Article

CLINICAL REHABILITATION

Clinical Rehabilitation
26(12) 1105–1113

DOI: 10.1177/0269215512444633
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Study of the therapeutic effects of a hippotherapy simulator in children with cerebral palsy: a stratified single-blind randomized controlled trial

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Abstract

Objective: To investigate whether hippotherapy (when applied by a simulator) improves postural control and balance in children with cerebral palsy.

Design: Stratified single-blind randomized controlled trial with an independent assessor. Stratification was made by gross motor function classification system levels, and allocation was concealed.

Subjects: Children between 4 and 18 years old with cerebral palsy.

Interventions: Participants were randomized to an intervention (simulator ON) or control (simulator OFF) group after getting informed consent. Treatment was provided once a week (15 minutes) for 10 weeks.

Main measures: Gross Motor Function Measure (dimension B for balance and the Total Score) and Sitting Assessment Scale were carried out at baseline (prior to randomization), end of intervention and 12 weeks after completing the intervention.

Results: Thirty-eight children participated. The groups were balanced at baseline. Sitting balance (measured by dimension B of the Gross Motor Function Measure) improved significantly in the treatment group (effect size = 0.36; 95% CI 0.01–0.71) and the effect size was greater in the severely disabled group (effect size = 0.80; 95% CI 0.13–1.47). The improvements in sitting balance were not maintained over the follow-up period. Changes in the total score of the Gross Motor Function Measure and the Sitting Assessment Scale were not significant.

Conclusion: Hippotherapy with a simulator can improve sitting balance in cerebral palsy children who have higher levels of disability. However, this did not lead to a change in the overall function of these children (Gross Motor Function Classification System level V).

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Keywords
Cerebral palsy, gross motor function, hippotherapy, horseback riding therapy, controlled trial

Received: 7 December 2011; accepted: 18 March 2012

Introduction

The terms 'hippotherapy' and 'therapeutic horseback riding' are used to describe treatment strategies that use the movement of the horse for improving postural control and/or balance[1,2] and general function or mobility.[1,3] Preliminary phase I research suggests that both hippotherapy and horseback riding therapy may be beneficial for patients with spinal cord injury,[4,5] multiple sclerosis[6] or cerebral palsy.[3,7–16]

Hippotherapy simulators that 'imitate' the movements of a horse are available to buy and, as a result, this therapy has become more accessible to patients.[17–19] However, the research evidence to support the use of this technology in routine care has been limited; only three papers were identified following a comprehensive literature search.[17–19] Quint and Toomey,[19] using a matched pair design and within pair randomization, suggested that treatment on a hippotherapy simulator can lead to improvement in static posture, however, they also noted that similar improvements were also seen on people who used a static saddle. Kuczyński and Słonka,[17] using a quasi-controlled study design, demonstrated that sagittal plane stability may have increased following three months of treatment using a hippotherapy simulator, however, they did not study as to whether the changes in sway resulted in an improvement in activity and/or participation. Zurek et al.[18] is not reviewed as the outcome measure (skin temperature of lower limbs) was not related to postural control or mobility.

The first review of horseback riding therapy[3] came to the conclusion that, although there is some evidence of benefit associated with horseback riding, rigorous studies with larger samples were needed to prove that this treatment worked. A more recent review[2] of all studies using hippotherapy, horseback riding therapy and hippotherapy simulators concludes that there may be some evidence for the use of these therapies in the rehabilitation of children with cerebral palsy but the authors also acknowledge that more rigorous research is required to prove the clinical benefits associated with treatment. Two of the eight papers that met the inclusion criteria in the latter review[2] used a hippotherapy simulator;[17,19] all other papers used traditional hippotherapy.

The aim of this study was to quantify the therapeutic effects of hippotherapy simulators in the rehabilitation of children with cerebral palsy using a protocol similar to those used in hippotherapy or horseback riding therapy studies.[9,20] The specific objectives were to investigate whether hippotherapy (when applied by a simulator) may improve postural control and balance in children with cerebral palsy.

