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| **CRITICALLY APPRAISED TOPIC** |

**FOCUSED CLINICAL QUESTION**

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| In children with Down syndrome ages zero to three years, is physical therapy using a neurodevelopmental treatment approach effective in preventing complications such as pain, physical inactivity, or obesityafter age three? |

**AUTHOR**

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| **Prepared by** | Olivia DeSena Fleming | **Date** | 12/4/18 |
| **Email address** | olivia\_desena@med.unc.edu | | |

**CLINICAL SCENARIO**

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| The patient who prompted this clinical question was a 10-month old male with Down syndrome who was treated with physical therapy using a neurodevelopmental treatment (NDT) approach in his home. He was delayed in achieving gross motor milestones, had generalized hypotonia, and could not sit independently or belly crawl. He qualified for comprehensive early intervention services at no cost to the family through the North Carolina Infant-Toddler program and Medicaid. He often demonstrated excessive hip abduction, which resulted in difficulty coordinating functional movement patterns. Excessive hip abduction was discouraged by hand placement to “facilitate” better quality of movement in functional patterns. Physical therapists who treat children with Down syndrome often attempt to improve quality of movement through treatment approaches like NDT to reduce abnormal compensatory motor patterns. They claim that abnormal movement patterns are related to long-term complications such as pain or poor efficiency of movement, that can lead to a sedentary lifestyle and obesity.1 This clinical scenario inspired exploring the long-term effectiveness of and necessity for neurodevelopmental physical therapy for young children with Down syndrome. |

**SUMMARY OF SEARCH**

[Best evidence appraised and key findings]

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| * Eight studies were located that met the inclusion/exclusion criteria, including 4 randomized controlled trials, 2 systematic reviews with meta-analysis, 1 quasi-experimental non-randomized two-group study, and 1 non-randomized two-group study. No study was relevant to all aspects of the clinical question. * There was no statistically significant difference in change of rate of motor development between children who received NDT intervention and children who received an active control intervention such as developmental skills therapy or an infant learning program. * There was no statistically significant difference in quality of movement between children who received NDT intervention and children who received developmental skills therapy. |

**CLINICAL BOTTOM LINE**

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| Physical therapy using a neurodevelopmental treatment approach does not improve motor development to a greater extent than active control interventions, such as developmental skills therapy or infant learning programs, in children with Down syndrome. Other evidence-based interventions, provided by physical therapists or other providers, should be explored to promote life-long health for this patient. |

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| ***This critically appraised topic has been individually prepared as part of a course requirement and has been peer-reviewed by one other independent course instructor*** |

*The above information should fit onto the first page of your CAT*

**SEARCH STRATEGY**

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| **Terms used to guide the search strategy** | | | |
| **P**atient/Client Group | **I**ntervention (or Assessment) | **C**omparison | **O**utcome(s) |
| Down syndrome  Trisomy 21 | Neurodevelopmental therapy  Neurodevelopmental treatment  Neuro-developmental treatment  NDT  Bobath concept  Physical therapy  Physiotherapy  Early Intervention |  | Pain  Inactivity  Sedentary  Obese  Obesity |

**Final search strategy (history):**

*Show your final search strategy (full history) from PubMed. Indicate which “line” you chose as the final search strategy.*

1. “down syndrome” OR “trisomy 21”
2. “neurodevelopmental therapy” OR “neurodevelopmental treatment” OR “bobath concept”
3. “physical therapy” OR physiotherapy
4. “early intervention”
5. pain OR inactivity OR sedentary OR obese OR obesity
6. #1 AND #2 *(5 results; relevant but more results desired)*
7. #1 AND #3 AND #5*(27 results; relevant)*
8. #1 AND #4 *(138 results; many irrelevant)*
9. #1 AND #3 AND #4 *(18 results; relevant)*
10. **#6 OR #7 OR #9 *(final search + filters: ages birth-18 years, English)***

*In the table below, show how many results you got from your search from each database you searched.*

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| **Databases and Sites Searched** | **Number of results** | **Limits applied, revised number of results (if applicable)** |
| **PubMed**  **CINAHL**  **Web of Science** | 50  14  13 | 32 – Applied Filters: Ages birth-18 years, English  12 – Applied Filters: English  10 – Applied Filters: English,  Exclude: Proceedings Paper, Editorial Material |

## **INCLUSION and EXCLUSION CRITERIA**

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| **Inclusion Criteria** |
| Study included children with Down syndrome  Intervention used physical therapy; OR intervention used NDT approach to physical therapy; OR measured pain, physical activity, or obesity following motor intervention  Peer reviewed journal article |
| **Exclusion Criteria** |
| Abstracts, conference proceedings, letters to the editor, dissertations, narrative review articles  Not published in English |

**RESULTS OF SEARCH**

**Summary of articles retrieved that met inclusion and exclusion criteria**

*For each article being considered for inclusion in the CAT, score for methodological quality on an appropriate scale, categorize the level of evidence, indicate whether the relevance of the study PICO to your PICO is high/mod/low, and note the study design (e.g., RCT, systematic review, case study).*

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| **Author (Year)** | **Risk of bias (quality score)\*** | **Level of Evidence\*\*** | **Relevance** | **Study design** |
| **Harris (1981)2** | **PEDro: 7/11** | **Level 2b**  (large standard deviations) | **High** | **Randomized controlled trial** |
| **Mahoney (2001)3** | **Downs and Black Checklist: 7/13^** | **Level 2b** | **High** | **Prospective, quasi-experimental, non-randomized two-group study** |
| **Valentín-Gudiol (2017)4** | **AMSTAR: 10/11** | **Level 1a** | **Low** | **Systematic review with meta-analysis** |
| **Angulo-Barroso (2008)5** | **PEDro: 5/11** | **Level 2b**  (72% follow up) | **High** | **Randomized controlled trial** |
| **Connolly (1993)6** | **Downs and Black Checklist: 5/13^** | **Level 4**  (poor control of confounders, used retrospective data for comparison) | **Mod** | **Non-randomized two-group study** |
| **Ottenbacher (1986)7** | **AMSTAR: 2/11** | **Level 3a**  (included non-randomized pre-experimental studies) | **Mod** | **Systematic review with meta-analysis** |
| **Ulrich (2001)8** | **PEDro: 7/11** | **Level 2b**  (large confidence intervals) | **Low** | **Randomized controlled trial** |
| **Ulrich (2011)9** | **PEDro: 5/11** | **Level 2b**  (64% follow up; large standard deviations) | **Low** | **Randomized controlled trial** |

