Towards the validation of the International Trauma Interview for Post-Traumatic Stress Disorder and Complex Post-Traumatic Stress disorder, and the role of core beliefs in the development and maintenance of CPTSD

Zoe Wagland

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Declaration

I hereby declare that the work presented in this thesis has not been submitted for any other degree or professional qualification, and that it is the result of my own independent work.

Zoe Wagland

01/10/2023

Date

Abstract

Background

Complex post-traumatic stress disorder (CPTSD) was added to the International Classification of Diseases 11th edition (ICD-11) as a sibling diagnosis to post-traumatic stress disorder (PTSD) (WHO, 2018). To date the only validated measure for CPTSD is the International Trauma Questionnaire (ITQ) (Redican et al., 2021). However, the current gold standard for diagnosis is a clinician interview (Siqveland et al., 2017). For the reliable diagnosis of CPTSD, it is important that a diagnostic interview protocol be developed. The International Trauma Interview (ITI) (Roberts et al., 2019), is based on the ITQ and intends to fill the need for an interview CPTSD measure, however validation is necessary.

This thesis is also concerned with the relationship between CPTSD and negative core beliefs (NCBs). An NCB is defined as a core belief or schema detailing negative beliefs about the self. This relationship may help to shed light on how CPTSD is developed and maintained, and how CPTSD may be treated. Research already shows how PTSD relates to NCBs, and this has informed the successful use of cognitive behavioural therapies for PTSD.

Research questions

1) What research already exists about the correlation between CPTSD and NCBs?
2) What NCBs are correlated with CPTSD when CPTSD is measured with the ITQ?
3) Is the ITI a reliable and valid assessment tool for CPTSD?

Methods

A meta-analysis was conducted to collate data published in pre-existing studies that explore associations between DSO symptoms and NCBs, with the view to understand what is already known, and identify gaps in the literature. The search strategy identified studies measuring the relationship between NCBs and proxy measures of DSO symptoms. R values were extracted and analysed in a random effects meta-analysis.

In order to address gaps in the literature and establish the relationship between NCBs and a direct measure of PTSD/CPTSD, an online survey (n=2,144) was also conducted to collect empirical data based on the findings from the meta-analysis. A measure of NCBs (core beliefs questionnaire, Wong et al., 2017) is administered alongside the ITQ. Correlational and reliability analyses were run.

Finally, this thesis aimed to provide a provisional validation of the ITI for assessment of PTSD and CPTSD. Participants (n=25) were recruited from NHS psychology services and administered both the ITQ and the ITI. These data were analysed for validity and reliability. Concurrent validity was measured by the agreement between the ITI and ITQ using Pearson's *r*, internal reliability was analysed with Cronbach's Alpha, and clinical utility was analysed qualitatively.

Results

The results of the meta-analysis suggest moderate positive correlations between CPTSD symptoms and NCBs. Further research using direct measures of CPTSD symptoms and using clinical populations was recommended.

The results of the large-sample study show very strong correlations between NCBs and PTSD/CPTSD symptom profiles. Some types of NCBs are strongly

associated with CPTSD, NCBs are less significantly correlated with NCBs. Steps must be taken to replicate these findings with clinical populations to draw conclusions for therapeutic practice.

The ITI showed promise as a CPTSD assessment tool but the sample in this thesis was too small to be counted as a standalone validation study. Further research is required to establish the validity and reliability of the English language version of the ITI.

Discussion

The meta-analysis indicated positive, moderate correlations between NCBs and proxy measures of DSO symptoms. Gaps in the literature are identified as weaknesses in reporting of data by published studies. Many studies omitted demographic data, power analyses, and the use of proxy measures causes issues with validity of results.

The large-sample online survey study revealed strong correlations between specific NCBs and CPTSD symptom profiles, and the negative self-concept DSO symptoms were the most strongly correlated. There was no significant difference in endorsement of NCBs between participants with PTSD and non-symptomatic profiles. CPTSD symptom profiles correlated significantly more strongly with NCBs than either PTSD or non-symptomatic profiles. This indicates that there is a significant difference between the cognitive structure of CPTSD and PTSD/non-symptomatic profiles.

Dedication

This thesis is dedicated to Rita Woodbridge, George and Ruth Wagland, Mike, Gina, and Sam Wagland, and Shaune Murray.

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Contents

List of tables

List of figures

Glossary of terms

Abbreviation	Term
AD	Affect dysregulation
CBQ	Core beliefs questionnaire
CPTSD	Complex post-traumatic stress disorder
DR	Disturbed relationships
DSM	Diagnostic and statistical manual for mental disorders
DSO	Disturbances in self-organisation
ICD-11	International classification of diseases 11th edition
ITEM	International trauma experience measure
ITI	International trauma interview
ITQ	International trauma questionnaire
NCB	Negative core beliefs
NICE	National Institute for Clinical Excellence
PD	Personality disorder
PTSD	Post-traumatic stress disorder
WHO	World Health Organisation

1 Introduction

1.1 Classification of post-traumatic disorders

Post-traumatic stress disorder (PTSD) was first included in the International Classification of Diseases, 10th edition (ICD-10) published by the World Health Organisation (WHO, 1992). Research following the publication of ICD-10 was used to propose a cognitive model of PTSD (Ehlers, & Clark, 2000), validate diagnostic tools (Blake et al., 1995), and develop treatment protocols (Marcus et al., 1997; Sherman, 1998).

A variety of publications emerged arguing that the existing concept of PTSD did not fully encompass the range of symptoms experienced by individuals with complex trauma backgrounds (Herman, 2015; van der Kolk, 2005). It was also identified that the ICD-10 criteria yielded unusually high comorbidity of PTSD and personality disorders (PDs) when compared with the prevalence of PDs in the general population (Oldham, 1994; Weissman, 1993) and differentiation between PTSD and PDs was difficult for the practicing clinician (Bollinger et al., 2000).

Similarities between CPTSD and PDs include interpersonal difficulties, social isolation, negative view of the self, and a correlation with experience of trauma (Felding, et al., 2021; Frost, et al., 2020; Powers, et al., 2022). While these symptoms are common between the two disorders (WHO, 2018), there are differences made clear in the ICD-11. For example, interpersonal difficulties in CPTSD is characterised by consistent withdrawal from social contact, perhaps due to the belief that others are dangerous (Frost, et al., 2020). Whereas interpersonal difficulties in PDs may be better described as a pattern of intense idealisation of a particular person, and the subsequent sabotaging of that relationship or withdrawal

following rejection (Frost, et al., 2020). The end result of both behaviours is a general difficulty in maintaining relationships but a detailed examination of the cause of this difficulty reveals distinct patterns of behaviour. Similarly, negative view of the self in CPTSD is a pervasive, global belief in the self as worthless and a failure, while a PD symptom profile requires a fluctuation between periods very high self-worth, followed by intense feelings of worthlessness (Frost, et al., 2020).

It was clear from further research that clarification in both the PD and PTSD diagnostic criteria was necessary (Ford, & Courtois, 2014) and arguments were made for the addition of a complex PTSD (CPTSD) disorder to the 2018 ICD 11th edition (ICD-11) (Ford, & Courtois, 2014; Herman, 1992; Ide, & Paez, 2000). As a result of this, a reconfigured definition of PTSD and the novel sibling diagnosis of CPTSD were listed in the ICD-11. The goal of the ICD-11 was also to increase clinical utility of each diagnosis listed (Maercker, 2021). To this end, the revised description of PTSD contains clear core symptoms, concise definitions, and guidelines on differentiating between CPTSD and PDs.

The research in this thesis will reference ICD-11 diagnostic criteria, and research based on ICD-11 measures, with exceptions where ICD-11 evidence is unavailable. This is because the ICD-11 is more clinically relevant, (the most up to date and commonly used diagnostic system in Scotland where this research is taking place) and the only diagnostic manual that currently lists CPTSD as a disorder. The ICD-11 is therefore more relevant to the population used in the research associated with this thesis.

1.1.1 Diagnostic criteria

The ICD-11 requires the presence of an index event for the diagnosis of both PTSD and CPTSD. The index event is defined as the single "worst" traumatic event which is thought to be the main cause of the client's distress (WHO, 2018). Assessment of the index event relies on the client's autobiographical memory and their ability to assess each event for traumatic significance. Whilst this may be more straightforward for clients with only one index event, for the client with multiple traumatic events or poor recall of an event, identification of the main index event may be more complicated (Peirce et al., 2009).

The diagnosis of PTSD, as listed in the ICD-11, involves symptoms classified into three symptom clusters: re-experiencing in the here and now, avoidance, and sense of current threat (WHO, 2018). The domain of re-experiencing is defined as unpleasant, unintentional recollections of an event (often experienced as flashbacks or nightmares) resulting in the person believing that they are reliving the traumatic event in the present moment (Brewin 2015; Ehlers et al., 2004). Dreams are accompanied by significant loss of sleep and feelings of horror (Miller et al., 2017).

The avoidance symptom cluster embodies behaviours employed designed to reduce or eliminate contact with people, places, and activities which may serve as triggers (WHO, 2018). This can include avoidance of internal reminders through suppression of thoughts or feelings related to the index event (Powers et al., 2022).

Sense of current threat is described as persistent feelings of heightened threat, which may be indicated by the presence of hypervigilance and an exaggerated startle response (WHO, 2018). Sense of current threat is generally pervasive

throughout the day, and the person may experience hypervigilance and hyperarousal (Hyland et al., 2020).

The ICD-11 definition of CPTSD requires that the above PTSD symptom clusters be present, as well as symptoms relating to the domains of affect dysregulation, negative self-concept, and disturbed relationships (WHO, 2018). These three symptom clusters are collectively known as disturbances in self-organisation (DSO). The inclusion of PTSD symptoms along with additional symptom clusters is indicative of CPTSD being a sibling disorder of PTSD. That is, the two disorders are related and share similar aetiology but there are differences in presentation and associated risk factors (Ben-Ezra et al., 2018; Karatzias et al., 2017).

In CPTSD, affect dysregulation may be recognised by level of reactivity to emotionally challenging situations. For example, poor emotion regulation can be exemplified by hyper-reactivity (emotional outbursts at inappropriate moments) or hypo-reactivity (numbing or flattening of emotional reactions) (Ford & Courtois, 2014). The symptom cluster of negative self-concept is defined by the ICD-11 as including negative beliefs about the self, feelings of guilt or shame, and a pervasive feeling of worthlessness (Gilbar 2020; Glück et al., 2017; Steen et al., 2023). Many people with CPTSD believe that the world would be better off if they were dead, or that anything they attempt is doomed to fail (Banz et al., 2022; Karatzias et al., 2019).

The final symptom cluster, disturbed relationships, is defined as difficulties in maintaining long-term relationships and strong feelings of being distanced from others (WHO, 2018). The traumatised person may feel unable to make emotional

connections and may isolate themselves form others who they were previously close to (Heim et al., 2022; Karatzias et al., 2023).

The ICD-11 rounds off the diagnostic descriptions for both PTSD and CPTSD by detailing that the symptoms must be present for several weeks and cause a significant level of impairment in the domains of social and occupational functioning (Brenner et al., 2019). The CPTSD symptoms and functional impairment must be demonstrated to be related to the identified index event, either through timeline (emergence of symptoms following the index event) or by identifying how the client's cognitions have changed as a result of the index event to cause the symptoms (Roberts et al., 2019).

Since CPTSD was added to the ICD-11 relatively recently, there is a need for validation of diagnostic tools for CPTSD and the development of a model that integrates pre-existing CPTSD research into a model that explains the development and maintenance of ICD-11 CPTSD and PTSD disorders (Hyland et al, 2023). Diagnosis of CPTSD is required for clients to access appropriate treatment services and for research into CPTSD to be conducted (Gelezelyte et al., 2022; Karatzias, & Levendosky, 2019). Presently, CPTSD is being diagnosed via clinical judgement and a self-report diagnostic tool, but the ideal would be the availability of validated self-report and clinician-administered tools for screening and diagnosis, designed around the criteria for CPTSD as listed in the ICD-11 (Bisson et al., 2020; Siqveland et al., 2017). Additionally, a cognitive model that integrates both PTSD and CPTSD would allow for greater understanding of how the two disorders develop, are maintained, and how the treatment for the two should be approached (Hyland et al., 2023).

1.2 Assessment of post-traumatic stress disorder and complex post-traumatic stress disorder

1.2.1 Self-report and clinician-administered

The assessment of PTSD and CPTSD takes the form of self-report questionnaires, or a clinician-led structured interview (Bauer et al., 2013). The clinician-led interview typically comprises items that the clinician must ask the client, with prompts for use in clarifying answers and attaining a greater level of detail. Self-report measures typically involve the client receiving a piece of a paper with items listed alongside a scoring system (typically a 1-5 Likert scale).

Both methods of assessment have benefits and drawbacks, for example, self-rated scales enable the use of quantitative data to illustrate the severity of a person's disorder and may be less susceptible to social desirability bias. However, it is possible for a client to misunderstand an item and therefore give an inaccurate response (Stone et al., 1999; Visted et al., 2017). Additionally, overlap of symptomology with other disorders such as may represent a significant hurdle to diagnosis via solely self-report measures (Ford, & Courtois, 2014).

Interviews are presently considered to be gold standard for diagnosis of a condition, due to generally higher levels of disclosure from the client (Fincher et al., 2015). Guidelines from the National Institute for Clinical Excellence (NICE) recommend that questionnaires be used for screening, while diagnosis should involve speaking with a health professional, as this represents a valuable opportunity to parse out exactly which difficulties are related to PTSD or CPTSD and which may be better explained by substance abuse or other medical conditions (NICE, 2018).

While some have demonstrated that results from self-report measures are reliable and appropriate for use in diagnosis (Ashbaugh et al., 2016; Steketee et al., 1996; Van Praag et al., 2020), this is not always the case. PTSD has been shown to be over-diagnosed by self-report measures, with up to 40% of individuals diagnosed with PTSD believing that they had been incorrectly diagnosed (Stevens et al., 2013). Stevens et al. (2013) focussed on the diagnostic concordance between validated self-report and interview measures, finding that clients previously diagnosed solely on the basis of self-report psychometric scales did not fit any published diagnostic criteria for PTSD. It was discovered that items listed on self-report scales may be misleading or confusing, and in fact a client's PTSD symptoms may be more accurately described as resulting from the presence of physical pain or fatigue caused by the index event (e.g., endorsement of the diagnostic criteria of difficulty concentrating may be caused by physical discomfort from an injury, rather than the inferred presence of rumination) (Stevens et al., 2013).

The clinician-administered PTSD scale (CAPS-5) is a clinician-administered measure of PTSD that was designed for use with the diagnostic criteria outlined in the 5th edition of the diagnostic and statistical manual for mental disorders (DSM-5) (Weathers et al., 2018). The CAPS-5 comprises 20 items and measures symptoms relating to nine symptom clusters. The CAPS-5 has been used successfully in clinical practice as well as research (Krüger-Gottschalk et al., 2022; Rameckers et al., 2021) and has produced reliable results when compared with other measures of DSM-5 PTSD (Lee et al., 2022; Resick et al., 2023). Since the CAPS-5 uses DSM-5 diagnostic criteria, there are symptom clusters in this PTSD assessment tool that may be more suited to labelling as CPTSD symptomology. For example, the CAPS-5 measures negative alterations in mood and cognition and alterations in

arousal and reactivity, both of which bear a meaningful resemblance to the DSO symptom clusters of negative self-concept and emotional dysregulation (Krüger-Gottschalk et al., 2022). This means that clinicians and researchers in the UK and around the world cannot make full use of the CAPS-5 because the ICD-11 criteria are the official diagnostic standards for the vast majority of countries. A clinician-administered measure of CPTSD that matches ICD-11 criteria is therefore required.

It is evident that the diagnosis of such a complex disorder as PTSD requires more than the sole use of self-report measures. It follows, therefore, that the same is true of CPTSD. The ideal resolution is that self-report and clinician-administered measures be used in conjunction. It is suggested (NICE, 2018) that self-report measures be used for screening clients for relevant symptoms and individuals with clinically relevant scores subsequently be given the opportunity to attend a clinician interview.

At present the only validated English-language diagnostic tool for CPTSD is the international trauma questionnaire (ITQ), a self-report measure, which, considering the evidence of over-diagnosis above, is not sufficient as a stand-alone diagnostic tool. It is necessary to develop and validate clinical interviewing styles and protocols to allow for the interview assessment of CPTSD.

1.2.2 International trauma questionnaire

The ITQ is a self-report measure designed to capture all aspects of the ICD-11 PTSD and CPTSD diagnoses. It was published in 2018 and has been validated in English-speaking UK populations (Cloitre et al., 2018). The ITQ uses 18 self-report items measured on a 5-point Likert scale, six items relating to PTSD symptom clusters, and six relating to DSO, as well as six functional impairment items relating

to both symptom clusters. Respondents are instructed to answer the PTSD questions in relation to how much they have been bothered by each symptom in the past month and are instructed to answer the DSO items in relation to how they typically feel, think about themselves, and relate to others. Probable Diagnosis of CPTSD requires the endorsement of at least one of two symptoms from each of the six PTSD and DSO clusters, plus endorsement of functional impairment associated with these symptoms. The ICD-11 taxonomic structure dictates that a person may only receive a diagnosis of PTSD or CPTSD, but not both.

The English language ITQ has been validated using British samples in Wales and Scotland (Hyland et al., 2017; Karatzias et al., 2016; Murphy et al., 2020). Translations of the ITQ have been validated in China (Ho et al., 2019), Denmark (Hansen et al., 2021), Germany (Haselgruber et al., 2020), French Canada (Cyr et al., 2022), and Lithuania (Kazlauskas et al., 2018). A review by Redican et al. (2021) identified 32 published studies using the ITQ as an assessment tool for PTSD and CPTSD. It was found that clinical studies consistently reported the ITQ as effectively distinguishing between PTSD and CPTSD at different levels of severity, as well as identifying sub-clinical levels of symptomology. It is evident that the ITQ is becoming a reliable self-report assessment tool for screening for PTSD and CPTSD. However, there is a lack of validation data for the interview version of the ITQ, the International Trauma Interview (ITI).

1.2.3 International trauma interview

The ITI was developed subsequently to the ITQ and comprises 18 items rated on a 5-point Likert scale measuring the presence of symptoms over the most recent three months (Roberts et al., 2019). Further details on the structure of the ITI can be found in section 5.10.3.

Presently, the ITI has been validated in a Swedish sample by Bondjers et al (2019). The resulting diagnostic rates were 16% PTSD and 6% CPTSD, with satisfactory inter-rater reliability (α=.76) and convergent validity. Bondjers et al (2019) concluded that these results indicated that the Swedish translation of the ITI is a reliable and valid measure of PTSD and CPTSD.

The ITI has been successfully used by Gelezelyte et al (2022) in a Lithuanian study into sexual abuse and suicide risk (n=103). Results of reliability and validity analyses performed by Gelezelyte et al (2022) indicated very good internal reliability (α = .93) and moderate agreement between the ITI and ITQ (κ = .49). The ITI has not yet been validated in an English-speaking population, and as such is not yet approved for use in research or clinical practice in this population.

Since clinician interviews are the gold standard for diagnosis (Siqveland et al., 2017) it is necessary for the English version of the ITI to be validated. The best-case scenario is that the ITQ can be used to screen for PTSD and CPTSD and then the ITI be used to confirm or disconfirm ITQ results.

Chapters five and six of this thesis will focus on the validation of the ITI for use in assessment of ICD-11 PTSD and CPTSD. Validation of the ITI is a necessary step in the process of enabling widespread access to CPTSD diagnoses and treatment because, as previously stated in this chapter, clinician-administered interviews are perceived to be more reliable than self-report measures, and at present the only tools validated for use are self-report questionnaires (ITQ, ITI etc.).

1.2.4 Clinical utility

Practical clinical utility of a diagnostic tool is vital to ensure appropriate usage. Since the purpose of many changes made to the ICD-11 was to improve the

clinical utility of the PTSD and CPTSD criteria (Maercker et al., 2013), an evaluation of the clinical utility of the ITI would be a valuable addition to extant literature. Successful analysis of the clinical utility of the ITI would support the use of the interview protocol alongside the ethos of improved clinical utility set out in the ICD-11. An aspect of clinical utility is the use of the assessment output in planning care pathways for clients. A clinically useful ITI must be used by clinicians to develop treatment plans based on the most prominent symptoms experienced by the individual, as well as simply determining which disorder is present. Previous research has demonstrated that the ITQ is clinically useful in a refugee population (Vallières et al., 2018), so a similar evaluation of the ITI could aim to find comparable results.

1.3 Cognitive model of complex post-traumatic stress disorder

The most influential cognitive model of PTSD was proposed by Ehlers and Clark (1999). They theorise that PTSD manifests, in part, as a result of negative appraisals of the index event as a confirmation of pre-existing negative beliefs. Put simply, an index event causes PTSD when it is seen as an experience with global negative implications for one's future, and when the index event is viewed as evidence in support of a negative belief about the self or the world (e.g., "nobody cares about me") or causes a shattering of previously held positive beliefs about the self or the world. Ehlers and Clark (1999) also propose that previously held beliefs influence the strategies a person may use to cope with the aftermath of an index event. For example, a person believing that people with emotional problems are inferior may use suppression of emotion to deal with difficult thoughts and feelings. This maladaptive method of coping may prevent improvement in symptoms

(Freichel et al., 2022; Zerach 2023). This will mean that the index event cannot be appropriately processed and will increase the overall presence of PTSD symptoms.

Negative core beliefs (NCBs) play multiple roles in this model, impacting the appraisal of the index event and experiences following the index event, perception of current threat, and the perpetuation of PTSD symptoms (Chukwuorji et al., 2019; Ehlers & Clark, 1999; George et al., 2016). Research has also been conducted to investigate the correlational relationship between cognitive factors and PTSD symptoms (Dunmore et al., 2001). More recently, the memory and identity (M&I) model of CPTSD (Hyland et al., 2023) has been developed and does integrate the role of NCBs in the context of the development and maintenance of CPTSD.

Figure 1.1 Ehlers and Clark (1999) cognitive model of PTSD

The M&I theory of CPTSD (Hyland et al., 2023) proposes that negative beliefs about the self (including thoughts of being as powerless, worthless, or abandoned) are impacted by the experience of traumatic events and can contribute to the experience of CPTSD/PTSD symptoms. For example, the traumatic event causes thoughts of vulnerability, memories of the traumatic event are processed in the context of personal vulnerability, the individual feels the need to be on constant

vigilance for danger, and their perception of themselves as an independent, strong person is damaged, leading to poor self-concept. In this way, the M&I theory of CPTSD shows how NCBs can, in conjunction with a traumatic experience, lead to hypervigilance and negative self-concept.

Figure 1.2. Memory and identity theory of CPTSD (Hyland et al., 2023)

Part of this thesis will address the relationship between NCBs and PTSD/CPTSD/DSO symptoms with the view to contributing support to the M&I theory of CPTSD. The meta-analysis conducted as a part of this thesis does not include the DSO symptom negative self-concept. This is due to the fact that the definition of negative self-concept used in previously published literature varied and did not reflect the symptom definition described in the ICD-11. The ICD-11 defines the negative self-concept symptom as specifically relating to or caused by a traumatic event, while the definition used in previous non-CPTSD research very closely resembles the definition of NCBs. This conceptual overlap in the existing literature meant that negative self-concept was excluded from the meta-analysis.

1.4 Aims / Conceptual framework

The principle aim of this thesis is better understand the condition/symptoms of CPTSD and how they are best measured. Further, in order to investigate the

currently existing evidence around a possible link between NCBs and increased CPTSD symptomology, a meta-analysis was conducted to review previous studies showing correlations between proxy measures of DSO symptoms and NCBs. A survey study aimed to address flaws identified by the meta-analysis and provide a comparison between a direct measure of CPTSD and NCBs. Finally, this thesis aimed to assess the validity and reliability of the ITI to diagnose CPTSD and PTSD.

The validation of the ITI is important because without evidence in support of its psychometric properties, the ITI cannot be used with confidence in clinical practice to diagnose clients. There is presently no alternative clinician-administered tool for use in diagnosing CPTSD, so positive results would mean that clients are able to receive the diagnosis of CPTSD from a clinician interview as opposed to using the self-report questionnaire which is currently being used.

In addition, the exploration of the relationship between NCBs and severity or presence of CPTSD symptoms may have implications for the treatment of CPTSD and will represent a contribution to knowledge in terms of how CPTSD develops and is maintained. Similarly, the meta-analysis detailed in the next chapter represents unique contribution to knowledge in regard to the NCBs associated with DSO symptoms. The aim of this analysis was to provide a synthesis of current knowledge on the relationship between NCBs and DSO symptoms, which then informed the development of the study detailed in chapters three and four.

A small number of studies have published research on the relationship between cognitive factors and CPTSD. The first such study analysed the role of negative cognitions in CPTSD (Karatzias et al., 2018), and found that negative cognitions about the self, the world, and self-blame significantly more prevalent in a

CPTSD subgroup than a PTSD subgroup. Previous work using the posttraumatic cognitions inventory (PTCI) used in Karatzias et al., (2018) was published by Foa and Ehlers (1999) and found that the PTCI was reliable at distinguishing between individuals with PTSD and those without symptoms. Limitations of Karatzias et al., (2018) include the lack of results to indicate the efficacy of the PTCI in distinguishing between individuals with PTSD and those without symptom endorsement. These results would have been necessary to determine the reliability of the PTCI as a tool for distinguishing between all three groups (CPTSD, PTSD, and non-symptomatic). Additionally, the PTCI uses very negatively worded items. This may be an issue in terms of accurate assessment of core beliefs, as the participant's transient mood may be negatively affected by reading the strongly negatively phrased statements (Goodwin, & Williams, 1982; Hankins, 2008).

More recently, it was found that endorsement of NCBs mediated the relationship between childhood trauma and severity of CPTSD symptoms (Vasilopoulou et al., 2019). Older adults (>64 years of age) with higher levels of childhood trauma and elevated schemas associated with disconnection form others perceived themselves as inadequate, socially isolated, and defective. These feelings mirror diagnostic criteria listed in ICD-11 CPTSD (specifically the negative self-concept and disturbed relationships criteria). Through this study, it is suggested that NCBs have a significant lifetime effect on individuals, including the development of CPTSD. An idea which is supported by research showing the long-term rigidity of Schemas (Riso et al., 2006).

Limitations of Vasilopoulou et al (2019) include the mean age of the sample (m=71.4, SD=4.6) and the relatively small sample size (n=42). The older age of the participants means that results cannot be generalised to younger populations and the

small sample size gives the results relatively low statistical power. Despite these limitations, the study had high levels of significance and was the first study to investigate the specific relationship between CPTSD symptoms, trauma severity, and endorsement of NCBs.

The broad aims of this thesis are to identify the pre-existing literature regarding the association between proxy measures of NCBs and DSO symptoms, and to conduct a large-sample study to address the gaps in this pre-existing literature and establish correlations between NCBs and a direct measure of PTSD and CPTSD. The final aim of this thesis is to provide a preliminary validation of the ITI as a diagnostic tool for PTSD and CPTSD.

1.4.1 Gaps in current literature

The first study in this thesis aimed to address the absence of any study looking at collation and synthesis of data concerning the relationship between NCBs and DSO symptoms, and to identify the flaws with the current research. Previous research has analysed correlations between NCB endorsement and experience of symptoms that fit the definition of individual DSO symptoms (Estevez et al., 2016; Ke & Barlas, 2020; Thimm 2013). However, no study has yet brought these findings together to show what is currently known about this relationship and direct future research. The first study therefore searched databases for pre-existing research on correlations between measures of NCBs and measures of two DSO symptoms (affect dysregulation and difficulties in relationships) and analysed the strength and direction of these correlations.

The second study covers gaps in current research relating to the flaws identified in the first study. Flaws such as sample size calculations, reporting of

demographic data, and over-use of undergraduate samples were common in the research identified in study one and represent a significant gap in the literature. In addition, study two addresses the lack of any research into the relationship between NCBs and CPTSD/PTSD symptom profiles involving a younger sample of participants. Vasilopoulou et al. (2019) did use a direct measure of NCBs and a validated measure of PTSD/CPTSD symptomology, but the sample was older, and the results were therefore not generalisable to any younger populations. Additionally, all studies included in study one used proxy measures of DSO symptoms. Study two addressed this by using a direct measure of DSO and PTSD symptoms.

The third and final study in this thesis addressed the lack of a clinician-administered diagnostic tool for PTSD and CPTSD. There exists a self-report measure of PTSD and CPTSD symptoms as per the ICD-11 but a clinician-administered tool has not yet been validated, and is greatly needed (Gelezelyte et al., 2019; Siqveland et al., 2017), as self-report measures are suitable only for screening for possible symptoms (Ford, & Courtois, 2014; Stevens et al., 2013; Visted et al., 2017). This study aimed to contribute to the preliminary validation of the ITI as it may be used to diagnose PTSD and CPTSD. An English-language version of this assessment tool has not yet been assessed in this way, though the ITI had been analysed for reliability and validity in Lithuanian and Swedish (Bondjers et al., 2019; Gelezelyte et al., 2021). The validation of the English language version would constitute a substantial contribution to CPTSD research and clinical practice.

1.5 Research questions

1) What does the current literature show regarding the relationship between DSO symptoms and NCBs?
2) How are NCBs related to ICD-11 PTSD and DSO symptoms?

3) Is the ITI a reliable and valid tool for assessing ICD-11 PTSD and CPTSD?

The first question to be addressed is investigated in the next chapter via a meta-analysis of the existing research into correlations between NCBs and proxy measures of DSO symptoms. The relationship between NCBs and PTSD/DSO symptoms is addressed in chapters three, four, and seven, and the analysis of the ITI as a measure for CPTSD and PTSD is detailed in chapter five, six, and seven.

1.6 Thesis structure

This thesis is comprised of seven chapters: (1) Introduction: summary of the purpose, background research, and setting for this thesis. This is the present chapter and has discussed two cognitive models of PTSD and one model of CPTSD. The aims and structure of the thesis have been set out and rationalized. (2) Meta-analysis: identification of the current evidence about associations between proxy measures of DSO symptoms and endorsement of NCBs. This chapter introduces the idea of NCBs in greater detail and deals with the present evidence for the correlation between NCBs and DSO. (3) Methodology 1: procedure and data analysis of a survey undertaken to observe the relationships between a direct measure of CPTSD and a measure of NCBs. This chapter presents the methodology of an online study that was developed to address issues with current research into the correlation between NCBs and CPTSD symptoms and provide evidence that may support the M&I theory of CPTSD (Hyland et al., 2023). (4) Results 1: results of the survey data analysis. This chapter presents the results of the data analysis of the online survey that was planned in chapter three. (5) Methodology 2: methodological approach to the preliminary validation of the ITI. This chapter shows the methodological approach to the interviewing of participants for the ITI validation, the measures used, and the data analytic plan. (6) Results 2: outcome of the preliminary ITI validation

data analysis. This chapter presents the data resulting from the recruitment and data analysis plan in chapter five. (7) Discussion: addresses the thesis aims and research questions and draws final conclusions from the available data. This final chapter summarises the findings of all previous chapters, interprets the results, and discusses the findings of this thesis in the context of previous research.

2 Study one: systematic review and metanalysis of core beliefs and the disorders of self-organisation symptoms of complex post-traumatic stress disorder

2.1 Introduction

2.1.1 Summary

This chapter presents the results of a systematic review and meta-analysis concerning the associations between two disturbances in self-organisation (DSO) symptoms (affect dysregulation and difficulties in relationships) and negative core beliefs (NCBs). Two meta-analyses were conducted. First, a meta-analysis on the association between NCBs and affect dysregulation (AD), and secondly on the association between NCBs and disturbed relationships (DR). Because of the conceptual overlap between DSO negative self-concept and NCBs, it would not be meaningful to explore their association as part of this review. As discussed in introduction to this thesis, this association will be used to inform recommendations for future research to understand the cognitive structure of complex post-traumatic stress disorder (CPTSD).

2.1.2 Chapter aims

This review aims to collate and synthesise existing research on the relationship between AD and DR and NCBs using proxy measures of DSO symptoms to provide an evaluation of current evidence and develop a basis for future research into the relationship between CPTSD and NCBs.

2.1.3 Schemas and core beliefs

The term ‘schema’ refers to ‘‘relatively enduring internal structures of stored generic or prototypical features of stimuli, ideas, or experience that are used to

organize new information in a meaningful way thereby determining how phenomena are perceived and conceptualized'' (Clark et al., 1999, p. 79). This is a broad definition, encompassing patterns of thought relating to the self (self-schemas), how one should act in different situations (event-schemas), and how the world works (world-schemas). This chapter will focus on self-schemas.

Similarly, a negative core belief is an enduring, negatively framed, inflexible belief about the self, others, and/or the world at large, informed by information gathered about oneself from others, and from past experiences (Clark & Wells, 1995; Heimberg et al., 2010). While core beliefs and schemas could be argued to be distinct cognitive facets by staunch cognitive behaviourists, the two terms are often used interchangeably in published works (Dozois et al., 2014; Waller et al., 2001). Therefore, negative core beliefs and early maladaptive schemas (EMSs) will be grouped together under the heading of NCBs in this thesis.

2.1.4 Negative core beliefs in trauma response

It has been suggested by previous research that those with a post-traumatic stress disorder (PTSD) diagnosis present with more NCBs (Karatzias et al., 2016; Naderi et al., 2015; Testa, 2008). Indeed, disruption of core beliefs has been shown to correlate with PTSD-type symptoms (Galloucis et al., 2000), and experience of a traumatic event that re-activates a previously held NCB is a risk factor for PTSD symptoms (Boudoukha et al., 2016). Change in core beliefs following a traumatic event is common (Kaufman et al., 2018). This research is demonstrative of the idea that NCBs or disruption of adaptive core beliefs may play a role in disorders of traumatic stress. However, these studies do not concern CPTSD symptoms, nor the international classification of diseases (ICD-11) reconfiguration of PTSD.

However, there remains a lack of research exploring the association between CPTSD and NCBs. NCBs are identified and modified in many therapeutic treatment modalities for PTSD, predominantly of cognitive behavioural orientation (Bourdon et al., 2021; Müller-Engelmann, & Steil, 2017) and prior to implementing such therapies for CPTSD, it would be useful to explore whether NCBs are as relevant in CPTSD as they are in PTSD. If a relationship is found between CPTSD and NCBs, then this indicates that cognitive behavioural interventions might be particularly useful for the treatment of CPTSD. This is important considering that there are currently few published studies on the efficacy of interventions for the treatment of CPTSD as per ICD-11.

According to The World Health Organisation (WHO) (WHO, 2019), CPTSD shares three clusters of symptoms with PTSD (re-experiencing in the here and now, avoidance, and sense of threat), and includes three additional DSO symptom clusters. The three DSO symptoms are negative self-concept, AD, and DR. With a relationship between PTSD and NCBs solidly established (Ahmadian et al., 2015; Dekel et al., 2013), it is essential to explore the relationship between NCBs and DSO symptoms.

2.1.5 Objectives

Taking into consideration the research summarized above, this chapter aims to collate and synthesise data from correlational studies that have identified the relationship between NCBs and proxy measures of DSO symptoms. This chapter will address the following questions: 1) what is already known about the strength and direction of the correlations between NCBs and DSO symptoms? 2) what is needed to be able to better understand the relationship between NCBs and CPTSD symptoms?

2.2 Method

2.2.1 Protocol registration

The study protocol was registered with The International Prospective Register of Systematic Reviews (PROSPERO) (PROSPERO ID CRD42021216521) on the 16th of February 2021 (https://www.crd.york.ac.uk/PROSPEROFILES/216521_PROTOCOL_20210204.pdf).

2.2.1.1 Changes to registered protocol

It was necessary to make some changes to the protocol due to unexpected findings in the search results. The initial protocol registration included the third DSO symptom (negative self-concept), but it was found that proxy measures of negative self-concept also closely matched the description of NCBs. The DSO symptom of negative self-concept is defined in the ICD-11 as "beliefs about oneself as diminished, defeated or worthless" (WHO, 2019). This does share some similarity with the definition of NCBs, meaning that there is conceptual overlap between NCBs and negative self-concept (Gibson, & Francis, 2019; Waller et al., 2001). This may cause issues when attempting to demonstrate an association between the two concepts. If the difference between NCBs and negative self-concept is semantic rather than conceptual, any meta-analysis may in fact be measuring the correlation between the same variable twice.

The definition of NCBs could be expanded to include world- and other-beliefs, which are distinguishable from negative self-concept. However, the inclusion of world- and other- beliefs is beyond the scope of the current review. In order to resolve the issue of the conceptual overlap between negative self-concept and self-

NCBs, negative self-concept was excluded from this analysis. This review will instead focus on the relationship between the remaining two DSO symptoms, AD and DR, and measures of self-directed NCBs. It was determined that the current published literature does not accurately reflect the clinical definition of DSO negative self-concept in a way that can be meaningfully correlated with NCBs, since the two are treated as the same construct in relevant research.

Similarly, the initial protocol listed NCBs and maladaptive schemas as separate entities, as well as negative automatic thoughts (NATs). While there are nuanced arguments for NCBs and maladaptive schemas being two separate concepts (James et al., 2004), it was found that NCBs and maladaptive schemas are used interchangeably in many published studies (Dozois et al., 2014; Mizara et al., 2012). Indeed, the young schema questionnaire (YSQ) has been used in studies claiming to be studying NCBs (Brotchie, 2004; Waller et al., 2001). Maladaptive schemas were therefore collapsed into the NCBs category.

Preliminary searches also found that the definitions of NATs varied across published literature, some studies using NAT to mean perfectionistic thoughts (Flett et al., 2016), and few using the NAT concept from cognitive behavioural theory that was intended to be used when the protocol was written (Hiçdurmaz, & Öz, 2016). The finding that the intended definition of NATs could not be consistently matched meant that any correlation analysis may not be measuring correlation between a DSO symptom and the NAT as defined in the present study. For this reason, NATs were removed from the searches.

The first registration of the protocol also listed an intention to make recommendations for clinical and research practice. However, most studies in the

analysis did not recruit clinical populations and so the data cannot be used to propose directions for practitioners. It was always intended to identify implications for research, which is where most recommendations will be made.

To reflect the above changes to the protocol, the title, research questions, and data analysis plan were updated (for example, mentions of "Core Beliefs" and "Maladaptive Schemas" became "Negative Core Beliefs"). All changes to the protocol were updated in the PROSPERO registry on the 13th of February 2021.

2.2.2 Identification of key terms

At the time of database searching there were no published studies of correlations between DSO symptoms and NCBs, so it was necessary to use proxy measures of DSO symptoms. Database thesauruses and dictionaries were consulted to identify suitable terms related to AD and DR to include in the search strategy. The term "schema" was included in the search strategy as it is typically used interchangeably with "core beliefs" in published research (Dozois et al., 2014; Waller et al., 2001).

Definitions of AD and DR were operationalised to follow the definition of these symptoms as listed in the ICD-11. AD describes problems with emotion regulation such as heightened emotional reactivity, excessive expression of anger, or emotional numbing. DR describes difficulties in sustaining relationships, little interest in socialising, or avoidance of relationships (World Health Organisation, 2018). A study was considered for inclusion if it compared a measure of NCBs to a measure meeting one of these descriptions.

A primary search was conducted on the 19th of October 2020, revealing 708 results. A further search was carried out on 10th of October 2022 and resulted in

1,052 articles. Databases searched were MEDLINE, CINHAL, PsychInfo, PsychArticles, PubMed, and Web of Science. The full search strategy can be found in Table 2.1.

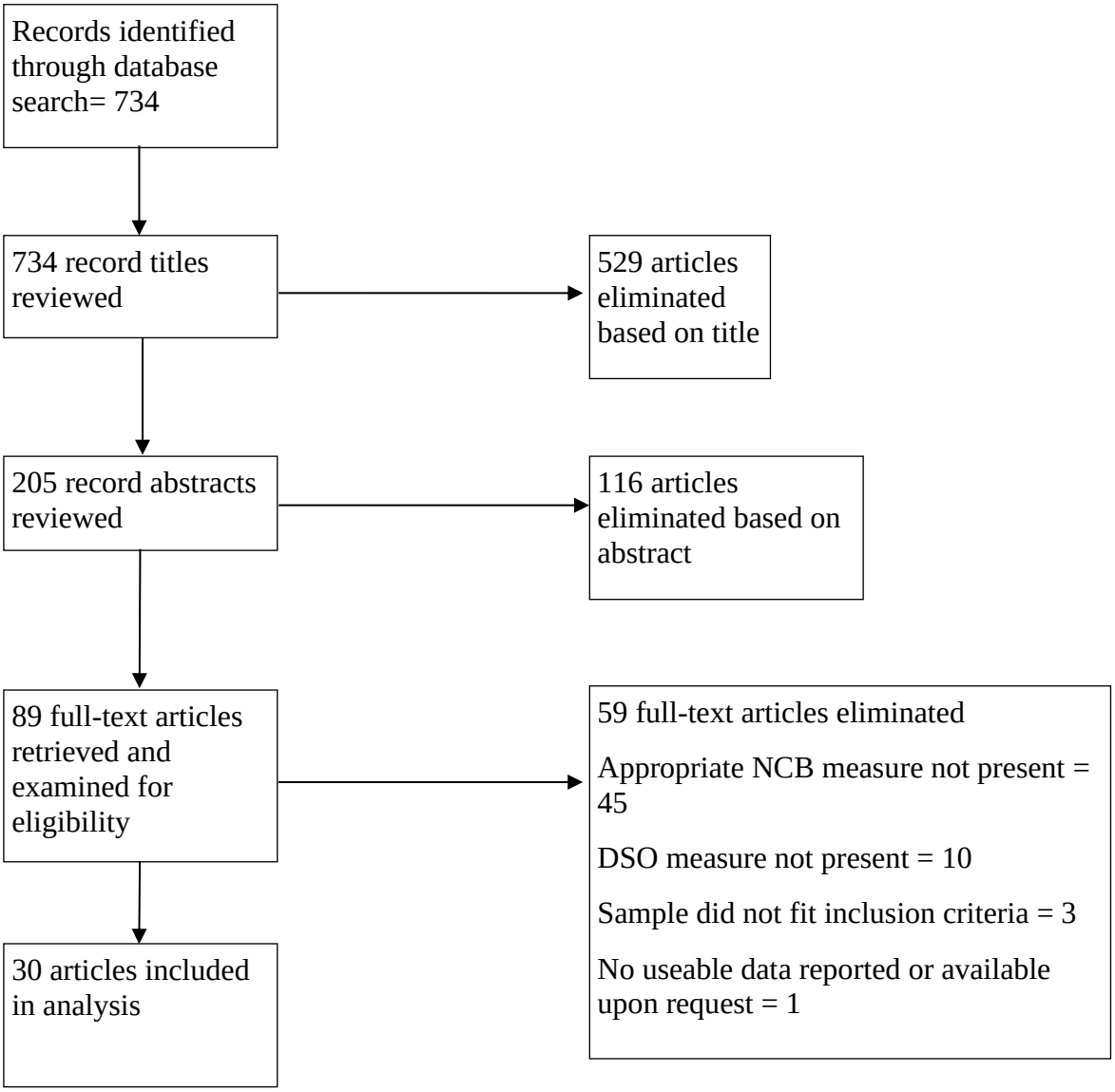
Table 2.1. Search strategy

No.	Terms	Results	Theme
1	“core bel*” OR “schema” OR “belief”	153,247	Core beliefs
2	“DSO” OR “disturbance* in self-organi#ation”	968	DSO
3	"Interpersonal Relations" OR “Interpersonal difficulties” OR “interpersonal relationships” OR “interpersonal problems”	213,501	Interpersonal
4	"affective dysregulation" OR "affect regulation" OR “affective” OR “emotional regulation”	336,860	Affective
5	S1 AND (S2 OR S3 OR S4)	734	Total

2.2.3 Inclusion/exclusion criteria

To minimise heterogeneity, only studies involving adult participants were included in analysis. Studies were only considered for inclusion if they were published in English and provided quantitative data on the relationship between a measure of NCBs and a measure relating to either AD or DR. To be included in this study, an article must have also used a measure that assessed either AD (e.g., anger, aggression, or distress intolerance) or DR (e.g., intimate relationship dissatisfaction, use of interpersonal violence, or disconnection from others). Doctoral dissertations were not considered for inclusion as the standard peer review process had not been completed. Conference posters or abstracts were considered for inclusion if useable data were published. Authors of one study were contacted for their data, but no reply was received (Khalili et al., 2022).

Figure 2.1. PRISMA flowchart of article elimination



2.2.4 Data extraction

Title and abstract review was completed by ZW, full text review was completed by ZW and GM, and any disagreements resolved through discussion between ZW and GM. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (Moher et al., 2015) flowchart detailing number of studies screened, and full-text reviews completed can be found in Figure 2.1.

Data extraction was completed in line with PRISMA guidelines and verified by a second researcher (GM). Appendix 9.1 shows a list of excluded studies.

2.2.5 Data synthesis and analysis

2.2.5.1 Model choice

A random-effects meta-analytical model was used. The random-effects model is suited to meta-analyses with studies using different samples. The assumption made by a random-effects model is that the true effect sizes differ between studies due to factors such as different measurement tools, intervention protocols, or sample characteristic differences (Barili et al., 2018). The variance expected in a random-effects meta-analysis is from within- and between-studies. Heterogeneity is expected in this model, and when interpreting the output importance is placed on the identification of sources of heterogeneity (Borenstein et al., 2010).

Alternatively, the fixed-effects model assumes that all studies included in the analysis share a common true effect size and any differences between observed effect sizes are due to sampling error only (Barili et al., 2018). This means that there are no methodologically significant differences between the samples used in each study and little to no heterogeneity is expected (Borenstein et al., 2010). Since no heterogeneity arising from the differences between samples was anticipated,

procedural/protocol differences, and measures used, a random-effects model was chosen (Riley et al., 2011). The random-effects correlation analysis was performed on Comprehensive Meta-Analysis (CMA) software using random effects analysis.

2.2.5.2 R-values

R-values were used to estimate the strength of association between the variables of interest. The *r*-value (Pearson's correlation coefficient) was used as it is a commonly reported measure of the strength of a correlation between two variables. The *r*-value represents the strength and direction of a correlation, with a positive value indicating a positive association, a negative value indicating a negative association, and a value of zero meaning no correlation between the variables (Akoglu, 2018). Two meta-analyses were performed; one to assess the relationship between NCBs and AD and one to measure correlation between NCBs and DR.

In some cases, multiple relevant *r*-values were reported within a single paper. For example, Thimm (2013) reported correlations between each subscale of the Inventory of Interpersonal Problems (IIP) and the total YSQ score, resulting in 120 unique *r*-values. In these cases, each *r*-value was converted to Fisher's Z value, the average of these values was taken and then converted back into an *r*-value. This method was proposed by Alexander (1990) and overcomes the known bias that comes from averaging *r*-values for use in meta-analysis.

Thresholds applied for effect size interpretation are as follows: an *r*-value of ≥.50 indicates a large effect size, *r*-value of .30 to .49 indicates a moderate effect size, and an *r*-value of <.30 indicates a small effect size. These values were taken from Cohen (2013) and were commonly used in behavioural science.

2.2.5.3 Heterogeneity

The I^2 value was used to indicate heterogeneity, where 0 to 40 indicates minimal heterogeneity, 30 to 60 may represent moderate heterogeneity, 50 to 90 may represent substantial heterogeneity, and 75 to 100 indicates considerable heterogeneity (Higgins et al., 2022). Heterogeneity was defined as excess variation in effect size between studies. Some variance in effect size is to be expected due to differences in assessment tools used and populations, however, substantial to considerable heterogeneity within a meta-analysis may be due to methodological issues across several studies and would indicate the need to be cautious of conclusions drawn from the results.

2.2.5.4 Risk of bias

Assessment of risk of bias was completed by ZW and verified by a second reviewer using an adapted version of the Agency for Healthcare Research and Quality (AHRQ) assessment tool as presented in Dudley et al., (2016). The adapted AHRQ uses seven criteria that each study is rated on; unbiased selection of cohort, transparency of power calculation, adequate description of sample, validated tool used for DSO symptom measurement, validated tool for NCB measurement, transparency of handling missing data, and use of appropriate analytic methods. Each study is scored either “Yes”, “Partial”, “No”, or “Unclear” Ratings of “No” or “Unclear” score one point, and “Yes” or “Partial” scores zero. Basis for partial or unclear ratings varied between criteria and is detailed in 9.2. The total score for each study is calculated to give a score out of seven where a score of 1-2= low risk of bias, 3-5= moderate risk of bias, and 6-7= high risk of bias. The outcome of the risk of bias assessment can be found in the results section below.

2.2.5.5 Grading of recommendations, assessment, development, and evaluations

Quality of outcome evidence was assessed using the grading of recommendations, assessment, development, and evaluations (GRADE) system, which comprises five main criteria; risk of bias (the quality of evidence and study limitations), imprecision (the accuracy of the results overall), inconsistency (the similarity of effect size between studies and any unexplained heterogeneity), indirectness (the relevance of the outcome of interest to the population of interest), and publication bias (over-publication of studies with large or significant effects, and non-publication of non-significant results) (Guyatt et al., 2008).

In GRADE, cross-sectional evidence begins as low quality and is upgraded or downgraded based on each of the outcome criteria listed in the paragraph above. The overall GRADE score is relevant to the interpretation of the reported effect size and the judgement of its accuracy. Very low GRADE ratings suggest that any 'true effect' may be very different from the reported estimate, and high GRADE ratings offer greater confidence that meaning that the 'true' and estimated effects are likely very similar.

Risk of bias was assessed by identifying possible sources of bias in each study that contributed data to the analysis. This includes considering the AHRQ assessment of bias for each study, as well as identifying GRADE-specific criteria (failure to develop and apply eligibility criteria, failure to control confounding variables, and flawed measurement of exposure and outcome). Appendix 9.3 is adapted from (Balshem et al., 2011) and identifies in detail the causes of upgrading or downgrading GRADE score due to risk of bias. (Guyatt et al., 2011C).

