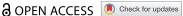




BASIC RESEARCH ARTICLE



Validation of ICD-11 PTSD and DSO using the International Trauma Questionnaire in five clinical samples recruited in Denmark

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Background: The 11th version of the International Classification of Diseases (ICD-11) revised the diagnosis of Posttraumatic Stress Disorder (PTSD) and introduced Complex PTSD as a sibling disorder to PTSD. As the Danish Health Authorities will implement the ICD-11 in 2022, it is more relevant than ever to introduce a measure that enables the identification of ICD-11 PTSD and CPTSD.

Objective: The primary aim of the present study was to test the construct validity of the ICD-11 conceptualization of PTSD and DSO in five clinical samples using translated versions of the International Trauma Questionnaire (ITQ).

Method: Data from existing studies of adult survivors of sexual abuse (n = 385), women in shelters (n = 147), psychiatric outpatients endorsing an ICD-10 diagnosis of PTSD (n = 111), a heterogenous sample of psychiatric outpatients (n = 178) and refugees and torture survivors (n = 385) was used for the current study. Confirmatory factor analyses were conducted to test the internal structure of the ITQ, and regression models were conducted to test the convergent and discriminant validity of the factor solutions for each sample.

Results: Findings supported the ICD-11 formulation of PTSD and disorders in selforganization (DSO) as a representation of the latent structure of the ITQ across five Danish clinical samples. Uniquely for women in shelters, however, the model displayed an unacceptable fit. A revised operationalization of re-experiencing proved a better fit when 'recurrent nightmares' was exchanged with symptoms of intense emotional reactions to reminders of the trauma for women in shelter as well as ICD-10 PTSD psychiatric outpatients.

Conclusion: This study supports the use of a Danish translated version of the ITQ to assess symptoms of ICD-11 PTSD and DSO for the introduction of ICD-11 in 2022. Future research is needed to further explore the operationalization of re-experiencing across different trauma exposed populations.

Validación del tept y DSO de la CIE-11 usando el cuestionario internacional de trauma en cinco muestras clínicas reclutadas en **Dinamarca**

Antecedentes: La décimo primera versión de la Clasificación Internacional de Enfermedades (CIE-11) revisó el diagnóstico de Trastorno de Estrés Postraumático (CIE-11) e introdujo el TEPT complejo como un diagnóstico hermano del TEPT. Como las autoridades de salud danesas implementarán la CIE-11 en el 2022, es más relevante que nunca introducir una medición que permita la identificación del TEPT y el TEPT complejo de acuerdo a la CIE-11. Objetivo: El principal objetivo del presente estudio fue probar la validez del constructo diagnóstico de la conceptualización del TEPT y de las Alteraciones en la Auto-Organización (DSO por sus siglas en inglés) en cinco muestras clínicas usando versiones traducidas del Cuestionario Internacional de Trauma (ITQ por sus siglas en inglés).

Método: Se usaron para el presente estudio, datos de estudios va existentes de sobrevivientes adultos de abuso sexual (n = 147), pacientes psiquiátricos ambulatorios con diagnóstico de TEPT de acuerdo a la CIE-10 (n = 111), una muestra heterogénea de pacientes psiquiátricos ambulatorios (n = 178) y refugiados y sobrevivientes de tortura (n = 385). Se usaron análisis factoriales confirmatorios para probar la estructura interna del ITQ, y se aplicaron modelos de regresión para probar la validez convergente y discriminante de las soluciones factoriales para cada muestra.

Resultados: Los hallazgos apoyaron la formulación de ls CIE-11 del TEPT y de los desórdenes en la auto-organización (DSO) como una representación) de la estructura latente del ITQ en 5 muestras clínicas danesas. Sin embargo, en el caso de las mujeres de los centros de acogida, el modelo mostró un ajuste inaceptable. Una operacionalización revisada de la re-experimentación probó ser más ajustada cuando 'pesadillas recurrentes' fue reemplazada

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PALABRAS CLAVE

Cuestionario Internacional de Trauma; Validación; CIE-11 TEPT y TEPT-C; Psicometría; Muestras Clínicas; Análisis factorial confirmatorio

关键词

国际创伤问卷; 效度; ICD-11 PTSD和CPTSD; 心理 测量; 临床样本; 验证性因 素分析

HIGHLIGHTS

- · Scores from the ITQ validly represent ICD-11 PTSD and DSO across five traumaexposed populations recruited in Denmark (n = 1197).
- · Results suggest that symptoms of trauma-related re-experiencing might differ depending on population or recency of the trauma.

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por los síntomas de reacciones emocionales intensas ante recordatorios del trauma para mujeres en los centros de acogida así como a los pacientes psiquiátricos ambulatorios con TEPT según la CIE-10.

Conclusión: Este estudio apoya el uso de la versión traducida en danés del ITQ para evaluar síntomas de TEPT y DSO de acuerdo a la CIE-11 para la introducción de la CIE-11 en el 2022. Se requiere futura investigación para explorar la operacionalización de la reexperimentación en diferentes poblaciones expuestas al trauma.

在丹麦招募的五个临床样本中使用国际创伤问卷的ICD-11 PTSD和DSO的 效度摘要

背景: 第11版《国际疾病分类》 (ICD-11) 修订了创伤后应激障碍 (PTSD) 的诊断, 并将复杂 性PTSD引入了PTSD的同胞障碍中。由于丹麦卫生当局将在2022年施行ICD-11,因此是引入 -项能识别ICD-11 PTSD和CPTSD的测量比以往任何时候更切题

目的: 本研究的主要目的是使用国际创伤问卷 (ITQ) 的翻译版本在五个临床样本中检验 PTSD和DSO的ICD-11概念的结构效度。

方法: 本研究使用来自对性虐待成年幸存者 (n = 385), 庇护所中的女性 (n = 147), 有ICD-10 PTSD诊断的精神科门诊患者 (n = 111), 一个精神科门诊患者的混杂样本 (n = 178) 以及难民 和酷刑幸存者 (n = 385) 的数据。进行验证性因素分析以检验ITQ的内部结构,并进行回归 模型以检验每个样本中因素结果的收敛和区分效度。

结果: 研究结果支持了ICD-11的PTSD组成和自组织疾病 (DSO), 以代表跨五个丹麦临床样品 中ITQ的潜在结构。但是,该模型仅在庇护所中的女性表现出不可接受的拟合。对庇护所中 的女性样本和ICD-10 PTSD精神科门诊患者样本的对再体验修订,'反复的噩梦'换成对创伤 提示物有强烈的情绪反应症状时, 拟合变好。

