

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

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON20875

### Source

NTR

### Brief title

B-Positive

### Health condition

Bipolar disorder

Wellbeing

Recovery

Positive Psychology

Bipolaire Stoornis

Welbevinden

Herstel

Positieve Psychologie

## Sponsors and support

**Primary sponsor:** Prof. dr. Ernst Bohlmeijer<br>

University of Twente<br>

Psychology, Health and Technology<br>

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7500AE Enschede

**Source(s) of monetary or material Support:** The Netherlands Organisation for Health Research and Development (ZonMw)

## Intervention

## Outcome measures

### Primary outcome

The primary outcome wellbeing is measured with the Mental Health Continuum – Short Form.

### Secondary outcome

Secondary outcomes include personal recovery (measured with the Questionnaire about the Process of Recovery), relapse (semi-structured telephone interviews), social role participation as part of recovery (Social Role participation Questionnaire), depressive symptoms (Quick - Inventory of Depressive Symptomatology), manic symptoms (Altman Self-Rating Mania Scale), anxiety symptoms (State-Trait Anxiety Inventory), positive emotion regulation (Responses to Positive Affect Questionnaire), positive emotions (Positive and Negative Affect Schedule) and Self-compassion (Self-compassion Scale – Short Form). Economic evaluations are performed using the EQ-5D-5L and the Trimobs and iMTA 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 personal recovery, it is important to strive for complete mental health, which encompasses both the absence of mental illness and the presence of well-being. One prominent field focussing on the improvement of well-being, is positive psychology. This is your life is a generic self-help positive psychology intervention developed at the University of

Twente, which aims to increase well-being. The current study aims to assess the effectiveness of This is your life adjusted for people with bipolar disorder in the euthymic phase.

## **Study objective**

The primary hypothesis of the study is that a well-being intervention ('This is your life') offered to bipolar disorder (BD) patients in remission in addition to usual care (CAU) is more (cost-)effective than CAU only.

## **Study design**

Directly prior to the start of the intervention a baseline measurement is completed (T0) and four weeks after start of the intervention a mid-treatment measurement is conducted (T1). Directly following the intervention a post measurement will be conducted (T2: approximately three months after baseline). Additionally, two follow-up measurements are conducted, six months (T3) and twelve months after baseline (T4).

## **Intervention**

We aim to adapt the multi-component positive psychology intervention 'This is your life' as a group intervention for BD. The 8-week intervention focuses on six components, including personal strengths, resilience, post-traumatic growth, and positive relationships. The intervention consists of 8 meetings of 2 hours and home exercises.

## **Contacts**

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## Eligibility criteria

### Inclusion criteria

In order to be eligible to participate in this study, a subject must meet the following criteria: 1) four or more supportive sessions in the last year and 2) residual depressive symptoms.

### Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study: 3) suffer from an acute mood episode or 4) have current addiction problems

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	12-08-2018
Enrollment:	112
Type:	Actual

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion

Date: 12-10-2017

Application type: First submission

## 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
NTR-new	NL6541
NTR-old	NTR6729
Other	843001803 : ZonMw

## Study results