Multidisciplinary Lifestyle-enhancing Treatment for long-term severe mentally ill Inpatients: Sheltered Housing

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Objectives:This research aims to develop an appropriate lifestyle intervention for patients living in sheltered housing services of GGz Central, based on input of patients and directly involved. Does applying this lifestyle treatment result in a...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON46233

Source
ToetsingOnline

Brief title
The MULTI_sh study

Condition

- Other condition
- Schizophrenia and other psychotic disorders

Synonym
chronic psychiatric patients, severe mentally ill

Health condition

patienten met EPA(ernstige psychiatrische aandoeningen)

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Centraal (Amersfoort)
Source(s) of monetary or material Support: Stichting Zorginnovatiefonds

Intervention

Keyword: Lifestyle, Severe mentally ill, Sheltered Housing, Treatment

Outcome measures

Primary outcome

Primary outcome:

The primary outcome measure is the increase in metabolic health after 6 months.

Secondary outcome

Secondary Outcome Measure:

- Metabolic Health:Lipids, Fastin Glucose (values in blood sample)

- Activity: measured 5 consecutive days with an accelerometer

- Quality of Life: measured by the EuroQol 5D and WHOQoL-Bref

Study description

Background summary

Introduction and rationale:
Unhealthy eating habits and lack of physical activity are risk factors for many diseases (including metabolic syndrome) and contribute to a shortened lifespan of 15-30 years in people with severe mental illness (SMI). Literature, mainly including short-term hospitalized or outpatients, show strong positive effects of activation on both physical and mental health. However, studies in long-term care are limited. In recent years, implementation of a lifestyle enhancing treatment intervention in clinical settings in GGz Centraal has demonstrated to be effective. The question is whether this kind of lifestyle intervention in sheltered housing is applicable and effective.

Study objective

Objectives:
This research aims to develop an appropriate lifestyle intervention for patients living in sheltered housing services of GGz Central, based on input of patients and directly involved. Does applying this lifestyle treatment result in a positive effect in health and quality of life of patients and what is the influence of contextual factors, personal- and disease characteristics?

Study design

Study design:
In this intervention study, we use an experimental design. Municipal locations are paired based on the number of participants to generate equal cluster sizes. These paired clusters are randomly allocated to the control or intervention arm by means of a random number generator by an independant person (not involved in this project). At the start of the lifestyle treatment patients in the experimental and control group are invited to participate in the baseline screening. After six months, following a post-test on all outcome measures.

Intervention

Treatment intervention:
The intervention in this study consists of formulating a lifestyle intervention, by patients en directly involved. This plan is based on physical activities, healthy nutrition/eating habits and psycho education on life style. After formulation of the plan it wil be executed for a six month period.

Study burden and risks

There are no implications that lifestyle enhancing treatment is associated with risks. Burdens in measuring activity with the accelerometer 5 consecutive days are negligible.

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

severe mentally ill patients living in sheltered housing facilities

Exclusion criteria

Incapacitated patients, without informed consent from their legal representative

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-07-2017
Enrollment:	168
Type:	Actual

Ethics review

Approved WMO Date:	03-07-2017
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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
ClinicalTrials.gov	NCT03157557
CCMO	NL61552.075.17