

One-Year Retention of Gait Speed Improvement in Stroke Survivors After Treatment With a Wearable Home-Use Gait Device

Brianne Darcy (✉ brie@moterumtechnologies.com)

Moterum Technologies, Inc.

Lauren Rashford

Moterum Technologies, Inc.

Nancey T. Tsai

Moterum Technologies, Inc.

David Huizenga

Moterum Technologies, Inc.

Kyle B. Reed

University of South Florida

Stacy J.M. Bamberg

Moterum Technologies, Inc.

Research Article

Keywords: Stroke, Gait, Gait Speed, Walking Speed, Gait Treatment, iStride, Gait Device

Posted Date: February 4th, 2022

DOI: <https://doi.org/10.21203/rs.3.rs-1300386/v1>

License: © ⓘ This work is licensed under a Creative Commons Attribution 4.0 International License.

[Read Full License](#)

Abstract

Background: A majority of stroke survivors experience gait impairments, some of which persist into the chronic phase of stroke. Treatment with the iStride™ gait device has been shown to improve symmetry, gait speed, and functional balance for chronic stroke survivors. In this study, we examine the long-term gait speed changes up to twelve months after treatment with the iStride™ gait device.

Methods: Eighteen individuals (mean 56.7 years, range 44-77 years) at least one-year post-stroke (mean 59.7 months, range 13-308 months) participated in this single group, before-after study with multiple follow-ups. Participants completed 12 treatment sessions (three times per week over four weeks) with the gait device. During each session, participants ambulated over ground on the gait device for a goal of 30 minutes. Gait speed was measured using the Ten-Meter Walk Test at a comfortable pace at baseline and at five follow-up sessions after the treatment period: one week, one month, three months, six months, and twelve months. All study aspects were performed in the home environment of each participant and under the guidance of a licensed physical therapist. Gait speed changes were analyzed using repeated-measures ANOVA from baseline to each follow-up time frame, comparison to the minimal clinically important difference threshold, evaluation of functional ambulation category changes, and subjective questionnaires.

Results: Participants retained more than a 0.21 m/s gait speed improvement at all post-treatment time frames, $p < 0.01$. Additionally, 94% of participants improved their gait speed beyond the minimally clinical important difference during one or more post-treatment measurements. 88% of participants subjectively reported a gait speed improvement.

Conclusion: The findings of this study indicate that this four-week treatment protocol using the iStride™ gait device in the home environment may result in meaningful, long-term gait speed improvement for chronic stroke survivors with hemiparetic gait impairments.

Trial Registration: NCT03649217. Registered August 28, 2018 – Retrospectively registered for 11 participants who were consented before August 28, 2018; seven participants were consented after August 28, 2018.

Background

Over 7 million stroke survivors currently live in the United States [1], and early projections indicate this figure may rise to over 10 million in the next decade [1-3]. Improvements in medical interventions have reduced mortality [4, 5], however the disability after stroke is often long-term and remains an economic burden globally [1] and personal affliction for well over 60% of stroke survivors [6-8] and their caregivers [9]. Impairments after stroke can be widespread with effects to multiple physiologic systems. However, when questioned on rehabilitation goals, a majority of stroke survivors cite improving gait as a top priority [10, 11]. Gait dysfunction is experienced by more than 80% of stroke survivors [12] and

approximately 30-40% of stroke survivors have limited to no walking ability, even after completion of traditional rehabilitation [13, 14].

The motivation to improve gait is multi-faceted. Impaired gait is inefficient, with a metabolic cost 40-50% higher than neurologically intact individuals [15], which can lead to difficulties performing daily activities [16]. Especially when asymmetric, impaired gait contributes to abnormal joint loading and musculoskeletal complications, which can result in pain and further disability [17]. Additionally, impaired gait is associated with an increased risk of falls [12, 18] which compromises safety and contributes to the seven-fold higher risk of fractures seen in individuals with a history of stroke [19, 20]. Adding to the potential physical consequences of falls, fear of falling can further limit community participation, which contributes to mental health issues related to isolation, among other things [19]. The need to enhance gait training outcomes post-stroke is critical, however, access to effective, long-term treatment can be insufficient, especially for chronic stroke survivors with limited access to clinical environments and/or resources.

The assessment of gait function provides unique insight not only into the disability status and rehabilitation needs of stroke survivors, but their overall health as well. The most studied and utilized measurement of gait function is the measurement of self-paced gait speed [7, 21]. Despite its simplicity, the utility of gait speed measurement is heavily emphasized in medical literature with its clinical value stated to rival routinely measured vital signs such as blood pressure and pulse [22]. While commonly associated with quality of life, general health status, and functional abilities, gait speed measurement has additionally been praised for its predictive value with factors such as mortality [23], falls [24], and community participation [25]. Its versatility enables utilization for multiple settings, including home environments [26], earning gait speed the highest level of outcome measure recommendation by an expert chronic stroke panel (StrokEDGE) [27].

The iStride™ gait device [28] (Moterum Technologies, Inc.) has demonstrated the ability to beneficially improve gait patterns, including gait speed, of stroke survivors with hemiparetic gait impairments [29, 30]. The device was designed to reduce the spatial and temporal gait asymmetries experienced in hemiparetic gait patterns by modifying interlimb coordination during overground walking. The gait device is worn on the foot of the non-paretic limb. While the user ambulates, the device's custom wheel shape causes a posterior translation of the non-paretic limb during mid-stance. This mechanism creates an excessive lengthening of steps on the device side and a subsequent dynamic weight shift to the paretic limb. These exaggerated gait mechanics essentially provide a subtle neurological 'trigger' prior to and during the swing phase of the paretic limb. Over time and through repeated use of the device, this trigger results in improved patterns, including symmetry and speed, when the device is removed, and the user returns to natural walking [29].

A feasibility study published in the Journal of NeuroEngineering and Rehabilitation tested whether the altered coordination created by the device could beneficially improve gait asymmetries experienced by stroke survivors with hemiparesis. After 12 clinic-based treatment sessions, each of the six participants

improved step length symmetry, and four out of six participants improved double support symmetry. Additionally, all participants improved on each of the functional outcome measures, which included assessments of gait velocity, risk for falls, and functional endurance [29]. The iStride™ device and its associated motion can be seen in Figure 1. Published manuscripts describe its development and mechanism of action in greater detail [29-32]. A video interview with a participant is also available [33].

