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Document:

Study Protocol and Statistical Analysis Plan

Official Study Title:

Development and Feasibility study of the home-based gait rehabilitation service
by using the insole-type gait measurement device for children with cerebral palsy

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Prospective Clinical Study Protocol

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

- Title: Development and Feasibility study of the home-based gait rehabilitation service by using the insole-type gait measurement device for children with cerebral palsy

2. Summary of study plan

Study objective	This study aims to assess the usability and satisfaction of utilizing insole gait analysis devices for monitoring and providing feedback on the walking status of children with cerebral palsy exhibiting walking impairments in a home environment. Additionally, adherence to a home-based exercise program developed in this study will be evaluated.
Study design overview	Investigator-led exploratory clinical study
Target number of subjects and calculation basis	Ten children with cerebral palsy exhibiting gait disturbances were selected. Given the lack of prior studies using the same equipment as this study and the limited number of similar studies with varying results, it is challenging to statistically determine an accurate sample size based on previous research. This study aims to explore the clinical significance of data obtained using an insole-based gait analysis system in a home setting. Therefore, the target sample size was set considering clinical conditions.
Inclusion and exclusion criteria	<ol style="list-style-type: none">1) Inclusion criteria<ol style="list-style-type: none">① Patients diagnosed with cerebral palsy aged 7 to 18 years old② Patients classified as Gross Motor Function Classification System level 1 or 2③ Individuals who visited Severance Hospital, comprehended the study, agreed to participate, and submitted the informed consent form2) Exclusion criteria<ol style="list-style-type: none">① Individuals with complications such as severe foot deformities where the sensors of the insole gait analysis device cannot be recognized② In addition to above, individuals with clinically significant findings deemed inappropriate for this study by the study director or person in charge based on medical judgment



Study Methods	<p>The screening test is conducted after obtaining consent, and it involves assessing whether the subject can independently walk more than 10 meters, regardless of the use of assistive devices, following an evaluation of their baseline symptoms and signs.</p> <p>Subjects who pass the screening test are provided with information about their current walking status and what constitutes normal walking. Following the initial evaluation, they are instructed to participate in the 6-week home exercise program and how to record an exercise log. Additionally, researchers provide participants with an insole gait analysis device and instruct them on its operation, encouraging prolonged usage to ensure that usage time and walking patterns are recorded.</p> <p>Based on the collected measurement data, feedback is provided over the phone at weeks 3 to 4. After completing the 6-week home exercise program, a final evaluation is conducted in the same manner as the initial evaluation. Satisfaction with the insole gait analysis device is assessed only at the time of the final evaluation.</p> <p>Usage and satisfaction with the insole gait analysis device will be analyzed, and evaluation indicators will be compared before and after the home exercise program. Additionally, adherence to the home exercise program will be evaluated through exercise logs.</p>
Evaluation variable	<ol style="list-style-type: none">1. Primary outcome<ol style="list-style-type: none">1) 6-minute Walking Test2. Secondary outcomes<ol style="list-style-type: none">1) Body Composition Analysis2) Grip Strength Test3) Spatiotemporal Parameters of Walking4) 10-meter Walking Test5) Pediatric balance scale6) Gross motor function measurement7) Korean version of Cerebral Palsy Quality of Life (if the participant is aged 8 or younger), Korean version of KIDSCREEN-52 Children & Adolescents (if the participant is aged over 8), Korean version of KIDSCREEN-52 Parents (if the participant is aged over 8)8) (only at the end of the experiment) Satisfaction Survey for the Device
Data analysis and statistical methods	<ol style="list-style-type: none">1. Primary and secondary outcomes: The difference before and after the home-based exercise program is presented as descriptive statistics, and the change in performance is compared through a paired-sample T test if the normality assumption is satisfied, and a Wilcoxon singed-rank test if it is not.



	2. Satisfaction evaluation: Satisfaction with the home-based exercise program using an insole-type gait analyzer is analyzed and presented using descriptive statistics.
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3. Study background and theoretical basis

Walking is a crucial daily activity that requires complex coordination of muscular systems [1]. It is essential for bone and muscle health, cardiovascular fitness, and activities of daily living, making it an important indicator of prognosis and patient function [2, 3]. Gait disturbance is one of the most common symptoms observed in neurological diseases, and improving gait function in patients with gait disturbances is also one of the primary goals of rehabilitation therapy [4]. In particular, pediatric gait disturbances can arise from various and complex causes and symptoms, including paralysis, spasticity, hypokinesia, and ataxia, associated with neurological diseases [5]. Unlike adults, children are still growing and developing, necessitating appropriate evaluation and rehabilitation therapy at each stage. Notably, reports indicate that once children reach school age, their activity levels can decrease by 13% to 53% compared to their typically developing peers [6]. Research suggests that this decrease in activity levels can persist into adulthood [7]. Studies indicate that this can lead to musculoskeletal [8] and cardiovascular complications [9], making comprehensive management essential [10].

Many studies have already explored prescribing exercise under medical supervision or monitoring. Unlike the past, when wearable sensors could only monitor heart rate, advancements in miniaturized sensors and wireless technology now enable kinematic analysis. As a result, there is a growing trend in research focusing on remotely analyzing gait patterns and posture [11]. For patients with gait disturbances, it is important not only to be able to walk but also to walk accurately, resembling normal gait as closely as possible. This is significant for preventing musculoskeletal disorders and promoting overall health. New technologies are expected to greatly aid in enhancing the health of these individuals. However, most of the devices used in research are prototypes, and their actual clinical application remains limited [12].

An insole-type gait analysis measurement device monitors gait by placing sensor-equipped insoles inside the shoes. This system is relatively inexpensive and easy to use. Additionally, the spatiotemporal parameters of gait obtained using this method show a high correlation with the results of 3D gait analysis, which is considered one of the most standardized methods for quantitative gait analysis [13]. While there are many studies utilizing insole-type gait analysis systems within hospital settings, there is a lack of research on their use in outdoor or home environments. Therefore, this study aims to explore the feasibility and efficacy of a home-based gait rehabilitation service that provides monitoring and feedback on gait using a commercially available insole-type gait measurement device for school-aged children diagnosed with cerebral palsy.

4. Purpose of the study

This study aims to assess the usability and satisfaction of utilizing insole gait analysis devices for monitoring and providing feedback on the walking status of children with cerebral palsy exhibiting walking



impairments in a home environment. Additionally, adherence to a home-based exercise program developed in this study will be evaluated.

5. Risk/benefit analysis

The assessment items used in this study are widely utilized in standard clinical settings to compare the effects before and after treatment. However, not all tests are performed at every clinical visit; selection depends on the clinical physician's judgment. For the purposes of this research, all validity assessments will be conducted. Furthermore, to minimize the risk of falls during testing, the assessments will be conducted under the supervision of an examiner.

The potential risks associated with these minimal hazards are outweighed by the benefits participants will gain from the study. Participants will receive information about their muscle mass, walking and balance abilities, and feedback on how their gait metrics compare to normal walking standards. Additionally, the real-time monitoring of home exercise programs and the collected gait data can contribute to research related to the treatment and prognosis of diseases, thereby advancing medical knowledge and improving the quality of care. Therefore, the potential benefits obtained through this research are expected to outweigh the risk.

6. Number of target audience and basis for calculation

Given the absence of prior studies utilizing the same equipment as this study and the limited number of similar studies reporting diverse results, it is challenging to statistically determine an accurate sample size based on previous research. This study aims to explore the clinical significance of data obtained using an insole-based gait analysis system in a home setting. Taking clinical conditions into consideration, the target sample size has been set at 10 participants.

7. Subject selection/exclusion criteria

1) Inclusion criteria

- ① Patients diagnosed with cerebral palsy aged 7 to 18 years old
- ② Patients classified as Gross Motor Function Classification System level 1 or 2
- ③ Individuals who visited Severance Hospital, comprehended the study, agreed to participate, and submitted the informed consent form

2) Exclusion criteria

- ① Individuals with complications such as severe foot deformities where the sensors of the insole gait analysis device cannot be recognized
- ② In addition to above, individuals with clinically significant findings deemed inappropriate for this study by the study director or person in charge based on medical judgment



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

- 1) Although this study does not involve the use of medical devices, the information on the wellness device used in the study is as follows
 - Item name: Insole type gait analyzer
 - Model name: LARN8
 - Classification number: R-R-G34-GS-434
 - Manufacturer: Gilon Co., Ltd.
 - Principle of operation and appearance: This product is designed to assess the decline in walking ability and the functional recovery following treatment. It consists of both hardware and software (app). When the user wears the shoes equipped with the device and starts walking, the accelerometer sensor embedded in the device detects the user's movements and measures walking speed, walking distance, and step count, providing insights into the user's gait pattern.
- 2) The wellness device used in this study will be managed according to usage precautions and storage methods at a designated location (the Motion Analysis Lab on the 2nd floor of Severance Hospital).



