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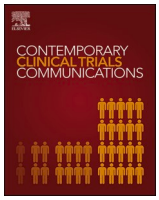

Balance chiropractic therapy for cervical spondylotic radiculopathy: A randomized controlled trial☆

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ABSTRACT

Objective: To assess the clinical effectiveness of the balance chiropractic therapy (BCT) compared with traction therapy (TT) for patients with cervical spondylotic radiculopathy.
Methods: Subjects were enrolled from four hospitals. Eligible patients will be randomized to one of the two arms: the treatment group and the control group. In the treatment group, patients received the BCT for 20 days, while patients in the control group received TT. Patients visited the physician at 1- and 3-month follow-up. The primary outcome was pain severity measured with a Visual Analog Scale (VAS). Secondary outcomes included cervical curvature measured using the Borden method, a composite of functional status measured by the Neck Disability Index (NDI), patient health status (evaluated by the SF-36 health survey) and adverse events (AEs) as reported in the trial.
Results: Of the 240 randomly assigned patients, 120 participants were assigned to the BCT and 120 to the TT. 231 (96.3 %) provided follow-up data at 1 and 3 months. There were no significant differences in baseline data between the two groups ($P > 0.05$), indicating good comparability. According to the results, after BCT and TT treatment, the pain VAS score, cervical curvature, NDI scores and SF-36 scores of two groups was significantly improved ($P < 0.05$). Furthermore, at 20 days of treatment and 1 and 3 months of follow-up, the participants in the BCT group showed superior treatment outcomes on both primary and secondary measures.
Conclusion: The BCT may be a novel strategy for the treatment of the cervical spondylotic radiculopathy.
Trial registration: Clinical Trials.gov Identifier: NCT02705131. Registered on March 10, 2016, https://clinicaltrials.gov/study/NCT02705131?cond=NCT02705131&rank=1&tab=table.

1. Introduction

Cervical spondylosis is a very common disorder and Cervical Spondylotic Radiculopathy (CSR) is the most common type of spinal degenerative disease, accounting for about 60–70 % of all cervical spondylosis [1,2]. The incidence of CSR tends to increase year by year due to aging, lifestyle changes and work or life stress. The symptoms of CSR, including pain and numbness of the neck and arms, as well as restricted movement of the neck, greatly affect the quality of life of patients. The agents currently approved for treatment and/or prevention of CSR include operative treatment and non-operative treatment categories (e. g. physical therapy, drugs, traction, manipulation, functional exercise, etc.). Many studies have suggested that non-operative therapy has more evident effects on the optimized scheme of CSR [3–5]. However, there are currently very few randomized, parallel-controlled trials to verify the treatment efficacy of non-operative means in treating CSR. The balance chiropractic therapy (BCT) helps restore cervical radiculopathy by regulating the balance between the dynamic and static systems of the cervical spine.

We conducted a single-blinded, randomized controlled trial to compare the treatment effects of the BCT with the traction therapy (TT) that considered as a routine and non-surgical therapy. We hypothesized

☆ The study was approved by the Ethics Committee of Affiliated Hospital of Shaanxi University of Chinese Medicine (No. SZFYIEC-PJ-2016[01]).

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that at the end of the 20-day intervention period, patients in the BCT group would have a greater reduction in musculoskeletal pain and greater improvements in neck function, cervical curvature and health-related quality-of-life scores than those in the control group. The results of this study will provide evidence regarding the therapeutic effects and safety of BCT as an intervention for CSR.

2. Materials and methods

2.1. Study design and setting

This clinical trial is a multicenter, single-blind, randomized controlled design. Subjects were enrolled from four hospitals: (1) The affiliated Hospital of Shaanxi University of Chinese Medicine, (2) Shaanxi Provincial Hospital of Chinese Medicine, (3) Xi'an Hospital of Traditional Chinese Medicine (TCM), and (4) Xi'an Honghui Hospital. The study was approved by the Ethics Committee of Affiliated Hospital of Shaanxi University of Chinese Medicine (No. SZFYIEC-PJ-2016[01]). Each participating center obtained local Institutional Review Board approval. All study participants will sign the written informed consent prior to participation. Outcome evaluation and statistical analysis will be performed by independent investigators who are blinded to patient allocation.