The gait device was designed to be lightweight and portable, therefore, offering the potential for gait treatment to occur outside of clinical environments, a likely benefit for individuals with mobility restriction and difficulty accessing clinical settings. To investigate the feasibility and efficacy of treatment with the gait device in natural settings, a recent study explored treatment with the gait device in participants' homes [30]. Outcome measures centering on the functional aspects of gait that could be routinely measured in home settings were selected, including gait speed. Results after 12 treatment sessions revealed clinically relevant improvements, beyond the minimal detectable change or minimal clinically important difference, for both gait speed and functional balance, indicating an immediate post-treatment benefit for the home use translation of this device [30]. Retention of these gait improvements, however, remains undetermined, making the relevant, long-term clinical value unknown.

The objective of this study was to explore the long-term effects of treatment with the gait device in the home environment for individuals with gait impairments from chronic stroke. Specifically, this study investigates retention of the post-treatment therapeutic effect observed for gait speed by evaluating several follow-up time frames after the treatment period. Our hypothesis is that the gait speed improvement attained after gait device treatment will be sustained through all measured time frames.

Methods

Selection Criteria

Inclusion and exclusion criteria were identified as follows. Inclusion criteria: (1) age 21-80, (2) one or more cerebral stroke (all on the same side), (3) stroke occurred at least six months previously, (4) gait asymmetry but can walk independently with or without a cane, (5) no evidence of severe cognitive impairment that would interfere with understanding instructions, (6) not currently receiving physical therapy, (7) no evidence of one-sided neglect affecting ambulation, (8) adequate walking space within the home, and (9) weight less than 250 pounds. Exclusion Criteria: (1) uncontrolled seizures, (2) pregnancy, (3) metal implants (stents), (4) chronic obstructive pulmonary disease, (5) uncontrolled high blood pressure, (6) myocardial infarction within the last 180 days, (7) head injury within the last 180 days, or (8) a history of a neurologic disorder other than stroke. Additionally, during the period of treatment with the gait device, participants were excluded if the supervising physical therapist observed concerns regarding the participant's ability to complete the treatment safely. Recruitment occurred during the months of July 2018 through September 2018. Treatment occurred between July 2018 and December 2018. All study-related follow-up was completed in December 2019.

Eighteen individuals with chronic stroke participated in this study which features the long-term follow-up results from our home-based iStride™ study [30]. This prior study reported results from a sample size of 21 participants. We derived the sample size for this study using power analyses from two previous studies using the gait device [29, 32]. In the first study [32], the t-test was powered between pre-treatment and post-treatment data in healthy individuals and calculated an effect size of 0.68 for step length difference, resulting in an estimated minimal sample size of 18 participants. We initially included a higher number of participants since we expected more variation when testing on individuals with stroke. The second study [29], based on a pilot in-clinic study using the device with individuals with stroke, calculated an effect size of 0.71 for gait speed. A power analysis based on gait speed showed that 21 participants would obtain a power of 0.85. This power analysis does exclude one participant who started at a very fast walking speed of 1.14m/s (and ended with a speed of 1.45m/s), which is uncommonly fast for an individual with stroke; all of our participants in this study started with a gait speed less than 1.0m/s. Note that these studies used step length asymmetry as a primary measure (which is not a variable in this study). Between the one-week and twelve-month follow-up sessions, three out of the 21 participants did not complete all follow-up sessions. Since we are reporting repeated-measures statistical tests in this study, only the results of the 18 participants who completed all outcome assessments at all time periods will be included.

Experimental Setup

The study followed a single group, before-after design with multiple follow-ups. Eligibility verification included an initial phone screen followed by a home visit to confirm compliance with eligibility criteria and to assess the home environment for suitability of device treatment. After consenting to participate, the participants' gait parameters were measured at baseline (approximately one week before starting treatment with the gait device), followed by four weeks of iStride™ device treatment. After treatment with the gait device was complete, gait parameters were measured at five follow-up time frames: one week, one month, three months, six months, and twelve months post-treatment. At the final follow-up session, participants were provided a questionnaire regarding their clinical trial experience and subjective observed gait changes after treatment with the gait device. All study aspects were performed within the participant's home environments by licensed physical therapists. Each participant signed a consent form that was approved by the Western Institutional Review Board prior to their study inclusion.

Treatment Sessions

The participants were treated using the gait device in their home environment three times per week for four weeks (for a target of 12 treatment sessions). During each treatment session, the participant wore the device on their non-paretic foot. An approximate height-matched platform was worn on the paretic foot. The participants ambulated over ground on the gait device for a goal of 30 minutes during each treatment session, unless unable to complete due to fatigue. Rest breaks were provided at five-minute

intervals (or more frequently if requested by the participants). Ambulation on the device was supervised by licensed physical therapists who provided the level of mobility assistance needed for participant safety and comfort while ambulating on the device. No other treatment or physical therapy services were provided to the participants during the treatment period.

Gait Assessments

Assessments of gait patterns occurred at baseline (approximately one week before treatment) and at five follow-up time frames: one week, one month, three months, six months, and twelve months after the treatment period. Gait speed was measured using the Ten-Meter Walk Test (10MWT) performed at their comfortable gait speed. Standardized therapist procedures and testing instructions were maintained for uniformity. Due to the nature of home environment testing, spatial conditions of some homes required some participants to perform a turn during the 10MWT to complete the full distance. Testing setups were kept consistent within each participant's environment and across all time frames for consistency. Figure 2 shows the study procedures and timeline.

Data Analysis

A one-way repeated measures ANOVA test was conducted with gait speed as the dependent variable and time frame as the independent variable (baseline and five follow-up time frames). Sphericity was evaluated using Mauchly's test for sphericity, and corrections using Greenhouse-Geisser estimates were applied if sphericity had been violated. When statistical significance was found, a post-hoc test was performed with Bonferroni corrections. All statistical tests were based on an alpha value of 0.05. Statistical analyses were performed using SPSS Version 26 software (IBM Corporation, Armonk, NY).

