StayFine: a personalized monitoring and intervention app to prevent relapse of anxiety and mood disorders in youth and young adults

Published: 19-06-2019
Last updated: 07-03-2025

To prevent or postpone relapse of anxiety and depression in youth and young adults, with StayFine; a guided app-based modular intervention. Secondary objectives are to explore the effect on other relevant outcomes and to study potential moderators...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48325

Source
ToetsingOnline

Brief title
StayFine: relapse prevention of anxiety and mood disorders in youth

Condition

- Other condition
- Mood disorders and disturbances NEC

Synonym
Blue, fear

Health condition

angststoornissen en -symptomen

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Adolescents, Anxiety, Depression, Relapse Prevention

Outcome measures

Primary outcome

The primary outcome is time to relapse over 3 years (that is, cumulative incidence of anxiety and/or depression relapse) in the intervention condition in comparison to the control condition, based on a semi-structured clinical interview (K-SADS).

Secondary outcome

Secondary outcomes are number of relapses, reduction of anxiety or depressive symptoms, and comorbid symptomatology and quality of life. Potential working mechanisms of the intervention will be examined; change in emotional regulation, beliefs, coping, activity, sleep, coping, flourishing, daily means, fluctuations and inertia of affect and activity level and heart rate. In addition, pre-treatment daily emotions and fluctuations will be examined as predictor of the treatment effect and subsequent time intervals of two weeks will be used to explore transition points to resilient stages versus relapse and potential differential mechanisms of change.

Study description

Background summary

Anxiety and depressive disorders are the most common mental health disorders and are associated with large impairment in current and lifelong functioning and increased suicide risk, even more so in youth. Many youths and young adults with anxiety or depressive disorders continue to experience new episodes into adulthood, resulting in high personal and societal costs both in adolescence and adulthood. As an estimate, 60% of adolescents relapse within three years after an episode of an anxiety or depressive disorder. If this relapse can be prevented, the chronic course of these disorders into later adolescence and adulthood may be broken. However, relapse prevention is hardly studied in youths internationally, and, to date, there is no intervention available for adolescents in the Netherlands. It is hypothesized that less youth will relapse over the course of three years after using a guided app-based modular intervention (monitoring + intervention) over the course of three years, as compared to youths that only monitor their symptoms with the app.

Study objective

To prevent or postpone relapse of anxiety and depression in youth and young adults, with StayFine; a guided app-based modular intervention. Secondary objectives are to explore the effect on other relevant outcomes and to study potential moderators of treatment outcome. Additionally, potential pretreatment daily affect, fluctuations of affect, and inertia of affect will be explored and the acceptability of the intervention including monitoring will be established.

Study design

A randomized controlled trial comparing the guided app-based modular StayFine intervention (monitoring + intervention) to monitoring only.

Intervention

The guided app-based modular StayFine intervention consists of eight modules, of which three are mandatory and three others are assigned based on a personalization procedure. The intervention is based on the well-established Preventive Cognitive Therapy (PCT) for relapse prevention for adults and adapted and supplemented for anxiety in adolescents. The PCT modules consist of psycho education, cognitive restructuring, positive affect and a relapse prevention plan. The following modules were added to PCT; behavioral activation, exposure, wellness and sleep. An app-buddy can be included to provide support. In both conditions adolescents monitor their symptoms five

times in three years and feedback and treatment advice is given in case of relapse. In the control condition only monitoring takes place.

Study burden and risks

There are minimal risks associated with this trial, the only conceivable but negligible risk is violation of privacy as patient data are transmitted over the internet. However, the assessments will be made as secure as possible and meet the quality criteria of the Dutch norm NEN7510.
There is some degree of burden because monitoring at baseline and follow up takes up some time. Participants will receive reminders through email or the app to adhere to the monitoring. Also the participants that choose to use the wearable, will wear the wearable that looks like a watch. We expect this to be a small burden, especially if participants also wear a watch on the other arm; however the other study procedures are low-threshold because they can be done via the participant's phone or computer. Also, the expected therapeutic effect, to prevent relapse, is considered as a possible benefit for the participant in both the monitoring and intervention condition. Therefore, we think the small burden and minimal risk are justified in this study.

Contacts

Public
Universiteit Utrecht

Gezondheidslaan 65
Oss 5342 JW
NL
Scientific
Universiteit Utrecht

Gezondheidslaan 65
Oss 5342 JW
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)

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 of 13-21 years
- Daily access to a mobile phone with iOs or Android software
- Adolescents do NOT currently 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 (K-SADS), 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 PTSD or OCD, or 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, unspecified anxiety disorder, other specified anxiety 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
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-01-2020
Enrollment:	254
Type:	Actual

Medical products/devices used

Generic name:	StayFine app
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	19-06-2019
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	06-12-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	24-02-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	30-09-2021

Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	25-02-2025
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL67637.041.19