Clinical Practice Guideline: **Intensive Model of Therapy**

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Product: **Specialty**

Related Policies:
CPG 135: Physical Therapy Medical Policy/Guideline
CPG 155: Occupational Therapy Medical Policy/Guideline
CPG 166: Speech-Language Pathology/Speech Therapy Guideline
CPG 257: Developmental Delay Screening and Testing

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GUIDELINES

American Specialty Health – Specialty (ASH) considers Intensive Model of Therapy (IMOT) programs (occupational, speech and/or physical therapy services as described below) as not medically necessary for all indications including but not limited to cerebral palsy and other neurologic disorders. IMOT is considered unproven as there is insufficient evidence to conclude that IMOT demonstrates improved long-term and short-term outcomes over less intensive/frequent care.

ASH considers suit therapy or the home use of a suit therapy device for the treatment of any condition including, but not limited to, cerebral palsy or other neuromuscular conditions as unproven.

Patients must be informed verbally and in writing of the nature of any procedure or treatment technique that is considered experimental/investigational or unproven, poses a significant health and safety risk, and/or is scientifically implausible. If the patient decides to receive such services, they must sign a Member Billing Acknowledgment Form (for Medicare use Advance Beneficiary Notice of Non-Coverage form) indicating they understand they are assuming financial responsibility for any service-related fees. Further, the patient must sign an attestation indicating that they understand what is known and unknown about, and the possible risks associated with such techniques prior to receiving these services. All procedures, including those considered here, must be documented in the medical record. Finally, prior to using experimental/investigational or unproven procedures, those that pose a significant health and safety risk, and/or those considered scientifically implausible, it is incumbent on the practitioner to confirm that their professional liability insurance covers the use of these techniques or procedures in the event of an adverse outcome.

DESCRIPTION/BACKGROUND

Intensive Model of Therapy (IMOT) was developed in Poland for treating children and adults with cerebral palsy and other neurologic disorders. This therapy involves performing exercises over an extended period of time — typically 5 days a week for 4 hours a day. The time in the program may be a 3-week period or longer. Different centers may alter this extended period of time. As an example, one center treats patients 2-6 hours a day for 5 days a week for 3 full weeks. The time and duration of each intensive therapy session will fluctuate case by case depending on the patient's diagnosis, age, stamina, strengths/weaknesses, and needs. Proponents of IMOT state that studies have shown that a 3-week session of intensive therapy helps a child realize the same goals it would usually take a full year of traditional therapy to achieve. They conclude that patients with neuromuscular challenges need this focused and intense approach that provides time to practice the skills they need to learn — like sitting, standing, or walking. However, these claims are premature currently, as the research is not sufficient to support their statements.

IMOT programs focus on exercises to increase strength and endurance, work to decrease unwanted reflexes, and teach new improved motor patterns through repetition and correct posture. A unique feature of IMOT is the preparation time used prior to exercise, which may be massage. Some clinics use a device called the Universal Exercise Unit. This allows the patients to work on balance and functional skills such as kneeling, sitting, or standing with less assistance. Prolonged static stretching is also achieved using universal exercise units or "cages." The "monkey cage" is a rigid metal cage with three walls and a top panel upon which pulley systems may be arranged to stretch and strengthen muscles. Following stretching, each joint is ranged through diagonal patterns similar to proprioceptive neuromuscular facilitation (PNF) patterns. The "spider cage" utilizes bungee straps wherein the subject can be supported while learning to weight-shift, jump, kneel, half-kneel, and step up and over objects. The "spider cage" is proposed to allow for controlled and independent movement and appears to have the effect of decreasing pathological and neurological reactions that affect mobility. The "spider cage" is used as a tool for implementing neurodevelopmental treatment (NDT), one of the most popular and clinically accepted methods for "(re)programming" the central nervous and neuromuscular systems and "teaching" the brain more normal motor skills. The NDT approach devised by the Bobaths in the 1940's encourages children with neuromuscular deficits to 1) learn more normal movement patterns, 2) change positions comfortably in different environments, and

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3) improve quality of movement and functional skills. Vertical and quadruped standers are utilized in IMOT for additional weight-bearing and proprioception through all extremities.

Another unique intervention utilized in IMOT is a therapeutic suit. Therapeutic suits such as the Adeli and NeuroSuit are proposed to assist in re-training the central nervous system by allowing the child to overcome increasingly complex pathological movement and to execute and repeat previously unknown movement patterns. The Adeli suit is an adaptation of the Penguin suit used by Russian cosmonauts to counteract the effects of weightlessness in space. The Penguin suit, which provides resistance to movement, decreases muscle atrophy, and reduces development of osteoporosis and apraxic gait in anti-gravity conditions, was created in 1971 by the Russian space program. The Adeli ("little penguin") suit consists of a head piece, vest, shorts, knee pads and special shoes upon which elastic cords with bungee-type characteristics are fastened over flexor and extensor muscles while also providing correct limb alignment. The theory behind the Adeli suit is that once the body is in proper alignment with support and pressure through all joints, intense movement therapy can be performed that will [re]educate the brain to recognize correct movement patterns and muscle activity. The NeuroSuit frames the body providing support and resistance simultaneously. Claims are that it improves and changes proprioception (pressure from the joints, ligaments, muscles), reduces a patient's undesired reflexes, facilitates proper movement, and provides additional weight bearing distributed strategically throughout the body. This additional weight bearing provides strong feedback to the brain which helps create new improved patterns of movement such as when walking while the body is maintaining a more upright, correct posture. The NeuroSuit is worn for two-hour periods and can be used either by qualified physical or occupational therapists. It is made of a vest, shorts, knee and elbow pads, gloves, shoe attachments, and a hat if necessary. All these pieces are interlocked by bungee type cords. These cords assist with proper alignment of the body and essentially frame the body from the outside (external skeleton).

