Cover page for ClinicalTrials.gov

Name of the document:

Study protocol and Statistical Analysis Plan

Official Title of the Study:

Development and Data Collection Study of a Home-Based Gait Rehabilitation Service Using an Insole-Type Gait Analyzer, Activity Tracker and Self-Report Application.

NCT number

NCT06410755

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Prospective Clinical Research Protocol

1. Research Title, Phase, Protocol Identification Number, and Revision History

- Research Title: Development and Data Collection Study of a Home-Based Gait Rehabilitation Service Using an Insole-Type Gait Analyzer, Activity Tracker and Self-Report Application.

2. Research Protocol Summary

Research Objective	To simultaneously utilize an activity tracker and an insole-type gait analyzer for patients with gait disorders, monitoring gait, activity levels, and physiological signals at home while providing integrated feedback. This aims to assess the system's usability and satisfaction, analyze changes in gait indicators and physical function before and after monitoring, and verify its efficacy.
Research Design Overview	Researcher-Initiated Exploratory Clinical Study 6 weeks, randomized controlled trial
Medical Devices for clinical trials	Insole-type gait analyzer
Target Sample Size and Calculation Basis	80 patients with objective gait impairment but capable of independent walking This study explores whether data obtained from home use of an insole-type gait analyzer, activity tracker, and self-report application is clinically significant. The target subject number was set considering clinical conditions. Calculation Basis: The target subject number was set by considering clinical conditions, aiming to recruit 1 subject per week, 4 subjects per month.
Selection and exclusion criteria	1. Inclusion Criteria 1) Adults aged 19 years or older 2) Patients with a modified Rankin Scale (mRS) score of 2-3 who are ambulatory 3) Individuals visiting Severance Hospital in Yongin who understand the study, provide informed consent, and complete the consent form 2. Exclusion Criteria 1) Individuals with contraindications to weight-bearing on the lower limbs, such as severe lower limb joint contractures, osteoporosis, or untreated fractures 2) Progressive or unstable brain disease 3) Individuals with clinically significant findings deemed medically inappropriate for this study by the principal investigator or responsible staff, beyond the above criteria
Research Method	After obtaining informed consent, a screening examination is conducted. The screening assesses whether the subject can independently walk at least 10 meters, regardless of assistive device use, following a review of baseline symptoms and signs. Subjects passing the screening test are randomly assigned to either the experimental group or the control group, and both groups undergo an initial evaluation. Subsequently, subjects receive comprehensive information regarding their physical condition, appropriate exercise intensity (heart rate), and walking status (based on normal walking criteria), followed by instruction on the home exercise program. The researcher provides the experimental group with both an activity tracker and

	an insole-type gait analyzer and instructs them on usage. Participants are instructed to wear the devices as much and as long as possible to record usage time, exercise volume, and gait patterns. They are also instructed to respond daily via an application to five surveys: sleep, mood, exercise time, pain, and appetite, completed after waking and before bedtime. Based on the collected measurement data (heart rate, gait data, etc.), the researcher provides integrated feedback via phone call once a week. In contrast, the control group receives neither wearable devices nor data-based feedback. After 6 weeks, the home exercise program ends, and a final evaluation identical to the initial assessment is conducted. The experimental group also completes satisfaction evaluations for the activity tracker, insole-type gait analyzer, and application. During the study period, any device malfunctions are addressed and recorded. Device usage rates and satisfaction levels in the experimental group are analyzed, and pre- and post-program evaluation metrics for both groups are compared and analyzed.
Evaluation Variables	1) Primary Evaluation Variables - 6-Minute Walk Test results 2) Secondary Evaluation Variables - 10m walk test - Body composition analysis results - Spatiotemporal parameters of gait - Korean version of the Mini-Mental State Examination (K-MMSE) - Geriatric Depression Scale (GDS) - Korean Sarcopenia Screening Questionnaire - Korean version of the International Physical Activity Questionnaire (K-IPAQ) - Handgrip strength test results - Clinical Vulnerability Scale - Health-Related Quality of Life Assessment (EQ-5D) - Mini Nutritional Assessment (MNA) - Activities of Daily Living and Instrumental Activities of Daily Living Assessment (ADL & I-ADL assessment) - Simple Physical Performance Battery (SPPB) - Timed Up and Go Test (TUGT) - Berg Balance Scale (BBS) - Cybex Isokinetic Exercise Test - Correlation coefficient between IPAQ responses and average exercise values recorded on smartphones - IPAQ response rate variation - Application survey response rate and daily data recording count on wearable devices - (For the experimental group only) Satisfaction survey regarding the use of the K-QUEST-based 12-item 5-point scale insole-type gait analyzer
Data Analysis and Statistical Methods	1) Primary and Secondary Evaluation Variables: Descriptive statistics will present differences before and after the home exercise program. Changes in performance will be compared using paired t-tests. Differences in survey response rates will be presented using descriptive statistics, and changes in response rates will be compared using correlation analysis.

	2) Satisfaction Evaluation: Satisfaction with the home exercise program utilizing the insole-type gait analyzer, activity tracker, and application will be analyzed and presented using descriptive statistics.

3. Research Background and Theoretical Basis

Importance of Gait and Lifestyle Habit Management Gait is a movement performed daily through the complex coordination of the central and peripheral nervous systems and the musculoskeletal system. Damage to the gait system due to degenerative brain diseases, peripheral nerve damage, osteoarthritis, etc., can lead to changes in gait patterns. This directly correlates with reduced cardiopulmonary function and diminished ability to perform activities of daily living. Furthermore, maintaining healthy lifestyle habits in modern society plays a crucial role in preventing chronic diseases and improving quality of life. Since various lifestyle factors—including exercise, diet, and sleep—interact, systematic management is essential. Particularly for the elderly or those with degenerative diseases, monitoring appropriate exercise intensity and gait status through objective and safe methods is vital.

Advancements in Remote Monitoring Using Wearable Technology While wearable sensors once only enabled simple heart rate measurement, recent miniaturization of sensors and advancements in wireless technology have made kinematic analysis possible. This has led to increasing attempts to precisely analyze gait patterns and posture remotely. Activity trackers utilize accelerometers and optical sensors to track physiological information such as activity levels, heart rate, and sleep, and are useful for monitoring exercise intensity (e.g., predicting VO2max).

Insoles-type gait analyzers are devices worn inside shoes to measure spatiotemporal parameters of walking. They offer the advantages of being easy to use and inexpensive, while showing high correlation with standardized 3D gait analysis results. Additionally, smartphone applications, when linked with these devices, serve as an efficient medium for collecting patient-reported outcome (PRO) data such as pain, mood, and appetite without requiring hospital visits.

Limitations of Previous Research and the Need for This Study To promote the health of patients with gait disorders, interventions must simultaneously focus not only on increasing the quantity of walking but also on improving the quality of gait to approximate normal walking and maintaining appropriate exercise inten sity. However, existing studies have generally been limited to fragmented approaches, such as using only activity trackers to monitor activity levels or only gait analyzers to observe gait patterns. Furthermore, most studies used prototype devices, limiting their practical clinical application, and often failed to provide healthcare professionals with specific feedback based on the collected data. Research cases that comprehensively monitor and ma nage lifestyle habits, exercise intensity, and gait patterns in outdoor or home environments remain scarce.

Research Purpose Therefore, this study utilizes a framework combining a commercially available activity tracker, an insole-type gait analyzer (for gait patterns), and a self-reporting application. Through this, we aim to explore the feasibility and utility of a home-based rehabilitation service that comprehensively monitors patients' lifestyle factors and gait status in a home environment and provides personalized feedback based on this data.

