

Efficacy of exercise with the hybrid assistive limb lumbar type on physical function in mobility-limited older adults: A 5-week randomized controlled trial[☆]

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ABSTRACT

Background: Sarcopenia and frailty often worsen in older adults because of declines in activities of daily living and social connections that are associated with chronic diseases and traumatic injuries such as falls and fractures. Exercise intervention for sarcopenia can take >3 months to improve muscle mass, muscle strength, and walking speed. Thus, a specialized intervention system for shorter periods of time is needed. In this study, we aimed to evaluate the short-term efficacy of an exercise program using the wearable cyborg Hybrid Assistive Limb (HAL) lumbar type in physical function in mobility-limited older adults who do not require transition to long-term care. **Methods:** This randomized, single-blind, parallel-group study involved 79 community-dwelling older adults with physical frailty or locomotive syndrome assigned to an intervention group ($n = 40$) with the HAL lumbar type exercise program or a control group ($n = 39$) without the exercise program. The intervention group underwent trunk training (including trunk and hip flexion, standing and sitting from a single sitting position, and squats) and gait training (treadmill and parallel bars) twice a week for 5 weeks while wearing the HAL lumbar type. The 10-m usual and maximum walking speeds, Timed Up and Go test results, 5-times chair-standing test results, 5-question Geriatric Locomotive Function Scale (GLFS-5) scores, body-fat percentage, and muscle mass were measured before and after the intervention and analyzed using the intention-to-treat method. **Results:** The intervention (23 % male; mean age, 74.7 ± 4.7 years) and control (21 % male; mean age, 75.1 ± 4.1 years) groups did not differ significantly in baseline characteristics. Seventy-seven participants completed the program; two withdrew for personal reasons. The mean difference (standard error) between the groups for the primary outcome (usual walking speed) was 0.35 (0.04) m/s; the time-by-group interaction was significant ($p < 0.001$). Secondary outcomes (maximum walking speed, Timed Up and Go test results, 5-times chair-standing test results, and GLFS-5 scores) significantly improved in the intervention group. Body composition was unchanged in both groups.

Abbreviations: BMI, body mass index; BBS, Berg Balance Scale; CVC, Cybernic Voluntary Control; HAL, Hybrid Assistive Limb; RCT, randomized controlled trial; TUG, Timed Up and Go; GLFS-5, 5-question Geriatric Locomotive Function Scale.

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Conclusions: A 5-week exercise program using the HAL lumbar type is a promising option for community-dwelling older adults with limited mobility who do not require nursing care, resulting in clinically meaningful improvements in most physical functions within a short period.

1. Introduction

Frailty and sarcopenia are considered major public health challenges (Dent et al., 2019; Ofori-Asenso et al., 2019; Petermann-Rocha et al., 2022). In recent years, frailty has been recognized as a multidimensional phenotype that includes physical, psychological, and social frailty (Hoogendijk et al., 2019; Xue et al., 2008). Furthermore, it has been suggested that sarcopenia is a major component of physical frailty. As there has been an increased focus on optimizing exercise interventions to prevent and improve frailty and sarcopenia in older adults, there have also been growing expectations for the development and implementation of robot-based exercise programs (Miura et al., 2021; Wall et al., 2015; Yasunaga et al., 2022). The Hybrid Assistive Limb (HAL) (Cyberdyne, Japan) is the world's first wearable cyborg. It is characterized by its human-machine fusion technology that facilitates movement via bioelectric potential signals, which are movement commands transmitted from the brain and spinal cord to the muscles when the user attempts to move their body, thereby reflecting their will to move (Kawamoto et al., 2010). This technology enables the user to learn how to move their body and apply their strength in real time. To date, three types of HALs have been developed: lower-limb, single-joint, and lumbar types. Previous studies on the HAL lower-limb type have reported improved function, even in chronic stages of spinal cord injury (Grasmücke et al., 2017), stroke (Kawamoto et al., 2013; Yoshimoto et al., 2015), cerebral palsy (Mataki et al., 2020; Matsuda et al., 2018), and progressive neuromuscular disease (Nakajima et al., 2021).

The HAL lumbar type used in this study was initially developed to reduce caregiver burden (Hara and Sankai, 2010); it is more compact and easier to handle than the conventional lower-limb type, and its application to patients is underway. Previous studies have investigated the efficacy of rehabilitation programs for patients with heart failure (Kato et al., 2021), as well as exercise training for patients with Parkinson's disease (Kotani et al., 2020). The effects of exercise therapy with the HAL lumbar type have been explored for a wide range of outcomes; these include studies monitoring the worsening of low-back pain and adverse events (Miura et al., 2021), immediate changes in low-back pain and hip flexibility (Yasunaga et al., 2022), and cardiopulmonary strain during squatting exercises (Watanabe et al., 2019). Nevertheless, most of these studies have been conducted in symptomatic patients. Confirmation of the efficacy of the HAL lumbar type in improving physical function would justify its deployment at relevant facilities (e.g., nursing homes) and in the community.

