



AOTA Evidence Briefs

Multiple Sclerosis

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

MS #11

Comprehensive outpatient rehabilitation to improve quality of life for persons with progressive multiple sclerosis

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.

Level: IIA3a

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

Clinical bottom line

A comprehensive long-term outpatient program aimed at teaching coping and skill maintenance appears to have decreased fatigue and multiple sclerosis signs and symptoms for clients with progressive multiple sclerosis. Occupational therapy was among the services included in the program.

(See also the study by Di Fabio, Choi, Soderberg, and Hansen, 1997 [*MS Brief #12*].)

The program studied integrated occupational therapy and physical therapy with support services (e.g., social work, therapeutic recreation, nutrition education) to help the participants maintain their physical functioning and improve their coping skills. Treatment occurred over 1 year, once a week for 5 hours.

Sample

Seventy-five persons with multiple sclerosis were evaluated for participation in the study. Of these, 46 were either accepted and then admitted to the Fairview Multiple Sclerosis Achievement Center (Minneapolis), or wait-listed for admission. Twelve participants were men and 34 were women; their average age was 49.6 years. All had chronic progressive multiple sclerosis and disability severe enough not to be able to work a full day without special provisions or to walk beyond 200 meters (about 219 yards) without assistance.

Procedures

The treatment group consisted of the first 20 persons accepted for the study; the control group consisted of the 26 who were put on the waiting list. Assignment thus was not random, but analysis of the participants before the treatment began showed no **significant** (see *Glossary*) differences between the groups.

By the end of the study, 7 members of the treatment group and 6 members of the control group had dropped out. Thus the final sample was 33. Analysis of the baseline scores of these participants showed no significant differences.

Outcomes

The researchers were interested in three outcome areas: *signs and symptoms of multiple sclerosis* and *fatigue* (both as measured by the MS-Related Symptom Checklist), and *functional status*—specifically bed mobility, wheelchair propulsion, bed transfers, ambulation, and skin status (as measured by corresponding components of the Rehabilitation Institute of Chicago Functional Assessment Scale [RIC-FAS]).

Analyses

The researchers compared the scores of the treatment and control groups following intervention, while controlling for baseline scores.

Results

The treatment group demonstrated **significant** (see *Glossary*) decreases in fatigue when compared with the control group, but members were not significantly more functional.

Significance and **effect sizes** (*r*) (see *Glossary*) for outcome measures comparing the treatment and control groups for DiFabio et al. (1998)

Outcome	Significance	Clinical effect (<i>r</i>)	Size of effect
Symptom frequency	Nonsignificant	0.13	Small
Functional status	Nonsignificant	0.03	Negligible
Fatigue	Significant	0.49	Medium

Limitations

First, the participants were not randomly assigned to the groups (**randomization**) (see *Glossary*). Second, the sample size may have been too small to show significant differences (**sample size bias**) (see *Glossary*). Third, the researchers did not provide enough information on the interventions used during therapy to allow for replication of the study (**treatment specification**) (see *Glossary*). Fourth, participants in the treatment group who improved may have done so because of the attention they received, rather than because of the intervention itself (**attention bias**) (see *Glossary*). Fifth, the evaluators were not **blinded** (see *Glossary*) to group status. Finally, because of the length of the study, people on the waiting list may have received treatment that improved their fatigue and function (**contamination bias**) (see *Glossary*).

Reference

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.

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.

blinded/blinding—Blinding refers to the practice of keeping members of the research study unaware of which group a participant is assigned to (treatment or control) in the study. Single blinding usually refers to keeping study participants unaware of whether they are receiving the experimental or the sham treatment. Double blinding usually refers to keeping the participants and those who are administering the treatment unaware of who is receiving the experimental and who is receiving the sham treatments. In some cases, where it is impossible to blind those administering treatment, the individuals who are administering the outcome measures can be blinded to group status.

Studies in which blinding does not occur can have significant biases. When the participants know that they are receiving the experimental treatment, they often get better because they think they ought to (this is often referred to as the placebo effect). When researchers know that a participant is receiving the experimental treatment, they often subconsciously favor those participants when evaluating them on outcome measures. For instance, when timing a participant in the treatment group, researchers may unknowingly stop the watch a little faster or slower so the treatment participant seems to do better.

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 treatment. Although related to significance, it is not 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
<0.10	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

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.

sample size bias—Significance is strongly related to sample size. A study that has too small a sample will not show significance (a type II error), even when a treatment effect is present. Some research studies that are nonsignificant demonstrate a trend toward the treatment having the desired effect, suggesting that a larger sample is needed to detect a significant treatment effect. On the other hand, too large a sample can prove just about anything.

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.

treatment specification—One of the goals of research is to ensure that any results can be replicated by others. In addition, clinician who are going to use researched protocols as part of their treatment need enough information about the treatment to implement it. Many treatment studies fail to clearly state the treatment intervention received by the experimental group, making replication and clinical application impossible.

■ 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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