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Assessing the Impact of Real-Time Visual Feedback during Treadmill Training on Walking Improvement in Stroke Patients

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Abstract: After a stroke, most patients often suffer reduced walking ability and balance. Restoring walking ability and improving balance are major goals of stroke rehabilitation. Treadmills are often used in clinical setups to achieve this goal. The objective of this study is to assess the efficacy of different approaches and determine their comparative effectiveness, such as real-time sagittal visual feedback during treadmill training with the conventional mirror feedback treadmill training program of the same intensity in stroke patients. The Real-time Visual feedback after Stroke in Treadmill training (REVISIT) trial is a two-arm randomized control trial. Thirty eligible stroke survivors undergoing rehabilitation were randomly assigned to either real-time visual sagittal feedback along with the front mirror (experimental) group or only the front mirror treadmill training (control) group for 5-6 weeks. All participants underwent 15 sessions of treadmill training, with each session lasting up to 15 minutes at a safe speed of their choosing. The REVISIT (experimental) groups received real-time, visual sagittal view feedback of the involved lower limb trajectory along with the routine front mirror view during treadmill training and they were requested to alter their gait pattern. The trial contributed to the existing innovation and modifications of incorporating real-time visual feedback during treadmill training in post-stroke gait rehabilitation. The findings will help in the design of a gait rehabilitation program with a treadmill for post-stroke subjects to improve walking speed and balance for those who have greater difficulties in community ambulation.

Introduction

Stroke is a major catastrophic public health concern globally and in India, it is among the primary contributors to both mortality and morbidity (Jones et al., 2022). In 2005, around 5.8 million individuals suffered from stroke, also known as cerebrovascular illness. Out of these, two-thirds were residents of low- to middle-income nations. However, there is a lack of trustworthy population-based studies on this subject (Dalal et al., 2008). The latest data on the occurrence, severity, and death rates of strokes consistently reveal differences between countries and varying levels of impact, especially in low- and middle-income countries (LMICs). While additional national stroke clinical registries were found, the data available from these newly discovered registries was restricted. Identifying the areas where crucial data is insufficient, obsolete, or the rankings of countries can aid in promoting further study or attracting increased policy focus. Current information on the occurrence and distribution of strokes, as well as the existence of national databases that track stroke cases, are crucial for offering proof to enhance medical procedures and endorse policy choices

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(Thayabaranathan et al., 2022). The discovery of a decrease in stroke death rates in two countries that previously had among the highest stroke mortality rates is significant. Establishing a connection between hospital data and death records can be a valuable method to determine if the decrease in stroke mortality is due to improved treatment or a reduction in the number of cases. This approach can also enhance the reliability of findings from repeated incidence studies (Thrift et al., 2017). Slow walking speed and poor balance are strong predictors of physical inactivity and community life restrictions (Murray et al., 2020). The comprehensive review presents evidence indicating that individuals with stroke who possess the ability to walk experience improved walking speed and increased distance when undergoing treadmill training without body weight support, as compared to receiving no intervention or non-walking intervention. Furthermore, these benefits persist beyond the training time. Individuals who undergo electromechanical-assisted gait training, along with physiotherapy, following a stroke have a higher probability of attaining autonomous walking compared to those who solely undergo gait training without the use of such devices (Polese et al., 2013). According to the initial evidence found in a review, Motor imagery (MI) appears to be a promising method for assisting with the recovery of lower-limb motor function in stroke patients (Mehrholz et al., 2017). An investigation revealed that persons with chronic stroke have less leg muscle activation while engaging in robot-assisted walking as compared to walking on conventional ground. Moreover, the application of robot-assisted treadmill training with minimal assistance and direction seems to elicit a muscle activation pattern that is both more balanced and more similar to that of individuals without physical impairments (Coenen et al., 2012). A Study suggested that treadmill walking is more efficient than outside walking in enhancing spatial and temporal gait features (Langhammer and Stanghelle, 2010). Therefore, the Real-time Visual feedback after Stroke in Treadmill training (REVISIT) trial aims whether the visual feedback of the sagittal view of the involved side during treadmill gait training enhances the walking speed and balance of individuals who have had a stroke.