The NeuroSuit offers similar benefits as the Adeli suit; however, the NeuroSuit is currently the only therapeutic suit that offers upper extremity components. The elbow pads and gloves have hooks to which bungee cords can be attached and facilitate positioning out of flexor synergy patterns typically seen in children with CP.

EVIDENCE REVIEW

Intensive therapy is described inconsistently throughout the research. Some literature describes it as sixteen weeks, five days per week for 50-minute sessions; others describe four weeks, four days per week for 45-minute sessions. Some researchers suggest that increasing the frequency and duration of therapy sessions, then allowing a rest break before resuming traditional therapy, may produce significant and long-lasting changes in strength, tone, posture, and gross motor performance. Some literature refers to intensive therapy based on the intervention rather than the frequency and duration of the therapy. When used in this way, researchers will talk about an intensive intervention, such as Constraint-Induced Movement Therapy or Intensive Bimanual Therapy, and refer to either short-length, high-duration (‘day camp’) or long-length, low-duration (distributed model) to distinguish between what is similar to IMOT with regards to frequency and duration and routine, traditional care. Often the choice of therapy model (day camp or distributed) may be based on school schedules and proximity to clinical settings. Intensive “day camp models” lasting 2-3weeks are often used for school-aged children, conveniently fitting within school holidays. For preschool children, more distributed practice models (~2 h/d) spanning a greater number of weeks have been applied in the children's daily environment. The choice of distributed practice for this population is practical since extended hours of daily training are not feasible in young children.

Sakzewski et al. (2014) authored a paper on the state of the evidence for intensive upper limb therapy approaches for children with unilateral cerebral palsy. Targeted upper limb therapies such as constraint-induced movement therapy, bimanual training, and combined approaches were discussed. With regards to this guideline, it will not discuss the effectiveness of these types of interventions but rather the dose (duration and frequency), intensity and context (to some degree). Models of therapy delivery in this review were broadly categorized as short-length, high duration or long-length, low-duration (distributed model). There has been considerable variation in both the total dose of therapy provided as well as the proportion of direct ‘‘hands on’’ intervention provided by therapists and indirect therapy via use of home/preschool programs. Based on articles included, short-length, high duration therapy models had been carried out over a two to four-week period, with frequency ranging from 2 to 7 sessions per week. Session times (duration) ranged from 1.5 to 6 hours, with the total dose of direct ‘‘hands on’’ therapy varying between 18 and 126 hours. Accompanying home practice was required in most studies with the expected dose between 21 and 240 hours. Distributed models of intervention ranged from 5 to 10 weeks in length with between 1 and 3 sessions per week. The dose of direct therapy ranged from 8 to 90 hours, with proportionally greater expectations for home practice (28–168 hours). A direct comparison of home versus center-based constraint induced movement therapy (*n* = 14) demonstrated no immediate differences between the two therapy contexts. There was some suggestion of greater gains by the home base group at 3 months post-intervention, supporting the notion of generalization of skills. However, the sample size is too small to make a definitive conclusion regarding context. Findings also suggest that intervention can be carried out effectively by family members, teachers, or students as long as they receive training and supervision from therapists. The idea that positive outcomes have been reported regardless of the provider suggest that supplementing physical or occupational therapists with trained non-health care providers may decrease costs. To date, there has been no direct comparison of intensive versus distributed models of constraint-induced movement therapy. The optimum timing, dose, and impact of repeat episodes of intensive upper limb therapies require further investigation. Authors concluded that key components of service provision should be that therapy should be goal directed, using contemporary motor learning–based approaches such as constraint-induced movement therapy or bimanual task-oriented therapy and be provided at an adequate dose. Most studies used a therapy dose varying from 40 to more than 120 hours, and therapy can be effectively provided individually or in group sessions, augmented by a home program.

