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**The Efficacy and Effectiveness
of Psychological Interventions
for Symptoms of Complex PTSD in Adults**

by

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Thesis Abstract

The notion of complex posttraumatic stress disorder (CPTSD) is a longstanding yet contentious one: it has only recently been included as a diagnostic entity in its own right in the most recent version of the International Classification of Diseases (ICD-11: World Health Organization, 2018), and, after considerable debate, was not incorporated into the latest version of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5: American Psychiatric Association, 2013). As such, the evidence base for how best to treat difficulties associated with complex trauma remains patchy. Further, most studies and meta-analyses to date have focused on highly controlled research trials across quite disparate populations, so our understanding of which interventions may be effective to the majority of clients seeking help for difficulties associated with CPTSD in “real-world” clinical practice (namely, those whose complex trauma originated in childhood), remains very limited.

Chapter one of this thesis presents the results of a meta-analysis of the efficacy and effectiveness of psychological interventions for adult survivors of complex, childhood trauma, considering both randomized, controlled trials and non-RCTs. This meta-analysis showed that many interventions are effective in reducing symptoms of PTSD in this population; uncontrolled effect sizes (pre- to post-treatment) and controlled effect sizes (treatment versus control group measures at post-treatment) were generally largest for trauma-focused and “phase based” treatments compared to those aimed at initial safety and stabilization. Uncontrolled effect sizes were generally larger for RCTs ($d = 1.02$) compared with uncontrolled trials ($d = 0.7$). However, very few studies examined the effects of treatment on additional symptoms of complex PTSD (emotion dysregulation, negative self-concept, and interpersonal functioning), or more general measures of distress or functioning, which may arguably be of greater importance to many people seeking help with their difficulties.

Chapter two presents the findings of a large-scale ($n = 634$) “real-world” study of outcomes associated with a safety and stabilization group intervention, “*Survive and Thrive*”, for women survivors of complex trauma as implemented in routine clinical care within two NHS Adult Mental Health services. This study found that *Survive and Thrive* appears to be acceptable, safe, and effective in reducing overall psychological distress and symptoms of PTSD, depression, and anxiety, with pre- to post-treatment effect sizes ranging from 0.5 – 0.81 (Cohen’s d) and proportions of participants achieving clinically significant improvements in symptoms ranging from 23 – 40% - at least, among those who complete treatment. However, the lack of a control group and high drop-out rate (46%) means that these preliminary findings are likely over-estimates of overall effectiveness and acceptability for the population of treatment-seeking women as a whole and must therefore be treated with caution. We hope the findings will contribute to the evidence base for psychological interventions for complex PTSD, ultimately allowing clients greater choice of evidence-based treatments for their longstanding and debilitating difficulties.

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Chapter 1 Systematic Review & Meta-analysis

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Efficacy of Psychological Interventions on Symptoms of
Complex PTSD for Adult Survivors of Childhood Trauma:
Systematic Review and Meta-Analysis.

by

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1.1 ABSTRACT

Complex PTSD is a prevalent, highly debilitating condition which has been included for the first time in the ICD-11. Considerable evidence indicates that adult survivors of trauma beginning in childhood have more complex, chronic, and severe symptoms and functional impairment, and demonstrate poorer treatment outcomes compared with those who first experienced trauma in adulthood. However, our understanding of what interventions are efficacious in reducing symptoms of complex PTSD in this population remains limited. In this meta-analysis, we examined the efficacy of psychological interventions for symptoms of complex PTSD in adult survivors of childhood trauma. 25 randomized, controlled trials ($n = 2,923$) met criteria for inclusion in the analysis of controlled, post-treatment effects, and a further 28 non-randomized, controlled and uncontrolled trials were added to a supplementary analysis of uncontrolled pre- to post-treatment effects ($n = 3,316$). Results indicated that psychological interventions were efficacious in reducing symptoms of PTSD, with uncontrolled (pre- to post-intervention, across all studies) and controlled (post-treatment, across RCTs only) effect sizes of $g = 1.02$ (“large”), and $g = 0.58$ (“medium”), respectively. Gains appeared to be maintained at follow-up. The minority of studies that examined additional “disorders of self-organization” characteristic of complex PTSD demonstrated similar efficacy for improvements in affect dysregulation (uncontrolled ES: $g = 1.08$, controlled ES: $g = 0.54$), though smaller effects on interpersonal functioning, negative self-concept, and dissociation. Subgroup analyses revealed that trauma-focused and phase-based therapies yielded larger effect sizes than present-focused interventions, and individual and combined individual + group interventions were more efficacious than group interventions alone. However, heterogeneity was very high and there was some evidence of attrition and publication biases, suggesting effect sizes obtained may be inflated, and that more research is required to elucidate “what works for whom” in the treatment of adult survivors of childhood abuse.