Methods

This was a single-blind stratified randomized control study with an independent assessor. The sampling frame was children between the ages of 4 and 18 years old with cerebral palsy (Gross Motor Function Classification System[21] levels I–V) who attend schools run by the Department of Education of the Government of Aragon (Spain). The study was approved by the Spanish Regional Ethics Committee (CEICA) (reference number CP04/06/08). Informed consent was obtained from the legal representative of the child (parent or tutor for those under the care of state).

Participants who met the inclusion and exclusion criteria previously published[22] were accepted to trial. Children who refused to participate or could not attend the sessions were not enrolled. Baseline measurements were taken in participants who were eligible to participate and for whom we had consent. After the baseline measurements were taken (Table 1), the participants were stratified based on the Gross Motor Function Classification System level and then randomized (using a concealed

Table 1. Comparison of the group at baseline for demographical variables (age and gender), composition of groups (distributed in Gross Motor Function Classification System levels) and the outcome measures (Gross Motor Function Measure and Sitting Assessment Scale)

Sociodemographic variables	Control group	Intervention group	*P*-value
Mean age (SD)	9.05 (7.58–10.53)	9.95 (8.80–11.10)	0.504a
Gender (male:female)	10:9	14:5	0.179b
GMFCS level I	2	2	0.834b
GMFCS level II	2	1	
GMFCS level III	3	2	
GMFCS level IV	3	4	
GMFCS level V	9	10	
Total Gross Motor Function Measure	42.75 (19.02)	40.91 (17.50)	0.758a
Gross Motor Function Measure dimension B	29.84 (15.04)	25.68 (15.40)	0.405a
Sitting Assessment Scale	15.58 (5.81)	15.21 (5.93)	0.848a

There were no significant differences between the groups. The data was processed with appropriate statistical tests (a: independent sample *t*-test for ratio level variables and b: chi-squared test for categorical variables). The corresponding *P*-values are reported. GMFCS, Gross Motor Function Classification System.

random allocation method) to one of two groups: an intervention group and a control group. In the intervention group, the 15-minute session (once a week for 10 weeks) consisted of sitting on the hippotherapy simulator with active extension of the trunk while the simulator was switched ON in the WORKOUT mode. In the control group, the 15-minute session (once a week for 10 weeks) consisted of sitting on the hippotherapy simulator with active extension of the trunk while the simulator was switched OFF. Therefore the children in the control group did not receive the rhythmic movement from the simulator (it was similar to sitting on a barrel or another device in which they maintained this sitting position as in other published studies).[9,20] The children who consented, and for whom baseline measurements were taken, were considered as drop-outs if they did not attend the treatment sessions. Further details of the methods and the hippotherapy simulator are described by Herrero et al.[22]

The measures for this study were gross motor function, measured with the Gross Motor Function Measure-66[23] and sitting balance measured by the balance component of the Gross Motor Function Measure (dimension B) and the Sitting Assessment Scale.[24] The assessors were trained to use the above measures in a consistent way. A questionnaire was completed at the beginning of the study to collect the sociodemographic variables previously described in the literature as potentially confounding. The baseline equivalence was tested using an appropriate statistical test (chi-squared test or the *t*-test) for each of outcome variables (Table 1) and the appropriate descriptive statistics are reported with *P*-values.

Using an intention-to-treat approach (with last value carried forward in case of missing data), effect size of treatment (Cohen's *d*)[25] and odds ratios,[26] along with respective 95% confidence interval (CI), are reported. Data were initially analysed for the whole group. As stratification was done prior to randomization, the analysis was repeated for groups split on the Gross Motor Function Classification System levels I–V. The data were analysed for Total Gross Motor Function Measure scores, dimension B of Gross Motor Function Measure and the Sitting Assessment Scale.

Primary end-point was the end of treatment (when compared to baseline) and secondary end-point was end of follow-up (when compared to baseline).

Results

Thirty-eight children participated and four children dropped out (Figure 1), however, data from all 38 participants study were considered for analysis.