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

- 1) Overview of study design
 - This is a researcher-led, exploratory clinical study designed with random assignment and lasts for 6 weeks.
- 2) Experimental group
 - The insole-wearing group is instructed to wear the insole gait analysis device as frequently and for as long as possible during outdoor activities. Participants receive feedback during 3rd to 4th week via telephone. Following a period of 6 weeks, an evaluation of the usability and satisfaction of the insole gait analysis device will be conducted.
- 3) Control group
 - Not applicable
- 4) Random assignment
 - Not applicable

10. Study method

- 1) Screening method
 - The screening test is conducted after obtaining consent, and it involves assessing whether the subject can independently walk more than 10 meters, regardless of the use of assistive devices, following an evaluation of their baseline symptoms and signs.
- 2) Evaluation indicators before and after in intervention program: As the primary outcome measure, the 6-minute walk test will be used. Secondary outcome measures include body composition analysis, digital grip



strength measurement, spatiotemporal gait parameters, the 10-meter walk test, the Pediatric Balance Scale, the Gross Motor Function Measure, quality of life questionnaires for children with cerebral palsy and their parents, and a satisfaction survey. If conducting an assessment is not feasible, the reason for the inability to assess will be documented.

① 6-minute Walking Test

The 6-minute walk test is a useful indicator for assessing walking endurance and estimating cardiopulmonary function. It measures the maximum distance (in meters) that a subject can walk in 6 minutes. The subject may rest if necessary, but is encouraged to cover the maximum possible distance during the test.

② Body Composition

To determine the appendicular muscle mass, a body composition analysis based on bioelectrical impedance analysis is performed [14]. To correct for differences in muscle mass due to height, the appendicular skeletal mass is calculated and divided by the square of the height.



③ Grip Strength Test

To assess grip strength, which can predict overall muscle strength, the subject follows the examiner's instructions and stands in a neutral shoulder position with the elbow fully extended. Then the subject grips the dynamometer with maximum force for 5 seconds. Measurements are taken alternately for the dominant hand and the non-dominant hand, with each hand being measured three times. The average value is used for evaluation. A 60-second rest period between each measurement is provided to prevent muscle fatigue [15, 16].

④ Spatiotemporal Parameters of Walking

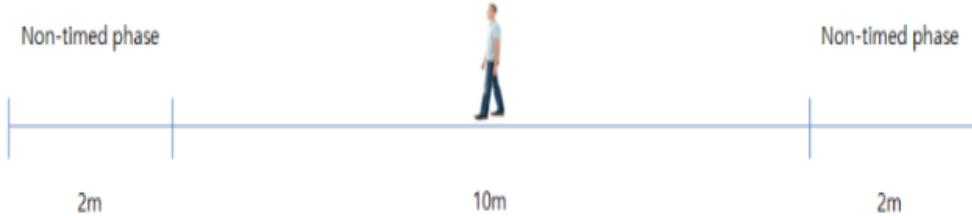
While the subject performs activities at home wearing an insole-type gait analyzer, spatiotemporal parameter data of the gait are collected. This data includes the number of steps, calories burned, activity time, activity distance, walking speed, stride length, and left-right gait balance.

⑤ 10-meter Walking Test

Following the examiner's instructions, the subject walks a total of 14 meters at their usual walking speed, with or without assistive devices. The examiner records the time taken to walk 10 meters, starting from 2



meters after the starting point to 2 meters before the finish line. The walking speed is measured in two conditions: comfortable speed and maximal speed (when the subject attempts to walk as quickly as possible) [17].



⑥ Pediatric balance scale

The assessment tool developed to evaluate functional balance in children consists of the following detailed items.

The subjects perform a total of 14 items according to the examiner's instructions. Each item can be attempted up to three times. The examiner records the scores based on the criteria in the following assessment sheet [18, 19].

Pediatric Balance Scale	
1	Seated position to standing position
2	Standing position to sitting position
3	Transfer
4	Standing without support
5	Sitting without support
6	Standing with eyes closed
7	Standing with your feet together
8	Standing with one foot in front
9	Standing on one foot
10	Rotating 360 degrees
11	Turning to look back
12	Picking up an object off the floor
13	Placing alternate foot on step / footrest
14	Reaching forward with extended arm

⑦ Gross motor function measurement

The standardized observational assessment tool for measuring gross motor function development in children consists of the following evaluation items. The subjects perform 17 lying and rolling items, 20 sitting items, 14 crawling and kneeling items, 13 standing items, and 24 walking, running, and jumping items according to the examiner's instructions. The examiner records the scores based on the criteria in the following assessment sheet [20].



Check (3) the appropriate score: if an item is not tested (NT), circle the item number on the right column

Item	A: LYING & ROLLING	SCORE	NT
1.	SUP, HEAD IN MIDLINE: TURNS HEAD WITH EXTREMITIES SYMMETRICAL	0□ 1□ 2□ 3□	1.
*	2. SUP: BRINGS HANDS TO MIDLINE, FINGERS ONE WITH THE OTHER.....	0□ 1□ 2□ 3□	2.
3.	SUP: LIFTS HEAD 45°	0□ 1□ 2□ 3□	3.
4.	SUP: FLEXES R HIP & KNEE THROUGH FULL RANGE.....	0□ 1□ 2□ 3□	4.
5.	SUP: FLEXES L HIP & KNEE THROUGH FULL RANGE.....	0□ 1□ 2□ 3□	5.
*	6. SUP: REACHES OUT WITH R ARM, HAND CROSSES MIDLINE TOWARD TOY.....	0□ 1□ 2□ 3□	6.
*	7. SUP: REACHES OUT WITH L ARM, HAND CROSSES MIDLINE TOWARD TOY	0□ 1□ 2□ 3□	7.
8.	SUP: ROLLS TO PR OVER R SIDE	0□ 1□ 2□ 3□	8.
9.	SUP: ROLLS TO PR OVER L SIDE.....	0□ 1□ 2□ 3□	9.
*	10. PR: LIFTS HEAD UPRIGHT	0□ 1□ 2□ 3□	10.
11.	PR ON FOREARMS: LIFTS HEAD UPRIGHT, ELBOWS EXT., CHEST RAISED.....	0□ 1□ 2□ 3□	11.
12.	PR ON FOREARMS: WEIGHT ON R FOREARM, FULLY EXTENDS OPPOSITE ARM FORWARD.....	0□ 1□ 2□ 3□	12.
13.	PR ON FOREARMS: WEIGHT ON L FOREARM, FULLY EXTENDS OPPOSITE ARM FORWARD	0□ 1□ 2□ 3□	13.
14.	PR: ROLLS TO SUP OVER R SIDE	0□ 1□ 2□ 3□	14.
15.	PR: ROLLS TO SUP OVER L SIDE	0□ 1□ 2□ 3□	15.
16.	PR: PIVOTS TO R 90° USING EXTREMITIES	0□ 1□ 2□ 3□	16.
17.	PR: PIVOTS TO L 90° USING EXTREMITIES.....	0□ 1□ 2□ 3□	17.

