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Cycle ergometer in the improvement of gross motor function of children with cerebral palsy: a systematic review with meta-analysis

Cicloergômetro na melhora da função motora grossa de crianças com paralisia cerebral: uma revisão sistemática com meta-análise

Cicloergómetro en la mejora de la función motora gruesa de niños con parálisis cerebral: una revisión sistemática con metaanálisis

Amanda Marques Catelli[1], Laís Andrieli Ferreira Gattino[2], Luigi Antônio da Campo[3], Philipe Souza Corrêa[4], Fernanda Cechetti[5]

ABSTRACT | Cerebral palsy is a group of neurological disorders that causes innumerable deficits, mainly related to motor function, compromising movements and their selective control. Among the various therapies available to try to soften this process, the cycle ergometer appears as a stationary apparatus that aims to facilitate the movement of the lower limbs. Therefore, this study aimed to analyze the effects of the cycle ergometer on the gross motor function of children with cerebral palsy by the *Gross Motor Function Measure (GMFM-66)* scale. This was a systematic review, with inclusion of randomized clinical trials published until July 2017. The search was performed in MEDLINE (PubMed), *Physiotherapy Evidence Database* (PEDro), SciELO, and Embase. The *Cochrane Handbook* Scale was used to evaluate the methodological quality of the investigations. We selected articles that applied the cycle ergometer in children with cerebral palsy, compared to children with cerebral palsy in the control group or other intervention, and that assessed gross motor function with GMFM. The review included three articles and a total of 127 patients. The results have shown a not statistically significant increase in GMFM-66 values, not relevant for clinical improvement. This systematic review has found great heterogeneity in the studies addressing this area and, despite the increase in values in the group that used the cycle ergometer, there was no statistical difference compared to the control group, showing that it does not benefit the gross motor function of this population, when evaluated by GMFM-66.

Keywords | Exercise; Cerebral Palsy; Randomized Controlled Trial.

RESUMO | A paralisia cerebral é um grupo de desordens neurológicas causadora de inúmeros déficits, principalmente relacionados à função motora, comprometendo os movimentos e o seu controle seletivo. Dentre as diversas terapias disponíveis para tentar amenizar esse processo, o cicloergômetro aparece como um aparato estacionário que tem por finalidade facilitar a movimentação dos membros inferiores. Portanto, o objetivo deste estudo foi analisar os efeitos do cicloergômetro na função motora grossa de crianças com paralisia cerebral através da escala *Gross Motor Function Measure* (GMFM-66). Trata-se de uma revisão sistemática, com inclusão de ensaios clínicos randomizados publicados até julho

[1]Undergraduate student of Physical Therapy by Universidade Federal de Ciências da Saúde de Porto Alegre (UFCSPA) – Porto Alegre (RS), Brazil. Email: amandamcatelli@gmail.com. Orcid: 0000-0002-3000-4286
[2]Undergraduate student of Physical Therapy by Universidade Federal de Ciências da Saúde de Porto Alegre (UFCSPA) – Porto Alegre (RS), Brazil. Email: laisgattino@hotmail.com. Orcid: 0000-0002-9766-0421
[3]Master in Rehabilitation Sciences by Universidade Federal de Ciências da Saúde de Porto Alegre (UFCSPA) – Porto Alegre (RS), Brazil. Email: luigi.adacampo@gmail.com. Orcid: 0000-0002-6107-7808
[4]Master in Rehabilitation Sciences by Universidade Federal de Ciências da Saúde de Porto Alegre (UFCSPA) – Porto Alegre (RS), Brazil. Email: philipescor@hotmail.com. Orcid: 0000-0001-7633-1066
[5]Professor of the Graduate Program in Rehabilitation Sciences by Universidade Federal de Ciências da Saúde de Porto Alegre (UFCSPA) – Porto Alegre (RS), Brazil. Email: nandacechetti@gmail.com. Orcid:0000-0003-1776-179X