Andersen et al. (2013) completed a review on intensive upper extremity training for children with hemiplegia. Authors conclude that both constraint-induced movement therapy (CIMT) and intensive bimanual training lead to improvements in upper extremity function. They surmise that intensity is a key factor, but the minimum intensity required (number of hours per day and days per program) to achieve positive outcomes remains to be determined. They also state that it cannot be determined whether functional gains persist or if periodic bursts of intensive goal-directed upper limb intervention are required to maintain and generalize the gains made. Sakzewski et al. (2014) authored a meta-analysis on the efficacy of upper limb therapies for unilateral cerebral palsy. When looking at doses, of the two studies noted, one compared an average of 114 hours of constraint-induced to 47 hours of bimanual treatments; the other compared 72 hours of constraint-induced to 44 hours of bimanual occupational therapy (OT). Together, authors suggest that 40 hours of therapy was adequate to yield meaningful clinical changes in upper limb use and individualized outcomes. One study also directly compared 126 with 63 hours of constraint-induced therapy in a small group of 3- to 6-year-old children and found that no benefit was conferred by the additional time. The exact critical threshold dose of intervention required to achieve meaningful changes in upper limb function remains unknown. It remains unclear whether there are differences in efficacy of intensive versus distributed models of therapy, and between interventions primarily providing direct hands-on therapy by therapists and indirect therapy relying on caregivers delivering intervention via home programs. Authors pose these questions for further research given the state of the evidence: what is the critical threshold dose of intervention and is there a dose age relationship? And is there additional benefit of intensive short-duration interventions versus distributed models of care and does the context of therapy delivery (home, school, clinic, community) impact outcomes?

Bower et al. (2001) aimed to determine whether motor function and performance is better enhanced by intensive physiotherapy or collaborative goal setting in children with cerebral palsy. More specifically, whether intensive physiotherapy accelerates the acquisition of motor function and performance over a six-month period, and if so, to determine if the effect is cumulative. During routine three-month periods the median amount of physiotherapy given was around six hours, whereas during each of the two intensive three-month treatment periods the median amount of physiotherapy given was 44 hours. The cost of providing intensive therapy to 28 children over the six-month period was $75,765 on the basis that only therapy received by the child was paid for at the rate of $30 per hour. No child received the full intensity of treatment offered which was 120 hours for the six-month treatment period. Throughout the trial the therapy given was described by each physiotherapist involved and was found to consist of a mixture of muscle stretching, passive corrective manual handling, positioning, including the use of equipment, orthoses and casting as considered necessary, muscle strengthening and active movement in addition to gross motor skill training along developmental and functional lines as considered appropriate by the child's physiotherapist. Treatment was primarily targeted at gross motor abilities and not manual dexterity. After the first three months of the treatment period, there was a difference of 3.1 percentage points in favor of intensive physiotherapy in the dimensions of the Gross Motor Function Measure (GMFM) scores in which aims and goals had been set compared with routine amounts of therapy in the equivalent dimensions, and a difference of 0.3 percentage points in favor of intensive therapy in similar dimensions of the GMFM scores compared with routine amounts in the equivalent dimensions after the second three months of treatment period. During the 6-month treatment period children receiving routine amounts of therapy (*n*=27) improved their mean total GMPM score by 3.3 percentage points and children receiving intensive amounts of therapy (*n*=28) improved their mean total score by 1.3 percentage points. There were no statistically significant differences in the GMFM or Gross Motor Performance Measure (GMPM) scores between aim and goal-directed therapy or between routine and intensive amounts of therapy at any of the later assessments. In summary there were no statistically significant differences in the scores achieved between intensive and routine amounts of therapy in either function or performance or between aim-directed or goal-directed therapy. In addition, in the current study intensive therapy where children were treated five times a week for six months showed low compliance and therapy was considered tiring and stressful by many of the participants who were glad when the intensive therapy ended.

Increasing the frequency of weekly treatments over a long period is very demanding for the children and their families and as such, could jeopardize the efficacy of intensive therapy. Authors stated that it is doubtful that more prolonged trials of therapy beyond routine care would show a different result, partly on account of the failure to show a greater change after 6 months than after the 2 weeks of intensive therapy given in their previous study (Bower et al., 1996).

Trahan and Malouin (2002) completed a pilot study on intermittent intensive physiotherapy in children with cerebral palsy. This pilot study was designed to: 1) determine the feasibility of a rehabilitation program combining intensive therapy periods (4 times/week for 4 weeks) separated by periods without therapy (8 weeks) over a 6-month period in young and severely impaired children with cerebral palsy (CP); and 2) measure the changes in gross motor function after enhanced therapy periods (immediate effects) and rest periods (retention). Physical therapy (PT) (in phases A, Bt1, and Bt2) consisted of an individual session of 45 minutes. During phase A (baseline), the children underwent conventional physical therapy (twice a week). The duration of phase A ranged from 8 to 20 weeks (staggered baseline). In phase B (experimental), intensive physical therapy (4 times a week) was provided over a 4-week period (phase Bt) followed by an 8-week rest period without any treatment (phase Br). This first sequence of 12 weeks' duration (Bt1: 4 weeks; Br1: 8 weeks) was repeated (Bt2: 4 weeks; Br2: 8 weeks) for a total experimental phase duration of 24 weeks PT administered throughout the study by the children's treating physiotherapist, was the regular therapy based on the neurodevelopmental approach described by Mayston (1992). This approach uses techniques of handling to guide the child's movements with carefully graded stimulation. The rehabilitation program of all children also included OT, which focused on the upper-extremity function (manipulation, prehension), hand–eye coordination tasks, and perceptual training. OT treatments followed a schedule similar to that set for the PT treatments. During the therapy periods, treatments were carried out at the rehabilitation center and children generally used transportation services provided by the center. During phase Br, when all treatments (PT and OT) were discontinued, the children did not come to the center and parents were given general advice without a specific home program. In conclusion, this pilot study showed that children with severe impairments who had quadriplegia improved their motor performance when short periods of high treatment frequency alternated with longer periods of rest. The short periods of intense therapy were well tolerated, and the motor performance of the children did not deteriorate during the rest periods without therapy.

