Bipolar disorder is an often disabling mental illness with a lifetime prevalence of 1%-2%, a high risk of recurrence of manic and depressive episodes, a lifelong elevated risk of suicide and a substantial heritability. The course of illness is frequently characterised by progressive shortening of interepisode intervals with each recurrence and increasing cognitive dysfunction in a subset of individuals with this condition. Clinically, diagnostic boundaries between bipolar disorder and other psychiatric disorders such as unipolar depression are unclear although pharmacological and psychological treatment strategies differ substantially. Patients with bipolar disorder are often misdiagnosed and the mean delay between onset and diagnosis is 5-10 years. Although the risk of relapse of depression and mania is high it is for most patients impossible to predict and consequently prevent upcoming episodes in an individual tailored way. The identification of objective biomarkers can both inform bipolar disorder diagnosis and provide biological targets for the development of new and personalised treatments. Accurate diagnosis of bipolar disorder in its early stages could help prevent the long-term detrimental effects of the illness.

The Bipolar Illness Onset study aims to identify (1) a composite blood-based biomarker, (2) a composite electronic smartphone-based biomarker and (3) a neurocognitive and neuroimaging-based signature for bipolar disorder. The study will include 300 patients with newly diagnosed/first-episode bipolar disorder, 200 of their healthy siblings or offspring and 100 healthy individuals without a family history of affective disorder. All participants will be followed longitudinally with repeated blood samples and other biological tissues, self-monitored and automatically generated smartphone data, neuropsychological tests and a subset of the cohort with neuroimaging during a 5 to 10-year study period. The study has been approved by the Local Ethical Committee (H-7-2014-007) and the data agency, Capital Region of Copenhagen (RHP-2015-023), and the findings will be widely disseminated at international conferences and meetings including conferences for the International Society for Bipolar Disorders and the World Federation of Societies for Biological Psychiatry and in scientific peer-reviewed papers. NCT02888262.
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