To monitor for the meaningfulness of gait speed changes, we compared both the study group average and each individual's gait speed change to the minimal clinically important difference (MCID) for gait speed improvement [32]. The MCID refers to the smallest amount of change in an outcome that might be considered 'important' to the patient or clinician. Additionally, the speed of an individual's gait also corresponds with their ability to participate within the community. These classifications are often referred to as functional ambulation categories. Gait speeds less than 0.4m/s correspond with 'home ambulators', speeds between 0.4m/s and 0.8m/s correspond with 'limited community ambulators', speeds between 0.8m/s and 1.2m/s are considered 'unlimited community ambulators', and speeds greater than 1.2m/s relate to normal speeds [25]. To monitor for changes in expected community participation ability, each participant's walking speed was categorized and compared to the respective functional ambulation category during each study time frame. Finally, participant responses to a questionnaire regarding clinical trial experience and subjective gait observations after treatment were manually tabulated for the percentage of positive or negative responses to each questionnaire item.

Results

Participants

Twenty-three participants were initially included for study participation. Figure 2 shows the study activities and the total number of participants after each study phase. Key study activities are listed within each phase, and reasons for non-participation are available to the right of each phase heading. The discussed results and analysis center on the 18 study participants that completed all assessments through the twelve-month follow-up.

The demographic characteristics of the 18 study participants are shown in Table 1.

Table 1. Participant Demographics

ID	Sex	Weight (lbs)	Age (years)	Time Since Stroke (Months)	Side of Hemiparesis
A	M	160	53	24	Left
B	F	180	77	15	Left
C	F	200	44	14	Left
D	M	190	63	53	Left
E	F	189	47	28	Right
F	F	222	69	89	Left
G	F	134	46	308	Left
H	F	183	50	80	Left
I	M	220	61	22	Left
J	M	240	51	50	Left
K	M	188	62	28	Left
L	F	250	58	92	Left
M	F	150	54	21	Right
N	M	235	52	130	Right
O	M	175	64	30	Right
P	M	198	55	13	Right
Q	F	172	53	32	Left
R	M	134	61	46	Left
	9 Male	Average 190.0	Average 56.7	Average 59.7	5 Right
	9 Female			Median 31	13 Left

Statistical Findings

Repeated-measures ANOVA revealed statistical significance for gait speed (measured using the 10MWT at comfortable gait speed) after treatment with the gait device $F(2.871, 48.815) = 9.195, p < 0.001$, (Greenhouse-Geisser used to correct assumption of sphericity). Post hoc analysis revealed significant differences from baseline to all follow-up time frames, $p < 0.01$. Comfortable walking speed increased 0.27 m/s (51.2 %, $p < 0.001$) from baseline to one week post-treatment, 0.28 m/s (52.9%, $p = 0.002$) from

baseline to one month post-treatment, 0.25 m/s (47.3%, $p=0.006$) from baseline to three months post-treatment, 0.24 m/s (46.0%, $p=0.001$) from baseline to six months post-treatment, and 0.21 m/s (39.7%, $p=0.001$) from baseline to twelve months post-treatment. No statistically significant changes occurred between any of the post-treatment follow-up periods, $p>0.999$. Figure 3 shows the mean gait speed and associated p-values at each of the six time frames.

Treatment Compliance

The 18 study participants completed an average of 11.7 treatment sessions and 290 minutes on the device (out of an available 360 minutes of device treatment). Documented primary reasons for reduced completion included scheduling conflicts and fatigue.

Minimal Clinically Important Difference

Gait speed changes of the individual participants, mean improvements by time period, and percentages of participants exceeding the gait speed MCID [34] threshold of 0.16m/s at each time frame are shown in Table 2. Numbers in bold indicate an improvement beyond the MCID value. Importantly, the average magnitude of gait speed improvement at each post-treatment time frame exceeds the MCID by 0.05m/s or more.

Table 2. Individual participant gait changes compared to MCID.

Percentage of Time Frames Change > MCID	ID	Baseline Gait Speed (m/s)	Gait Speed Change (m/s) 1Wk Post	Gait Speed Change (m/s) 1Mo Post	Gait Speed Change (m/s) 3Mo Post	Gait Speed Change (m/s) 6Mo Post	Gait Speed Change (m/s) 12Mo Post
100%	A	0.20	+0.44	+0.75	+0.72	+0.56	+0.46
	B	0.21	+0.27	+0.35	+0.51	+0.29	+0.30
	C	0.25	+0.45	+0.65	+0.49	+0.66	+0.45
	D	0.30	+0.16	+0.23	+0.20	+0.34	+0.29
	E	0.44	+0.22	+0.27	+0.23	+0.27	+0.23
	F	0.53	+0.20	+0.25	+0.28	+0.37	+0.29
	G	0.63	+0.40	+0.41	+0.39	+0.37	+0.38
80%	H	0.61	+0.56	+0.49	+0.59	+0.30	+0.07
	I	0.75	+0.19	-0.05	+0.18	+0.27	+0.41
	J	0.46	+0.13	+0.17	+0.18	+0.23	+0.27
60%	K	0.78	+0.61	+0.67	+0.50	-0.13	+0.06
	L	0.98	+0.43	+0.32	-0.17	+0.29	+0.06
	M	0.39	+0.21	+0.14	+0.01	+0.21	+0.20
	N	0.64	+0.14	+0.14	+0.19	+0.22	+0.27
40%	O	0.86	+0.33	+0.22	-0.15	-0.16	-0.06
20%	P	0.39	+0.11	+0.12	+0.20	+0.15	+0.07
	Q	0.91	-0.03	-0.09	+0.13	+0.17	+0.05
0%	R	0.22	+0.10	+0.03	+0.05	0.00	0.00
	Mean	0.53	+0.27	+0.28	+0.25	+0.24	+0.21
	% of Participants >MCID	n/a	72.2%	66.7%	72.2%	77.8%	61.1%

Legend: m/s meters per second, Wk week, Mo month, Post post-treatment, MCID minimal clinically important difference

Functional Ambulation Categories

At baseline, seven of the participants were classified as home ambulators, eight as limited community ambulators, and three as unlimited community ambulators [25]. Importantly, after the device treatment, only one participant remained a home ambulator throughout the remainder of the study period. The remaining participants in this initial category improved one or two functional ambulation categories. Twelve months post-treatment, one participant remained a home ambulator, nine were classified as limited community ambulators, and eight improved to unlimited community ambulators. Notably, the number of unlimited community ambulators more than doubles beyond one month post-treatment. Additionally, one to two participants achieved a gait speed categorized as “normal speed” during four of the five assessments after treatment with the gait device. Figure 4 shows the number of participants in each functional ambulation category during all study time frames.

