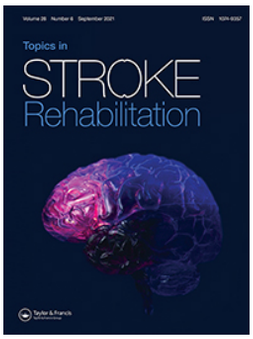

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ARTICLE



# Wearable gait device for stroke gait rehabilitation at home

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**ABSTRACT**

**Background:** Hemiparesis is a common disabling consequence of stroke that leads to abnormal gait patterns marked by asymmetries in step length, stance, and swing phases. Asymmetric gait patterns are correlated with decreased gait velocity and increased susceptibility to falls that can lead to serious injuries and hospitalizations.

**Objective:** In this single group, before and after study, treatment with the iStride™ gait device, designed to improve the gait patterns of individuals with hemiparesis, is adapted to the home environment. Previously tested in clinical settings, this study investigates if using the iStride™ gait device within the home environment can provide safe and effective gait treatment for individuals with hemiparetic gait impairments caused by stroke.

**Methods:** Twelve 30-minute sessions of walking on the device were administered in each participant's home environment. Twenty-one participants who were more than one-year post-stroke received the treatment. The Ten-Meter Walk Test, Timed Up and Go Test, Berg Balance Scale, Functional Gait Assessment, and Stroke Specific Quality of Life Scale were performed before and one week after treatment. Safety, treatment plan compliance, and subjective responses were also recorded during the study period.

**Results:** Results demonstrate statistically significant improvement on all five outcome measures from before treatment to one week after the last treatment session ($p < 0.01$) using two-tailed paired t-tests. 76% of participants improved beyond the small meaningful change or minimal detectable change on three or more outcome measures. 67% of participants improved clinically in gait speed and on at least one of the fall risk assessment inventories. 81% of the participants were able to perform the treatment in their home without assistance before the end of week three.

**Conclusions:** The results indicate that the iStride™ gait device can facilitate effective, safe, and home-accessible gait treatment opportunities for individuals with hemiparesis from stroke.

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**KEYWORDS**
Stroke; Gait; Rehabilitation; Walking Speed; Orthotic Devices; iStride

## Introduction

Stroke is a leading cause of disability in the United States.[1] Effective rehabilitation interventions initiated early after stroke can enhance the recovery process and minimize functional disability. However, despite rehabilitation efforts, approximately 50%-60% of stroke survivors still experience some degree of motor impairment, and approximately 50% are at least partially dependent in activities of daily living (ADLs) after traditional rehabilitation.[2] Limited functional ambulation is one factor that leads to other issues in self-care.

A common disabling consequence of stroke, hemiparesis, leads to an abnormal gait pattern marked by asymmetries in step length, stance, and swing phases.[3] Other consequences include decreased gait speed,[4] which is shown to correlate with hospitalization risk, quality of life, and mortality,[5] as well as an elevated risk for falls.[4] The overall fall rate for community-dwelling stroke survivors ranges from 40%[6] to 73%.[7] Falls can result in serious adverse consequences including injury, institutionalism, and even death, directly or indirectly.[8] Altered gait may also predispose individuals to social isolation, contributing to other morbidities, such as depression.[9,10] Therefore, continued improvement in gait speed, symmetry, fall risk, and overall quality of gait should be essential goals not only for initial therapy but over the long term as well. Some of the currently used methods and devices targeting stroke hemiparesis include functional electrical stimulation,[11] body-weight support,[12] rhythmic auditory cueing,[13] transcranial magnetic stimulation,[14] and full-body gait exoskeletons.[15]

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**Trial registration**: NCT03649217, https://clinicaltrials.gov/ct2/show/NCT03649217

Alternative approaches focus on changing the relative motion of each foot. A split-belt treadmill independently moves each tread at different speeds to improve symmetry.[16] While the ability to adapt interlimb symmetry for chronic stroke survivors has been demonstrated after split-belt treadmill treatment, the benefits only partially transfer to overground walking.[17] Additionally, high equipment cost and low availability have likely limited its widespread use. The iStride™ gait device used in this study was designed to mimic the action of a split-belt treadmill and correct asymmetric gait mechanics experienced post-stroke.[18] Unlike a split-belt treadmill, however, this device is used during overground walking, which limits the need to transfer the context of learning from treadmill to overground.[19] Details on how the device works including its effect on the gait patterns of both healthy participants and post-stroke participants in the clinic setting is discussed below and can be found in previous papers.[20–23] A video interview with one of the previous participants is also available.[24]

The gait device is completely passive and does not require an external power source for operation. As such, it can be worn for extended periods of time and potentially in different environments, such as one's own home and even outside. Therefore, the objective of this study was to assess if using the gait device within the home environment can safely provide accessible, convenient, and effective gait treatment opportunities for individuals with hemiparetic gait impairments from stroke. Given the practical challenges of the home environment compared to clinical settings, the focus of our study was to assess potential improvement of the functional aspects of gait with the hypothesis that using this device in the home environment will safely yield clinically relevant improvements in gait and mobility.

