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Name of the document:

Study protocol and Statistical Analysis Plan

Official Title of the Study:

Analyzing Gait Pattern Using Insole-type Gait Analyzer in Patient with Gait Disturbance

NCT number

NCT06442982

Date of the document:

February 4, 2025

Severance_20240531

Prospective Clinical Study Protocol

1. Title, stage, protocol identification number, revision history, etc.

- Title: Analyzing Gait Pattern Using Insole-type Gait Analyzer in Patient with Gait Disturbance
- Stage: phase 4

2. Summary of study plan

Study objective	We explore the usefulness of information from insole-type gait analyzer in adults with subjective gait and balance disorders.
Study design overview	We analyze the collected data from gait wearing insole-type gait analyzer for subjective gait and balance disorders.
Drugs/medical devices for clinical trials	Insole-type gait analyzer
Target number of subjects and calculation basis	600 adults with subjective gait or balance disorders This study investigates whether clinically significant data could be obtained using insole-type gait analyzer, with the number of subjects determined considering clinical conditions.
Inclusion and exclusion criteria	1. Inclusion criteria 1) adults aged 19 and over (based on the age on their national ID at the time of consent) 2) adults complaining subjective gait or balance disorders 3) individuals who voluntarily agree to participate in the study and sign a consent form 2. Exclusion criteria 1) individuals unable to walk independently on flat ground for more than 6 minutes 2) individuals who cannot read ordinary print with glasses due to visual reasons 3) individuals who cannot understand conversation even with a hearing aid due to auditory reasons 4) individuals with clinically significant disorders in the cardiovascular,

	gastrointestinal, respiratory, or endocrine systems 5) individuals considered clinically unsuitable for the trial by the trial manager or person in charge based on significant medical findings.
Study Methods	After obtaining consent - A history survey, a sarcopenia questionnaire, and the International Physical Activity Questionnaire (IPAQ) are conducted. - The Timed up and go test is performed wearing the Insole-type gait analyzer
evaluation variable	As the purpose is data collection, no evaluation variables are set in this study
Data analysis and statistical methods	This study evaluates the validity of data collected by the insole-type gait analyzer but does not conduct data analysis and statistical analysis

3. Study background and theoretical basis

Gait and balance disorders are common symptoms in the elderly, with reports indicating that 35% of those over 70 years old exhibit these issues. Gait and balance are maintained through complex interactions involving the musculoskeletal system, various sensory functions with proprioceptors, and cognitive attention. These disorders are not only closely linked to degenerative brain diseases such as dementia and Parkinson's disease but also to musculoskeletal disorders like osteoarthritis and spinal stenosis, serving as indicators for disease prognosis and functional status assessment. Moreover, gait and balance disorders can occur in the absence of medical conditions due to aging, potentially leading to increased falls, complications, and higher personal and societal costs. Therefore, early diagnosis and assessment of these disorders are crucial in geriatric medicine.

Traditionally, expensive specialized equipment such as cameras and pressure sensors installed in controlled environments, have been used to assess various kinematic changes during the gait cycle, such as stride variations and bilateral stepping differences. However, these tools have practical limitations in clinical settings. Although insole-type gait analyzer have been developed and commercialized, they have only been tested on healthy adults. Their usefulness in patients with gait disorders remains unverified.

This study aims to evaluate the usefulness of insole-type gait analyzer in adults with subjective gait and balance disorders by analyzing the collected data during gait.

4. Purpose of the study

We explore the usefulness of information from insole-type gait analyzer in adults with subjective gait and balance disorders.

5. Risk/benefit analysis

This study involves participants wearing non-intrusive devices during walking, posing minimal medical risk. To minimize the risk of potential falls during assessments, participants will walk indoors under the supervision of examiners.

Participants will receive information about stride length and pressure changes in both feet during walking. The accumulated data could be utilized in future research related to disease treatment and prognosis, contributing to advancements in medicine and the improvement of patient care. Therefore, the benefits from this study are expected to outweigh the potential risks."

