A pilot randomized controlled trial investigating the feasibility, acceptability and preliminary (cost-)effectiveness and implementation of a combined lifestyle intervention for outpatients with a severe or chronic psychiatric illness (CHAPTER)

Published: 30-05-2023
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The objective of the study is to investigate the feasibilty, acceptabilty, implementation and preliminary (cost-)effectiveness of the intervention on recovery, health and lifestyle variables.

Ethical review	Approved WMO
Status	Completed
Health condition type	Psychiatric disorders NEC
Study type	Interventional

Summary

ID

NL-OMON53239

Source
ToetsingOnline

Brief title
CHAPTER pilot RCT

Condition

- Psychiatric disorders NEC
- Lifestyle issues

Synonym
Mental disorder, psychiatric disorder

Research involving
Human

Sponsors and support

Primary sponsor: Lentis (Groningen)
Source(s) of monetary or material Support: Lentis

Intervention

Keyword: Lifestyle, Mental health, Psychiatry, Recovery

Outcome measures

Primary outcome

The primary outcome is the feasiblity and acceptability of the intervention and

study procedures

Secondary outcome

Secundary outcomes are

-the preliminiary effects on recoveyr, health, and lifestyle variables,

-the preliminary costeffectiveness of the intervention,-

-the subjectively experienced effects of the intervention

-the barriers and fascilitators for implementation of the intervention in daily

practice

-the goals of participants during the intervention

Study description

Background summary

There is an urgent need for new and low-coast approaches in the prevention and treatment of mental disorders. Lifestyle interventions, targeted at changing habits in multiple domains, might be such a new approach. Lifestyle interventions are known to improve somatic health, which is important for

individuals with a psychiatric illness since unhealthy lifestyle choices and somatic illness are common in this population leading to a life expectancy loss of 10-20 years and high rates of somatic comorbidity. The effects of lifestyle interventions in individuals with a psychiatric illness on somatic health and mental health are promising, but effects on other domains of recovery are unknown. Research is needed to answer questions on efficacy, feasibility and acceptability of combined lifestyle interventions in outpatients with a psychiatric disorder.

Study objective

The objective of the study is to investigate the feasibilty, acceptabilty, implementation and preliminary (cost-)effectiveness of the intervention on recovery, health and lifestyle variables.

Study design

This pilot aims to recruit outpatients from multiple departments of Lentis with a psychiatric disorder. The participants will be randomized to receive a lifestyle intervention at onset of the trial (intervention group) or to receive a delayed lifestyle intervention when the trial is finished (control group). All participants will continue their treatment as usual during the trial. Participants are screened on inclusion criteria and health risks (somatic screening) before randomization.

Before, during and after the intervention both groups will be assessed on their recovery, (broad) health and lifestyle behavior using questionnaires, somatic assessments and daily diaries.

A subset of participants will be invited for an interview in which the experiences and subjective effects of the training and study procedures will be assessed.

Information on the barriers and fascilitators of implementation of the intervention will be collected through the trainers.

Intervention

The lifestyle intervention targets healthy changes of habits in one or more of the following domains: nutrition, physical activity, relaxation, sleep, spirituality and substance use. The intervention consists of 12 weekly group sessions and 3 3-weekly follow-up sessions. Besides, the participants are provided with homework to practice with lifestyle in their daily life.

Study burden and risks

No severe risks are expected from the intervention or study procedures.

The intervention is expected to be beneficial to the participant in multiple domains of health and recovery.

The measurement burden is 6 hours, with a total time investment of 8 hours. This is spread over 6 months, resulting in a time investment of less than 20 minutes a week.

The intervention sessions have a total duration of 30-37.5 hours, with 36 hours of homework. Attendance is recommended, but not mandatory.

Contacts

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Lentis (Groningen)

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Treated in an outpatient clinic of Lentis;
- Treated in specialist mental health care;
- Adult (18+);
- Capable to read, write and speak in the Dutch language;
- Available and capable to attend the intervention at set moments and locations;
- Capable to follow the research procedures.

Exclusion criteria

- Main diagnosis of eating disorder or obsessive-compulsive disorder;
- In current crisis, severe symptoms, suicidality, self-mutilation or distorted reality;
- Receiving guidance for at least three times in one or more lifestyle domains on a frequent basis (at least once every other week) in the past year;
- Other implications for lifestyle interventions that cannot be overcome (e.g. due to physical illness, use of certain medication such as clozapine or intellectual disability);
- (Temporary) Hospitalization or living in a supported housing facility;
- Inability to comply with the study requirements as mentioned in the participant information letter, judged by the research team;
- No informed consent is given.

Study design

Design

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

Primary purpose: Health services research

Recruitment

NL
Recruitment status: Completed

Start date (anticipated):	06-10-2023
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	30-05-2023
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	18-12-2023
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	NL83935.042.23