

Compassion-focused therapy for self-criticism

No registrations found.

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

Summary

ID

NL-OMON26546

Source

Nationaal Trial Register

Health condition

Eligible participants will be recruited at the participating sites. We aim to recruit 10 subjects at each site.

For the site with patients with PDs, eligible participants are patients of > 18 years with PDs who are undergoing treatment at Scelta, GGNet in Apeldoorn. Based on a previous study (Oostendorp & Chakhssi, 2017), the study population can be described as predominantly female (over 80%) and with an average age of 25 years (SD = 7) at admission. All patients have one or more personality disorders as a primary diagnosis, with borderline, avoidant, and dependent personality disorder as the most prevalent.

For the site with patients with PTSD, eligible participants are patients of > 18 years with PTSD who are undergoing treatment at TCT, Dimence in Almelo. The study population can be described as having PTSD as a primary diagnosis.

Sponsors and support

Primary sponsor: Not applicable.

Source(s) of monetary or material Support: University of Twente

Intervention

Outcome measures

Primary outcome

The primary outcome is the twice a week assessed level of self-critical beliefs. These beliefs are assessed before the baseline phase using the Dutch version of the Forms of Self-Criticizing/ Attacking and Self-Reassuring Scale (FSCRS; Sommers-Spijkerman et al., 2018). Each participant then chooses three to five self-critical beliefs, resulting from the questionnaire, which they consider to be central to their symptoms. Participants will rate each of their beliefs on a visual analog scale (VAS) from 0 to 100%. The self-critical beliefs are rated twice a week during baseline, treatment and follow-up phases.

Secondary outcome

PDs severity is assessed with the Personality Inventory for DSM-5 Brief Form (PID-5-BF; American Psychological Association, 2013; Dutch version: Heijden et al., 2014). The PID-5-BF is a 25-item self-rated measure for maladaptive personality trait assessment. Each item can be rated on a 4-point scale (0 to 3). The overall measure has a range of scores from 0 to 75, with higher scores indicating greater overall personality dysfunction. The total score will be used as a measure for PD severity in the current study. The PID-5-BF has adequate reliability and validity (Anderson, Sellbom, & Salekin, 2016), which has been replicated in Dutch samples (Bastiaens et al., 2016).

Self-compassion is assessed with the 12-item Self-Compassion Scale—Short Form (SCS-SF; Neff, 2003; Dutch version: Raes et al., 2011). The total score varies between 12 and 84, with higher scores reflecting higher levels of self-compassion. Previous research has shown that the Dutch version of the SCS-SF has adequate psychometric qualities (Raes et al., 2011).

PTSD symptom severity is assessed with the PTSD Checklist for DSM-5 (PCL-5; Weathers, Litz, Keane, Palmieri, Marx, & Schnurr, 2013; Dutch version: Boeschoten, Bakker, Jongedijk, & Olff, 2014). The PCL-5 is a 20 item (5 point Likert) self-report measure that assesses the 20 DSM-5 symptoms of PTSD. Total scores range from 0 to 80. Participants' responses are indexed to the traumatic event that they identified as resulting in most self-criticism. The PCL-5 has demonstrated strong psychometric properties and high quality of efficiency for predicting PTSD diagnosis (Blevins, Weathers, Davis, Witte, & Domino, 2015). Research on the psychometric properties of the Dutch version of the PCL-5 is ongoing. Several studies have found good psychometric properties for the PCL-5, with good internal consistency (Bovin, Marx, Weathers, Gallagher, Rodriguez, et al., 2016; Sveen, Bondjers, Willebrand, 2016; Van der Meer, Bakker, Schrieken, Hoofwijk, & Olff, 2017)

Study description

Background summary

Rationale: Self-criticism is associated with a wide range of psychiatric disorders including personality disorders (PDs) and post-traumatic stress disorders (PTSD). Effective treatment of

self-criticism may significantly reduce the burden and improve the quality of life of these patients. However, conventional treatments are only moderately successful in ameliorating self-criticism. An alternative form of treatment which may offer a helpful strategy for improving self-compassion in these patients is compassion-focused therapy (CFT). CFT is aimed at cultivating compassion, particularly self-compassion, and facilitates the ability to reduce self-criticism. Despite some preliminary, promising evidence that patients with PDs and PTSD may benefit from compassion-based interventions in terms of mental health and well-being, it remains as yet unclear whether CFT may help patients with PDs and PTSD decrease their self-criticism.

Objective: The primary aim of the current study is to examine whether CFT is effective for reducing self-criticism in patients with PDs or PTSD.

Study design: A multiple baseline case series design with 3-7 weeks baseline phase, 12 weeks treatment phase and a 6 weeks follow-up phase.

Study population: This study will take place with adult patients (> 18 years) at two sites, one with PD patients, and one with PTSD patients. Respectively, GGNet Scelta, personality disorders treatment center and Dimence, trauma center.

Intervention (if applicable): The CFT protocol consists of 12 sessions of 1-2 hours.