Methods:

The RE-VISIT trial is a single-blinded, two-arm 1:1 randomized control trial designed to assess the effect of real-time sagittal view visual feedback on walking speed and balance following treadmill training. The RE-VISIT trial was confirmed according to the CONSORT reporting guidelines (Bennett, 2005). Before data collection, approval from the Ethics committee was obtained by the ethical standards of Meenakshi Medical College Hospital and Research Institute, and all participants provided informed consent before their involvement in the study. The study design flowchart is depicted in Figure 1.

Study

Settings and Participant Recruitment

The catchment (recruitment) area for this trial was conducted at the physiotherapy outpatient Department (OPD) at the Meenakshi Academy of Higher Education and Research (training Centre of the trial) and physiotherapy OPD at Meenakshi Ammal Dental College and Hospital, 7 km from the training Centre. Interested individuals can also voluntarily refer themselves in response to advertisements.

Eligibility criteria of the participants

Individuals aged 25 years and older who have experienced a single stroke (hemorrhagic or ischemic) lasting at least 3 months and who are capable of independently walking a distance of 50 meters with or without a single-sided mobility aid were eligible for inclusion. Additionally, participants needed to be able to provide informed consent.

Blinding

Clinical physiotherapists and post-graduate students in physiotherapy (assessors) were responsible for conducting assessments. However, they were unaware of the group assignments and training programs, ensuring blinding during the process. The assessors carried out clinical evaluations, collected socio-demographic-related information, and measured walking speed and balance. The group assignments were disclosed to the intervention therapists.

Exclusion criteria

Stroke survivors using ankle-foot orthosis (AFO), in addition to stroke, patients with neurological, orthopaedic, cardiac, respiratory, and other medical conditions were also included. Contra-indications for treadmill walking include a body weight of > 150 kg (weight limit of body-weight support harness). Stroke patients with visual impairment and/or moderate to severe visual-spatial neglect.

Sample size

The estimated sample size for our study was 42 participants, determined using G*Power 3.0 software. This software is a popular standalone tool extensively utilized for conducting power analysis on statistical tests frequently applied in social and behavioral research (Kang, 2015).

