

Effects of Hippotherapy on Balance and Gait in Ambulatory Children with Spastic Cerebral Palsy

Final Report for Horses and Humans Research Foundation
 May 15, 2015

This project, initiated September 30, 2010, was completed on December 30, 2014. As noted in prior progress reports, recruitment was difficult with an excessive loss of participants, particularly in the control group. In an effort to assist with recruitment we added 2 additional sites in 2013 and although they improved the numbers, many of the additional participants only managed to replace lost participants. Below is a table of participant's by state.

Time Line Update: The primary PI received the final data from the Florida site in late December. The data entry for the Florida site was completed in early January. The scoring of the video recordings of assessments was also completed at the end of December.

The primary PI began data analysis in January. Due to the small numbers in the control group and the fact that, despite randomization, the groups were not similar at baseline the analysis took longer than expected. The PI worked with other researchers within the university to brainstorm ideas to best analyze the data. Numerous data analyses were run from mid-January through mid-May. Finally by utilizing percent changes for between group analysis and absolute numbers for within group analysis the research team believe they have completed the best data analysis possible. As a result of missing data for several assessments on many of the participants, we were only able to analyze for a pre-post and second post intervention type of study. We had too many participants who did not complete the second post assessment to be able to include that data in the analysis. Work on the manuscript began in April for the first few sections. With the data analysis and results completed it is expected that a manuscript will be finalized by the end of June/early July with submission to a peer reviewed journal. With the numerous assessments that were completed this manuscript is especially challenging to write in a format that adheres to most journal's word limits.

Recruitment numbers by site:

State	Screened	Not eligible	Dropped Out	Completed
California	16	6	3	7
Texas	8	6	1	1
Florida	5	0	1	4
Arizona	3	1	1	1
Total	32	13	6	13

Budget: At the end of this written report is the final budget for the project. With the reduced number of participants, treatment costs and personnel costs for assessments were significantly under budget. Supplies were also under budget as we did not need as many assessment forms. With the reduced number of participants it was decided not to utilize a statistician, therefore that money was not used for the study. The final cost of the study was \$22,464.23. HHRF provided initial monies in the amount of \$25,000.00 leaving a balance of \$2,535.77 that was returned to the Foundation in April 2015.

Results: Despite randomization, the control group was less impaired at baseline than the treatment group on all test measures utilized in the study. The treatment group also had more of the younger children (3-4 year olds.) In between group analysis revealed significant differences between the pre and posttest measurements (using percent change) in the pediatric balance scale ($p=.011$) only. In the within group analysis, the control group did not demonstrate any significant changes on any of the measures between pretest and either posttest assessment period. In comparison, the treatment group showed significant improvement on the pediatric balance scale from pretest to posttest 1 ($p=.02$) and posttest 2 ($p=.02$). Similar findings occurred with the Activities Scale for Kids (ASK) with a significant improvement from pretest to posttest 1 ($p=.025$) and posttest 2 ($p=.016$). For the Pediatric Quality of Life – CP version statistically significant differences were not found until posttest 2 ($p=.03$) from the pretest baseline. Although a trend toward improvement in distance walked on the 1 minute walk test was observed it was not statistically significant by posttest 2 ($p=.057$). No significant improvement was observed on the Assessment of Preschool Children’s Participation (APCP) measure.

We are still discussing what these findings actually mean. Because the treatment group was more impaired, we recognize they had more room for improvement which might explain some of our findings. We also noted on the APCP that older and less impaired children had higher scores as they participated in more activities. Because of the length of our study we also noted that time of year may have played a role in the child’s ability to participate in activities, or more importantly how often parents were around their children in order to observe actual activities. (i.e. was the majority of the prior 4 months on which they were reporting during the summer or school year). This may explain why we had no significant finding on this measure of participation, while there were changes in the ASK, which only asks about participation for the past 2 weeks.

Summary: As researchers we have learned several lessons regarding the running of a multicenter study that was more pragmatic in nature than some clinical trials. Lesson one is that a dedicated project manager needs to be part of the process, or if a faculty member is going to serve that role they need a significant amount of release time to monitor the details of the study. With either method (project manager or faculty member), the cost for this individual’s time should be included in future proposals for multicenter studies. We significantly underestimated the time required to monitor a project of this nature. Although we had recruited and hired conscientious individuals to assist with the study, we found without regularly checking on how assessments were completed (including use of all forms) that some individuals made unilateral decisions on not completing some portions of the assessments. This may have been due compliance issues with very young children. Therefore, we had more missing data than we had anticipated at the beginning of the study.

Additionally the length of this study may have been too long for this age group. The longer time-frame may have contributed to the recruitment/retention problem. Research has shown that early intervention in the formative years has more impact than later, so parents are searching and trying new treatments when their children are younger. Although researchers are suggesting we need longer term analysis of treatment interventions, asking parents to not start any new therapies for their 3-4 year old children for 6 months may be asking too much of them. We believe this is why we had such a high dropout rate for the 3-4 year olds in our control group. This may also be a contributing factor in the lack of second posttest follow-up assessments. We will continue to analyze our results as we finalize our initial manuscript.

