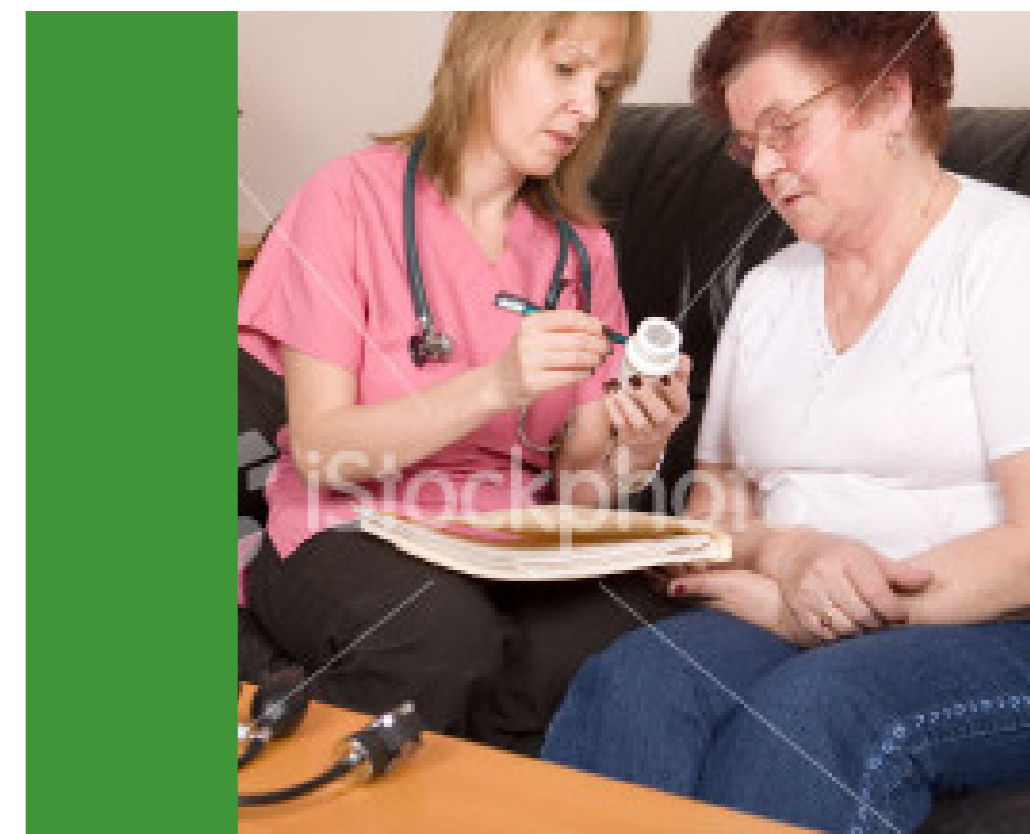


- More patients treated with orlistat lost 5% or more of their initial weight in year one (48.8% and 50.5% of patients in the 60 mg and 120 mg groups respectively compared with placebo (30.7%: $p < 0.001$)
- Approximately 34% of patients in the orlistat groups sustained weight loss of 5% or greater over two years compared with 24% in the placebo group ($p < 0.001$)
- Orlistat provided greater improvement than placebo in serum lipid levels, and blood pressure and was well tolerated, although treatment resulted in a higher incidence of gastrointestinal events.

Orlistat in the Long term Treatment of Obesity in Primary Care Settings



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Aims of the study

The study evaluated the efficacy of orlistat in producing and maintaining long-term weight loss, and in improving obesity-related risk factors in individuals who are obese and who receive limited dietary and behavioral counseling in a primary care setting.

Treatments being studied

60 mg of orlistat TID

120 mg of orlistat TID

Treatment period

2 years

Design of the study

Randomized, double blind, parallel-group, placebo-controlled study conducted in 17 primary care centers in the United States

- After a 4-week single-blind, placebo lead-in period, 635 patients were randomized to receive placebo (n=212), 60 mg of orlistat TID (n=213), or 120 mg of orlistat TID (n=210) with main meals for 52 weeks
- All patients were started on a reduced-energy diet at the onset of this four week placebo lead-in period and followed this diet during the subsequent 52 weeks of double-blind treatment (placebo n=91; 60 mg orlistat n=120; 120mg orlistat n=117)
- Patients then received the same treatment for a second year in combination with a weight-maintenance diet intended to prevent further weight loss
- To enter the double blind phase, patients must have completed the placebo run-in phase with 75% compliance, determined by counting the capsules returned by the patients at specified visits and calculating the number of capsules that had been consumed each day.

Primary endpoint

Changes in bodyweight

Secondary endpoint

- Serum lipid levels (total cholesterol, low density lipoprotein, [LDL] cholesterol, high density lipoprotein, [HDL] cholesterol, very low density lipoprotein cholesterol, triglycerides and lipoprotein [a])
- Blood pressure
- Fasting blood glucose, and insulin levels
- Waist circumference.

Number of patients in the study

796 women and men, over 18 who were obese body mass index (BMI) of 30–44 kg/m²

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Inclusion/exclusion criteria & demographics

796 women and men, over 18 who were obese body mass index (BMI) of 30–44 kg/m²

Exclusions:

- Women who were pregnant, lactating or of childbearing potential and not taking contraceptive measures.

Other patients excluded from the study are those with:

- Weight loss of more than 4 kg during the previous three months
- A history of significant cardiac, renal, hepatic or gastrointestinal disorders
- Uncontrolled hypertension or any other clinically significant condition
- Gastrointestinal surgery for weight-reducing purposes
- Bulimia or laxative and/or substance abuse
- Abnormal laboratory measures (values greater than or equal to 10% greater than the reference value for the normal range and sufficient to require medical follow-up by the study physician)
- Changes in smoking habits in the last six months
- Use of any drug that might influence body weight or food intake during the 8 weeks before screening.

Main results

- Patients treated with orlistat lost significantly more weight (7.08 plus or minus 0.54 kg and 7.94 plus or minus 0.57 kg for the 60 mg and the 120 mg orlistat groups respectively) than those for the placebo (4.14 plus or minus 0.56 kg) in year one (p < 0.001) and sustained more of this weight loss during year two
- More patients treated with orlistat lost 5% or more of their initial weight in year one (48.8% and 50.5% of patients in the 60 mg and 120 mg groups respectively compared with placebo (30.7%: p < 0.001)
- Approximately 34% of patients in the orlistat groups sustained weight loss of 5% or greater over two years compared with 24% in the placebo group (p < 0.001)
- Orlistat provided greater improvement than placebo in serum lipid levels, and blood pressure and was well tolerated, although treatment resulted in a higher incidence of gastrointestinal events.

Conclusions by the researchers

This large, long term study indicates that orlistat is an effective adjunct to dietary intervention in the treatment of obesity in primary care settings.

Key messages

- Obesity is associated with increased morbidity and mortality
- Weight loss of 5-10% of initial bodyweight helps improve the health of obese patients
- There is evidence that one of the most significant benefits of pharmacotherapy for obesity lies in the long-term maintenance of weight loss
- Some pharmacotherapy drugs have been removed from the marketplace due to severe adverse effects
- There is a need for effective and safe therapeutic options that are accessible to primary care with limited ancillary resources to effect dietary and lifestyle changes
- Patients treated with orlistat lost significantly more weight (7.08 plus or minus 0.54 kg and 7.94 plus or minus 0.57 kg for the 60 mg and the 120 mg orlistat groups respectively) than those for the placebo (4.14 plus or minus 0.56 kg) in year one (p < 0.001) and sustained more of this weight loss during year two