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Anti-gravity treadmill training for children with cerebral palsy: A systematic review and meta-analysis

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Abstract--Background: Walking dysfunction in children with cerebral palsy (CP) contributes to significant limitations in participating properly in daily living activities. Various types of treadmills have emerged to address this obstacle such as the antigravity treadmill (AGT) which aims towards reducing the effect of gravity on its users. Aim: This systematic review examines the literature on the effectiveness of (AGT) on walking abilities in children with CP. Methods: Protocol registration (CRD42020164202) in April 2020 was followed by six electronic database searches for randomized clinical trials (RCTs), examining the effectiveness of AGT on walking and balancing abilities in children with CP. The included studies were assessed for quality using the Physiotherapy Evidence Database (PEDro) scale. Results: Three studies of good quality met the inclusion criteria. AGT was significantly associated with improved walking velocity and cadence, while stride length showed insignificant difference between groups (SMD= 0.07, 95%CI 0.06 to 0.08, $p < 0.00001$), (SMD= 12.29, 95%CI 9.58 to 14.99, $p < 0.00001$) and (SMD= 0.07, 95%CI -0.08 to 0.23, $p < 0.36$). Moreover, there was significant improvement in favor of AGT regarding anteroposterior, mediolateral, and overall stability (SMD= -0.47, 95%CI -0.59 to -0.35, $p < 0.00001$), (SMD= -0.37, 95%CI -0.48 to -0.25, $p < 0.00001$) and (SMD= -0.51, 95%CI -0.62 to -0.40, $p < 0.00001$) respectively. Conclusion: Research into the effectiveness of AGT for children with CP is in its preliminary stages; however, AGT appears to improve gait and balance in children with CP. Further RCTs are needed to draw clear clinical guidelines regarding AGT for children with CP.

Keywords---antigravity treadmill, cerebral palsy, children, AlterG.

Introduction

Walking is supposed to be one of the most important essential components of activities of daily living¹. Since children diagnosed with cerebral palsy (CP) have different forms of walking abnormalities with adverse consequences on their participation in home, school, and community, the ultimate goal of rehabilitation for those children is to improve their quality of life². Motorized treadmills have long been used frequently in physical therapy practice, particularly for persons with neurological disabilities only when they have a sufficient walking stability³. Different unloading locomotor training approaches had been emerged to help individuals with CP to gain better walking performance, to facilitate the work of the therapist and prolong the duration of the therapy session such as Partial body-weight-supported treadmill exercise using harness system, Robotic-assisted

treadmill exercises , and anti-gravity treadmill exercises (Alter-G)⁴. Such therapy relies on motor learning concepts which admit that task-specific repetitive practices improve functional outcomes⁵.

The anti-gravity treadmill (AGT) which is known as lower body positive pressure support has been developed as a technological advancement for the body weight support; It works to lessen gravity's impact on the patient by providing positive pressure unit enclosing the patient in which the unweighing mechanism depends on Differential Air Pressure technology developed by NASA to create a lift force^{6,7}. This machine has the advantage over partial body-weight-supported treadmill exercise which causes a great discomfort driven from the harness which influences the continuity of the therapy as well as difficulty of accurately assessing the amount of active interaction between the patient and the robot during the robotic-assisted treadmill exercises⁸. Clinical trials examined (Alter-G) for children suffering from CP showed promising results as Alter-G provides a safe and easier rehabilitation training especially for those with poor muscle strength^{9,10}. It's also reported that Alter-G can improve the walking abilities, balance and muscle strength⁶. Up to our knowledge, the effectiveness of Alter-G anti-gravity treadmill has not been analyzed systematically on children with CP. So, this systematic review aims to examine the literature on the effectiveness of using Alter-G anti-gravity treadmill exercises on walking abilities in children with CP.

Materials and Methods

The protocol of this review was accepted for registration in PROSPERO on 28th April 2020 (CRD42020164202).