1.2 INTRODUCTION

1.2.1 Post-Traumatic Stress Disorder (PTSD)

Post-traumatic stress disorder (PTSD) first appeared as a diagnostic entity in the Diagnostic and Statistical Manual (DSM-III) in 1980, and in the International Classification of Diseases (ICD-10) in 1992. It describes a set of chronic, clinically significant difficulties following the experience of a traumatic event, defined as “*an extremely threatening or horrific event or series of events*” (ICD-11: World Health Organization, 2018), or “*a traumatic event involving actual or threatened death, serious injury, or sexual violence*” (DSM-5: American Psychiatric Association, 2013). Although the nature and classifications of symptoms differ between conceptualizations, they all have in common three broad categories of symptoms: (1) re-experiencing of the traumatic event(s), in the form of intrusive memories, flashbacks, or nightmares; (2) avoidance of reminders of the traumatic event(s); and (3) persistent perceptions of heightened current threat (hyperarousal or hypervigilance). Lifetime prevalence of PTSD is around 8% in the US (Kilpatrick et al., 2013) and UK (Karatzias et al., 2019a), and comorbidity with other mental health difficulties such as depression, anxiety, and substance misuse is very high, at around 80% (Brady, Killeen, Brewerton, & Lucerini, 2000; Breslau, Davis, Andreski, & Peterson, 1991).

National clinical guidelines (e.g. National Institute of Clinical Excellence (NICE), 2018; American Psychiatric Association, 2017) recommend individual, trauma-focused, psychological interventions such as cognitive processing therapy (CPT) (Resick & Schnicke, 1992), cognitive therapy for PTSD (CT-PTSD) (Ehlers, Clark, Hackmann, McManus, & Fennell, 2005), prolonged exposure therapy (PE) (Foa, Hembree, & Rothbaum, 2007), or narrative exposure therapy (NET) (Schauer, Elbert, & Neuner, 2011) for the treatment of PTSD in adults. Although these trauma-focused therapies differ in their primary target and implementation, they share in common “*purposeful, reflective remembering*” of specific traumatic memories (trauma memory processing, or TMP), through which trauma narratives are made more coherent, beliefs and emotions associated with trauma memories are adjusted,

and the ability to differentiate between events occurring in the present and the past is enhanced (Ford, 2018; Schnyder et al., 2015).

Several meta-analyses indicate that trauma-focused therapies are efficacious in reducing symptoms of PTSD (e.g. Bisson et al., 2007; Bisson, Roberts, Andrew, Cooper, & Lewis, 2013), and typically outperform pharmacological treatments (Watts et al., 2013). However, not everyone benefits from trauma-focused interventions, and dropout rates are significantly higher than those of other approaches, indicating they may not be acceptable to a significant proportion of help-seeking adults (Lewis, Roberts, Gibson, & Bisson, 2020; Najavits, 2015). This may be especially true for individuals with more complex and chronic presentations, for whom tolerance of distress associated with revisiting trauma memories may be more difficult.

