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Name of the document:

Study protocol and Statistical Analysis Plan

Official Title of the Study:

Research on Development of Home-based Gait Rehabilitation Service Using Insole-type Gait Analyzer

NCT number

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Prospective Clinical Study Protocol

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

- Title: Research on development of home-based gait rehabilitation service using insole-type gait analyzer

2. Summary of study plan

Study objective	We provide at-home gait status monitoring and feedback using an insole-type gait analyzer for patients with gait disorders, to confirm usability and satisfaction and analyze the difference in gait indicators before and after monitoring to confirm its effectiveness.
Study design overview	Investigator-led exploratory clinical study 6-week, randomized controlled study
Drugs/medical devices for clinical trials	Insole-type gait analyzer
Target number of subjects and calculation basis	30 patients with objective gait impairment but able to walk independently. This study explores the clinical significance of data obtained by utilizing an insole gait analyzer at home, and the target number of subjects was set in consideration of clinical conditions. Calculation basis: The target number of subjects was set considering clinical conditions with the goal of recruiting 1 subject per week and 4 subjects per month.
Inclusion and exclusion criteria	1. Inclusion criteria 1) Adults over 19 years of age 2) Patients with a score of 2-3 on the Modified Rankin Scale who are ambulatory 3) Patients who visited Yongin Severance Hospital who understood and agreed to the study and completed the informed consent form 2. Exclusion criteria 1) Those with contraindications to lower extremity weight bearing such as severe lower extremity joint contractures, osteoporosis, or untreated fractures 2) Progressive or unstable brain disease 3) In addition to above, those who have clinically significant findings that are

	deemed inappropriate for this study in the medical judgment of the study director or person in charge
Study Methods	A screening test is conducted after obtaining consent. The screening test assesses whether participants, regardless of their use of assistive devices, can walk independently for more than 10 meters, following an inquiry into their baseline symptoms and signs. Subjects who pass the screening test are randomized into an experimental and a control group, both of which undergo an initial assessment, are provided with information about their current gait status and normal gait and are instructed in a home-based exercise program. The researcher provides the insole gait analyzers to the experimental group, trains them on how to use them, and instructs them to wear them as much and for as long as possible so that their usage time and gait patterns are recorded. The researcher provides feedback over the phone once a week based on the collected measurement data. The control group was not provided with an insole-type gait analyzer or feedback on their exercise. At the end of the home-based exercise program after 6 weeks, an exit assessment is conducted, identical to the initial assessment, and the experimental group is asked to rate their satisfaction with the insole gait analyzer. Measures are taken and recorded when a device malfunction occurs, the use and satisfaction level of the insole-type gait analyzer in the experimental group are analyzed, and evaluation indicators before and after the program for the experimental and control groups are compared.
evaluation variable	1) Primary evaluation variable - 6-minute walking test results 2) Secondary evaluation variable - Body composition analysis results - Spatiotemporal parameters of gait - Korean Mini-Mental State Examination (K-MMSE) - Shortened Geriatric Depression Assessment (S-GDSK) - Korean sarcopenia screening questionnaire - Korean version of the short-term International Physical Activity Questionnaire (K-IPAQ) - Hand grip strength test - Clinical Frailty Scale

	- EuroQol-5 dimension (EQ-5D) - Mini Nutritional Assessment (MNA) - Assessment of activities of daily living and instrumental activities of daily living (ADL & I-ADL assessment) - Simple Physical Performance Assessment (SPPB) - Timed Up and Go test (TUGT) - Berg Balance Scale (BBS) - Cybex isokinetic strength test - (Experimental group only) K-QUEST-based 12-question, 5-point scale satisfaction survey related to the use of an insole-type gait analysis system
Data analysis and statistical methods	1) Primary and secondary evaluation variables: The difference before and after the home-based exercise program is presented as descriptive statistics, and the change in performance is compared through a paired-sample T test. 2) Satisfaction evaluation: Satisfaction with the home-based exercise program using an insole-type gait analyzer is analyzed and presented using descriptive statistics.

3. Study background and theoretical basis

Gait is a daily movement that involves complex coordination between the central and peripheral nervous systems and the musculoskeletal system[1]. Damage to any of the systems involved in gait, such as degenerative brain disease, peripheral nerve damage, and osteoarthritis, can lead to changes in gait[2-4]. Gait plays an important role in healthy skeletal and muscle development. Improvement of cardiorespiratory function, it is closely related to the performance of daily life movements. Gait plays a critical role in healthy skeletal and muscular development, and is closely related to cardiorespiratory function and the performance of activities of daily living, making the ability to walk an important indicator of prognosis and patient functional status[5,6].

Many studies have already attempted to prescribe exercise under the management or monitoring of medical staff. While wearable sensors have previously been used to monitor heart rate, advances in miniaturized sensors and wireless technology are enabling kinematic analysis, and researchers are increasingly looking to remotely analyze gait patterns and posture[7]. Especially for patients with gait disorders, interventions to help them not only walk, but also to walk accurately and as close to normal gait as possible are important for the prevention of musculoskeletal diseases and health, and recent technologies are expected to help improve the health of subjects. However, the devices used in most studies have been prototypes, and their clinical use is limited[8].

An insole-type gait analyzer monitors walking by wearing an insole equipped with a sensor inside a shoe and is inexpensive and easy to use. In addition, the spatiotemporal parameters of gait obtained using this are presented as having a high correlation with the results of 3- dimensional gait analysis [9], which is considered the most

standardized study method among quantified analysis methods of gait. However, while many studies have utilized insole-type gait analyzers in hospital settings, few studies have utilized them in out-of-hospital settings such as outdoors or at home. Therefore, this study seeks to explore the feasibility and effectiveness of a home-based gait rehabilitation service that provides monitoring and feedback on gait using a commercially available insole-type gait analyzer.

