Cover page for ClinicalTrials.gov

Name of the document:

Study protocol and Statistical Analysis Plan

Official Title of the Study:

A Pilot Study to Verify the Effectiveness and Safety of the Electrically Powered Orthopedic Exercise Device on Gait Ability in Patients with Gait Disorders: Investigator-Initiated, Single-Center, Single-Group Clinical Trial

NCT number

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Prospective Clinical Trial Protocol

1. Study title, stage, plan identification number, revision history, etc.

- Study title: A Pilot Study to Verify the Effectiveness and Safety of the Electrically Powered Orthopedic Exercise Device on Gait Ability in Patients with Gait Disorders: Investigator-Initiated, Single-Center, Single-Group Clinical Trial
- Study phase: phase 4

2. Summary of study plan

Research Purpose	This study aims to evaluate the improvement in gait function of patients with gait disorders when using an electrically powered orthopedic exercise device compared to when they are not using it. Furthermore, it assesses user satisfaction and device safety to explore its feasibility in clinical settings.
Research design overview	Investigator-led exploratory clinical study
Clinical Trial Medical Devices	Electrically Powered Orthopedic Exercise Device
Target number of subjects and basis for calculation	30 patients with Gait disorders This study aims to compare and analyze changes in gait indicators between the non-wearing and wearing conditions of the Electrically Powered Orthopedic Exercise Device to verify its effectiveness in improving gait function and ensure its safety. The target sample size was determined considering clinical setting. Calculation Basis: The sample size was determined considering clinical circumstances with the goal of recruiting three participants per month.
Selection and exclusion criteria	1. Selection criteria 1) Adults aged 19 years or older 2) Patients experiencing subjective gait or balance disorders 3) Individuals who visited Yongin Severance Hospital, understood the study, voluntarily agreed to participate, and signed the consent form 4) Patients with a Functional Ambulatory Category (FAC) score of less than 4 5) Individuals who can sit on the edge of a bed without assistance and stand for 10 seconds with or without support 6) Individuals with sufficient cognitive ability to follow and understand simple instructions (Mini-Mental State Examination score ≥ 20) 2. Exclusion criteria 1) Individuals with contraindications to weight-bearing in the lower

	extremities, such as severe lower extremity joint contractures, osteoporosis, or untreated fractures 2) Individuals who cannot wear the device due to skin diseases or open wounds 3) Individuals with a significant discrepancy in lower extremity length 4) Individuals with severe lower extremity deformities or joint contractures 5) Individuals unable to maintain a sitting or standing posture independently 6) Individuals with severe cognitive impairment (Mini-Mental State Examination score < 20), delirium, or severe speech impairment preventing cooperation in wearing the device 7) Individuals unable to stand or walk for extended periods due to underlying conditions such as orthostatic hypotension or reduced cardiopulmonary function 8) Pregnant or potentially pregnant individuals 9) Individuals with other clinically significant conditions deemed inappropriate for this study by the principal investigator or research team based on medical judgment
Research Methods	After obtaining informed consent, clinical information is collected, and a screening test is conducted. The screening includes an interview regarding the participant's baseline symptoms and signs, as well as a physical activity questionnaire. Participants who pass the screening undergo an evaluation of gait function and balance ability without wearing the Electrically Powered Orthopedic Exercise Device. Afterward, the patient wears the electrically powered orthopedic exercise device for a total of four adaptation sessions. In each session, the patient performs short-distance walking within 10 meters while wearing the device to explore the appropriate assistive mode and level of support that match their physical condition. No evaluations are conducted while wearing the device during sessions 1, 2, and 3. After the 4th session, an evaluation identical to the one conducted without the device is performed while wearing it, and a satisfaction survey is conducted. Any device malfunctions are addressed and documented, and the type, severity, and frequency of side effects, such as pain associated with device use, are recorded. The evaluation results from the non-wearing and wearing conditions of the Electrically Powered Orthopedic Exercise Device, along with the satisfaction survey results, are compared.