2.2. Study population

2.2.1. Diagnostic and inclusion criteria

The study population consists of individuals aged 18–75 years with CSR. The diagnostic criteria of CSR refer to in the Guidelines for the Diagnosis and Treatment of Cervical Spondylosis (2011 edition) promulgated by the Chinese Association of Rehabilitation Medicine's cervical spondylosis branch. The symptoms and signs include syndromes of pain and numbness distributing along spinal nerve roots, and positive intervertebral foramen extrusion and/or brachial plexus pull tests. Moreover, the clinical manifestations and imaging are consistent with the clinical syndromes.

2.2.2. Exclusion criteria

Subjects were excluded if they have disorders such as thoracic outlet syndrome, tennis elbow, carpal tunnel syndrome, cubital tunnel syndrome, periarthritis of the shoulder, tenonitis of biceps brachii, or a diagnosis of acute spinal cord injury, acute spinal cord inflammation, or symptoms of cervical vertigo and abnormal changes on trans cranial Doppler (TCD). Subjects were also excluded with pathologies associated with the liver, kidney, hematopoietic endocrine, cardiovascular or nervous systems and other severe primary diseases, or fractures, osteoarticular tuberculosis, osteomyelitis, bone tumor, severe osteoporosis, or mental disabilities, or other bodily weaknesses that cannot withstand the stimulation of BCT. Moreover, the trial excluded individuals who have any acute infectious disease, gastric or duodenal ulcer with acute perforation, or treated areas of severe skin damage or skin diseases. In addition, subjects who have received surgical treatment for CSR or neck injury, or have received radiofrequency therapy to a cervical intervertebral disc, minimally invasive surgery, ozone, acupuncture and moxibustion, other manipulations or block therapy within 2 weeks, were also excluded. Lactating or pregnant female patients and patients who are participating in other clinical trials related to cervical spondylosis were excluded from current study as well.

This study was conducted in accordance with patient protection principles as outlined in the Declaration of Helsinki, and approved by the appropriate Institutional Review Boards. Each participant had signed the written informed consent before undergoing any examination or study procedure in compliance with Good Clinical Practice. We utilized a central randomization management system (CRMS) to identify all persons aged 18–75 years who meet the diagnostic criteria of CSR and have a pain score between 40 and 80 according to the Visual Analog Scale (VAS). Patients who initially meet these eligibility criteria first completed the additional baseline testing (mainly including a VAS, the Borden Index, the Neck Disability Index (NDI) and the 36-item Short Form health survey (SF-36)) and then were randomly assigned to either the BCT or the TT group.

2.3. Sample size

We calculated the sample size for this two-arm trial on the basis of comparing BCT versus TT, using the superiority test formula: $n1 = n2 = 2[(t\alpha/2+t\beta)s/\delta]2$. Where $t\alpha/2$and $t\beta$ are constants, s is the estimated standard difference and δ is the mean value of the VAS for neck pain. According to the statistical study, $\alpha = 0.05$, $\beta = 0.1$. Based on the literature and preliminary experimental studies [6]., $s = 1.09$, $\delta = 0.5$, calculated $n1 = n2 = 99$, and the shedding rate was calculated as 20 %, the total number of cases was 240 [[7]].

2.4. Randomization and allocation

This clinical trial is a multicenter, randomized, parallel-controlled design. When the participants meet the inclusion or exclusion criteria and have signed the Informed Consent Form, researchers accessed the CRMS and then input stratification factor according to the system's prompt. The CRMS would display a participant identification code and a random number. The participant identification code or the random number is the only form of patient identity that distinguishes the treatment group from the control group. The flow of participants in the study, including the numbers analyzed for short-term and 3-month follow-up.

