

Subject informed consent form

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

Subject informed consent form

Dear patients:

shalom! The doctor has initially diagnosed you as having low back pain, and now invites you to participate in the clinical randomized controlled study of "intelligent moxibustion robot" in the treatment of lower back pain. You need to understand that participation in this clinical study is completely voluntary. Please read the following carefully before deciding to participate.

1. Informed notification

1.1 Research purpose: This topic adopts the method of "intelligent moxibustion robot" to treat low back pain. Through the observation of the clinical efficacy of this disease, it provides an objective basis for clinical practice, so as to provide a more optimized treatment method for clinical practice.

1.2 Conditions for study subject inclusion:

① It conforms with the diagnostic criteria of low back pain and the syndrome differentiation criteria of cold and wet lumbar muscle strain;

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

③ Nearly 2 weeks ago;

④ The course of the disease is controlled within 8 years;

⑤ Informed consent, willing to cooperate with the whole treatment;

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

⑦ Patients should reserve at least one contact information to

facilitate follow-up;

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

Those who meet the above 8 items can only be included in this study.

1.3. Subject needs to cooperate: After enrollment, subjects should cooperate with us to complete the relevant scale filling, draw serum samples, and go to the hospital for treatment on time every week, and cooperate with the completion of the scale filling on time. This study needs 1 week of treatment for 2 courses. Also, the subject had the responsibility to report to the physician any physical and mental changes during the trial, regardless of whether the subject had considered related the changes to the study.

1.4 Reasons for the possible termination of the trial: A few people may terminate the trial with adverse events such as mugwort fall, tobacco cough, and scald during the treatment. If there is any situation related to the termination of the trial, we promise that we will do our best to give the best treatment.

1.5 Possible benefits of participating in the trial: According to our previous clinical experience, the subjects' condition and quality of life will improve somewhat after two courses of treatment.

1.7 Confidentiality of personal Information: When participating in this study, the subjects' personal privacy will be kept strictly confidential to the extent permitted by law.

1.8 If the subject has any questions during the entire course of the

study, he / she can consult to the outpatient clinic or call the investigator's mobile phone to obtain more information.

2. Agree to sign

Subjects stated that:

I have been informed of the purpose, content and methods of the study, and I have fully understood the nature, significance, possible risks and benefits of the study. I have the right to volunteer or refuse to participate in this study. My personal information data will be kept confidential.

I fully understood the above content, and after full consideration, I made a decision independently: I volunteered as the subject of "clinical randomized controlled study of" intelligent moxibustion robot "for the treatment of low back pain", and was willing to accept the research requirements and cooperate with researchers. I voluntarily and actively cooperate with the relevant examinations and fulfill the rights and obligations of the subjects to ensure the final completion of this study.

Subjects signed: _____

Phone number: _____

date: _____