# Try Tailored Psychotherapy for Fibromyalgia

BY BRUCE JANCIN
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PARIS — Success rates for nonpharmacologic therapy in patients with fibromyalgia are climbing to previously unattainable levels by tailoring psychotherapy in accord with patient characteristics.

It is best to intervene before the physical and psychological impairments have hardened. Also, combining the tailored psychotherapy with an exercise training program seems to be important, mental health researchers said at the annual European Congress of Rheumatology.

Saskia van Koulil, Ph.D., summarized her recent comprehensive review of the published literature on nonpharmacologic therapies for fibromyalgia (Ann. Rheum. Dis. May 2007;66:571-81) as showing modest and inconsistent benefits. In many studies, 30% or less of treated patients had at least a 50% improvement in symptoms and functioning, and the benefits typically faded over 6 months or more of follow-up.

But this poor showing is probably attributable to a past tendency to take a one-size-fits-all approach to psychotherapy for what is in reality a quite heterogeneous syndrome, said Dr. van Koulil of Radboud University Nijmegen (the Netherlands).

She and her colleagues have developed a validated brief self-report screening instrument (Int. J. Behav. Med. March 2008; 15:211-20) to help differentiate the two major cognitive and behavioral patterns fibromyalgia patients exhibit: pain-avoidance behavior, which is an extension of the well-established psychological fear-avoidance model, and a pain-persistence pattern, in which patients ignore their pain and persist in painful activities to their detriment. The two patterns are equally common.

Fibromyalgia patients with a pain-avoidance pattern are more likely to benefit from operant-behavioral therapy focused on changing observable pain behaviors, while those with a predominantly pain-persistence pattern tend to fare better with cognitive-behavioral therapy addressing maladaptive thoughts. For patients who have elements of both patterns, either form of therapy appears to be appropriate, according to Dr. van Koulil.

She presented a randomized trial in which 216 fibromyalgia patients were assigned either to a multimodal intervention—including tailored psychotherapy—or to a usual-care control group. All had high levels of psychological distress as an inclusion criterion, in light of evidence that nonpharmacologic therapies are most effective in such patients.

The intervention consisted of small, 3-hour-long group sessions twice weekly for 8 weeks. Half of each session was devoted to tailored group psychotherapy, the other half to exercise training, which included pool exercise, aerobics, and relaxation therapy. The patient's significant other attended 3 sessions so therapists could address social reinforcement issues.

At the end of the intervention, patients rated its usefulness as 8.2 out of a possible 10. They also showed highly clinically relevant 80%-90% reductions on measures of pain, fatigue, functional disability, and anxiety.

More important, at 6-month follow-up 57% of the multimodal intervention group maintained a clinically significant improvement as defined by at least a 0.5–standard deviation gain over baseline on physical functioning measures, compared with 29% of controls. And 49% in the intervention arm showed a similar improvement in psychological functioning, compared with 28% of controls.

Based upon these favorable results, the tailored nonpharmacologic intervention will be implemented nationally at the other Dutch university medical centers, Dr. van Koulil added.

Kati Thieme, Ph.D., reported on 125 fibromyalgia patients randomized to cognitive-behavioral therapy, operant-behavioral therapy, or a control group. Patients were followed for 12 months, at which point she and her colleagues looked retroactively at various pretreatment patient characteristics to see which ones separated subsequent responders from nonresponders.

The psychotherapy consisted of 15 once-weekly 2-hour sessions conducted in small groups codirected by a psychologist and a rheumatologist. The control group met on the same schedule for therapist-guided general discussions of the medical and emotional problems of fibromyalgia, with no therapist recommendations. Spouses attended 4 sessions. Patients were encouraged to increase their level of physical activity.

At 1 year follow-up, clinically meaningful improvements in pain intensity measures were documented in 54% of patients in the operant-behavioral therapy group, a statistically similar 45% of the cognitive-behavioral therapy group, and 5% of controls. In the operant-behavioral therapy group, 58% had significant reductions in physical impairment, as did 38% in the cognitive-behavioral therapy group and 7.5% of controls, according to Dr. Thieme of the University of Heidelberg (Germany).

In the cognitive-behavioral group, responders had higher baseline levels of affective distress and physical impairment than did nonresponders. Responders also displayed less-pronounced pain behaviors at baseline, lower coping ability, and less enabling behavior on the part of spouses.

Responders to operant-behavioral therapy had greater baseline physical impairment than nonresponders. Responders also had more mental catastrophizing, more pain behaviors, markedly more physician visits, and more solicitous spouse behaviors than nonresponders to cognitive-behavioral therapy.

Clinically significant deterioration in pain behaviors and physical impairment were reported by 48% of subjects in the control group, which implies that social discussion of fibromyalgia-related problems in the absence of therapeutic intervention may be counterproductive, Dr. Thieme cautioned.

A prospective outcome study is warranted to confirm the hypothesis that tailoring therapy according to the patient characteristics identified in this trial actually results in better outcomes, she continued.

A noteworthy finding was the low attrition rate in both tailored-therapy studies. Clinical trials in fibromyalgia patients typically feature a very high dropout rate, regardless of whether they involve pharmacologic or nonpharmacologic treatments. But participants in the tailored-therapy trials were clearly engaged: The dropout rate in Dr. van Koulil's study was 5.5%. It was similar in the psychotherapy arms of Dr. Thieme's study, compared with 50% in the control group.

Her study was funded by the German Research Council.

Dr. van Koulil's was supported by the Dutch Arthritis Association. ■

# TMS Shows Efficacy for Treating Migraine With Aura

BY DIANA MAHONEY
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BOSTON — Transcranial magnetic stimulation may be a promising new weapon in the pain relief arsenal of patients with chronic migraine with aura, findings of a clinical trial show.

Brain stimulation with magnetic pulses, delivered via a portable stimulation device held to the back of the head, eliminated migraine pain in about 39% of patients who were randomized to its use, according to data presented by Dr. Richard Lipton, professor of neurology and epidemiology at the Albert Einstein College of Medicine, New York.

Transcranial magnetic stimulation (TMS) is a method of focal brain simulation based on the principle of electromagnetic induction, whereby a powerful, rapidly changing extracranial magnetic field generates small intracranial currents, Dr. Lipton explained. The technology has shown promise in the treatment of various neurologic and psychiatric diseases. It is thought to interrupt neuronal excitability in the motor cortex of the brain, which has been implicated as a trigger in the cascade of migraine events, he said.

Previous studies have shown that early treatment with TMS, delivered in the clinic via a large, tabletop device, reduces pain in patients who experience migraine with aura, Dr. Lipton reported at the annual meeting of the American Headache Society.

The current study sought to assess the efficacy of the treatment when it was delivered via a portable, handheld device designed specifically to facilitate at-home treatment. In a multicenter, double-blind, parallel-group sham controlled study, 201 outpatients aged 18-68 years with a history of migraines with aura (as defined by the International Classification of Headache Disorders, 2nd ed.) were randomized to either active treatment with the TMS device or sham treatment with an identical device that similarly buzzed and vibrated but did not emit magnetic pulses. Patients were included in the study if they experienced one to eight migraines per month, and if they did not overuse headache medications.

All of the patients were directed to use their devices at the onset of aura by holding the device to the back of the head and pushing the button two times to emit two brief pulses. The patients recorded their levels of pain and symptoms in an electronic diary both at the time of treatment and then after treatment at 30 minutes, 1 hour, 2 hours, 24 hours, and 48 hours. The primary end point for the current study was pain elimination at 2 hours.

The final analysis included 164 patients, mean age 39 years, who completed the study. The majority of patients treated themselves when they were either pain free (31%) or had mild pain (40%). Nearly one-third of the patients applied the treatment when they were in moderate (23%) or severe (6%) pain, noted Dr. Lipton.

The 2-hour pain-free rates were 39% for the TMS group and 22% for the sham treatment group, yielding an absolute risk reduction of 17%, Dr. Lipton reported. "In other words, for every seven people who use a transcranial magnetic stimulator to treat a migraine attack, one person will be pain free at 2 hours," he said.

**The 2-hour pain-free rates were 39% for the TMS group and 22% for the sham treatment group.**

**DR. LIPTON**

The rates of associated symptoms "were equal or lower than the sham treatment rates," and the number of adverse events and the number of patients experiencing adverse events were similar between both groups, Dr. Lipton reported.

The results are not as good as those achieved with standard antimigraine drugs, such as aspirin, antiemetics, triptans, or some of the new investigational drugs, but the availability of a noninvasive, nondrug treatment is important because it avoids the side effects of migraine medications, Dr. Lipton said. Future studies in patients with migraine without aura are on the horizon, he said.

Funding for this study was provided by Neuralieve Inc., developers of the TMS device, which has not yet received marketing clearance from the Food and Drug Administration. ■

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