

# Efficacy of simulated equestrian therapy in improving gait parameters among children with Down syndrome: a randomized controlled trial

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### ABSTRACT

**OBJECTIVES:** To compare the effectiveness of Simulated Equestrian Therapy (SET) and Standard Physical Therapy (SPT) in improving gait parameters among children with Down syndrome (DS).

**METHODS:** This single-blinded, randomized controlled trial was conducted at Dar-ul-Sukun Institute and Dr. Zaiuddin Hospital, Karachi, Pakistan, from April to August 2023. Sixty individuals, meeting the selection criteria were randomly assigned to either the treatment group (n=30) receiving SET or the control group (n=30) undergoing SPT. Nevertheless, two participants from each group either discontinued the treatment or failed to comply with the therapy and 56 participants (n=28 in each group) were included for analysis. Safety measures included recording blood pressure and heart rate before and after each session. Temporal gait parameters were assessed using the 10-Meter Walk Test at baseline, 6 weeks, and 12 weeks. Data was analyzed using Medcalc software.

**RESULTS:** Temporal gait parameters were analyzed for 56 (33 males and 23 females) children with DS in both groups. Mean age of patients in SET and SPT groups was  $7.89 \pm 1.7$  and  $8.07 \pm 0.76$  years respectively. Baseline showed similar scores in both groups. At 6 weeks, SET demonstrated significant improvement in cadence (1.78 SPM to 1.35) and gait velocity (2.11 MPS to 2.79), paralleled by SPT (cadence: 2.01 to 1.32 SPM, gait velocity: 2.12 to 2.83 MPS). Between-group analysis revealed no significant differences.

**CONCLUSION:** Both SET and SPT effectively improve gait parameters in children with Down syndrome. The comparable outcomes highlight SET as a viable alternative, providing clinicians and caregivers additional options for personalized therapeutic approaches.

Clinical Trial Registration Number: NCT05912803

**KEYWORDS:** Down Syndrome (MeSH); Developmental Disabilities (MeSH); Gait (MeSH); Physical Therapy Modalities (MeSH).

**THIS ARTICLE MAY BE CITED AS:** Siddiqui M, Farooqui S, Rizvi J, Soomro BA. Efficacy of simulated equestrian therapy in improving gait parameters among children with Down syndrome: a randomized controlled trial. Khyber Med Univ J 2024;16(1):38-44. <u>https://doi.org/10.35845/kmuj.2024.23508</u>

### INTRODUCTION

Down Syndrome (DS) is a chromosomal condition prevalent in the pediatric population that imposes significant medical and societal burdens.<sup>1</sup> It constitutes roughly 8% of all congenital abnormalities.<sup>1,2</sup> DS arises from various causes, including complete trisomy 21 (94%), mosaicism (2.4%), or translocations (3.3%).<sup>3</sup> Its main characteristics encompass fluctuating degrees of intellectual disability and a distinctive facial appearance marked by

small ears, a flat nose, upward-slanting eyes with small white spots in the irises, a protruding tongue, small hands and feet, and a short neck. Additionally, individuals with DS exhibit short stature, generalized joint laxity, and hypotonia.<sup>46</sup> Hypotonia and joint laxity contribute to reduced balance and coordination, delaying the development of gross motor skills. These factors also give rise to musculoskeletal issues and misalignment in the lower extremities, leading to inefficient and abnormal movement patterns that compromise

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Date Submittee:October 08, 2023Date Revised:December 22, 2023Date Acceptee:December 28, 2023

#### mobility and daily functioning.

Consequently, this population's challenges are exacerbated, and the vicious circle of difficulties continues.<sup>3,7,8</sup> As mentioned earlier, the cumulative effects of these factors place considerable stress on the feet, altering the gait pattern in these individuals.<sup>3</sup> People with DS exhibit a unique gait pattern often called chaplain's gait, characterized by a slow walking speed, small step length, reduced cadence and larger step width.<sup>9</sup>

Children with DS face considerable motor development challenges, including reduced coordination, precision, and effectiveness in movement compared to typically developing peers. These difficulties manifest in awkward, uncoordinated movements and a limited ability to coordinate multiple joint movements.<sup>10</sup> To address these challenges, children with DS often engage in various rehabilitative therapies, with physical therapists playing a crucial role within the multidisciplinary care team through early intervention and the prevention of future complications." Despite the necessity of these interventions, current literature points to a significant issue with the DS population's adherence to traditional long-term therapies. This highlights the critical need for more engaging and enjoyable therapeutic approaches. Simulated Equestrian Therapy (SET), a play-based intervention that utilizes an exercise toy, offers an innovative solution by actively

involving children with DS in their treatment, potentially making the process more enjoyable and effective. This study was planned to explore the impact of SET on improving gait patterns in children with DS.