2.5. Treatment group

In the treatment group, patients were requested to be in the sitting position and receive the following treatments: (1) balancing tendon-regulation: a to-and-fro kneading motion is applied three times to relax the muscles in the nuchal midline: splenius capitis, splenius cervicis and the trailing edge of sternocleidomastoid, respectively. Then manipulations of plucking and relaxing the tendons were applied five to seven times over the same area with a force that the patients can tolerate. Finally, rolling the region along the upper back of bladder median for five to seven times, (2) balancing osteopathy: firstly, with the patient adopting an upright sitting position, the practitioner holds the patient's occiput and jaw between his hands and pulls upward forcefully for 9 s and then relaxes for 3 s. While stretching the neck, the physician turns the patient's head to the front, back, left and right at an angle of roughly 45° three times and then obliquely wrenches the neck at the position that corresponds with the pathological features of the clinical examination and X-rays; if the lesion sites are at C1 to C3, or C4 to C6, or C7 to T1 within the cervical spine unit, the neck was flexed at 15°, 0°, or 30–45°, respectively. The patient then repeatedly rotated their neck to left or right side to roughly 40° degrees on its own at the stretching state of cervical vertebra, and then rotated toward the affected side to the limit of the angle as well as bending the neck forward while the physician gave a vertical pulling and extending force to the patient's neck. One or more snapping sounds were heard if the procedure has been successful, (3) balance collaterals-dredging: first, holding the participant's upper limb and then quickly shaking that upper limb up and down forcefully with a low-amplitude jittery motion, repeated three times. Next, for the ear-lifting method, kneading-pressing and pulling with the thumb and forefinger were then applied to the region of the upper, middle and lower three parts of the helix, respectively, for 30 s with a force that the patient can tolerate. Lastly, pressing with the thumb was repeatedly applied five to seven times along the DU meridian with focus on the acupoints DU4 (Mingmen), DU14 (Dazhui), DU17 (Naohu) and DU20 (Baihui).

The patients received BCT once every other day for 20 min each

session and five treatments constitute a course. The patients were given two courses (a total of 10 times in 20 days) and visited the physician at 1- and 3-month follow-up.

2.6. Control group

In the control group, patients received TT. The patients were sitting comfortably and wearing a cloth bag for occipital-jaw traction, with their head bending forwards at an angle of about 10–15°. The traction weight for cervical spondylosis starts at 3 kg and gradually increased to the maximum weight of 6 kg in increments of 0.5 kg each time. The treatment was performed 30 min at a time every other day for a total of 10 times in 20 days.

2.7. Outcome measures

The outcome measures included the primary outcome and secondary outcomes. The primary outcome was pain severity measured with a Visual Analog Scale (VAS). Secondary outcomes included cervical curvature measured using the Borden method, a composite of functional status measured by the Neck Disability Index (NDI), patient health status (evaluated by the SF-36 health survey) and adverse events (AEs) as reported in the trial. Specific methods have been discussed in the previous article [8]. All the outcome measures were obtained at baseline, 20 days of the treatment duration and 1- and 3-months follow-up in all patients.

2.7.1. The X-ray measurement of cervical curvature

The schematic diagram for Borden's method is shown in Fig. 1: in the lateral radiographs of the cervical vertebrae, line A runs between the posterosuperior margin of C2's odontoid process and the posteroinferior margin of the C7 vertebra. A fitting curve along the posterior margin of the cervical vertebrae is line B. We defined the vertical distance from the midpoint of C4 vertebra's posterior margin to line A as the longest distance between lines A and B, which was taken as the curvature of the cervical vertebrae, line C) [8–10].

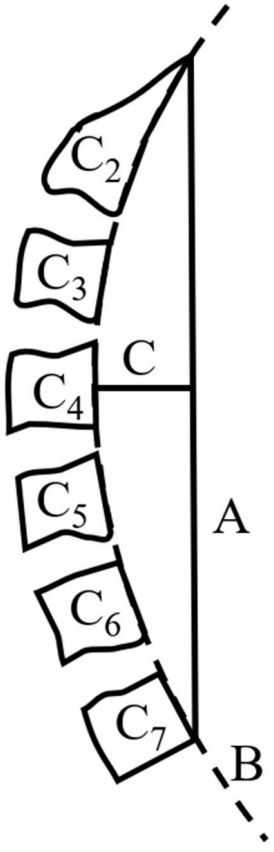

Fig. 1. The schematic diagram for Borden's method, which is a measure of the curvature of the cervical vertebrae [10].

2.8. Statistical analysis

All data were analyzed statistically using SAS 9.4 version statistical software. Measurement data were expressed as mean ± standard deviation ($\bar{x} \pm s$), and analyzed using a *t*-test; rates were compared using the chi-square test. $P < 0.05$ was used to indicated that the difference was statistically significant.

