Certificate of Approval

DAUH-IRB

Dong-A University Hospital Institutional Review Board

Tel +82-51-240-2572,2577

FAX +82-51-231-2140

#26, Daeshingongwon-ro, Seo-gu,

Busan, 49201, Republic of Korea

THE FOLLOWINGS WERE APPORVED :

BOARD ACTION DATE : May 18, 2022

STUDY NO : DAUHIRB-22-089

Request of Study Plan Review

INVESTIGATOR : Sang-Mung Cheon (NU)

SPONSOR : a national project

TITLE : Development of Machine Learning-based Classification Models for the Severity of Motor Symptoms in People with Parkinson's Disease and Verification of the Effect of Customized Interventions

APPROVAL INCLUDES:

ALL CONDITIONS OF APPROVAL PREVIOUSLY ESTABLISHED BY DAUH IRB

FOR THIS RESEARCH PROJECT CONTINUE TO APPLY. And 'Informed consent was waived because of the retrospective nature of this study'

CONTINUING REVIEW REPORT INTERVAL : Etc. (May 17, 2024)

OTHER INSTITUTION : N/A

IF YOU HAVE ANY QUESTIONS, CONTACT DAUH IRB (Tel: 82-51-240-2577)

This is to certify that the information contained herein is true and correct as reflected in the records of the DAUH Institutional Review Board. We certify that DAUH IRB is in full compliance with Good Clinical Practice as defined under the Korea Food and Drug Administration (KFDA) regulations and the International Conference on Harmonisation (ICH) guidelines.

Roh Mee Sook

Chairperson

May 18. 2022

Date

ALL DAUH IRB APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:

1. Conduct the research as required by the protocol.

2. Use only the Consent Form bearing the DAUH IRB "APPROVED" stamp.

3. Provide non-Korean speaking subjects with a certified translation of the approved Consent Form in the subject's first language. The translated version must be approved by the DAUH IRB.

4. Obtain pre-approval from the DAUH IRB of any changes in the research activity (except when necessary to protect human subjects; immediately report to the DAUH IRB any such emergency changes for the protection of human subjects).

5. Report to the DAUH IRB the death, hospitalization, or serious illness of any study subject.

6. Promptly report to the DAUH IRB any new information that may adversely affect the safety of the subjects or the conduct of the trial.

7. Provide reports to the DAUH IRB concerning the progress of the research, when requested.

8. Obtain pre-approval of study advertisements from the DAUH IRB before use.

9. Conduct the informed consent process without coercion or undue influence, and provide the potential subject sufficient opportunity to consider whether or not to participate.

Korea FDA regulations require that the DAUH IRB conduct review of approved research. You will receive Continuing Review Report forms from the DAUH IRB. These reports must be returned even though your study may not have started.

Dong-A University Hospital Institutional Review Board

Information sheets and consent forms for research subjects

Version 2.0 May 10, 2022

Human Subjects Manual

- Project Title: Development of Machine Learning-based Classification Models for the Severity of Motor Symptoms in People with Parkinson's Disease and Verification of the Effect of Customized Interventions

You have been asked to participate in a clinical trial. Before you decide whether or not you want to participate in this study, you should read the information sheet and consent form carefully. It is important that you understand why this study is being conducted and what it will do. The principal investigator, Sang-Myung Cheon, who is conducting this study, will explain the study to you. This study will only be conducted on a voluntary basis. Please read the following carefully before deciding whether you want to participate and, if necessary, discuss it with your family or friends. Your signature means that you have been told about the study and the risks, and your signature on this document means that you (or your legal representative) want to participate in this study.

1. Study purpose

The purpose of this study is to establish a new exercise intervention paradigm to improve the clinical diagnosis and classification techniques of Parkinson's disease and the effectiveness of exercise interventions by identifying the clinical characteristics and unilateral asymmetric motor symptom body segment expression

sites in patients with Parkinson's disease, developing a severity classification model, improving the severity classification model based on machine learning, applying a combined motor-cognitive exercise program, and validating the effectiveness of exercise interventions tailored to each patient.

2. Who will participate in the study

The study will be conducted on patients who have been diagnosed with Parkinson's disease by a neurologist and will initially randomize 70 participants, 50 in the idiopathic Parkinson's disease group and 20 in the control group. The secondary study will include an additional 30 patients who have been diagnosed with idiopathic Parkinson's disease by a neurologist to further the study.

