Pollock A, Baer G, et al. Physiotherapy treatment approaches for the recovery of postural control and lower limb function following stroke. Cochrane Database of Systematic Reviews 2007, Issue 1, Art # CD001920.

Design: Meta-analysis of clinical trials

PICOS:

- **P**atient population: adults with clinical diagnosis of ischemic or hemorrhagic stroke
- **I**nterventions: Physical therapy (PT) treatments aimed at improving postural control or lower limb function, including gait
    - Studies aimed at improving upper limb function were excluded
- **C**omparison intervention: Several comparisons were separately made, with three basic approaches in mind: neurophysiologic, orthopedic, and motor learning
    - Neurophysiological versus motor learning
    - Neurophysiological versus orthopedic
    - Neurophysiological versus mixed
    - Motor learning versus orthopedic
    - Motor learning versus mixed
    - These were combined into three categories: (1) neurophysiological versus "other," (2) motor learning versus "other," and (3) mixed versus "other"
    - "Neurophysiological" approaches involve the therapist moving the patient through patterns of movement with the patient being essentially passive; "orthopedic" emphasized muscle strengthening and compensation with the noninvolved side; "motor learning" stresses the importance of active involvement of the patient rather than being passive as in the neurophysiological approaches
- **O**utcomes: Primary outcomes were measures of disability, measured as (1) global dependency scales, or (2) functional independence in mobility
- **S**tudy types: controlled trials, either randomized or quasi-randomized, with or without blinding of participants, therapists, and assessors

Study selection:

- Multiple electronic databases (MEDLINE, Cochrane Stroke Register, EMBASE, and others were searched through May 2005
- Reference lists of clinical trials were hand searched
- Physical therapy e-mail discussion lists were solicited for any unpublished or ongoing trials of PT and stroke
- Two independent reviewers assessed articles for meeting inclusion criteria and for methodological quality, with emphasis on control of bias (randomization, allocation concealment, blinding of assessors, completeness of follow-up)

Pertinent results:

- Although 20 trials with 1087 participants met inclusion criteria, 3 trials with 78 participants were not included in the analyses because they did not provide data on the outcomes which were chosen for analysis
- Comparison #1, neurophysiological versus other approaches, did not show significant differences between approaches for disability or impairment
- Comparison #2, motor learning versus other approaches, similarly did not show significant differences between approaches for disability or impairment
- Comparison #3, mixed versus other approaches, did not show significant differences between mixed and other approaches
    - However, for comparison of a mixed approach versus no treatment, 5 studies with 427 participants the mixed approach was significantly more favorable than no treatment for functional independence
    - Because different scales were used (Fugl-Meyer score, Rivermead Mobility Index, and Functional Independence Measure), the pooled treatment effect was calculated in terms of standard mean differences, which express treatment effects as standard deviations (SD) by which one treatment differs from another
    - The effect size was 0.94 SD (95% confidence interval, 0.08 to 1.80)
    - By convention, a treatment effect of 0.2 SD is considered small, an effect of 0.5 SD is considered moderate, and an effect of 0.8 or more is considered large
    - Therefore, the effect size for mixed treatment over no treatment was large, but the 95% confidence intervals included a very small effect (0.08 SD) and a very large treatment effect (1.80 SD)
    - One of the 5 studies was quasi-randomized (allocation was to assign every other patient to mixed treatment or no treatment, alternating them as they entered the study), and this study did not have blinded assessment of outcome; the risk of bias was high
    - This quasi-randomized study also showed the largest treatment effect of any of the 5 studies; when it was removed from the analysis, the treatment effect was much smaller and no longer “statistically significant;” the pooled treatment effect of the remaining 4 studies was 0.28 (95% CI, -0.03 to 0.58)

Authors’ conclusions:

- The review was undertaken in response to questions posed by physical therapists in Scotland, aiming to identify which of several “different treatment approaches” were more effective than their alternatives
- There are fundamental issues in trying to address this question; one of them is the dubious merit of basing physical therapy interventions on named “approaches”
    - Documentation of the techniques of physical therapy is generally brief in published literature, often due to space limitations in journals
    - Verbal description of complex interpersonal interactions between therapist and patient may be inadequate to allow accurate descriptions of the treatments received

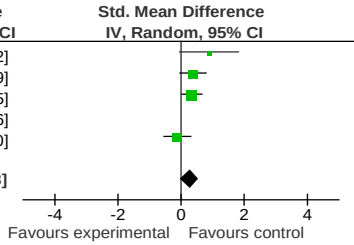
- Difficulties in poor definitions of terminology whose meaning may change over time can make literature searching problematic
- Methodological limitations are common in the literature; randomization and blinding are often not done or are too poorly described to be certain that bias was controlled as well as possible
- Despite all of these limitations and difficulties with literature interpretation, there is limited evidence that physical therapy interventions using a mix of components are more beneficial than no treatment for recovery of functional independence after stroke: some PT is better than none
- There is therefore a sound rationale for physical therapists to use a selection of treatments, regardless of how they are classified in terms of "approaches"

Comments:

- The discussion of the conceptual difficulties in assessing the effects of PT identifies many of the reasons that strong evidence of PT is elusive; interventions and outcomes are poorly described
- There appears to be an error in the discussion in the first paragraph of page 10, which describes the effect of removing one biased study from the analysis of mixed PT versus no treatment; it states that the standardized mean difference was 0.39, with 95% CI from 0.15 to 0.63
- In the results section on page 9 under "comparison 03.03," the pooled effect size with the biased study removed is 0.28 (95% CI, -0.03 to 0.58)
- Page 9 is correct and page 10 is incorrect, as shown by analysis with RevMan with Ozdemir 2001 removed from the analysis:

	Mixed treatment			No treatment				Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Duncan 1998	26.1	2.51	10	22.6	4.7	10	9.0%	0.89 [-0.04, 1.82]
Duncan 2003	26.84	3.7	44	25.46	3.5	48	27.8%	0.38 [-0.03, 0.79]
Green 2002	11	2.9	81	10	2.9	80	35.7%	0.34 [0.03, 0.65]
Ozdemir 2001	100.84	14.19	30	51.5	13.38	30	0.0%	3.53 [2.70, 4.36]
Wade 1992	12.2	4.3	48	12.7	4.2	41	27.5%	-0.12 [-0.53, 0.30]
Total (95% CI)			**183**			**179**	**100.0%**	**0.28 [-0.03, 0.58]**

Heterogeneity: Tau² = 0.04; Chi² = 5.49, df = 3 (P = 0.14); I² = 45%
Test for overall effect: Z = 1.78 (P = 0.07)



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- Although "statistical significance" is lost in this analysis, the data are pooled with a random effects model, which is a reasonable but not a necessary analysis; since the value of I^2 is less than 50%, a fixed effect model could also summarize the data; if this is done, the effect is still fairly small but statistical significance is not lost:

	Mixed treatment			No treatment				Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI
Duncan 1998	26.1	2.51	10	22.6	4.7	10	5.0%	0.89 [-0.04, 1.82]
Duncan 2003	26.84	3.7	44	25.46	3.5	48	25.4%	0.38 [-0.03, 0.79]
Green 2002	11	2.9	81	10	2.9	80	44.7%	0.34 [0.03, 0.65]
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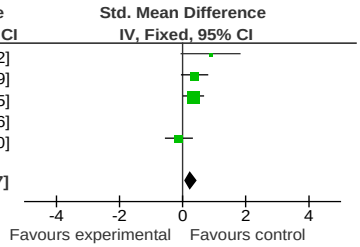
Wade 1992	12.2	4.3	48	12.7	4.2	41	24.9%	-0.12 [-0.53, 0.30]
Total (95% CI)			**183**			**179**	**100.0%**	**0.27 [0.06, 0.47]**

Heterogeneity: Chi² = 5.49, df = 3 (P = 0.14); I² = 45%
Test for overall effect: Z = 2.50 (P = 0.01)



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- Clearly, both analyses are marginal in terms of statistical significance, and there is no real difference in effect size; the important point is that when a biased study with a very large effect size (3.5 SD) is removed, it becomes

clear that this study had a disproportionate influence on the pooled effect size of 0.94 SD, and that the difference between “statistically significant” and “statistically not significant” is arbitrary

- Collectively, the difficulties of definition and classification of PT that the authors identify in the PT literature are likely to obscure the effects of PT when randomization and blinding are carefully done

Assessment: High quality meta-analysis which provides some evidence that physical therapy is likely to assist stroke patients in regaining functional independence, and that no one PT approach can be recommended over any other approach