Evaluation variables	1. Primary evaluation variables - 10m walk test 2. Secondary evaluation variables - 6-minute walk test - Gait spatiotemporal parameters - Timed Up and Go test - Berg Balance Scale - A satisfaction survey on the use of electric orthopedic exercise devices using a 12-item 5-point scale based on K-QUEST
Data analysis and statistical methods	1) Primary and Secondary Evaluation Variables: This study is a preliminary investigation into the safety and efficacy of a powered orthopedic exercise device. Gait and balance functions are assessed both with and without wearing the device. The primary evaluation variable is the walking speed measured in the 10m walk test. The results are analyzed using a paired t-test, with a significance level of 0.05. If the p-value is less than 0.05, the difference before and after wearing the device is considered statistically significant. Secondary evaluation variables, including the 6-minute walk test, gait spatiotemporal parameters, Timed Up and Go test, and Berg Balance Scale, are also analyzed using a paired t-test, with a significance level set at 0.05. In addition, a linear mixed model will be used to analyze the data, incorporating both the individual characteristics of participants due to repeated measures and fixed effects. 2) Satisfaction Evaluation: The satisfaction survey results are analyzed using descriptive statistics, assessing the mean, standard deviation, minimum, and maximum values for each item. If the mean score for an item is 4 or higher, it is considered a positive evaluation; if it is 2 or lower, it is considered a negative evaluation.

3. Research background and theoretical basis

Aging is a global trend, and consequently, the prevalence of age-related diseases is increasing.[1,2] Gait disorders are common among the elderly and can result not only from various underlying conditions affecting gait but also from the decline in physiological and neurological functions associated with the normal aging process. [3]

Gait is a fundamental daily activity that requires the coordinated integration of the central and peripheral nervous systems, as well as the musculoskeletal system. Therefore, impairments in any of these systems—including the

nervous, cardiovascular, respiratory, or musculoskeletal systems—can lead to gait dysfunction.[4-6] Gait disorders negatively impact quality of life by increasing the risk of falls, reducing the ability to perform activities of daily living (ADLs), and limiting physical activity.[3,7] Accordingly, various approaches to maintaining and improving gait function in older adults are being actively explored.[8]

Currently, gait aids such as canes and walkers are commonly used to support individuals with gait impairments. These devices help redistribute body weight by providing a broader base of support, thereby assisting with balance and stability. However, they do not directly facilitate the movement of the lower limbs. To enhance gait function, numerous studies have investigated repetitive lower-limb movement training using bicycles or robotic devices. However, the extent of functional improvement resulting from such training remains unclear, and the long-term efficacy is still uncertain. [9]

Recent advancements in sensing technology for joint motion and actuator efficiency have led to the development of wearable assistive devices that are significantly more compact and lightweight compared to conventional robotic systems. This study aims to evaluate the effectiveness of a newly developed electrically powered orthopedic exercise device in patients with gait disorders by assessing changes in gait parameters upon wearing the device, thereby exploring its clinical feasibility.

4. Purpose of the study

This study aims to assess whether gait function improves in patients with gait disorders when using an electrically powered orthopedic exercise device compared to when not using it. It also evaluates the device's effectiveness, user satisfaction, and safety to explore its feasibility in clinical settings.

5. Risk/Benefit Analysis

The participant's gait ability, both with and without the electrically powered orthopedic exercise device, will be assessed using the 10m Walk Test. All additional gait and balance assessments conducted in this study are widely used in clinical practice and pose minimal medical risk. To minimize the risk of falls during the assessment, sufficient practice will be conducted under the supervision of the tester before the test, and the test will be conducted in an environment with a safety bar installed.

Through this study, participants will receive information regarding their physical function, including motor and balance abilities, as well as gait parameters. The accumulated data collected during the study will contribute to the improvement and advancement of gait rehabilitation devices and the development of rehabilitation services. Additionally, the findings will be utilized in research related to disease treatment and prognosis, ultimately contributing to medical advancements and the improvement of clinical care quality. Therefore, the potential benefits

of this study are expected to outweigh any associated risks.

6. Number of Target Audience and Basis for calculation

This study will be conducted on all patients visiting Yongin Severance Hospital who agree to participate in the study and meet the selection criteria. Yongin Severance Hospital Among the patients, the goal was to recruit 3 subjects per month, and the target number of subjects was set at 30 considering the dropout rate and clinical conditions.

