Self-management of daily and acute stress in real-time for individuals with a psychiatric disorder

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Ethical review	Approved WMO
Status	Pending
Health condition type	Psychiatric disorders NEC
Study type	Interventional

Summary

ID

NL-OMON49351

Source
ToetsingOnline

Brief title
Self-management of daily and acute stress

Condition

- Psychiatric disorders NEC

Synonym
psychiatric disorder

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Centraal (Amersfoort)
Source(s) of monetary or material Support: zorgondersteuningsfonds overgebleven pensioengelden van de Stichting de Open Ankh

Intervention

Keyword: E-health, Psychiatric Disorder, Self-management, Stress

Outcome measures

Primary outcome

The main study parameters/endpoints in the effect evaluation are: perceived

acute and daily stress levels (and patterns over time), stress coping

behaviours and quality of life.

Secondary outcome

not applicable to this study

Study description

Background summary

Psychiatric disorders are life-long disorders characterized by stigma (Holubova et al., 2019) and social and communication impairments (American Psychiatric Association, 2013). Patients with schizophrenia, depression, anxiety, personality disorders, bipolar disorder, depression and autism spectrum disorders (ASD) experience more stress than the general population (Connor et al., 2007; Ghorbani et al., 2008; Streit et al., 2016). This is partly due to more negative life events, less social support and les self-confidence (Faravelli et al., 2007; Goodyer et al., 1985; Pruessner et al., 2011). Patient with a psychiatric disorder are less able to deal with stress due to inadequate and ineffective coping strategies. Chronic stress also negatively affects the quality of life (Bishop-Fitzpatrick et al., 2018; Hong et al., 2016; Jepsen et al., 2019) and the course of the disorder (Chabungbam et al., 2007).
In short, there is a need for real-time support of people with psychiatric disorders in self-managing their stress in their daily life. Existing signalling schemes are not an adequate solution, because a lot of individuals with psychiatric disorders lack the capability to proactively act upon such schemes. There is a wide array of mental health applications available, but recent review studies showed that the majority of these apps lack scientific evidence about their efficacy (Byambasuren et al., 2018; Donker et al., 2013; Lui, 2017). For individuals with ASD, who need specific ways of communication and visualisation, multiple apps are available that help them engage in social contact and that offer ready-made or do-it-yourself visual schedules for daily

living tasks and time management (e.g. AutThere, Daymate, Psymate). However, none of the available digital tools developed for individuals with ASD focus on supporting proactive self-managing of stress in daily lives. Therefore, we developed the application SAM (Stress Autism Mate) in our former study. SAM is tailor made for patients with autism, since they have special needs for the feel and touch of the application. SAM was tested and used for four weeks and has been proven to reduce daily stress, to improve stress coping strategies and to improve the QoL of individuals with ASD, for the short and longer term. The SAM study participants were also more able to ask for help when needed. Because of the success of SAM, we want to do further research with SAM and research its possibilities. First the design and content (algorithms and communication) of the application will be further optimized and tailored to individuals using the application. Also, additional algorithms will be developed in which we combine data from different measurement moments to give more insight into individual stress patterns over time. This resulting new version of the app will be tested again among a group of individuals with autism. Second, feedback given by patients participating in our former study were the lack of the opportunity to signal and cope with acute stress moments. They were curious whether a wearable added to SAM could make a difference in their daily life stress and emotion regulation experience additionally to the already accomplished benefits of SAM. To do so, possibilities and limitations of adding physiological measurements to the prototype app SAM to be able to measure acute stress will be explored. To this end, an already existing wearable, to be determined, will be added to the use of SAM to detect acute stress using physiological measurements (e.g. heart rate, heart rate variability, of skin conductance) (Hufnagel et al., 2017; Kim et al., 2018). Finally, as part of this project, the application will be converted to be accessible for individuals with psychiatric disorders, like depression, schizophrenia, bipolar disorder, anxiety, personality disorder (e.g. stress signalling application, STAPP). The effectiveness of different functions of the application for individuals with different psychiatric disorders will be tested in this study.
The approach of SAM and STAPP is based on the positive health movement defining health not as the absence of illness but as the capability to cope with health impairments (Huber et al., 2011).

Study objective

The objective of the proposed project is to develop knowledge and algorithms that can be used in a mobile application combined with a wearable that supports individuals with ASD and other psychiatric disorders in self-managing their stress (daily and acute stress) in real time. And to investigate whether self-managing stress decreases perceived acute and daily stress, improves stress coping behaviours and quality of life for different psychiatric

conditions.

Study design

To evaluate the effectiveness of the adjusted SAM and the STAPP application, we use an aggregated single-case study design. We use this method to detect intra-individual effects of an intervention on behavioural change (Spreen et al., 2010). In this particular study, we are not only interested in whether the intervention works for a particular client but also whether its effect can be generalized on population level. In this aggregated single-case study, multiple cases or participants are involved and repeatedly measured over time (Shadish & Sullivan, 2011). *While group designs typically give information about the effect of a treatment on *an average case*, and single-case designs give information about the effect on a specific case, a set of single-case studies combines the strengths of both designs* (Van den Noortgate, & Onghena, 2015).

Intervention

A mobile application that supports individuals with a psychiatric disorder in self-managing their daily and acute stress. The applications will consist of three functionalities: monitoring, feedback, and advice. Using the application, individuals monitor their stress levels in real time, they receive feedback about their stress levels over the past days, and if needed receive advice on managing their stress. They also receive feedback and advice on acute moments of stress. The project aims to develop the knowledge and technology needed for this. The ultimate goal is to improve their functional performance and perceived quality of life.

Study burden and risks

A very important requirement for the success of this project is the participation of the target group. Without their active involvement in the study, we will not be able to develop an application that suits their needs and preferences and test the effectiveness and usability of the application.
A burden could be that individuals with psychiatric disorders and their families have to invest time into this project to get a tailor-made application. A risk may be that the individuals become more aware of the stressful things in their lives due to participation in this project. This could negatively affect their state of mind. On the other hand, involved individuals get direct access to tools to cope with this daily stress and the opportunity to improve their resilience and their coping strategies with respect to daily experienced stress. An algorithm is built in the application that urges individuals to contact their practitioner whenever stress levels are very high.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study a subject must meet the following criteria:
Having a clinical psychiatric diagnosis according to the DSM V: depression, anxiety personality disorder, obsessive compulsive disorder, autism spectrum disorder, psychotic disorder or bipolair disorder, an IQ above 85. Age above 18 years.

Exclusion criteria

IQ under 85

no understanding of the dutch language

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2020
Enrollment:	140
Type:	Anticipated

Ethics review

Approved WMO

Date:	02-09-2020
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL73308.028.20