Most of these studies raised questions about the specificity of the effects observed, either because of a lack of information about the therapy provided or because of methodological concerns related to the outcome measures, the duration of therapy and compliance with treatments.

Tsorlakis et al. (2004) evaluated the effectiveness of neurodevelopmental treatment (NDT) on gross motor function of children with CP, and particularly to investigate the effect of intensive NDT intervention. The hypothesis was that the children in the intensive therapy group would improve more over time than the children in the reference non-intensive therapy group. Participants were 34 children (12 females, 22 males; mean age 7y 3mo [SD 3y 6mo], age range 3 to 14y) with mild to moderate spasticity and hemiplegia (*n*=10), diplegia (*n*=12), and tetraplegia (*n*=12). Therapy was individualized for each child's condition and was dictated by the child's unique clinical needs. Differences in therapy were influenced by variations in the children's severity level and not by differences in therapists' techniques. Each child had a therapist (instead of one therapist for all children) who administered the therapy and set the intervention goals, in accordance with the principles of NDT, thereby minimizing the danger of personal bias. This was preferred for reasons of internal validity because the children would be unfamiliar with their therapist, which could affect their cooperation and performance. All the therapists had been NDT certified for at least 5 years, with clinical experience for more than 10 years. Parents had the responsibility for, and a justifiable interest in, ensuring their children complied with the program. The difference (2 or 5 sessions) in intensity of the therapy between the two groups was, therefore, maintained over the whole study. The NDT intervention occurred over 16 weeks in children with mild to moderate spasticity and a distribution of hemiplegia, diplegia, and quadriplegia improved their gross motor function as measured with the GMFM. This improvement was significant for both groups. Furthermore, intensive NDT intervention had a greater effect on children's motor function than reference non-intensive intervention. This conclusion suggests more intensive NDT in CP may be a better option, however the small sample size reduces the power of the results. More research is necessary to confirm results.

Christiansen and Lange (2008) aimed to compare the effect of the delivery of the same amount of intermittent versus continuous physiotherapy given to children with CP. This was organized either in an intermittent regime four times a week for 4 weeks alternating with a 6-week treatment pause, or a continuous once or twice a week regime, both for a total of 30 weeks. Therapy was administered according to generally accepted physiotherapeutic principles. A prospective, randomized controlled design was used. Twenty-five children (16 males, nine females; median age 3 y, range 1 y-8 y 1 mo) participated. The children were stratified by age and function level (all levels represented) using the Gross Motor Function Classification System and assigned to continuous or intermittent treatment. The Gross Motor Function Measure 66 (GMFM-66) was used as the outcome measure before and after intervention. Statistical analysis revealed that both groups increased their GMFM scores during intervention (intermittent group $p=0.028$; continuous group $p=0.038$), while there was no significant difference comparing delta scores between groups ($p=0.81$). Compliance was significantly higher in the intermittent group ($p=0.005$), but there was no association between GMFM score and compliance. The study shows that organizing physiotherapy in two markedly different ways yields identical outcome measures for children with CP. Ustad et al. (2009) examined effects of blocks of daily physiotherapy in 5 infants with cerebral palsy. Intervention consisted of two 4-week periods of daily physiotherapy, interrupted by 8 weeks of physiotherapy as usual. The children were assessed every 4th week using the Gross Motor Function Measure. Compliance was noted as high. All infants showed gross motor progress compared with baseline but separating effect of daily physiotherapy from physiotherapy as usual was inconclusive. Parents did prefer the intensive treatment alternative. Authors concluded that blocks of intensive therapy can be an alternative to regular dosage of physiotherapy, but until further studies are conducted, the physiotherapy intervention, intensity, and frequency should be tailored to meet the needs of each individual infant and family. Again, the sample size was very small and thus the power of the study is not adequate to confirm conclusions.

Arpino et al. (2010) compared the efficacy of intensive versus non-intensive rehabilitative treatment in children with cerebral palsy. A meta-analysis of the studies published between January 1996 and July 2007 was performed using studies including infants/children/adolescents (1-18 years old). Authors concluded that intensive therapy tended to have a greater effect than non-intensive. The effect of intensive treatment tended to be apparently stronger for children 2 years of age. Authors concluded that their meta-analysis showed that, in children with cerebral palsy, intensive conventional therapy may improve the functional motor outcome, but the effect size seemed to be modest. These results should be taken with caution as the studies included, and methodology used was of low quality. Elgawish and Zakaria (2014) assessed gross motor progress in children with spastic (quadriplegic and diplegic) CP treated with intensive physical therapy (PT) as compared with a matched group treated with a standard PT regimen. Out of 45 patients with spastic CP aged 2-6 years, 25 patients were assigned to an intensive therapy group (group A), whereas 20 patients were assigned to standard therapy (control group B). Patients were classified according to the gross motor function classification system. The intervention program was administered for 16 weeks, with sitting and walking as the treatment goal. The gross motor function measures 88 and 66 (GMFM-88 and GMFM-66) and gross motor performance measure (GMPM) were used for assessment at baseline, at 8 weeks, and at 16 weeks after intervention. At baseline, there were no statistically significant differences between the two groups. After 8 and 16 weeks, both groups improved significantly for all measures, except sitting for the GMFM-88. No statistically significant differences were found between the two groups for GMFM-66 scores after 8 weeks, however significant differences existed after 16 weeks with Group A performing better. Statistically significant differences were found between the two groups for GMFM-88 and GMPM scores after 8 and 16 weeks, again with Group A performing better. Authors concluded that intensive PT regimens were more beneficial than standard therapy in spastic CP, especially in children with a low functional level. However, this was not tested statistically in the proper way. Results should be considered with caution given both groups improved across all time periods and for all measures and for other methodologic reasons.

