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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

# **Summary**

### ID

NL-OMON27875

**Source** Nationaal Trial Register

Brief title

**Health condition** 

Bipolar disorder, recurrent depression

### **Sponsors and support**

Primary sponsor: GGZ Drenthe Source(s) of monetary or material Support: Zorginovatiefonds, 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

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.

# Contacts

#### Public

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# **Eligibility criteria**

### **Inclusion criteria**

Outpatients with a diagnosis op 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
Туре:	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 opinionDate:28-11-2019Application type:First submission

# **Study registrations**

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

ID: 49295 Bron: ToetsingOnline

4 - LIFE: development of a personalized lifestyle intervention for patients in psych ... 2-06-2025

Titel:

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

No registrations found.

# In other registers

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

# **Study results**

#### Summary results Not applicable.