Cover page for ClinicalTrials.gov

Name of the document:

Study protocol and Statistical Analysis Plan

Official Title of the Study:

Study to verify effectiveness and safety of at-home gait rehabilitation using a hip-assisted wearable robot to improve gait in stroke patients, Investigator Initiated, Single center, Single group trial

NCT number

-

Date of the document:

July 01, 2026

Prospective Clinical Study Protocol

1. Study Title, Phase, Protocol Identification Number, and Amendment History, etc.

- Study Title:

Study to verify effectiveness and safety of at-home gait rehabilitation using a hip-assisted wearable robot to improve gait in stroke patients, Investigator Initiated, Single center, Single group trial

2. Study Protocol Summary

Study Objective	To determine whether home-based rehabilitation gait training (a total of 4 sessions over 2 weeks) using a powered orthopedic exercise device, performed by a physical therapist or occupational therapist visiting the home directly under a physician's diagnosis and prescription, is safe and feasible
Overview of Study Design	Investigator-initiated exploratory clinical study 2 weeks, Exploratory study
Investigational Medical Device	Powered orthopedic exercise device
Target Number of Subjects and Basis for Calculation	8 patients diagnosed with stroke This study provides robot-assisted gait training in the home or an indoor space near the home using a powered orthopedic exercise device, and the target number of subjects was set taking clinical circumstances into account. Basis for calculation: The goal is to enroll 8 subjects from among visitors to Yongin Severance Hospital before completion of subject recruitment, and the target number of subjects was set at 8 taking into account the dropout rate and clinical circumstances. In addition, a realistically achievable number of subjects was reflected with reference to the results of previous studies.
Inclusion and Exclusion Criteria	1. Inclusion Criteria 1) Adults aged 19 years or older and under 80 years 2) Persons diagnosed with cerebral infarction or intracerebral hemorrhage confirmed by magnetic resonance imaging or computed tomography 3) Persons for whom at least 1 month has elapsed since the diagnosis of stroke 4) Persons showing a spastic hemiplegic gait pattern due to stroke 5) Patients with a Functional Ambulatory Category score below 4 6) Persons who can sit without assistance at the edge of a bed and can stand for 10 seconds with or without assistance 7) Persons with sufficient cognitive ability to follow simple instructions and understand the content and purpose of the study (Mini-Mental State Examination score >= 20)

	2. Exclusion Criteria 1) Persons with contraindications to lower-extremity weight bearing, such as severe lower-extremity joint contracture or an untreated fracture 2) Persons for whom wearing the device is difficult due to skin disease or open wounds 3) Persons with a severe difference in the length of the two lower extremities 4) Persons with severe deformity or joint contracture in the lower extremities 5) Persons unable to maintain a sitting posture or a standing posture on their own 6) Persons with severe lower-extremity spasticity (Modified Ashworth Scale (MAS) grade 2 or higher) 7) Persons who cannot cooperate with gait therapy using the robot-assisted orthopedic exercise device due to severe cognitive decline (Mini-Mental State Examination score < 20), delirium, or severe language function impairment 8) Persons who cannot maintain prolonged standing or walking due to underlying conditions such as orthostatic hypotension or reduced cardiopulmonary function 9) Persons with other concomitant conditions affecting gait, such as peripheral neuropathy or parkinsonism due to alcoholism or severe diabetes 10) Pregnant women or patients with the possibility of pregnancy 11) Persons currently participating in another clinical trial 12) Persons at high risk in the event of a fall or bleeding due to a coagulation disorder or the like 13) Persons with a height less than 140 cm or greater than 190 cm 14) Persons for whom wearing the robot is not possible 15) Persons with clinically significant findings that, in the medical judgment of the principal investigator or a sub-investigator, are considered inappropriate for this study other than the above
Study Method	After obtaining written consent, a screening test is performed. In the screening test, after taking a history of the subject's baseline symptoms and signs, the past history and medication history are confirmed, vital signs are measured, and a physical examination is conducted, and the overall gait status such as whether assistive devices are used during gait and the gait pattern is assessed. Subjects who pass the screening test undergo the initial assessment within 7 days. The initial assessment is conducted including the 2-Minute Walk Test, spatiotemporal gait parameters, the Berg Balance Scale, and subjects who complete the initial assessment begin robot-assisted gait training on the same day. After the initial assessment, gait training using the powered orthopedic exercise device gait-assist robot is performed in the home or an indoor space near the home twice a week for 2 weeks, a total of 4 times, for 30 minutes each. The interval between each intervention visit is set not to exceed 5 days. After the end of the 2 weeks of robot-assisted gait training, on the day of completion, the end-of-study assessment is performed identically to the initial assessment, and a satisfaction

	assessment for the powered orthopedic exercise device is conducted. In addition, when a device abnormality occurs, measures are taken and the relevant details are recorded, the usability of the powered orthopedic exercise device is analyzed, the gait and balance function assessment results in the non-wearing/wearing states of the powered orthopedic exercise device are statistically compared before and after gait training, and the burden and satisfaction assessments of the powered orthopedic exercise device are analyzed.
Assessment Variables	1) Primary endpoint - TUQ (Telehealth Usability Questionnaire) 2) Secondary endpoints - 2-Minute Walk Test - Spatiotemporal parameters of gait - Berg Balance Scale - 12-item, 5-point-scale satisfaction questionnaire related to use of the powered orthopedic exercise device, based on K-QUEST
Data Analysis and Statistical Methods	1) Subject characteristics: The general characteristics of subjects are analyzed using descriptive statistics. Continuous variables are presented as means and standard deviations. Categorical variables are presented as frequencies and percentages. 2) Primary endpoint: As an exploratory study to explore the effectiveness and safety of home-based robot-assisted gait training, the TUQ (Telehealth Usability Questionnaire) is set as the primary endpoint. At the end of the intervention, the usability of the powered orthopedic exercise device is assessed using a questionnaire constructed based on the Telehealth Usability Questionnaire (TUQ) items. The TUQ is a tool developed to assess the usability of telehealth implementations and services; it was constructed by integrating items from telehealth-related questionnaires and computer usability questionnaires, and includes usefulness, ease of use and learnability, interface quality, interaction quality, reliability, satisfaction and future use. The TUQ results are analyzed using descriptive statistics, and the mean, standard deviation, median, minimum, and maximum are calculated for each item and for the total score. 3) Secondary endpoints: The walking distance and spatiotemporal gait parameters, hip kinematics, and Berg Balance Scale calculated by performing the 2-Minute Walk Test before the start of the intervention in session 1 and after the end of the intervention in session 4 of robot-assisted gait rehabilitation therapy are compared and analyzed using the Wilcoxon signed-rank test, with statistical significance set at a p-value less than 0.05. At this time, both the median and quartiles and the mean and standard deviation are

	confirmed as descriptive statistics. 4) Satisfaction assessment: The satisfaction results for home-based robot-assisted gait training are analyzed using descriptive statistics to calculate the mean, standard deviation, minimum, and maximum of each item. For each item, a mean value of 4 points or higher is interpreted as a positive evaluation, and 2 points or lower as a negative evaluation.

3. Study Background and Rationale

Of the approximately 2.6 million registered persons with disabilities in Korea, 1.45 million are registered with physical or brain-lesion disabilities, accounting for 55% of the total, and functional impairment of the upper and lower extremities is reported to arise from various causes such as stroke, cerebral palsy, spinal cord injury, and muscular disease (Source: Statistics Korea, 2020). In particular, according to a 10-year follow-up study analyzing factors related to long-term functional level in the field of stroke rehabilitation, 48.3% of patients at 6 months and 43.6% at 12 months after onset showed mild or greater motor function decline, confirming a very high demand for improvement of lower-extremity dysfunction and gait disturbance. Gait plays a critical role in healthy skeletal and muscular development[1-3] and is very closely associated with improvement of cardiopulmonary function and the performance of activities of daily living, so restoration of gait ability is regarded as the most central goal of rehabilitation therapy.

