Severerance: M20_20240805

Prospective Clinical Study Protocol

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

2024.08.05

[Severance Hospital]

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Prospective Clinical Study Protocol

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

- Title: Study to verify effectiveness and safety of at-home gait rehabilitation using wearable exoskeletal robot to improve gait in stroke patients, Investigator Initiated, Single center, Single group trial
- Stage: phase 4

2. Summary of study plan

Study objective	To evaluate the feasibility of a home-based robotic-assisted gait rehabilitation service using wearable exoskeletal robot for stroke patients
Study design overview	Investigator-initiated exploratory clinical study 4 weeks, pilot study
Drugs/medical devices for clinical trials	Wearable exoskeletal robot
Target number of subjects and calculation basis	Sixteen patients diagnosed with stroke This study aims to provide robotic-assisted gait training using wearable exoskeletal robot either at home or in nearby indoor spaces. The target number of participants was set based on clinical conditions. Rationale: The target number of participants was determined to be 16, considering a recruitment goal of two participants per month from among the outpatients at Yongin Severance Hospital, while accounting for dropout rates and clinical conditions.
Inclusion and exclusion criteria	1. Inclusion criteria 1) adults aged 19 to 79 years (based on the age on their national ID at the time of consent) 2) individuals diagnosed with cerebral infarction or intracerebral hemorrhage confirmed by MRI or CT. 3) patients who have passed at least one month since stroke diagnosis. 4) individuals exhibiting spastic hemiplegic gait patterns due to stroke. 5) patients with a Functional Ambulatory Category score of less than 4. 6) individuals who can sit on the edge of a bed without assistance and stand for

	10 seconds with or without assistance. 7) individuals with sufficient cognitive ability to follow simple instructions and understand the study's content and purpose (Mini-Mental State Examination score >= 20) 2. Exclusion criteria 1) individuals with severe joint contractures or osteoporosis, or untreated fractures that contraindicate weight-bearing on the lower limbs. 2) individuals with skin conditions or open wounds that prevent device usage. 3) individuals with significant differences in leg length. 4) individuals with severe deformities or joint contractures in the lower limbs. 5) individuals at high risk of fractures due to conditions like osteoporosis. 6) individuals unable to maintain a sitting or standing position independently. 7) individuals with severe lower limb spasticity (Modified Ashworth Scale grade 2 or higher). 8) individuals with severe cognitive impairment (Mini-Mental State Examination score < 20), delirium, or severe language impairment that hinders cooperation with wearable exoskeletal robot gait training. 9) individuals unable to maintain prolonged standing or walking due to conditions like orthostatic hypotension or cardiopulmonary impairment. 10) individuals with conditions affecting gait, such as peripheral neuropathy, Parkinsonism, or those with alcohol dependence or severe diabetes. 11) pregnant women or those who could become pregnant. 12) individuals participating in other clinical trials. 13) individuals at high risk of falls or bleeding due to conditions like coagulopathies. 14) individuals shorter than 140 cm, taller than 190 cm, or weighing over 80 kg. 15) individuals with other clinical findings deemed inappropriate for the study by the principal investigator or study coordinator.
Study Methods	After obtaining informed consent, a screening test is conducted. The screening test includes a review of the participant's baseline symptoms and signs, medical history, and medication usage, followed by a physical examination and assessment of gait status, including the use of assistive devices and gait patterns. Participants who pass the screening test undergo an initial assessment within seven days.

	The initial assessment includes physical function tests such as the 10-meter walk test, the Timed Up and Go (TUG) test, and the Berg Balance Scale, along with quality of life and Beck Depression Inventory assessments. Participants who complete the initial assessment begin robotic-assisted gait training within two days. The training is conducted using a wearable exoskeletal robot for gait training at home or in nearby indoor spaces. The training lasts for four weeks, with sessions held 2-3 times per week, totaling 10 sessions, each lasting 30 minutes. After four weeks, the robotic-assisted gait training concludes, and within two days, an endpoint assessment identical to the initial assessment is performed. Satisfaction with the wearable exoskeletal robot is also evaluated. Any device malfunctions are addressed and documented. The usage and satisfaction levels of the wearable exoskeletal robot are analyzed, and pre- and post-training assessment metrics are compared.
Evaluation variable	1. Primary outcome measure - Walking speed in the 10-meter walk test 2. Secondary outcome measures - body composition analysis results - spatiotemporal parameters of gait - Timed Up and Go Test (TUGT) - Berg Balance Scale (BBS) - Satisfaction survey related to the use of the wearable exoskeletal robot based on the 12-item, 5-point K-QUEST scale
Data analysis and statistical methods	1) Primary and secondary outcome measures As a preliminary study exploring the efficacy and safety of home-based robotic-assisted gait training, the primary outcome measure is the walking speed in the 10-meter walk test before and after the intervention. The efficacy of the intervention will be evaluated by comparing pre- and post-intervention results using the Wilcoxon signed-rank test, with a p-value less than 0.05 indicating a significant difference due to the intervention.

	Secondary outcome measures include quality of life scale, depression scale, body composition results, spatiotemporal gait parameters, Timed Up and Go Test, and Berg Balance Scale. These will also be compared pre- and post-intervention using the Wilcoxon signed-rank test, with statistical significance set at a p-value less than 0.05. 2. Satisfaction evaluation Satisfaction with the home-based robotic-assisted gait training will be analyzed using descriptive statistics to determine the mean, standard deviation, minimum, and maximum values for each item. Items with a mean score of 4 or higher will be interpreted as positive, while items with a mean score of 2 or lower will be interpreted as negative.

3. Study background and theoretical basis

Out of the 2.6 million registered disabled individuals in Korea, 1.45 million are registered with physical and brain disabilities, accounting for 55% of the total registered disabilities (Source: Statistics Korea, 2020). Various causes such as stroke, cerebral palsy, spinal cord injury, and muscular dystrophy lead to functional impairments in the upper and lower limbs. According to a 10-year follow-up study on long-term functional levels in stroke rehabilitation, 48.3% of patients showed moderate to severe motor function decline at 6 months post-stroke, and 43.6% at 12 months, indicating a high demand for improving lower limb function and gait disabilities. Gait plays a crucial role in healthy skeletal and muscular development, improving cardiopulmonary function,[1-3] and performing daily activities, making the acquisition of walking ability a primary goal in rehabilitation therapy.

