Study Protocol

the Official Title of the study:

Clinical Study of Intelligent MoxibustionRobot in the Treatment of Low Back Pain: a Randomized Controlled Clinical Trial

date of the document: 2022.12.15

Title: **Clinical study of intelligent moxibustion robot for low back pain: a randomized clinical controlled experiment**

Background / Introduction: Moxibustion treatment has a clear effect on low back pain, but the degree of standardization of moxibustion operation is low and almost completely depends on manual labor, and the degree of standardization of treatment needs to be improved

Expected sample size: **80 people / group, and 160 people in 2 groups**

(According to the pass software, 62 people per group, and 80 people per group are estimated receivable, according to the shedding rate of 20%)

(To reduce shedding, priority outpatients / telephone follow-up)

(Sample size estimation method, at the end of this article)

Ranking standard:

1. Diagnosis criteria for low back pain

Diagnosis standard of traditional Chinese medicine

With reference to the published in 2018 by yu Xiaoping, fang zhu yuan editor of traditional Chinese medicine class "much starker choices-and graver consequences-in planning textbooks" traditional Chinese medicine " (the 3rd edition) in the description of cold wet type lumbar muscle strain, clinical performance see the waist area cold pain, rainy days, hot is slow (main), or see the waist turn adverse, cold form, body heavy (time), to see the moss white greasy tongue, pulse see heavy and slow. The patients whose syndrome type meets the above cold and wet syndrome performance should meet the judgment criteria of TCM syndrome.

Diagnostic criteria for western medicine

According to the diagnostic criteria in document 1-2 of the Guidelines for the Treatment of Low Back Pain formulated by the European Union:

(1) Symptoms: localized lumbar and back pain and ipsilateral muscle tension or spasm (the pain does not radiate to the distal end of the knee joint), limited functional activity, and recurrent symptoms;

(2) Signs: physical examination, erector spinal muscles have obvious tenderness, sometimes can touch the abnormal muscle pain points or cord muscle spasm, nervous system examination without abnormal, no obvious muscle strength loss, sensory disorders, nerve root pull test (-), morning, bending activity, sedentary or long standing after pain aggravation;

(3) Imaging examination: routine examination of X-ray, CT plain scan without lumbar spine and intraspinal tumors;

(4) No history of lumbar back surgery.

References involved:

[1] O Airaksinen, J I Brox,C Cedraschi,et al.on behalf of the COST B13 Working Group on Guidelines for Chronic Low Back Pain.European guidelines for the management of chronic no nspecificlow back pain[J].Eur Spine J,2006,15(Suppl.2):S192-S300.

[2] TROYER M R.Differential Diagnosis of Endometriosis in a Young Adult Woman With Nonspe cific Low Back Pain[J].Phys Ther,2007,87(6):801-810.

2. Inclusion criteria:

① Compliance with the diagnostic criteria for low back pain and the syndrome differentiation criteria

for cold and wet lumbar muscle strain

② Sex is not limited, and the age is controlled between 25 years and 70 years old

③ Not nearly 2 weeks ago

④ The disease course was controlled within 8 years

⑤ Informed consent and willing to cooperate with the whole treatment

⑥ They agreed to record the scale score and volunteered to participate in this trial

⑦ Patients reserve at least one contact information for easy follow-up

⑧ To reduce the shedding rate, the inpatients should be preferentially included

⑨ Patients with lumbar disc herniation, lumbar disc bulging, sacral canal cyst, nerve root compression, and lumbar bone hyperplasia were included

Those who meet the above 9 items can only be included in this study.

Exclusion criteria:

① Patients did not meet the inclusion criteria Patients who did not meet the inclusion criteria for the diagnosis of this topic

② The patient is in pregnancy or lactation

③ Patients are allergic to moxibustion smoke, and it is difficult to accept moxibustion treatment

④ The patient had diseases of the blood and immune system

⑤ The patient had cardiac, hepatic, and renal insufficiency

⑥ The patient suffered from mental illness and failed to cooperate with moxibustion

⑦ Low back pain caused by lumbar spine and spinal canal tumors, lumbar scoliosis, bladder diseases, and gynecological diseases

⑧ Patients with a previous history of lumbar spine surgery

blind method:

RCT randomization (difficult to implement blind method, intuitive difference between robot moxibustion and artificial moxibustion)

(Because of this experiment, total blindness cannot be achieved. Unlike drugs that can mask it,

In this experiment, the patients and the doctors saw the real "robot" or "artificial", which could not be done too much blind method.