Questionnaire Responses

Survey items included questions regarding subjective observations of potential gait changes, functional independence changes, and clinical trial experience. (Note: survey responses are only available for 17 of the 18 participants). Fifteen of 17 participants (88%) reported noticing an improvement in their walking speed, 12 of 17 participants (71%) reported improved functional independence, and 17 of 17 (100%) reported a positive clinical trial experience with the iStride™ device.

Discussion

The objective of this study was to investigate the long-term gait speed effects after treatment with the iStride™ gait device in the home environment for individuals with gait impairments from chronic stroke. A review of the participants' gait speed changes over the study period demonstrates notable positive results across the measured time frames.

When assessing the therapeutic value of outcome measure improvement, it is important to consider the magnitude of the change. The minimal clinically important difference (MCID) defines the smallest amount an outcome must change to be considered ‘meaningful’ to patients [35]. For survivors of stroke, several gait speed MCID values have been proposed, and a MCID value 0.16m/s [34] was selected for comparison in our study (a conservative measurement compared to MCID values of 0.1 m/s [36] and 0.13 m/s [37] used in other studies). In our sample, 94% of participants exceeded this MCID during one or more post-treatment time frames. As a group, immediately post-treatment (one-week post-treatment time frame), the average improvement in gait speed measured 0.27 m/s, exceeding the MCID by more than 0.1 m/s. This improvement reached a peak one month post-treatment where the group's gait speed improvement reached 0.28 m/s and the average speed of our participants reached 0.812 m/s, which also surpasses the ‘unlimited community ambulator’ functional ambulation category threshold. Interestingly, the highest percentage of participants (77.8%) demonstrated improvement beyond the MCID threshold at six months post-treatment. Between one week post-treatment and twelve months post-treatment, our group still maintained a statistically significant improvement and beyond 0.2 m/s gait speed gain, which

remains above the associated MCID value. These results are supported by the vast majority of participants (88%) that reported a subjective gait speed improvement as noted by questionnaire results at study completion.

While multiple gait treatment techniques and technologies cite the ability to improve the gait speed of stroke survivors, comparison to studies of various overground gait intervention approaches indicates an improvement of this magnitude (which is also retained and fosters an expected improvement in community participation ability) may be quite unique [38]. Specifically, a 2009 analysis of seven studies and nearly 400 participants found an average gait speed improvement of 0.07m/s after overground gait training [14]. Another study by DePaul and colleagues [39] used a motor-learning-science-based overground walking program, which resulted in an average 0.14m/s gait speed improvement. Finally, a study by Park et al. [40] compared the effects of gait training overground versus treadmills and found the largest gait speed improvement, from any of the training conditions, to be 0.1m/s. The reported gait speed improvements from the present study of >0.21 m/s, across all time frames, are approximately two to three times greater than those reported by these gait-focused studies and additionally highlight retention, a critical factor not demonstrated in the prior mentioned studies.

To examine our study results in the context of overall health, we compared the retained gait speed changes (twelve months post-treatment) to important health metrics impacted by gait speed in the literature. Since walking involves the entire body (i.e., integrating cardiopulmonary systems with neurological and musculoskeletal systems), the speed of walking can provide a window into an individual's overall health. Gait speed has been shown in numerous studies to be strongly associated with quality of life [24], disabilities [41], and survival [23] in older adults (however, it is important to note that these studies generally investigate populations older than 65 years and the average age of our participants was approximately 57 years).

The relationship of gait speed to mortality was investigated by Studenski et al. [23] using a pooled analysis of nine cohort studies comprising 34,485 individuals (65 years and older, similar numbers of men and women). Participants were followed for between six and 21 years. This study confirmed significant increases in survival per 0.1 m/s of gait speed and produced five and ten-year survival tables for each sex. Relating these findings to our data reveals an expected increased average survival of three years, with some participants potentially adding up to seven years of life expectancy based on their improved gait speed.

Purser et al. studied hospital inpatients in a Department of Veterans Affairs (VA) study with 1,388 participants (65 years and older, mean 74.2 years; 98% male) and followed the participants for twelve months [42]. This study showed that for each 0.1 m/s increase in gait speed, participants had improved health status, improved physical function, reduced basic and instrumental disabilities, as well as decreased hospitalization days and the associated costs. Specifically regarding hospitalizations, each 0.1 m/s increase in gait speed corresponded to 2.3 fewer hospitalization days. Applying these figures to our data yields a potential reduction of approximately five days of hospitalization, per participant.

Lastly, a study by Perera et al. investigated disabilities using a pooled analysis of seven cohort studies comprising 27,220 individuals (65 years and older, similar numbers of men and women) [41]. This study demonstrated gait speed to predict three-year incidence of bathing/dressing dependence, mobility difficulty, as well as a composite outcome of disability and mortality. The risk of disability using the composite outcome decreased 30% for each 0.1 m/s increase in gait speed. Applying the 30% reduction in disability risk to our population indicates a potential three-year disability risk reduction of 65%. While future studies could confirm these projected outcomes after treatment with the gait device, the potential impact on critical health aspects appears considerable.

Stroke survivors with limited ability to participate in their communities show a decline in emotional well-being after stroke [43, 44]. Therefore, maximizing community participation post-stroke has gained recognition as an important goal of stroke rehabilitation [45]. In Figure 4, we present changes to functional ambulation categories during the study period, which reveals a decrease in the number of home ambulators and a subsequent increase in the number of limited community, unlimited community, and normal speed ambulators, after treatment with the gait device. Moreover, 11/18 of the participants (61%) improved and maintained a greater functional ambulation category at their twelve-month follow-up session compared to baseline. Among these individuals were six of the seven participants that began the study as home ambulators. Additionally, this group includes all six participants that were two years or less post-stroke and the most chronic participant who was 25+ years post-stroke at baseline. These interesting results highlight the value of treatment in the immediate two-year post-stroke time frame and further emphasize that meaningful improvement is achievable even many years post-stroke.