## Methods

### *Participants*

Thirty-six participants with chronic stroke were initially identified and cleared inclusion and exclusion criteria for joining the clinical trial. Inclusion and exclusion criteria are available in Table 1.

Participants were recruited through Internet marketing provided by third-party assistance. After reviewing eligibility with the principal investigator by phone, the participants were visited at their home for further verification of compliance with eligibility criteria and assessment of the home environment for suitability of device treatment. After these visits, 13 participants were excluded from the study due to: a lack of 25 feet of walking space for treatment in the home (four participants), medical instability (three participants), and inability or unwillingness to comply with the treatment protocol (six participants). Of the 23 participants that were enrolled in the study, one participant was stopped after five sessions due to previously undisclosed severe ataxia, and a second participant was removed due to inattention and cognitive issues interfering with ambulation ability on the device. In total, the analysis includes the 21 participants who completed the four-week protocol and one-week follow-up session. Demographics of the 21 participants who participated in the trial are provided in Table 2. Participants signed a consent form that was approved by the Western Institutional Review Board before participation in the study. Recruitment occurred during the months of July 2018 through September 2018. Treatment and assessments occurred between July 2018-December 2018. This manuscript was written according to the STROBE Guidelines.

Sample size was derived using power analyses from two previous studies using the iStride™ gait

**Table 1.** Inclusion and Exclusion Criteria.

| Inclusion Criteria | Exclusion Criteria |
|---|---|
| Age 21–80 | Uncontrolled seizures |
| One or more cerebral strokes, all on same side | Pregnancy |
| Most recent stroke occurred at least six months ago | Metal Implants (stents) |
| Gait asymmetry but can walk independently with or without a cane | Chronic Obstructive Pulmonary Disease (COPD) |
| No evidence of severe cognitive impairment that would interfere with understanding of instructions | Dementia |
| Not currently receiving physical therapy | Uncontrolled high blood pressure |
| No evidence of one-sided neglect affecting ambulation | Myocardial Infarction within last 180 days |
| Adequate walking space | Head Injury in the last 90 days |
| Weight <250lbs | No history of a neurological disorder other than stroke |

**Table 2.** Participant Demographics.

| Total, n | 21 |
|---|---|
| Sex, n (%) | |
| Male | 10 (47.6) |
| Female | 11 (52.4) |
| Age in years, mean (SD), range | 55.67 (8.58), 41–77 |
| Time since stroke in months, mean (SD), range | 61.29 (64.89), 13–308 |
| Weight in pounds, mean (SD), range | 188.57 (32.04), 134–250 |
| Side of hemiparesis, n (%) | |
| Right | 5 (23.8) |
| Left | 16 (76.2) |
| AFO Usage, n (%) | |
| Yes | 6 (28.6) |
| No | 12 (57.1) |
| Partial | 3 (14.3) |

Abbreviation: AFO, ankle-foot orthosis.
*Partial: participants who use their AFO occasionally at baseline, but did not during the study

device.[21,23] In the first study,[21] 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 subjects. We initially included a higher number of subjects in our current study since we expected more variation when testing on individuals with stroke. The second study,[23] 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 shows that 21 subjects would obtain a power of 0.85. This power analysis does exclude one subject who started at a very fast walking speed of 1.14 m/s (and ended with a speed of 1.45 m/s), which is uncommonly fast for an individual with stroke; all of our subjects in this study started with a gait speed less than 1.0 m/s. Note that these studies used step length asymmetry as a measure (which is not a variable in this study).

### Device Description

The device is worn over the shoe on the non-paretic foot during overground ambulation. The wheels are designed such that downward force (as occurring in stance phase) moves the device backward relative to the ground. Similar to error augmentation, this backwards motion exaggerates the user's existing step length asymmetry while walking on the device. This subsequently results in a more symmetric pattern when the device is removed and the user returns to natural walking.[25] Additionally, the motion of the device has a destabilizing effect on the non-paretic lower extremity, facilitating increased usage of the paretic lower extremity during the gait cycle. The iStride™ and its generated motion can be seen in Figure 1.

### Experimental Procedure

After consenting to participate in the study, an initial visit was conducted with each participant approximately one week prior to beginning the treatment. At the initial visit, licensed physical therapists obtained all functional outcome measures without and prior to using the gait device. This data was used to determine baseline mobility data from which subsequent values could be compared.

Following the initial visit, 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). The participants ambulated on the gait device for a goal of 30 minutes during each treatment session, unless unable to

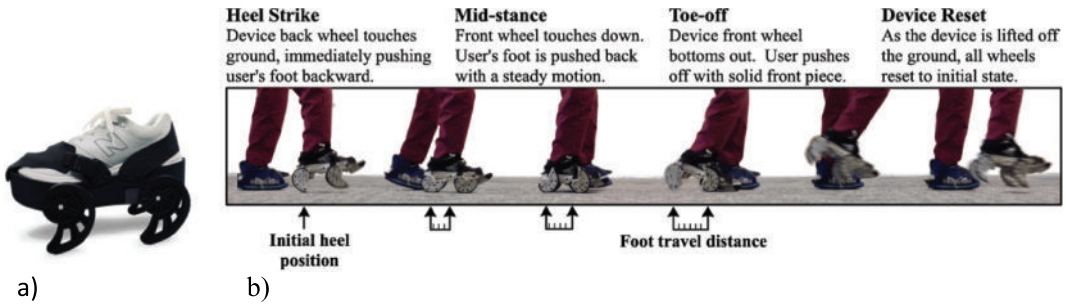


**Figure 1.** a) the iStride™ device; b) iStride™ device motion: As the user takes a step, the device pushes the nonparetic foot backward during stance. This exaggeration of the step length asymmetry is believed to yield a more symmetric gait pattern once the device is removed and the user returns to overground walking without the device. In addition, the device promotes strengthening of the paretic leg by slightly destabilizing the nonparetic leg, encouraging further engagement of the paretic leg. A flexible height-matched platform worn on the paretic foot equalizes the added height of the device.

complete due to fatigue. Rest breaks were provided at five-minute intervals (or when requested by the participants). Ambulation on the device was supervised by licensed physical therapists who were trained to provide the level of mobility assistance needed to ensure participant safety and comfort while ambulating on the device. No other treatment was provided by the physical therapists. Outcome measures were assessed again one-week post-treatment. Consistent with baseline testing, participants were not wearing the gait device during the post-treatment assessment.

## Outcomes

Participants' gait parameters were measured at baseline and one-week post-treatment. The primary outcome measure was the Ten-Meter Walk Test (10MWT) performed at their comfortable gait speed. Secondary outcome measures included: the Timed Up and Go (TUG) test, Berg Balance Scale (BBS), Functional Gait Assessment (FGA), and the Stroke Specific Quality of Life (SS-QOL) scale. The 10MWT was used to assess gait speed. The TUG, BBS, and FGA were used to assess overall gait, functional balance, and risk for falls. SS-QOL was used to assess the participants' perceived quality of life related to stroke symptoms.

To assess the safety of iStride$^{TM}$ device usage in the home environment, we monitored levels of assistance provided by the physical therapists and adverse events. After each treatment session, the physical therapists documented each time they provided physical assistance to participants to ensure mobility safety, fall prevention, or general participant comfort. The amount of assistance was rated using classifications from the Functional Independence Measure (FIM) seven-level scoring scale.[26] Additionally, therapists documented compliance with the treatment plan completion, total minutes each participant walked on the device, and subjective participant comments to generate device feedback. Efforts to reduce bias included the selection of outcome measures with high reliability and validity for the stroke population as well as standardization of protocol execution and personnel training. Additionally, it was required that no concurrent physical therapy services were being received by the participants to avoid confounding variables in the clinical trial.

## Data Analysis

We performed a variety of analyses to assess the selected outcomes.

*Statistical Analysis.* To determine the statistical significance of outcome measure changes before and after device treatment, scores on functional outcome measures (10MWT, TUG, BBS, FGA, and SS-QOL) were compared before and one-week after device treatment using two-tailed paired t-tests.

*Comparison Relative to Minimal Detectable Change, Minimal Clinically Important Difference, and Small Meaningful Change.* To understand the clinical value of the changes in our outcome measures, we compared average and individual outcome measure changes to threshold values of minimal detectable change (MDC), minimal clinically important difference (MCID) and/or small meaningful change.

MDC values are used to define a change in score that is not attributed to chance or measurement error. MCID and small meaningful change values can be used to assess improvement that is considered 'clinically meaningful' to the patient or clinician. For the outcome measures utilized in this study, several of these threshold parameters are available for comparison to our study population. However, each of the above parameters is not available for each outcome measure we used; therefore, we examined a combination of these values. Small meaningful change and MCID values are available for the 10MWT. MDC values are available for the TUG, BBS, and FGA. Additionally, we observed that multiple threshold values within a given parameter (such as MDC) are occasionally reported for each of the outcome measures. For example, MDC values for the BBS are reported as 2.5[27], 4.13[28], and 4.66[29] in various studies. The study by Liston & Brouwer (1996)[27] using an MDC value of 2.5 was selected for our comparison as their sample provides the most comparable 'time since stroke' of approximately 44 months. Note that the SS-QOL

does not have an accepted total score MDC or MCID so it is excluded from this comparison.

***Change in Gait and Fall Risk Classifications.*** In addition to whether the improvement surpassed the MDC, MCID, or small meaningful change for each outcome measure, we evaluated whether each participant improved on classifications of community ambulation and fall risk.

Gait speed is used as a measure of the overall gait health of a stroke survivor[5] and participants are typically classified into one of four classes of gait function based on their speed: Home Ambulators (HA; gait speeds <0.4 m/s), Limited Community Ambulators (LCA; gait speeds between 0.4 m/s and 0.8 m/s), Full Community Ambulators (FCA; gait speeds between 0.8 and 1.2 m/s), and Normal Speed (NS; gait speeds greater than 1.2 m/s).[30] We tracked each participant's functional ambulation category before and after device treatment to determine changes that are indicative of the participant's community participation ability.

