OBJECTIVES: Patient-reported outcomes (PROs) are necessary as endpoints in clinical trials of new treatments, particularly with the Food and Drug Administration’s (FDA) guidance on PROs. Their prominence is driven by the value of assessing the impact of the disease on the patient. The Depression and Family Functioning Scale (DFFS) is a PRO that measures the impact of depression on family functioning. Psychometric analyses were conducted to assess the reliability, validity, and responsiveness of the DFFS according to the FDA’s PRO guidance.

METHODS: A prospective, 2-year observational study in the United Kingdom (n = 586) collected data at baseline and month 2 on 15 items assessing family functioning (interferes with care of child, finances, leisure, and family life/home; negative impact on family life/home question; partner and family interactions and quality of relationships; partner and family arguments/interference; partner interrupting arguments; impacts on leisure, and family life/home; patient takes care of partner vs. partner takes care of patient). Factor analyses resulted in a single factor, confirming the unidimensional nature of the DFFS. Item-total correlations with the DFFS total score were highly satisfactory (Cronbach's alpha = 0.85 at baseline, 0.89 at month 2). Correlations confirmed the unidimensional nature of the DFFS. Internal consistency (Cronbach's alpha corrected for item pairs) was statistically significant (0.67 - 0.85). Hypothesized correlations with other measures of disease severity and levels of sexual functioning were generally in the predicted direction, and many were statistically significant, substantiating the discriminating ability of the DFFS. Effect size estimates were moderate to large, greater in patients less than those nonresponders, divided by the SD of change in nonresponders (n = 58 patients). Internal consistency: Cronbach's coefficient alpha (n = 58 patients). The DFFS was developed to understand and assess the impact of depression on family functioning in patients with major depressive disorder (MDD) compared to the SF-12. The SF-12 was generated primarily through in-depth interviews with patients and was designed to assess the impact of depression on the patient’s perspective.

RESULTS: The DFFS was developed to establish the reliability, validity, and responsiveness of the DFFS and its usefulness in summarizing and communicating the impact of depression on family functioning. Factor analyses resulted in a single factor, confirming the unidimensional nature of the DFFS. Item-total correlations with the DFFS total score were highly satisfactory (Cronbach's alpha = 0.85 at baseline, 0.89 at month 2). The DFFS performed well in this broader context of assessing the impact of depression on partner relationship and patient functioning. It has the potential to provide important information that is not traditionally captured in clinical practice or research and will facilitate a more comprehensive evaluation of treatments of MDD.

CONCLUSIONS: The psychometric analyses strongly support the reliability, validity, and responsiveness of the DFFS and its usefulness in summarizing and communicating the impact of depression on family functioning. The DFFS is a valuable tool for assessing the impact of depression on family functioning in patients with MDD.

The DFFS was developed to understand depression as a family illness and assess its impact on family functioning. Focus groups with patients and clinicians were conducted to identify the family impact of depression and to determine its importance for clinical trials. The DFFS was designed to be used in clinical trials of patients with MDD to assess treatment impact. The DFFS is a valuable tool for assessing the impact of depression on family functioning in patients with MDD.

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