

IPT for psychotrauma; The mediating role of interpersonal problems in the relationship between IPT and Posttraumatic Stress Disorder (PTSD)

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Question: Does IPT affect the degree of interpersonal problems? And can this explain part of the effect on the trauma-related complaints? Hypothesis: Changes in PTSD during IPT treatment are explained by a decrease in interpersonal problems

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48634

Source

ToetsingOnline

Brief title

IPT for PTSD: the mediating role of interpersonal problems

Condition

- Other condition
- Anxiety disorders and symptoms

Synonym

Posttraumatic Stress Disorder, Psychotrauma

Health condition

Psychotrauma en stressorgerelateerde stoornissen

Research involving

Human

Sponsors and support

Primary sponsor: Parnassia Bavo Groep (Den Haag)

Source(s) of monetary or material Support: PsyQ-ParnassiaBavogroep

Intervention

Keyword: Interpersonal problems, IPT, mediation, PTSD

Outcome measures

Primary outcome

Decrease in the severity of PTSD complaints

Decrease of Interpersonal problems

Secondary outcome

Decline of general complaints

Study description

Background summary

Posttraumatic stress disorder (PTSD) is a severe limiting disorder that occurs widely (Kessler, Chiu, Demler, et al. 2005). Almost every person in his life is confronted with trauma (50-90%) (Kessler, Sonnega, Bromet, Hughes, & Nelson, 1995) 8% of these people develops PTSD (Breslau, Kessler, Chilcoat, Schultz, Davis & Andreski, 1998).

The evidence-based treatments for PTSD are all based on the paradigm that patients must expose themselves to memories of their trauma and preventing avoidance, the so-called exposure-based treatments. Eye Movement Desensitization Reprocessing (EMDR), Imaginary Exposure (IE) are the two leading evidence based treatments for PTSD in the Netherlands. Both treatments are focused on exposure.

Exposure treatments, however, ignore another important problem within PTSD. PTSD entails intrinsic & relational interpersonal and psychosocial problems. These social factors play a key role in PTSD (Brewin, Andrews & Valentine, 2000). People with PTSD become distrustful, withdrawn, have increased vigilance in contact with people (Bleiberg & Markowitz, 2005; Riggs, Byrn, Weathers &

Litz, 1998) and this involves a great burden for the patient's environment (Beckham, Lytle & Feldman, 1996).

In addition, it appears that patients often find the treatment of PTSD very intensive and frightening by exposing them to memories of the trauma (Foa, Keane & Friedman, 2000). Because of this they are inclined to stop treatment prematurely or do not even dare to start it.

For these reasons, treatment for interpersonal and social aspects, such as Interpersonal Psychotherapy (IPT), could be an alternative. A recently randomized study by Markovitz, Petkova, Neria, Van Meter, Zhao, Hembree, Lovell, Biyanova & Marshall (2015) in which 110 patients with chronic PTSD were treated with IPT, Imaginary Exposure (IE) or relaxation therapy showed that IPT has the same effect as IE on reducing the PTSD symptoms in this patient group compared to progressive relaxation. This study also indicated that in patients with comorbid depression, IPT had slightly more effect on the symptoms than on patients without depressive symptoms.

Now that there is first proof of IPT to be effective in psychotrauma, the question arises as to why this method of treatment is also effective in PTSD.

Mechanism of action behind IPT

IPT works by strengthening interpersonal relationships. Lipsitz & Markowitz (2013) assume that the interpersonal problems are solved by IPT and that symptom reduction occurs. Improving social support and reducing interpersonal stress causes emotions to be processed and improve social skills.

It could be that this presumed working mechanism of IPT also works in this way for PTSD patients. Patients recover from their isolation, experience less stress in contact with others, so there is more room to process their emotions. It is possible that patients, because of these psychosocial improvements, are more likely to expose themselves to memories of the trauma, which further helps to reduce PTSD symptoms. From the pilot study by Markowitz, Milrod, Bleiberg & Marshall (2009), prior to their aforementioned RCT on IPT, PE and PR from 2015, this also emerged. After the IPT treatment, patients themselves dared to expose themselves more to memories of the trauma and avoided it less.

Study objective

Question:

Does IPT affect the degree of interpersonal problems? And can this explain part of the effect on the trauma-related complaints?

Hypothesis: Changes in PTSD during IPT treatment are explained by a decrease in interpersonal problems

Study design

Design:

Using an observational study, patients with trauma-related complaints with a

cut off score of 44 or greater on PCL 5 will be offered treatment with IPT.

Patients receive 14 weekly treatment sessions according to the IPT protocol. The adapted IPT protocol as described by Markowitz is used. This protocol has been specially adapted for psychotrauma.

The IPT treatment will be carried out by GZ, KP and basic psychologists who have followed an IPT course especially prior to the research. Within this course attention is paid to familiarizing with the adapted protocol IPT with PTSS from J.C. Markowitz (2017). During treatment, the practitioners are supervised by a recognized IPT supervisor to ensure quality of the treatment.

Measurements

After inclusion (PCL-5 cut-off score 44>), a pre-measurement is taken. Then measurements take place after 3 weeks, 6 weeks, 10 weeks and after 14 weeks the final measurement.

- * PTSD complaints: Post Traumatic Stress Disorder Checklist (PCL 5)
- * Interpersonal problems: Inventory of interpersonal problems (IIP-32)
- * Social and social functioning: Outcome Questionnaire-45 (OQ-45)?

Intervention

14 sessions Interpersonal psychotherapy

Decrease the three previously mentioned questionnaires

Study burden and risks

Patients receive 14 weekly treatment sessions according to the IPT protocol. The adapted IPT protocol as described by Markowitz is used. This protocol has been specially adapted for psychotrauma. It is an EB standard treatment for people with depression and is not invasive.

Filling in the questionnaires takes 30 minutes time. They are frequently used questionnaires.

After inclusion (PCL-5 cut-off score 44>), a pre-measurement is taken. Then measurements take place after 3 weeks, 6 weeks, 10 weeks and after 14 weeks the final measurement.

Questionnaires that are then taken are:

- PTSD complaints: Post Traumatic Stress Disorder Checklist (PCL 5)
- Interpersonal problems: Inventory of interpersonal problems (IIP-32)
- General complaints: Outcome Questionnaire-45 (OQ-45)

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

- Age between 18-65 years old
- Trauma related problems: cut off score 44> on the Posttraumatic Stress Checklist-5 (PCL-5)
- Sufficient knowledge and skills in the Dutch language
- Having previously recieved treatment of PTSD
 - a) Received previously evidence based treatment of PTSD
 - b) This treatment took place less than 2 years ago
 - c) This treatment was an evidennce based exposure treatment
 - d) This treatment has lasted at least 5 sessions or more
- The patient is prepared to cooperate with the research and has signed an informed consent.

Exclusion criteria

- Addiction problems
- Psychotic disorder
- Bipolar disorder
- Intellectual disability
- Antisocial, schizotypic and schizoid personality disorder
- Patients should not start with or have just started using psychotropic drugs.
- Patients should not start treatment where interpersonal relationships are intended to be reduced as in familytherapy for example.

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 28-01-2019

Enrollment: 34

Type: Anticipated

Ethics review

Approved WMO

Date: 18-06-2019

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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
CCMO	NL65890.058.18