结论: 本研究支持使用丹麦语版ITQ来评估ICD-11 PTSD和DSO的症状, 以在2022年引入ICD-11。需要未来研究进一步探索不同创伤暴露人群的对再体验修订。

1. Introduction

With the publication of the 11th version of the International Classification of Diseases (ICD-11) in 2018, the World Health Organisation (WHO, 2018) presented a revised formulation of posttraumatic stress disorder (PTSD) and a new related but distinct disorder of complex PTSD (CPTSD). ICD-11 PTSD include three symptom clusters of 1) reexperiencing the trauma here and now, 2) avoidance of traumatic reminders, and 3) persistent sense of threat. In addition to the symptoms of PTSD, CPTSD is characterized by symptoms from each of three additional symptom clusters related to disturbances of self-organization (DSO); affective dysregulation, negative self-concept and disturbances in relationships. CPTSD was included in the ICD-11 to describe more complex symptom presentations that are associated with repeated or prolonged exposure to traumatic stressors such as childhood abuse, domestic violence and torture (Cloitre, Garvert, Brewin, Bryant, & Maercker, 2013). Previous Danish studies (Hyland et al., 2017; Palic et al., 2016) have supported the construct validity of ICD-11 propositions for posttraumatic stress-disorders using aggregate measures of symptoms, and recently, the International Trauma Questionnaire (ITQ), a self-report measure specifically designed to operationalize the ICD-11 disorders has been published (Cloitre et al., 2018).

The final version of the ITQ has undergone substantial development regarding the operationalization of re-experiencing and DSO-symptoms from the original draft (Cloitre et al., 2013) to the final version (Cloitre et al., 2018). The ITQ includes six items to assess symptoms of PTSD and six items that assess symptoms of DSO and additional items assessing functional impairment related to PTSD and DSO separately. The ITQ is the only existing self-report measure that enables assessment of both ICD-11 PTSD and DSO (Cloitre et al., 2018) and has been validated internationally with studies conducted in Europe (Karatzias et al., 2017; Murphy et al., 2020), the Middle East (Gilbar, Hyland, Cloitre, & Dekel, 2018; Karatzias, Hyland, Ben-Ezra, & Shevlin, 2018; Vallières et al., 2018), Asia (Ho et al., 2020; Mordeno, Nalipay, & Mordeno, 2019), Africa (Owczarek et al., 2019), and North America (Cloitre et al., 2019).

As the Danish Health Authorities will implement the ICD-11 in 2022, the introduction of an accurate measure in Danish that can identify symptoms of both disorders is more relevant than ever. The present study therefore aims to test the validity of the ICD-11 constructs of PTSD and DSO using a Danish translated version of the ITQ across clinical samples of trauma survivors. This is done using confirmatory factor analysis (CFA) to test the internal structure of the ITQ and by testing the relationship between symptoms of ICD-11 disorders and traumaexposure as well as other indicators of mental health (Pedhazur & Schmelkin, 1991). Additionally, the original proposition for the ICD-11 conceptualization of PTSD and CPTSD was based on symptoms typically observed among refugees and survivors of torture, survivors of sexual abuse in childhood and domestic violence, in short, severe and often repeated traumatypes from which escape is difficult or impossible (Maercker et al., 2013). An additional aim of this study was to examine the validity of the ICD-11 formulation of PTSD and DSO among populations exposed to these types of trauma.

1.1. Internal structure

Previous studies (Ho et al., 2020; Hyland et al., 2017; Karatzias et al., 2017; Murphy et al., 2020; Shevlin et al., 2018) have shown that the latent structure of the ITQ is best represented by two models: a) A correlated six-factor model distinguishing between clusters of symptoms and b) a two-factor second-order model where the correlations between symptom clusters are explained by two second-order factors reflecting PTSD and DSO. Results from previous studies suggest that the second-order model has a better fit in clinical and highly trauma-exposed samples in studies that have used the ITQ (Cloitre et al., 2018; Hyland et al., 2017; Karatzias et al., 2017; Møller et al., 2019; Vallières et al., 2018), and in studies using other measures for the PTSD and DSO constructs (Hyland et al., 2017; Nickerson et al., 2016; Tay, Rees, Chen, Kareth, & Silove, 2015), whereas the first-order model has displayed a better fit in general population and non-clinical samples studies using the ITQ (Ben-Ezra et al., 2018; Ho et al., 2020; Shevlin et al., 2017). However, research testing the latent structure of the ITQ in different clinical populations of trauma survivors are lacking but important to further explore the internal structure of the ITQ. This is an important contribution of the present study that is conducted with five different clinical samples recruited from treatment facilities for refugees and torture survivors, psychiatric outpatients, adult survivors of sexual abuse, and from women shelters, where women exposed to partner- and family related violence (e.g. physical, psychological and sexual abuse) can seek acute refuge.

1.2. Convergent and discriminant validity

While internal structure analysis is useful for testing whether it is valid to treat a set of indicators as reflecting the same latent construct, analysis of relationships to other constructs is useful to test the validity of assuming that the model reflects the construct it purportedly measures (Pedhazur & Schmelkin, 1991). Depression and anxiety are known comorbid disorders of PTSD (Spinhoven, Penninx, Van Hemert, De Rooij, & Elzinga, 2014), and recent theoretical advances argue that this comorbidity is reflective of the disorders' shared internalizing nature (Kotov et al., 2017). Recent research has extended this evidence to the ICD-11

disorders associated with traumatic stress. Specifically, anxiety has been linked to ICD-11 PTSD and DSO, whereas DSO and not PTSD has been associated with depression (Ho et al., 2020; Hyland et al., 2017). Additionally, the distress associated with PTSD and DSO has also been reflected by an inverse relationship to general well-being (Ben-Ezra et al., 2018).

1.3. Hypotheses

Based on existing evidence, we expect that support for the appropriateness of the latent structure reflecting the ICD-11 diagnoses of PTSD and DSO will be replicated across five clinical samples recruited in Denmark. For the analyses of convergent and discriminant validity, we expect that the validity of using the ITQ to identify PTSD and DSO will be supported by positive relationships between PTSD and DSO to cumulative trauma-exposure and negative relationships to general well-being. Furthermore, we expect that DSO would be associated with higher levels of depression and that both PTSD and DSO will be associated with higher levels of anxiety.

