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One year weight loss in the TRAMOMTANA study. A randomized controlled trial.

<u>Tur JJ</u>¹, <u>Escudero AJ</u>, <u>Alos MM</u>, <u>Salinas R</u>, <u>Terés E</u>, <u>Soriano JB</u>, <u>Nicola G</u>, <u>Urgelés JR</u>, <u>Pagán A</u>, <u>Cortes B</u>, <u>González X</u>, <u>Burguera B</u>.

Author information

Abstract

BACKGROUND: Morbid obesity is a major health problem and bariatric surgery is currently the most effective therapy available to induce **weight loss** in these patients. This report describes 1-year changes in **weight** and metabolic parameters, in a trial designed to examine the effects of a nonsurgical approach, Intensive Life style Intervention (ILI) on the therapy of morbid obesity.

METHODS: The primary outcome was change in body **weight**. Patients were randomized to ILI (n = 60) or conventional obesity therapy (COT) (n = 46). The ILI group received behavioural therapy and nutritional/physical activity counselling. The COT group received the standard medical treatment available for these patients. A third group consisted of the patients already included in our bariatric surgery waiting list (n = 37).

FINDINGS: We present here 1-year data showing that patients who received ILI with no restrictions in calorie intake had a greater percentage of **weight loss** than patients receiving COT (-11·58% vs -0·4%; P < 0·001). Importantly, 31·4% of patients included in the ILI group were not morbidly obese after 6 months of intervention. This number increased to $42\cdot8\%$ after 12 months of intervention.

INTERPRETATION: ILI was associated with significant **weight loss** compared with COT in a group of morbidly obese patients. The **weight loss** effect was already obtained after 6 months of ILI intervention. These results seriously question the efficacy of the COT approach to morbid obesity. Furthermore, they underscore the use of ILI programmes in the hospital setting to effectively treat morbidly obese patients and might help to reduce the number of candidate patients for bariatric surgery.

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