4. Research Objectives

Monitoring of gait status, exercise intensity, pain, sleep, appetite, and other lifestyle factors in a home environment for patients with gait disorders using an insole-type gait analyzer, an activity tracker, and a linked self-reporting mobile application, and providing feedback on these factors. This aims to analyze the usability and satisfaction of each device and compare changes in gait indicators before and after monitoring to confirm the utility of the home-based monitoring system.

5. Risk/Benefit Analysis

This study will administer the 6-minute walk test, the Timed Up and Go test (TUG), and the 10m walk test to assess walking ability. These tests are widely used standardized assessment tools in clinical settings, and the medical risk associated with the tests themselves is very low. However, to minimize the risk of falls during testing, participants will undergo sufficient practice before the tests. The examiner will supervise throughout the entire process, and testing will be conducted in an environment equipped with safety bars.

Additionally, the activity tracker used in this study collects physiological data such as heart rate using non - invasive photoplethysmography (PPG) technology. This technology illuminates the skin with light-emitting diodes and measures reflected and transmitted light. While rare cases of skin irritation or infection have been reported during prolonged wear, the incidence rate is known to be very low. The smart insole is manufactured to the same specifications as commercially available insoles and replaces the user's existing insole. As a device used in everyday wear environments, it contains no invasive elements, and no significant adverse reactions have been reported to date.

Participants in this study can receive objective information about their physical function, including grip strength, muscle mass, walking and balance abilities, physical activity levels, and heart rate. They can also understand their functional level through feedback comparing measured walking and heart rate metrics against normal standards, and receive education on home exercise programs based on age-appropriate exercise intensity guidelines.

Furthermore, the gait data, heart rate information, and lifestyle survey results collected through this study can validate the utility of real-time monitoring for home-based exercise programs and be utilized in future research related to disease treatment and prognosis prediction. This is expected to contribute to the expansion of medical knowledge and the improvement of clinical care quality. Considering these points collectively, the benefits obtainable through this research are judged to outweigh the potential risks that may arise from it

6. Target Sample Size and Calculation Basis

This study will be conducted on all patients visiting Yongin Severance Hospital who consent to participate and meet the selection criteria. The target is to recruit one subject per week, four subjects per month, from among Yongin Severance Hospital visitors. Considering dropout rates and clinical conditions, the target number of subjects was determined to be 80.

7. Subject Selection/Exclusion Criteria

(1) Inclusion Criteria

1) Adults aged 19 years or older

2) Patients with a Modified Rankin Scale (mRS) score of 2-3 who are ambulatory

3) Individuals visiting Yongin Severance Hospital who understand the study, provide informed consent, and complete a consent form

(2) Exclusion Criteria

1) Individuals with contraindications to lower limb weight-bearing, such as severe lower limb joint contractures, osteoporosis, or untreated fractures

2) Progressive or unstable brain disease

3) Individuals with clinically significant findings deemed medically inappropriate for this trial by the principal investigator or responsible personnel, in addition to the above

8. Information and Management of Investigational Medicinal Products/Medical Devices

This study does not conduct a clinical trial; however, the information and management methods for the medical device used in this study are as follows.

(1) Insole-type gait analyzer

1) Product Name: Gait Analyzer

2) Classification Number: A30110.01

3) Packaging Unit: 1 set

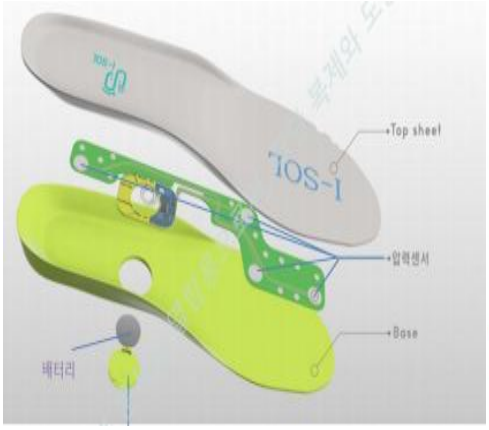
4) Medical Device Class: Class 1

5) Model Name: mobiCARE-MC100

6) Manufacturer: Gilon Co., Ltd.

7) License Number: 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) Usage Method and Precautions - Refer to the attached document

(2) Fitbit inspire 2

1) Item Name: Activity Tracker

2) Sensors and Components
- 3-axis accelerometer, optical heart rate monitor, infrared sensor for blood oxygen (SpO2) measurement, vibration motor, ambient light sensor

3) Operating Environment: Temperature 0 – 40 °C, Maximum Operating Altitude: 8,534m

4) Battery Certification and Number

- Certification Authority: National Radio Research Agency

- Certification number: R-C-XIRA-FB424

- KC Certification Type: Certificate of Conformity for Broadcasting and Telecommunications Equipment

5) Certification Authority and Number

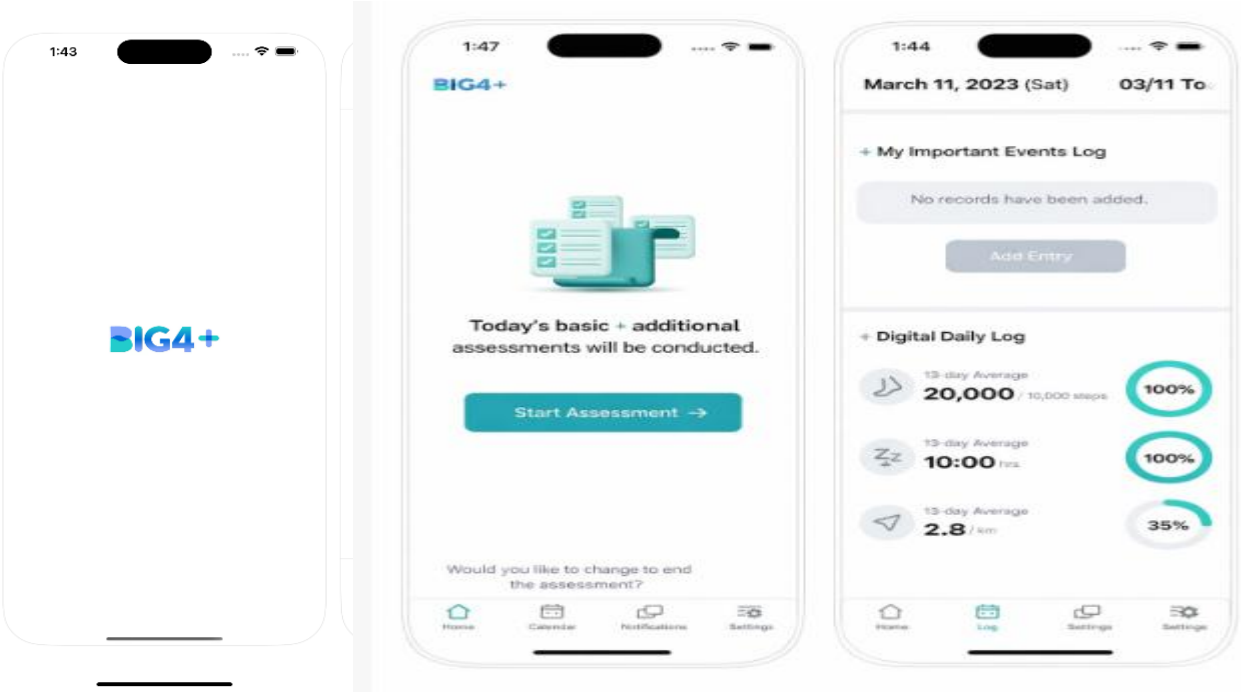
- Certification Body: Korea Testing Laboratory

- Certification Number: YU10211-22004

- KC Certification Type: Safety Confirmation Report Certificate

6) Manufacturer: Fitbit

(3) Big 4+ Homespital version



1) Item Name: Smartphone Application

2) Manufacturer: DigitalMedic Co., Ltd.

