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The Effect of Intensive Suit Therapy Compared to Traditional Physical Therapy on Gross Motor Function in Children with Cerebral Palsy

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Clinical Scenario: I am currently seeing a number of patients whose parents are questioning whether or not intensive physical therapy is appropriate for them. One patient is a four-year-old boy with cerebral palsy. His mother is currently taking him to Portland for intensive suit therapy for 3 weeks. These intensive sessions occur five days a week for five hours each day. After completing his three weeks at intensive, the patient will then return to getting physical therapy once a week in a traditional outpatient pediatric clinic.

My Clinical Question: Do young children with cerebral palsy demonstrate greater gross motor function with intensive physical therapy or traditional physical therapy?

Clinical Question PICO

Population: children with cerebral palsy, age 4, with GMFCS level III-V
Intervention: intensive suit therapy, five days a week for five hours, for a total of three weeks
Comparison: traditional pediatric therapy, 1 day a week for one hour, for a total of three weeks
Outcome: Gross Motor Function Measure -66 (GMFM-66)

Overall Clinical Bottom Line: Based on the results from the studies conducted by Bailes, et al. and Bar-Haim, et al. intensive suit therapy does not improve gross motor function more than traditional physical therapy interventions. The article by Bailes, et al. was methodologically weak making it difficult to draw conclusions that related to my clinical question. The article by Bar-Haim, et al. was strong in methodology and it found that over a ten month period, traditional neurodevelopmental treatment resulted in greater gross motor function improvements when compared to intensive treatment in the Adeli suit. Both articles had populations that matched my clinical situation, although the comparison group in each was different than the treatment I would provide. Bar-Haim, et al. used a comparison group that received ten hours of treatment each week, while I am only treating my patient for one hour a week. Overall, more research is needed to address the efficacy of intensive suit therapy. Specifically, a study comparing intensive suit therapy in short bursts (four, one month sessions) to one visit a week on gross motor function for an entire year would be valuable. Future studies should use an appropriate comparison group, a longer intervention period, and have strong internal validity. Higher quality evidence is needed to justify the use of intensive suit therapy for this population given the cost and time commitment.

Search Terms: suit therapy, Adeli suit, cerebral palsy, gross motor function, space suit, child, pediatric, physical therapy

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Article: Bailes, A., Greve, K., and Schmitt, L. (2010). Changes in two children with cerebral palsy after intensive suit therapy: A case report. *Pediatric Physical Therapy*: 22; 76-85.

Clinical Bottom Line: Although this study found improvements in standing skills after three weeks of suit therapy, it is not possible to state if these changes are clinically significant over a three week period. Neither subject improved in walking skills after intensive suit therapy. As this was two case studies, there are many issues with the study's internal validity. The lack of blinding may have affected the measured results. Lack of a control group makes it impossible to attribute the changes solely to the intensive suit therapy, as traditional physical therapy could also result in these same changes with less cost and time commitment. Costs of intensive therapy are high. Overall, this study suggests that suit therapy may have a positive impact on standing skills, but a randomized controlled trial is needed to confirm if this is a clinically significant improvement.

Article PICO

Population: Two children with spastic dipelgic cerebral palsy, seven and eight years old
Intervention: Therasuit method, four hours/day, 5 days/week, for 3 consecutive weeks
Comparison: None
Outcomes: Pediatric Evaluation of Disability Inventory (PEDI), GMFM-66 Dimensions D & E, 3-dimensional gait analysis

Blinding: There was no blinding done in this study. Although there was no way to blind subjects or physical therapists providing treatment, the authors could have blinded the assessors administering the outcome measures.

Controls: There was no control group for this experiment as it was a case study. Therefore, we have nothing to compare the outcomes with to determine changes that may occur with maturation or traditional physical therapy interventions.

Randomization: Randomization was not used in this study due to the fact there was only two subjects and each was going to receive the Therasuit intervention.