In preparation for this randomized controlled trial (RCT), we conducted a feasibility study among 22 frail and pre-frail community residents (mean age = 72.6 years) in 2019. The primary endpoint was the completion rate; the secondary endpoint was the 10-m usual walking speed. The majority of the participants (20 of 22) were able to complete the 10-week program of 20 exercise sessions; 2 participants withdrew from the study owing to knee and hip pain. No other significant adverse effects occurred during the program. Pre- and post-program comparisons among those who completed the program showed a significant increase in the usual 10-m walking speed, as well as a trend for improvement in exercise self-efficacy. These results indicated the feasibility of an exercise program using the HAL lumbar type to improve walking speed, which is an indicator of physical frailty.

As life expectancy increases among older adults, there is a corresponding need to extend healthy life expectancy and maintain physical, mental, and social health over the life course. Chronic diseases, new illnesses, and traumatic injuries (e.g., fractures caused by falls) occur more frequently with age, and these events can lead to a decline in

activities of daily living and social connections (Dent et al., 2019). Declines in physical activity and fitness may also be exacerbated by family events. In a meta-analysis of exercise interventions for sarcopenia, the duration of trials that improved muscle mass, muscle strength, and walking speed was 3 months or longer (Yoshimura et al., 2017). Therefore, it is important to have an established professional intervention system that can be enacted for short periods of time when needed. In this study, we aimed to examine the short-term efficacy of an exercise program using the wearable cyborg HAL lumbar type in improving physical function among mobility-limited older adults not requiring transition to long-term care.

2. Material and methods

2.1. Study design

This was a randomized, single-blind, parallel-group study. Study participants were assigned by a stratified block randomization method using a computerized random number generation program. Each block was set to four participants per sex, and the participants were randomly assigned to the intervention and waitlist control groups in the order of enrollment (Fig. 1). As the intervention program was expected to be effective, a waitlist control group was established for ethical considerations.

Third-party allocation was used to assign study participants, and researchers responsible for data analysis were blinded to group assignment. Outcomes were assessed by staff who administered the exercise program at the facility. As it was difficult to perform blind measures in this study, program implementation and outcome assessment were assigned to different staff members for each participant to reduce bias to the extent possible. Outcomes were measured before and after the 5-week intervention period.

2.2. Participants

We recruited participants via public relations magazines and flyers. This was done with the cooperation of relevant sections of Fujisawa City Hall and Kamakura City Hall in Kanagawa Prefecture, senior citizen facilities, exercise facilities, senior clubs, social welfare councils, and local media. Inclusion criteria were as follows: participation in the Kanagawa Prospective "ME-BYO" Cohort Study (ME-BYO cohort., 2021; Nakamura et al., 2023); men and women aged 65–85 years; participants able to wear the HAL (standard body size for HAL: height, 140–180 cm; weight, ≤80 kg); cutoff score of ≥6 on the 5-question Geriatric Locomotive Function Scale (GLFS-5) (Kobayashi et al., 2022; Seichi et al., 2012) or usual walking speed <1.0 m/s (diagnostic criteria for frailty or pre-frailty according to the Japanese version of the Cardiovascular Health Study) (Satake and Arai, 2020; Satake et al., 2017); and participants not certified for long-term care. Participants were excluded if they (1) did not provide informed consent; (2) had difficulty completing the questionnaire; (3) had difficulty communicating in Japanese; (4) had difficulty wearing the HAL owing to body-size discrepancies (e.g., in terms of weight, thigh length, lower leg length, or waist width) or major body deformities; (5) were judged by a physician as unsuitable for wearing or using the HAL (e.g., owing to the inability to perform standing/walking exercises); (6) were unable to apply electrodes (e.g., due to skin diseases or allergies); (7) were unable to use fall prevention measures in combination; or (8) were deemed unsuitable for the intervention program in view of the physical and psychological burden that they may be subjected to.

The sample size calculation was based on the results of a 10-m usual walking speed by a feasibility study conducted in 2019. We estimated that a sample size of at least 74 participants was required to detect differences between groups, while accounting for 80 % power, an effect size of 0.66, and a two-sided $\alpha = 0.05$. The final sample size was set at 80 participants in anticipation of dropouts during the course of the study and situations where several applicants signed up at the same time.

