B-Positive: Enhancing well-being in patients with bipolar disorder.

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

Summary

ID

NL-OMON50299

Source
ToetsingOnline

Brief title
B-Positive

Condition

- Manic and bipolar mood disorders and disturbances

Synonym
Manic depression, Manic depressive illness

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Twente
Source(s) of monetary or material Support: ZonMW doelmatigheidsonderzoek

Intervention

Keyword: Bipolar Disorder, Positive Psychology, Recovery, Wellbeing

Outcome measures

Primary outcome

(1) The primary outcome well-being is measured with the Mental Health Continuum - Short Form (MHC-SF).

Secondary outcome

Secondary outcomes include:

(2) Personal recovery is measured with the Questionnaire about the Process of Recovery (QPR).

(3) Relapse is assessed with semi-structured telephone interviews, where participants are asked to retrospectively describe their mood in the past nine months.

(4) Social participation as part of recovery is measured with the Short Social Role Participation Questionnaire (s-SRPQ).

(5) Depressive symptoms are measured with the Quick - Inventory of Depressive Symptomatology Self-Report (QIDS-SR).

(6) Manic symptoms are assessed with the Altman Self-Rating Mania Scale (ASRM).

(7) Anxiety symptoms are measured with the subscale 'anxiety symptoms' of the Hospital Anxiety and Depression Scale (HADS-A).

(8) Positive emotion regulation is measured with the subscale 'dampening' of Responses to Negative Affect Questionnaire (RPA).

(9) Positive emotions are measured with the subscale 'positive emotions' of the Positive and Negative Affect Schedule (PANAS).

(10) Self-compassion is assessed with the Self-compassion Scale - Short Form

(SCS-SF)

(11) Positive relations is assesed with the subscale 'positive relations' of

the Scales of Psychological Well-being (SPWB)

(12) Cost-effectiveness analyses are performed using the EQ-5D-5L and the TiC-P

questionnaire on Costs Associated with Psychiatric Illness.

Study description

Background summary

Bipolar disorder (BD) is characterized by recurrent manic or (hypo)manic phases, alternating with (euthymic) states in which patients are relatively symptom free. The prevalence of BD is estimated at 1,3% in the Netherlands. Current treatment for BD in the euthymic phase often focuses on symptomatic and functional recovery, but residual subthreshold depressive symptoms often remain between episodes and form an important risk factor for recurrence. In order to reach full recovery, it is important to strive for personal and complete mental health recovery, which encompasses both the absence of mental illness and the presence of well-being. One prominent field focusing on the improvement of well-being, is positive psychology. Living to the Full is a positive psychology intervention developed at the University of Twente, which aims to increase well-being. The current study therefore aims to assess the effectiveness of Living to the Full for people with bipolar disorder in the euthymic phase.

Study objective

The primary objective of this study is to evaluate whether the eight-week multicomponent well-being intervention 'This is your life' as an adjunct to usual care (CAU) offered to BD patients in the euthymic phase, is effective in the short and long term in improving well-being.

Secondary objectives of the study are:
(1) To study whether the intervention This is your life in addition to CAU is more effective in the short and long term in improving outcomes of personal recovery, social role participation, and symptoms of depression, anxiety and mania than CAU only.
(2) To find out whether This is your life is more effective in reducing relapses into depressive, (hypo)manic or mixed episodes in euthymic patients

with BD in the long term than CAU only.
(3) To explore possible working mechanisms for intervention effects of This is your Life, including positive emotions, positive emotion regulation, self-compassion and positive relations.
(4) To evaluate the cost-effectiveness of the intervention This is your life in addition to CAU for the treatment of euthymic patients with BD compared to CAU only.

Study design

This study concerns a pragmatic randomized non-blinded multicenter trial. The intervention group receives the intervention 'This is your Life' in addition to CAU. The control group receives CAU only. Measurements take place at baseline (T0), mid-treatment (T1), post-intervention (T2) and follow-up 6 (T3) and 12 (T4) months from baseline.

Intervention

We aim to adapt the multi-component positive psychology intervention 'This is your Life' as group intervention for BD. 'This is your Life' has been developed at the University of Twente and is based on empirically validated theories within positive psychology, including Seligman*s well-being theory (PERMA model) and Ryff*s Theory of psychological well-being. 'This is your Life' focuses on six components in positive psychology: (1) positive emotions, (2) discovering and using personal strengths, (3) optimism and hope, (4) self-compassion, (5) resilience and post-traumatic growth and (6) positive relationships. The intervention consists of 8 meets of 2 hours and takes place in groups of 10 patients.
From September 2020, the intervention will be delivered online. This will not affect the intensity or content of the intervention. Also, the intervention will still be given by two trained therapists from the participating treatment centers.

Study burden and risks

The burden associated with participation in the study is relatively low. Participation is free and can be stopped at any time and without explanation, if the patient wishes so, by telling the principal investigator. We ask participants to fill out questionnaires at five measurement points. At each measurement point, this will take approximately 36 minutes on average at each measurement point. No relevant burden is expected from filling out the questionnaires, which are all commonly used and well-validated. During the sessions, participants are asked to try particular positive psychological exercises. Moreover, part of the group intervention is to talk about personal experiences. Additionally, part of the intervention are homework exercises. Since the extent to which these exercises are performed is voluntary, we do not

expect a high burden from the homework exercises.
No great risks are expected from participation in the intervention. 'This is your Life' has been carried out several times by the University of Twente and no negative events have occurred. However, since the effect of positive psychology interventions for individuals with BD is relatively unclear, the consequences for participants in the intervention group are not fully predictable. It cannot be ruled out that interventions enhancing positive behaviours, cognitions or emotions such as 'This is your life' might heighten the risk for a manic phase. Since the intervention is carried out in treatment centers specialized on bipolar disorder, possible participants excluded due to severe symptoms of depression or mania, will find themselves in a protective environment where professionals are able to take care of them. Also, certain parts of the intervention might be confronting for participants by reviving certain cognitions or behaviours they usually try to avoid (e.g. memories).
From September 2020, the intervention will be given online. However, we do not expect any additional risks from this change in delivery mode (see also point E9).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

(1) Current diagnosis of BD I or BD II.
(2) Between the ages of 18-65.
(3) Four or more supportive sessions in the last year with a psychiatric nurse.
(4) Presence of subsyndromal depressive or (hypo)manic symptoms (assessed using the 7-point Clinical Global Impression Scale - Bipolar Disorder). Participants are included if they score between 2 (minimal symptoms) and 4 (moderate symptoms) for depressive symptoms or between 1 (no symptoms) and 3 (light symptoms) for manic symptoms.

Exclusion criteria

(1) Currently in treatment for addiction problems.
(2) Optimal level of positive mental health (assessed using the Mental Health Continuum-Short Form) (Lamers, Westerhof, Bohlmeijer, ten Klooster, & Keyes, 2011). Participants are excluded if they flourish, indicated by a score of 4 or 5 on at least one item of the emotional well-being subscale together with a score of 4 or 5 on at least 6 of the 11 remaining items of the Mental Health Continuum-Short Form.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-08-2018
Enrollment:	112
Type:	Actual

Ethics review

Approved WMO Date:	29-03-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-09-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-11-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-06-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-10-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-07-2020

Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL62997.044.17