3. Results

3.1. Basic data

According to the inclusion and exclusion criteria, of the 240 randomly assigned patients, 120 participants were assigned to BCT and 120 to TT. 231 (96.3 %) provided follow-up data at 1 and 3 months are shown in Fig. 2. There were no significant differences in baseline data of age, height, weight, gender, pain VAS score, cervical curvature, NDI score and SF-36 score between the two groups ($P > 0.05$), indicating good comparability (Table 1).

3.2. The pain VAS scores

According to the results, after BCT and TT treatment, the pain VAS score of the two groups was significantly reduced, and the reduction degree of pain VAS score of the BCT group was significantly better than that of the TT group ($P < 0.05$) (Table 2 and Fig. 3).

3.3. Radiological evaluation of cervical curvature

The results showed that cervical curvature improved in both groups after BCT and TT treatment, but the BCT group showed better results at 20 days ($P < 0.05$) of treatment and 3 months of follow-up ($P < 0.05$) (Table 3 and Fig. 4).

3.4. NDI score

Both BCT and TT treatments improved subjects' NDI scores, and the BCT group showed better results at 20 days of treatment and 1 and 3 months of follow-up ($P < 0.05$) (Table 4 and Fig. 5).

3.5. SF-36 date

According to the results, after 20 days of treatment, the SF-36 scores of subjects in both groups were significantly improved compared with those before treatment. After 1 month and 3 months of follow-up, the BCT group had better advantages in Physical Functioning, Role-Physical, Bodily Pain, General Health and Social Functioning ($P < 0.05$) (Table 5 and Fig. 6).

3.6. Adverse events

There were 4 adverse events in this study, which were all mild adverse reactions, and the symptoms disappeared (no sequelae) after treatment, and the judgment was not related to the intervention measures. During the treatment period, in the traction therapy group, 1 patient had upper respiratory tract infection, 1 patient had toothache, 1 patient had skin laceration on his right hand due to his own fall, and 1 patient had soft tissue contusion on his right hand due to his own fall, all of which were determined by the doctor to be unrelated to the intervention means of this study, and the symptoms of the subject were improved after professional treatment.

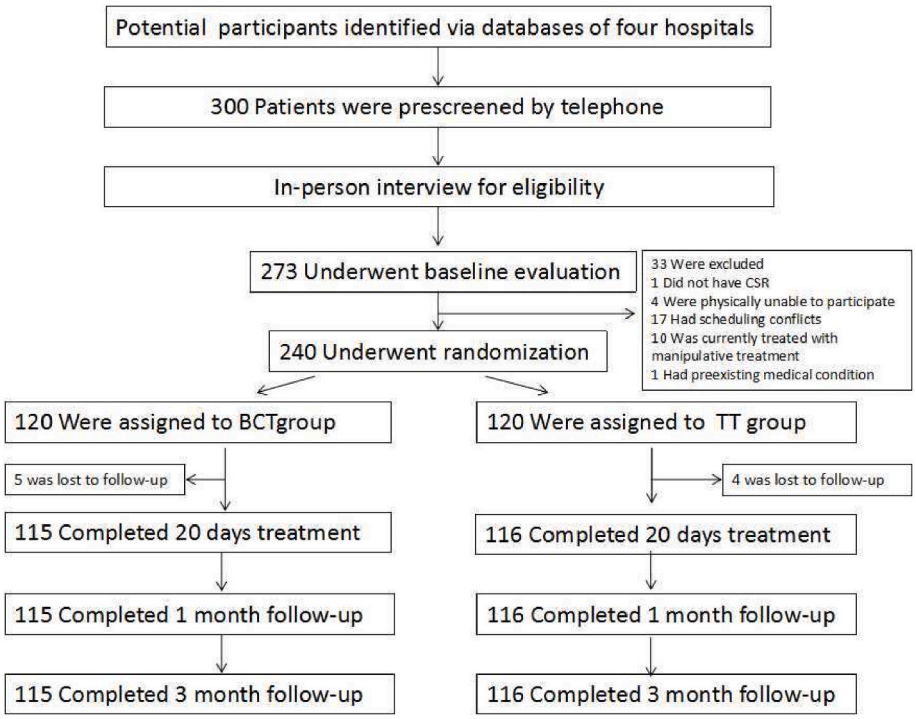

Fig. 2. Flow diagram of recruitment process, group allocation and participation in the two interventions. All participants who completed a follow-up were included in the corresponding analysis. 240 subjects underwent randomization in the study and nine stopped the experiment, eliminating zero. The total analysis group had the same distribution as those in the scheme group, and 115 cases were BCT in the group, and 116 cases were in the TT treatment group.