7. Criteria for selection/exclusion of subjects

(1) Selection criteria

1) Adults aged 19 years or older
2) Patients experiencing subjective gait or balance disorders
3) Individuals who visited Yongin Severance Hospital, understood the study, voluntarily agreed to participate, and signed the consent form
4) Patients with a Functional Ambulatory Category (FAC) score of less than 4
5) Individuals who can sit on the edge of a bed without assistance and stand for 10 seconds with or without support
6) Individuals with sufficient cognitive ability to follow and understand simple instructions (Mini-Mental State Examination score ≥ 20)

(2) Exclusion criteria

1) Individuals with contraindications to weight-bearing in the lower extremities, such as severe lower extremity joint contractures, osteoporosis, or untreated fractures
2) Individuals who cannot wear the device due to skin diseases or open wounds
3) Individuals with a significant discrepancy in lower extremity length
4) Individuals with severe lower extremity deformities or joint contractures
5) Individuals unable to maintain a sitting or standing posture independently
6) Individuals with severe cognitive impairment (Mini-Mental State Examination score < 20), delirium, or severe speech impairment preventing cooperation in wearing the device
7) Individuals unable to stand or walk for extended periods due to underlying conditions such as

orthostatic hypotension or reduced cardiopulmonary function

8) Pregnant or potentially pregnant individuals

9) Individuals with other clinically significant conditions deemed inappropriate for this study by the principal investigator or research team based on medical judgment

8. Research equipment

Information on the equipment and management methods used in this study are as follows.

(1) Electric orthopedic exercise device (Angel SUIT H10)

1) Product name: Electric orthopedic exercise device

2) Classification number: A67020.02

3) Packaging unit: 1 set

4) Medical device class: Class 2

5) Model: Angel SUIT H10

6) Manufacturer: Angel Robotics Co., Ltd.

7) Appearance

8) Principle of action, method of use, precautions for use - Refer to the attached document

9) Product License Number: 25-4093

(2) Device Management

The Electrically Powered Orthopedic Exercise Device used in this study will be stored in the Rehabilitation Function Testing Room.

1) Security

The device, provided by Angel Robotics, will be stored according to the storage environment conditions specified in the instructions. It will be managed in a designated area equipped with a locking mechanism, located on the 2nd floor of the Rehabilitation Function Testing Room at Yongin Severance Hospital.

2) Infection Control

The device manager will perform thorough disinfection procedures before and after each use to minimize the risk of cross-infection between participants. Additionally, participants will be instructed to use hand sanitizer

available in the testing area to ensure proper personal hygiene management before wearing the device.

3) Device Receipt and Inventory Management

Prior to the start of the study, the electrically powered orthopedic exercise device will be received through a handover process between the research team and Angel Robotics personnel. The medical device manager will manage the device's location and condition through inventory logs and conduct regular inventory checks.

4) Application Method and Duration per Participant

Each participant undergoes a total of four sessions using the electrically powered orthopedic exercise device according to the manual, with each session lasting 20 minutes. After the final session, an evaluation is conducted while wearing the device, which takes approximately 60 minutes.

5) Return and Inventory Log

After use, the device will be returned to the Rehabilitation Function Testing Room. Upon return, its condition will be inspected, and the usage date and status will be recorded in the inventory log.

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

(1) Research design overview

This is a researcher-led exploratory study. The subject's gait indices (walking speed, spatiotemporal parameters, walking endurance, etc.) were evaluated while the subject was not wearing the electric orthopedic exercise device and then while wearing it. The collected gait indices were analyzed to determine their validity and safety. This is a preliminary study to evaluate.

(2) Experimental Group and Evaluation Procedures

1) Participant Selection:

This study includes a single test group with a total of 30 participants. The selection of participants for the electrically powered orthopedic exercise device and the overall study process will be conducted under the prescription and guidance of a rehabilitation medicine specialist, and supervised by assistants (physicians and occupational therapists). The examiner will collect clinical information and conduct a screening assessment for each participant.

2) Evaluation Phase Without Device:

After the screening test, participants undergo assessments of walking ability and balance without wearing the electrically powered orthopedic exercise device. A 10-minute rest period is provided between each assessment. If the participant wishes, additional rest time is allowed and recorded in the case report form. The assessments include the 10-Meter Walk Test, the 6-Minute Walk Test, the Timed Up and Go Test, and the Berg Balance Scale. These evaluations are conducted in the rehabilitation function testing room on the second floor of the facility

under the supervision of the research team (physician and either a physical or occupational therapist).

