

General Evidence

Citation	Design/Method Sample/Setting	Variables and Intervention	Outcome Measures	Results/Analysis	Limitations	Quality and Nursing Implications
<p>Hunter, C.N., Abdel-Aal, H.H., Elsherief, W.A., Farag, D.E., Riad, N.M., & Alsirafy, S.A. (2021). Mirtazapine in cancer-associated anorexia and cachexia: A double-blind placebo-controlled randomized trial. <i>Journal of Pain and Symptom Management</i>, 62(6), 1207–1215. https://doi.org/10.1016/j.jpainsymman.2021.05.017</p>	<p>Design: Double-blind placebo-controlled randomized controlled trial</p> <p>Method: Participants were randomized to receive mirtazapine 15 mg or placebo daily for 8 weeks.</p> <p>Sample: n =120 patients with incurable solid tumors receiving active treatment with a mean age of 54 years, 72% male, 28% female.</p> <p>Setting: Single center in Egypt.</p>	<p>Independent Variable(s): Mirtazapine</p> <p>Dependent Variable(s): Appetite scores, weight, lean body mass, hand grip strength, depression score, quality of life, fatigue, adverse events (AEs), overall survival, inflammatory markers</p> <p>Intervention: Mirtazapine 15 mg orally once daily at bedtime for 28 days, followed by optional additional 28 days</p>	<p>Appetite measured on visual analog scale with scores ranging from 0-10 (higher is better)</p> <p>Functional Assessment of Anorexia-Cachexia Therapy (FAACT) (anorexia/cachexia subscale)</p> <p>Hospital Anxiety and Depression Scale (HADS-D)</p> <p>Body weight and lean body mass</p> <p>Hand grip strength with hand dynamometer</p> <p>AEs reported using Common Terminology Criteria for Adverse Events</p> <p>Overall survival</p> <p>Inflammatory markers (CRP, IL-6, YKL-40)</p>	<p>Baseline characteristics were equal with the exception of patient receipt of amitriptyline being more prevalent in the placebo arm and lean body mass being higher in mirtazapine arm.</p> <p>No significant difference in outcome measures between groups.</p> <p>Appetite scores increased in mirtazapine arm (p < 0.0001) and placebo arm (p < 0.0001) from baseline to day 28.</p> <p>Both groups had significant improvement in body weight and other secondary outcome measures at 2 months compared to baseline without significant differences between groups.</p> <p>Increase in mean HADS-D score was less in the mirtazapine arm (p = 0.0002).</p> <p>Sleepiness was greater and of higher grade in the mirtazapine arm but not placebo. Hand tremors (3 of 48 or 6.2%), hallucinations (3 of 48 or 6.2%), and abnormal dreams 1 of 48 or 2/1%) were higher in the mirtazapine arm.</p>	<p>Borderline small sample size</p> <p>Risk of bias in sample characteristics</p> <p>Missing outcome measures in 11.5% of patients who received the study drug at least once</p>	<p>The quality of evidence of this trial is good. Methodology is sound and results are reported reliably. It is uncertain if these findings that evaluated patients with cachexia can be applied to the general population of patients with cancer and anorexia.</p> <p>This study does not show any significant findings that would warrant a change in practice or educational opportunities for helping patients manage cancer-related anorexia. It is important to recognize that the results do not support offering mirtazapine for anorexia in patients with advanced cancer and cachexia, considering the lack of benefit compared to placebo and risk for side effects. However, prescribing mirtazapine for depressive symptoms, as the medication is intended, was shown to have a significant effect and therefore gave nurses confidence in this medication for treatment of depression.</p>