The effect of treadmill training in children with Cerebral Palsy: A Systematic Review of Randomised controlled trials

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Abstract: This study aims to investigate the effect of treadmill training on gross motor skills and gait parameters in children with Cerebral palsy.A review of Randomised controlled trials was performed usingPreferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) methodology. Six databases Embase, AMED, Medline, CINAHL, PEDro and Web of Science were searched. Data were extracted and assessed using Cochrane Collaboration's tool and PEDro scale. Four studies were included, with a total of 100 participants. The risk of bias across studies was considered low in most domains. The studies received a score ranged from four to eight on PEDro scale. Two studies reported a statistically significant improvement of gross motor skills. Gait speed improved statistically after treadmill training in one trial. No serious adverse effects of treadmill training were reported. The results provide limited evidence on the positive effect of treadmill training on motor development and gait parameters. Further research should confirm this improvement and the size of it clinically also the long-term effects.

Key Words: Foot Position, Knee Moment, Sit To Stand

Introduction

Cerebral palsy is a life-long condition characterised by mobility and postural abnormalities as a result of a static disorder in the brain, which is usually diagnosed early in life [1,2]. A recent meta-analysis demonstrated that the prevalence of CP has

been stable at 2.11 per 1,000 live births during the last 30 years [3,4].

CP is considered to be the most common cause of childhood motor disabilities, which have a huge impact on the quality of life, health, education and ADL participation of this population and their families [5,6]. The Gross Motor Function Classification System (GMFCS) scale is a five-level scale used to classify patients with motor dysfunction based on the functional abilities [5].

Motor dysfunction in cerebral palsy is a combination of neuromuscular and musculoskeletal problems that interrupt the gross and fine motor functions [7]. Consequently, individuals with CP experience a delay in the development of skills such as postural control, balance and movement. With regard to mobility, such as walking, one study with a large sample size (n=451) that was conducted at four sites in the USA concluded that 58.2% of children with CP walk independently, while 11.3% walk with the support of a walking aid and 30.6% are unable to walk [8]. On this basis, a relatively high proportion (around one-third) of children with cerebral palsy are unable to walk, which adversely impact on functional independence and highlights the need for more therapeutic choices to address this disability. The communication, social life and the quality of life of children with CP who walk independently are better and able to be a part in social activities compared with those who need walking assistance or non-ambulatory transport (GMFCS level V) [9].

Whilst there is no ultimate treatment for CP, different therapy programmes share the goal of improving the motor function level of patients with CP and addressing the accompanying abnormalities and secondary deficits. Body weight-supported treadmill training (BWSTT) is one of the most popular interventions that clinically implemented for this population [10]. Treadmills could enable patients to practice early indoor gait training also uphill walking, which enhance endurance,

physical fitness, muscle strength and motor skills [10,11,12].

An additional potential advantage of BWSTT was reported by Kurz et al. [13] who found that body weight supported training could enhance the process of neuroplasticity in children with CP. This occurs as a result of the sensorimotor experience during body-weight supported system, which eventually leads to the emergence of new neural pathways able to carry out the functions of the impaired areas of the brain. Some studies believed that the improvement in gait speed as well as muscle strength after body weight supported training was related to these neural changes [13,14]. This advantage might be gained from all types of treadmill as a result of the task-oriented and repetitive movement they provide. Previous research suggested that treadmill training might have a positive impact on overall gross motor function and gait velocity; also it is a safe choice for gait rehabilitation in children and adolescents with CP [15,16].

The effect of treadmill training on gait and gross motor skills has been widely studied. One quasi-randomised controlled trial compared the effects of six-week treadmill training at home on patients with CP to those of conventional physiotherapy. It was found that although both groups showed significant improvements in functional outcomes, the intervention group presented these improvements earlier than the control group during the different assessment points (pre, post-intervention, 1-month and 4-month follow-up) [17]. This earlier attainment of improvements could have a positive economic effect for families and communities if less time is needed to achieve a specific goal. Utilising a treadmill clinically or at home may be preferable to ground walking, as only limited space is required and allow for early patient participation and gait training [18].

However, critics argued that body weight-supported treadmills are not more effective or superior to the same amount of over-ground gait training [19]. They suggested

that training with these devices does not emulate the real-life environment of steps, uneven surfaces and dual tasking, which over-ground walking at home or in the community can offer. A systematic review in 2009[15] evaluated the effects of treadmill training on gait velocity and motor function for patients with CP. No decisive conclusion was reached as to whether BWSTT is effective for this population or not, due to the small total sample (n=48). Consequently, a type two error may have occurred, as the sample size in each study was small.