TOTAL DIMENSION A

Item	B: SITTING	SCORE	NT
*	18. SUP, HANDS GRASPED BY EXAMINER: PULLS SELF TO SITTING WITH HEAD CONTROL.....	0□ 1□ 2□ 3□	18.
19.	SUP: ROLLS TO R SIDE, ATTAINS SITTING	0□ 1□ 2□ 3□	19.
20.	SUP: ROLLS TO L SIDE, ATTAINS SITTING	0□ 1□ 2□ 3□	20.
*	21. SIT ON MAT, SUPPORTED AT THORAX BY THERAPIST: LIFTS HEAD UPRIGHT, MAINTAINS 3 SECONDS	0□ 1□ 2□ 3□	21.
*	22. SIT ON MAT, SUPPORTED AT THORAX BY THERAPIST: LIFTS HEAD MIDLINE, MAINTAINS 10 SECONDS	0□ 1□ 2□ 3□	22.
*	23. SIT ON MAT, ARM(S) PROPPING: MAINTAINS, 5 SECONDS	0□ 1□ 2□ 3□	23.
*	24. SIT ON MAT: MAINTAIN, ARMS FREE, 3 SECONDS	0□ 1□ 2□ 3□	24.
*	25. SIT ON MAT WITH SMALL TOY IN FRONT: LEANS FORWARD, TOUCHES TOY, RE-ERECTS WITHOUT ARM PROPPING	0□ 1□ 2□ 3□	25.
*	26. SIT ON MAT: TOUCHES TOY PLACED 45° BEHIND CHILD'S R SIDE, RETURNS TO START	0□ 1□ 2□ 3□	26.
*	27. SIT ON MAT: TOUCHES TOY PLACED 45° BEHIND CHILD'S L SIDE, RETURNS TO START.....	0□ 1□ 2□ 3□	27.
28.	R SIDE SIT: MAINTAINS, ARMS FREE, 5 SECONDS	0□ 1□ 2□ 3□	28.
29.	L SIDE SIT: MAINTAINS, ARMS FREE, 5 SECONDS	0□ 1□ 2□ 3□	29.
*	30. SIT ON MAT: LOWERS TO PR WITH CONTROL	0□ 1□ 2□ 3□	30.
*	31. SIT ON MAT WITH FEET IN FRONT: ATTAINS 4 POINT OVER R SIDE.....	0□ 1□ 2□ 3□	31.
*	32. SIT ON MAT WITH FEET IN FRONT: ATTAINS 4 POINT OVER L SIDE.....	0□ 1□ 2□ 3□	32.
33.	SIT ON MAT: PIVOTS 90°, WITHOUT ARMS ASSISTING	0□ 1□ 2□ 3□	33.
*	34. SIT ON BENCH: MAINTAINS, ARMS AND FEET FREE, 10 SECONDS.....	0□ 1□ 2□ 3□	34.
*	35. STD: ATTAINS SIT ON SMALL BENCH	0□ 1□ 2□ 3□	35.
*	36. ON THE FLOOR: ATTAINS SIT ON SMALL BENCH	0□ 1□ 2□ 3□	36.
*	37. ON THE FLOOR: ATTAINS SIT ON LARGE BENCH	0□ 1□ 2□ 3□	37.

TOTAL DIMENSION B



Item	C: CRAWLING & KNEELING	SCORE	NT
38.	PR: CREEPS FORWARD 1.8m (6')	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/>	38.
*	39. 4 POINT: MAINTAINS, WEIGHT ON HANDS AND KNEES, 10 SECONDS	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/>	39.
*	40. 4 POINT: ATTAINS SIT ARMS FREE	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/>	40.
*	41. PR: ATTAINS 4 POINT, WEIGHT ON HANDS AND KNEES	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/>	41.
*	42. 4 POINT: REACHES FORWARD WITH R ARM, HAND ABOVE SHOULDER LEVEL	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/>	42.
*	43. 4 POINT: REACHES FORWARD WITH L ARM, HAND ABOVE SHOULDER LEVEL	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/>	43.
*	44. 4 POINT: CRAWLS OR HITCHES FORWARD 1.8m(6').....	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/>	44.
*	45. 4 POINT: CRAWLS RECIPROCALLY FORWARD 1.8m (6').....	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/>	45.
*	46. 4 POINT: CRAWLS UP 4 STEPS ON HANDS AND KNEES/FEET.....	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/>	46.
47.	4 POINT: CRAWLS BACKWARDS DOWN 4 STEPS ON HANDS AND KNEES/FEET	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/>	47.
*	48. SIT ON MAT: ATTAINS HIGH KN USING ARMS, MAINTAINS, ARMS FREE, 10 SECONDS	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/>	48.
49.	HIGH KN: ATTAINS HALF KN ON R KNEE USING ARMS, MAINTAINS, ARMS FREE, 10 SECONDS	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/>	49.
50.	HIGH KN: ATTAINS HALF KN ON L KNEE USING ARMS, MAINTAINS, ARMS FREE, 10 SECONDS	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/>	50.
*	51. HIGH KN: KN WALKS FORWARD 10 STEPS, ARMS FREE	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/>	51.

TOTAL DIMENSION C

Item	D: STANDING	SCORE	NT
*	52. ON THE FLOOR: PULLS TO STD AT LARGE BENCH.....	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/>	52.
*	53. STD: MAINTAINS, ARMS FREE, 3 SECONDS	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/>	53.
*	54. STD: HOLDING ON TO LARGE BENCH WITH ONE HAND, LIFTS R FOOT, 3 SECONDS	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/>	54.
*	55. STD: HOLDING ON TO LARGE BENCH WITH ONE HAND, LIFTS L FOOT, 3 SECONDS.....	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/>	55.
*	56. STD: MAINTAINS, ARMS FREE, 20 SECONDS	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/>	56.
*	57. STD: LIFTS L FOOT, ARMS FREE, 10 SECONDS	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/>	57.
*	58. STD: LIFTS R FOOT, ARMS FREE, 10 SECONDS	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/>	58.
*	59. SIT ON SMALL BENCH: ATTAINS STD WITHOUT USING ARMS.....	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/>	59.
*	60. HIGH KN: ATTAINS STD THROUGH HALF KN ON R KNEE, WITHOUT USING ARMS.....	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/>	60.
*	61. HIGH KN: ATTAINS STD THROUGH HALF KN ON L KNEE, WITHOUT USING ARMS	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/>	61.
*	62. STD: LOWERS TO SIT ON FLOOR WITH CONTROL, ARMS FREE	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/>	62.
*	63. STD: ATTAINS SQUAT, ARMS FREE	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/>	63.
*	64. STD: PICKS UP OBJECT FROM FLOOR, ARMS FREE, RETURNS TO STAND	0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/>	64.

TOTAL DIMENSION D



Item	E: WALKING, RUNNING & JUMPING	SCORE	NT
*	65. STD, 2 HANDS ON LARGE BENCH: CRUISES 5 STEPS TO R	0□ 1□ 2□ 3□	65.
*	66. STD, 2 HANDS ON LARGE BENCH: CRUISES 5 STEPS TO L	0□ 1□ 2□ 3□	66.
*	67. STD, 2 HANDS HELD: WALKS FORWARD 10 STEPS	0□ 1□ 2□ 3□	67.
*	68. STD, 1 HAND HELD: WALKS FORWARD 10 STEPS.....	0□ 1□ 2□ 3□	68.
*	69. STD: WALKS FORWARD 10 STEPS	0□ 1□ 2□ 3□	69.
*	70. STD: WALKS FORWARD 10 STEPS, STOPS, TURNS 180°, RETURNS	0□ 1□ 2□ 3□	70.
*	71. STD: WALKS BACKWARD 10 STEPS.....	0□ 1□ 2□ 3□	71.
*	72. STD: WALKS FORWARD 10 STEPS, CARRYING A LARGE OBJECT WITH 2 HANDS.....	0□ 1□ 2□ 3□	72.
*	73. STD: WALKS FORWARD 10 CONSECUTIVE STEPS BETWEEN PARALLEL LINES 20cm (8")APART	0□ 1□ 2□ 3□	73.
*	74. STD: WALKS FORWARD 10 CONSECUTIVE STEPS ON A STRAIGHT LINE 2cm (3/4") WIDE	0□ 1□ 2□ 3□	74.
*	75. STD: STEPS OVER STICK AT KNEE LEVEL, R FOOT LEADING	0□ 1□ 2□ 3□	75.
*	76. STD: STEPS OVER STICK AT KNEE LEVEL, L FOOT LEADING	0□ 1□ 2□ 3□	76.
*	77. STD: RUNS 4.5m (15'), STOPS & RETURNS.....	0□ 1□ 2□ 3□	77.
*	78. STD: KICKS BALL WITH R FOOT	0□ 1□ 2□ 3□	78.
*	79. STD: KICKS BALL WITH L FOOT.....	0□ 1□ 2□ 3□	79.
*	80. STD: JUMPS 30cm (12") HIGH, BOTH FEET SIMULTANEOUSLY	0□ 1□ 2□ 3□	80.
*	81. STD: JUMPS FORWARD 30 cm (12'), BOTH FEET SIMULTANEOUSLY	0□ 1□ 2□ 3□	81.
*	82. STD ON R FOOT: HOPS ON R FOOT 10 TIMES WITHIN A 60cm (24") CIRCLE.....	0□ 1□ 2□ 3□	82.
*	83. STD ON L FOOT: HOPS ON L FOOT 10 TIMES WITHIN A 60cm (24") CIRCLE.....	0□ 1□ 2□ 3□	83.
*	84. STD, HOLDING 1 RAIL: WALKS UP 4 STEPS, HOLDING 1 RAIL, ALTERNATING FEET.....	0□ 1□ 2□ 3□	84.
*	85. STD, HOLDING 1 RAIL: WALKS DOWN 4 STEPS, HOLDING 1 RAIL, ALTERNATING FEET	0□ 1□ 2□ 3□	85.
*	86. STD: WALKS UP 4 STEPS, ALTERNATING FEET.....	0□ 1□ 2□ 3□	86.
*	87. STD: WALKS DOWN 4 STEPS, ALTERNATING FEET	0□ 1□ 2□ 3□	87.
*	88. STD ON 15cm (6") STEP: JUMPS OFF, BOTH FEET SIMULTANEOUSLY	0□ 1□ 2□ 3□	88.