Finally, the TUG, BBS, and FGA are used as indicators of fall risk in groups such as the elderly, stroke survivors, and individuals with Parkinson's disease. The participant's score on each of these assessments are compared before and after device treatment to determine relative changes to their fall risk. The TUG test uses a threshold of 13.5 seconds as a cutoff for reduced fall risk based on community-dwelling older adults.[31] For the BBS and FGA, various fall risk cutoff values are reported in the literature for different patient populations that are studied. In a study by Simpson et al. (2011), the authors studied the fall rate in a similar population of ambulatory community-dwelling post-stroke individuals and found that predicted falls increased sharply for the stroke group as the BBS score fell below 44.[32] This threshold value was selected for comparison based on similarity of study population. The FGA does not have a specific fall indicator cutoff for the population of chronic stroke survivors, so we examined two related values: 22 points for community-dwelling older adults[33] and 15 points for individuals with Parkinson's disease.[34]

## Results

The results of this study show a statistically significant improvement on all five of the outcome measures from before treatment (baseline) to one week after their last treatment session (1 Wk post), $p < .01$ for all five outcome measures. Table 3 shows the averages and statistics across the 21 participants for the five outcome measures using two-tailed paired t-tests.

### *Minimal Detectable Change, Minimal Clinically Important Difference, and Small Meaningful Change*

The average improvement on four of the outcome measures is higher than the minimal detectable change (MDC), minimal clinically important

**Table 3.** Statistical Analysis of Five Outcome Measures.

| Outcome Measure | | Mean | SD | SE | T | p-value |
|---|---|---|---|---|---|---|
| **10MWT (m/s)** | Baseline | 0.551 | 0.245 | 0.053 | T (20) | |
| Small Meaningful Change = 0.06[35] | 1 Wk Post | 0.820 | 0.313 | 0.068 | | |
| MCID = 0.16[36] | Difference | 0.269 | | | 7.450 | 0.0001 |
| **TUG (seconds)** | Baseline | 19.20 | 8.06 | 1.76 | T (20) | |
| MDC = −3.5[37] | 1 Wk Post | 14.39 | 5.74 | 1.25 | | |
| | Difference | −4.81 | | | −6.428 | 0.0001 |
| **BBS (points)** | Baseline | 43.52 | 6.41 | 1.40 | T (20) | |
| MDC = 2.5[27,38] | 1 Wk Post | 47.43 | 4.82 | 1.05 | | |
| | Difference | 3.91 | | | 3.790 | 0.001 |
| **FGA (points)** | Baseline | 15.00 | 4.89 | 1.07 | T (20) | |
| MDC = 4.2, 14.1%[39] | 1 Wk Post | 19.43 | 4.56 | 0.99 | | |
| | Difference | 4.43 | | | 5.727 | 0.0001 |
| | Difference (%) | 37.8 | | | 4.487 | 0.0002 |
| **SS-QOL (points)** | Baseline | 165.05 | 23.84 | 5.47 | T (18) | |
| N/A | 1 Wk Post | 181.58 | 25.29 | 5.80 | | |
| | Difference | 16.53 | | | 3.027 | 0.007 |
| | Difference (%) | 11.1 | | | 3.150 | 0.006 |

Abbreviations: 10MWT, Ten-Meter Walk Test; m/s, meters per second; TUG, Timed Up and Go Test; BBS, Berg Balance Scale; FGA, Functional Gait Assessment; SS-QOL, Stroke Specific Quality of Life Scale; MCID, minimal clinically important difference; MDC, minimal detectable change; 1 Wk Post, one-week post-treatment; N/A, not applicable

**Table 4.** Progress Compared to the Small Meaningful Change, Minimal Clinically Important Difference, or Minimal Detectable Change.

| ID | 10MWT* (SMC/MCID) | TUG (MDC) | BBS (MDC) | FGA (MDC) | |
|---|---|---|---|---|---|
| **A** | + (•) | + | + | + | |
| **B** | + (+) | + | + | + | |
| **C** | + (+) | + | + | + | **100%** |
| **D** | + (+) | + | + | + | |
| **E** | + (+) | + | + | + | |
| **F** | + (•) | + | + | + | |
| **G** | + (+) | + | + | • | |
| **H** | + (•) | + | • | + | |
| **I** | + (+) | + | • | + | |
| **J** | + (+) | • | + | + | |
| **K** | + (+) | • | + | + | **75%** |
| **L** | + (•) | + | • | + | |
| **M** | + (+) | + | + | • | |
| **N** | + (+) | • | + | + | |
| **O** | + (+) | • | + | + | |
| **P** | + (•) | • | + | + | |
| **Q** | + (+) | • | • | + | |
| **R** | • (•) | • | + | + | **50%** |
| **S** | + (+) | + | • | • | |
| **T** | + (+) | + | • | • | |
| **U** | + (+) | • | • | • | **25%** |

Abbreviations: 10MWT, Ten-Meter Walk Test; TUG, Timed Up and Go Test; BBS, Berg Balance Scale; FGA, Functional Gait Assessment; SMC, small meaningful change; MDC, minimal detectable change; MCID, minimal clinically important difference

\+ specifies a beneficial change greater than the threshold value

• Specifies a change less than the threshold value

* In the 10MWT column, the symbol outside the parenthesis specifies a change related to the SMC threshold value. The symbol inside the parenthesis specifies a change related to the MCID threshold value. Percentages correspond to the SMC threshold values for the 10MWT.

difference (MCID), and/or small meaningful change value based on the studies referenced within the columns of Table 3.