Various methods for gait rehabilitation training have been proposed,[4] but robot-assisted gait training has recently drawn attention. Continuous and repetitive training is important for functional recovery after central nervous system injury,[5,6] through which neuroplasticity can be induced and reinforced. Robot-assisted gait training has the advantage of guiding the patient to walk accurately, close to normal gait, and enabling repetitive performance of consistent movements. It can also compensate for the limitations of conventional rehabilitation therapy, in which variability can arise not only from differences in the experience and knowledge of physical therapists or occupational therapists but also from their physical abilities. Robot-assisted gait training has shown improvements in physical function such as increased lower-extremity muscle strength and improved gait and balance abilities, and various types of gait-assist robots are being tried in clinical settings. In particular, wearable gait-assist robots can provide more precise and active training compared with treadmill-based gait-assist robots,[5] and can maximize training effects by implementing an environment similar to actual walking. They also have the advantages of being relatively compact and easy to move, and adjustable to individual patient characteristics.

As we experienced the COVID-19 pandemic, the demand to use healthcare services not only at medical institutions but also in the home environment increased. With the advancement of sensors, materials, short-range communication, and mobile applications, rehabilitation robots have also greatly advanced, but to date their use has been mainly limited to within medical institutions. Accordingly, this study aims to explore the feasibility of a gait rehabilitation service that provides robot-assisted gait training in the home environment using a powered orthopedic exercise device, a gait-assist robot.

4. Study Objective

To determine whether at-home rehabilitation gait training (a total of 4 sessions over 2 weeks) using a powered orthopedic exercise

device, performed by a physical therapist or occupational therapist visiting the home directly under a physician's diagnosis and prescription, is safely feasible.

5. Risk/Benefit Analysis

The 2-Minute Walk Test and the Berg Balance Scale are used as items to assess gait ability in this study. These are tests widely used in clinical practice and carry a very low medical risk. To minimize the risk of falls that may occur during the tests, the tests will be conducted after sufficient practice under the examiner's supervision beforehand, in an environment equipped with a safety bar or with the examiner in close proximity.

Use of the powered orthopedic exercise device may cause musculoskeletal pain, skin abrasions, bruising at the site of wear, dizziness, and theoretically there is also a possibility of falls. In addition, an unexpected response of the actuator may disrupt the gait rhythm, causing fatigue, discomfort, or musculoskeletal injury due to loss of balance. To minimize such risks, subjects will be thoroughly educated on how to put on and take off the device and on how to respond to hazardous situations before study participation, and during gait training the researcher will continuously accompany the subject while holding the device's handle to prepare for the risk of falls. If an adverse reaction or hazardous situation occurs, the investigator will operate the emergency switch to immediately stop control and assistive-force generation, and a mechanical joint-range-of-motion limiting device will be installed on the powered orthopedic exercise device so that no excessive load is placed on the joints.

Through this study, participants can be provided with information about their physical functions, such as their gait and balance abilities, and can experience rehabilitation services including systematic robot-assisted gait training in the home environment. The data accumulated during the study period will be used to improve and advance gait rehabilitation devices and to develop at-home services. Furthermore, these data may be used in research related to the treatment and prognosis of disease, thereby contributing to the advancement of medicine and to improving the quality of care. Therefore, the benefits obtainable through this study are expected to outweigh its potential risks.

6. Target Number of Subjects and Basis for Calculation

The goal is to enroll 8 subjects from among visitors to Yongin Severance Hospital before completion of subject recruitment, and the target number of subjects was set at 8 considering the dropout rate and clinical circumstances. In addition, a realistically achievable number of subjects was reflected with reference to the results of previous studies.

7. Subject Inclusion/Exclusion Criteria

(1) Inclusion Criteria

1) Adults aged 19 years or older and under 80 years
2) Persons diagnosed with cerebral infarction or intracerebral hemorrhage confirmed by magnetic resonance imaging or computed tomography
3) Persons for whom at least 1 month has elapsed since the diagnosis of stroke
4) Persons showing a spastic hemiplegic gait pattern due to stroke
5) Patients with a Functional Ambulatory Category score below 4
6) Persons who can sit without assistance at the edge of a bed and can stand for 10 seconds with or without assistance

7) Persons with sufficient cognitive ability to follow simple instructions and understand the content and purpose of the study (Mini-Mental State Examination score >= 20)

(2) Exclusion Criteria

1) Persons with contraindications to lower-extremity weight bearing, such as severe lower-extremity joint contracture or an untreated fracture
2) Persons for whom wearing the device is difficult due to skin disease or open wounds
3) Persons with a severe difference in the length of the two lower extremities
4) Persons with severe deformity or joint contracture in the lower extremities
5) Persons unable to maintain a sitting posture or a standing posture on their own
6) Persons with severe lower-extremity spasticity (Modified Ashworth Scale (MAS) grade 2 or higher)
7) Persons who cannot cooperate with gait therapy using the robot-assisted orthopedic exercise device due to severe cognitive decline (Mini-Mental State Examination score < 20), delirium, or severe language function impairment
8) Persons who cannot maintain prolonged standing or walking due to underlying conditions such as orthostatic hypotension or reduced cardiopulmonary function
9) Persons with other concomitant conditions affecting gait, such as peripheral neuropathy or parkinsonism due to alcoholism or severe diabetes
10) Pregnant women or patients with the possibility of pregnancy
11) Persons currently participating in another clinical trial
12) Persons at high risk in the event of a fall or bleeding due to a coagulation disorder or the like
13) Persons with a height less than 140 cm or greater than 190 cm
14) Persons for whom wearing the robot is not possible
15) Persons with clinically significant findings that, in the medical judgment of the principal investigator or a sub-investigator, are considered inappropriate for this study other than the above

8. Medical Device Information and Management

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

Model name: AM-H10 — top row: Front / Back; bottom row: Left side / Right side



(1) Powered Orthopedic Exercise Device, H10®

1) Product name: Powered orthopedic exercise device

2) Classification number: A67020.02

3) Packaging unit: 1 set

4) Medical device class: Class II

5) Model name: Angel SUIT H10

6) Manufacturer: Angel Robotics Co., Ltd.

7) License number: Approval (Import) No. 25-4093

8) External appearance

9) Intended use: A powered device used for muscle strengthening and restoration of joint motion.

10) Operating principle, method of use, and precautions for use - refer to the attached document

(2) Device Management

The powered orthopedic exercise device used in this study is equipment held within the hospital, is used together with a robot transport bag and gait-assist aids, and is managed as follows.

1) Security

The medical device used in this study is stored in accordance with the storage environment conditions specified in the storage method and is managed in a designated location equipped with a separate locking mechanism (the Rehabilitation Function Test Room on the 2nd floor). The medical device manager is responsible for device dispensing, usage records, and security checks. (Refer to the attached document)

2) Infection Control

The medical device manager conducts thorough disinfection procedures before and after equipment use between each session to minimize the risk of cross-infection between subjects, and supervises subjects' personal hygiene management using the hand sanitizer provided in the indoor space where gait training is conducted before the equipment is worn.

3) Medical Device Transport and Retrieval

Transport and retrieval of the robot-assisted orthopedic exercise device used in the study, between the home of the subject undergoing robot-assisted gait training and the location where the gait-assist robot is stored (the Rehabilitation Function Test Room on the 2nd floor), are carried out by the research staff using a vehicle and on foot.

9. Study Design

(1) Overview of Study Design

This is an investigator-initiated exploratory study conducted over 2 weeks.

