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1. *Title:*

Prodromes and predictors of bipolar disorder: a longitudinal evaluation of patients presenting a first manic episode

2. *Scientific abstract:*

Rationale: Bipolar disorder (BD) is still characterized by poor outcomes in terms of psychosocial functioning that might have consequences in the quality of life of patients and caregivers. In addition, the burden of disease is high for societies. The diagnosis delay contributes to increase morbidity and mortality. Since early diagnosis and treatment improve the clinical course and response to treatment, the study of the early phases of the disease is a main focus in recent years. Nonetheless, few prodromal symptoms have been identified so far. In addition, they lack in specificity. As a consequence, the detection of prodromes and early prognostic factors is of paramount importance to improve the prognosis and treatment outcomes in BD. Longitudinal studies are needed in order to follow the clinical course from manifestation of the first episodes.

Aims: 1. To identify the prodromes of bipolar disorder in patients with a first manic episode; 2. To characterize the clinical, neuropsychological, genetic, magnetic resonance imaging (MRI) features of patients with a first manic episode; 3. To build predictive models evaluating severity of illness and functioning at follow-up.

Design: A two-year prospective longitudinal study of patients presenting with a first manic episode.

Methods: Sociodemographic and clinical information will be collected. The patients will undergo an evaluation with semi-structured interviews assessing psychiatric symptoms, neurocognitive and functional variables at baseline, at one year and at the end of the study period (two years). At baseline, prodromes will be investigated through the Bipolar Prodrome Symptom Scale-Retrospective. An MRI scan will be performed at baseline. A blood extraction will be performed with the same timing. As for statistics, a Cox regression model will be performed in order to understand predictors of poor outcomes in BD. Based on previous research, a total sample of 112 patients should be enrolled in the study.

Possible results and contributions: This study is expected to characterize prodromes of BD. Also, predictors of higher severity of illness and poorer functioning of BD resulting from the predictive model are expected to have an important impact in the every-day clinic of psychiatrists in terms of therapeutic strategies and allowing the improvement of the prognosis of patients at the early stages of BD.

3. ***Keywords:*** prodromes, bipolar disorder, functioning, severity, cognition, predictive model, early stages, biomarkers