



# Effect of hippotherapy on balance, functional mobility, and functional independence in children with Down syndrome: randomized controlled trial

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## Abstract

Impaired muscle strength, proprioceptive and vestibular deficits, and orthopedic dysfunction are common disorders associated with Down syndrome (DS). Hippotherapy uses the horses' multidimensional movement to improve posture, balance, and overall function, both motor and sensory. Research evidence supports hippotherapy as an effective, medically recognized intervention for the rehabilitation of gross motor skills. The aim of this study was to determine the effect of hippotherapy on balance, functional mobility, and functional independence in children with DS. Thirty-four children with DS were randomly assigned to the experimental (hippotherapy) and control groups after the initial assessment. Both groups received physiotherapy including balance exercises, and the experimental group also received hippotherapy as an integrative therapy. Pediatric Balance Scale (PBS), Timed Up and Go Test (TUG), and Functional Independence Measure for Children (WeeFIM) were used before and after the intervention. Baseline outcome measures (PBS, TUG, WeeFIM) were statistically similar between groups ( $p > 0.05$ ). After the intervention, PBS and TUG scores improved in both groups ( $p < 0.05$ ). On the other hand, WeeFIM scores improved just in the hippotherapy group ( $p < 0.05$ ).

**Conclusion:** Therefore, providing hippotherapy as an integrative therapy to physiotherapy will be more effective in improving the functional independence of children with DS.

**Trial registration:** NCT05297149 (March 2022, retrospectively registered).

## What is Known:

- Hippotherapy has an improvement effect on balance and functional independence in different diseases and age groups, but the evidence is limited in DS.
- There is limited evidence about the effect of hippotherapy on functional mobility in different diseases and age groups, but there is no evidence in DS.

## What is New:

- Hippotherapy is a safe and effective approach to support improvement in functional independence in children with DS.

**Keywords** Hippotherapy · Functional mobility · Functional independence · Balance · Down syndrome

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## Abbreviations

DS	Down syndrome
AHA	American Hippotherapy Association
PBS	Pediatric Balance Scale
TUG	Timed Up and Go Test
WeeFIM	Functional Independence Measure for Children
BMI	Body mass index
GMFM	Gross Motor Function Measure

## Introduction

The motor deficits associated with Down syndrome (DS) are defined as general clumsiness and slowness of movement, longer movement and reaction times, balance and postural deficits, and variable motor synergies that persist throughout adulthood [1]. Hypotonia, hyperflexibility, impaired muscle strength, proprioceptive and vestibular deficits, and orthopedic dysfunction are common impairments associated with DS. These problems result in delayed achievement of motor development milestones. Children with DS learn to walk and many other basic skills later than their typically developing peers. This in turn affects their ability to participate in home, school, social, and community activities [2].

Studies have shown that these motor deficits, particularly those related to balance, coordination, and postural control, are associated with a decreased level of functional mobility and functional independence [3]. A Canadian study examined motor skills in children with DS up to the age of 6 years and demonstrated a decrease in the rate of motor skill development between 3 and 6 years of age. They attributed this decrease to underdevelopment of balance, speed, and coordination skills [1]. Children with DS have poor balance due to higher instability and inefficient compensatory mechanisms including the altered center of pressure displacement and trunk stiffening that predisposes them to falls [4]. It has also been reported that impaired balance in individuals with DS persists into adolescence [3].

Functional mobility refers to the ability to move from one place to another, including standing, walking, squatting, and climbing stairs, in order to carry out daily life activities [5]. As such, functional mobility is a fundamental component of basic (e.g., dressing, eating) and instrumental (e.g., using the phone, using public transport, taking medication) activities of daily living. People with DS have lower functional mobility compared to their typically developing peers [6]. Also, physical activity level which is predictive of functional mobility is found to be lower in DS adults than in peers without disability [7]. One of the primary goals of families and health professionals is to enable children to live functionally in society. Functional independence is defined as the capacity to do something unaided, i.e., having the motor and cognitive skills necessary to perform the

activity. It has been shown that functional independence is impacted in children with DS [1, 3]. The American Hippotherapy Association (AHA) defines hippotherapy as a physical, occupational, and speech-language therapy strategy that uses equine movement as part of an integrated intervention program to achieve functional outcomes [8]. Horse-riding requires postural adjustments and dissociation of the pelvic and shoulder girdles, resulting in trunk correction reactions and tonic adjustments that dynamically seek postural stability and control [9].

