Cost-effectiveness of a tailored lifestyle intervention in patients with serious mental illness: the SMILE-study

Published: 26-10-2017
Last updated: 13-01-2025

Primary Objective: To reduce weight after in persons with SMI in outpatient psychiatric treatment settings who are treated by Flexible Assertive Community Treatment teams (FACT-teams) after 1 year.Secondary Objective(s): To reduce cardiovascular...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON47451

Source
ToetsingOnline

Brief title
SMILE (Serious Mental Illness Lifestyle Evaluation)

Condition

- Other condition

Synonym
mental health disorder, Mental illness

Health condition

Serious Mental Illness, Obesity, cardiovascular disease.

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cost-effectiveness, intervention study, Lifestyle, Serious Mental Illness

Outcome measures

Primary outcome

Weight loss (kg).

Secondary outcome

Central obesity, lipids (LDL, HDL and total cholesterol, triglycerides),

diastolic and systolic blood pressure, glucose metabolism, quality of life,

self-management of one*s health or chronic condition and societal costs after 1

year follow-up.

Study description

Background summary

Cardiovascular disease is one of the leading causes of the estimated 20-25 years reduced life expectancy for persons with serious mental illness (SMI). This excess cardiovascular mortality is primarily attributable to obesity, diabetes, hypertension, dyslipidemia and lifestyle factors (6). Additionally, cardiovascular disease in persons with SMI contributes to enormous societal costs. The reduction of these cardiovascular risks have been associated with perfoming lifestyle interventions. However, evidence concerning the costs-effectiveness of lifestyle interventions in outpatient psychiatric treatment settings is lacking.

Study objective

Primary Objective: To reduce weight after in persons with SMI in outpatient psychiatric treatment settings who are treated by Flexible Assertive Community Treatment teams (FACT-teams) after 1 year.

Secondary Objective(s): To reduce cardiovascular risks (central obesity, lipids, blood pressure, glucose), improve quality of life, and reduce health care costs in persons with SMI in outpatient psychiatric treatment settings who are treated by FACT-teams after 1 year.

Study design

To evaluate the cost-effectiveness of a tailored lifestyle intervention in persons with serious mental illness (SMI) in outpatient psychiatric treatment settings in comparison to usual care.

Intervention

A tailored lifestyle intervention aiming at a healthy diet, increased physical activity.

Study burden and risks

Risks associated with participation in this study are deemed minor. Possible extra risk which is associated with the intervention includes injury as a result of indoor or outdoor physical activity. However, as the primary physical activity is walking outdoors, this is considered a minor risk. Apart from that, risks involving venapuncture (such as minor bruising, hematoma, bleeding complications, fainting or infections) could occur. However patients involved in the study have annual laboratory check-ups. The laboratory assessments are measured at baseline and after 12 months, this study will make use of the patient*s annual (from the annual somatic screening) check-ups whenever possible in order to avoid extra visits to the laboratory.

Contacts

Public
Vrije Universiteit

De Boelelaan 1085
Amsterdam 1081HV
NL
Scientific
Vrije Universiteit

De Boelelaan 1085
Amsterdam 1081HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with serious mental illness
Age *18 years old
Body mass index *27
Willing to and able to sign informed consent (mentally competent)

Exclusion criteria

*Contra-indications (to be assessed by the treating physician/psychiatrist) 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:	Other
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-01-2018
Enrollment:	260
Type:	Actual

Ethics review

Approved WMO Date:	26-10-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-10-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-01-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20617

Source: NTR
Title:

In other registers

Register	ID
CCMO	NL60315.029.17
OMON	NL-OMON20617