Boost My Mood. Pilotstudy of a m-health application for youngsters with depressive symptoms or depressive disorders.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON45983

Source
ToetsingOnline

Brief title
Boost My Mood.

Condition

- Mood disorders and disturbances NEC

Synonym
Depression, Mood Disorder

Research involving
Human

Sponsors and support

Primary sponsor: Trimbos-instituut

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: adolescents, depression, mobile health application, young adults

Outcome measures

Primary outcome

The primary study outcome is depression. Depressive symptoms are assessed with a Dutch translation of the Inventory of Depressive Symptoms-Self-Report (IDS-SR; Rush et al., 1986, 1996). This survey has 30 items which measure depressive symptoms in the last seven days.

Secondary outcome

The Boost My Mood (BMM) app is an application for smartphones with which youngsters are able to work towards decreasing their depressive symptoms. The BMM app has four themes: better mood, better sleep, less rumination, and less stress. For each theme, the app provides tips, psycho-education, and exercises (derived from interventions proven effective) and testimonials (based on interviews with youngsters). Also, the app provides a diary for daily self-monitoring, via which youngsters can monitor their symptoms. In the dairy, the youngsters evaluate their experienced mood, quality of sleep, amount of rumination and stress with a mark. The diary also provides an opportunity to monitor (social) activities that have been undertaken. All diary input is summarized in an overview, via which the youngsters gain insight into whether certain themes of app content contribute to a decrease in their symptoms. The app also sends positive and encouraging notifications and push-messages, provided that the youngsters agreed to receive these messages. The goal of

these messages is e.g. to stimulate app use, to stimulate completing exercises that have been started, and to provide feedback.

The primary study outcome is depression. Depressive symptoms are assessed with a Dutch translation of the Inventory of Depressive Symptoms-Self-Report (IDS-SR; Rush et al., 1986, 1996). This survey has 30 items which measure depressive symptoms in the last seven days.

In addition to items tapping into depressive symptoms, the survey will contain questions about sleep, ruminations, anxiety and stress.

Sleep will be assessed with a Dutch translation of the Glasgow Sleep Effort Scale (GSES; Broomfield & Espie, 2005). The GSES has 7 items which measure the extent to which youngsters worry about their sleep.

Rumination will be assessed with a Dutch translation of the Penn State Worry Questionnaire (PSWQ; Meyer et al., 1990; van Rijsoort et al., 1997). The PSWQ is a self-report to measure one*s inclination to ruminate. The survey has 16 items tapping into the amount, intensity and loss of control over rumating.

Experienced stress will be assessed with a Dutch translation of the Perceived Stress Scale (PSS; Cohen et al., 1983). The PSS has 14 items which measure the extent to which youngsters experienced stress in the last month.

Anxiety will be assessed with the state-anxiety scale of the Dutch Zelf-Beoordelings vragenlijst (Self-evaluation questionnaire; Van der Ploeg, 2000). The state-anxiety scale has 20 items which assess the amount of experienced anxiety during a specific moment.

Study description

Background summary

Nearly one out of five Dutch persons between 18 and 65 years old has been depressed at least once. A depression leads to a person not or hardly being able to function in daily life. Depressions often follow a recurring pattern: more than half of the people with depression experiences another depression later on. Most depressions develop during adolescence. Therefore, it is highly important that depression in adolescents is recognized and treated early, and that relapse is prevented. These efforts will have a positive influence on the course of the depression and will decrease the likelihood of another episode.

Unfortunately, most adolescents with depression do not currently receive treatment. They only turn to treatment when they have severe problems. Youngsters have little trust in regular treatment and they prefer to deal with their problems independently, by themselves. Also, available treatments do not always fit the needs of the youngster, leading to them terminating the treatment prematurely. New and easy accessible forms of treatment are therefore warranted. Mobile-health (m-health) provides youngsters the opportunity to deal with their problems individually. In the current era, in which information and communication is increasingly digitally provided, integrating m-health in the current range of treatment and prevention programs is a logical step.

