AOTA Evidence Briefs
Multiple Sclerosis

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

MS #12

Outpatient rehabilitation to improve quality of life for patients with severe multiple sclerosis

Di Fabio, R. P., Choi, T., Soderberg, J., & Hansen, C. R. (1997). Health-related quality of life for patients with progressive multiple sclerosis: Influence of rehabilitation. *Physical Therapy, 77*, 1704–1716.

Level IIB3a

Nonrandomized controlled trial, less than 20 participants per condition, low internal validity, high external validity

Clinical bottom line

A long-term outpatient rehabilitation program may have caused a small improvement in the quality of life for clients with severe multiple sclerosis. This improvement was **nonsignificant** (*see Glossary*) when compared with the outcomes for a control group. The program included occupational therapy.

(See also Di Fabio, Soderberg, Choi, Hansen, and Schapiro, 1998 [*MS Brief #11*].)

Sample

The original study participants were 44 patients with multiple sclerosis. Nineteen were admitted to the Multiple Sclerosis Center. The remaining 25 were put on a wait-list for admission and thus became the control group. All had chronic progressive multiple sclerosis and disability severe enough that they could not work a full day without special provisions and could not walk farther than 200 meters (about 219 yards) without assistance. Thirteen patients dropped out of the study, 7 from the treatment group and 6 from the control group, leaving a final sample of 31. Six were men, 25 women. Their average age was 47.4 years.

Procedures

This finding emerged from a study of the effects of a program designed to assist clients in maintaining both physical and mental function, rather than to restore "normal" function. The participants spent 5 hours at the Fairview Multiple Sclerosis Achievement Center (Minneapolis) 1 day a week for 1 year. The interventions included physical therapy for balance, coordination, gait, transfers, endurance training, and range of motion; occupational therapy for use of the upper extremities to eat and dress, and for enhancement of communication skills, attention span, and other cognitive abilities; structured recreation experiences; counseling from a chaplain; and social work services.

Outcomes

The outcomes of interest to the researchers were *physical and emotional health*—specifically general health perceptions, physical function, energy/fatigue, emotional well-being, social function, physical pain, role limitations due to emotional problems, and role limitations due to physical problems (all as measured by the SF-36, a 36-item short form health survey); *disease-specific issues related to multiple sclerosis patients*—specifically sexual function, cognitive function, health distress, change in health, and overall quality of life (all as measured by the Multiple Sclerosis

Quality-of-Life Questionnaire [MSQOL]); and *function*—specifically bed mobility, wheelchair propulsion, bed transfers, ambulation, and skin status (all as measured by corresponding components of the Rehabilitation Institute of Chicago Functional Assessment Scale [RIC–FAS]).

Analyses

The researchers looked at the difference in the scores of each group at baseline and after the intervention.

Results

At the 1-year follow-up assessment, both groups showed a decrease in physical function as indicated by the RIC–FAS scores, but the treatment group showed less than the control group.

Significance and **effect sizes (*r*)** (see Glossary) for outcome measures comparing the treatment and control groups for DiFabio et al. (1997)

Outcome	Significance	Clinical effect (*r*)	Size of effect
RIC-FAS	NA	0.16	Small
SF36			
Physical health	NA	0.24	Small
Physical role limitation	NA	0.22	Small
Bodily pain	NA	0.08	Negligible
General health	NA	0.05	Negligible
Fatigue	NA	0.15	Small
Social function	NA	0.25	Small
Emotional role limit	NA	0.20	Small
Emotional wellness	NA	0.04	Negligible
MSQOL			
Social support	NA	0.04	Negligible
Cognitive	NA	0.11	Small
Health distress	NA	0.30	Medium
Health change	NA	0.11	Small
Overall QOL	NA	0.07	Negligible

Limitations

First, the researchers did not report whether the difference between the treatment and control groups was **significant** (*see Glossary*). Because of the small sample size and the small difference size, it is likely that the results were not significant. Second, participants were not randomly assigned to groups (**randomization**) (*see Glossary*). Third, changes in treatment status may have been due to the attention the treatment group received, not the intervention itself (**attention bias**) (*see Glossary*). Fourth, the wait-listed control group may have received treatments unrelated to the study (**contamination bias**) (*see Glossary*). Finally, there were 13 dropouts (**lost to follow-up**) (*see Glossary*).

Reference

Di Fabio, R. P., Soderberg, J., Choi, T., Hansen, C. R., & Schapiro, R. T. (1998). Extended outpatient rehabilitation: Its influence on symptom frequency, fatigue, and functional status for persons with progressive multiple sclerosis. *Archives of Physical Medicine and Rehabilitation, 79,* 141–146.

Glossary

attention bias—Also known as the Hawthorne effect, participants who receive some form of attention during treatment will often change their behavior, not because of the treatment per se, but because they are receiving attention. This bias is most frequently seen when the control group is wait listed or receives no treatment.

contamination bias—Participants in a control group receive some treatment that may have improved their outcome. This could be the start of a new medication or some form of therapeutic intervention. This type of bias is highly likely in longitudinal studies. This bias will mask the effect of treatment.

effect sizes (Cohen's *r*)—An effect size is a measure of clinical significance. It provides information about the magnitude of effect of the treatment. Although related to significance, it is not as influenced by the size of the sample. Therefore, it is possible to have an outcome on which the treatment had a large effect (e.g., the treatment group improved a lot more than the control group) and still have a nonsignificant result. If the results have a large effect but no significance, this means that this effect may be sample specific and not generalizable outside the study. There are many different types of effect sizes. What is reported here is Cohen's *r*. Cohen's *r* can be interpreted in a manner similar to a Pearson's correlation coefficient:

Effect size *r*	**Size of the effect**
<0.99	Negligible
0.10 – 0.29	Small
0.30 – 0.49	Medium
>0.50	Large

Cohen, J. (1977). *Statistical power analysis for behavioral sciences.* New York: Academic Press.

lost to follow-up—Participants who are lost to follow-up may differ from those who remain in the study; for instance, they may be sicker or have family members who are less supportive. If those who were lost to follow-up remained in the study, the results might have been different. In general, a study with more than 20% lost to follow-up is probably biased.

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 (like 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.

randomization—Randomization refers to the practice of assigning participants to either the treatment or control group using random allocation. Random allocation methods include flipping a coin or using a random number table. Randomization is meant to prevent the possibility that the experimenter might subconsciously let his or her opinions and preferences influence into which group a participant goes. Randomization also helps to ensure that the two groups are essentially equal on many demographic variables, although randomization does not always create equal groups.

Nonrandomized studies are not considered to be true experiments but are often referred to as quasi-experimental. Serious biases can occur when studies are non-randomized.

significance (or significant)—A statistical term, this refers to the probability that the results obtained in the study are not due to chance, but to some other factor (such as 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 the control group. However, if you read the study you 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 believe that a 1-foot increase will improve his or her client's function.

■ Terminology used in this document is based on two systems of classification current at the time the evidence-based literature reviews were completed: *Uniform Terminology for Occupational Therapy Practice—Third Edition* (AOTA, 1994) and *International Classification of Functioning, Disability and Health (ICIDH-2)* (World Health Organization [WHO], 1999). More recently, the *Uniform Terminology* document was replaced by *Occupational Therapy Practice Framework: Domain and Process* (AOTA, 2002), and modifications to *ICIDH-2* were finalized in the *International Classification of Functioning, Disability and Health* (WHO, 2001).

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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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