Park (2016) attempted to investigate the effect of physical therapy frequency based on neurodevelopmental therapy on gross motor function in children with cerebral palsy. The study sample included 161 children with cerebral palsy who attended a convalescent or rehabilitation center for disabled individuals or a special school for children with physical disabilities in South Korea. Gross Motor Function A total of 93 boys and 68 girls were recruited. The age range was 6–15 years. Measure data were collected according to physical therapy frequency based on neurodevelopmental therapy for a period of 1 year. Results demonstrated the differences in gross motor function according to physical therapy frequency were significant for crawling, kneeling, standing, and Gross Motor Function Measure total score. The differences in gross motor function according to frequency of physical therapy were significant for standing in Gross Motor Function Classification System Level V. Authors concluded that intensive physical therapy was more effective for improving gross motor function in this population of children with cerebral palsy. In particular, crawling and kneeling, and standing ability showed greater increases with intensive physical therapy. Although there was a significant effect between gross motor function and physical therapy frequency, the correlation coefficients were small, thus caution should be taken with study interpretation.

Størvold et al. (2018) investigated the association between physical therapy frequency and gross motor improvement in children with cerebral palsy (CP). This was a prospective cohort study of 442 children aged 2-12 years in which the outcome was change in reference percentiles for the Gross Motor Function Measure (GMFM-66) between two subsequent assessments ($n = 1056$). Results noted a dose response association between physical therapy frequency and gross motor improvement. Mean change was 4.2 percentiles larger for physical therapy 1-2 times per week and 7.1 percentiles larger for physical therapy >2 times per week, compared to less frequent physical therapy when analyzed in a multivariable model including multiple child and intervention factors. The only statistically significant confounder was number of contractures which was negatively associated with gross motor improvement. Authors concluded that when gross motor improvement is a goal for children with CP, more frequent physical therapy should be considered. They also emphasize that contractures should be addressed in order to optimize gross motor improvement for children with cerebral palsy.

Hsu et al. (2019) assessed the effects of intensive exercise-based therapy on improvement in gross motor function in children with CP. Authors searched for randomized clinical trials evaluating the effects of therapeutic exercise training by using Gross Motor Function Measurement (GMFM) 66 and 88 among children with CP. Studies that used interventions in addition to therapeutic exercise were excluded from the present meta-analysis. Exercise intensity was defined using the number of training hours per day and duration of intervention (in weeks). The effects of the number of daily training hours and program duration on GMFM improvement were evaluated using meta-regression. Results: The comprehensive search returned 270 references, and 13 of 270 references met the eligibility criteria. The 13 trials recruited 412 children with CP. These trials measured motor improvements by using GMFM-66 (n = 8) and GMFM-88 (n = 5). The GMFM scores in the children who received the therapeutic intervention did not show significantly greater improvement than those of the children who received standard care. Meta-regression analysis revealed that the improvement in GMFM scores was positively associated with the number of daily training hours (point estimate = 0.549; $p = 0.031$). Authors included that intensive physical exercise improved CP outcomes in the intervention and standard therapy groups. An increase in the number of daily training hours improved in CP outcomes in the children who received standard therapy.

Das et al. (2019) summarized and evaluated the effectiveness of physiotherapy interventions in children with CP. Only studies with a systematic review or meta-analysis on PT interventions in children diagnosed with CP were included. Thirty-four systematic reviews were identified that distinguished 15 different interventions. Moderate evidence of effectiveness was found for constraint-induced movement therapy for upper limb recovery, goal-directed/functional training, and gait training to improve gait speed. Conflicting evidence was found for the role of exercises on strength training and cardiorespiratory training. Neurodevelopmental therapy (NDT) was found ineffective as an intervention.

This review suffered from limitations such as including reviews that had small sample size and that had considered heterogeneity of treatment interventions. Hence, the effectiveness of most PT interventions is found to be limited. On the basis of the present evidence, functional goal-oriented approaches are found to be effective and future research is required to determine the best ways to improve functional outcomes in children with CP.