This therapeutic intervention uses the horse's multidimensional movement to improve posture, balance, and overall function, both motor and sensory. Research evidence supports hippotherapy as an effective, medically recognized intervention for the rehabilitation of gross motor skills and mobility [10, 11]. One of the potential mechanisms of action of hippotherapy is thought to be rhythmic and repetitive stimuli of the horse's movements, sensory feedback, and the rider's movements to adapt to these stimuli and feedback [12].

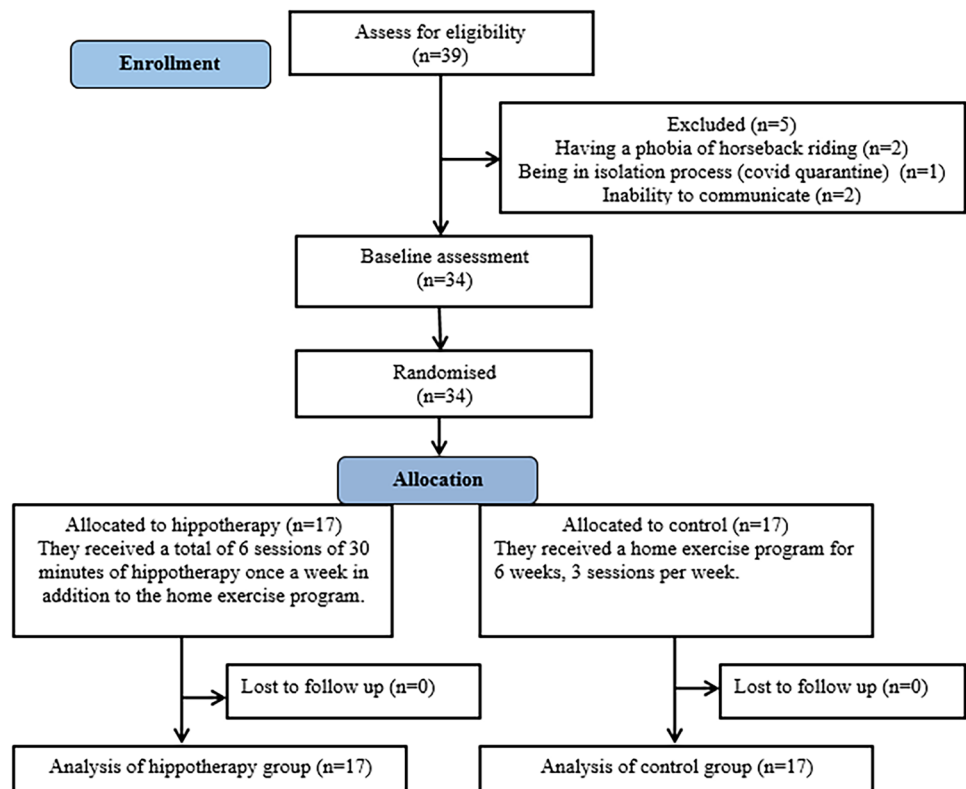
Considering the motor and functional effects of DS and the potential benefits of hippotherapy, our review of the literature yielded a limited number of studies on the effectiveness of hippotherapy in DS [9, 12–14]. Therefore, we conducted this study to examine the effect of hippotherapy on balance, functional mobility, and functional independence in children with DS.

## Materials and methods

The prospective randomized controlled study was conducted in the Antalya Equestrian Sports Club between November 2020 and January 2021 after obtaining ethical approval from the Haliç University Non-Interventional Clinical Research Ethics Committee (22.10.2020/139). To ensure that the rights of all participants are protected, the researchers strictly adhered to the Declaration of Helsinki and the ethical principles in designing and conducting clinical research.

## Participants

Thirty-four children aged 4 to 14 years who lived in Antalya and were diagnosed with DS were recruited from the Unimpeded Cafe Unit of Antalya Municipality. After an initial assessment, the participants were randomly assigned to the experimental (hippotherapy) ( $n = 17$ ) or control ( $n = 17$ ) group by computerized prospective randomization (randomization.org) (Fig. 1). Informed consent was obtained from the children's legal guardians. Exclusion criteria were having a history of previous hippotherapy intervention, a phobia related to horse-riding, epileptic seizures, atlantoaxial instability, and any orthopedic (instability of the spine, hip, or shoulder luxation, scoliosis

**Fig. 1** Flow diagram of the planned protocol pathway

with deviation greater than or equal to 30 degrees), neurological (uncontrolled epilepsy, hydrocephalus/shunt), cardiovascular (serious heart diseases, hypertension), or pulmonary disease (allergies to grasses, animals, and dust) that would prevent participation in hippotherapy.

A paper case report form named the sociodemographic and clinical evaluation form was prepared by the authors. This form included the participants' names, gender, age, height, weight, education levels, exercise habits, exercise type, and the outcome measure results obtained from the study. To protect participants' confidentiality, these forms and the signed consent forms were stored in a locked file cabinet belonging to one of the researchers.

## Outcome measures

All participants in both groups were assessed using the Pediatric Balance Scale (PBS), Timed Up and Go Test (TUG), and Functional Independence Measure for Children (WeeFIM) within the week before and again within the week after completion of the 6-week intervention.

### Pediatric balance scale

The PBS is a modified version of the Berg Balance Scale that is used to assess functional balance skills in children. The scale consists of 14 items that are scored from 0 (lowest function) to

4 (highest function) with a maximum score of 56 points. Lower scores indicate poorer balance. The PBS has been validated for use in children with neuromotor dysfunction [15].

### Timed up and go test

The TUG assesses balance and functional mobility. The time required for the person to stand up from a chair, walk 3 m forward, return to the chair, and sit down again was recorded. Times of 14 s or more are interpreted as a high risk of falling [16, 17].

### Pediatric functional independence measure for children

The WeeFIM is a pediatric version of the Functional Independence Measure (FIM) that was developed to measure a child's consistent functional performance in essential daily functional skills (independence in self-care, sphincter control, transfers, locomotion, communication, and social cognition). It is an 18-item, 7-level ordinal scale instrument (score range: 18–126) and can be used for children with developmental disabilities aged 6 months to 21 years [18, 19].

### Intervention

Both groups performed a home balance exercise program 3 days a week for a total of 6 weeks. In addition, the experimental

group also participated in a hippotherapy program once a week for 6 weeks. Hippotherapy sessions were conducted by a physiotherapist with specialized training and certification in hippotherapy.

### Home exercise program

The home exercise program involved the most common preferred exercises for balance training that are easy to apply and do not require equipment and a special environment [20]. The home exercise program consisted of the following balance training exercises: one leg standing on foam with eyes open and closed, double leg standing on foam with eyes open and closed, walking in tandem with eyes open and closed, balance exercises on an inclined surface, balance exercises in the squat, and jumping over an obstacle on the ground. All participants performed the 30 min of exercises under parental supervision, 3 times per week for 6 weeks. The physiotherapist carried out video calls to the children and parents to control and motivate their adherence to the home exercise program within the scope of telehealth.

### Hippotherapy program

The hippotherapy program was applied by a physiotherapist and the program consisted of 6 weekly sessions that take 30 min. Sessions were conducted with the same farm horse used for hippotherapy on an indoor manege sand floor. For the best results, the appropriately matched horse was used for each child and the same horse was used throughout the entire program. During the sessions, the horse was always led by an experienced horse handler, and specially trained side walkers accompanied the physiotherapist to assist the child while riding to ensure safety. All children wore a lightweight helmet approved for horseback riding and a safety belt with handles. The usual equipment for hippotherapy included a saddle pad, a flat surcingle (strap fixed on the horse to keep the pad where the children sit in place), stirrups attached to the surcingle (when required), a halter, and a lead chain.