Search Strategy

A comprehensive systematic literature search was performed by two independent authors in the following electronic databases: PubMed, Scopus, Web of Science, Cochrane, OVID and Google Scholar to identify all relevant articles published from inception through July 2021. Various combinations of keywords were used in the search terms including "cerebral palsy" "antigravity treadmill" "AlterG Anti-Gravity Treadmill" "Lower Body Positive Pressure Treadmill". The included Search terms were exploded from Medical Subject Headings (MeSH) headings and synonyms. Additionally, a manual search through reviewing the reference lists and citation tracking of the included studies and previous relevant articles was conducted to identify papers that may have been missed in the electronic database searches.

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Inclusion and Exclusion Criteria

Studies were included if they fulfilled the following criteria: (a) Participants included in the studies were children or adolescents diagnosed with CP \leq 18 years old; (b) the study group received AGT; (c) the control group received conventional, placebo or any other treatment; or no treatment; (d) Measured outcomes: Primary outcome measures that are related to walking motor abilities (e.g. gait and balance). Secondary measures those are reflective to physiological and structural integrity (e.g. radiographic assessment); (e) Study design Randomized Clinical Trial (RCT) and Controlled Clinical Trial (CCT). The review was limited to studies published in peer-reviewed journals with full text available in the English language. Studies in vitro research, computer-modeled research, or studies published only in abstract or dissertation were excluded.

Study Selection

Initially, all the yielded citations were exported to Mendeley software which removes any duplicate. Title and abstract filtration were done by three authors independently to determine whether criteria for inclusion were met. Then the full-text filtration for the retrieved studies was conducted by two independent authors. Any conflict was resolved by the senior author.

Quality Assessment

The methodological quality of the included studies was assessed by two independent authors using the Physiotherapy Evidence Database scale (PEDro) quality assessment tool which has demonstrated evidence of reliability¹¹. This tool has 11 items, designed for rating the methodological quality of randomized trials. Each item, except for Item 1, contributes one point to the total PEDro score (range 0 to 10 points). The quality classified as high and low according to the total score; articles with more than six points are considered to be of high quality (6-7 is good and 8-10 is excellent quality), while a score less than six is identified as low quality (4-5 is fair and lower than four is poor quality¹².

Levels of evidence

Updated Guidelines for Systematic Reviews by van Tulder et al.¹³ were used by an independent author to categorize the evidence of the included studies into five levels according to the quality and consistency of studies Table 1. Consistency of outcomes was considered if all studies agreed in favor of study or control group while other studies are inconclusive, on the other hand inconsistency was considered in case of absence of high quality RCTs or conflicting results between two RTCs in which one clearly favors study and the other clearly favors control¹⁴.

Table 1
Levels of evidence (adapted and modified from van Tulder Et. al¹³)

Strong	Consistent findings among multiple* high-quality RCTs
Moderate	Consistent findings among multiple low-quality RCTs and/or one high-quality RCT

Limited	One low-quality RCT
Conflicting	Inconsistent findings among multiple trials
No evidence	No RCTs

Multiple* > 3 RCTs defined by author

RCT: Randomized Controlled Trials

Data Extraction

Data extraction from the included studies was done by two authors. Data included the following: 1 Details of the demographic characteristics of the study population including age, sex, and diagnosis; 2 intervention details including content, time and frequency of sessions, 3 outcome measures, 4 the results.

Statistical analysis

We analyzed data from the included studies using Review Manager (RevMan – version 5.2), The Nordic Cochrane Center, The Cochrane Collaboration, Copenhagen, Denmark), and Microsoft Excel 2010 (Microsoft Corp., Redmond, WA, USA). A formal meta-analysis was conducted for all outcomes if the data were sufficient. We expressed pooled continuous effect measures as the mean difference (MD) with 95%CI. We explored and quantified between-study statistical heterogeneity using the I² test. Because heterogeneity is reasonable, we used the fixed-effect model in all analyses. We considered 2-sided statistical analysis testing setting the α -error level at 0.05. Also, we tested the preferential effect of each study on the overall result of our meta-analysis by performing multiple sensitivity analyses removing one study in each step.