3) Pre-Adaptation Phase:

After the evaluations without the device, a total of four adaptation sessions are conducted, during which the participant wears the device and performs short-distance walking within 10 meters. These sessions are designed to help the participant become familiar with the operation and wearing method of the H10 device. Appropriate device settings are configured for each participant to minimize any potential inexperience or anxiety during use. Participants must complete all four adaptation sessions, and each session should be conducted within a two-week interval.

4) Evaluation Phase:

After completing all four adaptation sessions, participants undergo assessments of walking ability and balance while wearing the electrically powered orthopedic exercise device. A 10-minute rest period is provided between each assessment. If the participant wishes, additional rest time is allowed and recorded in the case report form. The assessments include the 10-Meter Walk Test, the 6-Minute Walk Test, the Timed Up and Go Test, and the Berg Balance Scale. These evaluations are conducted in the rehabilitation function testing room on the second floor of the facility under the supervision of the research team (physician and either a physical or occupational therapist). After the evaluations are completed, a usability and satisfaction survey regarding the electrically powered orthopedic exercise device is conducted.

(3) Random assignment and control group

This pilot study had a single-group design and did not include randomization or a control group.

10. Study Method

(1) Screening method

The examiner will interview the participant regarding baseline symptoms and signs, check vital signs to ensure the participant's medical stability, and then proceed with the following assessments.

1) Korea-Mini Mental State Examination

A test that assesses the degree of overall cognitive impairment, taking into account a person's level of education [10], and the test assesses time and place perception, attention and calculation, memory, language, and spatial and temporal organization. The examiner asks questions corresponding to the items on the test sheet below and record a score for the answers.

Patient's Name: _____ Date: _____

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

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

2) Functional Ambulation Index Evaluation (Functional Ambulation Category)

Assessment of the subject's walking function.[11] The examiner observes the subject's gait and records a score based on the criteria in the assessment sheet below.

Stage	Desciption
0	Unable to walk or requires assistance from two or more people.
1	Requires continuous support from one person to maintain balance or shift body weight.
2	Requires intermittent assistance from one person to aid with balance or coordination.
3	Requires supervision or verbal cues without physical contact.
4	Able to walk independently on level surfaces but needs assistance on stairs, slopes, or uneven ground.
5	Able to walk independently.

3) Manual Muscle Test (Medical Research Council Scale) – Hip Joint, Knee Joint, Ankle Joint

The participant's muscle strength is assessed by group according to the criteria in the table below.[12] The participant's posture is positioned accordingly, and the evaluation scores are recorded.

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]

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) Range of Motion (ROM) Assessment – Lower Extremities

The participant's range of joint motion is assessed[13], with angles recorded according to the form below while the participant is in a supine position.

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			

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

Tests that assess various aspects of an individual's daily physical activity[14], and it can provide information about activity level. The examiner questions the subject based on the questionnaire below, records related information, calculates the total activity time and intensity, and classifies it as 'low', 'medium', and 'high'.

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

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

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

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

☐ **none**

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

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

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

☐ **none**

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

_____ **days per week** ⇨ 3b. How much time in total did you usually spend walking on one of those days?

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

☐ **none**

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

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

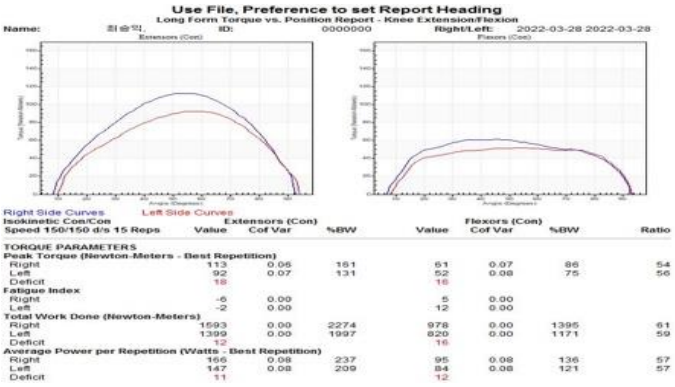
_____ **hours** _____ **minutes**

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

6) Cybex Isokinetic Exercise Test

The Cybex isokinetic exercise test measures lower limb muscle strength and exercise capacity.[15] Participants