Corresponding address: Fernanda Cechetti – Rua Sarmento Leite, 245 – Porto Alegre (RS), Brazil – CEP: 90050-170 – Phone: (51) 3303-8776 – Email: nandacechetti@gmail.com –
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de 2017. A busca foi realizada nas bases de dados: MEDLINE (PubMed), *Physiotherapy Evidence Database* (PEDro), SciELO e Embase. Para a avaliação da qualidade metodológica das investigações foi utilizada a escala da *Cochrane Handbook*. Foram selecionados artigos que aplicaram o cicloergômetro em crianças com paralisia cerebral, comparadas a crianças com paralisia cerebral no grupo-controle ou em outra intervenção, e que avaliaram a função motora grossa com a GMFM. A revisão incluiu três artigos e um total de 127 pacientes. Os resultados mostraram um aumento nos valores da GMFM-66, porém não significativo estatisticamente nem relevantes para uma melhora clínica. Por meio desta revisão sistemática, verificou-se uma grande heterogeneidade nos estudos que abordam esta área e que, apesar do incremento de valores no grupo que realizou o cicloergômetro, não houve diferença estatística quando comparado ao grupo-controle, demonstrando não beneficiar a função motora grossa dessa população quando avaliada pela GMFM-66.
Descritores | Exercício; Paralisia Cerebral; Ensaio Clínico Controlado Aleatório.

RESUMEN | La parálisis cerebral es un grupo de desórdenes neurológicos causantes de innumerables déficits, principalmente relacionados con la función motora, y que compromete los movimientos y su control selectivo. Entre las diversas terapias disponibles para intentar amenizar ese proceso, el cicloergómetro aparece como un aparato estacionario que tiene por finalidad facilitar el movimiento de los miembros inferiores. Por lo tanto, este estudio buscó analizar los efectos del cicloergómetro en la función motora gruesa de niños con parálisis cerebral por medio de la escala *Gross Motor Function Measure* (GMFM-66). Se trata de una revisión sistemática, con la inclusión de ensayos clínicos aleatorizados publicados hasta julio de 2017. La búsqueda se realizó en las bases de datos: MEDLINE (PubMed), *Physiotherapy Evidence Database* (PEDro), SciELO y Embase. En la evaluación de la calidad metodológica de las investigaciones se utilizó la escala de Cochrane Handbook. Se seleccionaron los artículos que aplicaron el cicloergómetro en niños con parálisis cerebral, comparados a niños con parálisis cerebral en el grupo control o el grupo intervención, y que evaluaron la función motora gruesa con la GMFM. La revisión incluyó tres artículos y un total de 127 pacientes. Los resultados mostraron un aumento en los valores de la GMFM-66, pero no fueron significativos estadísticamente ni relevantes para una mejora clínica. Por medio de esta revisión sistemática, se verificó una gran heterogeneidad en los estudios sobre esta área y que, a pesar del incremento de valores en el grupo que realizó el cicloergómetro, no hubo diferencia estadística cuando comparado al grupo control, demostrando que no benefició la función motora gruesa de esa población cuando evaluada por la GMFM-66.
Palabras clave | Ejercicio; Parálisis Cerebral; Ensayo Clínico Controlado Aleatorio.

INTRODUCTION

Cerebral palsy (CP) is a group of permanent and nonprogressive neurological disorders occurring in the fetus and the developing child brain, causing mainly motor impairment, which directly affects movements and posture[1]. Its incidence in developed countries ranges from 1.5 to 5.9/1,000 live births, and in developing countries, such as Brazil, it has an estimated rate of 7.0/1,000 live births[2]. Regarding etiology, it is not yet well defined, but it is known that children born prematurely and underweight are more likely to develop CP. Other risk factors include multiple births, maternal infection during pregnancy, family history, pelvic position at delivery, perinatal infections, and untreated diseases[3,4].

