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

Gepubliceerd: 28-11-2019 Laatst bijgewerkt: 15-05-2024

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27875

Bron
Nationaal Trial Register

Verkorte titel
LIFE

Aandoening

Bipolar disorder, recurrent depression

Ondersteuning

Primaire sponsor: GGZ Drenthe
Overige ondersteuning: Zorginovatiefonds, GGZ Drenthe

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

the number of steps per day)

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Insufficient command of the Dutch language

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	28-11-2019
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

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

Ethische beoordeling

Positief advies

Datum:	28-11-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49295
Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
Not applicable.