Faccioli et al. (2023) provided an updated overview of the state of knowledge, regarding the management and motor rehabilitation of children and young people with cerebral palsy. Four guidelines, 43 systematic reviews, and 3 primary studies were included. Considering the subject's multidimensional profile, age and developmentally appropriate activities were recommended to set individual goals and interventions. Only a few approaches were supported by high-level evidence (i.e., bimanual therapy and constraint-induced movement therapy to enhance manual performance). Several task-specific approaches to improve gross motor function and gait were reported (e.g., mobility and gait training, cycling, backward gait, and treadmill), due to low-level evidence. Increasing daily physical activity and countering sedentary behavior were advised. Based on the available evidence, non-invasive brain stimulation, virtual reality, action-observation therapy, hydrotherapy, and hippotherapy might be complementary to task or goal-oriented physical therapy programs. Authors concluded that a multiple-disciplinary family-centered evidence-based management is recommended. All motor rehabilitation approaches to minors affected by cerebral palsy must share the following fundamental characteristics: engaging active involvement of the subject, individualized, age and developmentally appropriate, goal-directed, skill-based, and preferably intensive and time-limited, but suitable for the needs and preferences of the child or young person and their family, and feasible considering the implications for themselves and possible contextual limitations.

With regards to the Adeli suit or NeuroSuit, it is suggested that the Adeli suit can provide 30 to 80 pounds of pressure and approximation through the joints and provide dynamic proprioceptive input to improve the neuromuscular and vestibular systems. Changes in the activity of vestibular nystagmus indicate the ability to maintain balance and orientation in space. Semenova (1997) describes a new method for the restorative treatment of patients with residual-stage infantile cerebral palsy. The method is based on proprioceptive correction using an “Adeli-92” device, which is a modified space suit used in weightless conditions. The “Adeli-92” allows intensification and some extent of normalization of afferent proprioceptive mobility-controlling input. Eighty percent (80%) of the patients presented with impaired function of the labyrinths, resulting in increased muscle tone and pathological reflexes. Positive clinical effects were obtained in 70% of patients, with improvements in walking and self-care ability. The positive effects of this method were demonstrated objectively using electroencephalography, electroneuromyography, studies of somatosensory evoked potentials, and studies of the vestibular system. Sixty-two percent (62%) of the patients presented with adequately distributed muscle tone in static and dynamic conditions at the end of the study. According to Semenova, when a child with CP is positioned vertically, pathological reflexes affect the child's ability to maintain balance. Implementing the Adeli suit treatment with dynamic proprioceptive correction daily for several weeks appears to decrease the influence of pathological reflexes and tone, indicating changes in cortical and reticular structures.

In a study by Bar-haim et al. (2006), NDT was compared to the Adeli Suit Treatment (AST) in twenty-four children with CP for four weeks, five days per week for two-hour sessions. The original Russian protocol for using the Adeli suit was used, including 1) massage, 2) passive stretching, 3) application of the suit with the body in proper alignment, and 4) rigorous exercises and functional activities in weight bearing. The results of intensive therapy with AST versus NDT revealed significant improvements in GMFM and mechanical efficiency index of stair-climbing scores in one month within the AST group and in nine months within the NDT group, predominantly in children with higher motor function. However, when the retention of motor skills was tested nine months after treatment, there was no significant difference between the AST and NDT groups. Authors suggest that the AST provides resistance across the major muscle groups improving strength, endurance, posture, coordination, gait deviations, and function of the most important branch of the anti-gravity system—the vestibular system. Given the nervous system of premature and neurologically damaged children does not receive the unique and crucial pressure and input typically experienced from the second week of gestation, the infant is deprived of vital tactile and sensory stimulation. Therapeutic suits such as the Adeli and NeuroSuit are proposed to assist in re-training the central nervous system by allowing the child to overcome increasingly complex pathological movement and to execute and repeat previously unknown movement patterns. More studies are needed to provide evidence to support use of these suits to improve outcomes. Bailes et al. (2011) conducted a randomized controlled trial to examine the effects of suit wear during an intensive therapy program on motor function among 20 children with cerebral palsy. The children were randomized to an experimental (TheraSuit) or a control (control suit) group and participated in an intensive therapy program. The Pediatric Evaluation of Disability Inventory (PEDI) and Gross Motor Function Measure (GMFM)–66 were administered before and after treatment (four and nine weeks), as well as an assessment of parent satisfaction. There were no significant differences found between the groups. There were significant within-group differences found for the control group on the GMFM-66 and for the experimental group on the GMFM-66, PEDI Functional Skills Self-care, PEDI Caregiver Assistance Selfcare, and PEDI Functional Skills Mobility. There were no adverse events reported.

Almeida et al. (2017) conducted a systematic review to evaluate the available evidence on the effects of interventions based on the use of therapeutic suits in the treatment of impairments and functional limitations of children with cerebral palsy. The review included 13 studies: two evaluated the Full Body Suit; two the Dynamic Elastomeric Fabric Orthose; three TheraTogs; and six tested the TheraSuit/AdeliSuit protocols. The review found that the quality of evidence for the Full Body Suit, the Dynamic Elastomeric Fabric Orthose and the TheraSuit/AdeliSuit protocols was very low for body structure and function outcomes, and the evidence for TheraTogs was low quality. Regarding the activity outcomes, the review noted that the Full Body Suit and TheraSuit showed very low-quality evidence while the evidence for TheraSuit/AdeliSuit protocols were of low quality. The review concluded that the low quality of evidence suggests caution in recommending the use of these therapeutic suits. Martins et al. (2016) reported on a systematic review and meta-analysis that examined the efficacy of suit therapy on functioning in children and adolescents with cerebral palsy (CP). The review included four randomized controlled trials (*n*=110). Two RCTs compared Adeli suit treatment (AST) with neurodevelopmental treatment (NDT); one study compared modified suit therapy with conventional therapy; and the other compared TheraSuit with a treatment classified as other therapy approach. Small effect sizes were found for gross motor function at post-treatment and follow-up. The review noted limitations that included the small number of studies, the variability between them, and the low sample sizes. The authors noted that there is a need for better evidence to examine and prove the effects of short intensive treatment such as suit therapy on gross motor function in children and adolescents with CP.