4. Purpose of the study

We provide home-based gait monitoring and feedback to patients with gait disorders using an insole-based gait analyzer to analyze usability and satisfaction, and confirm its effectiveness by analyzing the difference in gait metrics before and after monitoring.

5. Risk/benefit analysis

The 6-minute walk test and the Timed up and go test are used to assess walking ability in this study. These tests are widely used in clinical settings and have very low medical risk. In order to minimize the risk of falls that may occur during the test, the test will be conducted in an environment where a safety bar is installed after sufficient practice under the supervision of the tester before the test.

This study will provide study participants with information about their physical functioning, including their hand strength, muscle mass, gait and balance abilities, and provide feedback on how their measured gait metrics compare to normal gait standards. In addition, the efficacy of real-time monitoring of home-based exercise programs and the gait data collected may be used in study related to the treatment and prognosis of disease, contributing to the advancement of medicine and the improvement of quality of care. Therefore, the benefits of this study are expected to outweigh the potential risks.

6. Number of target audience and basis for calculation

This study will be conducted on all patients visiting Yongin Severance Hospital who agree to participate in the study and meet the selection criteria. The goal was to recruit 1 patient per week and 4 patients per month among patients visiting Yongin Severance Hospital, and the target number of patients was determined to be 30 considering the dropout rate and clinical conditions.

7. Subject selection/exclusion criteria

(1) Selection criteria

1) Adults over 19 years of age

2) Patients with a score of 2-3 on the modified Rankin scale who are able to walk

3) Patients who visited Yongin Severance Hospital who understood and agreed to the study and completed the informed consent form

(2) Exclusion criteria

1) Those with contraindications to lower extremity weight bearing such as severe lower extremity joint contractures, osteoporosis, or untreated fractures

2) Progressive or unstable brain disease

3) In addition to above, those who have clinically significant findings that are deemed inappropriate for this study in the medical judgment of the study director or person in charge

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

Although this study does not conduct clinical trials, information and management methods for medical devices 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

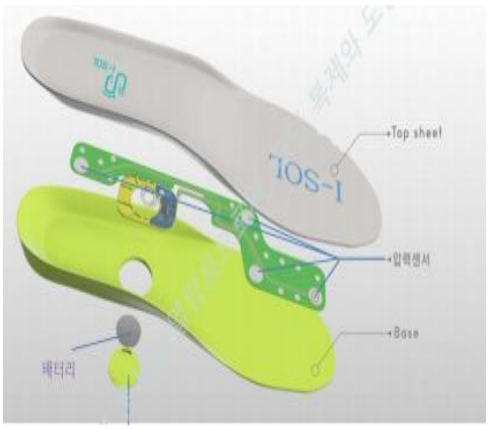
4) Medical device grade: Grade 1

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.)

(1) Overview of study design

This is a researcher-led, exploratory clinical study designed with random assignment and lasts for 6 weeks.

(2) Experimental group

The experimental group wears the insole gait analyzer and is asked to wear the insole gait analyzer as much and as long as possible during outdoor activities. Researchers provide feedback to subjects once a week based on the collected measurement data. After 6 weeks, usability and satisfaction evaluation of the insole type gait analysis system will be conducted.

(3) Control group

The control group is trained in the same exercise program as the experimental group, but not receives the insole gait analyzers and not receives any exercise feedback.

(4) Random assignment

In this clinical trial, researchers will assign registration numbers to subjects and conduct randomization using a randomization table using Excel.

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 at least 10 meters independently regardless of their use of assistive devices.

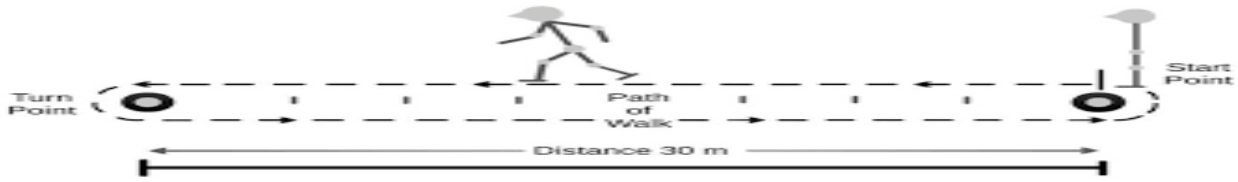
(2) Evaluation indicators before and after the intervention program

1) Primary evaluation indicator

① 6-minute walking test

While wearing the insole gait analyzer, the subject performs a 6-minute gait test, which is the test that most closely approximates everyday walking[10], and the examiner provides feedback on the gait by comparing the average parameter data extracted from the insole gait analyzer to a normal gait reference. The above evaluation is a test conducted to evaluate walking endurance, and the evaluation method is as follows.

a) Install a colored cone with 30m on the floor and prepare a stopwatch.
b) Instruct the subject to travel as many times as possible in a straight line of 30m for 6 minutes.
c) Teach that they can rest and stop during the test and use only permitted phrases ('You're doing well', 'Keep going').
d) The examiner records the total distance traveled and the pattern and occurrence time of the abnormal gait.