Results

The results of the initial literature search yielded 528 articles. After duplicate removal using Mendeley software, 389 references remained for title and abstract review. According to the predefined eligibility criteria, 18 studies were retrieved for full-text evaluation. Finally, a total of three RCTs^{4,15,16} were eligible for inclusion Table 2, they were published between 2014 and 2019. The reasons of exclusion were also presented in The PRISMA flowchart Figure 1. A total of 89 children and adolescents were included across the three studies, ranged from 6-14 years old, diagnosed with spastic diplegic CP in two studies (n=60)^{15,16}, and mixed population of both hemiplegic and diplegic children in the other one⁴. The physical ability score ranged between levels (I-III) on Gross Motor Functional Scale^{4,15,16}.

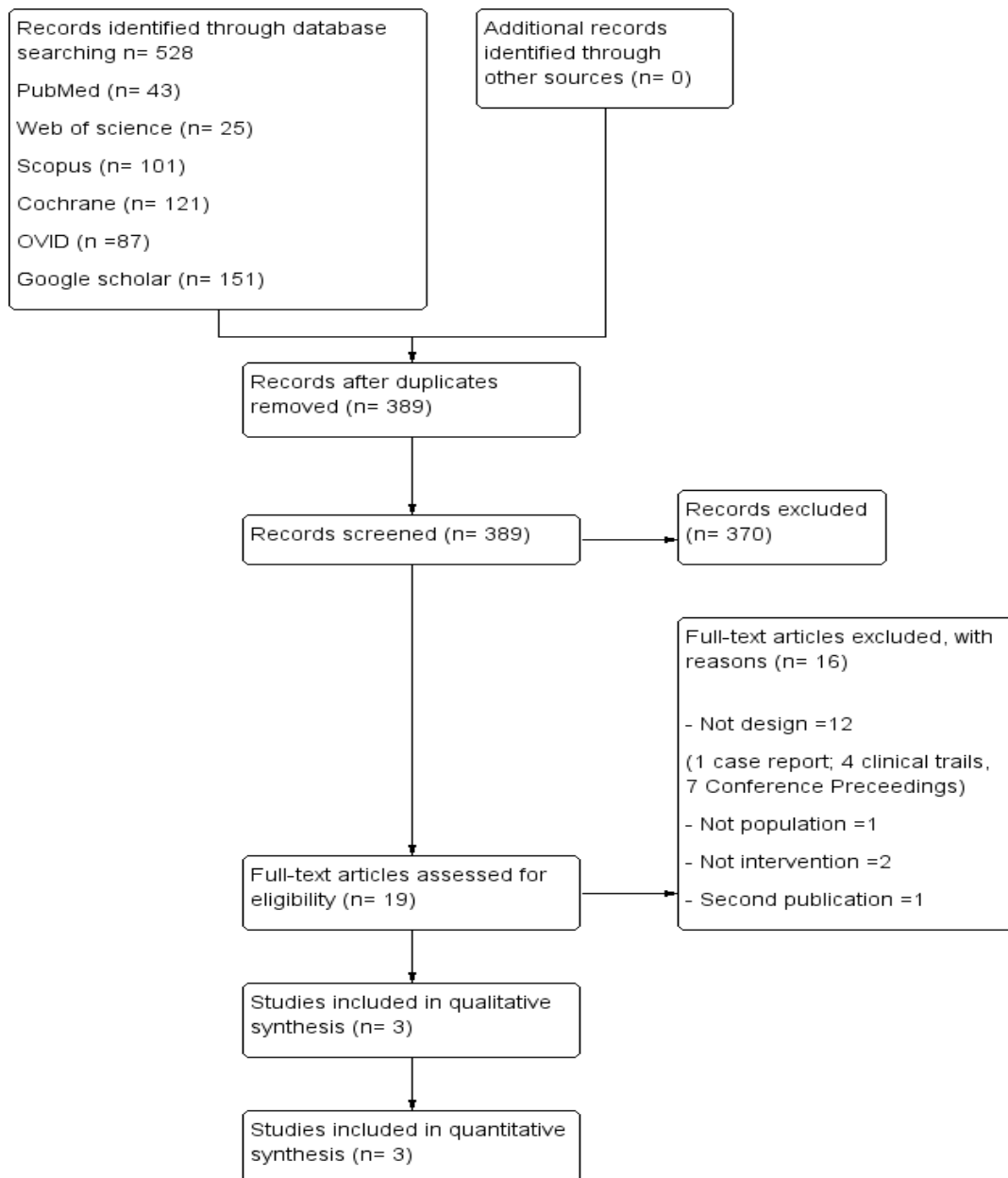


Figure (1): PRISMA flow chart

Intervention

The study group of the included studies (n=39) received AGT training. Duration of each session ranged between 20-45 min, while the frequency of sessions ranged between 3: 5 sessions per week. The duration of AGT training ranged between 1:3 months. Table 2 The mode of application of the AGT training intervention in the included studies contained a warm-up preparatory interval for 5:15 minutes^{15,16}, then body weight bearing support in the enclosed chamber adjusted to decrease

50-70% of the child's body weight bearing during gait⁴, with initial walking speed adjusted at 75% of child's comfortable walking speed according to his/ her walking pattern, weight, and endurance^{15,16}. With progression of treatment, the body weight bearing support decreased and a walking speed was increased. The control group received traditional physical therapy consisted of neuro-developmental treatment for abnormal reflexes inhibition, stretching and strengthening exercises of lower limb muscles, balance and gait training (n=30)^{15,16}, Partial Body Weight Supported Treadmill (PBWST) training intervention (n=10)⁴.