TOTAL DIMENSION E

⑧ Korean version of Cerebral Palsy Quality of Life (CP-QoL) Parents Report (if the participant is aged 8 or younger), Korean version of KIDSCREEN-52 Children & Adolescents (if the participant is aged over 8), Korean version of KIDSCREEN-52 Parents (if the participant is aged over 8)

To assess the quality of life of children with cerebral palsy and their parents, the CP-QoL Parent Report is used for subjects under 8 years old. For those aged 8 and above, the KIDSCREEN-52 Children & Adolescents and the parent versions are used. The detailed items of each questionnaire are as follows [21].

- KIDSCREEN-52 Children & Adolescents



1. Physical Activities and Health

In general, how would you say your health is?					
1.	<input type="radio"/> excellent	<input type="radio"/> very good	<input type="radio"/> good	<input type="radio"/> fair	<input type="radio"/> poor
Thinking about the last week ...					
	not at all	slightly	moderately	very	extremely
2. Have you felt physically fit and well?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. Have you been physically active (e.g. running, climbing, biking)?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. Have you been able to run well?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Thinking about the last week ...					
	never	almost never	sometimes	almost always	always
5. Have you felt full of energy?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

2. Feelings

Thinking about the last week ...					
	not at all	slightly	moderately	very	extremely
1. Has your life been enjoyable?	<input type="radio"/>				
2. Have you felt pleased that you are alive?	<input type="radio"/>				
3. Have you felt satisfied with your life?	<input type="radio"/>				
Thinking about the last week ...					
	never	almost never	sometimes	almost always	always
4. Have you been in a good mood?	<input type="radio"/>				
5. Have you felt cheerful?	<input type="radio"/>				
6. Have you had fun?	<input type="radio"/>				

3. General Mood

Thinking about the last week ...					
	never	almost never	sometimes	almost always	always
1. Have you felt that you do everything badly?	<input type="radio"/>				
2. Have you felt sad?	<input type="radio"/>				
3. Have you felt so bad that you didn't want to do anything?	<input type="radio"/>				
4. Have you felt that everything in your life goes wrong?	<input type="radio"/>				
5. Have you felt fed up?	<input type="radio"/>				
6. Have you felt lonely?	<input type="radio"/>				
7. Have you felt under pressure?	<input type="radio"/>				



4. About Yourself

Thinking about the last week ...		never	almost never	sometimes	almost always	always
1.	Have you been happy with the way you are?	never <input type="radio"/>	almost never <input type="radio"/>	sometimes <input type="radio"/>	almost always <input type="radio"/>	always <input type="radio"/>
2.	Have you been happy with your clothes?	never <input type="radio"/>	almost never <input type="radio"/>	sometimes <input type="radio"/>	almost always <input type="radio"/>	always <input type="radio"/>
3.	Have you been worried about the way you look?	never <input type="radio"/>	almost never <input type="radio"/>	sometimes <input type="radio"/>	almost always <input type="radio"/>	always <input type="radio"/>
4.	Have you felt jealous of the way other girls and boys look?	never <input type="radio"/>	almost never <input type="radio"/>	sometimes <input type="radio"/>	almost always <input type="radio"/>	always <input type="radio"/>
5.	Would you like to change something about your body?	never <input type="radio"/>	almost never <input type="radio"/>	sometimes <input type="radio"/>	almost always <input type="radio"/>	always <input type="radio"/>

5. Free Time

Thinking about the last week ...		never	almost never	sometimes	almost always	always
1.	Have you had enough time for yourself?	never <input type="radio"/>	almost never <input type="radio"/>	sometimes <input type="radio"/>	almost always <input type="radio"/>	always <input type="radio"/>
2.	Have you been able to do the things that you want to do in your free time?	never <input type="radio"/>	almost never <input type="radio"/>	sometimes <input type="radio"/>	almost always <input type="radio"/>	always <input type="radio"/>
3.	Have you had enough opportunity to be outside?	never <input type="radio"/>	almost never <input type="radio"/>	sometimes <input type="radio"/>	almost always <input type="radio"/>	always <input type="radio"/>
4.	Have you had enough time to meet friends?	never <input type="radio"/>	almost never <input type="radio"/>	sometimes <input type="radio"/>	almost always <input type="radio"/>	always <input type="radio"/>
5.	Have you been able to choose what to do in your free time?	never <input type="radio"/>	almost never <input type="radio"/>	sometimes <input type="radio"/>	almost always <input type="radio"/>	always <input type="radio"/>

6. Family and Home Life

Thinking about the last week ...		not at all	slightly	moderately	very	extremely
1.	Have your parent(s) understood you?	not at all <input type="radio"/>	slightly <input type="radio"/>	moderately <input type="radio"/>	very <input type="radio"/>	extremely <input type="radio"/>
2.	Have you felt loved by your parent(s)?	not at all <input type="radio"/>	slightly <input type="radio"/>	moderately <input type="radio"/>	very <input type="radio"/>	extremely <input type="radio"/>
Thinking about the last week ...		never	almost never	sometimes	almost always	always
3.	Have you been happy at home?	never <input type="radio"/>	almost never <input type="radio"/>	sometimes <input type="radio"/>	almost always <input type="radio"/>	always <input type="radio"/>
4.	Have your parent(s) had enough time for you?	never <input type="radio"/>	almost never <input type="radio"/>	sometimes <input type="radio"/>	almost always <input type="radio"/>	always <input type="radio"/>
5.	Have your parent(s) treated you fairly?	never <input type="radio"/>	almost never <input type="radio"/>	sometimes <input type="radio"/>	almost always <input type="radio"/>	always <input type="radio"/>
6.	Have you been able talk to your parent(s) when you wanted to?	never <input type="radio"/>	almost never <input type="radio"/>	sometimes <input type="radio"/>	almost always <input type="radio"/>	always <input type="radio"/>

7. Money Matters

Thinking about the last week ...		never	almost never	sometimes	almost always	always
1.	Have you had enough money to do the same things as your friends?	never <input type="radio"/>	almost never <input type="radio"/>	sometimes <input type="radio"/>	almost always <input type="radio"/>	always <input type="radio"/>
2.	Have you had enough money for your expenses?	never <input type="radio"/>	almost never <input type="radio"/>	sometimes <input type="radio"/>	almost always <input type="radio"/>	always <input type="radio"/>
Thinking about the last week ...		not at all	slightly	moderately	very	extremely
3.	Do you have enough money to do things with your friends?	not at all <input type="radio"/>	slightly <input type="radio"/>	moderately <input type="radio"/>	very <input type="radio"/>	extremely <input type="radio"/>



8. Friends

Thinking about the last week ...					
	never	almost never	sometimes	almost always	always
1. Have you spent time with your friends?	never	almost never	sometimes	almost always	always
2. Have you done things with other girls and boys?	never	almost never	sometimes	almost always	always
3. Have you had fun with your friends?	never	almost never	sometimes	almost always	always
4. Have you and your friends helped each other?	never	almost never	sometimes	almost always	always
5. Have you been able to talk about everything with your friends?	never	almost never	sometimes	almost always	always
6. Have you been able to rely on your friends?	never	almost never	sometimes	almost always	always

9. School and Learning

Thinking about the last week ...					
	not at all	slightly	moderately	very	extremely
1. Have you been happy at school?	not at all	slightly	moderately	very	extremely
2. Have you got on well at school?	not at all	slightly	moderately	very	extremely
3. Have you been satisfied with your teachers?	not at all	slightly	moderately	very	extremely