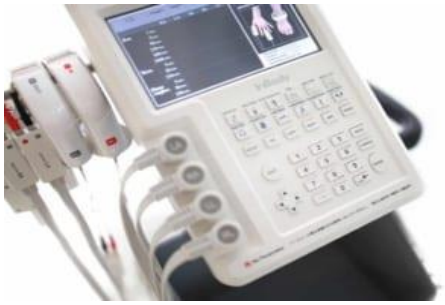


2) Secondary evaluation indicators

① body composition analysis

This is a test performed to check the subject's limb muscle mass, and the test method is as follows.

a) Perform body composition analysis[11] based on bioimpedance analysis.
b) To ensure accurate measurement, the test subject is instructed to empty his/her bladder before the test and not to consume caffeinated beverages, eat, drink, or perform strenuous exercise for one hour prior to the test.
c) To correct for muscle mass differences due to height, use the calculated value of limb muscle mass (Appendicular skeletal mass) divided by the square of the height.



② Spatiotemporal parameters of walking

Spatiotemporal parametric data of gait collected while the subject is performing a home-based activity wearing an insole gait analyzer, recording total steps, steps per minute, gait speed (km/h), distance walked (m), stride length (m), and swing phase rate (%).

③ Korean version - Mini Mental State Examination

A test that assesses the degree of overall cognitive impairment, taking into account a person's level of education[12], and the test assesses time and place perception, attention and calculation, memory, language, and spatial and temporal organization. The examiner asks questions corresponding to the items on the test sheet below and record a score for the answers.

Patient's Name: _____ Date: _____

Instructions: Score one point for each correct response within each question or activity.

Maximum Score	Patient's Score	Questions
5		"What is the year? Season? Date? Day? Month?"
5		"Where are we now? State? County? Town/city? Hospital? Floor?"
3		The examiner names three unrelated objects clearly and slowly, then the instructor asks the patient to name all three of them. The patient's response is used for scoring. The examiner repeats them until patient learns all of them, if possible.
5		"I would like you to count backward from 100 by sevens." (93, 86, 79, 72, 65, ...) Alternative: "Spell WORLD backwards." (D-L-R-O-W)
3		"Earlier I told you the names of three things. Can you tell me what those were?"
2		Show the patient two simple objects, such as a wristwatch and a pencil, and ask the patient to name them.
1		"Repeat the phrase: 'No ifs, ands, or buts.'"
3		"Take the paper in your right hand, fold it in half, and put it on the floor." (The examiner gives the patient a piece of blank paper.)
1		"Please read this and do what it says." (Written instruction is "Close your eyes.")
1		"Make up and write a sentence about anything." (This sentence must contain a noun and a verb.)
1		"Please copy this picture." (The examiner gives the patient a blank piece of paper and asks him/her to draw the symbol below. All 10 angles must be present and two must intersect.) 
30		TOTAL

④ Korean version of Short form of Geriatric Depression Scale

This is a test used to assess the level of depression in older adults[13] and able to assess quickly the level of depression in the elderly and identify risk. The examiner asks the subject questions according to the questionnaire below, checks items according to the answers, and scores them according to the evaluation method.

This consists of 15 items and is the most used version due to its brevity and ease of use. It can typically be completed in 5 to 7 minutes. Each item on the GDS is scored 0 or 1, depending on whether the symptom of depression is absent or present according to the patient's response. The total score is calculated by summing up the scores for each item. Generally, a score of 0 to 5 is considered normal, depending on the setting and clinical judgment. Scores of 5 or more suggest depression, with scores of 10 or higher almost always indicative of depression.

Geriatric Depression Scale

Date: Patient Name:

	Yes	No	
1. Are you basically satisfied with your life?	0	1	
2. Have you dropped many of your activities and interests?	1	0	
3. Do you feel that your life is empty?	1	0	
4. Do you often get bored?	1	0	
5. Are you are you in good spirits most of the time?	0	1	
6. Are you afraid something bad is going to happen to you?	1	0	
7. Do you feel happy most of the time?	0	1	
8. Do you often feel helpless?	1	0	
9. Do you prefer to stay at home, rather than going out and doing new things?	1	0	
10. Do you feel you have more problems with memory than most?	1	0	
11. Do you think it is wonderful to be alive?	0	1	
12. Do you feel pretty worthless the way you are now?	1	0	
13. Do you feel full of energy?	0	1	
14. Do you feel your situation is hopeless?	1	0	
15. Do you think that most people are better off than you are?	1	0	
Total (over 5 indicates depression)			

⑤ Korean version of Sarcopenia Screening Questionnaire

Questionnaire that evaluates the decrease in muscle strength and functional performance along with a decrease in muscle mass[14] 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

⑥ Functional Ambulation Category

Assessment of the subject's walking function[15]. The examiner observes the subject's gait and records a score based on the criteria in the assessment sheet below.

Classification	Definition
0	Absolute inability to walk even with external help.
1	Requires external help to be able to walk.
2	Only able to walk on flat surfaces and known spaces like home.
3	Able to walk inside and outside of home but limited distances.
4	Able to walk anywhere but with obvious limp or need of technical assistance.
5	Normal deambulation.

⑦ 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** ⇨

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

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

or

☐ **none**

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** ⇨

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

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

or

☐ **none**

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 solely for recreation, sport, exercise or leisure.

_____ **days per week** ⇨

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

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

or

☐ **none**

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.

⑧ Grip Strength Test

A test that evaluates the subject's grip strength, and the evaluation method is as follows.

a) The subject sits in the correct posture and bends the elbows to 90 degrees.

b) Place the handle of the measuring device between the first and second joints of each finger and hold it tightly according to the examiner's instructions.

c) Measure the left and right three times each and record the maximum value.

