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The effects of a Mindfulness-based stress reduction (MBSR) program on patients being treated for chronic pain. Preliminary results of a randomized controlled clinical trial

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Abstract

Introduction. The traditional understanding of chronic pain has recently been questioned in light of the evidence supporting, as well as the understanding of central sensitization as a pain processing mechanism, the key role of psychosocial factors and patients' adaptive strategies. Mindfulness-based stress reduction (MBSR) focuses on increasing awareness and acceptance of moment-to-moment experiences, including difficult emotions and physical discomfort.

Aim. To examine the effects of a psychoeducational 'MBSR' intervention on the functional and psychosocial outcomes of patients with chronic pain.

Study design. Two-arm randomized controlled trial with repeated measures design. Setting: Pain Therapy Clinic, Lecco Hospital. Participants: Patients with chronic pain (n= 60 currently enrolling). Methods. Patients were randomly assigned to psychoeducation (intervention group) and usual care or to usual care only (control group). The intervention involved an 8-week MBSR program (2 hours per week) in focus groups of 5-9 people, and the MBSR program was performed 2 times (1-2 months after enrollment and 10-11 months after enlistment). The outcomes assessed included chronic pain (pain intensity and pain interference) assessed with the Brief Pain Inventory (BPI) (primary outcome) and secondary outcomes such as: quality of life, adherence to the intervention, awareness and self-care, drug intake and therapeutic compliance. Data were collected 6 months (T1) and 15 months (T2) after enrollment. Calculated sample size in total of 149 patients (75 vs 74 patients per group) (α= 0.05, β= 0.80).

Preliminary results. Participants: n=29 intervention group vs n=31 control group (currently enrolling). Two out of 31 patients attended fewer than four sessions and were considered drop-outs at T1 (dropout rate = 6.5%) Patients in the intervention group revealed significantly greater reductions in the impact of chronic pain in terms of pain intensity (worst pain in the last 24 hours, p<.001; pain now, p<.001) and in terms of pain interference (interference with mood, p= .003; interference with relationships with other people, p= .032) at T1, and in terms of pain intensity (worst pain in the last 24 hours, p< .012; pain on average, p=.026; pain now, p<.016) and in terms of pain interference (interference with mood, p<.011; interference with sleep, p<.021) at T2. A significant difference emerges in favor of the intervention group in the perceived quality of life assessed with the EQVAS score at T2 (58.9 vs 55.6, $t_{(58)}$ = - 3,053, p= .033).

Conclusions. This study seeks to add value to the benefits of MBSR for improving the management of patients being treated for chronic pain.