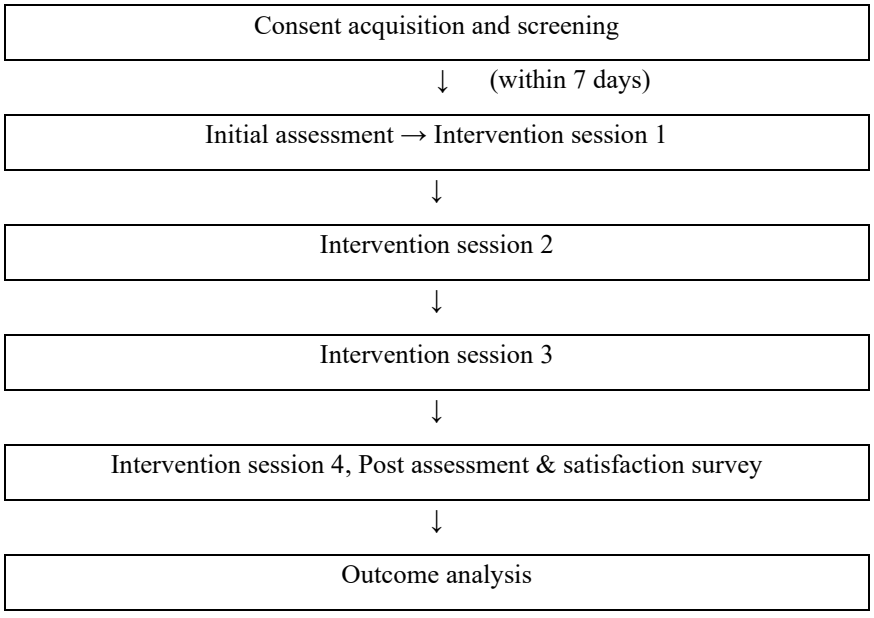
(2) Study Group

This study includes only a single trial group, with a total of 8 subjects to be included. Selection of the gait training group and the entire treatment process using the powered orthopedic exercise device are carried out in accordance with the prescription and guidance of a rehabilitation medicine specialist, and will be conducted under the supervision of 2 members of the research staff (holders of a physical therapist or occupational therapist license). Participants wear the powered orthopedic exercise device in an indoor space such as their home or a gym near their home and receive robot-assisted gait training twice a week for 2 weeks, a total of 4 sessions of 30 minutes each. The interval between each intervention visit is set not to exceed 5 days.

(3) Randomization and Control Group

This exploratory study was designed as a single-group design and did not include randomization or a control group.

(4) Flow Chart



10. Study Methods

(1) Screening Method

Screening assessment is conducted after a rehabilitation medicine specialist sufficiently explains the study to the subject and obtains written consent, in the physician's office, an independent space within Yongin Severance Hospital, a medical institution.

1) Vital signs

The subject's blood pressure, pulse, and body temperature are checked.

2) Physical examination

A. Manual muscle strength assessment (lower extremities)

The subject's lower-extremity manual muscle strength and joint range of motion are assessed with reference to the table below. Assessment must be performed with the subject lying supine or prone, and the examiner may assist when changing positions.

No.	Symbol	Grade	Grade definition
0		Zero	No muscle contraction on inspection or palpation
1	(Tr)	Trace	Slight contraction is present, but no joint movement
2-	(P-)	Poor Minus	Moves through a partial range of motion in a gravity-eliminated position
2	(P)	Poor	Moves through the full range of motion in a gravity-eliminated position
2+	(P+)	Poor plus	Moves through the full range of motion in a gravity-eliminated position, and moves up to 1/2 of the range against gravity
3-	(F-)	Fair Minus	Moves through the full range of motion in a gravity-eliminated position, and moves beyond 1/2 of the range against gravity
3	(F)	Fair	Moves through the full range of motion against gravity
3+	(F+)	Fair Plus	Moves through the full range of motion against gravity, and can resist slight resistance
4	(G)	Good	Moves through the full range of motion against gravity, and can resist moderate resistance
5	(N)	Normal	Moves through the full range of motion against gravity, and can resist maximal resistance

Joint range of motion assessment (lower extremities)

The subject's lower-extremity manual muscle strength and joint range of motion are assessed with reference to the table below. Assessment must be performed with the subject lying supine or prone, and the examiner may assist when changing positions.

Joint Range of Motion Assessment Sheet *Lower Extremity* | *Date:* _____ *Examiner:* _____

Rt.	**Reference ROM (°)**	**Motion**	**Joint**	**Motion**	**Reference ROM (°)**	**Lt.**
	125	Flexion	Hip	Flexion	125	
	10	Extension	Hip	Extension	10	
	45	Abduction	Hip	Abduction	45	
	10	Adduction	Hip	Adduction	10	
	45	External rotation (E/R)	Hip	External rotation (E/R)	45	
	45	Internal rotation (I/R)	Hip	Internal rotation (I/R)	45	
	140	Flexion	Knee	Flexion	140	
	0	Extension	Knee	Extension	0	
	20	Dorsiflexion (D/F)	Ankle	Dorsiflexion (D/F)	20	
	40	Plantarflexion (P/F)	Ankle	Plantarflexion (P/F)	40	

B. Joint spasticity assessment (Modified Ashworth Scale, MAS) (lower extremities)8

This is a test to determine the degree of impairment of function or stability caused by the spasticity of the subject's three major lower-extremity joints (hip, knee, and ankle), and the assessment criteria are as follows.

Grade	**Characteristics**
0	No increase in muscle tone when the affected limb is moved. (No increase in muscle tone)
1	When the affected limb is flexed and extended, slight resistance is felt at the end of the range of motion, and muscle tone shows a slight increase. (slight increase at the final stage of ROM)
1+	When the affected limb is moved, slight resistance is felt from the latter half (below 1/2) of the range of motion, and muscle tone shows a slight increase. (slight increase within the latter 50% of ROM)
2	A more marked increase in muscle tone through most of the range of motion, but the affected limb is easily moved. (appears throughout the ROM; passive movement is possible)
3	A considerable increase in muscle tone; passive movement is difficult. (passive movement is difficult)
4	The affected limb is rigid; passive movement is impossible. (rigidity in extension and flexion)

Joint Spasticity Assessment Sheet

Joint	Muscle	Right	Left	Joint	Muscle	Right	Left
Hip	Flexors			Knee	Flexors		
	Extensors				Extensors		
	Abductors			Ankle	Dorsi-flexors		
	Adductors				Plantar-flexors		
	Int. rotators			Foot	Invertors		
	Ext. rotators				Evertors		

C. Functional Ambulation Category (FAC) assessment9

This is performed to assess the subject's postural stability during gait, and the assessor observes the subject's gait and records it according to the criteria below.

Level	Description
0	Ambulation is not possible, or requires assistance from 2 or more persons
1	Requires continuous support from 1 person to maintain balance or to shift body weight
2	Requires intermittent assistance from 1 person to help with balance or coordination
3	Requires supervision or verbal cueing, without physical contact
4	Can walk independently on level ground, but requires assistance on stairs, slopes, or uneven/unstable surfaces
5	Can walk independently

D. Korean Mini-Mental State Examination (K-MMSE)10

This is a standardized assessment tool for evaluating the subject's cognitive function and the presence of cognitive decline, and can be assessed within a short time. The assessment consists of orientation, registration, attention and calculation, recall, language function, and visuospatial construction ability, and the examiner asks the subject questions or presents tasks according to the assessment items and records the score based on the responses.

Item	Score	Content
I. Orientation to time	5	1. Year 2. Month 3. Day 4. Day of the week 5. Season (1 point each)
II. Orientation to place	5	1. Country 2. Province/City 3. Name of the current place 4. Floor 5. Type of place (1 point each)
III. Registration	3	Airplane, Pencil, Pine tree (1 point each)
IV. Attention and calculation	5	Serial subtraction of 7: 100-7, -7, -7, -7, -7 (1 point each)
V. Recall	3	Airplane, Pencil, Pine tree (1 point each)
VI. Language	8	1. Naming (2): (wrist)watch, ballpoint pen 2. 3-stage command (3): “Take the paper, fold it in half, and give it to me” 3. Repetition (1): “Seeing once is better than hearing a hundred times”

		4. Read and obey (1): “Close your eyes” 5. Writing (1): write a sentence about today’s mood or weather
VII. Visuospatial construction	1	Copy the figure (1): intersecting pentagons
Total	30	

(2) Assessment Indicators Before and After the Intervention Program

Before and after the intervention program, the research staff administers the following tests or questionnaires to the subject at the subject's home. The pre-intervention assessment is performed before the start of the intervention in the first session, and the end-of-study assessment is performed after the end of the last session, session 4.