Various methods for gait rehabilitation training have been proposed,[4] with robotic-assisted gait training recently gaining attention. Continuous and repetitive training is essential for functional recovery following central nervous system injuries,[5,6] as it induces and enhances neuroplasticity. Robotic-assisted gait training facilitates accurate and repetitive walking patterns close to normal gait, overcoming discrepancies due to the therapist's experience, knowledge, and physical capabilities. Reports have shown that robotic-assisted gait training improves lower limb strength, gait and balance abilities, reduces depression, and enhances quality of life.[7] Various forms of gait-assistive robots are being attempted in clinical settings. Wearable gait-assistive robots,[5] compared to treadmill-based robots, offer precise and active training similar to actual walking, maximizing training effects. They are relatively compact, easily portable, and adjustable to individual patient characteristics.

The COVID-19 pandemic has increased the demand for healthcare services at home as well as within medical institutions. Despite significant advancements in rehabilitation robots due to developments in sensors, materials, near-field communication, and mobile applications, their use has been limited to medical institutions. This study aims to explore the feasibility of providing a home-based gait rehabilitation service using a wearable exoskeletal robot.

4. Purpose of the study

Through pre- and post-intervention assessments, the study aims to determine the effectiveness of home-visit rehabilitation gait training using a wearable exoskeletal robot, conducted by a rehabilitation therapist under a doctor's diagnosis and prescription. This intervention consists of 10 sessions over four weeks, aiming to improve the gait function of stroke patients. Additionally, the study will evaluate the effectiveness and safety of home-based rehabilitation services by assessing patient satisfaction with the robotic-assisted gait training and conducting physical examinations post-intervention.

5. Risk/benefit analysis

The study will use the Timed Up and Go Test (TUGT) to assess gait ability. This test is widely used in clinical settings and has a very low medical risk. To minimize the risk of falls during the test, participants will undergo sufficient practice under the supervision of the examiner before conducting the test in an environment equipped with safety bars.

Participants in this study will receive information about their muscle mass, gait, and balance abilities, and will benefit from systematic robotic-assisted gait training at home. The accumulated data during the study will be used to improve and enhance gait rehabilitation devices and to develop home-based services. Additionally, this data will contribute to research related to disease treatment and prognosis, thereby advancing medical knowledge and improving the quality of care. Therefore, the benefits gained from this study are expected to outweigh the potential risks.

6. Target number of subjects 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 goal is to recruit two participants per month from the hospital's outpatients, with a target number of 10 participants, considering dropout rates and clinical conditions.

7. Subject Inclusion/exclusion criteria

1) Inclusion criteria

(1) adults aged 19 to 79 years (based on the age on their national ID at the time of consent)

(2) individuals diagnosed with cerebral infarction or intracerebral hemorrhage confirmed by MRI or CT.

(3) patients who have passed at least one month since stroke diagnosis.

(4) individuals exhibiting spastic hemiplegic gait patterns due to stroke.

(5) patients with a Functional Ambulatory Category score of less than 4.

(6) individuals who can sit on the edge of a bed without assistance and stand for 10 seconds with or without assistance.

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

2) Exclusion criteria

(1) individuals with severe joint contractures or osteoporosis, or untreated fractures that contraindicate weight-bearing on the lower limbs.

(2) individuals with skin conditions or open wounds that prevent device usage.

(3) individuals with significant differences in leg length.

(4) individuals with severe deformities or joint contractures in the lower limbs.

(5) individuals at high risk of fractures due to conditions like osteoporosis.

(6) individuals unable to maintain a sitting or standing position independently.

(7) individuals with severe lower limb spasticity (Modified Ashworth Scale grade 2 or higher).

(8) individuals with severe cognitive impairment (Mini-Mental State Examination score < 20), delirium, or severe language impairment that hinders cooperation with wearable exoskeletal robot gait training.

(9) individuals unable to maintain prolonged standing or walking due to conditions like orthostatic hypotension or cardiopulmonary impairment.

(10) individuals with conditions affecting gait, such as peripheral neuropathy, Parkinsonism, or those with alcohol dependence or severe diabetes.

(11) pregnant women or those who could become pregnant.

(12) individuals participating in other clinical trials.

(13) individuals at high risk of falls or bleeding due to conditions like coagulopathies.

(14) individuals shorter than 140 cm, taller than 190 cm, or weighing over 80 kg.

(15) individuals with other clinical findings deemed inappropriate for the study by the principal investigator or study coordinator.

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

This study does not involve clinical trials; however, the following information and management methods pertain to the medical devices used in this study.

1) Wearable exoskeletal robot

(1) Item name: Wearable exoskeletal robot

(2) Classification number: A67080.01

(3) Packaging unit: 1 set

(4) Medical device class: Class III

(5) Model name: M20-A-C3, M20-B-C3

(6) Manufacturer: Angel Robotics Co., Ltd.

(7) Approval number: No. 22-857

(8) Appearance

엔젤렉스 M20-C

(9) Intended use: A robotic automation system used for muscle reconstruction and joint movement recovery

(10) Mechanism, usage, and precautions: Refer to the attached document

2) Device management

The wearable exoskeletal robot used in this study will be provided as one unit along with a robot transport cart and gait aid tools, managed as follows:

(1) Security

The medical device used in this study will be stored according to the specified storage environment conditions in a designated location (Spring County Jai Banquet Hall storage room) equipped with a locking mechanism. Cooperation has been obtained from the institution's responsible person for the use of this location and locking mechanism, and the medical device manager is responsible for security checks. (Refer to the attached document)

(2) Infection control

The medical device manager will conduct thorough disinfection procedures between sessions to minimize the risk of cross-infection between participants. Before using the equipment, the manager will supervise the personal hygiene of participants using hand sanitizers available in the indoor space where the gait training is conducted.

(3) Device transport and retrieval

The robotic-assisted orthopedic exercise device used in the study will be transported and retrieved using a robot transport cart between the banquet hall where the gait training is conducted and the storage room where the device is kept. These areas are connected spaces.