^Scoring includes items for internal validity: bias, internal validity: confounding

\*Indicate tool name and score

\*\*Use Portney & Watkins Table 16.1 (2009); if downgraded, indicate reason why

**BEST EVIDENCE**

The following 2 studies were identified as the ‘best’ evidence and selected for critical appraisal. Rationale for selecting these studies were:

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| * **Harris (1981):** While this study is older, neurodevelopmental physical therapy still follows similar treatment principles as it did in the 1980s. It is a randomized controlled trial and has a lower risk of bias than the other studies that used NDT as the intervention. It is relevant to the clinical question, as it studied neurodevelopmental therapy in infants with Down syndrome. Although the outcomes are not the outcomes of interest, they were measured by validated tools: the Bayley Scales of Infant Development and the Peabody Developmental Motor Scales. * **Mahoney (2001):** Although this study had high potential for confounding and therefore scored low on the Downs and Black Checklist, it is a field-based study that could be reflective of real-world effects of neurodevelopmental therapy in young children with Down syndrome. It had a larger sample size than many of the other studies, with 50 total participants. Children were followed for 12 months, so it can provide relevant insight into effects of lengthy treatment. It used appropriate validated outcome measures, including the Bayley Scales of Infant Development, the Peabody Developmental Motor Scales, and the Gross Motor Function Classification System.   The other studies that were strongly considered were **Valentín-Gudiol (2017)** and **Angulo-Barroso (2008)**. Valentín-Gudiol et al provided a recent high-quality systematic review with meta-analysis, but neither the outcomes nor intervention aligned with the clinical question. Angulo-Barroso et al was one of the only studies to measure physical activity outcomes, but the intervention did not align with the clinical question. The trial also had a high risk of bias, including not blinding assessors and not performing an intention to treat analysis despite 72% follow up for primary physical activity outcomes. Additionally, it would be more difficult to compare one of these studies that implemented a treadmill intervention to one of the studies above that implemented NDT. By choosing two studies with similar populations, interventions, and outcomes, the results of the research were less heterogeneous and more easily compared. |

**SUMMARY OF BEST EVIDENCE**

**(1) Description and appraisal of “The effects of early motor intervention on children with Down syndrome or cerebral palsy: a field-based study” by Mahoney et al, 2001.**