perform knee extension movements from a 90-degree to a 0-degree angle at a speed of 60 degrees per second for 5 repetitions and at 150 degrees per second for 15 repetitions. The test evaluates the following parameters of lower limb strength: Peak Torque, Total Work, Average Power per Repetition, and Fatigue Index.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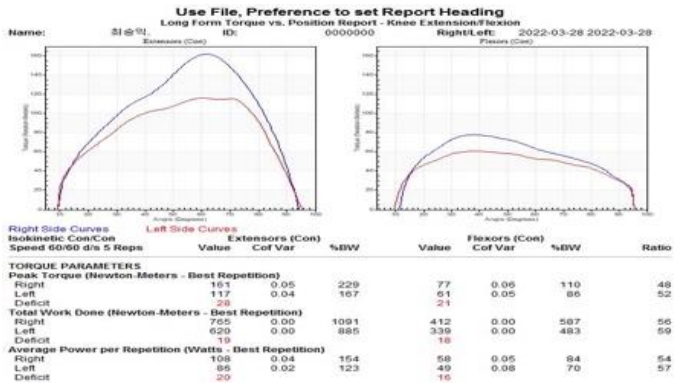
Long Form Torque vs. Position Report - Knee Extension/Flexion

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

Right Side Curves Left Side Curves

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


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

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

Right Side Curves Left Side Curves

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

7) Pregnancy Questionnaire

The examiner (a licensed physician) will conduct a pregnancy questionnaire to determine whether the participant is currently pregnant or has the potential to be pregnant. This assessment will include inquiries about the date of the participant's last menstrual period and their average menstrual cycle.

(2) Evaluation of Gait Function and Balance Ability in Non-Wearing and Wearing Conditions of the Electrically Powered Orthopedic Exercise Device

Participants will perform each of the following assessments once under both conditions:

A. Non-Wearing Condition (Off Status)

B. Wearing Condition (On Status)

1) Primary Evaluation Indicator

① 10-Meter Walk Test

The 10-Meter Walk Test[16] is used to assess gait speed in patients undergoing rehabilitation for neurological and

musculoskeletal disorders. Participants wear an insole-type gait analyzer and walk a 10-meter straight path at a consistent pace while the time taken is measured to evaluate gait ability.

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

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

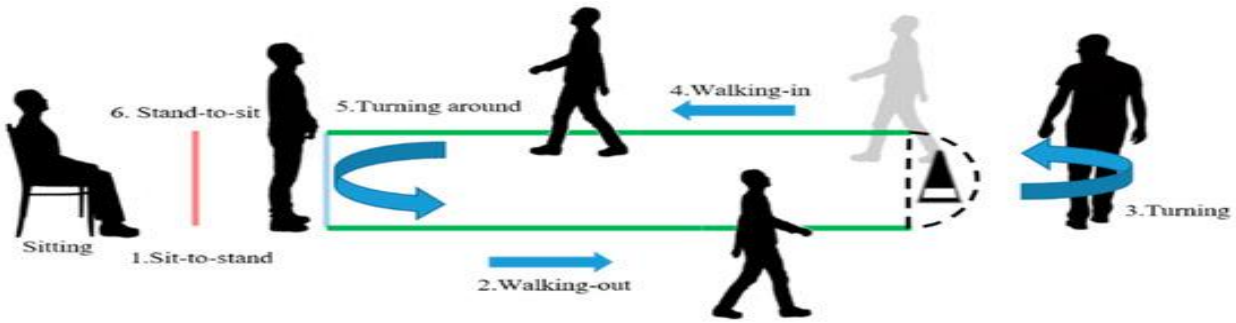
2) Secondary Evaluation Indicator

① Timed Up and Go (TUG) Test

This test[17] evaluates both gait speed and balance ability during walking. The assessment is conducted as follows:

a) Place a chair with armrests (46 cm in height) and position a cone 3 meters away from the chair. Instruct the participant to sit in the chair.

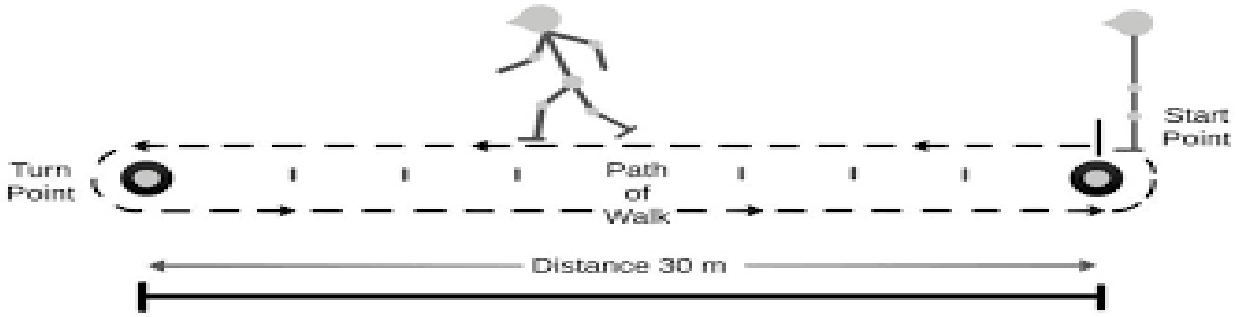
b) During the preparation phase, the participant should sit with their back against the chair and arms resting on the armrests. Upon the command "Start," the participant stands up, walks 3 meters, turns around the cone, walks back to the starting point, and sits down again.



② 6-Minute Walk Test

Participants perform the 6-Minute Walk Test, which closely simulates daily walking activities,[18] while wearing an insole-type gait analyzer. The examiner compares the average parameter data extracted from the analyzer with normal gait standards to provide feedback on the participant's walking. This test assesses gait endurance and is conducted as follows:

a) Set up colored cones marking a 30-meter straight path on the floor and prepare a stopwatch.
b) Instruct the participant to walk back and forth along the 30-meter path as many times as possible within 6 minutes.
c) Inform the participant that they may rest or stop during the test if needed. Only permitted phrases such as "You're doing well" or "Keep going" should be used for encouragement.
d) The examiner records the total distance covered, abnormal gait patterns, and the time of occurrence of any gait deviations.



③ Berg Balance Scale (BBS)

This test assesses both static and dynamic balance.[19] The examiner instructs the participant to perform the following 14 tasks and evaluates their performance based on the scoring criteria for each item.

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

④ Spatiotemporal Parameters of Gait : While the participant performs the test wearing an insole-type gait analyzer, spatiotemporal gait parameters[20] are collected and recorded. These parameters include total step count, cadence,

walking speed, walking distance, and stride length.

a) Step Count: The total number of steps taken during walking.

b) Cadence: The number of steps taken per minute, measured in steps per minute (spm).

c) Self-Selected Walking Speed: The participant's walking speed when walking naturally at a comfortable pace.

d) Distance: The total distance covered during walking, measured in meters (m).

e) Stride Length: The distance between the heel of one foot to the heel of the same foot during consecutive steps. Measured in meters (m), stride length is adjusted for height to account for differences in body size.

(3) Recording of Adverse Events and Device Malfunctions

1) The examiner records the type and frequency of any safety incidents that occur while the participant is walking, as well as the reasons for any device malfunctions.

2) In cases where side effects, such as pain, occur, the following details are investigated and documented: Type of side effect, Severity, Frequency of occurrence, Name of adverse event, Onset and resolution dates, Nature of the side effect, Causal relationship with device use

(4) Satisfaction Evaluation

Participants will complete a satisfaction survey regarding the Electrically Powered Orthopedic Exercise Device, based on the Korean version of the Quebec User Evaluation of Satisfaction with Assistive Technology (K-QUEST 2.0).[21] The survey consists of 10 items, each rated on a 5-point scale to assess satisfaction with the assistive device and related services. Participants are instructed to provide reasons if they select any response other than "Very Satisfied".

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

	One	2	3	4	5
Are you satisfied with the specifications (size, height, length, width) of the smart insole? reason : _____					
How much does the smart insole weigh? reason : _____					
Is it convenient to adjust (fix and lock) the parts (accessories) of the smart insole? reason : _____					

Do you think smart insoles are safe and sturdy? reason : _____					
Are you satisfied with the durability (long-term usability) of the smart insole? reason : _____					
Was it convenient to use the smart insole? reason : _____					
Do you think smart insoles are comfortable to wear? reason : _____					
Are you satisfied with the effectiveness of the smart insole (effectiveness suited to the purpose of use)? reason : _____					
Are you satisfied with Smart Insole's service and delivery program (delivery process and time required)? reason : _____					
Are you satisfied with the professional service (information and precautions) you received while using the smart insole? reason : _____					

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

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

(5) Definition of Analysis Population, and Management Plan for Missing and Outlier Data

1) Definition of Analysis Population

The analysis population includes all participants who have completed the evaluations of gait and balance

abilities under both non-wearing and wearing conditions of the Electrically Powered Orthopedic Exercise Device. Data will be analyzed in conjunction with participants' age, diagnosis, physical function assessments, and other extracted information.