1) Primary Assessment Indicator

① TUQ (Telehealth Usability Questionnaire)

At the end of the intervention, the usability of the powered orthopedic exercise device is assessed using a questionnaire constructed based on the Telehealth Usability Questionnaire (TUQ) items.11

The TUQ is a tool developed to assess the usability of telehealth implementations and services; it was constructed by integrating items from telehealth-related questionnaires and computer usability questionnaires, and includes usefulness, ease of use and learnability, interface quality, interaction quality, reliability, satisfaction and future use.12

Response format: Strongly disagree (1) - Disagree (2) - Neutral (3) - Agree (4) - Strongly agree (5)

Usefulness		1	2	3	4	5
1	This home-based rehabilitation service helped me access rehabilitation therapy without visiting a medical institution.					
2	This home-based rehabilitation service saved me the time of traveling to a hospital or clinic.					
3	This home-based rehabilitation service met my rehabilitation needs.					
Ease of Use and Learnability						
4	This system (device and service) was simple to use.					
5	It was easy to learn how to use this system (device and service).					
6	I was able to become skilled at using this system quickly					
Interface and Device Operation Quality						
7	The way of interacting with this system was pleasant.					
8	I liked using this system.					
9	This system was designed to be easy to understand and simple.					
10	This system had all the functions I wanted					

Quality of Interaction with the Therapist						
11	Through this service, I was able to communicate smoothly with the therapist.					
12	Through this service, I was able to clearly hear the therapist's guidance and explanations					
13	Through this service, I was able to sufficiently convey my condition and opinions to the therapist.					
14	The interaction with the therapist through this service felt similar to an in-person interaction.					
Ease of Use and Learnability						
15	I think the treatment visit through this service was of the same level as visiting the hospital in person.					
16	When a mistake occurred during use of the device, I was able to easily correct or recover from it.					
17	When a problem occurred, the system or service clearly indicated how to resolve it.					
Interface and Device Operation Quality						
18	Through this service, I was able to communicate comfortably with the therapist.					
19	I think the home-based rehabilitation service is an acceptable way to receive treatment.					
20	I am willing to use this home-based rehabilitation service again in the future.					
21	Overall, I am satisfied with this home-based rehabilitation service.					

3) Secondary Assessment Indicators

① 2-Minute Walk Test

The 2-Minute Walk Test is a clinical assessment method for evaluating the subject's gait endurance and functional gait ability, and is useful for identifying changes in gait performance before and after the intervention by measuring the total distance walked over a set time.13 Measurement is performed by having the subject walk for 2 minutes at a comfortable speed and then recording the total distance traveled during that time in meters (m). During the test, the subject may sit or stand to rest partway through if necessary, and if an assistive device is needed, the assistive device normally used is applied identically. In this study, the 2-Minute Walk Test is performed under identical conditions before and after the intervention to compare the change in total walking distance. In addition, during the 2-Minute Walk Test, gait analysis is also performed using the gait analysis program mounted on the robot, and hip kinematics are measured. The assessment is performed both with assistive force provided and with assistive force removed after donning the robot, for a total of two measurements.



② Spatiotemporal Parameters of Gait

These are spatiotemporal gait parameter data collected while the subject wears an insole-type gait analyzer and performs the activity during assessment; the left/right total step count, cadence, gait speed, walking distance, stride length, and swing ratio are recorded.

1) Step count: Steps measured while walking

2) Cadence: The number of steps measured over 1 minute, in units of Steps/min (spm); normal is 70 steps/min or more for those under 65 years and 60 steps/min or more for those 65 years and older.

3) Gait speed: The speed of walking, in units of km/h; normal is 2.0 km/h or more for those under 65 years and 1.5 km/h or more for those 65 years and older.

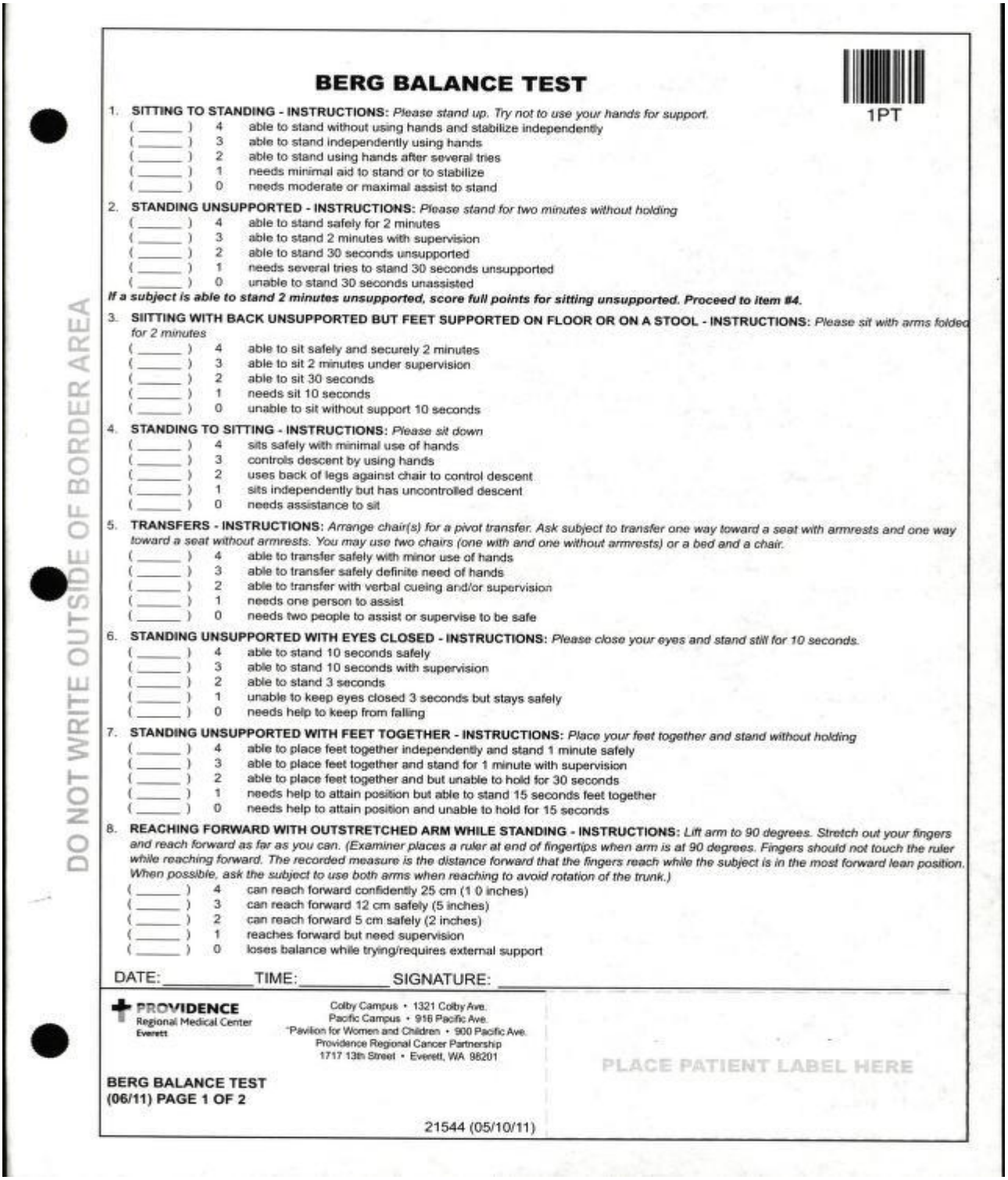
4) Distance: The total distance traveled measured during walking (unit: m)

5) Stride length: Represents the distance from one heel to the same heel. The unit of distance is m, and to correct for differences arising from height, stride length is calculated by dividing by height; normal is 0.5 m/height or more for those under 65 years and 0.4 m/height or more for those 65 years and older.