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| **Aim/Objective of the Study/Systematic Review:** |
| The study had four purposes:   * To determine the effect of early motor intervention on rate of motor development in children with Down syndrome or cerebral palsy * To compare the effects of two treatment approaches, neurodevelopmental treatment and developmental skill intervention, on quality of motor performance * To determine the effect of frequency of motor intervention on motor performance * To determine the effect of provider specialization (no physical therapy training, physical therapy training, or physical therapy training with NDT specialization) on motor performance |
| **Study Design**  [e.g., systematic review, cohort, randomised controlled trial, qualitative study, grounded theory. Includes information about study characteristics such as blinding and allocation concealment. When were outcomes measured, if relevant]  Note: For systematic review, use headings ‘search strategy’, ‘selection criteria’, ‘methods’ etc. For qualitative studies, identify data collection/analyses methods. |
| * Prospective, quasi-experimental, non-randomized two-group design * No blinding of study subjects or families; blinding of outcome raters for quality of movement * No allocation concealment * Outcomes were measured at baseline and after 12 months of intervention * No intention to treat analysis was performed |
| **Setting**  [e.g., locations such as hospital, community; rural; metropolitan; country] |
| * Interventions took place at 9 sites across 6 states (New York, Virginia, Florida, Ohio, Alabama, Colorado)   + 4 neurodevelopmental treatment (NDT) sites (intervention group)     - 3 sites were “hospital-based rehabilitation clinics”3     - 1 site was a “comprehensive center-based early intervention program”3   + 5 developmental skills (DevS) sites (control group)     - 4 sites were “university research and training programs”3     - 1 site was a publicly funded metropolitan early intervention program |
| **Participants**  [N, diagnosis, eligibility criteria, how recruited, type of sample (e.g., purposive, random), key demographics such as mean age, gender, duration of illness/disease, and if groups in an RCT were comparable at baseline on key demographic variables; number of dropouts if relevant, number available for follow-up]  Note: This is not a list of the inclusion and exclusion criteria. This is a description of the actual sample that participated in the study. You can find this descriptive information in the text and tables in the article. |
| * **Number/Diagnosis:** The study included 50 participants with either Down syndrome (DS) or cerebral palsy (CP).   + 28 children were part of the NDT group. In the NDT group, 11 children had DS, and 17 children had CP.   + 22 children were part of the DevS group. In the DevS group, 16 children had DS, and 6 children had CP. * **Eligibility Criteria:**   + Inclusion criteria not explicitly stated, although the study included children ages 0-3 with Down syndrome or cerebral palsy who were participating in early motor intervention.   + Children were excluded if intervention was stopped during the trial period, there were large amounts of missing data, or the children had very severe motor impairment. * **Recruitment/Sample Type:** The sample was a convenience sample of children who were already receiving motor intervention. * **Key Demographics:**   + **Age:** The mean age of the children at the start of the study was 14 months.   + **Sex:** 48% of the children were male.   + **Diagnostic Descriptors:** At the beginning of the study, the children varied from level I to level V (least to most motor impairment) on the Gross Motor Function Classification System (GMFCS). The majority of children with Down syndrome (15 of 27) functioned at GMFCS level II. The mean Peabody Gross Motor age of the children with Down syndrome was 7.5 months. The mean motor development rate (Peabody Gross Motor age/chronological age) of the children with Down syndrome was 0.55.   + **Previous Intervention:** The children had been receiving early motor intervention services before the study began, starting at the mean age of 6.5 months.   + **Ethnicity:** The ethnicities of the children in the sample were 6% Asian, 14% African-American, 20% Hispanic, and 60% white.   + **Families:** The mothers of the children were on average in their early 30s, had 2-3 children, had completed 2 years of college, and 48% worked outside the home.   + **Comparability at Baseline:** There were no statistically significant differences between groups (NDT and DevS) or between diagnoses (DS and CP) in gross motor classification at baseline. * **Number of Dropouts/Number Available for Follow-Up**   + Of the original pool of 72 children, 12 were excluded due to missing data or because motor intervention was stopped during the 12-month period.   + Data describing characteristics of treatment sessions was not available for 7 of 50 participants due to therapist non-compliance.   + Outcomes were available for all 50 participants for motor development rate at pre-test and post-test. |
| Intervention Investigated  [Provide details of methods, who provided treatment, when and where, how many hours of treatment provided] |
| *Control* |
| * The group of children who received motor intervention with a focus on developmental skills (DevS) served as an active control group. * Treatment was provided by early interventionists (55%) or physical therapists (45%). 40% of providers had training in NDT. They worked at sites that reported that their primary approach to motor intervention focused on developmental skills. * Interventionists/therapists continued using the same treatment techniques that they used before the study. There was no standard focus or setting for therapy. 20 of 22 therapists kept a treatment log describing characteristics of sessions.   + **Primary focus of therapy:**     - 62% specific motor skills     - 55% general motor activity/play     - 54% quality of movement     - 29% tone/posture/alignment   + **Parental/professional involvement:**      - 80% of sessions included recommendations to parents, and 58% of providers recommended motor activities in a natural environment.     - Parents were present for 73% of sessions, and other professionals were present for 45% of sessions.   + **Location:** 54% of services were provided in a classroom/center, 38% in the home, and 8% in a clinic. * There was no standard dose of therapy because treatment was continued as usual.   + **Duration of intervention:** Interventions were performed for mean 12.4 months (standard deviation 1.7 months) for children with DS and mean 13.5 months (standard deviation 2.9 months) for children with CP.   + **Duration of sessions:** 78% of sessions lasted longer than 45 minutes, 4% of sessions lasted 31-45 minutes, and 18% of sessions lasted 30 minutes or less.   + **Number of sessions:** Children received mean 35.4 intervention sessions (standard deviation 19.4 sessions). * The children also received other family services as described in Table 3 of the article.3 The mothers of children receiving DevS generally reported receiving greater child information, family education activities, Early Intervention systems engagement, family psychological services, and resource assistance than the NDT group. |
| *Experimental* |
| * The group of children who received motor intervention with a focus on NDT served as the experimental group. * Treatment was provided by physical therapists. 77% were NDT certified. They worked at sites that reported that their primary approach to motor intervention focused on neurodevelopmental treatment. * Therapists continued using the same treatment techniques that they used before the study. There was no standard focus or setting for therapy. 23 of 28 therapists kept a treatment log describing characteristics of sessions.   + **Primary focus of therapy:**     - 73% specific motor skills     - 65% quality of movement     - 47% tone/posture/alignment     - 16% general motor activity/play   + **Parental/professional involvement:**      - 51% of sessions included recommendations to parents, and 31% of therapists recommended motor activities in a natural environment.     - Parents were present for 41% of sessions, and other professionals were present for 27% of sessions.   + **Location:** 74% of services were provided in a classroom/center, 24% in a clinic, and 2% in the home. * There was no standard dose of therapy because treatment was continued as usual.   + **Duration of intervention:** Interventions were performed for mean 12.9 months (standard deviation 1.4 months) for children with DS and mean 15.0 months (standard deviation 3.7 months) for children with CP.   + **Duration of sessions:** 55% of sessions lasted 31-45 minutes, 23% of sessions lasted longer than 45 minutes, and 22% of sessions lasted 30 minutes or less.   + **Number of sessions:** Children received mean 42.9 intervention sessions (standard deviation 27.2 sessions). * The children also received other family services as described in Table 3 of the article.3 The mothers of children receiving NDT generally reported receiving less child information, family education activities, Early Intervention systems engagement, family psychological services, and resource assistance than the NDT group. |