Study: This case study involved use of the Therasuit method to treat two children (age seven and eight) with spastic, dipelgic cerebral palsy. This method involved suit therapy for four hours a day, five days a week over a period of three consecutive weeks. The therapy was administered by physical therapists and occupational therapists trained in the protocol. Inclusion criteria included: GMFCS level III, previous experience with the Therasuit method, ability to follow instructions, and not currently taking oral anti-spasticity medication. Exclusion criteria included: hip subluxation >35%, severe scoliosis, intrathecal baclofen pump, autism, psychiatric or behavioral disorders, progressive encephalopathy , attention deficit disorder, or uncontrolled seizures. Each subject began the protocol wearing the suit for only thirty minutes on day one, and an additional thirty minutes was added each day until the subjects were wearing the Therasuit for 2.5 hours a day during the intervention. Both subjects had bungee cords

applied to their suits over abdominals, back extensors, obliques, gluteals, and scapular stabilizers to increase core stability during activity. The sequence of therapeutic activities for each subject were as followed: hot packs and massage, stretching and ROM, donning of the Therasuit, trunk and lower extremity strengthening activities, upper extremity pulleys, sensory activities (jumping and swinging), fine motor activities, balance, coordination and finally gross motor activities (standing and ambulation). Table 1 displays the goals and specific activities completed with each subject.

Table 1: Goals and Activities for the Two Subjects

Subject One: 8 year old female	Subject Two: 7 year old male
GOALS: ambulating without Lofstrand crutches for community distances and increased independence with self-care skills. ACTIVITIES: single limb stance, ambulation without an assistive device, stairs, curbs, jumping, balance, dressing skills	GOALS: getting up from the floor, ambulating without single point canes for short distances. ACTIVITIES: knee walking, floor to stand activities, stairs, balance, ambulation and hamstring stretching.

Outcome Measures: Although multiple outcomes measures were used in this study, the results for the GMFM dimension D and E most closely match the clinical PICO. The authors cite the *Gross Motor Function Measure User's Manual* what states the GMFM is "valid, reliable, and responsive to change for children with cerebral palsy" although it does not give specific values[1]. A MCID was not stated for the GMFM and one was not found online addressing a clinically important difference in scores over a period of three weeks.

Study Losses: Both subjects in this case study completed the protocol. There were no study losses.

Summary of Internal Validity: Internal validity for this study as poor. As a case study, limitations in randomization and blinding exist. There was no way to blind therapist and subjects. Lack of assessor blinding from the treatment protocol could have influenced the results. There was no need for subjects to be similar at baseline since there was no control group. The lack of control group does make it difficult to attribute the changes to only the intervention and not to other factors that were not controlled for. The one positive factor influencing internal validity was the use of a valid and reliable outcome measure, the GMFM.

Evidence: Table 2 and Table 3 present the Gross Motor Function Measure scores for each subject prior to and following Therasuit intervention.

Table 2: GMFM Data for Subject 1

	Baseline	Post-intervention	Change
GMFM Dimension D	29/39	30/39	+1.0
GMFM Dimension E	41/72	40/72	-1.0

As seen in Table 2, subject one make a slight improvement in GMFM dimension D (standing).

The subject regressed slightly in dimension E (walking, running and jumping) over the three week intervention. As there was only one subject and no control group, there is no way to calculate between group comparisons.

Table 3: GMFM Data for Subject 2

	Baseline	Post-intervention	Change
GMFM Dimension D	23/39	25/39	+2.0
GMFM Dimension E	19/72	19/72	0.0

As seen in Table 3, subject two in this case study saw a two point improvement in GMFM dimension D scores (standing skills). All items on the GMFM are scored on a scale from 0-3, depending on the percentage of the skill attained. Out of the thirteen total skills in the standing section, the subject either made a two point improvement on one single item or a single point improvement on two items. The subject had no change in dimension E scores (walking, running and jumping) over the three week period. There was no control group to make between group comparisons.

