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Effectiveness and cost-utility of a Mediterranean lifestyle program in the prevention and treatment of subclinical, mild and moderate depression in primary care: Study protocol

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Objective: To analyze the effectiveness and cost-utility of a Mediterranean lifestyles program as a coadjuvant treatment for primary care patients suffering from subclinical, mild or moderate depression. The effectiveness of a monitoring by ICTs, and the effectiveness of the intervention in chronic comorbid pathology will also be analyzed.

Methodology: Design: Randomized multicentre pragmatic clinical trial in 3 parallel groups. Subjects: Primary care patients with subclinical, mild or moderate depression. Sample Size: We will recruit 339 patients to achieve a reduction of at least 4.8 points on the Beck depression scale.

Interventions: Three interventions will be carried out: 1) Usual antidepressant treatment with psychological advice and / or psychotropic drugs by the primary care physician (TAU); 2) TAU + Mediterranean lifestyle (ML): program that will work weekly in 8 sessions of 2 hours in a group to improve the following aspects: daily

physical activity + adherence to the Mediterranean diet + sleep hygiene + careful exposure to the ambient light; 3) TAU + Mediterranean lifestyle (previous point) + monitoring using TICs. Measurements: The main variable will be the depressive symptomatology evaluated by the BDI II. The secondary variables will be the quality of life, chronic comorbid pathology, the use of health and social resources, and personal variables related to adherence to the program (self-efficacy, activation, sense of coherence, literacy in health and procrastination).

Conclusions: The expected results are that the patients that will receive the intervention based on the lifestyles modifications will improve their depression symptomatology. Furthermore, the patients assigned to TICs group will have better results due to the empowerment.

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