Thinking about the last week ...					
	never	almost never	sometimes	almost always	always
4. Have you been able to pay attention?	never	almost never	sometimes	almost always	always
5. Have you enjoyed going to school?	never	almost never	sometimes	almost always	always
6. Have you got along well with your teachers?	never	almost never	sometimes	almost always	always

10. Bullying

Thinking about the last week ...					
	never	almost never	sometimes	almost always	always
1. Have you been afraid of other girls and boys?	never	almost never	sometimes	almost always	always
2. Have other girls and boys made fun of you?	never	almost never	sometimes	almost always	always
3. Have other girls and boys bullied you?	never	almost never	sometimes	almost always	always



- KIDSCREEN-52 Parents

1. Physical Activities and Health

In general, how would your child rate her/his health?						
1.	<input type="radio"/> excellent	<input type="radio"/> very good	<input type="radio"/> good	<input type="radio"/> fair		
	<input type="radio"/> poor					
Thinking about the last week ...						
	not at all	slightly	moderately	very	extremely	
2.	Has your child felt physically fit and well?	<input type="radio"/> not at all	<input type="radio"/> slightly	<input type="radio"/> moderately	<input type="radio"/> very	<input type="radio"/> extremely
3.	Has your child been physically active (e.g. running, climbing, biking)?	<input type="radio"/> not at all	<input type="radio"/> slightly	<input type="radio"/> moderately	<input type="radio"/> very	<input type="radio"/> extremely
4.	Has your child been able to run well?	<input type="radio"/> not at all	<input type="radio"/> slightly	<input type="radio"/> moderately	<input type="radio"/> very	<input type="radio"/> extremely
Thinking about the last week ...						
	never	almost never	sometimes	almost always	always	
5.	Has your child felt full of energy?	<input type="radio"/> never	<input type="radio"/> almost never	<input type="radio"/> sometimes	<input type="radio"/> almost always	<input type="radio"/> always

2. Feelings

Thinking about the last week ...						
	not at all	slightly	moderately	very	extremely	
1.	Has your child felt that life was enjoyable?	<input type="radio"/> not at all	<input type="radio"/> slightly	<input type="radio"/> moderately	<input type="radio"/> very	<input type="radio"/> extremely
2.	Has your child felt pleased that he/she is alive?	<input type="radio"/> not at all	<input type="radio"/> slightly	<input type="radio"/> moderately	<input type="radio"/> very	<input type="radio"/> extremely
3.	Has your child felt satisfied with his/her life?	<input type="radio"/> not at all	<input type="radio"/> slightly	<input type="radio"/> moderately	<input type="radio"/> very	<input type="radio"/> extremely



Thinking about the last week ...

	never	almost never	sometimes	almost always	always
4. Has your child been in a good mood?	never <input type="radio"/>	almost never <input type="radio"/>	sometimes <input type="radio"/>	almost always <input type="radio"/>	always <input type="radio"/>
5. Has your child felt cheerful?	never <input type="radio"/>	almost never <input type="radio"/>	sometimes <input type="radio"/>	almost always <input type="radio"/>	always <input type="radio"/>
6. Has your child had fun?	never <input type="radio"/>	almost never <input type="radio"/>	sometimes <input type="radio"/>	almost always <input type="radio"/>	always <input type="radio"/>

3. General Mood

Thinking about the last week ...

	never	almost never	sometimes	almost always	always
1. Has your child felt that he/she does everything badly?	never <input type="radio"/>	almost never <input type="radio"/>	sometimes <input type="radio"/>	almost always <input type="radio"/>	always <input type="radio"/>
2. Has your child felt sad?	never <input type="radio"/>	almost never <input type="radio"/>	sometimes <input type="radio"/>	almost always <input type="radio"/>	always <input type="radio"/>
3. Has your child felt so bad that he/she didn't want to do anything?	never <input type="radio"/>	almost never <input type="radio"/>	sometimes <input type="radio"/>	almost always <input type="radio"/>	always <input type="radio"/>
4. Has your child felt that everything in his/her life goes wrong?	never <input type="radio"/>	almost never <input type="radio"/>	sometimes <input type="radio"/>	almost always <input type="radio"/>	always <input type="radio"/>
5. Has your child felt fed up?	never <input type="radio"/>	almost never <input type="radio"/>	sometimes <input type="radio"/>	almost always <input type="radio"/>	always <input type="radio"/>
6. Has your child felt lonely?	never <input type="radio"/>	almost never <input type="radio"/>	sometimes <input type="radio"/>	almost always <input type="radio"/>	always <input type="radio"/>
7. Has your child felt under pressure?	never <input type="radio"/>	almost never <input type="radio"/>	sometimes <input type="radio"/>	almost always <input type="radio"/>	always <input type="radio"/>

4. About Your Child

Thinking about the last week ...

	never	almost never	sometimes	almost always	always
1. Has your child been happy with the way he/she is?	never <input type="radio"/>	almost never <input type="radio"/>	sometimes <input type="radio"/>	almost always <input type="radio"/>	always <input type="radio"/>
2. Has your child been happy with his/her clothes?	never <input type="radio"/>	almost never <input type="radio"/>	sometimes <input type="radio"/>	almost always <input type="radio"/>	always <input type="radio"/>
3. Has your child been worried about the way he/she looks?	never <input type="radio"/>	almost never <input type="radio"/>	sometimes <input type="radio"/>	almost always <input type="radio"/>	always <input type="radio"/>
4. Has your child felt jealous of the way other girls and boys look?	never <input type="radio"/>	almost never <input type="radio"/>	sometimes <input type="radio"/>	almost always <input type="radio"/>	always <input type="radio"/>
5. Has your child wanted to change something about his/her body?	never <input type="radio"/>	almost never <input type="radio"/>	sometimes <input type="radio"/>	almost always <input type="radio"/>	always <input type="radio"/>

5. Free Time

Thinking about the last week ...

	never	almost never	sometimes	almost always	always
1. Has your child had enough time for him/herself?	never <input type="radio"/>	almost never <input type="radio"/>	sometimes <input type="radio"/>	almost always <input type="radio"/>	always <input type="radio"/>
2. Has your child been able to do the things that he/she wants to do in his/her free time?	never <input type="radio"/>	almost never <input type="radio"/>	sometimes <input type="radio"/>	almost always <input type="radio"/>	always <input type="radio"/>
3. Has your child had enough opportunity to be outside?	never <input type="radio"/>	almost never <input type="radio"/>	sometimes <input type="radio"/>	almost always <input type="radio"/>	always <input type="radio"/>
4. Has your child had enough time to meet friends?	never <input type="radio"/>	almost never <input type="radio"/>	sometimes <input type="radio"/>	almost always <input type="radio"/>	always <input type="radio"/>
5. Has your child been able to choose what to do in his/her free time?	never <input type="radio"/>	almost never <input type="radio"/>	sometimes <input type="radio"/>	almost always <input type="radio"/>	always <input type="radio"/>



6. Family and Home Life

Thinking about the last week ...		not at all	slightly	moderately	very	extremely	
1.	Has your child felt understood by his/her parent(s)?	not at all	<input type="radio"/>				
2.	Has your child felt loved by his/her parent(s)?	not at all	<input type="radio"/>				

Thinking about the last week ...		never	almost never	sometimes	almost always	always	
3.	Has your child been happy at home?	never	<input type="radio"/>				
4.	Has your child felt that his/her parent(s) had enough time for him/her?	never	<input type="radio"/>				
5.	Has your child felt that his/her parent(s) treated him/her fairly?	never	<input type="radio"/>				
6.	Has your child been able to talk to his/her parent(s) when he/she wanted to?	never	<input type="radio"/>				

7. Money matters

Thinking about the last week ...		never	almost never	sometimes	almost always	always	
1.	Has your child had enough money to do the same things as his/her friends?	never	<input type="radio"/>				
2.	Has your child felt that he/she had enough money for his/her expenses?	never	<input type="radio"/>				

Thinking about the last week ...		not at all	slightly	moderately	very	extremely	
3.	Does your child feel that he/she has enough money to do things with his/her friends?	not at all	<input type="radio"/>				

8. Friends

Thinking about the last week ...		never	almost never	sometimes	almost always	always	
1.	Has your child spent time with his/her friends?	never	<input type="radio"/>				
2.	Has your child done things with other girls and boys?	never	<input type="radio"/>				
3.	Has your child had fun with his/her friends?	never	<input type="radio"/>				
4.	Have your child and his/her friends helped each other?	never	<input type="radio"/>				
5.	Has your child been able to talk about everything with his/her friends?	never	<input type="radio"/>				
6.	Has your child been able to rely on his/her friends?	never	<input type="radio"/>				