While a total of 20 exercise sessions were provided during the feasibility study, improvements were apparent after the completion of 10 sessions. Therefore, in this study, the sample size in the 10-times program was calculated to examine the effect of a shorter period.

2.3. Exercise program utilizing the HAL lumbar type

The wearable cyborg HAL lumbar type (HAL-FB02, Cyberdyne Inc., Ibaraki, Japan) has two modes. The Cybernic Voluntary Control (CVC) mode provides appropriate motion assistance based on the intensity of biopotential signals generated according to the user’s intention to move. This mode assists the user’s movements in accordance with their pre-programmed posture. The Cybernic Autonomous Control mode can support the user’s weight for reducing movements caused by trunk flexion as a gravity-compensation algorithm. Biopotential signals emitted from the body are detected via electrodes set on the user’s waist. The detected bio-signals are processed by the built-in computer in the HAL, and the power unit in the hip joint is operated by adjusting the level and timing of the assist torque according to the user’s intention to move, thereby supporting their movement. The CVC mode was used during training with the HAL; the assist torque at the hip and lower back was controlled by triggering the bioelectric potential signal generated by the voluntary muscle contraction of the user. At the start of training, the HAL assist level was optimally set to provide good motion support.

Training was conducted twice a week for a total of 10 sessions to the

extent that good automatic movement could be maintained during assisted standing. The program was conducted by a HAL specialist trainer and a physical therapist. An initial assessment of the participants’ activities of daily living was conducted prior to the start of the program, which consisted of walking training on a treadmill and parallel bars, as well as training (trunk and hip flexion, standing and sitting from a single sitting position, squats, and lunges) while wearing the HAL. The basic flow of each 90-min training session was as follows: (1) vital check, 10-m walk; (2) stretching; (3) warm-up (walking); (4) exercise using the HAL lumbar type; (5) cool down; and (6) 10-m walk. Exercises using the HAL lumbar type were performed for a maximum of three sets with a 30-s rest between sets at a load that allowed 15 repetitions per set for each exercise.

The exercise program consisted of 10 sessions divided into three STEPs: STEP1 (early program), acquisition of movement form; STEP2 (mid-program), appropriate and progressive increase in load; and STEP3 (late program), acquisition of decreased function. In addition, the program disciplines and their application levels were selected according to each participant’s level of physical function, such as strength and functional disability (Figs. 2,3,4). No specific intervention was provided to the control group.

2.4. Outcome measures

The following assessments were conducted before and at the end of the intervention program. The primary outcome was the 10-m usual walking speed (m/s) (Saito et al., 2022). The participants walked 10 m at their usual speed, and the time required was measured once with a stopwatch after a practice trial; the instruction given to the participants was “walk at your usual walking speed.” Exercises were performed on a flat indoor area. The time was recorded when the toes of either foot crossed the line between the start and end points. The walking speed of