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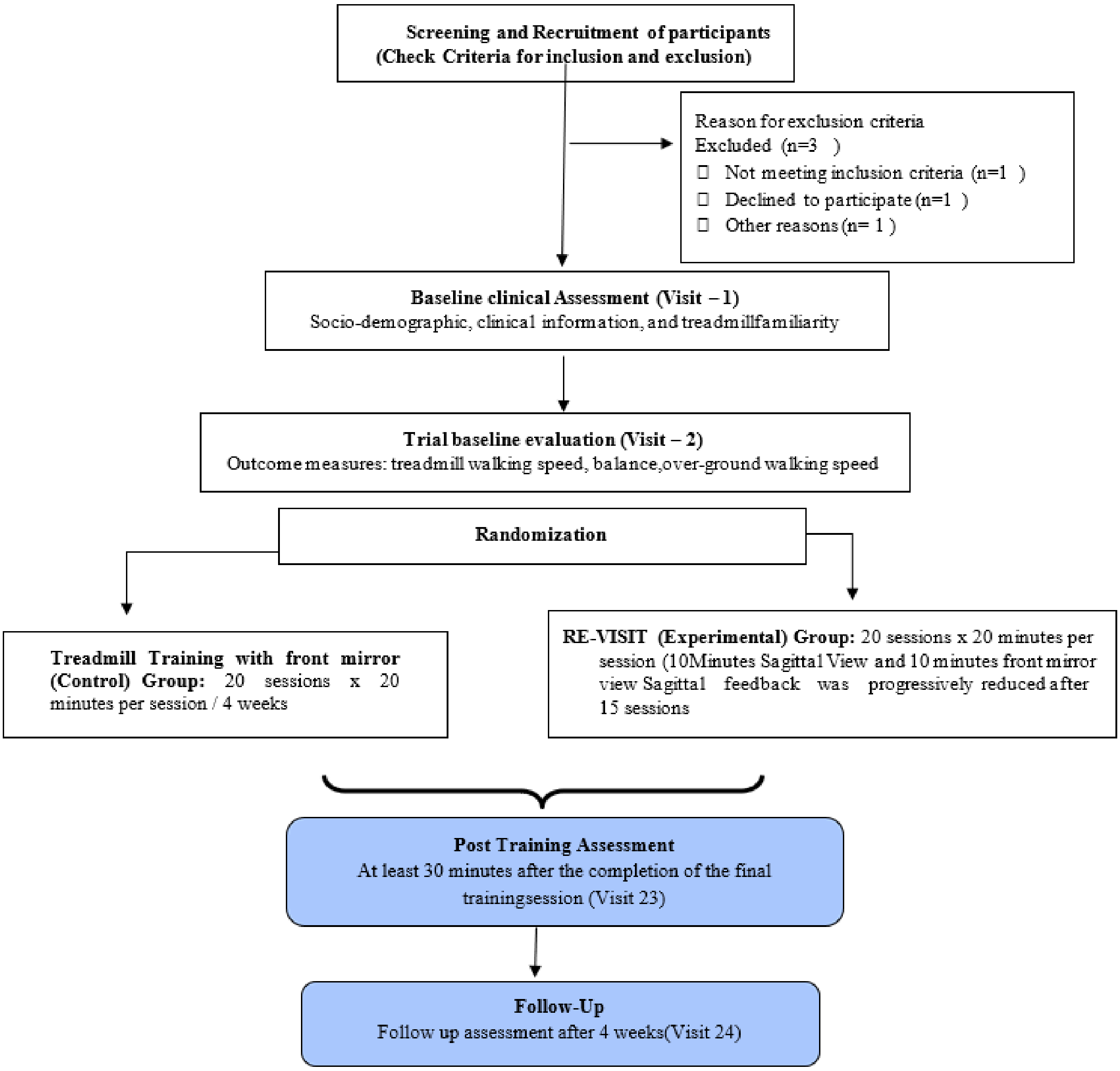

Figure 1. RE-VISIT trial study design flow chart.

Procedure

All participants, including both the experimental (RE-VISIT) and control groups, were instructed to walk on the treadmill while utilizing a body support safety harness and a postural mirror placed in front of them. They followed an identical schedule of training sessions. During the initial visit, a brief session of treadmill familiarization was conducted, and participants were asked to determine their self-selected or preferred walking speed. This self-selected walking speed was recorded and maintained throughout the training sessions. Each 20-minute session was divided by a compulsory break time of 5 minutes. Rest time or breaks with each 10-minute sub-session shall be provided based on the requirement. The participants were wearing the same type and brand of shoes of the size and fit provided at the training centre during the training and assessment of outcomes. Participants assigned to the RE-VISIT group (intervention group) underwent treadmill gait training similar to the control group during the initial sub-session (10 min) and in the second sub-session, the participants were provided with a real-time visual display of the sagittal view of their involved side while walking on the treadmill displayed in the screen front of them. Real-time visual feedback of the sagittal view of the affected side was provided during the first 15 sessions and gradually diminished (faded) throughout the remaining 5 sessions. During fading, the feedback was available for a full 10 min until the beginning of sub-session 2 of session 16, 8 min at the beginning of sub-session 2 of session 17, 6 min at the beginning of sub-session 2 of session 18, 4 min of the beginning of sub-session 2 of session 19, and 2 min of the beginning of sub-session 2 of session 20 (final).