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

1) Study design overview

This investigator-initiated exploratory study will be conducted over a period of four weeks.

2) Experimental group

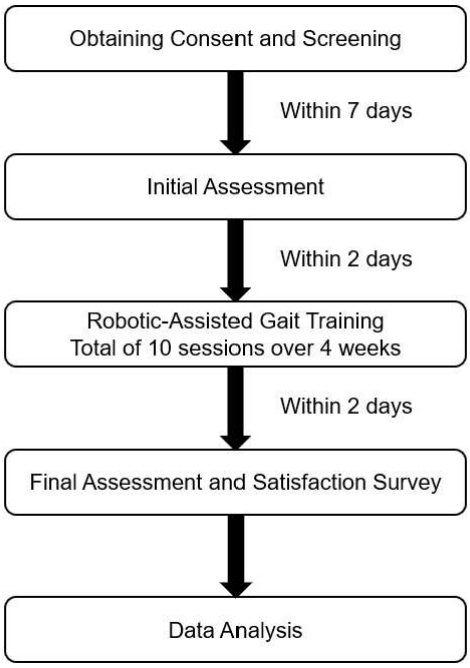
This study will include a single test group with a total of 10 participants. The selection of participants and the entire treatment process using the wearable skeletal robot will be conducted according to the prescription and guidance of a specialist in rehabilitation medicine, under the supervision of two occupational therapists. Participants will receive robotic-assisted gait training twice a week for 30 minutes over four weeks, either at home or in nearby

indoor spaces such as a gym.

3) Randomization and control group

This preliminary study follows a single-group design without randomization or a control group.

4) Flowchart



10. Study Methods

1) Screening methods

The screening evaluation will be conducted by a specialist in rehabilitation medicine in an independent space, such as a consultation room, at Yongin Severance Hospital. After providing a thorough explanation of the study to the participants and obtaining their consent, the following steps will be taken:

(1) Vital signs

- The examiner checks the participant's blood pressure, pulse, and temperature.

(2) Physical examination

① Manual muscle testing (lower limbs)

- The examiner evaluates the participant's lower limb manual muscle strength and joint range of motion according to the table below. The evaluation should be performed with the participant lying down or in a prone position, and the examiner can assist in changing positions if necessary.

Score	Description
0	No palpable or observable muscle contraction
1	Palpable or observable contraction, but no motion
1+	Moves limb without gravity loading less than one half available ROM[b]
2–	Moves without gravity loading more than one half ROM[b]
2	Moves without gravity loading over the full ROM[b]
2+	Moves against gravity less than one-half ROM[b]
3–	Moves against gravity greater than one-half ROM[b]
3	Moves against gravity less over the full ROM[b]
3+	Moves against gravity and moderate resistance less than one-half ROM[b]
4–	Moves against gravity and moderate resistance more than one-half ROM[b]
4	Moves against gravity and moderate resistance over the full ROM[b]
5	Moves against gravity and maximal resistance over the full ROM[b]

[b]ROM = range of motion.

② Joint range of motion assessment (lower limbs)[8]

- The examiner evaluates the participant's lower limb manual muscle strength and joint range of motion using the table below as a reference. The assessment should be performed with the participant in a lying down or prone position, and the examiner can assist with position changes if necessary.

< Joint Range of Motion Assessment Guide >

Lower Extremity										
Rt.						Lt.				
			125	flexion	Hip	flexion	125			
			10	extension		extension	10			
			45	abduction		abduction	45			
			10	adduction		adduction	10			
			45	E/R		E/R	45			
			45	I/R		I/R	45			
			140	flexion	Knee	flexion	140			
			0	extension		extension	0			
			20	D/F	Ankle	D/F	20			
			40	P/F		P/F	40			

③ Spasticity assessment (Modified Ashworth Scale, MAS) (lower limbs)[9]

- The examiner evaluates the degree of spasticity in the participant's three major lower limb joints (hip, knee, ankle) to determine the extent of functional or stability impairment. The evaluation criteria are as follows:

Score	
0	No increase in muscle tone
1	Slight increase in muscle tone, manifested by a catch and release or by minimal resistance at the end range of motion when the part is moved
1+	Slight increase in muscle tone, manifested by a catch, followed by minimal resistance throughout the remainder (less than half) of the range
2	More marked increase in muscle tone throughout most of the range, but affected part is easily moved
3	Considerable increase in muscle tone, passive movement is difficult
4	Affected part is rigid

< Joint Spasticity Assessment Guide >

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		

④ Functional Ambulation Category (FAC)[10]

- The examiner evaluates the participant's postural stability during walking by observing and recording their gait according to the criteria 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.

⑤ Mini-Mental State Examination (MMSE)[11]

- A standardized tool used to evaluate cognitive function and screen for dementia in a short period. The examiner asks the participant questions from the questionnaire and records the score based on 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

(3) Bone Density Test[12]

The examiner evaluates the patient's risk of osteoporosis based on their medical history and current medications. If the patient is suspected to be at risk for osteoporosis but has not undergone testing in the past two years, a bone density test using dual-energy X-ray absorptiometry (DEXA) will be performed. Osteoporosis is diagnosed when the bone density of the spine or hip has a T-score of less than -2.5.[13]

(4) Pregnancy Test

The examiner assesses the patient's potential for pregnancy through medical history and measurement of chorionic gonadotropin hormone levels in urine.[14]

2) Pre- and post-intervention evaluation variables

Before and after the intervention program, the research team will conduct the following tests or surveys on

participants in an independent space at Yongin Severance Hospital. The final evaluation will be conducted within 2 days after the intervention ends.