Therefore, to maximize blinding, staff are advised to communicate with the patient in the following manner:

1. Multicenter trials, human and robot groups respectively in independent experimental centers
2. Ensure that the "artificial group" does not know the existence of moxibustion robot, so as not to ask patients to use the robot or artificial moxibustion psychological bias and other situations, affect the treatment effect.
3. In terms of "robot group", patients can know that moxibustion can be operated by hand with common sense, and the robot is a new scientific research product. In order to ensure that the patient has no bias against the robot, so as to avoid psychological factors affecting the effect.

So to inform the patient that the ingredients in the robot is the same, but the robot has a little advantage in tobacco control and temperature control.)

Group method: random number table method

160 patients were numbered in the order of enrollment (come, come),
Using random numbers tables, 160 patients were randomly and equally divided into two groups (chart below)

机器人组(15)					人工组(15)				
4	14	24	6	8	12	18	23	26	17
30	10	19	1	20	29	2	3	7	13
25	5	16	27	9	11	15	21	28	22

机器人组(10)					人工组(10)				
8	20	3	12	2	11	18	14	13	4
16	6	15	10	19	5	7	1	17	9

机器人组（40）					人工组（40）				
35	65	8	73	26	22	7	57	36	66
31	24	13	54	78	14	46	49	17	64
19	58	38	15	5	55	56	20	4	27
79	12	1	52	33	45	3	63	41	76
42	68	67	50	2	16	47	11	51	20
6	44	10	29	34	39	70	69	32	80
62	23	60	48	75	40	25	53	71	72
43	61	30	18	37	28	77	59	9	74

Intervention mode:

Artificial moxibustion group vs. intelligent thunder-fire moxibustion group

1. Selection of points:

Taking taking: referring to the planning textbook "Treatment of Acupuncture and Moxibustion" of national Universities of Traditional Chinese Medicine edited by Gao Shutong, taking nephroshu, large intestine, YaoYangguan and a point.

Positioning: Select according to relevant provisions of National Standard for Positioning of Acupuncture and Acupuncture (formulated by national GB1234-90 standard).

Kidney yu: in the waist, when the second lumbar spinous process, the side open 1.5 inches. Two bilateral holes were selected each time.

Large intestine yu: in the waist, when the fourth lumbar spinous process, the side open 1.5 inches. Two bilateral holes were selected each time.

Waist Yang: in the waist, when the posterior midline, the fourth lumbar spinprocess in the depression.

2. Course of treatment:

10 treatments for 40min.

(Each patient does it 5 times a week, and patients are usually treated for 2-3 weeks)

3. The operation mode of the moxibustion robot

(Artificial moxibustion, acupoints, technique, duration, all the same)

Enter the setting page of intelligent thunder and fire moxibustion "free moxibustion", and use the rocker to control the six degrees of freedom robotic arm in the lumbar back of patients —— kidney yu, large intestine yu, waist yangguan, a right point.

After positioning, ignite and install the lightning fire moxibustion moxa strip, and set the moxibustion operation —— on the operation page

Kidney Yu BL23, left and right 2 points, linear reciprocating moxibustion (10min)

intestinal BL25, left and right 2 points, linear reciprocating moxibustion (10min)

DU3, single point, rotary moxibustion (10min)

A is point Pain point, if unilateral pain, sparrow peck moxibustion (10min), if bilateral pain, reciprocating moxibustion (10min)

A total of 40min was used

The operation method of reciprocating moxibustion is: plane straight reciprocating moxibustion, the mechanical arm holds the ignited thunder fire moxibustion line above the above two acupoints;

The operation method of rotary moxibustion is as follows: plane rotary moxibustion, the mechanical arm holds the ignited lightning fire moxibustion bar for parallel reciprocrotary moxibustion above the above acupoints, with a rotary radius of 4cm;

The operation method of sparrow pecking moxibustion is: the mechanical arm holds the selected point, and uses the moxibustion, and the lifting range is 5cm, giving strong warm stimulation; the moxibustion distance is manually adjusted according to the tolerance temperature of the patient.

Note: Visit the ward at any time, observe the skin condition and the heat resistance of the patient, and take the patient comfort.

