Sense-IT in patients with borderline personality disorder

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21447

Source
NTR

Brief title
TBA

Health condition

Borderline personality disorder

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: GGNet

Intervention

Outcome measures

Primary outcome

Body awareness (MAIA-2)

Secondary outcome

Emotion regulation (DERS)

Study description

Background summary

The current study will examine the feasibility, acceptance and potential (clinical) added value of Sense-IT, an ambulatory biofeedback (heart rate based) application for smartwatch and smartphone, for patients with borderline personality disorder.

Study objective

1. Patients with BPD experience the Sense-IT as user friendly.
2. Patients with BPD accept the Sense-IT technology, measured in compliance and satisfaction.
3. Therapists are satisfied with the use of Sense-IT during treatment.
4. Sense-IT improves body-awareness in patients with BPD.
5. Sense-IT improves emotion regulation in patients with BPD.

Study design

The baseline duration will vary from 2 to 6 weeks over the participants, with participants randomly allocated to baseline lengths. The SENSE-IT intervention consists of 2 weeks. The last phase is a 2 weeks follow-up phase.

Intervention

The Sense-IT consists of an application with two sides:
1. The smartwatch side of the application displays heart rate as measured by the smartwatch internal sensors on a scale from 1 to 10. At first use, an individual mean baseline heart rate and standard deviation during rest is determined. Then a threshold criterion can be established for informing users of rising and falling heart rates (i.e. a change of .5, 1 or 1.5 times the standard deviation). The user is visually and (optionally) tactilely informed of this change via the watch. The smartwatch application serves as a monitor to become aware of the change in heart rate where changes are only indicated when subjects are not involved in medium to intense physical activity as measured with the on-board accelerometer.
2. The smartphone side of the application: after the smartwatch vibrated as a signal of a significant change in heart rate, the smartphone application serves as a diary that can be used to make notes about the change in physiological arousal.

Contacts

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Eligibility criteria

Inclusion criteria

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

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

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2021
Enrollment:	10
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	02-07-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50372
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9597
CCMO	NL65285.044.18
OMON	NL-OMON50372

Study results