Discussion: The data collected to measure gross motor function indicate minimal changes, with some improvements and some regressions. Standing skills improved for both subjects over the three week intervention. As there is no MCID, one cannot say if this change is clinically significant over the three week period. When looking at walking, running and jumping, there was either no change or a regression in these skills following intensive therapy, indicating this intervention did not significantly improve gross motor function in these areas. Since there was no control group, there is no way to determine if changes made were due to maturation or the actual intervention received.

Applicability of Study Results

Benefits v. Costs: According to this study, there was some improvement in standing ability after three weeks of Therasuit intervention. No improvements in walking, running or jumping in these two subjects were noted. The costs to implement Therasuit intensive treatment are quite steep. The suits have to be purchased from the Therasuit Company along with other equipment such as the spider cage and all are very expensive. Cost to the patient's family for four hours of therapy on a daily basis would be very expensive, especially if not covered by their insurance company. Although some insurance companies will cover intensive therapy, it quickly depletes the child's therapy benefits for the year limiting his/her access to other services.

Feasibility of Treatment: The main factor limiting the feasibility of this protocol is the equipment and training needed to perform Therasuit intensive treatment. Training on the Therasuit method is a multiple month process that involves traveling to a training facility. Equipment can only be purchased from a small number of vendors and it is quite expensive. The authors of the study were very detailed at presenting their protocol, thereby making it easy to implement with adequate training and equipment. Although the authors of this study state "parents are satisfied with intense therapy programs," there is some concern about compliance and satisfaction with therapy on a daily basis.

There was not a significant need for home exercise with this protocol. A patient would have to be covered on an insurance plan for it to be financially feasible.

Summary of External Validity: The poor internal validity of this study also limits its external validity. As it was a two person case study, it is impossible to generalize the results to the general population of children with cerebral palsy. Of the two subjects, subject two is most like the patient in my clinical scenario. They are both male, with lower functional abilities prior to the start of the intervention. My patient would have goals similar to those set for subject two in this study.

Article: Bar-Haim, S., Harries, N., Belokopytov, M., Frank, A., Copeliovitch, L., Kaplanski, J., and Lahat, E. (2006). Comparison of efficacy of adeli suit and neurodevelopmental treatments in children with cerebral palsy. *Developmental Medicine and Child Neurology*: 48; 325-330.

Clinical Bottom Line: This is a high quality, randomized, controlled trial (PEDro score 7/10). The results indicate that intensive treatment in the Adeli suit leads to significant improvements in gross motor function over the month long treatment session. Subjects receiving traditional NDT method had greater improvements over the long term ten month period. Due to a lack of statistics provided, statistical computation was not possible. The internal validity of the study was strong, and the article PICO was a good match to my clinical scenario. The Adeli suit method has great costs associated with training and equipment, therefore one must consider whether these findings justify the expense. It seems the best choice to improve gross motor function, according to this study, would be a traditional NDT approach that resulted in long term significant improvements even after intervention completion.

Article PICO

Population: Twenty four children with cerebral palsy, GMGCS levels II-IV, 6-12 years old
Intervention: Four weeks of treatment in the Adeli suit, 2 hours/day, 5 days/week, 20 total sessions
Comparison: Four weeks of neurodevelopmental treatment, 2 hours/day, 5 days/week, 20 total sessions
Outcomes: Gross Motor Function Measure (GMFM), Mechanical Efficiency Index during stair climbing measured at completion of treatment and 9 month follow-up

Blinding: Due to the nature of the physical therapy provided, there was no way to blind the patient or therapists providing treatment to group allocation. The therapist administering the GMFM was blinded from treatment groups and scores from previous measures.

Controls: The control group received neurodevelopmental treatment from physical therapists trained in this intervention and at least seven years experience. The control and intervention groups received equal number of treatment sessions and hours. Subjects from both groups discontinued all other therapies during the study.

Randomization: Twenty four subjects were randomly divided into two groups by a computer program. Subjects were stratified according to age and GMFCS level. This stratification was necessary in order to ensure similar groups at baseline.