⑨ Clinical Frailty Scale

Test to assess the health status and frailty of elderly[18] and assesses the health and vulnerability of the elderly after the program ends. The scale ranges from 1 to 9, with each level described through specific criteria that reflect the degree of fitness or frailty, a higher score means poorer health.

score	name	detailed description
1	very healthy	Exercising regularly and living an active life
2	healthy	Exercising regularly and living an active life, but have had an illness or accident in the past
3	Have a well-managed disease	Although there are some limitations due to illness or accidents, the ability to live independently
4	slightly vulnerable	There are some limitations due to illness or accidents, and it is difficult to conduct daily life independently.
5	vulnerable	There are many limitations due to illness or accidents, and it is difficult to conduct daily life independently.
6	Moderately vulnerable	Have many limitations due to illness or accident and are unable to perform daily activities without assistance
7	Severely Vulnerable	Completely dependent, unable to get out of bed without assistance
8	Very Severely Vulnerable	Completely dependent, unable to move even in bed
9	terminally ill	Patients expected to die within 6 months

⑩ European Quality of Life-5 Dimensions

It consists of items evaluating exercise ability, self-management, daily activities (work, study, housework, family or leisure activities), pain/discomfort, and anxiety/depression[19], and examiner evaluates according to the form below.

Participants will be asked to answer each question with 3 items, and a higher score means more health problems, minimum score is 5 and maximum score is 15.

Health-related quality of life assessment		
item	step	Mark O
athletic ability	I have no trouble walking	
	I have some trouble walking.	
	I can't walk.	
selfcare	I have no trouble taking a bath or getting dressed.	
	I have some trouble bathing or dressing myself.	
	I cannot bathe or dress myself.	
activities of daily living	I have no trouble doing my daily activities.	
	I have some difficulty doing daily activities on my own.	
	I cannot do daily activities on my own.	
pain and discomfort	I have no pain or discomfort.	
	I have some pain or discomfort.	
	I have very severe pain or discomfort.	
anxiety and depression	I am not anxious or depressed.	
	I feel somewhat anxious or depressed.	
	I am very anxious or depressed.	

⑪ Mini-Nutritional Assessment

An assessment of nutritional status and risk of undernutrition or malnutrition using questionnaire to assess the nutritional status of a subject[20], and the examiner records a score based on the criteria in the questionnaire below.

Mini Nutritional Assessment
MNA®

Nestlé Nutrition Institute

Last name: First name:

Sex: Age: Weight, kg: Height, cm: Date:

Complete the screen by filling in the boxes with the appropriate numbers.
Add the numbers for the screen. If score is 11 or less, continue with the assessment to gain a Malnutrition Indicator Score.

Screening

A Has food intake declined over the past 3 months due to loss of appetite, digestive problems, chewing or swallowing difficulties?
0 = severe decrease in food intake
1 = moderate decrease in food intake
2 = no decrease in food intake ☐

B Weight loss during the last 3 months
0 = weight loss greater than 3kg (6.6lbs)
1 = does not know
2 = weight loss between 1 and 3kg (2.2 and 6.6 lbs)
3 = no weight loss ☐

C Mobility
0 = bed or chair bound
1 = able to get out of bed / chair but does not go out
2 = goes out ☐

D Has suffered psychological stress or acute disease in the past 3 months?
0 = yes 2 = no ☐

E Neuropsychological problems
0 = severe dementia or depression
1 = mild dementia
2 = no psychological problems ☐

F Body Mass Index (BMI) (weight in kg) / (height in m²)
0 = BMI less than 19
1 = BMI 19 to less than 21
2 = BMI 21 to less than 23
3 = BMI 23 or greater ☐

Screening score (subtotal max. 14 points) ☐☐
12-14 points: Normal nutritional status
8-11 points: At risk of malnutrition
0-7 points: Malnourished
For a more in-depth assessment, continue with questions G-R

Assessment

G Lives independently (not in nursing home or hospital)
1 = yes 0 = no ☐

H Takes more than 3 prescription drugs per day
0 = yes 1 = no ☐

I Pressure sores or skin ulcers
0 = yes 1 = no ☐

J How many full meals does the patient eat daily?
0 = 1 meal
1 = 2 meals
2 = 3 meals ☐

K Selected consumption markers for protein intake
- At least one serving of dairy products (milk, cheese, yoghurt) per day yes ☐ no ☐
- Two or more servings of legumes or eggs per week yes ☐ no ☐
- Meat, fish or poultry every day yes ☐ no ☐

0.0 = if 0 or 1 yes
0.5 = if 2 yes
1.0 = if 3 yes ☐.☐

L Consumes two or more servings of fruit or vegetables per day?
0 = no 1 = yes ☐

M How much fluid (water, juice, coffee, tea, milk...) is consumed per day?
0.0 = less than 3 cups
0.5 = 3 to 5 cups
1.0 = more than 5 cups ☐.☐

N Mode of feeding
0 = unable to eat without assistance
1 = self-fed with some difficulty
2 = self-fed without any problem ☐

O Self view of nutritional status
0 = views self as being malnourished
1 = is uncertain of nutritional state
2 = views self as having no nutritional problem ☐

P In comparison with other people of the same age, how does the patient consider his / her health status?
0.0 = not as good
0.5 = does not know
1.0 = as good
2.0 = better ☐.☐

Q Mid-arm circumference (MAC) in cm
0.0 = MAC less than 21
0.5 = MAC 21 to 22
1.0 = MAC 22 or greater ☐.☐

R Calf circumference (CC) in cm
0 = CC less than 31
1 = CC 31 or greater ☐

Assessment (max. 16 points) ☐☐.☐
Screening score ☐☐.☐
Total Assessment (max. 30 points) ☐☐.☐

Malnutrition Indicator Score
24 to 30 points ☐ Normal nutritional status
17 to 23.5 points ☐ At risk of malnutrition
Less than 17 points ☐ Malnourished

References
1. Vellas B, Villars H, Abellan G, *et al.* Overview of the MNA® - Its History and Challenges. *J Nutr Health Aging.* 2006; **10:456-465.**
2. Rubenstein LZ, Harker JO, Salva A, Guigoz Y, Vellas B. Screening for Undernutrition in Geriatric Practice: Developing the Short-Form Mini Nutritional Assessment (MNA-SF). *J. Gerontol.* 2001; **56A**: M366-377
3. Guigoz Y. The Mini-Nutritional Assessment (MNA®) Review of the Literature - What does it tell us? *J Nutr Health Aging.* 2006; **10:466-487.**

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For more information: www.mna-elderly.com

⑫ Assessment of activities of daily living and instrumental activities of daily living (ADL & I-ADL assessment)

This assessment uses a questionnaire that assesses the nutritional status of subjects to determine their nutritional status and whether they are undernourished or at risk of being undernourished, and the examiner records a score based on the criteria in the questionnaire below.