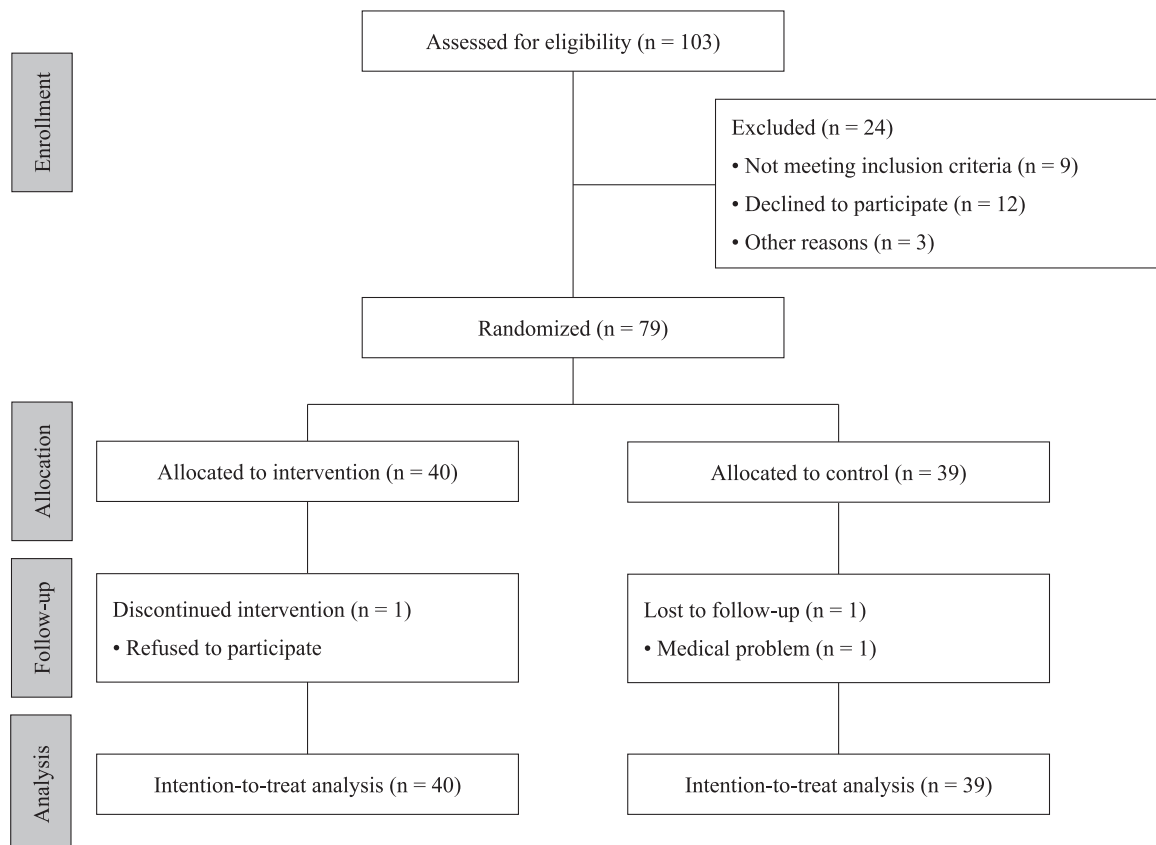


Fig. 1. Study flow of the randomized controlled trial.

		Functional level					
		Low		High			
Exercise level	Easy	Applicable items	Operation	Applicable items	Operation	Applicable items	Operation
		Difficult		Warm-up		Warm-up	
Treadmill walking	7 min or 70 m			Treadmill walking	12 min	Treadmill walking	15 min
Trunk forward/backward tilt 1		Trunk forward/backward tilt 2	No support	Trunk forward/backward tilt 2	No support	Trunk forward/backward tilt 2	No support
Trunk forward/backward tilt 2	No support	Trunk forward/backward tilt 3	Balance disc sole or seat	Trunk forward/backward tilt 3	Balance disc sole or seat	Trunk forward/backward tilt 3	Balance disc sole or seat
Standing and sitting 1	Raise the seat and pick up choice	Standing and sitting 2	Pickup	Standing and sitting 2	Pickup	Standing and sitting 3	Put your hands on your knees
Standing and sitting 2		Standing and sitting 3	Put your hands on your knees	Standing and sitting 3	Put your hands on your knees	Standing and sitting 4	No support
Squat 1	Half + with support	Standing and sitting 4	No support	Standing and sitting 4	No support	Squat 3	Half + no support
Squat 2	Parallel + with support	Squat 2	Parallel + with support	Squat 2	Parallel + with support	Squat 4	Full + with support
Good morning 1	Pickup	Squat 3	Half + no support	Squat 3	Half + no support	Squat 5	Full + no support
Hip exercise 1	With support	Steps up and down 1	two-tiered	Steps up and down 1	two-tiered	Steps up and down 2	3 steps or Reebok 1
		Steps up and down 2	3 steps or Reebok1	Steps up and down 2	3 steps or Reebok1	Steps up/down 3	4 steps or Reebok 2
		Squat 2	Parallel + with support	Squat 2	Parallel + with support	Lunge 1	Rear step + no support
		Squat 3	Half + no support	Squat 3	Half + no support	Lunge 2	Front half + with support
		Squat 4	Parallel + no support	Squat 4	Parallel + no support	Lunge 3	Front half + no support
		Hip exercise 1	With support	Hip exercise 1	With support	Lunge 4	No support
		Auxiliary disciplines (muscle strengthening training)	Tubes, dumbbells, etc.	Auxiliary disciplines (muscle strengthening training)	Tubes, dumbbells, etc.	Hip exercise 2	No support
						Good morning 2	No support
						Auxiliary disciplines (muscle training)	Tubes, dumbbells, etc.

Fig. 2. Exercise program utilizing the Hybrid Assistive Limb lumbar type. The program disciplines and their application levels were selected according to each participant’s level of physical function, such as strength and functional disability.

the participants who were clearly too fast or too slow compared to their usual walking speed was re-measured. The time required was measured to the nearest 1/100th of a second. The walking speed was calculated by dividing the distance (10 m) by the time required and expressed in m/s.