Study: This randomized controlled trial included a sample size of twenty four children; twelve in the intervention group and twelve in the control group. Inclusion criteria for the study included: diagnosis of cerebral palsy, age six to twelve, GMFCS level II-IV, no orthopedic surgery or spasticity management in the last six months, not a candidate for surgery for at least a year, and parental agreement for randomization into either treatment group. Exclusion criteria included: hip dislocation, scoliosis, high degree of spasticity, poorly controlled epilepsy, hydrocephalus, and progressive encephalopathies and myopathies. The intervention group received four weeks of intensive treatment in the Adeli suit. The control group received four weeks of neurodevelopmental treatment (NDT). Both groups received twenty total sessions over a period of four weeks.

Table 4: Study Design

Intervention Group	Control Group
1. Massage before fitting of the suit 2. Passive stretching of all limbs 3. Application of suit 4. Suit exercises (walking, sit→stand, jumping, climbing stairs and ladders)	1. Passive stretching of lower extremities 2. Techniques to reduce spasticity and facilitate normal movement patterns 3. Walking, sit → stand
Treatment provided by Russian PTs who were experts in the Adeli suit method	Treatment provided by PTs with NDT training and seven years of experience

Outcome Measures: The outcomes measures used in this study were the GMFM-66 and metabolic cost of stair climbing. For the purposes of my clinical scenario, only results of the GMFM will be analyzed as it best matches the clinical PICO. The GMFM-66 was performed prior to treatment, at the end of treatment, and at a nine month follow-up appointment. Although no mention was made in the article regarding validity and reliability of the outcome measure, Russell, et al. report the reliability of the GMFM-66 to have an intra-class correlation coefficient equal to .9932[1]. Russell, et al. also report the outcome measure has been validated both for populations of children with cerebral palsy and Down's Syndrome[1]. Wei, et al. report test-retest reliability to be .9666 and validity of the GMFM-66 to be .9782 in a study of children with cerebral palsy under the age of three[2].

Study Losses: There were no reported study losses. Three of the twenty four patients were given an additional week to complete the twenty sessions required in the study.

Summary of Internal Validity: The internal validity of this study is good. Where able, blinding was used appropriately, and the groups were randomized. Subjects were found to be similar at baseline, and a valid outcome measure (the GMFM) was used. One small threat to the internal validity may be the validity of the mechanical efficiency index used during stair climbing, as it was not mentioned. This is not important to me, as it is not the outcome measure I am interested in for my clinical scenario.

Evidence: The data collected during this study is summarized in Table 5 below.

Table 5: Gross Motor Function Measure-66 Scores: Mean Score (Standard Error of Measurement)

	Intervention Group- Mean (SEM)	Control Group- Mean (SEM)
Baseline	54.0 (4.0)	52.2 (3.0)
1 month	55.0 (4.1)*	52.9 (3.0)
10 months	54.7 (4.0)	54.1 (3.1)**

*reported significantly different from baseline measurement ($p<.037$)

**reported significantly different from baseline measurement ($p<.006$)

When looking at the data reported, one can see the intervention group averaged a one point improvement during the four weeks of treatment. The authors report this is a clinically significant difference ($p<.037$), although lack of raw data made statistical calculations impossible. The control group receiving NDT also made improvements in gross motor function over the month of treatment by an average of .70. At the ten month follow-up, the group receiving Adeli suit treatment regressed in gross motor function by an average of .30 from their scores at the end of the intervention. The control group continued to make improvements over the nine months following intervention, with an average of 1.2 points improvement in those nine months. Again there is no way to do between group comparisons for this data due to missing information about standard deviations for the change scores.

