

Feasibility, acceptance and potential improvement of trauma-focused therapy in PTSD patients with a smartphone application - a pilot study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON50227

Source

ToetsingOnline

Brief title

Addition of the SUPPORT COACH in PTSD treatment

Condition

- Anxiety disorders and symptoms

Synonym

posttraumatic stress, PTSD

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

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

Intervention

Keyword: App, Feasibility, Posttraumatic stress disorder, Treatment efficacy

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 traumafocused 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 psychotherapy

Study objective

In the present study, we aim to investigate the SUPPORT Coach as a tool to enhance traditional trauma-focused psychotherapy. Research questions concern:

1. 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?

2. 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 design

A pilot randomised controlled trial with patients with a PTSD diagnosis scheduled for trauma focused psychotherapy. The 48 patients will be split in two groups and 24 will be randomly allocated to the intervention group and 24 patients will be allocated to the control group.

Measurements take place prior to therapy, during the first 12 therapy sessions and a post treatment measurement will take place directly before or in the first 5 minutes of therapy session 13.

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).

Study burden and risks

The burden and risks associated with participation are negligible. Patients follow their own traumafocused psychotherapy and in addition, patients in the intervention condition will receive access to the SUPPORT Coach. Therapists and patients will make procedural arrangements in case of any emergency and the SUPPORT Coach provides an emergency button.

In the intervention condition patients will be asked to contribute 550 minutes to the study. Patients in the control group will contribute for 190 minutes. Up

untill now, no (serious) adverse events have been noted in the use of the SUPPORT Coach.

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

- * Adults, minimum 18 years of age
- * Referred to a mental health care institute for traumafocused 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 co-morbidity, 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
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	12-02-2018
Enrollment:	48
Type:	Actual

Ethics review

Approved WMO	
Date:	15-11-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	15-05-2018
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	24-07-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	29-10-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	01-02-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	30-01-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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: 28504
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL63180.018.17
OMON	NL-OMON28504