# **METHODS**

### Sample, Design and Settings

This single-blinded, randomizedcontrolled trial was conducted in the Department of Rehabilitation of Dar-ul-Sukun Institute and Dr. Ziauddin Hospital, Karachi, Pakistan. This research was carried out in accordance to the Declaration of Helenski. The ethical review for this trial was obtained from the Ziauddin University ERC committee under reference code #6803223MHREH, dated March 14, 2023.

The sample size was determined to be 48 participants, divided equally into two groups, to achieve a 95% confidence level and 80% power, considering a 70% anticipated outcome rate and a 5% margin of error.<sup>12</sup>

In this study, 62 participants were screened, and from this pool, 60 individuals meeting the selection criteria were randomly assigned to either the treatment group (n=30) receiving SET or the control group (n=30)undergoing Standard Physical Therapy (SPT). The random allocation was facilitated by employing a simple random sampling technique with the use of sealed envelopes. Consent was obtained from the parents, and assent was secured from the subjects. Nevertheless, two participants from each group either discontinued the treatment or failed to comply with the therapy. In the end, 56 participants (n=28 in each group) were included for analysis (Figure 1).

The participants and their guardians were blinded to the group allocations. Individuals referred by a physician diagnosed with DS based on characteristic features, aged 6–12 years, and having a gross motor function classification (GMFCS) of level I were included. The child's motor skill status, assessed through the standardized GMFCS questionnaire, determined their GMFCS level at the screening.

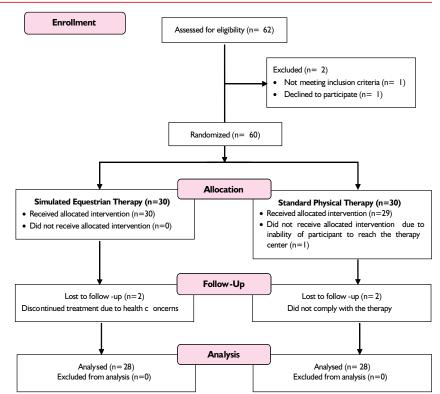


Figure 1: CONSORT Flow Diagram

Those participants who already had a similar intervention within the last year or had any atlantoaxial instability, behavioral, cognitive or severe visual impairment were excluded from the study.

#### **Pre-requisites for Intervention**

Each participant's blood pressure (BP) and heart rate (HR) were recorded before and after each session to ensure safety. Those participants, who failed to achieve regular resting readings as defined by the American Heart Association or felt uncomfortable, even after rest were provided with a compensatory session, and their scheduled session was cancelled. Each participant was assessed at baseline after 6 and 12 weeks of intervention using the 10-meter walk test (10MWT).<sup>17</sup> Each group received the treatment three times a week for three months. Each session's duration was 30-45 minutes on average, which varied with the weekly progression.



Mechanical Simulator used in phase I of SET



Wooden Simulator used in phase II of SET

Figure 2: Simulators Used in Simulated Equestrian Therapy

Weeks	Exercise plan for SET (Phase-II)	Exercise Plan for SPT					
0-2	Practicing catching and throwing	Practicing throwing and catching balls outside of their base of support Walking on a 5 cm thick balance beam of 1 yard.					
3-5	Placing the ball, and rings on the target	Maintenance of balance over a tilt board during sitting, standing, and squatting positions for 3-5 minutes each					
6-8	Performing target hitting on a game of dart	Walking up and down stairs to collect objects Passing over 5 cm obstacles like cones and foam blocks					
9-12	Stretching to the head, feet, and tail of the horse	Maintenance of stability by unilateral standing, alternatively, with eyes open for 10 seconds to 1 minute Kicking and jumping activities					

### Table I: Weekly progression of exercises in SET and SPT group

### Intervention Group

SET was administered in two phases under the supervision of an experienced physical therapist, utilizing two horse simulators (mechanical and wooden), as illustrated in Figure 2.

### **Protocol for SET**

**Warm-up:** To stimulate the vestibular and proprioceptive senses, the child performed a swinging motion on the wooden rocking horse simulator for 5 minutes in an anterior and posterior direction as a warm-up. This pattern mimicked the rhythmic movement of a horse's pelvis to provide a near-realist experience to the rider.