Function: Health monitoring and clinical assessment tool-based lifestyle factor recording, including location information collection, distance traveled measurement, step count, fitness information collection, sleep tracking, and smartphone usage

(4) Device Management

The medical devices used in this study will be provided to participants. Participants will be instructed on precautions for device use and storage methods. Prior to distribution, equipment will be managed at a designated location (Rehabilitation Functional Testing Lab, 2nd Floor, Yongin Severance Hospital). (Refer to the attached document)

9. Study Design (Trial Group·Control Group, Allocation, Blinding, and Flowchart, etc.)

(1) Research Design Overview

This is an investigator-initiated exploratory clinical study designed with random assignment and conducted over 6 weeks.

(2) Experimental Group

The experimental group consists of a single group using all three devices: the insole-type gait analyzer, activity tracker, and self-reporting application. Participants are instructed to wear the insole-type gait analyzer and activity tracker as much and as long as possible during outdoor activities. They are also instructed to self-report daily life factors such as sleep quality before bedtime, exercise volume, mood, pain, and appetite via the self-reporting application linked to the activity tracker.

At the study start, participants receive the insole-type gait analyzer and activity tracker from the examiner and receive training on the home-based self-exercise program and how to use each device and the self-reporting application. The researcher provides weekly feedback to participants via telephone, synthesizing data collected through the insole-type gait analyzer, activity tracker, and self-reporting application.

At the midpoint of the study (Week 3), participants visit the hospital for a check-up on the usage status of the insole-type gait analyzer, activity tracker, and self-reporting application, and complete the same physical activity questionnaire administered during the initial assessment. After the 6-week intervention concludes, a final assessment identical to the initial evaluation is conducted. Participants return only the activity tracker and complete an evaluation of usage and satisfaction regarding the insole-type gait analyzer, activity tracker, and self-report application.

(3) Control Group

The control group receives the same exercise program education as the experimental group but is not provided with the insole-type gait analyzer and does not receive exercise feedback.

(4) Randomized Assignment

This clinical trial will be conducted by the investigator assigning a registration number to each subject and performing randomization using an Excel-based randomization table.

10. Research Methods

(1) Screening Method

The examiner will conduct a medical history interview to assess the subject's baseline symptoms and signs, check vital signs to confirm medical stability, and determine whether the subject can walk independently for at least 10 meters with or without assistive devices.

(2) Pre- and Post-Intervention Program Evaluation Indicators

1) Primary Evaluation Indicators

① 6-Minute Walk Test

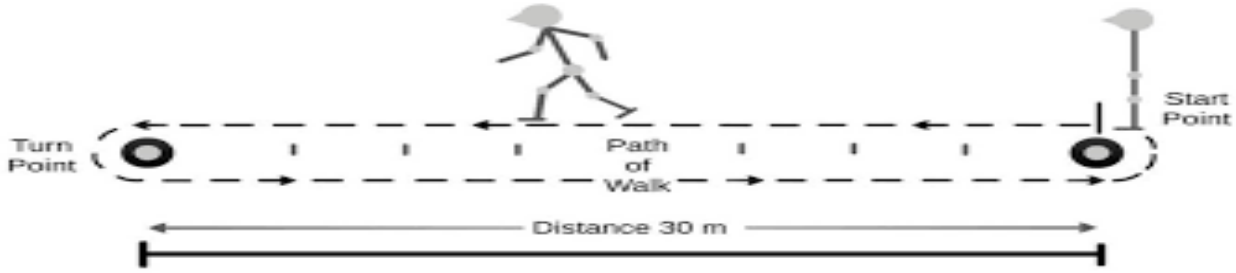
The subject performs the 6-minute walk test[10] while wearing an insole-type gait analyzer, simulating daily walking as closely as possible. The examiner provides feedback on gait by comparing the average parameter data extracted from the insole-type gait analyzer to normal gait standards. This evaluation assesses walking endurance and is conducted as follows.

a) Set up colored cones marking a 30m distance on the floor and prepare a stopwatch.

b) Instruct the subject to walk back and forth as many times as possible along the 30m straight distance for 6 minutes.

c) Inform the subject that they may rest during the test and may stop, using only permitted phrases ('You're doing well', 'Keep going').

d) The examiner records the total distance traveled, the pattern of abnormal gait, and the time of occurrence



2) Secondary Evaluation Indicators

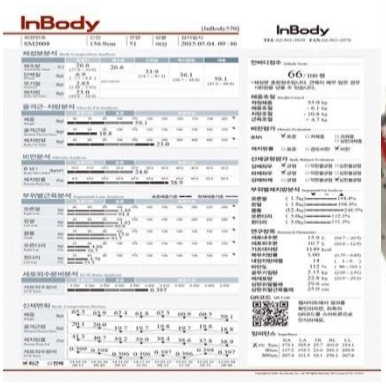
① Body Composition Analysis

This test is performed to assess the subject's limb muscle mass. The testing method is as follows.

a) Conduct body composition analysis based on bioelectrical impedance analysis[11]

b) To ensure accurate measurement, the subject is instructed to empty their bladder before the test and to avoid caffeine-containing beverages, food intake, alcohol consumption, and vigorous exercise one hour prior to the test.

c) To correct for differences in muscle mass due to height, appendicular skeletal mass (ASM) is calculated and used by dividing it by the square of height.



② Spatiotemporal Parameters of Gait

Spatio-temporal gait parameter data collected while the subject wears an insole-type gait analyzer at home and performs activities, recording total steps, steps per minute, walking speed, walking distance, stride length , and swing phase ratio.

③ Korea-Mini Mental State Examination (K-MMSE)

This test assesses the overall degree of cognitive impairment, considering the subject's educational level.[12] It evaluates orientation to time and place, attention and calculation ability, memory, language, and spatial -temporal construction ability. The examiner asks questions corresponding to the items on the test sheet and records scores for the responses.

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** ⇨

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.

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. Geront*. 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?*			

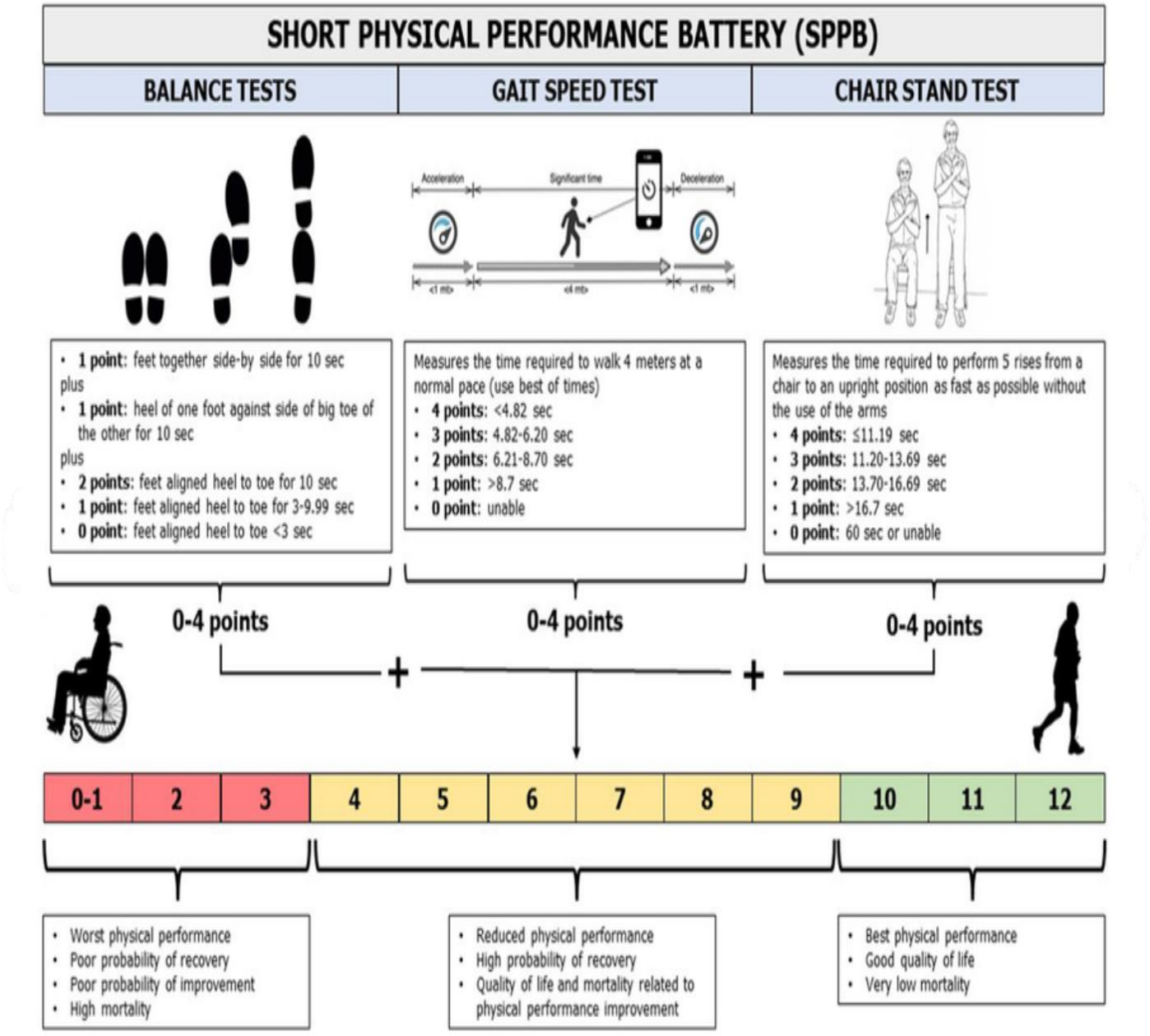
⑬ Short Physical Performance Battery (SPPB)

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.

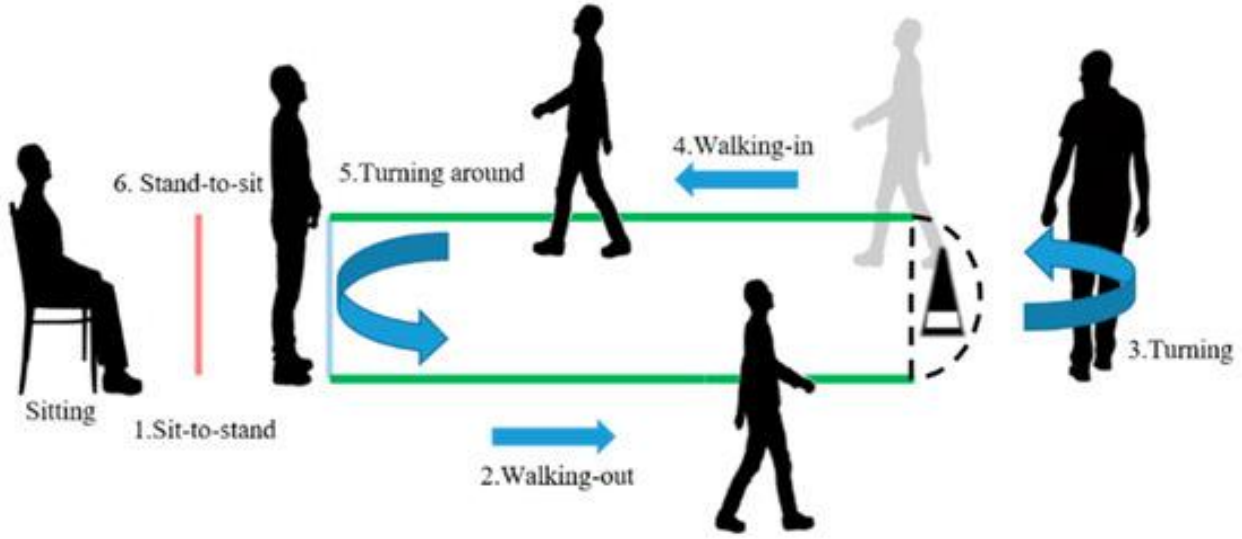


⑭ Timed up and go test (TUG)

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.

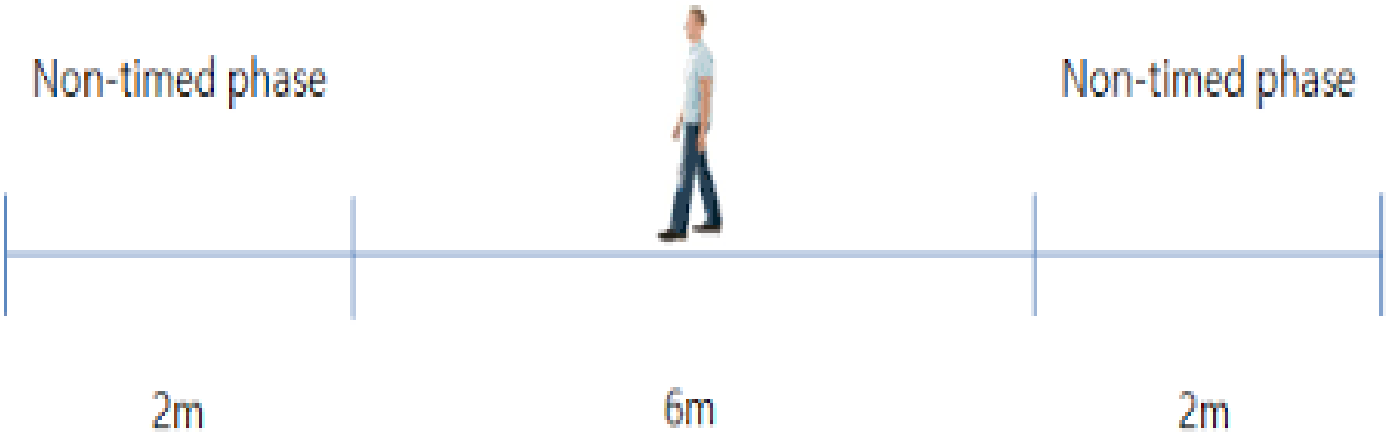


⑮ 10-Meter Walk Test

The 10-Meter Walk Test16 is used to assess gait speed in patients undergoing rehabilitation for neurological and Severance: H10_250409 musculoskeletal disorders. Participants wear an insole-type gait analyzer and walk a 10-meter straight path at a consistent pace while the time taken is measured to evaluate gait ability.

a) A total straight path of 14 meters is prepared, with the first and last 2 meters serving as non-measurement zones.

b) b) Participants are informed that their walking speed will be measured over the 10-meter section and are instructed to walk at a comfortable pace.



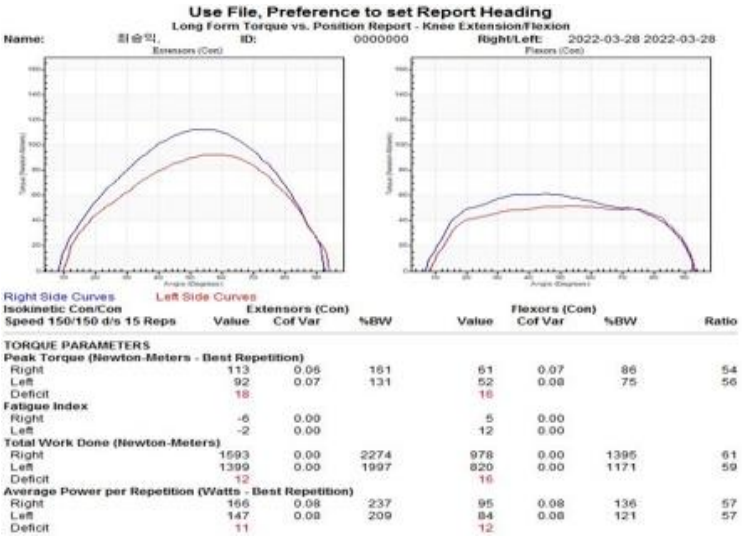
⑯ Berg Balance Scale

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

⑰ 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.

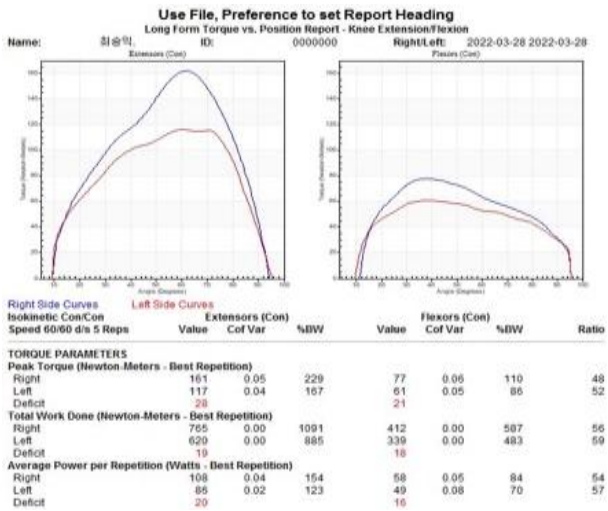


Use File, Preference to set Report Heading
Long Form Torque vs. Position Report - Knee Extension/Flexion

Name: 최승익, ID: 0000000 Right/Left: 2022-03-28 2022-03-28

Right Side Curves Left Side Curves

Isokinetic Con/Con Speed 150/150 d/s 15 Reps	Extensors (Con) Value	Cof Var	%BW	Flexors (Con) Value	Cof Var	%BW	Ratio
TORQUE PARAMETERS							
Peak Torque (Newton-Meters - Best Repetition)							
Right	113	0.06	161	61	0.07	86	54
Left	92	0.07	131	52	0.08	75	56
Deficit	18			16			
Fatigue Index							
Right	-6	0.00		5	0.00		
Left	-2	0.00		12	0.00		
Total Work Done (Newton-Meters)							
Right	1593	0.00	2274	978	0.00	1395	61
Left	1399	0.00	1997	820	0.00	1171	59
Deficit	12			16			
Average Power per Repetition (Watts - Best Repetition)							
Right	166	0.08	237	95	0.08	136	57
Left	147	0.08	209	84	0.08	121	57
Deficit	11			12			



Use File, Preference to set Report Heading
Long Form Torque vs. Position Report - Knee Extension/Flexion

Name: 최승익, ID: 0000000 Right/Left: 2022-03-28 2022-03-28

Right Side Curves Left Side Curves

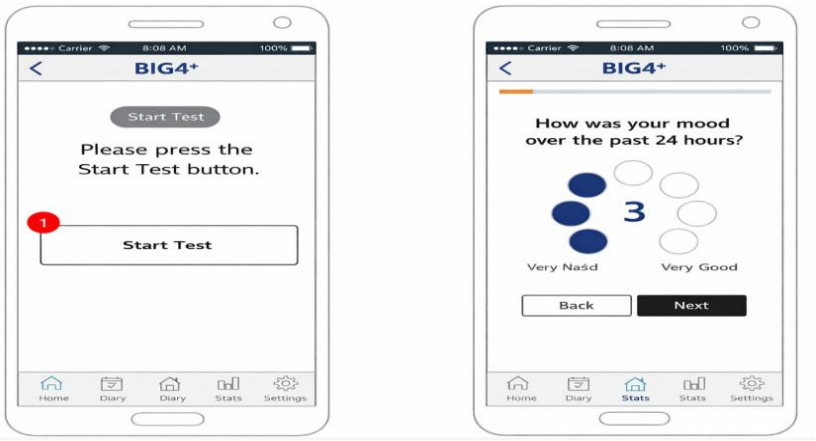
Isokinetic Con/Con Speed 60/60 d/s 5 Reps	Extensors (Con) Value	Cof Var	%BW	Flexors (Con) Value	Cof Var	%BW	Ratio
TORQUE PARAMETERS							
Peak Torque (Newton-Meters - Best Repetition)							
Right	161	0.05	229	77	0.06	110	48
Left	117	0.04	167	61	0.05	86	52
Deficit	28			21			
Total Work Done (Newton-Meters - Best Repetition)							
Right	765	0.00	1091	412	0.00	587	56
Left	620	0.00	885	339	0.00	483	59
Deficit	19			18			
Average Power per Repetition (Watts - Best Repetition)							
Right	108	0.04	154	58	0.05	84	54
Left	86	0.02	123	49	0.08	70	57
Deficit	20			16			

⑱ Application Survey Response Rate

Based on the application usage instructions provided by the examiner, the subject completes the following 5 surveys before bedtime. The subject's weekly response rate is calculated based on their survey records: the number of responses out of 5 surveys completed and the number of days out of 7 days responses were submitted.

$$\frac{number\ of\ individual\ survey\ responses}{5} \times \frac{number\ of\ weekly\ responses}{7} \times 100 = Survey\ response\ rate\%)$$

1- Mood Survey



As shown in the figure above, the subject starts the survey using the application installed on their smartphone and records their mood state. The scale is a 1-7 point Likert scale; the subject checks the corresponding mood state, presses the next button, and moves to the next survey.

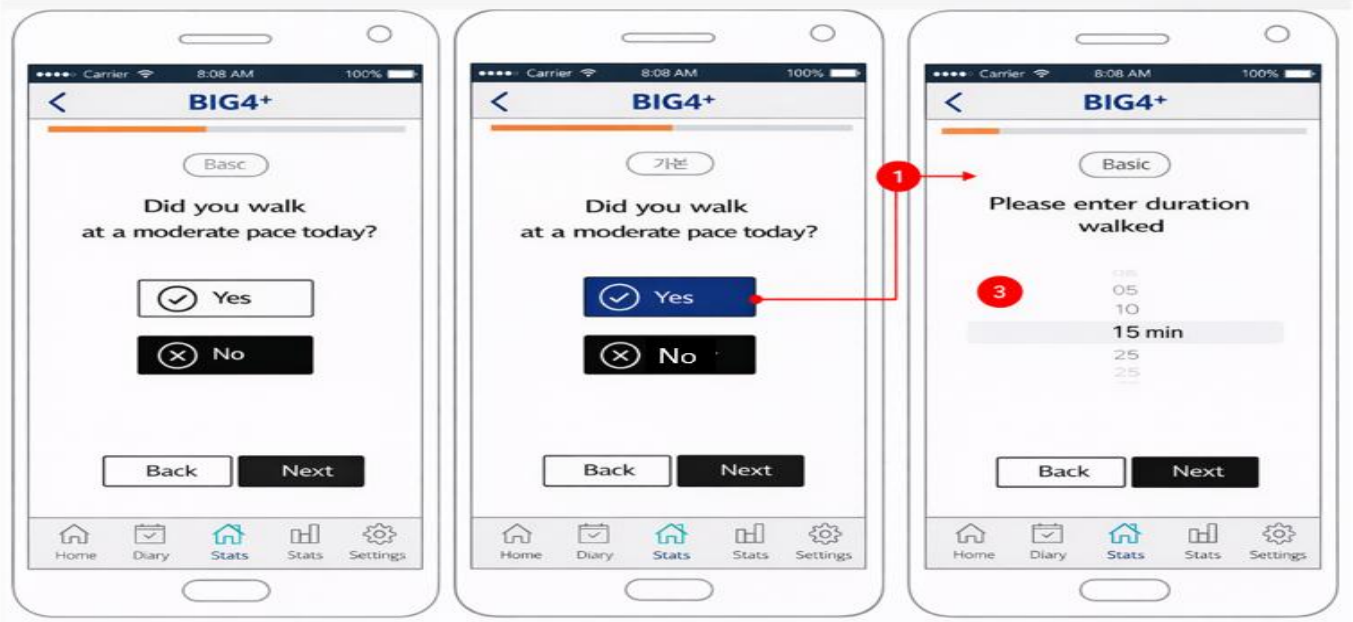
2- Appetite & Sleep Survey

As shown in the figure above, participants record their appetite throughout the day. The scale is a 1-7 point Likert scale. They check the corresponding appetite level, press the next button, and proceed to the next test. And the second figure above, record satisfaction with the previous night's sleep and sleep duration. The sleep satisfaction scale is a 1–7-point Likert scale. Check the corresponding sleep level, press the Next button, record the sleep duration, and proceed to the next test.