2. Method

2.1. Participants and procedures

Secondary data from four ongoing research projects in Denmark was used with a total of 1197 participants. All data was collected at baseline before treatment. These include:

Sample 1 Adult survivors of childhood sexual abuse attending one of three outpatient regional treatment facilities in Denmark (N = 385; $M_{age} = 36.6$, SD = 12.01, range = 18-71) between January 2018 and February 2020. Majority of participants were women (85.6%) and all were Caucasian. Exclusion criteria from the study included a current alcohol or substance abuse, a diagnosis of a psychotic disorder, self-harming behaviour, engagement in treatment elsewhere, and diagnosis of a severe personality disorder. This sample was administered a Danish translated version of the ITQ.

Sample 2: Women enrolled at one of four Danish women shelters between May 2017 and September 2019 following exposure to partner and family related violence. In Denmark, women shelter's offer emergency safety and thus, all women were experiencing physical, psychological or sexual violence at the time of enrolment. The women were screened within the first 10 days of their stay $(N = 147; M_{age} = 34.6 \text{ years}, SD = 10.1, range = 18-79;$ (Dokkedahl et al., 2019). Women with substance abuse problems and psychotic symptoms were not eligible for enrolment at the shelters. This sample was administered a Danish translated version of

Samples 3 and 4: Two samples of psychiatric outpatients recruited from multisite governmentally funded mental health clinics from December 2017 to September 2019. One sample (N = 111) were patients included because they had an ICD-10 PTSD diagnosis, were aged between 18 and 65 years and capable of speaking and understanding Danish $(M_{\text{age}} = 41.67 \text{ years, SD} = 11.89, \text{ range } 18-65, 58,6\%$ (n = 65) men). Traumatized refugees were excluded. The other sample represents a heterogenous psychiatric population that were included in the present study if they had reported at least 1 traumatic event $(N = 178, M_{\text{age}} = 34.13 \text{ years}, SD = 12.94, range}$ 18-65, 73,6% (n = 131) women)) These samples were administered a Danish translated version of the ITQ.

Sample 5: Refugees and torture survivors attending treatment at a specialized outpatient clinic in Denmark (N = 385, $M_{age} = 43.48$, SD = 10.02, range = 14-71). Participants were recruited between 2016 and February 2019. The participants were equally distributed between men (n = 200; 51.9%)and women (n = 185; 48.1%) across multiple nationalities. The majority were Syrian refugees (n = 182; 47.3%). Patient inclusion criteria included refugees and survivors of torture or other organized violence outside Denmark suffering from PTSD or patient's relatives experiencing PTSD symptoms. Exclusion criteria included residents without asylum status or legal stay in Denmark, a diagnosis of a psychotic disorder, diagnosis of a severe personality disorder, or self-harming behaviour. For patients with limited Danish language proficiencies, Arabic and Bosnian translated versions of the Danish version of the ITQ or assistance of interpreters were used in the assessment procedure. See (Vang et al., 2019) for an assessment and discussion of the consequences of using interpreters in assessing trauma symptoms using the ITQ in a subsample of the present sample.

All data-collections were conducted according to the European General Data Protection Regulations and approved by the relevant authorities.

2.2. Measures

2.2.1. Trauma exposure

Different measures of cumulative trauma-exposure were used across the samples:

Sample 1: The participants were asked whether they had experienced a total of 19 sexually abusive acts as a child (see Shevlin, Murphy, Elklit, Murphy, & Hyland, 2018 for further details). The reported acts were added into one total score. The mean was 7.93 (SD 3.99, n = 361), range 1–19.

Sample 2: The Conflict Tactic Scale-Revised (CTS-2) was used to assess victimization and perpetration of intimate partner violence (Straus, Hamby, Boney-McCoy, & Sugarman, 1996). Only the 20 items assessing victimization have been included in this analysis. All items that were added into a total score. The mean was 7.57 (SD 3.17, n = 125), range 0–14.

Samples 3 and 4: The Life Event Checklist (LEC) was used to examine direct exposure and witnessing of traumatic events (Gray, Litz, Hsu, & Lombardo, 2004). In addition to the original 16-items on the LEC, individual items assessing traumatic childhood exposure were included (i.e. childhood physical abuse, childhood sexual abuse and childhood neglect; (Moller, Augsburger, Elklit, Sogaard, & Simonsen, 2020)). The mean of direct and witnessed exposures for ICD-10 PTSD patients was 8.24 (SD 4.64, n = 111), range 1–30. The mean of direct and indirect exposures for the heterogenous patient sample was 6.54 (SD 4.06, n = 178), range 1–22.

Sample 5: Traumatic exposure was assessed with four dichotomous questions constructed by the clinic for the purpose of their assessment. These mapped the exposure to torture, traumatic flight, war and captivity prior to the patients' arrival in Denmark. The mean was 3 (SD 0.92, n = 385), range 2–4.

2.2.2. Mental health measures

2.2.2.1. ICD-11 PTSD and DSO. The ITQ is a 12item self-report measure for assessment of ICD-11 PTSD and CPTSD. Items are scored on a five-point Likert scale from 0 ('Not at all') to 4 ('Extremely'). Respondents are asked how much each PTSD symptom has bothered them over the last month and DSO symptoms are answered in terms of how much the respondents typically experience the symptoms. The initial version of the ITQ including multiple items for re-experiencing and DSO-clusters were used at the beginning of data-collection for some samples. Items consistent with the final version of the ITQ was used for the current analysis, and items assessing functional impairment were unavailable for all samples but the psychiatric outpatient samples. Symptoms considered endorsed with scores of two ('Moderately') or more. For a probable diagnosis of PTSD, one symptom is required in each of the clusters for re-experiencing, avoidance and sense of threat as well as a score of two or more on one of the three questions assessing associated functional impairment. For a probable diagnosis of CPTSD, one symptom is required in each of the clusters for affective dysregulation, negative self-concept and disturbed relationships in addition to a diagnosis of PTSD. Similarly, a score of two or more is required on one of the three questions assessing functional impairment related to DSO. The ITQ was translated into Danish by researchers from the Psychiatric

Research Unit in Region Zealand and the Danish National Centre for Psychotraumatology and professionally back-translated. This back-translation was approved by the authors of the measure (M. Cloitre, communication Personal with L. November 19th, 2019). Cronbach's alpha for the ITQ in the present study ranged between .73 and .92 for the PTSD subscale, .77 and .86 for the DSO subscale, and .81 to .85 for the full scale across the samples. The ITQ is a freely available measure and can be accessed in different languages along with other available ICD-11 stress-related measures on: https://www.traumameasuresglobal.com.