If there is discomfort, immediately stop the treatment, symptomatic treatment

4. Follow-up:

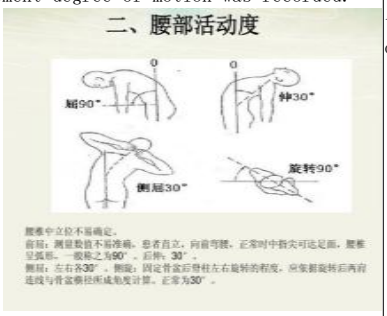
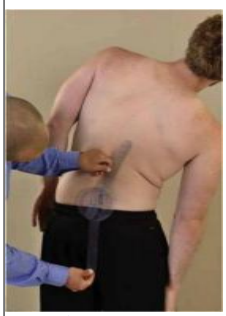
Each patient is registered with their mobile phone number,

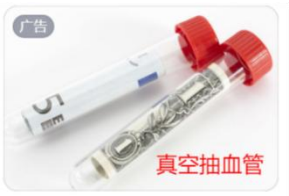
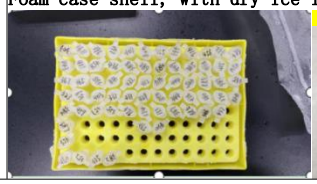
VAS score, JOA score, RMDQ score, and SF-36 score were observed and recorded before, after 5 times, after 10 times of treatment and 2 weeks after completion of treatment (follow-up).

The values of lumbar joint motion, Schober test and serum inflammatory response factors were observed and recorded before and after 10 treatments.

Outcome indicators:

name of index	Judgment factors	operating steps	The date of measurement
Visual analogue scale （VAS score）	subjectivity		Before enrollment. After 5 treatments, an average of 1 week. Through all treatments -- after 10 treatments, an average of 2 week. 2 weeks after treatment.
Japanese Orthopaedic Association Score--Low Back Pain （JOA Low Back Pain Score）	subjectivity		Before enrollment. After 5 treatments, an average of 1 week. Through all treatments -- after 10 treatments, an average of 2 week. 2 weeks after treatment.

36-items short form health survey (SF-36)	subjectivity		Before enrollment. After 5 treatments, an average of 1 week. Through all treatments -- after 10 treatments, an average of 2 week. 2 weeks after treatment.
Roland Morris Disability Questionnaire (RMDQ)	subjectivity		Before enrollment. After 5 treatments, an average of 1 week. Through all treatments -- after 10 treatments, an average of 2 week. 2 weeks after treatment.
Range of motion of the waist joint	objective	A professional protractor was used to measure the waist, and the mobility of the upright forward flexion, posterior extension, left and right lateral flexion, left and right rotation, and the movement degree of motion was recorded.   ROM | lumbar scoliosis: _ activity https: / / www.sohu.com/a/405887556_120052195	Before enrollment. Through all treatments -- after 10 treatments, an average of 2 week.
Schober Test	objective	**The subject was upright and marked at 5cm below and 10cm below the lumbosacral junction. Subjects were required to bend forward as far as possible to measure the distance (cm) between the lumbosacral junction and the marker. Lumbar mobility was indicated using the increased distance.** https://www.bilibili.com/video/av245564019/?vd_source=20b953596f4eec1878458ceea7334faf Determine whether the lumbar spine is limited	Before enrollment. Through all treatments -- after 10 treatments, an average of 2 week.

Serum inflammatory response factor: Venvenous blood 4 mL, isolated serum, Detection by the ELISA method 1. Serum tumor necrosis factor (TNF-α), 2. Interleukin IL 1 β, respectively 3, the interleukin IL 6, and the 4. Serum thromboxane B2 (TXB 2) level.	Material content	1. Collect **Serum separation tubes (hospital-provided),** 4 mL of venous blood, Before and after treatment, 2 times in total 2. Place Whole blood specimens collected in serum separation tubes were left at room temperature for 2 hours or 4 oC overnight,  3. Centrization Then centrifuged at 1,000 g for 20 min and the supernatant was removed,  4. Freeze Place the supernatant in the frozen storage tube (the last received test tube), which can be inserted in the plastic box hole for easy storage. Refrigerator preservation.-20 ℃ (save for one month) or-80℃ to avoid repeated freezing and thawing.   5. Post inspection After the collection, it will be packaged and mailed to the testing center for testing **Foam case shell, with dry ice inside,**  	Before enrollment. Through all treatments -- after 10 treatments, an average of 2 week.

Number of tasks per hospital:

1. 80 people in Shanxi Acupuncture and Moxibustion Hospital

Zhang Tiansheng, No.2, Beiyuan Street, Pingyang Road, Taiyuan city, Shanxi Province, 13466838493

2. 30 people from Xinghualing District Hospital of Traditional Chinese Medicine

The Hospital of Traditional Chinese Medicine, Xinghualing District, Taiyuan City, Shanxi Province (No.5,

Datong Road), Xingting, 13903435942

3. 30 people from Yongji City Hospital of Traditional Chinese Medicine

Yongji City Hospital of Traditional Chinese Medicine, No.38, South of Hedong Avenue, Yongji City, Yuncheng City, Shanxi Province, 13994986319

4. Lingqiu County Hospital of Traditional Chinese Medicine, 20 people

Qiao Wei, Xinjian Road Hospital of Traditional Chinese Medicine, Lingqiu County, Datong City, Shanxi Province 15035293780

Hospitals should recruit as soon as possible, such as the recruitment of patients due to the epidemic and other factors, timely communication and overall arrangements.