The main motor disorders arising from this disease are muscle hypertonia followed by reduced muscle strength and decreased selective control of movement[5], usually accompanied by sensory, perceptual, cognitive, and communicative changes, behavioral disorders, and reduced cardiorespiratory fitness[6]. For being a permanent disorder, it also affects adulthood, presenting difficulties in social and work life[1]. This motor disadvantage leads these individuals to remain long periods without physical or aerobic activities, or harming their cardiopulmonary capacity, stability, muscle strength, and agility[7]. To ease this process, there are several treatment alternatives, and the cycle ergometer, a stationary device that allows cyclic rotations in passive, active, and endurance modes, may be considered one such possibility, promoting an activity that is safe and fully adaptable to the disabilities of this population[8].

Studies have shown that the cycle ergometer exercise improves several parameters, such as muscle strength and endurance, along with torso control in sitting position[9,10]. However, these results are presented only in a small sample and are often conflicting. Studies with the use of cycle ergometer in the population with CP are still scarce and present little information about the physiological effects and technical principles of aerobic exercises.

The Gross Motor Function Measure (GMFM) scale has been one of the most chosen to quantify the evolution of patients after the intervention, because it allows evaluating children with CP from 5 months to 16 years old and is mainly directed to the physical capacity of this population[11]. It is a numerical rating scale, in which a higher score implies better gross motor function[12]. An update of the GMFM with 66 items is also widely used and validated for assessment of children with CP (GMFM-66), with items from all dimensions, although in reduced number[12]. The Brazilian version showed excellent intra and inter-rater reliability values.

Therefore, this systematic review aims to assess the effects of cycle ergometer in the gross motor function of children with cerebral palsy by the GMFM-66 scale.

METHODOLOGY

Design and search strategy

This systematic review was registered with protocol CRD42017079436 at Prospero and is in accordance with the guidelines of PRISMA Statement and Cochrane Collaboration. The search for articles was conducted in the following databases: MEDLINE (PubMed), Physiotherapy Evidence Database (PEDro), SciELO, and Embase, from the beginning of the publications in the databases until July 2017. The selected keywords were "Cerebral Palsy" (MeSH and entry terms), "Aerobic Exercise" (MeSH and entry terms), "Randomized Controlled Trial" (MeSH and entry terms), and their synonyms, individually or in combination.

Eligibility criteria, intervention, and participants

We have included articles of randomized controlled trials addressing children with CP who performed therapeutic intervention with cycle ergometer and evaluating gross motor function by GMFM-66, compared to groups of children with CP who performed another therapy or conventional physical therapy.

Main outcome, study selection, and data extraction

The main outcome analyzed was the GMFM-66 scale[14], comparing mean and standard deviation values before and after intervention with cycle ergometer. Two independent reviewers accessed the titles and abstracts of all the articles selected in the search strategy. When abstracts did not present complete information, the full articles were analyzed. Then, the same reviewers examined the full preselected articles to carry out the final selection. Data extraction was held by two independent reviewers using a standard form.

Assessment of the risk of bias

The analysis of the methodological quality of the articles was descriptive, according to the method proposed by Cochrane Collaboration, considering the following characteristics of the studies: random sequence, hidden allocation, blinding of researchers (who administers the training), blinding of the evaluator of the results, intention-to-treat analysis, description of losses and exclusions. The intention-to-treat analysis was regarded as all randomized patients analyzed who reached the end of the study[15].

Data analysis

The meta-analysis was performed using the random effects model. The size of the effect was calculated using the difference between the mean and the standard deviation of the difference between the mean. Statistical heterogeneity was assessed using Cochran's Q test and inconsistency test (I^2), in which values above 25% and 50% indicated moderate and high heterogeneity, respectively. An alpha value ≤0.05 and a 95% confidence interval (95%CI) were considered statistically significant. All the analyses used the software Review Manager 5.1. Sensitivity analyses were performed considering patient characteristics (PC) and intervention characteristics (cycle ergometer).

