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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23664

Source
Nationaal Trial Register

Brief title
Be Positive Be Interactive

Health condition

Major Depressive Disorder

Sponsors and support

Primary sponsor: PsyQ Parnassia Groep
Source(s) of monetary or material Support: Health~Holland

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Apart from psychometrics, we measure Quality Of Life and (to a limited extent) physical health parameters.

Study description

Background summary

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.

Study objective

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

Study design

1-3-2021: start of inclusion

Intervention

NA

Contacts

Public
PsyQ
Rutger Goekoop

088 - 3573107
Scientific
PsyQ
Rutger Goekoop

088 - 3573107

Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2021
Enrollment:	150
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	04-02-2019
Application type:	First submission

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
NTR-new	NL7494
CCMO	NL522562.058.15

Study results