



AOTA Evidence Briefs

Multiple Sclerosis

**A product of the American Occupational Therapy Association's Evidence-Based Literature Review Project*

MS #15

Rehabilitation may reduce disability and improve mental quality of life in multiple sclerosis patients

Solari, A., Filippini, G., Gasco, P., Colla, L., Salmaggi, A., La Mantia, L., et al. (1999). Physical rehabilitation has a positive effect on disability in multiple sclerosis patients. *Neurology*, 52, 57–62.

Level: IA1a

Randomized controlled trial, 20 or more participants per condition, high internal validity, high external validity

Why research this topic?

Few studies have examined the effects of inpatient rehabilitation on people with multiple sclerosis, and most lack a comparison group that does not receive treatment. By having a group that does not receive treatment, researchers eliminate the possibility that factors other than the intervention (e.g., skill of therapist, spontaneous remission) may be causing an improvement. Thus, a need exists for more research on the effectiveness of rehabilitation with this population.

What did the researchers do?

Solari et al. (1999), variously affiliated with the Istituto Nazionale Neurologico C. Besta (Milan, Italy), the Ospedale Santo Spirito (Casale Monferrato, Italy), and the Fondazione Clinica Pro Juventute Don C. Gnocchi (Milan), designed a study to test the effects of an inpatient rehabilitation program on people with multiple sclerosis.

All 304 inpatients and outpatients consecutively admitted to the Istituto Nazionale Neurologico C. Gesta between January 1995 and April 1997 were eligible for participation in the study. From this group, the researchers selected 50 using three criteria for inclusion (clinically definite or laboratory-supported multiple sclerosis; a score between 3.0 and 6.5 on the Expanded Disability Status Scale [EDSS]; and an age of 18–65 years) and six criteria for exclusion (for example, cognitive **impairments** [see *Glossary*] that might interfere with participation and one or more exacerbations of the disease within the preceding three months). Twenty-two of the patients were men, and 28 were women. Their average age was 44.7 years.

The researchers randomly assigned the 50 patients to a treatment group (n=27) or a **control group** (see *Glossary*; n=23). The treatment group received 45 minutes of inpatient rehabilitation twice a day for three consecutive weeks. At the end of the three weeks, they also received instruction in a home exercise program.

The therapeutic approach differed according to the patient's level of impairment and disability, and included passive (stretching, mobilization) and active interventions. For patients with an EDSS score ≤ 4.5 , the main goals were normalizing postural control, facilitating normal gait pattern, increasing the range of movement, and maximizing muscle power and endurance. For patients with an EDSS score > 4.5 , instruction on appropriate use of mobility aids and orthoses as well as refinement of compensatory strategies were also part of the program (p. 58).

The control group received one day of individual instruction in a home exercise program. As with the treatment group, the therapists differentiated between patients with EDSS scores equal to or below 4.5 and those with EDSS scores greater than 4.5, also providing the latter with instruction in the use of mobility aids and orthoses.

The researchers were interested in the following outcome areas: *disability* (as measured by the three subscales of the motor domain [self-care, transfers, and locomotion] of the Functional Independence Measure [FIM]); *impairment* (as measured by the EDSS); and *quality of life* (as measured by the eight subscales of the Short Form Health Survey Questionnaire [SF-36; physical functioning, role limitation—physical, bodily pain, general health, vitality, social functioning, role limitation—emotional, and mental health], which produce eight individual scores and two composite scores, physical and mental). Measures were taken before the study began, at the end of the treatment period (week 3), and at two follow-up periods (weeks 9 and 15).

What did the researchers find?

For the disability outcome, the researchers considered a change of at least two points in the FIM motor domain scores to be clinically **significant** (see *Glossary*). Thirteen patients in the treatment group showed such an improvement at week 3, compared with two in the control group. This difference was not only clinically significant but also statistically significant. The corresponding numbers at week 9 were 12 and 1, and again the difference also was statistically significant. At week 15, 1 patient in the intervention and 2 in the control group maintained improvement, but this difference was **not statistically significant** (see *Glossary*).

The groups differed significantly at weeks 3 and 9 on all three subscales of the FIM motor domain, and on two of the three subscales (self-care and locomotion) at week 15. The difference favored the treatment group.

For the impairment outcome, the researchers considered a change of at least two points in the EDSS score to be clinically significant. At weeks 3, 9, and 15, both groups showed almost no improvement at all in impairment. Indeed, across the entire study period, only one patient, from the treatment group, gained as much as one point.

For the quality-of-life outcome, at weeks 3, 9, and 15, the treatment group showed a significantly greater improvement than the control group on the general health and mental health scales of the SF-36; at weeks 3 and 15, on the vitality scale; and at week 9, on the role limitation—emotional and social functioning scales. Further, the treatment group showed a significantly greater improvement than the control group at weeks 3 and 9 on the mental composite score, but this difference was not maintained at 15 weeks.

What do the findings mean?

For therapists and other providers, the findings suggest that rehabilitation can reduce disability and improve mental quality of life in patients with multiple sclerosis for a short and medium length of time.

What are the study's limitations?

The study has two limitations. First, there may have been a “floor effect” for physical quality of life; that is, the patients were “physically compromised” at the start of the study (p. 61), and the scale may not have been sensitive enough to detect improvements. Second, the results may not be generalizable to all patients with multiple sclerosis because the researchers had so many criteria for exclusion.

Glossary

control group—A group that received special attention similar to that which the treatment group received, but did not receive the treatment.

impairments—“Abnormalities of body structure and appearance and with organ or system function, resulting from any cause” (*International Classification of Impairments, Disabilities, and Handicaps*, 1980, p. 14).

nonsignificant (or no significance)—A statistical term that refers to study findings that are likely to be due to chance differences between the groups rather than to other factors (e.g., the treatment of interest). A nonsignificant result is not generalizable outside the study. Like significance, a nonsignificant result does not indicate the clinical effect. Often studies will show nonsignificant results, yet the treatment group’s mean will be better than the control group’s. This is usually referred to as a trend in the right direction. Because significance is closely determined by sample size, nonsignificant results would often become significant if the sample size were increased.

significance (or significant)—A statistical term that refers to the probability that the results obtained in the study are not due to chance, but to some other factor (e.g., the treatment of interest). A significant result is likely to be generalizable to populations outside the study.

Significance should not be confused with *clinical effect*. A study can be statistically significant without having a very large clinical effect on the sample. For example, a study that examines the effect of a treatment on a client's ability to walk may report that the participants in the treatment group were able to walk significantly longer distances than those in the control group. However, after reading the study, one may find that the treatment group was able to walk, on average, 6 feet, whereas the control group was able to walk, on average, 5 feet. Although the outcome may be statistically significant, a clinician may not feel that a 1-foot increase will make his or her client functional.

This work is based on the evidence-based literature review completed by Vidyalakshmi Sundar, BS, and Marian Arbesman, PhD, OTR/L. For more information about the Evidence-Based Literature Review Project, contact the Practice Department at the American Occupational Therapy Association, 301-652-6611, x 2040.



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