Additionally, reviewing the participants' gait speeds over the twelve-month period appears to reveal several unique patterns of gait speed change and retention. Some participants improved their functional ambulation category post-treatment and maintained this improvement through the twelve-month follow-up, such as Participants A and C, for example. Others demonstrated initial improvement post-treatment but returned to their original ambulation category by the twelve-month follow-up (such as Participant H), and yet others continued to improve their gait speed over the twelve-month period, despite no further treatment (such as Participant I). Future studies would be useful to differentiate these trends, as well as the specific characteristics that may have influenced treatment responsiveness and retention.

Limitations

There are several limitations to our study. As noted in our inclusion criteria, the clinical trial participants did not receive any additional physical therapy treatment from the clinical trial physical therapists or external physical therapists during the treatment period. However, six participants (Participants D, H, J, K, O, and P) did resume some form of additional physical therapy treatment between the one-week follow-up and twelve-month follow-up. The possibility of additional physical therapy influencing retention of the device treatment effects is a consideration, especially for Participants D, H, J, and O who remained above the gait speed MCID during their period of additional physical therapy. Participants K and P did not

maintain gait speed improvement beyond the MCID during their periods of their additional physical therapy services. It is important to note that two-thirds of our participants (12 out of 18 participants) did not receive any additional physical therapy treatment throughout the study duration.

Additionally, when possible, consistent physical therapists were used with each of the participants in this study. This consistency, while minimizing interrater reliability issues, does not permit blinding of therapists and may introduce bias into the outcomes assessments. Also, repeated outcomes testing could introduce a practice effect. Finally, the small sample size limits the generalizability of our findings as well as the interpretation of our results.

Conclusions

The present study supports the usage of a four-week iStride™ gait treatment protocol for chronic stroke survivors in their home environment. Results indicate that the described treatment has the potential to result in long-term, meaningful gait speed improvement for individuals with hemiparetic gait impairments. This treatment appears unique in its ability to facilitate clinically significant gait speed changes, which have been correlated with decreased disability and improved quality of life, in a relatively short time frame and from the home environment. Additionally, our findings provide additional support to the notion that novel treatments can enhance recovery, even many years post-stroke. These promising results warrant further study to elucidate the full impact of this home-use gait treatment device.

List Of Abbreviations

m/s: meters per second

Wk: week

Mo: month

Post: post-treatment

MCID: minimal clinically important difference

Declarations

Ethics approval and consent to participate

Participants signed a consent form that was approved by the Western Institutional Review board prior to participation in the study.

Consent for publication

Not applicable

Availability of data and materials

The data that support the findings of this study are available from the corresponding author, Brianne Darcy, upon reasonable request.

Competing interests

Author KBR has a patent (US 9,295,302) related to this work. A management plan has been implemented and followed to reduce any effects of these conflicts of interest. The gait device is related to a commercial product by Moterum Technologies, Inc. Authors BD, LR, DH, and SB receive a salary from Moterum Technologies. All authors have stock options in Moterum Technologies, Inc.

Funding

Funding for this study was provided by Moterum Technologies, Inc., Salt Lake City, UT.

Author's Contributions

DH, KBR, and LR designed the experiments. LR screened and consented participants and oversaw execution of the study protocol. BD aided in data acquisition. BD, SB, DH, NT, and KBR analyzed and interpreted the data. BD wrote the manuscript. SB, DH, NT, and KBR provided critical feedback on the manuscript. All authors read and approved the final manuscript.

Acknowledgements

The authors would like to thank the study participants and physical therapists for their time and efforts associated with participation in this study.

References

1. Virani SS, Alonso A, Benjamin EJ, Bittencourt MS, Callaway CW, Carson AP, et al. Heart Disease and Stroke Statistics-2020 Update: A Report From the American Heart Association. *Circulation*. 2020;141(9):e139-e596.
2. Heidenreich PA, Trogon JG, Khavjou OA, Butler J, Dracup K, Ezekowitz MD, et al. Forecasting the future of cardiovascular disease in the United States: a policy statement from the American Heart Association. *Circulation*. 2011;123(8):933-44.

3. Billinger SA, Arena R, Bernhardt J, Eng JJ, Franklin BA, Johnson CM, et al. Physical activity and exercise recommendations for stroke survivors: a statement for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke*. 2014;45(8):2532-53.
4. Center for Disease Control and Prevention. Vital Signs: Recent Trends in Stroke Death Rates - United States, 2000-2015 [Available from: <https://www.cdc.gov/mmwr/volumes/66/wr/mm6635e1.htm>].
5. Lackland DT, Roccella EJ, Deutsch AF, Fornage M, George MG, Howard G, et al. Factors influencing the decline in stroke mortality: a statement from the American Heart Association/American Stroke Association. *Stroke*. 2014;45(1):315-53.
6. Prencipe M, Ferretti C, Casini AR, Santini M, Giubilei F, Culasso F. Stroke, Disability, and Dementia. *Stroke*. 1997;28(3):531-6.
7. Eng JJ, Tang PF. Gait training strategies to optimize walking ability in people with stroke: a synthesis of the evidence. *Expert Rev Neurother*. 2007;7(10):1417-36.
8. Mayo NE, Wood-Dauphinee S, Cote R, Durcan L, Carlton J. Activity, participation, and quality of life 6 months poststroke. *Arch Phys Med Rehabil*. 2002;83(8):1035-42.
9. Opara JA, Jaracz K. Quality of life of post-stroke patients and their caregivers. *J Med Life*. 2010;3(3):216-20.
10. Harris JE, Eng JJ. Goal Priorities Identified through Client-Centred Measurement in Individuals with Chronic Stroke. *Physiotherapy Canada Physiotherapie Canada*. 2004;56(3):171-6.
11. Bohannon RW, Andrews AW, Smith MB. Rehabilitation goals of patients with hemiplegia. 1988;11(2):181-4.
12. Li S, Francisco GE, Zhou P. Post-stroke Hemiplegic Gait: New Perspective and Insights. *Front Physiol*. 2018;9:1021.
13. Jorgensen HS, Nakayama H, Raaschou HO, Olsen TS. Recovery of walking function in stroke patients: the Copenhagen Stroke Study. *Arch Phys Med Rehabil*. 1995;76(1):27-32.
14. States RA, Pappas E, Salem Y. Overground physical therapy gait training for chronic stroke patients with mobility deficits. *Cochrane Database Syst Rev*. 2009(3):CD006075.
15. Reisman DS, Binder-MacLeod S, Farquhar WB. Changes in metabolic cost of transport following locomotor training poststroke. *Topics in stroke rehabilitation*. 2013;20(2):161-70.
16. Olney SJ, Monga TN, Costigan PA. Mechanical energy of walking of stroke patients. *Arch Phys Med Rehabil*. 1986;67(2):92-8.
17. Patterson KK, Sibley KM. Arthritis and associated limitations in community-dwelling Canadians living with stroke. *BMC Neurol*. 2016;16:114.
18. Batchelor FA, Mackintosh SF, Said CM, Hill KD. Falls after stroke. *Int J Stroke*. 2012;7(6):482-90.
19. Liu T-W, Ng Gabriel YF, Chung Raymond CK, Ng Shamay SM. Decreasing Fear of Falling in Chronic Stroke Survivors Through Cognitive Behavior Therapy and Task-Oriented Training. *Stroke*. 2019;50(1):148-54.