Outcome measures: Assessments

Patient socio-demographic, clinical characteristics, and baseline measurements Information like age, gender, type of stroke, duration of a stroke, treadmill experiences

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questions, and visual feedback experience questions. *Baseline measurements:* Before random allocation, the baseline assessment (T0) was conducted. The post-intervention assessment (T1) was performed for both groups to compare the immediate effect after the treatment phase. Additionally, the 4-week follow-up assessments (T2) were carried out to observe any retention effects from the treatment. The schedule based on the Standard Protocol Items Recommended for Interventional Trials (SPIRIT) (Chan et al., 2013) was provided in Table I.

Statistical analysis

The statistical analysis was conducted using IBM SPSS Statistics 21.0 software (IBM Corp., Armonk, NY, USA). Descriptive statistics were employed to calculate the mean, median, maximum, minimum, and standard deviation of walking speed for each walking condition, along with the characteristics of the participants. The change in walking speed and BBS (Berg Balance Scale) between T0, T1, and T2 was calculated by subtracting the baseline measurements from the corresponding values. To calculate the change, the walking speed value was determined by subtracting the baseline walking value. To assess statistically significant variances in the deviations of highest walking speeds across the three various conditions affecting performance, the altered value of walking speed must be utilized in the repeated measures ANOVA. A post hoc analysis, specifically the Tukey test, was conducted to pinpoint the disparities between the performance conditions accurately. For each experimental condition, correlation analyses (Pearson/Spearman) were employed to determine if there is a correlation between the change in walking speed and Compliance and motivation (ad-hoc). Additionally, Analysis of Covariance (ANCOVA) was tilized to examine the effects of BBS score on walking speed. The statistical significance value is when $p<0.05$.

Results

Depiction and flow of subjects through the trial

A study was conducted in which 62 stroke patients admitted to the Clinical Rehabilitation Ward were recruited and underwent baseline tests. Out of the individuals screened for eligibility, 42 participants who satisfied the inclusion criteria were selected to take part in the clinical trial. Among the remaining 62 subjects who did not qualify for the program, 12 were excluded due to not meeting the inclusion criteria, 6 were in an unstable condition, and 2 declined participation for personal reasons. All the eligible patients completed the program, actively participating in 20 training sessions. The experimental and control groups showed resemblances in terms of baseline data, that is, age, sex, height, weight and body mass index (BMI), side of hemiplegia, chronicity, impairment, and baseline walking ability. Importantly, no notable distinctions were observed in these baseline characteristics among the groups. Additionally, the interval of stay was nearly 4 weeks for both groups, and no adverse medical events were reported during the program. All subjects completed the final examination, further highlighting the high completion rate. The detailed demographic and clinical characteristics can be found in Table I & Figure 2, which reinforces the lack of statistically significant variances among the groups.