Although treadmill has found to be the second most studied intervention for children with CP [10], research that assess its impact is lacking and to the author's knowledge, no existing evidence in the form of systematic reviews that include a high level of research and provide definitive evidence for care providers and decision-makers has been found. In light of this, this paper presents a systematic review to investigate whether treadmill training could offer an effective choice to improve the functional level, particularly gross motor skills and gait parameters, for patients with cerebral palsy who are under 19 years old, and if this type of intervention has adverse effects on this population.

Materials and methods

This systematic review is according to the principles of the preferred reporting items for systematic reviews and meta-analyses (PRISMA) guidelines [20]. The electronic databases AMED, CINAHL, EMBASE, Medline, PEDro and Web of Science (ISI) were investigated. In order to enhance the efficiency of the electronic search, Keywords, MeSH-terms and their combinations were used based on the Population, Intervention, Comparison, and Outcome (PICO) model [21]. Keywords used were Cerebral palsy, treadmill, gross motor function and gait. Secondary searches included Reference lists of the included studies were screened for relevant trials. Finally, to minimise the risk of publication bias, unpublished studies and

theses were searched for from the following sources: ICTRP, metaRegister of Controlled Trials, ISRCTNR, and Open Thesis Database.

Articles were included if they are: Randomised controlled trials (RCTs) published in English or Arabic during the time span from 2000 to 2014 that investigate treadmill training effects on primarily the functional outcomes (measured by the Gross Motor Function Measure (GMFM-88 or GMFM-66)) as a primary outcome and at least one of the gait parameters as a secondary outcome in patients with bilateral CP (under 19 years). However, they were excluded if: treadmill training was used to assess the effect of the virtual reality technique or the studies were published only as abstracts or conference proceedings.

Titles of articles obtained though the literature search were read through by the first author. Then abstracts and full articles were read through independently by the three authors to determine whether criteria for inclusion were potentially met. Selection results from the three authors were compared, and disagreements were resolved by discussion.Review Manager 5.2 software [22] was used in the process of data extraction [23]. Data were extracted and organized based on patient, intervention, type of comparison, and outcome (PICO). The Cochrane Collaboration's tool [24] and the PEDro scale, which is a valid and reliable means of assessing the internal and external validity of RCTs [25,26], were therefore used to assess the quality of the included studies.

Through the process of data analysis, the authors of the included studies were contacted in the case of unreported means, standard deviations or effect size. If no response was received, the effect size and confidence intervals (CI) were calculated only for the studies that did not provide these values. To calculate the effect size and confidence interval, the mean change of each group was calculated firstly, if it was

not provided, by subtracting the pre-group mean from the post mean.

Secondly, the standard deviation of the mean change was calculated, if it was not provided, as described by Higgins and Green [24]. Finally, these values (mean change and standard deviation) and the number of participants were used to calculate the effect size and CI [27].

Results

A total of 576 references were identified. After duplicates were removed, the titles and abstracts of 395 references were screened and 346 were excluded for different reasons. The remaining 13 papers were screened for eligibility based on full text screening, of which nine were excluded due to different reasons as shown in Figure 1. The four included studies [28-31] were randomised controlled trials (RCTs) with a total number of 100 participants (86 participants after drop-outs).

The comparison of intervention characteristics such as the type of intervention, time period and intensity of intervention, treadmill speed and the percentage of body weight support across the studies revealed heterogeneous values that made it difficult to conduct a meta-analysis. A narrative synthesis of the findings of the four included studies was therefore conducted. Results are summarised in Table 1.

Even though Bryant et al. [28] had three intervention groups (a treadmill group, a bike group and a control group), only the comparison of interest (between the treadmill group and control group) was reviewed.

The assessments were carried out pre- and post-treatment, whilst only two studies conducted additional follow-up assessment [28,29]. All studies measured functional outcomes using the Gross Motor Function Measure (GMFM). A total score of GMFM-88 was reported in two studies [29,30], compared to GMFM-66 in the other two studies [28,31]. Regarding the sub-scores of GMFM, dimensions D and E were measured only in Bryant et al. [28]

and Su et al. [31]. All studies [28-31] reported whether treadmill training had any adverse effects.