6) Swing ratio: The proportion of the swing phase within one gait cycle, in units of %; normal is 30% or more for those under 65 years and 28% or more for those 65 years and older.

③ Berg Balance Scale

This test assesses static and dynamic balance14 and has been used in previous studies as a test to evaluate outcomes after robot-assisted gait therapy.15 The examiner instructs the subject to perform the following 14 movements and then scores each according to its scoring criteria. Scores are rated from 0 to 56 points.



DO NOT WRITE OUTSIDE OF BORDER AREA

BERG BALANCE TEST

1PT

1. **SITTING TO STANDING - INSTRUCTIONS:** *Please stand up. Try not to use your hands for support.*
   (_____) 4 able to stand without using hands and stabilize independently
   (_____) 3 able to stand independently using hands
   (_____) 2 able to stand using hands after several tries
   (_____) 1 needs minimal aid to stand or to stabilize
   (_____) 0 needs moderate or maximal assist to stand
2. **STANDING UNSUPPORTED - INSTRUCTIONS:** *Please stand for two minutes without holding*
   (_____) 4 able to stand safely for 2 minutes
   (_____) 3 able to stand 2 minutes with supervision
   (_____) 2 able to stand 30 seconds unsupported
   (_____) 1 needs several tries to stand 30 seconds unsupported
   (_____) 0 unable to stand 30 seconds unassisted

If a subject is able to stand 2 minutes unsupported, score full points for sitting unsupported. Proceed to item #4.

3. **SIITTING WITH BACK UNSUPPORTED BUT FEET SUPPORTED ON FLOOR OR ON A STOOL - INSTRUCTIONS:** *Please sit with arms folded for 2 minutes*
   (_____) 4 able to sit safely and securely 2 minutes
   (_____) 3 able to sit 2 minutes under supervision
   (_____) 2 able to sit 30 seconds
   (_____) 1 needs sit 10 seconds
   (_____) 0 unable to sit without support 10 seconds
4. **STANDING TO SITTING - INSTRUCTIONS:** *Please sit down*
   (_____) 4 sits safely with minimal use of hands
   (_____) 3 controls descent by using hands
   (_____) 2 uses back of legs against chair to control descent
   (_____) 1 sits independently but has uncontrolled descent
   (_____) 0 needs assistance to sit
5. **TRANSFERS - INSTRUCTIONS:** *Arrange chair(s) for a pivot transfer. Ask subject to transfer one way toward a seat with armrests and one way toward a seat without armrests. You may use two chairs (one with and one without armrests) or a bed and a chair.*
   (_____) 4 able to transfer safely with minor use of hands
   (_____) 3 able to transfer safely definite need of hands
   (_____) 2 able to transfer with verbal cueing and/or supervision
   (_____) 1 needs one person to assist
   (_____) 0 needs two people to assist or supervise to be safe
6. **STANDING UNSUPPORTED WITH EYES CLOSED - INSTRUCTIONS:** *Please close your eyes and stand still for 10 seconds.*
   (_____) 4 able to stand 10 seconds safely
   (_____) 3 able to stand 10 seconds with supervision
   (_____) 2 able to stand 3 seconds
   (_____) 1 unable to keep eyes closed 3 seconds but stays safely
   (_____) 0 needs help to keep from falling
7. **STANDING UNSUPPORTED WITH FEET TOGETHER - INSTRUCTIONS:** *Place your feet together and stand without holding*
   (_____) 4 able to place feet together independently and stand 1 minute safely
   (_____) 3 able to place feet together and stand for 1 minute with supervision
   (_____) 2 able to place feet together and but unable to hold for 30 seconds
   (_____) 1 needs help to attain position but able to stand 15 seconds feet together
   (_____) 0 needs help to attain position and unable to hold for 15 seconds
8. **REACHING FORWARD WITH OUTSTRETCHED ARM WHILE STANDING - INSTRUCTIONS:** *Lift arm to 90 degrees. Stretch out your fingers and reach forward as far as you can. (Examiner places a ruler at end of fingertips when arm is at 90 degrees. Fingers should not touch the ruler while reaching forward. The recorded measure is the distance forward that the fingers reach while the subject is in the most forward lean position. When possible, ask the subject to use both arms when reaching to avoid rotation of the trunk.)*
   (_____) 4 can reach forward confidently 25 cm (1 0 inches)
   (_____) 3 can reach forward 12 cm safely (5 inches)
   (_____) 2 can reach forward 5 cm safely (2 inches)
   (_____) 1 reaches forward but need supervision
   (_____) 0 loses balance while trying/requires external support

DATE:_____TIME:_____ SIGNATURE: _____

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BERG BALANCE TEST
(06/11) PAGE 1 OF 2

21544 (05/10/11)

BERG BALANCE TEST

1PT

1. **SITTING TO STANDING - INSTRUCTIONS:** *Please stand up. Try not to use your hands for support.*
   (_____) 4 able to stand without using hands and stabilize independently
   (_____) 3 able to stand independently using hands
   (_____) 2 able to stand using hands after several tries
   (_____) 1 needs minimal aid to stand or to stabilize
   (_____) 0 needs moderate or maximal assist to stand

2. **STANDING UNSUPPORTED - INSTRUCTIONS:** *Please stand for two minutes without holding*
   (_____) 4 able to stand safely for 2 minutes
   (_____) 3 able to stand 2 minutes with supervision
   (_____) 2 able to stand 30 seconds unsupported
   (_____) 1 needs several tries to stand 30 seconds unsupported
   (_____) 0 unable to stand 30 seconds unassisted

If a subject is able to stand 2 minutes unsupported, score full points for sitting unsupported. Proceed to item #4.

3. **SIITTING WITH BACK UNSUPPORTED BUT FEET SUPPORTED ON FLOOR OR ON A STOOL - INSTRUCTIONS:** *Please sit with arms folded for 2 minutes*
   (_____) 4 able to sit safely and securely 2 minutes
   (_____) 3 able to sit 2 minutes under supervision
   (_____) 2 able to sit 30 seconds
   (_____) 1 needs sit 10 seconds
   (_____) 0 unable to sit without support 10 seconds

4. **STANDING TO SITTING - INSTRUCTIONS:** *Please sit down*
   (_____) 4 sits safely with minimal use of hands
   (_____) 3 controls descent by using hands
   (_____) 2 uses back of legs against chair to control descent
   (_____) 1 sits independently but has uncontrolled descent
   (_____) 0 needs assistance to sit

5. **TRANSFERS - INSTRUCTIONS:** *Arrange chair(s) for a pivot transfer. Ask subject to transfer one way toward a seat with armrests and one way toward a seat without armrests. You may use two chairs (one with and one without armrests) or a bed and a chair.*
   (_____) 4 able to transfer safely with minor use of hands
   (_____) 3 able to transfer safely definite need of hands
   (_____) 2 able to transfer with verbal cueing and/or supervision
   (_____) 1 needs one person to assist
   (_____) 0 needs two people to assist or supervise to be safe

6. **STANDING UNSUPPORTED WITH EYES CLOSED - INSTRUCTIONS:** *Please close your eyes and stand still for 10 seconds.*
   (_____) 4 able to stand 10 seconds safely
   (_____) 3 able to stand 10 seconds with supervision
   (_____) 2 able to stand 3 seconds
   (_____) 1 unable to keep eyes closed 3 seconds but stays safely
   (_____) 0 needs help to keep from falling

7. **STANDING UNSUPPORTED WITH FEET TOGETHER - INSTRUCTIONS:** *Place your feet together and stand without holding*
   (_____) 4 able to place feet together independently and stand 1 minute safely
   (_____) 3 able to place feet together and stand for 1 minute with supervision
   (_____) 2 able to place feet together and but unable to hold for 30 seconds
   (_____) 1 needs help to attain position but able to stand 15 seconds feet together
   (_____) 0 needs help to attain position and unable to hold for 15 seconds

8. **REACHING FORWARD WITH OUTSTRETCHED ARM WHILE STANDING - INSTRUCTIONS:** *Lift arm to 90 degrees. Stretch out your fingers and reach forward as far as you can. (Examiner places a ruler at end of fingertips when arm is at 90 degrees. Fingers should not touch the ruler while reaching forward. The recorded measure is the distance forward that the fingers reach while the subject is in the most forward lean position. When possible, ask the subject to use both arms when reaching to avoid rotation of the trunk.)*
   (_____) 4 can reach forward confidently 25 cm (1 0 inches)
   (_____) 3 can reach forward 12 cm safely (5 inches)
   (_____) 2 can reach forward 5 cm safely (2 inches)
   (_____) 1 reaches forward but need supervision
   (_____) 0 loses balance while trying/requires external support

DATE:_____ TIME:_____ SIGNATURE: _____

DO NOT WRITE OUTSIDE OF BORDER AREA

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21544 (05/10/11)

Total: _____ / 56

A. Home-Based Robot-Assisted Gait Training

The subject's robot-assisted gait training is conducted together with the research staff (physical therapist or occupational therapist) in accordance with the prescription and guidance of a rehabilitation medicine specialist, as follows. The gait training program begins on the initial assessment day and is conducted at the home or in an indoor space similar to the home environment; transportation support such as a vehicle is not provided.