(1) Primary outcome measure

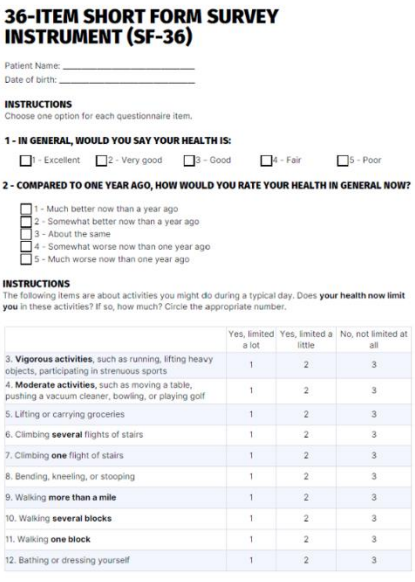
① 10MWT (10 meter walk test)

A simple and effective clinical evaluation method used to measure the walking speed of participants, useful for assessing functional recovery and changes in gait ability. The measurement method involves timing how long it takes to walk 10 meters, then dividing 10 by the time taken to record the walking speed (m/s).

(2) Secondary outcome measures

① Health-related quality of life measurement (36-item Short Form Survey Instrument, SF-36)

A self-reported survey consisting of 36 items used to assess participants' overall health-related quality of life. The evaluation tool measures satisfaction with overall health, with scores ranging from 0 to 100.[15]



36-ITEM SHORT FORM SURVEY INSTRUMENT (SF-36)

Patient Name: _____
Date of birth: _____

INSTRUCTIONS
Choose one option for each questionnaire item.

1 - IN GENERAL, WOULD YOU SAY YOUR HEALTH IS:

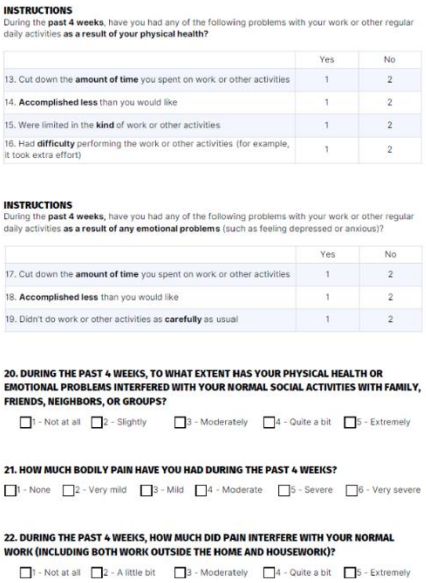
☐1 - Excellent ☐2 - Very good ☐3 - Good ☐4 - Fair ☐5 - Poor

2 - COMPARED TO ONE YEAR AGO, HOW WOULD YOU RATE YOUR HEALTH IN GENERAL NOW?

☐1 - Much better now than a year ago
☐2 - Somewhat better now than a year ago
☐3 - About the same
☐4 - Somewhat worse now than one year ago
☐5 - Much worse now than one year ago

INSTRUCTIONS
The following items are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much? Circle the appropriate number.

	Yes, limited a lot	Yes, limited a little	No, not limited at all
3. **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	1	2	3
4. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
5. Lifting or carrying groceries	1	2	3
6. Climbing **several** flights of stairs	1	2	3
7. Climbing **one** flight of stairs	1	2	3
8. Bending, kneeling, or stooping	1	2	3
9. Walking **more than a mile**	1	2	3
10. Walking **several blocks**	1	2	3
11. Walking **one block**	1	2	3
12. Bathing or dressing yourself	1	2	3



INSTRUCTIONS
During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health?**

	Yes	No
13. Cut down the **amount of time** you spent on work or other activities	1	2
14. **Accomplished less** than you would like	1	2
15. Were limited in the **kind** of work or other activities	1	2
16. Had **difficulty** performing the work or other activities (for example, it took extra effort)	1	2

INSTRUCTIONS
During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

	Yes	No
17. Cut down the **amount of time** you spent on work or other activities	1	2
18. **Accomplished less** than you would like	1	2
19. Didn't do work or other activities as **carefully** as usual	1	2

20. DURING THE PAST 4 WEEKS, TO WHAT EXTENT HAS YOUR PHYSICAL HEALTH OR EMOTIONAL PROBLEMS INTERFERED WITH YOUR NORMAL SOCIAL ACTIVITIES WITH FAMILY, FRIENDS, NEIGHBORS, OR GROUPS?

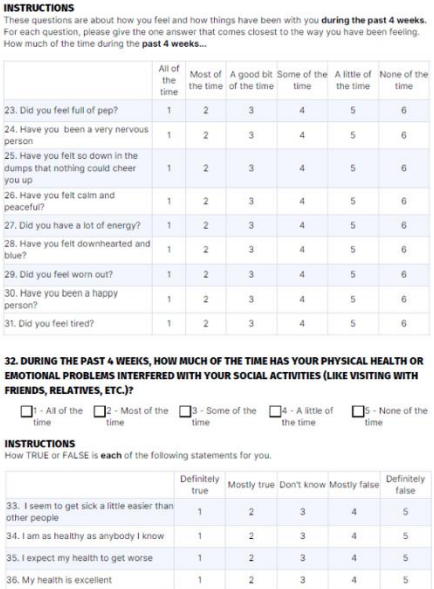
☐1 - Not at all ☐2 - Slightly ☐3 - Moderately ☐4 - Quite a bit ☐5 - Extremely

21. HOW MUCH BODILY PAIN HAVE YOU HAD DURING THE PAST 4 WEEKS?

☐1 - None ☐2 - Very mild ☐3 - Mild ☐4 - Moderate ☐5 - Severe ☐6 - Very severe

22. DURING THE PAST 4 WEEKS, HOW MUCH DID PAIN INTERFERE WITH YOUR NORMAL WORK (INCLUDING BOTH WORK OUTSIDE THE HOME AND HOUSEWORK)?

☐1 - Not at all ☐2 - A little bit ☐3 - Moderately ☐4 - Quite a bit ☐5 - Extremely



INSTRUCTIONS
These questions are about how you feel and how things have been with you **during the past 4 weeks.** For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the **past 4 weeks...**

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
23. Did you feel full of pep?	1	2	3	4	5	6
24. Have you been a very nervous person	1	2	3	4	5	6
25. Have you felt so down in the dumps that nothing could cheer you up	1	2	3	4	5	6
26. Have you felt calm and peaceful?	1	2	3	4	5	6
27. Did you have a lot of energy?	1	2	3	4	5	6
28. Have you felt downhearted and blue?	1	2	3	4	5	6
29. Did you feel worn out?	1	2	3	4	5	6
30. Have you been a happy person?	1	2	3	4	5	6
31. Did you feel tired?	1	2	3	4	5	6

32. DURING THE PAST 4 WEEKS, HOW MUCH OF THE TIME HAS YOUR PHYSICAL HEALTH OR EMOTIONAL PROBLEMS INTERFERED WITH YOUR SOCIAL ACTIVITIES (LIKE VISITING WITH FRIENDS, RELATIVES, ETC.)?