3- Physical Activity Survey

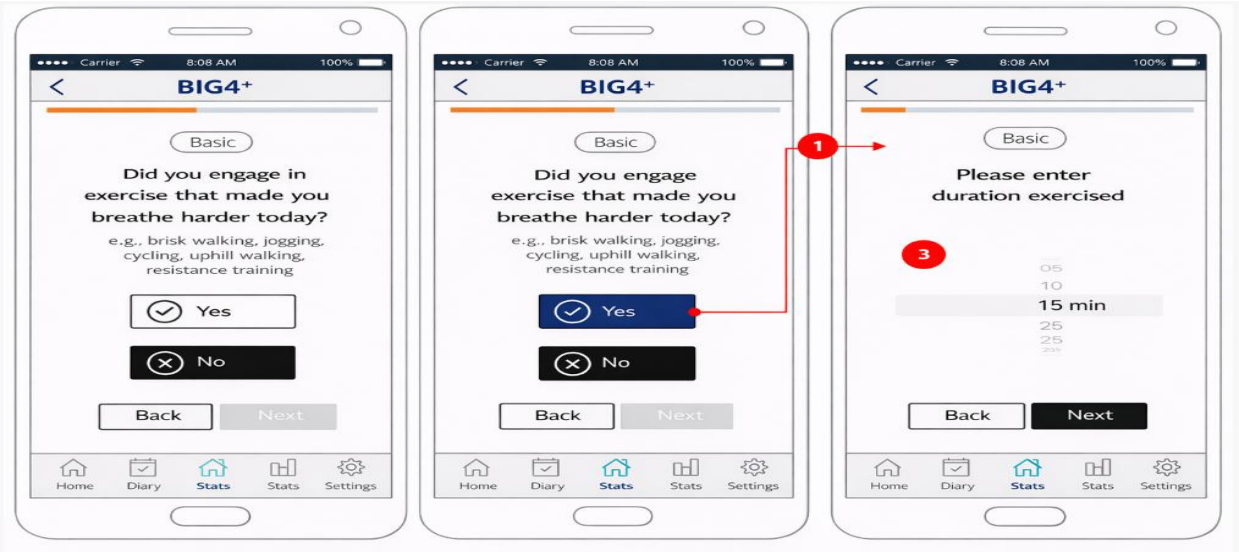
The subject completes the survey based on the International Physical Activity Questionnaire (IPAQ)[20,21] regarding walking activity, moderate-intensity exercise, and vigorous-intensity exercise as follows.

■ Walking Activity Survey



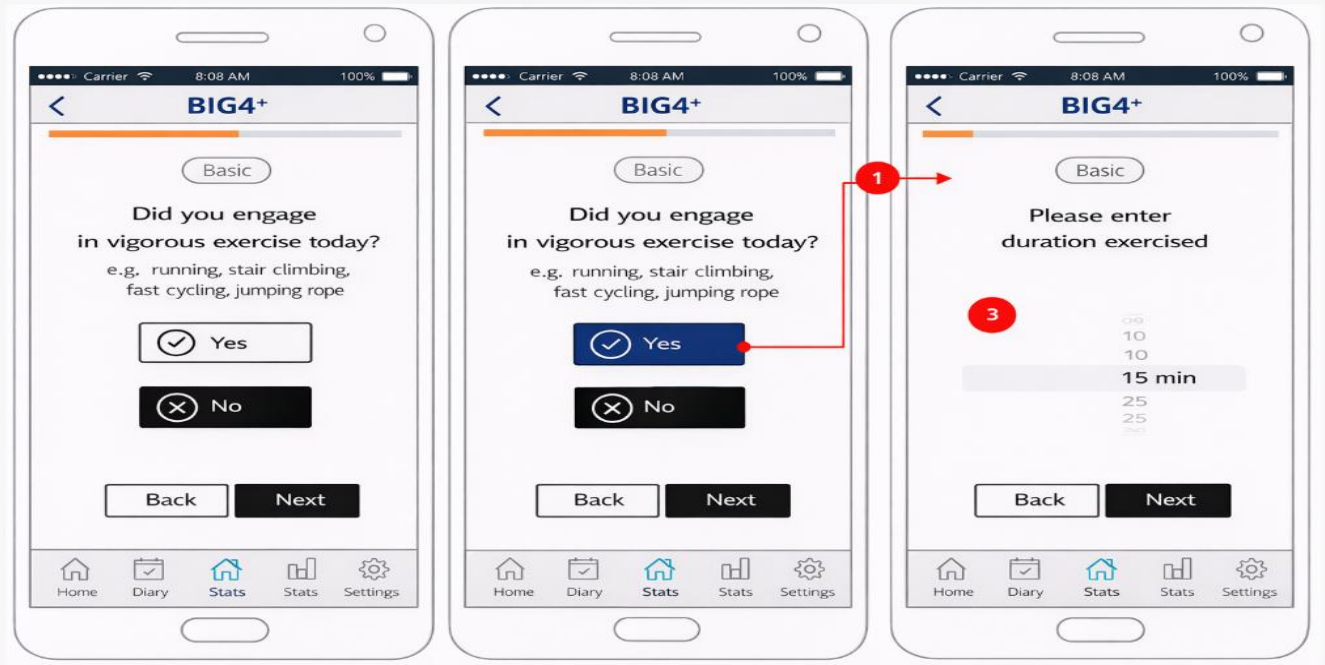
As shown in the figure above, check whether walking occurred. If walking occurred, record the walking time and proceed to the moderate-intensity exercise questionnaire. If no walking occurred, proceed directly to the moderate-intensity exercise questionnaire.