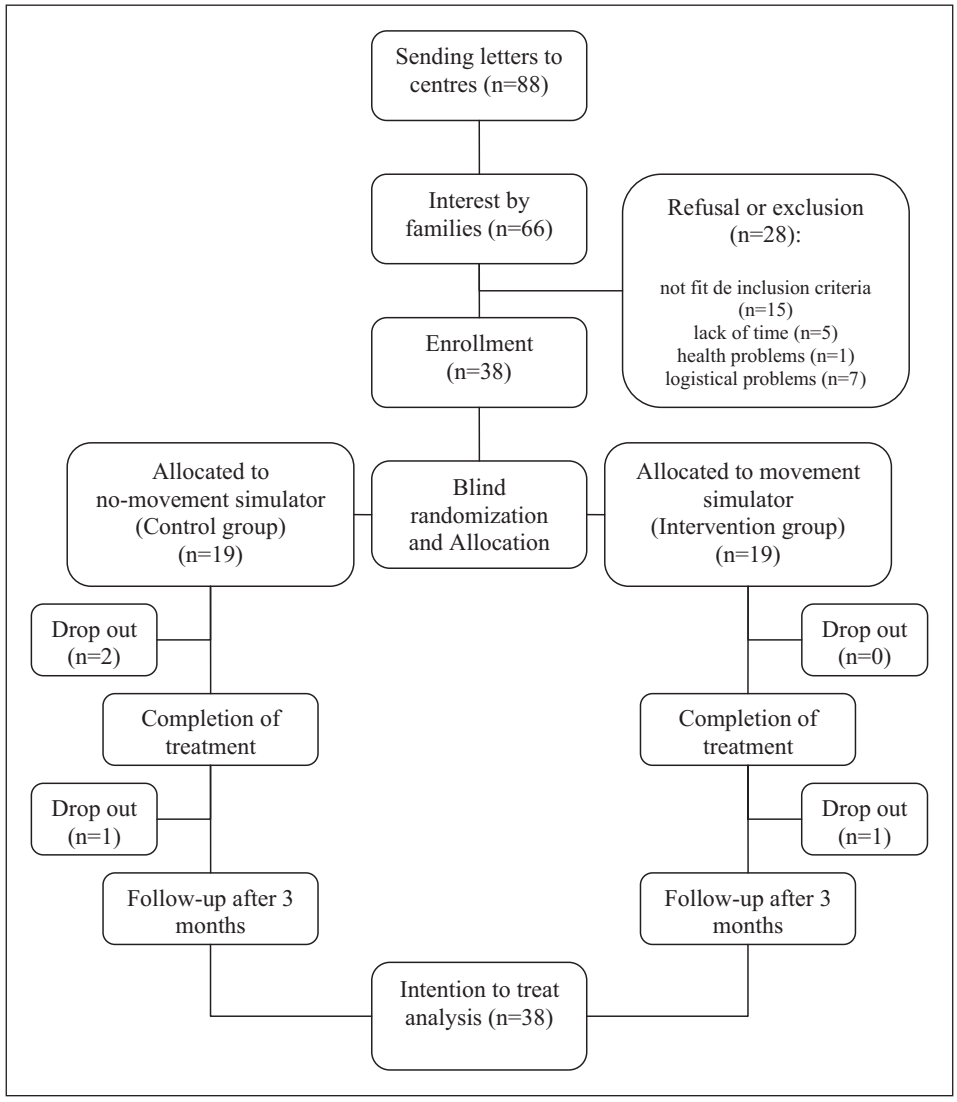

Figure 1. Consort diagram.

After randomization, both groups were comparable at baseline (Table 1). The sample was biased towards children with higher levels of disability; 19 children (50%) were classified as Gross Motor Function Classification System level V.

The Sitting Assessment Scale was a very insensitive measure. One child improved by one point, two children improved by two points and one child deteriorated by four points. Although we have presented the appropriate inferential statistics in Tables 2 and 3, the results will not be presented or discussed further. The rest of the results will focus on the Gross Motor Function Measure only. For the subgroup analysis, data for Gross Motor Function Classification System level V is only presented because the subsamples of levels I–IV were too small to carry out a meaningful analysis.

