

Version date: 2023/04/25

Version number: V4.0

## Informed Consent Form

### Information Page

**Dear Sir or Madam,**

We invite you to participate in a randomized controlled trial of acupuncture for obesity treatment. A total of 160 participants with obesity will be enrolled in the trial. Participation in the trial is completely voluntary. The research team needs to assess your condition in accordance with the protocol for the trial.

Before you decide whether to participate in the trial, please read the following information carefully. It will help you to understand the trial and why it is important, particularly the trial procedure, benefits, risks, and discomforts associated with participating in the trial. You can discuss with your family and friends, or ask the research doctor for information to assist decision making. If you decide to participate in the trial, you are required to sign the informed consent form. You will also receive your own copy of the signed document.

The trial has been reviewed and approved by the Ethics Committee of Chengdu Sport University.

### Introduction

#### 1. Research background and research objectives

As economic development progresses and living standards improve, overweight and obesity have emerged as a major global public health challenge. As a chronic metabolic disease, obesity is not only an independent risk factor for cardiovascular disease, diabetes, and cancer, but also exerts a negative impact on people's psychological and social functions. Emerging evidence points to potential weight-loss effects of acupuncture as a traditional Chinese medicine therapy. However, there are still controversies over the efficacy of acupuncture, mainly due to a lack of understanding of the underlying mechanisms. The trial aims to study the efficacy of acupuncture on obesity by assessing measures from samples of blood, urine, and feces, as well as collecting physiological and psychological/social indicators. Our findings will provide support for the clinical application of acupuncture in treating obesity, and offer new insights into the underlying mechanisms of acupuncture treatment for obesity.

The study will be conducted at Chengdu Sport University and Chengdu University of Traditional Chinese Medicine. Participants who meet the eligibility criteria are invited to participate.

#### 2. Who will be invited to participate in this study?

People who meet the following criteria will be invited:

- 1) BMI  $\geq 28$  kg / m<sup>2</sup> (based on the obesity criteria in Chinese adults).
- 2) Adults aged 18 – 35 years.
- 3) Having not received any weight-loss measures in the past 3 months.
- 4) Voluntarily participating in the trial and signing informed consent.

People who meet any of the following criteria will be excluded:

- 1) Secondary obesity caused by drugs or other diseases.

Version date: 2023/04/25

Version number: V4.0

- 2) Psychosis, liver and kidney dysfunctions or other relevant diseases.
- 3) Skin diseases, severe allergic or scar constitution.
- 4) Pregnant or lactating women or those planning to conceive during the trial.
- 5) Having participated in other clinical trials.

Your research doctor will help to determine your eligibility based on the assessments.

### **3. What will I do if I participate in the research?**

Before you are enrolled in the study, history of disease and basic physical examination will be used to determine whether you are eligible to participate.

If you meet the eligibility criteria and are willing to participate, the following procedures will be followed.

We will collect samples of blood, urine, and feces, and assess physiological and psychological/social measures. All the procedures are free of charge. Data collected will help doctors to have a comprehensive review of your health condition. These procedures are safe and will not have any adverse effects on your health.

As a study participant, you will need to take some responsibilities. You will go for regular follow-up visits to specific locations at specific timepoints. You are also expected to report to the doctor any changes in your physical and mental health, regardless of whether these changes are believed to be related to the trial.

### **4. Benefits of participation in the trial**

If you participate in the trial, you will receive free acupuncture treatment and free physical examinations related to the trial.

The trial will help the research team to examine the efficacy of acupuncture for obesity treatment, which will support potential use in clinical practice in future.

The acupuncture used in this trial is a tested treatment for obesity. You can consult researchers for other alternatives. However, it is not recommended to use treatments other than the specified procedures in the trial to maintain scientific rigor and validity.

### **5. Potential adverse reactions, risks, discomforts, and inconveniences of participating in the trial**

If any adverse reactions or events possibly caused by acupuncture occur during the trial, please contact the research doctor. Our research doctor will help to manage these events. If the adverse reactions or events are confirmed to have caused harm to your body during the trial, compensation will be provided for the damages.

If you experience any discomforts, medical conditions, or accidents during the trial, please inform the research doctor, regardless of whether they are related to the acupuncture treatment. The research doctor will determine the appropriate medical treatments at his/her discretion.

There may be potential inconveniences associated with attending follow-up visits and completing questionnaires.

### **6. Related expenses**

Version date: 2023/04/25

Version number: V4.0

If you participate in the trial, you will receive free study treatments until its conclusion. Additionally, before the trial and during follow-up visits, we will provide free evaluations of your physiological, psychological, and social functions. Participants will also receive travel subsidies.

In addition, the research team will prevent and address any damages arising from the trial. If adverse events occur, a medical expert committee will assess their relation to the trial. The research team will adhere to the Clinical Technical Operation Specifications for Traditional Chinese Medicine to cover expenses or compensate for any trial-related damages.

Tests and treatments for conditions deemed unrelated to the trial will not be reimbursed.

### **7. Confidentiality**

All data collected during the trial will be kept confidential. Your medical records will be maintained by the research team and will only be accessible to the research team, ethics committees, and authorized administrative staff. Your personal information will not be disclosed in any research reports related to this trial.

We will make every effort to protect the privacy of your information in accordance with the laws and regulations in China.

### **8. More information for the trial**

You are welcome to ask any questions about the trial at any time and will receive prompt responses. If any important new information arises that could affect your willingness to participate, our research doctor will inform you promptly.

### **9. Voluntary participation and withdrawal from the trial**

You may decide at your discretion whether to participate. You are free to refuse participation or withdraw from the study at any time without affecting your relationship with the research team, your medical treatments, or any other rights.

For your best interests, the research doctor or investigator may suspend your participation at any time during the trial. If you withdraw from the trial for any reason, you may be asked about your use of acupuncture. If deemed necessary by the research doctor, you may also be advised to undergo laboratory tests and physical examinations.

### **10. What should I do now?**

The decision to participate in the trial is yours (and/or your family's).

Before making your decision, please consult your research doctor with any questions.

Thank you for reviewing this information. If you choose to participate, please inform your research doctor, who will then arrange the study procedures.

Version date: 2023/04/25

Version number: V4.0

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### Signature Page

#### Consent statement

I have read the above information for the trial and discussed the trial with the research doctor. All my questions have been satisfactorily addressed.

I am aware of the risks and benefits of participating in the trial. I understand that participation is voluntary, and I confirm that I have had sufficient time to consider this. I also understand:

1. I can consult the research doctor for more information at any time.
2. I can withdraw from the trial at any time without facing discrimination or retaliation, and my medical treatments and other rights will remain unaffected.
3. I understand that if I withdraw from the trial, especially due to acupuncture treatments, I should inform the research doctor about any changes in my medical condition and complete necessary laboratory tests and physical examinations, as these are important for the trial.
4. If I require other treatments due to changes in my medical condition, I will seek advice from the research doctor in advance or promptly inform him or her of the relevant information.
5. I agree that the research team, ethics committees, and administrative staff for research can review my information.
6. I will keep a signed and dated copy of the informed consent form.

I have decided to participate in the trial, and promise to follow the research doctor's advice.

Patient's Signature:

Year/Month/Day:

Mobile Phone:

I confirm that I have explained the details of the trial to the participant, including the rights, benefits and risks, and have provided a copy of the signed informed consent.

Research Doctor's Signature:

Year/Month/Day:

Mobile Phone: