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Ocena czynników wpływających na skuteczność terapii integracji sensorycznej u dzieci w wieku przedszkolnym i wczesnoszkolnym

Assessment of factors influencing the effectiveness of sensory integration therapy in preschool and early school-aged children

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The feasibility and effect of robot-assisted gait training frequency on gait functions in children with cerebral palsy – A single blinded, randomized pilot study

Wykonalność i wpływ częstości treningu chodu wspomaganego robotem na funkcje chodu u dzieci z mózgowym porażeniem dziecięcym – Próba pojedynczo ślepa, randomizowana, badanie wstępne

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Abstract

Introduction. The aim of this study is to investigate the feasibility and the effect of Robot-assisted gait training (RAGT) frequency on gait functions in children with diplegic cerebral palsy (CP). We hypothesized that RAGT with the increased frequency (4 times a week) will result in greater improvements than RAGT with the common frequency (2 times a week).

Material and methods. Fourteen participants with diplegic CP were assigned to two groups that received only RAGT at different frequencies. The treatment group (TG) received 24 sessions while the control group (CG) received only 12 sessions over 6 weeks. Gross motor function measure (GMFM) D, GMFM E, walking distance (6 minute-walk test), speed (10 meter-walk test), balance (Pediatric balance scale), and the quality of gait (Edinburgh visual gait score) were assessed. Data was collected twice, before and after RAGT intervention period. Also, the feasibility was assessed by the safety and the rates of recruitment, compliance, and adherence.

Result. There was significant improvement in GMFM D, GMFM E, walking distance, balance, and the quality of gait in both groups ($p < 0.05$). Walking speed has been significantly improved only in TG. The difference in the quality of gait is greater in TG ($p < 0.01$) compared to CG ($p < 0.05$). The recruitment rate was 70%. 100% of recruited participants complied with and adhered to the intervention. No adverse events were reported.

Conclusion. RAGT with the increased frequency could induce greater improvement in gait functions than RAGT with the common frequency in children with diplegic CP.

Keywords

rehabilitation, robotics, walking, cerebral palsy

Streszczenie

Wstęp. Celem badania jest ocena wykonalności oraz efektu częstości treningu chodu wspomaganego robotem (RAGT) na funkcje chodu u dzieci z diplegicznym mózgowym porażeniem dziecięcym (MPD). Zakładamy, że RAGT przeprowadzane z większą częstotliwością (4 razy w tygodniu) przyniesie większą poprawę niż RAGT realizowane z częstością standardową (2 razy w tygodniu).

Materiały i metody. Do badania zakwalifikowano czternaścioro uczestników z diplegicznym MPD, którzy zostali losowo przydzieleni do dwóch grup otrzymujących RAGT w różnych częstościach. Grupa terapeutyczna (TG) przeszła 24 sesje, podczas gdy grupa kontrolna (CG) - 12 sesji przez 6 tygodni. Oceny objęły miarę funkcji motorycznej brutto (GMFM) części D i E, odległość przebytego dystansu (test chodu na 6 minut), szybkość (test chodu na 10 metrów), równowagę (pediatryczna skala równowagi) oraz jakość chodu (Edynburska skala oceny chodu). Pomiary przeprowadzono przed rozpoczęciem interwencji oraz po jej zakończeniu. Dodatkowo oceniono wykonalność badania, biorąc pod uwagę bezpieczeństwo, wskaźniki rekrutacji, przestrzegania protokołu oraz zaangażowania w interwencję.

Wyniki. Stwierdzono istotną statystycznie poprawę w GMFM D i E, odległości przebytego dystansu, równowadze oraz jakości chodu w obu grupach ($p < 0,05$). Poprawa szybkości chodu była istotna statystycznie tylko w grupie TG. Różnica w jakości chodu była większa w TG ($p < 0,01$) w porównaniu do CG ($p < 0,05$). Wskaźnik rekrutacji wyniósł 70%. Wszyscy zrekrutowani uczestnicy byli w pełni zaangażowani w proces terapeutyczny i przestrzegali zaleceń, nie zgłoszono żadnych niepożądanych zdarzeń.

Wnioski. RAGT przeprowadzane z większą częstością może indukować większą poprawę funkcji chodu niż RAGT z częstością standardową u dzieci z diplegicznym MPD.

Słowa kluczowe

rehabilitacja, robotyka, chód, mózgowe porażenie dziecięce

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Introduction

Cerebral palsy (CP) is defined as a group of disorders that affect mobility and posture with heterogeneous impairments such as muscle tone alternation, reduced selective motor control, joint contracture, postural control impairment and weakness of muscles [1]. Basal ganglia - brainstem (BG-BS) system appears to be required for the automatic regulation of posture muscle tone [2]. Children with CP do not have muscle tightness and skeletal abnormalities at birth, but over time, loss of control over the BG-BS system may lead to excessive spasticity that causes shortening of the muscles and soft tissues and then fixed skeleton abnormalities [3]. Muscle strength is one of the determinants of independent walking in CP children [4].

Lokomat, one of RAGT devices, provides repetitive task-specific motor training and modulates afferent input to spinal cord to generate rhythmic gait patterns that may be transformed to overground walking [5]. The intensive repetitions of the rhythmic stepping during RAGT stimulates neuroplasticity and possibly leads to brain reorganization [6] by facilitating cortical activities associated with motor control of walking. There is evidence that the best activation of locomotor network has been observed during RAGT compared to a treadmill walking and to a conventional over-ground gait training [7].

RAGT with Lokomat is known to be beneficial to regaining the gait balance by improving kinematics of the lower limbs [8] and to improving functional capability and locomotor function for daily activities in CP children [9]. However, the effectiveness of RAGT in children with CP is still controversial [10]. Most of the studies report heterogenous frequencies of RAGT sessions from 2 to 5 times per week.

To date, this is the only research that investigated the effectiveness of training frequency of RAGT with Lokomat on the functional gait parameters in CP children.

Materials and methods

In our study, each group requires 64 participants (effect size d = 0.5, alpha error probability = 0.05, Power = 0.8) by G*Power estimate. 14 children, with diplegic CP, aged 6-14 years, approximately 10% of estimate, were enrolled in this study as a preliminary pilot trial. All participants were enlisted from Zayed Higher Organization for People of Determination in the United Arab Emirates between July and September 2022. Prior to their involvement, all participants willingly provided written informed consent. Inclusion criteria were children with spastic diplegia; being able to walk independently with or without walking aids on at least 10 meters; classified as level I, II and III in the gross motor function classification system (GMFCS). Children were excluded if they had received botulinum toxin injections or had undergone surgical intervention within the last year or had participated in another Lokomat training regime within the last 3 months. In addition, children were excluded if they have: (a) fixed contractures and/or with bone instability; (b) seizure disorder that is not controlled by medication (if on medication, must not have had a seizure in the last 12 months); (c) baclofen infusion pumps in situ.

Randomization was performed into two groups using computer generated sequencing. To ensure balance between two groups, GMFCS level (I, II and III) were used as the stratified variable. The study employed a single-blind design, ensuring that participants were unaware of their group assignment. Additionally, the assessors responsible for measuring outcomes conducted their evaluations without any knowledge of the participants' group affiliations.

In this study, the feasibility was assessed by measuring the recruitment rate, completion rate, adherence rate, and conducting a safety assessment, all of which were done concurrently with the evaluation of the intervention outcomes.

Further studies using a big sample size will be needed to clarify the feasibility. The study received ethical approval from the Research Ethics Committee of University of Sharjah (Reference number: REC-21-06-22-01-S). The study was registered on ClinicalTrials.gov (Identifier: NCT05412485).

Outcome measures

Gait functions were measured by walking distance (6-minute walk test, 6MWT), speed (10-meter walk test, 10MWT), balance (Pediatric balance scale, PBS), and quality of gait (Edinburgh visual gait score, EVGS). In addition, Gross motor function measure-88 (GMFM-88) dimension D (standing) and E (walking, running, and jumping) were assessed. Assessments were done twice, before and after the RAGT period. Also, the feasibility was assessed by the safety and the rates of recruitment, compliance, and adherence.

Interventions

Treatment group (TG) received 24 sessions of Lokomat (four sessions per week) while control Group (CG) received twelve Lokomat sessions (two sessions per week) for six weeks. Each session lasted 30 minutes. The timeline of the study protocol is shown in Fig 1. Physiotherapists, who were certified for Lokomat training, provided RAGT to participants in this study. Lokomat recommendations [11] have been followed during the interventions.

The intensity of training was increased gradually by changing gait speed, body weight support level and the guidance force of Lokomat according to the ability of the participant. The physiotherapist was always present to secure safety, follow the progression, and raise the participant’s awareness to maintain proper posture and correct patterns of the gait. Virtual reality games were used to motivate the participants with verbal encouragement by the therapist.

Data analysis and statistical method

The statistical analyses were done using SPSS 28 (IBM-SPSS version 28, Chicago, IL). Difference between groups at baseline was tested by independent t-test or Mann Whitney U test or Fisher's exact test. The normality of each variable was tested using Shapiro-wilk Test. To analyze the difference between groups before and after RAGT. A paired t-test or Wilcoxon’s signed-rank test were used. The statistical significance level was set at $p< 0.05$ for all tests.

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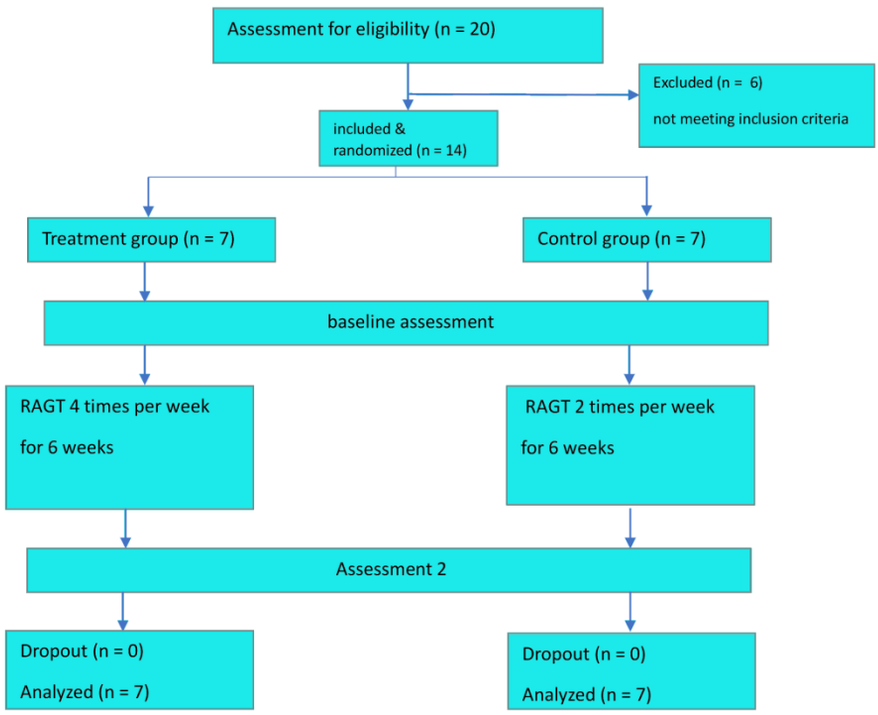

Figure 1. Flow chart of the study (RAGT: Robotic assisted gait training)

Result

20 patients were initially screened and 14 of them were eligible. Therefore, our recruitment rate was 70%. All 14 participants, representing 100% of the sample, completed the intervention phase and the outcome measurement. No participants showed lack of compliance with or intolerance to either frequency regimen. The study adherence rate was consistent for both TG and CG. Participants attained 100% of the required visits without missing appointments. Among fourteen CP children, seven were assigned to TG and the other seven to CG. No significant differences were found between groups for the age, height, weight, and the level of GMFCS distribution (Table 1A). At the baseline, functional characteristics of the participants for GMFM D, GMFM E, balance (PBS), walking distance (6MWT) and speed (10MWT) and the quality of gait (EVGS) did not significantly differ between groups (Table 1B). No safety issues occurred, and no side effects were reported by the parents or the participants during the intervention period.

Table 1A. Clinical characteristics of the study participants at the baseline

Variable	Treatment Group, n = 7	Control Group, n = 7	P value
Gender [n]			
Male	5 (71.4%)	6 (85.7%)	
Female	2 (28.6%)	1 (14.3%)	
Age [years]	9 (± 2.83)	10.4 (± 2.99)	0.337
Height [cm]	128.4 (± 19.1)	130 (± 26.2)	0.900
Weight [kg]	33.3 (± 13.9)	34.7 (± 19)	0.875
GMFCS level [n]			
I	1	1	
II	4	4	
III	2	2	
Walking aids			
None	3	4	
Walker	4	2	
Crutches	0	1	

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Table 1B. baseline functional characteristics of the participants

Variable	Treatment Group, n = 7	Control Group, n = 7	P value
GMFM D [%]	42 (27.37)	40.3 (24.66)	0.805
GMFM E [%]	32.9 (28.65)	34 (23.6)	0.898
PBS [score]	17 (17.3)	20 (16.76)	0.607
10MWT [m/s]	0.9 (0.69)	0.85 (0.41)	0.839
6MWT [m]	194 (116.2)	174.76 (98.85)	0.949
EVGS Right [score]	14.86 (4.33)	18.43 (4.89)	0.174
EVGS Left [score]	14.57 (4.077)	17.7 (4.23)	0.182

Values are presented as mean (± SD) except gender and GMFCS level and walking aids.
*Abbreviation: GMFM D, Gross motor function measure-88 dimension D; GMFM E, Gross motor function measure-88 dimension E; PBS, Pediatric balance scale; 10MWT, 10-meter walk test; 6MWT, 6-minute walk test; EVGS, Edinburgh visual gait score; GMFCS, gross motor function classification system. *p < 0.05 by independent t-test or Mann Whitney U test (for continuous variables) or Fisher's Exact test (for categorical data).*

There were significant therapeutic effects in GMFM D and E, balance, walking distance, and the quality of gait in both groups (Table 2, Fig 2-4). Only TG showed a significant improvement in walking speed measured by 10MWT. The quality of gait, as measured by EVGS, improved more in TG than in CG.

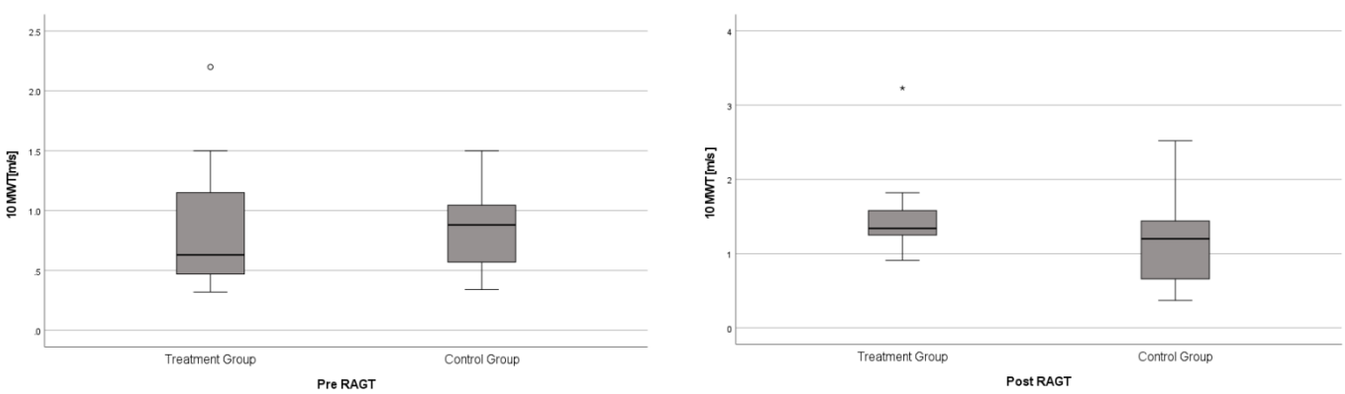

Figure 2 Post-intervention median difference between treatment group and control group for 10-meter walk test

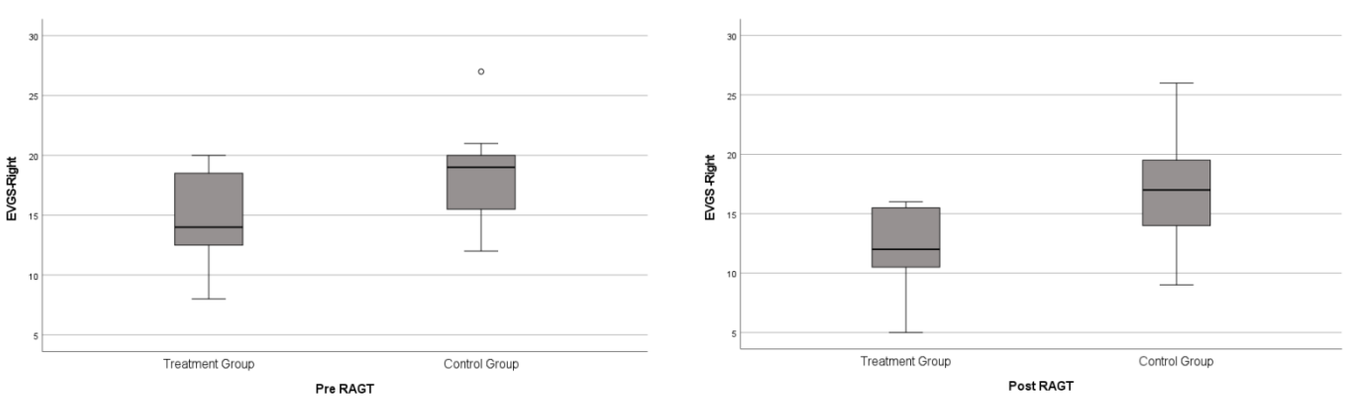

Figure 3 Post-intervention median difference between treatment group and control group for Edinburg visual gait scale (right sided)

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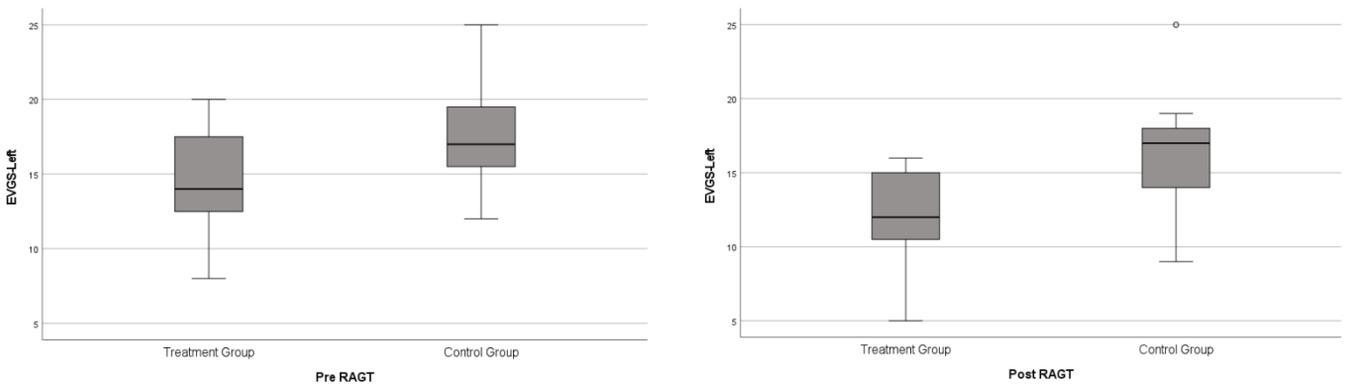