☐1 - All of the time ☐2 - Most of the time ☐3 - Some of the time ☐4 - A little of the time ☐5 - None of the time

INSTRUCTIONS
How TRUE or FALSE is **each** of the following statements for you.

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
33. I seem to get sick a little easier than other people	1	2	3	4	5
34. I am as healthy as anybody I know	1	2	3	4	5
35. I expect my health to get worse	1	2	3	4	5
36. My health is excellent	1	2	3	4	5

② Beck depression inventory (BDI)[16]

An evaluation tool designed based on clinical depressive symptoms. It consists of 21 self-reported items where

patients check and record their scores in areas such as affective cognition and motivation. Scores range from 0 to 63.

Beck's Depression Inventory

This depression inventory can be self-scored. The scoring scale is at the end of the questionnaire.

1.
0 I do not feel sad.
1 I feel sad
2 I am sad all the time and I can't snap out of it.
3 I am so sad and unhappy that I can't stand it.

2.
0 I am not particularly discouraged about the future.
1 I feel discouraged about the future.
2 I feel I have nothing to look forward to.
3 I feel the future is hopeless and that things cannot improve.

3.
0 I do not feel like a failure.
1 I feel I have failed more than the average person.
2 As I look back on my life, all I can see is a lot of failures.
3 I feel I am a complete failure as a person.

4.
0 I get as much satisfaction out of things as I used to.
1 I don't enjoy things the way I used to.
2 I don't get real satisfaction out of anything anymore.
3 I am dissatisfied or bored with everything.

5.
0 I don't feel particularly guilty
1 I feel guilty a good part of the time.
2 I feel quite guilty most of the time.
3 I feel guilty all of the time.

6.
0 I don't feel I am being punished.
1 I feel I may be punished.
2 I expect to be punished.
3 I feel I am being punished.

7.
0 I don't feel disappointed in myself.
1 I am disappointed in myself.
2 I am disgusted with myself.
3 I hate myself.

8.
0 I don't feel I am any worse than anybody else.
1 I am critical of myself for my weaknesses or mistakes.
2 I blame myself all the time for my faults.
3 I blame myself for everything bad that happens.

9.
0 I don't have any thoughts of killing myself.
1 I have thoughts of killing myself, but I would not carry them out.
2 I would like to kill myself.
3 I would kill myself if I had the chance.

10.
0 I don't cry any more than usual.
1 I cry more now than I used to.
2 I cry all the time now.
3 I used to be able to cry, but now I can't cry even though I want to.

11.
0 I am no more irritated by things than I ever was.
1 I am slightly more irritated now than usual.
2 I am quite annoyed or irritated a good deal of the time.
3 I feel irritated all the time.

12.
0 I have not lost interest in other people.
1 I am less interested in other people than I used to be.
2 I have lost most of my interest in other people.
3 I have lost all of my interest in other people.

13.
0 I make decisions about as well as I ever could.
1 I put off making decisions more than I used to.
2 I have greater difficulty in making decisions more than I used to.
3 I can't make decisions at all anymore.

14.
0 I don't feel that I look any worse than I used to.
1 I am worried that I am looking old or unattractive.
2 I feel there are permanent changes in my appearance that make me look unattractive.
3 I believe that I look ugly.

15.
0 I can work about as well as before.
1 It takes an extra effort to get started at doing something.
2 I have to push myself very hard to do anything.
3 I can't do any work at all.

16.
0 I can sleep as well as usual.
1 I don't sleep as well as I used to.
2 I wake up 1-2 hours earlier than usual and find it hard to get back to sleep.
3 I wake up several hours earlier than I used to and cannot get back to sleep.

17.
0 I don't get more tired than usual.
1 I get tired more easily than I used to.
2 I get tired from doing almost anything.
3 I am too tired to do anything.

18.
0 My appetite is no worse than usual.
1 My appetite is not as good as it used to be.
2 My appetite is much worse now.
3 I have no appetite at all anymore.

19.
0 I haven't lost much weight, if any, lately.
1 I have lost more than five pounds.
2 I have lost more than ten pounds.
3 I have lost more than fifteen pounds.

20.
0 I am no more worried about my health than usual.
1 I am worried about physical problems like aches, pains, upset stomach, or constipation.
2 I am very worried about physical problems and it's hard to think of much else.
3 I am so worried about my physical problems that I cannot think of anything else.

21.
0 I have not noticed any recent change in my interest in sex.
1 I am less interested in sex than I used to be.
2 I have almost no interest in sex.
3 I have lost interest in sex completely.

INTERPRETING THE BECK DEPRESSION INVENTORY

Now that you have completed the questionnaire, add up the score for each of the twenty-one questions by counting the number to the right of each question you marked. The highest possible total for the whole test would be sixty-three. This would mean you circled number three on all twenty-one questions. Since the lowest possible score for each question is zero, the lowest possible score for the test would be zero. This would mean you circles zero on each question. You can evaluate your depression according to the Table below.