2) Management Plan for Missing and Outlier Data

If missing data occur due to participant withdrawal or dropout, a Complete Case Analysis will be used, analyzing only fully observed cases. Data from sessions with missing values will be excluded from the analysis. Outliers identified through boxplots and interquartile ranges will also be excluded to maintain data integrity and enhance the accuracy and reliability of the research. Information on participants excluded from the analysis will be documented.

(6) Pre- and Post-Condition Comparative Analysis

Upon completion of all evaluations under both non-wearing and wearing conditions of the Electrically Powered Orthopedic Exercise Device, the examiner will perform a comparative analysis of the collected participant data using a paired t-test. A significance level of $p < 0.05$ will be used as the criterion for statistical significance. In addition, a linear mixed model will be used to analyze the data, incorporating both fixed effects and individual variability of participants resulting from repeated measurements.

11. Research Procedure and Evaluation

Phase	Screening/Assessment/Adjustment	Adjustment	Adjustment	Adjustment/Assessment
Session	1	2	3	4
Written consent form	O			
Inclusion/Exclusion Criteria	O			
Clinical Information Collection and Screening Assessment	O			
Primary Outcome Measure Assessment	O			O
Secondary Outcome Measure Assessment	O			O

Wearing the electrically powered orthopedic exercise device	O	O	O	O
Satisfaction survey				O

*Each session should be conducted within a two-week interval.

12. Criteria for study discontinuation and withdrawal

(1) Termination and early suspension

1) If a subject participating in the study withdraws consent before the end of the study

- If consent is withdrawn, only the research participant information collected up to that point will be used for research. Stored for 3 years after completion of research and then destroyed

(2) Drop out in the middle

1) If the subject or his/her legal representative requests discontinuation of participation in the clinical trial
2) If serious side effects occur
3) If the medical team determines that the subject has a serious medical need that prevents the clinical study from continuing.
4) If used concurrently with surgery, drugs, or other medical devices that may affect safety and efficacy evaluation
5) If the subject does not follow the investigator's instructions or does not comply with the provisions of the consent form, which affects the evaluation of the effectiveness.
6) In cases where continuous observation is not possible due to the subject's non-participation
7) If other clinical trial personnel determine that there is a problem with the clinical trial progress
8) If a serious illness or accident that may affect the patient's function occurs during the study period

We will reconfirm the voluntary intention of the research participant to determine whether it is not subject to early discontinuation of the study, and if the participant is still willing to provide information to the study, the information collected up to the point of discontinuation will be anonymized. Can be used for research

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

(1) Safety Monitoring and Evaluation : To ensure participant safety, the principal investigator will act as the safety monitor and conduct ongoing safety evaluations

1) As this is a preliminary case study with minimal invasive procedures and low risk, monitoring will be conducted under the supervision of the principal investigator. Source documents, Case Report Forms (CRF), and the study protocol will be cross-checked to ensure data integrity and review participant safety data.

2) Participants have the right to withdraw from the study at any time if they experience discomfort. The principal investigator or study personnel will fully explain this right and obtain confirmation during the consent process.

(2) Violation and Deviation Reporting

In the event of study violations or deviations, the situation, corrective actions, and recurrence prevention measures will be promptly reported to the Institutional Review Board (IRB) in writing.

If a participant sustains an injury or if a new incident occurs during the evaluation, immediate treatment and monitoring will be provided, along with a thorough investigation into the cause. Treatment will follow the hospital's standard procedures. These incidents will be included in interim reports and documented in the study publication. Given the low likelihood of future adverse events, no additional research budget has been allocated for further treatment costs.

14. Data Analysis and Statistical Considerations

(1) Primary and Secondary Evaluation Variables : Differences in gait function and balance ability between the non-wearing and wearing conditions of the Electrically Powered Orthopedic Exercise Device will be analyzed using descriptive statistics. The analysis will present the mean, standard deviation, median, minimum, and maximum values. Changes in performance will be compared using a paired t-test. In addition, a linear mixed model will be used to analyze the data, incorporating both the individual characteristics of participants due to repeated measures and fixed effects.