Table 2
Summary of included studies' characteristics

Author	Population			Intervention		Outcome Measure(S)	Main Results
	Number	Age	Diagnosis	Content	Parameters		
Aras ⁴ et al, 2018	Total :29 AGT group: 9 (6 M: 3 F) RATE group: 10 (6 M: 4 F) PBWSTE group:10 (6M:4 F).	6-14 Y	Spastic diplegic/hemiplegic (20:9) CP.	AGT group: anti-gravity treadmill exercises RATE group: robotic assisted treadmill exercises PBWSTE group: partial body weight supported treadmill exercises.	All groups 45 min five times a week for 4 weeks	1- 3D gait analysis (TS parameters) 2- 6 MWT 3- GMFM-66 (parts D&E) 4- Open-circuit indirect calorimetry.	-TS parameters showed significant improvement in RATE & AGT groups superior to PBWSTE group. -There was no statistically significant difference among the groups in terms of the GMFM-D, E and 6 MWT. -Significant decrease in oxygen consumption in AGT & RATE groups only.
Emara ¹⁵ 2014	Total :30 SG= 15 (9 M; 6 F) CG: 15 (9 M: 6 F)	6-8 Y	Spastic diplegic CP	SG: AGT training+ NDT P.T program CG: NDT P.T program	SG: (NDT P.T program + 20 min AGT training), 3 times per week for 3 months CG :1 hour, 3 times a week for 3 months	1- Balance assessment using Biodex stability.	-Significant improvement in favor of the SG in all measured variables of the dynamic balance test
El-Shamy ¹⁶ 2017	Total: 30 SG=15 (10 M: 5 F) CG= 15 (8 M: 7 F)	8-12 Y	Spastic diplegic CP	SG: AGT training+ Traditional P.T program CG: Traditional P.T program	SG: PT program+ 20 min 3 times a week for 3 months CG :1 hour 3 times a week for 3 month	1- Gait assessment using Pro-Reflex motion analysis system 2- Balance and fall risk assessment using Biodex balance system	Significant improvement in favor of the SG in all the measured parameters

