 整體來說，在過去六個月期間你有感到十分焦慮嗎?*

完全沒有

小部份時間

有時

大部份時間

全部時間

*四. 如果你必須在背部維持現狀不變的情況下繼續生活，你會有甚麼感受？*

十分愉快

某程度上愉快

沒有愉快或不愉快

某程度上不愉快

十分不愉快

*五. 你現時的活動能力如何？*

只限於床上

基本上不能活動

些微的運動及勞動

有限度的運動及勞動

活動不受限制

*六. 你在穿上衣服後的外觀如何？*

很好

好 可

以接受

差勁

十分差勁

*七. 在過去六個月期間你曾感到十分沮喪以至於任何事物也不能讓你開懷嗎？*

經常

大多數時間

有時

很少數時間

完全沒有

*八. 你在休息時背部有感到疼痛嗎?*

經常

大多數時間

有時

很少數時間

完全沒有

*九. 你現時在工作/學校的活動能力為多少?*

正常的 100%

正常的 75%

正常的 50%

正常的 25%

正常的 0%

*十. 以下哪一項最能夠描述你軀幹的外觀?(軀幹的定義為人的身體除去頭部及四肢)*

很好

好 可

以接受

差勁

十分差勁

*十一. 下例哪一項最能準確地描述你因背部疼痛而所需要服用的藥物?*

無 一

般止痛藥 (每星期服用一次或更少)

一般止痛藥 (天天服用)

特效止痛藥 (每星期服用一次或更少)

特效止痛藥 (天天服用)

其他:______________________ ______________________________

藥物名稱 使用程度(每星期或更少或天天)

*十二. 你的背部疼痛有否影響你做家務的能力?*

沒有

少許

某程度上有

很大程度上有

經常有

*十三. 整體來說，你在過去六個月期間有感到安寧和平靜嗎？*

經常

大多數時間

有時

很少數時間

完全沒有

*十四. 你有否感到你背部的狀況對你的人際關係構成影響？*

沒有

少許

某程度上有

很大程度上有

經常有

*十五. 你以及/或你的家人有否因為你背部的問題而在經濟方面遇到困難？*

極有

很大程度上有

某程度上有

少許

沒有

*十六. 整體來說，在過去六個月期間你有否感到失落和灰心？*

完全沒有

很少數時間

有時

大多數時間

經常

*十七. 在過去三個月期間你有否因背痛而向學校/公司請假？如有，共有多少天？*

零天

一天

兩天

三天

四天或以上

*十八. 你背部的狀況有否阻礙你和家人/朋友外出？*

從來沒有

很少數時間

有時

大多數時間

經常

*十九. 你現時背部的狀況會否讓你覺得自己仍有吸引力?*

會，很有吸引力

會，某程度上有吸引力

無影響

否，沒有甚麼吸引力

否，完全沒有吸引力

*二十. 整體來說，你在過去的六個月裏感到愉快嗎?*

完全沒有

很少數時間

有時

大多數時間

經常

*二十一. 你對你背部治療的成效感到滿意嗎?*

十分滿意

滿意

不是滿意也不是不滿意

不滿意

非常不滿意

*二十二. 如果你的背部再次遇到同類的情況你會否接受同樣的治理?*

一定會

可能會

不清楚

可能不會

一定不會

*多謝你的合作，如有任何意見請填寫在以下的空位上。*

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