RESULTS

Study selection

As shown in Figure 1, the studies were initially selected by searching descriptors, resulting in a total of 1,250 articles.

After removing the duplicates (n=110), the titles and abstracts of the remaining 1,140 articles were read to select only randomized and controlled clinical trials, and 15 articles were selected. In the second step, they were read in full to verify their inclusion or exclusion in the research, and only three studies of the 15 initially preselected were chosen for inclusion. Two independent reviewers searched and evaluated the articles, and later discussed their methodological quality. In case of disagreement between reviewers, the resolution took place by a consensus between them.

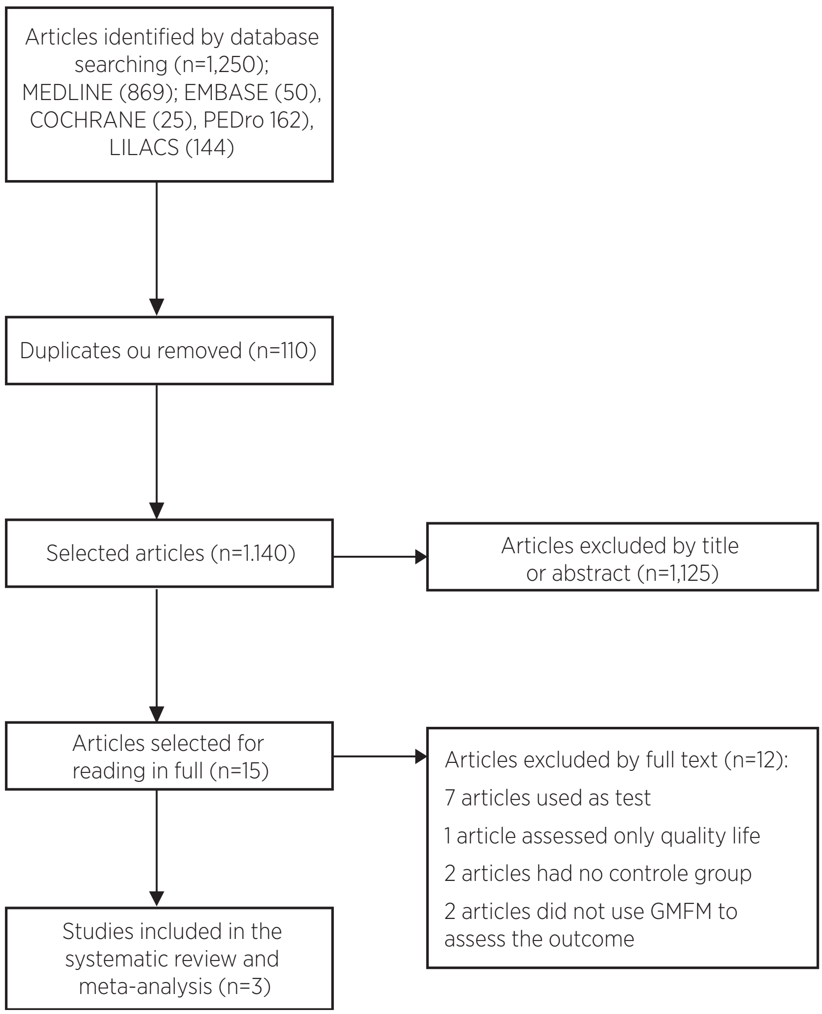


Figure 1. Diagram of article selection
GMFM: *Gross Motor Function Measure.*

Study description

Table 1 shows the characteristics of the included studies. The three studies assessed a total of 127 patients with CP, which included diplegic and hemiplegic children, aged 6 to 12 years and with function levels I and II by the Gross Motor Function Classification System (GMFCS)[16]; children with bilateral CP aged 8 to 17, with GMFCS IV and V[17]; and diplegic children aged 7 to 18, with I to III levels[18].