Table 2. Results for the whole group (19 children in each group)

Outcome measure (sample size: *n*)	M1: Baseline measurement mean (SD)	M2: End of treatment measurement mean (SD)	M3: End of study measurement mean (SD)	Treatment effect (M2–M1) mean (SD)	Effect size for treatment period (95% CI)	Follow-up effect (M3–M1) mean (SD)	Effect size for entire study period (95% CI)
Gross Motor Function Measure (dimension B)							
Control (19)	29.84 (15.04)	29.95 (14.87)	30.11 (14.94)	0.11 (2.60)	0.36* (0.01 to 0.71)	0.26 (3.31)	0.25 (–0.10 to 0.60)
Experimental (19)	25.68 (15.4)	26.95 (14.65)	27.05 (15.26)	1.26 (3.68)		1.37 (5.37)	
Total Gross Motor Function Measure							
Control (19)	42.75 (19.02)	43.02 (18.40)	44.24 (19.76)	0.27 (2.81)	0.27 (-0.07 to 0.62)	1.50 (2.78)	0.25 (–0.10 to 0.60)
Experimental (19)	40.91 (17.50)	42.23 (15.63)	43.54 (17.16)	1.31 (4.63)		2.63 (5.75)	
Sitting Assessment Scale							
Control (19)	15.58 (5.81)	15.84 (5.70)	15.84 (5.70)	0.26 (0.65)	–0.59 (–0.92 to –0.26)	0.26 (0.65)	–0.59 (–0.92 to –0.26)
Experimental (19)	15.21 (5.93)	15.00 (5.82)	15.00 (5.82)	–0.21 (0.92)		–0.21 (0.92)	

Treatment effect is the difference between values of the treatment period (period of time between the end of the 10 sessions of treatment and the beginning of the study). Follow-up effect is the difference between values of the follow-up period (period of time between 12 weeks after completion of the 10 treatment sessions and the beginning of the study).
*Indicates that the result is significant.

Table 3. Results for subgroup Gross Motor Function Classification System level V (9 children in the control group and 10 children in the experimental group)

Outcome measure (sample size: *n*)	M1: Baseline measurement mean (SD)	M2: End of treatment measurement mean (SD)	M3: End of study measurement mean (SD)	Treatment effect (M2–M1) mean (SD)	Effect size for treatment period (95% CI)	Follow-up effect (M3–M1) mean (SD)	Effect size for entire study period (95% CI)
Gross Motor Function Measure (dimension B)							
Control (9)	17.88 (12.78)	17.00 (10.98)	17.33 (11.48)	–0.89 (2.84)	0.80* (0.13 to 1.47)	–0.56 (4.12)	0.41 (–0.12 to 1.02)
Experimental (10)	15.11 (8.78)	17.44 (8.49)	17.22 (9.05)	2.1 (4.40)		1.9 (7.26)	
Total Gross Motor Function Measure							
Control (9)	28.14 (14.68)	28.84 (13.95)	28.46 (13.82)	0.7 (2.53)	0.56 (–0.02 to 1.14)	0.32 (2.70)	0.42 (–0.18 to 1.02)
Experimental (10)	28.43 (12.07)	31.29 (8.59)	31.11 (8.12)	2.86 (4.72)		2.68 (7.25)	
Sitting Assessment Scale							
Control (9)	11.00 (5.52)	11.44 (5.63)	11.44 (5.63)	0.44 (0.88)	–0.74 (–1.22 to –0.26)	0.44 (0.88)	–0.74 (–1.22 to -0.26)
Experimental (10)	11.56 (5.90)	11.11 (5.30)	11.11 (5.30)	–0.4 (1.33)		–0.4 (1.33)	

Treatment effect is the difference between values of the treatment period (period of time between the end of the 10 sessions of treatment and the beginning of the study). Follow-up effect is the difference between values of the follow-up period (period of time between 12 weeks after completion of the 10 treatment sessions and the beginning of the study).
*Indicates that the result is significant.

The main results from the study are fully presented in Table 2 (whole group) and Table 3 (subgroup of Gross Motor Function Classification System level V).

The results of the whole group show that at the end of the treatment period, the Total Gross Motor Function Measure in the treatment group had improved in 11 children while in the control group it had improved in 8 children (OR = 1.89; 95% CI 0.5–6.9). With respect to Gross Motor Function Measure dimension B, it improved in 10 children in the experimental group while it improved in 5 children in the control group (OR = 3.11; 95% CI 0.8–12.1). The effect size is significant for the Gross Motor Function Measure dimension B during the treatment period (Table 2).