| **Outcome Measures**  [Give details of each measure, maximum possible score and range for each measure, administered by whom, where] |
| Outcomes most related to the clinical question are as follows:   * **Peabody Developmental Motor Scales (PDMS): Gross Motor Age Equivalent**    + The PDMS is a standardized outcome measure that assesses gross and fine motor development for children ages 0 to 83 months.10 The PDMS gross motor scale includes skill items related to reflexes, balance, non-locomotor, locomotor, and receipt and propulsion of objects.10 It has been updated since this study to the second edition, the PMDS-2.   + The PDMS gross motor scale has 170 items that are scored on a 3-point scale, with 0 indicating unable to perform the item, 1 indicating partial credit, and 2 indicating full credit.10 The scores are summed for a raw score that corresponds to a gross motor age equivalent. The minimum age equivalent is 0 months and the maximum age equivalent is 83 months.10   + The authors used the **Peabody gross motor age equivalent** to calculate children’s **motor development rate** (Peabody gross motor age/chronological age). They calculated **motor development gain** using a proportional change index (rate of development during intervention/rate of development before intervention).   + The PDMS was administered by “trained research assistants.”3   + It is not clear where testing was performed, although it was likely performed where the child received motor intervention. * **Toddler Infant Motor Evaluation (TIME)**   + The TIME is a standardized outcome measure that the authors used to measure quality of movement in children between 4 months and 3.5 years.11 The TIME measures quality of movement in seven dimensions: “mobility, atypical mobility, component analysis, transition analysis, hypertonicity, hypotonicity, and atypical positions.”3 The dimensions were scored in as many of the following positions that the child could achieve with therapist facilitation: supine, prone, sitting, bear, kneeling, and standing. The authors state that the measure was adapted, but do not specify how.   + The TIME subtests are scored on an ordinal scale that varies for each subtest, which are converted to standard scores with a mean of 10 and standard deviation of 3.11 It is unclear what minimum and maximum TIME scores are without purchasing the assessment, which costs $485.12   + Two therapists who were blinded to treatment group and time of observation who helped develop the TIME instrument administered this outcome measure. The therapists’ interrater reliability was r > 0.90 for each dimension of movement.   + Children were assessed remotely by video observation. All children were videotaped in various motor positions with therapist facilitation to assess quality of movement. |
| **Main Findings**  [Provide summary of mean scores/mean differences/treatment effect, 95% confidence intervals and p-values etc., where provided; you may calculate your own values if necessary/applicable. You may summarize results in a table but you must explain the results with some narrative.] |
| The following table shows change before and after intervention in Peabody Developmental Motor Scales motor age, motor development rate, and motor development gain for children with Down syndrome, which is related to PICO outcome physical activity.  **Effect of Intervention on Rate of Motor Development**   |  |  |  | | --- | --- | --- | |  | **Children with DS in NDT Group**  **(n = 11)** | **Children with DS in DevS Group**  **(n = 16)** | | Variable | Mean ± SD | Mean ± SD | | **Length of observation** (months) | 12.9 ± 1.4 | 12.4 ± 1.7 | | **Peabody motor age: pretest** (months) | 7.6 ± 2.8 | 7.5 ± 2.6 | | **Peabody motor age: posttest** (months) | 14.0 ± 3.5 | 13.2 ± 3.1 | | **Peabody motor development rate: pretest** (motor age/chronological age) | .52 ± .15 | .56 ± .16 | | **Peabody motor development rate: posttest** (motor age/chronological age) | .51 ± .11 | .51 ± .12 | | **Motor development gain** (Proportional Change Index: rate of development during intervention/rate of development before intervention) | 1.01 ± .38 | .88 ± .38 |  * The children in the NDT group and DevS group made similar gains in Peabody motor age over the course of the 12 month intervention (6.4 and 5.7 months, respectively). * The children in the NDT group made a motor development gain of 1.01, indicating that they maintained a steady rate of motor development. The children in the DevS group made a motor gain of 0.88, indicating that their rate of motor development decreased. However, the authors reported that there were no significant differences between groups in rate of development. The between-groups difference in motor development gain was 0.13; 95% CI (-0.16, 0.42 points).\*   \*95% CI calculated by CAT author.  The authors performed multivariate analysis of variance to assess effects of diagnosis, treatment, and intervention on change in quality of movement as measured by TIME scores for the entire sample.3   * There was a significant intervention effect (p < .001) for both NDT and DevS motor interventions on all seven dimensions of quality of movement. Specific TIME scores were not reported. * There was no significant difference between “interactions of intervention with treatment” on TIME scores, meaning that children in DevS and NDT groups made similar improvements on quality of movement. * There was no significant interaction between intervention, diagnosis, and treatment, meaning that children with Down syndrome in DevS and NDT groups made similar improvements on quality of movement.   The authors also investigated the effect of several variables on rate of motor development after intervention.   * They found that rate of motor development at pre-test contributed significantly to rate of motor development at post-test (p < .001). * Factors that did not contribute significantly to rate of motor development at post-test were diagnosis (DS vs. CP), treatment model (NDT vs. DevS), and provider training (general motor interventionists, licensed physical therapist, or licensed physical therapist with NDT certification). * Number of sessions did not reach statistical significance (p < .001), but p-values 0.004 and 0.007 in two models led the authors to conduct a post hoc analysis investigating effect of number of intervention sessions on rate of motor development.   The following table shows a post hoc analysis of the effect of number of intervention sessions on rate of change in motor development for the entire sample.  **Effect of Treatment Frequency on Rate of Motor Development**   |  |  |  |  | | --- | --- | --- | --- | | **Variable** | **Low Intensity**  **(n = 22)** | **High Intensity**  **(n = 23)** | **P-value** | | Number of sessions per year\* | 19.0 ± 8.1 | 56.1 ± 17.1 | .000 | | Motor development rate at pre-test (months)\* | 0.50 ± 0.21 | 0.51 ± 0.14 | .794 | | Rate of change in motor development during intervention (Proportional Change Index)\* | 0.83 ± 0.31 | 1.14 ± 0.62 | .041 | | \*Scores reported as mean ± SD | | | |  * After 12 months of intervention, the children who received fewer sessions (mean 19 per year) demonstrated a significant decrease (p < 0.05) in rate of motor development after 1 year (PCI = 0.83). The children who received more sessions (mean 56 per year) demonstrated a significant increase (p < 0.05) in rate of motor development after 1 year (Proportional Change Index = 1.14). The difference between low and high intensity groups in motor development gain was 0.31; 95% CI (0.02, 0.60).\*   \*95% CI calculated by CAT author. |
| **Original Authors’ Conclusions**  [Paraphrase as required. If providing a direct quote, add page number] |
| “Field-based motor intervention may have very limited effects. Some of the assumptions of process-oriented approaches, such as neurodevelopmental treatment, may be flawed. Results from this study also lend caution to the belief that functional skill training will, in itself, enhance the effectiveness of motor intervention procedures. We suspect that effective models of motor intervention need to incorporate instruction of parents and other primary caretakers to address issues of continuity in experience. They also need to address children’s functional performance limitations as much as, if not more than, they target delays and abnormalities in motor devleopment.” (p. 161-162)3 |
| **Critical Appraisal** |
| **Validity**  [Summarize the internal and external validity of the study. Highlight key strengths and weaknesses. Comment on the overall evidence quality provided by this study.] |