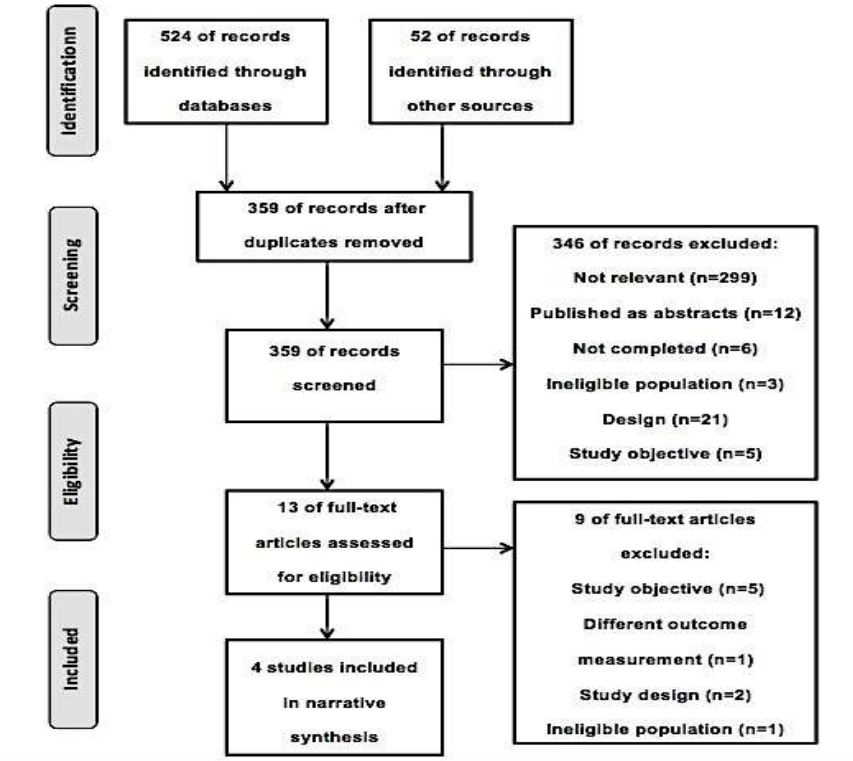

Figure 1: PRISMA flow diagram [20]

The risk of bias assessment with the Cochrane collaboration's tool in all studies revealed low risk in Selection, performance, attrition and reporting bias. However, detection bias was reported to be at high risk in only 2 studies [29,31]. Other potential source of bias was unclear in Bryant et al. [28] since some participants did not attend the assessment without clear reasons. Also the provision of treatment at home in Johnston et al. [29], where parents controlled the session, revealed a high risk of potential bias, particularly in terms of the certainty of treatment intensity and child adherence records.

The methodological quality of three studies [28,30,31] found to be good, scoring seven, eight and six out of ten on the PEDro scale respectively. Johnston et al.[29] scored four, which was considered to be low quality (Table 2). In addition, the effect size and confidence interval were

calculated for two studies [28,29] since they were not provided (Table 3).

Table 1: Characteristics of included studies

Interventions	Participants	Methods	Outcomes
- EG: treadmill training with partial body weight support - CG: Physiotherapy (stretching, exercises on a mat, standing or swimming) - 6 weeks, 30 minutes, 3x/w	24 participants, Country: UK, Age (8-17 ys), GMFCS: IV-V, Dyskinetic (n= 14) Spastic (n= 21)	RCT	**Primary:** - Motor function skills (GMFM: 66; 88E; 88D).
- EG: Treadmill training exercise programme (without body weight support) with stretching - CG: Mat activities; balance; gait training; functional gross motor activities - 12 weeks, 45 minutes, 3x/w	22 participants, Country: Greece, Age (13-19), GMFCS:I-II-III, Spastic CP (Diplegia, Tetraplegia)	RCT	**Primary:** - Gross motor function skills (GMFM) - Self selected walking speed (10-M walk test) **Secondary:** - Spasticity (Modified Ashworth Scale)
- EG: Treadmill training exercise programme (without body weight support) with stretching - CG: Mat activities; balance; gait training; functional gross motor activities - 12 weeks, 30 minutes, 5x/w	34 participants, Country: USA, Age (mean: 9 ys 6 months), GMFCS: II-III-IV, Spastic CP (Diplegia, Triplegia, Quadriplegia)	RCT	**Primary:** - Gait speed (3D motion analysis) **Secondary:** - Cadence and stride length (3D motion analysis) - Gross motor function skills (GMFM) - Physical function (Pediatric Outcomes Data Collection Instrument) - Strength, spasticity and motor control (computerised dynamometer)
- EG: Partial body weight support treadmill training - CG: conventional gait training - 12 week before crossover, 10 weeks washout period then 12 weeks after crossover, EG: 25 minutes, 2x/w, CG: 30 minutes, 3x/w.	10 participants (data taken from each twice: total 20 participants), Country: Hong Kong, Age (8-14 ys), GMFCS: II-III-IV-V	RCT: Two-period crossover	**Primary:** - Gross motor function skills (GMFM-66)