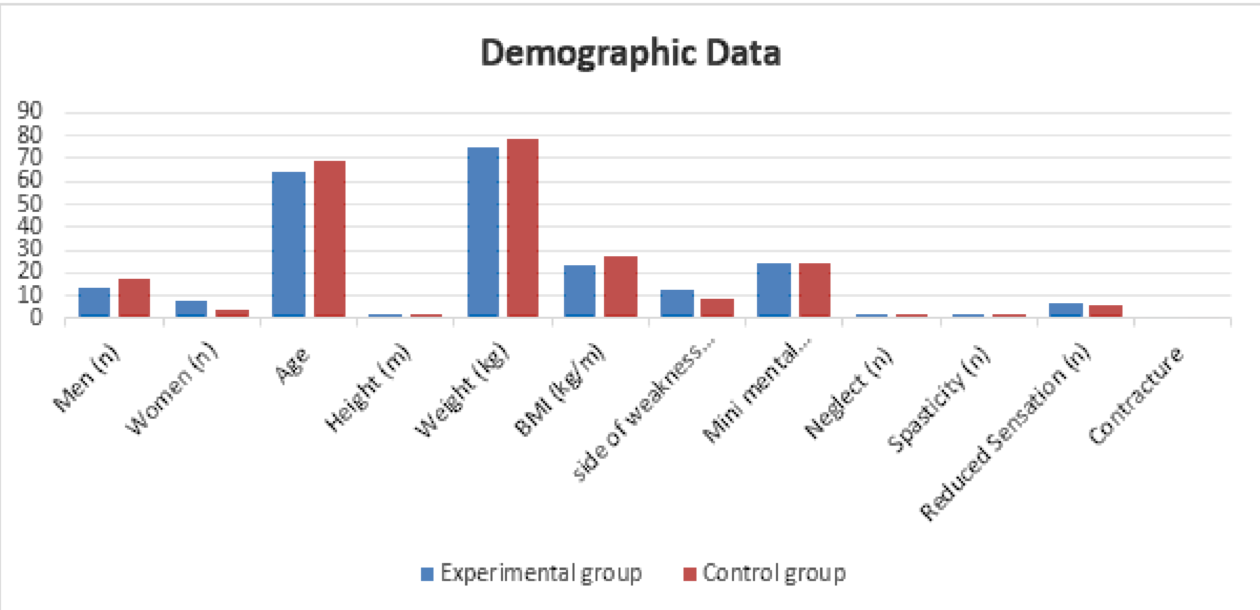

Figure 2. Demographic data.

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Table 1. Schedule of enrollment, intervention, and assessment, the SPIRIT guidelines.

Study period	Screening	Baseline (T0)	Training sessions		Intervention period in W				Post-intervention assessment (T1)	Follow up T2
Time (weeks)	-8 to -1	0	S1 to S16	S17 to S20	1	2	3	4	5	4 W after discharge
Patient data	x									
Informed participants	x									
Data related to demographics	x									
Medical Records	x									
Allocation (post T0)		x								
Treadmill training Control group			x	x	x	x	x	x	x	
Intervention group			x	fade	x	x	x	x	x	
Walking speed		x								x
Balance (BBS)		x								x
Compliance and motivation (ad-hoc)									x	
Patient diary		X	x	x	x	x	x	x	x	
Routine PT	x	X	x	x	x	x	x	x	x	
Adverse effects		X	x	x	x	X	x	x	x	

Berg Balance Scale – BBS, Weeks - W, S – session (Session 1 (S1) through Session 20 (S20)

Adherence to the intervention

The patients had control over the strength of their walking movements, both on a treadmill and outdoors. On the treadmill, the minimum speed allowed was 0.1 m/s, while walking outside had a time limit of 20 minutes. The analysts motivated the patients to proliferation or sustain the workload daily. The average quickness achieved throughout treadmill exercise was 0.61 m/s, ranging from 0.45 to 1.2 m/s on a level surface. The average duration of each treadmill walking session was 15 minutes, resulting in a total exercise time of 110 minutes (Table III). During the training period and assessments, all participants showed interest, motivation, and cooperation without experiencing any adverse effects related to the intervention. They attended an average of 20 sessions, with an interquartile range of 32 - 45 out of a total of 20 sessions available. In the first week, the session began with a treadmill speed of 0.5 m/s and ended with a speed of 0.6 m/s. By the 6th week, the initial treadmill speed increased to 0.8 m/s and reached 2.0 m/s by the completion of the trial. On average, they walked 687 m in 20 minutes during week 1, and in week 6, they covered 817 m in 15 minutes. According to the 10-point Borg scale, their observed action was rated between 'moderate' and 'strong' (score of 3) at the start of the program and between 'strong' and 'very strong' (score of 5) at the end of the program in week 6. During the assessment sessions, a total of 21 participants 8 from the Over Ground Group (OGG) and 13 from the Treadmill Group (TMG) utilized assistive devices while undertaking the 10-meter Walk Test and 6-Minute Walk Test. Among these subjects, 8 individuals (4 from each group) the therapist provided gentle support to help maintain balance during their gait analyses. All participants completed all calculations, except for the 6-minute walk test, which was not performed by 6 individuals (3 from the OGG and 3 from the TMG). They were excluded because this test was introduced to the study after they had already started their training, and these individuals had previously indicated that they were able to walk greater distances.