1) Warm-up Exercise Before Donning

The subject performs 5 minutes of stretching exercises before donning the powered orthopedic exercise device gait-assist robot.

2) Application of the Powered Orthopedic Exercise Device

The powered orthopedic exercise device, the medical device used in this study, is equipment that assists hip joint movement during gait; the assessor applies this equipment to the subject and conducts gait training. The robot is driven by power supplied from a rechargeable battery, and the actuator can be controlled by setting assistance parameters through a mobile device. Power supplied from the battery operates the main controller, and the main controller controls the wearable part connected to the actuator based on angle information obtained from the encoder of the drive unit and the inertial measurement unit (IMU). This device receives commands from a mobile device connected via Bluetooth communication and performs the function of assisting flexion and extension of the hip joint. The therapist conducts training with the goal of walking for as long as possible in a pattern as close to normal gait as possible. The gait training program is conducted for 30 minutes per session, twice a week, for a total of 4 sessions over 2 weeks.16 The interval between each intervention visit is set not to exceed 5 days.

All training sessions are conducted under the supervision of 2 members of the research staff (physical therapist or occupational therapist); if a 30-minute session cannot be continued due to reasons such as the subject's reduced muscular endurance or pain, gait training is ended, and the actual session time performed and the reason for early termination are recorded.

3) Recording Adverse Reactions and Device Malfunctions

- The research staff (physical therapist or occupational therapist) records the type and number of occurrences of safety incidents that arise while the subject is performing gait training, the reasons for device malfunctions, etc
- Even when an adverse effect such as pain occurs, the type, severity, and number of occurrences of the adverse effect, the adverse reaction name, the date of onset/resolution, the pattern of the adverse effect, the causal relationship, are investigated and recorded.

(4) Satisfaction Assessment

The subject completes a satisfaction assessment questionnaire for the home-based rehabilitation service using the robot-assisted orthopedic exercise device, consisting of 12 items on a 5-point scale based on the Korean version of the assistive technology device satisfaction assessment (K-QUEST 2.0).17 This questionnaire consists of 12 items for assessing satisfaction, and satisfaction with the assistive device and the services used in relation to it is indicated on the 1-5 point scale below. The subject is instructed to provide a reason if any item other than “very satisfied” is entered.

1: Very dissatisfied. 2: Dissatisfied 3: Neutral 4: Satisfied. 5: Very satisfied

Severance: H10_home_20260518

	1	2	3	4	5
Are you satisfied with the dimensions (size, height, length, width) of the powered orthopedic exercise device? Reason: _____					
How is the weight of the powered orthopedic exercise device? Reason: _____					
Is it convenient to adjust (fix and lock) parts (accessories) of the powered orthopedic exercise device? Reason: _____					
Do you think the powered orthopedic exercise device is safe and sturdy? Reason: _____					
Are you satisfied with the durability (usable over a long period) of the powered orthopedic exercise device? Reason: _____					
Was the method of using the powered orthopedic exercise device convenient? Reason: _____					
Do you think wearing the powered orthopedic exercise device is comfortable? Reason: _____					
Are you satisfied with the effectiveness (effect suited to the intended use) of the powered orthopedic exercise device? Reason: _____					
Are you satisfied with the service and delivery program (delivery process, time required) of the powered orthopedic exercise device? Reason: _____					
Are you satisfied with the repair and maintenance service of the powered orthopedic exercise device? Reason: _____					
Are you satisfied with the professional services (information, precautions) provided while using the powered orthopedic exercise device? Reason: _____					
Are you satisfied with the after-sales service (ongoing management service) of the powered orthopedic exercise device? Reason: _____					

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

	Mark with O
1. Dimensions	
2. Weight	
3. Convenience	

4. Safety	
5. Durability	
6. Usability	
7. Comfort	
8. Effectiveness	
9. Service delivery	
10. Repair and maintenance service	
11. Professional service	
12. After-sales management service	

(5) Definition of the Data Analysis Population and Plan for Handling Missing Values and Outliers

1) Definition of the Data Analysis Population

The data analysis population is the group of all subjects who receive robot-assisted gait training, and analysis is conducted on the gait parameter data extracted from them, together with age, diagnosis, and physical function assessments.

2) Plan for Handling Missing Values and Outliers

When missing values arise due to discontinuation of study participation or dropout, they are handled using an analysis method that uses only completely observed cases (Complete Case Analysis). That is, data from sessions in which missing values occurred are excluded from the analysis. Outliers identified using box plots and quartiles are also excluded from the analysis to maintain data completeness and enhance the accuracy and reliability of the study, and information on the subjects excluded from the analysis is presented.

(6) Comparative Analysis of Pre-Post Differences

After the gait training program using the powered orthopedic exercise device is completed and the end-of-study assessment and satisfaction survey are conducted, the assessor performs a comparative analysis of the collected subject data.

11. Study Procedures and Assessment

Phase	Screening	Intervention and Assessment			
Visit	**1**	**2**	**3**	**4**	**5**
Written consent form	O				
Inclusion/exclusion criteria	O				
Demographic information and past history	O				
Primary endpoint assessment					
TUQ (Telehealth Usability Questionnaire)					O
Secondary endpoint assessment					
2-Minute Walk Test (with robot assistive force provided/removed)		O			O
Spatiotemporal parameters of gait					
Berg Balance Scale					
Satisfaction with robot-assisted gait rehabilitation therapy					O
At-home robot-assisted gait training		O	O	O	O

12. Anticipated Adverse Effects and Precautions for Use

(1) Anticipated Adverse Effects

The powered orthopedic exercise device used in this study may cause musculoskeletal pain or skin abrasions, and although none have been reported, theoretically there is also a possibility of falls. In addition, dizziness or bruising at the site of wear may occur due to prolonged gait training using the device.

Accordingly, the following safety mechanisms and precautions for use are intended to minimize adverse effects. Nevertheless, an unexpected response of the actuator may disrupt the walking rhythm, causing fatigue and discomfort; in such cases the investigator will operate the emergency switch to stop control, thereby stopping the generation of assistive force. Although there is a potential risk of musculoskeletal injury that may occur from losing balance and falling during this process, before gait training the investigators are thoroughly familiarized with how to don and doff the device in preparation for hazardous situations, and during gait training the researcher continuously stays with the subject while holding the handle of the powered orthopedic exercise device throughout the training process to prepare for the risk of falls. When the risk of a fall increases, a fall can be prevented by firmly gripping the handle of the powered orthopedic exercise device. In any case, a mechanical joint-range-of-motion limiting device is installed on the powered orthopedic exercise device so that no strain is placed on the joints.

If an adverse event occurs, the test will be stopped and reported to the researcher so that first aid can be administered, and the subject will be excluded from the test and this will be reported.