20. Kanis J, Oden A, Johnell O. Acute and long-term increase in fracture risk after hospitalization for stroke. *Stroke*. 2001;32(3):702-6.
21. Wonsetler EC, Bowden MG. A systematic review of mechanisms of gait speed change post-stroke. Part 2: exercise capacity, muscle activation, kinetics, and kinematics. *Top Stroke Rehabil*. 2017;24(5):394-403.
22. Fritz S, Lusardi M. White paper: "walking speed: the sixth vital sign". *J Geriatr Phys Ther*. 2009;32(2):46-9.
23. Studenski S, Perera S, Patel K, Rosano C, Faulkner K, Inzitari M, et al. Gait speed and survival in older adults. *JAMA*. 2011;305(1):50-8.
24. Middleton A, Fritz SL, Lusardi M. Walking speed: the functional vital sign. *J Aging Phys Act*. 2015;23(2):314-22.
25. Perry J, Garrett M, Gronley JK, Mulroy SJ. Classification of walking handicap in the stroke population. *Stroke*. 1995;26(6):982-9.
26. Bohannon RW. Measurement of gait speed of older adults is feasible and informative in a home-care setting. *J Geriatr Phys Ther*. 2009;32(1):22-3.
27. Bushnell C, Bettger JP, Cockcroft KM, Cramer SC, Edelen MO, Hanley D, et al. Chronic Stroke Outcome Measures for Motor Function Intervention Trials: Expert Panel Recommendations. *Circ Cardiovasc Qual Outcomes*. 2015;8(6 Suppl 3):S163-9.
28. Reed KB, Handzic, Ismet, inventor; University of South Florida, assignee. Gait Altering Shoes. USA patent 9,295,302. 2016 March 29, 2016.
29. Kim SH, Huizenga DE, Handzic I, Ditwiler RE, Lazinski M, Ramakrishnan T, et al. Relearning functional and symmetric walking after stroke using a wearable device: a feasibility study. *J Neuroeng Rehabil*. 2019;16(1):106.
30. Huizenga D, Rashford L, Darcy B, Lundin E, Medas R, Shultz ST, et al. Wearable gait device for stroke gait rehabilitation at home. *Top Stroke Rehabil*. 2020:1-12.
31. Handzic I, Vasudevan E, Reed KB. Developing a Gait Enhancing Mobile Shoe to Alter Over-Ground Walking Coordination. *IEEE Int Conf Robot Autom*. 2012;2012:4124-9.
32. Handzic I, Barno EM, Vasudevan EV, Reed KB. Design and Pilot Study of a Gait Enhancing Mobile Shoe. *Paladyn*. 2011;2(4).
33. WEDU Quest. Gait Enhancing Mobile Shoe [Television series episode]: PBS; 2016.
34. Tilson JK, Sullivan KJ, Cen SY, Rose DK, Koradia CH, Azen SP, et al. Meaningful gait speed improvement during the first 60 days poststroke: minimal clinically important difference. *Phys Ther*. 2010;90(2):196-208.
35. McGlothlin AE, Lewis RJ. Minimal Clinically Important Difference: Defining What Really Matters to Patients. *JAMA*. 2014;312(13):1342-3.
36. Perera S, Mody SH, Woodman RC, Studenski SA. Meaningful change and responsiveness in common physical performance measures in older adults. *J Am Geriatr Soc*. 2006;54(5):743-9.

37. Bohannon R, Andrews A, Glenney S. Minimal Clinically Important Difference for Comfortable Speed as a Measure of Gait Performance in Patients Undergoing Inpatient Rehabilitation after Stroke. *Journal of physical therapy science*. 2013;25:1223-5.
38. Dickstein R. Rehabilitation of gait speed after stroke: a critical review of intervention approaches. *Neurorehabil Neural Repair*. 2008;22(6):649-60.
39. DePaul VG, Wishart LR, Richardson J, Thabane L, Ma J, Lee TD. Varied overground walking training versus body-weight-supported treadmill training in adults within 1 year of stroke: a randomized controlled trial. *Neurorehabil Neural Repair*. 2015;29(4):329-40.
40. Park I-m, Lee Y-s, Moon B-m, Sim S-m. A Comparison of the Effects of Overground Gait Training and Treadmill Gait Training According to Stroke Patients' Gait Velocity. *Journal of Physical Therapy Science*. 2013;25:379-82.
41. Perera S, Patel KV, Rosano C, Rubin SM, Satterfield S, Harris T, et al. Gait Speed Predicts Incident Disability: A Pooled Analysis. *The journals of gerontology Series A, Biological sciences and medical sciences*. 2016;71(1):63-71.
42. Purser JL, Weinberger M, Cohen HJ, Pieper CF, Morey MC, Li T, et al. Walking speed predicts health status and hospital costs for frail elderly male veterans. *J Rehabil Res Dev*. 2005;42(4):535-46.
43. Suttiwong J, Vongsirinavarat M, Hiengkaew V. Predictors of Community Participation Among Individuals With First Stroke: A Thailand Study. *Ann Rehabil Med*. 2018;42(5):660-9.
44. Egan M, Davis CG, Dubouloz CJ, Kessler D, Kubina LA. Participation and well-being poststroke: evidence of reciprocal effects. *Arch Phys Med Rehabil*. 2014;95(2):262-8.
45. Jalayondeja C, Kaewkungwal J, Sullivan PE, Nidhinandana S, Pichaiyongwongdee S, Jareinpituk S. Factors related to community participation by stroke victims six month post-stroke. *Southeast Asian J Trop Med Public Health*. 2011;42(4):1005-13.