Table 1
Baseline Characteristics of Patients ($\bar{x} \pm s$, n (%)).

Variable		BCT	TT	*P* value
Age		44.32 ± 11.34	47.58 ± 10.69	0.257
Height		165.62 ± 7.76	165.22 ± 7.15	0.689
Weight		63.87 ± 11.06	62.96 ± 9.86	0.5106
Gender	Male	42(36.52)	40(34.48)	0.7461
	Female	73(63.48)	76(66.52)	
VAS		54.40 ± 16.66	51.24 ± 17.37	0.1597
Cervical Curvature		3.92 ± 3.80	4.43 ± 3.47	0.2836
NDI		16.57 ± 6.60	15.64 ± 6.28	0.2704
SF-36	PF	72.96 ± 17.87	72.76 ± 14.76	0.9269
	RP	30.65 ± 34.26	25.86 ± 31.95	0.2729
	BP	52.90 ± 16.41	55.28 ± 15.14	0.2513
	GH	57.92 ± 14.19	55.86 ± 14.32	0.2733
	SF	64.67 ± 13.88	66.81 ± 15.65	0.2736
	VT	60.00 ± 14.96	60.73 ± 14.53	0.706
	RE	37.39 ± 37.50	33.94 ± 40.58	0.6203
	MH	66.19 ± 17.28	68.03 ± 15.50	0.3943

PF: Physical Functioning, RP: Role-Physical, BP: Bodily Pain, GH: General Health, SF: Social Functioning, VT: Vitality, RE: Role-Emotional, MH: Mental Health.

Table 2
VAS score pre and post treatment ($\bar{x} \pm s$).

Group	Baseling	20 days	1 month	3 months
BCT	54.40 ± 16.66	27.17 ± 18.77	25.09 ± 20.32	23.76 ± 20.58
TT	51.24 ± 17.37	33.37 ± 17.43	31.20 ± 18.06	29.60 ± 18.55
P value	0.1597	0.0103	0.0165	0.0253

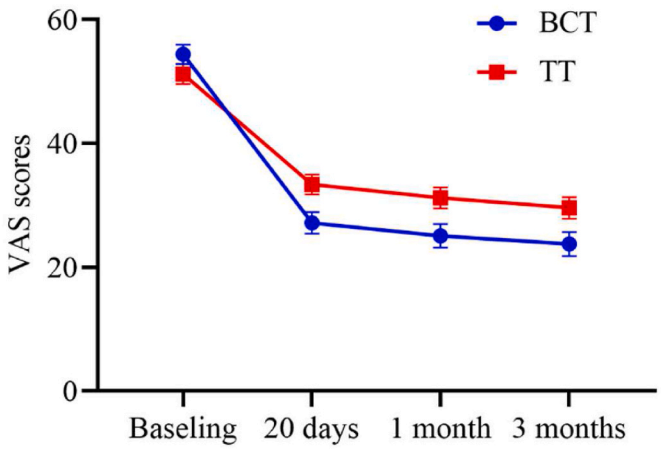

Fig. 3. VAS score pre and post treatment.

Table 3
Radiological evaluation of cervical curvature ($\bar{x} \pm s$).

Group	Baseling	20 days	3 months
BCT	3.92 ± 3.80	6.80 ± 2.65	6.99 ± 2.69
TT	4.43 ± 3.47	5.76 ± 3.49	6.03 ± 3.42
P value	0.2836	0.0118	0.0186

4. Discussion

CSR is one of the most common types of cervical disease. The prevalence of CSR accounts for about 70 % of that of cervical spondylosis [11]. Normal human spine stability system is maintained in two parts. One is endogenous stability, including vertebral body, attachment, intervertebral disc and connected ligament structure, static balance. The other one is exogenous stability, mainly the adjustment and control of the neck and waist muscles, which is the original motive force of the spine movement, making the spine can carry out various physiological activities for dynamic balance. CSR is a relatively common nerve disease caused by nerve root dysfunction, which is usually due to mechanical