The secondary outcomes included the following assessments of physical function: 10-m maximum walking speed (m/s) and walking cadence (usual and maximum) (steps/min), Timed Up and Go (TUG) test (s), two-step test (score), 5-times chair-standing test (s), Functional Reach Test (cm), grip strength (kg), Berg Balance Scale (BBS) (score), and GLFS-5 (score). Body composition was evaluated using the following parameters: body mass index (BMI) (kg/m²), fat (%), and muscle mass (kg).

The 10-m maximum walking speed was assessed by asking the participant to walk for a distance of 10 m at maximum speed and measuring the time required (Saito et al., 2022). The instruction was to “walk as fast as possible”; other aspects of this test were identical to those of the 10-m usual walking speed assessment. The walking cadence was determined by dividing the number of steps taken during each of the usual and maximum 10-m walk tests by each walking speed (min).

For the TUG test, the participants were instructed to get up from the chair, walk a distance of 3 m as quickly as possible, change direction, and return to the chair to sit down (Podsiadlo and Richardson, 1991); participants were instructed not to run. Two trials were performed, and the shorter time being used for analysis. The time (s) required was measured with a stopwatch.

In the two-step test, the maximum two-step distance (cm) was measured when the participants took two steps forward with maximum effort. This distance was then divided by the participants’ heights (cm) to obtain the two-step test score (Muranaga, 2001; Muranaga and Hirano, 2003; Yoshimura et al., 2015). The two-step test was performed three times in succession; the first trial was excluded as a practice run; the average value from the second and third trials was used as the representative value.

The 5-times chair-standing test (s) required the participants to stand up from chairs without arms and sit down as quickly as possible. The time required for the participants to perform this action five times was measured using a stopwatch (Bohannon et al., 2010).

The Functional Reach Test (Duncan et al., 1990) was performed



Fig. 3. Trunk forward/backward tilt training with the Hybrid Assistive Limb lumbar type.

using a measuring stick. The participants stood upright and held their right arm horizontally, with the left hand placed at the side of the body (basic posture). They were then instructed to extend their right hand as far forward as possible. Two trials were performed with a short break in between, and the highest value obtained was used for the analysis.

Grip strength was measured using a Smedley grip strength meter (TKK5401, Takei Kiki Kogyo Co.). After a short rest, two maximal effort trials were performed separately for the left and right sides. The average of the higher values on the left and right sides was used for analysis.

The BBS was used to evaluate the participants' ability to balance. It consists of 14 items rated on a 5-point scale (from 0 to 4) and has a maximum score of 56 (Berg et al., 1992; Kornetti et al., 2004). The GLFS-5 includes five questions that assess locomotive syndrome severity. A 5-point Likert scale is used, with the total score ranging from 0 to 20. The higher the score, the greater the severity of locomotive syndrome; scores of 6 or more were judged to be positive for locomotive syndrome (Kobayashi et al., 2022; Seichi et al., 2012). BMI was recorded, and body composition (fat [%], muscle mass [kg]) was measured with a body composition measuring device (Inbody430, InBody Co., Ltd.).

2.5. Statistical analysis

Unpaired *t*-tests and χ^2 tests were used to compare participant characteristics between the groups before the intervention. Two-way repeated measures of analysis of variance was used to determine effect sizes (partial η^2), and group-time interactions were examined for all outcomes. Intention-to-treat analysis was used to examine the minimal



Fig. 4. Squat training with the Hybrid Assistive Limb lumbar type.

effect of the program. Specifically, baseline values were inserted for missing values (last observation carried forward approach). All statistical analyses were conducted with IBM SPSS Statistics Ver. 27 (IBM Corp, Tokyo, Japan). The level of statistical significance was set at 5 %.

3. Results

3.1. Participant characteristics

Fig. 1 shows the flowchart of this RCT. In total, 79 participants were recruited and allocated to the intervention and control groups. There were no significant differences in baseline characteristics between the two groups (Table 1). All participants had an inclusion criteria GLFS-5 score of 6 or higher. Fifteen participants (37.5 %) in the intervention group and 16 (41.0 %) in the control group had a usual walking speed of <1.0 m/s.

No serious adverse events such as accidents, fractures, hospitalization, or death occurred during the program. Of the 79 study participants, 77 completed the program. Two participants (one person each in the intervention and control groups) withdrew from the study owing to personal reasons.

