

Addition of the SUPPORT Coach in PTSD treatment

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28504

Source

NTR

Brief title

SUPPORT Coach app for PTSD

Health condition

Post-Traumatic Stress Disorder (PTSD), Posttraumatic stress symptoms, Trauma related complaints (e.g. anxiety, depression)

Sponsors and support

Primary sponsor: Academic Medical Center (AMC), Amsterdam

Source(s) of monetary or material Support: Stichting tot Steun VCVGZ

Intervention

Outcome measures

Primary outcome

Potential improvement of trauma-focused therapy: Does usage of the SUPPORT Coach app in-between treatment sessions potentially enhance the efficacy of traditional trauma-focused therapy in terms of PTSD symptom reduction? Measured by the difference in PCL-5 score reduction (continuous) between the intervention- and control condition at the start of

therapy session 6 and 13 of the trauma-focused psychotherapy.

Secondary outcome

Feasibility and acceptance of the SUPPORT Coach app as an adjunct to traditional trauma-focused psychotherapy. Are patients willing to use the SUPPORT Coach as an additional tool in between therapy sessions? How often would they use the app and are they able to use the app on their own

Study description

Background summary

Posttraumatic stress disorder (PTSD; life time prevalence in the Netherlands 7.4%) can occur after a traumatic event. Effective psychological treatments are available, but approximately one-third of the treated patients do not benefit sufficiently and residual symptoms are a considerable problem. The need to optimize treatment warrants moving beyond traditional methods. Mobile mental health is a promising development in this regard. In the proposed study, the aim is to investigate the feasibility, acceptability and potential efficacy of the SUPPORT Coach, a smartphone application that helps to understand and cope better with PTSD symptoms, as a tool complementary to traditional trauma-focused therapy

Study objective

We hypothesize that the usage of the SUPPORT Coach app by patients with PTSD in addition to their trauma-focused therapy will lead to a reduction of post-traumatic stress symptoms compared to patients in treatment that do not use the app.

Study design

The primary outcome is assessed at multiple time points:

1. Before treatment (baseline)
2. A measurement at the start of the first 12 treatment sessions
3. Posttreatment at the 13th session

Secondary outcomes are assessed pre- and post-treatment and by means of log files during the intervention period

Intervention

The intervention group receives access to the SUPPORT Coach, a mobile application aiming to help people better understand and self-manage their PTSD symptoms. The SUPPORT Coach includes psychoeducation, a self-test with a monitoring feature, and, most importantly, various exercises and tools to cope with PTSD symptoms. Examples are deep breathing, progressive muscle relaxation, and positive imagination exercises (www.amc.nl/supportcoach).

Contacts

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Eligibility criteria

Inclusion criteria

- Adults, minimum 18 years of age
- Referred to a mental health care institute for trauma-focused psychotherapy for PTSD following one or more traumatic experiences
- Meet the DSM-5 diagnostic criteria for PTSD as confirmed by the CAPS-5
- In possession of a mobile phone working on ANDROID/IOS operating systems
- Have sufficient understanding of the Dutch language (speaking, writing, listening)

Exclusion criteria

- Having current high risk for suicide according to M.I.N.I-C
- Having serious psychiatric comorbidity, i.e. psychotic illness, bipolar affective disorder, substance-related disorders,

severe personality disorder or mental retardation • Not having access to a smartphone with an internet connection

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	15-10-2017
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion	
Date:	22-12-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50227
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6734
NTR-old	NTR6912
CCMO	NL63180.018.17
OMON	NL-OMON50227

Study results