

## ABSTRACT

### **TITLE: Group psychoeducation for persons with bipolar disorder in Rwanda: A study protocol for a randomized controlled trial**

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**Background:** The efficacy of psychoeducation as an add-on treatment to pharmacotherapy is well documented in treating symptoms and in relapse prevention for persons with bipolar disorder in western countries. Yet, no studies on psychosocial interventions for persons with bipolar disorder have been conducted in a low-income country in Africa.

**Aim:** To develop a bipolar group psychoeducation program contextualized to the Rwandese setting, and determine its effect on symptom severity, medical adherence, and internalized stigma.

**Methods:** A culturally adapted guide manual was developed by local mental health professionals, including nurses, psychologists, and medical doctors. In-depth interviews with participants were held prior to and will be held following the intervention to address the cultural aspect of living with bipolar disease and the impact of the program. A two-armed randomized controlled trial has been set up at the tertiary mental health hospitals in Rwanda, with an intervention- and a waiting-list-arm. A sample size of at least 50 in each arm was calculated as a requirement. The study's primary outcome measure will be the difference in relapse rate measured on the Young Mania Rating Scale and Hamilton Depression Scale-17. Differences in mean change on scales for medical adherence and internalized-stigma will be secondary outcomes. Data will be analyzed according to the intention-to-treat principle. Participants will be assessed subsequently at baseline, at the end of the intervention period, and three months and 12 months' post-intervention.

**Discussion:** This study will be one of the first intervention trials on bipolar disorder in a low-income country. If proven successful in reducing morbidity and increasing the quality of life in persons with bipolar disorder, it is anticipated that the psychoeducation program can be implemented at the district and community level and act as inspiration for other low-resource settings.

**Trial registration:** ClinicalTrials.gov, Identifier: NCT04671225, registered in November 2020.

**Keywords:** Global Mental Health, Bipolar Disorder, Psychosocial Interventions, Psychoeducation, Low and Middle-Income Countries, Rwanda.