Impact of intervention

The treadmill group demonstrated significant advantages in various parameters, including distance concealed in the Six-Minute Walk Test, walking speed in six-minute and ten-meter intervals, bilateral stride length (SL), and step width (SW). However, there were no distinguished variances in cadence among the groups, as indicated in Table III. From the six-minute walk test paralleled to the baseline, the fourth-week training group outperformed the control group by walking an additional 25 meters (95% CI 6–42) after two weeks and 32 meters (95% CI 15–60) after four weeks. It should be noted that both groups exhibited lower speed, distance walked, stride length, step width, and cadence compared to healthy individuals of the same age, as reported by (Steffen et al., 2002; Langhammer and Lindmark, 2007).

there were not any observed changes among the groups in terms of the percentage of increase for the treadmill group (14.64±5.32%) and the over-ground group (11.47±4.37%) or for session duration (treadmill group: 26±6 minutes, over the ground group: 31±5 minutes). These improvements were attained by a rise in step length of 0.06 meters (95% CI - 0.17 to 0.28) and a rise in the cadence of six steps per minute (95% CI 1–13) at a relaxed speed. Additionally, there was an increase in step length of 0.07 meters (95% CI 0.02 – 0.08) and an increase in the cadence

Table 2. The baseline data for subjects in the two distinct groups were examined, and the level of significant variances between the groups was evaluated at a *p-value*<0.05.

Baseline demographic data for patients			
	Randomized (n=42)		
characteristic	The experimental group (n=21)	Control group (n=21)	*p-value*
Men (n)	13.0	17.0	0.4
Women (n)	8.0	4.0	
Age (Years), Mean (SD)	64.0 (11.1)	69.0 (12.3)	0.81
Height (m), Mean (SD)	1.64 (0.09)	1.60 (0.07)	0.6
Weight (kg), Mean (SD)	75.0 (13.0)	79.0 (16.0)	0.2
BMI (kg/m^2)	23.0 (3.4)	27.0 (3.9)	3.1
Side of weakness, n right (%)	12.0 (37.0)	9.0 (23.0)	0.9
Time after stroke (days)	417.0 (1,031)	376.0 (964.0)	0.7
Mini-mental Examination score	24.38 (3.2)	23.87 (4.7)	2.3
Neglect (n) (0-2)	2.0	2.0	0.9
Spasticity (n) (0-4)	2.0	2.0	0.4
Reduced Sensation (n)	7.0	6.0	0.8
Contracture (0-2)	0.36 (0.64)	0.41 (0.72)	0.72

Table 3. Means (SD) outcomes measures for experimental and control group.

Descriptive measurements						
Outcomes	Treadmill group	Control group	*p-values*	Effect size[a]	*p-values*	Effect size[a]
6MWT (m)	282.6 (142.7)	279.4 (140.2)	0.04	0.14	0.002	0.28
10-m (m/s)	0.07 (0.04)	0.059 (0.05)	0.02	0.16	0.001	0.2
Step length (m)	0.31 (0.12)	0.29 (0.13)	0.03	0.12	0.003	0.27
Step width (cm)	6.9 (4.7)	6.7 (4.9)	0.01	0.19	0.21	0.05
Cadence (steps/minutes)	92 (26.1)	89.2 (30.1)	0.69	0.003	0.02	0.14
Pulse at rest	77 (11.2)	77.0 (9.8)	0.48	0.02	0.9	0.01
Pulse inactivity	98.0 (15)	10.0 (13.2)	0.31	0.02	0.81	0.001

Values are means (SD); 6MWT, Six-Minute Walk Test ; The level of significance was set at *p*<0.05 for variances among the groups with time as a covariate. [a]Guidelines from Cohen (2013) 0.01 - small effects; 0.06 - medium effect; 14 - large effect.

