

# Psychedelic Use and Placebo Response

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

**Introduction** Previous work demonstrated the proportion of potential PBO responders as measured with the Placebo Response Propensity Scale (PRPS) increased with disease severity. This work uses the PRPS to classify the proportion of potential PBO responders by disease severity in those with and without psychedelic use.

**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,  $\geq 18$  years old, were recruited using a random stratified sampling framework. Participants with completed demographic background questions, the anxiety (GAD7) and depression (PHQ9) screening questionnaires, the PRPS and were asked to self-report use of psychedelics. The proportion of PBO responders by psychedelic use are identified in those with no/mild, moderate, and severe anxiety and depression and summarized using descriptive statistics.

**Results** Of the 2978 participants, 4.2% (126) reported using a psychedelic in the last 12 months. Relative to those not using a psychedelic, those reporting use of a psychedelic were younger (33.5 vs. 44.5 years;  $p < 0.01$ ), more likely to be male (60.7% vs. 47.5%;  $p < 0.01$ ) and had a higher proportion of potential PBO responders based on the PRPS scores (38.10% vs. 25.42%;  $p < 0.01$ ). Across all disease severity classifications using the PHQ9 for depression and GAD7 for anxiety, the propensity for PBO response was highest in those reporting psychedelic use.

**Conclusion** Adequately assessing efficacy signals in psychiatric trials may be complicated by PBO response. The potential for PBO response is higher in those that report using psychedelics overall and across all disease severity classifications relative to those not using psychedelics. Including measures of potential PBO response within trials allows assessment of results with and without those with a high propensity for PBO response allowing for more confidence when trying to establish a true signal of efficacy. This may be particularly important in trials testing psychedelic compounds.

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## Keywords

Keywords
Placebo response
Anxiety
Depression
Psychedelics
Placebo Response Propensity Scale

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**Disclosures** None

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