■ Moderate-Intensity Exercise Survey



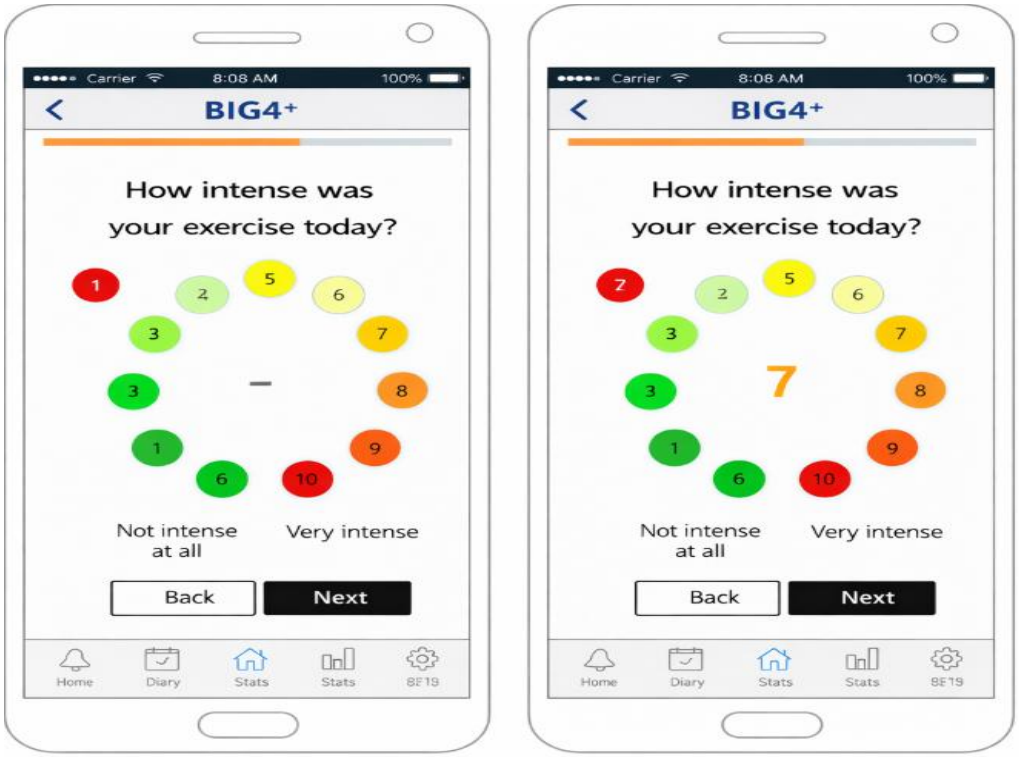
As shown in the figure above, check whether moderate-intensity exercise was performed. If performed, record the duration of moderate-intensity exercise and proceed to the high-intensity exercise survey. If not performed, proceed directly to the high-intensity exercise survey.

■ Vigorous-Intensity Exercise Survey



As shown in the figure above, check whether vigorous intensity exercise was performed. If performed, record the vigorous intensity exercise time and proceed to the exercise intensity survey. If not performed, proceed directly to the exercise intensity survey

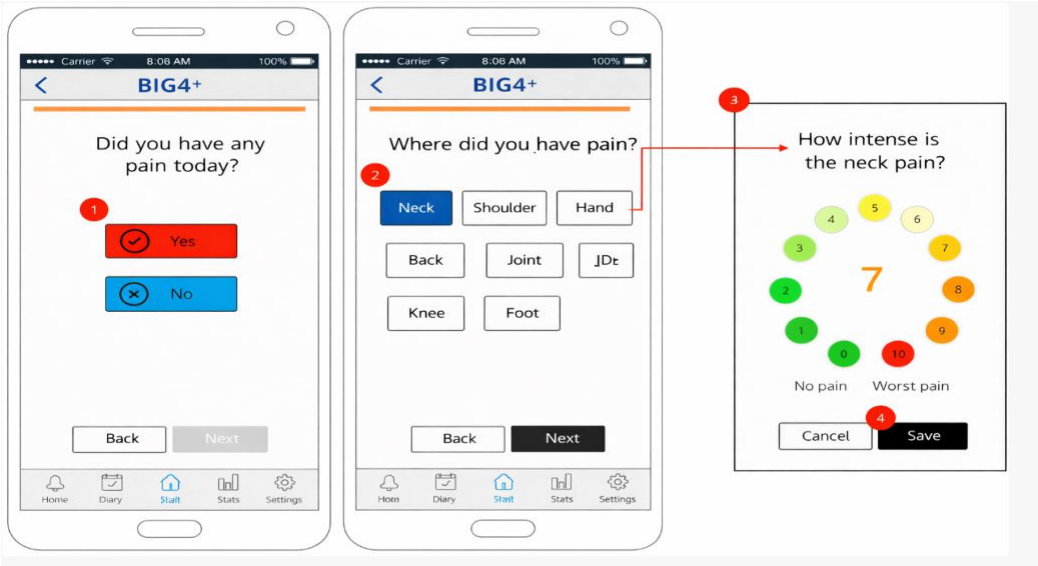
■ Subjective Exercise Intensity Survey



As shown in the figure above, record the intensity of today's exercise. The exercise intensity scale is a 0-10 Likert scale. Check the corresponding intensity level, press the Next button, and proceed to the pain survey.

4- Pain Survey

The subject completes a survey related to walking activity, moderate-intensity exercise, and high-intensity exercise based on the Visual Analog Scale (VAS)[22] as follows.



As shown in the figure above, check whether pain is present. If pain is present, select each item (neck, shoulder, wrist, lower back , hip joint, knee, ankle) and score it on a 0-10 Likert scale. Then end the test. If no pain is present , end the test immediately.

⑲ Correlation coefficient between the Korean Short-Form International Physical Activity Questionnaire (K-IPAQ) and the average value of exercise recorded in the application

K-IPAQ is a test that evaluates an individual's daily physical activity from various aspects and can provide information on activity levels. The examiner asks the subject questions based on the questionnaire below, records relevant information, calculates total activity time and intensity, and classifies it as 'light', 'moderate', or 'vigorous'. The examiner administers the Korean version of the International Physical Activity Questionnaire (K -IPAQ) to the subject at three points: baseline, 3 weeks, and 6 weeks. Correlation analysis is then performed using the questionnaire results and the exercise data recorded by the subject via the application to extract the correlation coefficient value.

⑳ Changes in Responses to the Korean Short -Form International Physical Activity Questionnaire (K-IPAQ)

The examiner calculates the change rate by using a paired sample t -test to compare the difference in response rates, utilizing the results of the Korean version of the Short Form International Physical Activity Questionnaire administered at baseline and at 6 weeks.

(3) Home Exercise Program Education

Participants' gait parameter data is extracted through the primary assessment variable, the 6-Minute Walk Test. Feedback is provided based on the following normal gait criteria. Following the pre-intervention assessment, exercise education is provided individually according to the patient's age, gender, underlying conditions, and muscle strength and endurance.

1) Providing Information on the Subject's Gait Status and Normal Gait Criteria

The examiner provides feedback on gait to the experimental group participants by comparing the average values of the gait parameters extracted from the above gait assessment against the normal gait criteria. The extracted gait parameters and normal gait criteria are as follows. The control group does not undergo this process.

① Step count: The number of steps measured while walking after linking the insole-type gait analyzer with a smartphone application

② Cadence: Number of steps measured per minute, unit: Steps/min (spm). Normal cadence is 70 steps/min for those under 65 years old and 60 steps/min or higher for those aged 65 and over.[27]

③ Gait Speed: The speed of walking, measured in km/h. Normal values are 2.0 km/h for t hose under 65 and 1.5 km/h or higher for those aged 65 and over.[28]

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

⑤ Stride Length: Represents the distance from one heel to the same heel. The unit is meters (m). To correct for differences caused by height, stride length is divided by height. Normal values are 0.5 m/height for those under 65 and 0.4 m/height or higher for those aged 65 and over.[28]

⑥ Swing ratio: The percentage of the swing phase within one gait cycle, measured in %. For those under 65, 30% is normal, and for those 65 and older, 28% or higher is normal.[29]

2) Home Exercise Program Education

The researcher instructs all subjects on the following program.