The treadmill group showed improvements in their walking distance and walking speed when compared to the outdoor walking group. However, the increase was more significant in the treadmill group compared to the outdoor walking group. During the duration of the training period, of five steps per minute (95% CI - 1 to 11) paralleled to the control group when walking as fast as probable, as shown in table IV.

Discussion

This study's primary findings can be summarized in two key aspects. Firstly, the treadmill group demonstrated significant improvements in both walking speed and distance (Basak and Dutta, 2016; Basak and Biswas, 2016; Drużbicki et al., 2018; Schröder et al., 2019). immediate positive effect. However, once the training was discontinued, the paybacks gradually thrown down. The rate of failure was in reverse related to the duration of the working out period, suggesting that longer training periods yielded more sustained benefits. The baseline data revealed that the participants had moderate mobility levels. On average, they were three months post-stroke. In

Table 4. Analysis of Gait Parameters.

		T0		T1		T2	
Single limb support duration (%)		Mean (SD)	95% CI	Mean (SD)	95% CI	Mean (SD)	95% CI
TMG	Paretic Side	23.4±6.1	20.6-27.6	26.2 ± 7.6*	24.9-31.9	30.8±5.6**	27.2-34.5
	Non Paretic side	33.1±3.6	30.9-36.3	36.0±4.9	34.7-40.6	35.6±5.8	35.0-40.2
OGG	Paretic Side	21.0±4.3	18.0-26.0	23.4±3.7*	22.7-29.8	26.8±6.2**	23.2-30.4
	Non Paretic side	31.7±3.4	29.8-35.2	33.6±4.5	33.0-38.9	32.4±3.3	33.8-39.0

T0 - baseline; T1 - post-training; T2 - follow-up; P - Paretic side; NP - Non Paretic side; TMG - Treadmill Group; OGG - Over the Ground Group; Statistic effect for T0 x T1 and T0 x T2; *p<0.05 **p< 0.01

Bishnoi et al., 2022; Khant et al., 2023). They achieved a bilateral step length that was either equal to or greater than the outdoor walking group, accomplishing this in a shorter duration of time. Initial studies indicated that visually-guided treadmill gait training had a positive impact on chronic stroke patients, resulting in enhancements in walking speed, balance, and levels of physical activity (Ada et al., 2013; Gama et al., 2017; Park et al., 2018). These outcomes suggest that treadmill walking is an effective period and valuable rehabilitation tool. During the training period, the data similarly matched their findings (Bowen, 2001; Tilson et al., 2010). Secondly, exercising on the treadmill also led to enhancements in walking ability on level surfaces, as evidenced by the positive results from the Six-Minute Walk Test and the 10-meter walk test. These findings suggest that this form of exercise can be highly beneficial in areas where climatic conditions often hinder outdoor actions. Additionally, walking on a treadmill may be more motivating compared to walking in passageways, which is typically the substitute for outdoor walking in clinical or rehab settings. The primary outcome of this trial indicates that, over three months, treadmill training without body weight support, along with over-ground walking training conducted three times a week, proved to be more effective than nope exercise in enhancing walking performance (distance and speed) and overall fitness in individuals recovering from a stroke and residing in the community. For patients with moderate motor function deficits, psychotherapists can enhance the strength of treadmill training to promote improvements in walking ability, with the assurance that these gains will carry over to regular walking patterns. Our findings indicate that the training intervention had an comparison to healthy older individuals, the participants covered only half the usual distance within a six-minute walking period (Hesse et al., 1995) and the walking speed over a 10-meter distance was 45% of the normal pace (Moseley et al., 2005). Although the improvement of 20 meters in the walking period achieved by the three-month experimental group compared to the control group may seem unsure, it is liable to have clinical significance. This gain exceeds the clinically imperative variance stated by those in the communal with dissimilar chronic conditions by 12 meters (Maki et al., 2006). The improvements in walking distance were reflected in the enhancements of equally relaxed and fast walking speed. The increase in speed was accomplished by augmenting step length and cadence together. The magnitude of the improvement in mutually fast and comfortable walking speed is greater later than three months. In this trial, the intervention tested involved using a treadmill (without body weight support) and performing over-ground walking with physical activity administered by a single analyst. This approach differs from other trials (Montero-Odasso et al., 2004; Rosengren et al., 1998) in terms of not providing body weight support and relying on assistance from a single therapist. We observed that both groups experienced enhancements in endurance, gait speed, and recovery of lower limb motor function impairments, nonparetic step-length, and duration of paretic single limb support immediately after completing the training and during the follow-up period.