Table 4 shows each participant's change in the individual outcomes compared to the available MDC, MCID, or small meaningful change threshold values. The values utilized for each of the tested outcome measures are referenced within Table 3. For the 10MWT, results show that 20/21 (95%) of participants improved beyond the small meaningful change and 15/21 (71%) improved beyond the MCID indicating a clinically meaningful gait speed improvement. For the TUG, BBS, and FGA, 62%, 67%, and 76% of participants improved beyond the MDC, respectively, indicating improvement beyond the measurement error of these tests.

### *Change in Gait and Fall Risk Classifications*

Figure 2 shows the individual results for gait speed (measured using the 10MWT), TUG, BBS, and FGA. The slope of each line indicates the improvement and the background shading represents the different categories of fall risk or functional ambulation. The line color and marker style are used to highlight whether the participant changed fall risk or functional ambulation category. Figure 2 (a) shows that 13 participants improved at least one functional ambulation category and one participant improved two categories. Importantly, of the seven participants who were the most limited, in the HA category, six out of seven improved from a HA to LCA.

Figure 2(b-d) shows changes on the three fall risk prediction measures (TUG, BBS, and FGA) before and after device treatment. Figure 2(b), 2(c), and 2 (d) show that 44%, 67%, and 22% or 83% of participants reduced fall risk as indicated by threshold values of the TUG, BBS, FGA (community-dwelling older adult cutoff) and FGA (Parkinson's disease cutoff), respectively. Note that one participant crossed both FGA cutoff values.

### *Fall Risk Combined*

Figure 3 shows the combined changes in fall risk categories across the 21 users. The data show that the number of people who were at high risk of falls across all three categories improved from 11 people at baseline to only two users at the one-week follow-up. Likewise, we only had one participant start as a low fall risk on all three categories at baseline, but after four weeks of use, we had nine participants become low fall risk across all categories.

### *Safety, Adverse Events, and Compliance*

There were a total of 245 treatment sessions across 21 participants, with 178,516 total steps taken on the device. The number of participants requiring assistance, as well as the amount of assistance required from the therapist, is displayed in Figure 4(a). Only actual 'assistance' from the therapist (i.e., minimal assistance and above) is documented in this figure. The act of supervision or simple contact (i.e., contact guard without the provision of physical assistance) is not reported. On the first visit, 11 out of 21 participants required assistance from their therapist with assistance levels rated as moderate assistance (modA) or less. At the second visit, this number was decreased to eight out of 21 participants with one participant requiring modA, and seven requiring minimal assistance (minA). By the fourth visit, less than 25% of participants

