

Word of the day: patient perspectives in a Phase 4, open-label study of adjunctive brexpiprazole in major depressive disorder

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Methodological Issue Being Addressed There is a need to ensure that the patient perspective is incorporated in major depressive disorder (MDD) clinical trials. The methodology presented here supports the design and utilization of a 'word of the day' analysis in a Phase 4 study of MDD.

Introduction In clinical research, patient-reported outcomes are valuable to enhance clinical decision-making and health-care policy. Initiating patient-centric conversations is important for improving treatment outcomes. The aim of this work was to develop a 'word of the day' technique to evaluate patients' experiences - in their own words - of living with MDD, and to explore the effect of adjunctive brexpiprazole on the patient experience.

Methods The 'word of the day' technique was developed in two stages. The first stage involved generation of a list of meaningful words via semi-structured, qualitative interviews with patients with MDD in the United States. In the interviews, patients were asked to describe, using single words, a 'good', 'average', and 'bad' day of living with depression. In the second stage, a selection of words most frequently mentioned by patients for each valence (i.e., positive, neutral, or negative) were used as a pre-specified exploratory efficacy endpoint in the ENGAGE study; an 8-week, Canadian, Phase 4, single-arm, open-label, interventional study of adjunctive brexpiprazole 0.5-2 mg/day in patients with MDD and inadequate response to antidepressant treatment (NCT04830215). In the ENGAGE study, patients selected one word from the word list to describe how they felt that day, and recorded the selected word in a diary (completed daily from baseline to Week 4, and twice weekly from Week 5 to Week 8). Patients were unaware of the valence of each word. Using observed cases data, the overall weekly proportion of each type of word (positive, neutral, or negative) was calculated (i.e., the average weekly proportion of each type of word across all patients).

Results Twenty patients participated in the qualitative interviews, generating a total of 133 words. Five words of each valence were selected for use in the ENGAGE study (positive: happy, productive, joyful, energetic, optimistic; neutral: blah, normal, content, relaxed, hopeful; negative: tired, sad, unmotivated, pessimistic, irritable). During Week 1 of the ENGAGE study (n=119), 7.9%, 33.1%, and 59.0% of the selected words were positive, neutral, and negative, respectively. During Week 8 (n=95), 14.2%, 40.5%, and 45.3% of the selected words were positive, neutral, and negative, respectively.

Conclusion Analyses of ‘word of the day’ patient experience data from patient diaries may provide valuable insights into patients’ perspectives of the effects of study drugs in clinical trials. In this study of patients with MDD and inadequate response to antidepressant treatment, the proportion of positive words increased during treatment with adjunctive brexpiprazole, and the proportion of negative words decreased.

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Guidelines I have read and understand the Poster Guidelines

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