| * **Downs and Black checklist score:** 7/13. Internal validity (bias) - Blinding of subjects: No; Blinding of assessors: Yes; Data dredging made clear: Yes; Same time period for outcomes between groups: Yes; Appropriate statistical tests: Yes; Reliable compliance: Yes; Accurate outcome measures: Yes. Internal validity (confounding/selection bias) – Recruitment from same population: No; Recruitment over same time period: Unable to determine; Randomization of subjects: No; Allocation concealed: No; Adjustment for confounding: No; Loss to follow-up taken into account: Yes. * **Strengths:** The authors used the Peabody Developmental Motor Scales, a standardized outcome measure with strong psychometric properties, to assess motor development.13 There were no significant differences between groups in gross motor classification at baseline. To limit bias, therapists who assessed quality of movement were blinded to treatment group and time of observation. The authors performed appropriate statistical analyses to address each hypothesis, and did not inflate positive findings in discussion. The study was reflective of real-world early motor intervention settings. * **Limitations noted by the authors:** There was no true control group that received no treatment. The active control group is not a major limitation because it is reflective of a typical comparison treatment, but a no-treatment control group would be helpful to determine if any motor intervention is more effective than no motor intervention. Because of the real-world nature of the study, there was a lack of control over confounding variables. There was a relatively small sample size, which may have resulted in Type II error. * **Additional limitations:** Subjects were “excluded” if parents stopped early motor intervention services during the trial period, if there were large amounts of missing data, or if they had very severe motor impairment with little potential for improvement. This led to the “inclusion” of only 50 of 72 children (69%) that were originally considered for the study, which could be interpreted as a high level of dropouts which were not included in statistical analyses. Although the authors report that both motor interventions improved quality of movement scores at a statistically significant level, they did not report effect size of intervention on quality of movement. The interventions were extremely variable in setting, duration, goals of treatment, number of sessions, and other interventions received. Therapists were grouped by treatment approach based on the site where they worked, not individually, even though providers at each site may have varied substantially in treatment approach. The motor interventions provided (NDT vs. DevS) may have been more similar than the authors intended, since 40% of therapists at DevS sites had training in NDT, and both groups focused primarily on improving specific motor skills. Except for general focus of therapy, it is unclear how treatment was provided during sessions. The authors state that the Bayley Scale of Mental Development was used at pre-test and post-test, but these outcomes are not reported. |
| **Interpretation of Results**  [This is YOUR interpretation of the results taking into consideration the strengths and limitations as you discussed above. Please comment on clinical significance of effect size / study findings. Describe in your own words what the results mean.] |
| * Quality of Movement: TIME scores improved significantly for both NDT and DevS groups, indicating that 12 months of either neurodevelopmental treatment or developmental skills treatment improves quality of movement for young children with Down syndrome or cerebral palsy. However, it is not possible to determine clinical significance/the extent to which treatment improves quality of movement because effect size was not reported. * Treatment approach: There was a nonsignificant difference in children’s rate of change in motor development with Down syndrome in NDT vs. DevS groups (mean proportional change index 1.01 and 0.88, respectively). This may have been due to Type II error, or lack of statistical power from small sample size causing failure to detect a significant difference between groups. However, if no Type II error was made, this suggests that simpler motor intervention approaches like developmental skills therapy are just as effective as NDT. * Effect of NDT on rate of development: On average, the children with Down syndrome who received NDT maintained the same rate of gross motor development after intervention (proportional change index = 1.01). The authors interpreted this maintenance in rate of motor development as a clinically undesirable effect because they assumed that motor development is a linear process. However, Gross Motor Function Measure growth curves for children with Down syndrome show that rate of motor development is greatest in infancy, and slows with increased age.14 Specifically, infants with Down syndrome rapidly improve gross motor function, whereas children between 18 months and 3 years have a slower rate of gross motor development.14  Children in this study matured from an average age of 14 months at pre-test to an average age of 24 months at post-test, meaning that their rate of motor development would naturally be expected to decrease during the intervention period. Therefore, contrary to the authors’ beliefs, maintenance in rate of motor development could be interpreted as a positive treatment effect. However, neither comparison values from a no-treatment control group nor an MCID are available to distinguish what magnitude of change in rate of motor development would be considered a clinically desirable treatment effect. * Provider qualifications: There was significant impact of provider qualifications on rate of motor development after 12 months of intervention. If there was no Type II error due to sample size, this means that developmental therapists or other motor interventionists without expensive PT qualifications and certifications would make more sense economically to serve this population. * Number of sessions: Greater frequency of motor intervention may be needed to increase change in rate of motor development for young children with Down syndrome. It appears that higher frequency (mean 56 yearly sessions) resulted in an increase in rate of motor development, whereas lower frequency (mean 19 yearly sessions) resulted in a decrease in rate of motor development. However, due to the between-groups proportional change index 95% CI (0.02, 0.60), it is possible that that greater frequency of sessions could cause only a small 0.02 increase in change in rate of development. |
| **Applicability of Study Results**  [Describe the relevance and applicability of the study to your clinical question and scenario. Consider the practicality and feasibility of the intervention in your discussion of the evidence applicability.] |
| This study is relevant to the clinical question because it included children with Down syndrome between the ages of 0 to 3 years, and used NDT as the experimental intervention. Motor interventions using NDT or developmental skills approaches are typical of Early Intervention services provided to young children with developmental disabilities. Early motor intervention provided through the local Durham Child Developmental Services Agency is often delivered by physical therapists, several of whom use NDT treatment principles, or by developmental therapists, who typically focus on age-appropriate functional play. The outcomes studied do not provide information about long-term effects of NDT as desired, but quality of movement and rate of development are still relevant to payer and parent interests.  These results are not convincing that NDT is better than other motor intervention models, nor do they demonstrate that any approach to early motor intervention promotes clinically significant improvements in rate of development or quality of movement in children with Down syndrome. Although maintenance of rate of development after intervention may indeed be a clinically significant treatment effect, it is not possible to claim meaningful effects without a true control group or specific reference values for change in rate of development. It is unclear if either motor intervention caused clinically meaningful improvements in quality of movement because TIME values were not reported. Even if a therapist were to provide early motor intervention to a child with Down syndrome based on theoretical assumptions, this study does not establish which specific treatment approaches are most effective. It does appear that a higher number of sessions, at least once weekly, could potentially increase rate of motor development. However, based on these findings, it is certainly possible that early motor intervention is unnecessary. |

**(2) Description and appraisal of “Effects of neurodevelopmental therapy on motor performance of infants with Down’s syndrome” by Harris, 1981**

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| **Aim/Objective of the Study/Systematic Review:** |
| The purpose of this study was to determine the effect of physical therapy using an NDT approach on rate of motor and mental development in infants with Down syndrome. |
| **Study Design**  [e.g., systematic review, cohort, randomised controlled trial, qualitative study, grounded theory. Includes information about study characteristics such as blinding and allocation concealment. When were outcomes measured, if relevant]  Note: For systematic review, use headings ‘search strategy’, ‘selection criteria’, ‘methods’ etc. For qualitative studies, identify data collection/analyses methods. |
| * Two-group, single-blinded randomized controlled trial * Participants were grouped by age, sex, and pre-test Peabody Developmental Motor Scales scores and then randomized into neurodevelopmental treatment (NDT) or control groups * Method of randomization not stated * No allocation concealment * No blinding of subjects (infants); no blinding of therapists; blinding of assessor to treatment group at post-test * Outcomes measured at baseline and after 9 weeks of intervention * No intention to treat analysis performed due to 100% follow-up * T tests performed to evaluate differences between groups at pre-test and post-test * An a priori alpha level and statistical analysis plan were not reported |
| **Setting**  [e.g., locations such as hospital, community; rural; metropolitan; country] |
| * All participants were part of Down’s Syndrome Infant Learning Program at University of Washington in Seattle. * Intervention was provided in children’s homes. |
| **Participants**  [N, diagnosis, eligibility criteria, how recruited, type of sample (e.g., purposive, random), key demographics such as mean age, gender, duration of illness/disease, and if groups in an RCT were comparable at baseline on key demographic variables; number of dropouts if relevant, number available for follow-up]  Note: This is not a list of the inclusion and exclusion criteria. This is a description of the actual sample that participated in the study. You can find this descriptive information in the text and tables in the article. |
| * **Number/Diagnosis:** The study included 20 participants with Down syndrome. * **Eligibility criteria** were not explicitly listed, but can be inferred from details listed in study methods.   + The study included infants with Down sydrome who were medically safe for physical therapy.   + Children who had scheduled cardiac surgery during the study period were excluded. * **Recruitment/Sample Type:** The sample was a convenience sample of children who were enrolled in the Down’s Syndrome Infant Learning Program at the University of Washington. Two children were enrolled in similar additional infant learning programs. * **Diagnostic Descriptors:**    + The mean Bayley Mental Developmental Quotient was 82.19 for the experimental group and 83.40 for the control group.   + The mean Bayley Motor Developmental Quotient was 69.19 for the experimental group and 70.61 for the control group.   + The mean Peabody Gross Motor Developmental Quotient was 66.76 for the experimental group and 64.61 for the control group. * **Key demographics:**   + **Age:** The age of the children ranged from 2.7 to 21.5 months at pre-test. The mean age of the children at pre-test in the experimental group and control group was 10.91 months and 9.45 months, respectively.   + **Sex:** The study included 11 female and 9 male infants. The experimental group included 5 female and 5 male infants, and the control group included 6 female and 4 male infants.   + **Comparability at Baseline:** The experimental and control groups were comparable at baseline in age, Bayley Mental developmental quotient, Bayley Motor developmental quotient, and Peabody Gross Motor developmental quotient. * **Number Available for Follow-Up:** All 20 participants were available for follow-up. |
| **Intervention Investigated**  [Provide details of methods, who provided treatment, when and where, how many hours of treatment provided] |
| *Control* |
| The control group received no intervention apart from continued participation in the weekly infant learning program at the University of Washington. Specific program components were not specified. |
| *Experimental* |
| * **Methods:** The experimental group received physical therapy using the NDT approach. NDT techniques used to treat hypotonia included “joint approximaton through the spine and extremities, bouncing, tapping, and resistance to movement.”2 The therapist facilitated developmental motor patterns such as “pivoting in prone, rolling prone to supine and supine to prone, prone progression on abdomen, reciprocal creeping, and moving into and out of the sitting position using trunk rotation.”2 Additionally, “righting, equilibrium, and protective responses were facilitated in prone and supine for younger infants, and in quadruped, sitting, and standing” for older infants.2 Parents observed treatment sessions but were not taught specific therapy techniques in order to prevent confouding. * **Treatment provider:** The treatment provider was not explicitly stated, but was most likely the author of the study, who is a physical therapist. * **Dose:** Treatment was provided for approximately 40 minutes, 3 times per week for 9 weeks. * **Location:** Therapy was provided in children’s homes, except for one child who was treated at the Experimental Education Unit at the University of Washington. |
| **Outcome Measures**  [Give details of each measure, maximum possible score and range for each measure, administered by whom, where] |
| * **Bayley Scales of Infant Development (BSID): Mental Developmental Quotient and Motor Developmental Quotient**   + The BSID is a standardized outcome measure that screens 5 developmental domains: cognitive, language, motor (gross and fine motor), social-emotional, and adaptive for children ages 16 days to 42 months.15 This study measured cognitive and motor domains. It has been updated twice since this study to the third edition, the BSID-III.   + The BSID-III cognitive and motor subtests have total possible raw scores ranging from 1 to 19 points, indicating lowest to highest development achieved.16 These scores are converted to composite cognitive or motor developmental quotient scores. Composite scores have a mean of 100 and standard deviation of 10, and range from 45 to 155 points.15,16   + The assessor was not explicitly stated, but was most likely the author of the study, who is a physical therapist. * **Peabody Developmental Motor Scales (PDMS): Gross Motor Developmental Quotient**   + The PDMS is a standardized outcome measure that assesses gross and fine motor development for children ages 0 to 83 months.10 The PDMS gross motor scale includes test items related to reflexes, balance, non-locomotor, locomotor, and receipt and propulsion of objects.10 It has been updated since this study to the second edition, the PMDS-2.   + The PDMS gross motor scale has 170 items that are scored on a 3-point scale, with 0 indicating unable to perform the item, 1 indicating partial credit, and 2 indicating full credit.10 The PDMS-2 Gross Motor Quotient is calculated by summing items to generate a raw score that corresponds to standard scores and Gross Motor Quotient scores.17,18 The Gross Motor Quotient composite scores have a mean of 100, reflecting typical gross motor development, and standard deviation of 10.17 The PDMS-2 range in Gross Motor Quotient scores includes a minimum score of 55 and maximum score of 150.18   + There is a moderate to high correlation between the BSID-III and the PDMS-2 Gross Motor Quotient scores for children who are older than 6 months.19   + The assessor was not explicitly stated, but was most likely the author of the study, who is a physical therapist. * **Four individualized treatment goals**    + Objectives were set for each individual infant based on achievable developmental milestones corresponding to NDT treatment approach. An example of these goals is: “Maintain prone on elbows with head at 45 degrees for 15 seconds; bring head past midline when tipped laterally to left and right, two out of three times in each direction; sit propped with weight on hands for 10 seconds; and demonstrate forward protective extension when rolled forward on therapy ball three out of four times.”2   + Scoring: The four treatment objectives were scored on a pass or fail basis. One point was awarded for each treatment goal met, resulting in a minimum score of 0 and a maximum score of 4.   + Assessor: The primary assessor was not explicitly stated, but was most likely the author of the study, who is a physical therapist. 100% inter-rater reliability was achieved when another therapist separately tested these objectives at post-test. * For all outcome measures, the assessment location was not explictly stated, but was most likely in the treatment location, the child’s home. |
| **Main Findings**  [Provide summary of mean scores/mean differences/treatment effect, 95% confidence intervals and p-values etc., where provided; you may calculate your own values if necessary/applicable. Use a table to summarize results if possible.] |
| **Post-test developmental quotient gain scores**   |  |  |  |  | | --- | --- | --- | --- | | **Variable** | **Experimental (n = 10)** | **Control (n = 10)** | **t** | | Bayley Mental Developmental Quotient\* | -6.03 ± 6.89 | -0.75 ± 12.40 | -1.174 | | Bayley Motor Developmental Quotient\* | -3.30 ± 17.10 | 2.24 ± 10.60 | -0.870 | | Peabody Gross Motor Developmental Quotient\* | 4.00 ± 10.20 | 6.93 ± 10.90 | -0.622 | | \*Scores reported as mean ± SD | | | |  * There was no statistically significant difference between groups on change made on any of the developmental quotient scores. * Although these differences were not significant, the control group trended towards more desirable change than the experimental group on all developmental quotients. Both the experimental and control groups decreased in rate of mental development, but the experimental group decreased by mean 5.28 points more than the control group; 95% CI: (-14.07, 3.51 points).\* The experimental group decreased on the Bayley Motor Developmental Quotient whereas the control group increased, resulting in a mean 5.54 point difference in favor of the control group; 95% CI: (-18.01, 6.93 points).\* Both the experimental and control groups increased in Peabody Gross Motor Developmental Quotient, but the control group increased by mean 2.93 points more than the experimental group; 95% CI: (-12.18, 6.32 points).\*   \*95% CI calculated by CAT author.  **Post-test individual therapy objectives**   |  |  |  |  | | --- | --- | --- | --- | | **Variable** | **Experimental (n = 10)** | **Control (n = 10)** | **t^** | | Individual therapy objectives (N = 4)\*^ | 3.20 ± 0.79 | 2.30 ± 1.25 | -1.924 | | \*Scores reported as mean ± SD; ^p = 0.05 | | | |  * The author reported that there was a statistically significant difference in favor of the experimental group on individual therapy objectives (p = 0.05). The infants in the experimental group achieved on average 0.9 more goals than the infants in the control group; 95% CI: (0.0, 1.80 goals).\* The inclusion of zero in the confidence interval is consistent with borderline statistical significance. An a priori alpha level and statistical analysis plan were not reported.   \*95% CI calculated by CAT author. |
| **Original Authors’ Conclusions**  [Paraphrase as required. If providing a direct quote, add page number] |
| The author concluded that the lack of significant difference between groups on the three developmental quotient gain scores was due to small sample size, incongruence between NDT treatment objectives and items on the Bayley and Peabody scales, and that a feasible outcome measure sensitive enough to detect subtle changes in postural tone did not exist. |
| **Critical Appraisal** |
| **Validity**  [Summarize the internal and external validity of the study. Highlight key strengths and weaknesses. Comment on the overall evidence quality provided by this study.] |
| * **PEDro score**: 7/11. Eligibility criteria: No; Random allocation: Yes; Concealed allocation: No; Baseline comparability: Yes; Blinding of subjects: No; Blinding of therapists: No; Blinding of assessors: Yes; Adequate follow-up: Yes; Intention to treat analysis: Yes; Between-group comparisons: Yes; Point measures and variability: Yes. * **Strengths:** The author acknowledged the importance of age, sex, and pre-test motor ability on rate of development using supporting research and ensured that groups were similar at baseline. Appropriate outcome measures were used: the Bayley Scales of Infant Development and Peabody Developmental Motor Scales. The author established 100% inter-rater reliability for the only non-standardized outcome measure, individual therapy objectives. The therapist was blinded to treatment group for individual therapy objectives. There was 100% follow-up. Specific NDT treatment techniques used in the experimental group were specified. The study had good external validity because both experimental and control groups received interventions that were typical in the field. * **Limitations noted by the authors:** The small sample size may have resulted in Type II error. Treatment effects from NDT physical therapy may not be detected by the Bayley and Peabody Scales. No outcome measured was used to assess change in postural tone, which was one of the general objectives of NDT. * **Additional limitations:** There was very large variability for all primary outcomes, including standard deviations larger than the mean for all post-test developmental quotient gain scores, and wide 95% confidence intervals for difference between means. Statistical significance level was not established a priori. There was also relatively large variability in age, with participants ranging in age from 2.7 to 21.5 months at pre-test, so infants would have large variability in individualized developmental goals. It is unclear what type of treatment the experimental and control group received in the weekly infant learning program. It is also unclear whether the experimental group continued their involvement in the weekly infant learning program during the study period, although it appears that they did. Allocation was not concealed. Outcomes were measured immediately after 9 weeks of treatment, so long-term effects of treatment are unknown. |
| **Interpretation of Results**  [This is YOUR interpretation of the results taking into consideration the strengths and limitations as you discussed above. Please comment on clinical significance of effect size / study findings. Describe in your own words what the results mean.] |
| There were no statistically significant differences between groups on any of the three developmental quotients. Despite statistical insignificance, each of the quotient scores trended towards favor of the control group, albeit with very wide confidence intervals. These results suggest that NDT physical therapy was not superior to the control infant learning program in achieving improved rate of mental or motor development. There was a borderline statistically significant difference in favor of the experimental group in meeting approximately 1 more individual therapy objective than the control group. However, the results from quotient scores are more meaningful because they are standardized outcome measures with strong psychometric properties, whereas the individual therapy objectives were designed by the author of the study and varied for each infant.  It is difficult to interpret clinical significance of changes in quotient scores for several reasons. The wide variability in all outcomes makes it difficult to pinpoint true change achieved in the sample. The study is dated, and the Peabody and Bayley scales have since been updated, so current available information on psychometric properties of the tools may not apply to the original scales. Although there is an established MCID of 8.39 for the PDMS-2 total standard score, there is no established MCID for the Gross Motor Developmental Quotient, so it is difficult to interpret clinically significant change on the outcome of interest for this study.20 Using available information that the Peabody Gross Motor Developmental Quotient has a mean of 100 and standard deviation of 10,17 a change in motor quotient by 4 points in the NDT group appears to be small, clinically insignificant change. The Bayley Scales of Infant and Toddler Development-III (Bayley-III) do not have an established MCID because they are designed to be a screening tool.21 However, knowing that the Bayley developmental quotients also have a mean of 100 and standard deviation of 10, a decrease in mental quotient  by 6 points and motor quotient by 3 points seems to be clinically insignificant change.15 The results suggest that NDT does not produce clinically meaningful improvement in motor or mental function of young children with Down syndrome. |
| **Applicability of Study Results**  [Describe the relevance and applicability of the study to your clinical question and scenario. Consider the practicality and feasibility of the intervention in your discussion of the evidence applicability.] |
| This study is relevant to the clinical question because it included children with Down syndrome between the ages of 0 to 3 years, and used NDT as the experimental intervention. The NDT intervention methods were clearly specified, and would feasibly be implemented in an early intervention physical therapy setting. The outcomes studied do not provide information about long-term effects of NDT as desired, but developmental quotients and therapy goals are a good way to measure short-term progress.  For clinical decision making, it would have been helpful to know specifics about treatment included in the control infant learning program, and whether or not the NDT group continued participation in the infant learning program during the study. Assuming that the NDT group did continue participation in the control intervention, this would suggest that the intervention effects in each group both resulted from the control infant learning program. In this case, it appears that NDT has no clinically important treatment effect for children with Down syndrome. Overall, I would not be inclined to utilize the NDT treatment approach with a young patient with Down syndrome, and would seek alternative clinical approaches supported by evidence that are cost-effective and acceptable to the family. |