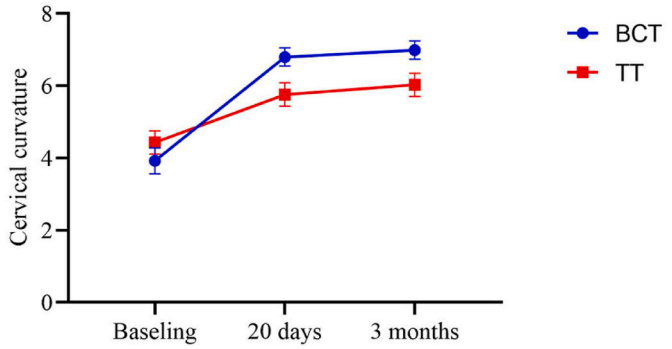

Fig. 4. Radiological evaluation of cervical curvature.

Table 4
NDI score pre and post treatment ($\bar{x} \pm s$).

Group	Baseling	20 days	1 month	3 months
BCT	16.57 ± 6.60	8.95 ± 5.37	6.80 ± 4.96	5.43 ± 4.21
TT	15.64 ± 6.28	10.84 ± 5.01	9.09 ± 4.39	7.61 ± 4.19
P value	0.2704	0.0062	0.0003	0.0001

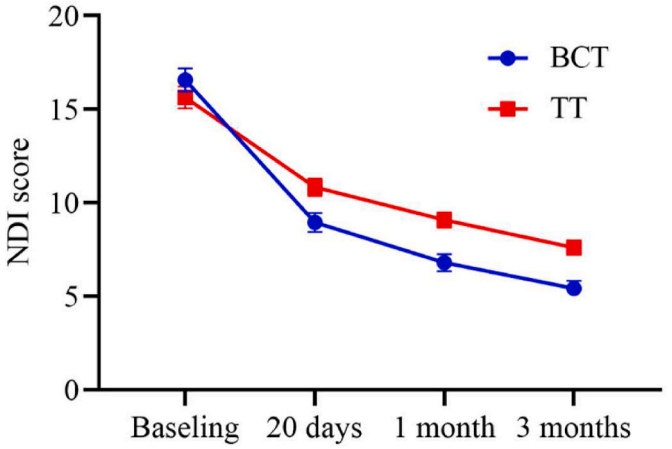

Fig. 5. NDI score pre and post treatment.

compression; however, inflammatory cytokines released from the damaged intervertebral disc may also cause symptoms [12]. CSR due to retrogressive changes in cervical vertebrae can cause hyperosteogeny of the cervical vertebrae and changes in muscles, tendons, joint capsules and other tissues. CSR can also lead to loosening and movement of the adjacent intervertebral joints to stimulate and/or compress nerve roots, thereby giving rise to hyperemia, edema, adhesion and other aseptic inflammation in tissues around the nerve root as well as to pain, numbness, reflective changes in the area dominated by the nerve root. The orthopedic of TCM theory holds that both the static system (e.g. ligaments, joint capsules, etc.) and the dynamic system (e.g. muscles, intervertebral discs, small joints, etc.) are critical in maintaining normal position and function of the cervical spine. The imbalance of both static and dynamic forces can result in a loss of posterior column stability, ultimately leading to rapid degeneration of the cervical intervertebral discs and causing a series of syndromes distributing along the spinal nerve roots (such as pain, numbness of the neck, shoulder and arm, etc.) [13,14]. Therefore, intervention measurements aiming at correcting the imbalance between these two systems of the cervical vertebrae and relieving the pain greatly affect people's lives and work. Feng's spinal manipulation can be used to correct the transposition of spinous processes of cervical vertebrae, restore the internal and external (anatomic

Table 5
SF-36 date pre and post treatment ($\bar{x} \pm s$).