6. Target number of subjects and calculation basis

This study investigates whether clinically significant data could be obtained using insole-type gait analyzer. Considering clinical conditions, the target sample size has been determined as 600 participants.

7. Subject Inclusion/exclusion criteria

1) Inclusion criteria

(1) adults aged 19 and over (based on the age on their national ID at the time of consent)

(2) adults complaining subjective gait or balance disorders

(3) individuals who voluntarily agree to participate in the study and sign a consent form

2) Exclusion criteria

(1) individuals unable to walk independently on flat ground for more than 6 minutes

(2) individuals who cannot read ordinary print with glasses due to visual reasons

(3) individuals who cannot understand conversation even with a hearing aid due to auditory reasons

(4) individuals with clinically significant disorders in the cardiovascular, gastrointestinal, respiratory, or endocrine systems

(5) individuals considered clinically unsuitable for the trial by the trial manager or person in charge based on significant medical findings.

8. Information and management of clinical investigational drugs/medical devices

The information and management methods of the medical device used in this study are as follows.

1) Insole-type gait analyzer

(1) Item name: Gait analysis system

(2) Classification number: A30110.01

(3) Packaging unit: 1 set

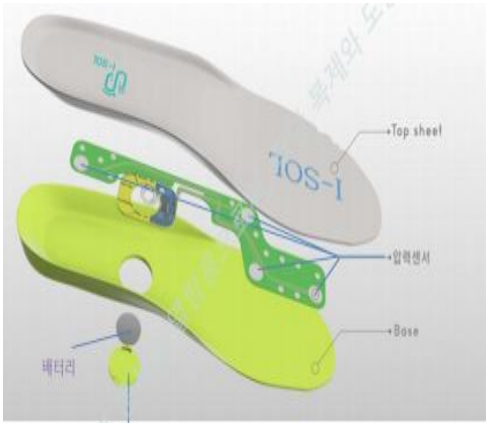
(4) Medical device grade: Grade 1

(5) Model name: mobiCARE-MC100

(6) Manufacturer: Gilon Co., Ltd.

(7) Permit number: Manufacturing Report No. 20-1753

(8) Principle of operation and appearance



Shape and Structure - Operating Principle

This product is a machine designed to understand the decline in walking ability and functional recovery following therapy. It consists of hardware and software (app). When a patient wears shoes equipped with the device and begins walking, pressure sensors and speed sensors installed in the device measure the pressure of the foot on the ground, the area of the foot that makes contact, walking speed, walking distance, and the number of steps to inform the patient of their walking pattern.

The sensors are comprised of pressure sensors and accelerometers. The accelerometer measures the acceleration acting on the sensor, and the pressure sensor operates on the principle that resistance changes when force is applied to the sensor, thereby measuring the corresponding voltage to determine pressure.

(9) How to use and precautions - refer to the attached document

2) Device management

Medical devices used in this study are managed in a designated location (Rehabilitation Function Testing Room on the 2nd floor of Yongin Severance Hospital) in accordance with the precautions for use and storage method. (Refer to attached document)

9. Study design (test group·control group, allocation, blinding and flow chart, etc.)

This study aims to explore the usefulness of collected data and does not establish a control group. Patients with subjective gait and balance disorders will wear insole-type gait analyzer and walk, then the collected data will be examined."

10. Study Method

1) Screening method

The examiner asks about the subject's underlying symptoms and signs and check vital signs to ensure that the subject is medically stable and to determine whether the subject can walk independently on flat ground

2) Korean version of Sarcopenia Screening Questionnaire

Questionnaire that evaluates the decrease in muscle strength and functional performance along with a decrease in muscle mass and it is highly related to aging and chronic diseases. The evaluation method is conducted by having the examiner ask the subject about the following questionnaire, and the scores for the answers are recorded.

It consists of 5 questions, and each question is scored 0-2 points. The higher the score, the higher the risk of sarcopenia. If the score is 4 or higher, sarcopenia may be suspected.