SD: standard deviation, BBS: Berg Balance Scale, GLFS-5: 5-question Geriatric Locomotive Function Scale, BMI: body mass index

3.2. Primary outcome

The mean usual walking speed approximated the frailty criterion (<1.0 m/s) in both groups before the intervention. After the program, the usual walking speed (mean [95 % confidence interval]) in the intervention group increased to 1.43 [1.35, 1.51] m/s. The difference in the mean (standard error) change between the intervention and control groups was 0.35 (0.04) m/s; the time-by-group interaction was

Table 1
Baseline characteristics of the study participants.

	Intervention group (n = 40)		Control group (n = 39)		p-value
	Mean	SD	Mean	SD	
Age, years	74.7	4.7	75.1	4.1	0.686
Male sex, n (%)	9	(22.5)	8	(20.5)	0.830
Physical function					
Walking speed: usual (m/s)	1.05	0.23	1.03	0.21	0.806
Walking cadence: usual (steps/min)	109	13.4	107	12.3	0.523
Walking speed: max (m/s)	1.47	0.28	1.47	0.29	0.994
Walking cadence: max (steps/min)	128	17.1	126	14.8	0.584
2-step test (score)	1.21	0.21	1.24	0.22	0.605
Timed Up and Go test (s)	8.3	3.3	8.1	1.7	0.652
5-times chair standing test (s)	11.9	3.8	11.1	2.5	0.247
Functional Reach Test (cm)	29.0	7.1	28.7	6.0	0.863
Grip strength (kg)	23.0	8.6	21.9	6.1	0.508
BBS (score)	53.4	6.6	54.4	2.0	0.366
GLFS-5 (score)	8.5	2.9	8.1	2.4	0.482
Body composition					
BMI (kg/m ²)	22.9	3.1	22.2	3.0	0.290
Fat (%)	29.4	7.7	29.2	5.9	0.885
Muscle mass (kg)	37.5	7.5	36.3	5.5	0.421

significant (Table 2).

3.3. Secondary outcomes

Regarding physical function, the intervention group showed improvements in all items except functional reach and grip strength, and the time-group interaction was significant. No changes in body composition were observed in either group (Table 2).

4. Discussion

This study examined the effects of a 5-week exercise program using the wearable cyborg HAL lumbar type to improve physical function in mobility-limited older adults. Most physical functions improved significantly in the intervention group. The mean difference in usual walking speed (mean [standard error]) was 0.35 [0.04] m/s. The minimum clinically meaningful change in usual walking speed was 0.05 m/s, and a change of 0.10 m/s was considered substantial (Perera et al., 2006). Thus, while the influence of the 10-m walk exercise in each session of the program cannot be ruled out, the amount of change in the intervention group was well above the threshold for clinically meaningful change. Furthermore, the fact that all participants completed the scheduled twice-weekly exercise sessions (for a total of 10 sessions) without any adverse events reflected the overall safety of the exercise program.

Few investigations of the HAL lumbar type have used rigorous study designs such as RCTs. In a previous RCT, 28 patients with chronic heart failure underwent cardiac rehabilitation therapy (sit-to-stand exercises repeated over 6–10 days) with or without the HAL (Kato et al., 2021). While the Short Physical Performance Battery and 6-min walking distance were significantly improved in both groups, the knee extensor muscle strength was only improved in the HAL group. The increase in lower extremity muscle strength was not due to muscle hypertrophy but was attributed to neurological factors such as an increased discharge rate of motor units. A study of a 5-times-weekly exercise program conducted among 16 frail older adults (eight each with Parkinson's disease and non-Parkinson's disease) who had experienced gait disturbance showed significant improvements in physical function (as reflected by gait speed, the TUG test, and the chair-standing test) in both groups (Kotani et al., 2020). The limitations of this previous study included the small sample size and the use of convenience sampling.

To date, studies using the HAL lumbar type have primarily focused

on the administration of rehabilitation programs, and the lack of validation of HAL efficacy with high-quality research designs has been a challenge. In the present study, we clarified the efficacy of the HAL lumbar type in improving physical function by conducting an RCT in older adults who were physically frail or had locomotive syndrome and were not certified as nursing care recipients.

All secondary outcomes, with the exception of grip strength, functional reach, and body composition, improved significantly in the present study. In the 5-times chair-standing test, based on the Asian Working Group for Sarcopenia 2019 (Chen et al., 2020), the mean preintervention value in the intervention group was equivalent to the standard 12 s or higher. However, it improved to 9.2 (95 % confidence interval: 8.4, 10.1) s after the intervention. The difference in change (mean [standard error]) between the intervention and control groups was -1.7 [0.6] s, and the time-by-group interaction was also significant. These results suggest that voluntary performance improved following the short 5-week program. The immediate improvement in physical function with this short-term intervention may be due to the fact that appropriate instruction in physical movement form, as well as low-impact, high-frequency voluntary exercise with the HAL, induced nervous system signals to the muscles; this is supported by the results of previous studies (Kotani et al., 2020; Miura et al., 2021; Yasunaga et al., 2022).