Discussion: Overall, this study shows that intensive treatment in the Adeli suit results in significant improvements in gross motor function at the conclusion of one month of treatment ($p<.037$). The decrease in gross motor function during the following nine months suggests that patients receiving Adeli suit treatment may not retain the skills they developed after treatment concludes. Although the control NDT group did not make significant improvements during the month of treatment, this group did continue to improve following the intervention. In fact, the NDT group had significantly improved gross motor function ($p<.006$) nine months after the conclusion of the intervention. This suggests that Adeli suit treatment could result in short term gains quickly, although long term improvements in gross motor function may best occur with traditional NDT methods. The study does not address if treatment in the Adeli suit at a lower frequency (once to twice a week) would also result in improved gross motor function.

Applicability of Study Results

Benefits v. Costs: There are many costs associated with Adeli suit treatment. The suits must be purchased from Russia, at quite an expense. In addition, the suits do not adjust well as the child grows, so multiple suits must be purchased for different sized children. To become an expert in this method, additional training is necessary that requires extra travel costs. The high cost of ten hours of physical therapy is not typically covered by insurance companies. Due to all the costs associated with this intervention, the reported short term benefits from the Adeli suit do not justify the increased cost for the clinic.

Feasibility of Treatment: One major difficulty in reproducing this protocol in my clinic is the lack of information provided about the control group. The control treatment was vague, making it difficult to

compare to a typical pediatric treatment. Again, a main limiting factor is the availability of training for physical therapists and equipment needed for the Adeli suit method. The number and duration of treatment sessions are typical for an intensive program, although it may be difficult for patients and families to maintain this schedule for multiple weeks. Furthermore, not all patients will have insurance policies that will allow for this type of intervention. No patient pain was reported for either treatment group.

Summary of External Validity: The strong internal validity of this study builds to the strength of the external validity. The subjects in this study are a little older than the clinical patient, although the GMFCS levels appear to make him an appropriate match. The clinical patient does have an insurance company that will cover intensive therapy. The larger sample in this study allows the results to be generalized to a broader population of children with cerebral palsy.

Synthesis/Discussion: There are only two published articles in peer reviewed journals addressing the efficacy of intensive suit therapy on gross motor function of children with cerebral palsy at this time. One additional article was found on the website for the suit manufacturer, however manufacturer bias must be considered. The Bailes, et al., two case studies lacked quality and had a low PICO score (1/10). Its small sample size and lack of comparison group diminishes its strength. The assessing physical therapist was not blinded to treatment received which may result in unintentional bias potential depending on his/her beliefs about the Therasuit.

The second study by Bar-Haim, et al. had much higher methodological quality. The subjects were recruited from all over the nation of Israel, and the exclusion criteria did not limit the population in a way that shaped the results they were looking for. The treatments provided in the two groups were dramatically different. Treatment in the Adeli suit was very structured and specific. Lack of NDT protocol and interventions provided is troublesome. Twenty four is a large number of subjects for a pediatric study but no power analysis was done. The GMFM-66 is a valid and reliable outcome measure.

Taking both studies results into account, intensive suit treatment has not been proven more beneficial than traditional therapy to improve gross motor function. Bailes, et al. found improvements in standing skills after suit therapy, but there was no comparison control group. Therefore, the results do not answer the clinical question as to if suit therapy is better than traditional therapy for gross motor skill development. The second study by Bar-Haim, et al. found significant improvements in gross motor function after one month of intensive Adeli suit therapy. Additionally, subjects receiving Adeli suit therapy were found to regress in gross motor skills during the nine months following treatment. Long term, this study found that the best results over a ten month period were seen in subjects who received traditional NDT interventions. Whether or not the improvements seen in both groups were due to the increased frequency of treatments or the interventions alone was not addressed.

References:

1. Russell, D.J., et al. (2002). *Gross Motor Function Measure (GMFM-66 & GMFM-88) User's Manual.* London: Mac Keith Press.

2. Wei, S., et al. (2006). “Reliability and validity of the GMFM-66 in 0 to 3-year old children with cerebral palsy.” *American Journal of Physical Medicine and Rehabilitation*: 85(2), 141-147.