

# Beyond the window of risk? Psychiatric and functional outcome in adult bipolar offspring, a longitudinal study

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To provide insights into 1) the risk to develop BD and other psychiatric disorders after age 30, and 2) explore functional outcome at adult age and study the link between (early)psychiatric outcome and functional outcome. Moreover, compare the...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Manic and bipolar mood disorders and disturbances
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON49802

### Source

ToetsingOnline

### Brief title

Dutch Bipolar Offspring Study

### Condition

- Manic and bipolar mood disorders and disturbances

### Synonym

bipolar disorder; bipolar spectrum disorders; manic depressive illness

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam

**Source(s) of monetary or material Support:** Onderzoeksprogramma GGZ ZonMW - postdoc fellowship 2018

## Intervention

**Keyword:** Bipolar Disorder, daily functioning, longitudinal, offspring

## Outcome measures

### Primary outcome

- Lifetime diagnosis of bipolar spectrum disorder based upon the Structured Clinical Interview for DSM-IV axis I disorders (SCID-I; First, Spitzer, Gibbon, & Williams, 1997).

### Secondary outcome

- Functional outcome based upon the WHO-DAS 2.0, the Global Assessment of Functioning, and quality of life using the EQ-5D
- Diagnoses of psychiatric disorders based upon the SCID-I
- Daily mood fluctuations as measured by experience sampling (mobile assessment)
- Daily functioning as measured using passive behavioural techniques including physical activity, social activity and daily rhythm

## Study description

### Background summary

BD is a mood disorder characterized by episodes of depression and (hypo)mania alternated (in most patients) by periods of euthymic mood and is known for its recurrent and often chronic display with high interpersonal and societal impact, such as partner violence, job loss, and suicide. BD affects 1-2% of the population. One of the key challenges in the field of bipolar disorder (BD) is early recognition. The early trajectories of the illness are non-specific and often result in a diagnostic delay of 5-10 years. Since the peak age of onset of BD is between adolescence and young adulthood, there is a lost opportunity for adequate treatment during a crucial time window for interpersonal and psychosocial development (e.g., educational performance, first work experience). As in two-thirds of the BD patients the illness onsets with one or multiple episodes of unipolar depression (UD), a particular diagnostic

challenge is to identify individuals with UD who are at risk for BD and those who are not.

To date, the strongest risk factor for BD is a positive family history for BD. Children of patients with BD (bipolar offspring) are therefore an ideal population to study early trajectories of BD, especially when studied in a longitudinal perspective. Worldwide only six longitudinal bipolar offspring studies exist. In the past decades, these six studies have revealed important insights on the risk and early trajectories of BD. Studies show that the risk to develop BD ranges from 10-20% and most often debuts with a (mild) depressive episode. Bipolar offspring are in general at high-risk to develop mood disorders (>50%) and lifetime risk for psychopathology is estimated at 60-75%. However, none of these studies had the opportunity to follow bipolar offspring beyond the age of 30 years old. This is problematic as the first manic episode can still emerge during middle adulthood. Existing risk estimates and early trajectories of BD may therefore be incomplete. Therefore, much uncertainty exists with regards to BD prevalence, switch rates from UD to BD and associated risk factors in bipolar offspring. More knowledge regarding the risk determinants for switching to mania can help us to develop more specific treatment algorithms or risk calculators for healthcare professionals. Therefore we will study the onset and development of BD in adult bipolar offspring now aged 32-42 years of age applying a longitudinal design. To our knowledge, there are no studies on functioning in bipolar offspring reaching adult age. This is important to put prior findings of high rates of psychopathology in perspective, especially since recent studies show that regardless of current psychopathology or history of psychiatric diagnoses in adulthood, childhood psychopathology, even sub-syndromal, is associated with an adverse transition into adulthood in terms of health, legal system, personal finances and social functioning.

## **Study objective**

To provide insights into 1) the risk to develop BD and other psychiatric disorders after age 30, and 2) explore functional outcome at adult age and study the link between (early) psychiatric outcome and functional outcome. Moreover, compare the functional outcomes to a group of healthy control in the same age range.

## **Study design**

Longitudinal study

## **Study burden and risks**

This is a non-therapeutic study. The burden of the study for participants is considered low. The burden includes time during the on-site assessment including interviews (approximately 2.5 hours) and filling out questionnaires

(approximately 1.5 hours) and participation in the smartphone study including experience sampling (5 times a day for 14 consecutive days, 1-2 minutes) and passive behavioural monitoring (14 consecutive days).

## Contacts

### Public

Erasmus MC, Universitair Medisch Centrum Rotterdam

Wytemaweg 8  
Rotterdam 3015CN  
NL

### Scientific

Erasmus MC, Universitair Medisch Centrum Rotterdam

Wytemaweg 8  
Rotterdam 3015CN  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

In order to be eligible to participate in this study, bipolar offspring must meet all of the following criteria: Provided past consent to be re-contacted for future studies or contacted the research team by themselves. Give written informed consent for the current study. Healthy controls should be between 30 and 45 years old, and give written informed consent for the current study.

## Exclusion criteria

Subjects with a cognitive impairment sufficient to interfere with their ability to provide informed consent or complete study questionnaires. Healthy controls will be excluded when they have self-reported severe psychiatric disorders at present or in the past, or if they have a parent with bipolar disorder, schizophrenia, or major depressive disorder at present or in the past.

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

**Primary purpose:** Diagnostic

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	13-07-2020
Enrollment:	190
Type:	Actual

## Ethics review

Approved WMO	
Date:	13-02-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	
Date:	29-07-2020
Application type:	Amendment

Review commission:

METC Erasmus MC, Universitair Medisch Centrum Rotterdam  
(Rotterdam)

## 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	NL68580.078.19