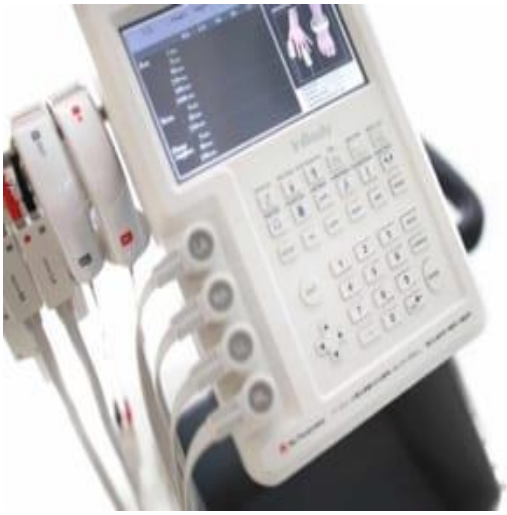
Total Score_____Levels of Depression

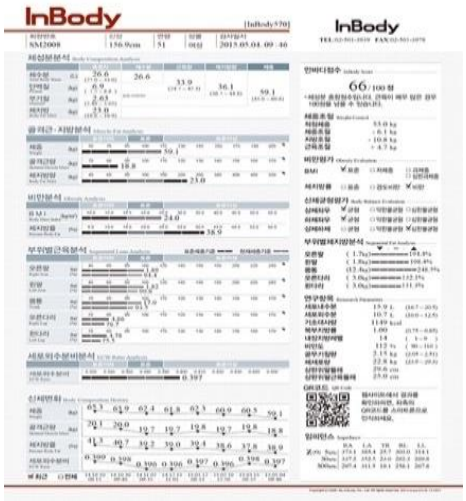
1-10_____These ups and downs are considered normal
11-16_____Mild mood disturbance
17-20_____Borderline clinical depression
21-30_____Moderate depression
31-40_____Severe depression
over 40_____Extreme depression

③ Body composition analysis

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

- Perform body composition analysis[17] based on bioimpedance analysis.
- To ensure accurate measurement, the test subject is instructed to empty his/her bladder before the test and not to consume caffeinated beverages, eat, drink, or perform strenuous exercise for one hour prior to the test.
- To correct for muscle mass differences due to height, use the calculated value of limb muscle mass (Appendicular skeletal mass) divided by the square of the height.





④ Spatiotemporal parameters of walking

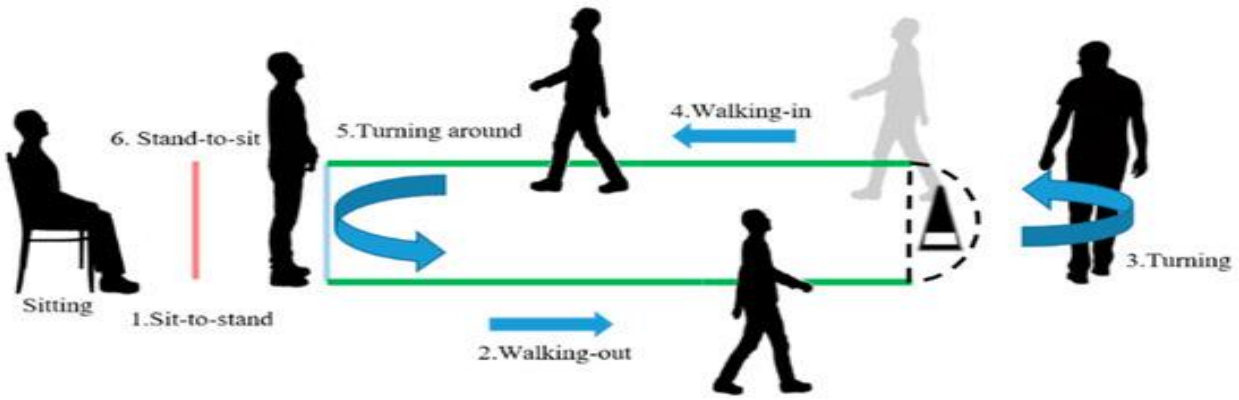
Spatiotemporal parametric data of gait collected while the subject is performing a home-based activity wearing an insole gait analyzer, recording total steps, steps per minute, gait speed (km/h), distance walked (m), stride length (m), and swing phase rate (%).

- Step count: The number of steps measured while walking.
- Cadence: The number of steps taken per minute, with the unit being steps/min (spm). Normal values are ≥ 70 steps/min for those under 65 years old and ≥ 60 steps/min for those 65 years and older.
- Gait speed: The speed of walking, with the unit being km/h. Normal values are ≥ 2.0 km/h for those under 65 years old and ≥ 1.5 km/h for those 65 years and older.
- Distance: The total distance traveled while walking, measured in meters (m).
- Stride length: The distance from the heel of one foot to the heel of the same foot in the next step. The distance is measured in meters (m), and it is normalized for height by dividing stride length by height. Normal values are ≥ 0.5 m/height for those under 65 years old and ≥ 0.4 m/height for those 65 years and older.
- Swing ratio: The percentage of the gait cycle that is in the swing phase, with the unit being %. Normal values are ≥ 30% for those under 65 years old and ≥ 28% for those 65 years and older.

⑤ Timed up and go test (TUG)

The above test assesses walking speed along with balance ability during walking[18], and this is performed as follows.

- 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.
- 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.



⑥ Berg Balance Scale

The following tests evaluate static and dynamic balance,[19] and have been used in previous studies to assess

progress after robotic-assisted gait therapy.[20] The examiner instructs the participant to perform the following 14 tasks and evaluates them according to specific criteria. Scores range from 0 to 56.

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

3) Satisfaction evaluation

Participants will complete a satisfaction survey for the home-based rehabilitation service using the wearable exoskeletal robot, based on the Korean version of the Quebec User Evaluation of Satisfaction with assistive Technology (K-QUEST 2.0).[21] This survey consists of 12 items on a 5-point scale. Participants rate their satisfaction with the assistive device and related services as follows:

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

Participants are instructed to provide reasons if they do not select "very satisfied" for any item.

	1	2	3	4	5
Are you satisfied with the specifications (size, height, length, width) of the wearable exoskeletal robot? Reason: _____					
How do you find the weight of the wearable exoskeletal robot? Reason: _____					

Is it convenient to adjust (fix and lock) parts of the wearable exoskeletal robot? Reason: _____					
Do you think the wearable exoskeletal robot is safe and sturdy? Reason: _____					
Are you satisfied with the durability (long-term usability) of the wearable exoskeletal robot? Reason: _____					
Was the method of using the wearable exoskeletal robot convenient? Reason: _____					
Do you think the wearable exoskeletal robot is comfortable to wear? Reason: _____					
Are you satisfied with the effectiveness (purposeful use) of the wearable exoskeletal robot? Reason: _____					
Are you satisfied with the service and delivery program (delivery process, time required) of the wearable exoskeletal robot? Reason: _____					
Are you satisfied with the repair and maintenance service of the wearable exoskeletal robot? Reason: _____					
Are you satisfied with the professional services (information, precautions) provided while using the wearable exoskeletal robot? Reason: _____					
Are you satisfied with the after-sales service (continuous maintenance service) of the wearable exoskeletal robot? Reason: _____					

- Please mark the three items participants consider most important among the 12 satisfaction items.

