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Subject Name (InC): Subject Screening Number:

Research on early standardized electronic cognitive training technology for elderly depression with cognitive impairment

Informed consent form

Dear Patients,

You will be invited to participate in the "Research on Early Standardized Electronic Cognitive Training Techniques for Early Geriatric Depression with Cognitive Impairment.". Before you decide whether to participate in this study, please read the following as carefully as possible, which can help you understand the study and why the study was conducted, the procedure and duration of the study, and the benefits, risks, and discomforts that may be brought to you after participating in the study. If you wish, you can also discuss with your family and friends and then carefully decide whether to participate in this study. When a researcher explains and discusses an informed consent form to you, you can always ask questions and ask him/her to explain to you what you don't understand.

The research will be carried out at Beijing Anding Hospital, affiliated with Capital Medical University. This research was supported by the Beijing Municipal Science and Technology Commission.

[Project Introduction]

Senile depression (LLD) is the most common mental illness in the elderly, and the prevalence of population aging is on the rise, and it has become one of the important factors affecting the quality of life of the elderly. 50-70% of elderly depression is accompanied by different degrees of cognitive impairment, and elderly depressed patients with cognitive impairment have a greater risk of dementia transformation, worse prognosis, and higher recurrence rate, which seriously endangers the quality of life and social function of patients and increases the economic burden of society and family. Therefore, early intervention

strategies to provide evidence-based support for older depression with cognitive impairment are imminent.

At present, domestic and foreign guidelines do not provide a clear and effective treatment plan for elderly patients with cognitive impairment, and the overall efficacy and tolerability of drug therapy for elderly patients with depression and cognitive impairment are poor. Studies have confirmed that cognitive training can significantly improve the overall cognitive function and function of multiple cognitive domains in healthy elderly people, mild cognitive impairment (MCI) and Alzheimer's disease (AD), and the results of previous studies have also preliminarily confirmed the cognitive improvement effect of cognitive training on elderly patients with depression. The objective of this study was to compare the efficacy of conventional SSRIs combined with electronic cognitive training (intervention group) and single conventional SSRIS drug therapy (control group) for cognitive impairment in elderly patients with cognitive impairment in patients with cognitive impairment. Establish a set of standardized and operable electronic cognitive intervention techniques for elderly people with cognitive impairment and depression applicable to all types of psychiatric hospitals at all levels.

[How the study was conducted]

After you fully understand the pros and cons of this project and decide to volunteer for this study, you will need to sign an informed consent form. Next, the research doctor will perform relevant screening tests on your protocol, including asking for your medical history, measuring vital signs, measuring scales, and safety tests. If all of your results meet the requirements of the program, you can continue to participate in this study. The selection/exclusion criteria for this programme are as follows.

Admission Criteria (All 7 must be met)

1) Inpatient or outpatient patients, age ≥ 60 years old (including 60 years old), gender is not limited;

2) Meet the diagnostic criteria for single-time or recurrent major depressive disorders in

diagnostic and Statistical Manual of Mental Disorders-Fourth Edition (DSM-V);

3) The total score of HRDS-17 at the time of screening ≥ 18 points;

4) Montreal Cognitive Assessment Scale (MoCA) < 26 points at the time of screening;

5) UrineAD-7cNTP ≥ 1.5ng/ml;

6) Primary school education level or above, able to understand the content of the scale;

7) The patient himself signs the informed consent form.

Exclusion criteria (exclude if 1 is met)

1) Those with a history of epilepsy or coronary heart disease or other serious unstable physical diseases;

2) Participated in another interventional clinical study in the past 1 month;

3) Previous or current diagnosis of other mental illnesses in line with DSM-V;

4) In the past 2 weeks, they are taking antidepressants, nootropics and other psychiatric drugs;

5) Severe aphasia, visual and hearing impairment, etc. can not complete the scale assessment;

6) Pregnant, lactating women or those planning to become pregnant;

[Scope of this study]

The study will be conducted in Beijing Anding Hospital, affiliated to Capital Medical University, and a total of 128 participants participated in the study.

[How the research was conducted]

After you fully understand the pros and cons of this study and voluntarily participate in this study, you will need to sign an informed consent form. Next, you will move on to a 52-week study with 8 fewer visits to the hospital during the study phase.

Subjects were randomly divided into intervention and control groups, as follows:

Screening visits: Participants were screened for general information gathering, symptom

assessment, cognitive function assessment, and concise international neuropsychiatric interview questionnaires to determine that they met the inclusion criteria for the study.