① Exercise Program Structure

a) Warm-up: 5-10 minutes of low-intensity (<40% VO2 max) or moderate-intensity (40-60% VO2 max) activity

b) Stretching: Perform for 10 minutes after the warm-up

c) Main Exercise: Tailored to the patient's fitness level, consisting of 20-30 minutes of aerobic exercise (using a stationary bike or treadmill, or walking), strength training at 60-80% of the patient's maximum strength (1 set of 10-15 repetitions per muscle group, performed 2-3 times), and flexibility training (upper and lower body stretching) d) Cool-down: Perform 5-10 minutes of low-intensity (<40% VO2 max) or moderate-intensity (40-60% VO2 max) 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, use resting heart rate, maximum heart rate, and exercise intensity. Resting heart rate is measured after lying down and resting for 3-5 minutes. The maximum heart rate is calculated using $(220 - \text{age})$. Exercise intensity is expressed as a percentage of the maximum heart rate, representing the ratio of the heart rate during exercise to the maximum heart rate. The target heart rate is set according to the following formula.

$$Target\ Heart\ Rate = (\text{HRmax} - \text{HRrest}) \times \text{Exercise Intensity} + \text{HR rest}$$

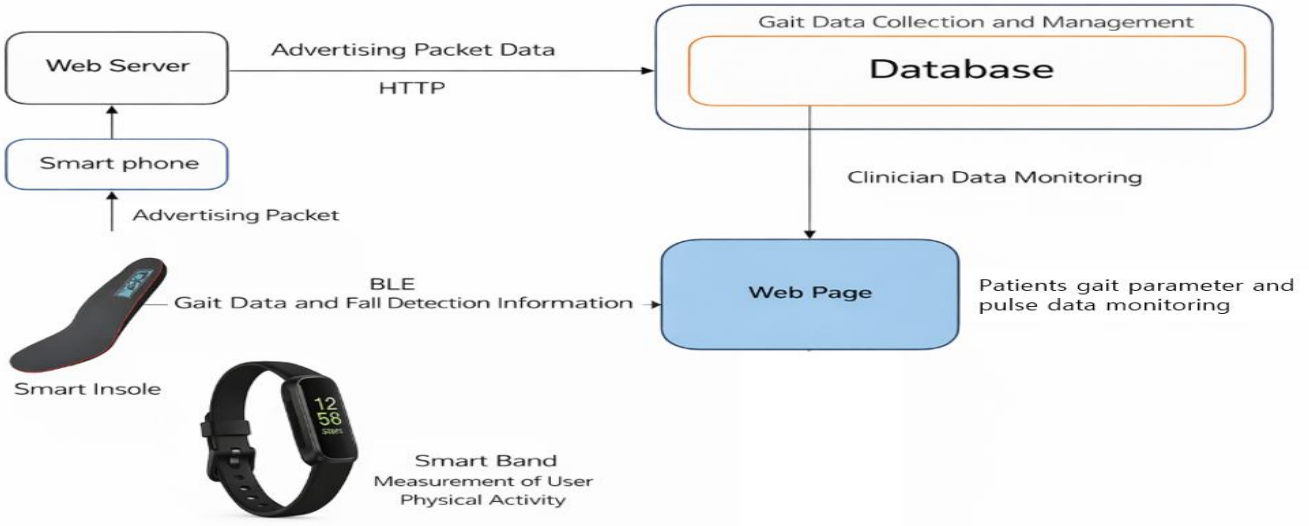
Aerobic exercise is performed at 60% intensity for 20-60 minutes, 3-5 times per week. Low-intensity exercise is performed for patients unable to tolerate high-intensity exercise.

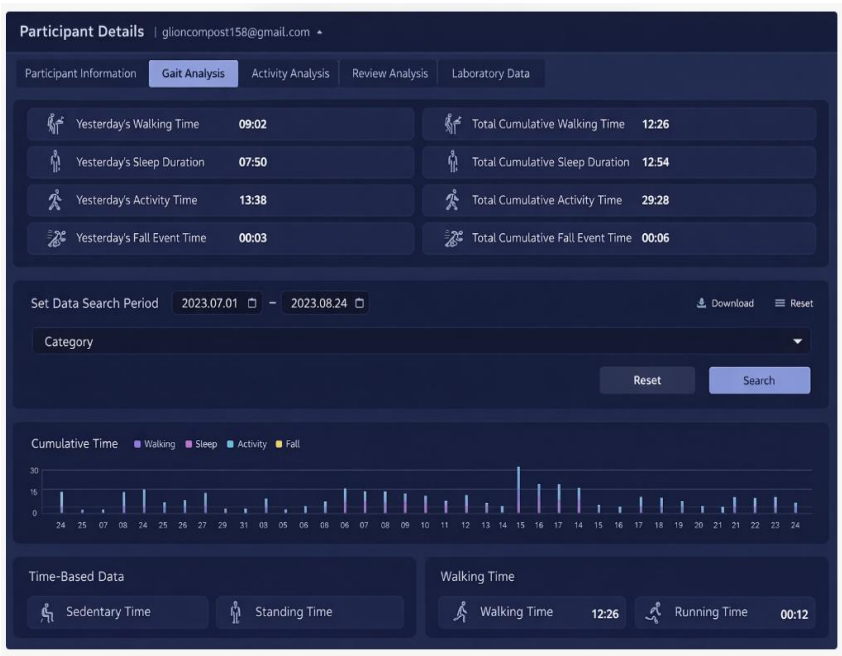
(4) Subject Monitoring Methods

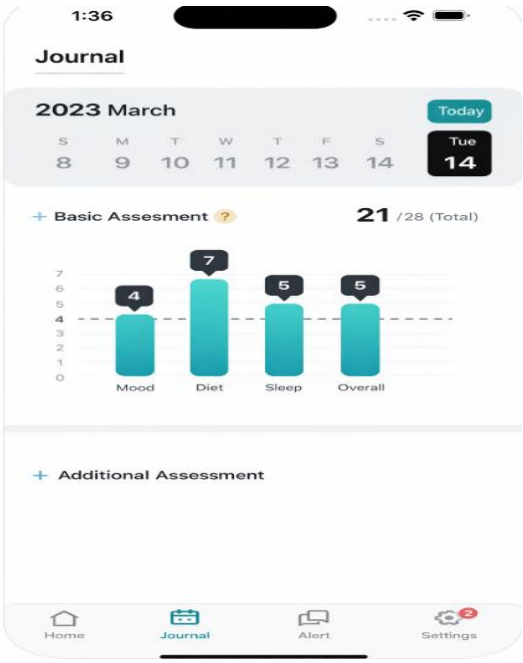
1) Home Exercise Monitoring

The researcher provides weekly feedback via phone to the experimental group using the insole-type gait analyzer, tailored to the collected exercise volume and gait level of the subject. The stability of data collection is verified, and any abnormalities are addressed and recorded via phone or in-person visit.

Gait data collection via the insole-type gait analyzer is conducted by connecting the analyzer to the subject's smartphone, transmitting measured data to a web server. The medical device company provides the researcher with data sorted by the analyzer's product serial number once per week. The researcher monitors the subject's activity level, identifies differences between the subject's gait metrics and normal standards, and provides weekly feedback via phone. The control group does not undergo these procedures.







(5) Satisfaction assessment

Experimental group participants return the insole-type gait analyzer and activity tracker to the examiner and complete a 12-item, 5-point scale satisfaction survey for the insole-type gait analyzer, activity tracker, and application. This survey is 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: _____					

- 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	

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 activity tracker? reason: _____					
How does the activity tracker weigh? reason: _____					
Is it convenient to adjust (fix and lock) the parts (accessories) of the activity tracker? reason: _____					
Do you think activity tracker is safe and sturdy? reason: _____					
Are you satisfied with the durability (long-term usability) of the activity tracker? reason: _____					
Was it convenient to use the activity tracker? reason: _____					
Do you think activity trackers are comfortable to wear? reason: _____					

Are you satisfied with the effectiveness of the activity tracker (effectiveness suited to the purpose of use)? reason: _____					
Are you satisfied with Activity tracker's service and delivery program (delivery process and time required)? reason: _____					
Are you satisfied with the repair and maintenance services for activity tracker? reason: _____					
Are you satisfied with the professional service (information and precautions) you received while using the activity tracker? reason: _____					
Are you satisfied with Activity tracker's after-sales service (continuous management service)? reason: _____					

- 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

36 months after IRB approval (e.g. October 2023 - October 2026)

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 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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