Belizón-Bravo et al. (2021) assessed the effects of interventions with the dynamic suit orthoses (DSO) on the altered spatio-temporal gait parameters (STGPs) in children with CP. A total of 12 studies were included, which showed great heterogeneity in terms of design type, sample size, and intervention performed (two employed a Therasuit, three employed the Adeli suit, three employed Theratogs, one employed elastomeric tissue dynamic orthosis, one employed a full-body suit, one employed external belt orthosis, and one employed dynamic orthosis composed of trousers and T-shirt). The studies of higher methodological quality showed significant post-intervention changes in walking speed (which is the most widely evaluated parameter), cadence, stride length, and step length symmetry. Although the evidence is limited, the intervention with DSO combined with a program of training/physical therapy seems to have positive effects on the STGPs in children with CP, with the functional improvements that it entails. Despite the immediate effect after one session, a number of sessions between 18 and 60 is recommended to obtain optimum results. Future studies should measure all STGPs, and not only the main ones, such as gait speed, in order to draw more accurate conclusions on the functional improvement of gait after the use of this type of intervention.

Baptista et al. (2023) investigated the effect of the Therasuit method on the gross motor function of children with autism spectrum disorder (ASD) in a case series. The study was conducted with 9 male children (42.1 + 4.1 months old) with ASD who received the Therasuit protocol for 4 weeks (20 sessions). The Gross Motor Function Measure (GMFM-88) was used to assess the children's gross motor function before and after the Therasuit method intervention. In dimension B, several skills showed improvement, including transfer to sitting, lean forward and return, trunk rotation without support, and transfer from sitting to all 4 stances. In dimension C, an increase was observed in skills such as being prone to all 4 stance transfers and reaching above the shoulders. In dimension D, maximum scores were achieved in skills such as pulling to stand on a large bench without assistance. The dimensions with the greatest impairment were D and E, corresponding to gross motor skills in orthostasis and dynamic skills in orthostasis, respectively. The findings suggest that the Therasuit method is a promising resource for treating motor impairments in children with ASD. However, further studies with a larger sample size, an adequate control condition, and random assignment of participants would be needed to provide stronger evidence of the method's effectiveness in this population.

Intensive interventions are provided to young children with unilateral cerebral palsy (UCP), classically focused on the upper extremity despite the frequent impairment of gross motor function. It is hypothesized that Hand-Arm Bimanual Intensive Therapy Including Lower Extremities (HABIT-ILE) effectively improves manual dexterity and gross motor function in school-aged children. Araneda et al. (2023) sought to verify if HABIT-ILE would improve manual abilities in young children with UCP more than usual motor activity. Young children were assessed at baseline (T0), 2 weeks after baseline (T1), and 3 months after baseline (T2). Subjects were matched (age at inclusion, lesion type, cause of cerebral palsy, and affected side) and pairs randomization was performed. Health care professionals and assessors of main outcomes were blinded to group allocation. At least 23 young children (in each group) aged 12 to 59 months with spastic/dyskinetic UCP and able to follow instructions were included. Exclusion criteria included uncontrolled seizures, scheduled botulinum toxin injections, orthopedic surgery scheduled during the 6 months before or during the study period, severe visual/cognitive impairments, or contraindications to magnetic resonance imaging. Intervention included two weeks of usual motor activity including usual rehabilitation (control group) vs 2 weeks (50 hours) of HABIT-ILE (HABIT-ILE group). Primary outcome was Assisting Hand Assessment (AHA); secondary outcomes was Gross Motor Function Measure-66 (GMFM-66), Pediatric Evaluation of Disability Inventory-Computer Adaptive Test (PEDI-CAT), and Canadian Occupational Performance Measure (COPM). Of 50 recruited young children (26 girls [52%], median age; 35.3 months for HABIT-ILE group; median age, 32.8 months for control group), 49 were included in the final analyses. Change in AHA score from T0 to T2 was significantly greater in the HABIT-ILE group. Changes in GMFM-66, PEDI-CAT daily activities, COPM performance, and satisfaction scores were greater in the HABIT ILE group. In this clinical trial, early HABIT-ILE was shown to be an effective treatment to improve motor performance in young children with UCP. Moreover, the improvements had an impact on daily life activities of these children.