(2) Satisfaction Evaluation : Satisfaction with the Electrically Powered Orthopedic Exercise Device will be analyzed using descriptive statistics to determine the mean, standard deviation, minimum, and maximum values for each item. (An average score of 4 or higher will be interpreted as positive satisfaction, an average score of 2 or lower will be interpreted as negative satisfaction)

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

(1) Protection of the subject's personal information

When seeking consent for a study, the study is explained to the subject and consent is obtained in a separate space in the consultation room of the rehabilitation medicine outpatient clinic.

All information collected from this study will be kept confidential and will not be disclosed to anyone other than the research staff involved in the study. And, it will be used only for research purposes. Sensitive personal information that can identify individuals will not be shared with institutions outside the hospital and will undergo a deidentification process regarding whether or not personal information will be provided to third parties. Anonymization is the subject It is done by using a unique number, and 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 the device company. Ownership of the data belongs to the hospital.

(2) Maintaining confidentiality of research data

In the case of document materials, they will be stored in a locked device to prevent exposure to others, and stored on a computer with restricted access, and managed by the researcher in charge.

(3) Preservation of records

In accordance with the Enforcement Rules of the Bioethics and Safety Act, research-related materials involving human subjects must be retained for three years after the conclusion of the study. Documents containing personal information will be destroyed after the retention period following Article 16 of the Enforcement Decree of the Personal Information Protection Act. However, if further retention of the data is necessary for follow-up studies or record accumulation, an extension may be approved through review by the institutional committee.

16. Management, storage, and disposal plans for collection of human-derived materials, genetic information, etc.

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

17. Method of recruiting subjects and consent procedures

After approval from Yongin Severance Hospital IRB, Yongin Severance Hospital Among the visitors, those who voluntarily decided to participate in this study and agreed to participate were interviewed in a private space, provided with an IRB-approved explanatory document for the subjects, and consent forms were obtained.

After providing sufficient explanation about clinical trial participation, consent forms should be written in a non-oppressive environment, and when writing the consent form, it should be explained that consent can be withdrawn at any time at will, so that participants can participate in the clinical trial. In addition, the willingness to participate

in the study should be confirmed during the research test, so that consent can be withdrawn at any time at will.

18. Protection measures when recruiting vulnerable subjects

This study does not recruit vulnerable subjects.

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

(1) Research Director

name	Affiliation	specialty	spot	phone call
Kim Na-young	Yonsei University Medical school Yongin Severance Hospital	Rehabilitation Medicine	Assistant Professor	031-5189-8163 Kny8452 @yuhs.ac

(2) Test Manager

The test manager checks whether the subjects at the test institution meet the selection criteria and manages the overall process of the experiment.

name	Affiliation	specialty	spot	phone call
Kim Na-young	Yonsei University Medical school Yongin Severance Hospital	Rehabilitation Medicine	Assistant Professor	031-5189-8163 Kny8452 @yuhs.ac
Yang Hui-woo	Yonsei University Industry-Academic Cooperation Foundation	Occupational therapy	Researcher	010-7360-4439 Rehab5@yuhs.ac

(3) Device Manager

name	Affiliation	spot	phone call
Yang Hui-woo	Yonsei University Industry-Academic Cooperation Yonsei University Medical school	Researcher	010-7360-4439 Rehab5@yuhs.ac

20. Research location and period

(1) Location of research

Institution name	location	phone call
Yonsei University College of Medicine Yongin Severance Hospital	Giheung -gu, Yongin-si, Gyeonggi-do Dongbaekjukjeon-daero 363 (Middle East)	031-5189-8891

(2) Period

12 months after IRB approval

21. Data Safety Monitoring Plan

Safety inspector (The principal investigator) will monitor the overall progress of the study, including the status of the study, whether the selection criteria for the enrolled subjects are met, the appropriateness of the consent acquisition procedure, whether there are any violations/deviations from the study plan, and whether there are any adverse reactions in the subjects, at monthly intervals, to ensure the completeness of the data.

22. Research implementation plan (schedule)

Development details	Detailed progress schedule (months)											
	1	2	3	4	5	6	7	8	9	10	1 1	1 2

Research plan and IRB approval	■											
Recruitment of subjects	■	■	■	■	■	■	■	■	■	■	■	
Research procedure performance and follow-up period	■	■	■	■	■	■	■	■	■	■	■	■

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