This study also used GLFS-5 to evaluate leg and back pain. The mean value of GLFS-5 was above the cutoff value for locomotive syndrome (6 points) in both groups before the intervention. After the intervention, the mean [95 % confidence interval] for the intervention group was 4.4 [3.3, 5.4] points and below the cutoff value. The difference in change (mean [standard error]) in the control group was -3.3 [0.4] points, and the time-by-group interaction was also significant. In a prior before-and-after comparison study (Miura et al., 2021), 33 participants with locomotive syndrome underwent training with the HAL lumbar type three times a week for 4 weeks; significant improvements were observed in the Visual Analog Scale for pain. The authors considered that the HAL, which can detect nerve and muscle action potentials in the lumbar erector spinae muscles and support the user's movements by adjusting the level and timing of torque, as well as coordinate voluntary joint movement via the user's intention, was able to induce positive feedback on the nerves and muscles (Miura et al., 2021). Thus, it is expected that individuals who use the HAL would not be affected by frailty and locomotive syndrome, which are reversible conditions in the short term. Furthermore, these individuals would likely have increased mobility and less pain, thereby leading to increased self-efficacy in exercise participation and improved engagement in social activities.

Strength of this study was the use of a randomized controlled design. To our best knowledge, no prior RCTs have been conducted on the HAL lumbar type, which has been primarily utilized in rehabilitation programs. Furthermore, this study was able to demonstrate clinically meaningful improvements in both primary and secondary outcomes in the short period of 5 weeks.

This study had some limitations. First, outcome assessors were not blinded to group allocation. The program implementation and outcome evaluation were assigned to different staff members for each participant to avoid bias as much as possible. Although this approach was adopted due to limited staffing and operational issues with the intervention, the possibility of measurement bias could not be completely ruled out. Second, the participants in this study entered the program of their own volition. Therefore, selection bias may have occurred due to the possibility that the participants were more concerned about their own health and physical function than other older adults. Additional work is needed to disseminate the program to prioritized populations, such as older adults who are socially isolated or indifferent to exercise. Third, since this study focused on limited mobility, walking speed was used as the sole criterion for assessing frailty, rather than using a validated scale such as the Fried criteria. Hence, this study could have potentially overlooked other critical physical, cognitive, and functional declines

Table 2
Effects of exercise program using the Hybrid Assistive Limb lumbar type.

	Baseline	Post-intervention	Between-group difference in change following intervention ^a Mean (standard error)	Time-by-group interaction ^b		
	Mean (95 % CI)			F-value	p-value	Partial η^2
Physical function						
Walking speed: usual (m/s)						
Intervention	1.05 (0.98, 1.12)	1.43 (1.35, 1.51)	0.35 (0.04)	93.63	<0.001	0.55
Control	1.03 (0.96, 1.10)	1.06 (0.98, 1.14)				
Walking cadence: usual (steps/min)						
Intervention	109 (105, 113)	120 (116, 123)	9.9 (2.0)	24.33	<0.001	0.24
Control	107 (103,111)	108 (105, 112)				
Walking speed: max (m/s)						
Intervention	1.47 (1.38, 1.56)	1.75 (1.65, 1.85)	0.25 (0.04)	38.77	<0.001	0.34
Control	1.47 (1.38, 1.56)	1.49 (1.39, 1.59)				
Walking cadence: max (steps/min)						
Intervention	128 (123,133)	133 (128, 139)	6.2 (2.5)	6.03	0.016	0.07
Control	126 (121,132)	125 (119, 131)				
2-step test (score)						
Intervention	1.21 (1.14, 1.28)	1.34 (1.27, 1.40)	0.12 (0.02)	32.60	<0.001	0.30
Control	1.24 (1.17, 1.31)	1.24 (1.17, 1.31)				
Timed Up and Go test (s)						
Intervention	8.3 (7.5, 9.2)	7.0 (6.2, 7.7)	-1.1 (0.3)	19.83	<0.001	0.21
Control	8.1 (7.2, 8.9)	7.8 (7.1, 8.6)				
5-times chair-standing test (s)						
Intervention	11.9 (10.9, 12.9)	9.2 (8.4, 10.1)	-1.7 (0.6)	9.61	0.003	0.11
Control	11.1 (10.0, 12.1)	10.1 (9.3, 11.0)				
Functional Reach Test (cm)						
Intervention	29.0 (26.9, 31.1)	31.9 (29.9, 33.8)	2.0 (1.2)	2.91	0.092	0.04
Control	28.7 (26.7, 30.8)	29.6 (27.6, 31.6)				
Grip strength (kg)						
Intervention	23.0 (20.7, 25.4)	24.1 (21.8, 26.4)	0.5 (0.6)	0.65	0.423	0.01
Control	21.9 (19.5, 24.3)	22.5 (20.1, 24.9)				
BBS (score)						
Intervention	53.4 (51.8, 54.9)	54.5 (52.9, 56.0)	0.6 (0.3)	4.28	0.042	0.05
Control	54.4 (52.8, 55.9)	54.8 (53.3, 56.4)				
GLFS-5 (score)						
Intervention	8.5 (7.7, 9.3)	4.4 (3.3, 5.4)	-3.3 (0.4)	87.49	<0.001	0.53
Control	8.1 (7.2, 8.9)	7.3 (6.2, 8.3)				
Body composition						
BMI (kg/m ²)						
Intervention	22.7 (21.8, 23.7)	22.7 (21.7, 23.6)	0.1 (0.1)	0.50	0.484	0.01
Control	22.4 (21.4, 23.3)	22.2 (21.3, 23.1)				
Fat (%)						
Intervention	29.2 (27.0, 31.4)	28.0 (25.7, 30.3)	0.2 (0.4)	0.29	0.595	0.00
Control	29.2 (27.0, 31.4)	27.8 (25.4, 30.1)				
Muscle mass (kg)						
Intervention	37.2 (35.1, 39.3)	37.8 (35.8, 39.9)	-0.1 (0.1)	0.13	0.721	0.00
Control	36.3 (34.2, 38.4)	37.0 (34.9, 39.1)				

