Serious Mental Illnes Lifestyle Evaluation

Gepubliceerd: 16-11-2017 Laatst bijgewerkt: 13-01-2025

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

Samenvatting

ID

NL-OMON20617

Bron
NTR

Verkorte titel
SMILE

Aandoening

Obesitas, cardiovasculaire aandoeningen en ernstige psychiatrische problematiek.

Ondersteuning

Primaire sponsor: Vrije Universiteit Amsterdam
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Weight (kg)

Toelichting onderzoek

Achtergrond van het onderzoek

Cardiovascular disease is the leading cause of the estimated 20-25 years reduced life expectancy for persons with serious mental illness. This excess cardiovascular mortality is primarily attributable to obesity, diabetes, hypertension, and dyslipidemia. Obesity in particular has been associated with a sedentary lifestyle, limited physical activity and an unhealthy diet in persons with serious mental illness. Evidence concerning the costs-effectiveness of lifestyle interventions in outpatient psychiatric treatment settings is lacking. Therefore, this study to evaluates the cost-effectiveness of a lifestyle intervention in persons with serious mental illness in outpatient psychiatric treatment settings in comparison to usual care. The study will consist of an economic evaluation alongside a cluster randomized controlled trial.

The lifestyle intervention aims at a healthy diet and increased physical activity and consists of group sessions including personal action plans and makes use of elements of motivational interviewing and goal setting. Main study parameters/endpoints include: weight loss (primary outcome), cardiovascular risks (central obesity, lipids, blood pressure, glucose metabolism), quality of life, health related self-efficacy and societal costs after 1 year follow-up.

Onderzoeksopzet

Baseline, 3 months, 6 months and 12 months

Onderzoeksproduct en/of interventie

Lifestyle intervention consisting of group sessions focussing on nutrition and fysical activity

Contactpersonen

Publiek

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The Netherlands
020 5989946

Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

patient with SMI

age ≥18

body mass index ≥27

willing to and able to sign informed consent (mentally competent)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Contra-indications for participation due to acute psychiatric crisis or somatic diseases (e.g. bariatric surgery, cancer, heart attack or stroke)

Subjects with a cognitive impairment sufficient to interfere with their ability to provide informed consent, complete study questionnaires, or participate in a group intervention.

Women who are pregnant, breastfeeding, or planning a pregnancy during the course of the study

Subjects not able to communicate in the Dutch language

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2018
Aantal proefpersonen:	260
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	16-11-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47451
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6660
NTR-old	NTR6837
Ander register	METc (VUmc) // ZonMw : 2017.418 // 80-84300-98-72012
CCMO	NL60315.029.17
OMON	NL-OMON47451

Resultaten