(2) Precautions for Use

1) General Precautions

- Use the product only after accurately understanding how to use it.
- Since this product is not water-resistant, take care to avoid malfunction due to water or other liquids.
- Use the product after properly donning all wearable parts.
- Depending on the patient's condition, use the product together with gait-assist aids such as a walker, forearm crutches, or a manual body-weight-support gait trainer.
- When the product is not in use, always turn off the power and store it with the battery removed.

2) Precautions Before Use

- Before donning the product, first check the patient's condition, skin condition.
- Don the product after wearing appropriate clothing and footwear.
- When donning the product, take care that the wearable parts do not excessively compress the body.
- Check that the size of the product has been properly adjusted.
- Before operating the product, check that the remaining battery level is sufficient.

3) Precautions for Use

- Always use the product in accordance with the method of use.
- Operate the product after checking that the wearable parts are properly worn.
- If you stop operation during use, always inform the patient first.
- During use, periodically check the condition of the patient and the product, and if there is any abnormality, stop using it.
- In an emergency situation, promptly stop operation of the product and remove the battery.
- If the red light on the battery indicator comes on, stop use and replace it with a charged battery.

4) Precautions After Use

- After removing the product, check the condition of the skin that the wearable parts contacted and whether there is any pain.
- Check the condition of the product.
- After use, check that the power of the mobile app and the product has been turned off.
- After use, terminate the Bluetooth communication with the mobile device.

5) Precautions for Storage and Charging

- Charge the battery by installing it in the correct orientation.
- Take care that water or liquids do not come into contact with the battery and charger.
- If overheating occurs during battery charging, immediately stop charging and disconnect the power.
- If damage occurs to the exterior of the battery or charger, stop use.
- When the battery is fully charged, disconnect it from the charger.
- When the battery charger is not in use, disconnect it from the outlet and store it.
- Do not place it near hot objects such as fire or heaters.
- Do not store it in a location exposed to direct sunlight or in a hot and humid place.
- Do not store it in an environment with excessively low temperature.
- Do not store it in a location affected by magnets or magnetism.
- When not in use for a long period, store it with the battery removed.

13. Criteria for Study Discontinuation and Withdrawal

If a subject participating in this clinical trial discontinues study participation, only the information of the study subject collected up to that point will be used in the study, and it will be stored for 3 years after the end of the study and then destroyed.

(1) Completion and Early Discontinuation

1) When a subject participating in the study or their legal representative withdraws consent before the end of the study

- If consent is withdrawn, only the information of the participant collected up to that point will be used in the study, and it will be stored for 3 years after the end of the study and then destroyed

2) When a serious adverse effect occurs

(2) Withdrawal

The participant's voluntary intention to withdraw is reconfirmed to ensure that the discontinuation is not premature. If the participant is still willing to provide their information to the study, the data collected up to the point of withdrawal may be anonymized and used in the study.

1) When medical staff determine that the subject has a serious medical need that precludes continuation of the clinical study
2) When surgery, medication, or another medical device that may affect the safety or effectiveness assessment is used concomitantly
3) When the subject fails to comply with the investigator's instructions or does not adhere to the matters set forth in the consent form, thereby affecting the effectiveness assessment
4) When continuous observation is not possible due to the subject's non-participation
5) When the principal investigator otherwise determines that there is a problem with conducting the clinical trial

(3) Handling of Discontinuation and Withdrawal

1) When a study subject withdraws, the reason for withdrawal and the clinical trial-related data collected up to withdrawal are recorded and stored
2) If a study subject refuses or is unable to proceed with a home visit during the trial, the well-being of the study subject must be confirmed and the reason clarified
3) A subject who has withdrawn is included in the statistical processing for the effectiveness and safety assessments unless there is a valid reason or basis

14. Criteria, Methods, and Reporting Methods for Safety Assessment Including Adverse Reactions

(1) Assessment Criteria

For the safety of participants, this study plans to have the principal investigator perform monitoring as a safety monitor and assess safety.

1) Symptoms reported by the subject regarding adverse reactions occurring during or after the intervention in the study subject (e.g., whether there is musculoskeletal pain or skin lesions during gait training)
2) Physical examination (e.g., whether there are musculoskeletal abnormalities and skin lesions (erythema, edema, etc.) at the site of application of the robot-assisted orthopedic exercise device)
3) Safety assessment related to falls
   - Number of falls
   - Level of injury sustained by the subject due to a fall (simple contusion, fracture, other injury, etc.)
   - Other

(2) Assessment Method

1) A statistical analysis is performed to assess the severity and type of adverse reactions reported by the subject or identified by physical examination, and the frequency, type, and severity of adverse reactions occurring in the study subject.
2) The safety analysis is performed at a significance level of < 0.05 (two-sided).

(3) Adverse Event Reporting

1) Reporting scope: All subjects participating in this clinical trial
2) Adverse Event Assessment Criteria
   - The cause of an adverse event is assessed according to the following criteria.

   A. Medical Device Problem

      When an adverse event occurs due to malfunction, failure, or damage of the medical device even though it was used in compliance with the manufacturer's intended purpose, method of use, and precautions

   B. Procedural Problem

When the medical device was used normally and there was no problem with the patient's condition or underlying disease, but an adverse event occurred due to the operator's procedure

C. Patient Problem

When the medical device was used normally and there was no problem with the operator's procedure, but an adverse event occurred due to the patient's condition or underlying disease

D. Unassessable

When the adverse event report content does not match the actual product, or when the cause of occurrence cannot be identified because multiple causes acted in combination

3) Adverse Event Assessment Method

- The clinical trial personnel ensure that, when an adverse reaction occurs in a subject during the clinical trial, the symptoms of the adverse reaction, the date of onset, the date of resolution, can be recorded on the adverse reaction record form.

4) Adverse Event Reporting Method

- This content is reported in accordance with the regulations related to medical device clinical trials, the standard operating procedures (SOPs) stipulated by the medical device clinical trial institution, and the IRB regulations of this hospital.

I. Definition of Terms

- "Safety information" means data or information related to the safety and effectiveness of a licensed, certified, or notified medical device, including cases of adverse-effect occurrence.
- "Adverse-effect information" means cases of adverse effects of a medical device that have occurred domestically or abroad during the handling or use of the medical device, or cases in which the occurrence of adverse effects is of concern.
- "Side effect" means, among adverse-effect information, any unintended result that occurs or is suspected to have occurred due to normal use of the medical device, and includes unintended desirable results.
- "Adverse event" means an undesirable result among side effects, and does not necessarily have to have a causal relationship with the relevant medical device.
- "Serious adverse event" means an adverse event that falls under any one of the following items.
  I. A case resulting in death or a life-threatening adverse effect
  II. A case requiring hospitalization or prolongation of hospitalization
  III. A case resulting in irreversible or serious disability or functional decline
  IV. A case resulting in a congenital anomaly or defect
- "Unexpected adverse event" means an adverse event that differs in severity, specificity, or outcome compared with the matters licensed, certified, or notified for the medical device

II. The safety assessment criteria refer to the assessment criteria used because, when an anticipated adverse effect or adverse reaction occurs, its severity must be assessed and recorded on the case report form.

III. The safety assessment method presents the statistical analysis method and assessment criteria for comparative assessment of the study group regarding adverse effects, adverse medical device reactions, and the incidence of adverse reactions associated with the investigational medical device.

IV. Adverse Reaction Reporting

- Serious adverse reactions at each institution must be reported by electronic mail to the clinical trial coordinator and monitoring personnel within 48 hours from the point of awareness.
- The principal investigator must report serious adverse reactions to the institutional IRB in accordance with the institutional IRB regulations, and must provide an additional written report containing detailed information in accordance with the protocol.
- In the case of a death or a life-threatening event, the sponsoring institution must report to the Minister of Food and Drug Safety within 7 days from the date the principal investigator is informed of or becomes aware of this fact, and in the case of other serious and unexpected adverse reactions, within 15 days from the date the principal investigator is informed of or becomes aware of this fact.