Interventions lasted six[17] or twelve[16,18] weeks, but with an average duration of 30[17], 40[16], and 60[18] minutes, and the latter was the only one detailing the application of cycle ergometer. All of them were performed three times a week, with application in the lower limbs. Regarding training intensity with the cycle ergometer, in the study of Bryant et al.[17], exercise intensity was 75% of the load determined in the initial evaluation for as long as possible. Chen et al.[16] applied the cycle ergometer with load determined by endurance, which allowed the child to ride for 20 minutes without effort, being increased according to the skill; and Fowler et al.[18] carried out the intervention with 70% to 80% of the maximum heart rate.

Concerning the control groups, they differed in carrying out the activities, and one study did not perform any intervention[18]; the other encouraged the maintenance of customary and general physical activities at home and at school, under the supervision those responsible, with telephone calls assisting in the adherence to the protocol[16]; and in the last study, in addition to a third comparison group (treadmill as activity), the participants in the control group performed regular physical therapy activities during this period, such as stretching, exercises on the floor and the aquatic environment (swimming)[17].

All the articles analyzed the GMFM-66[16-18] and other outcomes, such as bone mineral density of lumbar spine and distal femur[16], trunk muscle strength[16], lower limb muscle strength, such as knee flexion and extension torque[16,18], gait speed[17], running and walking test[17], GMFM-88D ("standing" domain), and GMFM-88E ("walk, running, and jumping" domain)[17]. Only one article carried out follow-up assessment[17].

Table 1. Description of articles included in the systematic review

Author, year	Patients (n)	Training protocol	Training intensity	Outcomes analyzed	Results
Bryant E. et al., 2013[17]	35 patients with bilateral CP – aged between 8 and 17 years and GMFCS IV and V; cycle ergometer (n=11), treadmill (n=12), control (n=12)	3 times a week, for 6 weeks, with sessions of about 30 minutes	Cycle ergometer: for as long as possible with 75% of the load determined in the initial assessment. Treadmill: increase of 0.1 km/h every 10 seconds, until the patient could no longer increase. Control: conventional physical therapy	GMFM-66, GMFM-88D, GMFM-88E	There was an increase in the value of the GMFM-66 in all groups, without, however, any intra or intergroup significant value
Chen C. et al., 2013[16]	30 diplegic or hemiplegic CP patients – aged between 6 and 12 and GMFCS I and II; cycle ergometer (n=14) and control (n=16)	3 times a week, for 12 weeks, with 40-minute sessions	Cycle ergometer: load determined by endurance, which allowed the child to ride for 20 minutes without effort, being increased according to their ability. Control: general physical activities	GMFM-66, muscle strength of knee flexors and extensors, torso muscle strength, bone mineral density	There was an increase in the GMFM-66 score in both groups, without inter and intragroup significant difference
Fowler, E. et al., 2010[18]	62 patients diplegic CP patients – aged between 7 and 18 and GMFCS I to III; cycle ergometer (n=31) and control (n=31).	3 times a week, with a total of 30 sessions within 12 weeks, for 60 minutes – 30 of muscle building and 30 of cardiovascular endurance	Cycle ergometer: division between strength (power cords ranging from 1 – weaker – to 10 – stronger) and endurance (heart rate should be maintained in the target range from 70% to 80% of the maximum HR, for 15 to 30 minutes)	GMFM-66, 600-Yard Walk-Run Test, Thirty-Second Walk Test, peak knee extension and flexion	There was significant difference in the pre and post-intervention value in the cycle ergometer group (intragroup), but not compared to the control (intergroup)

GMFM: *Gross Motor Function Measure*; GMFCS: *Gross Motor Function Classification System*; HR: heart rate.