1.2.2 Complex PTSD (CPTSD)

Increasing evidence indicates that trauma which is prolonged, repeated, and interpersonal in nature (e.g. sexual, physical, or emotional abuse), and which occurs at developmentally sensitive periods (e.g. childhood), is associated with significantly greater risk of a range of additional difficulties, such as dissociation, affect dysregulation, fragmented sense of self, low self-esteem, and difficulties forming and sustaining relationships (Finkelhor & Browne, 1985; McCann & Pearlman, 1990; Terr, 1991). Consequently, a number of researchers have argued that “*in the vast majority of patients with PTSD, this diagnosis does not adequately describe the full extent of their suffering*” (van der Kolk & McFarlane, 1996), and have proposed several alternative conceptualizations of their difficulties, such as Disorders of Extreme Stress (DESNOS: Herman, 1992a; van der Kolk, Pelcovitz, Roth, Mandel, & et al., 1996). Of these, Herman’s notion of “complex PTSD” (Herman, 1992a) has become the most widely accepted, and has been included for the first time in the most recent International Classification of Diseases (ICD-11; World Health Organization, 2018).

In order to satisfy ICD-11 criteria for CPTSD, individuals must meet all criteria for classic PTSD (re-experiencing, avoidance, and hyperarousal), plus three additional persistent and debilitating “disorders of self-organization” (DSOs), namely: (1) affect dysregulation; (2) negative self-concept; and (3) disturbances in relationships. The lifetime prevalence of ICD-11 CPTSD has been recently estimated at between 4 and 13% in the US and UK, respectively (Cloitre et al., 2019a; Karatzias et al., 2019a).

Our understanding of the clinical course of the post-traumatic stress disorders in adults is extremely poor (Alaggia, Collin-Vézina, & Lateef, 2019; Koenen et al., 2017; Lewis et al., 2019), although the considerable heterogeneity in terms of the nature and chronicity of trauma experienced, type and number of symptoms, and comorbidity with other mental health difficulties is widely acknowledged (see e.g. Cloitre et al., 2019; Galatzer-Levy & Bryant, 2013). The course of PTSD is often chronic and unremitting, with between one-third and one-half of people who meet criteria for PTSD reporting symptoms for many years after the original traumatic event (Kessler et al., 2005; Koenen et al., 2017): however, those with clinical levels of PTSD symptomology wait an average of 12 years before seeking help – considerably longer than for the more common conditions of depression and anxiety (Wang et al., 2005). Qualitative studies suggest that common barriers to disclosure and help-seeking among adults with PTSD include lack of knowledge about trauma and its consequences, trauma-related avoidance of distress, limited social support, perceived negative consequences (such as not being understood or believed, being regarded as weak or incompetent, and family conflict), and feelings of shame and guilt (see Lemaigre, Taylor, & Gittoes, 2017; Sayer et al., 2009). Unfortunately, even when survivors do seek professional help, it seems that recognition rates of post-traumatic stress disorders, and subsequent referrals to and take-up of specialist mental health services, remain low (Ehlers, Gene-Cos, & Perrin, 2009; Lewis et al., 2019; Tully, Bhugra, Lewis, Drennan, & Markham, 2021).

Given that rates of comorbidity with other psychiatric conditions are especially high among adult survivors of repeated, interpersonal trauma (in particular, problematic

substance use, depression, and personality disorders), and that disclosure and help-seeking behaviours appear especially difficult, it is likely that the chronicity of symptoms and rates of under-reporting and under-recognition are likely to be especially high in the subpopulation of adults with complex forms of PTSD.

Many researchers argue that the additional disorders of self-organization in complex PTSD make it more difficult for individuals to engage with and benefit from trauma-focused therapy. Instead, they endorse a “phase-based” or sequenced approach to treatment, starting with an initial, skills-focused “safety and stabilization” (S & S) phase to educate clients on the nature and effects of trauma and develop helpful strategies to manage dysregulated emotions and cope with distress. This phase can help clients better prepare for subsequent work on reprocessing of trauma memories (TMP), and reconnecting with others and hopes for the future (Cloitre et al., 2011; Courtois & Ford, 2012; Herman, 2015; Herman, 1992b).