Imprecision was assessed using 95% confidence intervals (CI), where a wider range in CI represents lower precision (Guyatt et al., 2011D). According to GRADE, a CI excluding the null line on a forest plot (see 2.4.8 for forest plots) is representative of a lower likelihood of imprecision. Where the pooled CI bar did not cross the null line, a rating of moderate or high certainty was given. Imprecision was downgraded if the pooled 95% CI bar does cross the null line and neither upgraded nor downgraded if the pooled bar did not cross the null line. Also taken into consideration was the overall width of the CI bars. Wide-spread bars also resulted in a downgrading of certainty, as this indicates a wider range of results from published studies and undermines the overall certainty that can be had in the results.

Inconsistency was primarily measured in this analysis using the I^2 heterogeneity statistic. Inconsistency was rated down for each analysis if the I^2 statistic was ≥50%, neither upgraded nor downgraded for values between 30 to 50% and upgraded for a value lower than 30% (Ades et al 2012 Guyatt et al 2011A).

Indirectness was assessed by counting the number of studies collecting data from non-clinical populations, since the current population of interest is clinical. There are currently no strict guidelines on assessing indirectness, rather Guyatt et al., (2011A) recommend considering main sources of indirectness and rating down for any considerable issues. Indirectness was rated down two levels when all studies in an analysis recruited a non-clinical population, rated down one level when a third of all studies recruited a clinical sample, not rated down when half or more recruited non-clinical samples, and rated up one level when 100% of included studies recruited clinical samples.

Publication bias is scrutinised by the over-publication of positive or significant results, reliance on “easy-to-collect” data, and over-publication of large studies (Guyatt et al., 2011C). To identify publication bias, this chapter will consider data from funnel plots, sample sizes, methods of data collection (e.g., automatically collected data, or secondary data). It is difficult to objectively assess for publication bias since there is no reliable method to measure the absence of negative or non-significant results in publications (Guyatt et al., 2011C). Publication bias was rated down where there was a high risk of publication bias as assessed by a funnel plot and trim and fill analysis, not down rated if there was no evidence of publication bias and upgraded with the discovery of exceptionally low evidence of publication bias (Guyatt et al., 2011C).

2.3 Results

2.3.1 Characteristics of included studies.

A total of 30 studies were included in this review, nine of which were included in the AD meta-analysis and 27 were included in the DR analysis. The majority of studies were undertaken in the United States of America.

Studies recruited between 40 and 848 participants (M=239, SD=156) for an overall total of 6,939 participants. Typically, studies recruited from undergraduate populations (n=15) or from general populations (n=9). A total of 723 participants from six studies were recruited from clinical populations (any population receiving mental health support or treatment), and 23 studies recruited a total of 6,216 participants from non-clinical populations. Studies included in the DR analysis recruited a total of 6,455 participants (M=230, SD=154) and studies included in the AD analysis recruited 2,476 participants in total (M=275, SD=243)

Included studies were published between 2005 and 2021, and the vast majority (N=26) used a variation of the YSQ to measure NCBs. The Evaluative Beliefs Scale (N=2), Pathogenic Beliefs Scale (N=1), and Self-Defeating Beliefs Scale (N=1) were also used to measure NCBs. In terms of DSO symptom assessment, a wide variety of assessment tools were used relating to the either AD or DR (see Table 2.2 below).

2.3.2 Outcome statistics

Full outcome data extracted and processed for analysis can be found in Table 2.3. Some relevant *r*-values reported in included studies were significant at the $p<.05$ level (AD N=0; DR N=20), and a majority were significant to $p<.01$ (AD N=18; DR N=41) or $p<.001$ (AD N=38; DR N=90). A minority were found to be significant at $p<.0001$ (AD N=3; DR N=6) and some were non-significant (AD N=6; DR N=33).

For the DR meta-analysis, a pooled *r*-value of 0.366 (95% CI 0.32-0.41) was found, along with a significance of $p<.001$. These outcome statistics indicate that there is a small but still significant positive correlation between DR and the endorsement of NCBs. I^2 was 73.28 for DR meta-analysis, indicating considerable to substantial heterogeneity.

The AD meta-analysis revealed an overall pooled *r*-value of 0.425 (95% CI 0.35-0.50) and significance of $p<.001$, indicating a moderate, statistically significant, positive correlation between AD and NCBs. The I^2 value for the AD meta-analysis was 78.15, indicating considerable to substantial heterogeneity.

Table 2.2. Characteristics of included studies

Primary author	Year	Sample (n)	DSO measure	NCB measure	Sample	Country
Disturbed Relationships						
Aafjes-van Doorn	2021	210	OQ-45	PBS-SF	Psychotherapy clinic outpatients	America
Allen	2017	171	IIP-C-IRT	SDBS	Undergraduates	America
Baugh	2019	231	TCRS	EBS	General population	America
Blisset	2006	206	PAQ	YSQ-SF	Female Undergraduates	United Kingdom
Calvete	2007	298	CTS2	EBS	Undergraduates	Spain
Crawford	2007	301	AQ; IDA	YSQ-SF	Undergraduates	America
Dumitrescu	2012	182	DAS	YSQ-SF-3	General population	Romania
Eftekhari	2016	200	EMSQ	YSQ-SF	General population	Iran
Ertürk	2020	291	AQ	YSQ-SF-3	General population	Turkey
Estevez	2016	168	DAQ	YSQ-SF	General population	Spain
Evraire	2014	303	ECR-R	YSQ-SF	Undergraduates	America
Gay	2013	409	CTS2; RSQ	YSQ-SF	Undergraduates	America
Gilbert	2013	87	LHA-A	YSQ-SF-3	Community forensic mental health service users	Australia
Hassija	2018	305	CTS2	YSQ-SF	Undergraduates	America
Janovsky	2019	117	IIP-32	YSQ-SF-3	General Population	Australia
Kachadourian	2013	174	CTS2	YSQ	Male perpetrators of interpersonal violence	America
Ke	2020	142	TEIQue	YSQ-SF-3	Undergraduates	Singapore
LaMotte	2016	83	CTS2	YSQ-SF	Female general population	America
LaMotte	2016	83	CTS2	YSQ-SF	Male general population	America
Messman-Moore	2007	382	IIP; IASC	YSQ-2	Undergraduates	America
Mojallal	2014	150	IIP-64	YSQ-SF	Undergraduates	Iran
O'Connor	2018	246	EMSQ	YSQ-SF	General population	Iran

Primary author	Year	Sample (n)	DSO measure	NCB measure	Sample	Country
Shorey	2015	106	PAI	YSQ-L3	Male substance users	America
Smyth	2017	312	CTS2	YSQ-SF-3	Undergraduates	America
Tremblay	2009	848	AQ	YSQ-SF	Undergraduates	Canada
Thimm	2013	106	IIP-C	YSQ-SF	Psychiatric outpatients	Norway
Yoo	2014	304	PCS; SOS	YSQ-SF	Undergraduates	South Korea
Affect Dysregulation						
Calvete	2007	298	RSQ	YSQ-SF	Female victims of interpersonal violence	Spain
Ertürk	2020	291	DERS	YSQ-SF-3	General public	Turkey
Gilbert	2013	87	STAXI-2	YSQ-SF-3	Community forensic mental health service users	America
Ke	2020	142	TEIQue; CSI	YSQ-SF-3	Undergraduates	America
McKee	2012	40	STAXI-2	YSQ-2	Male perpetrators of interpersonal violence	Ireland
Simons	2017	364	DTS	YSQ-SF-3	Undergraduates	America
Smyth	2017	110	PANAS; DERS; ADS-S	YSQ-SF-3	Undergraduates	America
Tremblay	2009	848	AQ	YSQ-SF	Undergraduates	Canada
Yakin	2018	296	DERS	YSQ-SF-3	General population	Amsterdam, Turkey

ADS-S; Anger Disorders Scale-Short, AQ; Anger Questionnaire, CSI; Coping Strategies Inventory, CTS2; Revised Conflict Tactics scale, DAQ; Displaced Aggression Questionnaire, DAS; Dyadic Adjustment Scale, DERS; Difficulties in Emotion Regulation Scale, DTS; Distress Tolerance Scale, EBS; Evaluative Beliefs Scale, ECR-R; Experiences in Close Relationships-Revised, EMSQ- Enrich Marital Satisfaction Questionnaire, IASC; Inventory of Altered Self-Capacities, IDA; Index of Dating Abuse, IIP; Inventory of Interpersonal Problems, IIP-32; Inventory of Interpersonal Problems Short Form, IIP-64; Inventory of Interpersonal Problems Long Form, IIP-C; Inventory of Interpersonal Problems-Circumplex, IIP-C-IRT; Inventory of Interpersonal Problems-Circumplex-Item Response Theory, LHA-A; Life History of Aggression-Aggression Scale, OQ-45; The Outcome Questionnaire, PAI; Personality Assessment Inventory, PANAS; Positive and Negative Affect Schedule, PAQ; Parental Attachment Questionnaire, PBS-SF; Pathogenic Beliefs Scale-Short Form, PCS; Peer Connectedness Scale,

RSQ; Relationship Styles Questionnaire, SDBS; Self-Defeating Beliefs Scale, SOS; Social Orientedness Scale, STAXI-2; State-Trait Anger Expression Inventory-2, TCRS; Trust in Close Relationships Scale, TEIQue; Trait Emotional Intelligence Questionnaire, YSQ; Young Schema Questionnaire, YSQ-2; Young Schema Questionnaire 2nd edition, YSQ-L3; Young Schema Questionnaire Long Form 3, YSQ-SF; Young Schema Questionnaire-Short Form, YSQ-SF-3; Young Schema Questionnaire-Short Form-3

Table 2.3. Outcome data for included studies

Primary author	*r*-value(s)	Transformed Fishers' Z values	Mean fishers' Z	Final *r*-value
Disturbed Relationships				
Aafjes-van Doorn	0.45[3], 0.43[3]	0.49, 0.46	0.47	0.44
Allen	0.66[3]			0.66
Baugh	0.32[3]			0.32
Blisset	0.39[4], 0.45[4], 0.49[4], 0.44[4], 0.48[4], 0.50[4]	0.41, 0.49, 0.53, 0.47, 0.52, 0.55	0.49	0.46
Calvete	0.27[3], 0.28[3]	0.28, 0.29	0.28	0.28
Crawford	0.47[2], 0.48[2], 0.54[2], 0.43[2]	0.51, 0.52, 0.60, 0.46	0.52	0.48
Dumitrescu	0.18[2]			0.18
Eftekhari	0.54[1]			0.54
Ertürk	0.24[3], 0.48[3], 0.34[3], 0.38[3], 0.36[3], 0.53[3]	0.25, 0.52, 0.35, 0.40, 0.38, 0.59	0.42	0.39
Estevez	0.34[3], 0.28[3], 0.16[1], 0.23[2], 0.15[1]	0.354, 0.288, 0.161, 0.234, 0.151	0.2378	0.23
Evraire	0.59[2], 0.08	0.67, 0.08	0.38	0.36
Gay	0.23[2], 0.23[2], 0.12[1], 0.18[2], 0.14[2], 0.04, 0.64[2], 0.30[2], 0.45[2], 0.18[2], 0.32[2], 0.08	0.23, 0.23, 0.12, 0.18, 0.14, 0.04, 0.76, 0.31, 0.49, 0.18, 0.33, 0.08	0.26	0.25
Gilbert	0.6, 0.18, 0.11, 0.11, 0.26[1], 0.30[1], 0.17, 0.05, 0.24[1], 0.29[1], 0.33[1], 0.11, -.15, -.13, 0.15, 0.15, -.01, -.04	0.69, 0.18, 0.11, 0.11, 0.27, 0.31, 0.17, 0.05, 0.25, 0.30, 0.34, 0.11, -0.15, -0.13, -0.01, -0.4, 0.15, 0.15	0.14	0.14
Hassija	0.22[1], 0.25[1], 0.30[2], 0.02, 0.29[1], 0.18[1], 0.25[2], 0.25[2], 0.27[2] 0.37[2], 0.06, 0.31[2], 0.18[2], 0.25[2]	0.22, 0.26, 0.31, 0.02, 0.30, 0.18, 0.26, 0.26, 0.28, 0.39, 0.06, 0.32, 0.18, 0.26	0.23	0.23
Janovsky	0.64[3], 0.63[3], 0.62[3], 0.59[3], 0.59[3], 0.58[3], 0.57[3], 0.56[3], 0.55[3], 0.55[3], 0.53[3], 0.47[3], 0.47[3], 0.46[3], 0.42[3], 0.32[3], 0.26[3], 0.23[3]	0.75, 0.74, 0.72, 0.67, 0.67, 0.66, 0.65, 0.63, 0.62, 0.62, 0.59, 0.51, 0.51, 0.50, 0.45, 0.33, 0.27, 0.23	0.56	0.51
Kachadourian	0.13, 0.21[2]	0.13, 0.21	0.17	0.17
Ke	0.34[2], 0.51[2], 0.07, 0.32[2]	0.35, 0.56, 0.07, 0.33	0.33	0.32

Primary author	*r*-value(s)	Transformed Fishers' Z values	Mean fishers' Z	Final *r*-value
LaMotte (male subgroup)	0.40[3]	0.42, 0.44	0.43	0.40
LaMotte (female subgroup)	0.22[1]	0.22, 0.37	0.30	0.29
McKee	0.64[2], 0.58[2], 0.26, 0.45[2], 0.14, 0.46[2], 0.45[2], 0.06 0.44[2], 0.50[2]	0.76, 0.66, 0.27, 0.49, 0.14, 0.50, 0.49, 0.60, 0.47, 0.55	0.49	0.46
Messman-Moore	0.34[2], 0.39[2], 0.49[2], 0.35[2]	0.35, 0.41, 0.54, 0.37	0.42	0.39
Mojallal	0.97[3], 0.34[3], 0.41[3], 0.27[3], 0.52[3], 0.53[3], 0.89[3], 0.81[3], 0.58[3], 0.70[3], 0.24[3], 0.56[3], 0.65[3], 0.92[3], 0.17[1], 0.26[3], 0.12, 0.31[3], 0.13, 0.08, 0.25[3], 0.24[3], 0.30[3], 0.42[3], 0.33[3], 0.24[3], 0.15, 0.36[3], 0.13, 0.13, 0.18[1], 0.31[3], 0.18[1], 0.08, 0.20[1]	0.09 0.35, 0.44, 0.28, 0.58, 0.59, 0.42, 0.13, 0.66, 0.87, 0.63, 0.25, 0.78, 0.59, 0.17, 0.27, 0.12, 0.32, 0.13, 0.08, 0.26, 0.25, 0.31, 0.45, 0.34, 0.25, 0.15, 0.38, 0.13, 0.13, 0.18, 0.32, 0.18, 0.08, 0.20,	0.47	0.44
O'Connor	0.29			0.29
Shorey	0.47[3], 0.41[3], 0.15, 0.34[3], 0.56[3]	0.51, 0.44, 0.15, 0.35, 0.63	0.42	0.40
Smyth	0.32[2]			0.32
Tremblay	0.38[3], 0.51[3], 0.40[3], 0.32[3], 0.40[3], 0.23[3], 0.38[3], 0.22[3], 0.29[3], 0.47[3], 0.39[3], 0.29[3], 0.08[1], 0.30[3], 0.16[3]	0.40, 0.56, 0.42, 0.33, 0.42, 0.23, 0.40, 0.22, 0.30, 0.51, 0.41, 0.30, 0.08, 0.31, 0.16,	0.34	0.33
Thimm	0.43[3], 0.42[3], 0.46[3], 0.50[3], 0.56[3], 0.36[3], 0.44[3], 0.42[3], 0.50[3], 0.69[3], 0.41[3], 0.58[3], 0.52[3], 0.22[1], 0.32[3]	0.46, 0.45, 0.50, 0.55, 0.63, 0.38, 0.47, 0.45, 0.55, 0.85, 0.44, 0.66, 0.58, 0.22, 0.33	0.50	0.46
Yoo	0.38[3], 0.44[3]	0.40, 0.47	0.44	0.41
Affect Dysregulation				
Calvete	0.24, 0.14[1]	0.52, 0.40	0.46	0.43
Ertürk	0.60[2], 0.57[2], 0.22[2], 0.44[2], 0.33[2], 0.48[2], 0.34[2], 0.38[2], 0.36[2], 0.53[2]	0.69, 0.65, 0.22, 0.47, 0.34, 0.52, 0.35, 0.40, 0.38, 0.59	0.46	0.43

Primary author	*r*-value(s)	Transformed Fishers' Z values	Mean fishers' Z	Final *r*-value
Gilbert	0.24[2], 0.29[2], 0.18, 0.33[2], 0.30[2], 0.44[3], 0.31[2], 0.18, 0.41[3], 0.41[3], 0.61[3], 0.35[3], 0.04, 0.38[3], 0.36[3], 0.34[2], 0.12, 0.12	0.25, 0.30, 0.18, 0.34, 0.31, 0.47, 0.32, 0.18, 0.44, 0.45, 0.71, 0.37, 0.04, 0.40, 0.38, 0.35, 0.12, 0.12	0.32	0.31
Ke	0.56[2], 0.48[2], 0.17[1], 0.37[2], 0.56[2]	0.50, 0.63, 0.44, 0.34	0.48	0.44
McKee	0.57[2], 0.57[2], 0.26, 0.65[2], 0.34[1]	0.65, 0.65, 0.27, 0.78, 0.35	0.54	0.49
Simons	0.48[4], 0.42[4], 0.46[4]	0.50, 0.45, 0.52	0.49	0.45
Smyth	0.53[2], 0.37[2], 0.63[2]	0.59, 0.39, 0.74	0.57	0.52
Tremblay	0.33[3], 0.33[3], 0.28[3], 0.28[3], 0.30[3], 0.23[3], 0.30[3], 0.20[3], 0.24[3], 0.33[3], 0.35[3], 0.25[3], 0.02, 0.21[3], 0.13[3]	0.34, 0.34, 0.29, 0.29, 0.31, 0.31, 0.23, 0.20, 0.25, 0.34, 0.37, 0.26, 0.02, 0.21, 0.13	0.26	0.25
Yakin	0.61[3], 0.58[3], 0.49[3], 0.34[3], 0.54[3]	0.71, 0.66, 0.54, 0.36, 0.61	0.58	0.52

Table 2.4. Analysis outcome data

	r	Lower limit	Upper limit	P	I^2
Disturbed Relationships	0.366	0.323	0.408	<.001	73.28
Affect Dysregulation	0.425	0.345	0.498	<.001	78.15

Figure 2.2. Forest plot for DR meta-analysis

Study name	Correlation	Lower limit	Upper limit	Z-Value	p-Value
Aafjes-van Doorn	0.440	0.324	0.543	6.794	0.000
Allen	0.660	0.566	0.737	10.276	0.000
Baugh	0.323	0.202	0.434	5.058	0.000
Blisset	0.459	0.344	0.561	7.068	0.000
Calvete	0.276	0.168	0.378	4.867	0.000
Crawford	0.481	0.389	0.563	9.051	0.000
Dumitrescu	0.180	0.035	0.317	2.435	0.015
Eftekhari	0.540	0.434	0.631	8.480	0.000
Ertürk	0.394	0.292	0.487	7.069	0.000
Estevez	0.233	0.085	0.371	3.049	0.002
Evraire	0.358	0.256	0.452	6.488	0.000
Gay	0.253	0.160	0.342	5.211	0.000
Gilbert	0.138	-0.075	0.339	1.273	0.203
Hassija	0.230	0.121	0.334	4.070	0.000
Janovsky	0.509	0.361	0.632	5.994	0.000
Kachadourian	0.171	0.023	0.312	2.258	0.024
Ke	0.319	0.163	0.460	3.897	0.000
LaMotte A	0.406	0.209	0.572	3.853	0.000
LaMotte B	0.287	0.076	0.473	2.641	0.008
McKee	0.455	0.167	0.671	2.987	0.003
Messman-Moore	0.394	0.306	0.476	8.109	0.000
Mojallal	0.436	0.296	0.557	5.665	0.000
O'Connor	0.290	0.171	0.401	4.654	0.000
Shorey	0.397	0.223	0.546	4.263	0.000
Smyth	0.320	0.217	0.416	5.830	0.000
Tremblay	0.326	0.264	0.385	9.835	0.000
Thimm	0.463	0.299	0.601	5.086	0.000
Yoo	0.411	0.313	0.500	7.578	0.000
Pooled	0.366	0.323	0.408	15.194	0.000
Prediction Interval	0.366	0.150	0.549		

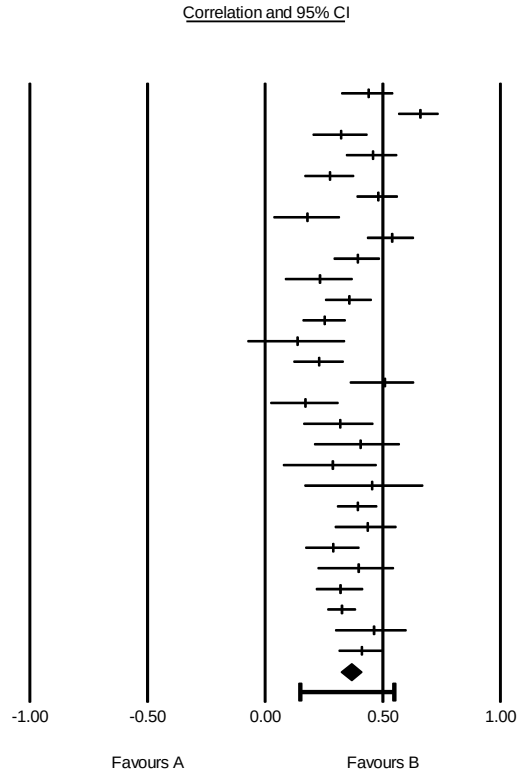
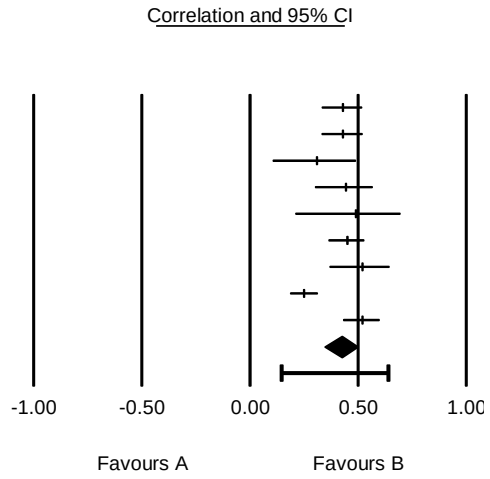


Figure 2.3. Forest plot for AD meta-analysis

Study name	Correlation	Lower limit	Upper limit	Z-Value	p-Value
Calvete	0.430	0.333	0.518	7.899	0.000
Ertürk	0.430	0.331	0.519	7.805	0.000
Gilbert	0.310	0.106	0.489	2.938	0.003
Ke	0.444	0.301	0.567	5.626	0.000
McKee	0.490	0.211	0.695	3.261	0.001
Simons	0.450	0.364	0.528	9.209	0.000
Smyth	0.520	0.369	0.644	5.962	0.000
Tremblay	0.250	0.186	0.312	7.425	0.000
Yakin	0.520	0.432	0.599	9.865	0.000
Pooled	0.425	0.345	0.498	9.518	0.000
Prediction Interval	0.425	0.147	0.640		

Statistics for each study



2.3.1 Forest plot

2.3.1.1 Disturbed relationships

Overall, the evidence in this analysis was very consistent. The 95% CI for all but one study did not cross the null line. This distribution of the evidence indicates strong agreement between the outcomes of studies. This single non-significant result is made up for by the large number of studies included in this analysis, many of which have very strongly significant positive results.

Affect dysregulation

Figure 2.3 shows the forest plot for the AD meta-analysis. All included studies have positive, significant correlations between AD and NCBs (Higgins et al., 2022). That is, experience of AD symptom is positively correlated with NCB endorsement. The pooled effect shows a moderate effect size of 0.425 (95% CI 0.35-0.50).

2.3.2 Risk of bias assessment

Detailed risk of bias assessment for all studies can be found in Table 2.5. Risk of bias scores ranged from three to five out of a maximum of seven, indicating a moderate risk of bias generally across studies. Of interest, only three of the included studies detailed a power calculation to justify their sample size, no studies were able to demonstrate an unbiased recruitment strategy, but all studies did use an appropriate validated measure of DSO symptoms. The lowest scoring article achieved two (low risk of bias) and the highest scoring article received five (high risk of bias), while the majority scored four (high risk of bias).

ZW completed the risk of bias assessment for all included studies, and a third of studies (N=10) were corroborated by second reviewer MA. MA was provided all scoring criteria and returned her verdict to ZW. Agreement between reviewers was achieved in 86% of cases on the first pass. Cases of disagreement resulted in refinement of scoring criteria, for example, it was made explicit that the YSQ is not considered a robust, validated measure of NCBs (for reasons discussed below). It was also necessary to clarify definitions of "unclear" ratings in each category, as these were under-used in the first pass of bias assessment. On the second pass of the same studies, agreement was 100%.

During the risk of bias assessment, the quality of the tools used to measure DSO symptoms and NCBs was investigated. In this process it was discovered that the most commonly used tool for measuring NCBs (the YSQ) has a conflicting evidence base. Factor structure of the YSQ varies substantially across published studies. One of the most frequently used versions of the YSQ is the 3rd Short Form (YSQ-SF3) and the disagreement in factor structure is seen most vividly here. The original publication of the YSQ-SF3 purports to measure 18 schemas over five domains (groupings of similar schemas) (Young et al., 2003). However, subsequent validation studies have provided evidence in support of; 14 schemas over five domains (Soygüt et al., 2009), 18 schemas over three domains (Saritaş, & Gençö, 2011), 18 schemas over four domains (Sakulsriprasert et al., 2016), 18 schemas with no domain analysis (Lee et al., 2015), and 17 schemas with no domain analysis (Alfasfos, 2009).

The issue with this uncertainty is that the studies included in this review analysed the collected data based on inconsistent research, and some individual schema subscales may not be supported by the full body of research about the YSQ-

SF3. Similar issues are found in validation research for the long form (Oei, & Baranoff, 2007; Schmidt et al., 1995; Young, 1994), third long form (Saggino et al., 2018; Yalcin, Lee, & Correia, 2020), and short form (Baranoff et al., 2006; Cui et al., 2011; Van Vlierberghe et al., 2010) versions of the YSQ. The second versions of both the long and short form YSQ rarely appear in published literature. For these reasons, any that used any version of the YSQ as a measure of NCBs were given unfavourable assessments on that criterion in the risk of bias assessment.

Table 2.5. Risk of bias assessment outcome

	Unbiased cohort selection	Sample size calculation presented	Adequate description of cohort	Validated DSO symptom assessment tool	Validated NCB assessment tool	Missing data low or well-handled	Appropriate analytic methods	Score
Disturbed Relationships								
Aafjes-van Doorn	No	No	Yes	Yes	Yes	Yes	Yes	2
Allen	No	No	Partial	Yes	Yes	Yes	Yes	2
Baugh	No	No	Partial	Yes	Yes	Yes	Yes	2
Blisset	No	No	Partial	Yes	No	Unclear	Yes	4
Calvete	No	No	Yes	Yes	No	No	Yes	4
Crawford	No	No	Partial	Yes	No	Partial	Yes	3
Dumitrescu	No	No	Partial	Yes	No	Unclear	Yes	4
Eftekhari	No	Yes	Partial	Yes	No	Partial	Yes	2
Ertürk	No	No	Partial	Yes	No	Partial	Yes	3
Estevez	No	No	Yes	Yes	No	Partial	Yes	3
Evraire	Unclear	No	Partial	Yes	No	No	Yes	4
Gay	No	No	Partial	Yes	No	No	Yes	4
Gilbert	Unclear	No	Yes	Yes	No	No	Yes	4
Hassija	No	No	Partial	Yes	No	No	Yes	4
Janovsky	No	Yes	Partial	Yes	No	Partial	Yes	2
Kachadourian	No	No	Yes	Yes	No	No	Yes	4
Ke	No	No	Partial	Yes	No	No	Yes	5
LaMotte	No	No	Partial	Yes	No	No	Yes	4
Messman-Moore	No	No	Partial	Yes	No	No	Yes	4
Mojallal	No	No	Partial	Yes	No	No	Yes	4
O'Connor	No	Yes	Partial	Yes	No	No	Yes	3
Shorey	No	No	Yes	Yes	No	No	Yes	4

	Unbiased cohort selection	Sample size calculation presented	Adequate description of cohort	Validated DSO symptom assessment tool	Validated NCB assessment tool	Missing data low or well-handled	Appropriate analytic methods	Score
Smyth	No	No	No	Yes	No	Yes	Yes	4
Tremblay	No	No	Partial	Yes	No	No	Yes	4
Thimm	Unclear	No	Partial	Yes	No	No	Yes	4
Yakin	No	No	Partial	Yes	No	No	Yes	4
Yoo	No	No	Partial	Yes	No	Partial	Yes	3
Affect Dysregulation								
Calvete	No	No	Yes	Yes	No	No	Yes	4
Crawford	No	No	Partial	Yes	No	Partial	Yes	3
Ertürk	No	No	Partial	Yes	No	Partial	Yes	3
Gilbert	Unclear	No	Yes	Yes	No	No	Yes	4
Ke	No	No	Partial	Yes	No	No	Yes	5
McKee	No	No	Partial	Yes	No	No	Yes	4
Simons	No	No	Partial	Yes	No	No	Yes	4
Smyth	No	No	No	Yes	No	Yes	Yes	4
Tremblay	No	No	Partial	Yes	No	No	Yes	4
Yakin	No	No	Partial	Yes	No	No	Yes	4

Each “No” or “Unclear” scores one point, each “Yes” or “Partial” scores zero.

Score of 1-2= Low risk of bias, 3-5= moderate risk of bias, 6-7= high risk of bias

2.3.3 Funnel plots

2.3.3.1 Disturbed relationships

Figure 2.4 shows the potential for publication bias in the DR analysis. Standard error in this context is a measure of variability across samples, calculated from the number of participants in the sample and the standard deviation (Deeks et al., 2022). While funnel plots are recommended by GRADE for detection of potential publication bias, there are known issues, including subjectivity of interpretation, inaccuracy, and alternative explanations for plot asymmetry (Lau et al., 2006). However, in the absence of a more reliable alternative, funnel plots remain the prevailing method of detecting publication bias, with recommendations for caution when interpreting results or making inferences from funnel plot results (Guyatt et al., 2011C). The funnel plot in Figure 2.4 shows a relatively symmetrical plot, with few outliers and an even number of studies on both sides of the estimated overall effect size line. This indicates that publication bias was not detected. Figure 2.5 represents the output for a trim and fill analysis for the DR studies. The trim and fill analysis suppresses the studies with extreme effect sizes, on both the left and right sides (this is the trim process) and then estimates and imputes potentially 'missing' studies (this is the fill process) (Shi, & Lin, 2019). This analysis leaves a symmetrical funnel plot that can be used to observe the presence of publication bias (Sutton et al., 2000).

There are methodological issues associated with the use of the trim and fill method. The primary issue is that the imputation of missing studies makes assumptions that may or may not be correct (Guyatt et al., 2011C). However, while the suppressed and imputed studies may not be entirely accurate, there is not yet a

preferred method of analysing publication bias without comparable methodological issues (Guyatt et al., 2011C).

The funnel plot for DR in Figure 2.4 was mostly symmetrical, with no imputed or suppressed studies from the trim and fill analysis in Figure 2.5. This means that publication bias in this case has not been detected.

2.3.3.2 Affect dysregulation

Figure 2.6 and

Figure 2.7 show funnel plots for the AD analysis. A minimum of 10 studies is required for a reliable funnel plot to be generated (Lau et al., 2006). The AD analysis is just below the threshold of this requirement, so it should be noted that the output of this plot will be interpreted with caution as there was insufficient data. The funnel plot in Figure 2.6 is asymmetrical with only two studies to the left of the estimated overall effect size line, and the majority on the right of the line. The funnel plot inf is symmetrical, with one study removed and one study added by the trim and fill analysis. In this case, it can be said that publication bias is suspected by the funnel plots.

Figure 2.4 Funnel plot for DR analysis

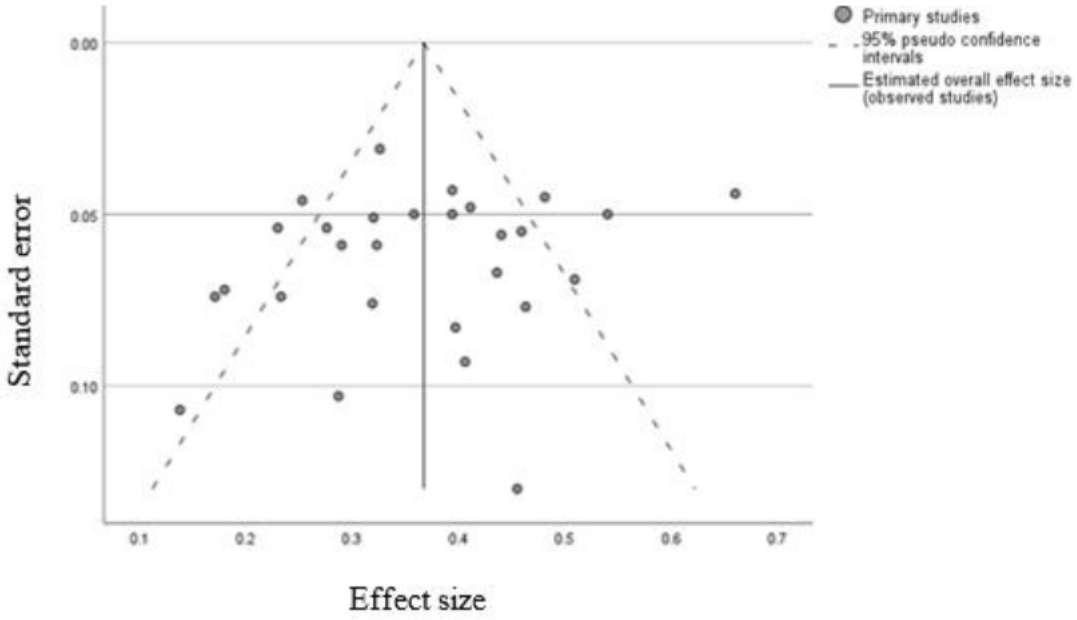


Figure 2.5 Trim and fill funnel plot for DR analysis

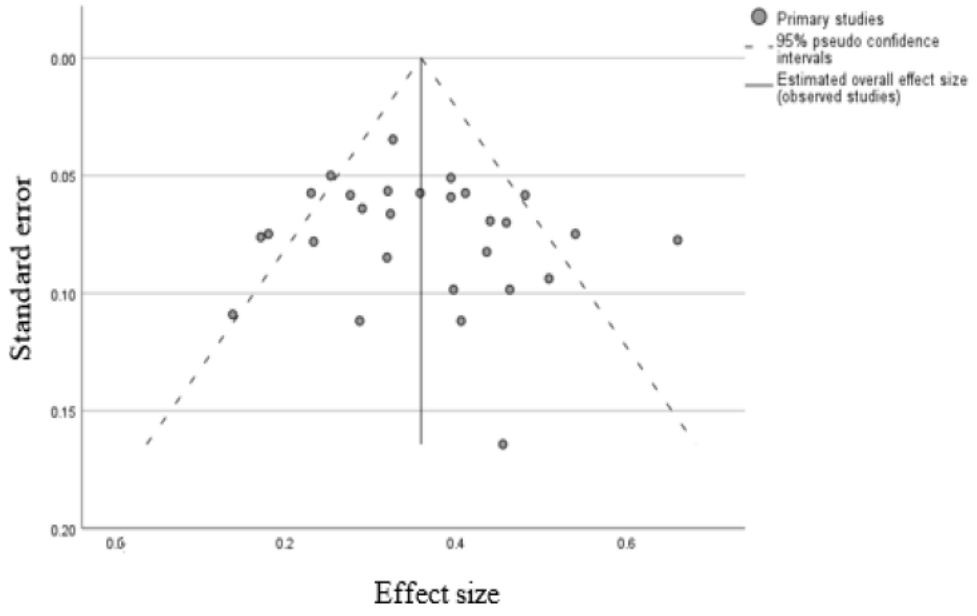


Figure 2.6. Funnel plot for AD analysis

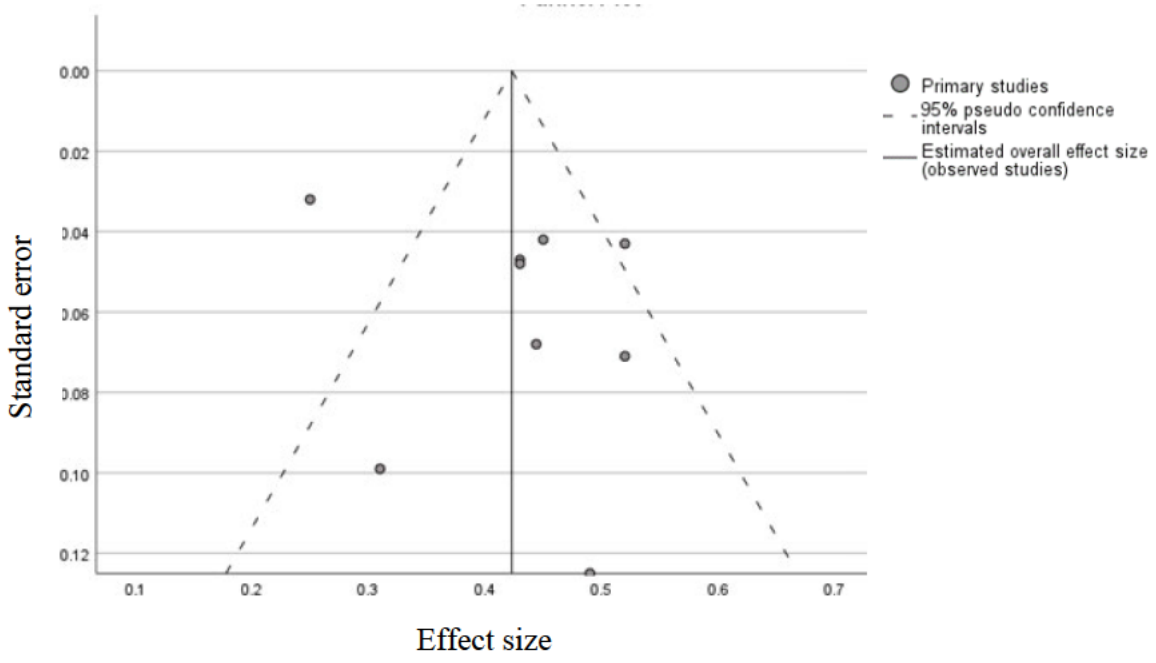
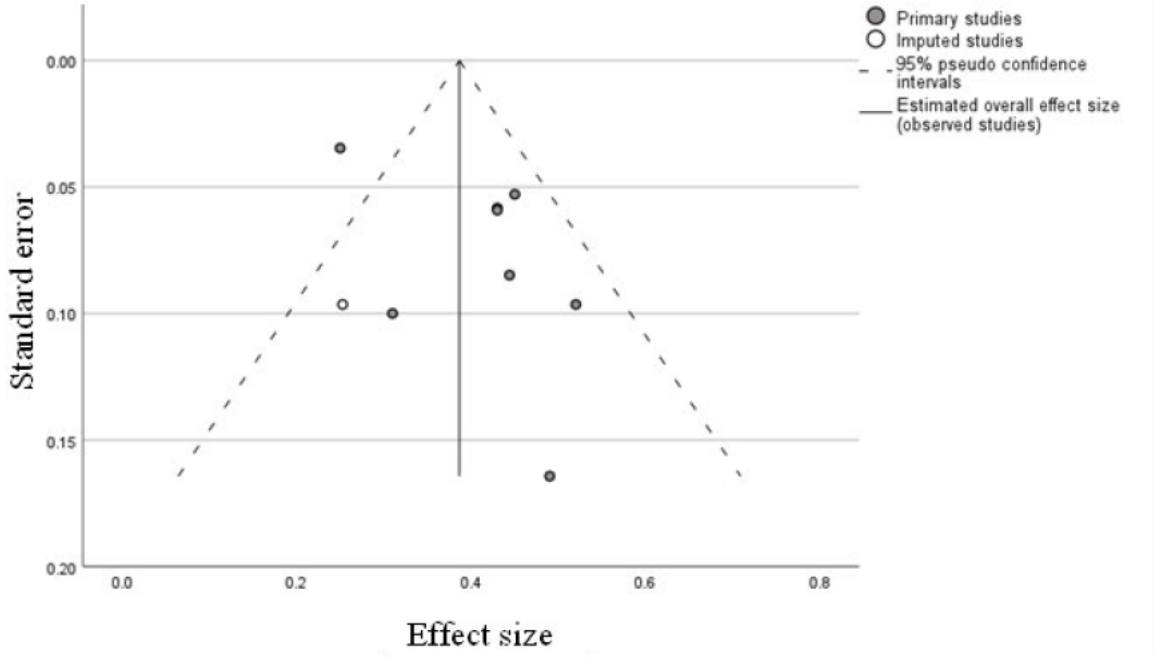


Figure 2.7. Trim and fill funnel plot for AD analysis



2.3.4 Grading of Recommendations, Assessment, Development, and Evaluations

2.3.4.1 Disturbed relationships

The prevalence of high risk of bias in the studies included in the DR analysis indicates that the evidence should be rated down one level. The amount of bias introduced by the methodological decisions in the included studies may have significantly altered the estimated effect from the true effect. The CI bar does cross the null line for one study, but the pooled CI bar does not. The CI bars are also generally not spread out. This indicates that it can be said with moderate certainty that imprecision did not affect the estimated effect. Due to the very high I^2 value, this analysis was rated down one level for inconsistency. High indirectness is present in this analysis. Four studies recruited clinical samples, meaning that there is a substantial difference between the population of interest and the sample recruited. The GRADE assessment is therefore downgraded by two levels. Publication bias is given a rating of moderate certainty since the funnel plot is symmetrical. Publication bias was therefore not detected. The GRADE rating was therefore neither upgraded nor downgraded. Since the evidence in this analysis began with low certainty (as described in 2.2.5.5) and it is not possible to rate below very low certainty, the overall GRADE score for this analysis is very low. This means that the quality of the evidence here is poor and there are steps that must be taken to improve the quality of future research.

2.3.4.2 Affect dysregulation

Due to the moderate to high risk of bias indicated in many studies by the AHRQ, the rating for risk of bias in the AD analysis was downgraded. The risk of bias may have significantly affected the observed effect. None of the CI bars cross

the null line and the cars tend towards being closely gathered. This means that imprecision is unlikely to have had an impact on the estimated effect, and the overall GRADE rating was not downgraded. Due to the very high I^2 value, this analysis was rated down one level for inconsistency. High indirectness was also found in this analysis, since only three included studies recruited clinical samples. The analysis was therefore downgraded by one level. Publication bias resulted in downgrading since the funnel plot was asymmetrical. Publication bias was suspected and is therefore likely to have changed the estimated effect from the true effect. Like the DR analysis, the overall score for the quality of the evidence in this analysis was very poor. Steps must again be taken to improve the quality of future research to ensure the reliability of conclusions drawn.

Table 2.6. GRADE risk of bias outcome

	Risk of bias	Imprecision	Inconsistency	Indirectness	Publication bias	Overall
DR	-1	-1	-1	-2	0	-4
AD	-1	0	-1	-1	-1	-3

2.4 Discussion

2.4.1 Main findings

The aim of this review was to collate existing research on the relationship between AD and DR symptoms and NCBs using proxy measures of the included DSO symptoms, and to provide a basis for making recommendations regarding future research into the relationship between CPTSD and NCBs. It has been found that there are significant, positive correlations between AD and DR, and NCBs in published studies to date.

This indicates that the DSO symptoms of DR and AD are associated with endorsement of NCBs. The hypothesis of this review was that there would be a

significant association between DSO symptoms and NCBs, and this can be confirmed to a certain extent.

The data used in the meta-analyses are limited by the relatively small number of relevant studies in the AD analysis and the fact that some studies had low power due to small sample sizes. The meta-analyses also revealed substantial heterogeneity in both analyses, indicating that the degree of correlation between NCBs and the DR and AD symptoms varies between studies. A majority of studies were carried out in the USA on either undergraduates or other general population samples so generalisability of the findings to clinical populations is low. There is a need for further research in this area in clinical samples.

Many studies recruited undergraduate students as their sample, some of which received course credit for their participation. The use of undergraduate samples who take part in studies for course credit is common but has a number of significant limitations. The population of undergraduate courses tends be less representative of the general population, leaning female and younger in age (Dickinson et al., 2012), and the motivation for participating being course credit may mean that the study measures were completed with suboptimal effort (DeRight, & Jorgensen, 2015; Ross et al., 2016). These issues with sampling mean that the findings of many studies in this review may not be generalisable to other populations, and the risk of bias is increased. Therefore, there is a need for research into the relationship between DSO symptoms and NCBs in clinical populations before intervention-based research can be conducted to explore the effectiveness of cognitive schema therapy for ICD-11 CPTSD.

2.4.2 DR discussion

The DR meta-analysis included 27 studies, a relatively large number for a meta-analysis, so the strong positive correlation was made with high power. This lends credibility to the conclusions drawn, and the lack of publication bias found in the funnel plots indicates that this large body of evidence is likely to be representative of the true effects in the populations studied.

However, the I^2 heterogeneity in this analysis was considerable to substantial. This level of heterogeneity indicates that there is a substantial amount of error. Causes of this could be due to the different populations included in each study, the use of poor schema assessment tools such as the YSQ (see section 2.5.4 for methodological issues associated with use of YSQ), or differences in proxy measures of DSO symptoms. This amount of heterogeneity indicates that conclusions must be drawn with some hesitancy. However, the GRADE assessment for this analysis showed low levels of imprecision (another way of measuring heterogeneity) when measured using the overlap of CI. These conflicting findings indicate that, while the outcomes of all the papers were mostly all positive, some were much stronger than others. This can be observed in the fact that all but one study (Gilbert et al., 2013) had a positive effect size. This means that it is highly likely that the true effect is positive, but there is currently a wide range that the true effect could fall within.

The heterogeneity observed in these analyses is an indicator that more accurate research in the topic area of NCBs in DSO symptom experience is needed. Heterogeneity could be minimised by running studies with samples representative of the general clinical population, using more reliable measures, and studies with more consistent methodology (Ioannidis, 2008; Lau et al., 1998).

Risk of bias in this analysis was moderate overall. While only three studies described a power calculation to justify the sample size used (implications of this discussed in 2.6.3), all studies did use validated tools to measure DSO symptoms, and missing data or rate of attrition (addressed in only 9 studies) was typically below 20%. The risk of bias in this analysis could have been lowered by an attitude of transparency and the inclusion of small pieces of information (i.e., power calculation, demographic data etc.).

Overall, there is a positive association with NCB endorsement and DR symptom experience. Further research is needed to identify how this relationship functions and to address sources of bias.

2.4.3 AD discussion

The positive correlation found in the AD analysis indicates that there is a mild positive association between AD symptomology and NCB endorsement. However, there are a number of issues with the data available and therefore the outcomes of the analysis. For example, only nine studies were included in the analysis, which is a relatively small number of data points to be drawing conclusions from. This means that there may be data missing, unrepresented populations, and publication bias, and further research is required to address these issues before any conclusions can be drawn with confidence. This all indicates that the small positive correlation may not represent the ‘true’ effect.

A risk of publication bias was suggested by the asymmetrical funnel plot, as well as the trim and fill analysis. This is unsurprising as analyses with smaller numbers of included studies does increase the likelihood of publication bias (Sutton et al., 2000), It may therefore be likely that there is a bias in this area towards

publishing studies with larger positive effect sizes, and the outcome of this analysis may be artificially inflated. The outcome should be regarded with caution, and further research should be conducted.

Heterogeneity as measured by the I^2 in this analysis is higher than the DR analysis, indicating that the spread of outcomes is wider in the AD analysis. There is also less overlap between the CIs, possibly due to the current lack of evidence in this area, or possible methodological inconsistencies and sources of bias. Again, this indicates that there is a wide range where the true effect size may fall, and further rigorous research is needed to reduce bias and narrow the range of effect sizes.

The risk of bias of the included studies was moderate overall. No studies described a power calculation to justify the sample size used, and rate of attrition was addressed in only one study, but all studies did use validated tools to measure DSO symptoms.

The most common issue relating to risk of bias was the absence of a sample size calculation. A study that does not perform and publish a sample size calculation may not have recruited a large enough sample to limit bias and cannot be said to have a sample that is representative of the population (Simundic, 2013). A too-small sample is also at risk of having a larger standard deviation, and therefore giving observed effect sizes further from the true effect size (Sullivan, & Feinn, 2012). Any study included in this review that did not publish a sample size calculation may have recruited an underpowered sample. Some studies included in this review without a sample size calculation did recruit very large samples, so this does reduce the risk of inaccurate results. In addition, many studies report non-significant results.

Overall, the evidence analysed here may tentatively indicate that NCB endorsement has a positive association with AD symptom. Again, further research is needed to identify the nuances of this association and reduce sources of bias, as well as increase the volume of data in this area.

2.4.4 Implications for research

Implications for research inferred from this study should be viewed with caution due to the proxy measures used for DSO symptoms, and significant heterogeneity in both analyses.

Future experimental research should seek to test for a causal link between NCBs and AD and DR, using a validated measure of CPTSD (for example, the international trauma questionnaire (ITQ) (Cloitre et al., 2018) or the international trauma interview) (Roberts et al., 2019) rather than proxy measure of DSO symptoms. Such research can potentially shed light onto the temporal link between the two constructs- which comes first, and therefore which may cause the other. A longitudinal understanding of the development of NCBs and DSO symptoms will help with understanding the mechanisms of the relationship between DSO symptoms and NCBs.

