

Mindfulness-based Therapies

The results of the reviewed studies are consistent with a meta-analysis of 12 randomized clinical trials of mindfulness-based therapy (MBT) for symptom-based conditions including FMS and IBS.(43) The meta-analysis was conducted in 2013 and thus not included in this CPG's systematic review.

For QoL outcomes, the meta-analysis included two clinical trials for FMS and three clinical trials for IBS, with a total of 411 participants across studies.(43) The meta-analysis showed small to moderate effect sizes for MBT compared to waitlist or support group controls for enhanced QoL (95% CI: 0.19 to 0.59). There was also evidence that MBT reduced pain (95% CI: -0.37 to -0.03), symptom severity (95% CI: -0.54 to -0.26), and depression (95% CI: -0.40 to -0.07) as compared to control.

The Work Group systematically reviewed evidence related to this recommendation (40-42) and considered the assessment of the evidence put forth in the 2014 CMI CPG. Therefore, this is a *Reviewed, New-replaced* recommendation. The Work Group's confidence in the quality of the evidence was very low. The body of evidence had some limitations including indirectness and few studies. However, this was balanced by there being consistent benefits across trials. Some of the trials were large and well-designed, and the benefits outweighed the potential harms. Thus, the Work Group decided upon a *Weak for* recommendation.

Additional research is needed to support offering mindfulness-based therapies, delivered by trained professionals, using different delivery modalities (e.g., digital media) and for patients of all sexes with CMI, including those with symptoms of FMS, IBS, or ME/CFS.

Recommendation

5. There is insufficient evidence to recommend for or against the use of biofeedback modalities in patients with CMI and symptoms consistent with fibromyalgia, irritable bowel syndrome, or myalgic encephalomyelitis/chronic fatigue syndrome.

(Neither for nor against | Reviewed, New-added)

Discussion

While this CPG's systematic evidence review found no direct studies on biofeedback modalities in patients with CMI, evidence of biofeedback on CMI is gained indirectly via studies on FMS, IBS, or CFS. An RCT by Windthorst et al. (2017) compared Heart Rate Variability Biofeedback Therapy (HRV-BF) to Graded Exercise Training (GET) in patients with CFS.(44) The RCT, which included 28 female patients with CFS, found significant improvements in mental functioning after HRV-BF over time, but not after GET. All participants had eight, 50-minute weekly individual training sessions. Thirteen had training in HRV-BF and 15 in GET. The patients kept diaries and recorded their intensity of fatigue, daily activities, and training at home. The RCT found a significant improvement in mental functioning at the five month follow-up with HRV-BF, but not GET. Adverse events were reported and included one patient with a migraine (HRV-BF), one with depression (GET), and one with weight gain (GET).(44)

A literature review by Reneau et al. (2020) examined the effect of Heart Rate Variability Biofeedback on FMS-related chronic pain using the Theory of Symptoms Self-Management.(45) The SR found only one study that enrolled patients with FMS only and that used FMS pain in the outcome measures, HRV-BF as an intervention, was peer-reviewed in English, and included adult participants (aged >17 years). The study