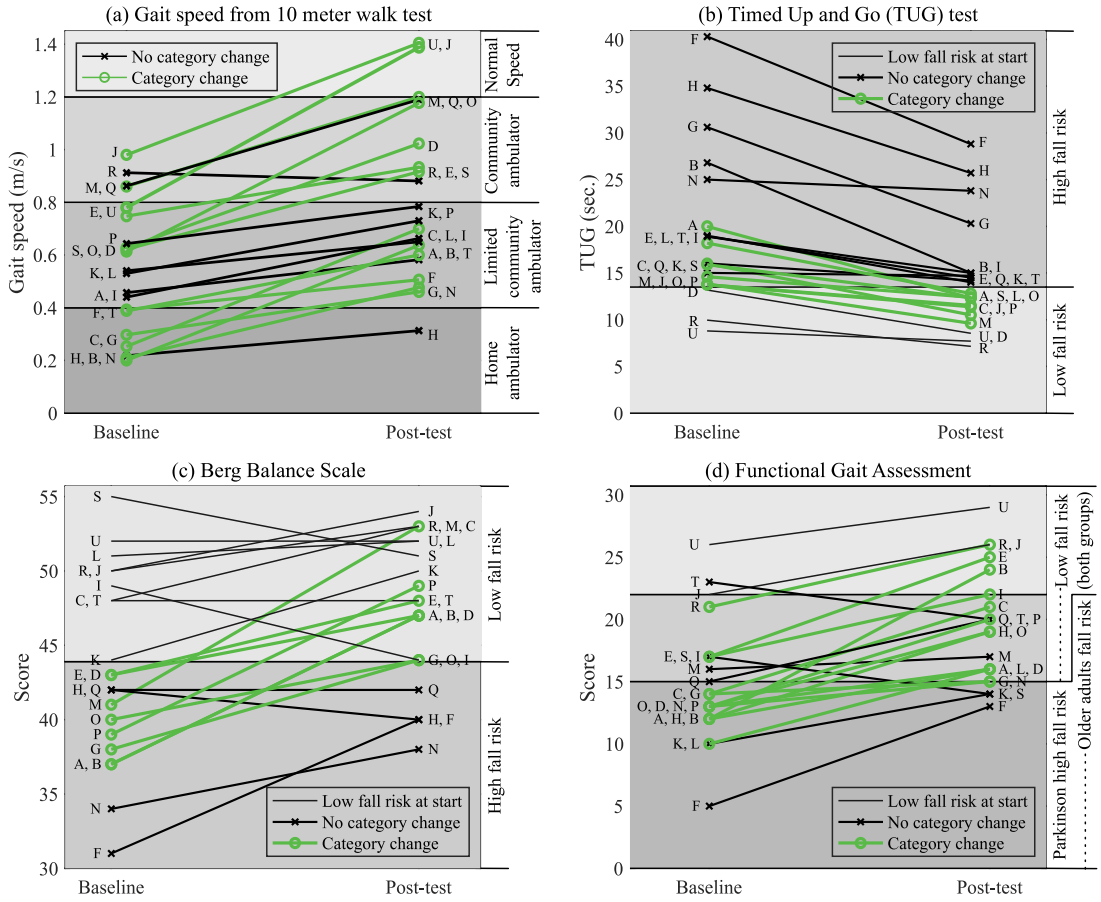


**Figure 2.** Changes from baseline to one-week post-treatment for four outcome measures. Letters A-U correspond to the participant IDs in Table 4. Gray highlighted background indicates different levels and categories of walking ability. Line-color and marker-style indicate whether that participant changed category during this treatment or not.

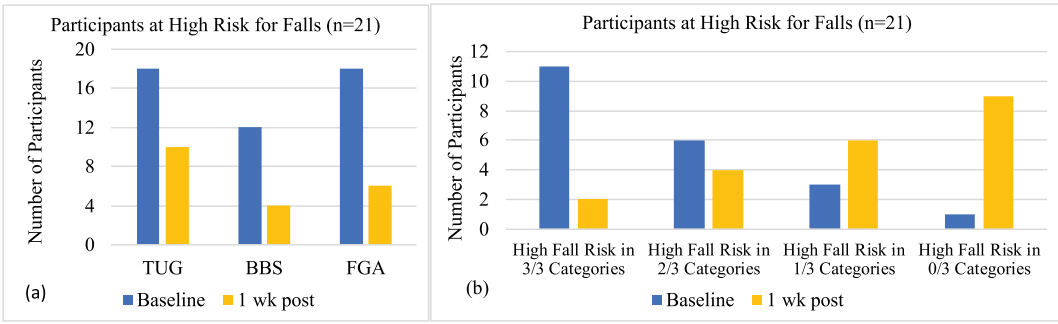


**Figure 3.** Summary of fall risk for participants (n = 21) as measured by TUG, BBS, and FGA for Baseline and 1-week post.

required assistance from their therapist. By visit eight, the same three participants continued to require minimal assistance throughout the remainder of 12 visits. It is important to note that these numbers also included fluctuations in assistive device usage during the treatment period. For example, Participant R quickly progressed his ability to use the device without therapist assistance while using a single point cane at visit three. In order to progress his independence and provide an additional physical challenge to the participant, the therapist began to wean him off his cane at visit seven. This resulted in the need for increased assistance from the therapist for three of the remaining visits. Figure 4(b) shows assistance levels without the four participants who required the most assistance throughout the trial. After visit three,

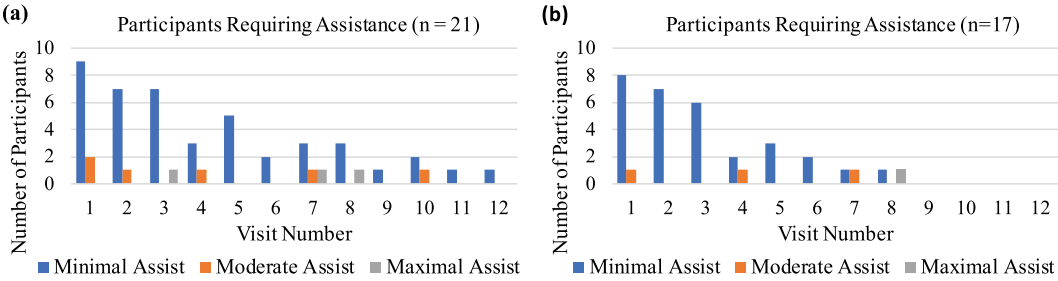


**Figure 4.** (a) Total participants (n = 21) requiring assistance. (b) Assistance information after removal of data from four participants requiring the most consistent assistance (n = 17). The majority of participants were able to train without assistance within three weeks.

assistance from the physical therapist decreased sharply, with these 17 participants (over 80% of all participants) not requiring physical assistance after visit eight.

