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
LIFE

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

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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
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.