Psychological distress: Psychological distress was measured differently across the samples:

2.2.2.2. Other trauma-related symptoms. The Revised Trauma Symptom Checklist (TSC-26) was used among sample 1 and 2, survivors of childhood sexual abuse (M = 58.9, SD = 12.78, n = 327) and women in shelters (M = 35.78, SD = 15.83, n = 117). It includes three subscales measuring negative affect, somatization and dissociation (Briere & Runtz, 1989; Krog & Duel, 2003). The experiences are measured on a four-point Likert scale ranging from 0 ('Never') to 3 ('Very often'). For the current study, a total summed score across the items were used to indicate severity of trauma-related distress. The TSC displayed acceptable internal stability with Cronbach's alpha = .89 and .93 for survivors of childhood sexual abuse and women in shelters, respectively.

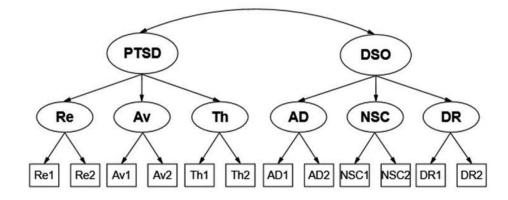
2.2.2.3. Hopkins Symptom Checklist (HSCL). Several language versions of the Hopkins Symptoms Checklist (HSCL-25) (for example Arabic, Bosnian, Russian and Danish) were used among refugees and torture survivors (sample 5) to operationalize anxiety and depression. The HSCL with 25 items is a widely used tool for screening depression and anxiety because of its brevity, simplicity, and its wellpsychometric documented properties Hovens, & Rodenburg, 2001). Three scores can be calculated: the total score is the average of all 25 items, while the anxiety score is the average of the 15 anxiety items (1 through 15, M = 47.38, SD = 8.24, n = 240) and the depression score is the average of the 10 depression items (16 to 25, M = 31.26, SD = 5.90, n = 253). The items are reported on a four-point scale, ranging from 1 ('Not at all') to 4 ('extremely'). The total score is highly correlated with severe emotional distress (Hesbacher, Rickels, Morris, Newman, & Rosenfeld, 1980). For the current study, subscale scores on anxiety (Cronbach's alpha = .86) and depression (Cronbach's alpha = .84) were used separately.

2.2.2.4. Bech-19. The Bech-19 is a 19-item scale that was used among survivors of sexual assault (sample 1) to operationalize anxiety and depression. The Bech-19 screens for depression (items 1-6), anxiety (items 7-14) and interpersonal sensitivity (items 15-19). The scale has been validated in a study of 850 Danish psychiatric outpatients and displayed excellent psychometric qualities as well as unidimensionality for the scales for anxiety and depression (Bech, Bille, Moller, Hellstrom, & Ostergaard, 2014). For the current study, subscale scores on anxiety (Cronbach's alpha = .81, M = 14.70, SD = 26.02, n = 385) and depression (Cronbach's alpha = .84, M = 15.29, SD = 23.4, n = 385) were used separately.

2.2.2.5. General well-being. General well-being was measured using the 5-item WHO-5 in the samples of psychiatric outpatients and women in shelters (samples 2, 3 and 4). The WHO-5 was developed by the Psychiatric Research Unit, Mental Health Centre North Zealand in Denmark and has been found to support valid identification of depression and subjective well-being (Topp, Ostergaard, Sondergaard, & Bech, 2015). It is scored on a six-point Likert scale ranging from 0 ('Never') to 5 ('All of the time'). For the current study, a total summed score across the items was used to indicate levels of general psychological well-being. Cronbach's alpha was .84 for survivors of childhood sexual abuse (M = 8.93,SD = 4.67, n = 372), .88 for women in shelter (M = 6.73, SD = 5.17, n = 143), .99for ICD-10 PTSD psychiatric outpatients (M = 7.18, SD 0 4.70, n = 107) and 1.0 for the heterogenous sample of psychiatric outpatients (M = 6.70, SD = 4.60, n = 169).

2.3. Statistical analyses

Initially, descriptive statistics and diagnostic rates were computed for all samples. Analysis progressed in three linked stages. Firstly, for the internal structure analysis, two factor-models were computed to test competing models of the latent structure of the ITQ across the samples: A six factor first-order model reflective of the symptom clusters of PTSD and DSO as per the ICD-11 with 51 parameters, and a two factor second-order model reflective of the ICD-11 configuration of the relationships of the symptom clusters with 43 parameters (Figure 1). Secondly, for the analysis of convergent and divergent validity, the best fitting model was included in a series of regression analyses. Cumulative trauma-exposure were included as predictors of the latent variables in one set of analyses also including age and sex as exploratory variables, whereas the latent variables were included as predictors of other mental health



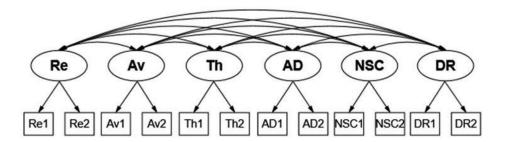


Figure 1. Competing models of the latent structure of the ITQ. Re: Re-experiencing. Av: Avoidance. Th: Threat. Ad: Affective dysregulation. NSC: Negative self-concept. Dr: Disturbed relationships.

indicators in another set of analyses. All analyses were conducted using robust maximum likelihood (Yuan & Bentler, 2000) in Mplus (Muthén & Muthén, 2018) using the full 5-point scale version of the ITQ. Missing data was handled using maximum likelihood.

Individual models were fitted to the two psychiatric samples. The fit of the models was evaluated using a standard range of model fit indices (Kline, 2011). Conventionally, models that have a nonsignificant chi-square test (χ^2) reflect an acceptable fit, and Comparative Fit Index (CFI, Bentler, 1990) and Tucker-Lewis Index (TLI, Tucker & Lewis, 1973) values \geq .90 and \geq .95 reflect acceptable and excellent model fit, respectively. Models with SRMR values below \leq .08 and \leq .05 reflect acceptable and excellent model fit, respectively, and models with a Root Mean Square Error of Approximation (RMSEA, Jöreskog & Sörbom, 1993) values below $\leq .08$ and $\leq .05$ reflect acceptable and excellent model fit, respectively. Differences in the RMSEA values of 0.015 are held to indicate meaningful differences between the models (Chen, 2007). Finally, the Bayesian Information Criterion (BIC, Schwarz, 1978) was used to compare model fit with a difference of 10 or more points lower on the BIC indicating superior model fit (Raftery, 1995). RMSEA and the BIC are sensitive to the number of parameters in the models and thereby penalize model-complexity and award more parsimonious models.