Double-blind treatment period (52 weeks): You are randomly divided into intervention or control groups. The intervention group received a 52-week training of SSRIs antidepressants combined with electronic cognition (1 time a day for 60 min, 4 days a week), and the control group subjects received SSRIs for 52 weeks and used electronic products as required by the protocol (4 days a week, once a day for 60 min). In the baseline period, 2 weekends, 4 weekends, 8 weekends, 12 weekends, 26 weekends, 38 weekends and 52 weekends, the subjects were assessed for cognitive function, symptomatology and adverse events, and the cognitive function improvement of the two groups of subjects was compared.

For your safety, you will be assessed by a professional clinician for vital signs measurement, routine physical examination, and relevant scale assessment at each visit. We monitor the concentration of antidepressants during treatment to ensure that they are within a safe range. During the screening period, 4 weekends, 12 weekends, 38 weekends and 52 weekends, blood routines, biochemical examinations and electrocardiograms are performed.

For your safety, if you develop any meaningful clinical manifestations throughout the follow-up period, the research physician will follow up on these abnormalities of yours and continue to follow them until they return to normal or plateau. After examination and evaluation of the abnormality, the research physician will determine whether you can continue to participate in the study.

If you decide not to participate in a study at any stage during your study, or if your doctor asks you to terminate your study, your study doctor will follow you up for the last time. This is to ensure that you are in good health.

If you do not continue to participate in this study, the study doctor will provide you with other treatment options.

Once you have completed your research, your research doctor will discuss with you how to proceed with the treatment of your disease.

[Withdrawal and Termination of Research]

During your treatment, your doctor will deal with unavoidable or already occurring adverse reactions. However, if your condition changes or adverse reactions do not allow you to continue treatment according to the protocol set out in this study, your doctor will likely have you withdraw from the study. Exit Criteria:

1) The occurrence of a serious adverse event or the requirement to discontinue the current treatment regimen due to the adverse event;
2) Withdrawal of informed consent;
3) The investigator believes that it should be withdrawn from safety considerations;
4) Serious violations of the research protocol, such as not being treated according to the plan, poor compliance, etc.;
5) Persons who attempted suicide, committed suicide, or seriously injured themselves during the study period;
6) Manic or hypomanic episodes occurred during the trial.

After you withdraw from this study, your study physician will work with you about your subsequent treatment.

[What you need to do]

- Provides an accurate history of past illness and current personal circumstances.
- Tell the research doctor about any health problems you have during your studies.
- Medication and cognitive training as required, visits as required.
- Do not participate in other medical studies.
- Follow the guidance of researchers and research doctors.
- If there is anything unclear you can always ask.

[How to use your personal information]

By signing this written informed consent, you authorize the research physician and his/her assistants to collect and process your personal information, including: your basic information, your disease status data, any personal information obtained during your participation in this

study, and any results obtained during follow-up visits and examinations.

To the extent permitted by law, we will make every effort to protect your personal privacy and will keep your identifying information as private as possible. Any public report related to this study will not disclose your personal identity, and only relevant experts of the Ethics Committee, monitors/auditors, research doctors have access to your medical records and use your personal information for the purposes of administration, conduct of research, research and data analysis.

[If you have questions or difficulties, who should you contact]

If you have any questions about this study, or if you have any questions and any discomfort during the trial, please contact your research doctor promptly by telephone number. If you have any questions related to your own interests, please contact the Ethics Committee of Beijing Anding Hospital by phone.

Informed consent signature page

[Subject Statement]

I have read and listened to the researchers and have had the opportunity to discuss and ask questions about this study with a doctor, and all the questions I have asked have been satisfactorily answered. Knowing the purpose, nature, and possible benefits and risks of the study, knowing that my participation in the study was voluntary, I confirmed that I had sufficient time to consider it, and that I could consult my doctor for more information at any time and that I could withdraw from the study at any time without discrimination or retaliation. I agree that the ethics committee, the research doctor, have access to my medical records, and I allow the research doctor to use my data information. I have read this informed consent form and agreed to participate in this study. I promise that the past medical history and other health information I provide is true and reliable. I have been given an informed consent form with the date and signature of me and the research doctor.

Subject Signature: ____

Contact: _____

[Researcher's Statement]

As a researcher, I have given the subjects a detailed description of the purpose and nature of the trial, the possible benefits and risks of the subject, and the efficacy and side effects of existing treatments, giving him/her sufficient time to read the informed consent form, discuss it with others, and answer questions related to the study. I have informed subjects that they can withdraw from the trial at any time without affecting future treatment. I have informed the subject of the contact details if the problem occurs, and I have informed the subject that he/she can withdraw from the study at any time.

Investigator Signature: _____

Contact: _____