The results of this review indicate a positive association between DSO symptoms and NCBs but cannot be used to determine causation. Causation cannot be assumed from cross-sectional, correlational studies since it cannot be said whether the NCBs existed before or after the DSO symptoms, and there is no proposed mechanism for how one may have developed from the other. Demonstrating evidence for causation would require further research, including longitudinal studies to show the development of NCBs and DSO symptoms over time. Additional

research is therefore required to further define the temporal ordering of the relationship and to make subsequent, better-informed recommendations for clinical practice.

The above is necessary before recommendations can be made for therapies to address NCBs or DSO symptoms, as well as further research with clinical samples. The studies included in this review were mostly non-clinical samples, which may be logistically sensible, but does not accurately represent the population of interest for therapeutic intervention. Further research is therefore recommended with clinical samples.

Furthermore, future research into the relationship between DSO symptoms and NCBs should employ measures of NCBs other than the YSQ. As discussed above, the YSQ has significant participant burden due to its length and attempts to identify consistent factor structures have given varied results (Oei, & Baranoff, 2007). Alternative measures of NCB measurement such as the Core Beliefs Questionnaire (Wong et al., 2017) should therefore be used in future research exploring the association between DSO and NCBs.

To correct the presence of publication bias, studies with negative results should be published, as well as studies with larger sample sizes and rigorous protocol design. Protocols for studies in progress should be registered, and any non-significant findings that are not to be published in a peer reviewed journal should be made public. Negative results are less likely to be published but are important for identifying true effects, so this procedure of registering negative results in protocol registries would allow this data to be made available.

2.4.5 Strengths and limitations

A pre-specified published protocol was used for data extraction, synthesis, and quality assessment, the PRISMA checklist and flowchart were used (Page et al., 2021) and the Cochrane Handbook (Lasserson et al., 2022) guidelines were followed wherever possible. The use of these best practices lends credibility to the outcomes and the conclusions drawn. Changes to the protocol are listed above and have been recorded on the PROSPERO pre-registration site. Additionally, full text screening, data extraction, and quality evaluation was confirmed by a secondary researcher to minimise evaluator bias and error.

In terms of publication bias, the methods used in this analysis are the best available, but empirical publication bias measurement is difficult to achieve at present, particularly for meta-analyses of observational studies (Lau et al., 2006). All known methods do carry some inherent risk of subjectivity or statistical manipulation (Guyatt et al., 2011C). Publication bias is not the only explanation for an asymmetrical funnel graph. Population choice, study protocol, and other methodological issues can impact the effect size of a published study and therefore the symmetry of the funnel graph (Guyatt et al., 2011C). To mitigate these issues with funnel graph interpretation, additional sources of information were sought. Mean number of participants, authors' declarations of conflicts of interest, and funding sources were also considered as qualitative data when rating risk of publication bias, as recommended by GRADE guidelines (Guyatt et al., 2011C).

Furthermore, despite being planned in the initial protocol registered with PROSPERO, the association between NCBs and Negative Self Concept was not explored in the present review due to conceptual overlap between existing measures

for the two constructs. Further research should focus on the relationship between specific NCBs and CPTSD symptomology, including Negative Self Concept.

2.5 Conclusion

In conclusion, the research questions detailed in section 2.1.5 of this chapter can confidently be answered. Current knowledge on the topic of the relationship between AD/DR and NCBs indicated a moderate positive correlation. In order to better understand the relationship between NCBs and CPTSD symptoms, experimental research with larger sample sizes must be conducted to provide further evidence in support of the correlation. Research beyond that may then identify a mechanism of causation. This is a vital step before conducting research involving schemas as a target for CPTSD therapies. Future research should also use direct measures of all three DSO symptoms and a more reliable measure of NCBs.

3 Study two: online survey methodology

3.1 Introduction

3.1.1 Summary

This chapter will present the research design, ethical approval, procedure, measures, and analysis plan of an online, cross-sectional survey study that recruited 2,144 participants. The background and rationale for this study can be found in chapter one, the results in chapter four, and the discussion in chapter seven. This chapter also describes the cohort via demographic data.

This study generated quantitative data relating to demographics, types of trauma experienced, levels of post-traumatic stress disorder (PTSD) and complex PTSD (CPTSD) symptoms experienced, and negative core beliefs (NCBs) endorsed by the respondent. The aim of this study is to analyse the relationship between NCB endorsement and PTSD/CPTSD symptom profile.

3.1.2 Chapter aims

This chapter will present the methodology of a study looking at the differences between NCBs in participants with PTSD, CPTSD symptoms, and participants with no symptoms. The methodology presented in this chapter was developed to answer the question “How are NCBs related to PTSD and disturbances in self-organisation (DSO) symptoms as detailed in the 11th edition of the International Classification of Diseases?”. This research is required in supporting the memory and identity (M&I) model of CPTSD (Hyland et al., 2023), which will lead into theoretically driven research in the field and the identification of potential treatment pathways for CPTSD. The results of the methodology presented in this chapter will also contribute to the current understanding of the role of NCBs in these

conditions across different demographic groups. This will allow for the development of research-informed assessment and treatment practices that can be tailored made across different groups.

3.2 Meta-analysis findings

The findings from the meta-analysis presented in chapter two of this thesis suggest that there was a moderate positive correlation between the symptoms of affect dysregulation (AD) and disturbed relationships (DR) and NCBs. The studies included in the meta-analysis used proxy measures of DSO symptoms, as there is presently a very small number of published studies that measure the correlation between a validated measure of CPTSD symptoms and a measure of NCBs (Greenblatt-Kimron et al., 2023; Karatzias et al., 2018; Vasilopoulou et al., 2020). Analysis of studies using proxy measures was necessary but reduces the validity of the results and subsequently conclusions drawn from the analysis. The meta-analysis concluded that it was necessary to conduct further research using validated measures of CPTSD symptoms and NCBs. This chapter will therefore build upon this conclusion and use validated measures in investigate the relationship between PTSD/CPTSD symptomology and NCBs.

It was also identified that a majority of research exploring associations between NCBs and DSO symptoms has employed the young schema questionnaire (YSQ). At present there is significant disagreement about the factor structure of the YSQ (see section 2.5.4 of this thesis for detail about this issue), and a major limitation of the meta-analysis presented in this thesis was the heavy reliance of published research using the YSQ. The recommendation from the meta-analysis was for future research to use an alternative measure of NCBs, such as the core beliefs questionnaire (CBQ). Previous research has shown the CBQ to be a reliable

assessment tool for NCBs in social anxiety (Wong et al., 2017). The CBQ is therefore a useful tool for assessing NCBs, and the present study identified the CBQ as a potentially reliable tool for measuring NCBs in PTSD and CPTSD populations. The reliability of the CBQ was assessed and presented as an alternative to the YSQ in these populations.

In the introduction chapter to this thesis, it was discussed that there is presently no cognitive model of post-traumatic disorders that can also be applied to CPTSD. Ehlers and Clark (1999) did propose a cognitive model of PTSD that has since been widely accepted, but research into the inclusion of CPTSD in this model has yet to be carried out. It is important that we understand how CPTSD is developed and maintained, and what are the cognitive factors that are associated with CPTSD in order to develop appropriate treatments for this debilitating condition. The research described in this chapter represents a first step towards a cognitive model of CPTSD, by understanding the role that NCBs play in CPTSD compared to PTSD and non-diagnosed presentations.

3.3 Research design

A number of different designs were considered for this work as outlined below. These include longitudinal, retrospective, or cross-sectional, and in-person or online. The strengths and weaknesses of each approach in answering the main research questions are described as follows.

3.3.1 Cross-sectional design

The cross-sectional design entails taking measurements from a sample at one time point. This design allows for quick gathering of data (Setia, 2016) and is ideal for research questions requiring correlational analyses without analysis of

longitudinal data to assess causation (Wang, & Cheng, 2020), or questions dealing with the prevalence of a disease in a population (Kesmodel, 2018) or the validation of a measurement tool (Kesmodel, 2018). Since the research questions for this chapter are designed to investigate reliability, differences between groups at one time point, and prevalence of PTSD/CPTSD in the selected population, a cross-sectional design is appropriate.

Cross-sectional designs are prone to certain types of bias, however. Due to the measure being taken at only one time point, it is possible that some participants may be experiencing an unusually greater or lesser symptom burden. Therefore, when asked about their experience with symptoms in the preceding four weeks, their answers may not be an accurate representation of their typical symptom profile (Wang, & Cheng, 2020). Symptoms of mental health disorders do fluctuate over time and with experiences (Chopra et al., 2014; Green, & Graham, 2022), so while it is possible that some participants reported less significant symptoms than they usually experience, this is a realistic illustration of the experience of mental health difficulties and therefore lends generalisability to the study.

Additionally, the prevalence of PTSD and CPTSD depends on the survivability of the condition. Even if the number of cases of CPTSD goes down, this may not represent recovery from the illness so much as it indicates the rate of suicide in that population (Boerma, Sommerfelt, & Bicego, 1992; Setia, 2016). Unfortunately, this is an unavoidable flaw in cross sectional research, and would be exacerbated with the use of longitudinal design (Czeisler et al., 2021). It was therefore determined that cross sectional design was the most appropriate approach for this study, also considering the available resources for this work.

3.3.2 Online survey design

Online survey approach to data collection taken in this chapter was vital to the collection of a large sample from a large population. Fast and cheap collection of quantitative data from large groups of people is one of the advantages of online surveys (Andrade, 2020). Online participation allows participants to take part when and where they wanted to, reducing participant burden (Ball, 2019). This allowed for the inclusion of participants who would otherwise be too busy or live too remotely to take part (Evans, & Mathur, 2018). However, despite the ability to collect a large amount of data, there are flaws inherent in the online survey data collection method.

Online administration of self-report psychometrics introduces a certain amount of selection bias (Nayak & Narayan, 2019). For example, only those people with access to a computer and an internet connection in their home are able to take part, and online samples tend to consist of younger participants (Nayak & Narayan, 2019). This excludes many people in lower socioeconomic groups, elderly people, and those less computer-literate (Ball, 2019; Hargittai et al., 2019). Despite this drawback, online surveys allow researchers to reach communities that would otherwise be unable to participate, for example, those unable to leave their home due to disability or mental health difficulties or when researching sensitive topics, as in the case of this study (Wright, 2005). Additionally, rates of computer literacy in the elderly have now increased such that many older people are moderately confident (Hargittai et al., 2019). The Office for National Statistics (ONS) reported an increase in adults with an internet connection from 86% in 2015 (Office for National Statistics, 2015) to 89% in 2016 (Office for National Statistics, 2016), 96% in 2020 (Office for National Statistics, 2020). This continued increase in access to internet

means that online surveys can access a greater proportion of the general public year on year.

Online survey designs lend more secure anonymity to respondents, which can be both a benefit and a drawback (Ball, 2019). As stated above, sensitive topics can be more easily researched, but anonymity means that participants do sometimes respond falsely, and it is difficult to detect survey fraud in online spaces (Bohannon, 2016). To mitigate this risk as far as possible, the online survey company used in this study (detailed in section 3.7.1) has integrated fraud detection protocols and automatically discards any datasets that appear to have been answered illegitimately by measuring the amount of time taken to respond to each item.

Despite the potential drawback to the online survey design, it was determined that this was the most appropriate approach to the present study. The required sample size could be recruited within time and financial constraints, sources of bias could be mitigated as far as possible, and the population of interest could be most easily reached via online survey. For these reasons, the study went ahead using online survey.

3.4 Rejected study designs

3.4.1 Longitudinal design

A longitudinal survey design would have been an option to allow for the tracking of NCB change over time and before/after exposure to traumatic events. However, in addition to increased participant burden and rate of attrition, this was cost-prohibitive. NCBs are also very deeply held and do not change over a short period of time without intervention (Riso et al., 2006). A suitable interval time as indicated by existing literature would not have been achievable in the timeline of this

PhD (Fernández-González et al., 2021; Simard et al., 2011). The majority of published studies analysing the correlation between NCBs and the symptoms of a mental health disorder only measure at one time point (Pilkington et al., 2021). A longitudinal design is not only unnecessary to answer the research question detailed in this chapter, but it would also exceed time constraints and may only produce results already gleaned from a cross-sectional design.

3.4.2 Retrospective design

Retrospective data collection was considered as an alternative to prospective data. The method would have included asking participants to report their beliefs about themselves from before their most traumatic event, and then their present beliefs, then analysing the change between the two time points. However, the amount of time passing since the index event could have been upwards of a decade, meaning that participants' memory of their beliefs before the index event would have been deteriorated by time, a process that is exacerbated by PTSD and trauma (Bryant et al., 2007; Jelinek et al., 2006; Joseph, 1999). The potential inaccuracy of the results resulting from such a retrospective study would have damaged the integrity of any conclusions drawn.

3.4.3 In-person design

In order to collect data from a large enough sample to capture population characteristics, a very large sample size was needed. A goal of c. 2,000 participants was set based on the needs of another project sharing the data collected in this process (see section 3.7.2 for power calculations and rationale). Such a large sample would allow for the ascertainment of practical effect size (a crucial aspect in determining practical significance of a statistically significant p-value) (Khalilzadeh, & Tasci, 2017) and narrow confidence intervals (Lantz, 2013). A sample of such size

could be obtained through costly and time-consuming field work. Even after contact is made with such large samples, attrition for in-person research is very high. Dobie et al., (2002) who contacted 2,545 participants succeeded in recruiting only 282 participants for in-person participation.

A paper and pencil recruitment method would require accessing a pool of trauma-exposed individuals, meeting them face-to-face, and facilitating their participation. As detailed in chapters five and six of this thesis, accessing such a population face to face is logistically complicated. Approval is required from gatekeepers, cooperation from clinical professionals, and there is greater participant burden (Ball, 2019). These barriers were such that it would not have been possible to access participants, screen for inclusion, collect responses, and debrief needed to meet the 2,000-person target within any reasonable timescale.

Additionally, collection of a sample size comparable to that recruited in this chapter by in-person research methods would be prohibitively expensive both financially and in terms of work hours. For example, the estimated time for a single participant to complete the questionnaires online was 25 minutes. Two researchers collecting this data by pencil and paper survey would have to work for 1,786 hours each, or 45 fulltime work weeks. Remuneration for these researchers at a postdoctoral pay grade of £21/hour would amount to £37,520 each. This timescale is not workable, and such funds to pay researchers are not available. It was therefore not possible to conduct this study in-person in the timescale available to complete this work.

3.5 Research questions

The aim of this study was to investigate how NCBs are related to international classification of diseases 11th edition (ICD-11) PTSD and DSO symptoms. The following research questions were considered in the design of the study:

1) Does the CBQ produce reliable measurements of NCBs in participants endorsing PTSD/CPTSD symptoms?
2) Do participants meeting diagnostic requirements for CPTSD score more highly on the CBQ than participants meeting requirements for PTSD and those that do not meet requirements for either disorder?
3) Which NCBs are most likely to be endorsed by participants meeting requirements for CPTSD compared to participants meeting requirements for PTSD and neither?

3.6 Ethical considerations

3.6.1 Ethical approval

Ethical approval was sought and gained from Edinburgh Napier University (ENU) School of Health and Social Care Research Integrity Committee through the online Worktribe ethics application portal. The application was submitted on 29/03/2023 and approved on 18/05/2023 (REF Number 3026271).

3.6.2 Confidentiality and anonymity

Participants were informed of their right to anonymity in the consent form (see appendix 9.9), privacy notice (see appendix 9.8), and participant information sheet (PIS) (see appendix 9.7) at the beginning of their participation. No identifiable

data (i.e., name, date of birth etc.) was gathered and TGM assigned participant numbers to be used as identifiers for individual cases in the dataset.

All anonymous survey data were stored on password-protected university computers, on university premises, and inside locked rooms. All data were processed in line with Edinburgh Napier University guidelines. During the discussion chapter of this thesis, any names used to discuss individual participants are pseudonyms. This is also the case with any journal publications made as a result of data collected in this study.

3.6.3 Informed consent

Informed consent was gained through the online survey before participants took part in the study. There was a potential risk to the participants in this study, due to the discussion of potentially sensitive or triggering traumatic events. To mitigate this risk as much as possible, participants were informed of their rights to withdraw at any point in time without penalty and they were informed that the study would ask about sensitive topics before they agreed to take part. Participants were also referred to appropriate external resources for support following their participation in the study.

Participants were offered financial compensation for completion of the survey. However, they were not paid if they did not complete all questionnaires on the survey. This did introduce the potential for coercion, with the risk that some participants might have completed the survey solely to be paid. This is an issue inherent in TGM's (N.B., TGM is not an acronym) business design (see section 3.7.1 for more detail on the survey platform). Efforts were taken to mitigate this, including minimization of participant burden and emphasis placed on ensuring that participants

knew what would be asked of them before agreeing to take part in the study. Participant burden was minimized by only administering questionnaires that were relevant to the research questions, and allowing for the questionnaires to be completed at a time and place that was convenient to the participant. Response patterns were also analysed by TGM to check for participants answering questions without reading the instructions to be paid quickly. Two such cases were identified and excluded before the data was provided for analysis.

Participants were requested to read the privacy notice (in appendix 9.8) before agreeing to consent. This described what the study would entail and how their data would be treated and stored to ensure confidentiality and anonymity. If a participant was still interested after reading these documents, they were presented with the consent form (in appendix 9.9), and if any statement on the consent form was disagreed with, the participant was redirected to a debrief page and their data was not collected.

3.6.4 Data storage and protection

Online survey platform TGM was company used for data collection. After a participant completed the psychometrics, their data were stored in password protected files on TGM's secure servers until the full dataset was collected. After the dataset was complete, a password-protected link to the file of anonymised data was emailed to the research team to download and for analysis.

Participant information and data were stored on university drives and processed on a university laptop. The laptop was password-protected, as was the data folder, and the laptop was kept in a locked drawer when not in use. This was a university requirement, so that university cyber security could protect all participant

data. A data management plan was submitted to ENU governance and approved before ethical approval was submitted. These processes were designed to be in line with ENU research and data protection guidelines (Edinburgh Napier University, 2019).

3.6.5 Source of data

The data in this study were sourced in collaboration with another PhD student. The collaborators on this project had secured funding to collect data from an online survey and were using the same questionnaires that the present study intended to use. Collaborators collected the data via a recruitment organisation and were passed on for analysis in this study.

Because this study acquired data in collaboration with another study, full control over the order and number of assessment tools was not possible. In the survey, there were a total of 12 psychometric tools, presented in a set order (i.e. non-randomised presentation). This induced the possibility of response fatigue (Jeong, et al., 2023) but previous research has shown that response fatigue only becomes a major concern at around the two-hour mark (Hess, et al., 2012; Jeong, et al., 2023), and estimated completion time for the survey in the current study was under one hour.

3.7 Participants

3.7.1 Recruitment

Participants were recruited online via the online survey platform TGM. Participants were recruited as a part of a collaborative study between another researcher at Edinburgh Napier University. TGM maintain nationally representative survey panels in 130 countries. Members of the public in these countries can sign up

to receive notifications on their mobile phones, if there is a recruiting study for which they match the inclusion criteria. After agreeing that they meet the inclusion criteria for this study (detailed in 3.7.3), any participants choosing to take part in this survey were reimbursed for their time at a rate of 0.16 GBP per two minutes, with this survey taking approximately 25-30 minutes to complete (1.68-2.08 GBP).

Participants were already signed up with TGM as available to complete surveys and notified by either an email or an in-app notification. They then logged on, read the privacy notice and participant information sheet, and completed the consent form and psychometrics as they were presented. Survey completion was online, so participants were able to take part at any time that suited them during the recruitment window.

Participants were given the opportunity to email questions to the researchers and independent Edinburgh Napier University staff if they had any queries or concerns. Participants then read the information sheet and privacy notice, and completed their consent form through TGM software,

3.7.2 Sampling

The sample was a trauma-exposed group of adults from the UK. This population was selected because the topic of interest in this study is the relationship between NCBs and PTSD/CPTSD. Per the ICD-11 it is not possible for a diagnosis of PTSD or CPTSD to be conferred to a person who has not experienced a traumatic event. Therefore, any participant who did not meet the diagnostic criteria of exposure to a traumatic experience would not be included in this study. Many of the analyses in this thesis will be performed on only participants from this sample meeting PTSD

or CPTSD diagnostic criteria to allow for maximum clinical application of the results.

One of the key issues found in the results of chapter two of this thesis was the risk of bias in the included studies. Very few studies that assessed the correlation between NCBs and DSO symptoms published a power calculation to justify the sample size used. The present chapter aims to improve upon the research analysed in chapter two. To this end, a power calculation was completed to assess the number of participants needed to answer the research questions listed in 3.5. G*power (Faul et al., 2007) and a review of published articles detailing simulations of minimum sample requirements was used to identify the minimum participants needed for all analyses (see 3.9.2 for detail on data analysis plan). The largest required sample size indicated by power calculations was 470.

Fan et al. (2012) indicated that a minimum of 360 participants would be needed for a Kruskal-Wallis (K-W) test with unequal subgroups and an effect size of .80. G*power revealed that for the planned t tests with an alpha level of 0.05 and an effect size of .80, a minimum of 402 participants was necessary to achieve acceptable statistical power in this study. De Winter et al. (2009) concluded that a one-factor exploratory factor analysis with 24 loadings would be adequately powered with 470 participants. The minimum required sample size of this chapter is therefore 470.

Despite the needs of this study only requiring 470 participants, an initial goal of 1,599 participants was set. Primarily, this was because a power calculation performed by another project sharing this recruitment process revealed the need for 1,454 participants with an additional 10% to account for useable or incomplete data.

Toward the end of the data collection period, it was discovered the majority of participants were female. To ensure that a gender split of 50% was attained, participation was limited to male participants until 2,144 individuals were recruited. The initial recruitment target was exceeded, lending greater statistical power to this study.

Exceeding the 470 participants required by this study is almost exclusively a positive result. A larger sample means that population characteristics can be captured more comprehensively (Muhammad, Tasmin, & Aziati, 2020) and statistical power is greater (Lantz, 2013). In addition, the trauma-exposed population of the UK is very large. In studies measuring trauma exposure in the general population by self-report questionnaire, between 71% and 84% of adults reported experiencing a traumatic event at one point in their life (Briere, & Elliott, 2000; Elliott, 1997; Frans et al., 2005; Knipscheer et al., 2020; Mills et al., 2011). In order to recruit a representative sample of such a large population, as large a sample as possible is necessary.

Larger sample sizes do have their drawbacks, however. Exposing more participants than necessary to questionnaires about sensitive topics that may cause undue distress is ethically questionable (Faber, & Fonseca, 2014). In the ethical application for this study, the emotional impact on participants was discussed at length. To reduce distress, steps were taken to ensure that participants were aware of what they would be asked to do, including the completion of consent forms, reading the privacy notice, and the participant information sheet. Participants were also encouraged to leave the survey before completion if they believed they were experiencing emotional distress. These measures were determined by the School of

Health and Social Care Research and Integrity Committee to be appropriate for the proposed sample size and sufficient to offset potential emotional distress.

Additionally, when using large samples, it is important to not conflate statistical significance with significant effect size (Lantz, 2013). A large sample is more likely to return statistically significant values, so the interpretation of these values should only be in conjunction with practical effect sizes (Khalilzadeh, & Tasci, 2017). To ensure that the analysis of the outcomes of this study did not draw conclusions based on inflated p values, reported findings were discussed in the context of effect sizes and measures of effect magnitude (Berger, 2005).

3.7.3 Inclusion criteria

Participants taking part in the present study were required to be between the ages of 18 and 30, be able to read and write in English, and be able to give informed consent to taking part and having their data collected and analysed. The upper age limit was established due to the needs of another project using the same data being collected. This upper age limit requirement represented a significant restriction in the generalisation of the findings for this study. The conclusions drawn from this study cannot the generalised beyond the age category of 18-30 years. Clearly, the ideal would be to collect data from a wider age range, but the funding for the data collection was controlled by a project with strict requirements for participant upper age limit. To secure funding on a similar scale to recruit a comparable sample would have taken significant time investment beyond the scope of this thesis, given the other areas of work that have been completed. The decision was therefore taken to use the large sample with the upper age limit of 30 years and discuss the implications of this.

Participants were also required to have experienced at least one traumatic event in their lifetime. This criterion was implemented due to the ICD-11 diagnostic guidelines that PTSD and CPTSD follow a traumatic event. This did restrict the number of individuals who were able to complete the survey and introduced the ethical issue of asking participants to think about and answer questions about traumatic experiences. However, it was decided that it was more important to collect relevant data (i.e., data from participants who have experienced a traumatic event and therefore may be eligible to receive a diagnosis of PTSD or CPTSD) than collect data from individuals with no trauma history. Any participant not meeting the inclusion criteria as assessed by screening questions during the survey were directed to a debrief screen and thanked for their time.

3.7.4 Exclusion criteria

Participants not completing all measures were excluded from the sample, as well as any participants not agreeing to all statements on the consent form.

3.7.5 Participant characteristics

A total of 2,144 participants were recruited. Participants ranged in age from 18 to 30 (mean =24, SD=3.82). Most common highest educational achievement was A-levels or equivalent (n=653, 30.5%) or an undergraduate degree (n=600, 28%), 1,520 (70.9) identified as British, 104 (4.9%) as African, and 91 (4.2%) as British/Irish. Most participants did not meet criteria for either PTSD or CPTSD (n=1,179, 55.0%), the second most common outcome was endorsement of CPTSD criteria (n=734, 34.2%), and the least common outcome was endorsement of PTSD criteria (n=231, 10.8%). Full participant characteristics can be found in Table 3.1.

Table 3.1. Full participant characteristic data

	Neither PTSD nor CPTSD N (%)	PTSD N (%)	CPTSD N (%)	Total N (%)
Total	1,174 (54.7)	236 (11.0)	734 (34.1)	2,144 (100.0)
Gender				
Male	419 (35.7)	96 (40.7)	324 (44.1)	839 (39.1)
Female	744 (63.3)	139 (58.9)	404 (55.0)	1,287 (60)
Other	9 (0.8)	1 (0.4)	6 (0.8)	16 (0.7)
Ethnicity				
British	804 (68.5)	172 (72.9)	544 (74.1)	1,520 (70.9)
British/Irish	48 (4.1)	9 (3.8)	34 (4.6)	91 (4.2)
Chinese	11 (0.9)	0 (0.0)	4 (0.5)	15 (0.7)
Indian	48 (4.1)	0 (0.0)	28 (3.8)	84 (3.9)
Pakistani	34 (2.9)	12 (5.1)	17 (2.3)	63 (2.9)
Bangladeshi	19 (1.6)	2 (0.8)	13 (1.8)	34 (1.6)
Arab	14 (1.2)	1 (0.4)	7 (1.0)	22 (1.0)
Other Asian	18 (1.5)	2 (0.8)	12 (1.6)	32 (1.5)
Afro-Caribbean	19 (1.6)	3 (1.3)	5 (0.7)	27 (1.3)
African	64 (5.5)	10 (4.2)	30 (4.1)	104 (4.9)
Other	94 (8.1)	18 (7.6)	40 (5.4)	152 (7.1)
Religion				
Christian	396 (33.7)	98 (41.5)	270 (36.8)	764 (35.6)
Muslim	97 (8.3)	31 (13.1)	79 (10.8)	207 (9.7)
Jewish	4 (0.3)	0 (0.0)	13 (1.8)	17 (0.8)
Hindu	28 (2.4)	4 (1.7)	18 (2.5)	50 (2.3)
Buddhist	10 (0.9)	2 (0.8)	8 (1.1)	20 (0.9)
Sikh	12 (1.0)	1 (0.4)	8 (1.1)	21 (1.0)
Atheist	391 (33.3)	58 (24.6)	200 (27.2)	649 (30.3)
Agnostic	154 (13.1)	25 (10.6)	60 (8.2)	239 (11.1)
Other	82 (7.0)	17 (7.2)	78 (10.6)	177 (8.3)
Highest educational qualification				
None	26 (2.2)	4 (1.7)	20 (2.7)	50 (2.3)
O-level/GCSE	156 (13.3)	28 (11.9)	121 (16.5)	306 (14.2)
A-level	371 (31.6)	81 (34.3)	201 (27.4)	653 (30.5)
Technical qualification	51 (4.3)	10 (4.2)	46 (6.3)	107 (5.0)
Undergraduate	348 (29.6)	80 (33.9)	172 (23.4)	600 (28)
Diploma	50 (4.3)	11 (4.7)	42 (5.7)	103 (4.8)
Postgraduate	165 (14.1)	19 (8.1)	127 (17.3)	311 (14.5)
Other	7 (0.6)	3 (1.3)	5 (0.7)	15 (0.7)
Occupation				
Employed full time	565 (48.1)	113 (47.9)	386 (52.6)	1064 (49.6)
Employed part time	194 (16.5)	46 (19.5)	105 (14.3)	345 (16.0)
Unemployed looking for work	83 (7.1)	19 (8.1)	57 (7.8)	159 (7.4)
Unemployed not looking for work	35 (3.0)	8 (3.4)	44 (6.0)	87 (4.0)
Retired	1 (0.1)	0 (0.0)	2 (0.3)	3 (0.1)

	Neither PTSD nor CPTSD N (%)	PTSD N (%)	CPTSD N (%)	Total N (%)
Student	279 (23.7)	50 (21.2)	118 (16.1)	447 (20.8)
Disabled	17 (1.4)	0 (0.0)	22 (3.0)	39 (1.8)
Lifetime experience of mental health difficulties				
Previous	351 (30.0)	97 (41.1)	301 (41.0)	750 (35.0)
Current	137 (11.7)	42 (17.8)	185 (25.2)	364 (17.0)
Never	685 (58.3)	97 (41.1)	248 (33.8)	1030 (48.0)

3.8 Measures

3.8.1 International trauma exposure measure

Participants' exposure to traumatic events was assessed using the international trauma exposure measure (ITEM) (Hyland et al., 2021). The ITEM lists 21 experiences understood to fulfil the criteria required to qualify as a traumatic experience, as well as a 22nd option wherein the respondent is invited to detail any experiences they feel may be the cause of post-traumatic stress but were not specifically listed. The ITEM asks the respondent to identify whether the event occurred before age 12 (childhood), between 13 and 18 (adolescence), or after the age of 18 (adulthood). The respondent is then requested to identify the most significant traumatic event, and how many times the event occurred, as well as the exact time since the most recent occurrence of the event. The final question requires that the respondent identify the main emotion associated with the most significant event (fear, anger, disgust, sadness, shame, guilt, or no emotion).

The ITEM allows for identification of a number of traumatic events occurring during childhood, adolescence, and adulthood, as well as lifetime occurrence of trauma but does not ask that the respondent assign any level of severity to traumatic events, beyond identifying the most significant experience. The ITEM contains a number of broad categories of experience, as well as a free entry "other" response. It was therefore determined that the ITEM was suitable for use in

this study as a measure to ensure participants meet the inclusion criterion of having experienced at least one traumatic event in their lifetime. Full detail on the contents of the ITEM can be found in appendix 9.10.

3.8.2 Core beliefs questionnaire

The CBQ (Wong et al., 2017) trait subscale is a 17-item tool designed to measure the presence of negative core beliefs about the self. The client is instructed to respond to each statement on a scale of one (strongly disbelieve) to six (strongly believe). The CBQ has shown validity when used in samples with personality disorders (Reeves & Taylor, 2007), social anxiety (Andrea et al., 2018) and depression (Otani et al., 2018), with an initial validation Cronbach's alpha of 0.96 for the subscale used in this thesis.

The CBQ is scored on a 1-6 scale and totals are computed by adding together the scores of each item for an overall score indicating negative beliefs about the self. The minimum score is 17 and the maximum 102. In a validation study, it was found that respondents with diagnosis of social anxiety disorder scored an average of 57 (SD=21.65), and respondents without such a diagnosis scored an average of 25 (SD=10.27) (Wong et al., 2017). The CBQ can be found in appendix 9.12.

The CBQ is currently less widely used in research, and therefore has a lesser evidence base. It would have been possible to use the YSQ, which has a larger evidence base, and is more widely used in research to measure NCBs. However, the research base for the YSQ factor structure is conflicting, with studies reporting the presence of between 14 and 18 schemas and between three and five domains (Alfasfos, 2009; Lee et al., 2015; Sakulsriprasert et al., 2016; Saritaş, & Gençö,

2011; Soygüt et al., 2009; Young et al., 2003). This represents an unacceptable level of uncertainty as to what is really being measured. Additionally, even short versions of the YSQ contain 90 items (Onen, & Günes, 2021), which would have added to the already high participant burden and may have affected the ability of the participant to complete the remainder of the survey. The CBQ was therefore identified as an acceptable alternative, given that it contains only 17 items and reports a consistent unidimensional factor structure.

3.8.3 International trauma questionnaire

The International Trauma Interview (ITQ) (Cloitre et al., 2018) is an 18-item self-report measure which uses a 5-point Likert scale to assess PTSD and DSO symptoms with the view to measure criteria for PTSD and CPTSD. The ITQ was designed to be administered in clinical settings where it is desirable for client burden to be minimised. To this end, the ITQ follows ICD-11 guidelines in terms of simplicity, ease of use in both clinical and research settings, and maximisation of international applicability (Cloitre et al., 2018). The ITQ has been examined in a number of contexts and has shown Cronbach's Alpha scores of 0.87 for the PTSD subscale and 0.90 for the DSO subscale (Camden, et al, 2023).

The first six items on the ITQ relate to PTSD symptom clusters, and the client is requested to answer how much each symptom has bothered them over the last month from "Not at all" to "Extremely". The client is then asked how much the PTSD symptoms affect their social and occupational functioning. The subsequent six items on the ITQ measure DSO symptomology along the same Likert scale used for the PTSD symptoms, and then the same questions about the impact on their social and occupational functioning are asked. A score of ≥2 for any symptom item indicates an endorsement of the symptom cluster represented by that item. A

diagnosis of PTSD is applied if a client endorses PTSD symptomology but does not meet DSO symptom threshold. CPTSD is diagnosed if a client endorses both PTSD and DSO symptoms. If a client does not score ≥2 on at least one item in each symptom, the symptom is considered absent, and the participant does not meet diagnostic criteria. The ITQ can be found in appendix 9.11.

The ITQ was chosen for use in this research due to its status as a validated assessment tool for PTSD and CPTSD. The ITQ has been shown to accurately diagnose PTSD and CPTSD in a variety of populations (Cyr et al., 2022; Haselgruber et al., 2020; Murphy et al., 2020; Vang et al., 2021) so the data resulting from its use in research can be relied upon. The ITQ is a self-report measure and so carried with it inherent issues, such as the potential for participants to misunderstand items, or answer inaccurately. It was determined that the ITQ was the most suitable method of assessing PTSD and CPTSD symptoms in the context of collecting data from participants via online survey.

3.9 Procedure

3.9.1 Administration schedule

Following the recruitment procedure (detailed in 3.7.1), participants were presented with 11 self-report questionnaires in total. The demographics questionnaires, ITEM, ITQ and CBQ were presented first, second, fourth, and eleventh, respectively. The order of the measures was allocated randomly, with the exception of the ITEM, since an affirmative response to at least one traumatic event was required for participation in the study. Any participant responding that they had never experienced any traumatic event was thanked for their time and debriefed without the opportunity to complete the remainder of the questionnaires. There was a minor concern that participants completing all questionnaires may be fatigued by the

final questionnaire and not answer questions to the best of their ability. This was managed by allowing unlimited time for the completion of the questionnaires, participants could minimize the survey and return as long as they didn't close the browser. The smallest possible number of questionnaires were administered, to minimize the number of questions that each participant had to respond to as far as possible. Participants were also instructed to complete the questionnaires to the best of their ability, answering as honestly as possible, and the importance of this was explained in the participant information sheet and consent form.

After participants had completed the online survey, they were debriefed, reminded of their right to withdraw their data, and thanked for their participation. Participants were also encouraged at this time to contact the researchers if they had any questions about any part of the survey. After data collection was complete, the data were available to download and analyse. Analysis was conducted using IBM Statistical Package for the Social Sciences (SPSS) (version 26) by the analysis detailed below.

No identifiable participant data were being collected, and participants were distinguished by an ID number only. Once data were collected between the 25th of May and the 9th of June 2023, TGM provided a password protected link through which the research team was able to download the data in SPSS and Microsoft Excel format.

3.9.2 Data analysis

3.9.2.1 Descriptive statistics

Age, gender, religion, education level, experience of mental health difficulties, and ethnicity distribution of the sample were gathered. The outcome of

the ITQ was analysed to show the prevalence of those with no diagnosis, PTSD, and CPTSD endorsement. Prevalence of interpersonal vs non-interpersonal traumas and mean number of traumas were also calculated, as well as mean scores on each CBQ item for subclinical, PTSD endorsement, and CPTSD endorsement subgroups. Tables with the full data described here can be found in chapter four, Table 4.1 and table 4.2.

3.9.2.2 Reliability of CBQ to assess NCBs

Cronbach's Alpha (α) is the mainstream standard for internal reliability (McNeish, 2018), and was used in this analysis to assess internal reliability. However, α does demand some very stringent assumptions (normally distributed data, equal groups etc.) and may yield relatively conservative estimates of correlation (Revelle, & Zinbarg, 2009). A suitable alternative may have been the Omega coefficient (Kalkbrenner, 2023). However, artificially inflated correlation levels can be returned if the Omega coefficient is applied to a multidimensional measure (Bell, Chalmers, and Flora, 2023; Green & Yang, 2015). In order to confirm which version of the Omega coefficient should be used, a full analysis of the latent structure of the CBQ would be needed (Bell et al., 2023; Cortina et al., 2020; Green & Yang 2015; McNeish, 2018), which is beyond the scope of the current study. α was therefore identified as the most appropriate measure of internal reliability. Table 3.2 details acceptability values and interpretations (Bland, & Altman, 1997; Tavakol, & Dennick, 2011). Some argue that a result of $\alpha \geq 0.90$ suggests that some items on the scale are redundant, and should be revised (Streiner, 2003; Tavakol, & Dennick, 2011). However, since the purpose of the CBQ subscale used in this study is to measure only one aspect of core beliefs (that is, trait beliefs about the self) such a

homogenous result is not concerning in the way the same result would be for a more heterogeneous latent concept.

Table 3.2. α thresholds (Bland, & Altman, 1997; Tavakol, & Dennick, 2011)

Internal reliability	α
Poor	≤0.69
Acceptable	0.70-0.89
Very high	≥0.90

3.9.2.3 Correlation between PTSD/CPTSD symptomology and NCBs

Participants' ITQ scores were calculated following the scoring guidelines detailed in 3.8.3. Coding in SPSS was as follows: 1. not meeting symptom requirements for ICD-11 PTSD or CPTSD, 2. PTSD symptom requirements are met, and 3. CPTSD symptom requirements are met. Scoring guidelines detailed in 3.8.1 were followed for each participant to give an overall NCB score.

Tests for the assumptions of ANOVA were run; Levene's test of homogeneity of variances (Glass, 1966; Mishra et al., 2019) and Shapiro-Wilk (S-W) test of normality (Field, 2018; Razali, & Wah, 2011). Both assumptions were violated egregiously, so ANOVA could not be used to analyse this dataset, so the K-W test was identified as a suitable nonparametric test (Corder, & Foreman, 2014; McKight, & Najab, 2010; Ostertagova et al., 2014). Assumptions of the K-W test were met; observations are independent, dependent variable is ordinal., and sample size is large enough.

3.9.2.4 Differences in NCBs between symptom profiles

Two further analyses were conducted to examine more closely the differences between the endorsement of NCBs held by participants meeting thresholds for each subgroup. The above analysis in 3.9.2.3 determined that a difference between the groups does exist, this analysis looks at the direction and

nature of the differences between groups. An independent samples t-test was used here, as the groups were comprised of non-matched participants and categorical data (Nevill et al., 2002; Savalei, & Rhemtulla, 2013).

Instead of the standard reporting of the raw mean difference between each variable in the independent t-test, the standardised Cohen's d statistic was reported. This choice was made due to the ease of comparison of these results with results from other published works (Cahan, & Gamliel, 2011; Diener, 2010), and the unitless design allows for interpretation of the effect size by readers who may not be expertly familiar with the assessment tools used in this study and it may therefore not be clear to them whether the raw mean differences are large or small but Cohen's d can easily be interpreted with threshold guidelines (Table 3.3) (Andrade, 2020; Cohen, 1988;). Cohen's d is a standardised measure of difference for assessing mean differences between variables (Cohen, 1988; Cohen, 1992). More recent analyses based on quantitative data analysis in individual differences research have suggested guideline thresholds for this statistic to be 0.10 (small), 0.20 (medium), and 0.30 (large) (Gignac & Szodorai, 2016).

Table 3.3 Cohen's d threshold interpretation (Gignac &Szodorai, 2016)

Cohen's d	Interpretation
0.10	Small
0.20	Medium
0.30	Large

3.9.2.5 Individual CBQ items correlated with individual ITQ items

Spearman's rank correlation was used to measure correlation between scores on individual CBQ and ITQ items, as both variables are categorical, and Spearman is designed to work with such data (Croux, & Dehon, 2010). Thresholds

applied for effect size interpretation are detailed in Table 3.4. These values are taken from Dancey and Reidy, (2007). And are commonly used in psychological sciences (Akoglu 2018). The CBQ items of ‘I am a failure’ and ‘I am not worthwhile’ were removed from this analysis due to the conceptual similarity between these beliefs and the DSO symptom of negative self-concept.

Table 3.4. Spearman's rank coefficient thresholds (Dancey and Reidy, 2007).

3.10 Summary

This chapter detailed the process of collecting and analysing data from an online survey with the intention of using this data to contribute to a cognitive model of the differences between PTSD and CPTSD. The next chapter details the results of these analyses.

4 Study two: online survey results

4.1 Introduction

4.1.1 Summary

Chapter four of this thesis describes the results from the online study of negative core beliefs (NCBs) and post-traumatic stress disorder (PTSD) and complex PTSD (CPTSD) symptoms in a trauma-exposed sample (n=2,144). Method of dealing with missing data is detailed, followed by the process of synthesising data. Data collected on the types and number of traumatic experiences is presented and described, including the findings that interpersonal trauma was more common that non-interpersonal trauma, and types of trauma exposure as a risk factor for symptom endorsement. Findings relating to the core beliefs questionnaire (CBQ) to assess NCBs in the sample are presented and followed by the correlational findings between NCBs and different symptom profiles. It is shown that PTSD symptom profiles endorse fewer NCBs than participants with CPTSD endorsement. Results are interpreted in narrative form and strengths/limitations of the results are described.

4.1.2 Missing data

No incomplete surveys were accepted by the survey software, so no cases were eliminated for missing or incomplete data. Participants were able to skip individual items that they found personally upsetting or disturbing, but the survey software rejected any cases with greater than 10% missing data. There are of course ethical issues associated with allowing participants to complete questionnaires and then discarding their data. Requiring participants to respond to potentially distressing questions, only to not use their data in the research project, means that the time spent by the participant and the potential distress experienced did not produce any useable

data. This issue was mitigated as far as reasonably possible by informing participants that they should try to answer as many questions as possible, and that they would not be reimbursed if they did not complete the questionnaire. This was communicated in the participant information sheet, in highlighted text to draw attention to this statement. Contact emails for researchers and academic staff were provided for participants to contact if they experienced distress that they wished to discuss with someone involved in the study, and the consent form remined participants of their right to stop answering questions at any time.

An observational inspection of the dataset also revealed incomplete answers to the item “Any other event not listed (please specify)” on the international trauma exposure measure (ITEM) scale by four participants. These participants ticked the answer that they had experienced a traumatic event not listed in the ITEM but did not give detail on what these experiences were. These cases were not removed, as this missing data would not impact the analytical design planned for this study.

4.2 Results

4.2.1 Synthesis of international trauma questionnaire data

Each participants’ diagnostic outcome from the international trauma questionnaire (ITQ) was calculated from raw scores in Statistical Package for the Social Sciences (SPSS) (IBM Corp., 2019). Programming used to categorise participants by diagnostic outcome can be found in appendix 9.14. Since an inclusion criterion for participation in this study was lifetime exposure to at least one traumatic event, it was not necessary to check that participants met this diagnostic criterion, so diagnostic subgroup membership was based on ITQ outcome alone.

4.2.2 Participant experience of trauma

To be eligible all participants had experience of at least one traumatic event in their lifetime. Most frequently, trauma was experienced during adolescence, which is to be expected given the limited age range of the sample, and the vast majority of participants experienced multiple traumas. Death or illness of a close friend of family member were the most common index events, usually occurring one to five years ago, and sadness was the most common emotion associated with the event. Full data on participant experiences of trauma can be found in Table 4.1.

Appendix 9.15 details the events included on the ITEM, and whether each event is regarded as interpersonal or non-interpersonal. Broadly, an event is interpersonal if it involves the participant as a victim of another person or as a perpetrator against a person (Jowett et al., 2020; Sandberg et al., 2010). The most common type of traumatic experience across all categories was interpersonal (m=10.3, SD=7.6), the most common age range to experience a traumatic event was adolescence (m=4.4, SD=3.7), and participants endorsing CPTSD symptoms had the highest mean score on the CBQ (m=80.1, SD=22.9). For more details on these findings and mean scores for each ITQ subgroup on overall NCB endorsement, see table 4.2.

Table 4.1. Participant experiences of trauma

	Neither PTSD nor CPTSD N (%)	PTSD N (%)	CPTSD N (%)	Total N (%)
Lifetime trauma experience				
Overall trauma	1,174 (100.0)	236 (100.0)	734 (100.0)	2,144 (100)
Interpersonal	1,123 (95.6)	230 (97.4)	723 (98.5)	2,078 (96.9)
Non-interpersonal	869 (74.0)	204 (86.4)	614 (83.6)	1,67 (78.6)
Polytraumatisation	1,093 (93.0)	232 (98.3)	712 (97.0)	2,037 (95.0)
Experience of trauma during each stage of life				
Childhood	769 (65.5)	184 (77.9)	539 (73.4)	1,492 (69.5)
Adolescence	1,031 (87.8)	216 (91.5)	663 (90.3)	1,920 (89.0)
Adulthood	860 (73.2)	200 (84.7)	611 (83.2)	1,671 (77.9)
Nature of most significant traumatic event				
Illness	19 (1.6)	2 (0.8)	13 (1.8)	34 (1.6)
Close person died	138 (11.8)	28 (11.9)	112 (15.3)	278 (13.0)
Close person illness	191 (16.3)	37 (15.7)	73 (9.9)	301 (14.0)
Weapon life threat	32 (2.7)	6 (2.5)	29 (4.0)	67 (3.1)
Parent assault	24 (2.0)	8 (3.4)	42 (5.7)	74 (3.5)
Other person assault	39 (3.3)	6 (2.5)	34 (4.6)	79 (3.7)
Parent sexual assault	17 (1.4)	8 (3.4)	37 (5.0)	62 (2.9)
Other sexual assault	98 (8.3)	20 (8.5)	77 (10.5)	195 (9.1)
Sexual harassment	49 (4.2)	7 (3.0)	23 (3.1)	79 (3.7)
War or combat	7 (0.6)	1 (0.4)	2 (0.3)	10 (0.5)
Torture	4 (0.3)	1 (0.4)	1 (0.1)	6 (0.3)
Caused suffering	1 (0.1)	3 (1.3)	5 (0.7)	9 (0.4)
Witnessed suffering	80 (6.8)	9 (3.8)	28 (3.8)	117 (5.5)
Accident	31 (2.6)	8 (3.4)	9 (1.2)	48 (2.2)
Natural disaster	14 (1.2)	4 (1.7)	8 (1.1)	26 (1.2)
Non-natural disaster	12 (1.0)	1 (0.4)	7 (1.0)	20 (0.9)
Stalked	20 (1.7)	9 (3.8)	16 (2.2)	45 (2.1)
Bullied	104 (8.9)	22 (9.3)	49 (6.7)	175 (8.2)
Humiliation	80 (6.8)	10 (4.2)	39 (5.3)	129 (6.0)
Unloved	122 (10.4)	20 (8.5)	75 (10.2)	217 (10.1)
Neglected	54 (4.6)	16 (6.8)	42 (5.7)	112 (5.2)
Other	38 (3.2)	10 (4.2)	13 (1.8)	61 (2.8)
Time since most significant traumatic event				
<1 month	34 (2.9)	13 (5.5)	55 (7.5)	102 (4.8)
1-6 months	91 (7.8)	25 (10.6)	84 (11.4)	200 (9.3)
6-12 months	98 (8.3)	28 (11.9)	130 (17.7)	256 (11.9)
1-5 years	427 (36.4)	96 (40.7)	234 (31.9)	757 (35.3)
6-10 years	245 (20.9)	41 (17.4)	145 (19.8)	431 (20.1)
>10 years	279 (23.8)	33 (14.0)	86 (1.7)	398 (18.6)

	Neither PTSD nor CPTSD N (%)	PTSD N (%)	CPTSD N (%)	Total N (%)
Main emotion associated with event				
Fear	234 (19.9)	59 (25.0)	165 (22.5)	458 (21.4)
Anger	142 (12.1)	31 (13.1)	101 (13.8)	274 (12.8)
Disgust	75 (6.4)	14 (5.9)	65 (8.9)	154 (7.2)
Sadness	548 (46.7)	95 (40.3)	256 (34.9)	899 (41.9)
Shame	78 (6.6)	11 (4.7)	69 (9.4)	158 (7.4)
Guilt	35 (3.0)	12 (5.1)	43 (5.9)	90 (4.2)
No emotion	62 (5.3)	14 (5.9)	35 (4.8)	111 (5.2)

Table 4.2. Mean score and standard deviation for overall NCB endorsement and number of lifetime traumatic events experienced compared to ITQ symptom endorsement

	Neither m(SD)	PTSD m(SD)	CPTSD m(SD)	Total m(SD)
CBQ total score	55.6 (24.7)	58.4 (23.3)	80.1 (22.9)	64.3 (26.5)
Age	24.2 (3.8)	23.8 (3.8)	24.5 (3.7)	
ITEM				
Lifetime traumatic experiences	7.7 (5.5)	10.9 (7.2)	14.2 (8.7)	10.3 (7.6)
Lifetime interpersonal traumatic experiences	5.8 (4.4)	8.2 (5.7)	10.9 (6.8)	7.8 (5.9)
Lifetime non-interpersonal traumatic experiences	1.6 (1.5)	2.3 (1.9)	2.9 (2.6)	2.1 (2.1)
Childhood traumatic experiences	1.9 (2.2)	2.6 (2.8)	3.5 (3.9)	2.5 (3.1)
Adolescent traumatic experiences	3.4 (2.8)	4.7 (3.3)	5.9 (4.5)	4.4 (3.7)
Adulthood traumatic experience	2.4 (2.4)	3.5(3.3)	4.7 (4.4)	3.3 (3.5)

4.2.3 Reliability of core beliefs questionnaire to assess negative core beliefs in post-traumatic stress disorder and complex post-traumatic stress disorder

Internal reliability of the CBQ in participants endorsing PTSD and CPTSD criteria was assessed using Cronbach's alpha (α) in SPSS. Very high internal reliability (α=0.95) was found in the PTSD subgroup, and very high internal reliability (α=0.96) in the CPTSD subgroup. This is strikingly similar to the findings of Wong et al (2017) whose α analysis revealed an α of 0.96 for very strong internal reliability. The first research question for this study can therefore be answered in the affirmative; the CBQ is a reliable measure of core beliefs in individuals endorsing PTSD/CPTSD symptomology.

