

# Lifestyle Interventions for Severe Mentally Ill Outpatients in the Netherlands.

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON38658

### Source

ToetsingOnline

### Brief title

LION

### Condition

- Other condition
- Glucose metabolism disorders (incl diabetes mellitus)
- Lifestyle issues

### Synonym

diabetes type 2 and cardiovascular disease), overweight and cardiometabolic risk (increased risk of hypertension

### Health condition

overgewicht, hypertensie

## Research involving

Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen

**Source(s) of monetary or material Support:** ZonMW doelmatigheids programma, Leefstijl in Beeld (in natura, stelt webtool beschikbaar voor evaluatie)

## Intervention

**Keyword:** Cardiometabolic health, E-health, Lifestyle, nutrition and physical activity, Severe mentally ill

## Outcome measures

### Primary outcome

The primary outcome measure is waist circumference.

### Secondary outcome

Secondary outcomes include obesity/cardiometabolic risk (BMI, blood pressure, plasma triglycerides, cholesterol (LDL, HDL, and total cholesterol), fasting glucose and HbA1c), psychological outcomes (depressive symptoms, negative symptoms), outcomes for cost-effectiveness (quality of life, care consumption, registration of medication) and behavioural/environmental determinants of intervention success in both patients and nurses (like readiness to change, attitude). The somatic measurements including lab tests and most questionnaires are part of standard Routine Outcome Monitoring. Other information is collected using questionnaires. Measurements are taken at baseline, after 6 and after 12 months. For intervention participants, a small somatic assessment (BMI, waist circumference, blood pressure) is taken at 3 and 9 months to provide feedback on lifestyle changes.

# Study description

## Background summary

Patients with severe mental illness (SMI) have an increased cardiometabolic risk and the prevalence of type 2 diabetes is up to four times higher than in the general population of comparable age. Although monitoring the somatic health of SMI patients is now obligatory in The Netherlands, most comorbidities are left untreated due to a lack of knowledge, and fear that medication will interact with antipsychotic medication. Lifestyle intervention in high risk individuals from the general population has been shown to be (cost-) effective, and even more effective than early pharmacological treatment, to prevent type 2 diabetes and reduce cardiometabolic risk. This non-pharmacological intervention to reduce cardiometabolic risk may also be effective in SMI patients.

## Study objective

The aim of the current proposal is to compare the (cost)effectiveness of a 12-month multidimensional lifestyle approach for SMI outpatients to usual care to reduce cardiometabolic risk factors in SMI patients. Secondary research questions include whether the intervention decreases depressive and negative symptoms and whether the multidimensional lifestyle approach is cost-effective.

## Study design

Single blind clustered randomized controlled trial using a pragmatic design (<http://www.bmj.com/content/340/bmj.c1066>) to improve external validity. This research is Health Technology Assessment research, in the category \*early evaluation of promising care strategies\*, this means the evaluation of new interventions that have been proven effective on other settings or patients groups.

## Intervention

The 12-month intervention consists of biweekly 15-minute sessions. The self-management tool is based on e-health and is developed as the Traffic Light website ([www.leefstijlinbeeld.nl](http://www.leefstijlinbeeld.nl)). It is developed in and for the Dutch GGZ population. Several steps guide patient and nurse to better lifestyle habits. First, the Traffic Light method displays a risk profile with all lifestyle behaviors in green, orange or red, depending on the level of risk. Second, the patient decides which behavior he/she wants to change. The nurses use motivational interviewing (MI) techniques and the stages of change model to assist the patient in this process. Third, the Traffic Light is used to create a lifestyle plan. The nurse's role is to support patients in setting and achieving realistic goals. Finally, the Traffic Light model is used to sustain

change using behavioural techniques.

### **Study burden and risks**

The burden is low. Both the somatic and psychological aspects of the ROM-screening are part of routine care. One additional ROM-screening (at 6 months) is foreseen. Additional information is collected using questionnaires. The program will be part of regular care visits of the nurse with the patient, so no extra sessions are needed. Increasing risk awareness during the counselling is combined with the possibility to take action, reducing distress due to risk awareness alone. No adverse side effects of the measurements or program are foreseen.

## **Contacts**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

## Inclusion criteria

Included patients have at least one of the following risk factors:

- waist circumference > 102 cm (male) or > 88 cm (female);
- fasting glucose > 5.6 mmol/l; or HbA1c > 5.7 %
- BMI > 25 kg/m<sup>2</sup>.
- patient participates in yearly ROM-screening (routine screening for somatic and mental health)

## Exclusion criteria

Exclusion criteria:

- pregnancy;
- BMI < 19 kg/m<sup>2</sup>
- physical impairments that make daily physical activity impossible
- patients with primary diagnosis of Korsakov syndrome

## Study design

### Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	06-01-2014
Enrollment:	768
Type:	Actual

## Ethics review

Approved WMO

Date: 20-12-2013

Application type: First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Not approved

Date: 10-06-2015

Application type: Amendment

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date: 31-08-2015

Application type: Amendment

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

### In other registers

Register	ID
CCMO	NL44565.042.13