(Cost-) Effectivity of a personalized e-health intervention for patients with psychiatric disorders on waiting lists for treatment- a randomized controlled trial.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON57243

Source
ToetsingOnline

Brief title
The Wait time Study

Condition

- Other condition
- Mood disorders and disturbances NEC

Synonym
mental illness, psychological complaints

Health condition

en ook angststoornissen, aanpassingsstoornissen, persoonlijkheidsstoornissen, slaapstoornissen

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: eHealth, Mental Health, Outpatients, Randomized Controlled Trial

Outcome measures

Primary outcome

Difference in the slope of symptom severity change over time, measured by the Symptom Questionnaire-48, during the waiting period (between referral and intake) between the intervention group and the control group

Secondary outcome

Secondary endpoints are cost-effectiveness, quality of life, intake efficiency, effects on digital phenotyping, satisfaction and acceptability.

Study description

Background summary

Access to timely mental health care in the Netherlands has become increasingly challenging, with waiting times steadily increasing in recent years. Extended waiting times for treatment in mental health care can be harmful due to increased severity of symptoms, poorer treatment engagement and outcomes, reduced quality of life, and an elevated risk of self-harm or suicide. Existing literature suggests that unguided e-health interventions can be helpful and could provide rapid access to mental healthcare during the waiting period, without further burdening our healthcare professionals, facilities, or caregivers. We aim to enhance the effectiveness of this intervention through personalized allocation of e-health modules. We hypothesize that personalized e-health is not only more effective but also less costly from both healthcare

and societal perspectives compared to care as usual (CAU).

Study objective

The objective of this project is to test the clinical and cost effectiveness of utilizing the assessment of transdiagnostic dynamics of symptoms to provide a personalized e-health treatment intervention as an automated tool during the waiting list period before the psychiatric intake takes place. By implementing this approach, we aim to address the current gap in providing timely and effective interventions during the waiting period, ultimately improving patient outcomes and optimizing the utilization of mental healthcare resources.

Study design

A Randomized Controlled Trial (RCT) with two trial arms will be conducted: the intervention condition and the treatment as usual waiting list condition. Both trial arms will include repeated measures during the waiting period. Data will be collected by means of validated psychometric questionnaires. Psychometric questionnaires are completed at the moment of referral (baseline), and every month (for the e-health group) or every 3 months (for the TAU group) during the waiting time (for a maximum of 1 year), and at the moment of intake. Additionally, participants will be asked to install the Behapp app at the start of the study. This app will passively collect data from the participant's smartphone throughout the entire inclusion period (digital phenotyping). Participants in the intervention arm will gain access to a selection of modules that are available at the Therapieland website. Participants in the intervention condition will also be asked to complete a revised daily ecological momentary assessment (EMA) for a period of four weeks. The EMA data will assess the main trajectories of psychiatric symptomatology over time.

Intervention

The intervention arm will receive online access to a selection of existing online eHealth modules provided by Therapieland. Personalization will be achieved by employing both innovative and traditional methods to identify symptoms that are most influential for each individual patient, followed by tailored recommendations of eHealth modules.

Study burden and risks

The intervention group will undergo a monthly SQ-48 questionnaire (5 minutes) and the TAU group every 3 months, with an additional questionnaire (3 minutes) administered at the beginning and endpoint. The intervention arm will also be asked to complete a brief smartphone questionnaire daily (which takes approximately 2 minutes) through the m-Path app for the initial 4 weeks. The intervention arm benefits from timely access to e-health modules, which

could aid in understanding and self-management of symptoms. Data collected through daily EMA during the initial 4 weeks together with the results of the SQ-48 is used to select the modules fitting the specific symptom profile of the participant. Potential risks of e-health have not been extensively studied, but few and mild risks have been described in the literature. Thus, this study carries low burden and risk, with evidence suggesting potential benefits from the intervention.

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

A subject must:
- be referred to participating mental healthcare (GGZ) and awaiting intake
- be at least 18 years old

- provide written informed consent
- be able to read proficiently in the language the e-health module is offered in (i.e. Dutch, or English)

Exclusion criteria

- Participants who do not have access to a smartphone, tablet, computer, or laptop
- Participants who lack the necessary computer skills to complete e-health modules
- Patients referred to mental healthcare departments for psychotic disorders, bipolar disorders, mild intellectual disabilities, specialized eating disorder facilities or acute mental healthcare (*crisisdienst*)

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	31-03-2025
Enrollment:	408
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	24-01-2025
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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	NL87647.058.24