Figure 4 Post-intervention median difference between treatment group and control group for Edinburg visual gait scale (left sided)

Table 2. Differences within groups pre and post RAGT intervention

Outcome measure	Treatment group			Control group		
	Pre	Post	P value	Pre	Post	P value
GMFM D	42 (± 27.37)	56.77 (± 30.88)	0.018*	40 (± 24.66)	51.88(± 25.35)	(± 5.26)
GMFM E	32.9 (± 28.65)	43.44 (± 29.36)	0.018*	34 (± 23.60)	41(± 26.86)	0.018*
PBS	17(± 17.30)	22.9 (± 20.22)	0.027*	20 (± 16.76)	23.3(± 17.80)	0.018*
10MWT	0.9 (± 0.69)	1.59 (± 0.77)	0.001*	0.85 (0.41)	1.18(± 0.74)	0.017*
6MWT	194 (± 116.27)	232.2 (± 131.90)	0.018*	174.76(± 98.85)	193.7(± 116.20)	0.053
EVGS Right	14.86 (± 4.33)	12.14 (± 3.97)	< 0.001**	18.43 (± 4.89)	17 (± 5.69)	0.018*
EVGS Left	14.57 (± 4.08)	12 (± 3.83)	0.002*	17.7 (± 4.23)	16.43	0.025*

*Values are presented as mean ± SD. Abbreviation: Pre RAGT: pre-Robotic assisted gait training; GMFM D, Gross motor function measure dimension D; GMFM E, Gross motor function measure dimension E; PBS, Pediatric balance scale 10MWT,10-meter walk test; 6MWT,6- minute walk test; Edinburgh: Edinburg visual gait scale, *p < 0.05 by paired t-test or Wilcoxon's signed-rank test*

Discussion

This study aimed to investigate the effects of RAGT in different frequencies among children with diplegic CP. We hypothesized that RAGT with the increased frequency (4 times a week) will result in greater improvements than RAGT with the common frequency (2 times a week).

There are few previous studies on the efficacy of RAGT with Lokomat in children with CP [8,12,13] and the existing evidence for the effect of RAGT still remains inconsistent [15]. The application protocols for RAGT such as the number, the frequency, and overall duration of RAGT vary to a greater extent up to date [8, 12, 14, 16]. Interestingly, the most studies with a duration between 4 to 6 weeks reported positive results [8, 17]. In our study, after 6 weeks of RAGT, both groups showed improved GMFM, balance, walking distance, and the quality of gait. Specifically, gait speed and the quality of gait improved more in TG, who received more frequent interventions, than in CG.

GMFM

There were significant differences in GMFM scores between pre- and post-intervention in both groups, confirming findings from previous studies [8, 18, 19]. In a previous study, the improvement in GMFM D and E after RAGT was sustained for 3 months following a 5-week period in CP patients of a similar age range to our participants [20]. However, there are some studies that reported non-significant changes after RAGT [16, 17]. A recent study reported that 0.3%-4.9% is the minimal clinical significance difference (MCID) in the GMFM E [21], while another study showed that 2.6% of the score to be MCID [22]. Our results showed greater differences than suggested MCID, an average of 10.51% and 6.72% for TG and CG in GMFM E. The proposed MCID for GMFM D is 0.8%-5.2% according to previous studies [21,22]. Our study score of GMFM D showed an average of 14.65% and 11.6% for TG and CG which is higher than the suggested MCID.

The improvement in GMFM score in the participants in our study was significant in both groups. A previous study reported that GMFM score improved in children who received RAGT only, on the contrary, children who received conventional rehabilitation showed no significant improvement [14]. In our study, participants were excluded if they had participated in another

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Lokomat training regimen within the past 3 months and they completely discontinued any other physical therapy interventions prior to participating in our study. Therefore, GMFM improvement in our study could be related to the efficacy of the RAGT intervention regardless of the frequency of sessions.