Risk of bias

The studies of Fowler et al.[18] and Chen et al.[16] were considered unclear regarding the generation of random sequence, while the study of Bryant et al.[17] presented low risk of bias. As for the concealment of allocation of groups, all studies were considered "unclear," not explicitly exposing if there was concealment, thus favoring the occurrence of selection bias. For the blinding of participants and researchers, the studies of Bryant et al.[17] and Chen et al.[16] were considered "unclear," while the study of Fowler et al.[18] presented low risk of bias. For the blinding of the result evaluators, the studies of Fowler et al.[18] and Bryant et al.[17] presented low risk of bias, while the study of Chen et al.[16] presented a high risk of bias. All the studies presented low risk of bias concerning incomplete results, selective reporting, and other biases (Figure 2).

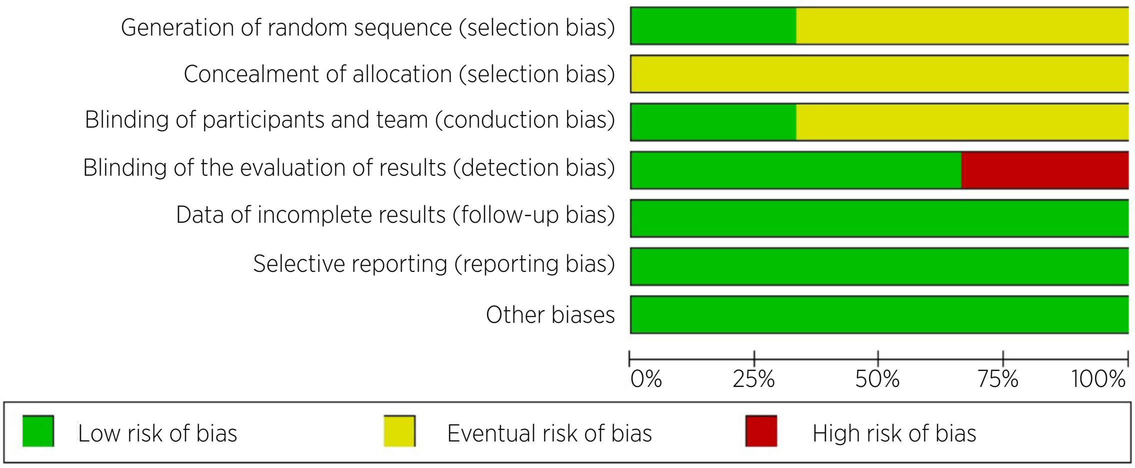


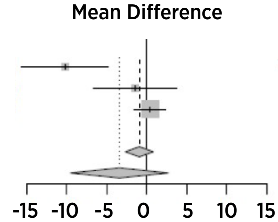
Figure 2. Analysis of the risk of bias

Intervention effects

The studies included in the review evaluating the GMFM scale score totaled 127 patients. In the meta-analysis, we have found that the interventions with cycle ergometer did not improve the GMFM scale score compared to the control group. The meta-analysis of studies showed the following results: Mean difference:−3.43 [95%CI= −9.56 to 2.69]; I2 85%, showing high heterogeneity (85%), which can be considered an important bias in the meta-analysis, as shown in Figure 3. The meta-analysis graph presents that, in the study of Bryant et al.17, the intervention group did not change its post-intervention values, while the control group increased its mean in 10.23 points, which is shown in the graph by the horizontal line on the far left, without touching the horizontal line in the center. Such result, even with a small difference between means, favors the therapy used in the control group.

The meta-analysis of the study of Chen et al.16 shows a slight increase in the mean score of the intervention group (2.0), but the control group presented a higher variation in the mean score (3.5); this is represented by the horizontal line touching the central vertical line, due to the small mean variation between the two groups, but higher in the control group. In the study by Fowler et al.18, the intervention group showed a higher mean scoring (0.9) compared to the control group (0.5), represented in the meta-analysis graph by the horizontal line centered under the vertical line, with a slightly higher deviation at the right, which favors the intervention with cycle ergometer compared to the control group; however, these results were not considered significant in the meta-analysis. In short, the grouping of the studies included in the meta-analysis did not bring a result that can facilitate the intervention with cycle ergometer for increasing the GMFM score, compared to therapies used in the control groups.

