An explorative and experimental study to assess the feasibility, acceptability, and effectiveness of early intervention with light, lifestyle and ImCT therapy in individuals at risk for severe mental illness

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

Summary

ID

NL-OMON53231

Source
ToetsingOnline

Brief title
Early intervention in people at risk for severe mental illness

Condition

- Psychiatric disorders NEC

Synonym
mood swings, prodromal symptoms of SMI

Research involving

Human

Sponsors and support

Primary sponsor: GGZ Eindhoven (Eindhoven)
Source(s) of monetary or material Support: GGzE

Intervention

Keyword: Bipolar Disorders, Early intervention, Imagery focused cognitive therapy, Light and lifestyle therapy

Outcome measures

Primary outcome

Changes in the level of mood and anxiety symptoms, as well as circadian rhythm

and activity levels measured at multiple time points, will give insight into

potential effectivity and support the importance of future randomized

controlled trials (RCT). Also, experience sample monitoring (ESM), adverse

(side) effects, drop-out rates and qualitative review of therapy will provide

feasibility and acceptability outcomes.

Secondary outcome

n.a.

Study description

Background summary

Severe mental illnesses (SMI) distinguished as bipolar disorder and psychotic spectrum disorders, substantially impair patients' engagement in functional and occupational activities and severely limit social and societal functioning (GGZ Standaarden, 2022; NIH, 2022; NIMH, 2018). Based on the Dutch definition of SMI 1.7% of the national population suffers from an SMI (GGZ Standaarden, 2022). Despite this, time between first symptoms and accurate SMI diagnosis, can add up to more than 9.5 years in the case of bipolar disorders. For the psychotic spectrum, an early detection and intervention program (UHR) carried out by

special EDI-Teams already exists, and has been found effective in limiting the transition to SMI with fifty percent. For bipolar disorders, no such program exists. This raises the question whether prodromal and subclinical symptoms of this disorder can be detected earlier and if transition into SMI can be limited. In light of current studies into the at-risk mental state, and the current development towards a possible transdiagnostic model for early detection and intervention of SMI (CHARMS-categories; (Liu et al., 2022)), the current study aims to contribute to limiting the transition into bipolar disorder. As a disturbance in circadian rhythm, as well as mood and anxiety symptoms are risk indicators for SMI in general and bipolar in specific, the current study evaluates an early intervention program for individuals at risk for developing an SMI, with a focus on bipolar symptomatology.

Study objective

In the current study, the feasibility, acceptability and effectivity of a new add-on early intervention program for individuals at risk for the development of bipolar disorder is evaluated. This intervention program entails psycho-education, light and lifestyle therapy in combination with Imagery focused Cognitive Therapy (ImCT). The program aims to contribute to early intervention by focusing on subclinical mood swings, anxiety symptoms, circadian rhythm and lifestyle factors such as activity level. We hypothesize a relationship between this early intervention and a significant improvement in mood symptoms, anxiety, subjective and objective sleep factors and lifestyle variables. Also, the feasibility, acceptability and associations with clinical improvement of symptoms will be studied.

Study design

The present research proposal concerns an experimental design with staggered baseline, and follow-up. Also, we aim to explore the working mechanisms of early intervention in this form by daily measurements of symptoms.

Intervention

In this protocol, a personalized early intervention program (lifestyle psycho-education and ImCT; lifestyle psycho-education and ImCT + bright light therapy; lifestyle psycho-education and ImCT + blue-light blocking glasses) will be assessed. During the course of the study, all patients keep receiving their regular consultation with their healthcare professional (to advise, monitor, and if necessary, adjust medication and treatment plan). All intervention elements are currently care as ususal (CAU) in patients with a bipolar disorder diagnosis and will now be studied in a population at risk for this diagnosis.

Study burden and risks

Risks for patients in this study are minimal, since all intervention elements are supported by evidence-based guidelines and are CAU within GGzE. Similar interventions have been successfully tested and applied in feasibility trials for patients groups with a diversity of diagnoses. The results of these studies suggest that these interventions are well tolerated and received. Additionally, studies have shown that regular mood monitoring can be a contributing factor to mood stability (Miklowitz et al., 2012; van der Watt et al., 2020). All patients, being individuals at risk for SMI, have regular appointments with their healthcare professional to monitor medication use, mental and daily functioning. Also, people at risk for SMI with suicidal related thoughts are not more likely to act on these thoughts while participating in this study since the urge to act on suicidal thought does not increase after talking about these thoughts. Since people at risk for SMI might not yet have a diagnosis and treatment plan, the intervention offered might burden them in terms of commitment and travel time. However, expectation is that patients found to be at risk for SMI will already be following treatment or will be on the waiting list for treatment. The extra burden for patients at risk for SMI is the daily self-monitoring (ESM), that require them to complete a questionnaire (5-10 min) at three at equidistant time points, as well as carrying a movement monitoring device for multiple days and completing questionnaires at baseline, end of treatment and follow-up (30 minutes). Finally, patients will be asked to participate in one extra appointment at the end of the treatment program, for a single qualitative review about the intervention.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

Must be bound to start the early intervention program being evaluated Aged 16-35, or > 35 by indication of the patients* treating clinician Sufficient knowledge of Dutch or English language Ability to give informed consent Willing to complete daily monitoring throughout the duration of the study

Exclusion criteria

Any current or previous neurological disorder or organic brain disease. IQ < 70 estimated by clinician. Current severe substance or alcohol misuse impacting treatment (clinicians assessment).

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-08-2024
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	21-09-2023
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL83962.028.23