Phase-I: This phase aimed to incorporate the horse gait movements of trot and gallop that are experienced while riding a real horse and to stimulate and strengthen the muscles, including the Deltoid, Bicep, Triceps, Hamstrings, Calf, Quadriceps, Latissimus Dorsi, Abdominals, and Back Extensors of the participant.<sup>22</sup> Unlike real Equestrian Therapy settings, the treatment environment was controlled to ensure the child's safety. Using measurement tape and markers, a block 10 feet in length and 5 feet in breadth was constructed in the treatment area for exercising in this phase. The child was asked to complete four rounds around this custom-built block while riding the mechanical walking horse. A rest period of 5 minutes was kept to maintain the participants' energy levels, which they utilized either in between or after this phase.

**Phase-II:** This phase focused on enhancing the child's motor

performance by stimulating and coordinating their vestibular, proprioceptive, and neuro-muscular systems. Adapted from Champagne, Corriveau, and Dugas,<sup>13</sup> the child engaged in goal-oriented activities on a wooden rocking horse simulator, performing 8-12 repetitions each in forward, backward, and lateral directions. Exercise specifics are outlined in Table I.

**Cool-down:** This phase was followed by the exercise phase, which consisted 5 minutes of anterior and posterior swinging on the wooden simulator and deep breathing exercises.

### **Control Group**

### Protocol for SPT

**Warm-up:** In the initial warm-up phase, the child sat on a therapy ball for 5 minutes and swinging in an anterior and posterior direction was performed to mimic the rhythmic movement of a horse's pelvis.

**Training Protocol:** This phase was adapted from Ghafar and Abdelraouf.<sup>14</sup> It included overall stability and body

balancing exercises performed in a controlled indoor environment to ensure the safety of the participants, strengthen the core and develop the coordination and balance required for task performance. Each activity was performed in a set of 2-3 with 8-12 repetitions. Details of the exercises are listed in Table I.

**Cool-down:** It was followed by the training phase, comprised of 5 minutes of swinging on a therapy ball in an anterior and posterior direction and deep breathing exercises.

### Outcomes and Measuring Parameters

Outcomes included 2 parameters of gait: cadence and gait velocity. Cadence is the number of steps a person takes in a minute.<sup>15</sup> One of the most important, accessible, and measurable parameters of gait and gait velocity is the speed of an individual while walking.<sup>16</sup> The outcome assessors measured the outcomes using the 10 MWT, blinded to the participant's allocation. The description of data collection using the outcome measure is as follows:

### **Table II: Demographic details of participants**

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Variables	Group	N	Mean ± S.D	Normality		
A (V)	SET	28	7.89±1.7	Reject Normality		
Age (Years)	SPT	28	8.07±0.76	Reject Normality		
	SET	28	136.50±7.43	Accept Normality		
Height (cm)	SPT	28	134.25±3.59	Reject Normality		
	SET	28	51.21±7.13	Accept Normality		
Weight (kg)	SPT	28	51.14±2.10	Accept Normality		

SET: Simulated Equestrian Therapy; S.D: Standard Deviation SPT: Standard Physical Therapy

standard physical therapy													
Variables		25 <sup>th</sup> Percentile		Median		75 <sup>th</sup> Percentile		Mean Rank		F		р	
		SET	SPT	SET	SPT	SET	SPT	SET	SPT	SET	SPT	SET	SPT
Cadence	Baseline	46.5	47	53.5	50	58	53	2.85	2.66	105.30	54.81	<0.001*	<0.001*
	6 <sup>th</sup> Week	46	47	52.5	50	57.5	53	1.78	2.01				
	12 <sup>th</sup> Week	46	46	52.5	49	57	52.5	1.35	1.32				
	Baseline	0.15	0.15	0.17	0.16	0.18	0.17	1.09	1.03	110.77	214.92	<0.001*	<0.001*
Gait Velocity	6 <sup>th</sup> Week	0.16	0.16	0.18	0.18	0.19	0.19	2.11	2.12				
	12 <sup>th</sup> Week	0.17	0.17	0.19	0.19	0.20	0.20	2.79	2.83				

 Table III: Comparing gait changes in down syndrome children: simulated equestrian therapy vs.

 standard physical therapy

p<0.001\* considered as highly significant; SET: Simulated Equestrian Therapy; SPT: Standard Physical Therapy

10 MWT has an excellent reliability of r=0.91.<sup>17</sup>

For the testing, a straight line of 10 meters was drawn on the ground with the help of measuring tapes and markers.

The line had two zones marked as acceleration and deceleration to record the walking time of the participants.

The participants were then asked to comfortably walk, at their usual speed, on a line following verbal cues.

A stopwatch was used to record the time, and steps were counted.

Incentives in candies, toys, and signaling cues were provided to the children who froze between the tests or could not follow verbal instructions.

Before the incorporation of testing, all the children were oriented from the testing environment to reduce their fear, confusion and agitation.

Testing was performed in a separate room to eliminate the environment's effects on the child's performance.

### **Statistical Analysis**

The data was analyzed using Medcalc software. 'Skewness and Kurtosis Rule of Thumb' was applied to test the normality of the data. Since the data was found to be skewed, 'Friedman's ANOVA' and 'Mann-Whitney U Test' for within and between the groups analysis were applied. Descriptive statistics are reported in terms of mean and standard deviation, whereas continuous variables are displayed as median (25<sup>th</sup> to 75<sup>th</sup> percentile, lowest to highest) and pvalue (< 0.05) considered significant.

### RESULTS

This study included 56 children with DS, comprising 33 males and 23 females, assigned to SET and SPT groups. Mean age of patients in SET & SPT groups was  $7.89 \pm 1.7$  years and  $8.07 \pm 0.76$  years respectively (Table II). Temporal gait parameters, including gait velocity and cadence, were assessed at baseline, after the 6<sup>th</sup> and 12<sup>th</sup> weeks of intervention.

### Within-Group Analysis

**Baseline Comparison:** At baseline, both the groups, SET and SPT, had similar scores.

**Baseline to 6<sup>th</sup> Week:** In the SET group, cadence mean rank decreased from 2.85 to 1.78 steps per minute (SPM), and gait velocity increased from 1.09 to 2.11 meters per second (MPS) in the 6<sup>th</sup> week of intervention, showing a significant performance improvement (p < 0.001). While, in the SPT group, there was a significant change in cadence from 2.66 to 2.01 SPM and gait velocity from 1.03 to 2.12 MPS, with p < 0.001.

 $6^{\text{th}}$  to 12<sup>th</sup> Week: The SET group exhibited a decrease in the mean rank of 1.78 to 1.35 SPM in the parameter of cadence and an increase in the mean rank of 2.11 to 2.79 MPS for gait velocity, indicating significant differences p <0.001. Likewise, effective results were reported in the SPT group, where the mean rank in cadence (2.01 to 1.32 SPM) and gait velocity (2.12 to 2.83 MPS) were also remarkable with a value of p  $<\!0.001.$  Details of the analysis are listed in Table III.

### **Between-Group Analysis**

The pair-wise comparison results indicated no significant differences between SET and SPT groups during different intervention points, as indicated by the constant value of Hodges-Lehmann median difference for cadence (-2.0000) and gait velocity (0.0000). The intention-to-treat analysis was applied to reduce potential bias in treatment effects due to attrition rate. Details of the analysis are listed in Table IV.

## DISCUSSION

Acquisition of proper gait patterns is of paramount importance for children diagnosed with DS. In addition to encountering delays in cognitive, psychosocial, developmental milestones, and motor skills development, children with DS also experience a compromised gait pattern that impacts their day-to-day activities. Hence, this study was conducted on 56 children with DS to evaluate the effects of SET compared to SPT in improving gait parameters. The results analyzed two temporal components of gait, velocity and cadence, using IOMWT and exhibited significant differences in baseline and post-intervention values. Baseline showed similar scores in both groups. Notably, SET demonstrated a significant improvement in cadence and gait velocity (1.09 to 2.11 MPS) at the 6<sup>th</sup> week, sustained at the 12<sup>th</sup> week (cadence: 1.78 to 1.35 SPM, gait velocity: 2.11 to 2.79 MPS), with p <0.001. SPT group also exhibited significant changes. Between-group analysis indicated no significant superiority of one therapy over the other.

This study analyzed participants' performance at three intervals (baseline, 6<sup>th</sup> and 12<sup>th</sup> weeks). Each gait parameter was discussed separately to highlight the independent impact of SET and SPT on them. While searching for comparative literature, the authors identified a considerable gap in the research depository for gait parameters utilizing similar treatment approaches, especially for children with DS; however, studies evaluating other spatial and temporal parameters were available.