	O 표시
1. Specifications	
2. Weight	
3. Convenience	
4. Safety	
5. Durability	
6. Usability	
7. Comfort	
8. Effectiveness	
9. Service delivery	

10. Repair and maintenance services	
11. Professional services	
12. After-sales service	

4) Home-based robotic-assisted gait training

The participant's robotic-assisted gait training is conducted in collaboration with the research team (physical therapist or occupational therapist) under the prescription and guidance of a rehabilitation medicine specialist as follows. The gait training program begins within 2 days of the initial assessment and is conducted at home or in an indoor environment similar to the home setting. No transportation support, such as vehicles, is provided.

(1) Warm-up exercises before wearing the robot

Participants perform stretching exercises for 5 minutes before wearing the wearable exoskeletal robot.

(2) Application of the wearable exoskeletal robot

The wearable exoskeletal robot used in this study is a medical device that assists the hip and knee joints during gait training to achieve a near-normal walking trajectory. The evaluator applies this device to the participant and provides gait training on level ground. The robot can provide assistive torque during various walking phases, automatically detected through combined information from ground contact sensors, encoders (incremental and absolute) of the actuators, and inertial measurement unit sensors. According to the polynomial assistive joint torque profile by gait phase, flexion torque is generated in the hip and knee joints during the swing phase, and extension torque is generated in the hip and knee joints during the stance phase, aiding the participant's gait. The therapist aims to train the participant to walk in a pattern as close to normal as possible for the maximum duration. The gait training program consists of 10 sessions over 4 weeks, conducted 3 times a week for 30 minutes each session.[22,23] All training sessions are conducted under the supervision of two research team members (physical therapists or occupational therapists). If the participant cannot continue the 30-minute session due to muscle endurance decline or pain, the gait training is terminated, and the actual session duration and the reasons for early termination are recorded.

(3) Recording adverse reactions and device malfunctions

- The research team (physical therapists or occupational therapists) records the types and frequencies of safety incidents and reasons for device malfunctions that occur during the participant's gait training.
- If adverse reactions such as pain occur, the type, severity, frequency, name of the adverse reaction, onset and resolution dates, characteristics, and causality are investigated and recorded.

5) Definition of analysis groups, missing data, and outlier management plan

(1) Definition of analysis groups

The analysis groups consist of all participants undergoing robotic-assisted gait training. The analysis includes their age, diagnosis, physical function assessments, and extracted gait parameter data.

(2) Missing data and outlier management plan

In cases of missing data due to study withdrawal or dropout, the Complete Case Analysis method is used, which analyzes only completely observed cases. Data from sessions with missing values are excluded from the analysis. Outliers identified using box plots and quartiles are also excluded from the analysis to maintain data integrity and enhance the study's accuracy and reliability. Information about the excluded participants is presented.

6) Comparative analysis of pre- and post-intervention differences

After the completion of the gait training program using the wearable exoskeletal robot, the evaluator performs a comparative analysis of the collected data from participants following the final assessment and satisfaction survey.

11. Study procedures and evaluation

Phase	**Screening / Initial assessment**	**Intervention**			**Final assessment**
week	**0**	**1**	**2**	**3**	**4**
written consent	O				
Inclusion/exclusion criteria	O				
Demographic information and antecedent history	O				
Primary outcome measure	O				O
10MWT (10 meter walk test)					
Secondary outcome measures	O				O

Health-related quality of life measurement					
Beck depression inventory					
Body composition analysis					
Spatiotemporal parameters of walking					
Timed up and go test (TUG)					
Berg Balance Scale					
Satisfaction evaluation					O
Home-based robotic-assisted gait training		O	O	O	O

12. Criteria for stopping and dropping out of the study

If a participant discontinues their participation in this clinical trial, only the information collected up to that point will be used in the study. The data will be stored for three years after the study ends and then destroyed.

1) Termination and early suspension

(1) Withdrawal of consent

If the participant or their legal representative withdraws consent before the end of the study, only the information collected up to that point will be used. The data will be stored for three years after the study ends and then destroyed.

(2) Occurrence of serious adverse events

2) Dropout

If the participant's early discontinuation is not due to withdrawal, their willingness to continue providing information for the study will be reconfirmed. If they agree, the information collected up to the point of dropout will be anonymized and used in the study.

(1) The medical team determines that there is a serious medical necessity preventing the participant from continuing in the clinical study.

(2) The participant uses concurrent surgery, medications, or other medical devices that may affect the safety and efficacy evaluations.

(3) The participant does not comply with the investigator's instructions or the terms of the consent form, affecting the evaluation of efficacy.

(4) The participant's absence prevents continuous observation.

(5) Other cases where the principal investigator determines there are issues in continuing the clinical trial.

3) Handling of discontinuation and dropout

(1) If a participant drops out, the reason for dropout and the clinical trial-related data collected up to the point of dropout will be recorded and stored.

(2) If a participant is unable to visit during the study, their status must be confirmed, and the reason for their absence must be clearly documented.

(3) Participants who drop out without valid reasons or justification will be included in the statistical analysis for efficacy and safety evaluation.

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

1) Evaluation criteria

To ensure the safety of study participants, the principal investigator will act as the safety monitor, conducting monitoring and evaluating safety.

(1) Symptoms reported by participants or identified through physical examinations during or after the intervention in the control and experimental groups (e.g., musculoskeletal pain and skin lesions during gait training).

(2) Physical examinations (e.g., musculoskeletal abnormalities and skin lesions such as erythema and edema at the site of the wearable exoskeletal robot application).