Recommendations for the inclusion of safety and stabilization components to treatment, and greater acknowledgement of difficulties with emotion regulation and intra- and inter-personal relating in survivors of complex trauma, are incorporated tentatively in the most recent guidelines for complex PTSD (e.g. International Society for Traumatic Stress Studies (Cloitre et al., 2012); The Matrix; NHS Education for Scotland, 2015; National Institute of Clinical Excellence (NICE), 2018). However, the notion of CPTSD as a distinct diagnostic construct, requiring a different approach to treatment, remains contentious (e.g. de Jongh et al., 2016; Resick et al., 2012), and the evidence base for treating CPTSD lags behind those of more established diagnoses. Some recent meta-analyses of randomized controlled trials indicate that psychological interventions can be effective in improving symptoms of CPTSD across a broad range of populations and settings (Coventry et al., 2020; Dorrepaal et al., 2014; Ehring et al., 2014; Karatzias et al., 2019b; Mahoney, Karatzias, Halliday, & Dougal, 2020). However, the degree of heterogeneity is generally very high, and subgroup analyses are generally insufficiently powered to detect differences in efficacy between therapeutic approaches.

1.2.3 CPTSD Related to Childhood Trauma

Accumulating evidence suggests that adults who experienced repeated interpersonal trauma in childhood are significantly more troubled compared to those who first experienced trauma later in life in terms of greater complexity and severity of symptoms (Briere, Kaltman, & Green, 2008; Briere & Rickards, 2007; Cloitre, Scarvalone, & Difede, 1997; Finkelhor, Ormrod, & Turner, 2007a; van der Kolk & McFarlane, 1996; Zlotnick et al., 1996), and day-to-day functioning (Cloitre, Miranda, Stovall-McClough, & Han, 2005). A number of explanations exist to explain the greater vulnerability of children to the long-term effects of trauma. First, individuals traumatized in childhood experience more trauma overall in terms of total number of events, multiple forms of abuse, and subsequent revictimization, and there is a clear dose-response relationship between cumulative trauma and extent of trauma symptomatology (Briere et al., 2008; Cloitre et al., 2009; Finkelhor, Ormrod, & Turner, 2007b; Turner, Finkelhor, & Ormrod, 2010).

Second, childhood is characterized by sensitive periods of rapid neurobiological development and greater neural plasticity, such that repeated trauma during this time is associated with significant and long-lasting alterations in stress responsivity, and both threat-based and attachment-based brain networks: there is now overwhelming evidence that these alterations have profound consequences for the development of emotional and cognitive control, sense of self, and effective relating with others (Cicchetti & Toth, 1995; Cloitre et al., 2009; Cole & Putnam, 1992; Lanius, Bluhm, & Frewen, 2011; Mikulincer & Shaver, 2012; Schore, 2001; van der Kolk, 2014).

Finally, several researchers have proposed that relationships with perpetrators are more complex when survivors are children, because the perpetrators of abuse are more likely to be adults in a caregiving role: as such, the relationship between survivor and perpetrator is not only characterized by a large power imbalance, but also increased feelings of betrayal and mistrust, shame, and stigmatization (Cole & Putnam, 1992; Finkelhor & Browne, 1985; Herman, 1992b) which appear to play a

powerful role in the development and maintenance of trauma symptomatology (Ozer, Best, Lipsey, & Weiss, 2003; Taylor, 2015).

Our understanding of how best to help adult survivors of childhood trauma remains limited. Trauma-focused treatments are reportedly less effective overall for survivors of childhood-onset abuse, but whether trauma-focused interventions are more effective than non-trauma-focused approaches in this population (Ehring et al., 2014; Karatzias et al., 2019b), or the converse (Dorrepal et al., 2014) remains unclear. Similarly, it is not clear whether the superiority of individual over group delivery seen for classic PTSD is also true for adult survivors of childhood trauma. Early treatments for survivors of childhood sexual abuse tended to favour group interventions (e.g. Alexander, Neimeyer, & Follette, 1991; Follette, Alexander, & Follette, 1991), on the premise that group therapy is superior in normalizing individuals' responses to trauma, providing opportunities for positive interpersonal interactions, and reducing the feelings of isolation and stigmatization so pervasive among survivors of childhood trauma (Briere, 1989; Courtois, 1988; Weinberg, Nuttman-Shwartz, & Gilmore, 2005; Yalom & Leszcz, 2005). However, one recent meta-analytic review concluded that individual treatments may be more effective than interventions delivered in groups for reducing symptoms of PTSD in adult survivors of childhood trauma (Ehring et al., 2014), similar to those with experiences of complex PTSD more broadly (Karatzias et al., 2019b).