4.2.4 Difference in negative core belief endorsement between all symptom profiles

The Kruskal-Wallis (K-W) test revealed a statistically significant difference between levels of PTSD/CPTSD/neither symptom endorsement and total CBQ score (H [2] =392.9, p<.001). The K-W test was also statistically significant between levels of ITQ symptom endorsement and individual CBQ items. Full K-W outcome data can be found in Table 4.3. This means that it can be said with confidence that PTSD presents with different levels of NCBs than CPTSD.

The findings of this analysis show that there is a statistically significant difference between the three subgroups. Participants in the CPTSD subgroup rated their belief in the CBQ items much more highly than those in the PTSD or neither subgroups. There was less of a difference between the neither and PTSD subgroups, but there remains a small increase in endorsement of CBQ items by those in the PTSD subgroup. This finding is true for the total CBQ score, as well as each individual item. Further analysis was conducted to determine the exact nature of the

differences in NCB endorsement between PTSD and CPTSD groups (see section 0 for this analysis).

Table 4.3. Full K-W outcome data

Group	H	Mean rank	*p*
CBQ total			
Neither	392.9	871.9	<.001
PTSD	392.9	931.9	<.001
CPTSD	392.9	1,438.9	<.001
I am unlikeable			
Neither	294.2	899.3	<.001
PTSD	294.2	967.7	<.001
CPTSD	294.2	1,383.6	<.001
I am foolish			
Neither	268.3	910.0	<.001
PTSD	268.3	955.9	<.001
CPTSD	268.3	1,283.6	<.001
I am inadequate			
Neither	261.3	911.2	<.001
PTSD	261.3	963.3	<.001
CPTSD	261.3	1,365.9	<.001
I am inferior			
Neither	275.7	908.7	<.001
PTSD	275.7	948.8	<.001
CPTSD	275.7	1,374.4	<.001
I am uninteresting			
Neither	175.3	947.0	<.001
PTSD	175.3	945.3	<.001
CPTSD	175.3	1,313.9	<.001
I am boring			
Neither	162.6	947.13	<.001
PTSD	162.6	947.2	<.001
CPTSD	162.6	1,304.8	<.001
I am dumb/stupid			
Neither	307.5	895/9	<.001
PTSD	307.5	965.5	<.001
CPTSD	307.5	1,389.7	<.001
I am a weak person			
Neither	267.5	906.8	<.001
PTSD	267.5	975.8	<.001
CPTSD	267.5	1,368.9	<.001
I am incompetent			
Neither	320.1	887.9	<.001
PTSD	320.1	988.5	<.001
CPTSD	320.1	1,396.3	<.001
I am unacceptable			
Neither	392.2	881.0	<.001
PTSD	392.2	907.5	<.001

Group	H	Mean rank	*p*
CPTSD	392.2	1,432.0	<.001
I am not a worthwhile person			
Neither	302.5	900.4	<.001
PTSD	302.5	945.7	<.001
CPTSD	302.5	1,388.7	<.001
I am a weird person			
Neither	113.4	962.4	<.001
PTSD	113.4	1,022.4	<.001
CPTSD	113.5	1,265.0	<.001
I am odd/peculiar			
Neither	130.1	954.0	<.001
PTSD	130.1	1,023.0	<.001
CPTSD	130.1	1,278.2	<.001
I am unimportant			
Neither	276.8	910.2	<.001
PTSD	276.8	938.3	<.001
CPTSD	276.8	1,375.3	<.001
I am physically unattractive			
Neither	151.7	957.0	<.001
PTSD	151.7	947.7	<.001
CPTSD	151.7	1,297.2	<.001
I am inept			
Neither	355.2	885.5	<.001
PTSD	355.2	941.5	<.001
CPTSD	355.2	1,413.9	<.001
I am undesirable			
Neither	214.1	924.0	<.001
PTSD	214.1	986.3	<.001
CPTSD	214.1	1,338.1	<.001
I am unlovable			
Neither	328.5	892.2	<.001
PTSD	328.5	946.4	<.001
CPTSD	328.5	1,401.7	<.001
I am a failure			
Neither	315.6	896.7	<.001
PTSD	315.6	942.7	<.001
CPTSD	315.6	1,395.7	<.001
I am defective			
Neither	301.7	891.7	<.001
PTSD	301.7	1,000.1	<.001
CPTSD	301.7	1,385.5	<.001

4.2.5 Differences in negative core belief endorsement between paired symptom profiles

A series of independent samples t-tests were run to identify the relationships between subgroup endorsement and scores on CBQ items. Levene's test of equality of variances was significant in seven cases for the PTSD/CPTSD subgroup analysis (I am not a worthwhile person, I am a weird person, I am odd/peculiar, I am physically unattractive, I am undesirable, I am a failure, I am defective), and one case in the PTSD/neither analysis (I am unacceptable). Four tables are presented below: Table 4.4 shows the independent samples t test output for items indicating equality of variances in the PTSD/CPTSD analysis, and Table 4.5 shows the same output for items that did not indicate equality of variances in the PTSD/CPTSD analysis. Table 4.6 and

Table *4.7* show the same for the PTSD/neither analysis. Post-hoc analysis using Bonferroni transformation was performed. Bonferroni is a relatively conservative method of adjusting alpha levels when multiple statistical tests are being performed concurrently (Cabin, & Mitchell, 2000). This is necessary because multiple simultaneous statistical tests increases the risk of a type I error (that is, concluding that the result of the analysis is significant when in fact, it is not), and the Bonferroni transformation indicates what p value should be achieved in order for a result to be considered statistically significant (Armstrong, 2014). A new alpha level was obtained by dividing .05 by 17 for each of the items on the CBQ, to give .0029. This means that in order to be considered significant, t tests in this analysis must reach a p value of <.0025. Overall, there was a statistically significant difference between the PTSD and CPTSD groups on the mean scores for CBQ items. Participants endorsing CPTSD symptoms endorsed higher levels of belief in CBQ

items than those in the PTSD symptom group. None of the t test analyses were significant in the PTSD/neither subgroup analysis.

A series of t tests (Table 4.4 through to Table 4.9) were run to compare pairs of subgroups to each other. First, the PTSD and CPTSD subgroups were analysed (Table 4.4 and Table 4.5). It was revealed that participants in the PTSD subgroup scored significantly ($p<.001$) lower on each individual CBQ item and the CBQ as a whole than participants in the CPTSD subgroup. Cohen's d measure of effect size is also ≥ 0.4 for each analysis, indicating that the effect size is large and subgroup membership between PTSD and CPTSD has a significant impact on the level of NCBs endorsed.

Secondly, PTSD and non-symptom endorsing subgroups were compared (Table 4.6 and Table 4.7). No significant difference ($p>.05$) was found in NCB endorsement between PTSD and non-symptomatic subgroups, and Cohen's d effect size was ≤ 0.19 for all analyses. This means that group membership in this case had no significant impact on the level of NCBs endorsed, and any effect sizes were small to nil.

Finally, t tests between CPTSD and non-symptom endorsing subgroups were run (Table 4.8 and Table 4.9). The greatest difference between subgroup NCB endorsement was observed in this analysis. All t tests were statistically significant and produced Cohen's d effect sizes of ≥ 0.5. This again indicates that subgroup membership has a significant impact on the level of NCBs endorsed.

Table 4.4. NCB endorsement difference between PTSD and CPTSD independent t test output where equal variances is assumed

CBQ item	Symptom subgroup	Mean	SD	t (df)	Cohen's d
Unlikeable	PTSD	2.89	1.576	**9.81** (963)	0.74
	CPTSD	4.03	1.528	**9.81** (963)	0.74
Foolish	PTSD	2.87	1.527	**9.71** (963)	0.77
	CPTSD	3.96	1.479	**9.71** (963)	0.77
Inadequate	PTSD	2.87	1.520	**9.51** (963)	0.73
	CPTSD	3.97	1.521	**9.51** (963)	0.73
Inferior	PTSD	2.79	1.487	**10.10** (963)	0.75
	CPTSD	3.94	1.521	**10.10** (963)	0.75
Uninteresting	PTSD	2.92	1.525	**8.65** (963)	0.65
	CPTSD	3.93	1.546	**8.65** (963)	0.65
Boring	PTSD	3.08	1.645	**7.57** (963)	0.57
	CPTSD	3.99	1.591	**7.57** (963)	0.57
Dumb/stupid	PTSD	2.69	1.590	**9.88** (963)	0.74
	CPTSD	3.85	1.555	**9.88** (963)	0.74
Weak person	PTSD	2.89	1.567	**9.31** (963)	0.71
	CPTSD	3.98	1.546	**9.31** (963)	0.71
Incompetent	PTSD	2.77	1.484	**9.73** (963)	0.74
	CPTSD	3.89	1.527	**9.73** (963)	0.74
Unacceptable	PTSD	2.49	1.554	**12.13** (963)	0.92
	CPTSD	3.90	1.523	**12.13** (963)	0.92
Unimportant	PTSD	2.87	1.596	**10.49** (963)	0.80
	CPTSD	4.09	1.525	**10.49** (963)	0.80
Inept	PTSD	2.64	1.485	**11.15** (963)	0.85
	CPTSD	3.84	1.406	**11.15** (963)	0.85
Unlovable	PTSD	2.77	1.521	**11.01** (963)	0.83
	CPTSD	4.04	1.533	**11.01** (963)	0.83
Total CBQ score	PTSD	58.44	23.387	**12.49** (963)	0.93
	CPTSD	80.17	22.954	**12.49** (963)	0.93

Bold=significant to the <.001 level

Table 4.5. NCB endorsement difference between PTSD and CPTSD independent t test output where equal variances is not assumed

CBQ item	Symptom subgroup	Mean	SD	t(df)	Cohen's D
Not worthwhile	PTSD	2.78	1.619	**10.40** (375.94)	0.79
	CPTSD	4.01	1.542	**10.40** (375.94)	0.79
Weird	PTSD	3.59	1.678	**5.68** (375.94)	0.43
	CPTSD	4.25	1.510	**5.68** (375.94)	0.43
Odd/peculiar	PTSD	3.45	1.625	**5.93** (375.94)	0.45
	CPTSD	4.13	1.498	**5.93** (375.94)	0.45
Unattractive	PTSD	3.16	1.692	**8.13** (375.94)	0.58
	CPTSD	4.14	1.585	**8.13** (375.94)	0.58
Undesirable	PTSD	3.08	1.636	**8.43** (375.94)	0.64
	CPTSD	4.07	1.516	**8.43** (375.94)	0.64
Failure	PTSD	2.90	1.569	**11.31** (375.94)	0.86
	CPTSD	4.18	1.467	**11.41** (375.94)	0.86
Defective	PTSD	2.94	1.563	**9.30** (375.94)	0.70
	CPTSD	3.98	1.472	**9.30** (375.94)	0.70

Bold=significant to the <.001 level

Table 4.6. NCB endorsement difference between PTSD and neither subgroups independent t test output where equal variances is assumed

CBQ item	Symptom subgroup	Mean	SD	t (df)	Cohen's D
Unlikeable	Neither	2.69	1.542	1.97 (1408)	0.14
	PTSD	2.91	1.583	1.97 (1408)	0.14
Foolish	Neither	2.73	1.510	1.49 (1408)	0.11
	PTSD	2.89	1.539	1.49 (1408)	0.11
Inadequate	Neither	2.72	1.542	1.71 (1408)	0.12
	PTSD	2.91	1.534	1.71 (1408)	0.12
Inferior	Neither	2.69	1.491	1.18 (1408)	0.08
	PTSD	2.81	1.496	1.18 (1408)	0.08
Uninteresting	Neither	2.93	1.594	0.01 (1408)	0.00
	PTSD	2.93	1.530	0.01 (1408)	0.00
Boring	Neither	2.99	1.639	0.73 (1408)	0.05
	PTSD	3.08	1.652	0.73 (1408)	0.05
Dumb/stupid	Neither	2.49	1.512	1.89 (1408)	0.14
	PTSD	2.70	1.584	1.89 (1408)	0.14
Weak person	Neither	2.70	1.566	1.71 (1408)	0.12
	PTSD	2.89	1.559	1.71 (1408)	0.12
Incompetent	Neither	2.53	1.468	2.39 (1408)	0.17
	PTSD	2.78	1.475	2.39 (1408)	0.17
Not worthwhile	Neither	2.65	1.541	1.31 (1408)	0.10
	PTSD	2.80	1.630	1.31 (1408)	0.10
Weird	Neither	3.41	1.662	1.93 (1408)	0.14

CBQ item	Symptom subgroup	Mean	SD	t (df)	Cohen's D
	PTSD	3.64	1.681	1.93 (1408)	0.14
Odd/peculiar	Neither	3.24	1.617	2.30 (1408)	0.17
	PTSD	3.51	1.636	2.30 (1408)	0.17
Unimportant	Neither	2.78	1.608	0.97 (1408)	0.07
	PTSD	2.89	1.598	0.97 (1408)	0.07
Unattractive	Neither	3.18	1.688	0.20 (1408)	0.01
	PTSD	3.20	1.703	0.20 (1408)	0.01
I am inept	Neither	2.48	1.403	1.72 (1408)	0.13
	PTSD	2.66	1.478	1.72 (1408)	0.13
Undesirable	Neither	2.90	1.646	1.86 (1408)	0.13
	PTSD	3.12	1.646	1.86 (1408)	0.13
Unlovable	Neither	2.63	1.554	1.43 (1408)	0.10
	PTSD	2.79	1.515	1.43 (1408)	0.10
Failure	Neither	2.77	1.649	1.45 (1408)	0.10
	PTSD	2.94	1.589	1.45 (1408)	0.10
Defective	Neither	2.64	1.549	2.81 (1408)	0.19
	PTSD	2.95	1.577	2.81 (1408)	0.19
Total CBQ score	Neither	55.57	24.737	1.91 (1408)	0.12
	PTSD	58.90	23.358	1.91 (1408)	0.12

Table 4.7. NCB endorsement difference between PTSD and neither subgroups independent t test output where equal variances is not assumed

CBQ item	Symptom subgroup	Mean	SD	t (df)	Cohen's D
Unacceptable	Neither	2.40	1.566	0.95 (518)	0.06
	PTSD	2.50	1.559	0.95 (518)	0.06

Table 4.8 NCB endorsement difference between CPTSD and neither subgroups independent t test output where equal variances are assumed

CBQ item	Symptom subgroup	Mean	SD	t (df)	Cohen's D
Inferior	Neither	2.69	1.491	**-17.722** (1,906)	0.83
	CPTSD	3.94	1.521	**-17.722** (1,906)	0.83
Dumb/stupid	Neither	2.49	1.512	**-18.908** (1,906)	0.89
	CPTSD	3.85	1.555	**-18.908** (1,906)	0.89
Incompetent	Neither	2.53	1.468	**-19.427** (1,906)	0.91
	CPTSD	3.89	1.527	**-19.427** (1,906)	0.91
Unacceptable	Neither	2.40	1.419	**-21.758** (1,906)	0.95
	CPTSD	3.90	1.523	**-21.758** (1,906)	0.95

CBQ item	Symptom subgroup	Mean	SD	t (df)	Cohen's D

Bold=significant to the <.001 level

Table 4.9 NCB endorsement difference between CPTSD and neither subgroups independent t test output where equal variances is not assumed

CBQ item	Symptom subgroup	Mean	SD	t (df)	Cohen's D
Unlikeable	Neither	2.69	1.542	**-18.488** (1,906)	0.87
	CPTSD	4.03	1.528	**-18.488** (1,906)	0.87
Foolish	Neither	2.73	1.510	**-17.537** (1,906)	0.82
	CPTSD	3.96	1.479	**-17.537** (1,906)	0.82
Inadequate	Neither	2.72	1.542	**-17.271** (1,906)	0.81
	CPTSD	3.97	1.521	**-17.271** (1,906)	0.81
Uninteresting	Neither	2.93	1.594	**-13.588** (1,906)	0.64
	CPTSD	3.93	1.546	**-13.588** (1,906)	0.64
Boring	Neither	2.99	1.639	**-13.196** (1,906)	0.62
	CPTSD	3.99	1.591	**-13.196** (1,906)	0.62
Weak person	Neither	2.70	1.566	**-17.474** (1,906)	0.82
	CPTSD	3.98	1.546	**-17.474** (1,906)	0.82
Not worthwhile	Neither	2.65	1.541	**-18.702** (1,906)	0.88
	CPTSD	4.01	1.542	**-18.702** (1,906)	0.88
Weird	Neither	3.41	1.662	**-11.426** (1,906)	0.53
	CPTSD	4.25	1.510	**-11.426** (1,906)	0.53
Odd/peculiar	Neither	3.24	1.617	**-12.216** (1,906)	0.57
	CPTSD	4.13	1.498	**-12.216** (1,906)	0.57
Unimportant	Neither	2.78	1.608	**-17.856** (1,906)	0.83
	CPTSD	4.09	1.525	**-17.856** (1,906)	0.83
Unattractive	Neither	3.18	1.688	**-12.669** (1,906)	0.59
	CPTSD	4.14	1.585	**-12.669** (1,906)	0.59
I am inept	Neither	2.48	1.403	**-20.455** (1,906)	0.96
	CPTSD	3.84	1.406	**-20.455** (1,906)	0.96
Undesirable	Neither	2.90	1.646	**-15.796** (1,906)	0.73
	CPTSD	4.07	1.516	**-15.796** (1,906)	0.73
Unlovable	Neither	2.63	1.554	**-19.510** (1,906)	0.92
	CPTSD	4.04	1.533	**-19.510** (1,906)	0.92
Failure	Neither	2.77	1.649	**-19.427** (1,906)	0.89
	CPTSD	4.18	1.467	**-19.427** (1,906)	0.89
Defective	Neither	2.64	1.549	**-18.981** (1,906)	0.88
	CPTSD	3.98	1.472	**-18.981** (1,906)	0.88
Total CBQ score	Neither	55.57	24.737	**-22.725** (1,906)	0.98
	CPTSD	80.17	22.954	**-22.725** (1,906)	0.98

Bold=significant to the <.001 level

4.2.6 Core belief questionnaire items correlation with international trauma questionnaire items

Spearman's rank coefficient was run to measure correlation between scores on individual CBQ and ITQ items. All item correlations were significant the p=<.001 and ranged from weak to very strong correlation. Full list of values can be found in Table 4.10.

The symptom most significantly correlated with each CBQ item was either feelings of failure or feelings of worthlessness. These are the negative self-concept symptoms of CPTSD, so a high level of correlation is unsurprising. All items on the CBQ were significantly positively correlated with items on the ITQ. CBQ items tended to be more strongly correlated with DSO items than PTSD items. This indicated a higher level of endorsement of NCBs in participants with higher levels of DSO symptomology than those without. The finding that all CBQ items correlated most strongly with the negative self-concept symptom cluster was unexpected. Given the WHO definition of negative self-concept, it was anticipated that the CBQ items "I am a failure" and "I am worthless" would correlate most strongly with negative self-concept, but that other items may correlate most strongly with other symptom clusters. This finding may imply a conceptual overlap between negative self-concept and endorsement of NCBs.

These findings support an affirmative response to research question two for this study. Participants with CPTSD do score more highly on the CBQ than participants with PTSD or subclinical symptomology. Research question three for this study can be answered very generally. All NCBs are more highly endorsed by participants with CPTSD symptomology compared to participants with sub-clinical and PTSD symptomology.

Table 4.10. All significant and non-significant correlations between individual NCB and individual ITQ items

	Unlikeable	Foolish	Inadequate	Inferior	Uninteresting	Boring	Dumb/stupid	Weak	Incompetent	Unacceptable	Weird	Odd	Unimportant	Inept	Undesirable	Unlovable	Defective
Nightmares	.28[3]	.26[3]	.29[3]	.26[3]	.21[3]	.20[3]	.28[3]	.27[3]	.30[3]	.33[3]	.19[3]	.19[3]	.27[3]	.20[3]	.31[3]	.25[3]	.29[3]
Flashbacks	.29[3]	.28[3]	.30[3]	.28[3]	.23[3]	.21[3]	.28[3]	.28[3]	.30[3]	.32[3]	.22[3]	.22[3]	.30[3]	.22[3]	.31[3]	.26[3]	.31[3]
Internal avoidance	.30[3]	.29[3]	.30[3]	.29[3]	.26[3]	.23[3]	.29[3]	.29[3]	.31[3]	.32[3]	.21[3]	.24[3]	.32[3]	.23[3]	.33[3]	.29[3]	.31[3]
External avoidance	.28[3]	.27[3]	.29[3]	.26[3]	.22[3]	.21[3]	.25[3]	.26[3]	.29[3]	.29[3]	.22[3]	.24[3]	.27[3]	.21[3]	.30[3]	.27[3]	.30[3]
Hypervigilance	.25[3]	.24[3]	.26[3]	.24[3]	.21[3]	.18[3]	.24[3]	.24[3]	.26[3]	.29[3]	.21[3]	.23[3]	.24[3]	.19[3]	.26[3]	.23[3]	.27[3]
Startle	.29[3]	.26[3]	.29[3]	.29[3]	.22[3]	.23[3]	.30[3]	.30[3]	.31[3]	.33[3]	.19[3]	.22[3]	.28[3]	.18[3]	.32[3]	.23[3]	.28[3]
Hyperactivation	.40[3]	.38[3]	.39[3]	.40[3]	.35[3]	.31[3]	.38[3]	.40[2]	.40[2]	.42[2]	.34[3]	.34[3]	.40[2]	.35[3]	.40[3]	.38[3]	.42[2]
Hypoactivation	.44[2]	.43[2]	.44[2]	.41[2]	.38[3]	.34[3]	.41[2]	.41[2]	.43[2]	.47[2]	.37[3]	.38[3]	.46[2]	.36[3]	.45[3]	.43[2]	.47[2]
Failure	.54[2]	.51[2]	**.58[2]**	**.54[2]**	**.50[2]**	**.46[2]**	.51[2]	.53[2]	**.54[2]**	.57[2]	**.41[2]**	.41[2]	.59[2]	**.48[2]**	.55[2]	.52[2]	**.65[1]**
Worthlessness	**.55[2]**	**.52[2]**	**.58[2]**	**.54[2]**	.49[2]	.45[2]	**.53[2]**	**.54[2]**	**.54[2]**	**.59[2]**	.40[2]	**.42[2]**	**.60[1]**	**.48[2]**	**.56[2]**	**.54[2]**	.63[1]
Emotional distance	.48[2]	.44[2]	.47[2]	.43[2]	.43[2]	.40[2]	.42[2]	.44[2]	.45[2]	.47[2]	.40[3]	.38[3]	.48[2]	.39[3]	.46[2]	.44[2]	.48[2]
Emotional difficulty	.41[2]	.38[3]	.41[2]	.38[3]	.39[3]	.37[3]	.37[3]	.37[3]	.40[2]	.43[2]	.36[3]	.36[3]	.43[2]	.34[3]	.43[2]	.41[2]	.43[2]

All values are significant to <.001. **Bold**=most significant symptom correlation for each CBQ item

[1]Strong effect size

[2]Moderate effect size

[3]Weak effect size

4.3 Summary

4.3.1 Key findings

Chapters three and four of this thesis described the methodology and results of an online survey study that looked to investigate the relationship between a measure of CPTSD and NCBs. There are significant differences and large effect sizes between the NCBs endorsed by the PTSD and CPTSD subgroups, as well as the CPTSD and non-symptomatic subgroup. There was no significant difference and small to nil effect sizes between NCBs endorsed by PTSD and non-symptomatic subgroups. This study showed positive correlations between both NCBs and overall CPTSD symptomology, as well as between NCBs and individual CPTSD symptoms.

4.3.2 Strengths and limitations

However, this work was limited by the available tools to assess CPTSD. At present, the only English language measures of CPTSD are self-report questionnaires, the ITQ (Cloitre et al., 2018) and the ITQ- children and adolescent version (ITQ-CA) (Cloitre et al., 2018; Haselgruber et al., 2020). However, despite being commonly used in the health sciences (Theofanidis, & Fountouki, 2018), self-report questionnaires have significant flaws when applied to diagnosis or assessment of mental health conditions.

Self-report questionnaires have been known to yield unreliable results due to respondents misunderstanding items (Stone et al., 1999; Visted et al., 2017), purposeful over-reporting of positive affect (Myers, 2000), and the prevalence of missing data (Theofanidis & Fountouki, 2018). Despite these methodological issues, self-report measures remain a vital tool for quick and easy assessment of mental health issues, particularly in research contexts where large sample sizes are required and logistical restraints prevent the use of a clinician-administered interview (Levis

et al., 2019) and in clinical practice when efficient allocation of resources is paramount (Lakkis, & Mahmassani, 2015).

In the case of this study, the issue of missing data was dealt with by the survey software, which required responses to a minimum number of items, and discarded cases where participants withdrew from the study before completing all questionnaires. Participants were provided with instructions on how to complete the survey, and the surveys administered are validated measures, meaning that it has been previously shown that participants are reliably able to complete the surveys accurately and without misunderstanding survey items, and contact details for researchers were provided in case participants required clarification. The decision to use online survey methodology was also a pragmatic one. As discussed in 3.4.3, an in-person design would have ensured that participants completed all items without missing any and without misunderstanding, but this would have significantly increased the risk of social desirability bias. The logistical issues associated with an in-person design would also have been beyond the means of the study.

5 Study three: international trauma interview validation methodology

5.1 Introduction

5.1.1 Summary

This chapter details the research design, process of ethical approval, procedure, measures, and analyses employed during the validation of the international trauma interview (ITI) for diagnosis of post-traumatic stress disorder (PTSD) and complex PTSD (CPTSD). The background and rationale for this analysis can be found in chapter one, the results in chapter six, and the discussion in chapter seven. Also discussed in this chapter, the process of training the researcher in administration of the ITI and the characteristics of the sample recruited.

This study recruited 25 participants using a cross-sectional design, generating both qualitative and quantitative data through use of the ITI, international trauma questionnaire (ITQ), and a clinical utility survey. The participants were able to receive a letter detailing the outcomes of the interview and completed psychometrics relevant to their treatment. The data gathered were analysed and are reported in the next chapter.

5.1.2 Chapter aims

Due to issues of reliability and accuracy, diagnosis of mental health conditions cannot be achieved solely on the basis of self-report data (Levis et al., 2019). It is usually recommended that the self-report tool be used in conjunction with a complementary assessment method, typically a clinician administered interview (Sysko et al., 2015) but may also include sourcing information from family members (Stadnick et al., 2017), depending on the disorder of interest. In the case of CPTSD, speaking to family members may not uncover symptoms that are

experienced internally by the client. A clinician-administered interview is consequently required to gain sufficient information to make a diagnostic judgement.

The ITI (Roberts et al., 2019) is one such interview. The ITI intends to diagnose CPTSD and PTSD accurately and reliably (see section 5.10.3 for full detail on the structure and development of the ITI). However, the ITI has not yet been validated in the English language. Validation is the process of showing that an assessment tool can reliably measure the presence of the disorder and return accurate estimates of symptom severity. This is a vital step that must be taken before the ITI can be used in research or clinical practice, and the present chapter aims to describe the method of a study to validate the ITI.

5.2 Research design

5.2.1 Cross-sectional design

This study used a cross-sectional observational design to gather data for analysis. The single time point is a design commonly used when validating mental health assessment tools (Finizia et al., 2012), including previously published validations of the ITI (Bondjers et al., 2019) and the related ITQ (Hyland et al., 2017; Murphy et al., 2020). The cross-sectional design has the benefit of low burden on participants, the reduced low need for time and resource investment (Wang, & Cheng, 2020), and matches the precedent set by Bondjers et al (2019), and Gelezelyte et al (2022).

5.2.2 Hybrid design

Finally, a hybrid design utilising online and in person participation options was considered. A solely in person study design was impossible due to pandemic restrictions, and an online only design would have unfairly excluded some

participants. Despite the fact that the application for ethical approval for this study was submitted while online research was the only option, the application detailed circumstances under which in person recruitment would take place. Namely, in the event that restrictions were lifted, and it was deemed safe for in person research to recommence. This approach allowed for the recruitment of online participants in the first instance, with the commencement of in person recruitment in the future.

The combined use of online and in person recruitment meant that no group of potential participants were excluded due to technological illiteracy or lack of facilities, and participants unable to travel to a recruitment site to meet could still take part. Additionally, this hybrid approach reflects the direction in which clinical practice appears to be moving, with may clinicians expressing desire for both in person and online treatment to be an option to maximise accessibility for all clients (Gentry et al., 2021). This design therefore has the added benefit of lending realism to this study.

5.2.3 Rejected study design

5.2.3.1 Longitudinal design

A longitudinal study was briefly considered for this study. The benefits to a longitudinal approach would have been the possibility to administer the ITI to participants on multiple instances to allow for the analysis of test-retest reliability (Aldridge et al., 2017). However, a pilot of a test-retest design conducted in the process of data collection for this thesis yielded unacceptable levels of attrition. High levels of attrition are common in test-retest studies and can result in the retest sample being more homogenous than the initial sample, with serious negative implications for the reliability of the data (Polit, 2014). It was determined that the poorer quality

data did not warrant the additional participant and researcher burden associated with a repeated interview.

5.2.3.2 In person only design

Development of this study began in March 2020, and initial plans were set for data collection to take place only in person. This is the standard procedure for validation of clinician-administered measures (Rivest-Beauregard et al., 2022; Weathers et al., 2018), and the intention was for this study to follow common research practice. Until the emergence of the Coronavirus pandemic, online or telehealth for mental health difficulties was spoken about in research as a possibility for the future but generally viewed as not the ideal (Grondin et al., 2019) and research focussed on concerns for the quality of the therapeutic relationship and ethical issues related to online clinical practice (Glueckauf et al., 2018; Norcross, & Wampold, 2019). Consequently, this study was intended to take place in person only.

However, during the planning phase of this study, the pandemic began. When clinical practice was forced to take place online, the plan for this study had to change rapidly. It would no longer be feasible to conduct this research in-person due to lockdown restrictions and health and safety measures to prevent the spread of the infection. Many psychological interventions were converted to online only formats (Tomaino et al., 2022), and many were suspended in order to maintain quality (Jurcik et al., 2021). This study was delayed due to ethics application backlogs and uncertainty around the course that the pandemic would take. It became evident that it would not be possible to conduct this research only in person, so an alternative had to be developed.

5.2.3.3 Online only design

Given the impossibility for an in person only study, the alternative that many research projects moved for was online only. The quality of evidence gained from online research has been shown to be of similar quality and content to that gathered in person (Woodyatt et al., 2016), achieve a better rate of response than traditional methods (Comer, 2021) and clinicians have reported a desire for video-based telehealth to be a standard in the future of their practice (Gentry et al., 2021). This indicates a shift in the practice of mental health research and practice to include online participation as an option.

The option of online participation was therefore considered for this study, though it did introduce a novel set of ethical issues (Lieggho & Caragata, 2020). For example, identifying secure and safe video call software (Fouqueray et al., 2023), keeping participants safe while discussing potentially distressing experiences, and the potential exclusion of participants who did not have access to a secure location and internet connection to join a video call (Konken & Howlett, 2022). During the early months of the pandemic, nearly all other researchers and clinicians were experiencing the same issues, so there emerged a wealth of information via peer discussion, debate forums, and opinion publications (Jurcik et al., 2021).

Through discussion with recruitment sites, access was gained to ‘Attend Anywhere’. The National Health Service (NHS) approved this video call software, as it uses encryption to ensure security of information and uses password protection to prevent unauthorised parties from joining a call uninvited. In terms of keeping participants safe, advice was again taken from NHS clinicians at recruitment sites. All video calls were conducted during office hours, when it would be possible to

immediately report concerns to an NHS clinician, participants were reassured of the option to halt the interview with no penalty if they felt distressed, and the interviewer regularly checked in with the participant to ensure that they felt able to continue.

However, the issue remained of how to ensure equality of access to participate in this study. While carrying out interviews by video call would have expanded the potential sample to include those unable to leave their homes due to disability or childcare responsibilities (Afzalan & Muller, 2018), some concerns remained. Specifically, the accessibility of participation for those unable to conduct an hour-long confidential meeting at home, those without internet connection or computer access (Konken & Howlett, 2022), and those uncomfortable with online participation.

5.3 Research questions

The specific aim of this study was to investigate whether the ITI is a reliable and valid tool for assessing international classification of diseases version 11 (ICD-11) PTSD and CPTSD. The following research questions were considered in the design of this study:

1) What is the level of diagnostic concordance between the ITI and the ITQ?
2) Does the English version of the ITI produce internally reliable scores?
3) What are the views of clinicians regarding the clinical utility of the ITI?

5.4 Hypothesis

The testable hypothesis of this study was that the ITI would be a reliable and valid tool for assessing ICD-11 PTSD and CPTSD. The basis of this hypothesis was the previous successful English language validation of the ITQ (Hyland et al., 2017; Murphy et al., 2020) upon which the ITI is based. Previous validations of the

ITI in non-English languages have also found results that would support the above hypothesis (Bondjers et al., 2019; Gelezelyte et al., 2022).

5.5 Ethical considerations

5.5.1 Ethical approval

Ethical approval was sought and gained from the National Health Service (NHS) West of Scotland Research Ethics Service (WoSRES) through the online Integrated Research Application System portal. Approval was granted by the WoSRES on 23/03/2021 (ref: 21/WS/0027).

An amendment to extend the end date of the study from 31/03/2023 to 31/07/2023 was submitted to WoSRES on 08/12/2022 and approved on 15/12/2022. A further amendment to add a recruitment site was approved on 28/01/2023 by ENU ethics committee and 18/04/2023 by WoSRES.

5.5.2 Confidentiality and anonymity

Participants were informed during initial contact that their privacy would be respected at all times and were provided a privacy notice to read. No paper notes were taken, and no hard copies of data were retained for longer than the amount of time taken to digitize records. Participant names were not recorded alongside their responses; instead, a participant number was assigned to each individual and this number was used in analysis of data.

Confidentiality was broken in the case that participants mentioned intention or thoughts of harming themselves or others. In these cases, after ascertaining that the participant had protective factors and a safe plan for the remainder of the day, a member of the referring clinical team was informed and requested to follow up with the participant. These limits to confidentiality were discussed with the participants

before the beginning of the interview. This is in line with the British Psychological Society's Code of Human Research Ethics (Oates et al., 2021).

During the discussion chapter of this thesis, any names used to discuss individual participants are pseudonyms. This is also the case with any journal publications made as a result of data collected in this study.

5.5.3 Informed consent

Ensuring informed consent was of utmost importance in this study. Since participants were being recruited through a care provider, it was essential that they knew that they had no obligation to take part. To this end, a referring clinician already known to the participant contacted the individual to discuss the possibility of taking part in the study. This included discussing the content of the participant information sheet (PIS) (in appendix 9.15), privacy notice (in appendix 9.24), and consent form (in appendix 0), gaining verbal consent for the researcher to contact the client, and informing the potential participant that any issue discussed with the researcher would be confidential with the exception of the feedback letter detailing the outcome of the interview and questionnaires or if the participant disclosed any thoughts of harming themselves or others or other exceptions to BPS confidentiality guidelines. The individual's preferred contact details (either phone or email) were then forwarded to the researcher, who waited at least 48 hours to allow the participant to read the PIS and to consider their options in terms of participation. After the minimum 48-hour consideration time, the researcher contacted the individual via their preferred method of contact. Introductions were made and the opportunity was given for participants to ask questions about the study and participation.

If interest was expressed, the participant was asked if they would like to participate in the study. Further consideration time was allowed if this was necessary or desirable. Individuals who decided they did not wish to participate were thanked for their time, and the referring clinician was informed of the decision. Participants were informed that they were able to withdraw at any time with no repercussions.

5.5.4 Data storage and protection

Anonymised demographics, participant codes and interview/questionnaire data were stored and processed on a university laptop, on university drives. The laptop was password-protected, as was the folder the data sat within, and the laptop was kept in a locked drawer when not in use. This decision was made to be in line with university data management guidance. A data management plan was submitted to ENU governance and approved before ethical approval was submitted. These processes were designed to be in line with ENU research and data protection guidelines (Edinburgh Napier University, 2019) guidelines.

5.5.5 Safety considerations

All participants were in active mental health treatment at their time of participation and were therefore receiving psychological support. They were able to discuss their results from the study with their primary clinician to minimise misinterpretation of the research processes. If needed on the day of a participant being interviewed, further support from the clinical team at the referring clinic was available. In the provided debrief form (in appendix 9.26), participants were also instructed to contact their primary care provider (GP or therapist) if they felt increasingly distressed over the hours or days following their participation in the study. As participants were receiving treatment, clinicians were also encouraged to only refer participants they thought were emotionally stable enough to tolerate

participation. This did of course have implications for the generalisability of this study, given that the only participants referred were not acutely mentally unwell, the findings would not be representative of the most unwell population. However, this was an ethical concern that could not be waived in favour of realism or generalisability. It would have been ethically unacceptable to allow a person to participate if it was thought that they were too mentally unwell.

Re-traumatisation was a concern in this study, as part of the ITI did require discussion of traumatic experiences (Mailloux, 2014; Robins & Wilson 2015). In order to avoid this, the participant was informed that they could stop the interview at any time and continue at a later date or withdraw completely, and the researcher kept observational notes on the participants' emotional state, taking into account verbal tone, content of speech, and facial expressions in both online and in person interviews, and body language in in-person interviews. The interview was called to a halt if it was deemed that re-traumatisation was a risk. Research has shown that participation in a study such as this can even support recovery for people with CPTSD (Matheson, & Weightman, 2021), provided trauma-informed practice is employed to avoid re-traumatisation (Ames, & Loebach, 2023).

5.6 Study setting

In total, three sites were included in this study. The two original sites were the Rivers Centre in NHS Lothian and the Glasgow Psychological Trauma Service in NHS Greater Glasgow and Clyde (Anchor Centre). Both centres provide one-to-one therapeutic support and group psychoeducation courses for individuals seeking treatment for trauma-related mental difficulties in their respective cities.

Veterans First Point (V1P) was added to the list of recruitment sites in April 2023 to supplement recruitment from the above sites. V1P is an NHS-run support service for ex-military personnel in Lothian. V1P offers individual therapy, group support and psychoeducation groups, and peer support.

5.7 Standardisation and training

5.7.1 Administration training

The researcher was trained in the administration of the ITI by one of the developers of the interview (NR) over a two-day period. This training involved an explanation of the questions, examples of how the items should be administered, and an opportunity to score a sample interview. A scoring calibration exercise was carried out twice to ensure that items would not be artificially inflated or under-scored by the researcher.

The importance of ensuring trauma-relatedness of each symptom was stressed during this training. Many people may meet one or two criteria for PTSD or CPTSD, but it is important to ensure that the symptoms being described were caused or worsened by a traumatic experience for an accurate diagnosis to be made.

5.7.2 Interview supervision

A random sample of three interviews were recorded, transcribed, and sent to NR for secondary scoring. NR left comments on the transcription with recommendations for interview technique and how each item should be scored. NR's judgements were reviewed by the researcher, and the advice was taken into account and applied at all subsequent interviews.

5.8 Participants

5.8.1 Recruitment

Recruitment of the clinical sample was through the three NHS mental health treatment centres described in section 5.6. Clinicians working at the treatment centres were asked to identify clients from treatment waiting lists who might benefit from additional PTSD/CPTSD assessment. These clients were contacted by the NHS clinician, informed about the study, and sent a copy of the participant information sheet (PIS), privacy notice, and consent form. Procedure following initial recruitment can be found in 5.11.

5.8.2 Sampling

The sample was taken from a clinical population of treatment-seeking individuals in South-East Scotland. A clinical sample was necessary since the practical application of the ITI will be with individuals seeking treatment for trauma-related disorders. This means that a non-clinical sample would be unnecessary and inappropriate. The findings of this study may be tentatively generalised to the wider UK, but a nationally representative sample should be recruited for further research. CPTSD is also a relatively uncommon disorder in the non-traumatised population, so a validation of the ITI in a non-traumatised sample would likely not yield enough participants meeting CPTSD criteria. Data were collected from this sample using the measures detailed in 5.10 and analysed in the manner described in 5.12.2.

A cross-section of qualitative data was also collected from referring clinicians to understand the utility of the ITI. The details of qualitative clinical utility data collection can be found in section 5.12.4. Participants were recruited through NHS trauma treatment centres to ensure that appropriate care was in place during the recruitment period.

5.8.3 Inclusion and exclusion criteria

5.8.3.1 Clinical sample inclusion criteria

Patients were eligible for inclusion of they were referred from one of the recruiting mental health centres, had a history of exposure to at least one traumatic life event, were able to give informed consent to be involved in the study and were able to fluently communicate in English. Clinical sample exclusion criteria included those without a history of exposure to at least one traumatic life event, those unable to give fully informed consent, or who were unable to speak and understand English. Those likely to be unable to emotionally cope with the requirements of the interview were also excluded

The inclusion and exclusion criteria for the clinical sample were selected in order to facilitate the efficient completion of the study and in order to ensure the continued welfare of the participants. Participants were required to be referred by one of the health centres involved in the study to ensure that they were receiving suitable clinical support, and to verify their traumatic history. History of exposure to at least one traumatic event was necessary for participation in this study as the existence of an index event is necessary to meet the criteria for PTSD or CPTSD.

The requirement that the participants be able to give their own informed consent was included as an ethical requirement. Finally, fluent communication in English was necessary because the English version of the ITI is the version being validated in this study and the additional variable of administering the ITI in any other language would be an unacceptable limitation to this study.

5.8.3.2 Researcher and clinician inclusion criteria

Invitations to contribute qualitative data on clinical utility were extended to researchers who have used the ITI in an empirical study and clinicians referring participants to the present study.

5.9 Participant characteristics

Twenty-eight participants were recruited to the study, of which three did not complete their participation or requested for their data to be removed after participation, leaving 25 cases for analysis. Incomplete data was rare in this sample, four participants missed either one or two items on the questionnaires, but all of these were within the range of acceptable missingness. All interviewed participants fully completed the interview portion of the study. Two participants declined to return their questionnaires, and so were treated as withdrawal cases. Withdrawing participants were debriefed and informed that their data were being destroyed. This represents a 10.7% attrition rate. The majority of participants were female (84%, n=21), and the largest age group was 36-45 (28%, n=7). Full participant characteristics can be found in Table 5.1.

5.10 Measures

5.10.1 International trauma exposure measure

Participants' exposure to traumatic events was assessed using the international trauma exposure measure (ITEM) (Hyland et al., 2021). The ITEM lists 21 experiences understood to fulfil the criteria required to qualify as a traumatic experience, as well as a 22nd option wherein the respondent is invited to detail any experiences they feel may be the cause of post-traumatic stress but were not specifically listed. For full detail on the ITEM, see section 3.8.1. The ITEM was

used in this chapter to determine whether participant met inclusion criterion of lifetime exposure to traumatic event.

Table 5.1. Sample demographics

	Percent (n)
Gender	
Female	84% (21)
Male	12% (3)
Nonbinary or other	4% (1)
Age	
18-25	16% (4)
26-35	24% (6)
36-45	28% (7)
46-55	20% (5)
56-65	12% (3)
Ethnicity	
Scottish	44% (11)
British	44% (11)
African	4% (1)
Berber Algerian	4% (1)
Not disclosed	4% (1)

5.10.2 International trauma questionnaire

The ITQ (Cloitre et al., 2021) is a 12-item self-report measure which uses a 5-point Likert scale to assess PTSD and DSO symptoms with the view to return a diagnosis of either PTSD, CPTSD, or non-clinical levels of symptoms. The ITQ was designed to be administered in clinical settings where it is desirable for client burden to be minimised. To this end, the ITQ follows ICD-11 guidelines in terms of simplicity, ease of use in both clinical and research settings, and maximisation of international applicability (Cloitre et al., 2018). Full description of the ITQ and item list can be found in 3.8.3.

The ITQ was used as an external criterion against which the individuals' responses to the ITI were compared. The ITI was developed subsequent to the ITQ,

using similar theory and research so it is reasonable to expect that the two measures are likely to give similar results when administered to the same client.

Because the ITQ was developed a few years before the ITI, a body of work validating the ITQ already exists. An initial Confirmatory Factor Analysis (CFA) was carried out by Cloitre et al (2018) with results in line with expectations based on previous research. Since the release of the ITQ into the public domain, translated versions have been validated in Chinese (Ho et al., 2019), Lebanese (Vallières et al., 2018), and Brazilian Portuguese (Donat et al., 2019). Each study yielded positive results and provided evidence in support of the validity and reliability of the ITQ.

Redican et al (2021) carried out a systematic review of validation studies of the ITQ. Thirty-two studies found one of two possibilities for the latent structure of the ITQ. One latent structure being a correlated six-factor model, with each symptom of PTSD and CPTSD being represented by one factor, or a two-factor second order model of PTSD symptoms and DSO symptoms. The main findings of this study are in support of the conceptual distinction between PTSD and CPTSD and the use of the ITQ as a reliable and valid measure of both. The ITQ is therefore a very good fit for use as a comparator in this study.

The studies included in Redican et al., (2021) recruited a variety of samples including in a general clinical population (Cloitre et al., 2018), a sample of treatment-seeking military veterans (Murphy et al., 2020) and a sample of children living in foster care (Haselgruber et al., 2020). The presence of studies confirming the reliability and validity of the ITQ indicated that the measure routinely provides accurate and useful results and is therefore a good fit for use in this study as a measure of diagnostic concordance.

5.10.3 International trauma interview

The ITI (Roberts et al., 2019) is a semi-structured interview protocol designed to diagnose ICD-11 PTSD and CPTSD. The ITI was designed following the success of the ITQ and as such, follows a similar structure. As with the ITQ, the ITI comprises two sections; the first part uses six items to measure symptom clusters relating to PTSD, and the second containing six items to assess DSO symptoms. Each symptom has two items, with each item having scripted follow-up questions such as “Can you tell me more about that?” and “How strong are these feelings?”. Functional impairment is also scored on a 5-point scale from zero (no adverse impact) to four (extreme, little or no functioning).

The clinician administering the interview is instructed to determine whether the symptoms described by the client represent a severe and persistent pattern of problems. This is assessed on a scale from 0 (Not at all) to 4 (extremely). Both parts of the interview contain two additional items pertaining to the functional impairment resulting from the symptoms experienced by the individual.

The overall scores from the ITI give an indication of the presence and severity of symptoms as they are experienced by the client. Both sections have an overall maximum score of 48, and the maximum possible score for each symptom cluster is eight. Moderate severity in terms of symptom is said to be indicated by a score of ≥2. In order to receive a diagnosis of PTSD, the client must score moderately on at least one item from each symptom cluster, as well as registering moderate functional impairment. Similarly, a diagnosis of CPTSD is defined as moderate presence of at least one item from each cluster, as well as functional impairment attributed to both PTSD and DSO symptoms. The symptoms must also be clearly related to the traumatic event and have been present for at least 3 months.

Trauma relatedness is assessed by the clinician administering the ITI. The client is asked whether the symptom began or got worse in the time following the traumatic experience, or if they believe that the symptom is trauma related. The clinician lists each symptom as “definite” if the symptom and be clearly attributed to the event, “probable” if the link is probable but not definitive, and “unlikely” if it is believed that the symptom is caused by a factor other than the index event.

Presently, only two studies exist on the validation of the ITI, carried out by Bondjers et al., (2019) and Gelezelyte et al., (2022). The Bondjers et al., (2019) validated the Swedish version of the ITI using a sample of 184 participants recruited via volunteer sampling from advertisements in local media and flyers at primary and psychiatric care facilities. Analysis revealed moderate inter-rater agreement (Krippendorff $\alpha = .76$), as well as evidence in support of internal reliability for both PTSD ($\alpha=.86$) and DSO ($\alpha=.89$).

Gelezelyte et al., (2022) recruited a Lithuanian sample of 103 trauma-exposed adults via social media, online groups of healthcare associations, and email lists of mental healthcare providers. Their analysis revealed 18% of the sample fulfilled criteria for PTSD and 21% for CPTSD. They discovered moderate agreement between the ITI and the ITQ for both CPTSD ($\kappa = .38$) and DSO criteria ($\kappa = .33$), but poor agreement for PTSD ($\kappa = -.08$) criteria if CTPSD cases were excluded.