ADC: Apparent diffusion Coefficient, AGT: Anti-gravity treadmill, CP: Cerebral Palsy, CG: Control Group, CST: Corticospinal Tract, DTI: Diffusion Tensor Imaging, F: Female, FA: Fractional Anisotropy, GMFM-66: Gross Motor Functional Measurement, M: Male, MD: Mean Diffusivity, 10 MWT: Ten-Meter Walking Test, min: minutes, 6 MWT: Six-Minutes Walking Test, NDT: Neuro-Developmental Treatment, O.T: Occupational Therapy, P.T: Physical Therapy, RD: Radial Diffusivity, SG: Study Group, TMS: Transcranial Magnetic Stimulation, TS: Temporospacial, TUG: Time-Up-and Go Test, Y: Years old.

Quality and level of evidence assessment

The PEDro score for methodological quality assessment and level of evidence scores of the included studies in this review are presented in Table 3. All of the three studies^{4,15,16}, were of high quality with mean PEDro score of 6.3. Level of evidence was moderate regarding the efficacy of AGT training on spatiotemporal gait parameters⁴, balance^{15,16}, energy consumption and functional gait assessment measurements⁴.

Table 3
Quality assessment

Study	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Total (0-10)
Ares et al. 2019	Yes	Yes	Yes	Yes	No	No	No	Yes	No	Yes	Yes	6
Emara et al. 2014	Yes	Yes	No	Yes	No	No	No	Yes	Yes	Yes	Yes	6
El-Shamy, 2017	Yes	Yes	Yes	Yes	No	No	Yes	Yes	No	Yes	Yes	7

Outcome Measures

Primary outcomes in our review are related to motor abilities including gait and balance. Energy consumption through open-circuit indirect calorimetry was considered as a secondary outcome (Protocol).

Primary Outcomes

Balance and risk of fall

Balance was assessed by the Biodex Balance System^{15,16}, while Elshamy assessed the risk of fall across participants¹⁶. Both studies revealed a significant improvement for both balance and risk of falls in the study group. These results elicit moderate evidence supporting the significant effect of anti-gravity treadmill training on balance of the participant. Both studies were combined on meta-analysis with a total population of 60. There was a significant improvement in favor of study group regarding anteroposterior, mediolateral and overall stability index as follows (SMD= -0.47, 95%CI -0.59 to -0.35, $p < 0.00001$), (SMD= -0.37, 95%CI -0.48 to -0.25, $p < 0.00001$) and (SMD= -0.51, 95%CI -0.62 to -0.40, $p < 0.00001$) respectively Figure (2,3,4).

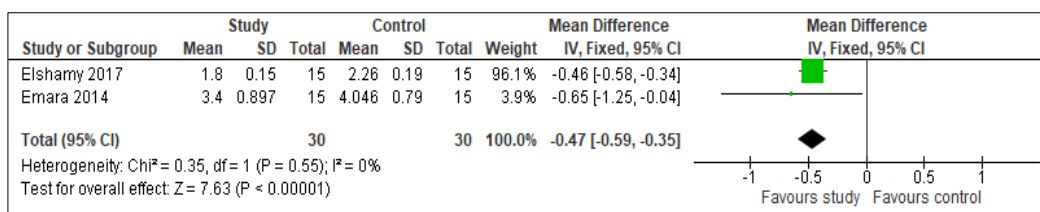


Figure (2): Comparison between study and control groups, outcome: 1.1 AP stability index.

