

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

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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.

|                             |                       |
|-----------------------------|-----------------------|
| <b>Ethische beoordeling</b> | Positief advies       |
| <b>Status</b>               | Werving gestopt       |
| <b>Type aandoening</b>      | -                     |
| <b>Onderzoekstype</b>       | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON20875

### Bron

Nationaal Trial Register

### Verkorte titel

B-Positive

### Aandoening

Bipolar disorder

Wellbeing

Recovery

Positive Psychology

Bipolaire Stoornis

Welbevinden

Herstel

Positieve Psychologie

## Ondersteuning

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

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**Overige ondersteuning:** The Netherlands Organisation for Health Research and Development (ZonMw)

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

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

## Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### Doel van het onderzoek

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.

## Onderzoeksopzet

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).

### **Onderzoeksproduct en/of interventie**

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.

## **Contactpersonen**

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## **Deelname eisen**

## **Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)**

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.

## **Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)**

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

## **Onderzoeksopzet**

### **Opzet**

|                  |                         |
|------------------|-------------------------|
| Type:            | Interventie onderzoek   |
| Onderzoeksmodel: | Parallel                |
| Toewijzing:      | Gerandomiseerd          |
| Blinding:        | Open / niet geblindeerd |
| Controle:        | Actieve controle groep  |

### **Deelname**

|                         |                       |
|-------------------------|-----------------------|
| Nederland               |                       |
| Status:                 | Werving gestopt       |
| (Verwachte) startdatum: | 12-08-2018            |
| Aantal proefpersonen:   | 112                   |
| Type:                   | Werkelijke startdatum |

## **Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)**

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

## **Ethische beoordeling**

Positief advies

Datum: 12-10-2017  
Soort: Eerste indiening

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

| Register       | ID                |
|----------------|-------------------|
| NTR-new        | NL6541            |
| NTR-old        | NTR6729           |
| Ander register | 843001803 : ZonMw |

## Resultaten