Group		BCT	TT	*P* value
PF	Baseling	72.96 ± 17.87	72.76 ± 14.76	0.9269
	20 days	85.26 ± 12.94	80.69 ± 13.41	0.009
	1 month	87.30 ± 11.03	83.19 ± 13.08	0.0104
	3 months	89.87 ± 9.94	86.12 ± 12.53	0.0125
RP	Baseling	30.65 ± 34.26	25.86 ± 31.95	0.2729
	20 days	60.22 ± 39.72	49.78 ± 42.67	0.0557
	1 month	75.22 ± 37.24	57.11 ± 43.84	0.0008
	3 months	80.87 ± 34.31	65.95 ± 41.49	0.0032
BP	Baseling	52.90 ± 16.41	55.28 ± 15.14	0.2513
	20 days	71.14 ± 13.95	65.55 ± 13.68	0.0024
	1 month	78.42 ± 14.96	69.41 ± 13.06	<0.0001
	3 months	81.71 ± 14.67	73.36 ± 13.37	<0.0001
GH	Baseling	57.92 ± 14.19	55.86 ± 14.32	0.2733
	20 days	62.79 ± 14.75	57.91 ± 13.97	0.0103
	1 month	65.27 ± 15.54	60.11 ± 14.32	0.0093
	3 months	67.62 ± 14.80	61.95 ± 14.49	0.0036
SF	Baseling	64.67 ± 13.88	66.81 ± 15.65	0.2736
	20 days	76.20 ± 15.08	72.84 ± 12.48	0.67
	1 month	79.57 ± 16.83	73.60 ± 13.27	0.0031
	3 months	83.15 ± 16.31	75.75 ± 11.57	<0.0001
VT	Baseling	60.00 ± 14.96	60.73 ± 14.53	0.706
	20 days	67.48 ± 13.63	64.22 ± 13.62	0.0708
	1 month	69.74 ± 13.68	67.59 ± 13.29	0.2264
	3 months	70.91 ± 12.38	69.57 ± 12.52	0.4129
RE	Baseling	37.39 ± 37.50	33.94 ± 40.58	0.6203
	20 days	68.70 ± 37.80	66.09 ± 42.16	0.6217
	1 month	77.10 ± 35.97	72.99 ± 37.28	0.3944
	3 months	82.90 ± 32.55	77.30 ± 36.94	0.223
MH	Baseling	66.19 ± 17.28	68.03 ± 15.50	0.3943
	20 days	71.20 ± 15.30	70.07 ± 15.08	0.5721
	1 month	73.32 ± 16.15	72.48 ± 13.04	0.6642
	3 months	74.75 ± 14.68	73.52 ± 13.29	0.5047

and compensatory) balance of the spine, change the relationship of compressed nerve roots to hyperplastic cervical vertebrae and protrusive intervertebral disks, remove adhesions, stimulate the nerve root, and relieve muscular spasms and synovial incarceration [15].

The effect of TCM on nerve root type cervical spondylosis is superior to other methods for treating CSR [16]. Other studies have shown that compared with the traditional traction method, the needle closure and loosening traction for the treatment of cervical spondylosis can significantly improve the symptoms quickly, such as the neck movement, the neck pain, and the numbness of the muscle [17]. Our randomized, controlled trial showed that BCT can significantly relieve pain for 20 days compared to TT ($P = 0.0103$). There were significant difference in pain score after 1-month ($P = 0.0165$) and 3-month ($P = 0.0253$) follow-up compared with control group. The primary outcomes indicate that BCT may be a successful intervention for CRS. The effect was evident in other measures of NDI, cervical curvature and quality of life.

For complementary and alternative medical treatments, the strongest evidence supports a modest effect for spinal manipulation compared with no treatment or other non-interventional treatments. With regard to other complementary and alternative treatments, although they have generally been found to be superior to no treatment, the evidence that they are superior to sham treatments or other treatments is weak, negative, or conflicting [18].

5. Limitations

Our study had some limitations. We did not use a double-blinded study design, since this would have required the use of sham BCT, for which no validated approach currently exists. Devising a sham intervention poses a set of unique challenges. In addition, the biologic mechanisms by which BCT might affect the clinical course of CSR remain unknown and further study is needed.