(3) Safety evaluation related to falls:

- Number of falls
- Severity of injuries caused by falls (e.g., bruises, fractures, other injuries)
- Other

2) Evaluation method

(1) Perform statistical analysis to evaluate the severity and type of adverse reactions and the incidence rates of adverse reactions in the experimental and control groups, based on reports from participants or physical examinations.

(2) Safety analysis will be conducted with a significance level of <0.05 (two-sided).

3) Adverse event reporting

(1) Reporting subjects: All participants in this clinical trial.

(2) Adverse event evaluation criteria:

- Evaluate the cause of adverse events according to the following criteria:
- Device-related issues: Adverse events caused by device malfunction, breakdown, or damage despite following the intended use, method of use, and precautions specified by the manufacturer.
- Procedural issues: Adverse events caused by the procedure itself when the device was used correctly and there were no issues with the patient's condition or underlying disease.
- Patient-related issues: Adverse events caused by the patient's condition or underlying disease when the device was used correctly and the procedure was performed correctly.
- Evaluation impossible: When the adverse event report does not match the actual product or multiple causes are involved, making it impossible to determine the cause.

(3) Adverse event evaluation method

- The clinical trial investigator will record symptoms, onset date, and resolution date of adverse reactions in an adverse reaction record form if an adverse reaction occurs during the trial.

(4) Adverse event reporting method:

- This content will be reported according to the regulations related to medical device clinical trials and the standard operating procedures (SOPs) specified by the clinical trial institution and the institution's IRB regulations.

I. Definition of terms

- "Safety information" refers to data or information related to the safety and efficacy of approved, certified, or reported medical devices, including cases of adverse effects.

- "Adverse effect information" refers to cases of adverse effects or potential adverse effects occurring domestically or internationally during the handling or use of medical devices.

- "Side effect" refers to any unintended result, suspected to have occurred due to normal use of the medical device, including unintended desirable results.

- "Adverse event" refers to undesirable outcomes among side effects, not necessarily having a causal relationship with the medical device.

- "Serious adverse event" refers to an adverse event that meets any of the following criteria:

a. Results in death or life-threatening adverse effects

b. Requires hospitalization or prolongation of existing hospitalization

c. Causes permanent or significant disability or incapacity

d. Results in congenital anomalies or birth defects

- "Unexpected adverse event" refers to an adverse event that differs in severity, specificity, or outcome from what is described in the approved, certified, or reported information of the medical device.

II. Safety evaluation criteria

Safety evaluation criteria refer to the standards for recording the severity of anticipated adverse effects and adverse reactions in case report forms.

III. Safety evaluation methods

The methods for safety evaluation include statistical analysis techniques and evaluation criteria for comparative assessment of the frequency of occurrence of adverse effects, abnormal device responses, and adverse reactions associated with clinical trial medical devices.

IV. Reporting adverse reactions

- Serious adverse reactions at each institution must be reported to the clinical trial coordinator and monitoring staff via email within 48 hours of awareness.

- The principal investigator must report serious adverse reactions to the institution's IRB according to IRB regulations and provide additional detailed reports as specified in the protocol.

- In cases of death or life-threatening situations, the principal investigator must report to the head of the Food and Drug Administration within 7 days of becoming aware of the event. For other serious and unexpected adverse reactions, the report must be submitted within 15 days.

4) Monitoring Plan for Participants Who Experience Adverse Events

(1) This is a preliminary case study with a low risk level, requiring minimal invasive intervention. Therefore, weekly monitoring will be conducted under the supervision of the principal investigator. This monitoring will ensure data completeness by cross-checking supporting documents, case report forms (CRF), and protocols, and reviewing safety data of the study participants.

(2) Participants who experience adverse events will be compensated according to the provisions of the compensation protocol in this study plan. Monitoring of the treatment progress will continue until the adverse reaction is resolved or until the participant's scheduled study completion.

(3) For participants who experience adverse events and do not refuse follow-up, the progress of the adverse events will be observed through reported symptoms and physical examinations at scheduled study visits.

5) As a preliminary case study with a low risk level requiring minimal invasive intervention, weekly monitoring will be conducted under the supervision of the principal investigator. This will ensure data completeness by cross-checking supporting documents, CRF, and protocols, and reviewing the safety data of study participants.

6) Participants in the study can decide to discontinue their participation at any time if they feel discomfort related to the study. The principal investigator or study coordinator will fully explain and confirm this when obtaining consent from participants.

7) In the event of any violations or deviations from the study, the situation and the researcher's actions and preventive measures will be promptly reported to the IRB in writing. Immediate treatment and observation will be provided if participants are injured or if new incidents occur during the evaluation, with a thorough investigation of the causes. Treatment will follow the hospital's standard procedures. These incidents will be reported in interim reports and included in the research paper. However, this study is considered to have a low likelihood of future adverse effects, and therefore no additional treatment costs have been budgeted.

14. Data analysis and statistical considerations

1) Primary and secondary outcome measures

This study is a preliminary exploration of the efficacy and safety of home-based robotic-assisted gait training. The primary evaluation variable is the walking speed measured by the 10-meter walk test before and after robotic-assisted gait rehabilitation. The pre- and post-intervention results will be compared using the Wilcoxon signed-rank test, with a p-value of less than 0.05 indicating a significant difference due to the intervention.

Secondary evaluation variables include quality of life scale, depression scale, body composition results, spatiotemporal gait parameters, Timed Up and Go test, and Berg Balance Scale. These will also be compared pre- and post-intervention using the Wilcoxon signed-rank test, with statistical significance set at a p-value of less than 0.05.

The results of the satisfaction with home-based robotic-assisted gait training will be analyzed using descriptive statistics, identifying the mean, standard deviation, minimum, and maximum values for each item. Items with an average score of 4 or higher will be interpreted as positive, while items with an average score of 2 or lower will be interpreted as negative.

2) Satisfaction evaluation:

The satisfaction with the home-based gait rehabilitation service using the wearable exoskeletal robot will be analyzed using descriptive statistics, presenting the mean, standard deviation, median, minimum, and maximum values.

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	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	Major	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	Phone

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

2) Period

24 months after IRB approval

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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