Each individual session started with brief greetings, contact with the horse, and 5 min of warm-up, and ended with 2 min of cool down. The 6-week program content was developed by adapting a hippotherapy program of the American Hippotherapy Association [8] according to the study goals and literature knowledge [13, 14]. The program of the relevant week was performed to each child. The activity was supported or assisted for children who could not do any of the activities in the program. For example, the toy was extended more for the child who had difficulty in taking the toy from the side with full rotation, or the lifting of the hip was supported for those who could not sit and stand up, and the amount lifted was considered sufficient [8, 14, 21]. The horse-riding duration consisted of repeating 5 min of

riding in the walk, 2 min rest, and 5 min in trot for 20 min in each session. The average speed in walk is 5–7 km/h. The average speed of the trot is 12–15 km/h. Between each gait was a break for 2 min. During the horse-riding, the stops were minimized and the total horse-riding time was followed by the side walker with a stopwatch. The hippotherapy team controlled the movements and speed of the horse by physically steering the horse and controlling the speed, or just giving verbal directions.

In week 1, the participants' tactile sensitivity and approach to the horse were observed. The tactile sense is trained. Balance training (maintaining the posture while the horse moves) with upper extremity movements was performed unsupported or supported according to children's requirements on horseback.

In week 2, the participants performed various exercises for tactile (e.g., touching the horse or lying on the barrel for feeling its warmth and skin), visual (e.g., perception of your own position and environment on the horse), auditory (e.g., verbal directions that support other senses provided by the physiotherapist), and vestibular sensory (e.g., position changes such as bending forward, backward, sideways, lying on the barrel) input on the horse, and whole-body balance exercises (e.g., sitting and standing in the saddle) on the horse were performed during this session.

In week 3, the participants performed strengthening exercises for the upper and lower extremities, and balance exercises. Balance and coordination were observed throughout the session.

In week 4, the participants continued the same training as previous week and in the last 5–10 min of the session, they performed the balance activities at a faster horse speed.

In week 5, the participants performed various exercises, mainly balance, and coordination, on the horse using balls. In addition, the balls were given to the side walkers on both sides of the horse and the participants did trunk rotation and flexion/extension movements. Participants who did not accept the balls provided were asked to perform the activities using one of their favorite toys. The difficulty of the movements was increased during the activity to make it more fun for the participants. The last 5–10 min continued with faster horse speed.

In week 6, the exercises performed in the previous week were continued, followed by activities that challenged the children's muscle activities and balance systems.

The participants in the control group were also included in the hippotherapy program after the study.

### Statistical analysis

The G-power v3.1 program (Universitat Kiel, Germany) was used to determine the sample size. In the literature, the effect size of hippotherapy on balance assessment was reported

as 1.59 that was both statistically and clinically significant [22]. Based on this study, with a 95% confidence level, 80% power, and effect size of 1.59, we calculated that a sample size of 17 participants in each group should be required, considering that there may be drop out, in two groups of 20 participants, and a total of 40 participants were needed in the study. Data were collected through case report forms, questionnaires, and direct observation and stored in patient files as well as SPSS data entry files. Data analysis was performed using SPSS version 25.0 statistical software (IBM Corp, Armonk, NY). Mean and standard deviation was calculated for all variables. Categorical variables were analyzed with the  $\chi^2$  test. The normality of the data was tested using kurtosis, skewness, and the Kolmogorov–Smirnov test. Independent samples *t*-test was used for between-group comparisons; paired samples *t*-test was used for within-group comparisons. ANCOVA was run to examine whether a change of outcomes results differed between the experimental and control groups while controlling gender and body mass index. Preliminary checks were completed to assess assumptions of normality, linearity, homogeneity of regressions slopes, and homogeneity of variance. Statistical significance was accepted for *p* values < 0.05.

## Results

A total of 34 children were included in the study (Fig. 1). The participants' mean age was  $10.12 \pm 3.30$  years for the hippotherapy group and  $8.18 \pm 2.74$  years for the control group. There were significant differences in gender distribution, weight, and body mass index (BMI) between the experimental and control groups ( $p < 0.05$ ), while no difference was found in terms of age or height ( $p > 0.05$ ) (Table 1).

