Reducing the rate and duration of re-admissions among patients with unipolar disorder and bipolar disorder using smartphone-based monitoring and treatment - the RADMIS trials

Reducing the rate and duration of re-admissions among patients with unipolar disorder and bipolar disorder using smartphone-based monitoring and treatment - the RADMIS trials: Study protocol for two randomized controlled trials

Background: Unipolar and bipolar disorder combined account for nearly half of all morbidity and mortality due to mental and substance use disorders, and burden society with the highest health care costs of all psychiatric and neurological disorders. Among these, costs due to psychiatric hospitalization are a major burden. Smartphones comprise an innovative and unique platform for the monitoring and treatment of depression and mania. No prior trial has investigated whether the use of a smartphone-based system can prevent re-admission among patients discharged from hospital. The present RADMIS trials aim to investigate whether using a smartphone-based monitoring and treatment system, including an integrated clinical feedback loop, reduces the rate and duration of re-admissions more than standard treatment in unipolar disorder and bipolar disorder. Methods: The RADMIS trials use a randomized controlled, single-blind, parallel-group design. Patients with unipolar disorder and patients with bipolar disorder are invited to participate in each trial when discharged from psychiatric hospitals in The Capital Region of Denmark following an affective episode and randomized to either (1) a smartphone-based monitoring system including (a) an integrated feedback loop between patients and clinicians and (b) context-aware cognitive behavioral therapy (CBT) modules (intervention group) or (2) standard treatment (control group) for a 6-month trial period. The trial started in May 2017. The outcomes are (1) number and duration of re-admissions (primary), (2) severity of depressive and manic (only for patients with bipolar disorder) symptoms; psychosocial functioning; number of affective episodes (secondary), and (3) perceived stress, quality of life, self-rated depressive symptoms, self-rated manic symptoms (only for patients with bipolar disorder), recovery, empowerment, adherence to medication, wellbeing, ruminations, worrying, and satisfaction (tertiary). A total of 400 patients (200 patients with unipolar disorder and 200 patients with bipolar disorder) will be included in the RADMIS trials. Discussion: If the smartphone-based monitoring system proves effective in reducing the rate and duration of readmissions, there will be basis for using a system of this kind in the treatment of unipolar and bipolar disorder in general and on a larger scale.

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