Activities	Requires No Help	Requires Modifications (such as the use of assistive technology)	Requires Help
Bathing/Showering: *Can you run the water at a safe temperature, clean yourself, and get in and out of the shower or bathtub?*			
Dressing: *Can you pick out your clothes, put them on and take them off?*			
Grooming: *Can you brush and floss your teeth, shave, and trim your nails?*			
Toileting: *Can you control bladder and bowel function, get to and on the toilet, and clean yourself?*			
Eating: *Can you feed yourself using utensils?*			
Transferring: *Can you get in and out of bed?*			
Mobility: *Can you walk or get around?*			
Shopping: *Can you shop for all your needs?*			
Cooking: *Can you plan and prepare meals, including cooking and cleaning up?*			
Managing Medications: *Can you get your medicine and take the correct dose at the correct time?*			
Housework: *Can you clean your home, such as washing dishes or dusting?*			
Laundry: *Can you wash and dry your clothes?*			

Instrumental Activities			
Transportation: *Can you drive or arrange other transportation for yourself?*			
Managing Finances: *Can you handle your money and pay your bills?*			
Communication: *Can you send mail, use the phone, email, or otherwise communicate with people?*			

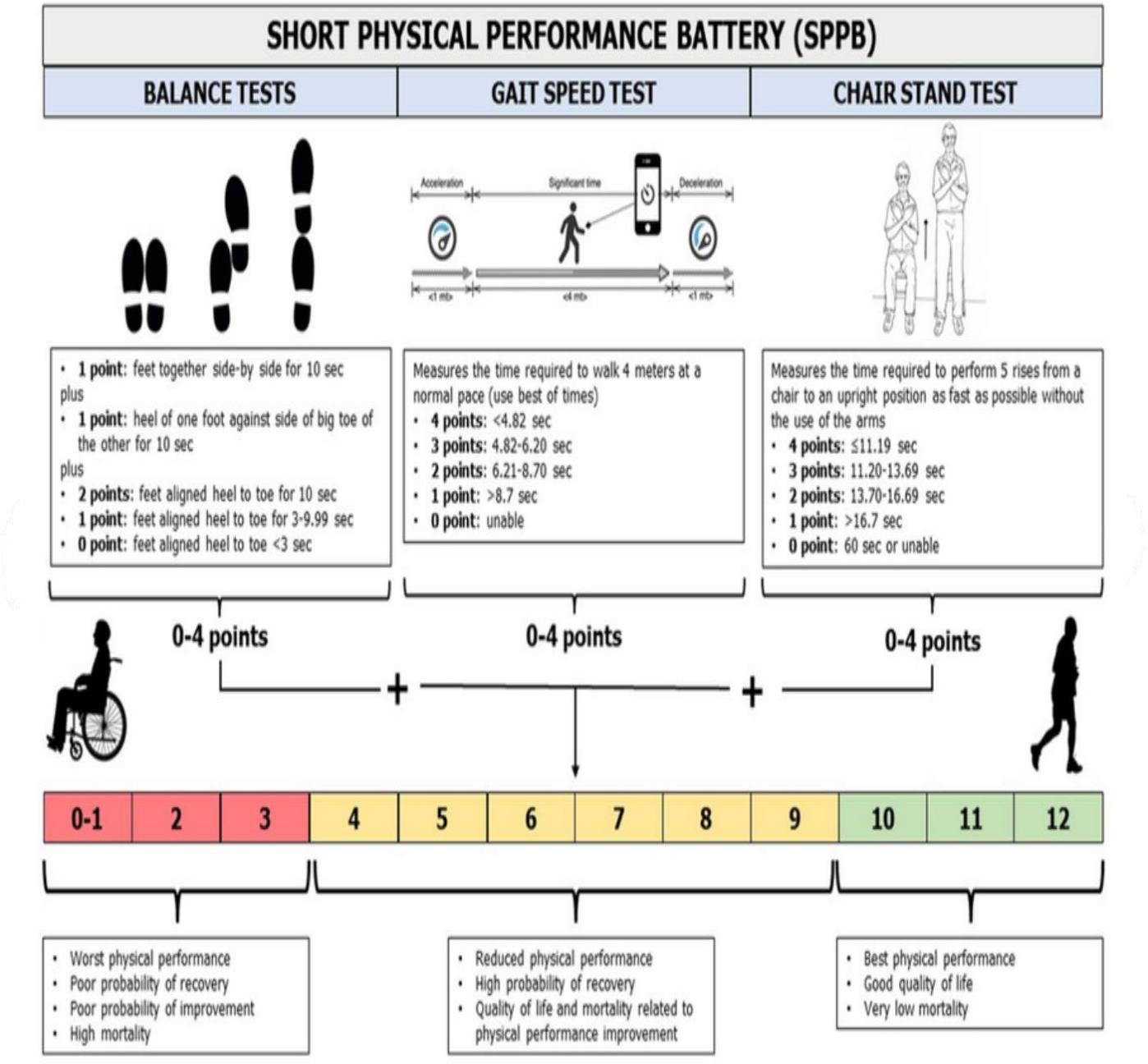
⑬ Short Physical Performance Battery (SPPB)

This is a test that evaluates three areas to assess a subject's lower extremity physical functioning[23], and it measures and records scores in three areas: balance, getting up from a chair, and walking speed.

a) Balance test: Line up feet in parallel and hold for 10 seconds. If possible, perform this test in a semi-upright position, then straighten feet and repeat 3 times.

b) Chair stand-up test: Perform the stand-up test 5 times from a chair. The examiner measures the time and records the score according to the criteria below.

