STATENS BEREDNING FÖR MEDICINSK OCH SOCIAL UTVÄRDERING

Bilaga till rapport

Vård för personer som utsatts för sexuellt våld – psykologiska insatser för personer med komplex PTSD/ Psycological interventions for persons with complex PTSD rapport 381 (2024)

Bilaga 3 Studier med hög risk för bias/Appendix 3 Studies with high risk of bias

Dorrepaal et al. 2012

Author	*Dorrepaal et al*
Year	*2012*
Country	*The Netherlands*
Reference	*[1]*
Study design	*Multicentre RCT*
Setting	*Clinical*
Recruitment	*Referred for stabilizing treatment by mental health clinicians, between June 2005 and February 2006*
Population	*Patients with complex PTSD and severe comorbidity*
Inclusion criteria	*The subjects had to meet (1) criteria for PTSD according to the Structured Diagnostic Interview for DSM-IV axis I disorders and (2) for complex PTSD according to the Structured Interview of Disorders of Extreme Stress. Furthermore, (3) sexual and/or physical abuse before the age of 16 was required. Exclusion criteria were (4) the presence of antisocial personality disorder, (5) current psychotic episode, (6) dissociative identity disorder or (7) severe alcohol or drug dependence or abuse (likely to interfere with attendance) as assessed by Structured Clinical Interviews for DSMIV axis I and II disorders. (8) Subjects currently under exposure treatment or seeking such treatment were also excluded*
Follow up	
Intervention	*In addition to TAU, 20 additional 2-hour treatment meetings held weekly. The groups comprised 8–12 participants and 2 therapists, who were experienced psychotherapists, psychiatrists or psychiatric nurses who had received training and supervision from the first author. To verify treatment progress and integrity, all the sessions were recorded. The therapists also completed a checklist that measured treatment adherence after every session. These checklists were used to screen for protocol violations throughout the study20-week group treatment in addition to treatment as usual (TAU).*
Participants (n)	*38*
Drop-outs (n)	*7*

Comparison	*TAU given by a psychotherapist, psychiatric nurse or psychiatrist, including medication. TAU was not protocolized but was tailored to the individual needs of the patients and did not include exposure therapy.*
Participants (n)	*33*
Drop-outs (n)	*5*
Outcomes	*Core Symptoms. (1) The severity of PTSD was established using the Davidson Trauma Scale (DTS [40]), (2) The SIDES was used to assess symptom severity for each domain of complex PTSD [8].* *Secondary Outcome Measures. (1) The Borderline Personality Disorder Severity Inventory IV [41], (2) The Dissociative Experiences Scale (DES [42])*
Comments	
Risk of bias	*High*

Dumarkaite et al. 2021 och 2022

Author	*Dumarkaite et al.*
Year	*2021, 2022*
Country	*Lithuania*
Reference	*[2] [3]*
Study design	*RCT*
Setting	*Non-clinical (University)*
Recruitment	*Self-recruitment via adverts and information via web and e-mail to university students*
Population	*University students*
Inclusion criteria	*Who were 18 years old or older; were fluent in Lithuanian; had access to a device with Internet; had experienced one or more traumatic events during their life; met the clinical significance criteria for PTSD, CPTSD, or disturbances in self-organization symptoms with or without functional impairment as measured with the International Trauma Questionnaire*
Follow up	*Pre-intervention, post-intervention, and 3-month follow-up*
Intervention	*Online mindfulness-based intervention. The intervention was designed as a self-help program (focusing on psychoeducation and mindfulness techniques training) with the possibility of messaging with a psychologist. The intervention consisted of eight modules: (1) Introduction, (2) Awareness and non-judgment of physical senses, (3) Physical senses in everyday life, (4) Awareness and non-judgment of thoughts, (5) Thoughts in everyday life, (6) Awareness and non-judgment of emotions, (7) Emotions in everyday life, and (8) Summary.* *The intervention lasted for 8 weeks.*
Participants (n)	*42*
Drop-outs (n)	*23*

Comparison	*Waiting list*
Participants (n)	*42*
Drop-outs (n)	*5*
Outcomes	*PTSD and CPTSD-specific disturbances in self-organization symptoms, anxiety, depression and positive mental health*
Comments	
Risk of bias	*High*

van Vliet et al. 2021

Author	*van Vliet et al.*
Year	*2021*
Country	*The Netherlands*
Reference	*[4]*
Study design	*RCT*
Setting	*Clinical*
Recruitment	*Participants were recruited from two out-patient mental health organisations in The Netherlands from 5 September 2016, and the last follow-up assessment was on 28 August 2020.*
Population	*Persons with PTSD and a victim of repeated sexual and/or physical abuse*
Inclusion criteria	*Persons aged between 18 and 65 years and diagnosed with PTSD as measured by the Clinician-Administered PTSD scale for DSM-5 (CAPS-5). Furthermore, they had to be a victim of repeated sexual and/or physical abuse before the age of 18 by a caretaker or a person in a position of authority, as identified by the LEC-5.*
Follow up	*Before, during and after treatment and at 3- and 6-month follow-ups*
Intervention	*A phase-based treatment condition (8 sessions of Skills Training in Affect and Interpersonal Regulation (STAIR), followed by 16 sessions of Eye-Movement Desensitization and Reprocessing (EMDR) Therapy.*
Participants (n)	*64*
Drop-outs (n)	*10*
Comparison	*A trauma-focused treatment condition (16 sessions of EMDR therapy)*
Participants (n)	*57*
Drop-outs (n)	*13*
Outcomes	*Symptoms of PTSD and complex PTSD, and other forms of psychopathology*
Comments	
Risk of bias	*High*

Referenser

1. Dorrepaal E, Thomaes K, Smit JH, van Balkom AJ, Veltman DJ, Hoogendoorn AW, Draijer N. Stabilizing group treatment for complex posttraumatic stress disorder related to child abuse based on psychoeducation and cognitive behavioural therapy: a multisite randomized controlled trial. Psychother Psychosom. 2012;81(4):217-25. Available from: https://doi.org/10.1159/000335044.
2. Dumarkaite A, Truskauskaite-Kuneviciene I, Andersson G, Kazlauskas E. The Effects of Online Mindfulness-Based Intervention on Posttraumatic Stress Disorder and Complex Posttraumatic Stress Disorder Symptoms: A Randomized Controlled Trial With 3-Month Follow-Up. Front Psychiatry. 2022;13:799259. Available from: https://doi.org/10.3389/fpsyt.2022.799259.
3. Dumarkaite A, Truskauskaite-Kuneviciene I, Andersson G, Mingaudaite J, Kazlauskas E. Effects of Mindfulness-Based Internet Intervention on ICD-11 Posttraumatic Stress Disorder and Complex Posttraumatic Stress Disorder Symptoms: a Pilot Randomized Controlled Trial. Mindfulness (N Y). 2021;12(11):2754-66. Available from: https://doi.org/10.1007/s12671-021-01739-w.
4. van Vliet NI, Huntjens RJC, van Dijk MK, Bachrach N, Meewisse ML, de Jongh A. Phase-based treatment versus immediate trauma-focused treatment for post-traumatic stress disorder due to childhood abuse: randomised clinical trial. BJPsych Open. 2021;7(6). Available from: https://doi.org/10.1192/bjo.2021.1057.