Main study parameters/endpoints: The main study parameter is change in self-reported self-criticism.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients will receive their usual care during the study. The burden of this study pertains to 12 additional CFT sessions including homework assignments. Participants are requested to weekly report, during the complete study period, their perceived level of self-criticism via a visual analogue scale (0-100%). Furthermore, questionnaires need to be filled in at the start of baseline, before and directly after the treatment phase, and at the end of the follow-up phase. The risk for adverse events due to participation in this study is negligible, the potential benefit of this study is that self-criticism may be reduced.

Study objective

Primary Objective: The primary aim of the current study is to examine whether CFT is effective for reducing self-criticism in patients with PDs or PTSD. We hypothesize that CFT reduces the level of self-criticism.

Secondary Objective(s): To examine the effect of CFT on PDs/PTSD severity and self-compassion. We hypothesize that CFT reduces PDs/PTSD severity and improves self-compassion.

Study design

The two mental health centers (sites) where the study will be performed are GGNet and

Dimence. At both sites, we will use a (nonconcurrent) multiple baseline across subjects design.

At GGNet, location Scelta, Apeldoorn, the site for patients with PDs, the multiple baseline case series design consists of three phases. First, a baseline phase where treatment-as-usual (TAU) given. To increase the internal validity, the baseline duration will vary from 3 to 7 weeks over the participants, with 2 participants randomly allocated to each of the 5 lengths. The second phase is the CFT intervention phase and consists of 12 weeks of weekly CFT group sessions that will be offered as add-on to TAU. The last phase is a 6 weeks follow-up phase where TAU is given.

T0 assessment: self-criticism, self-compassion, PDs/PTSD severity

T1 assessment: self-criticism, self-compassion, PDs/PTSD severity

T2 assessment: self-criticism, self-compassion, PDs/PTSD severity

T3 assessment: self-criticism, self-compassion, PDs/PTSD severity

At Dimence, location Team Complex Trauma (TCT), Almelo, the site for patients with PTSD, the multiple baseline case series design is similar to the GGNet site with the exception that CFT will be offered in an individual format. Thus, first, a baseline phase where TAU is given, will vary from 3 to 7 weeks over the participants, with 2 participants randomly allocated to each of the 5 lengths. The second phase is the CFT treatment phase and consists of 12 weeks of weekly individual CFT sessions, as add-on to TAU. The last phase is a 6 weeks follow-up phase where no CFT is given.

Participants are requested to report twice a week, during the complete study period, their perceived level of self-criticism on a visual analogue scale (0-100%). Furthermore, questionnaires regarding to self-criticism, self-compassion and PDs/PTSD severity need to be filled in at the start of baseline, before and directly after the intervention phase, and at the end of the follow-up phase.

Intervention

The intervention used in this study is Compassion Focused Therapy (CFT; Gilbert, 2005, 2010). CFT was initially developed by Paul Gilbert for clients who experience high levels of self-criticism and shame. CFT emphasizes the significance of our affiliative system in reducing threat-based protection system by allowing us to feel cared for and allowing us to be able to offer care to both ourselves and others (Gilbert, 2014). The primary aim of CFT is to help clients understand and respond to their distress from the perspective of a compassionate mind, which incorporates a range of compassion-based skills, attributes, and qualities (Gilbert, 2009). CFT is a treatment specifically designed to increase self-compassion and, therefore lessen self-criticism.

The CFT protocol (Kirby et al., 2019; Dutch translation: Pots et al., 2019), consisting of 12 sessions, was translated and adapted into a group-based and individual CFT protocol. In the protocol each session includes a therapist guidance of the treatment session. Each session includes psychoeducation (e.g., conceptualization of PDs/PTSD, self-compassion) followed by an in-session experiential exercise (e.g., soothing rhythm breathing), which participants are also asked to practice on their own between sessions (2 hours per week). The study therapists will assess the quality and compliance of the homework at the start of each session. The first part of the intervention (Sessions 1- 5) focuses on compassionate insights,

which is psychoeducation about the emotion regulation system, the skills of self-compassion, and mindfulness skills. The second part of the intervention (Session 6 – 8) focuses on the motivation to care, which is compassion of others, the compassionate self, and the relationship between the compassionate self and self-criticism. The third part of the intervention focuses on compassion in action (Session 9 - 12), which is the application of compassion in daily life and the conflicts that arise when applying compassion.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study on the site for PDs a subject must meet all of the following criteria:

- 1) is admitted to Scelta, GGNet, Apeldoorn,
- 2) has one or more DSM-5 personality disorders as primary diagnosis,
- 3) is aged between 18 and 65 years old,
- 4) has a high level of self-criticism at baseline (score FSCRS inadequate self > 20).

In order to be eligible to participate in this study on the site for PTSD a subject must meet all of the following criteria:

- 1) is admitted to Team Complex Trauma, Dimence, Almelo,
- 2) has a DSM-5 PTSD disorders as primary diagnosis,
- 3) is aged between 18 and 65 years old,
- 4) has a high level of self-criticism at baseline (score FSCRS inadequate self > 20).

Exclusion criteria

Insufficient Dutch language proficiency to be able to participate in the study and complete the questionnaires.

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:	Pending
Start date (anticipated):	05-01-2020
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion	
Date:	02-11-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8131
Other	NL70940.091.19, CMO Regio Arnhem-Nijmegen : METC 2019-5713

Study results

Summary results

Not applicable