Numerous researchers have studied gait parameters, and one among them is Sutherland DH, et al.,<sup>18</sup> who identified parameters of gait maturity in typically developing children and concluded that changes in gait over time in an individual are evident through its five spatiotemporal parameters, including gait velocity, step length, cadence, and duration of single-limb stance and ratio of pelvic span to ankle speed. Hence, the maturity of gait in DS can also be studied by analyzing these variables. Naito M, et al.,<sup>19</sup> claim that children with DS exhibit lower values of these parameters compared to peers of the same age; however, they argue that these parameters should improve with advancing age in DS. This study analyzed cadence and gait velocity amongst the given parameters of Sutherland DH, et al., and determined that cadence and gait velocity are inversely proportional to each other. Hence, in a child with DS, a decrease in cadence should result in an increased gait velocity, and our study has significantly supported this claim. Our findings are consistent with HW, et al., who investigated the effects of a threedimensional horse riding simulator with and without virtual reality training gaming on ten children with cerebral palsy and reported significant changes in all gait parameters, including gait velocity in the horse riding simulator group (pre 0.56±0.13, post 0.61±0.11) as well as the other group.<sup>19,20</sup> Current findings are also related to the claims of

Moriello G, et al., who studied the gait parameters in four children with DS following a combination of equestrian therapy with physical therapy and found significant changes in gait speed.<sup>21</sup> Similarly, Portaro S, et al., studied fifteen males with DS following a 6-month equestrian therapy protocol and reported a significant improvement in gait speed (pre 0.74±0.1, post  $0.89\pm0.12$ ).<sup>22</sup> Since our findings are similar to the studies that utilized real horse riding as a treatment, this protocol can be considered an adequate replacement for actual equestrian therapy in children with DS. Our findings are also related to Mutoh T, et who studied the effects of al., equestrian therapy on 24 children with CP and reported significant results in the improvement of both cadence (pre  $79.3 \pm 28.8$ , post  $104.4 \pm 24.3$ ) and gait velocity (pre 31.9±10.7, post  $38.8 \pm 13.5$ ) and Manikowska F, et al.,<sup>24</sup> who studied 16 ambulatory cerebral palsy children and reported significant findings of improvement in cadence and gait velocity after a single session of equestrian therapy. These findings make our protocol a considerable asset for children with disabilities, and thus, it can be applied to different developmental disabilities and can significantly contribute to their betterment.

Literature also suggests that anthropometric differences between genders predispose men to have a higher gait velocity and lesser cadence than women. Such differences have also been reported for DS.<sup>25</sup> However, our study neither significantly supports this claim nor observed gender-dependent variability of the spatiotemporal parameters. Moreover, the surfacing literature mentioning growth curves in DS advocates that these children attain motor function at a slower pace than their age-matched typically developing peers, which can lead to complications with progressing age. However, early interventions can combat this problem and significantly contribute to DS ageappropriate motor growth.<sup>26</sup> Literature also suggests that impaired children's recreational and exercise needs should be met through play-based therapies.27 Such approaches should be considered an essential component of a child's care plan; hence, this protocol can be considered a valuable addition.

### LIMITATIONS OF THE STUDY

Previous studies have been conducted on youth and adolescents with DS using SET; however, to the author's knowledge, no study on DS children was conducted; hence, our study is the first of its kind in evaluating gait parameters among DS children, which adds to the scarce literature. It will also serve as a basis for future research where this protocol can be generalized to a more significant sample, and a comparison between genders and age groups could be made. Despite the rigor, it has some limitations, too, including the absence of a follow-up period, which could have provided valuable insight into the long-term effectiveness of the protocols. Moreover, this study did not evaluate changes on the cellular level, which are essential to note in conditions like DS to contribute significantly to the betterment of this community. Furthermore, the induction of children with DS without stratification of its types could also raise a question on the application of this intervention, as the effectiveness can vary with the type of DS.

# CONCLUSION

This study suggests that both simulated equestrian therapy and standard physical therapy are effective in improving gait parameters among children with DS.. The comparable outcomes highlight the potential of SET as an alternative and potentially beneficial intervention, offering clinicians and caregivers additional options for tailoring therapeutic approaches based on individual preferences and needs. Studies with a follow-up period should be conducted to further evaluate the long-term benefits of SET.

### ACKNOWLEDGEMENTS

We thank the participants and their guardians for making this study possible. We would also like to thank the facility of Dar-ul-Sukun and Dr. Ziauddin Hospital for their support and compliance.

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### **AUTHORS' CONTRIBUTION**

Following authors have made substantial contributions to the manuscript as under:

**MS:** Concept and study design, acquisition, analysis and interpretation of data, drafting the manuscript, approval of the final version to be published

SF & BAS: Concept and study design, critical review, approval of the final version to be published

JR: Concept and study design, drafting the manuscript, critical review, approval of the final version to be published

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

### **CONFLICT OF INTEREST**

Authors declared no conflict of interest, whether financial or otherwise, that could influence the integrity, objectivity, or validity of their research work.

### **GRANT SUPPORT AND FINANCIAL DISCLOSURE**

Authors declared no specific grant for this research from any funding agency in the public, commercial or non-profit sectors

### **DATA SHARING STATEMENT**

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



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