"Beat-It: A pilot study on the practicality and effectiveness of a m-health application in improving emotion regulation in adolescents with externalizing disorder. "

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Impulse control disorders NEC
Study type	Interventional

Summary

ID

NL-OMON40187

Source
ToetsingOnline

Brief title
Beat-It

Condition

- Impulse control disorders NEC

Synonym
ADHD, Conduct Disorder

Research involving
Human

Sponsors and support

Primary sponsor: Yulius
Source(s) of monetary or material Support: Yulius & Lucertis

Intervention

Keyword: Adolescents, Disruptive disorder, Emotion regulation, M-Health

Outcome measures

Primary outcome

Primary study parameters are self-reported behavioural problems and

self-reported maladaptive emotion regulation strategies.

Secondary outcome

Secondary parameters are psychological problems and functioning of the

individual.

Study description

Background summary

Difficulties in emotion regulation in adolescents with the externalizing disorders ADHD , ODD and / or CD forms a basic problem. In these adolescents is often a chronic vulnerability: they react quickly and violently on emotional stimuli and their arousal will slowly return to the basic level. As a result, adolescents experience the feeling of being overwhelmed by emotions and do not know how to deal with its intensity. For many adolescents are this disruptive experiences, accompanied by mood swings, problems in self-control, impulsivity, and in some cases self-injury (Appelo - Wichers , Appelo , & Bos , 2008). To cope with this intense and overwhelming emotions Beat -It is developed. Beat -it is a smartphone application that can help adolescents with aggression problems to reduce their stress and agression (Bruil , 2011). With Beat -It adolescents positively influence their own performance without the presence of a therapist, independently and on their own strength. When they feel that their tension increaes and potentially can lead to an aggressive outburst, they may benefit from playing Beat It.

Study objective

The aim of present pilot study is to evaluate the effects of the use of the Beat-it app for adolescents with an externalizing disorder and emotion regulation problems.

The two central research questions of this study are the following:
1. Will self-reported behavioural problems of adolescents take off in the period that they use beat it?
2. Will the use of self-reported maladaptive emotion regulation strategies take off in the period that adolescents use Beat-it?

Study design

The design of this pilot study consists of an open random pre-post treatment design with a waiting list condition. All children who are enrolled received the intervention, or immediately, or at the end of the waiting period of 8 weeks.

Intervention

The intervention consists of the use of the application for a period of 8 weeks. The frequency of use will depend on the degree of need from the participant. During the intervention there will be monitoring adolescents. A telephone questionnaire regarding use of the application and state of mind of the participant will be taken weekly. In total there will be eight times of (short) telephone contact during the intervention period.

Study burden and risks

No risks are expected for the participating adolescents .

Use of Beat-It:
The average time investment will depend on the frequency of use by the adolescent. For 8 weeks, the application will be used as often as required by the participants. For each use the time investment will be between 5 minutes and 10 minutes .

Intervention:
At the start of the study the clients who have indicated that they are interested in participating will be contacted by telephone. During this telephone call they receive additional information and any questions will be answered. If the client is interested and has agreed to participate an appointment for the T0-measurement will be made directly. This telephone call will take about 30 minutes. During the T0-measurement a number of questionnaires will be filled in by both the adolescent and the parents with a duration of about 60 minutes. For the intervention group, the 8 -week intervention can be started. For the waiting list condition there wille be 8

weeks in which they receive their treatment as usual. Furthermore, a telephone questionnaire regarding use of the application and state of mind of the participant will be taken weekly with a duration of 15 minutes. After 8 weeks of intervention there will be a post-test (T1) in which all measurements of T0 are repeated with an added satisfaction questionnaire for adolescents. The duration of the post-test wil beabout 75 minutes for the adolscent and about 60 minutes for the parents.

Expected profit to reduce aggression problems independently, reduction of tension and aggression and achieve better emotion regulation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

1. All adolescents included in the study will be from 12 to 18 years of age.
2. All adolescents must have an official DSM-IV diagnosis ADHD, ODD or CD.
3. Adolescent are in the possesion of a smartphone with an Android based operating system. Suitable smartphones are made by Samsung, HTC, Huawei, Motorola, LG, Sony Ericsson en Acer. For a complete overview of suitable smartphones please check appendix K6 of the protocol.

4. Minimum total intelligence score must be 70. If the total intelligence score is not known, had been established by a non-COTAN approved test or has been performed more than to years previous to the start of the intervention, total intelligence score will be established using the short version of the Wechsler Intelligence Scale for Children third version (WISC-III-NL, Wechsler, 2005) for the adolescents younger than 16 years. If the adolescent is 16 years of age or older, the total intelligence score will be established using the short version of the Wechsler Adult Intelligence Scale * fourt edition * Dutch version (WAIS-IV-NL, Wechsler, 2012).
5. Both adolescents and at least one of the parents/legal guardians must have a reasonable understanding of the Dutch language.
6. Adolescents can only be included after a written informed consent has been signed by both parents or legal guardians and adolescents. It is important that parents and adolescents understand the information and are able to fill out the consent form.
7. During the intervention all medication used by the adolescent is permitted.
8. A score within the clinical range of the SDQ (parent version) has to be met.

Exclusion criteria

1. Adolescent with Axis-I disorders other than the discribed disorders will be excluded.
2. Adolescent who are not in the posession of or do not have acces to an android based smartphone can not be included.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-04-2014
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	25-03-2014
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

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	NL47331.101.14

Study results

Date completed:	01-04-2017
Actual enrolment:	26

Summary results

Trial is onging in other countries