BBS: Berg Balance Scale, GLFS-5: 5-question Geriatric Locomotive Function Scale, BMI: body mass index, CI: confidence interval
Boldface indicates statistical significance ($p < 0.05$).

^a Difference in mean change from baseline to post-intervention between the intervention and control groups.

^b p -values were generated using repeated measures analysis of variance.

associated with frailty. However, the incidence of disability in frail/pre-frail older adults with and without slow walking speed (cutoff <1.0 m/s) has been reported, with an increased risk in the slow walking speed group (Shimada et al., 2015). Therefore, walking speed should be considered a priority criterion. Fourth, the exercise program included several exercises that did not use the HAL lumbar type. Therefore, it was not possible to definitively attribute all study results to the effects of the HAL lumbar type. Future studies should take into account specific components of this intervention. In addition, a follow-up study is required to examine the impact of this intervention on ongoing post-intervention activities.

5. Conclusions

The study showed that an exercise program using the HAL lumbar type was able to improve physical function in community residents with physical frailty or locomotive syndrome, who were not in need of nursing care. Notably, most of the investigated physical functions improved to a clinically meaningful degree within a short period of 5 weeks. The exercise program developed in this study may be a promising option to facilitate the prompt resumption of community activities for mobility-limited older adults who do not require transition to long-term care.

CRedit authorship contribution statement

Yoshinobu Saito: Writing – review & editing, Writing – original draft, Project administration, Methodology, Formal analysis, Data curation, Conceptualization. **Sho Nakamura:** Writing – review & editing, Methodology, Data curation, Conceptualization. **Takashi Kasukawa:** Writing – review & editing, Investigation, Data curation. **Makoto Nagasawa:** Writing – review & editing, Data curation. **Yuko Oguma:** Writing – review & editing, Methodology, Data curation, Conceptualization. **Hiroto Narimatsu:** Writing – review & editing, Supervision, Project administration, Methodology, Funding acquisition, Conceptualization.

Declaration of competing interest

None.

Availability of data and materials

The datasets presented in this article are not readily available because data cannot be shared publicly due to ethical restrictions. Requests to access the datasets should be directed to data described in the manuscript that will be made available upon application and approval from the ME-BYO cohort office (contact via the corresponding author) for researchers who meet the criteria for data sharing.

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Ethics approval and consent to participate

This study was approved by the Research Ethics Review Committee of the Graduate School of Health Innovation, Kanagawa University of Health and Welfare (Approval No.: Hodai No. 30–008) and was conducted in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. All participants gave their informed consent prior to their inclusion in the study. The study protocol was registered in the University Hospital Medical Information Network (UMIN) clinical trial registration system (study ID UMIN000042352).

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.exger.2024.112536>.

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