Gait speed

Gait speed was measured by a 10-minute walk test. Our results showed the increased walking speed only in TG after RAGT. There are inconsistent results in walking speed after RAGT among CP patients in the previous studies though the majority of the previous RAGT studies showed improvement in walking speed [14, 17, 23, 24]. There are some studies reporting only slight increase or no change in walking speed [9, 25]. A study reported that the walking speed was increased significantly after RAGT for 4 weeks with a high frequency (5 sessions per week) [14]. An increase in walking speed in our TG might be associated with higher frequency as this previous study found. It is known that the repetitions in gait training in a safe environment improves both stride length, and cadence, thus, it will lead to an increase of walking speed as there is linear relationship between speed, stride length and cadence [26 - 27]. Our findings on walking speed suggest that a minimum frequency and quantity of gait training may be necessary to achieve functionally meaningful changes in gait speed.

The quality of gait

The quality of gait was measured by the Edinburgh visual gait score (EVGS). RAGT is the most intensive gait training method in terms of its high repetition of stepping within a limited time without a risk of fall. It has been reported that more repetition of gait training could contribute to enhanced neuroplasticity and motor re-learning eventually to restoration of gait functions [28, 29]. In our study, TG showed greater improvement than CG, with both groups experiencing significant improvements in gait quality. TG, having received double the amount of gait training, may have experienced more substantial improvements in gait quality.

To our knowledge, there is no previous study that measured the quality of gait in CP using EVGS after RAGT. One study that used the motion analysis system reported similar positive outcome after RAGT as CP children developed new gait strategies associated with greater motor improvement of lower limb in comparison with daily physical therapy alone [8]. Other studies that measured the quality of gait by the Gait Gillette index, and the gait symmetry index, found no significant differences after RAGT [30]. To date, there is insufficient evidence to support the effect of RAGT in altering the quality of gait with EVGS. A previous study proposed that 2.4 is the numerical value of MCID for the EVGS [31]. In our study, the EVGS score was improved greater than MCID only in TG.

Gait balance

Gait balance was measured using the Pediatric Balance Scale (PBS). In this study, PBS scores significantly improved in both TG and CG following RAGT. Few previous studies have evaluated the effectiveness of RAGT using PBS. A study reported improved PBS among spastic CP children post RAGT (3 times per a week for 10 weeks) [32]. Another previous study reported a similar result with the improved balance that lasted three months after RAGT [33]. The range from 3.66 to 5.83 is the numerical value of MCID for the PBS [34], the PBS improvement in our TG was 5.9 points which is greater than MCID suggested in the previous study.

Walking distance

In our study, walking distance was measured by a Six-minute walk test (6MWT) and increased in both TG and CG. The improvement in TG was two times greater compared to CG. Some previous studies found RAGT is more beneficial to 6MWT than other physiotherapy interventions, for example, the standard physiotherapy rehabilitation method [33], RAGT combined with another physiotherapy intervention [16], and treadmill training [17]. A recent study determined that the MCID of change in walking distance in 6MWT was 6–23 m with a discrete range of 4–28 m for participants classified as GMFCS I-II and a range of 9–19 m for those with GMFCS III [21]. Only TG in our study showed greater increase than MCID.

Conclusion

To our knowledge, our study is the first randomized pilot study to investigate the feasibility and effect of the increased frequency of RAGT in isolation with other therapies in children diagnosed with diplegic CP. We found improvement in most of the outcomes in both groups. Especially, walking speed and the quality of gait have been improved greater in TG (RAGT 4 times a week) than CG (RAGT 2 times a week). Further research is needed with a bigger sample size in different age groups of CP.

Study limitation

The small sample size is the limitation of this study. Intervention and data collection were conducted during the COVID-19 pandemic with precautionary measures. It was challenging for participants to attend a full period of intervention for 6 weeks with precautionary measures. Further analyses are required to underline the feasibility and effectiveness of increased frequency of RAGT in CP patients with a bigger scale randomized controlled trial. Participants only received RAGT at a different training frequency, thus, the possibility that an additional 60 min of training of TG could influence the results of our study cannot be excluded.

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