Limitations

Gait speed, a widely used and significant measure of functionality in clinical settings (Tabachnick et al., 2019), is strongly linked to functional independence. In our study,

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both of the participant groups, as demonstrated by (Chen et al., 2005), exhibited there were immediate enhancements in gait speed following the intervention and during the follow-up period. The normal increase in gait speed measurement of 0.08 m/s for both training groups, when assessed for individuals with chronic stroke, would be deemed a significant improvement, according to the definition provided by (Perera et al., 2006). Consequently, when the primary objective is to enhance gait speed, clinicians should exercise their medical findings to define the most suitable training method for each patient, considering aspects like patient preference, comfort, safety, and additional therapeutic objectives. The groups were compared based on recorded resting and activity-related pulse rates, which revealed no significant variances. During the activity, the pulse rates reached 67% of the extreme rates expressed by (Tanaka et al., 2001), signifying that both groups experienced a strength effect from the walking activity. However, the study has some limitations, including relatively small group sizes and a limited follow-up period. Therefore, caution should be exercised when interpreting the results. Nevertheless, we believe that the participants adequately represented the category of people with stroke. Both groups had similar drop-out rates, primarily due to acute illness. The findings suggest that treadmill exercise is more time-efficient than outdoor walking for stroke patients, and it also improves step length symmetry. When designing an exercise program for individuals with reduced function, it is crucial to select exercises that meet their specific needs and aim to achieve desired results in the shortest possible time. This study can provide valuable insights for planning such exercise programs.

Conclusion

To summarize, the utilization of treadmill walking training has proven to be effective in enhancing speed, walking distance, and overall quality of life (QOL) related to health. Nevertheless, the advantages diminish once the training is halted. Our findings suggest the necessity for continuous training, and the task at hand is to create suitable exercise programs within the community that stroke survivors are enthusiastic about and capable of attending regularly throughout their lives. In future research, we recommend incorporating a control group and expanding the inclusion criteria to encompass a wider array of scarcity strictness, while implementing random assignment stratified by motor function. Our study reveals a significant correlation between increased speed and step length, leading to an increase in step width. This finding holds particular significance as it suggests that individuals with stroke rely on increased step width as a balance maintenance strategy when accelerating, in contrast to healthy subjects.

Ethics approval

The authors conducted the study after obtaining ethical approval from the concerned institute by satisfying the regulations of the Institutional Ethical Committee (MMCH & RI IEC/Faculty/43/June/22)

Informed Consent Statement

To all of the participants and their primary caregivers, the study team explained the significance of the study. We got informed consent from each participant, and everyone consented to participate in the study. We attest that we have the necessary patient consent paperwork in hand. The patient(s) has given their approval in the enrolment form for his/her/their photos and other significant clinical details to be stated in the journal publication. The participants were aware that every attempt would be made to keep their identities a secret and that their names and initials would not be exposed in publications.

Data Availability Statement

The corresponding author can provide the data tabulated in this work upon request. Due to privacy and ethical constraints, the data are not available to the general public.

Conflicts of Interest

No conflicts of interest.

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