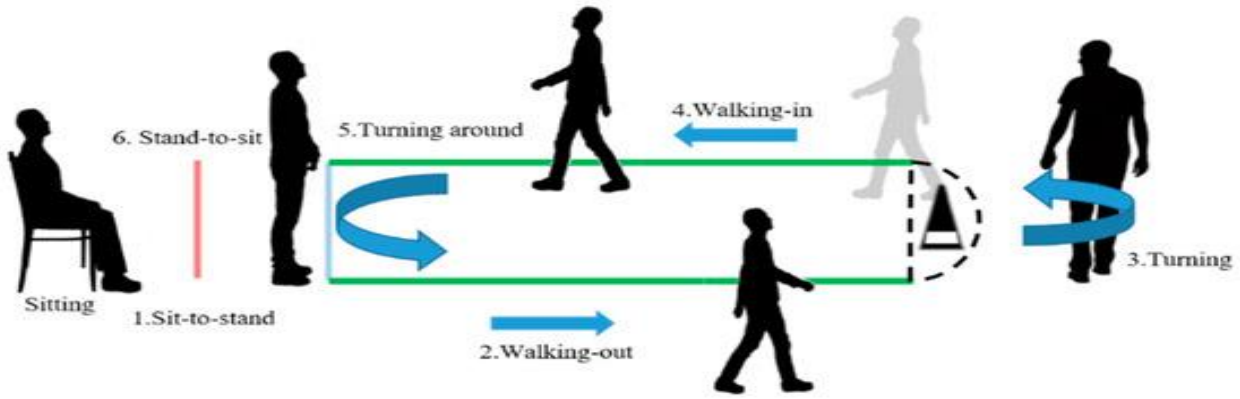
c) Walking speed test: After having the subject walk 3m, the examiner measures the time and scores according to the criteria below.



⑭ Timed up and go test (TUG)

The above test assesses walking speed along with balance ability during walking[24], 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.



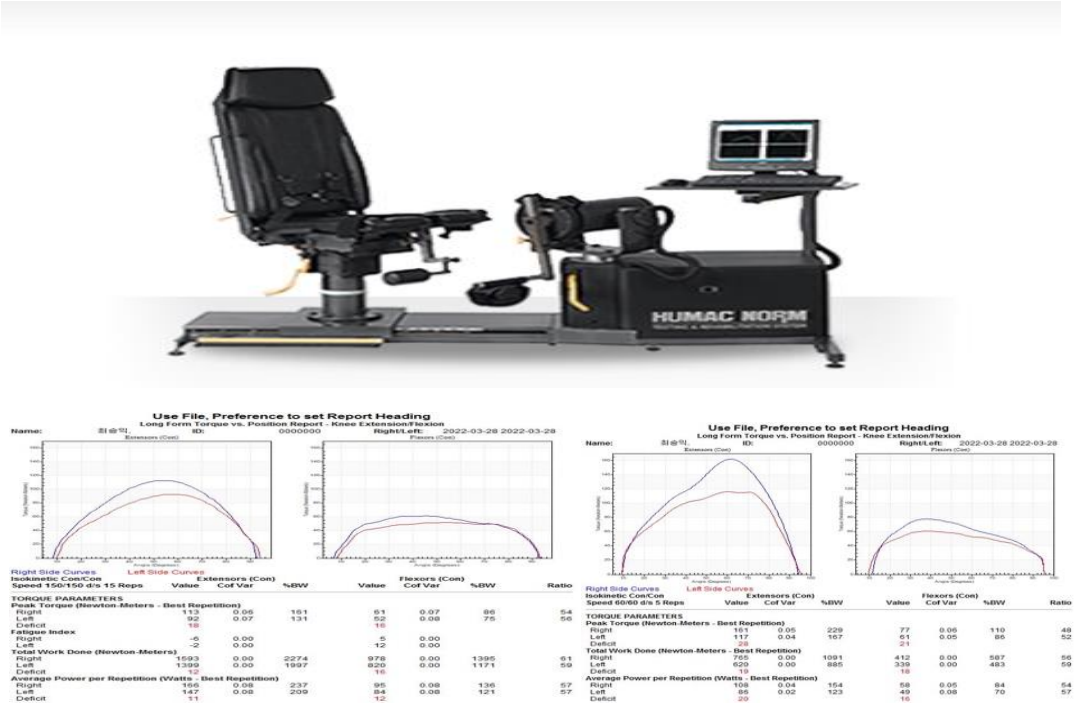
⑮ Berg Balance Scale

The above test assesses static and dynamic balance[25], in which the examiner instructs the subject to perform the 14 movements below and then scores them against a set of criteria.

