Study protocol of a multicenter randomized controlled trial of Mindfulness-Based Cognitive Therapy and Treatment as Usual in Bipolar Disorder

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Background: Despite multiple pharmacological interventions, people with bipolar disorder experience substantial residual mood symptoms, which affect the course and quality of life negatively. Limited data are available on how to optimize treatment for bipolar disorders, especially for those who suffer from persistent and residual depressive symptoms. Preliminary evidence suggests Mindfulness-Based Cognitive Therapy (MBCT) as a psychological treatment option for bipolar disorder. This study aims to investigate whether adding MBCT to treatment as usual (TAU) will result in symptomatic and functional improvements in bipolar patients compared to TAU alone.

Methods/design: This study is a prospective, evaluator blinded, multicenter, randomized controlled trial of comparing MBCT + TAU to TAU alone in 160 bipolar type I and type II patients. Assessments will be conducted at baseline (T0), and at 3 (T1), 6 (T2), 9 (T3), 12 (T4), and 15 (T5) months follow-up. Primary outcome is post-treatment depressive symptom severity (Inventory of Depressive Symptomatology- Clinician administered). Secondary outcomes are (hypo)manic symptom severity (Young Mania Rating Scale), anxiety symptom severity (State/Trait Anxiety Inventory), relapse rates (Structured Clinical Interview for DSM-IV Axis I Disorders), overall functioning (Functioning Assessment Short Test), mental health (Mental Health Continuum), and cost-effectiveness (EQ-5D-5L and Trimbos/iMTA questionnaire for costs associated with psychiatric illness). Possible primary outcome mediators will be measured as well, these include positive and negative rumination (Ruminative Response Scale and Responses to Positive Affect questionnaire), mindfulness skills (Comprehensive Inventory of Mindfulness Experience), and self-compassion (Self Compassion Scale).

Discussion: This study will provide valuable insight into the accessibility and (cost-)effectiveness of MBCT on clinician-rated and self-rated symptoms of bipolar disorder, relapse rates, mental health, and overall functioning.