RCT: Randomized controlled trial, CP: cerebral palsy, GMFCS: Gross Motor Function Classification System, CG: Control group, EG: Experimental group, GMFM: Gross Motor Function Measure, x/w: times per week

Study ID	Bryant et al. [28]	Chrysagis et al. [30]	Johnston et al. [29]	Su et al. [31]

Table 2: PEDro scores across included studies

Study ID:	Bryant et al. [28]	Chrysagis et al. [30]	Johnston et al. [29]	Su et al. [31]
Random allocation	Yes	Yes	Yes	Yes
Concealed allocation	Yes	Yes	Yes	Yes
Baseline comparability	Yes	Yes	No	Yes
Blind subjects	No	No	No	No
Blind therapist	No	No	No	No
Blind assessors	Yes	Yes	No	No
Adequate follow-up	Yes	Yes	No	Yes
Intention-to-treat analysis	No	Yes	No	No
Between group comparison	Yes	Yes	Yes	Yes
Point estimates and variability	Yes	Yes	Yes	Yes
Total score **(/10)**	**7**	**8**	**4**	**6**

Two studies [30,31] reported a statistically significant improvement (p0.007, p<0.01) in total gross motor function and the effect size ranged from small to large (d: 0.38 and η2p: 0.86 respectively) after 12 weeks of treadmill training compared to conventional physiotherapy. Bryant et al. [28] reported an improvement that was not significant in comparison to the control group.

With respect to dimensions D (standing) and E (walking, running, jumping), the results indicate that treadmill intervention was effective at improving standing in children with CP, with a statistically significant effect and large effect size found in two studies (p0.04, p<0.05) [28,31]. These studies also found an improvement in walking, running and jumping skills, although this was only significant with a large effect size in one study (p<0.05) [31].

As secondary outcomes, only two included trials studied gait speed [29,30] and only one trial studied cadence and stride length [29]. Lastly, step length was not measured in the included studies. The results indicate that there is a trend towards improvement for all gait parameters (speed, cadence, stride length). However, this improvement was only statistically significant (p0.000) with large effect size for gait speed in one

trial after treadmill training [30]. The statistical significant improvement in gait speed was maintained for additional follow-up (16 weeks). The results of this review concluded that treadmill training, in particular BWSTT and treadmill training without a body-weight supported system, is safe and feasible. Only one trial reported minor and insignificant side effects after using treadmill training that did not require any intervention.

Discussion

This review found only four RCTs that assessed the effectiveness of treadmill training compared to conventional physiotherapy on children and adolescents with CP from 2000 to 2014. Treadmill training has long been used for physiotherapy and rehabilitation purposes. It is considered to be the most second popular intervention for the cerebral palsy population [10], although no strong evidence on its efficacy is available and no review was able to draw a clear conclusion due to the small number of included studies with small sample size and low quality trials.

Chrysagis et al. [30], Su et al. [31] and Bryant et al. [28] found an improvement in total gross motor function. However, Chrysagis et al. [30] and Su et al. [31] were the only who reported this improvement as statistically significant with effect size ranged from small to large. However, the confidence interval of the effect size in Chrysagis et al. [30] was relatively wide and included zero, which is not clear if the effect is really present, since zero means no effect and the wide CI could be due to the small sample size or the variability of data [32,33]. The insignificant improvement that carried out only in Bryant et al. [28] was not retained at 12 and 18 weeks follow-up assessment. This insignificant improvement could be in relation to the training period, which was only six weeks compared to the other studies that lasted for 12 weeks. For the fourth trial [29], which had the highest training intensity of all the studies and was the only one to be conducted at

participants' homes, no improvement was found within or between groups. However, when the presence of clinical change was calculated, conventional physiotherapy was reported to result in better clinical changes in GMF skills than in the treadmill group. This could explain the negative effect size (-0.06) as a consequence of the better results of the control group.

