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The efficacy of adding group behavioral activation to usual care in patients with fibromyalgia and major depression: design and protocol for a randomized clinical trial

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Abstract

Background: Fibromyalgia and major depression frequently co-occur. Patients with both conditions have a worse prognosis and higher disability, and their treatment options are scarce. Behavioral activation (BA) may be an especially useful intervention for these patients, as it targets mechanisms of action that seem to be common to both disorders. Nevertheless, its efficacy has not been examined in people with both conditions. We describe the design and rationale of a randomized clinical trial aimed to evaluate the efficacy of adding BA (applied in groups) to usual care in order to reduce the severity of depressive symptoms (primary outcome) among Chilean women with fibromyalgia and major depression ($N = 90$). Pain intensity, fibromyalgia impact, pain catastrophizing and hypervigilance, physical health symptoms, environmental reward, and BA will be evaluated as secondary outcomes.

Methods: Women will be randomized to an experimental arm ($n = 45$) which will receive usual care (UC) for fibromyalgia with comorbid depression plus BA; and a comparison arm, which will receive only UC for fibromyalgia with comorbid depression (n = 45). Outcome assessment will take place at four time points: (1) at baseline, (2) when the experimental arm is under treatment (between sessions 6 and 7), (3) immediately after the experimental arm complete the treatment, and (4) at a 3-month follow-up. The following instruments will be used: Chilean version of the Patient Health Questionnaire-9 (PHQ-9), Composed Pain Intensity Index, Fibromyalgia Impact Questionnaire Revised (FIQ-R), Pain Catastrophizing Scale (PCS), Pain Vigilance and Awareness Questionnaire (PVAQ), Patient Health Questionnaire (PHQ-15), Reward Probability Index (RPI), and the Activation subscale of the Behavioral Activation for Depression Scale (BADS).

Discussion: We expect that, after treatment, the group receiving BA should experience greater reductions in the primary and secondary outcomes than the group receiving only UC. These reductions should be both statistically and clinically significant and will be maintained at follow-up. This study will contribute to facilitate the integrated treatment of fibromyalgia and depression.

Trial registration: ClinicalTrials.gov under the name "Testing Interventions for Patients with Fibromyalgia and Depression," Identifier: NCT03207828. Registered on 5 July 2017 (last update posted 21 September 2017).

Keywords: Fibromyalgia, Depression, Behavioral activation, Group intervention, Efficacy, Chile

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