1.2.4 Aims of Meta-Analysis

If the effects of trauma are indeed more severe, complex, and debilitating when first experienced in childhood, the timing of abuse may be an important source of heterogeneity in previous meta-analyses of treatment effectiveness in CPTSD. As such, it may be useful to examine this population on their own (c.f. Dorrepal et al., 2014; Ehring et al., 2014). The overall aim of this systematic review and meta-analysis was to examine the efficacy and effectiveness of psychological interventions in alleviating symptoms of complex PTSD in adult survivors of childhood trauma. Our primary analysis focused on evidence from randomized, controlled trials (RCTs).

However, because research in this area has been limited, and we were keen to achieve sufficient power for subgroup analyses of type of therapy and mode of delivery, we also carried out supplementary analyses of uncontrolled, (pre- to post-treatment effects, incorporating additional non-RCTs and uncontrolled trials. We hoped this would be useful to clinicians interested in applying the results of research trials to “real-world” clinical practice, not least in providing estimates of the size of changes which may be expected from pre- to post- treatment (see e.g. Stewart & Chambless, 2009; Westbrook & Kirk, 2005). Our research questions were as follows:

Research Questions

1. Are psychological interventions efficacious and effective in reducing symptoms of PTSD among adult survivors of childhood trauma?
 - a. Does treatment effectiveness differ according to the key focus of treatment (e.g. safety and stabilization, trauma memory processing, interpersonal functioning, or a combination)?
 - b. Does treatment effectiveness differ according to the mode of delivery (e.g. individual or group)?
2. Are psychological interventions effective in reducing symptoms of additional symptoms associated with complex PTSD among adult survivors of childhood abuse (e.g. disorders of self-organization (DSOs) or dissociation)?
3. What is the overall attrition rate for these psychological interventions, and does it differ according to (1) focus of treatment; (2) mode of delivery?

1.3 METHODS

1.3.1 Identification and Selection of Studies

Suitable articles were identified primarily through a systematic search of the electronic databases Web of Science, PsycINFO, Embase, Medline, and PTSDPubs (formerly PILOTS) from inception to 5th November 2020. Search terms included: (1) presence of childhood trauma ((child* adj4 (abuse or neglect or trauma* or violence or advers* or maltreat*)); AND (2) difficulties related to complex trauma (CPTSD or complex PTSD or complex trauma); AND (3) application of a psychological intervention (intervention or treatment of program* or therap* or psychotherapy). Results were limited to those published in English, dissertations or empirical articles (PsychINFO, Embase, and Medline), and / or peer-reviewed articles (PTSDPubs). Hand-searches of additional studies were conducted by screening references of relevant meta-analyses (Corrigan, Fitzpatrick, Hanna, & Dyer, 2020; Coventry et al., 2020; Dorrepaal et al., 2014; Ehring et al., 2014; Karatzias et al., 2019b; Kim & Kim, 2020; Mahoney, Karatzias, & Hutton, 2019; Melton et al., 2020), and searching for studies which had cited earlier trials.

1.3.2 Inclusion Criteria

Studies were included in the meta-analysis if they met the following criteria:

Participants: participants were adults (aged 18 yrs and over; no upper age limit) and the majority of the sample (at least 70%) reported significant childhood abuse or trauma. Participants were not required to meet diagnostic criteria for a post-traumatic stress disorder, given the differences in how complex trauma has been conceptualized and labelled over the past 30 years. Studies were not excluded if participants experienced additional difficulties such as chronic depression, personality disorder, substance misuse, or psychosis, or were taking medication for their symptoms.

Intervention: any psychological intervention designed to address symptoms and distress associated with repeated interpersonal trauma originating in childhood was eligible for inclusion in the meta-analysis. “Psychological intervention” is defined as a talk-based therapeutic intervention, delivered by trained therapists, and which references an established school of psychotherapy or psychological processes (Barth et al., 2016; Benish, Imel, & Wampold, 2008). Treatments needed to be manualized or described in sufficient detail to allow replication, and delivered in individual, group, or combined formats.