In the current project, an app has been developed for youngsters (16-21 years old) with depressive symptoms or depressive disorders. With the app, these youngsters will work independently towards decreasing their symptoms. This newly developed app will be implemented and evaluated in three different phases within the chain of care: as early intervention, as intervention for youngsters placed on waiting lists to receive treatment for depressive disorders, and as a relapse prevention intervention.

Study objective

The purpose of the overall project is to adapt an existing self management tool for adults to the needs of young people and how to implement the adapted app within the youth mental health. The overall project consists of three different phases with own sub-goals:

Phase 1: making the app suitable for young people
1.) To determine the main complaints and determinants of depression in young people
2.) To determine the goals of the adapted app for youth
3.) To Determine the extent to which the existing app meets the needs of young people
4.) Customize the app to the needs of young people

Phase 2: setting up implementation strategy
1.) To determine which people have a role in the implementation of the adapted app in three different phases of the treatment trajectory (early intervention, addition to the treatment and relapse prevention)
2.) Setting implementation goals in the three different stages of the treatment trajectory
3.) Drafting implementation plans for the three different stages of the treatment trajectory
4.) To develop implementation tools.

Phase 3: test implementation and pilot research
1.) To implement the adapted app in three different phases of the treatment trajectory (early intervention, addition to the treatment and relapse prevention)
2.) To determine the quality of implementation and to identify areas for improvement in the implementation process for future consolidation and upscaling.
3.) To determine the usefulness and efficacy of the app

Study design

Ad fase 3, objective 2: A process evaluation
Ad fase 3, objective 3: A naturalistic evaluation study (pre-test and two post-test measurements, after 1 and 3 months with 60 youngsters who have used the app as early intervention and as relapse prevention intervention), and a stepped-wedge study (30 youngsters start using the app 1, 2 or 3 weeks after being placed on a treatment waiting list)

Intervention

The Boost My Mood (BMM) app is an application for smartphones with which youngsters are able to work towards decreasing their depressive symptoms. The BMM app has four themes: better mood, better sleep, less rumination, less stress. Each theme consists of several parts: a diary (self-monitoring) via which youngsters can monitor their symptoms, background information about depressive complaints and tips to address these complaints (psycho education), several methods derived from the principles of cognitive behavioral therapy and other evidence based interventions, stories based on the experiences of youngsters with depressive symptoms (recognition and support), and testimonials from real life characters to encourage the user to try out exercises (modeling) and tips of other users of the app.
Thus, the app is used for the prevention, monitoring and relief of an illness (in this case a depressive disorder). This means that the app is consistent with the definition of a medical device, as described in the Dutch Wet op de medische hulpmiddelen.

Study burden and risks

Participants are requested to use the app for at least four weeks. Beneficial effects of the app on mood, sleep, rumination and stress are expected. The youngsters themselves decide which parts of the app they use and intensity of use. The part of the study in which youngsters use the app as early intervention or as relapse prevention intervention includes one pre-test and two post-test measurements (online surveys). Completing these surveys will take about 35 minutes. The youngsters who use the app while being placed on a waiting list, complete four questionnaires: one pre-test and three measurement during the period of app-use. In addition, youngsters are asked daily to evaluate the severity of depressive symptoms on a visual scale. In all cases, the BMM app will be introduced to youngsters by a (mental) health professional. Youngsters can turn to these professionals in cases of an increase in depressive symptoms. In the case the self-monitoring tool, the diary, shows that the youngster is not doing well, the app sends out an automatic notification with an advice to contact the (mental) health professional. Youngsters with an acute suicide risk will excluded.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-16-21 years old
-Depressive symptoms (early intervention), depressive disorder (waiting list) or completed treatment of depressive disorder (relapse prevention);
- Signed Informed Consent form
- Ability and willingness to download the app on a personal mobile device
- Ability and willingness to use the app
- Ability and willingness to participate in the study

Exclusion criteria

-Severe depressive symptoms (exclusion for the early intervention group),
-Suicide risk

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2019
Enrollment:	90

Type:	Actual

Medical products/devices used

Generic name:	Boost My Mood
Registration:	No

Ethics review

Approved WMO Date:	25-07-2018
Application type:	First submission
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	NL65545.041.18