3. Results

3.1. Descriptive statistics and diagnostic rates

Table 1 displays the mean scores and standard deviations on items on the ITQ across the samples. Refugees and torture survivors displayed the highest mean scores across the items. Table 2 displays diagnostic rates across the samples.

Overall, rates of CPTSD were higher than rates of PTSD for all samples. Notably, the inclusion of functional impairment as a criterion reduced the number of participants endorsing any diagnosis, particularly the rates of probable PTSD among the patients previously endorsing an ICD-10 diagnosis of PTSD.

3.2. Internal structure analysis

Results from the first stage of the analysis are reported in Table 3.

A significant chi-square test was found across most models; however, the chi-square test is known to be overly restrictive leading to rejection of appropriate models in larger samples (Tanaka, 1987) and should therefore not lead to model rejection alone. According to the remaining fit statistics, both models displayed an acceptable fit to the data to individual samples of adult survivors of childhood sexual abuse, refugees and torture survivors and psychiatric outpatients. There was mixed evidence for the fit of the models in the sample of women in shelters. The first-order model

Table 1. Means and standard deviations on the ITQ across the samples.

	Survivors of sexual abuse		Women i	n shelter	ICD-10 PT: outpa	,	Heterogen outpa	•	Refugees a survi	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
RE1	1.49	1.36	2.22	1.45	2.41	1.34	1.52	1.39	3.12	1.11
RE2	1.11	1.27	1.97	1.49	2.24	1.23	1.61	1.35	3.09	1.12
RE3	2.47	1.43	2.65	1.25	2.76	1.06	2.35	1.34	3.52	0.81
AV1	2.68	1.25	2.74	1.21	2.59	1.12	1.94	1.32	3.23	0.99
AV2	2.45	1.37	2.63	1.32	2.57	1.19	1.83	1.39	3.06	1.19
TH1	2.61	1.37	3.13	1.19	3.41	0.83	2.54	1.36	3.13	1.18
TH2	2.28	1.49	2.74	1.42	2.93	1.20	2.20	1.37	3.33	1.03
AD1	2.37	1.20	1.68	1.33	2.77	1.01	2.53	1.12	2.95	1.14
AD2	2.30	1.30	2.03	1.46	2.07	1.31	2.10	1.31	2.81	1.31
NSC1	2.48	1.34	2.08	1.46	2.42	1.46	2.80	1.32	2.47	1.50
NSC2	2.34	1.42	1.79	1.48	2.18	1.46	2.62	1.35	2.37	1.53
DR1	2.29	1.26	1.89	1.40	2.24	1.31	2.25	1.28	2.70	1.40
DR2	2.61	1.23	1.99	1.42	2.50	1.24	2.23	1.31	2.65	1.39

RE = Re-experiencing; AV = Avoidance; TH = Sense of Threat; AD = Affective Dysregulation; NSC = Negative Self-Concept; DR = Disturbed Relationship. One participant from the sample of women in shelter scored 0 on the ITQ as the only participant across the samples.

Table 2. Diagnostic rates across of ICD-11 PTSD and CPTSD.

	Wit	h functional impai	rment	Witho	Without functional impairment				
	No diagnosis	PTSD	CPTSD	No diagnosis	PTSD	CPTSD			
Survivors of sexual assault	N/A	N/A	N/A	53.7% (n = 202)	10.9% (n = 41)	35.4% (n = 133)			
Women in shelter	N/A	N/A	N/A	31% (n = 44)	31.7% (n = 45)	37.3% (n = 53)			
ICD-10 PTSD psychiatric sample	22.5% (n = 25)	21.6% ($n = 24$)	55.9% (n = 62)	20.7% ($n = 23$)	21.6% ($n = 24$)	57.7% (n = 64)			
Heterogenous psychiatric sample	31.8% (n = 54)	5.3% (n = 9)	60.1% ($n = 107$)	27.6% (n = 47)	5.6% (n = 10)	66.5% (n = 113)			
Refugees and torture survivors	N/A	N/A	N/A	8.6% (n = 34)	23.3% (n = 92)	68.1%(n = 269)			

Data on functional impairment was only available for some samples. Where possible, the number of participants meeting the diagnostic criterion was calculated for participants with and without the criterion for functional impairment. Supplementary Table 5 displays diagnostic rates for women in shelter and ICD-10 PTSD psychiatric outpatients using RE3 in place of RE1.

Table 3. Fit statistics for confirmatory factor analyses across samples.

Model	Chi ² (df)	р	CFI	TLI	RMSEA (90% CI)	SRMR	BIC
Survivors of childho	ood sexual abuse $(N = 3)$	385)					
First-order	86.557 (39)	<.001	0.948	0.913	0.057 (0.041-0.073)	0.036	14631.238
Second-order	90.621 (47)	<.001	0.953	0.934	0.049 (0.034-0.065)	0.040	14590.516
Women in shelter (N = 147)						
First-order	78.122 (39)	<.001	0.927	0.876	0.083 (0.056-0.110)	0.052	6124.339
Second-order	105.616 (47)	<.001	0.890	0.846	0.092 (0.069-0.116)	0.066	6111.556
ICD-10 psychiatric of	outpatients ($N = 111$)						
First-order	61.067* (39),	0.014	0.956	0.925	0.071 (0.033-0.105)	0.057	3951.865
Second-order	68.915* (47)	0.0203	0.956	0.939	0.065 (0.026-0.096)	0.059	3922.818
Heterogeneous psy	chiatric outpatients (N :	= 170)					
First-order	54.452* (39)	0.0511	0.984	0.973	0.048 (0.000-0.076)	0.031	6086.189
Second-order	77.394* (47)	0.0034	0.968	0.955	0.062 (0.036-0.086)	0.062	5998.499
Refugees and tortu	re-survivors ($N = 378$)						
First-order	48.245 (39)	0.15	0.991	0.985	0.025(0.000-0.046)	0.029	13353.349
Second-order	69.466(47)	0.02	0.978	0.969	0.036 (0.015-0.052)	0.040	13333.698

Discrepancies between N listed in this table and N listed in the description of participants are due to missing data. The second-order CFA of the psychiatric outpatient sample endorsing ICD-10 PTSD partially replicates an analysis of an existing study under review (2019).

displayed the best fit according to the CFI, TLI and SRMR in the sample of women in shelter, but the RMSEA indicated elevated levels of error in both models. However, the RMSEA is sensitive to sample size which might lead to over-rejection of models that are true in the population (Chen, 2007). Across all individual samples, a difference of more than 10 in the BIC-values indicated the second-order model as the most appropriate representation of the data consistent with the ICD-11 proposal for disorders related to stress. However, the difference in RMSEA values between the models did not surpass 0.015, suggesting that the models are close to being equivalent. In accordance with the theoretical proposition for ICD-11

PTSD and CPTSD, the second-order model was deemed the best representation of the internal structure of the ITQ for the individual samples and was carried on to the second step of analysis. Tables 4 and 5 display factor loadings for the second-order models across the samples for observed indicators and firstorder factors, respectively. For women in shelters, this allowed for a further exploration of sources of potential misfit.

Some standardized factor correlations for individual samples were above 1. Standardized coefficients above 1 frequently occur in cases of multicollinearity but is not necessarily indicative of model misspecification (Deegan, 1978). Similar findings have

Table 4. Standardized first-order factor loadings for the second-order model of the ITQ.

	RE ₁	RE ₂	AV_1	AV_2	TH₁	TH ₂	AD_1	AD_2	NSC ₁	NSC ₂	DR ₁	DR_2
Survivors of sexual abuse	.62	.72	.66	.85	.73	.65	.27	.36	.80	.89	.67	.73
Women in shelter	.23	.80	.67	.87	.61	.79	.43	.70	.90	.88	.83	.82
ICD-10 psychiatric outpatients	.60	1.03	.75	.71	.59	.85	.41	.65	.97	.92	.79	.76
Heterogenous psychiatric outpatients	.76	.93	.79	.85	.96	.72	.46	.55	.93	.96	.80	.84
Refugees and torture-survivors	.64	.70	.69	.76	.63	.51	.59	.72	.80	.90	.81	.77

All factor loadings were significant at $p \le .0001$ -level apart from AD2 that was significant at $p \le .001$. RE = Re-experiencing; AV = Avoidance; TH = Sense of Threat; AD = Affective Dysregulation; NSC = Negative Self-Concept; DR = Disturbed Relationship.

Table 5. Standardized second-order factor loadings for the second-order model of the ITQ.

Р	TSD	by	[DSO by		
RE	ΑV	TH	AD	NSC	DR	
.77	.78	.78	1.32	.63	1.01	
.59	.65	.90	.85	.72	.89	
.60	.89	.63	.95	.63	1.08	
.73	.98	.81	1.16	.70	.91	
80	59	1 07	95	76	.93	
	RE .77 .59 .60	RE AV .77 .78 .59 .65 .60 .89 .73 .98	.77 .78 .78 .59 .65 .90 .60 .89 .63 .73 .98 .81	RE AV TH AD .77 .78 .78 1.32 .59 .65 .90 .85 .60 .89 .63 .95 .73 .98 .81 1.16	RE AV TH AD NSC .77 .78 .78 1.32 .63 .59 .65 .90 .85 .72 .60 .89 .63 .95 .63 .73 .98 .81 1.16 .70	

All factor loadings were significant at $p \le .0001$ -level. RE = Reexperiencing; AV = Avoidance; TH = Sense of Threat; AD = Affective Dysregulation; NSC = Negative Self-Concept; DR = Disturbed Relationship.

previously been reported in an Asian sample (Ho et al., 2020) and a Swedish sample using the International Trauma Interview (Bondjers et al., 2019). The factor loadings were statistically significant and acceptable in size, apart from the item of recurrent nightmares in the sample of women in shelters that displayed a low factor loading (.232) that is inconsistent with theoretical considerations and existing empirical evidence (Brewin et al., 2017; Karatzias et al., 2016). Relatively lower factor loadings were also found for affective dysregulation among survivors of child sexual abuse. This was not further investigated as it aligns with existing evidence (Ben-Ezra et al., 2018). For a more thorough discussion of this cluster, see (Karatzias et al., 2018). For reexperiencing, existing research using previous versions of the ITQ has suggested that intense emotional distress (referred to as RE3) may be an equally appropriate indicator of re-experiencing compared to recurrent nightmares (RE1, (Karatzias et al., 2016)), and therefore, we tested the fit of a revised second-order model with RE3 replacing RE1. The fit of this model was acceptable and improved compared to the second-order model consistent with the ICD-11 criteria: Chi-square (47) = 82.365, p < .001, RMSEA (90% CI) = .073 (.046 - .098), CFI = .931, TLI = .903, SRMR = .064. Standardized factor loadings for RE2 and RE3 were .482 (p < .001) and .842 (p < .001), respectively, and re-experiencing loaded onto PTSD with .902 (p < .001). The revised second-order model displayed worse fit among survivors of child sexual abuse (Chi-square (47) = 127.342, p < .001, RMSEA (90% CI) = .067(.053 - .081), CFI = .914, TLI = .897, SRMR = .047),

improved fit to the original second-order model in ICD-10 PTSD psychiatric outpatients (Chi-square (47) = 56.310, p < .001, RMSEA (90% CI) = .042(.000 - .079), CFI = .982, TLI = .975, SRMR = .059), and comparable fit among the heterogenous psychiatric sample (Chi-square (47) = 74.456, p < .01, RMSEA (90% CI) = .058 (.031 - .082), CFI = .973,TLI = .962, SRMR = .059) and refugees and torture survivors (Chi-square (47) = 74.727, p < .01, RMSEA (90% CI) = .039 (.021 - .056), CFI = .973, TLI = .961, SRMR = .045). Consequently, the second-order model was carried into the second and third step of analysis for survivors of child sexual abuse, the heterogenous sample of psychiatric outpatients and refugees and torture survivors, whereas the revised second-order model was carried on for women in shelter and the sample of psychiatric outpatients endorsing ICD-10 PTSD. Full details of the factor loadings of the revised models can be seen in the supplementary materials as well as results from step 2 and 3 of the analyses for the ICD-10 PTSD psychiatric sample using the proposed ICD-11 model. PTSD correlated with DSO at p < .001across all samples at .50 for survivors of childhood sexual abuse, at .66 for women in shelter, at .78 for ICD-10 PTSD psychiatric outpatients, at .51 for the heterogenous sample of psychiatric outpatients, and at .69 for refugees and torture survivors.

3.3. Convergent and divergent validity

Table 6 displays the results from the second stage of the analysis testing the relationship between the latent variables and age, sex and trauma-exposure. There were modest relationships between all predictors and latent variables.

Table 7 displays the results from the third step of the analysis testing the relationship between the latent variables and other indicators of psychological distress and general well-being. Depression was consistently positively related to DSO across survivors of childhood abuse and refugees. Anxiety was statistically significantly linked to PTSD for survivors of childhood sexual abuse and refugees.

Table 6. Relationships between number of trauma-exposures and ICD-11 PTSD and DSO.

	PTS	SD	DS	0
	β	р	β	р
Survivors of childhood sexua	al abuse			
Sex	0.15	.232	-0.11	.230
Age	-0.01	.002	-0.00	.744
Cumulative trauma	0.02	.148	0.02	.050
Women in shelter (RE3)				
Sex	-	-	-	-
Age	0.11	.373	0.07	.634
Cumulative trauma	-0.1	.303	-0.18	.050
ICD-10 psychiatric outpatien	ts (RE3)			
Sex	-0.11	.341	0.01	.911
Age	0.04	.764	0.03	.765
Cumulative trauma	0.01	.919	0.11	.366
Heterogenous psychiatric ou	tpatients			
Sex	0.29	.058	0.02	.888
Age	0.01	.146	-0.01	.141
Cumulative trauma	0.08	.000	0.04	.031
Refugees and torture-survivo	ors			
Sex	0.19	.029	0.11	.069
Age	0.14	.006	0.06	.382
Cumulative trauma	0.04	.541	-0.03	.705

Sex was coded 0 = men, 1 = women. Estimates are standardized beta-values using the function stdyx in Mplus. RE3 indicates that the revised ICD-11 model is used for these samples. Values in bold were statistically significant at the $p \le .05$ level. The structural equation model were: Chi-square (77) = 176.453, p < .001, RMSEA (90% CI) = .061 (.049 - .073), CFI = .890, TLI = .862, SRMR = .049 for survivors of childhood sexual abuse, Chi-square (77) = 123.974, p < .001, RMSEA (90% CI) = .083 (.060 – .105), CFI = .880, TLI = .838, SRMR = .075 for the women in shelter, Chi-square (77) = 93.924, p = .092, RMSEA (90% CI) = .044 (.000 -.073), CFI = .969, TLI = .959, SRMR = .069 for ICD-10 PTSD psychiatric outpatients, Chi-square (77) = 120.328, p < .01, RMSEA (90% CI) = .058 (.037 - .077), CFI = .957, TLI = .944, SRMR = .062 for the sample of heterogenous psychiatric outpatients, and Chi-square (77) = 115.004, p = .003, RMSEA (90% CI) = .038 (.022 - .052), CFI = .962, TLI = .950, SRMR = .045 for refugees and torture survivors.

Table 7. Relationships between ICD-11 PTSD and DSO and psychological outcomes.

	Depression		Anx	riety	General w	ell-being	Other traum	a symptoms
	β	р	β	р	β	р	β	р
Survivors of childhood sexual abuse								
PTSD	0.12	.150	0.42	.000	-0.14	.009	0.19	.031
DSO	0.20	.029	0.41	.000	-0.49	.000	0.31	.000
Women in shelter (RE3)								
PTSD	-	-	-	-	-0.31	.067	0.25	.041
DSO	-	-	-	-	-0.18	.306	0.55	.000
ICD-10 PTSD psychiatric outpatients (RE3)								
PTSD	-	-	-	-	37	.114	-	-
DSO	-	-	-	-	13	.541	-	-
Heterogenous psychiatric outpatients								
PTSD	-	-	-	-	.02	.850	-	-
DSO	-	-	-	-	-0.52	.000	-	-
PTSD								
DSO								
Refugees and torture survivors								
PTSD	0.22	.028	0.64	.000	-	-	-	-
DSO	0.62	.000	0.20	.079	_	-	-	-

Estimates are standardized beta-values using the stdyx function in Mplus. Values in bold were statistically significant at the p ≤ .05 level. RE3 indicates that the revised ICD-11 model is used for these samples. The fit of the structural equation models were Chi-square (97) = 283.561, p < .001, RMSEA (90% CI) = .071 (.061 – .081), CFI = .906, TLI = .868, SRMR = .061 for the sample of survivors of sexual abuse, Chi-square (67) = 111.624, p < .001, RMSEA (90% CI) = .068 (.045 - .090), CFI = .926, TLI = .900, SRMR = .063 for women in shelter, Chi-square (57) = 67.685, p < .157, RMSEA (90% CI) CI) = .041 (.000 - .075), CFI = .980, TLI = .973, SRMR = .060 for ICD-10 PTSD psychiatric outpatients, Chi-square (57) = 94.314, p < .01, RMSEA (90% CI) = .062 (.039 - .084), CFI = .963, TLI = .949, SRMR = .062 for the heterogenous sample of psychiatric outpatients and Chi-square (67) = 111.624, p < .001, RMSEA (90% CI) = .035 (.018 - .049), CFI = .978, TLI = .970, SRMR = .043 for refugees and torture-survivors.

4. Discussion

The purpose of the present study was to test the construct validity of ICD-11 PTSD and DSO in five clinical samples. This was accomplished using translated versions of the ITQ, three of which correspond to the trauma-types following which the proposed symptoms of DSO were typically observed to evolve (Maercker et al., 2013). Findings from the internal structure analysis indicated that the ICD-11 formulation of PTSD