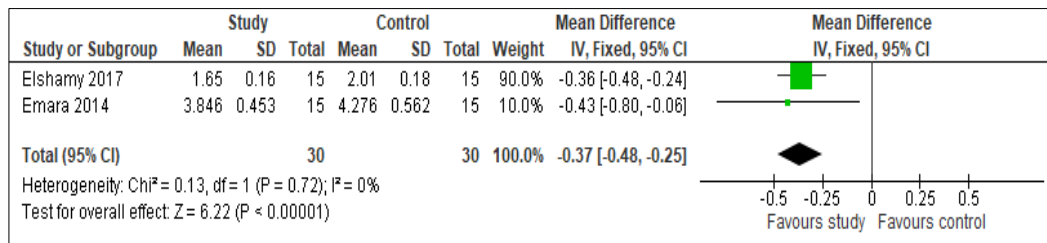


Figure (3): Comparison between study and control groups, outcome: 1.2 ML stability index.

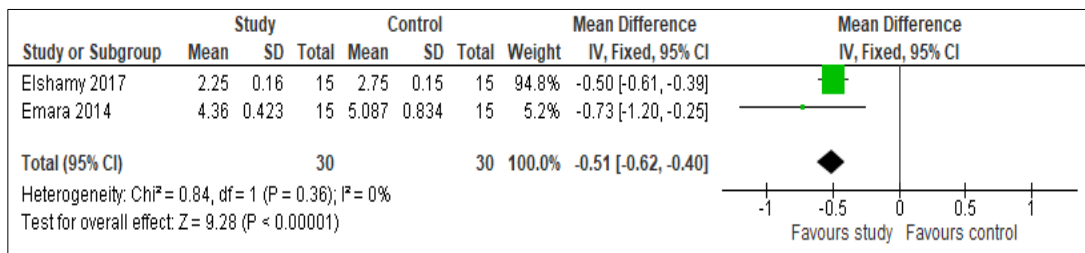


Figure (4): Comparison between study and control groups, outcome: 1.3 Overall stability index

Gait

The measures of spatiotemporal gait parameters were collected via multiple methods of gait analysis within two studies^{4,16}, including the outcome of walking speed, cadence, stride length, stride time, step time, step length, double support time and single-double support phase. El-shamy¹⁶ showed significant improvements in all their measured parameters for the study group compared to the control group. Whereas Aras et al.⁴ reported that there is no significant difference in walking speed, stride length, step time and single support with a significant improvement in cadence and stride time in the study group compared to control group of a similar intervention. These studies show moderate evidence regarding the effect of AGT on spatiotemporal gait parameters.

Both studies were combined on meta-analysis with a total population of 49 children with CP. There were significant improvement in favor of study group regarding walking velocity and cadence while stride length showed insignificant difference between groups as follows (SMD= 0.07, 95%CI 0.06 to 0.08, p< 0.00001), (SMD= 12.29, 95%CI 9.58 to 14.99, p< 0.00001) and (SMD= 0.07, 95%CI -0.08 to 0.23, p< 0.36) respectively Figure (5,6,7). Functional gait assessments were conducted by 6-minute walking test (6-MWT)⁴. and gross motor function measure D and E in Aras et al.⁴. They showed insignificant difference between both groups. These results showed moderate evidence regarding the efficacy of AGT on functional gait assessment.

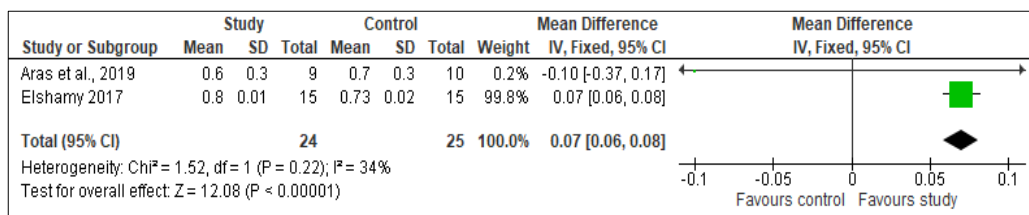


Figure (5): Comparison between study and control groups, outcome: 1.4 Velocity/speed (m/sec).