Comparator: any type of control group was acceptable, including (1) inactive / minimal-attention / waitlist, to control for spontaneous recovery; (2) active, to control for nonspecific effects of therapy such as expectations of improvement and attention by a warm and non-judgmental therapist; (3) *bona-fide* therapy with demonstrated efficacy in treating difficulties associated with childhood trauma.

Outcomes: We were interested in the effectiveness of interventions on the compound symptoms of complex PTSD, so an aggregate outcome measure such as the International Trauma Questionnaire (Cloitre et al., 2018) would have been ideal. However, very few studies have been published using this new measure to date. The primary outcome in this review was therefore PTSD symptom severity, either self- or clinician- rated, using standardized and validated instruments. Secondary outcomes were symptom severity related to the three additional disorders of self-organization (DSO) associated with complex PTSD: (1) affect dysregulation (AD); (2) negative self-concept (NSC); and (3) difficulties in relationships (DR). Finally, dissociation was also examined, as it is very common in CPTSD and represents a key feature of post-traumatic stress disorders such as DESSOS and developmental trauma disorder.

Study Design: randomized, controlled trials (RCTs) designed to compare the psychological intervention with a control group formed the main part of the analysis. Because we were also interested in exploring the overall pre- to post-treatment

effectiveness of psychological interventions on symptoms among a more ecologically-valid sample, we also conducted separate analyses of uncontrolled effect sizes using additional uncontrolled and non-randomized controlled studies identified during the initial search.

1.3.3 Exclusion Criteria

In order to enhance the external validity and relevance of this review to real-world clinical practice, minimal exclusion criteria were applied. Studies were excluded if (1) fewer than 70% of participants reported significant childhood trauma (or, if this was the case, data were not reported and analysed separately for child- and adult-trauma groups); (2) the intervention was not primarily psychological in nature (e.g. art therapy), or included multiple additional elements (such as exercise classes or practical support), which would make it difficult to determine the key active ingredient(s) of therapy.

1.3.4 Extraction and Coding of Data

Each study was coded according to a standardized set of variables including participant characteristics (mean age, proportion female), treatment and control group characteristics (type of therapy, mode of delivery, treatment duration), setting (community / residential), and sample size (ITT and completer) [see Table 1.1]. Overall attrition for each treatment group was calculated as the proportion of completers in each group compared with those who started treatment. If authors did not report one or either of these values, the attrition rate reported by the authors was used instead.

1.3.4.1 Coding of Therapy Type

Type of therapy was assigned to one of four categories on the basis of its primary focus of treatment. Interventions were classed as *trauma-focused* if their primary

therapeutic target was trauma memory processing (**TMP**), such as PE, CPT, CT-PTSD, NET, EFT-T, or EMDR (Ford, 2018). Interventions were classed as *present-focused* if their primary target was safety and stabilization (**S&S**), typically through psychoeducation and the practice of emotion regulation and / or interpersonal skills, such as STAIR, Survive and Thrive, Seeking Safety. Interventions which aimed to target S&S first, followed by TMP were classed as *phase-based*, such as STAIR+PE, DBT-PTSD (Cloitre et al., 2011), and those which focused primarily on interpersonal functioning were classed as such.

1.3.5 Appraisal of Study Quality

The methodological quality of each study was rated using the revised Cochrane Risk of Bias tool, RoB 2.0 (Sterne et al., 2019) [see Figure 1.2], which calculates risk of bias across five key domains: (1) randomization process; (2) deviations from intended interventions; (3) missing outcome data; (4) measurement of the outcome; (5) selection of reported result. 25% of included studies were selected at random using an online random number generator and assessed blind by an independent assessor (RM), and inter-rater reliability was calculated using Cohen's *kappa* in SPSS® (Cohen, 1960).

1.3.6 Effect Size Calculations

For each outcome, controlled effect sizes were calculated for the difference in post-treatment scores between each active treatment condition and the control (inactive control, active control, *bona fide* therapy). For the primary outcome of PTSD symptoms, clinician-rated, rather than self-rated measures were selected in all studies that reported both. We also calculated the uncontrolled (within-subjects, pre- to post-treatment change) effect size to gauge the overall magnitude of the effect of treatment for each condition (see e.g. Stewart & Chambless, 2009; Westbrook & Kirk, 2005).

