Serious Mental Illnes Lifestyle Evaluation

Published: 16-11-2017
Last updated: 13-01-2025

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

Summary

ID

NL-OMON20617

Source
NTR

Brief title
SMILE

Health condition

Obesitas, cardiovasculaire aandoeningen en ernstige psychiatrische problematiek.

Sponsors and support

Primary sponsor: Vrije Universiteit Amsterdam
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

Weight (kg)

Secondary outcome

cardiovascular risks (central obesity, lipids, blood pressure, glucose metabolism), quality of life, health related self-efficacy and societal costs.

Study description

Background summary

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.

Study design

Baseline, 3 months, 6 months and 12 months

Intervention

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

Contacts

Public
Marcel Adriaanse
Amsterdam
The Netherlands
020 5989946
Scientific
Marcel Adriaanse
Amsterdam
The Netherlands
020 5989946

Eligibility criteria

Inclusion criteria

patient with SMI
age ≥18
body mass index ≥27
willing to and able to sign informed consent (mentally competent)

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2018
Enrollment:	260
Type:	Anticipated

Ethics review

Positive opinion
Date: 16-11-2017
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47451
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results