We would like to thank the Foundation for their financial support of our project, but more importantly their patience in this long process. We are committed to having at least one peer reviewed manuscript published and will work diligently to make this occur.

Respectfully submitted,

Debbie Silkwood-Sherer PT, DHS, HPCS

Nancy H. McGibbon PT, MA, HPCS

ADDENDUM
March 19, 2015

A manuscript was completed and submitted to a peer reviewed journal. The editor and reviewers provided very positive feedback on the manuscript and study. However, they felt the results of the study, and the study itself, would be stronger if we had a more even number of control participants to treatment participants. They especially recommended including more children within the 3-4 year age group. The researchers are currently exploring the feasibility of following this recommendation.

DSS

**CENTRAL MICHIGAN UNIVERSITY
GRANT EXPENDITURE SUMMARY REPORT**

Date: 03/19/14

Effectiveness of Hippotherapy on Balance & Gait in Ambulatory Children with Spastic Cerebral Palsy
Project Period 09/21/2010 - 12/30/2014
Project Director: Deb Silkwood-Sherer
Previous Report Period: 09/21/2010 - 3/15/14
Current Report Period: 3/16/14-12/30/14

CMU Grant # P61347

DESCRIPTION	BUDGET	PREVIOUS EXPENSES	CURRENT EXPENSES	BALANCE
Treatment	\$ 15,750.00	\$ 6,843.25	\$ 4,875.00	\$ 4,031.75
Personnel	\$ 25,526.00	\$ 4,850.00	\$ 2,500.00	\$ 18,176.00
Permanent Equipment	\$ 1,610.00	\$ -	\$ -	\$ 1,610.00
Consumables	\$ 1,414.00	\$ 424.50	\$ 59.09	\$ 930.41
Consultants	\$ 700.00	\$ -	\$ -	\$ 700.00
Travel	\$ 5,000.00	\$ 2,912.39	\$ -	\$ 2,087.61
TOTAL EXPENDITURES	\$ 50,000.00	\$ 15,030.14	\$ 7,434.09	\$ 27,535.77

TOTAL EXPENDITURES TO DATE: \$ 22,464.23

Total Received to Date:	\$25,000.00
Total Expenses to Date:	\$22,464.23
Unspent Balance on Hand	\$2,535.77

MATCH ACCOUNT EXPENDITURES

DESCRIPTION	BUDGET	CURRENT EXPENSES	CURRENT EXPENSES	BALANCE
CMU - Postage	\$ 400.00	\$ 47.19	\$ -	\$ 352.81
Copying of data sheets	\$ 120.00	\$ 120.00	\$ -	\$ -
Graduate Assistant	\$ 4,500.00	\$ 1,525.00	\$ -	\$ 2,975.00
TOTAL EXPENDITURES	\$ 5,020.00	\$ 1,692.19	\$ -	\$ 3,327.81

TOTAL MATCH EXPENDITURES TO DATE: \$ 1,692.19

PRD/010/DAUGHITA
 REPORT: ZFRGM004

CENTRAL MICHIGAN UNIVERSITY
 CMU/PI ZFRGM004 Grant Summary Report

DATE: 04/06/2015
 TIME: 09:11

Grant: P61347 Effectiveness of Hippotherapy on Bal & Gait in Amb Children with Cerebral Palsy Periods: Apr 2015
 WBS Element: 613471 P61347 HIPPO THERAPY - EXTERNAL Begin Date: 09/21/2010
 Sponsor: 6500000341 Horses & Humans Research Fdn End Date: 12/30/2014
 Funds: 6300000000,430000000 Sponsored Program: 1150 Person Responsible: SILKWOOD-SHERER D
 Internal Reference:

Group / Sponsored Class	Budget	Current Period Expenses	Inception to Date	Open Encumbrances	Available Balance
G111000 REG FAC ACADEMIC YEAR SALARIES	6,930.00	0.00	0.00	0.00	6,930.00
G112000 TEMPORARY FACULTY SALARY	700.00	0.00	0.00	0.00	700.00
G114000 PA SALARIES	1,500.00	0.00	0.00	0.00	1,500.00
G116000 GRADUATE ASSISTANT SALARIES	0.00	0.00	0.00	0.00	0.00
G211000 SUPPLIES AND MATERIALS	3,024.00	0.00	483.59	0.00	2,540.41
G220000 TRAVEL	5,000.00	0.00	2,912.39	0.00	2,087.61
G230000 HONORARIUMS	0.00	0.00	0.00	0.00	0.00
G240000 OUTSIDE SERVICES	32,846.00	0.00	17,568.25	0.00	15,277.75
G331000 PARTICIPANT STIPENDS	0.00	0.00	1,500.00	0.00	1,500.00-
TOTALS:	50,000.00	0.00	22,464.23	0.00	27,535.77
G930000 PRIVATE REVENUES	50,000.00-	0.00	25,000.00-	0.00	25,000.00-
TOTALS:	50,000.00-	0.00	25,000.00-	0.00	25,000.00-

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Unspent funds
 2,535.77*