During the four weeks of treatment, two adverse events occurred. One of these participants did not complete the four-week treatment and therefore, was not included in the statistical analysis. During this event, the participant began to feel dizzy while walking and therefore experienced a controlled fall into the chair. The participant was not injured. Of note, this participant had severe ataxia with vestibular symptoms in addition to stroke-related hemiparesis. This participant did provide a history of dizziness with quick movements since her stroke; however, symptoms were described as infrequent. Following this event of dizziness during a treatment session, the participant was removed from the study to adhere to safety precautions. Participant O had a loss of balance that led to a controlled fall onto the floor. No injuries were sustained and, afterward, she was able to continue ambulating with the gait device for a total of 25 minutes.

Full treatment plan completion provided an opportunity for 360 minutes of walking on the gait device (12 days of 30 minutes per day). Compliance data show that the participants completed an average of 11.7 treatment sessions and 290 minutes on the device, with values ranging from 165 minutes to 360 minutes. The most common reason for reduced walking time on the device was fatigue, followed by scheduling conflicts, with these contributing to missed or shortened treatment sessions.

### *Subjective Responses*

A common report was that participants "could feel muscles working on the affected side that [they] had not felt since before the stroke" (Participant J). Participant B, who improved above the threshold parameters on 100% of the outcome measures, stated, "I can keep up with my friends now and go fishing." Participant K, who improved beyond the threshold parameters on 75% on the outcome measures, stated, "I haven't had any falls since using the device!" Participant T, who improved above the threshold parameters on 50% of the outcome measures, stated, "I have so much more confidence. I found myself in the park with my niece the other day. I haven't done that with her since my stroke four years ago." Importantly, the daughter of Participant N, who also improved above the threshold parameters on 75% of the outcome measures, reported, "This has done so much for my mom and it's given me some independence too." This statement highlights that the challenges caused by a stroke can affect not only the individual but their loved ones and caregivers as well. Interestingly, Participant U, who demonstrated the least amount of progress after gait device treatment (improving on one out of four outcome measures beyond the threshold parameters), reported feeling improved balance and improved walking speed. This statement reflects potential mechanisms at work even if clinical significance was not yet attained and may indicate that an extended treatment period could be beneficial for some individuals.

## Discussion

Restoring gait mechanics is a primary goal for stroke survivors.[40] It has been reported that less than 50% of stroke survivors regain the ability to ambulate independently in the community after experiencing a stroke.[30,41] Additionally,

the loss of independent ambulation, especially outdoors, has been reported to be one of the most disabling aspects for individuals after stroke.[42] To assess for meaningful changes in gait performance, we compared functional outcome measure changes to the MDC, MCID, or small meaningful change value for each outcome measure (Table 4). This comparison revealed that 100% of our participants improved beyond the available threshold parameter on at least one outcome measure and over 76% improved beyond the threshold on three out of four of the assessed outcome measures. Additionally, 14 out of 21 (67%) improved clinically (beyond the MCID) on gait speed and beyond the MDC threshold on at least one of the fall risk assessments. On gait speed alone, 20 out of 21 (95%) of our participants improved beyond the small meaningful change value and 15 out of 21 (71%) improved beyond the MCID for this specific measure, indicating an improvement that is not only above measurement error but likely clinically meaningful to the participant.

The comprehensive clinical value of gait speed is well documented in medical literature. The study population's average gait speed improvement of 0.27 m/s exceeds the MCID value of 0.16 m/s by more than 0.1 m/s. Due to the association and predictive value of gait speed with multiple health-related attributes including functional ability, balance confidence, health status, fall prediction, and mortality,[5] a gait speed improvement of this magnitude may contribute to additional positive health outcomes.

The speed of an individual's gait also relates to their ability to function independently in the home and community. Therefore, gait speed categories are often used to quantify the functional meaningfulness of gait speed improvement.[30] In 2007, Schmid et al. investigated if changes in gait classification correlate with improved function and quality of life in stroke survivors.[43] Results found that transition to a higher class of ambulation resulted in better function and quality of life, especially for household ambulators.[43] This means that the individual may be able to get to the bathroom in time for successful toileting, for example. In our sample, 13/21 (62%) changed to a more functional gait classification.[30] Further, of our participants categorized as 'home ambulators' at baseline, six out of seven improved from a 'home ambulator' to a 'limited community ambulator.' This improvement may provide further explanation for the statistically significant improvement in SS-QOL scores.

Analysis of the fall risk outcome measure data shows that 16/20 (80%) of our participants improved their risk for falls to below the fall risk threshold on at least one outcome measure. (Note that one participant began the study with a low fall risk on all outcome measures and therefore is not included in this analysis). Combining our results of both gait and fall risk data show that 11 out of 20 (55%) participants improved clinically in gait speed (beyond the MCID threshold value) and reduced their fall risk on at least one fall risk assessment measure (TUG, BBS, or FGA). Using the small meaningful change threshold value for gait speed, this percentage increases to 75%.

