Exercise and sessions of telephone-based cognitive behavioral therapy (CBT) can improve chronic, widespread pain, researchers found.

Phone-based CBT was associated with more than a five-fold improvement in reported symptoms over usual care, and exercise was tied to almost a fourfold increase, John McBeth, PhD, of the University of Manchester in England, and colleagues reported online in the *Archives of Internal Medicine*.

They noted, however, that combining the interventions was associated with only a slightly greater advantage than either intervention alone.

"Receiving both interventions was associated with a slight improvement in outcome, but was not substantially better than single treatments," they wrote.

Current guidelines recommend pharmacological, physical, and psychological therapies for fibromyalgia, which is defined by chronic, widespread pain.

In the U.K., there are no drugs approved for the treatment of fibromyalgia. CBT for patients with the condition is in demand, but there are not enough providers to deliver it, McBeth and colleagues wrote. Some studies have suggested, however, that over-the-phone delivery of CBT may be just as effective.

So the researchers randomized 442 patients with chronic, widespread pain to six months of treatment in one of four groups: telephone-based cognitive behavioral therapy, an exercise intervention, a combination of the two, or regular care.

CBT patients had an initial 45-to-60-minute assessment followed by seven weekly sessions of 30 to 45 minutes each, along with sessions at three and six months after randomization. The exercise intervention involved six instructor-led monthly appointments, along with at-leisure gym access, although participants were advised to go at least twice a week. On non-gym days, they were advised to engage in everyday activities such as walking.

The researchers noted that usual care in the U.K. is highly variable because there are no pharmacologic interventions. For this study, usual care was delivered by the family physician, but the precise nature of that care was not recorded.

Overall, they found that the proportion of patients reporting a positive outcome as assessed by a seven-point health assessment questionnaire was higher for all three intervention groups compared with routine care:

- Phone CBT plus exercise: 37.2% at six months and 37.1% at nine months
- Phone CBT alone: 29.9% and 32.6%
- Exercise alone: 34.8% and 24.2%
- Routine care: 8.1% and 8.3%

Logistic regression analysis found significant effects at nine months for telephone CBT alone (OR 5.4, 95% CI 2.3 to 12.8), exercise alone (OR 3.6, 95% CI 1.5 to 8.5), and the combination of the two (OR 6.2, 95% CI 2.7 to 14.4).

But they noted that the "significant antagonistic interaction" between the two single therapies at nine months.
The study was supported by Arthritis Research UK.

Neither the researchers nor the editorialists reported any conflicts of interest.

Patients also reported improvements in a number of secondary outcomes, including fatigue, sleep, and scores on assessments such as the General Health Questionnaire, the Vanderbilt Pain Management Inventory, and the Tampa Scale for Kinesiophobia.

After adjustment, however, a number of associations with these secondary outcomes were no longer significant, they said.

Also, there were no effects on chronic pain grade.

In further analyses, none of the treatments were cost-effective at six months, McBeth and colleagues reported, though at nine months, phone-based CBT had the highest probability of being cost-effective compared with regular care, at 70%.

Yet they noted that the finding was sensitive to imputation for missing data.

They said the study was limited because patients were recruited via questionnaire and not during general practice consultation, and the overall small number of patients may limit the power of the study.

In an accompanying editorial, Seth Berkowitz, MD, and Mitchell Katz, MD, of Los Angeles county department of health, wrote that McBeth and colleagues "make an important contribution by demonstrating that cognitive behavioral therapy and exercise, either alone or in combination, are superior to usual management of chronic widespread pain."

Such interventions are needed because there's little evidence that long-term opioid use is effective at reducing pain, they wrote. At the same time, more prescriptions for these drugs have been dispensed, while consequences such as overdose, diversion, and dependence, have simultaneously risen.

Yet they were cautious because the study didn't assess exactly what usual care meant, and unlike in the U.K., there are pharmacologic treatments approved for fibromyalgia, including duloxetine (Cymbalta), milnacipran (Savella), and pregabalin (Lyrica) in the U.S.

They also warned that the outcome measures focused on improvement in reported symptoms rather than functional assessment.

Still, they said they "welcome additional research that seeks to minimize the use of pharmacotherapy, with its unclear efficacy and attendant consequences, in favor of a regimen that focuses, in a truly patient-centered way, on teaching skills for self-management of symptoms and return to meaningful lives."

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