Baseline outcome measures (PBS, TUG, WeeFIM) were statistically similar between groups ( $p > 0.05$ ) (Table 2). For within-group analysis, PBS and TUG scores improved in both groups ( $p < 0.05$ ), and WeeFIM scores improved just

in the hippotherapy group ( $p < 0.05$ ) after the intervention. The presence of the control group enabled further analysis of the data to determine if the improvements noted were due specifically to the hippotherapy intervention or if they might be due to a different, unidentified factor. To address this question, ANCOVA analyses were performed using baseline scores on the assessment measures, participants' gender, and body mass index as covariates of interest. This analysis then compared the change from baseline to post-intervention for all of the assessment measures. This analysis found that WeeFIM changes were significant ( $p = 0.008$ ). PBS and TUG scores showed no significant differences in this ANCOVA analysis (Table 3).

## Discussion

In the current study, we compared the effects of hippotherapy combined with the home exercise program and home exercise programs on balance, functional mobility, and functional independence in DS children. It was determined that balance and functional mobility improved in both groups, but functional independence improved only in the hippotherapy group.

The horse's movements are transmitted to the brain, and the brain sends information to the body to generate new motor adjustments caused by adaptive behavior that occurs in response to sensory stimuli. Integrated sensory and motor stimulation transmitted to the entire sensory system, such as the visual and proprioceptive systems, play an important role in balance [23]. Previous studies on the effects of hippotherapy on balance have demonstrated improvement in different diseases and age groups [13, 22, 24]. Giagazoglou et al. determined that a 10-week hippotherapy intervention had positive effects on static balance and strength in 19 adolescents with intellectual disabilities [24]. Silkwood et al. observed a significant change in PBS scores indicating improved balance and coordination in their study of hippotherapy exercises in children with cerebral palsy, DS, and autism [22]. Similar to our study, Portaro et al. examined the effects of 6 months of hippotherapy on balance and gait

**Table 1** Baseline characteristics of children

	Hippotherapy group ( <i>n</i> = 17)	Control group ( <i>n</i> = 17)	<i>p</i> value
Age (years)	$10.12 \pm 3.30$	$8.18 \pm 2.74$	0.071
Gender			
Girls ( <i>n</i> %)	13 (76.5%)	6 (35%)	<b>0.016</b>
Boys ( <i>n</i> %)	4 (23.5%)	11 (65%)	
Height (cm)	$125.26 \pm 15.77$	$114.76 \pm 14.74$	0.053
Weight (kg)	$40.50 \pm 15.69$	$25.97 \pm 10.21$	<b>0.003</b>
BMI ( $\text{kg}/\text{m}^2$ )	$24.71 \pm 6.22$	$19.06 \pm 3.81$	<b>0.004</b>

Data are presented as mean  $\pm$  standard deviation or *n* (%)  
*BMI* body mass index

**Table 2** Comparison of baseline outcome results

	Hippotherapy group ( <i>n</i> = 17)	Control group ( <i>n</i> = 17)	<i>p</i> value
PBS	$51.82 \pm 2.70$	$50.41 \pm 3.32$	0.183
WeeFIM	$105.29 \pm 16.81$	$94.29 \pm 16.83$	0.066
TUG	$9.56 \pm 3.72$	$7.75 \pm 2.03$	0.088

Data are presented as mean  $\pm$  standard deviation or *n* (%)

*PBS* Pediatric Balance Scale, *WeeFIM* Functional Independence Measure, *TUG* Timed Up and Go Test