9. School and Learning

Thinking about the last week ...					
	not at all	slightly	moderately	very	extremely
1. Has your child been happy at school?	<input type="radio"/>				
2. Has your child got on well at school?	<input type="radio"/>				
3. Has your child been satisfied with his/her teachers?	<input type="radio"/>				

Thinking about the last week ...					
	never	almost never	sometimes	almost always	always
4. Has your child been able to pay attention?	<input type="radio"/>				
5. Has your child enjoyed going to school?	<input type="radio"/>				
6. Has your child got along well with his/her teachers?	<input type="radio"/>				

10. Bullying

Thinking about the last week ...					
	never	almost never	sometimes	almost always	always
1. Has your child been afraid of other girls and boys?	<input type="radio"/>				
2. Have other girls and boys made fun of your child?	<input type="radio"/>				
3. Have other girls and boys bullied your child?	<input type="radio"/>				



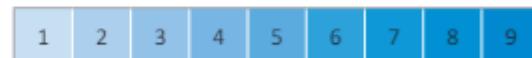
- CP-QoL (Parents Report)

Family & Friends

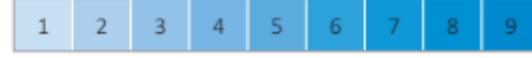
Q. How do you think your child feels about...



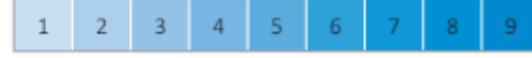
the way they get along with people generally?



the way they get along with you?



the way they get along with their brothers & sisters?



OR *my child doesn't have any brothers or sisters*

the way they get along with other children at preschool or school? (If your child attends more than one school, please think about the school where your child spends the most time).



OR *my child does not attend preschool or school*

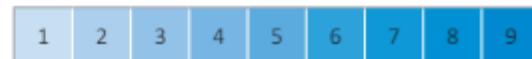
the way they get along with other children outside preschool or school?



the way they get along with adults?



the way they get along with their teachers and/or carers?



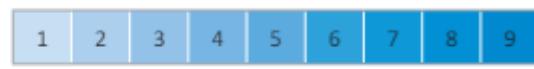


Family & Friends

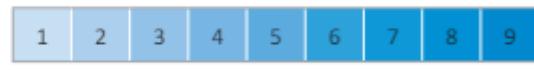
Q. How do you think your child feels about...



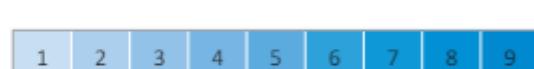
their ability to play on their own?



their ability to play with friends?



going out on trips with families?

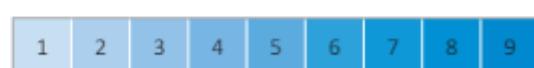


how they are accepted by their family?

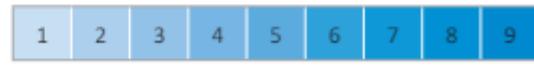


how they are accepted by other children at preschool or school? (If your child attends more than one school, please think about the school where your child spends the most time).

OR *my child does not attend preschool or school*



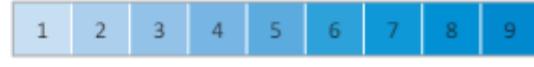
how they are accepted by other children outside of preschool or school?



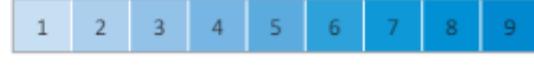
how they are accepted by adults?



how they are accepted by people in general?



being able to do things they want to do?





Participation

Q. How do you think your child feels about...



their ability to participate at preschool or school? (If your child attends more than one school, please think about the school where your child spends the most time).

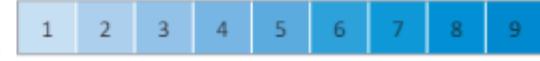
OR *my child does not attend preschool or school*



their ability to participate in sporting activities? (This question is asking how your child feels about their ability to participate in sport, not whether they can participate).



their ability to participate in social events outside of preschool or school?



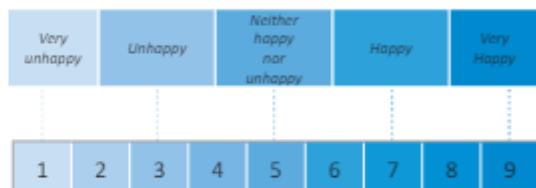
their ability to participate in their community?



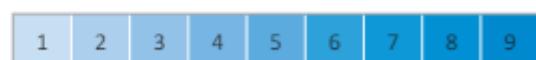


Communication

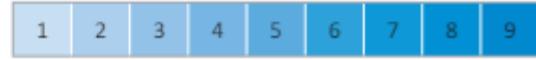
Q. How do you think your child feels about...



the way they communicate with people they know well (using any means of communication)?



they way they communicate with people they don't know well (using any means of communication)?



they way other people communicate with them?

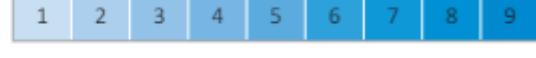


Health

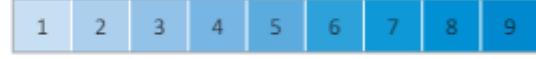
their physical health?



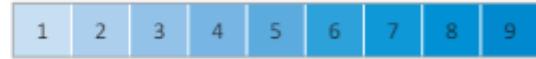
the way they get around?



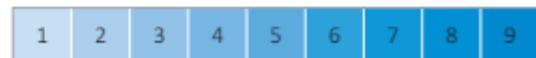
how they sleep?



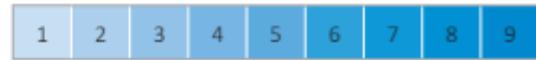
the way they look?



their ability to keep up academically with their peers?



their ability to keep up physically with their peers?





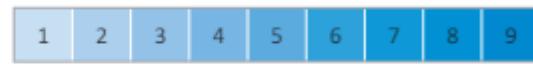
Health

Q. How do you think your child feels about...

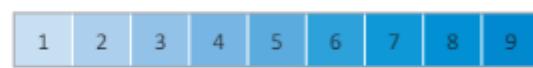
their life in general?



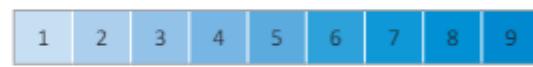
themselves?



their future?

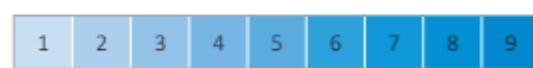


their opportunities in life?

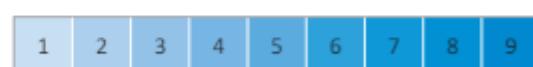


The next 3 questions are asking how your child feels about using parts of their body, not whether your child can use part of their body.

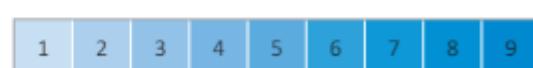
the way they use their arms?



the way they use their legs?

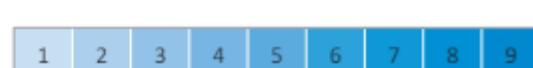


the way they use their hands?



The next 3 questions are asking how your child feels about their ability to complete daily activities, not whether your child can complete the activities.

their ability to dress themselves?





their ability to drink independently?

1	2	3	4	5	6	7	8	9
---	---	---	---	---	---	---	---	---

their ability to use the toilet by themselves?

1	2	3	4	5	6	7	8	9
---	---	---	---	---	---	---	---	---

Special Equipment

Q. How do you think your child feels about...



the special equipment they have at home (e.g. special seating, standing frames, wheelchairs, walkers)?

OR my child does not have any special equipment at home

the special equipment they have at their school?

(e.g. special seating, standing frames, wheelchairs, walkers)?

1	2	3	4	5	6	7	8	9
---	---	---	---	---	---	---	---	---

OR my child does not have any special equipment at school

the special equipment that is available in the community (ramps, escalators, wheelchair access)?