	Experimental Group			Control Group							
Study	**Total**	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Mean Difference**	**MD**	**95%-CI**	**Weight (fixed)**	**Weight (random)**
Bryant 2012	11	0.0	4.50	12	10.23	8.34		-10.23	[-15.65;-4.81]	10.6%	30.5%
Chen 2012	13	2.0	7.82	14	3.50	5.78		-1.50	[-6,72; 3.72]	11.4%	31.0%
Fowler 2010	29	0.9	3.90	29	0.50	3.86		0.40	[-1,60; 2.40]	78.0%	38.4%
Fixed effects model	**53**			**55**				**-0.94**	**[-2.71; 0.82]**	**100.0%**	**--**
Random effects model								**-3.43**	**[-9,56; 2.69]**	**--**	**100.0%**



Heterogeneity: $I^2 = 85\%$, $\tau^2 = 24.39$, $p < 0.01$

Figure 3. Meta-analysis of the articles included in the review

Secondary outcomes

Bryant et al.[17] also analyzed the GMFM-88D, which presented results with significant difference between the cycle ergometer and control groups, as well as between the treadmill and control groups. No significant differences were found for the GMFM-88E score between the cycle ergometer and control groups or between the treadmill and control groups.

In turn, Fowler et al.[18] have found significant improvement between initial and post-intervention values in knee flexion and extensor torque for the cycle ergometer group. No significant differences were found between the cycle ergometer and control groups, based on scores of change for any other result. The analyses of covariance results performed by Chen et al.[16] indicate that the intervention group with cycle ergometer presented more distal femoral bone mineral density and higher isokinetic torque of knee extensor and flexor muscles, compared to the control group after treatment.

DISCUSSION

This systematic review has shown that the cycle ergometer does not provide better benefits in gross motor function, measured by the GMFM-66, compared to conventional physical therapy[17] or other activities, such as walking, jogging, and recreational exercises at school or at home[16,18]. Added to this, the three selected studies showed increased post-treatment values compared to pre-treatment values in the intervention group, but only one study[18] presented intergroup statistically significant difference. It is worth highlighting that Wang and Yang[19] state that values above 3.7 points on this scale represent great improvement for these children; values above 1.6, a clinically significant improvement; and values below 1.6 do not bring improvement for this population.

Several factors may have led to this conclusion. The first of them would be the heterogeneity of the participants, clearly shown in the meta-analysis. The subjects involved in the study had varied topographies, and the GMFCS level was different in all the articles. Bryant et al.[17] suggest that greater commitment levels would present a higher benefit through interventions, and that muscular strength would have a considerable increase in weaker patients. However, they also mention that extremely compromised patients would not be able to start the activities described in the GMFM, having a score of zero, hindering the analysis of these patients by this scale, what could be the reason for the lack of a significant increase in the score[17]. In the analysis of the articles, we can also identify a high risk of bias, since no study carried out random allocation or reported how they conducted it, and this can be one of the reasons the control group presents better values in the score scale even without having carried out any intervention[18] or usual activities already carried out by the patients[16,17].

Another factor that Fowler et al.[18] reported regarding the variability of the subjects involved in the research is the response of these children before an intervention. They mention that this response is extremely complex and directly influenced by factors such as family dynamics and inherent characteristics of these children, as the degree of spasticity. Tone modulation was essential for patients to have a better adaptation to the cycle ergometer and also to improve performance over the weeks, since spasticity is a hyperexcitability of the muscle reflex that directly affects voluntary motor control[18].

The studies of Chen et al.[16] and Bryant et al.[17] report that the cycle ergometer may exert more positive effects on other studied variables, such as lower limb muscle strength, and not directly on the gross motor function of these children, based on the muscular strength evaluations carried out. In addition, Chen et al.[16] have found that bone mineral density increased significantly in the distal femur, unlike the trunk density, which underwent no changes with the use of cycle ergometer, probably by the constant mechanical load applied in the lower limb bones in the pedaling motion. Therefore, these results[16] support the idea that muscle strength, and not the GMFM-66 score, is correlated with an increase in bone density in the lower limbs of children with cerebral palsy[21]. This improvement in the muscle strength of lower limbs is mainly due to the fact that the cycle ergometer was applied in the lower limbs, in repetitive motions and with progression of endurance[16]. However, one could suppose that the increased strength of lower limbs provided by the cycle ergometer treatment would cause an effect on functional activities, such as standing and walking, but the authors did not verify such influence on the results of the GMFM.

In addition, another factor that could justify the fact that the cycle ergometer did affect the results is that the GMFM-66 has the tendency to score motor abilities and skills, and not the performance with which the individual performs the activities daily[11]. This is a scale carried out in a controlled environment, on a firm and soft surface, with materials available – such as bench, toys, exercise mat, and ladder –, without considering the daily environment of the child, as well as personal factors[14]. In addition, the GMFM-66 is little sensitive to assess changes in motor function of children above 5 years[22], and this can be considered a limitation of our study regarding the measuring instrument adopted.

Our study has not shown a significant improvement in the use of cycle ergometer, possibly because of the diversity of its application (aerobic and resisted exercise). Similarly, other studies[23,24] that evaluated interventions by aerobic and resisted exercises by the GMFM scale showed little variation in the score (insignificant in dimensions D and E), but mentioning that the score might not accurately reflect the activity capacity of participants. According to a review of exercise interventions performed by Ryan et al.[25], evidence indicates that aerobic exercise does not improve aspects such as gait speed, resistance to walking, or aerobic fitness. Their findings also showed that endurance training does not improve any aspect of the activity or participation in people with CP, but may improve muscle strength in children, adolescents, and young adults in the short-term and in children and adolescents in the medium term.

An important point to consider in these studies is the intervention time of the cycle ergometer. The general recommendation for any physical exercise in children with cerebral palsy is 12 weeks, allowing a good adaptation period[26]. Bryant et al. performed only six weeks of intervention and reported that some children still needed the help of therapists for learning and being able to ride independently[17]. The studies of Chen et al.[16] and Fowler et al.[18], in turn, meet the recommendations, since they carried out interventions with 12 weeks of duration. Therefore, the heterogeneity of the studies regarding treatment duration may have been a factor of interference in the result of the GMFM meta-analysis.

As limitations of our study, we highlight the heterogeneity of the selected studies, which did not allow us to analyze other variables, such as muscle strength and posture and gait parameters, which could present better responses in the cycle ergometer. Thus, we hope this review can extend the knowledge on CP intervention by cycle ergometer, showing that the specificity of the target audience and of the assessment tool applied is of paramount importance for obtaining positive results with this exercise modality. Concerning future studies, we suggest investigating the long-term effects of exercise, either with cycle ergometer or other approaches, in the function and health of people with CP. Further tests are required to include a greater monitoring, to examine in detail the effects of exercise during the life of individuals with CP.

CONCLUSION

The use of cycle ergometer as intervention in the treatment of cerebral palsy does not bring better benefits in gross motor function compared to the groups that performed regular physical activity, such as walking, jogging, recreational exercises at school and at home, or even compared to conventional physical therapy. The sensitivity of the GMFM scale to assess treatment with cycle ergometer seems to be directly related to the results found in this study, since there has not been a significant change of the values presented. In addition, the analysis in this review has shown a high heterogeneity in the studies, possibly by the different types of topography of this pathology, besides the age group, which is quite broad in studies on cerebral palsy. Thus, we suggest further studies in this area, covering a longer intervention time and more sessions, before the chronic motor impairment caused by cerebral palsy.

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