Increasing impact through technology: A randomized controlled trial to determine the effectiveness and cost-effectiveness of an innovative, data-supported, personalized treatment for anxiety and mood disorders.

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

Summary

ID

NL-OMON57147

Source
ToetsingOnline

Brief title
Innovative, data-supported, personalized treatment

Condition

- Other condition
- Anxiety disorders and symptoms

Synonym
Anxiety and depression

Health condition

angst en depressie

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Anxiety, Cost-effectiveness, Depression, eHealth

Outcome measures

Primary outcome

The primary endpoints are the effectiveness and cost-effectiveness of the DST.

The effectiveness of the DST will be measured by analyzing anxiety and

depression symptoms, general mental-health-related symptoms and functioning,

and quality of life. To determine the cost-effectiveness, we will look at the

costs related to the intervention, the use of healthcare resources (e.g., the

use of medication), and productivity losses.

Secondary outcome

- Acceptability of DST (CSQ-8)

- Feasibility of DST (usage data)

- Patient-centered care (therapeutic working alliance [WAI-SF], shared decision

making from patient perspective [collaboRATE survey]

- Patient empowerment [NEL]

- Client functioning (OMQ, SMQ)

Study description

Background summary

Mood and anxiety disorders affect 20% of adults and are among the top disorders causing health loss in the Netherlands. These two disorders harm the patient*s quality of life and lead to increasing work disability and absenteeism, resulting in high economic costs. Although therapy with evidence-based protocols is effective, not all clients benefit. The drop-out rate of therapy is high and recurrence and relapse are common. Moreover, clients are looking for modern ways of therapy, such as blended therapy - combining face-to-face sessions with online therapy or digital tools - or treatment supplemented with digital tool(s) such as a platform or app that allows them to take charge of their mental health issues in their own time and environment. The data-supported treatment (DST) through NiceDay is such a treatment concept, combining the smart use of technology with evidence-based interventions. NiceDay is a treatment platform for organizations and therapists offering personalized and accessible mental healthcare treatment for various mental health issues. The literature shows promising results regarding the effectiveness and efficiency of the DST. Preliminary data suggests that the DST is superior to usual care (UC) with reduced treatment time, but a rigorous scientific evaluation of both effectiveness and cost-effectiveness is lacking.

Study objective

The primary aim of the proposed study is to evaluate the effectiveness and cost-effectiveness of a DST for patients with anxiety and/or mood disorders in comparison to UC.
The secondary aims are: 1) to identify what works for whom by identifying potential moderators of treatment response to a DST for patients with anxiety and/or mood in comparison to UC, 2) to examine the acceptability of a DST, 3) to examine the feasibility of a DST, and 4) to examine whether the DST facilitates patient-centered care.

Study design

A multicenter randomized controlled superiority trial with two treatment arms, comparing the DST with UC in the Netherlands, with a 1-year follow-up. The study will use a concurrent mixed-methods approach, combining quantitative data from self-reported questionnaires and usage data (i.e., data on the utilization of various DST features), with qualitative data obtained through semi-structured interviews with patients and therapists.

Intervention

The DST is a new treatment concept for (digital) mental healthcare, made available by Niceday Healthcare Nederland B.V. NiceDay is a treatment platform for organizations and therapists offering personalized and accessible mental healthcare for various mental health issues. It is co-created with therapists and former patients and certified with ISO 27001 and NEN 7515. The platform consists of a NiceDay web portal for therapists and the NiceDay mobile application for patients. NiceDay includes the following features that therapists can provide to their patients: online communication via chat or (video) calls, an intervention toolbox, self-reported trackers, feedback questionnaires, administrative features, and other therapeutic resources. The DST treatment concept combines the use of the NiceDay features with evidence-based interventions and treatment principles: Cognitive Behavioral Therapy (CBT), Experience Sampling Assessment and Intervention (EMA/EMI), and feedback-informed treatment. The NiceDay features will enable therapists to apply EMA, EMI, and feedback-informed treatment principles in the patient*s treatment.

Study burden and risks

Regarding time investment, all participating patients will be asked to complete a set of questionnaire at baseline and 12, 24, 36, and 52 weeks after baseline (T0-T4). Filling out the questionnaires will take approximately 40-45 minutes per timepoint. Patients who have completed all the questionnaires (T0-T4) will receive a gift voucher worth 15 euro. In addition, a subsample of minimal 10 patients will participate in a semi-structured interview lasting approximately 45-60 minutes. They will be reimbursed with a gift voucher of 20 euro. A minimum of 5 therapists will participate in a semi-structured interview lasting approximately 45-60 minutes. They will be reimbursed with a gift voucher of 20 euro. No direct risks were reported in the three previous studies on the DST or came across while treatment centers used the NiceDay platform. Patients in both treatment arms will be treated by experienced therapists who will monitor their mental health during treatment and take precautions in case necessary. Hence, the risks related to the DST through NiceDay will be comparable to UC conform national guidelines. If the DST proves to be more effective compared to UC, participating patients can benefit from improved health outcomes.

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

• >= 18 years of age
• Main diagnosis of anxiety disorder (social anxiety disorder (300.23), panic disorder (300.01), agoraphobia (300.22), generalized anxiety disorder (300.02), other specified anxiety disorder (300.9), obsessive-compulsive disorder/hoarding disorder (300.3), and illness anxiety disorder (300.7)), and/or depressive disorder (major depressive disorder with single or recurrent episodes (296.20 - 296-36) and other specified depressive mood disorders (311))
• Being able to understand, read, and speak Dutch or English
• Having access to the internet and a smartphone

Exclusion criteria

• Known severe psychiatric comorbidity (e.g., psychosis, (severe) addiction that interferes with daily functioning, diagnosis of Bipolar Disorder I or II, eating disorder, Personality Disorders, traumatic brain injury, Intellectual Disability and/or General Medical Conditions with a life expectancy of less than one year)
• Severe or very severe level of Suicidality (preparing for suicide, recent suicide attempt)
• Having received psychological treatment in the prior 6 months for the same

anxiety or mood disorder (except for short-term treatment provided by POH-GGZ or student psychologist)
• Therapist judges that the patient is not suitable for receiving DST
• Not being able to complete the entire treatment at once (e.g., due to pregnancy).

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2025
Enrollment:	300
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	09-12-2024
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	NL87390.058.24