# Interleaving stimulation improving dyskinesia in Parkinson's disease: randomized, double-blind, controlled trial

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**Informed Consent for Subjects**

**Project Title:** Interleaving stimulation improving dyskinesia in Parkinson’ s disease: randomized, double-blind, controlled trial

**Project ID:**

**Project Version Number:**

**Informed Consent Version Number:**

**Research Institution:** Huashan Hospital affiliated to Fudan University

**Primary Investigator:** Jianjun Wu

You will be invited to participate in a clinical study. This notice provides you with some information to help you decide whether to participate in this study. Please read it carefully. If you have any questions, please enquire the researcher in charge of the study.

Your participation in this study is voluntary. This research has been reviewed and approved by the ethics committee of the research institution.

**Background:** Parkinson's disease (PD) is a common degenerative disease of the nervous system in the elderly. Clinically, the main symptoms of PD include static tremor, bradykinesia, muscle rigidity and disorders of postural and gait. The clinical utility of deep brain stimulation (DBS) for the treatment of PD has been well

established: the electrodes implanted in the deep nucleus of the brain can generate electrical pulse stimulation to restrain abnormal discharges in the brain, thus alleviating various symptoms of PD.

However, electrical stimulation may also related to some adverse events, such as stimulation-induced dyskinesia (SID), which manifests as involuntary twisting of the limbs and dance-like movements. Although reducing the stimulation parameters can mitigate the degree of dyskinesia, it can also comprise therapeutic efficacy, impairing the improvement of PD symptoms. Through alternately stimulating different contacts on the electrodes, the interleaving stimulation technique can simultaneously meet the demands of improving motor symptoms of PD and reducing the occurrence of dyskinesia. It is commonly applied when empirical programming modes fail to maintain the balance between motor symptoms improvement and overstimulation.

**Purpose:** The primary objective is to assess putative differences in the effect of interleaving stimulation and empirical stimulation with regards to dyskinesia control.

**Study Introduction：** Study participants will be PD patients undergoing DBS of the subthalamic nucleus (STN). Interleaving stimulation will be performed in the case of dyskinesia during empirical programming modes after surgery, and the effectiveness of interleaving stimulation will be evaluated. The study expects to recruit at least 50 patients.

**Study Process:** Patients with dyskinesia 3-month postoperatively will be randomly and blindly assigned to either the interleaving stimulation modes group

(ISG) or the empirical stimulation modes group (ESG). After 6 months of programming, the improvement of dyskinesia and motor symptoms between the two groups will be compared and adverse events will be recorded.

**Risk and Discomfort:** This study may have the risks of surgical operation, electrical stimulation and MRI/CT imaging. The corresponding expected risks are hereby notified. DBS is a clinically approved method for the treatment of PD. This study is mainly aimed to optimize the therapeutic effects of postoperative programming. In order to reduce relevant uncertainty, only patients with dyskinesia during postoperative empirical programming will be randomly grouped into ISG or ESG.

**Benefits:** Based on studying your individual medical status, we will provide you with necessary treatment recommendations.

**Cost:** The costs of DBS surgery and corresponding examinations will be paid by the subjects. And the costs of programming, follow-up and evaluation during the research will be paid by this study.

**Compensation:** You will not get paid for participating in this study. You will be reimbursed for your transportation expenses during the follow-up of this study. A single visit is RMB 200 yuan for local patients in Shanghai and RMB 500 yuan for patients transported from other cities.

As a research subject, you have the following responsibilities: provide the true information about your medical history and current physical condition; inform the research doctors about any problems that you may have encountered during this

study; tell the research doctors whether you have participated in other studies recently, or is currently participating in other researches.

**Confidential Issues:** If you decide to participate in this study, your participation and your personal information in the study will be protected as confidential. Only the research physicians and researchers will use your medical information for clinical study. The information may include your name, address, telephone number, medical history, and information obtained during your research visit. Your personal files will be kept in a locked filing cabinet, which will be available for research personnel only. To ensure that the research is conducted in accordance with the regulations, when necessary, members of the government administration department or the ethics committee can consult your personal data in the research institution. When the research results are published, your personal information will not be disclosed.

To bear the corresponding treatment costs and corresponding financial compensation for the trial-related damages incurred by the patients following the clinical trial protocol. You can choose not to participate in this study, or notify the investigator to withdraw from the study at any time. Your personal data will not be included in the study results, and any of your medical treatment and rights will not be affected.

If you need other treatments, or if you do not follow the study plan, or have a study-related injury or for any other reasons, the study physicians can terminate your further participation in this study.

You can learn about the information and research progress related to this

research at any time. If there is any newly occurred safety information related to the study, we will also inform you in time. If you have questions related to this study, or if you have any discomfort or injury during the study, or have questions about the rights of participants in this study, you can contact Chief Physician Jianjun Wu at 13391329019 (mobile phone number).

If you have any questions or appeals about the rights and well-being of participation in this study, you can contact the ethics committee of our institution at 021-528888045; contact person: Cuiyun Wu.

## Signed page of informed consent

I have read this informed consent form.

I have the opportunity to ask questions and all the questions have been resolved.

I understand that participation in this study is voluntary.

I can choose not to participate in this research, or I will withdraw after informing the researchers at any time without being discriminated against or retaliated. Any of my medical treatment and rights will not be affected by this.

If I need other treatment, or if I do not follow the research plan, or there is a research-related injury or for any other reason, the research physician can terminate my further participation in this research.

I will receive a signed copy of the "Informed Consent".

Subject's name: _____

Subject's signature: _____

Date: (Year/ Month/ Day)

I have accurately informed the subject of this document and asked him/her to read the informed consent form carefully and answer all the questions.

Researcher's name: _____

Researcher's signature: _____

Date: (Year/ Month/ Day)

（Note: If the subject is illiterate, the witness is required to sign. And if the subject is incapacitated, the agent's signature is required）