The gait device could likely be a safe gait treatment device for the home environment. Participants became accustomed to the device's motion after several visits, after which time there was a low likelihood that therapist safety intervention was necessary. These low assistance numbers potentially reveal an additional opportunity of study. A future study may consider involving and training caregivers to provide supervision (instead of a licensed physical therapist) once comfort and relative independence on the device is achieved. Eliminating the need for scheduling and having a licensed physical therapist present could result in greater availability and, therefore, increase treatment opportunities. Subsequently, this may facilitate ease of varying treatment durations (including long-term treatment) and lead to further detection of the most effective treatment parameters. Varying treatment plans and device usage durations may be beneficial to account for variations in participant abilities, as noted by the relatively large range of completed device minutes within our treatment compliance data.

### Study Limitations

One limitation of our study is that we do not have a control group, so we cannot absolutely ascertain that the improvements were the direct result of the device treatment. The improvements are unlikely

a result of just ambulating (and not the device) due to the long-term chronicity of our participants' hemiparetic gait problems coupled with the following reasons. Since each participants' results were compared to the MDC, MCID, or small meaningful change value giving a relative comparison of each measure to a statistical threshold, this reduces the likelihood of these improvements being related to chance, as each of these improvements would independently be considered significant by clinicians. Additionally, to hypothesize that the gait speed and balance improvements were caused only by walking, one must hypothesize that the altered step mechanics caused by the gait device did not impact the improvement, which is unlikely given the improvements shown on split-belt treadmills.[17] Further, Park et al.[44] evaluated individuals with chronic stroke who were categorized into either slow (<0.5 m/s) or fast (>0.5 m/s) walking groups. All individuals walked either overground or on a treadmill for 30 minutes twice a day, five days a week, for four weeks for a total of 20 hours of walking. Their data, as presented, show that the best group's improvement was 0.1 m/s. In our study, we achieved improvements of 0.23 m/s for slow walkers and 0.30 m/s for fast walkers with six total hours or less of walking on the device.

### *Home Setting Challenges*

We experienced challenges related to therapy in the home setting. Due to spatial conditions, floor layouts, and furniture placement within participants' home environments, many homes did not have 10M (approximately 33 ft) of straight walking space. As a result, the 10MWTs often included a "turn" to achieve the full distance of this outcome measure. Literature has shown that the biomechanics required during turning require increased time compared to straight-line walking.[45] As such, the gait speed of our participants is likely higher than that which is reported in this study but was kept relative to their own improvement. Future tests may elucidate whether there is statistically a significant benefit in the complex activity of turning with the use of this device. Additionally, one of our participants moved during the trial period resulting in a different environmental condition for testing and one participant had the flooring changed within their home. While environmental changes could have a small effect on testing in theory, therapists were instructed to mimic initial conditions when changes occurred, therefore minimizing the likelihood of any potential impact. These environmental changes reflect challenges to home-based treatment but are likely outweighed by the potential benefits of convenience, program adherence,[46] and improved access that home-based treatment facilitates.

## Conclusions

Individuals who suffer a stroke commonly receive rehabilitation services in the acute and subacute phases. However, likely due to the notion of recovery plateau depicted by prior research studies,[47] therapy services beyond one year after stroke are significantly less common.[48] This study focused on participants at least six-months post-stroke, with the average time since stroke being slightly greater than five years. The results of our analysis demonstrate that despite the chronicity of hemiparetic gait symptoms, clinically significant improvements were achieved resulting in faster gait speed and reduced fall risk. The subjective and personal impact of these improvements is demonstrated by responses on the SS-QOL, which demonstrated a statistically significant improvement. This work adds to an expanding pool of evidence[49,50] describing the potential for meaningful recovery in the chronic stroke population and highlights a growing need to modify traditional rehabilitation practice patterns.

With approximately 75–85% of individuals who survive their stroke ultimately discharged to home environments,[48] the ability to have effective gait treatment opportunities within the home could have a beneficial impact on the accessibility of stroke rehabilitation. A gait treatment device used in the home facilitates more opportunities for increasing quantity and duration of treatment, especially for those individuals with limited access to clinical environments. Enabling usage of the gait device in the home environment shows promise to be a feasible method to deliver effective, safe, and home-accessible gait treatment opportunities to individuals with hemiparesis from stroke.

## Disclosure of interest

Kyle B. Reed has a patent (US 9,295,302) related to this work that is licensed to Moterum Technologies, Inc. A management plan has been implemented and followed to reduce any effects of these conflicts of interest. Authors Brianne Darcy, Elizabeth Lundin, Ryan Medas, and S. Tyler Shultz have received payment as contractors for Moterum Technologies, Inc. The gait device is related to a commercial product offered by Moterum Technologies, Inc. Authors David Huizenga, Lauren Rashford, Brianne Darcy, Elizabeth DuBose, and Kyle B. Reed have stock options in Moterum Technologies, Inc.

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## Data availability Statement

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

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