Effectiveness of Lifestyle Interventions in Psychiatry.

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29575

Bron
NTR

Verkorte titel
ELIPS

Aandoening

severe mentally ill patients, metabolic syndrome, obesogenic environment.

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

Ondersteuning

Primaire sponsor: GGZ Friesland, Lentis, UMCG (RGOc, department of Epidemiology)
Overige ondersteuning: ZonMW (the Netherlands Organisation for health research and development)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Waist circumference (in cm).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

T0: Measurement before start of intervention;

T3: Measurement 3 months after start intervention;

T12: Measurement one year after start intervention.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Conditions that inhibit taking part of the measurements;

2. Not being able to sign an informed consent.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-11-2010
Aantal proefpersonen:	500
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	27-01-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2592
NTR-old	NTR2720
Ander register	ZonMW : 80-82305-97-11030
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A