Table 5.2. Items on the ITI and the symptom clusters represented

Item	Symptom
In the past month, have you had any upsetting dreams that replay part of (EVENT) or are clearly related to (EVENT)?	Re-experiencing
In the past month, have there been times when powerful images or memories have come into your mind in which you felt as though the event was happening again in the here and now, while you were awake?	Re-experiencing
In the past month, have you tried to avoid thoughts or feelings about (EVENT)?	Avoidance
In the past month, have you tried to avoid things that remind you of (EVENT), like certain people, places, or situations?	Avoidance
In the past month, have you been especially alert or watchful, even when there was no specific threat or danger?	Hypervigilance
In the past month, have you had any strong startle reactions?	Hypervigilance
In the past month, have these (PTSD SYMPTOMS) affected your relationships with other people and your social life? By social life we mean your ability to enjoy social events with other people, feel comfortable in a group of people, engage in community events. How so?	Impairment in social functioning
Are you working now?	Occupational impairment
When you are upset how easy is it for you to calm down?	Affect dysregulation
Do you often feel emotionally numb or shut down?	Affect dysregulation
Do you feel like a failure?	Negative self-image
Do you feel worthless or inferior compared to other people?	Negative self-image
Do you feel distant or cut off from other people much of the time?	Interpersonal difficulties
Do you have any close relationships?	Interpersonal difficulties
In the past month, have these problems in emotions, in beliefs about yourself and in relationships affected your social life?	Impairment in social functioning

Item	Symptom
Are you working now?	Occupational Impairment

Table 5.3. Questions asked to clinicians and researchers and the aspect of clinical utility represented

Item	Aspect of Clinical utility
How easy do you feel it was to apply the interview to this individual?	Ease of Application
How useful do you feel the interview would be for communicating information about this individual with other mental health professionals?	Professional Communication
How useful do you feel this interview would be for communicating information about the individual to themselves?	Client Communication
How useful is this interview for comprehensively describing all the important PTSD/CPTSD-related problems the individual has?	Comprehensive of Difficulties
How useful would this interview be for helping you to formulate an effective intervention for this individual?	Treatment Planning
How useful was this interview for describing the individual's global mental health?	Global Mental Health Utility

5.10.4 Clinical utility

Clinical utility was assessed through statements from therapists using the results from the ITI. There is currently no widely accepted empirical measure of clinical utility that is suitable for this application, so a series of questions were adapted from First et al., (2004).

First et al., (2004) proposed that clinical utility could be operationalised by; 1) the ease of application of a tool, 2) the level to which the tool facilitates communication with other professionals, 3) the level to which the tool facilitates communication with the client, 4) the level to which the tool provides a comprehensive overview of the client's difficulties, 5) the tool's utility in facilitating treatment planning, and 6) the ability of the tool to describe the client's global mental health. Clinicians and researchers were asked to respond to each question either positively or negatively and then provide a reasoning for their answer. A list of the adapted items and the facet of clinical utility they measure can be found in table 5.3.

The survey questions provide structure to facilitate discussion between clinicians, and the researcher for this study was able to ask follow-up questions to clarify or probe further. The survey also facilitates the suggestion of improvements to the ITI by encouraging clinicians to reflect on their experience of using the interview protocol.

5.11 Procedure

5.11.1 Administration schedule

Those agreeing to participation were sent a participant pack to complete at home and invited to attend a meeting with the researcher via Attend Anywhere

(access provided by NHS Anchor Trauma Centre) or face-to-face at a recruitment site. The participant pack contained all measures listed in section 5.10 (excluding the clinical utility measure). The meeting was arranged to take place at a time convenient to the participant. During this meeting, a copy of the completed consent form was collected, the ITI was administered and responses to the self-report measures were recorded.

After the ITI was completed, participants were thanked for their time, given the debrief sheet, and asked if they had any further questions. Participants were verbally informed that the referring clinician would be sent a written summary of the results of their interview to be incorporated into their onward care pathway, and that they could expect the results at the time of their next meeting with the clinician. Participants were also informed of this written summary by the referring clinician, by the researcher in the pre-interview contact with the participant, again at the meeting with the participant before commencing the interview, and in the debrief form that was given to each participant after participation. The fact that the interview and questionnaire outcomes would be shared with their referring clinician was vital to acquiring informed consent.

Participants' responses to questionnaires were entered into a digital data log as soon as reasonably possible after the conclusion of the assessment. This was to ensure both the participants' confidentiality and the security of the responses. Any hard copy completed psychometrics or consent forms were digitised and stored on university laptop in a password protected folder, as detailed in the data management plan, and then hard copies were destroyed. The data collected from all participants were collated into an SPSS spreadsheet and analysed in the manner detailed in section 5.12.

5.11.2 Clinician participants procedure

A group of clinicians and researchers with experience administering or working with the results of the ITI were recruited to collect data on the clinical utility of the ITI. Groups of referring clinicians were contacted to ask if they would like to give their opinions and an email was sent with the questions listed in Table 5.3. Any responding clinician was thanked for their responses and any necessary clarifying questions were asked. Thematic analysis (TA) was then conducted as outlined in 5.12.4.

5.12 Data analysis

5.12.1 Descriptive statistics

Age, gender, and ethnicity distribution of the sample were reported. Prevalence of interpersonal vs non-interpersonal traumas and mean number of traumas were also calculated. Outcomes of this analysis can be found in Table 5.1.

5.12.2 Concurrent validity

Average inter-item correlation and agreement on diagnostic outcome between the ITI and ITQ was used to measure internal reliability. This process involved matching the items on the ITI and the ITQ, measuring the correlation between paired items, and a second analysis measuring the correlation between total ITI and ITQ score. In the initial ethics application, a goal of 200 participants was set based on observation of sample sizes of between 136 and 423 being recruited by other similar studies (Bondjers et al., 2019; Haselgruber et al., 2019; Ho et al., 2019). Once it became clear that this goal was not reasonably achievable in the timeframe of this PhD, G*Power (Faul et al., 2007; Faul et al., 2009) was used to determine the minimum sample size requirements for the planned analysis. It was found that a minimum of 44 participants was needed in order to achieve an effect size of 0.5 and

an alpha (α) of ≤0.05. An α of ≤0.05 was necessary to indicate statistical significance, and an effect size of 0.5 was necessary to indicate a correlation level of at least moderate size (Faul et al., 2007; Faul et al., 2009).

The degree of concordance between the paired ITI and the ITQ items was measured using Pearson's Correlation (*r*) (see Table 5.4 for strength of association thresholds). Pearson's *r* was chosen due to its robust nature and ability to work with smaller sample sizes with appropriate bootstrapping (Bishara, & Hittner, 2012). Pearson's *r* is expressed as a decimal where a ranking of 1 is perfect agreement, 0 is representative of complete independence (neither agreement nor disagreement) and (-1) is perfect disagreement. The thresholds listed in Table 5.4 are set based on Akoglu, (2018).

Table 5.4. r thresholds

	Pearson's correlation (*r*)	
Strength of association	Positive correlation	Negative correlation
Null	0	0
Weak	0.1 to 0.3	-0.1 to -0.3
Moderate	0.4 to 0.6	-0.4 to -0.6
Strong	0.7 to 0.9	-0.7 to -0.9
Perfect	1	-1

5.12.3 Internal reliability

The ITI uses two items to measure each symptom in PTSD and CPTSD. In order to ensure that both items for each symptom are measuring the same concept, a split-half analysis was conducted. This involved measuring the correlation between each pair of items (i.e., correlation between both avoidance items, both negative self-concept items etc) using *r* (Demirci et al., 2014; Robinson, & Post, 1995). Cronbach's Alpha is also used to assess overall internal reliability, as used in previous reliability studies of the ITI (Gelezelyte et al., 2022) and according to

acceptability values and interpretations recommended by Bland, and Altman (1997) and Tavakol, and Dennick (2011) (see Table 5.5 for these values).

Table 5.5. α thresholds

Internal reliability	**α**
Poor	≤0.69
Acceptable	0.70-0.89
Very high	≥0.90

5.12.4 Clinical utility

Qualitative data collected for the analysis of clinical utility were analysed using thematic analysis (TA). The approach outlined in Willig and Rogers (2017), adapted from Braun, and Clarke, (2012) was used. This involves the following phases: familiarisation and encoding, theme development, review and define themes, and produce the report. Willig and Rogers (2017) do suggest 50 qualitative surveys as an appropriate number for TA in this manner, but since multiple participants were referred by a smaller number of clinicians, this would not be possible.

Both survey responses were read through thoroughly to create familiarisation and understand the content and intention of the responses. Statements were coded in nVivo to represent common statements between both responses, as well as unusual or outlying comments and comments that may contribute towards the answering of the research question about the clinical utility of the ITI. After coding, the intention was to organise codes into themes. However, due to the very small sample size and short responses, it was determined that there were not enough codes to support development of themes. Thematic analysis was therefore terminated at this stage and the results were written based on codes alone.

TA was therefore conducted with the maximum number of clinicians possible with the understanding that this information is to supplement the findings of the main ITI validation study and to assess the feasibility of the use of ITI outcomes in clinical work, rather than a standalone analysis. A table with codes emerging from this analysis can be found in Table 6.7.

6 Study three: international trauma interview validation results

6.1 Introduction

6.1.1 Summary

The second study in this thesis (chapters five and six) aimed to assess the reliability and validity of the English-language version of the International Trauma Interview (ITI). Study two found that the correlation between NCBs and endorsement of post-traumatic stress disorder (PTSD) or complex PTSD (CPTSD) symptoms would be more accurately ascertained, if it was possible to use a clinician-administered tool to diagnose CPTSD and PTSD rather than using a self-report questionnaire. There is also a general need in research and clinical practice for an English-language clinical interview protocol for diagnosing PTSD and CPTSD, since this is the gold standard for diagnosis (Sysko et al., 2015) that is presently unavailable for international classification of diseases version 11 (ICD-11) PTSD and CPTSD.

This chapter details the results of the ITI validation study. a description of the types of trauma experienced by participants is first presented, followed by the findings in relation to concurrent validity, internal reliability, and clinical utility. Finally, a narrative interpretation and discussion of the strengths and limitations of the results is presented. The aim of this study was to investigate whether the ITI is a reliable and valid tool for assessing ICD-11 PTSD and CPTSD.

6.2 Participants

In terms of trauma experience, every participant reported polytraumatisation. There was a mean of 4.56 traumatic events experienced during childhood, and only one participant reported no traumatic events in their childhood.

Participants experienced a mean of eight interpersonal traumas (e.g., abuse by another person, threatened by another person) and two non-interpersonal traumas (e.g., natural disaster, experience of a life-threatening illness). See Table 6.1 for data on traumatic experiences throughout life stages and interpersonal vs non-interpersonal trauma.

Each participant participating in the study was administered the ITI, and as such was given a preliminary diagnosis of PTSD (7.1%, n=2), CPTSD (78%, n=22), or clinically non-significant symptoms (4%, n=1). These results are similar to previous research completed with comparable treatment-seeking clinical samples (Cloitre et al., 2018). For detailed comparison of international trauma questionnaire (ITQ) and ITI outcome data, see Table 6.2.

Table 6.1. Mean number of traumatic experiences by life stage and type of trauma percent of participants who did not experience a traumatic event at each life stage or type of trauma

	Mean (SD)	Range	Percent not experienced (n)
Childhood	4.56 (3.01)	0-11	4% (1)
Adolescence	5.80 (3.53)	0-15	8% (2)
Adulthood	5.96 (3.81)	1-14	0% (0)
Lifetime total	16.32 (7.58)	5-35	0% (0)
Interpersonal	8.12 (2.78)	3-15	0% (0)
Non-interpersonal	1.84 (1.46)	0-6	20% (5)

Table 6.2. diagnostic agreement between ITI and ITQ.

	CPTSD %(n)	PTSD %(n)	Subclinical %(n)
ITI	88% (22)	8% (2)	4% (1)
ITQ	76% (19)	20% (5)	4% (1)

6.3 Reliability and validity of international trauma interview

6.3.1 Concurrent validity

Concurrent validity was assessed in comparison to the ITQ, a measure of PTSD and CPTSD which has previously been validated in the population used in this

study. Each participant's outcome (coded as PTSD, CPTSD, or subclinical) from the ITQ ad ITI were assessed for correlation using Pearson's correlation (*r*). There was a moderately positive significant relationship (r=.469, p=.018) between diagnostic decision from the ITI and the ITQ. This indicates moderate agreement between the ITQ and ITI, dropping to poor, non-significant correlation when looking at agreement on PTSD diagnosis or CPTSD diagnosis (full detail in Table 6.3).

Participant scores on individual ITQ and ITI were also measured for correlation using *r*. Outcomes from this analysis arranged by symptom cluster can be found in Table 6.4 and Table 6.5. This study found moderate to strong correlations between symptom measurement on the ITI and ITQ for nightmares, re-experiencing, PTSD functional impairment, worthlessness, feelings of being cut off from others, emotional distance from others, and impairment in occupational functioning. The positive, significant and non-significant concurrent validity results found in this study suggest that the English version of the ITI and ITQ have moderate to poor agreement, and further research is required to assess the causes of this finding. Research question one "What is the level of diagnostic concordance between the ITI and the ITQ?" can be answered as moderate to poor.

Table 6.3. Correlations between ITQ and ITI outcomes

	ITQ outcome	ITQ PTSD diagnosis	ITQ CPTSD diagnosis
ITI outcome	.469[1]		
ITI PTSD diagnosis		.102	
ITI CPTSD diagnosis			.266

[1]Significant to 0.05 level

Table 6.4. Correlations between PTSD symptom scores on ITQ and ITI

	Re-experiencing		***Avoidance***		***Perception of heightened current threat***		***Functional impairment***	
	Nightmares	Flashbacks	Internal	External	Hypervigilance	Startle response	Social	Work
Re-experiencing								
Nightmares	.62[3]							
Flashbacks		.45[1]						
Avoidance								
Internal			.24					
External				.34				
Perception of heightened current threat								
Hypervigilance					.07			
Startle response						.02		
Functional impairment								
Social							.48[1]	
Work								.67[3]
Other important part of life								.65[3]

[1]Significant to 0.05 level

[2]Significant to 0.01 level

[3]Significant to 0.001 level

Table 6.5. Correlations between CPTSD symptom scores on ITQ and ITI

		ITQ items							
		Affect dysregulation		***Negative self-concept***		***Disturbed relationships***		***Functional impairment***	
		Hyperactivation	Hypoactivation	Failure	Worthlessness	Cut off	Distanced	Social	Work
ITI items	***Affect dysregulation***								
	Hyperactivation	.28							
	Hypoactivation		.12						
	Negative self-concept								
	Failure			.34					
	Worthlessness				.55[2]				
	Disturbed relationships								
	Cut off					.63[3]			
	Distanced						.67[3]		
	Functional impairment								
	Social							.20	
	Work								.39
	Other important part of life								.53[2]

[1]Significant to 0.05 level

[2]Significant to 0.01 level

[3]Significant to 0.001 level

6.3.2 Internal reliability

Overall, the agreement between paired items is low to moderate, with only a few pairs being significantly correlated. The Cronbach's alpha (α) for ITI responses was 0.89, indicating acceptable internal reliability. Individual inter-item correlations produced null to moderate correlations, with few significant correlations. The strongest, most significant correlations were between (1) feelings of failure and feelings of worthlessness and (2) feeling cut off from others and emotional distance from others. These findings indicate that the items measuring the symptom clusters negative self-concept and difficulties in relationships present with high internal consistency. Other item pairs in the ITI did not correlate with each other, meaning that further research is needed to verify these findings and refine the administration of these items to improve correlation between item pairs.

The exception here is the items used to measure the emotional dysregulation symptom cluster. The two items used to measure emotional dysregulation assess opposite responses (i.e., hyperactivation and hypoactivation) so it is anticipated that these could be potentially negatively or non-significantly correlated for some. This was indeed the findings of study three; hyperactivation and hypoactivation were weakly negatively correlated.

Of interest, both items used to measure difficulties in relationships were moderately significantly correlated with nearly all other items in the DSO section of the ITI, with the exclusion of the emotional hyperactivation item. This may indicate that difficulties in relationships is a predictor of other symptoms in CPTSD, although further research is required to corroborate these findings.

Table 6.6. ITI inter-item correlations

	Nightmares	Flashbacks	Internal	External	Hypervigilance	Startle response	Hyperactivation	Hypoactivation	Failure	Worthlessness	Cut off
Flashbacks	.18										
Internal	.25	-.01									
External	.49[1]	.18	.18								
Hypervigilance	.41[1]	.28	.33	.13							
Startle response	-.05	-.11	.06	.01	.39						
Hyperactivation	-.02	.20	.12	-.08	.42[1]	.45[1]					
Hypoactivation	.20	.08	-.05	.27	.21	.15	-.02				
Failure	.46[1]	.16	.32	.27	.46[1]	.14	.22	.39			
Worthlessness	.62[3]	.06	.32	.30	.55[2]	.06	.16	.31	.92[3]		
Cut off	.39	.26	.26	.19	.48[2]	.32	.34	.43[1]	.56[2]	.59[2]	
Emotional distance	.36	.17	.16	.24	.29	.11	.38	.46[1]	.45[1]	.51[2]	.79[3]

[1]Significant to 0.05 level

[2]Significant to 0.01 level

[3]Significant to 0.001 level

Table 6.7. TA of clinician survey responses

Code (frequency)	Example
Useful in goal setting (3)	"People may be able to use the results to guide their choices of clinical goals" - Clinician 2
Supplementary to further clinical assessment (4)	"Somewhat helpful as part of other strands of information." - Clinician 2
	"Suitable additional information in routine letters or updates to other involved parties" – Clinician 1
Validating to participant (3)	"… the results were particularly validating for one participant I was working with" - Clinician 1
	"Useful in validating their perspective subjectively" – Clinician 2
Aspects of mental health not covered in ITI (2)	"There are many factors that could influence global mental health that are not covered eg [sic] additional stressors, protective factors, supportive structures etc." – Clinician 2

6.4 Clinical Utility

Survey responses from two clinicians were collected and analysed using thematic analysis (TA). Codes with frequencies and examples can be found in table 6.7. Seven clinicians were approached for survey responses, though only two responded. It is unclear as to why this was, since none of the other clinicians responded to email contact. It is possible that the workload experienced by clinicians referring to this study was too great, and the time to complete the questions was not available. In-person or phone contact with the clinician may have resulted in better response rates, but this was not possible due to time constraints, and the fact that this method of contact was not permitted by the ethics application.

TA with only two responses is difficult, as common themes are expected but may not be as meaningful as themes would be if found in a larger sample of comments. For the purposes of this study, the TA has been performed and will be discussed with a view to direct possible areas of future research.

Four codes were identified in the Thematic Analysis (TA) of two statements taken from clinicians who used the results of the ITI in their work with clients. The vast majority of this feedback was positive. Utility in setting treatment goals was mentioned three times, with clinicians being able to use the areas of higher scoring to speak to their clients about specific areas of difficulty that may be useful targets in therapeutic intervention. Use of the ITI as supplemental to additional clinical assessment was mentioned four times, as clinicians used their own judgement and outputs from self-report and standard intake assessments in conjunction with the ITI results to formulate the needs of their clients. Validation of subjective experience for the client was mentioned three times, giving confidence to participants that they understood the symptom structure of CPTSD and how their symptoms fit into the

clusters. This was useful for participants in gaining confidence to voice their feelings in therapy and take an active role in their recovery.

6.5 Summary

6.5.1 Key findings

In all, the results from the analysis of this data have some mixed results. Concurrent validity of the ITI when compared to the ITQ was significant and moderate, falling to non-significant and weak, which is not unusual for a self-report and clinician-administered measures (Gelezelyte et al. 2022). Internal reliability is at the upper threshold of acceptability (α=0.89). a value higher than this would call into question which concept was being measured by the ITI- it may have been possible that all items were measuring the exact same concept, rather than multiple aspects of a latent concept.

TA of clinician surveys revealed overall positive opinions, with only minor issues with the quantitative nature of the outcome not being suitable for comprehensively describing the issues faced by a person. Both clinicians stated that there were factors that influence a person's mental health that were not measured by the ITI (e.g., protective factors, support systems, external stressors). Implications for these findings are discussed in the next chapter.

Additionally, a finding that was unexpected but had great implications for the future of trauma-related research comes from study two. Previous research has always suggested that those with PTSD symptom profiles are more likely to endorse NCBs than those without such symptoms. However, this research was all conducted before the emergence of the CPTSD diagnosis. Study two indicated that people with PTSD are no more likely to endorse NCBs than those with no trauma-related

symptoms, and it is in fact those with CPTSD symptom profiles who have higher rates of NCB endorsement. It is therefore proposed that previous research did not know to differentiate between PTSD and CPTSD symptom profiles and participants with CPTSD artificially inflated the rates of NCB endorsement in samples incorrectly labelled as experiencing only PTSD. This suggestion means that any research into PTSD conducted prior to the publication of the ICD-11 may in fact be invalidated by the inclusion of CPTSD participants. Future research should take care to screen participants for both PTSD and CPTSD to avoid this error continuing.

6.5.2 Strengths and limitations

They key strengths of this study include the sample recruited; the clinical sample is representative of the population that the ITI will be used with most frequently. this means that the conclusions drawn from this study are more relevant to the target population than if this study had recruited a more accessible sample such as undergraduates or a general population sample.

The use of recorded and transcribed interviews as a calibration method is also a vital strength of this study. The opportunity to receive feedback on the administration and scoring of the interview allowed the researcher to administer the interview as intended, and in the same manner for each interviewee. This reduced researcher effects on the outcomes of the interviews and increased the consistency of the interview process.

However, as stated above, it was not possible to recruit the number of participants anticipated in the ethics application process, nor the number of participants indicated by the power calculation. This is egregious flaw in the study, and attempts have been made to mitigate this issue by indicating the conclusions

drawn as guidance rather than indisputable. It was unfortunately not possible to recruit the desired number of participants, despite the best efforts of all involved. Chapter seven discusses directions for future research that may build upon these preliminary findings.

7 Discussion

7.1 Summary of this thesis

The primary objectives of this thesis were therefore to answer the following questions:

1. What does the current literature show regarding the relationship between disturbances in self-organisation (DSO) symptoms and negative core beliefs (NCBs)?
2. How are NCBs related to international classification of diseases (ICD-11) post-traumatic stress disorder (PTSD), complex PTSD (CPTSD) and DSO symptoms?
3. Is the international trauma interview (ITI) a reliable and valid tool for assessing ICD-11 PTSD and CPTSD?

This thesis aimed to answer these questions in a three-stage process. Stage one involved a systematic review and meta-analysis to identify existing evidence about the relationship between proxy measures of DSO symptoms and NCBs. Stage two recruited participants into an online survey with the intention to answer research question two, and to address some of the limitations of previous literature as identified in stage one. Stage three attempted to provide a preliminary validation of the ITI as a measure of PTSD and CPTSD.

7.2 This thesis in the context of the pandemic

The work detailed in this thesis was undertaken during the COVID-19 pandemic and its aftermath. The impact of the pandemic has been heavily studied in recent years, showing that healthcare workers experienced very high rates of both traumatic exposure and post-traumatic symptoms (Chan et al., 2021; Marvaldi et al.,

2021; Salehi et al., 2021; Sanghera et al., 2020). An everyday level of traumatic exposure and decline in mental health was also experienced by the general population and those with no direct exposure to COVID-19-related trauma through front-line healthcare work (Chen et al., 2022; Holzinger et al., 2022; Jukes et al., 2022; Kauhanen et al., 2022; Lund et al., 2020). The real-world need for better understanding and diagnosis of trauma-related disorders has increased as exposure to trauma has become more commonplace throughout the pandemic. This includes the ability to diagnose PTSD and CPTSD accurately. PTSD was reorganized in the recently released ICD-11 and CPTSD is a new diagnosis that does not have any validated diagnosis tools, so there is an urgent need for a way of assessing both of these disorders.

An interview method of diagnosing CPTSD is therefore necessary for the future of CPTSD research and treatment. Interviews are considered the gold standard for diagnosis by National Institute for Clinical Excellence (NICE,2018). A self-report measure for the diagnosis of CPTSD and PTSD has previously been validated, but even a preliminary investigation of a diagnostic interview such as the ITI will be a step in the right direction towards appropriate methods of diagnosis for CPTSD being widely available for people who have been affected by traumatic life events.

Given the relative youth of the CPTSD diagnosis, a cognitive model integrating the development of PTSD and CPTSD has yet to be developed. Ehlers and Clark (1999) proposed a cognitive model of PTSD that may be expanded or adapted to include CPTSD, but before this happens, the cognitive structure of CPTSD must be better understood. Ehlers and Clark (1999) detail a mechanism by which a traumatic event may activate strongly held negative beliefs about the self, impacting the way a traumatic event and its aftermath is perceived, leading to the

development of PTSD. If CPTSD is to be integrated into this model, the relationship between NCBs and CPTSD symptom endorsement must be investigated.

7.3 Study one

In order to collate pre-existing data relating to the relationship between NCBs and CPTSD endorsement, the meta-analysis detailed in chapter two was conducted. Overall, a positive correlation was found between NCBs and proxy measures of the DSO symptoms, affect dysregulation and difficulties in relationships. However, there were major flaws in previous research which made it challenging to draw any reliable conclusions. For example, the majority of the samples used were non-clinical or non-trauma-exposed and therefore evidence is not generalisable to therapeutic practice, no studies examined the correlation between a direct measure of CPTSD and NCBs, and the overall quality of the published research was low.

It was concluded that there is a need for research into the relationship between a direct measure of CPTSD symptoms and NCBs in clinical and trauma-exposed populations before intervention-based research can be conducted to explore the effectiveness of cognitive behavioural therapies for ICD-11 CPTSD. Future recommendations for research indicated the use of a reliable measure of NCBs, higher quality research (i.e., reporting more detailed characteristics of the sample used, publication of a power calculation, etc.), and recruitment of clinical or trauma-exposed samples. A more detailed discussion of the findings from the meta-analysis can be found in section 2.6.

7.4 Study two

Following the outcomes of the meta-analysis, an online cross-sectional survey was conducted with the aim to identify differences between NCBs in participants with PTSD, CPTSD symptoms, and participants with no symptoms. The core beliefs questionnaire (CBQ) was identified as an appropriate measure of NCBs, and analyses were run to ensure internal reliability in the sample recruited. A trauma-exposed sample was recruited to ensure directness between the sample and population of interest, and the demographics of the sample were thoroughly reported.

The intention of this study was to fill in gaps in the literature around the relationship between NCBs and CPTSD symptoms and contribute to the integration of CPTSD into a cognitive model of post-traumatic disorders. The research questions that were answered in this study were:

1) Does the CBQ produce reliable measurements of NCBs in participants endorsing PTSD/CPTSD symptoms?
2) Do participants with CPTSD score more highly on the CBQ than participants with PTSD or subclinical symptomology?
3) Which NCBs are endorsed by participants with CPTSD symptomology compared to participants with sub-clinical and PTSD symptomology?

7.4.1 Discussion of findings

7.4.1.1 Reliability of CBQ to assess NCBs

The results described in section 4.3.3 of this thesis identified very high internal reliability (α=0.95) in the PTSD subgroup, and very high internal reliability (α=0.96) in the CPTSD subgroup. This is strikingly similar to the findings of Wong

et al (2017) whose α analysis revealed an α of 0.96 for very strong internal reliability. The internal reliability of the CBQ is reaffirmed in a new population and may be used as a reliable tool to assess NCBs in research into CPTSD and PTSD populations.

7.4.1.2 Differences in NCB endorsement between subgroups

The findings of the Kruskal-Wallis (K-W) analysis revealed statistically significant differences between subgroups in terms of endorsement of NCBs. This was confirmed by t tests performed to analyse paired subgroups. The results of these pairs revealed: (1) subgroup membership between PTSD and CPTSD has a significant impact on the level of NCBs endorsed, (2) group membership between PTSD and non-symptomatic subgroups had no significant impact on the level of NCBs endorsed, and (3) subgroup membership between CPTSD and non-symptomatic subgroups has a significant impact on the level of NCBs endorsed.

These findings are reflective of previous studies, for example, Vasilopoulou et al. (2019) found that all NCB domains were correlated with CPTSD symptomology to $p<.001$. Greenblatt-Kimron et al. (2023) also found higher levels of NCBs in a CPTSD subgroup than was found in a no-symptom or PTSD symptom subgroup, and Dutra et al. (2008) found significant differences in most NCB domains between PTSD and no-symptom groups. However, all these previous studies used the young schema questionnaire (YSQ) to assess NCBs (issues of reliability related to the YSQ are discussed in chapters two and three), and no study has yet presented findings relating to correlation between individual NCBs and individual PTSD/CPTSD symptom clusters without the use of the YSQ.

No significant difference found between NCB endorsement by participants with PTSD symptoms and those with no symptoms. These results indicate that there is no difference between the cognitive structure of those with PTSD and those without any symptoms, in terms of NCBs. These findings can be attributed to the nature of the specific scale that has been used for NCBs. This finding is also seen in Greenblatt-Kimron et al. (2023) (though a specific significance analysis is not performed in that study). Previous research aside from Greenblatt-Kimron et al. (2023) has not analysed the difference between all three subgroups. Similar research reports either the difference between PTSD and no-symptom groups, or CPTSD and non-CPTSD groups (Lian et al., 2023; Vasilopoulou et al., 2020).

7.4.1.3 Correlation between international trauma questionnaire (ITQ) symptom endorsement and NCBs

The results of this analysis revealed statistically significant ($p<.001$) inter-item correlations in each pair. The strength of the significant correlations ranged from weak to very strong. Vasilopoulou et al (2019) found similar results in a sample of adults over the age of 64. They found all schema domains on the Young Schema Questionnaire Short Form-3 were strongly significantly correlated with CPTSD symptomology. The findings of Vasilopoulou et al (2019) and study two in this thesis indicate that NCBs do correlate with CPTSD symptoms in adults <30 years old and >64. Further research us required to identify the cause of this association and confirm this association within additional age groups. This finding of correlation between specific NCBs may indicate that core beliefs could be a useful therapeutic target for treating CPTSD or differentiating between PTSD and CPTSD symptom profiles.

7.4.2 Implications

7.4.2.1 Research implications

Regarding research implications, the finding that the CBQ is a reliable measure of NCBs in PTSD and CPTSD supports the use of the CBQ in future research into NCBs in this population. Future research needing to measure NCBs in populations with PTSD/CPTSD symptomology should regard the CBQ as a valid measure. Future research may seek to identify the nature of the conceptual overlap between the negative self-concept symptom cluster and NCBs as measured by the CBQ. This should also include findings regarding the relationship between the other-belief subscale of the CBQ (a subscale measuring the respondent's NCBs regarding other people) and PTSD/CPTSD symptom endorsement. This would support the understanding of the nature of negative self-concept in CPTSD and differentiate this from endorsement of NCBs by people without CPTSD symptomology. This greater understanding of the nature of CPTSD symptoms and correlation with other-NCBs would contribute to the development of a cognitive model of CPTSD. This research would also further contribute to the development of treatment protocols for CPTSD.

The findings of this thesis support some assumptions made in Ehlers and Clark (1999). For example, study two supports the idea that prior experiences and beliefs directly impacts the development and maintenance of PTSD symptoms. However, findings from study two do not support causation, merely correlation. Additionally, study two found greater correlation between NCBs and DSO symptoms than between NCBs and PTSD symptoms, which were not integrated into Ehlers and Clark (1999) model of PTSD. In this way, the findings of study two both support and undermine this early cognitive behavioural model of PTSD.

Figure 7.1. Memory and Identity theory of CPTSD

The memory and identity (M&I) theory of CPTSD (Hyland et al., 2023) integrates NCBs in the form of negative identities. Hyland et al. (2023) state that negative identities result from the interaction of trauma exposure and individual vulnerabilities. Negative identities are deeply held thoughts about the self, including being worthless, alienated, unsafe, or powerless, and the individual may or may not be aware that they hold this belief. In this way, the negative identities in the M&I theory of CPTSD hold similarities with NCBs examined in chapters two, three, and four of this thesis. As illustrated in Figure 7.1, it is proposed that negative identities impact all symptoms of CPTSD and PTSD, excluding re-experiencing. The findings in study two of this thesis support the idea that negative identities may increase the impact of most PTSD and CPTSD symptoms, and NCBs correlated most poorly with both re-experiencing symptoms, supporting the assertion that negative identities may have lesser impact on those symptoms. However, the correlation between NCBs and re-experiencing did still exist, it is possible that there is an as-yet unobserved mechanism by which NCBs indirectly influence re-experiencing symptoms. Future research must test mediators of the relationship between NCBs and re-experiencing to clarify the cause of the correlation between NCBs and re-experiencing. In terms of

the cognitive model of CPTSD, study two of this thesis does contribute this research. The understanding that NCBs regarding worthlessness and inferiority are significantly correlated with CPTSD symptoms and are significantly different between the PTSD and CPTSD subgroups may be viewed as supporting evidence in favour of the M&I model of CPTSD (Hyland et al., 2023). Particularly the assertion that negative identities impact all three DSO symptoms, but only two of the three PTSD symptoms. M&I model illustrates very simply how it may be the case that CPTSD presentations correlate more strongly with NCBs then PTSD presentations.

Next steps in this topic area may include qualitative research to identify self-reported origins of NCBs, whether the individual believes these NCBs to be related to traumatic events or not. This should also include the assessment of world- and other- NCBs to confirm that the differences in NCB endorsement between PTSD and CPTSD subgroups also applies to beliefs about the world at large and other people. This will allow for more information to be gathered on the nature of these NCBs, possible origins, and treatment options. This would also contribute evidence toward assumptions made by the M&I model that negative identities are informed by individual vulnerabilities and trauma exposure.

Future research may also seek to develop a new tool to measure NCBs in CPTSD. This tool may include items that are conceptually distinct from negative self-concept, including NCBs about other people and the world at large, as well as items relating to coping mechanisms, type of trauma experienced and post-traumatic reactions, as suggested in M&I model of CPTSD. This would allow clinicians to gain a comprehensive understanding of their clients' worldview beliefs and beliefs about the event that may be identified as targets for therapy (Edmondson et al., 2011; Feldman, & Kaal, 2007; Park et al., 2012).

The finding that there is no statistically significant difference between NCB endorsement in PTSD and no-symptom groups highlights a gap in current research and raises questions that must be answered by further research. For example, the differences in NCB endorsement found in studies comparing PTSD and no-symptom groups are typically published prior to the release of the ICD-11 and therefore would have included CPTSD participants in the PTSD groups. It may be the case that the significant differences between PTSD and no-symptom groups were due to the non-detection of CPTSD in samples. That is, previous research that was conducted without a measure of CPTSD will have grouped participants with PTSD and CPTSD into the same sample under the PTSD group. Future research should seek to verify this finding that there is no significant difference between NCB endorsement in PTSD and no-symptom groups, ensuring that CPTSD participants are not included in the PTSD subgroup. Alternatively, it may be the case that individuals with PTSD hold significant but different NCBs than those with CPTSD, and the NCB scale used in this thesis did not accurately capture NCBs commonly associated with PTSD. This would mean that future research should use alternative NCB measures to assess levels of NCBs in participants with PTSD to determine if there are in fact strong NCBs that were simply not identified by this research. For example, negative identities such as fragmentation and unsafe are listed in M&I theory but were not appropriately measures by the CBQ. It would be pertinent to conduct research to measure these identities, and others suggested in M&I theory, and assess the possibility that these facets of identity may differentiate between PTSD and CPTSD symptom profiles. Treatment implications for these future findings may include recommendations for specific NCBs to be targeted in PTSD vs CPTSD, or even the

suggestion that NCBs be disregarded as a treatment option for PTSD. However, these recommendations cannot be made based on research that currently exists.

Since differentiation between CPTSD and other conditions such as personality disorders (PD) can be difficult in research and clinical settings (Ford, & Courtois, 2014; Powers et al., 2022), future research may also seek to measure differences in NCB endorsement between participants with CPTSD and PD. Differentiation between borderline PD (BPD) and CPTSD symptom profiles has long been a subject of discourse in academic publishing (Jowett et al., 2020A; Jowett et al., 2020B; Karatzias et al., 2023). The two disorders have similar risk factors in number and type of trauma exposure (Jowett et al., 2020A), and the symptom profiles could be described as similar on paper (Jowett et al., 2020B), meaning that clinicians faced with the need to diagnose a client with either BPD or CPTSD are assigned a very difficult and nuanced task. However, evidence does support the distinction between BPD and CPTSD, and clinical direction and guidelines included in assessment tools such as the ITI can mean that the differentiation has clinical utility (Karatzias et al., 2023). It is important, therefore, that further methods of correctly identifying BPD and CPTSD symptoms profiles are developed.

Specific NCBs have been shown to effectively discriminate between PD typologies (Butler et al., 2002; Kunst et al., 2020), and targeting core beliefs has shown improvement in personality disorder symptoms (Kellogg, & Young, 2006; Koppers et al., 2021; Videler et al., 2018). So, it may be possible to develop groupings of core beliefs that differentiate between PTSD, CPTSD, and PD. This would contribute to the understanding of the differences between the three disorders and may also provide a mechanism of assigning the correct diagnosis to clients in clinical practice. Also contributing to the ability to differentiate between CPTSD and

PD would be the validation of a clinician-administered measure of CPTSD. Since the ITQ is a self-rated questionnaire, it carries with it all flaws of self-report measures (e.g., respondents misunderstanding items, purposeful over-reporting of positive affect, missing data) (Myers, 2000; Stone et al., 1999; Theofanidis et al., 2018; Visted et al., 2017) and may not achieve the levels of reliability and accuracy required to make accurate diagnostic decisions that will influence the treatment pathway of a client (Levis et al., 2019; Sysko et al., 2015). The validation of a clinician-administered interview would allow for research into the differences between NCBs held by participants diagnosed with PD and CPTSD, rather than those simply reporting the experience of symptoms by means of a self-report questionnaire.

7.4.2.2 Clinical implications

From a clinical standpoint, the confirmation that PTSD, CPTSD, and no-symptom groups endorse different levels of NCBs highlights the need for inquiry into the role of NCBs in the development and maintenance of CPTSD. While the role that NCBs play in CPTSD is not currently fully understood, the association between NCBs and CPTSD symptom endorsement suggests that NCBs may be an important therapeutic target and their measurement could be an important part of the clinician's initial assessment, as well as a metric for assessing improvement in symptoms as treatment progresses.

The CBQ may be a useful tool for researchers and clinicians to use to differentiate between clients with PTSD and CPTSD, but this research did not use a clinical sample. Because the sample in study two was a trauma-exposed sample, rather than a clinical sample, it cannot yet be said that the CBQ will certainly be a

useful tool for differentiating PTSD and CPTSD in clinical settings. This is an empirical question for future research, but it can be suggested that the CBQ may provide useful data to supplement clinical judgement and provide a holistic picture of the client's experiences of their disorder.

Specific recommendations for therapies to treat PTSD and CPTSD cannot be made from this research, as a clinical sample was not used. However, therapies that may be tested in trials and future research may include the efficacy of targeting specific NCBs. For example, chapter four of this thesis found that emotional hyperactivation correlated most strongly with the belief of being unacceptable. A client presenting with CPTSD and a specific difficulty with emotional hyperactivation may therefore most benefit from a therapeutic intervention geared towards targeting this belief in order to improve this symptom. Additionally, the symptoms that make up the DSO cluster negative self-concept correlated with all NCBs more strongly than all other symptoms. This means that overall self-NCBs would be a suitable therapeutic target for clients finding this symptom cluster the most troubling (Karatzias et al., 2023). Future research should trial a therapeutic intervention that targets NCBs associated with the most troubling symptoms experiences by clients with CPTSD.

Karatzias and Cloitre (2019) proposed a modular approach to treatment for CPTSD as a method of combining existing therapies, including cognitive strategies to target individual CPTSD symptom clusters. For example, a combination of self-soothing exercises, self-compassion, and communication skills work to address emotional dysregulation, negative self-concept, and difficulties in relationships, respectively. Therapy interventions that target NCBs may include Cognitive Behavioural Therapy (CBT) activities such as cognitive reappraisal of automatic

thoughts, cognitive flexibility, and cognitive reprocessing (Jensen et al., 2022; Karatzias et al., 2019). A combination of these interventions with non-CBT therapies such as counselling or eye movement desensitization therapy (EMDR), may be administered in an order that addresses the most impairing symptoms and the symptoms most relevant to the client (Karatzias & Cloitre, 2019).

7.5 Study three

Study three in this thesis therefore aimed to answer the questions:

1. What is the level of diagnostic concordance between the ITI and the ITQ?
2. Does the English version of the ITI produce internally reliable scores?
3. What are the views of clinicians regarding the clinical utility of the ITI?

7.5.1 Discussion of findings

7.5.1.1 Concurrent validity

Concurrent validity was analysed using the average inter-item correlation between the ITI and the ITQ. There was a statistically significant moderate correlation between the overall diagnostic decision given by the ITI and the ITQ (r=.469, p=.018), dropping to poor, non-significant correlation when looking at agreement on PTSD diagnosis or CPTSD diagnosis. These results are similar but not as strong as the findings by Gelezelyte et al., (2022), who measured the reliability and validity of the ITI in a Lithuanian sample, Gelezelyte et al. (2022) found strong, significant agreement on PTSD and DSO diagnostic decision between the ITI and ITQ, dropping to poor when CPTSD participants were removed. Again, Gelezelyte et al. (2022) found stronger, more significant results, the only non-significant correlation being sense of threat.

One possible cause for the weaker findings of the present study is the sample size. Gelezelyte et al. (2022) recruited 103 participants, whereas study three in this thesis recruited only 25. This may have contributed to the difference in strength of the correlation. However, the overall significant results on this study are not to be dismissed simply due to the smaller sample, findings should be viewed as preliminary rather than conclusive.

7.5.1.2 Internal reliability

Internal reliability as measured by Cronbach's Alpha (α) was at the upper threshold of acceptable (α=0.89), indicating very good internal reliability. The only previous study to analyse internal reliability of the ITI is Bondjers et al. (2019) who used a Swedish translation and composite reliability analysis to indicate acceptable levels of internal reliability. These similar results indicate that the English ITI may be an internally reliable measure of PTSD and CPTSD.

No previous research has reported the inter-item correlations of the ITI, so these findings cannot be compared to other findings. However, based on the findings presented here the research question "Does the English version of the ITI produce internally reliable scores?" can be answered with the affirmative, though the small sample size presented here demands that this conclusion be regarded with caution.

7.5.1.3 Clinical Utility

Negative feedback from clinicians came in response to a question about the ability of the ITI to describe a client's global mental health difficulties. Both clinicians stated that there were factors that influence a person's mental health that were not measured by the ITI (e.g., protective factors, support systems, external stressors). This feedback is accurate, as the ITI only intends to assess the six

symptom clusters relating to PTSD and CPTSD as listed in the ICD-11 and does not claim to be a measure of global mental health. The overall mental health is better assessed using supplemental clinical assessment, as proposed by Vallières et al., (2018).

Clinical utility of the ITI has not previously been reported, and so there is no previous research to compare these findings to. However, previous research has shown that the ITQ is generally perceived as fit for purpose, with some minor issues (Vallières et al., 2018). Vallières et al. (2018) identified issues including clients requiring assistance from psychotherapists to complete the measure, issues with comprehension, and not measuring some symptoms associated with PTSD/CPTSD such as amnesia or difficulty concentrating. There are other behaviours and symptoms commonly comorbid with PTSD/CPTSD that may not be explicitly assessed by the ITI or the ITQ. For example, memory difficulties (Johnsen, & Asbjørnsen, 2008; Thome et al 2020), moral injury (Hall et al., 2022; Papazoglou et al., 2020) and alcohol or drug use (Davies et al., 2019; Simpson et al., 2019) are all commonly found alongside PTSD diagnoses, but are not measured by the ITI or ITQ, because these are not part of the ICD-11 diagnostic criteria. So it may be the case that supplemental assessment is required for a full picture of the client's global mental health.

7.5.2 Implications

7.5.2.1 Research implications

More research is needed with a larger sample size to comprehensively capture population characteristics of PTSD and CPTSD. The conclusions drawn from this study came from a sample that fell short of the number of participants

identified by the power calculation (n=44 identified by G*power, n=200 identified through a priori analysis of similar articles). Because of this, conclusions should be viewed with caution. However, the findings are promising and the levels of agreement between the ITI and ITQ could be replicated with larger samples. Future research should aim to contribute further data for analysis to support the claims in this study that the reliability and validity of the English version of the ITI is acceptable. This will provide additional empirical basis for the use of the ITI in clinical diagnostic work.

Further research should also assess the test-retest and interrater reliability of the ITI. There was protocol in this study to assess these aspects of reliability but due to attrition and low sampling, it was not possible to complete this analysis. These aspects of reliability are vital to ensure that the ITI is not reliant on transient participant characteristics such as mood or poor memory (McCrae et al., 2011; Polit, 2014) and that change in responses can be attributed to true change in the aspect being measured, rather than random variance in responses (Polit, 2014). The test-retest reliability of the ITI has not previously been evaluated, but interrater agreement has been found to be satisfactory in Swedish and Lithuanian samples (Bondjers et al., 2019; Gelezelyte et al., 2022). The need now is for the same analysis to be conducted with a UK sample with the English language ITI.

Future research around clinical utility is also necessary. In this study, two clinicians who used the outputs of the ITI were consulted on their thoughts about the utility of the ITI in formulating client needs and care pathways. This is a vital aspect of clinical utility, but the process of administering the ITI was not assessed for clinical utility. Future research should therefore consult clinicians who have experience of interviewing people using the ITI to identify areas of improvement for

instructions to the interviewer and scoring guidelines. This could include surveying clinicians who use the ITI once it is in use in standard clinical practice, or researchers who use the ITI in their research activities. These populations are the most likely to use the ITI on a daily basis and will provide the most insightful comments on how the ITI is received by participants and clients, and how useful the results are. This research will improve the ITI overall and allow for ease of use in clinical settings (First et al., 2004).

Similarly, future research could investigate the perceptions of interviewees being assessed by a clinician using the ITI. This could be done by partnering with clinicians to survey clients who are interviewed using the ITI, administering short and long form questions about their experience could be done by clients or completed on pen-and-paper questionnaires, as preferred by the participant. It is important that the interviewee understands the reasoning behind the questions being asked in the ITI, and that the interviewee believes that they are able to answer the questions to the best of their ability. Asking participants questions about their experience of being interviewed with that ITI may help to rephrase items to be clearer and communicate the purpose of the interview protocol more effectively (First et al., 2004; Pinninti et al., 2003).

7.5.2.2 Policy implications

Following further research listed in section 7.5.2.1 above, recommendations for policy may be made. For example, National Institute for Health and Care Excellence (NICE) guidelines make recommendations that recognition of PTSD and CPTSD should use validated measures (NICE, 2018) which may be updated to include the ITI as a reliable assessment tool for qualified clinicians to use for

diagnosis (following replication of the findings in this study with larger sample sizes and analysis of test-retest and inter-rater reliability).

In terms of national healthcare, it may also be possible to update National Health Service (NHS) standard practices to include administration of the ITI to assess both PTSD and CPTSD (once further research and testing with larger sample sizes has been conducted). This would be a significant advancement as there is presently no validated measure of both disorders for use by NHS clinicians.

7.5.2.3 Clinical implications

As discussed previously, the clinical implications of this study are limited due to difficulties in drawing reliable conclusions from small sample sizes. However, based on the findings of this study, recommendation can be made for the use of the ITI as a supplemental assessment tool for diagnosing PTSD and CPTSD, and should be subject to further validation research. The research in this thesis does not support the use of the ITI as a standalone assessment tool, so in clinical practice it must be used in conjunction with information from other sources such as the ITQ, and clinical judgement. Further research on the English version of the ITI is recommended.

7.6 Strengths and limitations of the thesis

Each analytic chapter of this thesis discusses the limitations of the data specific to each analysis, and these were detailed further in the discussion chapter. However, there are some overall limitations that must be considered. For example, the vast majority of the data collected is self-report in nature. The issues with self-report data includes social desirability bias (the tendency for participants to report either the responses they believe the researcher wants them to say, or responses that

they believe will give the researcher a higher opinion of them), and the possibility of participants misunderstanding the items on the questionnaire (Myers, 2000; Stone et al., 1999; Theofanidis et al., 2018; Visted et al., 2017) Additionally, the cross-sectional design of both studies mean that it is not possible to evaluate causal relationships or the sequence in which symptoms developed.

However, the self-report data and cross-sectional study design allowed for a very large sample to be recruited for study two of this thesis. This is a great strength, as it can confidently be said that the full population characteristics were captured, and the findings were very strong. The sample gathered was much larger than indicated by the power calculation performed in 3.7, which did bring with it the risk of artificially inflated p values, but this was mitigated with the use of Cohen's d as a standardised effect size. This reduced the risk of a type I error to within an acceptable limit.

The greatest limitation of this thesis is the small sample size in study three. The power calculation detailed in chapter five identified the need for 44 participants to achieve the desired statistical power, and the target for recruitment set in the ethics application was 200. However, the final sample for this study was 25, falling short by 19. This represents a significant flaw in the ability of this study to draw reliable conclusions, as the sample does not appropriately reflect the diversity of the population and does not give sufficient power to the analysis. Conclusions drawn from this data can therefore be regarded as suggestive rather than comprehensive.

One key aspect of reliability is interrater reliability (Bondjers et al., 2019; Gelezelyte et al., 2022), and the fact that study three did not analyse interrater reliability has negative implications for the ability to draw conclusions about the

suitability for the use of the ITI in clinical practice. While analysis of interrater reliability was in the ethics application and initial protocol for the ITI validation study, it quickly became apparent that this analysis would not be feasible. Very few participants agreed to have their interviews recorded, which is understandable, since the topic of the interview was of an extremely sensitive nature. This, coupled with the fact that recruitment overall was very poor, meant that the target sample of 10 recorded interviews was not achieved. However, this difficulty was seized and transformed into a strength instead. The two recorded interviews that were achieved were transcribed and sent to a trained clinician (as described in the ethics application and participant information pack) and feedback was provided to the primary researcher conducting the interviews. This feedback was vital in calibrating the administration of the ITI, as this novel interview protocol must be administered and scored as intended.

7.7 Conclusion

The primary objective of this thesis was to answer three main research questions. The results of this thesis, from the meta-analysis, survey study, and ITI validation study, have successfully provided answers to these questions, to a greater or lesser extent. Unfortunately, it was beyond the scope of this study to provide an extensive validation of ITI or an evaluation of how the ITI was perceived by participants.