Attached: Sample size calculation

1. According to the review paper, the effective rate of artificial moxibustion is about 76.19%
(Ref.: Effect of thunder-fire moxibustion combined with oblique round blade on electromyography and serum MMP 13 and PGE 2 levels in patients with lumbar intervertebral disc herniation)

Since the robot is a new product with unknown efficiency, it is assumed that it is equivalent to artificial efficiency

2. Statistically speaking, the response efficiency difference between the two groups is 10~15%, and the two groups are considered equivalent

3. Use the pass2011 software

Test type: Equivalent test

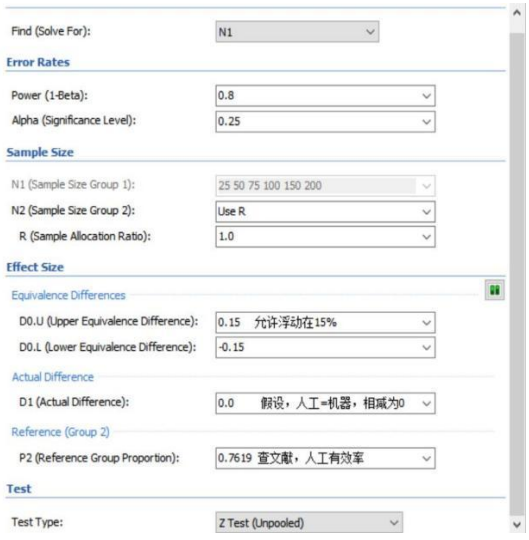
Calculation method: rate difference method

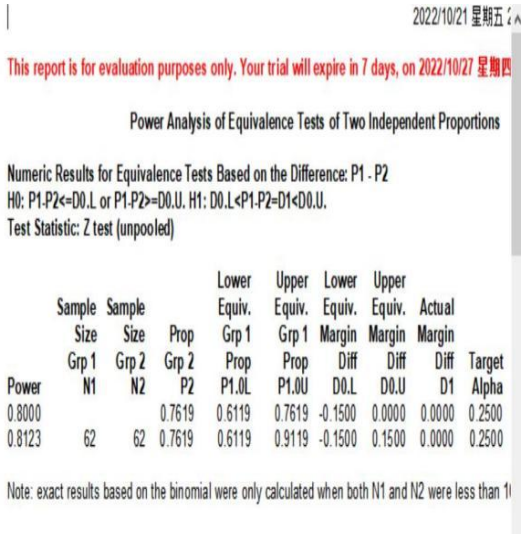
Efficiency difference value △: 15%,

Calculation result: 62 persons / group

The specific steps are described as follows:

Set, efficiency difference 15%. To 62 people / group, (the larger the value, the smaller the sample size)





Ethical approval document of Biomedical Research Ethics Committee of Shanxi Acupuncture Research Institute 伦审科 2022 第（020）号

project name	Clinical Study on the Treatment of Low Back Pain with Intelligent Moxibustion Robot: A Randomized Clinical Control Experiment		
Project category	foundation ● clinical ○ medicinal □		
project leader	Zhang Tiansheng	**Study start and end time**	2022.01.01 -- 2023.12.31
phone number	13466838493		
Project source	1.Shanxi Provincial Health Commission major scientific research project 2.Science and Technology Innovation Team of Shanxi University of Traditional Chinese Medicine		
Application unit	Shanxi Provincial Acupuncture and Moxibustion Hospital		
Submit review materials: ●Application for project ○ research paper □other			

Research main content:

A "thunder fire moxibustion intelligent robot" was developed jointly with Central North University to compare the traditional artificial moxibustion group by applying the moxibustion robot prototype to the clinic. Under the condition that the duration, acupoints and techniques of moxibustion are the same, 80 patients with low back pain with similar conditions were treated, and the relief of low back pain symptoms were observed after 10 times of moxibustion, so as to clarify the moxibustion efficiency, efficacy and safety of the moxibustion robot, and to provide a new direction for the research and development of intelligent moxibustion products.

examine bear fruit	**Ethics Committee opinion:** **Upon review, the experimental design and protocol of the study fully considered the principles of safety and fairness, and protected the experimental subjects' right of informed consent. There is no conflict of interest in the study content and findings.** ○ agreement □Consent after modification ●Retrial after modification ● disagree **Ethics Committee official seal:** **Date:** 2022.10.1