Figures



Figure 1

iStride™ device motion: As the user takes a step, the device pushes the nonparetic foot backward during stance. This exaggeration of the step length asymmetry yields a more symmetric gait pattern once the device is removed and the user returns to overground walking without the device. In addition, the device

encourages usage of the paretic leg by slightly destabilizing the nonparetic leg. A similar height but stationary platform is worn on the foot of the paretic limb for symmetry.

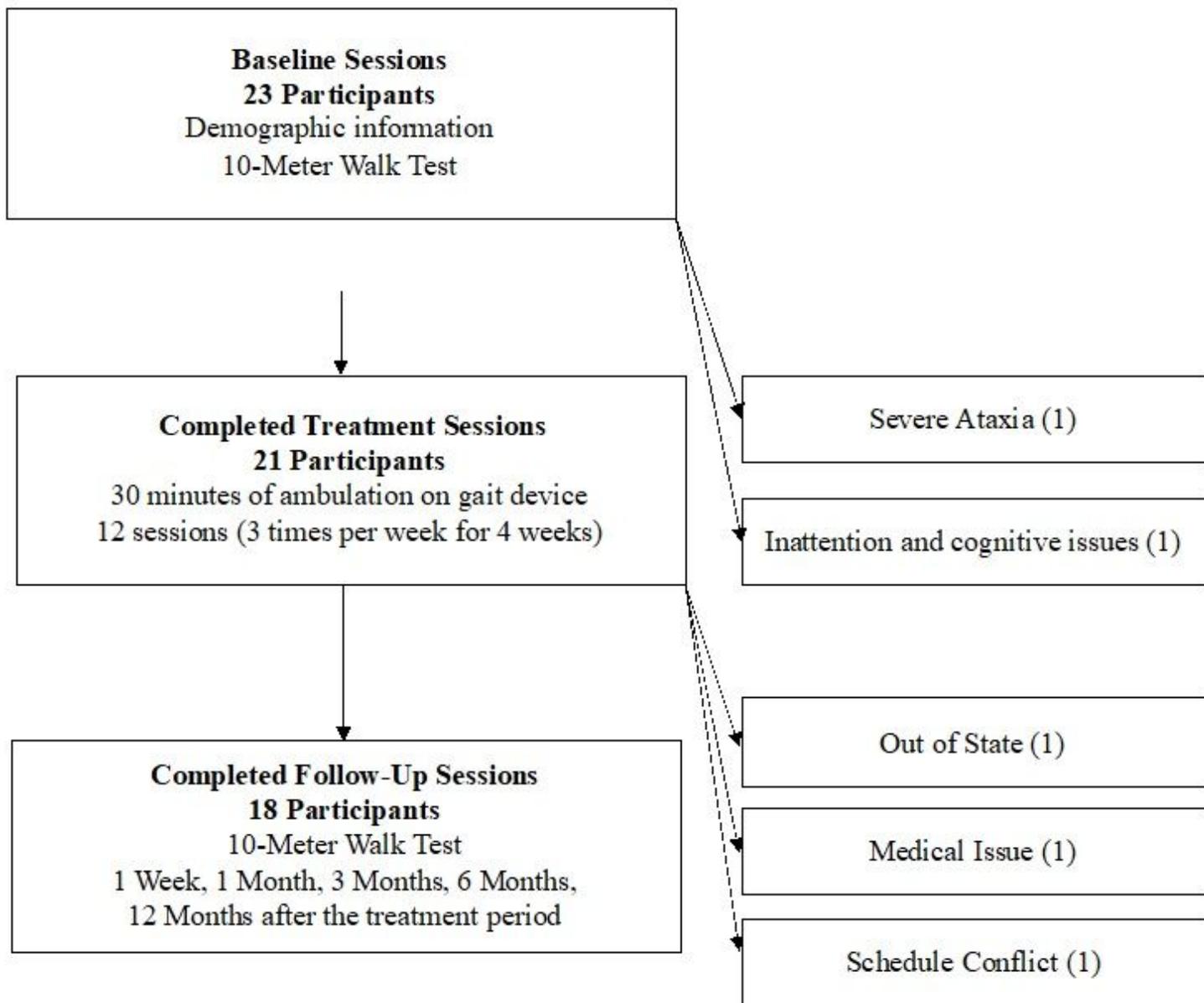


Figure 2

Study Participants at Each Stage. Key study activities are listed within each phase and reasons for non-participation are available to the right of each phase heading.