The three studies conducted in this thesis each produced findings and data that the following study used and built on. Study one began by collating and synthesizing existing data and identifying a number of gaps in the current literature around the relationship between NCBs and PTSD/CPTSD symptom profiles. Study two built on the work of study one, successfully filling the gaps in the literature and

identifying results that supported the M&I model of CPTSD and identifying the need for a clinician-administered assessment tool for ICD-11 PTSD and CPTSD. Finally, study three administered the ITI to a group of participants with the intention to supply evidence in support of the validity and reliability of the ITI. This final aim was partially filled, but of course further research is needed.

7.7.1 Research Question 1: What does the current literature show regarding the relationship between DSO symptoms and NCBs?

At the time of writing, the current literature is sparse on the subject of the correlation between DSO symptoms and NCBs. The available data on this correlation indicated mild to moderate positive relationships between individual DSO symptoms and NCBs. A strong conclusion could not be drawn at the conclusion of this review, due to the poor quality of the available evidence, and the use of proxy measures of DSO symptoms.

7.7.2 Research Question 2: How are NCBs related to ICD-11 PTSD, CPTSD and DSO symptoms?

The results and discussion of the studies in this thesis indicate that there is a strong, positive correlation between NCBs and CPTSD symptom endorsement. Participants with CPTSD symptomology endorsed NCBs more strongly than participants with PTSD or subclinical symptomology. Those meeting PTSD criteria did not endorse NCBs at a level differing from participants with subclinical symptoms. All NCBs most strongly correlated with the DSO symptom of negative self-concept, which again supports claims made in the M&I theory. A temporal or causal relationship could not be determined at this time, due to the cross-sectional nature of the study design.

7.7.3 Research Question 3: Is the ITI a reliable and valid tool for assessing ICD-11 PTSD and CPTSD?

This question can only be answered tentatively at present, given the issues with recruitment and the subsequent small sample size. Overall, it appears that the ITI is a reliable and valid tool for assessing ICD-11 PTSD and CPTSD. Observations from the interviewer indicated that discrepancies between the ITI and ITQ outcomes were mostly due to participant misunderstanding of the items on the ITQ, or due to symptom crossover between CPTSD and PD. Further research is certainly needed in this area before the ITI can, without reservation, be declared a valid and reliable measure of ICD-11 PTSD and CPTSD.

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9 Appendices

9.1 Table of screened and excluded studies

Authors	Year	Reason for exclusion
Akyunus & Gençöz	2019	Self-NCB measure not present
Baker et al	2016	Self-NCB measure not present
Barnow et al	2009	Self-NCB measure not present
Bartholomaeus & Strelan	2016	Self-NCB measure not present
Beretta et al	2005	Self-NCB measure not present
Besser et al	2008	Self-NCB measure not present
Birkley & Eckhardt	2019	Self-NCB measure not present
Borges & Dell'Aglio	2020	Sample not suitable
Bornstein et al	2005	DSO measure not present
Calevete et al	2005	Self-NCB measure not present
Casale et al	2016	Self-NCB measure not present
Chatav & Whisman	2009	Self-NCB measure not present
Collett et al	2016	DSO measure not present
Cracco et al	2020	Self-NCB measure not present
Daneshmandi et al	2018	Self-NCB measure not present
DePrince et al	2009	Self-NCB measure not present
Dorrestejin et al	2019	Self-NCB measure not present
Flett et al	2012	Self-NCB measure not present
Flett et al	2016	Self-NCB measure not present
Ford et al	2018	Self-NCB measure not present
Gude & Hoffart	2008	Self-NCB measure not present
Holmes et al	2019	Self-NCB measure not present
Huang & Murninghan	2010	Self-NCB measure not present
Ingram et al	1990	DSO measure not present

Ingram et al	2007	Self-NCB measure not present
Karbasdehi et al	2018	Self-NCB measure not present
Kawashima et al	2016	Self-NCB measure not present
Khalili et al	2022	Usable data not provided or made available upon request
Kimball et al	2019	DSO measure not present
Kneeland et al	2016	Self-NCB measure not present
Kopala-Sibley & Santor	2009	Self-NCB measure not present
Lau, Haigh et al	2012	Self-NCB measure not present
Leahy et al	2019	Self-NCB measure not present
Lightsey et al	2013	Self-NCB measure not present
Lightsey et al	2012	Self-NCB measure not present
Mahali et al	2020	Self-NCB measure not present
Mathew et al	2014	Self-NCB measure not present
Manser et al	2012	Self-NCB measure not present
Martin et al	2018	DSO measure not present
Mazloom et al	2016	Self-NCB measure not present
McKellar et al	1996	Self-NCB measure not present
Nicol et al	2022	Sample not suitable
Nordhal et al	2005	DSO measure not present
Norman et al	1988	Self-NCB measure not present
Peden et al	2000	DSO measure not present
Pirgablou et al	2013	Self-NCB measure not present
Quinlan et al	2018	Self-NCB measure not present
Quirk et al	2015	DSO measure not present
Soygüt & Savaşir	2001	Self-NCB measure not present
Stewart & Harkness	2016	Self-NCB measure not present
Suh et al	2019	Self-NCB measure not present
Swami & Mammadova	2012	Self-NCB measure not present

Thomas & Larkin	2020	Self-NCB measure not present
Tilden & Dattilio	2005	Self-NCB measure not present
Vaillaincourt-Morel et al	2019	Sample not suitable
Valdez et al	2013	Self-NCB measure not present
Vasilopoulou et al	2020	Single DSO measure not present
Wells et al	2016	Self-NCB measure not present
Yesilaprak et al	2019	DSO measure not present

9.2 AHRQ scoring criteria

AHRQ aspect	Criteria	Scoring
Unbiased selection of cohort	Inclusion/exclusion criteria and rationale clear Recruitment strategy and rationale described clearly Recruitment strategy free from bias (i.e., not advertising in specific publications, not only undergraduate students participating etc.)?	Yes- all criteria met Partial- two criteria met No- ≤ one criterion met, or recruitment strategy is deemed to be at risk of bias Unclear- it is not clear whether a criterion is met
Sample size calculation	A sample size calculation was conducted and published Actual recruitment meets target set using calculation (10% tolerance) If no calculation is published, sample size is adequate to detect effects at desired level	Yes- all criteria met Partial- sample size calculation conducted but recruitment target not met No- no sample size calculation published and/or small sample size Unclear- it is not clear whether any criterion was met
Adequate description of cohort	Reported age characteristics of sample Reported sex or gender characteristics of sample Reported education characteristics of sample Reported ethnicity characteristics of sample Reported employment characteristics of sample.	Yes- four or five criteria reported (if only four reported, omitted criterion must be ethnicity, education, or employment) Partial- two or three criteria reported, or four criteria reported with age or gender criteria omitted No- ≤ one criteria reported, or < four criteria reported with age or gender omitted
Validated DSO assessment tool	Valid and reliable measure used to measure presence of DSO symptom	Yes- validated measure used Partial- measure used is validated but validation research is of poor quality or inconclusive No- measurement tool is unvalidated Unclear- tool used to measure DSO symptom is not described
Validated NCB assessment tool	Valid and reliable measure used to measure presence of NCB (N.B. for the purposes of this paper, and due to the reasons listed in section **Error! Reference source not found.**, the YSQ is considered a non-validated tool)	Yes- validated measure used Partial- measure used is validated but validation research is of poor quality or inconclusive (i.e., use of YSQ) No- measurement tool is unvalidated Unclear- tool used to measure NCB is not described

Missing data low or well-handled	It is clear how missing or incomplete data was identified and accounted for Missing data does not exceed 20% Appropriate analytic methods were employed to minimise bias from missing data There is no reason to assume that any portion of data is missing	Yes- reported no missing or incomplete data, or all four above criteria met Partial- missing data exceeds 20%, or two to three criteria are met No- ≤ one criteria met Unclear- missing or incomplete data not referenced
Analytic methods appropriate	Analysis is appropriate for the type of data collected (i.e., categorical, continuous etc.) Number of variables appropriate for the sample size	Yes- both criteria met Partial- one criterion met No- neither criterion met Unclear- not enough information to determine suitability of analytic methods

9.3 Upgrading and downgrading GRADE risk of bias criterion

Risk of bias within study	Risk of bias across all studies	Interpretation across all studies	Downgrade?
Low risk of bias for all key criteria	Most studies are at low risk of bias	The true effect lies close to the estimated effect	Do not downgrade
Major risk of bias in one major criterion or minor risks of bias in multiple criteria	Most studies are at moderate risk of bias	Substantial possibility that the true effect differs from the estimated effect	Rate down one level
Major risk of bias in multiple major criteria	Most studies are at high risk of bias	It is likely that the true effect is substantially different from the estimated effect	Rate down two levels

9.5 Online survey study data management plan

SIMPLE DATA MANAGEMENT PLAN

PI: **Thanos Karatzias**

Project title: **Building and Testing a Novel Cognitive-Developmental Model for the Development and Maintenance of ICD-11 PTSD and CPTSD**

Project dates: **April 2023 – October 2025**

Project type: **PhD Student**

1. Lay description of the work (max 200 words):

There are currently no theoretical models for the development and maintenance of complex-PTSD, and current models of PTSD are often limited to cognitive mechanisms. This proposal will therefore aim to build and test a new conceptualisation for the development and maintenance of CPTSD and PTSD. The construction of the model will begin by illustrating how adverse and benevolent childhood experiences may act to increase or decrease susceptibility to developing PTSD or CPTSD after trauma exposure. To do this, latent classes of both ACEs and BCEs will be identified, as currently no research has identified typologies of BCEs independently of or concurrently with ACEs.

Secondly, the model will explore the mechanisms of event centrality, negative core beliefs and rumination as mediators in the relationship between ACEs/BCEs and PTSD/DSO symptomology. This research hypothesises that higher numbers and vulnerable typologies of ACE exposure will increase event centralisation, rumination, and negative core beliefs, which will contribute to the development and maintenance of the symptoms of PTSD and CPTSD. These associations will be stronger or different in CPTSD DSO symptoms. It is also proposed that higher numbers and invulnerable typologies of BCEs will protect against the development/maintenance of the conditions through decreasing maladaptive mechanisms.

2. Short description of methods used to collect and analyse the data

The data will be collected through online survey company TGM Research who maintain nationally representative survey panels in 130 countries. TGM Research will host the online survey, recruit 2000 appropriate participants matching the study criteria and collect the raw data from the measures provided by the research team.

All data from TGM respondents is encoded and presented as a unique ID in the first instance, and the data is presented anonymously and does not violate the provisions of the GDPR. The data will be provided in this form from TGM in excel and SPSS format, and downloadable to the research team via a password protected link. No identifiable participant data is being collected, and participants will be distinguished by an ID number only. Data will therefore be anonymous in any publications. Participant data will be stored and processed within separate password-protected files on the university network which will be accessed securely e.g., via Virtual Desktop/ VPN. Only the researcher will have

access to these files. Non-identifiable data will be entered into a Microsoft excel spreadsheet for storage and processing. All data will be held securely and treated in accordance with the BPS (2009) Code of Ethics and Conduct and BPS (2014) Code of Human Research Ethics guidelines documents and the study will adhere to the principles of Good Clinical Practice.

Data will be collated and analysed through programmes Excel, PDF, SPSS, R and MPlus on the researcher's secure device, and kept securely as outlined below. The methods of analysis will include descriptive statistics, latent class analysis, correlation coefficients and structural equation modelling.

3. What information or data is being collected generated and analysed in this work? (Including secondary data and publicly available information):

a. Types, File Format, software used, and scale:

A large set of quantitative data from 2000 participants will be gathered for this study. File types will include raw data stored in Microsoft Office Word and Excel, alongside CSV files. Analysed data will be stored in SPSS, R and MPlus outputs and written up in Word and PDF documents. The researcher will collect the following:

- Participants gender, age, residence, ethnicity, highest qualification, religion, employment status, income, and if the participant has received any past treatment for mental health difficulties. Since the data is being generated online, IP addresses will also be collected.
- Participants' scores on International Trauma Questionnaire (ITQ)
- Details on Participants' most important traumatic event (ITEM)
- Participants scores on The Adverse Childhood Experiences Scale (ACE)
- Participants scores on A Brief Positive School Experiences (B-PSEs)
- Participants scores on The Memories of Home and Family Scale Short Form (MHFS-SF)
- Participants scores on The Benevolent Childhood Experiences Scale
- Participants' scores on The Centrality of Events Scale (CES)
- Participants' scores on The Ruminative Response Scale (RRS) Brooding Subscale
- Participants' scores on the Core Beliefs Questionnaire (CBQ)

b. How will this be collected:

The data will be collected via the host company TGM Research. TGM Research will create, disseminate, and host the online survey, and will recruit 2000 appropriate participants matching the study criteria. TGM Research will collect the raw data from the measures provided by the research team and then provide this securely to the researcher via a password protected link.

All data from TGM respondents is encoded and presented as a unique ID, and the data is presented anonymously and does not violate the provisions of the GDPR. Additionally, the respondent by registering to the TGM panel consents to the processing of their data by TGM and by participating in the survey, they also consent to the collective data processing by TGM partners. Data for this project will be sent by TGM to the research team via SPSS and excel format – no PIIs will be collected for this project.

c. What is retention period of data/information/documents:

TGM Research will delete the data from their secure servers once the study is complete. Exclusive use of data will be maintained by the research team until the completion of the study project (estimated October 2025). After this time, the data will be available upon request from the University repository.

The Edinburgh Napier Data Management Policy states requires research data to be retained after project completion if they substantiate research findings, are of potential long-term value or support a patent for at least 10 years. The policy also requires that funders and/or sponsors requirements are met. Long term storage is provided through the University data repository.

4. How will the information or data be stored or curated

Data storage: Digital research data/information will be stored on the University's X:drive (V:Drive for students). University-managed data storage is resilient, with multiple copies stored in more than one physical location and protection against corruption. Daily backups are kept for 14 days and monthly backups for an additional year.

Metadata: All research data will be organized as per the Universities metadata standards http://staff.napier.ac.uk/services/research-innovation-office/research-data/Pages/Organising.aspx

Data preservation: The Edinburgh Napier Data Management Policy states requires research data to be retained after project completion if they **substantiate research** findings, are of potential long-term value or support a patent for at least 10 years. The policy also requires that funders and/or sponsors requirements are met. Long term storage is provided through the University data repository.

4. Summarise the main risks to the confidentiality and security of information:

Napier University meets the Cyber Essential standards for data stored in the X:Drive/V:drive.

All research data will be organized as per the Universities metadata standards http://staff.napier.ac.uk/services/research-innovation-office/research-data/Pages/Organising.aspx

Storage of digital data will be on university computer V-Drives. In these instances, firewall protection is in place to ensure security of data. All data processing will take place on university computers or on a virtual desktop on a home computer. This means that at all times data will be protected by university firewalls, and erasure of data from home pc hard drives is not necessary.

When collecting and transferring data to X:Drive/V:Drive or sharing with collaborators the risks and mitigations are:

It is unlikely but possible that data may be breached during the transfer from TGM Research to the university X:Drive/V:Drive, or when shared amongst the research team.

This may occur if data is transferred insecurely, to an incorrect recipient or third party, downloaded to a personal or insecure device which may become compromised, or if data is lost or altered during transfer.

These risks have been mitigated by the sole use of the university's secure storage by all of the research team ensuring that the data is stored securely at all times. Personal data will not be shared via any insecure means such as email. The data will be transferred by TGM Research via a password protected link, of which the download link and the password will be sent separately. This will limit the possibility of any data breaches from a third party or incorrect recipient.

5. Data sharing and access

Suitability for sharing: Data generated by the project (identified above) will be made open once appropriate changes have been made to honour assurances of confidentiality and anonymity.

Where data may not be freely available the metadata only will be made available in the repository and the datasets available on request and subject to a data sharing agreement

Discoverability: Datasets will be allocated a DOI and stored on our open access Research Repository in accordance with the University research data deposit process. The DOI and the datasets will be made available to the repository within three months of the end of the grant/project.

6. Governance of access to shared data

Who makes decision on whether a new user can access the data/information?

Not required when data is fully open. Where data may not be freely available a decision to share will be made jointly between the PI and the University data access panel

Are there any restrictions on making data/information available? Eg ethics, IP, confidentiality agreements. If so, please detail here:

No restrictions.

Researchers will have exclusive use of the data prior to publication. Exclusive use of data will be maintained by the research team until the completion of the study project (estimated October 2025). After this time, the data will be available upon request from the University repository. Where data may not be freely available the metadata only will be made available in the repository and the datasets available on request and subject to a data sharing agreement which will prohibit any attempt to breach confidentiality. The data sharing agreement will also include specific individuals to whom the data will be released, the purposes for the release of data, any constrains on publication of the data, and arrangements for data destruction or secure archiving on the part of the individuals using the data.

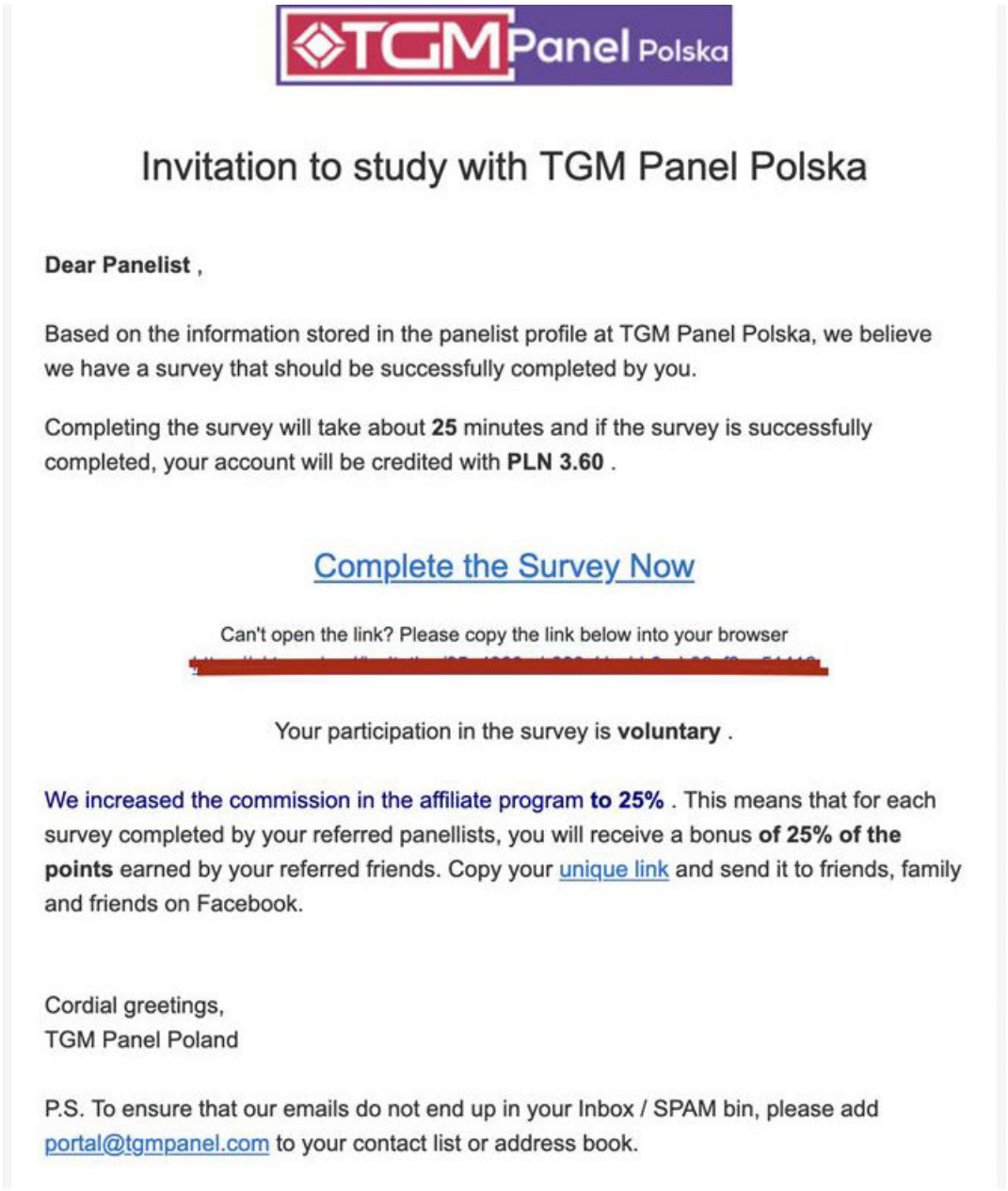
7. Responsibilities:

The first point of contact for all queries in relation to this data is the PI. Who will also have overall responsibility for the production and maintenance of metadata. Preparation and upload of the data will be carried out by the team with the support of the University's Information Services staff.

University policies

Data Management Policy & Procedures	*https://staff.napier.ac.uk/services/research-innovation-office/policies/Documents/Research%20Data%20Management%20Policy%202022.pdf*
Data Security Policy	*http://staff.napier.ac.uk/services/cit/infosecurity/Pages/InformationSecurityPolicy.aspx*
Data Sharing Policy	*http://staff.napier.ac.uk/services/secretary/governance/DataProtection/Pages/DataSharing.aspx*
Data Protection for Research	*https://staff.napier.ac.uk/services/governance-compliance/governance/DataProtection/Pages/ProcessingDataforResearch.aspx*

9.6 Online survey invitation to participate



TGM Panel Polska

Invitation to study with TGM Panel Polska

Dear Panelist ,

Based on the information stored in the panelist profile at TGM Panel Polska, we believe we have a survey that should be successfully completed by you.

Completing the survey will take about **25** minutes and if the survey is successfully completed, your account will be credited with **PLN 3.60** .

Complete the Survey Now

Can't open the link? Please copy the link below into your browser

Your participation in the survey is **voluntary** .

We increased the commission in the affiliate program **to 25%** . This means that for each survey completed by your referred panellists, you will receive a bonus **of 25% of the points** earned by your referred friends. Copy your unique link and send it to friends, family and friends on Facebook.

Cordial greetings,
TGM Panel Poland

P.S. To ensure that our emails do not end up in your Inbox / SPAM bin, please add portal@tgmpanel.com to your contact list or address book.

9.7 Online survey participant information sheet

Participant Information

You are invited to take part in a research study. Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. You may talk to others about the study if you wish. Please feel free to contact me if there is anything that is not clear or if you would like more information: sarah.guthrie@napier.ac.uk. Take as much time as you need to decide whether you wish to take part or not.

Project title: Building and Testing a Novel Cognitive-Developmental Model for the Development and Maintenance of ICD-11 PTSD and CPTSD

Principal Investigator: Professor Thanos Karatzias, School of Health and Social Care, Edinburgh Napier University

Research Team: Sarah Guthrie (Edinburgh Napier University, Scotland), Professor Thanos Karatzias (Edinburgh Napier University, Scotland), Professor Anna Bak-Klimek (Edinburgh Napier University, Scotland), Professor Mark Shevlin (Ulster University, Northern Ireland).

Research Purpose and Procedures: We are hoping to better understand how Post Traumatic Stress Disorder and Complex-Post Traumatic Stress Disorder develop after an individual has been exposed to a traumatic or stressful life event. To do this, we are considering the role of your positive and negative childhood experiences, your personal identity, and your thought patterns, and how these may or may not influence the later development of the conditions. You do not need to have a diagnosis to take part, but we are looking for individuals who have experienced traumatic or stressful life events.

By taking part in this research, you will be contributing to the understanding of mental health conditions, and how we may be affected by traumatic and stressful life events. We are recruiting adults from the general public based in the United Kingdom and Northern Ireland and you are invited to participate. This survey is open to members of the UK population aged 18-30 who have experienced a traumatic event. We have three key objectives for this research:

1. To assess the different types of positive and negative childhood experiences, and how these may be related to each other

2. To explore the impact of both positive and negative childhood experiences on the development and maintenance of PTSD and complex-PTSD

3. To examine if this relationship is impacted by thought patterns and personal identity, and if positive childhood experiences can protect against the conditions in any way.

You are under no obligation to participate in this survey. If you do choose to participate, it is expected to take approximately 25-30 minutes to complete the survey

Participants who are ineligible due to their age or who answer “never” to all trauma exposure items on the ITEM questionnaire will not be reimbursed, as well as those who withdraw from the study.

Survey Content:

In this survey, you will be asked to provide us with some demographic information including your gender, age, country of residence ethnicity, education level, religious beliefs, employment status, income, and if you have received any past treatment for any mental health difficulties. This information will be stored in a way that means it will not be able to be traced back to you and it will not be identifiable. This information will allow us to better understand the features of the population that has completed our survey.

Following this, you will be asked questions surrounding your experiences of traumatic and stressful life events, positive and negative childhood experiences, your current mental health status, your day-to-day functioning, your core beliefs about yourself and how you believe others see you, and your thinking patterns.

Risks and discomforts:

If you anticipate that answering the above questions will lead you to feel emotionally distressed or upset, please think carefully as to whether you would like to participate. If you choose to participate and find yourself becoming distressed at any time, you may stop and withdraw from the study. You can simply close the browser at any time. We believe, based on years of scientific evidence, that the risk of becoming distressed is very low. However, at the end of the survey we will provide you with information on organisations that provide free mental health services that should you feel in anyway distressed you can get in contact with. We do not think there are any other risks with this study, however, any study can have risks we are not aware of yet. We will strive to avoid any risks and will inform you as soon as possible should any risks arise.

Potential benefits:

Research using your data will help us to better understand how many people in the United Kingdom and Northern Ireland are affected by exposure to a traumatic or stressful life event, and how positive and negative childhood experiences may influence the way we react to these events and potentially influence our likelihood of developing PTSD or complex-PTSD. Your answers will also enable us to gain a better understanding of the proportion of the general population experiencing post-trauma related disorders as a result of traumatic and stressful life events and the factors which increase the risk for the development of such disorders. We hope this can help us to provide improved care and treatment for people affected by PTSD and CPTSD.

Provisions for confidentiality and data storage:

Your privacy is of upmost importance to us. All your responses will be kept strictly confidential, and all the data you provide will be completely anonymised. Your responses will only be accessible to members of the research team; however, the research team will never have access to any information that could be used to determine your identity. All your responses will be collected, stored, and used in full compliance with the European Commission's General Data Protection Regulations. All data collected will be stored on a password-protected, secured, and networked computer at Edinburgh Napier University. Although the research team will not have access to any of your personal information or contact details, TGM (the survey company) retains this information and may contact you in the future to invite you to participate in a follow-up study. There are, however, legal limits to confidentiality that you should be aware of. In exceptional circumstances, confidentiality of research data and records may be overridden by courts in the event of litigation or during investigation by lawful authority. In such circumstances, Edinburgh Napier University will take reasonable steps within the law to ensure that confidentiality is maintained to the greatest possible extent.

Voluntary participation and informed consent:

You don't have to take part in this study, you can refuse to take part if you want to. You can change your mind about participating in the study and opt out at any time even if the study has started. If you decide that you would like to participate in this study, you will be asked to provide informed consent by checking a box on the survey site. By doing so, you will be provided access to the survey questions. You will not be able to withdraw once you have submitted your responses.

Ethical Approval for this Study:

A favourable ethical opinion has been obtained the School of Health and Social Care Research and Integrity Committee at Edinburgh Napier University (REF: TBC).

Contact Details of Research Team:

Should you have any questions prior to, during, or after the research, you may contact the Principal Investigator of the project: Professor Thanos Karatzias, School of Health and Social Care, Edinburgh Napier University [redacted]

If you would like to discuss this study with an independent person, please contact Amanda Woodrow: [redacted]

9.8 Online survey privacy notice

Privacy notice

Name of Research Project: Building and Testing a Novel Cognitive-Developmental Model for the Development and Maintenance of ICD-11 PTSD and CPTSD

Description of Project: The study involves participants completing a series of self-report measures through the online survey platform TGM Research

Data Controller	Edinburgh Napier University
Purposes for collection/ processing	To validate a new cognitive-developmental model for the development and maintenance of ICD-11 PTSD and CPTSD
Legal basis	Art 6(1)(e), performance of a task in the public interest/exercise of official duty vested in the Controller by Statutory Instrument No. 557 (S76) of 1993 as amended, e.g. for education and research purposes. Where sensitive personal data is being processed the additional bases from Article 9 is: Art 9(2)(j) for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes. All staff involved in this project will receive data quality and management, confidentiality, and record-keeping training
Whose information is being collected?	Participants from the general UK population accessible from TGMs nationally representative survey panels
What type/classes/fields of information are collected?	• Participants' gender, age, residence ethnicity, highest qualification, religion, employment status, income, and if the participant has received any past treatment for mental health difficulties. • Participants' scores on International Trauma Questionnaire (ITQ) • Details on Participants' most important traumatic event (ITEM) • Participants scores on The Adverse Childhood Experiences Scale (ACE) • Participants' scores on A Brief Positive School Experiences (B-PSEs) • Participants' scores on The Memories of Home and Family Scale Short Form (MHFS-SF) • Participants' scores on The Benevolent Childhood Experiences Scale

	• Participants' scores on The Centrality of Events Scale (CES) • Participants' scores on The Ruminative Response Scale (RRS) Brooding Subscale • Participants' scores on the Core Beliefs Questionnaire (CBQ)
Who is the information being collected from?	Data is being collected directly from you as the participant in the study.
How is the information being collected?	Participant data is being collected through online survey company TGM Research
Is personal data shared externally?	No
How secure is the information?	Electronic information will be stored on the University network (which will be accessed remotely via secure methods e.g., Virtual Desktop or Virtual Private Network provided by the University) and therefore protected by university policies and procedures. TGM Research ensures that the research data we are provided with does not enable us to identify you. At the end of the project, the data will be stored within the university information repository, with all remaining copies of digital data being erased.
Who keeps the information updated?	Participants should advise the researcher of any updates to their personal data, where this is necessary. The researcher will have responsibility for keeping information updated if required.
How long is the information kept for?	Data will be retained in the university repository for 10 years. This does not include personal data such as dates of birth and ethnicity, which will be destroyed after the end of the project.
Will the data be used for any automated decision making?	No
Is information transferred to a third country? Outside the UK and not included in the adequate countries list.	No

Will the data from the ITI be transferred to any other third party?	No

You can access all the University's privacy notices using the following link: https://staff.napier.ac.uk/services/governance-compliance/governance/DataProtection/Pages/statement.aspx

You have a number of rights available to you with regards to what personal data of yours is held by the University and how it is processed – to find out more about your rights, how to make a request and who to contact if you have any further queries about Data Protection please see the information online using the following URL: https://staff.napier.ac.uk/services/governance-compliance/governance/DataProtection/Pages/default.aspx

9.9 Online survey consent form

Informed consent for research participation

Project title: Building and Testing a Novel Cognitive-Developmental Model for the Development and Maintenance of ICD-11 PTSD and CPTSD

Principal Investigator: Thanos Karatzias, School of Health and Social Care, Edinburgh Napier University.

Informed Consent Statement:

I understand that I will be asked questions surrounding my experiences of traumatic and stressful life events, my positive and negative childhood experiences, my current mental health status, my day-to-day functioning, my core beliefs about myself and how I believe others see me, and my thinking patterns.

I further understand that it will take approximately 25-30 minutes to complete this survey and that I may stop answering the questions at any time that I wish. I can close the browser at any time. I am aware that all information provided is anonymous, confidential, and will be stored by the Research Team in accordance with General Data Protection Regulations. I am aware that if this research upsets me in any way and wish to discuss or report any issues with the study, I can contact the research team directly (t.karatzias@napier.ac.uk). I understand I will not be able to withdraw once I have submitted my responses. I have read, or had read to me, the Participant Information Form for this project (Version 2 26/4/23) and I understand the contents. I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights.

I understand that data collected for the study may be shared with other researchers (on an anonymous basis). Data sharing will only be conducted as per UK Data Protection Act 2018 and UK GDPR (General Data Protection Regulation) subject to a suitable data sharing agreement with Edinburgh Napier University.

I give consent for this form to stored electronically on the Edinburgh Napier University secure research computer drive.

o By clicking on this button I consent to participate in this survey

o I am at least 18 years old

o I refuse to participate- [terminate respondents]

9.10 International Trauma Exposure Measure

INTERNATIONAL TRAUMA EXPOSURE MEASURE (ITEM)

OVERVIEW: The ***International Trauma Exposure Measure*** (ITEM) is a new checklist developed to capture traumatic life events, and their associated features, in a manner consistent with the definition of a traumatic event in the 11th version of the International Classification of Diseases.

The ITEM measures exposure to different traumatic life events across different developmental periods (childhood, adolescence, and adulthood); frequency of exposure to one's most distressing traumatic event; and the main emotion associated with one's most distressing traumatic event. The ITEM is freely available to the research and clinical communities and may be used without permission.

Please note that the ITEM uses educational descriptors to aid respondents to accurately identify the period of their life in which their trauma occurred. The educational descriptors used in this example are appropriate for the Irish context in which the scale was developed. These descriptors should be amended for the context in which you wish to use the ITEM.

The reference for the ITEM is as follows:

Hyland, P., Karatzias, T., Shevlin, M., McElroy, E., Ben-Ezra, M., Cloitre, M., & Brewin, C. R. (in press). Does requiring trauma exposure affect rates of ICD-11 PTSD and complex PTSD? Implications for DSM-5. *Psychological Trauma: Theory, Research, Practice, and Policy.*

9.13 Online survey debrief sheet

Participant Debriefing Sheet

Thank you for taking the time to complete this survey. The information that you have provided will help us better understand the development and maintenance of PTSD and complex PTSD, potential risk and protective factors in childhood, as well as the impact of unhelpful thought patterns and self-belief's after exposure to a traumatic or stressful life event in the UK general population. We believe that the information that you have provided will contribute greatly to improving the lives of people affected by trauma exposure. If completing this survey led you to feel upset and you would like to speak to a mental health professional, we recommend that you contact your General Practitioner (GP). Your GP will be able to refer you to an appropriate mental health professional. Alternatively, you may contact any of the charitable organisations below who provide free telephone support for individuals experiencing mental health distress, or the consequences of experiencing a traumatic or stressful life event: The Samaritans: 116 123

SANEline: 0300 304 7000

For further information about PTSD and complex PTSD, please visit https://www.ptsduk.org/

If you would like to discuss this study with an independent person, please contact Amanda Woodrow: [redacted]

Thank you again for your participation.

9.14 Instructions to SPSS to create diagnostic groups

Stage	Instructions to SPSS
1	* Compute PTSD category. COMPUTE PTSD_Category = 0. IF (ITQ1.1_Re > 2 OR ITQ1.2_Re > 2) AND (ITQ2.1_Av > 2 OR ITQ2.2_Av > 2) AND (ITQ3.1_Th > 2 OR ITQ3.2_Th > 2) AND (ITQ4.1_FI > 2 OR ITQ4.2_FI > 2 OR ITQ4.3_FI > 2) PTSD_Category = 1. EXECUTE.
2	* Compute CPTSD category. COMPUTE CPTSD_Category = 0. IF (PTSD_Category = 1) AND (ITQ5.1_Ad > 2 OR ITQ5.2_Ad > 2) AND (ITQ6.1_NSC > 2 OR ITQ6.2_NSC > 2) AND (ITQ7.1_DR > 2 OR ITQ7.2_DR > 2) AND (ITQ8.1_DSOFI > 2 OR ITQ8.2_DSOFI > 2 OR ITQ8.3_DSOFI > 2) CPTSD_Category = 1. EXECUTE.
3	* Label the categories. VARIABLE LABELS PTSD_Category "PTSD Category". VARIABLE LABELS CPTSD_Category "CPTSD Category".
4	* Value labels for categories. VALUE LABELS PTSD_Category 0 "Not met criteria" 1 "Met criteria". VALUE LABELS CPTSD_Category 0 "Not met criteria" 1 "Met criteria".

5	* Create diagnostic variable.
	STRING Diagnosis (A20).
	DO IF (PTSD_Category = 0 AND CPTSD_Category = 0).
	  COMPUTE Diagnosis = "No diagnosis".
	ELSE IF (PTSD_Category = 1 AND CPTSD_Category = 0).
	  COMPUTE Diagnosis = "PTSD diagnosis".
	ELSE IF (PTSD_Category = 1 AND CPTSD_Category = 1).
	  COMPUTE Diagnosis = "CPTSD diagnosis".
	END IF.
	EXECUTE.

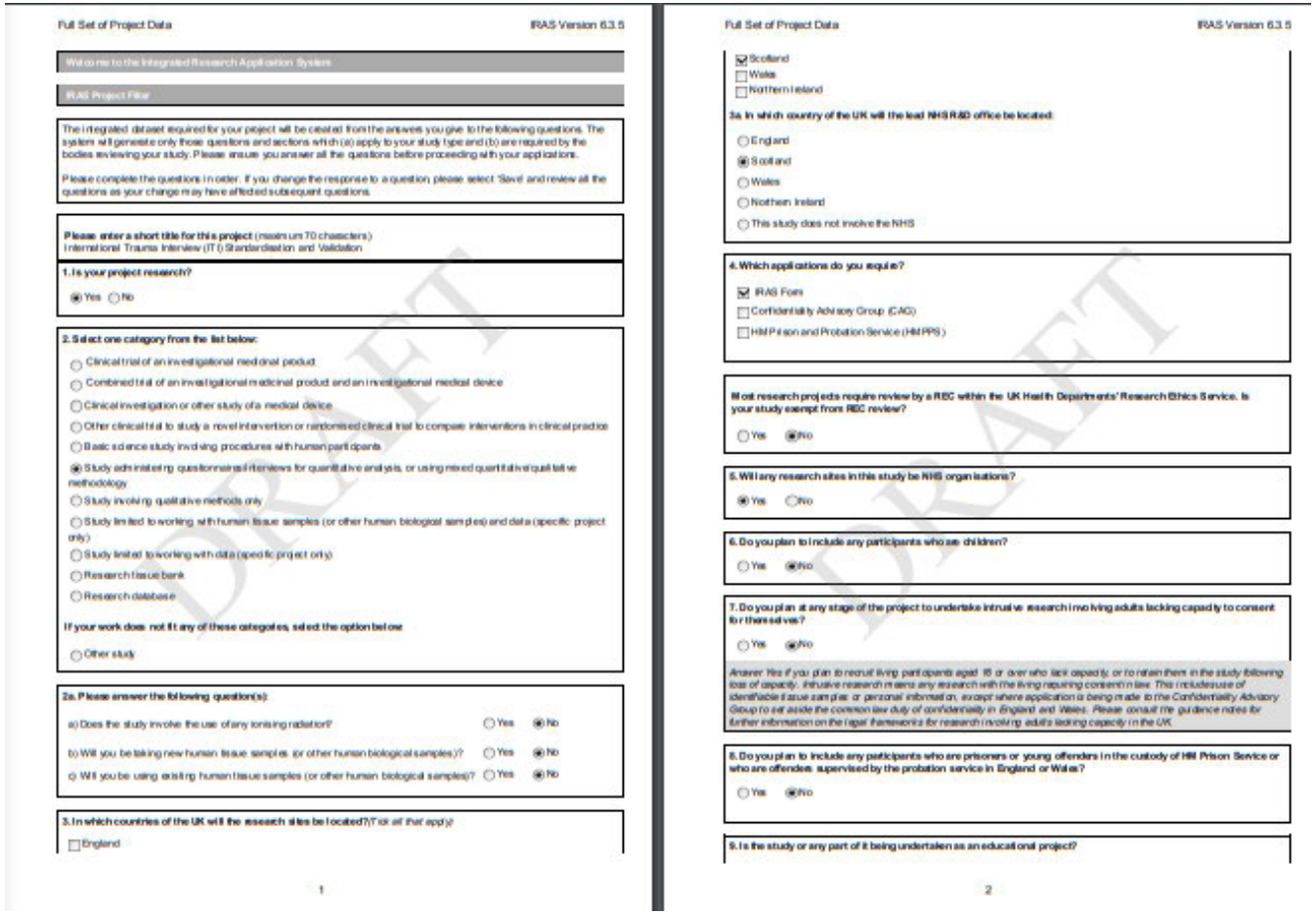
6	* Define missing values for Diagnosis. MISSING VALUES Diagnosis ('').
7	* Label the diagnosis variable. VARIABLE LABELS Diagnosis "Diagnosis".

8	* Value labels for diagnosis.
	VALUE LABELS Diagnosis
	  "No diagnosis" "No diagnosis"
	  "PTSD diagnosis" "PTSD diagnosis"
	  "CPTSD diagnosis" "CPTSD diagnosis".

9.15 Interpersonal and non-interpersonal traumatic events

Item	Interpersonal or non-interpersonal
You were diagnosed with a life-threatening illness.	Non-interpersonal
Someone close to you died in an awful manner.	Non-interpersonal
Someone close to you was diagnosed with a life-threatening illness or experienced a life-threatening accident.	Non-interpersonal
Someone threatened your life with a weapon (knife, gun, bomb etc.)	Interpersonal
You were physically assaulted (punched, kicked, slapped, mugged, robbed etc.) **by a parent or guardian**.	Interpersonal
You were physically assaulted (punched, kicked, slapped, mugged, robbed etc.) **by someone other than a parent or guardian**.	Interpersonal
You were sexually assaulted (anal, vaginal, or oral penetration, or any contact with sexual parts) **by a parent or guardian**.	Interpersonal
You were sexually assaulted (anal, vaginal, or oral penetration, or any contact with sexual parts) **by someone other than a parent or guardian**.	Interpersonal
You were sexually harassed (unwanted sexualized comments or behaviours).	Interpersonal
You were exposed to war or combat (as a soldier or as a civilian).	Interpersonal
You were held captive and/or tortured.	Interpersonal
You caused extreme suffering or death to another person.	Interpersonal
You witnessed another person experiencing extreme suffering or death.	Non-interpersonal
You were involved in an accident (e.g., transportation, work, home, leisure) where your life was in danger.	Non-interpersonal
You were exposed to a natural disaster (e.g., hurricane, tsunami, earthquake) where your life was in danger.	Non-interpersonal
You were exposed to a man-made disaster (e.g., terrorist attack, chemical spill, public shooting) where your life was in danger.	Non-interpersonal
Another person stalked you.	Interpersonal
You were repeatedly bullied (online or offline).	Interpersonal
You were humiliated, put down, or insulted by another person.	Interpersonal
You were made to feel unloved, unwelcome, or worthless.	Interpersonal
You were neglected, ignored, rejected, or isolated.	Interpersonal
Any other event not listed (please specify).	Either

9.16 Validation study ethics application



Full Set of Project Data IRAS Version 6.3.5

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
International Trauma Interview (ITI) Standardisation and Validation

1. Is your project research?

(•) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product
( ) Combined trial of an investigational medicinal product and an investigational medical device
( ) Clinical investigation or other study of a medical device
( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
( ) Basic science study involving procedures with human participants
(•) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
( ) Study involving qualitative methods only
( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
( ) Study limited to working with data (specific project only)
( ) Research tissue bank
( ) Research database

If your work does not fit any of these categories, select the option below

( ) Other study

2a. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation? ( ) Yes (•) No
b) Will you be taking new human tissue samples (or other human biological samples)? ( ) Yes (•) No
c) Will you be using existing human tissue samples (or other human biological samples)? ( ) Yes (•) No

3. In which countries of the UK will the research sites be located? (Tick all that apply)

☐ England

1

Full Set of Project Data IRAS Version 6.3.5

☑ Scotland
☐ Wales
☐ Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

( ) England
(•) Scotland
( ) Wales
( ) Northern Ireland
( ) This study does not involve the NHS

4. Which applications do you require?

☑ IRAS Form
☐ Confidentiality Advisory Group (CAG)
☐ HM Prison and Probation Service (HMPPS)

Most research projects require review by a REC within the UK Health Departments' Research Ethics Service. Is your study exempt from REC review?

( ) Yes (•) No

5. Will any research sites in this study be NHS organisations?

(•) Yes ( ) No

6. Do you plan to include any participants who are children?

( ) Yes (•) No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

( ) Yes (•) No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

( ) Yes (•) No

9. Is the study or any part of it being undertaken as an educational project?

2

◉ Yes ○ No

Please describe briefly the involvement of the student(s):
The researcher is a doctoral candidate at Edinburgh Napier University.
This project will form part of a doctoral thesis submission.

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

◉ Yes ○ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ◉ No

Integrated Research Application System
Application Form for Research administering questionnaires/interviews for quantitative analysis or mixed methodology study

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familiar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
International Trauma Interview (ITI) Standardisation and Validation

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

Towards the validation of the International Trauma Interview (ITI) for the ICD-11 diagnoses of Post-Traumatic Stress Disorder and Complex Post-Traumatic Stress disorder, and the role of core beliefs

A2-1. Educational projects

Name and contact details of student(s):

Student 1

Address [redacted]

Post Code
E-mail
Telephone
Fax

Give details of the educational course or degree for which this research is being undertaken:

Name and level of course/degree:
PhD Psychology

Name of educational establishment:
Edinburgh Napier University

Name and contact details of academic supervisor(s):

Academic supervisor 1

Title	Forename/initials	Surname
Professor	Thanos	Karatzias

Address [redacted]

Post Code
E-mail
Telephone
Fax

Academic supervisor 2

Address [redacted]

Post Code
E-mail
Telephone
Fax

Please state which academic supervisor(s) has responsibility for which student(s)
Please click "Save now" before completing this table. This will ensure that all of the student and academic supervisor details are shown correctly.

Student(s)	Academic supervisor(s)
Student 1 Miss Zoe Wagland	☑ Professor Thanos Karatzias
	☑ Dr Philip Hyland

A copy of a current CV for the student and the academic supervisor (maximum 2 pages of A4) must be submitted with the application.

A2-2. Who will act as Chief Investigator for this study?

○ Student
◉ Academic supervisor
○ Other

A3-1. Chief Investigator:

Title	Forename/Initials	Surname
Dr	Thanos	Karatzias

Post: Director of Studies, School of Health and Social Care
Qualifications
ORCID ID
Employer
Work Address [redacted]

Post Code

Work E-mail [redacted]
* Personal E-mail
Work Telephone
* Personal Telephone/Mobile
Fax

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*
A copy of a current CV (maximum 3 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and HRA/R&D reviewers that is sent to the CI.

Address [redacted]

Post Code
E-mail
Telephone
Fax

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):	
Sponsor's/protocol number:	N/A
Protocol Version:	N/A
Protocol Date	
Funder's reference number (enter the reference number or state not applicable):	N/A
Project website:	

Additional reference number(s):

Ref. Number Description	Reference Number

Registration of research studies is encouraged wherever possible. You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you have registered your study please give details in the "Additional reference number(s)" section.

A5-2. Is this application linked to a previous study or another current application?

○ Yes ◉ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language as comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments' Research Ethics Service, this summary will be published on the Health Research Authority (HRA) website following the ethical review. Please refer to the question specific guidance for this question.*

This study aims to provide an initial validation of the English International Trauma Interview (ITI) and explore its psychometric properties and clinical utility. Secondary aims include clarification around the relationship between maladaptive schemas and the development of complex post-traumatic stress disorder (CPTSD) symptoms later in life and to identify which schemas predict the diagnosis of post-traumatic stress disorder (PTSD) and CPTSD.

The ITI is a two-part semi-structured interview protocol consisting of items relating to symptoms of PTSD and disorders of social organisation (DSO). The first part is based on the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) and uses six items to assess the three symptom clusters commonly related to PTSD (re-experiencing, avoidance, and hypervigilance). The second part of the ITI relates to DSO, again consisting of six total items evaluating three symptom clusters (affect dysregulation, negative self-concept, and interpersonal difficulties). The results of this interview schedule can be interpreted to provide a suggested diagnosis of either PTSD, CPTSD, or non-clinically significant symptoms.

Participants will be recruited from outpatient facilities participating in the study. ITQ, demographic and information on schemas will be collected as self-report measures to be completed prior to a virtual meeting with the researcher. The meeting will take place via Attend Anywhere software. Clinicians from participating facilities will be asked to refer suitable clients. If the client agrees to participate, an appointment will be arranged for the participant to meet with the researcher virtually.

A small number of participants will be invited to attend a second virtual meeting with the researcher, where the ITI will be administered for a second time, to facilitate the assessment of test-retest reliability. Another group of participants audiotaped, and the recordings rated by trained clinicians who will assign a diagnosis. This will enable the analysis of inter-rater reliability.

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, R&D office or other review body as appropriate to the issue. Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

Participants' psychological distress:

The measures used in this study will ask about traumatic experiences, and thought patterns developed from a young age. These measures are regularly used in clinical practice and research. It is possible that speaking about index events may upset or distress participants.

With regards to asking about adverse experiences/trauma in particular, the research literature suggests very minimal risk that asking about trauma leads to any serious or long term consequences (Reid, 2007). A number of studies show that participants, both clinical and non-clinical, recognise the value and importance of trauma research (Cromer et al., 2006) and acknowledge that there may be a societal disadvantage to not asking about trauma, and improving understanding of its impact and effects (Becker-Blease & Freyd, 2006). One study found a minority of participants who reported negative feelings but these dissipated quickly and did not influence the participants overall appraisals of their participation (Legerski & Bunnell, 2010). Eynan et al. (2014) carried out a study to investigate suicidal thoughts in a recently discharged clinical population and found minimal reactivity with no increase in self harm. They conclude that if this type of research is conducted sensitively it is safe, even in a vulnerable clinical population.

Participants will be encouraged to state when they would prefer not to answer any specific questions, and the researcher carrying out the interview will continually assess outward signs of mental state throughout the interview with a view to terminate the interview if undue discomfort is perceived. Participants will be informed of their right to terminate the interview at any point if they feel unable to continue. Rapport with participants will be developed and used to encourage participants to exercise their right to withdraw.

The researcher will be able to contact the supervision team throughout the study for support and advice. The supervision team is comprised of qualified and experienced clinical psychologists who have experience working with patients and with conducting safe and effective research. The researcher will contact them immediately in any case where the participant becomes significantly distressed. Signposting after the interview and a debriefing session will be used to help the participant process their feelings and to ensure that they are in a fit state to leave the centre. Screening prior to participants' inclusion in the study is designed to identify and exclude any persons who may experience significant distress due to participation.