**Table 3** Within- and between-group differences in outcome results before and after the intervention

	Hippotherapy group			Control group			Analysis of covariance			
	Baseline	6th week	MD (95% CI)	p value <sup>a</sup>	Baseline	6th week	MD (95% CI)	p value <sup>a</sup>	F	p value for difference between groups <sup>b</sup>
<b>PBS</b>	51.82 ± 2.70	53.65 ± 2.47	2.04 (1.30 to 2.78)	< <b>0.001</b>	50.41 ± 3.32	51.41 ± 3.00	1.39 (0.57 to 2.21)	<b>0.001</b>	2.183	0.150
<b>WeeFIM</b>	105.29 ± 16.81	107.94 ± 14.28	3.82 (0.88 to 1.99)	<b>0.027</b>	94.29 ± 16.83	94.65 ± 16.79	0.40 (-1.61 to 2.41)	0.188	8.042	<b>0.008</b>
<b>TUG</b>	9.56 ± 3.72	8.67 ± 3.32	-1.09 (-1.67 to -0.51)	<b>0.005</b>	7.75 ± 2.03	7.31 ± 2.21	-0.73 (-1.38 to -0.09)	<b>0.041</b>	1.342	0.256

Data are reported as mean ± standard deviation

MD mean difference, CI confidence interval, PBS Pediatric Balance Scale, WeeFIM Functional Independence Measure, TUG Timed Up and Go Test

<sup>a</sup>Comparison between before and after the sessions using paired *t*-test

<sup>b</sup>Comparison between hippotherapy and control groups using ANCOVA test

in DS by assessing stabilometric, baropodometric, and gait before and after hippotherapy. They observed that hippotherapy provided functional improvement in walking speed, width, bilateral symmetry, and balance in DS [13]. Our findings contribute to the literature with the improvement in balance in children with DS receiving hippotherapy. However, since the improvement obtained was not statistically different from the control group, its contribution to improving the balance could not be determined exactly.

Hippotherapy may support achieving functional outcomes when used as part of an integrated treatment program [23]. Casady et al. reported significant improvements in all parameters on the 88-item Gross Motor Function Measure (GMFM) after 10 weeks of hippotherapy in 10 children with special needs, 7 of whom had cerebral palsy [25]. Another study including 13 children with cerebral palsy (aged 4–12 years) revealed improvement in body function and both gross and fine motor performance after 10 weeks of hippotherapy [21]. Champagne and Dugas evaluated the effect of hippotherapy on the development of gross motor function and postural control in two children with DS (aged 28 and 37 months) and reported improvement in fundamental motor skills (walking, running, and jumping) according to the GMFM and in postural control as assessed by multi-axial accelerometers [14]. McGibbon et al. [26] examined the immediate and long-term effects of hippotherapy on the symmetry of adductor muscle activity and functional ability in children with cerebral palsy and demonstrated improvement in gait symmetry and other functional motor skills. Similar to the literature, in the current study, significant improvement was obtained with hippotherapy on functional independence of children with DS assessed with WeeFIM. During all activities, postural control, the core connection is used for the expression, quality, and coordination of movement. The sensory input provided by the horse's movements and the motor responses induced in the pelvis and trunk has positive effects on postural control and core connection. Thus, better quality and coordinated movements emerge that enable people to be more independent in their daily life activities [27]. In our study, the occurrence of gains in functional independence in the group that received hippotherapy, unlike the group that received only home balance exercise, indicates the effects of mechanisms that support the cognitive and social behavior of horses as physiological-behavioral-evolutionary biology [12]. It has been reported in the literature that situations such as touching, showing affection, caring for the horse, the warmth of the horse, and breathing may be associated with the release of hormones, such as serotonin, oxytocin, and cortisol release [12, 28]. In addition, the environment in which the therapy is applied can be a constant stimulant. Hippotherapy is thought to increase the willingness and ability to participate in daily activities by thus supporting the cognitive-sensory-motor systems [12].

A study conducted on older adults indicated that there was no improvement in functional mobility assessed by TUG [29]. In another study evaluating the effect of hippotherapy on the elderly, improvement in TUG performance was obtained [23]. There is no consensus on the effectiveness of hippotherapy on functional mobility which is a motor skill related to the purposeful movement of the individual's body in space [30]. In this sense, the gains obtained with hippotherapy may not always be reflected in the performance of TUG, which is a bipedal evaluation on the floor. Accordingly, the present study determined that while functional mobility improved in both groups, there was no result that hippotherapy sessions provided an additional benefit in this improvement.