1	2	3	4	5	6	7	8	9
---	---	---	---	---	---	---	---	---

OR my child does not need any special equipment in the community



Pain and Bother

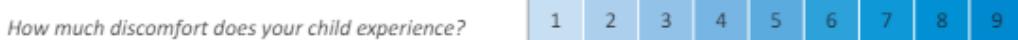
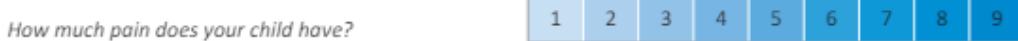
The next few questions ask about things that may bother your child.



Never Rarely Sometimes Often Always



Some final questions about your child





Access to Services

The next set of questions are about YOU and how you feel about your access to services

Q. How do you feel about...

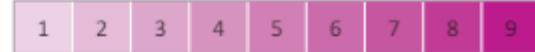
your child's access to treatment?



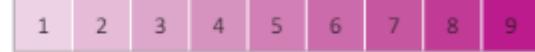
your child's access to therapy (for example, physiotherapy, speech therapy, occupational therapy)?



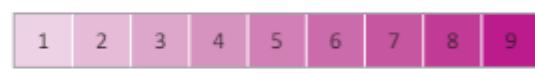
your child's access to specialised medical or surgical care?



your ability to get advice from a paediatrician?

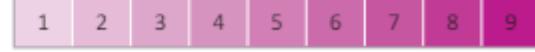


your access to respite care?

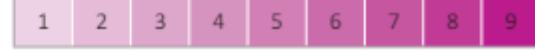


OR I have never tried to access respite care
(Please skip the next two questions on respite)

the amount of respite care you receive?



how easy it is to get respite?





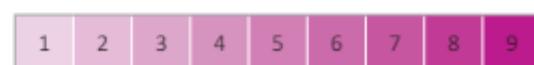
Access to Services

Q. How do you feel about...

your child's access to community services and facilities (e.g. kindergarten, childcare, after-school programs, holiday programs, community based groups such as cubs and brownies)?

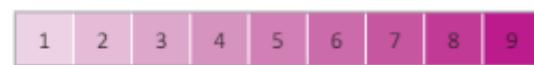


your child's access to extra help with learning at preschool or school?

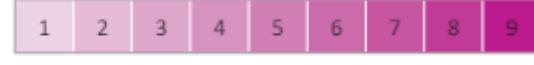


Your Health

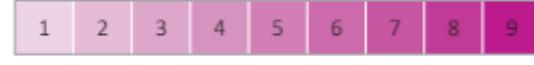
your physical health?



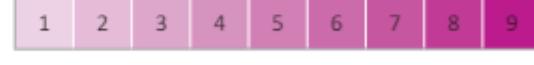
your work situation?



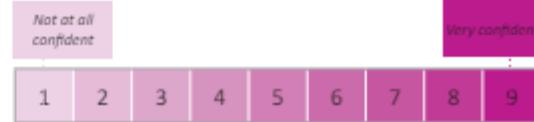
your family's financial situation?



How happy are you?



How confident are you that you can report how your child feels?





⑨ Satisfaction Survey for the Device (only at the end of the experiment)

Participants will complete a 12-item, 7-point scale satisfaction survey for the insole-type gait analysis system based on the Korean version of the Quebec User Evaluation of Satisfaction with Assistive Technology (K-QUEST 2.1). This survey is designed to assess user satisfaction, with evaluation items as follows [22, 23].

	7 Terrible	6 Unhappy	5 Mostly Dissatisfied	4 Mixed	3 Mostly Satisfied	2 Pleased	1 Delighted
Are you satisfied with the size of the device?							
Are you satisfied with the weight of the device?							
Are you satisfied with how easily you can move the device to the desired position?							
Are you satisfied with the appearance and design of the device?							
Are you satisfied with how easy it is to use the device?							
Are you satisfied with the amount of preparation time needed to operate the device?							
Are you satisfied with the performance and functionality of the device?							
Do you feel that the device meets your requirements well?							
Are you satisfied with the advice given when selecting the device?							
Are you satisfied with the time it took to receive the device?							
Are you satisfied with the assistance provided when the device experienced malfunctions?							
Are you satisfied with the instructions provided for the device?							



3) Home-based exercise program education and adherence evaluation

The researcher educates the participants on the following exercise program. The exercise program is based on the exercise recommendations for individuals with cerebral palsy outlined in the ACSM's Exercise Management for Persons with Chronic Diseases and Disabilities 4th edition [24].

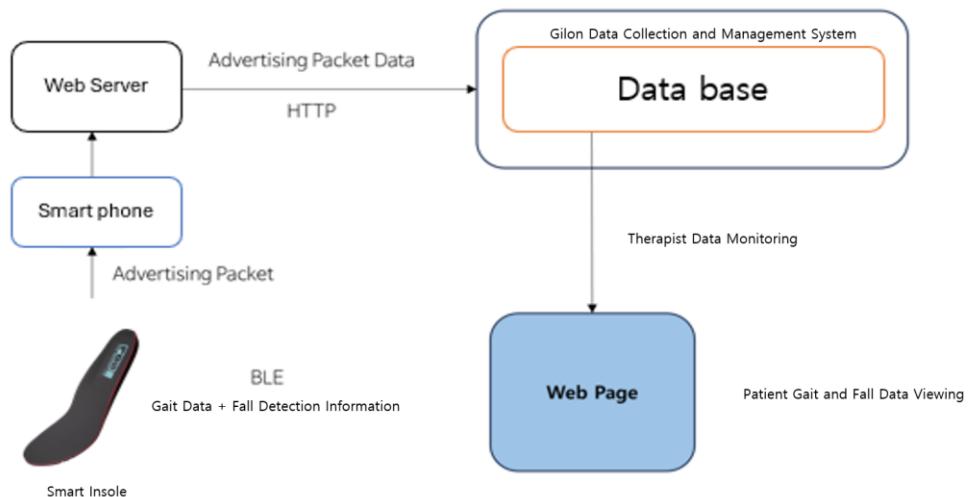
1 week of familiarization period was provided before the start of the protocol				
6 weeks of exercise protocol 3 days + 2/week				
Warm-up (10 min)	Flexibility (20 s/stretch)	Aerobic (20 min if conducted with strength training, otherwise, 40 min)	Strength (2 sets, 8-12 reps)	Cool-down (10 min)
<ul style="list-style-type: none"> Easy RPE < 3/10 Walking multiple times back and forth across the room for 4 min (aerobic warm-up) 5 sets of 10 reps that included elbow flexion, extension, shoulder abduction, flexion, extension, int.rot, ext.rot (strength warm-up) 	<ul style="list-style-type: none"> Below discomfort point Chair sit and reach (reaching their toes) Stretching of hip ext. rotators, abductors, knee extensor and flexor muscles, calf muscles, and other muscles as required 	<ul style="list-style-type: none"> Start at self-selected speed, gradually increase to an RPE of 3-5/10 Walking Stationary bicycle Arm ergometer 	<ul style="list-style-type: none"> 8 reps or 50-70% of 1RM 20 arm curls with a minimum of 2 kg object held in each hand Handgrip exercises (squeeze sponges or tennis balls) Sit-to-stand drills Lateral step-up Heel raises 	<ul style="list-style-type: none"> Easy RPE < 3/10 Breathing exercises for relaxation
DAY 1	DAY 2	DAY 3	DAY 4	DAY 5
Warm-up (10 min)	Warm-up (10 min)	Warm-up (10 min)	Warm-up (10 min)	Warm-up (10 min)
Flexibility (20 s/stretch)	Aerobic (40 min)	Flexibility (20 s/stretch)	Aerobic (40 min)	Flexibility (20 s/stretch)
Aerobic (20 min)	Cool-down (10 min)	Aerobic (20 min)	Cool-down (10 min)	Aerobic (20 min)
Strength (2 sets, 8-12 reps/exercise)		Strength (2 sets, 8-12 reps/exercise)		Strength (2 sets, 8-12 reps/exercise)
Cool-down (10 min)		Cool-down (10 min)		Cool-down (10 min)

4) Participants monitoring methods

- Data collection of participants' gait data through the insole-type gait analysis system is conducted by connecting the insole-type gait analysis system to the participant's smartphone, with the measured data transmitted to a web server. The medical device company provides the researcher with data sorted by product serial number once a week.
- Compliance evaluation of the exercise program will be based on exercise logs completed by the participants and their caregivers. Participants will record exercise duration and frequency for each of the five components: Warm-up, Flexibility, Aerobic, Strength, and Cool-down. They will also assess their performance level as 'weak, moderate, strong' for each component.
- The researcher will monitor participants' activity levels based on the data received from the medical device company. They will also compare participants' gait metrics with normal standards and provide feedback via telephone once every 3 to 4 weeks. The researcher will verify the stability of data collection and take corrective action if any anomalies occur, recording these actions accordingly.
- The extracted gait parameters include the following;
 - ① Step count: The extracted gait parameter is the step count measured during walking through the integration of the insole-type gait analysis system with the smartphone application. Users can view step counts per hour, per day, per week, and per month.



