Informed Consent Form-Information Page

Dear participant:

Your doctor has diagnosed you with constipation in Parkinson's disease.

You are invited to participate in a study titled “Efficacy of acupuncture for the treatment of constipation in Parkinson's disease：a multi-centre randomised controlled trial”.

Please read the following information as carefully as possible before you decide whether to participate in this study. It can help you understand why this study is being done, the procedures and duration of the study, the benefits, the risks you may face, and the discomfort you may experience if you participate in the study. You can discuss it with your relatives, friends, or ask your doctor for an explanation to help you make a decision.

Study background and objectives

Parkinson's disease (PD) is a kind of progressive neurodegenerative disease commonly in people over 50 years old. With the increase in the percentage of ageing people in the global population, the incidence of PD is also increasing. In recent years, PD related non-motor symptoms have attracted more attention than ever. Constipation is the most common and earliest non-motion symptom of PD which seriously affects the quality of patients’ life . Meanwhile, studies indicate that constipation may be one of the risk factors for the occurrence and development of PD. Furthermore, common drugs used to treat PD, such as dopamine agonists, anticholinergics and catechol-oxyl-methyltransferase inhibitors, can aggravate constipation.

Acupuncture, as a green treatment method, has gained global popularity in recent decades. In addition, acupuncture can delay the progression of PD to some extent. It can play an important role in reducing adverse reactions to medicine and improving non-motor symptoms. Electroacupuncture is often used to treat constipation and PD. Nevertheless, a high-quality randomised controlled trial (RCT) study on acupuncture treatment for constipation in PD patients has been found. Therefore, this study will investigate the efficacy of EA for treating constipation in PD through a multi-centre randomised controlled trial.

This study will be conducted at Yueyang Hospital of Integrated Traditional Chinese and Western Medicine, Longhua Hospital, Shanghai Municipal Hospital of Traditional Chinese Medicine, and Shuguang Hospital, which are all affiliated to Shanghai University of Traditional Chinese Medicine.

If you agree to take part in the study, you will need to do the following:

1. Before you are enrolled in the study, you will undergo some examinations to determine whether you can participate in the study. The doctor will ask about your medical history. A general physical examination will be conducted as well.

2. If you meet the inclusion criteria, you will be assigned to the waitlist control group or the intervention group for treatment according to the randomisation. Patients in the study have a 50 percent chance of being assigned to either group.

Waitlist Control group: Administration of conventional medications will be done for the treatment of PD. If the patients are without bowel movements for three or more consecutive days, they will be allowed to take oral lactulose solutions or glycerine enema by rectal injection depending on their conditions. Patients need be assessed before treatment, at week 4, week 8, week 12, week16 and week24.

Intervention group: Based on the same manner as in the waitlist control group, electroacupuncture will be performed: three times per week from week 1 to 8, two times per week for weeks 9 and 10, and one time per week for weeks 11 and 12. Patients need be assessed before treatment, at week 4, week 8, week 12, week16 and week24.

3. Possible benefits of participating in the study

You and society probably benefit from this research. Your condition and quality of life may improve. This study may have a good guiding effect on clinical treatment. However, it is not excluded that this trial may not improve your condition.

4. Possible adverse events, risks, discomfort, and inconvenience of participating in the study

If you experience any discomfort during the study period, changes in your condition, or any unexpected circumstances, whether it related to treatment or not, you should inform your doctor immediately. The doctor will make a judgment and initiate medical treatment as needed. During acupuncture clinical trials, some adverse events may occur, such as fainting (during the acupuncture process, patients may suffer from palpitation, sweating, nausea, vomiting or even fainting), stagnation of needles (difficulty in needle extraction, and pain in patients) and so on. When fainting occurs, the needle will be removed immediately. The participant will be asked to lie flat with his/her head slightly lower than their body. The participant will be given warm boiled water or sugar water. In general, the participants will recover after lying for a while. When the hysteresis needle occurs, skin near the needle will be gently tapped to relieve the tense skin and muscles, moxibustion will be applied on the hilt of the needle or another needle will be used to puncture the skin near the needle. If the

unidirectional twist is too large, the needle will be twisted in the opposite direction.

During the study period, you need to come to our outpatient on time for treatment and follow-up, and do some physical or chemical tests. These may cause trouble or inconvenience to you.

5. Is personal information confidential?

Your medical records (CRF, physical and chemical examination reports, etc.) will be kept in the hospital. Researchers, sponsor representatives, and ethics committees will be allowed access to your medical records. Any public report on this study will not disclose your personal identity. We will make every effort to protect the privacy of your personal medical data within the scope permitted by law.

6. You are voluntarily choose to participate in the study or drop out of the study.
Participation in the study depends entirely on your willingness. You may refuse to participate in the study or withdraw from the study at any time during the study without affecting your relationship with your doctor, loss of your medical treatment or other benefits.

Your doctor or researcher may discontinue your participation in this study at any time for your best interest.

If you withdraw from the study for any reason, you may be asked about the treatment you are taking in the study. You may also be asked to perform physical examinations if your doctor thinks it is needed.

If you do not participate in this study, or withdraw from the study, there are many other alternatives, such as exercise therapy, surgery, and so on. You do not have to choose to participate in this study in order to treat your illness.

If you choose to participate in this study, we hope that you will be able to complete the entire study process.

Informed Consent Form-Signature Page

Clinical study project name: Efficacy of acupuncture for the treatment of constipation in Parkinson's disease：a multi-centre randomised controlled trial

Research unit: Yueyang Hospital of Integrated Traditional Chinese and Western Medicine, Shanghai University of Traditional Chinese Medicine

Longhua Hospital, Shanghai University of Traditional Chinese Medicine

Shanghai Municipal Hospital of Traditional Chinese Medicine, Shanghai University of Traditional Chinese Medicine

Shuguang Hospital, Shanghai University of Traditional Chinese Medicine

Approval number : 2018-121

2019LCSY034

2019SHL-KY-07-02

2019-676-31-01

Fill in the corresponding Research unit and Approval number according to different centres.

Voluntary Subject Statement:

I have read the above introduction to this study and had the opportunity to discuss and ask questions about this study with my doctor. All my questions were satisfactorily answered.

I am aware of the risks and benefits of participating in this study. I understand that participation in the study is voluntary. I confirm that there is sufficient time to consider this and I understand that:

I can always ask my doctor for more information.

I can withdraw from the study at any time without being discriminated against or penalised and my medical rights and treatment will not be affected.

I am also aware that if I drop out of the study, especially I drop out of the study due to treatment reasons, it will be very beneficial to me and the study if I tell the doctor about the change in my condition and complete the required physical examination.

If I need to take any other treatment due to the change in my condition, I will consult my doctor in advance or inform him/her afterwards.

I grant access to my research materials to the ethics committee or the sponsor's representative.

I will receive a signed and dated copy of the informed consent. In the end, I agree to participate in the study and will try to follow my doctor's advice.

Subject's signature: Date:

Subject contact number:

Signature of subject's guardian: Date:

Guardian's contact number:

Subject's guardian is required to sign the informed consent if necessary.

Doctor's declaration

I have fully explained this study in detail to the above participant, including his/her rights and possible benefits and risks, and I have answered all his/her questions. To the best of my knowledge, the participant has been informed adequately and has consented to the trial.

Doctor's signature: Date:

Doctor contact number:

In the event of inconsistency or discrepancy between the Chinese version and the English version, the Chinese language version shall prevail.