A study on the effectiveness and efficiency of the NiceDay Smartphone Application in psychiatric patients with unipolar depression

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To examine whether indeed behavioral activation using the NiceDay smartphone app is more efficient and more effective in treating patients with unipolar depression than treatment as usual (TAU).

Ethical review	Approved WMO
Status	Will not start
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON47460

Source
ToetsingOnline

Brief title
NiceDay Efficiency Study

Condition

- Mood disorders and disturbances NEC

Synonym
Depression, mood disorder

Research involving
Human

Sponsors and support

Primary sponsor: Parnassia Bavo Groep (Den Haag)

Source(s) of monetary or material Support: Subsiidie van het Fonds Psychische Gezondheid / Mind

Intervention

Keyword: Behavioral activation, CBT, Cognitive Behavioral Therapy, Depression, Direct feedback, Effectiveness, Efficiency, Experience Sampling, NiceDay Smartphone application

Outcome measures

Primary outcome

The most important outcome measure of this study is *Speed of remission *, which is a measure of the speed with wich symptom reduction takes place as a result of the intervention. It is expressed a sthe area unbder teh curve that described symptom scores (on a depresison rating scale) versus time. Since the costs of the applied interventions are known at the level of minutes, it is possible to calculate the cost-effectiveness (efficiency) of NiceDay versus behavioral treatment as usual.

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 exercize, outdoor activities and emotional awareness. The effect of behavioral activation is comparable to that of Cognitive Bahavioral therapy (CBT), which is still the psychotherapy of preference for the treatment of unipolar depression. Behavioral activation, however, is much easier to perform and less costly than CBT.

Until now, patients were motivated to reach their activation goals by medical personell within an office building, or even behind a desk. NiceDay is a Smartphone application that allows for the automization and intensification of behavioral activation. By using mobile communication technology, it is possible to relay the effects of behavioral activation directly to the patiënt, 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 NiceDay activation to show a greater efficiency and efficacy than behavioral activation as usual.

NiceDay is unique in the sense that it uses the > 30 sensors that are part of every Smartphone to determine to what extent the user has reached his or her goals. This reduces the necessity of user input to a great extent, which makes NiceDay very user friendly. In that sense, NiceDay can be called the "Holter ECG of psychiatry", which attempts to identify problems of a patient's daily rhythm. Additionally, NiceDay is much like a pacemaker that corrects daily rhythms as soon as they appear to run out of control. NiceDay is therefore both a diagnostic and a therapeutic agent that enables patients to go anywhere they want and still carry their own professional coach with them.

Study objective

To examine whether indeed behavioral activation using the NiceDay smartphone app is more efficient and more effective in treating patients with unipolar depression than treatment as usual (TAU).

Study design

A prospective cohortstudy with a randomised, controlled (TAU) involving a 4 months' activation period (NiceDay activation <=> TAU) and a follow-up period of 8 months (the total daration of this study is therefore 1 year). Considering the nature of the intervention (Smartphone App) and the control condition (TAU), this study cannot be carried out in a (double)blinded fashion. This study will be conducted at various settings within PsyQ and does not involve a multicenter trial.

Intervention

NiceDay behavioral activation versus behavioral activation as usual, cross over.

Apart from behavioral activation, patients receive standard treatment for unipolar depression. This consists of a combination of pharmacotherapie

(provided by a psychiatrist) plus cognitive behavioral therapy (CBT) (provided by a psychologist with adequate CBT training).

Study burden and risks

Within the total timespan of this study (1 year), patients are asked to spend a total of 12-18 hours of time performing study-related procedures. The total number of visits to the outpatient clinic will be the same as that of treatment as usual (once every 2 weeks) up to a maximum of 12 visits, including follow-up. Patients are required to fill out a questionaire of 30 minutes at each visit. Risks for enrolled patiënts are considered minimal. The use of the Smartphone app is expected to convey minimal risk. No biomaterials will be sampled in these patients. There will be no physical examination. Chances of physical, physiological or psychological injury are considered minimal.

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

18-65 years old
Unipolar moderate-severe depression according to DSM-5 and MINI-PLUS
In possession of a Smartphone
Proposed treatment = Pharmacotherapy with CBT

Exclusion criteria

Insufficient command of the Dutch language
Insufficient command of the Smartphone
Comorbidity: Severe psychiatric disorders (personality disorders Axis II, addiction/intoxication)
Comorbidity: Severe medical conditions and physical disorders (Axis III)
Comorbidity: Severe psychosocial and environmental problems (Axis IV)
Use of medication that interferes with the use of NiceDay (severe sedatives for example)
Change of medication during treatment with behavioral activation

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:	Will not start
Enrollment:	187
Type:	Anticipated

Ethics review

Approved WMO Date:	23-12-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	05-09-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	26-09-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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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	NL52262.058.15