Component	Question	Scoring
Strength	How much difficulty do you have in lifting and carrying 10 pounds?	None = 0 Some = 1 A lot or unable = 2
Assistance in walking	How much difficulty do you have walking across a room?	None = 0 Some = 1 A lot, use aids, or unable = 2
Rise from a chair	How much difficulty do you have transferring from a chair or bed?	None = 0 Some = 1 A lot or unable without help = 2
Climb stairs	How much difficulty do you have climbing a flight of 10 stairs?	None = 0 Some = 1 A lot or unable = 2
Falls	How many times have you fallen in the past year?	None = 0 1–3 falls = 1 4 or more falls = 2

3) Korean version of the International Physical Activity Questionnaire (K-IPAQ)

Tests that assess various aspects of an individual's daily physical activity[16] and it can provide information about activity level. The examiner questions the subject based on the questionnaire below, records related information, calculates the total activity time and intensity, and classifies it as 'low', 'medium', and 'high'.

1a. During the last 7 days, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling,?

Think about *only* those physical activities that you did for at least 10 minutes at a time.

_____ **days per week** ⇨

or

☐ **none**

1b. How much time in total did you usually spend on one of those days doing vigorous physical activities?

_____ **hours** _____ **minutes**

2a. Again, think *only* about those physical activities that you did for at least 10 minutes at a time. During the last 7 days, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

_____ **days per week** ⇨

or

☐ **none**

2b. How much time in total did you usually spend on one of those days doing moderate physical activities?

_____ **hours** _____ **minutes**

3a. During the last 7 days, on how many days did you **walk** for at least 10 minutes at a time? This includes walking at work and at home, walking to travel from place to place, and any other walking that you did sblely for recreation, sport, exercise or leisure.

_____ **days per week** ⇨

or

☐ **none**

3b. How much time in total did you usually spend walking on one of those days?

_____ **hours** _____ **minutes**

The last question is about the time you spent sitting on weekdays while at work, at home, while doing course work and during leisure time. This includes time spent sitting at a desk, visiting friends, reading traveling on a bus or sitting or lying down to watch television.

4. During the last 7 days, how much time in total did you usually spend *sitting* on a **week day?**

____ **hours** _____ **minutes**

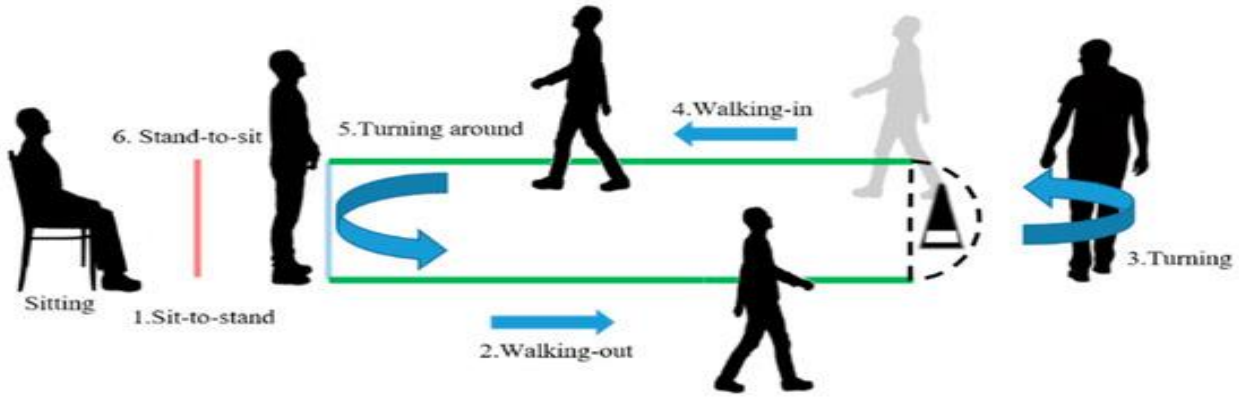
This is the end of questionnaire, thank you for participating.