- ② Calorie (Kcal): The unit for calorie expenditure is kcal (kilocalories). Users can view calories per hour, per day, per week, and per month.
- ③ Activity duration (min): The time spent active while wearing the insole-type gait measurement device, measured in minutes.
- ④ Activity Distance (km): The distance covered during activity, measured in kilometers. Users can check the activity distance per hour, per day, per week, and per month.
- ⑤ Walking Speed (m/s): The speed of walking, measured in meters per second. Users can view their walking speed per day, per week.
- ⑥ Stride Length (cm): Measured in centimeters, users can check the average stride length per day, per week, and per month. Stride length is evaluated based on the length relative to the user's height.
- ⑦ Walking Balance (Left-Right Disparity %): Walking balance can be evaluated based on the ratio of time each foot spends on the ground, measured in percentage. Users can view their walking balance per day, per week, and per month.



11. Standard medical examination and procedure for registered participants

For cerebral palsy patients capable of independent walking, regular outpatient visits are conducted to assess their physical activity levels through interviews and discussions with both the patient and their caregivers. If necessary, verbal education is provided on assistive devices and exercise methods.

12. Study procedures and evaluation

Phase	Screening/ Intervention	Intervention					Intervention/ Assessment
Week	1	2	3	4	5	6	
Written consent	O						



Inclusion/ Exclusion criteria	O					
Demographic information and antecedent history	O					
Primary outcome	O					O
Secondary outcome	O					O
Home-based exercise program	O	O	O	O	O	O
Phone calls (monitoring and feedback purpose)	O	O	O	O	O	O
Satisfaction evaluation						O

13. Criteria for stopping and dropping out of the study

- 1) Termination and early suspension
 - When a subject participating in the study withdraws their consent before the study ends.
 - If consent is withdrawn, the study participant's information collected up to that point is destroyed.
- 2) Dropout
 - If a subject continuously agrees to participate in the study but wishes to terminate their participation early due to personal reasons.
 - Reconfirm the voluntary intention of the study participant to ensure the study does not correspond to early discontinuation. If the participant still intends to provide information to the study, any information collected up to the point of withdrawal will be anonymized and can be used for the study.

14. Safety evaluation criteria, evaluation methods, and reporting methods, including adverse effects

- This study plans to monitor safety with the principal investigator serving as the safety inspector to ensure participant's safety.
- As the study involves minimal invasive interventions and poses low risk, monitoring will be conducted weekly under the supervision of the principal investigator. Data integrity will be ensured by comparing evidence documents, CRFs, and protocols, while reviewing participant safety data.
- Participants can decide to withdraw from the study at any time if they feel discomfort. The principal investigator or study coordinator will thoroughly explain and obtain consent from participants before enrollment.
- Any violations or deviations from the study protocol will be promptly reported to the IRB with documentation, along with the researcher's actions and measures to prevent recurrence.



- Immediate intervention and observation will occur if participants experience distress or new events during evaluations. Thorough investigation will be conducted into the cause, following the hospital's standard procedures for treatment, which will be reported in interim reports and included in research papers. However, considering the low likelihood of future adverse events, additional treatment costs are not included in the research budget.

15. Data analysis and statistical considerations

- 1) Primary and secondary outcomes: The differences between pre- and post-home-based exercise program are analyzed using descriptive statistics, presenting mean, standard deviation, median, minimum, and maximum values. If the changes in performance before and after the program follow a normal distribution, a paired T-test is conducted; if not, a Wilcoxon signed-rank test is used for comparison.
- 2) Satisfaction Evaluation: The satisfaction with the home-based exercise program utilizing smart insoles is analyzed using descriptive statistics, presenting mean, standard deviation, median, minimum, and maximum values.

16. Measures for protecting personal information and maintaining confidentiality of research data

- 1) Protection of participant personal information
 - When obtaining consent for the research, participants will be explained the research in a separate space within the outpatient counseling room of the Department of Rehabilitation Medicine.
 - All information collected from the study will remain confidential and will only be used for research purposes. Sensitive personal information that can identify individuals will not be shared with anyone outside the hospital and will undergo a deidentification process. Deidentification will involve using unique identifiers provided to participants for the insole-type gait analysis system, ensuring that extracted data is not personally identifiable. The deidentified data will be transmitted to the medical device company. Deidentification will only be reversed if necessary for individual treatment-related purposes. The medical device company will only have access to the final analysis results, with data ownership retained by the hospital.
- 2) Confidentiality of research data
 - Paper documents will be stored in locked cabinets to prevent unauthorized access, and digital data will be stored on computers with restricted access, managed by the responsible researcher.
- 3) Preservation of records
 - Research-related data will be preserved for three years in accordance with the regulations of the Bioethics Act. Documents containing personal information that have exceeded the retention period will be destroyed in accordance with the Personal Information Protection Act. However, if preservation of such data is necessary for subsequent research or record accumulation, an extension of the retention period will be requested through review by the Institutional Review Board.



17. Management, storage, and disposal measures for human-derived materials and genetic information

- This study does not involve the collection of human-derived materials or genetic information.

18. Participant recruitment method and consent procedure

- Following approval from the IRB of Severance Hospital, recruitment for this study will be conducted among visitors to Severance Hospital, who voluntarily decide to participate in the study and provide consent. Interviews will be conducted in independent spaces. Participants will be provided with the IRB-approved participant information sheet and consent form.
- Adequate explanation about participation in the clinical trial will be provided, and consent forms will be filled out in an environment free from coercion. Participants will be informed that they have the right to withdraw their consent at any time during the trial, and their decision to participate is voluntary. Additionally, during the conduct of research tests, the willingness of participants to continue their participation will be confirmed, ensuring that withdrawal of consent is possible at any time based on their own will.

19. Protection measures for recruiting vulnerable participants

- 1) As vulnerable subjects in clinical trials, ensuring neutrality in providing information and continuously assessing understanding to confirm the consent of participants and their guardians.
 - Ages 7 to 12: Obtain written consent from both the participant and guardian through a consent form expressed in appropriate, simple terms for the respective age group.
 - Ages 13 to 18: Obtain written consent from both the participant and guardian through a consent form documented in simple and appropriate language for their level of understanding.
 - If obtaining written consent is challenging for participants due to upper limb disabilities or similar reasons, use alternative methods such as obtaining a check mark indicating the maximum expression of their consent. In cases where this procedure is not feasible, obtain verbal consent followed by written consent from the caregivers.
 - If the participant is unable to communicate or incapable of understanding and signing the consent form due to intellectual disabilities, only obtain written consent from the caregiver. Evaluate the participant's understanding and capacity to consent through questioning about the research content after developmental assessment and explanation of the research.
 - Continuously verify whether the participant and guardian consent to participation in the research and explain that they can withdraw consent and discontinue participation in the research at any time. Explain that there will be no adverse effects on medical treatment processes due to refusal to participate in the research or withdrawal of consent during research participation



20. Principal investigator's information, research venue, and duration of study

1) Principal investigator and other research team members

	Affiliated organizations	Name	Phone/E-mail
Principal investigator	Severance Hospital	Juntaek Hong	+82 010 6517 7526 /GHDWNSXOR@yuhs.ac
Research team members	Yongin Severance Hospital	Na Young Kim	+82 031 5189 8163 /Kny8452@yuhs.ac
Research team members	Severance Hospital	Yerim Do	+82 010 7154 6011 /doyer62@gmail.com
Research team members	Yonsei University College of Medicine	Seung Ick Choi	+82 010 8821 5297 /rehab2@yuhs.ac

2) Research location: Severance Hospital (Seoul, Seodaemun-gu, South Korea, 03722)

3) Research duration: 24 months after IRB approval (e.g., November 2023 – November 2025)

21. Data safety monitoring plan

The safety inspector (Principal Investigator) intends to monitor the overall progress of the research, adequacy of participant selection criteria, appropriateness of the consent acquisition process, occurrences of deviations from the research protocol, and any adverse events in participants at monthly intervals to ensure the completeness of the data.

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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