Acceptance and potential clinical added value of Sense-IT in psychiatric patients with autism spectrum disorder and/or intellectual disability and/or borderline personality disorder: a proof-of-concept study.

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The main objective of the current proof-of-concept study is to explore the feasibility, acceptance and potential (clinical) added value of Sense-IT in a sample of psychiatric patients with ASD/ID/BPD and their psychiatric nurses.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Personality disorders and disturbances in behaviour
Study type	Observational non invasive

Summary

ID

NL-OMON50372

Source
ToetsingOnline

Brief title
Sense-IT in forensic psychiatric patients with ASD and/or ID and/or BPD

Condition

- Personality disorders and disturbances in behaviour

Synonym
and Intellectual disability; Mental retardation, Borderline personality disorder; Autism spectrum disorder; Autism

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Twente
Source(s) of monetary or material Support: GGNet in samenwerking met de Universiteit Twente.

Intervention

Keyword: Autism, Borderline personality disorder, Intellectual disability, Physiological reactivity

Outcome measures

Primary outcome

The main study parameters include the feasibility and acceptance of Sense-IT as

experienced by psychiatric patients with ASD/ID and/or BPD and psychiatric

nurses.

Secondary outcome

Secondary and tertiary parameters include:

- The potential (clinical) added value of Sense-IT in a sample of forensic

psychiatric patients with ASD/ID/BPD.

- The opinions of the participants (patients as well as staff) on the use of

Sense-IT and technology in general for improving clinical treatment.

Study description

Background summary

Disorders such as autism spectrum disorder (ASD), intellectual disability (ID) and/or borderline personality disorder (BPD) are prevalent disorders in psychiatric samples. Patients with ASD/ID and/or BPD are impaired in recognizing increases in their physiological emotional reactivity, and are

limited in their ability to cope with the emotional responses to stress that can result in challenging behaviours. The absence of treatments for improving and regulating emotional responses in ASD/ID and/or BPD is a major unmet clinical need. The use of wearable technology shows promise for improving recognition of physiological emotional reactivity and, thus, potentially reducing challenging behaviour. Therefore, the current study will explore the feasibility, acceptance and potential (clinical) added value of Sense-IT, a smartwatch application, in a sample of psychiatric patients with ASD/ID and/or BPD and their psychiatric nurses.

Study objective

The main objective of the current proof-of-concept study is to explore the feasibility, acceptance and potential (clinical) added value of Sense-IT in a sample of psychiatric patients with ASD/ID/BPD and their psychiatric nurses.

Study design

The current study is a proof-of-concept study in which Sense-IT is examined during inpatient psychiatric care at two sites of GGNet: FPA De Boog and Scelta. Sense-IT will be worn by participants during their therapeutic program and daily activities for the duration of two weeks.

Intervention

Sense-IT consists of one application for a smartwatch and a smartphone. The part on the smartphone serves as a diary. The part on the smartwatch displays heart rate as measured by the own sensors of the smartwatch on a scale of 1 to 5 dots. At first use, an individual baseline heart rate during rest is determined. If subsequently a significant change (e.g. > 5 beats per minute) in heart rate is registered, the user is informed by a vibrating signal and the addition of 1 dot. The smartwatch application serves as a monitor to become aware of the change in heart rate.

Study burden and risks

The risk for adverse events due to participation in this study is negligible, especially since Sense-IT is examined as a part of the inpatient treatment program and all patients are constantly monitored by forensic psychiatric nurses. Also, participation in this study is completely voluntarily, and participants can abort their participation at any time without any clarifications.

Contacts

Public
Universiteit Twente

Drienerlolaan 5
Enschede 7522 NB
NL
Scientific
Universiteit Twente

Drienerlolaan 5
Enschede 7522 NB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with ASD and/or ID
In order to be eligible to participate in this study, a subject must meet all of the following criteria:
1) is admitted to inpatient care at FPA De Boog, GGNet, Warnsveld
2) is diagnosed with ASD and/or ID according to DSM-5 criteria (APA, 2013)
3) is mentally competent and willing to participate in the study

Patients with BPD
In order to be eligible to participate in this study, a subject must meet all of the following criteria:
1) is admitted to inpatient care at Scelta, GGNet, Apeldoorn

2) is diagnosed with BPD according to DSM-5 criteria (APA, 2013)
3) is mentally competent and willing to participate in the study

Nurses
In order to be eligible to participate in this study, a subject must meet all of the following criteria:
1) is working at FPA De Boog, GGNet or at Scelta, GGNet

Exclusion criteria

Patients
A potential subject who meets any of the following criteria will be excluded from participation in this study:
1) is unable to read, speak or write the Dutch language
2) is using beta-blockers, Nurses
A potential subject who meets any of the following criteria will be excluded from participation in this study:
1) is unable to read, speak or write the Dutch language.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-11-2018
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	Sense-IT

Registration:	No

Ethics review

Approved WMO Date:	01-08-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	19-02-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 21447
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL65285.044.18
Other	NTR29261
OMON	NL-OMON21447
OMON	NL-OMON27963