3. Research methods

1) Measurement metrics

- Measures of clinical characteristics, including the Unified Parkinson's Disease Rating Scale (UPDRS), Hoehn and Yahr (H&Y), Mini-mental state examination (MMSE), and activities of daily living assessments by Schwab and England.

- Forward and backward straight-line walking, the 360° turning task on the more affected side at a preferred and as fast as possible speed

- Assessment of muscle strength and function, and dynamic stability: handgrip, 5 chair-to-stand time, 6-minute walk (or 2-minute in-place walk), -20% slow/preferred/+20% fast treadmill continuous walk

2) Research procedures

- The group of Parkinson's patients will be asked to take their anti-Parkinson's medication approximately 2-3 hours before the experiment (on-state), and the experiment will be conducted when they are feeling the full effects of the

medication.

- All participants will complete informed consent; measurements of body composition and anthropometry; measurements of clinical characteristics such as physical activity capacity questionnaire and medical history questionnaire; and assessments of gait task, muscle strength and function, and dynamic stability.

4. Length of study participation

You will be asked to participate in measurements for a total of 1 day and 2 hours for this study.

5. Dropping out of the study

You may withdraw from the study if you do not wish to participate for personal reasons, the study will be stopped if any injury is caused by the research methods, and the study will be stopped if, in the judgment of the researcher, it is necessary to stop the study.

6. Participants notes

1) This study is conducted for research purposes only.

2) All participants in this study will be asked to limit participation in any exercise program outside of their daily routine and to refrain from excessive alcohol consumption, exercise, and overwork during the study.

3) Pain from soft tissue and muscle damage may occur after the experiment. These symptoms usually resolve within 48 - 72 hours.

7. Benefits of participating in the study

The tests and results associated with this study will be provided at no cost to

you, and you will be paid $30 for your participation in this experiment. You will be given information about your current physical fitness and body composition. Experimental supervisors and assistants who are trained in first aid will be available to immediately deal with any accidental situations that may occur during the experiments in this study. In the event of any damage or adverse effects caused by your participation in this study, you may receive compensation in accordance with the Victim Compensation Convention.

8. Penalties for not participating in the study

You are free not to participate in this study, and there will be no penalty to you if you do not participate in this study.

9. Privacy and confidentiality

The following personal information will be collected from you as part of this study: name, gender, social security number (optional), address, and phone number. This information will be used for the study for one year and the information collected will be managed appropriately and in accordance with privacy laws. The information will be kept in a locked personal locker and will only be accessible to the principal investigator and co-investigators. We will do our best to ensure the confidentiality of all personal information obtained through the study. Your name and other personal information will not be used when the personal information obtained in this study is published in journals or conferences; however, if required by law, your personal information may be provided. In addition, the monitor, inspection personnel, and the Institutional Review Board may directly view the results of the study to verify the reliability of the procedures and data of this study within the scope of relevant regulations without violating the

confidentiality of the research subjects. By signing this consent form, you will be deemed to have been informed of these matters in advance and to be willing to allow them. After the study is completed, the research-related materials will be kept for one year and then destroyed.

10. Research inquiries

If you have any questions about this study or encounter any problems during the study, please feel free to contact the following principal investigators

Principal Investigator: Sang-Myung Cheon; Contact: 051-240-5298
Research Nurse: Minjung Kim; Contact: 051-243-5298
Researcher: Hwayoung Park; Contact: 051-200-7846

If you are a subject participating in a clinical study and have questions about ethical issues or subject rights, you can contact us directly at the following.

Dong-A University Hospital Clinical Research Review Board: 051-240-2577 / 2572
Clinical Research Protection Center Helpdesk: 051-240-2579

Consent form

1. I have read the study description and discussed it with the principal investigator.
2. I voluntarily agree to participate in this study.
3. not utilized for any purpose other than that agreed to by the personal information provider, and if you wish to refuse to use the personal information provided, you may request access, correction, or deletion through the person in charge of personal information management.
4. In accordance with relevant laws and regulations such as the Personal Information Protection Act, I, the undersigned, agree to the collection and utilization of personal information as described above.
5. I understand that I can withdraw from participation in this study at any time and that this decision will not harm me in any way.
6. Execute, sign, and date two copies of this instrument and retain one copy each as evidence of the above agreement.

Research subjects	Full name:	Signature:	Signature date:
Legal representative (if necessary)	Full name:	Signature:	Signature date:
	Relationship to human subjects:		
Inductees (if necessary)	Full name:	Signature:	Signature date:
Principal Investigator	Full name:	Signature:	Signature date: