Sense-IT in patients with borderline personality disorder

Gepubliceerd: 02-07-2021 Laatst bijgewerkt: 15-05-2024

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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21447

Bron
NTR

Verkorte titel
TBA

Aandoening

Borderline personality disorder

Ondersteuning

Primaire sponsor: None
Overige ondersteuning: GGNet

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Body awareness (MAIA-2)

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

GGNet
Farid Chakhssi

+31611707805

Wetenschappelijk

GGNet
Farid Chakhssi

+31611707805

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2021
Aantal proefpersonen:	10
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	02-07-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50372
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten