

MS #6

A cooling suit to improve function for multiple sclerosis patients who are sensitive to heat

Coyle, P. K., Krupp, L. B., Doscher, C., Deng, Z., & Milazzo, A. (1996). Clinical and immunological effects of cooling in multiple sclerosis. *Journal of Neurological Rehabilitation, 10,* 9–15.

Level IB1a

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

Clinical bottom line

Use of a cooling suit may promote better function in multiple sclerosis patients who are sensitive to heat. Thus occupational therapists might consider having their patients use such a suit before treatment.

(See also the study by Syndulko, Woldanski, Baumhefner, and Tourtellotte, 1995 [MS Brief #9].)

Sample

The participants in the study who produced this finding were 11 people with multiple sclerosis who were in relapse or remission. Six were men, 5 women, and they averaged 44 years in age. All were ambulatory and reported sensitivity to heat.

Procedures

All the participants experienced two 45-minute sessions, 1 week apart, wearing a commercial cooling garment. In one session their body temperature was lowered 1° C, in the other session, less than 0.5° C. The latter was considered a "sham" cooling. That is, the participants were led to believe that they were being cooled, but in fact they were not. The flip of a coin determined the order in which each participant experienced the sessions.

Outcomes

One hour before and 1 hour after each session, the participants underwent a standardized clinical evaluation. It focused on *visual acuity* (as measured by a hand-held pocket vision screen), *a 25-foot walk* (timed by a hand-held stopwatch), *muscle strength* (as measured by the British system rating scale), and *coordination* (as measured by tandem gait—alternately placing the heel of one foot directly in front of the toes of the other foot—and finger-to-nose testing). The same examiner, who was not **blinded** (*see Glossary*) to condition status, conducted all the evaluations.

Analyses

The participants acted as their own controls. That is, the results obtained while the participants were in the true cooling group were compared with the results obtained while they were in the sham cooling group.

Results

The group that experienced true cooling improved **significantly** (*see Glossary*) and the **effect sizes** (*see Glossary*) were large (see the Table), suggesting that this cooling had a large clinical effect for visual acuity, timed walk, and muscle strength.

Measures of changes in the participants' immune system also suggested beneficial outcomes.

Significance and effect sizes (*r*) for outcome measures comparing the treatment and control groups for Coyle et al. (1996)

Outcome	Significance	Clinical effect (r)	Size of effect
Visual acuity	Significant	0.60	Large
Timed walk	Significant	0.93	Large
Muscle strength	Significant	0.93	Large
Coordination	Nonsignificant*	N/A	

*(see Glossary)

Limitations

The evaluator was not blinded to group condition and therefore may have been biased. Also, the study would have benefited from using other functional measures as well as from soliciting participants' perceptions of using the cooling suit.

Reference

Syndulko, K., Woldanski, A., Baumhefner, R. W., & Tourtellotte, W. W. (1995). Preliminary evaluation of lowering tympanic temperature for the symptomatic treatment of multiple sclerosis. *Journal of Neurological Rehabilitation, 9,* 205–215.

Glossary

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.

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* can be interpreted in a manner similar to a Pearson's correlation coefficient:

Effect size <i>r</i>	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.

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.

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).

This work is based on the evidence-based literature review completed by Nancy Baker, ScD, OTR, and Linda Tickle-Degnen, PhD, OTR/L, FAOTA.

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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