In our study, the improvements in balance, functional independence, and functional mobility obtained with hippotherapy with a home-based exercise program are thought to be the result of the mobility that requires the rider's body to be adjusted continuously. When the horse moves, planar changes in the gravity center cause oscillations in the gravity center of the individual, stimulating the straightening-up reactions and postural balance [31–33]. Hippotherapy promotes sensorimotor stimulation with neuromuscular and proprioceptive facilitation. During the session, sensory integration takes place between the visual, vestibular, and proprioceptive systems. Stimuli from sensory receptors are directed to corresponding areas in the cortex. Continuous stimulation of these systems can improve postural control and balance [33–35]. The difference between the groups obtained in the WeeFIM functional independence scale, which shows performance in different daily living activities such as social interaction, self-care, and movement, reveals this situation. On the other hand, while there was an improvement after the intervention in the balance and mobility measurements evaluating certain activities with a 4-week program, no significant difference could be obtained in the comparison between the groups. It is predicted that a significant difference between groups can be obtained in these parameters with longer term and more frequent hippotherapy programs.

Considering baseline balance and functionality scores, it was determined that all parameters were poorer compared to the study that examined the healthy population norm values. Similarly, in studies comparing balance in children with DS and their healthy peers, it has been emphasized that DS affects motor development, leading to hypotonicity and delayed motor development, which contributes to decreased balance [36]. Beerse et al. conducted a study including 13 children with DS (5–11 years old) and 13 healthy peers and reported that children with DS required a longer time to complete the TUG test [37]. Nicolini-Panisson and Donadio used TUG to evaluate functional mobility in 459 healthy children (aged 3–18 years) as a normative data set and 40 DS children [17].

Decreased postural stability and sensorial problems are common in children with DS [38]. Postural instability is the inability to maintain balance under dynamic and static conditions. It was reported that hippotherapy has positive effects on postural balance in children with DS [39]. Scoliosis has a high incidence in patients with DS [40]. A study reported that hippotherapy combined with Schroth exercises was more effective on postural asymmetry and balancing ability more than Schroth exercises alone [41]. Although we are aware that the balance improved in both groups, this improvement was greater in the hippotherapy group.

A review reported that animal-child interaction can improve the cognitive-behavioral processes in adolescents with anxiety and/or depression disorders, autism spectrum disorders, and dyspraxia, as well as in those with infantile cerebral palsy, and attention-deficit hyperactivity disorder [12]. Also, another study conducted with autism spectrum disorder reported that stereotyped movements are significantly reduced by the horse's movements which increases a person's motivation and self-esteem [42].

A randomized controlled trial was conducted on the effectiveness of hippotherapy versus conventional neurorehabilitation alone and it was revealed that hippotherapy allows the enhancement of substantial neuroplastic changes in the injured brain with significant neurological recovery [43]. The WeeFIM measures the child's performance and has three main domains (self-care, mobility, and cognition). In our study, WeeFIM scores improved just in the hippotherapy group.

Despite randomization, the difference in demographic data between groups is the limitation of the study. Also, stratified randomization was not used due to the unpredictability of this situation. Another limitation of our study is the lack of a control group that received no intervention, which may have made the results of the intervention groups more meaningful. Additional studies on this subject will provide more evidence for the application of hippotherapy.

Research evidence supports hippotherapy as an effective, medically recognized intervention for the rehabilitation of gross motor skills. Physiotherapy programs incorporating hippotherapy are an effective approach to support improvement in functional independence in children with DS. We believe the widespread incorporation of hippotherapy in rehabilitation programs for children with DS would provide substantial benefits in terms of functional independence, which is the main goal of rehabilitation in children with DS.

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**Authors' contributions** All authors contributed to the study conception and design. Material preparation, data collection, and analysis were performed by Y.K. and S.S. The first draft of the manuscript was written by S.S. and D.T., and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

**Data availability** The data that support the findings of this study are available on request from the corresponding author.

## Declarations

**Ethical approval** The study was approved by the Haliç University Non-Interventional Clinical Research Ethics Committee (139/22.10.2020). This study was performed in line with the principles of the Declaration of Helsinki.

**Consent to participate** Written informed consent was obtained from the parents.

**Conflict of interest** The authors declare no competing interests.

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