Balance Section	Score
Sitting to standing	0 1 2 3 4
Standing unsupported	0 1 2 3 4
Sitting unsupported	0 1 2 3 4
Standing to sitting	0 1 2 3 4
Transfers	0 1 2 3 4
Standing with eyes closed	0 1 2 3 4
Standing with feet together	0 1 2 3 4
Reaching forward with outstretched arm	0 1 2 3 4
Retrieving object from floor	0 1 2 3 4
Turning to look behind	0 1 2 3 4
Turning 360 degrees	0 1 2 3 4
Placing alternate foot on stool	0 1 2 3 4
Standing with one foot in front	0 1 2 3 4
Standing on one foot	0 1 2 3 4
Total Score	_____ / 56

⑯ Cybex isokinetic strength evaluation

A test to measure lower extremity strength and power using the isokinetic exercise equipment CYBEX[26], and 5 repetitions of 60/60 degrees per second and 15 repetitions of 150/150 degrees per second are performed to measure Peak Torque (Nm), Total Work (J), Average power per repetition (W), and Fatigue Index (%) of the lower extremity muscles.



(3) Pre- and Post-Intervention Comparison Analysis and Outlier Management Plan

1) Pre- and Post-Intervention Comparison Analysis

Data from evaluations conducted before and after the home exercise program, utilizing the insole-type gait analyzer, will be compared and analyzed using paired sample t-tests. The significance level will be set at 0.05.

2) Outlier Management Plan

In case of missing data due to participant withdrawal or dropout, the analysis will be conducted using Complete Case Analysis, which only includes fully observed cases. Sessions with missing data will be excluded from the analysis. Outliers identified using box plots and quartiles will also be excluded from the analysis to maintain data integrity and enhance the accuracy and reliability of the study. Information on participants whose data have been excluded will be provided.

(4) Home-based exercise program training

The data of gait parameters of the subjects are extracted through the 6-minute gait test, which is the primary evaluation variable, and feedback is provided according to the normal gait criteria below, and exercise training is provided individually according to the patient's age, gender, medical conditions, and muscle strength and endurance after the pre-intervention evaluation.

1) Provide information about the subject's gait status and normal gait criteria

The examiner provides feedback on the gait of the experimental group subjects based on the average value of the gait parameters extracted from the above gait assessment and compared to the normal gait standard. The extracted gait parameters and normal gait criteria are as follows. The control group does not perform the above process.

① Step count: Steps measured while walking after linking the insole-type gait analyzer with the smartphone application.

② Cadence : The number of steps measured in one minute, measured in Steps/min (spm), with 70 steps/min for those under 65, and 60 steps/min or more for those over 65 is normal[27].

③ Gait speed : The speed of walking of which the unit is km/h, with 2.0 km/h being normal for those under 65 and 1.5 km/h or more being normal for those over 65 is normal[28].

④ Distance: The total moving distance measured while walking, measured in meters.

⑤ Stride length: Refers to the distance from one heel to the same heel. The unit of distance is m, and in order to compensate for differences caused by height, it is calculated by dividing the height by the stride length, and 0.5 m/height is normal for people under 65, and 0.4 m/height or more is normal for people over 65 is normal[28].

⑥ Swing ratio: The proportion of swing phase in one gait cycle, unit is %, 30% for under 65 years old, 28% for 65 years old and above is normal[29].

2) Home-based exercise program training

The researcher educates all subjects about the following program.

① Organize exercise program

a) Preparation: Perform 5-10 minutes of low-intensity (<40% VO2max) or moderate-intensity (40-60% VO2max) activity

b) Stretching: Performed for 10 minutes after warm-up

c) Main exercise: Consists of 20-30 minutes of aerobic exercise (using a bicycle, treadmill, or walking), strength exercise at 60-80% of the patient's maximum strength (10-15 sets per muscle) and flexibility training (upper and

lower extremity stretching), etc. depending on the patient's exercise ability

d) Cool down: Perform 5-10 minutes of low intensity (<40% maximal oxygen uptake) or moderate intensity (40-60% maximal oxygen uptake) cardiovascular and muscular endurance exercise

The intensity of aerobic exercise is set using the Karvonen target heart rate formula[30]. To calculate the target heart rate, the resting heart rate, maximum heart rate, and exercise intensity are used, and the resting heart rate is measured while lying down and resting for 3-5 minutes, and the maximum heart rate is calculated as $(220 - age)$. Exercise intensity is the ratio of heart rate during exercise to maximum heart rate, expressed as a percentage. The target heart rate is set according to the formula below.

$$Target\ Heart\ Rate = (maximum\ heart\ rate - resting\ heart\ rate) \times exercise\ intensity + resting\ heart\ rate$$

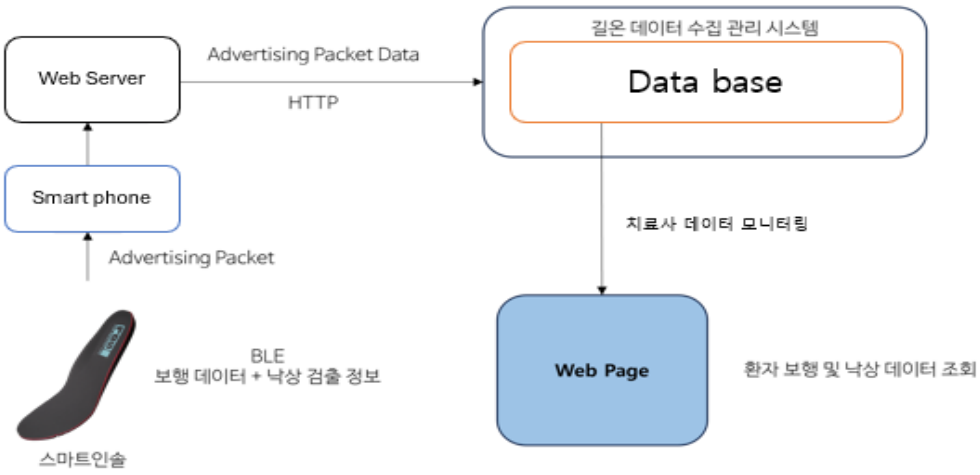
Aerobic exercise is performed 3-5 times a week for 20-60 minutes at 60% intensity, and low-intensity exercise is performed in patients who are unable to do high-intensity exercise.