4) Timed up and go test (TUG)

The participants will wear insole-type gait analyzer and undergo the Timed Up and Go test.

The above test assesses walking speed along with balance ability during walking, and this is performed as follows.

a) A 46 cm high armrest chair, a color cone is placed at a distance of 3 meters from the chair and the subject is instructed to sit on the chair.
b) In the preparation phase, the subject leans against the chair backrest and places his/her arms on the armrests, then stands up on the instruction "Start", walks 3 meters, turns around the color cone, returns to the starting point and sits down on the chair.



5) Data Verification

The measurement values of the accelerometer and pressure sensors recorded in the insole-type gait analyzer will be examined to determine the presence of missing or outlier data. We will explore the data collection frequency and analysis methods to extract clinically significant data.

11. Study procedures and evaluation

Phase	Screening/ assessment
week	1
written consent	O
Selection/exclusion criteria	O
Demographic information and antecedent history	O
Gait assessment	O

12. Criteria for stopping and dropping out of the study

1) Termination and early suspension

○ When a subject participating in the study withdraws their consent before the study ends

- If consent is withdrawn, the study participant's information collected up to that point is destroyed.

2) Dropout

○ If a subject continuously agrees to participate in the study but wishes to terminate their participation early due to personal reasons.

- Reconfirm the voluntary intention of the study participant to ensure the study does not correspond to early discontinuation. If the participant still intends to provide information to the study, any information collected up to the point of withdrawal will be anonymized and can be used for the study.

13. Safety evaluation criteria, evaluation methods, and reporting methods, including adverse reactions

1) In order to ensure the safety of study participants, this study plans to have the s conduct monitoring and evaluate safety as a safety inspector.

(1) As a observational study with little room for invasive intervention such as the need for separate procedures, the

risk level of the study is low, so monitoring will be conducted once a year under the supervision of the principal investigator, and the completeness of the data will be ensured by comparing the supporting documents, CRF, and protocol, and the safety data of the study participants will be reviewed.

(2) Participants in the study can decide to stop participating at any time if they feel uncomfortable with the study, and the principal investigator or study manager fully explains and confirms this to the participant when obtaining consent.

2) In the event of a violation or deviation from this study, the circumstances of the occurrence, the researcher's actions in response, and measures to prevent recurrence will be promptly reported to the IRB in writing.

- If the subject becomes suspicious or a new incident occurs during the evaluation, immediate treatment and observation will be provided, the cause will be thoroughly examined, and treatment will be provided according to the hospital's standard procedures. This will also be reported during the interim report and written in the study paper. However, this study did not calculate study costs for additional treatment costs because it was judged that the possibility of future side effects was low.

14. Data analysis and statistical considerations

This study evaluates the validity of data collected by the insole-type gait analyzer but does not conduct data analysis and statistical analysis

15. Measures to protect personal information and maintain confidentiality of study data

1) Protection of the subject’s identity

When seeking consent for study, the study is explained to the subject and consent is obtained in an independent space in the counseling room within the outpatient department of the Rehabilitation Medicine Department.

All information collected from this study will undergo a deidentification process to ensure that the personal information of participants remains anonymous and is not disclosed to anyone other than the research team involved in the study. Measures will be taken to securely manage personal information to prevent exposure. The process of deidentification will only be reversed if necessary for the individual's treatment-related purposes, with strict limitations in place.

2) Confidentiality of study materials

In the case of documentary data, it will be kept in a locked device to prevent it from being exposed to others, stored on a computer with restricted access, and managed by the researcher in charge.

3) Preservation of records

Study-related data are stored for 3 years in accordance with the Enforcement Rules of the Bioethics Act (Human subject researchers must keep records pursuant to Paragraph 1 for 3 years from the end of study), and among documents that have expired the retention period, subject related personal information shall be destroyed in accordance with Article 16 of the Enforcement Decree of the Personal Information Protection Act. However, if storage of the data is necessary for follow-up study, record accumulation, etc., the retention period must be extended after deliberation by the institutional committee.

16. Management, storage, and disposal measures when collecting human materials, genetic information, etc.

No human specimens or genetic information are collected in this study.

17. Subject recruitment method and consent procedure

After approval from the Yongin Severance Hospital IRB, among the visitors to Yongin Severance Hospital who decided and agreed to participate voluntarily in this study, interviews are conducted in an independent space, an explanatory statement approved by the IRB is provided, and consent forms are obtained.

After providing a sufficient explanation regarding participation in the clinical trial, the consent form must be completed in a non-oppressive environment, and when writing the consent form, participants must be explained that consent can be withdrawn at any time, so that they participate in the clinical trial. In addition, the intention to participate in the study is confirmed during the conduct of the study test, so that consent can be withdrawn at any time at the person's discretion.

18. Protection measures when recruiting vulnerable subjects

Participants who are considered to have impaired cognitive function or lack sufficient understanding of the content of the study or consent form due to cognitive impairment will be excluded from the study. Vulnerable subjects such

as research institution employees, researchers, or students who are employed by the sponsor, will be excluded from recruitment for this study.

19. Information on the principal investigator and participating researchers, location of study conduct, and study period

1) Principal investigator

name	Affiliated organization	Major	Job title	phone
Na Young Kim	Yonsei University College of Medicine Yongin Severance Hospital	rehabilitation medicine	Clinical Assistant Professor	031-5189-8163 Kny8452 @yuhs.ac

2) Test manager

The test manager checks whether the test subject meets the selection criteria at the testing institution and manages the overall process of the experiment.

name	Affiliated organization	Major	Job title	phone
Na Young Kim	Yonsei University College of Medicine Yongin Severance Hospital	rehabilitation medicine	Clinical Assistant Professor	031-5189-8163 Kny8452 @yuhs.ac

3) Medical device manager

name	Affiliated organization	Job title	phone
Seung Ick Choi	Yonsei University College of Medicine	Integrated course graduate student	010-8821-5297 rehab1@yuhs.ac

20. Location and duration of study

1) Location of study

Organization name	location	phonel
Yonsei University College of Medicine Yongin Severance Hospital	363 Dongbaekjukjeon-daero, Giheung-gu, Yongin-si, Gyeonggi-do	031-5189-8891

2) Period

48 months after IRB approval (e.g. June 2021 – May 2025)

21. Data safety monitoring plan

The safety inspector (principal investigator) monitors the overall study progress at monthly intervals to ensure the completeness of the data, including the status of the study, whether the registration subjects are suitable for the selection criteria, the appropriateness of the consent acquisition procedure, whether violations/deviations from the study plan have occurred, and whether the subjects have had adverse reactions.

22. Study plan (schedule table)

Detailed development items	Detailed schedule (months)											
	1	2	3	4	5	6	7	8	9	10	11	12
Study protocols and IRB approval	■											

Subject Recruitment	■	■	■	■	■	■	■	■	■	■	■	
Conduct of study procedures and follow-up period	■	■	■	■	■	■	■	■	■	■	■	■
	Detailed schedule (months)											
	13	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**
Subject Recruitment	■	■	■	■	■	■	■	■	■	■	■	■
Conduct of study procedures and follow-up period	■	■	■	■	■	■	■	■	■	■	■	■
	Detailed schedule (months)											
	25	**26**	**27**	**28**	**29**	**30**	**31**	**32**	**33**	**34**	**35**	**36**
Subject Recruitment	■	■	■	■	■	■	■	■	■	■	■	■
Conduct of study procedures and follow-up period	■	■	■	■	■	■	■	■	■	■	■	■
	Detailed schedule (months)											
	37	**38**	**39**	**40**	**41**	**42**	**43**	**44**	**45**	**46**	**47**	**48**
Subject Recruitment	■	■	■	■	■	■	■	■	■	■	■	
Conduct of study procedures and follow-up period	■	■	■	■	■	■	■	■	■	■	■	■

23. References

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