At the end of the follow-up period, the Total Gross Motor Function Measure in the treatment group had improved in 10 children while in the control group it had improved in 12 children (OR = 0.65; 95% CI 0.177–2.37). With respect to Gross Motor Function Measure dimension B, 9 children in the experimental group had improved while 5 children in the control group had improved (OR = 2.52; 95% CI 0.65–9.83). The effect size associated with these changes is not significant (Table 2).

The results of the level V subgroup analysis show that at the end of the treatment period, the Total Gross Motor Function Measure in the treatment group had improved in 8 children while in the control group it had improved in 4 children (OR = 2.7; 95% CI 0.65–11.04). With respect to Gross Motor Function Measure dimension B, 6 children in the experimental group had improved while 2 children in the control group had improved (OR = 3.9; 95% CI 0.68–22.7). The effect size is significant for the Gross Motor Function Measure dimension B during the treatment period (Table 3).

At the end of the follow-up period, the Total Gross Motor Function Measure in the treatment group had improved in 6 children and the Total Gross Motor Function Measure in the control group had improved in 4 children (OR = 1.88; 95% CI 0.30 - 11.62). With respect to Gross Motor Function Measure dimension B, 5 children in the experimental group had improved and 2 children in the control group had improved (OR = 3.5; 95% CI 0.47–25.90). The rest of the results are shown in Table 3. The effect size associated with these changes is not significant (Table 3).

Discussion

The main findings from this study were that hippotherapy, when applied with a simulator (for 15 minutes once a week), in addition to routine therapy, helps improving sitting balance in children with cerebral palsy and that this effect is better in people with higher levels of disability. However, the improvements in sitting balance, as achieved in this study, may have a smaller effect on overall functional performance. The carry-over effects of treatment were maintained in people with higher levels of disability which would suggest that improvements in sitting balance are likely to have occurred as a result of motor learning associated with the dynamic nature of the repetitive task training that was given to the children (mechanical hippotherapy in conjunction with additional tasks that required balance control). The providing of additional support seems not to have prevented learning from taking place as the Gross Motor Function Measure measurements are a reflection of the child's true capacity.

It is not possible to fully explain the smaller benefits seen in patients with higher levels of ability. It is possible that the duration of the sessions or the intensity of therapy (in terms of magnitude of displacement and velocity during the simulation and duration of the treatment) was insufficient for this patient group and hence the effects were smaller than expected for the participants who had a good level of ability. In this study we used a standardized therapy that all participants could engage with, as opposed to a customized therapy in future studies. There is a need to explore whether customized hippotherapy can lead to better outcomes for all participants. More modelling work (phase I) and phase II clinical trials are required[27] to identify an optimal way of prescribing treatment with mechanical hippotherapy.

There were some limitations within the study. We did not customize the hippotherapy simulator treatment to the ability of the children and hence it is possible that not all patients benefited equally. Further, we did not measure the kinematics of the

simulation and the response of the child (in terms of kinematics and muscle activation) hence we cannot fully explain the mechanism leading to improvements in balance. The duration of treatment was also limited to one 15-minute session per week (for a 10-week period). Apart from these limitations, there were limitations related to the sample: (1) sample was small and therefore a comparative analysis by Gross Motor Function Classification System levels could not be carried out; (2) the sample was biased towards the highest levels of disability (level V); (3) the study included children from a wide age group (4–18 years) and functional levels (Gross Motor Function Classification System levels I–V) on the assumption that all had the potential to benefit equally from the intervention.

This study has also some important strengths. One of them is that this is the first study analysing the effect of hippotherapy simulators in posture control and gross motor function in cerebral palsy children with standardized measurements, while other studies carried out with mechanical hippotherapy simulators did not use standardized measurements.[17,19] Besides, this study is a randomized controlled trial, including a control group and a larger sample of cerebral palsy children than most of the previous studies (except for Davi et al.[28]) regarding not only hippotherapy simulator studies, but also traditional hippotherapy or horseback riding therapy ones. This makes this article valuable as a starting point for studying the therapeutic effects of hippotherapy simulators in the treatment of cerebral palsy children. However more work is needed to identify how this therapy can be adapted for use in all patients with cerebral palsy. A significant body of research is needed to address these issues.