(5) Subject monitoring method

1) Home-based exercise monitoring

The researcher provides feedback over the phone once a week in accordance with the subjects' amount of exercise and walking level collected only to the experimental group using the insole-type gait analysis system. Check the stability of data collection, and if an abnormality occurs, take action andZW record it by phone or in person.

The insole gait analyzer collects the subject's gait data by connecting the insole to the subject's smartphone and sending the measured data to a web server, and the medical device company provides the data to the researcher once a week, sorted by the insole's product number. The researcher monitors the subject's activity level, checks the difference between the subject's walking index and normal standards, and provides feedback over the phone once a week. The control group does not do the above.



(6) Satisfaction evaluation

Subjects in the experimental group return the insole-type gait analyzer to the examiner and fill out a 12-item, 5-point scale satisfaction evaluation questionnaire for the insole-type gait analyzer based on the Korean version of the assistive device satisfaction test (K-QUEST 2.0)[32]. This questionnaire consists of 12 items to evaluate satisfaction, and satisfaction with assistive devices and related services is indicated on a scale of 1 to 5 below. If any items other than "very satisfied" are filled out, the subject is instructed to write a reason. The control group does not do the above.

1: Very unsatisfied 2: Not satisfied 3: Average 4: Satisfied 5: Very satisfied

	1	2	3	4	5
Are you satisfied with the specifications (size, height, length, width) of the smart insole? reason: _____					
How does the smart insole weigh? reason: _____					
Is it convenient to adjust (fix and lock) the parts (accessories) of the smart insole? reason: _____					
Do you think smart insoles are safe and sturdy? reason: _____					
Are you satisfied with the durability (long-term usability) of the smart insole? reason: _____					
Was it convenient to use the smart insole? reason: _____					
Do you think smart insoles are comfortable to wear? reason: _____					
Are you satisfied with the effectiveness of the smart insole (effectiveness suited to the purpose of use)? reason: _____					
Are you satisfied with Smart Insole's service and delivery program (delivery process and time required)? reason: _____					
Are you satisfied with the repair and maintenance services for smart insoles? reason: _____					
Are you satisfied with the professional service (information and precautions) you received while using the smart insole? reason: _____					
Are you satisfied with Smart Insole's after-sales service (continuous management service)? reason: _____					

Severance: smartinsole_20240408

- Among the 12 items regarding satisfaction, please mark the 3 items you consider most important.

	O sign
1. Specifications	
2. Weight	
3. Convenience	
4. Safety	
5. Durability	
6. Usability	
7. Comfort	
8. Effect	
9. Service delivery	
10. Repair and maintenance services	
11. Professional services	
12. After-sales service	

11. Study procedures and evaluation

Phase	Screening / Intervention	Intervention				Intervention/ Assessment	Whether or not to conduct a control group
week	1	2	3	4	5	6	
written consent	O						O
Selection/exclusion criteria	O						O
Demographic information and antecedent history	O						O
Primary evaluation indicator evaluation	O					O	O
Secondary evaluation indicator evaluation	O					O	O
Home-based exercise program	O	O	O	O	O	O	O
Phone monitoring and feedback	O	O	O	O	O	O	X
Satisfaction evaluation						O	X

12. Criteria for stopping and dropping out of the study

(1) Termination and early suspension

1) 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

1) 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 randomized controlled 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 week 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

(1) Primary and secondary evaluation variables: The differences before and after the home-based exercise program are analyzed using descriptive statistics to present the mean, standard deviation, median, minimum and maximum values, and the change in performance by group is compared through a paired-sample T test.
(2) Satisfaction evaluation: Satisfaction with the home-based exercise program using smart insoles is analyzed using descriptive statistics and the mean, standard deviation, median, minimum and maximum values are presented.

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 must be kept secret from anyone other than the researchers involved in the study and it is used for study purposes only. Sensitive personal information that can identify individuals will not be shared with organizations other than the hospital and will go through an anonymization process (deidentification). Anonymization is achieved by using the unique number of the insole-type gait analyzer issued to the subject, and data collected through the application will be stored in accordance with the medical device company's security policy and will be discarded after the end of the study, and will be de-identified before being forwarded to the medical device company. De-anonymization is limited to cases where it is necessary in relation to the individual's treatment. Only the final results of the analysis are disclosed to medical device companies and ownership of the data lies with the hospital.

(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

This study does not recruit vulnerable subjects.

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	Assistant Professor	031-5189-8163 Kny8452 @yuhs.ac
Seung Ick Choi	Yonsei University College of Medicine	Department of Integrative Medicine	Integrated course graduate student	010-8821-5297 rehab1@yuhs.ac
So Jeong Lim	Yonsei University Industry-Academic Cooperation Foundation	occupational therapy	researcher	010-2971-3773 rehab2@yuhs.ac
Hwi Woo Yang	Yonsei University Industry-Academic Cooperation Foundation	occupational therapy	researcher	010-7360-4439 rehab5@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

24 months after IRB approval (e.g. October 2023 - October 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	1 1	1 2
Study protocols and IRB approval	■											
Subject Recruitment	■	■	■	■	■	■	■	■	■	■	■	■
Conduct of study procedures and follow-up period	■	■	■	■	■	■	■	■	■	■	■	■
Detailed development items	**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	■	■	■	■	■	■	■	■	■	■	■	■

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