To further reduce distress and burden to participants, meetings will be scheduled to immediately precede or follow on from participants' initial clinical assessments.

Risk to researcher:

Appropriate risk assessments will be completed prior to arranging interview meetings, and NHS best practice guidelines will be followed at all times. Steps will be taken to minimise negative psychological impact on the researcher, including access to university support facilities, and regular contact with the supervision team.

Confidentiality:

Data will be anonymised and maintained in accordance with university and NHS guidelines. Digital data will be kept on a password protected University computer in a locked room. Hard copies of data will not be necessary. Participants' data will be anonymised by the use of initials where written information is stored, and a pseudonym where individual participants are discussed in published works. Participants will be advised of these measures taken to ensure their confidentiality.

It is recognised that confidentiality cannot be maintained in relation to certain disclosures. For example, where there is a risk of harm to the participant or others, this information will be passed on to the supervisory team and the appropriate contacts involved in the client's care. The participants will also be informed of this exception to the confidentiality guidelines. If a disclosure is made by a participant, the ITI will be immediately halted, the researcher will listen empathically, and facilitate the involvement of the participant's therapist/psychologist.

Informed consent and capacity:

Clinicians will be provided with information regarding inclusion criteria and participant information sheets to discuss with potential participants. They will obtain verbal consent from potential participants for the researcher to contact them. The researcher will liaise by telephone with the clinicians to obtain contact details, and discuss the potential participant's eligibility.

Participants will be given the Participant Information Sheet, which will be talked through with the researcher. The participant will be given the opportunity to ask any questions they may have. Consent forms will be signed by both the participant and the researcher once full understanding has been achieved.

It is also required that participants involved in this research have the capacity to consent to their own participation. The clinical staff will be able to give professional insight into potential participants' capacity to consent. If a potential participant is deemed to not have capacity to consent, they will be excluded from the study. If a concern about the person's capacity is raised by anyone at any point, data collection will be halted immediately.

Due to the fact that this study will be conducted via internet video chat, it will not be possible for consent to be gained through usual paper-and-pen methods. Instead, the consent form will be posted or emailed (as the participant prefers) to the participant, who will read and sign as they feel they are able to, and then return a copy of the signed consent form to the researcher before the interview is conducted.

Data protection:

Participant data collected during the study will be stored on a password protected University computer. This data will include answers to clinical measures and demographic data. No hard copy information will be collected, and at no point will participant names or identifiable information be stored.

COVID-19

Due to the ongoing global issues related to the COVID-19 pandemic, this research will take place via virtual meetings using Attend Anywhere software. Participants will be invited to attend a meeting with the researcher prior to their initial assessment with their primary clinician, which will use the same software. All data will be recorded on a University virtual desktop, which will allow for the researcher to work from home, but will provide the same level of data security as a University computer. The Virtual desktop is protected by two separate passwords and only accessible on a laptop

kept in a room to which only the researcher has access.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply.*

- ☐ Case series / case note review
- ☐ Case control
- ☐ Cohort observation
- ☐ Controlled trial without randomisation
- ☐ Cross-sectional study
- ☐ Database analysis
- ☐ Epidemiology
- ☐ Feasibility/ pilot study
- ☐ Laboratory study
- ☐ Meta-analysis
- ☑ Qualitative research
- ☑ Questionnaire, interview or observation study
- ☐ Randomised controlled trial
- ☐ Other (please specify)

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

1. Does the English version of the ITI if the ITI produce internally reliable scores, acceptable test-rest reliability, and acceptable interrater reliability?

A11. What are the secondary research question/objectives if applicable? *Please put this in language comprehensible to a lay person.*

2. Is the English version of the ITI a valid instrument?
3. What is the level of diagnostic concordance between the ITI and the ITQ?
4. Which childhood maladaptive schemas predict PTSD, and which predict CPTSD?
5. What are the thoughts of clinicians on the clinical utility of the ITI?

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

Types of reliability
A tool has good test-retest reliability when the assessment is applied to one person twice, usually with a gap of a few days in between, and similar results are found both times. In other words, the outcome of the tool does not change when applied to the same person on different days.
Inter-rater reliability is the degree of agreement between two raters scoring the same assessment carried out on the same person.

Types of validity
Construct validity is the level to which a particular tool actually measures what it claims to measure, whether the tool measures the intended construct.
Convergent and discriminative validity are the measures of similarity. Convergent validity can be established when two constructs are similar, while discriminative validity can be found when two constructs are very dissimilar. It is important to assess both of these when validating a new assessment tool (Campbell and Fiske, 1959).

Why does the ITI need to be validated?
The process of validating a new diagnostic tool involves the finding of empirical data to support the use of the tool. That is, providing support in favour of the reliability and validity of the ITI will ensure that clinicians using the ITI in future will know that they are using a measure which will give them true and accurate results.

All tools to be used in clinical practice must be validated, as it would be unethical to assess a client using a tool which may give inaccurate results. False results may lead the client and clinician to pursue a route of treatment which may be inappropriate, and not address the true cause of the client's issues. For example, if a clinician were to use an unvalidated PTSD questionnaire, the client may be given a false positive diagnosis of PTSD. This may cause the client to be incorrectly prescribed medication and use resources for therapeutic interventions which may be useless at best, or at worst cause more harm than no intervention.
It is vital that assessment tools to be used in NHS and private practice be validated so that time and financial resources can be allocated appropriately, and to enable the client to access treatment quickly and efficiently. Additionally, the presence of a validated measure for the assessment of both PTSD and cPTSD will further human understanding of the nature of both disorders and may provide a baseline against which future assessment tools can be measured.

Childhood Maladaptive Schemas (CMS)
It is understood that some thought patterns, or schemas, are formed based on experiences from childhood (Vasilopoulou et al, 2019). If events experienced in childhood are of a traumatic or abusive nature, the schemas formed as a result often include beliefs such as "the world is a cruel and unfair place" and "I am an unworthy person" (Vasilopoulou et al, 2019). These thought patterns are known as Childhood Maladaptive Schemas, as they can have negative impacts on the person later in life, causing anxiety and hypervigilance.

What is the relevance of CMS?
Previous research has linked the formation of CMS and PTSD in adult life (Meyer, Morissette, Kimbrel, Kruse, & Gulliver, 2013). In a retrospective study, Vasilopoulou et al, 2019 found that traumatic experiences were linked to maladaptive schemas in the Disconnection and Impaired Autonomy domains. However, this study used a relatively older sample (mean age=71.4) and small sample size (42 participants). The older age of the participants means that results cannot be generalised to younger populations and the small sample size gives the results relatively low statistical power. This is, to date, the only study to have investigated the link between CMS and severity or type of trauma.
The purpose of the inclusion of CMS in the present study is partially to facilitate the understanding of how cPTSD is developed. It is thought that greater understanding of the development of the disorder will enable earlier intervention through screening of appropriate individuals. This understanding by the wider scientific community may be passed on to those experiencing difficulties with cPTSD. It has been shown that a better understanding of one's own disorder facilitates self-acceptance, autonomy and control over treatment and can enable the person to engage more fully in their therapy.
The current literature indicates that there is a need to study the effect of schemas on ICD-11 CPTSD, as previous findings cannot be extrapolated without verification. An more varied participant pool is also required, as similar studies have mainly focussed on populations with unique experiences (military service, specific warzones, etc.). Further research is also required to verify the effect of maladaptive schemas developed as a result of traumatic experiences in childhood and using a younger population than Vasilopoulou et al (2019). If these voids in the literature are filled, it may be possible for future research and development to begin looking at treatment protocols for using information about schemas in therapeutic interventions for PTSD and CPTSD (Cockram, Drummond & Lee, 2010).

Diagnostic Concordance
This is the level to which two different tests can be said to agree with each other. In this instance, the level of diagnostic concordance between the ITQ and the ITI is relevant because the ITQ has previously been validated in empirical studies, meaning that it is a good tool to use to diagnose PTSD and CPTSD. If the ITI can be said to have good diagnostic concordance with the ITQ, it is reasonable to say that the ITI is a good measure of assessing PTSD and CPTSD.
What is the relevance of diagnostic concordance?
In diagnoses of PTSD and cPTSD, it is common that self-report measures (such as questionnaires) and clinician rated measures (such as interviews) are used alongside each other, so give a full picture of the client. It is important, therefore, that two measures to be used concurrently have a level of agreement. In this case, the ITI and the ITQ are likely to be used to assess the same client with a view to determine a diagnosis. It is important that both measures have a reasonable level of diagnostic concordance, or can be calibrated to ensure this, otherwise it may be the case that the ITI could give a result which does not agree with the ITQ, causing confusion as to what the client is experiencing.
In this study, the ITI will be assessed for diagnostic concordance with both the ITQ and a previously validated measure of PTSD. The purpose of this is to support the validity of the ITI, and to ensure that the ITI can be used alongside other measures of PTSD without causing unnecessary dispute over the nature of the client's troubles.

Clinical Utility
Clinical utility (CU) is a non-empirical measure of the practical applications of a particular tool. There is emphasis on the "usability" of tools to be brought into clinical practice because it is important that diagnostic tests can be applied to clients quickly and efficiently, with useful results. CU is often assessed by interviews or surveys given to clinicians, with the intent to find out their opinions on the practical applications of the tool, and the ease of use.

Why is CU important?
CU significantly affects the uptake and usage of assessment tools. For example, a questionnaire involving 100 questions may give highly accurate and reliable results, but is unlikely to be used in an appointment by a clinician due to time constraints, and will likely be difficult to understand for a client. Equally, a semi-structured interview with only two items might be much easier to administer, but the results would likely be less than useful. It is important that a balance be found between being thorough and being understandable, as this will ensure that a full picture of the client is gained with minimal use of extraneous resources.
The ITI aims to be accurate, and reliable, while maintaining the practicality of an easily understood tool. In order to ensure that this aim has been met, it is important that clinicians who have used the ITI are given the opportunity to voice their opinions on the ease of application and the relevance of the results. Clinicians will also be able to advocate for their clients, and indicate whether there are any wording issues where language is used that might not be easily understood by the client.

Summary
To summarise, the present study aims to validate the ITI, a new measure of PTSD and cPTSD, so that the ITI can be implemented in clinical practice. This is the first study of its kind to be carried out on an English-speaking population, but a previous study in Sweden gained positive results (Bondjers, Hyland, Roberts, Bisson, Willebrand, & Arnberg, 2019). It is hoped that evidence from this study will inform treatment protocols for cPTSD and best practice guidelines for assessment of cPTSD.

A13. Please summarise your design and methodology *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

Participants
It is intended that 200 participants will be identified through a consecutive series of referrals from participating treatment centres. The timeline for this project allows for this number of participants to be identified and interviewed over an 18-month period. Based on an a priori power analysis to determine the minimum sample size, it was deemed necessary to collect a sample of 200 participants in order to detect a small effect (f2=0.07), at a 0.9 level of power, with 3 predictor variables, and an alpha level of 0.05.

ITQ, demographics and information on schemas will be collected as part of participants' routine assessments and the ITI will be administered by the researcher for this study. Participants' suitability will be identified by clinicians at the referring centre, who will be able to ensure that participants meet the inclusion criteria. The clinician carrying out the initial assessment will ask clients if they wish to participate in the project. If the client states that they would be willing to participate, an appointment will be arranged for the participant to meet with the researcher for the ITI to be administered.

Measures
Demographics- this information will be collected via a questionnaire during the meeting with the researcher.

Trauma exposure- Fulfilment of the inclusion criteria "exposure to at least one traumatic life event" will be assessed by the completion of the ITEM.

International Trauma Questionnaire- a self-report questionnaire consisting of 18 items on a 5-point scale from "Not at all" (0) to "Extremely" (5) (Cloitre et al. 2019). This will be completed as a part of the participants' admission to Rivers Centre services.

The Core Beliefs Questionnaire (CBQ- (Wong, Gregory, Gaston, Repee, Wilson, & Abbott, 2017) is a 17-item tool designed to measure the presence of negative core beliefs about the self. The client is instructed to respond to each statement on a scale of one (strongly disbelieve) to six (strongly believe).

International Trauma Interview- The International Trauma Interview is a two-part semi-structured measure consisting of items relating to symptoms of PTSD and DSO. Section one of the ITI indicates PTSD severity (minimum score of 0, maximum score of 24) and the second half shows the significance of DSO symptoms (minimum score of 0, maximum score of 24). Taken together, the two halves of the ITI give a combined CPTSD score (minimum score of 0, maximum score of 48), and individual scores for each symptom cluster (minimum score of 0, maximum score of 8). This will be administered by the researcher at a meeting with the participant.

Clinical utility- Due to the lack of an empirical measure of clinical utility, it is proposed that clinical utility is assessed through reflection by the researcher, interviews with researchers elsewhere performing similar studies, and therapists using the results from the ITI. The questions listed below will be circulated to researchers currently working on validation studies for the ITI, with a request for their responses to be emailed back. The questions will address the six aspects of clinical utility identified by First, Pincus, Levine, Williams, Ustun, and Peele, (2004). Each of these aspects

will be assessed by questions adapted from Samuel and Widiger (2006). These questions are listed below and are rated on a 5- point Likert scale from 1= Not at all useful, to 5= Extremely useful with a discussion about each answer where appropriate.
-How easy do you feel it was to apply the interview to this individual?
-How useful do you feel the interview would be for communicating information about this individual with other mental health professionals?
-How useful do you feel this interview would be for communicating information about the individual to him or herself?
-How useful is this interview for comprehensively describing all the important PTSD/CPTSD-related problems the individual has?
-How useful would this interview be for helping you to formulate an effective intervention for this individual?
-How useful was this interview for describing the individual's global mental health?

Procedure

The study will take place in NHS Lothian and NHS Greater Glasgow and Clyde. Mental health practitioners who work in serious acute and tertiary services will be asked to refer to the study suitable participants who are coming off the waiting list for treatment but still require an assessment for PTSD or CPTSD. Following administration of the ITI, written feedback will be provided to the referring clinician to further inform participants' care plan. Due to COVID-19 restrictions, it is necessary for interviews to take place virtually. Where possible, if future circumstances allow, interviews may be conducted on the premises of the NHS treatment centre where the participant is receiving their treatment.

Participants will be provided the Participant Information Sheet by the referring clinician (Via email or post, as preferred by the client), who will then liaise with the researcher to arrange a virtual meeting using Attend Anywhere software. Once this meeting has been arranged, the researcher will contact the participant to supply questionnaires to be completed prior to the meeting (again, via post or email). This will include the ITQ, demographics questionnaire, and the Core Beliefs Questionnaire. The completion of these measures before the meeting will reduce the overall length of the meeting and therefore mitigate participant burden.

The meeting with the researcher will take place online using Attend Anywhere software, immediately preceding the participant's initial assessment with a trained clinician. The researcher will explain the procedure for the meeting, then review the Participant Information sheet and answer any questions which may arise. The consent form will be provided, read by the participant, and signed. The researcher will then follow the interview protocol for the ITI. This involves reading out each of the questions, listening to the responses, and asking any relevant follow-up questions to clarify the answer. The participant will be thanked for their time, provided with the debriefing sheet, and given the opportunity to ask any further questions they may have.

At the end of the first appointment, 20 participants will be invited to attend a second meeting with the researcher, where the ITI will be administered for a second time, in order to facilitate the assessment of test-retest reliability. This second meeting will follow the same procedure as the first. At the beginning of their meeting, 20 different participants will be asked to give permission for their interview to be audiotaped, the recordings transcribed, and the transcriptions to be sent to a number of trained clinicians who will rate the participant's responses and assign a diagnosis based on the outcome. This will enable the analysis of inter-rater reliability.
Consideration will be given to any participants' ongoing therapy, and if their participation in the study is deemed to be inappropriate on the basis of negative impact on the participants' mental health, they will be removed from the study. Signposting after the ITI is administered will include provision of helpline numbers and advice to contact healthcare providers.

Scoring of the responses to the interviews will take place after the meeting with the researcher. The participant's results will be communicated to the therapist at the Rivers centre via password protected email, and will be available for discussion with the participant at their next therapy session.

Researcher effects
Researcher effects will be minimised with the provision of effective training on the administration of the ITI. The transcribed interviews will also serve as an opportunity to reduce researcher effects; trained clinicians will review the entirety of a number of interviews delivered by the researcher and will therefore be able to flag any inconsistencies or potential researcher biases.

Timeline
This study will be carried out over the course of two years. Recruitment will begin in January 2021, with the first interviews being held soon thereafter. The data collection period will end in December 2021, with the final data analysis being carried out between December 2021 and February 2022. The write up of any papers and thesis chapters will begin in earnest at this time, with the view to end in February 2023. Interim analyses and reports with the supervisory team will occur at six-month intervals: March 2021, October 2021, March 2022, and October 2023.

At 4-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- [ ] Design of the research
- [ ] Management of the research
- [x] Undertaking the research
- [ ] Analysis of results
- [ ] Dissemination of findings
- [ ] None of the above

Give details of involvement, or if none please justify the absence of involvement.
Patients at the listed treatment centres will be involved as participants.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

At 5. What is the sample group or cohort to be studied in this research?

Select all that apply:

- [ ] Blood
- [ ] Cancer
- [ ] Cardiovascular
- [ ] Congenital Disorders
- [ ] Dementias and Neurodegenerative Diseases
- [ ] Diabetes
- [ ] Ear
- [ ] Eye
- [ ] Generic Health Relevance
- [ ] Infection
- [ ] Inflammatory and Immune System
- [ ] Injuries and Accidents
- [x] Mental Health
- [ ] Metabolic and Endocrine
- [ ] Musculoskeletal
- [ ] Neurological
- [ ] Oral and Gastrointestinal
- [ ] Paediatrics
- [ ] Renal and Urogenital
- [ ] Reproductive Health and Childbirth
- [ ] Respiratory
- [ ] Skin
- [ ] Stroke

Gender: Male and female participants

Lower age limit: 18 Years

Upper age limit: Years

At 7-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

1. Patients referred from one of the recruiting mental health centres
2. Patients with a history of exposure to at least one traumatic life event
3. Able to give informed consent to involvement in the study
4. Able to understand and speak English

At 7-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

1. Those without a history of exposure to at least one traumatic life event
2. Those unable to give fully informed consent
3. Unable to speak and understand English
4. Those likely to be unduly negatively affected by participation.

RESEARCH PROCEDURES, RISKS AND BENEFITS

At 8. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. These include seeking consent, interviews, non-clinical observations and use of questionnaires.

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (in mins, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Informed consent form	1	0	10 minutes	To be completed during the interview with the researcher
International Trauma Interview	1	0	1 hour	The interview protocol will administered during the interview with the researcher
International Trauma Interview	2	0	1 hour	For 20 of the 200 participants, the ITI will be administered twice, at two separate meetings with the researcher. Both occasions will be administered during the interview with the researcher
International Trauma Questionnaire	1	1	20 minutes	This will be administered during the interview with the researcher
Demographics	1	1	10 minutes	This will be administered during the interview with the researcher
Trauma exposure questionnaire	1	1	5 minutes	This will be administered during the interview with the researcher
Core Beliefs Questionnaire	1	0	5 minutes	This will be administered during the interview with the researcher
Clinical Utility questionnaire	1	0	30 minutes	These questions will be emailed to appropriate clinicians, who will respond with their answers. Follow-up questions may be asked by the researcher and, where possible, a Skype meeting arranged to discuss responses. This will enable the respondent to give their opinions from a location most convenient to them.

A21. How long do you expect each participant to be in the study in total?

160 participants will be in the study for a total of one hour from signing the consent form to debrief with the researcher. 20 participants being interviewed twice will be involved for two weeks, from signing the consent form to final debrief at the time of the second meeting with the researcher.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

This study requires data from a number of psychological measures, including an interview protocol which asks about information regarding traumatic experiences and troubling symptoms. It may cause some participants distress to divulge this information, but they will be informed and reminded of their right to withdraw at any time. Interviews will be carried out on NHS premises with trained mental health support staff on site. Participants will also be informed that their information will be kept safe and anonymous, with pseudonyms used in any published works.

The measures used in this study do represent a burden to participants which they would not otherwise have experienced. However, it is thought that the benefit of the measures (better understanding of the self and information that can be used in the planning of an onward care pathway) is greater than the burden put upon the participants.

To reduce participation burden in terms of the inconvenience of attending the interview meetings with the researcher will be scheduled to precede a meeting between the participant and the referring clinician.

Informed consent will be obtained before participants engage in the study. The Participant Information Sheet will contain descriptions of all the measures they will be asked to complete, and it will be made clear that a decision to not participate will not affect their treatment in any way. If a participant becomes distressed at any point during the interview, the researcher will halt the interview and speak empathetically with the participant until they feel able to either continue or take the decision to withdraw. If the participant becomes severely distressed, the researcher will immediately contact Rivers Centre staff and request support.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

◉ Yes ○ No

If Yes, please give details of procedures in place to deal with these issues:

The ITI includes questions regarding information about traumatic experiences and troubling symptoms. It will be made clear in the participant information sheet and on the consent form that the study is interested in trauma and participants will be asked to provide informed consent before completing the CBQ and the ITI. The researcher will be present during the completion of the ITI and will be available to provide support.

Whilst it is unlikely that there will be any long-term harm caused by participation in this study, there is a potential for short-term distress and/or disclosures of sensitive, previously unknown information. In the case of a disclosure indicating risk/ danger to the participant or others, confidentiality will be breached in line with BPS and NHS guidelines, a member of the participant's care team will be informed, and the necessary steps will be taken to protect the participant and others. Participants will be made aware of this exception to the confidentiality clause before participation.

A24. What is the potential for benefit to research participants?

Participants will have access to their results from the ITI, which may further their understanding of their condition, and the nature of their symptoms. Additionally, the information from the CBQ may be interpreted by their therapist to facilitate understanding of the development of their condition, and therefore provide an additional focus for their therapy (i.e. tackling a core belief to help to change negative thought patterns).

Participants will also have the knowledge that their participation is furthering the understanding of PTSD and cPTSD, and therefore improving treatments for themselves and others with similar mental health conditions. This may provide participants with a sense of autonomy and achievement in helping both themselves and others.

A26. What are the potential risks for the researchers themselves? *(if any)*

There is a minor risk that the participant might present a risk of harm to the researcher. This is to be expected in any research study of this nature. As the meetings between the researcher and the participants are slated to occur via video conference, the risk of physical harm to the researcher is extremely limited. Any verbal violence will be dealt with on a zero-tolerance policy, in line with NHS policies.

There is also a risk of psychological harm to the researcher, due to the necessity of hearing about multiple traumas and distressing symptoms. There will be mental health support available from the university, and the supervisory team will be contactable throughout the data collection period in the eventuality that the researcher requires additional support.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used? *For example, identification may involve a disease register, computerised search of social care or GP records, or review of medical records. Indicate whether this will be done by the direct care team or by researchers acting under arrangements with the responsible care organisation(s).*

Recruitment will occur through referral from the participating treatment centres. Staff will be asked to review their caseload, and screen any new admissions, to identify individuals who meet the inclusion criteria. Clinicians will then provide potential participants with a Participant Information Sheet, and obtain consent for the researcher to make contact with them. The researcher will not have any contact with the potential participant until they consent through their clinician.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

◉ Yes ○ No

Please give details below

Clinical care staff will be asked to review their current caseload to identify potential participants who may be eligible/interested in taking part. They will be provided with inclusion/exclusion criteria. The researcher will not be involved in this process.

A27-3. Describe what measures will be taken to ensure there is no breach of any duty of confidentiality owed to patients, service users or any other person in the process of identifying potential participants. *Indicate what steps have been or will be taken to inform patients and service users of the potential use of their records for this purpose. Describe the arrangements to ensure that the wishes of patients and service users regarding access to their records are respected. Please consult the guidance notes on this topic.*

Only the participants' clinical team will have access to their records. The researcher will have access to relevant questionnaire responses, but only after express permission is gained from participants through the signing of the consent form.

The Participant Information Sheet will contain information on exactly which responses the researcher will be given access to (ITQ, demographics, trauma data), and participants will be informed that they are well within their rights to deny any of this information being shared, and that this decision will not affect their treatment in any way. Before signing the consent form, the researcher will talk with the participant and ensure that they understand what information will be shared from the clinical team and that the participant gives permission for this to happen.

A27-4. Will researchers or individuals other than the direct care team have access to identifiable personal information of any potential participants?

○ Yes ◉ No

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

◯ Yes ◉ No

A29. How and by whom will potential participants first be approached?

The participants' main clinical contact at the Rivers Centre will inform the individual that there is a study running and that if they wished to participate they should read the Participant Information Sheet, take a few days to consider their options, and then return for a discussion about whether they would like to participate. Participants will be encouraged to weigh the benefits and potential costs with help from their clinical team.

A30-1. Will you obtain informed consent from or on behalf of research participants?

◉ Yes ◯ No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B, Section 6, and for children in Part B, Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

All participants will have the capacity to provide consent for themselves. Clinicians at the Rivers Centre will provide the information sheet, and after the participant has read the information sheet, the clinician will obtain verbal consent for the researcher to contact the potential participants.

Once verbal consent for contact from the researcher has been gained, the researcher will make contact to arrange a meeting. At the start of the meeting, the researcher will talk through the participant information sheet, and ask the participant if they would like to ask any questions. Once any questions have been answered, the participant will be asked to sign a consent form indicating that they understand what will be asked of them, and that they have been informed of their rights.

If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

◉ Yes ◯ No

A31. How long will you allow potential participants to decide whether or not to take part?

From reading the Participant Information Sheet provided by the clinical team, the participant will be allowed to take as long as they like before giving verbal permission for the researcher to contact them to arrange a meeting. This will be a minimum of 48 hours.

If the participant agrees to a meeting with the researcher, they will be asked to sign a consent form. If they feel they need to, they will be able to take the unsigned consent form away and arrange a follow up meeting with the researcher to sign the consent form and complete the ITI.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? *(e. g. translation, use of interpreters)*

As this is a validation study for the English version of the ITI, the inclusion criteria require that participants be able to communicate verbally in English. As a result, those who are unable to communicate verbally in English will be unable to participate. If necessary to mitigate literacy difficulties, the researcher and clinical team will be able to read out any information or consent forms.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? *Tick one option only.*

◯ The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.

◉ The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.

◯ The participant would continue to be included in the study.

◯ Not applicable – informed consent will not be sought from any participants in this research.

◯ Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

Both the researcher and participants will be in contact with clinical staff throughout the study. The window between giving consent and the end of data collection will be relatively short for each participant. Regardless, participants will be monitored by clinical staff and the researcher. Participants who miss appointments with the researcher will be contacted via phone call to ascertain whether they would like to continue with their participation.

If it is deemed that a participant has lost the capacity to consent at any time during their participation in the study, they will be withdrawn from data collection. Previously collected data will be retained for analysis and destroyed. This will be detailed in the consent form that each participant will sign before their participation.

If you plan to retain and make further use of identifiable data/tissue following loss of capacity, you should inform participants about this when seeking their consent initially.

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)? *(Tick as appropriate)*

- ☐ Access to medical records by those outside the direct healthcare team
- ☐ Access to social care records by those outside the direct social care team
- ☑ Electronic transfer by magnetic or optical media, email or computer networks
- ☐ Sharing of personal data with other organisations
- ☐ Export of personal data outside the EEA
- ☐ Use of personal addresses, post codes, faxes, emails or telephone numbers
- ☐ Publication of direct quotations from respondents
- ☐ Publication of data that might allow identification of individuals
- ☑ Use of audio/visual recording devices
- ☑ Storage of personal data on any of the following:
  - ☑ Manual files (includes paper or film)
  - ☐ NHS computers
  - ☐ Social Care Service computers
  - ☐ Home or other personal computers

☑ University computers
☐ Private company computers
☐ Laptop computers

Further details:
Anonymised participant data will be stored on password protected University virtual desktop for data analysis. Any hard copies of questionnaires and consent forms will be digitised and stored in the same manner, with the hard copy being destroyed at the earliest possible opportunity.

Up to 20 interviews will be audio recorded using a university-provided device. The recordings will be transcribed and the transcriptions stored on a password protected University virtual desktop. The transcribed interviews will be shared with clinicians trained in the scoring of the ITI via password protected and encrypted file transfer. This is so that the inter-rater reliability of the ITI can be assessed. Clinicians receiving the audio files will follow best practice guidelines in protection of data, and will be advised to delete the transcribed interviews as soon as they have been reviewed and scored.

A37. Please describe the physical security arrangements for storage of personal data during the study?

All identifiable data will be anonymised as soon as reasonably possible, at the point of digitisation. Hard copies of questionnaires will not be stored for any length of time beyond the time taken to complete digitisation. All digital data will be stored on a password protected University virtual desktop, in a room to which only the researcher have access. This is also the manner in which the data analysis will be carried out. Data will be stored using participant numbers will be used to maintain anonymity during data analysis.

A38. How will you ensure the confidentiality of personal data? *Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

Only the consent form will contain any identifiable participant data, and this will be scanned and subsequently destroyed as soon as reasonably achievable after the participant signs it. Each participant will be assigned a participant number and this will be used to refer to individual participants in published works.

All data will be held securely and treated in accordance with NHS Lothian's policies on Confidentiality and Data Protection as well as the BPS (2009) Code of Ethics and Conduct and BPS (2014) Code of Human Research Ethics guidelines documents and the study will adhere to the principles of Good Clinical Practice.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

The researcher will have access to demographics information, as well as completed copies of psychometric questionnaires relevant to the study. Consent for this will be gained via consent forms and verbal consent in the case of the researcher making initial contact via telephone call.

Storage and use of data after the end of the study

A41. Where will the data generated by the study be analysed and by whom?

The data will be analysed on Edinburgh Napier University campus by the researcher.

A42. Who will have control of and act as the custodian for the data generated by the study?

	Title	Forename/Initials	Surname
	Miss	Zoe	Wagland
Post	PhD Candidate		

Qualifications
Work Address
[redacted]
Post Code
Work Email
Work Telephone
Fax

A43. How long will personal data be stored or accessed after the study has ended?

○ Less than 3 months
○ 3 – 6 months
◉ 6 – 12 months
○ 12 months – 3 years
○ Over 3 years

A44. For how long will you store research data generated by the study?

Years: 10
Months:

A45. Please give details of the long term arrangements for storage of research data after the study has ended. *Say where data will be stored, who will have access and the arrangements to ensure security.*

Once the study has ended, the anonymised research data will be stored securely on the Edinburgh Napier University data storage repository. The data will be stored in accordance with Edinburgh Napier Data Management Policy guidelines for 10 years.

The 'end' of the study will be defined as the completion of the data analysis and submission of the write up for publication. All personal information will be retained for 3 years in accordance with NHS Lothian data archiving policy. This is essential from an audit perspective, as proof that the research took place. This information will be held on site at the Rivers centre and will be disposed of according to data protection guidelines after the designated retention period.

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

○ Yes ◉ No

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

○ Yes ◉ No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g.

financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

○ Yes ◉ No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

○ Yes ◉ No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

PUBLICATION AND DISSEMINATION

A50-1. Will the research be registered on a public database?

○ Yes ◉ No

Please give details, or justify if not registering the research.
This study is not a clinical trial or a randomised controlled trial, and it is understood that registration is not necessary for these types of studies.

Registration of research studies is encouraged wherever possible.
You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you are aware of a suitable register or other method of publication, please give details. If not, you may indicate that no suitable register exists. Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study? *Tick as appropriate.*

- ☑ Peer reviewed scientific journals
- ☐ Internal report
- ☑ Conference presentation
- ☐ Publication on website
- ☐ Other publication
- ☐ Submission to regulatory authorities
- ☐ Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- ☐ No plans to report or disseminate the results
- ☑ Other (please specify)

The study will be written up in doctoral thesis form at in the partial fulfilment of the requirements of the PhD Psychology course at Edinburgh Napier University

A52. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

There will be no identifiable personal data used in the write-up of this study. The data used will be summary scores with no identifiable personal information.

In the case of qualitative data analysis, all identifiable information such as names will be removed from quotes. Pseudonyms will be used in all analyses.

A53. How and when will you inform participants of the study results?

If there will be no arrangements in place to inform participants please justify this.
Participants will be able to indicate at the study debief whether they wish to receive summary results of the findings. These will be distributed by email upon completion of the study.

6. Scientific and Ethical Review

A54-1. How has the scientific quality of the research been assessed? *Tick as appropriate.*

- ☐ Independent external review
- ☐ Review within a company
- ☐ Review within a multi-centre research group
- ☑ Review within the Chief Investigator's institution or host organisation
- ☑ Review within the research team
- ☑ Review by educational supervisor
- ☐ Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review.
The methods were reviewed by all members of the chief investigator's supervision team who have previously conducted similar research. Monthly supervision meetings will take place, as will regular progress reviews throughout the duration of the project with both the supervision team and an independent advisor.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A56. How have the statistical aspects of the research been reviewed? *Tick as appropriate.*

- ☐ Review by independent statistician commissioned by funder or sponsor
- ☐ Other review by independent statistician
- ☐ Review by company statistician
- ☐ Review by a statistician within the Chief Investigator's institution
- ☐ Review by a statistician within the research team or multi-centre group
- ☑ Review by educational supervisor
- ☐ Other review by individual with relevant statistical expertise
- ☐ No review necessary as only frequencies and associations will be assessed – details of statistical input not required

In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.

	Title Forename/Initials	Surname
	Dr Philip	Hyland
Department		
Institution	Maynooth University	
Work Address	Education House	
	North Campus	

Post Code [redacted]
Telephone
Fax
Mobile
E-mail

Please enclose a copy of any available comments or reports from a statistician

A57. What is the primary outcome measure for the study?

Quantitative results indicating the significance of the reliability and validity of the ITI.

A58. What are the secondary outcome measures? *(If any)*

Quantitative data indicating the significance of the link between CMS and the presence of dPTSD in adulthood.

Qualitative data indicating clinicians' thoughts on the Clinical Utility of the ITI.

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size: 200
Total international sample size (including UK):
Total in European Economic Area

Further details:
160 participants will be interviewed once using the ITI protocol. of this 160, 20 will have their interviews recorded, transcribed, and sent to clinicians who will provide their own scoring of the responses in order enable the assessment of inter-rater reliability.

An additional 20 will be interviewed twice, roughly two weeks apart, in order to allow the assessment of test-retest reliability.

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

A61-1. Will participants be allocated to groups at random?

○ Yes ◉ No

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

Descriptive statistics will be used to describe the sample based on ethnicity, gender, age, and type of trauma. Inter-rater reliability will be assessed using Cohen's kappa where a value >.61 indicates acceptable agreement (Landis & Koch, 1977). Test-retest reliability will be assessed using paired t-tests and Kappa statistics. The fit of alternative factor models will be assessed using confirmatory factor analysis (CFA). Following the selection of the best fitting model, composite reliability analysis will be performed to determine the internal reliability of the ITI. A value of >.60 will indicate appropriate reliability.
Instrumental validity of the ITI will be assessed using ICD-11 PTSD and CPTSD diagnostic rates be compared to DSM-5 PTSD diagnostic rates using the z-test. Factorial validity of the ITI will be assessed using Confirmatory Factor Analysis (CFA), and concurrent validity will be assessed by assessing the associations between the ITI latent factors and Structural Equation Modelling (SEM).
Correlational analyses including Cohen's Kappa will be used to assess the concordance between results from the ITI

and the ITQ. That is, to ensure that both measures are not only diagnosing PTSD and CPTSD at the same rates, but also that the same clients are being diagnosed with the same disorder. Similar analysis will be carried out between the ITI and commonly used measures of PTSD symptomology, in order to support the hypothesis that the ITI is a good measure of symptoms related to PTSD.
Finally, summed PTSD/DSO scores based on the best fitting model of the ITI will be entered analysed using SEM to determine the relationship between childhood schemas and ICD-11 PTSD and CPTSD symptoms. At all stages, missing data will be managed using appropriate methods.
Analysis of clinical utility will classify statements from clinicians and researchers as either "positive", "negative", or "neutral". Thematic analysis will be carried out to identify commonalities between responses. Discussion on these outcomes will be used to draw conclusions on the efficacy of the use of the ITI in clinical settings.

B. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co-applicants, protocol co-authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

Post
Qualifications
Employer
Work Address

Post Code
Telephone
Fax
Mobile
Work E-mail

[redacted]

Post
Qualifications
Employer
Work Address

Post Code
Telephone
Fax
Mobile
Work E-mail

Post
Qualifications
Employer
Work Address

Post Code
Telephone
Fax
Mobile
Work Email

Post
Qualifications
Employer
Work Address

Post Code
Telephone
Fax
Mobile
Work Email

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status: ◯ NHS or HSC care organisation
◉ Academic
◯ Pharmaceutical industry
◯ Medical device industry
◯ Local Authority
◯ Other social care provider (including voluntary sector or private organisation)
◯ Other

Commercial status: Non-Commercial

If Other, please specify:

Contact person

Name of organisation
Given name
Family name
Address
Town/city
Postcode
Country

Telephone
Fax
E-mail

Legal representative for clinical investigation of medical device (studies involving Northern Ireland only)
Clinical investigations of Medical Devices that take place in Northern Ireland must have a legal representative of the sponsor that is based in Northern Ireland or the EU

Contact person

Name of organisation
Given name
Family name
Address
Town/city
Post code
Country
Telephone
Fax
E-mail

A65. Has external funding for the research been secured?

Please tick at least one check box

☐ Funding secured from one or more funders
☐ External funding application to one or more funders in progress
☑ No application for external funding will be made

What type of research project is this?

◯ Standalone project
◯ Project that is part of a programme grant
◯ Project that is part of a Centre grant
◉ Project that is part of a fellowship/ personal award/ research training award
◯ Other

Other – please state:

A66. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a co-sponsor listed in A64-1)? *Please give details of subcontractors if applicable.*

◯ Yes ◉ No

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

◯ Yes ◉ No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

Organisation
Address

[redacted]

Post Code
Work Email
Telephone
Fax
Mobile

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A69-1. How long do you expect the study to last in the UK?

Planned start date: 01/01/2021
Planned end date: 01/03/2023
Total duration:
Years: 2 Months: 2 Days: 1

A71-1. Is this study?

- ○ Single centre
- ◉ Multicentre

A71-2. Where will the research take place? *(Tick as appropriate)*

- ☐ England
- ☑ Scotland
- ☐ Wales
- ☐ Northern Ireland
- ☐ Other countries in European Economic Area

Total UK sites in study:

Does this trial involve countries outside the EU?

- ○ Yes ◉ No

A72. Which organisations in the UK will host the research? *Please indicate the type of organisation by ticking the box and give approximate numbers if known.*

- ☐ NHS organisations in England
- ☐ NHS organisations in Wales
- ☑ NHS organisations in Scotland 3
- ☐ HSC organisations in Northern Ireland
- ☐ GP practices in England
- ☐ GP practices in Wales
- ☐ GP practices in Scotland
- ☐ GP practices in Northern Ireland
- ☐ Joint health and social care agencies (eg community mental health teams)
- ☐ Local authorities
- ☐ Phase 1 trial units
- ☐ Prison establishments
- ☐ Probation areas
- ☐ Independent (private or voluntary sector) organisations
- ☐ Educational establishments
- ☐ Independent research units
- ☐ Other (give details)

Total UK sites in study: 3

A73-1. Will potential participants be identified through any organisations other than the research sites listed above?

- ○ Yes ◉ No

A74. What arrangements are in place for monitoring and auditing the conduct of the research?

The lead researcher will ensure that recruitment does not start until a favourable decision has been received from both the NHS and Edinburgh Napier University Ethics Committees.
The research will be delivered in line with the protocol, and no substantial changes to the protocol will be made without the prior approval of the ethics committee.
The study will comply with all ethical and legal requirements. Any concerns about governance will be raised with the University and NHS Trust, following the relevant local policies and procedures.
The Chief Investigator will take responsibility for reporting the results of the study, including the sharing of results with participants.

A76. Insurance/ indemnity to meet potential legal liabilities

Note: In this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

- ☐ NHS indemnity scheme will apply (NHS sponsors only)

☑ Other insurance or indemnity arrangements will apply (give details below)

This is covered by Edinburgh Napier University's Professional Indemnity insurance and Public and Products Liability Insurance
Please see attached documents for proof of insurance.

Please enclose a copy of relevant documents.

A76.2 What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? *Please tick box(es) as applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes: indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (protocol authors with NHS contracts only)
☑ Other insurance or indemnity arrangements will apply (give details below)

This is covered by the two policies mentioned at A76.1 above and Edinburgh Napier University's Clinical Trials policy
Please see attached documents for proof of insurance.

Please enclose a copy of relevant documents.

A76.3 What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS scheme as or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

☑ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)
☐ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Participants will only be recruited from NHS sites

Please enclose a copy of relevant documents.

A78. Could the research lead to the development of a new product/process or the generation of intellectual property?

◉ Yes ○ No ○ Not sure

9. Has the study been the subject of a scientific review/opinion (Expert Panel)?

○ Yes ○ No

If yes, please provide a copy of the review as part of your application.

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For further information please refer to guidance.*

Investigator identifier	
IN1	[redacted]
IN2	
IN4	

9.17 Validation study data management plan

DATA MANAGEMENT PLAN

0. Proposal name

Towards the validation of the International Trauma Interview (ITI) for the ICD-11 diagnoses of Post-Traumatic Stress Disorder and Complex Post-Traumatic Stress Disorder, and the role of core beliefs

1. Description of the data

2.2 Type of study

The main aim of this study is to provide evidence in support of the ITI being used as a diagnostic tool for Complex PTSD (CPTSD). Without this evidence, the ITI cannot be used by clinicians in clinical practice. There is presently no validated clinician-administered interview protocol, so the investigation of the ITI is important. This study will also look at the role of core beliefs in the development and maintenance of CPTSD. This is important to generally broaden human understanding of the cognitive structure of CPTSD but also to inform treatment approached by clinicians. For example, core beliefs known to contribute to the maintenance of CPTSD might be valid targets of Cognitive Behavioural Therapy. All this information will help in the diagnosing and treatment of CPTSD

1.2 Types of data

Both qualitative and quantitative data will be gathered. The researcher will collect the following:

- Participants' name, age, nationality, and gender
- Participants' scores on International Trauma Questionnaire (ITQ)
- Participants' scores on the Core Beliefs Questionnaire (CBQ)
- Details on Participants' most important traumatic event (ITEM)
- Participants' responses to the International Trauma Interview
- Observations of participants during the interview

1.3 Format and scale of the data

Data will be entered by participants on paper forms and entered by the researcher onto an electronic form. Collection of data from participants will take place during the video call interview. ITQ, CBQ, demographic and ITEM data will be collected from up to 200 participants on one occasion over the 18-month study period. The ITI data will be collected from the same 200 participants on up to two occasions during the same study period.

Only the consent forms and any audio recordings will contain any identifiable participant data. After recorded interviews occur, the recordings

will be transcribed, all identifiable data removed, and the audio recordings deleted. Data will be anonymous in any publications, and the only method of obtaining identifiable data on participants will be using the consent forms containing both participant names and participant numbers which will not be possible because they are held securely by the researcher and will not be shared.

Identifiable participant data will be stored and processed within separate password-protected files on the university network which will be accessed securely e.g. via Virtual Desktop/ VPN.. Only the researcher will have access to these files. Any paper notes will be held in a locked box and digitised as soon as reasonably possible. Non-identifiable data will be entered into a Microsoft excel spreadsheet for storage and processing.

All data will be held securely and treated in accordance with the BPS (2009) Code of Ethics and Conduct and BPS (2014) Code of Human Research Ethics guidelines documents and the study will adhere to the principles of Good Clinical Practice.

During the course of the research other University tools such as MS office documents, PDF, and SPSS may be used in the analysis and dissemination of the research findings.

2. Data collection / generation

2.1 Methodologies for data collection / generation

Participant data will be collected during one meeting with the researcher, with up to 20 participants being invited to a second meeting where a second round of ITI data will be collected. Up to 20 interviews will be audio recorded, transcribed, and the transcriptions transferred to another trained clinician via email in a password protected file. Participant identifiable information will be recorded on consent forms and will be held separately from their research data. At the end of research, all non-identifiable data will be stored within the university repository in accordance with policy, and all identifiable data will be destroyed.

During data gathering, the university-provided audio recording device will be stored in a locked safe along with any hard copy data awaiting digitisation. Paper copies will be destroyed as soon as reasonably achievable.

Participant identifiable information will be linked to their research data by a code accessible only to researchers, to enable data linkage and removal if requested by a participant and/or audit.

2.2 Data quality and standards

A trained and supervised PhD student researcher will administer measures to all participants. All measures will be valid and reliable, and the researcher will receive regular training to ensure consistency and reliability in administration and scoring.

Anonymity will be maintained to the highest standards reasonably achievable. All identifiable data will be removed and destroyed at the earliest

convenience, and no identifiable data will be included in any published works or presented in public forums.

3. Data management, documentation and curation

3.1 Managing, storing and curating data.

Research data will be stored on the University's V:drive. University-managed data storage is resilient, with multiple copies stored in more than one physical location and protection against corruption. Daily backups are kept for 14 days and monthly backups for an additional year.

3.2 Metadata standards and data documentation

All research data will be organized as per the Universities metadata standards http://staff.napier.ac.uk/services/research-innovation-office/research-data/Pages/Organising.aspx

3.3 Data preservation strategy and standards

The Edinburgh Napier Data Management Policy requires research data to be retained for 10 years after project completion if they substantiate research findings, are of potential long-term value or support a patent. The policy also requires that funders and/or sponsors requirements are met. Long term storage is provided through the University data repository.

4. Data security and confidentiality of potentially disclosive information

4.1 Formal information/data security standards

The university is Cyber Essentials standards compliant Certificate number – 6831201858139502

4.2 Main risks to data security

Each participant will receive a unique ID number upon giving consent to participate in the study. These codes will be generated randomly and can only be linked with the participant through viewing their consent forms, which will be kept in a password protected file on a University virtual desktop.

It may be necessary for some personal information to be collected in hard copy paper format (e.g. consent forms, responses to self-report measures, observational notes taken during meetings etc.). In these cases, all hard copy personal information will be stored in a locked drawer in a locked office to which only the researcher has access. Hard copy information will also be scanned into a computer and the paper copy destroyed via shredding at the earliest possible convenience.

Storage of digital data will be on university computer V-Drives. In these instances, firewall protection is in place to ensure security of data. All data processing will take place on university computers or on a virtual desktop on a home computer. This means that at all times data will be protected by university firewalls, and erasure of data from home pc hard drives is not necessary. Personal identifiable data will be destroyed after the completion of this study.

It is proposed that a small number of participant interviews are transcribed and sent to trained clinicians for assessment (this is intended to provide data to support inter-rater reliability). In these cases, it may be necessary to send personal data via email or an online file transfer site. Encryption and password protection will be used at all stages of this process.

5. Data sharing and access

5.1 Suitability for sharing

Data collected in this study will be stored for 10 years and will not be made available to other researchers (because of the small sample sizes involved). Summary data will be provided in publications, but the individual data will not be available given the risks this raises with identification of participants.

5.2 Discovery by potential users of the research data

Research articles arising from data gathered in this study will be made searchable via the journal within which they are published.

Datasets will be allocated a DOI and stored on our open access Research Repository in accordance with the University research data deposit process. The DOI and the datasets will be made available to the UK Data Service ReShare repository within three months of the end of the grant.

5.3 Governance of access

The decision to share research information with a new user will be made jointly between Zoe Wagland and Thanos Karatzias.

After the project, the data will be stored in the university repository.

In compliance with MRC policy, the study team will formally review access requests for proposals. All significant decisions (approval, referral back for further information, and decline) will be documented for subsequent independent review. An advisor with appropriate expertise, independent of the study, will be appointed to periodically review the outcomes of access requests post hoc. Individual requests may be referred to the advisor for advice if difficult issues arise, e.g. a risk to the data, participants, study, or to depletable resources.

5.4 The study team's exclusive use of the data

Exclusive use of data will be maintained by the research team until the completion of the study project (estimated March 2023). After this time, the data will be available upon request from the University repository.

5.5 Restrictions or delays to sharing, with planned actions to limit such restrictions

No data with identifiable information will be shared externally. To reduce the necessity for these limitations, participant data will be anonymised in the first instance, with no identifiable information being stored alongside outcome data. Informed consent will be gained from participants, including proposed dissemination processes. Current and potential future risks associated with this will be explained to research participants.

5.6 Regulation of responsibilities of users

External users will be bound by a data sharing agreement, which will prohibit any attempt to (a) identify study participants from the released data or otherwise breach confidentiality, (b) make unapproved contact with study participants. The data sharing agreement will also include specific individuals to whom the data will be released, the purposes for the release of data, any constrains on publication of the data, and arrangements for data destruction or secure archiving on the part of the individuals using the data.

6. Responsibilities

The first point of contact for all queries in relation to this data is the PI (Prof. Thanos Karatzias), who will also have overall responsibility for the production and maintenance of metadata. Preparation and upload of the data will be carried out by the team with the support of the University's Information Services staff.