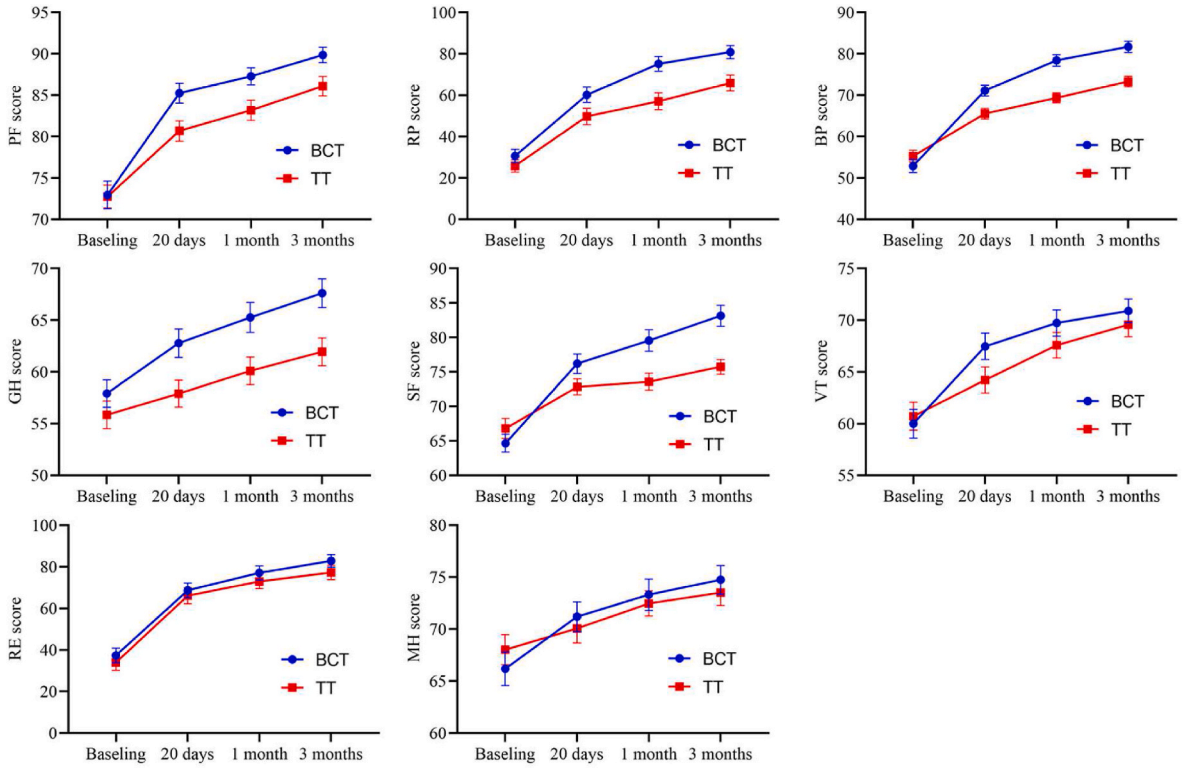

Fig. 6. SF-36 date pre and post treatment.

6. Conclusions

In this study, we found that BCT can significantly relieve neck pain, NDI, cervical curvature and quality of life of CSR patients, which therapeutic effect was significantly better than that of TT group. It indicated that the BCT may be a novel strategy for the treatment of the cervical spondylotic radiculopathy.

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Availability of data and material

The partial data used to support the findings of this study is available from the Clinical Trials Website(https://clinicaltrials.gov/study/NCT02705131?cond=NCT02705131&rank=1&tab=table). And other partial data are available on request from the corresponding author, upon reasonable request.

CRediT authorship contribution statement

Wenxiong Li: Conceptualization, Data curation, Writing – original draft. **Yaxin Chang:** Data curation, Writing – original draft. **Qi Feng:** Data curation, Writing – original draft. **Yan Cheng:** Investigation, Writing – review & editing. **Jichao Yin:** Investigation, Writing – review & editing. **Yindi Sun:** Investigation, Writing – review & editing. **Feng Yang:** Conceptualization, Writing – review & editing.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgments

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Abbreviations

BCT	Balance Chiropractic Therapy
CSR	Cervical Spondylotic Radiculopathy
NDI	Neck Disability Index
TCM	Traditional Chinese Medicine
TT	Traction Therapy
VAS	Visual Analog Scale
CRMS	Central Randomized Management System
AEs	Adverse Events
PF	Physical Functioning
RP	Role-Physical
BP	Bodily Pain
GH	General Health
SF	Social Functioning
VT	Vitality
RE	Role-Emotional
MH	Mental Health

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