The addition of STEPPS in the treatment of patients with bipolar disorder and comorbid borderline personality features: an open pilot study

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Ethical review	Approved WMO
Status	Pending
Health condition type	Manic and bipolar mood disorders and disturbances
Study type	Interventional

Summary

ID

NL-OMON44128

Source
ToetsingOnline

Brief title
STEPPS-BB

Condition

- Manic and bipolar mood disorders and disturbances

Synonym
bipolair disorder, manic-depressive illness

Research involving
Human

Sponsors and support

Primary sponsor: VU Medisch Centrum, Amsterdam

Source(s) of monetary or material Support: NWO

Intervention

Keyword: bipolair disorder, borderline personality features, integrated treatment, pilot study

Outcome measures

Primary outcome

The first primary outcome will be the symptomatic course of BD: occurrence, frequency, severity, and duration of manic and depressive symptoms. The second primary outcome will be the course, severity and burden of borderline personality features.

Secondary outcome

Secondary study parameter are: quality of life, mental healthcare consumption, and general psychopathological symptoms not related to bipolar disorder or borderline personality features.

Study description

Background summary

The prevalence of personality disorders (PD) in patients with a bipolar disorder (BD) is estimated at between 30% and 40%. This concerns personality disorders from cluster B and C, particularly the borderline personality disorder (BPD). The presence of personality disorder features negatively impacts the course of bipolar disorder. Patients with BD and a comorbid diagnosis of PD are more likely to be hospitalized, require more time to achieve symptom stabilization, have more chronic impairments in occupational and social functioning, are less compliant to medication, have greater levels of suicidality and utilize more psychiatric services than patients with BD alone (Bieling et al., 2007).
It is to be expected that specific interventions aimed at disfunctional personality features will have a positive impact on the course of bipolar disorder. The current study is specifically aimed at features of borderline (instable) personality disorder, which in part overlap with the symptoms of

bipolar disorder.

Study objective

Little research is being done on the effects of psychological treatment in patients with a bipolar disorder (BD) and comorbide borderline personality disorder (BPD) features. There are no recommendations included in the guideline for BD (Nolen et al., 2008). It is of great importance to test an integrated treatment in terms of improving mood stabilization, quality of life and reduced health consumptions.

The objective of the current study is to test the efficacy of STEPPS (Dutch: VERS) specifically aimed at features of borderline personality disorder, as an adjunctive intervention to treatment as usual (TAU). This may lead to an integrated intervention for this patient population to improve the course of bipolar disorder and quality of life, and to reduce the costs of treatment on a longer term.

Study design

To screen for the presence of borderline personality disorder (BPD) features in patients with a bipolair disorder (BD), patients will be ask to complete the questionnaire PDQ-4+. Respondents that have a positive score with regard to the presence of BPD will be invited for a diagnostic interview (SCID-II). This interview will start with the part concerning BPD and will be completed if patients score poitively on a minimum set of BPD-features. The diagnosis of bipolar disorder (BD) will be verified with modules A, C and D of the MINI-plus structured interview. BD patients with a comorbid BPD or a or a particular constellation of borderline personality features (see study population) who do not meet the exclusion criterion will be asked to participate the treatment trial. All respondents will be assigned to the experimental condition. The experimental condition includes "treatment as usual" (TAU) supplemented by training emotion regulation (STEPPS/VERS).

Intervention

STEPPS/VERS training was developed to improve emotional regulation in patients with borderline personality disorder. The group training (8-10 participants) consists 20 weekly meetings of approximately 2,5 hours. The training consists of four modules: psycho-education, emotion regulation skills, behaviour skills and planning how to deal with emotions. Family members are involved in the training to form a support group.

Study burden and risks

.STEPPS/VERS training has been applicated routinely in clinical practice for

patients with personality disorder. There are no unexpected risks, and participants may benifit directly from the intervention. The extra burden of all participants is undergoing a structured diagnostic interview and filling out rating scales and questionnaires on a regular basis. Both may be time-consuming and confronting.

Contacts

Public
VU Medisch Centrum, Amsterdam

A.J. Ernststraat 1187
Amsterdam 1081 HL
NL
Scientific
VU Medisch Centrum, Amsterdam

A.J. Ernststraat 1187
Amsterdam 1081 HL
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• age 18 - 65
• diagnosis of Bipolar Disorder-I, Bipolar Disorder-II, or Bipolar Disorder-NOS
• comorbid Borderline Personality Disorder or Borderline Personality Features (at least 3 of 9 DSM-IV-TR criteria, including at least impulsivity and anger bursts)

Exclusion criteria

• hospitalization for suicide risk
• current severe depressive episode (IDS-SR > 38)
• current severe manic episode (YMRS > 20)
• currently having a separate specialized treatment for substance abuse
• unable to understand Dutch language
• patients having received STEPPS/VERS in the past 2 years
• patients who participate external in a STEPPS/VERS training during inclusion
• patients currently receive a psychotherapy
• patients without informed consent
• unable to comply STEPPS protocol

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	11-03-2013
Enrollment:	25
Type:	Anticipated

Ethics review

Approved WMO

Date:	18-04-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	08-03-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL40029.029.12