7. Relevant institutional, departmental or study policies on data sharing and data security

Policy	**URL or Reference**
Data Management Policy & Procedures	http://staff.napier.ac.uk/services/research-innovation-office/Documents/Research%20Data%20Management%20Policy.pdf
Data Security Policy	http://staff.napier.ac.uk/services/cit/infosecurity/Pages/InformationSecurityPolicy.aspx
Data Sharing Policy	http://staff.napier.ac.uk/services/secretary/governance/DataProtection/Pages/DataSharing.aspx
Institutional Information Policy	http://staff.napier.ac.uk/services/research-innovation-office/Documents/Research%20Data%20Management%20Policy.pdf
Other:	
Other	

8. Author of this Data Management Plan (Name) and, if different to that of the Principal Investigator, their **telephone & email contact details**
Zoe Wagland, Researcher [redacted]

9.18 Validation study NHS letter of ethical approval

WoSRES

West of Scotland Research Ethics Service

West of Scotland Research Ethics Service Professor Thanos Karatzias
Director of Studies, School of health and social Care
Edinburgh Napier University
[redacted]

West of Scotland REC 1
West of Scotland Research Ethics Service
Ward 11
Dykebar Hospital
Grahamston Road
Paisley PA2 7DE
www.nhsggc.org.uk

Date 23 March 2021
Direct line 0141-314-0212
e-mail WosRec1@ggc.scot.nhs.uk

Dear Professor Karatzias **Study title:** **Towards the validation of the International Trauma Interview (ITI) for the IDC-11 diagnoses of Post-Traumatic Stress Disorder and Complex Post-Traumatic Stress disorder, and the role of core beliefs**

REC reference: **21/WS/0027**
Protocol number: **N/A**
IRAS project ID: **285376**

Thank you for your letter, responding to the Research Ethics Committee's (REC) request for further information on the above research and submitting revised documentation.
The further information was considered in correspondence by a Sub-Committee of the REC. A list of the Sub-Committee members is attached.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Good practice principles and responsibilities

The UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research. It also outlines the responsibilities of individuals and organisations, including those related to the four elements of research transparency:

1. registering research studies
2. reporting results
3. informing participants
4. sharing study data and tissue

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System. For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All research should be registered in a publicly accessible database and we expect all researchers, research sponsors and others to meet this fundamental best practice standard.

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database within six weeks of recruiting the first research participant. For this purpose, 'clinical trials' are defined as the first four project categories in IRAS project filter question 2. Failure to register a clinical trial is a breach of these approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee (see here for more information on requesting a deferral: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-research-project-identifiers/

If you have not already included registration details in your IRAS application form, you should notify the REC of the registration details as soon as possible.

Further guidance on registration is available at: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilities/

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter.

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit: https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/

N.B. If your study is related to COVID-19 we will aim to publish your research summary within 3 days rather than three months.

During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you haven't already done so, please register your study on a public registry as soon as possible and provide the REC with the registration detail, which will be posted alongside other information relating to your project. We are also asking sponsors not to request deferral of publication of research summary for any projects relating to COVID-19. In addition, to facilitate finding and extracting studies related to COVID-19 from public databases, please enter the WHO official acronym for the coronavirus disease (COVID-19) in the full title of your study. Approved COVID-19 studies can be found at: https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document “After ethical review – guidance for researchers” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

• Notifying substantial amendments
• Adding new sites and investigators
• Notification of serious breaches of the protocol
• Progress and safety reports
• Notifying the end of the study, including early termination of the study
• Final report
• Reporting results

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites taking part in the study, subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Indemnity insurance]		01 August 2020
IRAS Application Form [IRAS_Form_15022021]		15 February 2021
Letters of invitation to participant [Privacy Notice]	3.2	26 January 2021
Non-validated questionnaire [International Trauma Interview]	3.2	15 December 2019
Non-validated questionnaire [Clinical utility questionnaire]	1.2	28 January 2021
Non-validated questionnaire [Demographics questionnaire]	1.2	10 February 2021
Participant consent form [Consent form]	3.3	05 March 2021
Participant information sheet (PIS) [PIS]	3.4	05 March 2021
Research protocol or project proposal [Proposal]	4.2	28 January 2021
Response to Request for Further Information [REC Clarifications]		
Summary CV for Chief Investigator (CI) [Prof. Thanos CV]		11 February 2021
Summary CV for student [Student ZW CV]		
Summary CV for supervisor (student research) [Dr Phil Hyland CV]		
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Protocol]	1.4	05 March 2021
Validated questionnaire [Core Beliefs Questionnaire]		
Validated questionnaire [ITEM]		
Validated questionnaire [International Trauma Questionnaire (ITQ)]		

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: https://www.hra.nhs.uk/planning-and-improving-research/learning/ **IRAS project ID: 285376 Please quote this number on all correspondence**

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments

"After ethical review – guidance for researchers" *Copy to:* Dr Nina Hakanpaa

West of Scotland REC 1

Attendance at Sub-Committee of the REC meeting on 16 March 2021

Committee Members: *Name*	*Profession*	*Present*	*Notes*
Dr Katriona Brooksbank	Clinical Trial Manager (Vice Chair)	Yes	Chair of Meeting
Dr John D McClure	Statistician	Yes	
Also in attendance: *Name*		*Position (or reason for attending)*	
Mrs Kirsty Burt		Senior Co-ordinator	
Ms Ashley McLaren		REC Assistant	

9.19 Validation study IRAS amendment tool 09/12/2022

Amendment Tool

v1.6 06 December 2021

For office use

QC: No

Section 1: Project information

Short project title*:	International Trauma Interview (ITI) Standardisation and Validation
IRAS project ID* (or REC reference if no IRAS project ID is available):	285376
Sponsor amendment reference number*:	285376 Amendment 1
Sponsor amendment date* (enter as DD/MM/YY):	09 December 2022
Briefly summarise in lay language the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study. If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained (note: this field will adapt to the amount of text entered)*:	The study finish date is being extended from March 2023 to 31st of July 2023. This will allow a larger number of participants to be recruited to increase the overall power of the study.

Project type (select):	**Specific study**	
	Research tissue bank	
	Research database	
Has the study been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this amendment?:	**Yes**	No
What type of UKECA-recognised Research Ethics Committee (REC) review is applicable? (select):	**NHS/HSC REC**	
	Ministry of Defence (MoDREC)	
Is all or part of this amendment being resubmitted to the Research Ethics Committee (REC) as a **modified amendment** (i.e. a substantial amendment previously given an unfavourable opinion)?	Yes	**No**

Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?:	England	Wales	Scotland	Northern Ireland
	Yes	No	No	No

Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	Yes	**No**
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	Yes	**No**
Did the study involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the amendment introduce this?:	Yes	**No**
Did the study involve the use of research exposures to ionising radiation (not involving the administration of radioactive substances) OR does the amendment introduce this?:	Yes	**No**
Did the study involve adults lacking capacity OR does the amendment introduce this?:	Yes	**No**
Did the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?:	Yes	**No**
Did the study involve prisoners or young offenders who are in custody or supervised by the probation service OR does the amendment introduce this?:	Yes	**No**
Did the study involve children OR does the amendment introduce this?:	Yes	**No**
Did the study involve NHS/HSC organisations prior to this amendment?:	**Yes**	No
Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:	Yes	**No**

	England	Wales	Scotland	Northern Ireland
Lead nation for the study:	No	No	**Yes**	No
Which nations had participating NHS/HSC organisations prior to this amendment?	No	No	**Yes**	No
Which nations will have participating NHS/HSC organisations after this amendment?	No	No	**Yes**	No

Does this study only involve a single participating NHS organisation in Scotland?	Yes	**No**

Section 2: Summary of change(s)

Please note: Each change being made as part of the amendment must be entered separately. For example, if an amendment to a clinical trial of an investigational medicinal product (CTIMP) involves an update to the Investigator's Brochure (IB), affecting the Reference Safety Information (RSI) and so the information documents to be given to participants, these should be entered into the Amendment Tool as three separate changes. A list of all possible changes is available on the "Glossary of Amendment Options" tab. To add another change, click the "Add another change" box.

Change 1				
Area of change (select)*:	Study Design			
Specific change (select - only available when area of change is selected first)*:	Extension to study duration that will not have any additional resource implications for participating organisations - Please specify in the free text below			
Further information in particular, please describe why this change can be implemented within the existing resource in place at the participating organisations (free text - note that this field will adapt to the amount of text entered)*	There is currently no resource burden on participating organisations. Physical space is not required, the only addition will be further time for clinicians to refer participants to the study.			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	No	No	**Yes**	No
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	**All**		Some	
			Add another change	

Section 3: Declaration(s) and look for submission

Declaration by the Sponsor or authorised delegate

- I confirm that the Sponsor takes responsibility for the completed amendment tool
- I confirm that I have been formally authorised by the Sponsor to complete the amendment tool on their behalf

Name (first name and surname):*	Paula Stevenson
Email address:*	[redacted]

Look for submission

Please note: This button will only become available when all mandatory (*) fields have been completed. When the button is available, clicking it will generate a locked PDF copy of the completed amendment tool which must be included in the amendment submission. Please ensure that the amendment tool is completed correctly before locking it for submission.

Look for submission

After looking the tool, proceed to submit the amendment online. The "Submission Guidance" tab provides further information about the next steps for the amendment.

Section 4: Review bodies for the amendment

Please note: This section is for **information only**. Details in this section will complete automatically based on the options selected in Sections 1 and 2.

	Review bodies																	
	UK wide:						England and Wales:				Scotland:				Northern Ireland:				
	REC	Competent Authority MHRA - Medicines	Competent Authority MHRA - Devices	ARSAC	Radiation Assurance	**UK SW Governance**	REC (MCA)	CAG	IMPS	IRA and HCRW Approval	REC (NMA)	PSPP	SPS (PAEC)	**National coordinating function**	REC REC	REC Data Guardians	Prisons	National coordinating function	Category:
Change 1:						(Y)								(Y)					C
Overall reviews for the amendment:																			
Full review:						N								N					
Notification only:						Y								Y					
Overall amendment type:	Non-substantial, no study-wide review required																		
Overall Category:	C																		

9.20 Validation study IRAS amendment tool 30/01/2023

Amendment Tool
v1.6 06 December 2021

For office use
QC: No

Section 1: Project information

Short project title*:	International Trauma Interview (ITI) Standardisation and Validation
IRAS project ID* (or REC reference if no IRAS project ID is available):	285376
Sponsor amendment reference number*:	2678999 Am 1
Sponsor amendment date* (enter as DD/MM/YY):	30 January 2023
Briefly summarise in lay language the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study. If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained (note: this field will adapt to the amount of text entered)*:	Veteran's First Point (Argyle House, 3 Lady Lawson Street, Edinburgh EH3 9DR) has agreed to refer patients to this study. This will allow a larger number of participants to be recruited to increase the overall power of the study.

Project type (select):	**Specific study**			
	Research tissue bank			
	Research database			
Has the study been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this amendment?:	**Yes**		No	
What type of UKECA-recognised Research Ethics Committee (REC) review is applicable? (select):	**NHS/HSC REC**			
	Ministry of Defence (MoDREC)			
Is all or part of this amendment being resubmitted to the Research Ethics Committee (REC) as a **modified amendment** (i.e. a substantial amendment previously given an unfavourable opinion)?	Yes		**No**	
Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?:	England	Wales	Scotland	Northern Ireland
	No	No	**Yes**	No
Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	Yes		**No**	
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	Yes		**No**	
Did the study involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the amendment introduce this?:	Yes		**No**	
Did the study involve the use of research exposures to ionising radiation (not involving the administration of radioactive substances) OR does the amendment introduce this?:	Yes		**No**	
Did the study involve adults lacking capacity OR does the amendment introduce this?:	Yes		**No**	
Did the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?:	Yes		**No**	
Did the study involve prisoners or young offenders who are in custody or supervised by the probation service OR does the amendment introduce this?:	Yes		**No**	
Did the study involve children OR does the amendment introduce this?:	Yes		**No**	
Did the study involve NHS/HSC organisations prior to this amendment?:	**Yes**		No	
Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:	Yes		**No**	
	England	Wales	Scotland	Northern Ireland
Lead nation for the study:	No	No	**Yes**	No
Which nations had participating NHS/HSC organisations prior to this amendment?	No	No	**Yes**	No
Which nations will have participating NHS/HSC organisations after this amendment?	No	No	**Yes**	No
Does this study only involve a single participating NHS organisation in Scotland?	Yes		**No**	

Section 2: Summary of change(s)

Please note: Each change being made as part of the amendment must be entered separately. For example, if an amendment to a clinical trial of an investigational medicinal product (CTIMP) involves an update to the Investigator's Brochure (IB), affecting the Reference Safety Information (RSI) and so the information documents to be given to participants, these should be entered into the Amendment Tool as three separate changes. A list of all possible changes is available on the "Glossary of Amendment Options" tab. To add another change, click the "Add another change" box.

Change 1				
Area of change (select)*:	Participating Organisations			
Specific change (select - only available when area of change is selected first)*:	Addition of sites undertaking the same activities as existing sites			
Further information (free text - note that this field will adapt to the amount of text entered):	Veteran's First Point (Argyle House, 3 Lady Lawson Street, Edinburgh EH3 9DR) has agreed to refer patients to this study. They have agreed to speak to their clients and are able to provide physical space for interviews. A new site is being added to the list of recruitment sites.			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	No	No	**Yes**	No
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	All		**Some**	
			Add another change	

Section 3: Declaration(s) and look for submission

Declaration by the Sponsor or authorised delegate

- I confirm that the Sponsor takes responsibility for the completed amendment tool
- I confirm that I have been formally authorised by the Sponsor to complete the amendment tool on their behalf

Name (first name and surname):	Paula Stevenson
Email address:	[redacted]

Look for submission

Please note: This button will only become available when all mandatory (*) fields have been completed. When the button is available, clicking it will generate a locked PDF copy of the completed amendment tool which must be included in the amendment submission. Please ensure that the amendment tool is completed correctly before locking it for submission.

Look for submission

After looking the tool, proceed to submit the amendment online. The "Submission Guidance" tab provides further information about the next steps for the amendment.

Section 4: Review bodies for the amendment

Please note: This section is for **information only**. Details in this section will complete automatically based on the options selected in Sections 1 and 2.

	Review bodies																	
	UK wide:						England and Wales:				Scotland:				Northern Ireland:			
	REC	Competent Authority MHRA - Medicines	Competent Authority MHRA - Devices	ARSAC	Radiation Assurance	UKSW Governance	REC (MCA)	CAG	HMPPS	HRA and HCRW Approval	REC (AVMA)	BBPP	SPS (RAEC)	National coordinating function	HSC REC	HSC Data Guardians	Prisons	National coordinating function	Category:
Change 1:						(Y)								(Y)					New site
Overall reviews for the amendment:																			
Full review:						N								N					
Notification only:						Y								Y					
Overall amendment type:	Non-substantial, no study-wide review required																		
Overall Category:	New site																		

NHS
Health Research Authority

9.21 Validation study end of study declaration

Declaration of the end of a study

(For all studies except Clinical Trials of Investigational Medicinal Products)

To be completed in typescript by the Chief Investigator or sponsor representative and submitted to the Research Ethics Committee (REC) that gave a favourable opinion of the research within 90 days of the conclusion of the study or within 15 days of early termination

1. Details of Chief Investigator

Name:	Zoe Wagland
Address:	Edinburgh Napier University, [redacted]
Telephone	[redacted]
E-mail:	[redacted]

2. Details of study

Full title of study:	International Trauma Interview (ITI) Standardisation and Validation
IRAS ID:	285376
Name of REC:	West of Scotland REC 1
REC reference number:	21/WS/0027
Date of favourable ethical opinion:	23/03/2021

Sponsor:	Edinburgh Napier University

3. Study duration

Date study commenced:	31/03/2021
Date study ended	26/07/2023
Did this study terminate prematurely?	**No** If yes, please complete sections 4, 5 & 6. If no, please complete section 4 and then go directly to section 7.

4. Recruitment

Number of participants recruited	29
Proposed number of participants to be recruited at the start of the study	200
If different, please state the reason or this	Unforeseen issues with recruitment were experienced. There were not as many treatment-seeking individuals willing to participate, and NHS clinicians were unable to discuss the option to participate with their clients due to overworking.

5. Circumstances of early termination

What is the justification for this early termination?	

6. Potential implications for research participants

Are there any potential implications for research participants as a result of terminating the study prematurely? Please describe the steps taken to address them.	

7. Final report on the research

Have you submitted a Final Report?	Yes If no, please submit a Final Report within 12 months of the end of the study (or for paediatric CTIMPs, within 6 months). More information is available on the HRA website

8. Declaration

*Signature or Electronic Authorisation of Chief Investigator/sponsor representative: *Please print below or insert electronic signature	Zoe Wagland
Print name:	Zoe Wagland
Date of submission:	26/07/2023

9.22 Validation study NHS letter of access

2 November 2021
Miss Zoe Wagland
Edinburgh Napier University
Sighthill Campus
[redacted]

Dear Miss Wagland

Letter of Clinical Research Access – only valid until 31 March 2023 for study number 2021/0141 entitled 'Towards the validation of the International Trauma Interview (ITI) for the IDC-11 diagnoses of Post-Traumatic Stress Disorder and Complex Post-Traumatic Stress disorder, and the role of core beliefs'.

The UK Policy Framework for Health and Social Care Research outlines the responsibilities of researchers who undertake research in a clinical setting. The framework has been compiled by the Scottish Executive Health Department to ensure all research meets high scientific and ethical standards.

This Letter of Clinical Research Access defines the requirements of Lothian Health Board (the "Board"), subject to which, you are granted rights of Clinical Research Access to carry out Approved Research in the course of your current PhD programme of study at the Edinburgh Napier University.

On signature of this letter, subject to the Board undertaking appropriate Disclosure Scotland checks, you will be granted the right of Clinical Research Access which will continue, until such time as permission is withdrawn by the Board, in the circumstances mentioned in the next paragraph, or such time as you cease to be involved in Approved Research activity or you current study programme mentioned above.

In the event that you are in material breach of the requirements regarding Clinical Research Access as set out in this letter, or the Board considers that it is in the best interests of its patients, then in either circumstance the Board may withdraw Clinical Research Access with immediate effect by giving you written notice of this.

1. Definitions

"Approved Research" means research which has not only been approved by Edinburgh Napier University but has also received the approval of Lothian Health Board i.e. R & D Management approval, the necessary ethical approval and any further statutory approvals.

"Confidential Information" includes all information which has been specifically designated as confidential by the Board and any information which relates to the commercial and financial activities of the Board, the unauthorised disclosure of which would embarrass, harm or prejudice the Board.

"Principal Investigator" means, in relation to a specific unit of research undertaken in a specific location, the researcher responsible for the overall conduct of that research activity.

2. Confidentiality and Disclosure of Information

You must not divulge Confidential Information to any third party during the period of your research or any time thereafter without the proper authority having first been given. All Confidential Information belonging to the Board, together with any copies or extracts thereof, made or acquired by you in the course of research shall be the property of the Board and must be returned to the Principal Investigator on completion of the research to which they relate or on the termination of your employment whichever is the earlier date. You will be entitled to retain any copies or extracts made or acquired by you in the course

of research for references purposes only, provided that such copies or extracts are held and maintained in accordance with the provisions of the Data Protection Act 2018 and Caldicott principles.

3. Protection of Intellectual Property

The protection of intellectual property is an important matter, and you will abide by the requirements of the Board and the Edinburgh Napier University in relation to this matter. The Board and Edinburgh Napier University deal with intellectual property matters on a case-by-case basis.

4. Obligations Arising from Data Protection Act 2018/IT Security

Particular regard should be given to your responsibility to abide by the principles of the Data Protection Act 2018, a copy of which is available for reference in the Human Resources Department of the Board.

You must comply with the Board's Information Technology Security Policy on computer security, which is available within the Board R & D Department and on the Board Intranet site. Failure to comply with this will be brought to the attention of the University for investigation/action under the appropriate procedures. In addition failure to comply may lead to temporary or permanent withdrawal of permission to carry out research within the Board.

Patients

In the course of your duties you may have access to Confidential Information regarding patients. You must not divulge such Confidential Information to anyone other than authorised persons, for example, medical, nursing or other professional staff as appropriate, who are concerned directly with the care, diagnosis and/or treatment of the patient. Where, in the course of your clinical research activity, new information comes to light that will or may impact on patient care, you will forthwith advise the relevant personnel within the Board.

Staff

You must not divulge Confidential Information concerning individual members of staff to anyone without the authority of the individual concerned and the appropriate Principal Investigator. If you are in any doubt whatsoever as to the authority of a person or body asking for information on patients or staff, or your own authority to divulge information, you must seek advice from the Principal Investigator and/or the responsible person at your **University.**

These provisions are without prejudice to the NHS's stated commitments in the NHS Code of Openness. Further information is available from the Board's Human Resources Department.

5. Disclosure of Concerns

If you have any concerns about quality of service, health and safety, use of NHS money, or believe a colleague's conduct, performance or health may be a threat to patient care or to members of staff, you have a responsibility to raise these concerns without prejudice, directly with the Principal Investigator, your line manager or the responsible person at the University. If you are unable to, or wish not to raise these concerns directly with your line manager / Principal Investigator, you are encouraged to seek the advice of the Human Resources Department or Edinburgh Napier University as appropriate.

You are protected against any harassment or victimisation resulting from such a disclosure. Therefore in the event that you are subjected to any form of harassment or victimisation, formal action will be taken against the perpetrators.

Concerns related to any research misconduct or fraud should be addressed similarly.

6. Conflict of Interest

As a general principle, you should not put yourself in a position where your official and private interests conflict, nor must you make use of your official/research position to further your private interests.

7. Research Governance

You are required to observe those requirements of the Research Governance Framework which are applicable and binding on you. The Research Governance Framework is available in the R & D Department and on the Intranet under Organisational/R&D. The framework relates to the management and monitoring, ethics, science, finance, health and safety aspects of research.

8. Health and Safety

The Board has a written Health and Safety Policy. The Board has a duty to ensure, so far as is reasonably practicable, the health, safety and welfare at work of all its employees/individuals who work on the site. As an individual who works on the site, you have a duty to observe safe systems of work at all times, to take reasonable care of yourself and others who may be affected by your activities at work and to co-operate with the Board and others in meeting statutory requirements.

Additionally, you are required to report all accidents "near misses"/ incidents to the responsible person at the University and to use any safety equipment provided for your protection. Failure to comply with the provisions detailed above, without reasonable cause, will be brought to the attention of your employer for investigation/action under the appropriate procedures. In addition failure to comply may lead to temporary or permanent withdrawal of permission to carry out research within the Board.

9. Hepatitis B

For your own protection, you are advised to maintain Hepatitis B immunity status throughout the period during which you have been granted Clinical Research Access rights if your work brings you into contact with blood, other body fluids or fresh tissue.

10. Professional Registration

If your programme of study requires professional registration you must be fully registered with the appropriate professional body and maintain this registration throughout the period during which you have been granted Clinical Research Access rights. Evidence of this must be produced upon request.

11. Personal Property

The Board accepts no responsibility for damage to, or loss of, personal property. You are, therefore, advised to take out an insurance policy to cover your personal property.

If you need any further advice or guidance on any of the paragraphs set out above you should contact the responsible person at the University in the first instance.

If you agree to accept the conditions indicated above, please print this letter and sign the statement of acceptance and return to the Board's R & D Department. Please retain a second signed copy of this letter for future reference as you will be required to provide this for evidence of clinical research access to each Principal Investigator with whom you work.

Yours sincerely

Dr Heather Charles

Head of Research Governance

cc

9.23 Validation study participant information sheet

Participant information sheet

Towards the validation of a new Post-Traumatic Stress Disorder tool

Invitation

My name is Zoe Wagland, and I would like to invite you to take part in a study I am conducting as part of my PhD in Psychology. Joining the study is entirely up to you and you have the right to withdraw at any point in time. Before you decide we would like you to understand why the research is being done and what it would involve for you. Please take time to read through this document and ask any questions you may have.

Background to the study

The title of this study is "Towards the validation of the International Trauma Interview (ITI) for the ICD-11 diagnoses of Post-Traumatic Stress Disorder and Complex Post-Traumatic Stress Disorder, and the role of core beliefs". What this means is we are trying to provide evidence that the International Trauma Interview (ITI) is a good method of diagnosing both PTSD and Complex PTSD (CPTSD).

Presently there are no interview assessment tools that clinicians can use in the assessment and diagnosis of Complex PTSD (CPTSD). It is important to make sure that new assessment tools give results that are reliable enough to use in diagnosis and treatment. This study is looking at the reliability of the ITI to make sure that it can be used in clinical practice.

One of the minor aims of this study is looking at how a person's beliefs about themselves can contribute to the development of CPTSD. We hope to be able to show that certain beliefs can be adjusted in therapy to help reduce the severity of CPTSD.

Why have I been invited to take part?

We are inviting patients referred by NHS clinicians. NHS clinicians might refer a person if they would benefit from further assessment for Post-Traumatic Stress Disorder (PTSD) or Complex PTSD (CPTSD).

What does the study involve?

If you agree to participate in the study, you will be sent a participant pack including three questionnaires. These questionnaires will ask you about your PTSD symptoms, your beliefs about yourself, and the nature of your most important traumatic event. You will also be asked to fill out a demographic form with information such as your name, age, and ethnicity.

We will then arrange a time to meet via videocall using NHS-provided Attend Anywhere software. You will be able to ask any initial questions and I will collect your responses from the questionnaires and record your response on the consent form. I will then ask you the questions from the ITI and make a few notes on your answers. The video call should take no longer than around an hour. After this we will debrief, and your results will be sent to your clinician for discussion at your next meeting.

Some participants will be asked to give permission for their interviews to be audiotaped, transcribed, and the anonymous transcriptions sent to another trained clinician. It is important that we make sure that two different clinicians give the same interview the same score.

Other participants may be asked to attend a second meeting with the researcher where the ITI will be repeated. It is important that some participants do the interview twice so that we can make sure that the interview gives the same results for the same person even on different days. If you would like to take part but would prefer not to repeat the interview, this can be accommodated.

However, most participants will be asked to do the interview only once, without being recorded. If you would like to take part but would prefer not to be asked to do the interview twice and would not like to be recorded this can be accommodated.

Do I have to take part?

It is your decision to take part or not. Your standard of treatment and any future medical or psychological care will not be affected by a decision to not participate.

You are welcome to withdraw from the study at any time until your data had been fully anonymised. At this point it will be impossible or your data to be identified. If you decide to withdraw your data, all hard copy notes will be shredded, and digital data will be destroyed in line with University and NHS guidelines. It may not be possible to delete data after it has been anonymised and analysed, though identifiable data can be deleted if it hasn't already. If you decide to withdraw you would not have to give a reason, and your ongoing treatment would not be affected.

What are the discomforts or risks?

The questionnaires you will be asked to complete are used routinely in research and clinical practice, and therefore have no adverse effects associated with them that we are aware of. As the study does involve talking about your traumatic experience it is possible that you may experience some discomfort or distress. If you do experience distress, you are welcome to ask for a break, and the interviewing researcher is clinically trained and will be able to contact your referring clinician for support if needed.

What will happen to the information you collect about me?

All the information collected about you will be stored electronically on the University network. This means that your data is password-protected and stored on encrypted servers. The findings from your questionnaires and interviews will be collated and analysed with other participants' data. All identifiable information (such as your name, date of birth etc.) will be kept separately from your interview data and no identifiable information will be presented in public forums. Please read the privacy notice for full information on how your data will be stored and processed.

Who has reviewed the study?

The Edinburgh Napier University Research Ethics Committee, which has responsibility for scrutinising proposals for research conducted by staff and students, has provided a favourable ethical opinion for this study.

What to do next

If you would like to take part in this study, please read the privacy notice and complete the consent form. Your consent form must be collected before your participation in the study. You are welcome to choose one of the following methods of indicating your completion of the consent form; send the completed form by mail (please email Zoe Wagland for details) OR show the completed form to the researcher via webcam at the time of interview. No responses or participation can be recorded until after proof of the completed consent form has been received. If you wish a copy of the overall results from the study or if you have any difficulties or further questions, please contact the chief investigator using the contact details provided below.

Further information

If you have any questions about this study, you are welcome to contact the researcher Zoe Wagland [redacted] or a member of the supervisory team Thanos Karatzias [redacted]

If you would like to contact a person who knows about this study but is not directly connected with it you are welcome to speak to Lis Neubeck [redacted]

Thank you for taking the time to read the Participant information sheet and for considering taking part in this study. Please take the time to carefully read the privacy notice and the consent form before completing the consent form to indicate your consent to participate.

9.24 Validation study privacy notice

Name of Research Project: Towards the validation of the ITI for the ICD-11 diagnoses of Post-Traumatic Stress Disorder and Complex Post-Traumatic Stress Disorder, and the role of childhood maladaptive schema

Description of Project: The study involves 200 participants being interviewed using the International Trauma Interview (ITI) protocol. The interviews will be conducted and scored by a trained researcher, and a report of the results forwarded to the primary clinician associated with each participant.

Data Controller	Edinburgh Napier University
Purposes for collection/processing	To find the reliability of an interview assessment of Complex PTSD (CPTSD)
Legal basis	Art 6(1)(e), performance of a task in the public interest/exercise of official duty vested in the Controller by Statutory Instrument No. 557 (S76) of 1993 as amended, e.g. for education and research purposes. Where sensitive personal data is being processed the additional bases from Article 9 is: Art 9(2)(j) for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes. All staff involved in this project will receive data quality and management, confidentiality, and record-keeping training
Whose information is being collected?	Patients referred to the study by NHS clinicians.
What type/classes/fields of information are collected?	Name, age, gender ethnicity Details about most important traumatic event Thoughts and feelings about the event Symptoms relating to the event Beliefs about themselves
Who is the information being collected from?	Data is being collected directly from you as the participant in the study.
How is the information being collected?	Interview information is being collected by NHS-approved video call software and recorded on paper by the researcher. Paper notes will then be transferred to an electronic record and the paper copy destroyed.
Is personal data shared externally?	No
How secure is the information?	Paper notes will be locked in a filing cabinet until digitization at the earliest opportunity, after which time the paper copies will be shredded. Electronic information will be stored on the University network (which will be accessed remotely via secure methods e.g. Virtual Desktop or Virtual Private Network provided by the University) and therefore protected by university policies and procedures.

	Participant identifiable information will be linked to their research data by a code accessible only to the study researchers. This is to enable retrieval or removal if requested by a participant and/or audit. In the event that it is necessary to transfer data electronically, this will be done in password protected documents sent via encrypted email. Analysis of data will also take place on university-owned and protected computers. At the end of the project, all identifiable information will be removed from the data sets and data will be stored within the university information repository, with all remaining copies of digital data being erased.
Who keeps the information updated?	The researcher will have responsibility for keeping information updated if informed by participant/s that this is necessary..
How long is the information kept for?	Any voice recordings will be stored only until the end of the project. Written data will be retained in the university repository for 10 years. This does not include personal data such as dates of birth and ethnicity, which will be destroyed after the end of the project.
Will the data be used for any automated decision making?	No
Is information transferred to a third country? Outside the UK and not included in the adequate countries list.	No
Will the data from the ITI be transferred to any other third party?	If you have given consent for your interview to be recorded and transcribed, the anonymised transcription will be sent to a trained external clinician for secondary assessment.
You can access all the University's privacy notices using the following link: https://staff.napier.ac.uk/services/governance-compliance/governance/DataProtection/Pages/statement.aspx You have a number of rights available to you with regards to what personal data of yours is held by the University and how it is processed – to find out more about your rights, how to make a request and who to contact if you have any further queries about Data Protection please see the information online using the following URL: https://staff.napier.ac.uk/services/governance-compliance/governance/DataProtection/Pages/default.aspx	

9.25 Validation study consent form

Towards the validation of a new Post-Traumatic Stress Disorder tool

Participant identification number for this study:

Name of researcher: Zoe Wagland

Edinburgh Napier University requires that all persons who participate in research studies give their written consent to do so. Please read the following and sign it if you agree with what it says.

	Initial
I have read and understood the participant information sheet (version 3.4) and privacy notice (version 3.2).	
I give consent for this form to be stored electronically on Edinburgh Napier University secure research computer drive.	
I have had an opportunity to ask questions about my participation.	
I understand that I am under no obligation to take part in this study.	
I understand that I have the right to withdraw from this study at any stage without giving any reason. If I withdraw from the study, any non-identifiable data	
I have provided may still be used as part of the study.	
I understand that non-identifiable data will be shared with the research team.	
I understand that data collected for the study may be shared with other researchers (on an anonymous basis). Data sharing will only be conducted as per the UK Data Protection Act 2018 and UK General Data Protection Regulations.	

Please state yes or no to following questions:	Yes	No
I give permission for my interview to be audio recorded.		
I am aware that anonymised quotes may use my exact words in the publication of these findings.		
I would be interested in attending a repeat interview in two weeks' time		
I agree to participate in this study		
I give permission for my interview to be audio recorded.		

Name of Participant Participant's Signature Date

9.26 Validation study debrief sheet

Towards the validation of a new trauma assessment tool

Thank you very much for participating in this study. I would like to take this opportunity to remind you of your rights, including your right to withdraw your responses up until the time that your data is anonymised. I would also like to remind you that all your information and results will be anonymised before analysis, and a pseudonym will be used where appropriate during publication.

Moving forward from this point, I will write up a summary of your results and forward this to your primary clinician. This may be the person conducting your clinical assessment. This summary will be helpful in planning the treatment you receive in the future.

If you feel that you have been negatively affected by anything which we have discussed today, I advise you to contact your primary mental health care provider. This may be your Therapist, Psychiatrist, or GP. It may also be helpful to contact a helpline such as Samaritans on: 116 123, or to visit a community support website such as the Big White Wall: www.bigwhitewall.com.

Should you wish to be informed of any papers which make use of the data you have provided, please let me know. I will take a note of your name and email address and these will be stored securely on a password protected computer and only used to send you copies of published works directly resulting from your responses.

If you wish to withdraw your data, or if you have any questions please contact me at: zoe.wagland@napier.ac.uk, or the supervisor at: t.karatzias@napier.ac.uk.

9.27 Validation study letter to referring clinician

Re: **participant name**

To whom it may concern,

The above individual attended a meeting with myself on **date** during which time I interviewed them using the International Trauma Interview (ITI). The ITI is an interview protocol designed to assess for PTSD and Complex PTSD. I have attached below the outcome of the interview, along with responses to the self-report psychometrics administered.

The results of the ITI and ITQ responses meet the current threshold criteria for **PTSD/CPTSD/subclinical presentation**, though this is not a formal diagnosis as the ITI has not presently been validated as a diagnostic tool.

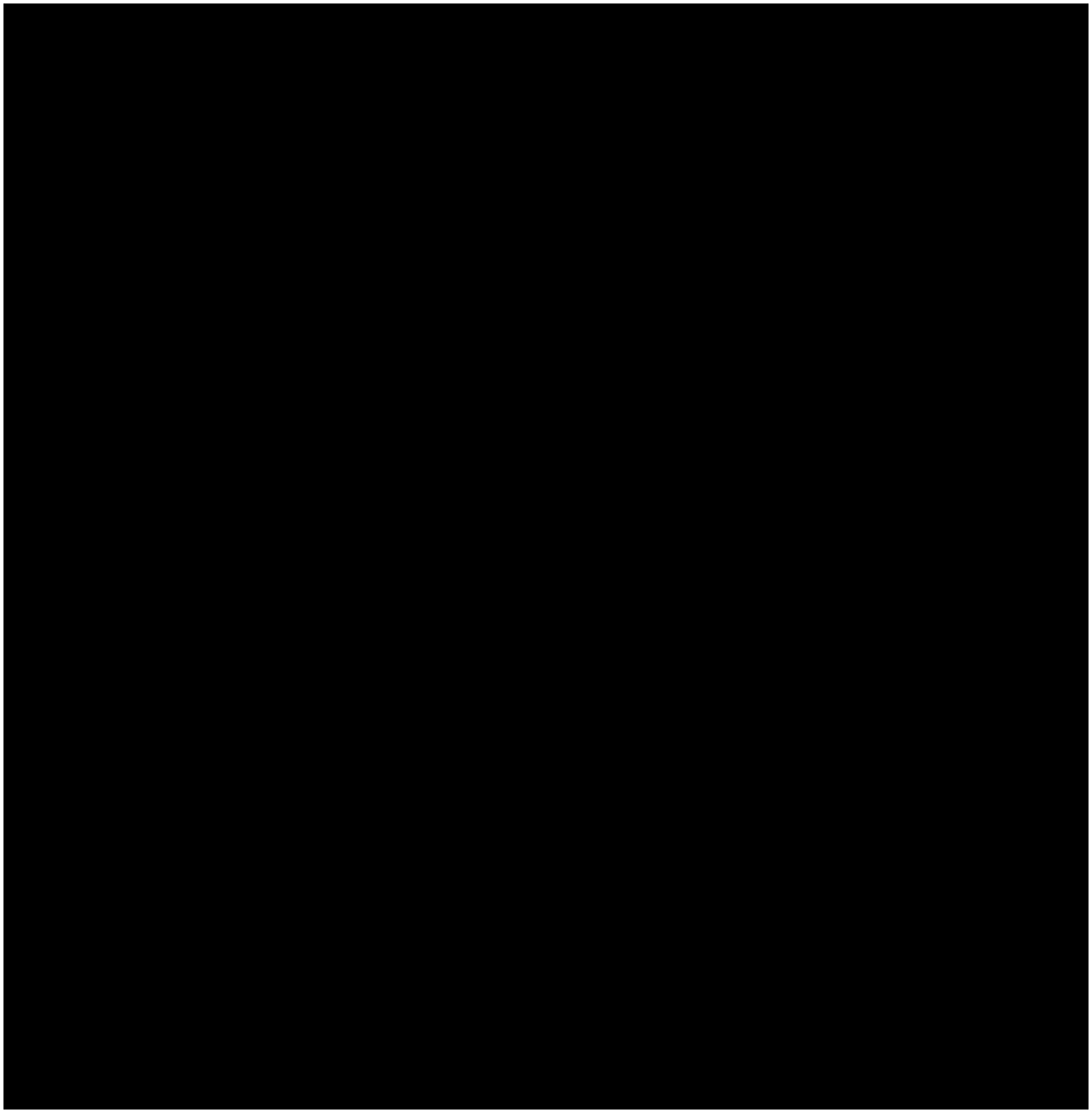
Andrew has given informed consent and has been informed of their rights, including their right to withdraw their data at any time. They have also been informed that the results of the interview with me will be available for discussion at their next meeting with you.

Thank you very much for this referral, the research we are undertaking is of vital importance for the improved assessment and diagnosis of Complex PTSD and we would readily welcome any other clients you believe may be suitable or may benefit from this interview.

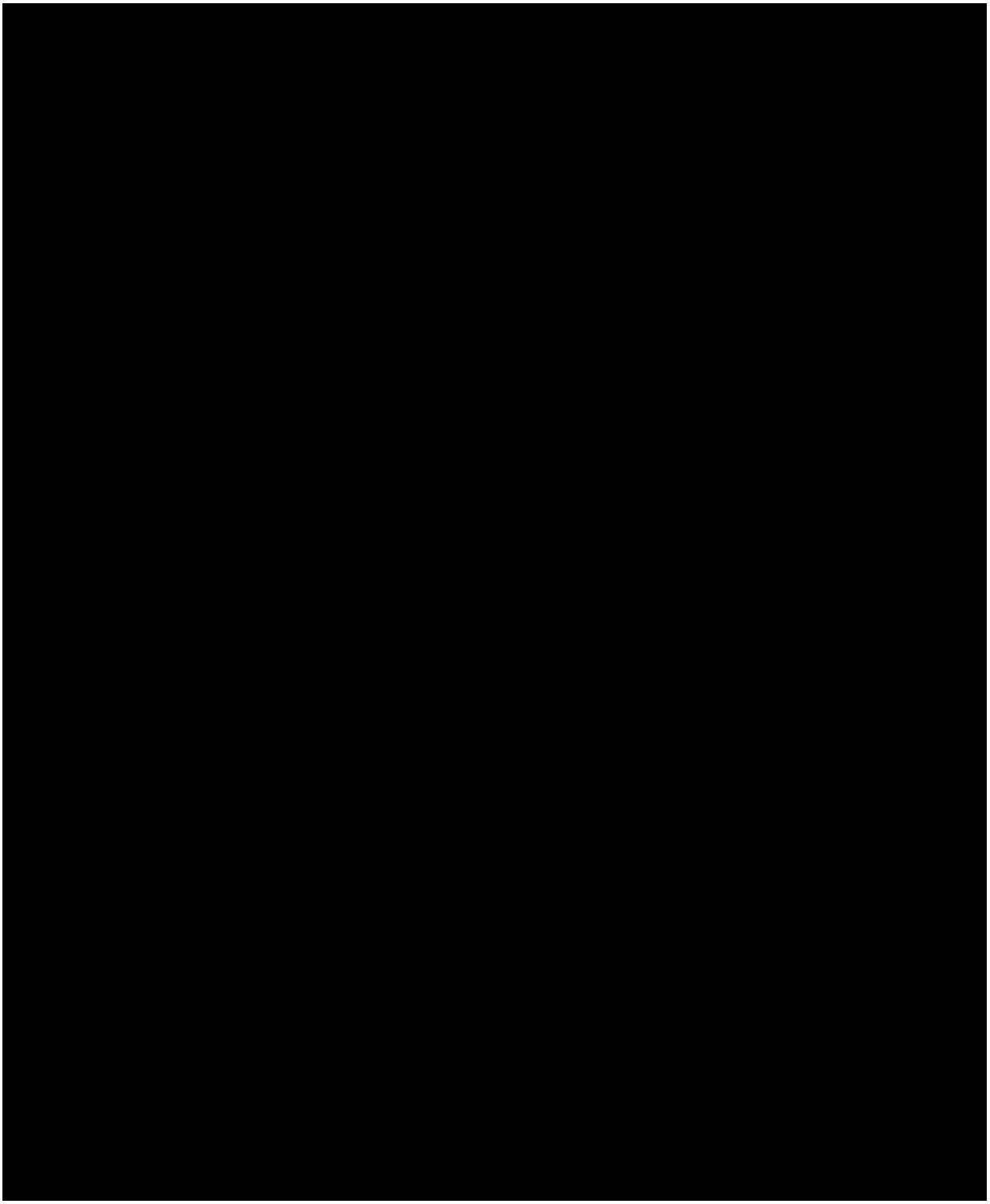
Yours Sincerely,

Zoe Wagland

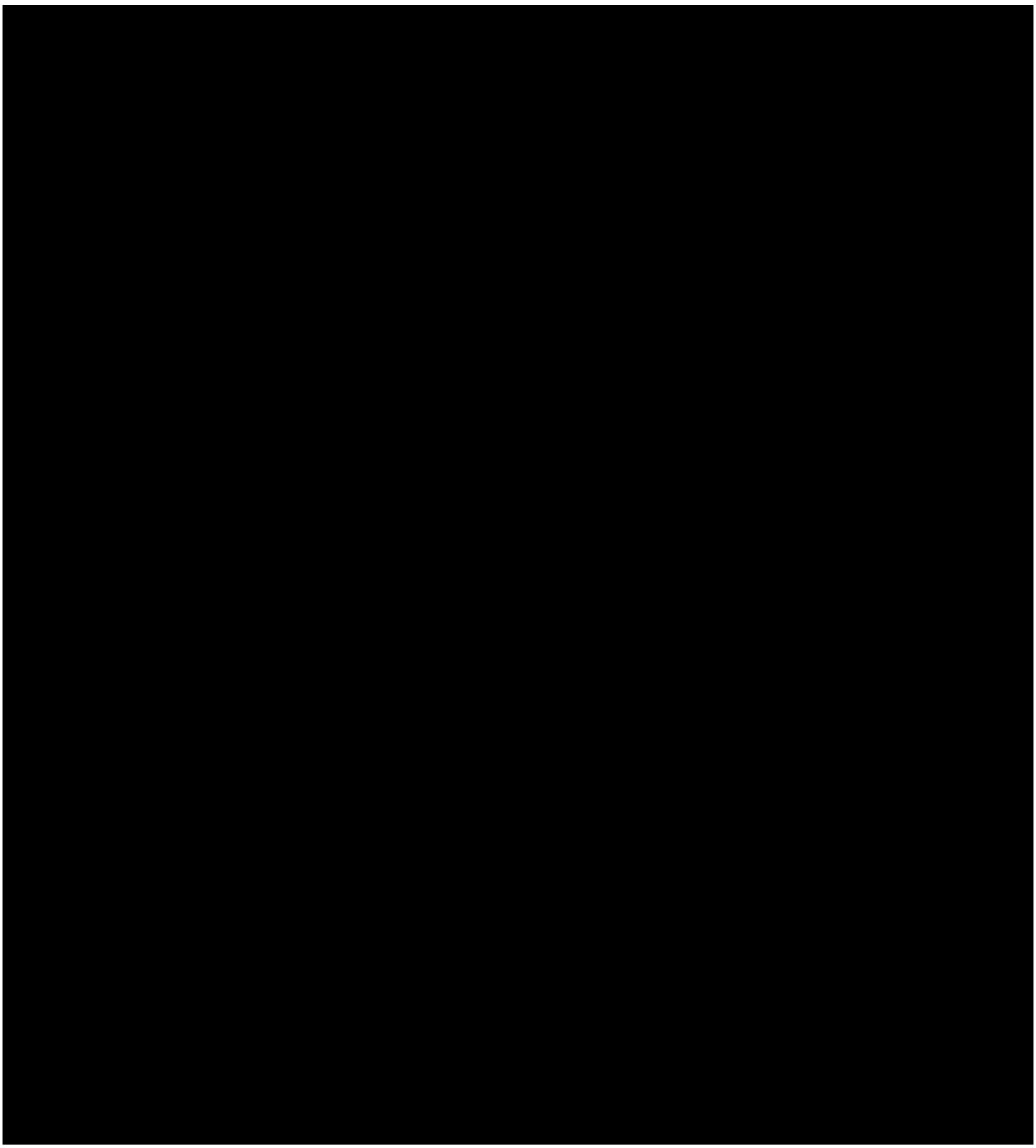
Core Beliefs Questionnaire (Wong et al., 2017)



International trauma questionnaire (Cloitre et al., 2018)



International Trauma Interview (Roberts et al., 2019)

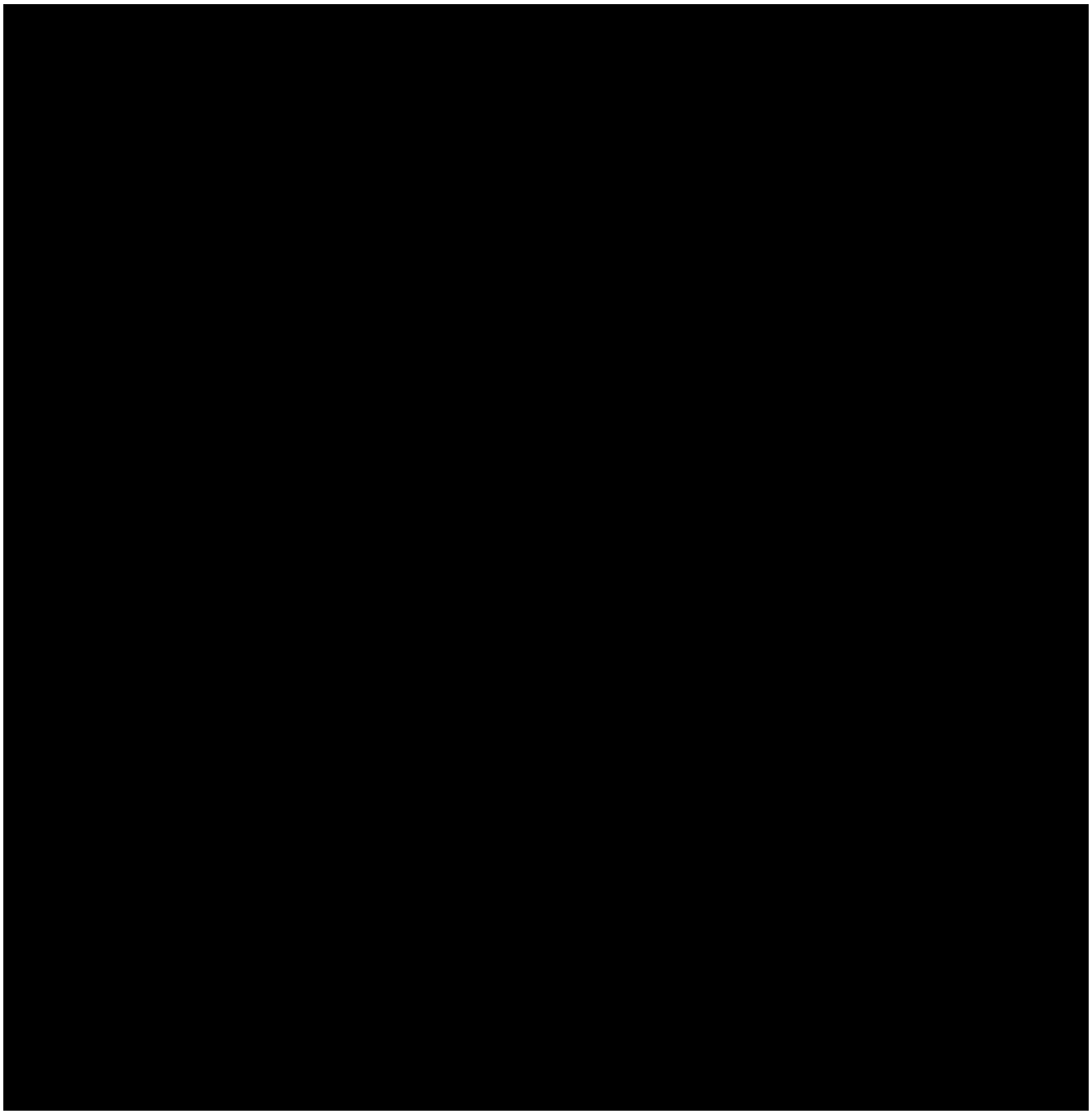


9.28 International Trauma Interview

International Trauma Interview (ITI) for ICD-11

PTSD and Complex PTSD

Test Version 3.2



9.29 Clinician survey

Clinical utility survey

We are interested in how useful the results of the ITI were in your clinical practice, as well as some other aspects of clinical utility. Please answer the questions below with as much detail as you are able. You do not need to respond to questions which do not apply to you (for example, if you have not used the interview protocol yourself).

How easy do you feel it was to apply the interview to this individual?

How useful do you feel the interview would be for communicating information about this individual with other mental health professionals?

How useful do you feel this interview would be for communicating information about the individual to him or herself?

How useful is this interview for comprehensively describing all the important PTSD/CPTSD-related problems the individual has?

How useful would this interview be for helping you to formulate an effective intervention for this individual?

How useful was this interview for describing the individual's global mental health?