Informed Consent Form

Dear patients:

You're invited to participate in a clinical trial of electroacupuncture on weight loss in obese patients with prediabetes. Please read the following content carefully before you decide to participate in this study or not. It may help you have an acquaintance with the study, including the research purpose, as well as benefits, risks, and discomfort after participating in the study. You can also discuss with your family and friends, or ask your doctor to explain it and to help you make decision.

Research Background

China currently has the highest proportion of obese and diabetic patients worldwide, leading to substantial social and medical burdens. Disrupted glucose metabolism in obese individuals, particularly when comorbid with diabetes, poses greater health risks than obesity alone. It is imperative to identify an effective and safe approach that concurrently addresses weight loss and enhances glucose metabolism in the treatment of obesity complicated by abnormal glucose regulation. Researches have demonstrated the potential of electroacupuncture therapy in reducing weight, lowering lipid levels, and ameliorating insulin resistance. This study utilizes rigorous high-quality randomized controlled trials to assess the clinical efficacy of electroacupuncture in promoting weight loss and improving glucose metabolism. The outcomes of this research are pivotal for developing optimized electroacupuncture treatment protocols tailored for obesity, offering essential support for the wider clinical implementation and promotion of electroacupuncture in the management of obesity.

The design of this research project adheres to the ethical principles protecting the rights and interests of the participants, in accordance with relevant laws and regulations of China and ethical guidelines including the Helsinki Declaration.

Requirements for Participation in the Study

Upon meeting the inclusion criteria and consenting to participate, the trial will proceed as below:

①Participants will be randomly assigned to two groups: the electroacupuncture group, incorporating pulse electrical stimulation based on traditional acupuncture methods, and the superficial acupuncture group, utilizing an acupuncture treatment with mild pain and minimal stimulation. Both groups will receive clinical treatment and observation over a 48-week period.
②Blood samples will be collected before treatment, at the 12th week during treatment, and at the 24th week after treatment. Body composition analysis and abdominal magnetic resonance imaging will be conducted before the start and after the completion of the treatment. Throughout the treatment process, assessments will be made using various relevant scales, including those measuring quality of life and appetite.
③Follow-up assessments, conducted within six months after the treatment's completion, will comprehensively evaluate the clinical efficacy of acupuncture treatment for patients.

Participation Benefits

Participating in this clinical trial offers potential benefits for your health. Participants will receive complimentary acupuncture treatment, health education, and regular assessments focused on glucose and lipid metabolism-related indicators.

Risks and Protection Measures for Participation

It is important to note the potential risks associated with participation. Adverse reactions to acupuncture, such as pain, bleeding and hematoma at the needle site, or fainting, could occur during the trial, leading to discomfort. If you experience any of these reactions, please promptly inform your acupuncturist and the clinical researcher. They will take immediate measures to address your discomfort and ensure the safety.

Costs of Participation

All treatments provided are entirely free of charge. Additionally, participants may receive a transportation allowance (500 RMB for each person) based on your completion of the trial.

Is Personal Information Kept Confidential?

The personal information provided for this research will be documented in the case report form. All data from the original medical records, including personal information and laboratory test reports, will be kept strictly confidential in compliance with legal regulations. Participants' names will be replaced by initials in Pinyin and an assigned number during the trial to ensure anonymity. In research summaries, articles, and public publications, participants will be identified solely by their initials in Pinyin and the assigned study number, if required.

The Ethics Committee or the project funding department may access participant data for the study when required by regulations. However, they are strictly prohibited from using this data for any purposes other than the study or disclosing it to other organizations without participants' permission.

How to Obtain More Information?

You are free to ask any questions related to this trial at any time.

Your doctor will provide you with their contact number to address your inquiries.

Your doctor will promptly notify you if there is any important new information during the trial that may affect your willingness to continue participating in the study.

Voluntary Participation and Withdrawal from the Study

Participation in this study is entirely voluntary and depends on your willingness.

You may refuse to participate in this study or withdraw from this study at any time during the study. If you choose to withdraw from this study, your benefits will not be affected and you will not be discriminated against or retaliated against for doing so. Your doctor or researcher may terminate your participation in this trial at any point in your best interest. Upon withdrawal, you may discuss your treatment options, and if necessary, undergo laboratory tests and physical examinations. Failure to comply will not lead to discrimination or retaliation.

We hope that if you choose to participate, you will complete the entire trial process.

What to Do Now?

It is up to you to decide whether to take part in this pilot study. You can discuss your decision with your family or friends. Before you make the decision to participate in the trial, ask your doctor as many questions as you can until you fully understand this trial study.

Ethical Committee

If you have any questions or need to inquire with someone other than the researchers or applicants, please consult the Ethics Committee of Shanghai Municipal Hospital of Traditional Chinese Medicine.

Contact Number: 021-56639828 **Contact Person:** Li Ling

Thank you for reviewing the aforementioned information. If you opt to participate in this clinical study, please inform your doctor, who will oversee all aspects related to the trial on your behalf.

Kindly provide your signature below. This informed consent form is duplicated for your records. Please keep this copy.