Improving physical health and lifestyle behaviors in patients with serious mental illness: a cluster randomized controlled trial on the effectiveness of the nurse-led GILL eHealth intervention

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Primary objective (after 1 year)- To evaluate the effectiveness of the nurse-led GILL eHealth intervention in patients with serious mental illnessSecundary objectives (after 1 year)- Improve metabolic syndrome severity- Improve fitness, physical...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Schizophrenia and other psychotic disorders
Study type	Interventional

Summary

ID

NL-OMON53725

Source
ToetsingOnline

Brief title
GILL

Condition

- Schizophrenia and other psychotic disorders

Synonym
chronic psychiatric disorder, Serious mental illness

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: eHealth, Lifestyle behaviours, Serious mental illness, Somatic screening

Outcome measures

Primary outcome

The primary study parameter is the metabolic syndrome severity, which is

operationalized by the Metabolic Syndrome Severity Score (MSSS).

Secondary outcome

Secondary study parameters are physical fitness, physical activity, perceived

lifestyle behaviours, quality of life, recovery, psychosocial functioning,

health related self-efficacy, health care utilization, and medication use.

Study description

Background summary

Patients with serious mental illness (SMI) have overall poor physical health. SMI reduces life expectancy with 15-20 years, primarily due to somatic comorbidity linked to cardiometabolic risk factors. Systematic somatic screening and lifestyle promotion are the basis to assist persons with serious mental illness in improving their somatic health, including reducing cardiometabolic risk.

The use of eHealth tools is recommended for the effective implementation of the structured somatic screening and lifestyle promotion. However, only a small number of these applications are specifically tailored for use for patients with serious mental illness. Thoroughly testing of eHealth interventions for patients with SMI is also sparse. For the Dutch patients with SMI, the GILL eHealth has been developed. It is, however, currently unknown whether the nurse-led GILL eHealth intervention program is effective in improving physical

health and lifestyle behaviors.

Study objective

Primary objective (after 1 year)
- To evaluate the effectiveness of the nurse-led GILL eHealth intervention in patients with serious mental illness

Secundary objectives (after 1 year)
- Improve metabolic syndrome severity
- Improve fitness, physical activity, lifestyle behaviors, quality of life, recovery, psychosocial functioning health related self-efficacy, and health care utilization
- Obtain insight in feasibility and acceptability to implementation about the GILL eHealth intervention

Study design

This study is a cluster randomized controlled trial with a follow-up period of 1 year. To evaluate the effectiveness of the intervention, it will be compared to usual care. Eligible participants will be randomly allocated to the GILL eHealth or usual care. This multicentre study will recruit 258 participants from approximately 20 teams (FACT, supported housing or long-stay wards) across the Netherlands. Including inclusion of participants, analysis and reporting phase, the total duration of the study will be 48 months.

Intervention

The provided intervention is the nurse-led GILL eHealth. This eHealth contains two modules: OurGILL and MyGILL. OurGILL focuses on systematic somatic screening and provides an overview of all somatic abnormalities. MyGILL is about lifestyle behaviours and provides the basis for drawing up a personalized lifestyle plan.

Study burden and risks

With participating, patients have the opportunity to adjust their lifestyle, which can possibly improve their mental and physical health.

Burden: During this study, the participants will be assessed at three points in time (baseline, 6- and 12-month follow-up). A selection of participants will take part in qualitative interviews. Patients of the intervention group will form a lifestyle behaviour plan. The lifestyle adaptation can been seen as a bit of a burden.

Risks: There are no risks when participating in this intervention

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Diagnosis of schizophrenia, other psychotic disorder and/or disorders defined as serious mental illness according to Delespaul consensusgroup at Maastricht University
- Aged from 18 to 65 years
- Body mass index (BMI) >= 27
- Access and ability to use internet

Exclusion criteria

- Contra-indications (to be assessed by the threating physician/psychiatrist) for participation due to acute psychiatric crisis or severe somatic diseases
- Pregnancy or breastfeeding in women at the time of inclusion
- Subjects with a cognitive impairment sufficient to interfere with their ability to provide informed consent, complete study questionnaires, or participate in the intervention
- Subject not able to communicate in the Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-05-2024
Enrollment:	258
Type:	Actual

Medical products/devices used

Generic name:	GILL eHealth
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	05-04-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-02-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-06-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-10-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NCT05533749
CCMO	NL81729.029.22