Liang et al. (2023) compared the efficacy of constraint-induced movement therapy (CIMT) and bimanual intensive training (BIT) with 36-hr interventional dosages for both motor and psychosocial outcomes in children with unilateral cerebral palsy (UCP). Participants included forty-eight children with UCP, ages 6 to 12 yr. The intervention included both

CIMT and BIT delivered via individual intervention for 2.25 hr/day, twice a week, for 8 wk. The Melbourne Assessment 2, Pediatric Motor Activity Log-Revised, Bruininks-Oseretsky Test of Motor Proficiency, ABILHAND-Kids measure, and Parenting Stress Index-Short Form were administrated at pretreatment, midterm, posttreatment, and 6 mo after intervention. An engagement questionnaire for investigating the child's engagement in the intervention was used to collect the perspectives of the children and the parents weekly. Children with UCP who received either CIMT or BIT achieved similar motor improvements. The only difference was that CIMT yielded larger improvements in frequency and quality of use of the more affected hand at the 6-mo follow-up. Similar child engagement and parental stress levels were found in the two groups. This study comprehensively compared the efficacy of motor and psychosocial outcomes for 36-hr dosages of CIMT and BIT. The promising findings support the clinical efficacy and feasibility of the proposed protocols. The core therapeutic principle of CIMT (i.e., remind the child to use the more affected hand) may be more easily duplicated by parents. Parents may have overestimated their child's engagement and given relatively higher scores; therefore, occupational therapists should also consider the opinions of the children themselves.

Few studies have examined the effect of intensive therapy on gross motor function and trunk control in children with cerebral palsy (CP). As a result, van Tittelboom et al. (2023) evaluated the effects of an intensive burst of therapy on the lower limbs and trunk by comparing qualitative functional and functional approaches. This study was designed as a quasi-randomized, controlled, and evaluator-blinded trial. Thirty-six children with bilateral spastic CP (mean age = 8 y 9 mo; Gross Motor Function Classification II and III) were randomized into functional (n = 12) and qualitative functional (n = 24) groups. The main outcome measures were the Gross Motor Function Measure (GMFM), the Quality Function Measure (QFM), and the Trunk Control Measurement Scale (TCMS). The results revealed significant time-by-approach interaction effects for all QFM attributes and the GMFM’s standing dimension and total score. Post hoc tests showed immediate post-intervention gains with the qualitative functional approach for all QFM attributes, the GMFM’s standing and walking/running/jumping dimension and total score, and the total TCMS score. The qualitative functional approach shows promising results with improvements in movement quality and gross motor function.

Carton de Tournai et al. (2024) determined the effectiveness of baby Hand-Arm Bimanual Intensive Therapy Including Lower Extremities (HABIT-ILE) to improve motor function in infants with unilateral CP (UCP). Infants were matched in pairs by age and lesion type and randomized to either the treatment or control group. Infants were assessed at baseline (T0) and 1 (T1) and 3 months (T2) follow-up. Inclusion criteria were aged 6 to 18 months at T0 (corrected age if preterm birth), a diagnosis or being at risk of UCP, and the ability to comply with the testing and training procedures. Exclusion criteria were uncontrolled seizures, botulinum toxin injections, orthopedic surgery, or specific intensive therapy within 6 months before and until the end of the study. Infants in the treatment group received 50 hours of baby HABIT-ILE over 2 weeks, while those in the control group continued their usual motor activities. The primary outcome was use of the more affected hand as measured using the Mini-Assisting Hand Assessment (Mini-AHA). Secondary outcomes included Canadian Occupational Performance Measure (COPM) performance and satisfaction scores, Gross Motor Function Measure-66 (GMFM-66) scores, and other motor and functional outcomes. Of the 48 infants entering the study, 46 (mean [SD] age, 13.3 [4.1] months; 27 boys [58%]) were included in the final analyses, with 24 in the treatment group and 22 in the control group. Group × assessment time interactions showed significant improvements that favored the treatment group for the Mini-AHA and for both parts of the COPM. Although both groups improved in the GMFM-66, there was no significant interaction. This randomized clinical trial demonstrates the feasibility of delivering 50 hours of HABIT-ILE over a 2-week period in infants with UCP. These findings show that the intervention is effective in improving motor abilities, as revealed by an increase in the use of the more affected hand in bimanual tasks and in enhanced reported functional goal outcomes.

PRACTITIONER SCOPE AND TRAINING

Practitioners should practice only in the areas in which they are competent based on their education, training, and experience. Levels of education, experience, and proficiency may vary among individual practitioners. It is ethically and legally incumbent on a practitioner to determine where they have the knowledge and skills necessary to perform such services and whether the services are within their scope of practice.

It is best practice for the practitioner to appropriately render services to a member only if they are trained, equally skilled, and adequately competent to deliver a service compared to others trained to perform the same procedure. If the service would be most competently delivered by another health care practitioner who has more skill and training, it would be best practice to refer the member to the more expert practitioner.

Best practice can be defined as a clinical, scientific, or professional technique, method, or process that is typically evidence-based and consensus driven and is recognized by a majority of professionals in a particular field as more effective at delivering a particular outcome than any other practice (Joint Commission International Accreditation Standards for Hospitals, 2020).

Depending on the practitioner's scope of practice, training, and experience, a member's condition and/or symptoms during examination or the course of treatment may indicate the need for referral to another practitioner or even emergency care. In such cases it is prudent for the practitioner to refer the member for appropriate co-management (e.g., to their primary care physician) or if immediate emergency care is warranted, to contact 911 as appropriate. See the *Managing Medical Emergencies (CPG 159 – S)* clinical practice guideline for information.

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