

***How do you Feelee?* Does an ordinary question a day supports youth in a forensic outpatient setting to become more emotional balanced?**

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Ethical review	Approved WMO
Status	Completed
Health condition type	Personality disorders and disturbances in behaviour
Study type	Interventional

Summary

ID

NL-OMON54390

Source

ToetsingOnline

Brief title

How do you Feelee?

Condition

- Personality disorders and disturbances in behaviour

Synonym

mentale problemen., Psychische en- of psychiatrische problemen

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Kwaliteit Forensische Zorg- Jeugd (KFZ-J)

Intervention

Keyword: adolescents, delinquent behavior., digital phenotyping, Emotion regulation, smartphone data

Outcome measures

Primary outcome

The primary outcome measure is self-reported emotion regulation of the adolescent that is measured by a short daily questionnaire during the baseline, intervention and follow-up phases.

Secondary outcome

The secondary outcome measures aim to get more insight in the working factors of the Feelee app in addition to TAU. Specifically, we focus on: emotional differentiation, self-reflection and awareness. In addition, treatment motivation and treatment relationship are included as treatment factors in the study. The secondary outcome measures are measured by pre- (T0), post- (T1) follow-up (Tf1) and a follow-up measurement 3 months after the end of the baseline phase (Tf2).

Study description

Background summary

Adolescents who frequently come in contact with the police and the judicial system often exhibit mental problems that manifested itself in delinquent behavior and internalizing problems (Frick & Marsee, 2005; Moffit, 1993, 2006, 2018; Ogloff et al., 2015). Treatment of these adolescents in the forensic outpatient youth care is complex. Not only the demand for help: adolescents who exhibit delinquent behavior often have, besides individual problems, also problems within the family, at school or at work (van Duin et al., 2017). In

addition, in practice, treatment often does not get off ground, because motivation for treatment among adolescents is very low and the treatment often depends on the treatment alliance between the adolescent and therapist (Carl, Schmucker & Lösel, 2020; Cullen et al., 2011).

Looking at existing treatments in forensic outpatient youth care, the common thread in treatments appears to be aimed at regulating emotions and thereby teaching adolescents skills to prevent future delinquent behavior (Day, 2009; Modecki, Zimmer-Gembeck & Guerra, 2017). However, in treatment practice, it appears that adolescents with delinquent behavior have great difficulty in recognizing, understanding and reflecting on emotions which are important steps in regulating emotions. The addition of the Feelee app to treatment as usual (TAU) in forensic outpatient care can support adolescents in this. Indeed, the Feelee app allows adolescents to keep track of emotions several times a day by using emojis (active data). In addition, the Feelee app collects data on the number of steps and hours of sleep per day (passive data). Separately and combined, the active and passive data provide great insight into emotions and underlying behaviors of the adolescent.

An initial exploration with the Feelee app in forensic outpatient treatment practice shows positive results: Feelee supports (1) adolescents to make sense of their emotions and underlying behaviors and (2) in treatment to have an approachable conversation about emotions and underlying behaviors (e.g., movement and sleep/wake rhythms). This study serves as an initial impact study to gain more insight into the workable factors of applying the Feelee app to TAU in the forensic outpatient setting. The focus is on emotion regulation as a common thread of treatments, specifically looking at the extent to which Feelee for adolescents contributes positively to recognizing, differentiating, reflecting on and on emotions. In addition, we will investigate whether Feelee can also be a supporting factor in increasing treatment motivation and strengthening the treatment relationship in treatment.

Study objective

The aim of the study is to gain more insight into the working factors of the Feelee app as a supportive tool to TAU in forensic outpatient settings. We examine whether the daily tracking of emotions by means of emojis together with the collected data on number of steps and hours of sleep per day in addition to TAU contribute effectively to improving emotion regulation in adolescents. We will also examine whether adolescents show progress on the underlying emotion regulation factors. Specifically, differentiating, reflecting and emotional awareness. Finally, we examine whether the use of the Feelee app to TAU also has a positive influence on the treatment motivation and treatment alliance. By studying both emotion and treatment factors, the study aims to contribute in an innovative way to improving existing treatments for adolescents who exhibit high levels of delinquent behavior.

Study design

This study involves a Single Case Experimental Design (SCED), which examines the application of the Feelee app to TAU on emotion and treatment factors. In the design participants will follow a 14-day baseline period in which various measurements take place in the form of a pre-test and daily questionnaire, but participants do not yet use the Feelee app. After the baseline phase, the intervention phase follows in which participants use the Feelee app daily for 4 weeks and discuss the outcomes in the overview with their therapist in their weekly treatment session. In addition, participants complete a short daily questionnaire. After 4 weeks of the intervention phase, a follow-up phase of 14-days will follow in which the short daily questionnaire will be continued, but participants will no longer use the Feelee app. Also, a post-measurement will take place after completion of the intervention phase and a follow-up measurement will take place after completion of the follow-up phase. The total duration of the study for participants, will be 8 weeks. For all participants, a one-time follow-up measurement will take place after 3 months after completion of the baseline phase.

Intervention

The intervention involves the application of the Feelee app to TAU. Participants will use the Feelee app for 4 weeks during the intervention phase. This includes (1) filling in daily an emoji that describes their emotion at that moment and (2) discussing the active emoji data and passive data (number of steps and hours of sleep per day) during the weekly treatment session. Treatment providers will receive a handout for this purpose that includes guidelines and examples about how the data can be discussed in treatment.

Study burden and risks

For participants the duration of this study is 8 weeks. Furthermore, a one-time follow-up measurement after 3 months will be conducted. During the baseline period (8 weeks), participants complete a short daily questionnaire. This takes a maximum of 5 minutes. In addition to the short daily questionnaire, participants will be asked to complete an extensive questionnaire as a pre-, post, follow-up and follow-up measurement. The duration for completing the extensive questionnaire will be around 45 minutes. In addition to the extensive questionnaires, during the follow-up (Tf1) and follow-up measurement after 3 months (Tf2) an interview with the participant will be conducted to get experiences of the adolescent regarding the use of the Feelee app for the further development of the Feelee app and possible treatment protocols. The entire interview is expected to take 30 minutes. Finally, during the intervention phase, participants will be asked to use the Feelee app for 4 weeks on a daily basis. This requires participants to fill out an emoji at least once a day. For the passive data (number of steps and hours of sleep per

day) the participant does not have to do anything. Participants receive appropriate compensation for their efforts in the form of a voucher. Finally, no risks are anticipated for participants that can be attributed to participation in this study.

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)

Inclusion criteria

- Adolescents aged between 12 and 23 years old
- At the time of the study in treatment at a forensic outreach youth care organization.
- Expected to be in treatment for at least another 3 months.
- Possess a smartphone with Android or IOS operating system.

- Have basic understanding about the use of a smartphone

Exclusion criteria

- Adolescents with serious psychiatric problems, such as psychosis or high risk of suicide
- Insufficient understanding of spoken and written Dutch language.
- Adolescents without a smartphone.

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Completed

Start date (anticipated): 03-08-2023

Enrollment: 24

Type: Actual

Medical products/devices used

Generic name: Feelee app

Registration: No

Ethics review

Approved WMO

Date: 13-04-2023

Application type: First submission

Review commission: METC Amsterdam UMC

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	NL78889.029.22