Although our study has focused on hippotherapy simulators, when we had to design the study, we reviewed literature related to hippotherapy simulators but also traditional hippotherapy. Regarding previous hippotherapy simulator research, our treatment protocol was similar to those used by Kuczyński et al.[17] (20 minutes microprocessor-controlled saddle riding, performed twice a week for three months) and Quint et al.[19] (sitting on a mechanical saddle 10 sessions of 10 minutes for four weeks). Our study was consistent with the results of Kuczyński et al.,[17] which showed that the therapy led to a noteworthy improvement in the postural performance of the cerebral palsy children in sagittal as well in frontal planes, although they did not use standardized measurements. Quint et al.[19] only measured pelvic mobility and not postural control or balance so comparison of results is not possible.

With regard to traditional hippotherapy or horseback riding therapy it is difficult to compare our results with the studies carried out because: (1) most of the studies were based on extremely small sample sizes of children; (2) many of these studies did not include a control group; (3) the length and duration of the programmes varied greatly. Some studies on traditional hippotherapy or horseback riding therapy have not found a therapeutical effect on Gross Motor Function Measure in cerebral palsy children[28–30] while others have shown therapeutical effects in all the Total Gross Motor Function Scores except dimension A,[31] in only dimension E[12,32] or in the total score and dimension E.[10,33]

In relation with our work, we think that three studies should be highlighted. The first, carried out by Sterba et al.,[10] because it suggests that significant changes could have been obtained in dimension B of the Gross Motor Function Measure if the sample had been larger. A second study, carried out by Hamill et al.,[30] used the same outcome measurements as us but did not show significant differences on Gross Motor Function Measure and Sitting Assessment Scale after a 10-week hippotherapy programme in three children with Gross Motor Function Classification System level V. The third one, a review carried out by Whalen and Case-Smith,[1] concluded that: (1) it cannot be determined as to whether or not riding twice per week produced a larger effect, but the evidence suggests that riding once per week is sufficient to achieve significant improvements in gross motor function and mobility; (2) it appears that a minimum of 8–10 weeks may be necessary to achieve positive effects and that longer interventions are more likely to yield improvements in gross motor function.

At present, there are no studies comparing the therapeutical effects of hippotherapy simulators with traditional hippotherapy.

From a clinical point of view, we think that a few aspects can be extrapolated from this research. On the one hand, from a mechanical point of view, the

foundations of the use of this kind of therapy are reasonable, as it is directly related to postural control and balance in the sitting position. On the other hand, although the use of hippotherapy simulators is controversial for some therapists because it is said that it only imitates the mechanical pattern of movement and loses all the psychological aspects related to traditional hippotherapy, we consider that this therapy can be very worthy in a clinical setting because a simulator has a low cost when compared with live horses (maintenance of animals, facilities and cost of insurance), it is safer than live horses for the users, more accessible to ride on it for children with restricted mobility and its use does not depend on environmental conditions. Besides, this technology can be easily installed in a clinical setting and it can be combined with physiotherapy-related activities and/or other technology (such as wii games) to make rehabilitation more fun and attractive for children, enhancing the motivational part of the therapy.

Clinical messages

- It is possible to implement a programme of balance training using a hippotherapy simulator for children with cerebral palsy.
- Treatment with a hippotherapy simulator primarily improves posture and balance.
- Greater effects of treatment were seen in children with higher levels of disability and the benefits of treatment continued even after treatment was discontinued.

Acknowledgements

The authors wish to express their appreciation to Patricia Carrera and Santiago Lamas, who helped the research team with statistic analysis, to the translators from the Institute of Modern Languages at San Jorge University, and specially to Dr Sybil Farmer from Keele University for reviewing methodology, data analysis and the presentation of results leading to the final version of the manuscript.

Conflict of interest

The authors declare that there is no conflict of interest.

Funding

This project was supported by Aragón Government with ref: PM059/2007 and title ‘Desarrollo de una plataforma avanzada de hipoterapia y estudio de su beneficio terapéutico’.

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