Effectiveness of Lifestyle Interventions in Psychiatry.

No registrations found.

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

Summary

ID

NL-OMON29575

Source
NTR

Brief title
ELIPS

Health condition

severe mentally ill patients, metabolic syndrome, obesogenic environment.

In Dutch: patienten met een ernstige psychiatrische aandoening, metabool syndroom, obesogene omgeving

Sponsors and support

Primary sponsor: GGZ Friesland, Lentis, UMCG (RGOc, department of Epidemiology)
Source(s) of monetary or material Support: ZonMW (the Netherlands Organisation for health research and development)

Intervention

Outcome measures

Primary outcome

Waist circumference (in cm).

Secondary outcome

1. 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). Length (in meters) and weight (in kg) are also measured, and BMI (kg/m2) calculated. Other physical outcome measures are Physical fitness (measured with the Six Minutes Walk Test and the consumption of a healthier diet (measured with a 3-day food diary, two weekdays and a weekend day);

2. Psychosocial outcome measures: Quality of life (SF 6D), psycho-social functioning (HoNOS) and negative and positive psychotic symptoms (PANSS), depressive symptoms (CDI);

3. Costs: Care consumption, including medication and costs of the intervention (extra staff, materials, training).

Study description

Background summary

Due to antipsychotic medication, genetic vulnerability and an unhealthy lifestyle, severe mentally ill (SMI) patients have a very high cardiometabolic risk. Nonetheless, evidence-based strategies to prevent the burden of somatic disease in these patients are lacking. Our aim is to investigate the (cost-) effectiveness of a combined lifestyle intervention (i.e. diet and exercise) on metabolic risk in SMI patients in an intramural setting. In the general population, this intervention has proven to be successful, whereas in SMI patients in an intramural setting, evidence is lacking. The study will be cluster randomised, meaning randomisation is carried out on team level. Long-term care teams of GGZ Friesland and Lentis, two large mental health organizations (GGZ) in the North of the Netherlands, will be randomised to the lifestyle intervention or the control condition. They receive care as usual. The study population includes SMI patients who primarily suffer from psychotic or bipolar disorders, who often use antipsychotic medication and who are in intramural long-term care. The intervention program will last for one year. It has been
adapted from existing lifestyle intervention programs that combine diet and exercise. Group sessions include five times per week easy accessible organized physical activities and once a week workshops in healthy nutrition, including ‘choose, buy and cook’. In addition, patients receive individual counselling to identify personal barriers and set individuals goals. After the first three months, staff members take over the program activities, supported by a lifestyle coach. Primary outcome measure is the difference in cardiometabolic risk, measured by waist circumference, and additionally by other components of the metabolic syndrome, between intervention and control. Secondary outcome measures are physical fitness, diet, quality of life, psycho-social functioning and psychotic symptoms. Per group, 240 patients will be needed. Data will be analysed with multilevel regression methods to take into account that patients live within one group. The economic evaluation takes consumption of care, waist

circumference and quality of life into account. Before the start of the intervention, baseline measurements are carried out. Follow up measurements are after 3 and 12 months.

Study objective

Training staff of severe mentally ill patients in stimulating a healthier lifestyle (more exercise, a healthier diet) of their patients will improve patients' metabolic health, decrease depressive symptoms and improve quality of life, at reasonable costs.

Study design

T0: Measurement before start of intervention;

T3: Measurement 3 months after start intervention;

T12: Measurement one year after start intervention.

Intervention

The intervention program will be aimed at more physical activity and a healthier diet. It includes daily, easy accessible physical activities, like exercise to music, low-intensity circuit training, sporting games, tai-chi workshops, and a daily 20 minutes walk. Patients receive weekly workshops in healthier choice of products, shopping and cooking. Staff is instructed how to order healthier products for patients who do not cook or buy groceries themselves. Chefs in hospital restaurants are encouraged to offer highly saturated snacks only once a week and present healthy foods more attractively. Patients and staff both receive information about ways to adopt a healthier lifestyle. Lastly, patients receive individual counseling about motivation for and goal setting in adopting a healthier lifestyle. Patients are actively encouraged to take part in the intervention, by personally inviting them for all organized activities. The intervention is first carried out by lifestyle professionals. The lifestyle professionals will train local staff, i.e. nurses, residential therapists, psycho-motor therapists, dieticians and occupational therapists, in taking over the activities. The lifestyle coaches will support staff in their activities throughout the year in order to reach sustainability of the intervention. Management will be involved in the structural embedding of all the activities in the daily routine of staff. Embedding the activities in daily care routine will prevent the loss of interest of staff after the intervention and thus prevent jojo-ing of patients’ weight.

The control group will receive care as usual, i.e. no daily organised physical activities and healthy diet workshops. As part of the care as usual, counseling and information is offered regarding their lifestyle.

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Eligibility criteria

Inclusion criteria

All patients with severe mental illness residing in a long term care facility, including sheltered living arrangements, on or off hospital grounds, can be included in this study.

Exclusion criteria

1. Conditions that inhibit taking part of the measurements;

2. Not being able to sign an informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2010
Enrollment:	500
Type:	Anticipated

Ethics review

Positive opinion

Date:	27-01-2011
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	NL2592
NTR-old	NTR2720
Other	ZonMW : 80-82305-97-11030
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A