

Abstract

Bipolar disorder (BD) is a variant mental health disorder that is often associated with periodic manic and depressive episodes. Like many other mental health disorders, BD is associated with an increased risk of weight gain that can contribute to the progression of BD. This study aimed to determine whether clinical trials have targeted weight management in obese BD patients by analyzing the proportional inclusion and exclusion of obesity-related terms in BD clinical trials. While the majority (61.9%) of obesity terms were found within the exclusion criteria of BD clinical trials, no statistically significant differences were noted between the inclusion and exclusion of obesity terms in BD clinical trials. Bipolar disorder clinical trials rarely acknowledged obesity terms within the inclusion or exclusion criteria, so future trials may still be warranted despite a lack of statistical significance.

Background

Bipolar disorder (BD) is a mental health disorder characterized by fluctuating episodes of mania (or hypomania) and depression. Between manic and depressive states, patients experience periods of normal mood and functioning. BD has been proven to increase the risk of obesity which collectively increases the risk of early mortality (Reilly-Harrington et al., 2018, 294). It should also be noted that obesity is an adverse effect of the antipsychotics used to combat the acute phase of the disease, but also of maintenance therapy with drugs such as lithium (Keck and McElroy, 2003, 1426). Researchers believe that obesity can contribute to the progression of BD by establishing cognitive and brain abnormalities, thus degrading functional capacity (Bora et al., 2019, 738). To date, very few credible weight loss interventions have been researched in BD populations; a greater need for weight loss interventions using randomized controlled trials (RCTs) is necessary to improve the corresponding health of BD populations (Tully et al., 2020).

Methods

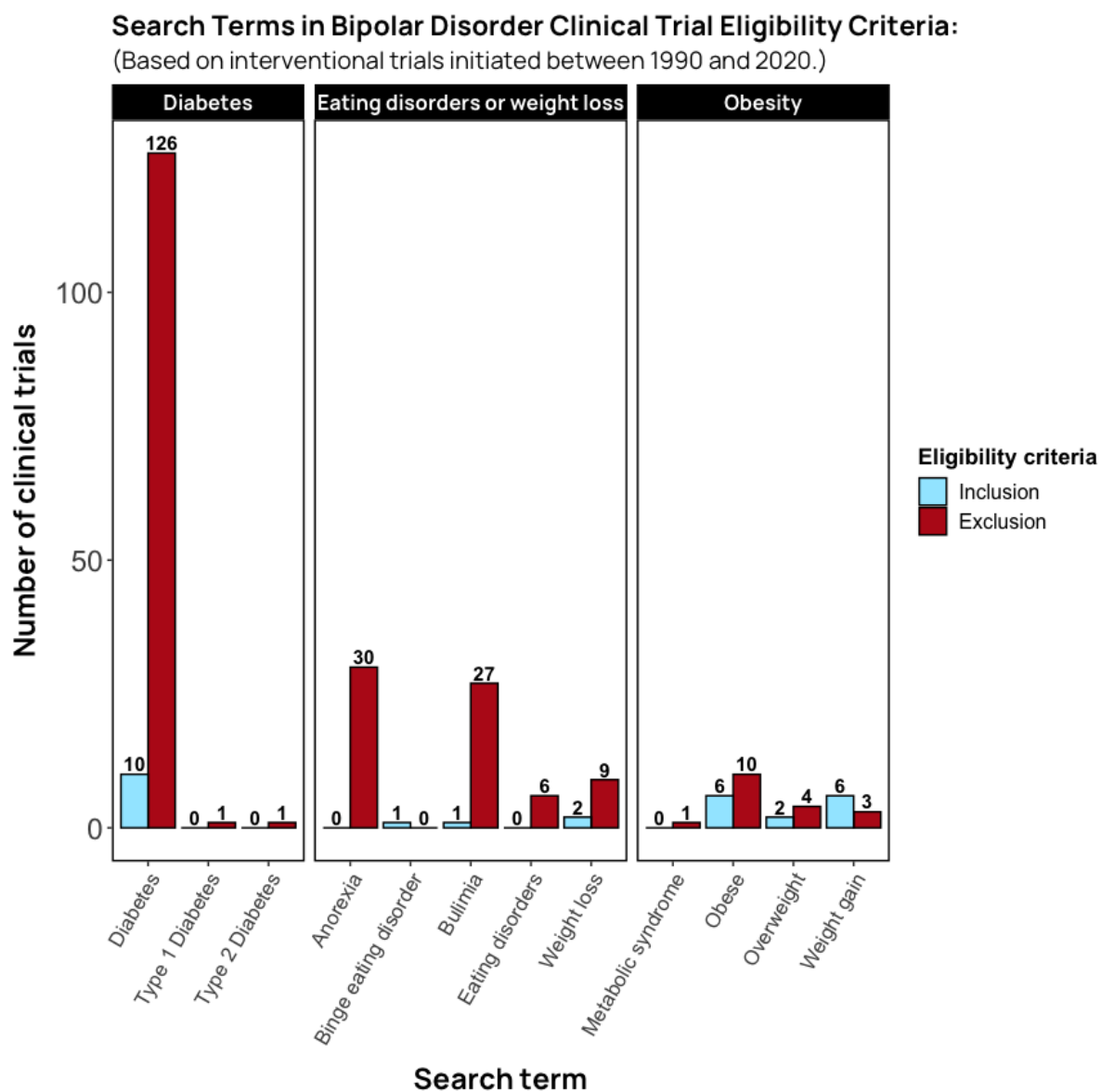
This study aimed to determine if obesity-related concerns were historically addressed in BD clinical trials. Researchers analyzed the inclusion and exclusion frequency of obesity-related terms in BD clinical trials from clinicaltrials.gov using Python 3.9.10. All completed interventional trials from 1990 to 2022 were considered eligible. Terms were collected, tallied, and organized for subsequent data analysis using Microsoft Excel. The data analysis included regression analysis, t-test paired two sample for means, and Pearson Correlation. All collected terms and their respective inclusion and exclusion frequencies are provided in Table 1 while Figure 1 illustrates the findings.