and DSO is an appropriate representation of the latent structure of the Danish translated version of the ITQ across clinical samples, although the model displayed suboptimal fit in the sample of women in shelters. A revised operationalization of re-experiencing using the symptom of intense emotional reactions to reminders of the trauma in place of recurrent nightmares was a better representation of posttraumatic distress in this group of participants as well as psychiatric outpatients endorsing an ICD-10 PTSD diagnosis. Women in shelters were screened within the first 10 days of their stay meaning that symptom patterns from this group of participants are reflective of acute distress experienced by individuals in crisis. In the DSM-IV and DSM-5, reactions to potentially traumatizing events within the first 30 days are diagnosed as acute stress disorder (ASD) that might transition into PTSD after 30 days. In the ICD-11 however, acute stress reactions are conceptualized as a normal reaction that may be a legitimate focus of clinical intervention, but not considered a disorder per se. In contrast, PTSD or CPTSD may be diagnosed at any time following exposure to a potentially traumatizing event if symptom- and functional impairment criteria are met over the course of several weeks. In a recent debate on the validity of ICD-11 PTSD and CPTSD, Cloitre et al. (2020) called for more research on the potential differences in the relative importance of specific symptoms across different populations experiencing complex trauma exposure. Findings from the current study are an important contribution to this debate. Our findings suggest that the operationalization of re-experiencing in the final ITQ may insufficiently identify distress that may be considered posttraumatic in individual in crisis as recurrent nightmares contributed only modestly to reexperiencing among women in shelters. This is notable, since women in shelter simultaneously displayed some of the highest average scores on PTSD symptoms, hereunder recurrent nightmares. Future research should explore whether this finding can be replicated, and if so, whether this difference is population specific, related to the recency of the traumatic event at the time of assessment, or other factors. Evidence from the present study suggests that the effect is not strictly population specific as the revised ICD-11 model provided a markedly improved fit in a sample of psychiatric outpatients previously diagnosed with ICD-10 PTSD. For now, it might be important to attend to symptoms of intense emotional distress as a potential supplementary indicator of posttraumatic distress when screening for re-experiencing among patients that may suffer from posttraumatic distress. Additionally, future research could contribute to exploring the presentation of affective dysregulation as findings from the present study suggests that there may be differences across different trauma-exposed populations with comparably weaker associations between hyper- and hypoarousal seen across all samples, a tendency particularly pronounced among survivors of childhood sexual abuse. However, fit statistics simultaneously suggested that the model displayed a very good fit to the data despite the low factor loadings.

Findings regarding the superiority of the secondorder model was equivocal across the individual samples. Evidence was particularly equivocal across the psychiatric outpatient samples with all fit indices apart from the BIC suggesting that the correlated 6-factor model was a better representation of the structure in the heterogenous sample, whereas the fit statistics converged around the second-order model for the sample of patients with an ICD-10 PTSD-diagnosis. It has previously been suggested that the first-order model best describes the structure of ICD-11 trauma-related disorders in community samples, whereas the second-order model is a more appropriate description of the data in highly trauma-exposed and clinical samples (Ho et al., 2020). Findings from the current study partly lend support to this distinction based on the differences across the psychiatric samples. However, findings from the current study also partly contradict this proposition as the first-order model displayed equal and sometimes superior fit to the clinical samples. The samples in the current study are drawn from populations that are often exposed to multiple traumatic events before they come into contact with mental health services, and research has previously demonstrated that comorbidity and severe psychiatric morbidity are common among survivors of childhood sexual abuse (McElroy et al., 2016), women in shelter (Elklit, Murphy, Jacobsen, & Jensen, 2018), psychiatric outpatients (Floen & Elklit, 2007), and refugees and torture survivors (Fazel, Wheeler, & Danesh, 2005). Findings from the present and previous studies have also shown that particularly ICD-11 PTSD is correlated with anxiety and particularly DSO is correlated with depression (Ho et al., 2020; Hyland et al., 2017), and that all three disorders are reflective of a higher order dimension of internalizing psychopathology (Kotov et al., 2017; Møller, Søgaard, Elklit, & Simonsen, 2021). Consequently, the close fit of the six-factor first-order model across these clinical samples could also be reflective of the presence of more disorders on the internalizing spectrum of psychopathology whose symptoms are partially overlapping and therefore not necessarily sufficiently represented by summarizing their relationships in factors of PTSD and DSO alone. It should be noted, however, that the hypothesis regarding the relationship between DSO and anxiety for the refugee sample was not supported.

Findings from the analysis on the relationships between other indicators of mental health and ICD-11 PTSD and DSO however supported the ICD-11 operationalization with consistently positive relationships to alternative indicators of psychological distress and consistently negative relationships to indicators of general well-being. Contrary to our expectations however, trauma-exposure was inconsistently related to PTSD and DSO. For the present study, trauma-exposure was not uniformly

operationalized across the samples. Patients from all samples have often been exposed to multiple and severe forms of trauma, and it is possible that the assessment of trauma-exposure has been too narrow to adequately reflect the importance of traumaexposure. Only psychiatric outpatients completed a comprehensive assessment of multiple trauma types, whereas all other samples were screened using referral-specific trauma-screening. Polyvictimization has previously been shown to explain differences in trauma symptomatology over and above single trauma types (Finkelhor, Ormrod, & Turner, 2007) which might contribute to explaining the lack of significant relationships for samples completing referral-specific screening.

4.1. Strengths and limitations

The current study has several strengths. It included five samples from clinical populations exposed to different types of trauma that are particularly likely to lead to DSO (Cloitre et al., 2013) and employed diverse measures of common mental health problems that are routinely used in clinical practice to support the validity of using the ITQ to identify symptoms of ICD-11 PTSD and DSO. However, several limitations should be acknowledged.

In most samples, psychotic symptoms and problems with substance abuse were reason for exclusion. This is an important limitation because participants with more severe symptomatology of both PTSD and CPTSD may have been excluded due to comorbid symptoms as psychotic-like experiences and ICD-11 PTSD and CPTSD has been shown to co-occur (Frost, Vang, Karatzias, Hyland, & Shevlin, 2019). A potential limitation to the study was an overrepresentation of female participants, which is partially explained by two of the included samples, i.e. female victims of intimate partner violence and victims of childhood sexual abuse. However, existing evidence regarding the psychometric properties of a previous version of the ITQ has supported the latent structure consistent with the ICD-11 proposal in a sample of male perpetrators of intimate partner violence (Gilbar et al., 2018), suggesting that the internal structure of the ITQ is not gender dependent. In the interpretation of findings from the study, it should be noted that participants with personality disorder were excluded from the sample of survivors of CSA and refugees and torture survivors.

5. Conclusion

The present study supports the validity of translated versions of the ITQ to identify symptoms of PTSD and DSO consistent with the ICD-11 proposal for disorders related to traumatic stress among highly trauma-exposed populations recruited in Denmark. Evidence from the current study also suggested that the final configuration of reexperiencing in ICD-11 PTSD may be suboptimal in reflecting re-experiencing among women victims of intimate partner violence and psychiatric outpatients endorsing the criteria for ICD-10 PTSD. Further research is required to replicate and explore potential explanations for this finding.

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The authors have no conflicts of interests to declare.

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Data availability statement

The data that support the findings of this study are available on request from the corresponding author, Maria Louison Vang. The data are not publicly available due to privacy reasons.

Ethics statement

As the manuscript is based on secondary data analysis, no Institutional Review Board approval or informed consent from participants has been obtained for this manuscript.

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