Placebo Response Propensity Scale (PRPS) Scores and Probability of Placebo Response by Disease Severity

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SUBMISSION DETAILS

What is the Methodological Question Being Addressed? Placebo (PBO) response can make the demonstration of efficacy difficult. An assessment administered at screening can serve as a measure of potential PBO response providing important information when assessing the true therapeutic impact of a novel treatment.

Introduction The Placebo Response Probability Scale (PRPS) is a measure of the propensity for PBO response that can be used to retrospectively assess or prospectively to minimize PBO response increasing confidence in the therapeutic value of compounds in development.

Methods A 2021 cross-sectional survey of US adults assessed health conditions, impact on health-related quality of life (HRQoL) and healthcare resource utilization. Participants, ≥18 years old, were recruited using a random stratified sampling framework to ensure demographic composition representative of the US population. Participants with anxiety, depression, schizophrenia, or bipolar completed the anxiety (GAD7) and depression (PHQ9) screening questionnaires as well as the PRPS. The proportion of PBO responders are identified in those with no/mild, moderate and severe anxiety and depression and summarized using descriptive statistics. NetraMark's DeepCrush Artificial Intelligence (AI) identified groups of items within disease severity clusters most likely to predict PBO response.

Results Of the 925 individuals participating in the study 32.3% (299) reported having psychiatric condition. The PHQ9 classified 25.4% (76), 49.2% (147) and 25.4% (76) having no/minimal, mild/moderate and severe depression, respectively. The GAD7 classified 27.1% (81), 54.5% (163) and 18.4% (55) having no/minimal, mild/moderate and severe anxiety, respectively. The propensity for PBO response was highest in those with the lowest PHQ9 and GAD7 scores. Of those with no/low depression classification 65% had a high probability of PBO whereas only 29% of those with severe depression had a high probability of PBO response. Of those with no/low anxiety classification 56% had a high probability of PBO whereas only 18% of those with severe anxiety had a high probability of PBO response. Using AI, PRPS items related to time with condition, expectations about medications and probability of taking a placebo mapped to PBO response and replicated in terms of cross validation.

Conclusion Although PBO response is likely to decrease with higher levels of disease severity required for trial entry, a significant number of potential PBO responders exist even in those with highest disease severity. Including a measures of potential PBO response within trials allows assessment of results with and without those with a high propensity for PBO response and /or the PRPS can be used for adaptive trial design.

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Keywords

Keywords
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Guidelines I have read and understand the Poster Guidelines

Disclosures if applicable None

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