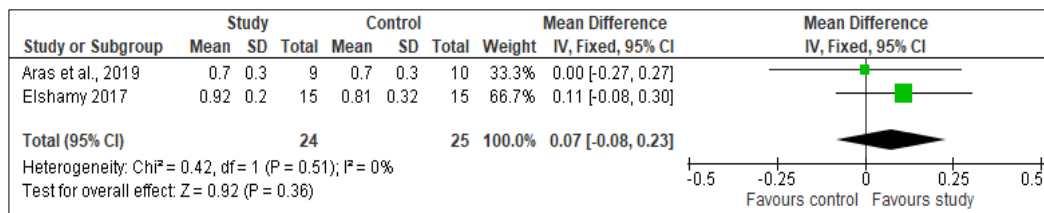


Figure (6): Comparison between study and control groups, outcome: 1.5 Stride length (m).

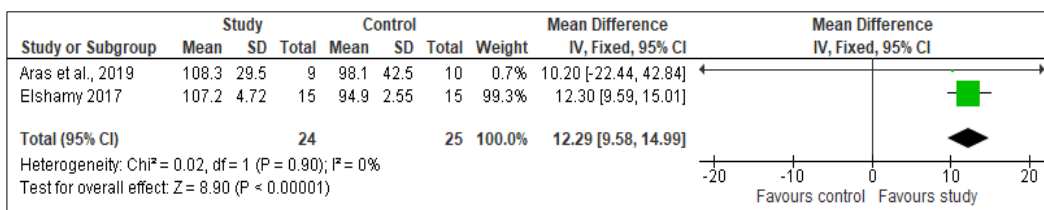


Figure (7): Comparison between study and control groups, outcome: 1.6 Cadence (step/min).

Secondary outcomes

Aras assessed energy consumption by open-circuit indirect calorimetry showed a significant improvement in favor of the experimental group, which demonstrated moderate evidence on the effectiveness of AGT on energy consumption.

Discussion

This review revealed promising results in using AGT to improve balance and gait parameters especially walking speed for children with CP, nevertheless evidence to support its clinical implementations could not be driven due to the small number and poor quality of the reviewed studies. The extensive and comprehensive search of relevant databases resulted in three eligible randomized controlled trials evaluating the effect of Alter-G treadmill on children with CP. All of the reviewed studies published between 2014 to 2018, which supports the novelty of AGT (The recency of all of the included studies support the novelty of this review). This novelty is proposed to be behind the limited number of well-designed clinical trials covering such topics, as only three studies were included. A moderate evidence in favor of AGT versus control to improve balance is drawn narratively from two studies^{15,16} and is supported by meta-analysis of the Biodex Balance System outcomes ($p < 0.00001$). Such improvement may be due to the

freedom that the child experiences during AGT without any external assistance from the therapist, which enables the child -through a series of trials and errors- to pick up the appropriate motor pathway that could enhance self-exploration and problem solving mechanisms⁴.

Concerning the influence of AGT on gait, one study reported a moderate level of evidence regarding the use of AGT to improve spatiotemporal gait parameters⁴ and also supported by meta-analysis ($p < 0.05$). These improvements in gait parameters especially walking speed is supposed to be as a result of strength gain in the lower extremity muscles after AGT⁴, which is thought to be due to increased muscle activation or motor unit recruitment¹⁷, this hypothesis is supported by the significant improvements in muscle hyper excitability after AGT⁹. On the other hand, the unloading feature provided by AGT is reported to decrease the ground reaction force and the muscle activity needed to carry the body weight, which lessen the forces and stresses exerted on the lower extremity joints¹⁸⁻²⁰ providing a facilitative environment for children with CP to experience more normalized walking pattern. Another notable observation was that; Despite the moderate evidence supporting the use of AGT to improve gait and balance, Aras⁴ showed insignificant difference between AGT and the partial body weight-supported treadmill exercise, however the positive changes in the partial body-weight supported treadmill exercise group were less than those in the AGT groups.

