Lifestyle Interventions for Severe Mentally Ill Outpatients in the Netherlands.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21055

Source
NTR

Brief title
LION

Health condition

Cardiometabolic health of severe mentally ill outpatients

Sponsors and support

Primary sponsor: GGZ Friesland, University Medical Center Groningen
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

Waist circumference.

Secondary outcome

Readiness to change (motivation on a 10 point scale), weight and height to calculate BMI, and the other components of the metabolic syndrome: blood pressure (systolic blood pressure in mmHg and diastolic blood pressure in mmHg), plasma triglycerides (in mmol/l), cholesterol (LDL, HDL, and total cholesterol in mmol/g, and the cholesterol ratio), glucose (hbA1c in mmol/l), and insulin resistance calculated from insulin and glucose levels (HOMA index for insulin resistance. Furthermore: Depressive symptoms, negative symptoms and quality of life.

Study description

Background summary

Patients with severe mental illness (SMI) have an increased cardiometabolic risk. The prevalence of obesity is 4-5 times higher
than in the general population, between 45-55%, and the prevalence of type diabetes is around 10-15%, which 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. In spite of the much increased attention for their excessive cardiovascular risk, evidence based strategies that can be implemented on a large scale to prevent the burden of somatic disease in severe mentally ill (SMI) patients are still lacking, partly because RCTs have been small and of short duration, or not feasible for large-scale implementation. 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. The intervention is based on a state-of-the-art intervention design, promoting active self-management using e-health tools and incorporating motivational techniques by nurses on top of exercise and other health promotion sessions and support from nurses. Secondary research questions include whether the intervention decreases depressive and negative symptoms and whether the multidimensional lifestyle approach is cost-effective. The self-management tools based on e-health are the Traffic Light website, and Heartville, a serious health game that was awarded the “Game for Health” on the TEDx 2012 in Maastricht, The Netherlands. 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. The website-generated lifestyle profile provides insight for patient and nurse. 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, in

which patients set their own goals on the chosen lifestyle areas, including what the patient's needs are to achieve the goals, such as family involvement. The nurse's role is to support patients in setting realistic goals. Finally, the Traffic Light model is used to sustain change: nurses support patients in the various phases of trial and error, and nurses will use MI and Stages of Change techniques at every step. In addition, the Traffic Light method contains features to support the role of the nurse in ensuring the
availability of payable exercise and health promotion activities, and up to date lifestyle knowledge in the team.
In this multicenter study, it is foreseen that 16 teams from 5 locations will deliver 32 nurses and 640 SMI outpatients. It is a
cluster randomized trial, since teams will be randomized, and data analysis will be clustered. The primary outcome measure is
waist circumference. Secondary outcomes include readiness to change (motivation), weight and height to calculate BMI, and
other risk factors including all the components of the metabolic syndrome. These include blood pressure, plasma triglycerides, cholesterol (LDL, HDL, and total cholesterol) and fasting glucose and HbA1c. Furthermore, the measurements include depressive symptoms, negative symptoms, quality of life, and registration of antipsychotic medication. These measures are part of standard Routine Outcome Monitoring measurements and are taken at baseline, after 6 and after 12 months. Additional assessment of weight, waist circumference and lifestyle is taken at 3 and 9 months for intervention participants to evaluate lifestyle progress. Cost-effectiveness analysis (CEA) takes into account care consumption, waist circumference and quality of life. A budget impact analysis is performed by extrapolating CEA results to yearly intervention costs.

In the period between obtaining funding and preparing the study, unexpected large changes in the organisation of mental health care took place. Budgets were restrained and care delivery shifted towards general mental health care, leading to necessary adjustments in study design. The initial sample size was estimated based on 64 nurses all including 10 patients leading to an target sample of 640 patients. The Medical Ethics Committee advised us to plan an extra 20% inclusion to account for clustering of the data, yielding a target sample of 768 patients. However, it became clear that inclusion of twelve patients per nurse was too high for proper implementation of the intervention due to increased workload of nurses. To compensate, more nurses were trained in order to include less patients per nurse, and inclusion criteria were broadened so that patients in sheltered living facilities could be included as well. With a sample of 250 patients, we are able to detect a significant reduction of 5.8% in waist circumference (primary outcome) and a reduction of 0.6 mmol/L in plasma glucose (alpha = 0.05, power 0.80), leading to a target sample of 250 patients. To correct for drop-out we aimed to include an additional 10%. The funding agency (ZonMW) and the Medical Ethics Committee have approved the adjusted study design and adjusted final sample size of 275 patients.

Study objective

1. A multidimensional lifestyle intervention, including aspects of increased awareness, motivation, self-management, diet,
exercise, and a supportive environment, improves or prevents deterioration of the

cardiometabolic risk factors of SMI outpatients;

2. The intervention decreases depressive and negative symptoms;

3. The multidimensional lifestyle approach is cost-effective.

Study design

Measurement before start of trial (T0), after 6 months (T1) and after 12 months, end of trial (T2).

Intervention

The intervention is based on a state-of-the-art intervention design, promoting active self-management using e-health tools and incorporating motivational techniques by

nurses on top of exercise and other health promotion sessions and support from nurses.

The self-management tools based on e-health are the Traffic Light website, and Heartville, a serious health game that was awarded the “Game for Health” on the TEDx 2012 in Maastricht, The Netherlands 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. The website-generated lifestyle profile provides insight for patient and nurse. 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, in which patients set their own goals on the chosen lifestyle areas, including what the patient’s needs are to achieve the goals, such as family involvement. The nurse’s role is to support patients in setting realistic goals. Finally, the Traffic Light model is used to sustain change: nurses support patients in the various phases of trial and error, and nurses will use MI and Stages of Change

techniques at every step. In addition, the Traffic Light method contains features to support the role of the nurse in ensuring the availability of payable exercise and health promotion activities, and up to date lifestyle knowledge in the team.

The intervention will take one year.

The intervention will be performed by nurses of FACT teams, who are specially trained. Every institution has at least 2 FACT teams. These teams will be randomised into training (two nurses per team) or no training (control condition).

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Eligibility criteria

Inclusion criteria

Severe mentally ill outpatients with at least one of the following risk factors:

1. Waist circumference > 102 cm (m) or > 88 cm (f);

2. Fasting glucose > 5.6 mmol/l;

3. BMI > 25 kg/m2.

Exclusion criteria

Pregnancy.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2014
Enrollment:	275
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	21-12-2012
Application type:	First submission

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
NTR-new	NL3606

Register	ID
NTR-old	NTR3765
Other	ZonMw : 837001006
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/Q