Table 1. Inclusion and exclusion frequencies of obesity terms in bipolar disorder clinical trials.

Term	Inclusion	Exclusion	Total	Inclusion Rate
Obesity	3	8	11	0.2727272727

Overweight	2	4	6	0.3333333333
Weight loss	2	9	11	0.1818181818
Weight gain	6	3	9	0.6666666667
Obese	3	2	5	0.6

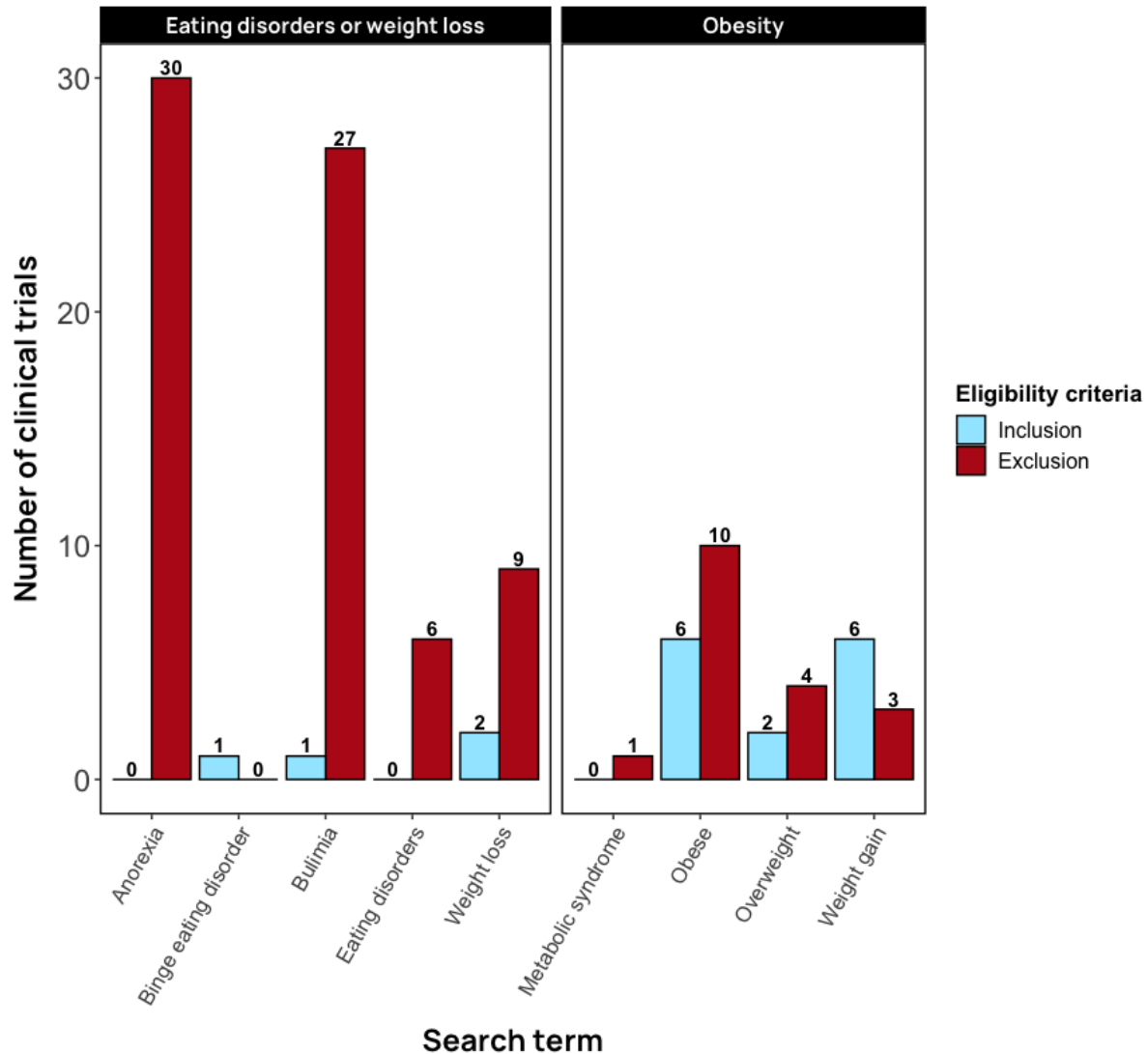
Figure 2. Comparison of inclusion and exclusion frequencies of obesity terms in bipolar disorder clinical trials.



(Source: www.clinicaltrials.gov)

Search Terms in Bipolar Disorder Clinical Trial Eligibility Criteria:

(Based on interventional trials initiated between 1990 and 2020.)



(Source: www.clinicaltrials.gov)

Results and Discussion

Overall, only 42 obesity-related terms were identified in BD inclusion and exclusion criteria. Of these terms, 16 (38.1%) were included in BD clinical trials compared to 26 (61.9%) excluded. These results were not deemed statistically significant by regression analysis or t-test standards. Additionally, no noteworthy relationship was established via Pearson Correlation. Interestingly, "weight loss" yielded an 18.18% inclusion rate while "weight gain" established a 66.67% inclusion rate. It's likely that an insufficient quantity of data contributed to the statistical insignificance.

Research has continuously identified a relationship between BD and weight gain, yet very few studies have investigated the effectiveness of weight loss interventions in BD populations. Based on the collected data, weight management has not been proactively addressed in BD clinical trials in any capacity. Considering the increased incidence of obesity in BD populations and the potential risk of BD progression, future clinical trials should target weight loss and weight management techniques to reduce the likelihood and improve the outcomes of obese persons with BD.

References

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