Based on these findings, we believe that; Although several methods of providing unweighting exist⁴, a recently developed technology uses air pressure to support the lower body; The antigravity treadmill, provides a level of comfort while exercising unmatched by other unweighting systems. This may be explained by no support was provided around the child's trunk as would be the case with more traditional body weight support. This freedom allowed the child to practice controlling the trunk's mass during the training and improve attention and awareness of the body position image in relation to his or her environment^{6,15}. So, An anti-gravity treadmill can provide the appropriate conditions for cerebral palsy training since it had the benefit of standard treadmill training which improves postural control mechanism needed to maintain the balance during the repetitive and rhythmic stepping and weight shift from one leg to the other^{21,22}, in addition to that the specific design to AGT with an inflatable fabric enclosure that covers the treadmill helping CP children walk on the treadmill by reducing their weights up to 80% and maintain their balance during locomotion²³ so, reduce the uncomfortable pressure points that normally occur in more traditional body weight support systems.

The reviewed studies were limited to children with spastic type of CP; hemiplegia and diplegia and with mild to moderate impairment; spasticity between 1:2 on modified Ashworth scale^{15,16} and gross motor function classification system level I: III^{4,16} who have higher abilities to gain motor functions than those with more severe impairments²⁴. The plan or protocol of applying AGT was greatly variable among reviewed studies; time of the session (20 - 45 min), frequency of sessions per week (3 -5), duration of therapy (1 - 3 months, existence of warm up and cool down intervals, the percentage of body weight support, and level of speed. such variability stands against proper translation of the research into clinical practice

as it put practitioners into doubt about which parameters stand for the best outcomes.

Establishing evidence-based practice requires ensuring a clear positive impact of the applied therapy on the child daily life activities within his environment^{25,26}, which can be clarified through consistent improvements on long term basis; Follow up evaluation of antigravity treadmill training on children with CP addressed only in Aras⁴ who reported persistent gains regarding gross motor function measures, 6MWT and energy consumption after three months' follow up comparing with post treatment evaluation.

Cost benefit of AGT is not well known but comparing it with other therapeutic modalities providing unloading environment such as underwater treadmill or partial body-weight supported treadmill, the economic benefit would be in favor of antigravity treadmill¹⁸. Investigating the effect of new therapeutic intervention for children with CP should cover all aspects of the child's life including health related quality of life (HRQOL), psychosocial well-being and impact on the family²⁷ as children with CP experience poor HRQOL related to the high burden and stress associated with their care^{27,28}.

Supplemental research evaluating the effect of AGT on HRQOL, psychosocial well-being and cost benefit ratio for children with CP should be targeted in order to have holistic view regarding the effect of AGT on children with CP. In addition, further research with larger sample size covering other types of CP with mild, moderate and severely impaired children as well as defining clear guidelines in operating AGT for children with CP is necessary to have more reliable outcomes.

Conclusion

Our review demonstrates that using AGT for children with CP is in its early stages and offers growing evidence for one of the most important gross motor abilities i.e. gait and balance. However, with such a small number of studies identified by this review, and heterogeneous populations, caution must be taken when drawing conclusions from the results of the studies and applying these to clinical practice. Further clinical trials are in need to fulfill the gap in knowledge and draw clear clinical guidelines of antigravity treadmill training for children with CP.

List of Abbreviation

Antigravity Treadmill: AGT
Cerebral Palsy: CP
Health Related Quality of Life: HRQOL
6-Minute Walking Test: 6-MWT
Randomized Controlled Trial: RCT
Timed UP and Go Test: TUG

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Declaration of Interest

The authors state that there's no financial/personal interest or belief that could affect their objectivity

Disclosure

The authors have no conflict of interest to declare concerning this systematic review. This systematic review was presented as an abstract in the 5th medical integrated students' research (MISR) conference

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