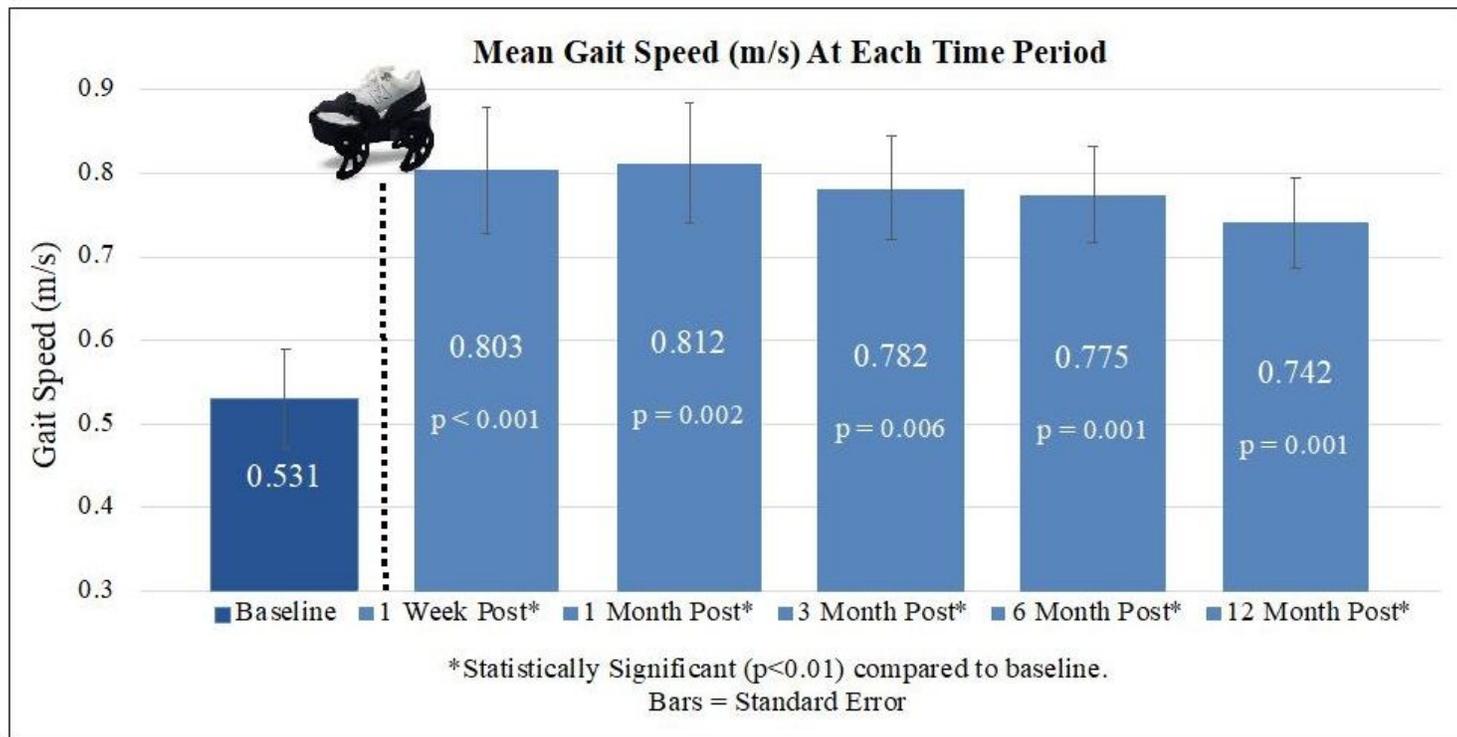


Figure 3

Mean gait speed at each time frame. The dotted line and iStride™ device image represent the sequence within the study activities that the device treatment occurred.

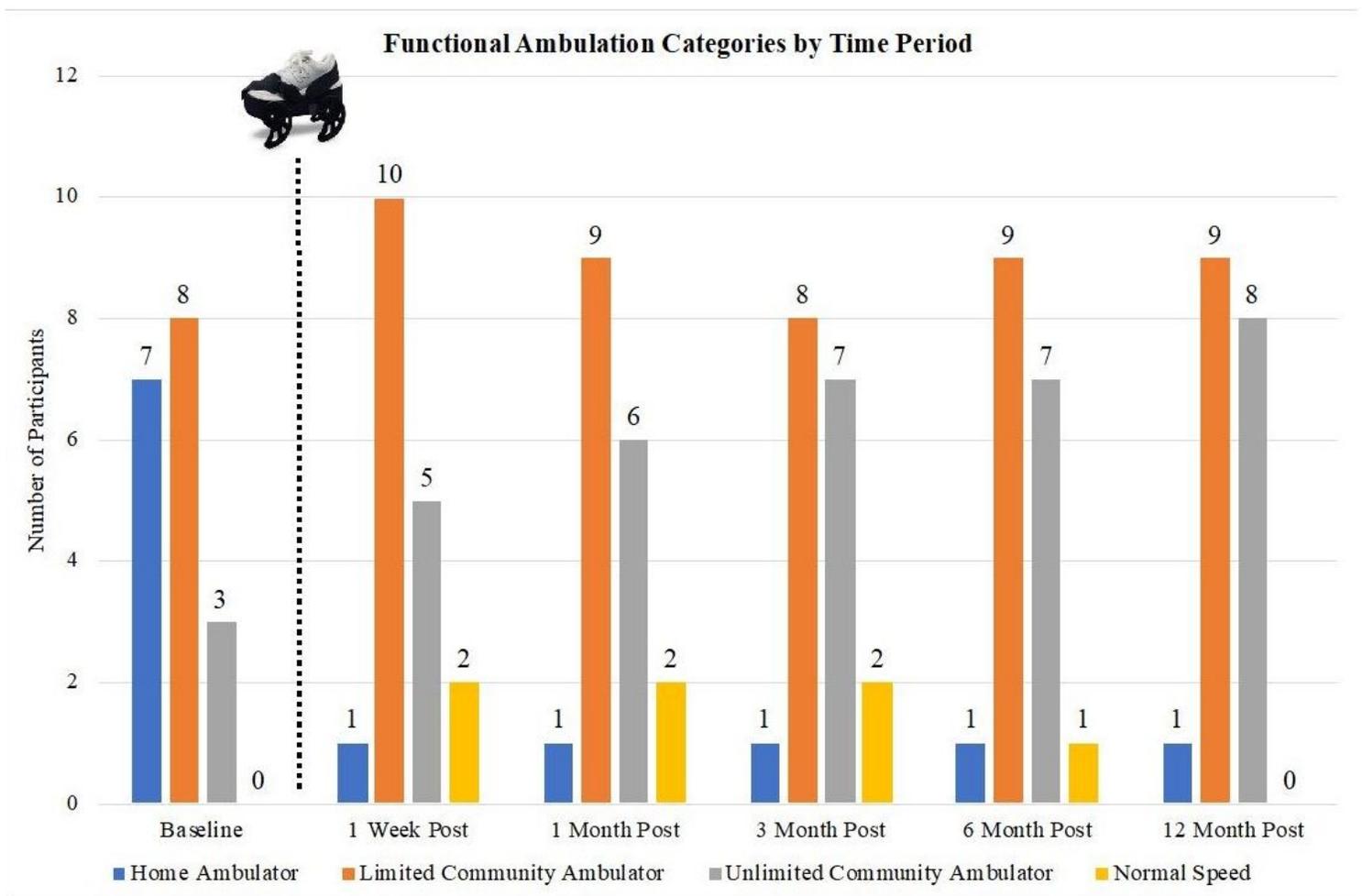


Figure 4

Number of participants in each functional ambulation category at each study time period.