Mattern-Baxter [34] supports these results by finding a general improvement in gross motor function. In addition, the results of Mutlu et al. [35] were consistent with Mattern-Baxter [34] with regard to the general trend of improvement in motor function; however, this improvement was not statistically significant. In contrast, Valentin-Gudiol et al. [36] and Valentin-Gudiol et al. [37] found no effect of treadmill training on gross motor function. One prospective study was found that 12 weeks of treadmill training improved GMF, particularly standing, walking, running and jumping which is consistent with the findings of this review [38]. However, this study lacked randomisation, with participants starting two 60-minute physiotherapy sessions weekly for eight weeks before starting treadmill training, which was provided only once per week. Consequently, this raises the question of whether the reported effects are caused by the treadmill training or the conventional physiotherapy.

Although the conclusion of Mattern-Baxter [34] and this systematic review supports that treadmill training is generally effective in enhancing gait parameters, particularly gait speed, Valentin-Gudiol et al. [36] and Valentin-Gudiol et al. [37] found no effect of treadmill training on gait parameters. Further research is required to elucidate the effects of treadmill training on cadence and stride length.

The treadmill training is a safe choice for gait rehabilitation. Bryant et al. [28], Chrysagis et al. [30] and Su et al. [31] stated that no adverse effects of treadmill training on participants were reported throughout the trial period. However, three

participants in the treadmill-training group in Johnston et al. [29] experienced knee pain and a blister under the ankle orthoses. generaly, these adverse incidents were considered insignificant and did not require intervention. A systematic review by Willoughby et al. [15] stated that partial BWSTT is safe and feasible to use as a gait training method for children with CP. Moreover, Borggraefe et al. [39] reported that robotic assisted treadmill training (RATT) is safe to use with children and adolescents. Adverse effects ranged from mild to moderate and included skin erythema and muscle and joint pain. There were no severe side effects for those who interrupted the continuation of the treatment. This systematic review did not find RCTs that investigated the effect of robotic-assisted treadmill training on gross motor skills, which highlights the need for high quality trials to study RATT since the increase use of this devise for neurological patients without solid evidence.

Despite the fact that three out of the four studies calculated the sample size and power analysis, the small sample size could lead to sampling bias and compromise the results in which it is not possible to detect a small amount ofimprovement that is clinically important.**In conclusion,** treadmill training might have a positive impact on gross motor development and gait speed in children and adolescents with cerebral palsy. However, the improvements are not retained for a long time and it has not yet been definitively determined whether treadmill training is clinically superior to conventional physiotherapy. Although not conclusive, this review does provide a choice and modality for physiotherapists to use throughout the long-standing rehabilitation journey of the cerebral palsy population without serious adverse events. Future research should also compare high-intensity and low-intensity treadmill training. Consequently, further research, randomised controlled trials with a large sample size and combining results in

a meta-analysis are all essential to provide more confidence and power regarding the evidence.

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Table 3: *P* value and effect size [95%CI] of primary and secondary outcomes.

Outcome	GMFM	GMFM-D	GMFM-E	Gait Speed	Cadence	Stride length
Studies No.	4	2	2	2	1	1
Bryant et al. [28]	Pre: $p>0.05$ Post: $p>0.05$ *d*:0.30 [-0.6 to 1.19]	Pre: $p>0.05$ Post: $p0.04$* *d*: 0.98 [0.05 to 1.9] Follow-up: significant decline $p0.04$	Pre: $p>0.05$ Post: $p>0.05$ *d*: 0.48 [-0.42 to 1.4]			
Chrysagis et al.[30]	Pre: $p0.673$ Post: $p0.007$* *d*: 0.38 [-0.50 to 1.26]			Pre: $p0.562$ Post: $p0.000$* *d*: 1.13 [0.19 to 2.07]		
Johnston et al. [29]	Pre: $p=$ not reported Post: $p0.66$ *d*: -0.06 [-0.83 to 0.71]			Pre: $p=$ not reported Post: $p>0.05$	Pre: $p=$ not reported Post: $p>0.05$	Pre: $p=$ not reported Post: $p>0.05$
Su et al. [31]	Pre: $p=$ not reported Post: $p<0.01$* $\eta 2p$: 0.86 [not reported]	Pre: $p=$ not reported Post: $p<0.05$* $\eta 2p$: 0.54 [not reported]	Pre: $p=$not reported Post: $p<0.05$* $\eta 2p$: 0.57 [not reported]			

P value (difference between CG & EG) = 0.05 or less is significant, >0.05 is not significant. EG: experimental group, CG: control group. GMF: gross motor function. *: statistically significant improvement. $\eta 2p$: partial eta squared.*d*: Cohen's *d*.

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