(4) Monitoring Plan for Subjects Who Experience an Adverse Event

1) As an exploratory case study with little need for separate procedures or invasive interventions and thus a low level of study risk, monitoring is performed once a week under the management and supervision of the principal investigator, and source documents, CRFs, protocols, are cross-checked to ensure data completeness and to review the safety data of study subjects.
2) For subjects who experience an adverse event, compensation will be provided in accordance with the subject-compensation provisions of this study protocol, and the course of treatment will be monitored until resolution of the adverse reaction or until the subject's scheduled end of the study.
3) For subjects who experience an adverse event, unless the subject refuses follow-up observation, the course of the adverse event that occurred is observed through the subject's reported symptoms and physical examination at the scheduled study visit.
4)

As an exploratory case study with little need for separate procedures or invasive interventions and thus a low level of study risk, monitoring will be performed once a week under the management and supervision of the principal investigator, and source documents, CRFs, protocols, will be cross-checked to ensure data completeness and to review the safety data of participants.

Participants in the study may decide to discontinue participation at any time when they feel discomfort about the study, and when obtaining consent from the participant, the principal investigator or study personnel sufficiently explain this and obtain confirmation.

In the event of a violation or deviation regarding this study, the situation of occurrence, the researcher's measures for it, and measures to prevent recurrence will be promptly reported in writing to the IRB.

If a subject is injured or a new event occurs during the performance of assessments, immediate treatment and observation will be provided, thorough examination of the cause will be conducted, and treatment will be provided in accordance with the hospital's standard procedures. This will also be reported in interim reports and described in the research paper. However, judging that the possibility of subsequent adverse effects in this study is low, research funding for additional treatment costs was not budgeted.

15. Data Analysis and Statistical Considerations

(1) Subject characteristics: The general characteristics of subjects are analyzed using descriptive statistics. Continuous variables are presented as means and standard deviations. Categorical variables are presented as frequencies and percentages.

(2) Primary endpoint: As an exploratory study to explore the effectiveness and safety of home-based robot-assisted gait training, the TUQ (Telehealth Usability Questionnaire) is set as the primary endpoint. At the end of the intervention, the usability of the powered orthopedic exercise device is assessed using a questionnaire constructed based on the Telehealth Usability Questionnaire (TUQ) items. The TUQ is a tool developed to assess the usability of telehealth implementations and services; it was constructed by integrating items from telehealth-related questionnaires and computer usability questionnaires, and includes usefulness, ease of use and learnability, interface quality, interaction quality, reliability, satisfaction and future use. The TUQ results are analyzed using descriptive statistics, and the mean, standard deviation, median, minimum, and maximum are calculated for each item and for the total score.

(3) Secondary endpoints: The walking distance and spatiotemporal gait parameters, hip kinematics, and Berg Balance Scale calculated by performing the 2-Minute Walk Test before the start of the intervention in session 1 and after the end of the intervention in session 4 of robot-assisted gait rehabilitation therapy are compared and analyzed using the Wilcoxon signed-rank test, with statistical significance set at a p-value less than 0.05. At this time, both the median and quartiles and the mean and standard deviation are confirmed as descriptive statistics.

(4) Satisfaction assessment: The satisfaction results for home-based robot-assisted gait training are analyzed using descriptive statistics to calculate the mean, standard deviation, minimum, and maximum of each item. For each item, a mean value of 4 points or higher is interpreted as a positive evaluation, and 2 points or lower as a negative evaluation.

16. Measures for Personal Information Protection and Maintaining the Confidentiality of Study Data

(1) Protection of the Subject's Personal Identity

When seeking consent for the study, the study is explained to the subject and consent is obtained in an independent space in the counseling room within the rehabilitation medicine outpatient department.

All information collected from this study is kept from being disclosed to persons other than the research staff involved in the study and is used only for research purposes. Sensitive personal information that can identify an individual is not shared with institutions outside the hospital and will undergo a de-identification process. De-identification is carried out by using a subject-specific number for the robot-assisted orthopedic exercise device, and data collected through the application are stored in accordance with the security policy of the medical device company and will be destroyed after the end of the study; they will also be received from the medical device company after being processed to make individual identification impossible. Cases of re-identification are limited to those necessary in relation to the individual's treatment. Only the final results of the analysis are disclosed to the medical device company, and ownership of the data belongs to the hospital.

(2) Maintaining the Confidentiality of Study Data

In the case of paper documents, they will be stored in a locking mechanism so as not to be exposed to others and stored on a computer with restricted access, to be managed by the responsible researcher.

(3) Preservation of Records

Study-related data are stored for 3 years in accordance with the Enforcement Rule of the Bioethics and Safety Act (a person conducting human-subject research must retain the records under Paragraph 1 for 3 years from the point at which the research ends), and among documents whose retention period has passed, matters concerning personal information are destroyed in accordance with Article 16 of the Enforcement Decree of the Personal Information Protection Act. However, if retention of the relevant data is necessary for follow-up research, accumulation of records, the retention period is extended following review by the institutional review board.

17. Measures for Management, Storage, and Disposal When Collecting Human-Derived Materials, Genetic Information, etc.

This study does not collect human-derived materials or genetic information.

18. Subject Recruitment Method and Consent Procedure

After approval by the Yongin Severance Hospital IRB, subjects who, among visitors to Yongin Severance Hospital, decide to voluntarily participate in this study and consent are interviewed in an independent space, provided with the subject information sheet approved by the IRB, and their written consent is obtained.

After sufficient explanation about participation in the clinical trial, the consent form is completed in a coercion-free environment, and the subject is informed at the time of completing the consent form that withdrawal of consent by their own will is possible at any time, so that they participate in the clinical trial. In addition, the intention to participate in the study is confirmed during the study tests, so that withdrawal of consent is possible at any time by the person's own will.

19. Protection Measures When Recruiting Vulnerable Subjects

This study does not recruit vulnerable subjects.

20. Information on the Principal Investigator and Participating Research Staff, Study Site, and Study Period

(1) Principal Investigator

Name	Affiliated Institution	Specialty	Position	Telephone
Kim Na Young	Yonsei University College of Medicine Yongin Severance Hospital	Rehabilitation Medicine	Assistant Professor	031-5189-8163 Kny8452@yuhs.ac

(2) Sub-Investigator

The sub-investigator confirms at the trial institution whether subjects meet the inclusion criteria and manages the overall process of the trial.

Name	Affiliated Institution	Specialty	Position	Telephone
Kim Na Young	Yonsei University College of Medicine Yongin Severance Hospital	Rehabilitation Medicine	Assistant Professor	031-5189-8163 Kny8452@yuhs.ac
Yang Hwi-woo	Yonsei University Industry-Academic Cooperation Foundation	Occupational Therapy	Researcher	010-7360-4439 rehab5@yuhs.ac
Lee So-Young	Yonsei University Industry-Academic Cooperation Foundation	Occupational Therapy	Researcher	010-9236-8499 rehab9@yuhs.ac

(3) Medical Device Manager

Name	Affiliated Institution	Position	Telephone
Yang Hwi-woo	Yonsei University Industry-Academic Cooperation Foundation	Researcher	010-7360-4439 rehab5@yuhs.ac

21. Study Site and Period

(1) Study Site

Institution Name	Location	Telephone
Yonsei University College of Medicine Yongin Severance Hospital	363 Dongbaekjukjeon-daero, Giheung-gu, Yongin-si, Gyeonggi-do (Jung-dong)	031-5189-8891

(2) Period

12 months after IRB approval

22. Data Safety Monitoring Plan

The safety monitor (principal investigator) monitors, at 1-month intervals, the overall progress of the study, including the study's progress status, the eligibility of enrolled subjects against the inclusion criteria, the appropriateness of the consent acquisition procedure, whether any protocol violations/deviations have occurred, and whether any subject adverse reactions have occurred, in order to ensure data completeness.

23. Study Execution Plan (Schedule)

Detailed Development Content	**Detailed Implementation Schedule (months)**											
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
Study planning and IRB approval	■											
Subject recruitment	■	■	■	■	■	■	■	■	■	■	■	
Performance of study procedures and follow-up observation period	■	■	■	■	■	■	■	■	■	■	■	■

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