**SYNTHESIS AND CLINICAL IMPLICATIONS**

[Synthesize the results, quality/validity, and applicability of the two studies reviewed for the CAT. Future implications for research should be addressed briefly. Limit: 1 page.]

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| **Evidence Synthesis**  The evidence reviewed suggests that early physical therapy using a neurodevelopmental treatment approach does not improve motor or mental rate of development beyond that of an active control group in infants and toddlers with Down syndrome. Although the studies reviewed used similar outcome measures and represented real-world early motor interventions, the evidence they present is limited because of the high risk of confounding and quasi-experimental design,3 failure to report complete outcome scores,3 small sample size,2,3 and wide variability in outcomes.3 Collectively, Mahoney et al and Harris found that outcomes between an NDT and active control group were not statistically significant in improving quality of movement TIME scores, Bayley Mental Developmental Quotient, Bayley Motor Developmental Quotient, Peabody rate of motor development, or Peabody Gross Motor Developmental Quotient. The only borderline significant difference found in either study in favor of the NDT group was for treatment objectives in the study by Harris, but the 95% confidence interval included 0, and the treatment objectives were not standardized and varied for each infant. Mahoney et al proposed the idea that more frequent motor intervention (at least once per week) may be necessary to achieve greater improvements in rate of development. However, this effect may be very small, and Harris provided treatment 3 times weekly yet still did not achieve clinically significant effects in developmental quotient scores. Unlike Mahoney et al, Harris acknowledged that infants with Down syndrome typically decline in rate of motor development with age, so a small decline or maintenance in motor developmental quotients with intervention could be considered a positive treatment effect. However, it is difficult to quantify potential clinical benefits of NDT because no studies have compared NDT to a no-treatment control group in this population, and no specific reference values exist for rate of motor development changes with aging for infants with Down syndrome. Even if NDT does create clinically important motor benefits, both of these studies show that comparison interventions such as developmental skills therapy or an infant learning program result in similar benefits. No existing evidence answers all aspects of the clinical question, but it can be inferred that if neurodevelopmental treatment does not produce greater short-term motor benefits than a control group for children with Down syndrome, it is unlikely to produce significant long-term benefits relating to pain, physical inactivity, or obesity.  **Implications for Clinical Practice**  These findings are important not only for physical therapists, but for children, families, taxpayers, and early intervention programs. These studies suggest that less costly or more simple interventions have the same treatment effect as neurodevelopmental treatment. Mahoney et al found that provider qualifications had no influence on rate of development after 12 months of intervention, suggesting that early motor interventionists such as developmental therapists can provide equal treatment effects as physical therapists with NDT certification. Because early intervention services such as physical therapy are mandated by Part C of the Individuals with Disabilities Education Act and receive public funding, providing early motor intervention to children with Down syndrome through less costly developmental therapists would make sense economically. Additionally, the question remains if any form of early motor intervention produces clinically significant improvements to warrant providing these services.  **Implications for Future Research**  In general, there are few recent studies that have investigated NDT as a treatment approach in children with Down syndrome. There are several potential reasons for this evidence gap, including variability in NDT approaches making it difficult to perform homogeneous high-quality research,22 lack of funding, evolving pediatric treatment approaches, studies performed for other diagnoses like cerebral palsy, and researchers’ views that NDT is not an effective treatment approach due to general lack of supporting evidence.22,23 In the future, other pediatric physical therapy treatment approaches and their effects on short- and long-term outcomes for children with Down syndrome and other developmental disabilities should be explored. Studies with larger sample sizes and stronger methodological quality are needed. Normative values and MCID for gross motor developmental quotients for children with Down syndrome should be established for the Peabody Developmental Motor Scales-2 in order to assess clinically significant change. One significant obstacle to performing studies with a no-treatment control group is the widespread belief and mandate that early motor intervention should not be denied to children with developmental motor delays.24 However, research comparing motor intervention to a no-treatment control group should be performed to help determine if early motor intervention is necessary for children with Down syndrome. |

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