StayFine RCT: app-based anxiety and depression relapse prevention in adolescents

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22807

Source
Nationaal Trial Register

Brief title
StayFine

Health condition

Anxiety disorders, depressive disorders.

Sponsors and support

Primary sponsor: GGZ Oost Brabant
Source(s) of monetary or material Support: ZonMw; GGZ Oost Brabant; Accare; RINO Zuid; University of Groningen

Intervention

Outcome measures

Primary outcome

Time to anxiety and/or depressive relapse over 36 months as assessed by a semi-structured interview.

Secondary outcome

Descriptives / potential moderators:
demographics, nr of previous episodes, previous care, comorbidity

Secondary outcomes
Depressive symptoms, anxiety symptoms, global functioning, quality of life

Exploratory endpoints
daily means, fluctuations and inertia of affect, heart rate

Potential mediators
emotional regulation, beliefs, coping, activity, stress, sleep, flourishing, activity level

Serious adverse events (suicidal behavior, hospitalization, death) and core symptoms of anxiety and depression will be monitored every three months.

Study description

Background summary

The current study examines the effectiveness of the StayFine app for relapse prevention of anxiety or depressive disorders in youth using a randomized controlled trial. In addition, ecological momentary assessment (EMA) is used to explore fluctuations in emotions, psychological factors as predictor of the treatment effect and potential differential mechanisms of change. A total of 254 healthy youths recovered from an anxiety and/or depressive disorder, aged 13-21 years old, will be recruited for the study. Participants will be randomized to either 1) use the StayFine app exclusively for monitoring, or 2) use the StayFine app for monitoring and interventions supported by an expert patient. Stratification blocks are of random size and depend on previous episodes (1/2/3 or more) and previous treatment (yes/no). The intervention is based on the well-established Preventive Cognitive Therapy (PCT) and Behavioral Activation for relapse prevention for adults and adapted and supplemented for anxiety in adolescents. In both conditions adolescents monitor their symptoms five times in three years and feedback and treatment advice is given in case of relapse. The primary outcome will be time to relapse. Secondary outcomes are the level and course of anxiety and depressive symptoms, number of relapses and quality of life. In addition, potential working mechanisms of the intervention will be examined.

Study objective

A guided app-based modular intervention (monitoring + intervention) is more effective than monitoring only in preventing relapse of anxiety and/or depression (in terms of time to relapse) in recovered youth aged 13 – 21 years up to three years follow-up.

Study design

Eligibility screening

T0; baseline

T1; post-intervention

T2; 12-month follow-up

T3; 24-month follow-up

T4; 36-month follow-up

In addition, a short screener for core symptoms of anxiety and depression is administered every three months and once extra after the first month.

Intervention

Monitoring: Ecological Momentary Assessment (EMA) of affect and activity level. Six times per day for two weeks.
Timepoints: T0-T4.

Intervention: StayFine guided app-based modular intervention. Each individual receives six of eight modules of which three are mandatory and three others are selected based on a personalization procedure. The intervention is based on Preventive Cognitive Therapy (PCT) with elements of Cognitive Behavioral Therapy (CBT) and Positive psychology. Modules are: psycho education (mandatory), cognitive restructuring (mandatory), positive affect, behavioral activation, exposure, wellness, sleep and a relapse prevention plan (mandatory). A chat group with peers, guided by an expert patient (EP) counselor, is part of the intervention as well.
Time point: after T0.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria at entry of the study:
- Age 13-21 years
- Adolescents who do NOT meet criteria of a current anxiety disorder (separation -, social – or generalized anxiety disorder, specific phobia, panic disorder, agoraphobia) or depressive disorder (major depressive -, persistent depressive -, disruptive mood dysregulation disorder or other specified depressive disorder) based on a semi-structured diagnostic interview (SCID-5 or SCID-junior), but DO meet the criteria for at least one PREVIOUS episode of one or the combination of the above mentioned disorders

Exclusion criteria

A potential subject who currently meets criteria of any of the following mental health problems will be excluded from participation in this study:
- alcohol or drug misuse
- previous hypomania and/or mania
- bipolar disorder
- previous and/or current psychotic episode

Other exclusion criteria include:
- only in remission of another anxiety or mood disorder than mentioned above at the inclusion criteria, namely premenstrual dysphoric disorder, depressive disorder due to another medical condition, substance/medication-induced depressive disorder, unspecified depressive disorder, selective mutism, substance/medication-induced anxiety disorder or anxiety disorder due to another medical condition, other specified anxiety disorder, unspecified anxiety disorder, and only in remission of PTSD or OCD and any other mental health disorder
- ongoing current treatment (more than twice a month) for a mental health disorder other than the disorders listed under the inclusion criteria.
- no or insufficient mastery of the Dutch language.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	16-12-2019
Enrollment:	254
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	15-12-2019
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	NL8237
Other	Medical Ethical Testing Committee Utrecht : 19/093; NL67637.041.19

Study results

Summary results
n/a