

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

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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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22807

Bron

Nationaal Trial Register

Verkorte titel

StayFine

Aandoening

Anxiety disorders, depressive disorders.

Ondersteuning

Primaire sponsor: GGZ Oost Brabant

Overige ondersteuning: ZonMw; GGZ Oost Brabant; Accare; RINO Zuid; University of Groningen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria at entry of the study:

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- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland
Status: Werving nog niet gestart
(Verwachte) startdatum: 16-12-2019
Aantal proefpersonen: 254
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: 15-12-2019
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
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NTR-new	NL8237
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Ander register Medical Ethical Testing Committee Utrecht : 19/093; NL67637.041.19

Resultaten

Samenvatting resultaten

n/a