Each 4-hour treatment session included cognitive behavioral therapy and exercise training.

Fibromyalgia: Tailored Tx Proved Successful

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ROME — A tailored combination of cognitive-behavioral therapy and physical exercise training has achieved the largest treatment benefit ever reported for fibromyalgia in a randomized, placebo-controlled clinical trial.

The durability of the results was particularly impressive. The large improvements in psychological and physical functioning that were documented at the end of the 8-week treatment program were maintained at the 6-month follow-up, Saskia van Koulil said.

The success of this customized treatment approach hinged upon a two-stage screening process. First, patients who have had their fibromyalgia for fewer than 5 years and were at high risk of long-term dysfunction were selected because prior studies indicated that such individuals tend to have better treatment outcomes in general.

Within this group of high-risk patients, specific cognitive-behavioral patterns seemed to drive their fibromyalgia pain and disability. It is possible to screen for these patterns of thought and behavior. One school of thought among clinical psychologists, including Ms. van Koulil, holds that there are two main patterns: pain avoidance and pain persistence. The treatment programs for the two are quite different, explained Ms. van Koulil of St. Radboud University Medical Center in Nijmegen, the Netherlands.

The high treatment success rate in this randomized trial validated this concept of the pain-avoidance and pain-persistence fibromyalgia subtypes, she said.

In her experience, close to two-thirds of patients with fibromyalgia of fewer than 5 years' duration have a high-risk profile. This is characterized by high levels of anxiety and/or negative mood on standard measures of distress, along with worse physical functioning, greater impact of fibromyalgia on daily life, and obvious maladaptive cognitive-behavioral patterns such as high levels of helplessness and worrying. This high-level psychological distress is an indicator of treatment motivation, Ms. van Koulil noted.

In the randomized trial, 158 high-risk fibromyalgia patients (95% of whom were women) were evaluated with a brief screening instrument for pain-avoidance behavior. Those with a high score were assigned to the pain-avoidance treatment group or a wait-list control arm, whereas patients with a low score were randomized to the pain-persistence group or the control arm.

The pain-avoidance subtype of fibromyalgia is characterized by fear of pain, hypervigilance, catastrophizing, and zealous avoidance of pain. In contrast, the pain-persistence subtype is characterized by an overactive lifestyle and low levels of pain avoidance.

Both subtypes end up via different routes at the same place, which is marked by functional disability, psychologic distress, fatigue, and chronic pain.

Of the study participants, 53% were categorized as pain avoidant, whereas

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47% were classified in the pain-persistence group.

Patients in both active-treatment arms received 16 twice-weekly treatment sessions in eight-patient groups, each session 4 hours in length, plus homework assignments. The first half of each session was devoted to cognitive-behavioral therapy (CBT), the second half to exercise training, which included aerobic exercises, either strength or flexibility training, and relaxation techniques. The patient's significant other attended the 3rd, 9th, and 15th sessions. A booster session was held 3 months after completion of the 8-week program.

The CBT was delivered by therapists with experience in CBT for rheumatologic conditions. Therapy was guided by a written manual. The exercise training was provided by physical therapists.

The pain-avoidance treatment regimen was tailored toward achieving increased daily activities, reduced fear of pain and pain-avoidance behaviors through titrated exposure, and a gradual gain in physical condition. The emphasis in the pain-persistence group was on learning to improve pacing and regulation of activities of daily life and physical exercise, along with altering pain-persistence cognitions.

In all, 60% of patients in the tailored-therapy arms experienced a clinically significant reduction in the impact of fibromyalgia on daily life, vs. 24% of controls.

Five of the six primary outcome end points in the study were changes from baseline in pain, fatigue, functional disability, negative mood, and anxiety as measured on the Impact of Rheumatic Diseases on General Health and Lifestyle scale, which is derived from the Arthritis Impact Measurement Scales. The sixth measure was change in the impact of fibromyalgia on daily life, as assessed by the 10-item Fibromyalgia Impact Questionnaire (FIQ).

The results were striking: In all, 60% of patients in the tailored-therapy arms experienced a clinically significant reduction in the impact of fibromyalgia on daily life, vs. 24% of controls.

Of the tailored-therapy patients, 67% had a clinically significant improvement in the physical function domain combining pain, fatigue, and functional disability, vs. 33% of controls.

And 62% of tailored-therapy patients demonstrated a clinically significant improvement in psychological function as reflected in reduced scores for negative mood and anxiety, compared with 33% of controls.

The improvements in the end points were consistently numerically greater in the pain-avoidance group than in the pain-persistence arm, but not significantly so.

Pain scores (which have a theoretical range of 6-25) went from a mean baseline of 20 in the pain-avoidance treatment arm to 16 at the end of treatment and 17 at 6 months of follow-up. In the pain-persistence arm, pain scores went from a baseline of 19 to 16, then 16 at follow-up. Pain scores were unchanged over time in the control arm.

Similarly, the impact of fibromyalgia on daily life as assessed by the FIQ (with a theoretical range of 0-100 points) went from a baseline of 66 to 48 at the end of pain-avoidance therapy, with a modest rebound to 50 at 6 months of follow-up.

In the pain-persistence arm, scores improved from a baseline of 57 to 47 at treatment's end and 43 at follow-up. Again, scores were flat over time in the control arms.

The encouraging results with tailored therapy in this study are particularly welcome because of the dearth of effective treatment options for fibromyalgia, Ms. Van Koulil said. ■

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