

# LIFE: development of a personalized lifestyle intervention for patients in psychiatric outpatient care

No registrations found.

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

## Summary

### ID

NL-OMON27875

### Source

NTR

### Brief title

LIFE

### Health condition

Bipolar disorder, recurrent depression

## Sponsors and support

**Primary sponsor:** GGZ Drenthe

**Source(s) of monetary or material Support:** Zorginnovatiefonds, GGZ Drenthe

## Intervention

## Outcome measures

### Primary outcome

Quality of life (defined as the sum score on a QoL questionnaire) en activity level (defined as the number of steps per day)

## Secondary outcome

Well-being, decreased psychiatric symptoms and metabolic parameters such as decreased body mass  
and decreased glucose level, blood pressure and lipid spectra

## Study description

### Background summary

Patients with a bipolar disorder or severe depression have 10 years shorter life expectancy compare to the general population. The most important causes are: somatic complications due to a sedentary habits and an unhealthy lifestyle related to their disorder and/or the side effects of psychotropics they are using. Lifestyle interventions are in general as effective as drugs-based interventions are. There is ample research on the efficacy of lifestyle interventions for outpatients with a psychiatric disorder. This study will investigate whether a personalized lifestyle intervention may help to improve the health and quality of live of outpatients with an affective disorder. The goal of the study is to develop a state-of-the art- lifestyle intervention that is achievable and acceptable for patients with a bipolar and severe recurrent depressive disorder. Topics are moving, diet, sleep and sustenance. The focus in on small changes that can be easily incorporated in the daily life of the patient. The planned duration is six months, with 9 weekly sessions and 9 biweekly sessions of 1.5 hours, interspersed with individuals sessions and group sessions. One individual from the personal surroundings (preferable a housemate) should also participate. All sessions include individual home work and start with a positive psychology intervention (PPI) of 10 - 15 minutes. This is an exploratory pilot study with a case series design without control group. Patients follow a lifestyle intervention and are assessed at baseline, after each module of the intervention en after the intervention (directly after and 6 months follow-up) with interviews/questionnaires.

### Study objective

The lifestyle intervention will result in increased activity of the participant and a higher quality of life.

### Study design

Baseline, halfway, end of intervention and 6 month follow-up, also small evaluation after each of the modules of the intervention.

## **Intervention**

A personalized lifestyle intervention will be investigated. Topics are moving, diet, sleep and sustenance. The focus is on small changes that can be easily incorporated in the daily life of the patient. The planned duration is six months, with 9 weekly sessions and 9 biweekly sessions of 1.5 hours, interspersed with individual sessions and group sessions.

## **Contacts**

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## **Eligibility criteria**

### **Inclusion criteria**

Outpatients with a diagnosis of bipolar disorder or chronic, recurrent depression  
Age 18 - 65 years  
Abnormal outcome on three out of five criteria for metabolic syndrome  
Availability of a buddy that will also participate

### **Exclusion criteria**

Insufficient command of the Dutch language

## Study design

### Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	28-11-2019
Enrollment:	30
Type:	Anticipated

### IPD sharing statement

**Plan to share IPD:** Undecided

#### Plan description

Given the small amount of subjects, IPD has not been discussed in detail. We are open for sharing data if researchers are interested.

## Ethics review

Positive opinion	
Date:	28-11-2019
Application type:	First submission

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 49295  
Bron: ToetsingOnline

Titel:

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

No registrations found.

## In other registers

Register	ID
NTR-new	NL8232
CCMO	NL72226.099.19
OMON	NL-OMON49295

## Study results

### Summary results

Not applicable.