De NiceDay Smartphone App: "De pacemaker van de psychiatrie"

Gepubliceerd: 04-02-2019 Laatst bijgewerkt: 18-08-2022

We hypothesise that digital remote treatment for patients with major depressive disorder is effective in reducing symptoms.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23664

Bron
Nationaal Trial Register

Verkorte titel
Be Positive Be Interactive

Aandoening

Major Depressive Disorder

Ondersteuning

Primaire sponsor: PsyQ Parnassia Groep
Overige ondersteuning: Health~Holland

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The most important outcome measure of this study is “Speed of remission ”, which is a measure of the speed with which symptom reduction takes place as a result of the therapy. Since the costs of the applied interventions are known at the level of minutes, it is possible to

calculate the costs of remote digital therapy.

Toelichting onderzoek

Achtergrond van het onderzoek

Behavioral activation is an evidence-based effective treatment for unipolar depression. The patient is motivated to reach daily goals such as eat, sleep and social rhythms, adequate amounts of physical exercise, outdoor activities and emotional awareness. The effect of behavioral activation is comparable to that of Cognitive Behavioral Therapy (CBT).
Until now, patients were motivated to reach their activation goals by psychologists and psychiatrists within an office building, or even behind a desk. However, in our current digital era, we can use a smartphone application (app) that allows for the automation and intensification of behavioral activation. By using mobile communication technology, it is possible to relay the effects of behavioral activation directly to the patient, at the precise time and location that is most relevant to the problem at hand (this is called ‘direct feedback’). Direct feedback shortens the delay between the expression of certain (healthy) behavior and the (positive) reinforcement of that behavior. This reduces stimulus contingency and clarifies the relationships between certain types of behavior and the consequences of that behavior.
Because of this, we expect 'digital therapy' to show a greater efficiency and efficacy than behavioral activation as usual.

Objectives of the study:
- To investigate the clinical course of depressive symptoms during digital outpatient therapy and follow up, both within-patient and between patients.
- To provide a health economic evaluation for digital outpatient treatment in routine mental healthcare.
- To explore the association of patient characteristics and specific therapeutic components with clinical progression or outcome.
- To explore the patient-therapist interaction during digital outpatient treatment.

This study will be conducted at various settings within PsyQ and does not involve a multicenter trial.

Doel van het onderzoek

We hypothesise that digital remote treatment for patients with major depressive disorder is effective in reducing symptoms.

Onderzoeksopzet

1-3-2021: start of inclusion

Onderzoeksproduct en/of interventie

NA

Contactpersonen

Publiek

PsyQ
Rutger Goekoop

088 - 3573107

Wetenschappelijk

PsyQ
Rutger Goekoop

088 - 3573107

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Participants are eligible if they are/have:
- 18 years or older
- unipolar moderate to severe depressive disorder (criteria DSM-5);
- possessing a smartphone.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients cannot participate if they:
- do not speak Dutch;
- have incompetent skills to manage smartphone (applications);
- have severe psychiatric comorbidities, i.e. psychosis, personality disorders, intoxications / addictions (axis II);
- have severe physical comorbidities (axis III);

- have severe psychosocial and environmental problems (axis IV)
- use drugs or medication which interferes with the use of the smartphone application (i.e. cannabis, strong sedatives / pain killers, alcohol abuse)

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2021
Aantal proefpersonen:	150
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	04-02-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7494
CCMO	NL522562.058.15

Resultaten