Effect sizes were expressed as standardized mean difference using Hedge's g , calculated from the means and standard deviations (SDs) reported in each study. Hedge's g is similar to Cohen's d but allows for the correction of variation between groups in terms of sample size and variance. Effect sizes of $g = 0.2$, 0.5 , and 0.8 were interpreted as "small", "medium" and "large", respectively, following the convention suggested by Cohen, 1988). Seven trials did not report the relevant means or SDs, or any other values from which these could be calculated, and were therefore not included in the meta-analysis.

1.3.7 Meta-Analysis

Meta-analyses were conducted using the computer software package RevMan 5.4 (Deeks, Higgins, & Altman, 2021; The Cochrane Collaboration, 2020). Pooled effect sizes were calculated using the DerSimonian-Laird random-effects model (DerSimonian & Laird, 1986), as substantial heterogeneity was expected among the studies. Heterogeneity was computed using the I^2 statistic, classified as low, moderate, and high for values of 25%, 50%, and 75%, respectively (Higgins, Thompson, Deeks, & Altman, 2003). Subgroup analyses were planned *a priori* to explore differences in efficacy between studies on the basis of: (1) type of therapy; and (2) mode of delivery. Pooled effect sizes were calculated for each subgroup, and statistical comparisons made between subgroups for which the number of observations (k) was 10 or greater (Deeks et al., 2021).

1.3.8 Publication Bias

Publication bias was assessed by visual inspection of funnel plots for asymmetry, the trim-and-fill procedure (Duval & Tweedie, 2000), and Egger's test (Egger, Smith, Schneider, & Minder, 1997), using the *Meta-Essentials* software package (Suurmond, van Rhee, & Hak, 2017).

1.4 RESULTS

1.4.1 Results of the Search

The initial search yielded 51,196 studies for consideration, once duplicates had been removed: of these, 50,870 were discarded following a screening of titles and abstracts, and 326 were retained for full-text review (see Figure 1.1). 273 of these studies did not meet the inclusion criteria, leaving 25 randomized controlled trials (RCTs) for inclusion in the main analysis, and 28 non-randomized, controlled or uncontrolled studies for use in additional analyses of uncontrolled, pre- to post-treatment effects.

1.4.2 Study Characteristics

Details of the 25 RCTs included in the main analysis are presented in Table 1.1. The intention-to-treat study sample comprised a total of 2,923 participants, with sample sizes ranging from 37 – 353 in each trial. The large majority of participants were women, with a median age of 35 – 40 years. Participants generally reported severe and complex histories of childhood trauma and re-victimization as adults, and the majority presented with chronic and significant mental health difficulties in addition to symptoms of PTSD, such as chronic depression, substance misuse, and / or personality disorder. A further 28 uncontrolled or non-randomized, controlled studies, were added to the 25 RCTs for supplementary analyses of uncontrolled, pre-to-post effect sizes across the study sample as a whole ($n = 53$).

Studies examined a variety of psychological interventions for adult survivors of complex trauma, divided into four categories according to the primary focus of treatment: *Present-Focused* therapies, generally focused on developing skills in order to enhance client's safety and stabilization (S&S: 9 trials); *Trauma-Focused* therapies, focused on trauma memory processing (TMP: 9 trials); a *Phase-Based*

approach, combining both S&S and TMP (4 trials), or *Interpersonal Therapy* (3 trials).

14 studies used an active control or a *bona-fide* therapy for PTSD as a comparator group, while 11 used a wait-list or minimal-attention group. Almost all study interventions were implemented in community settings, with the exception of two delivered in prison and one in residential care.

The primary outcome in this review was PTSD symptomology, assessed using standardized and validated quantitative measures. 13 studies used clinician-rated measures such as the Clinician Administered PTSD Scale (CAPS: Blake et al., 1995; Weathers et al., 2018), while the remainder used self-reported measures of PTSD. 11 studies reported at least one additional outcome associated with the three disorders of self-organization (DSOs) outlined in the ICD-11 criteria for complex PTSD (i.e. affect dysregulation, disturbances in relationships, and negative self-concept). 10 trials also assessed dissociation, a key feature of complex types of post-traumatic stress.

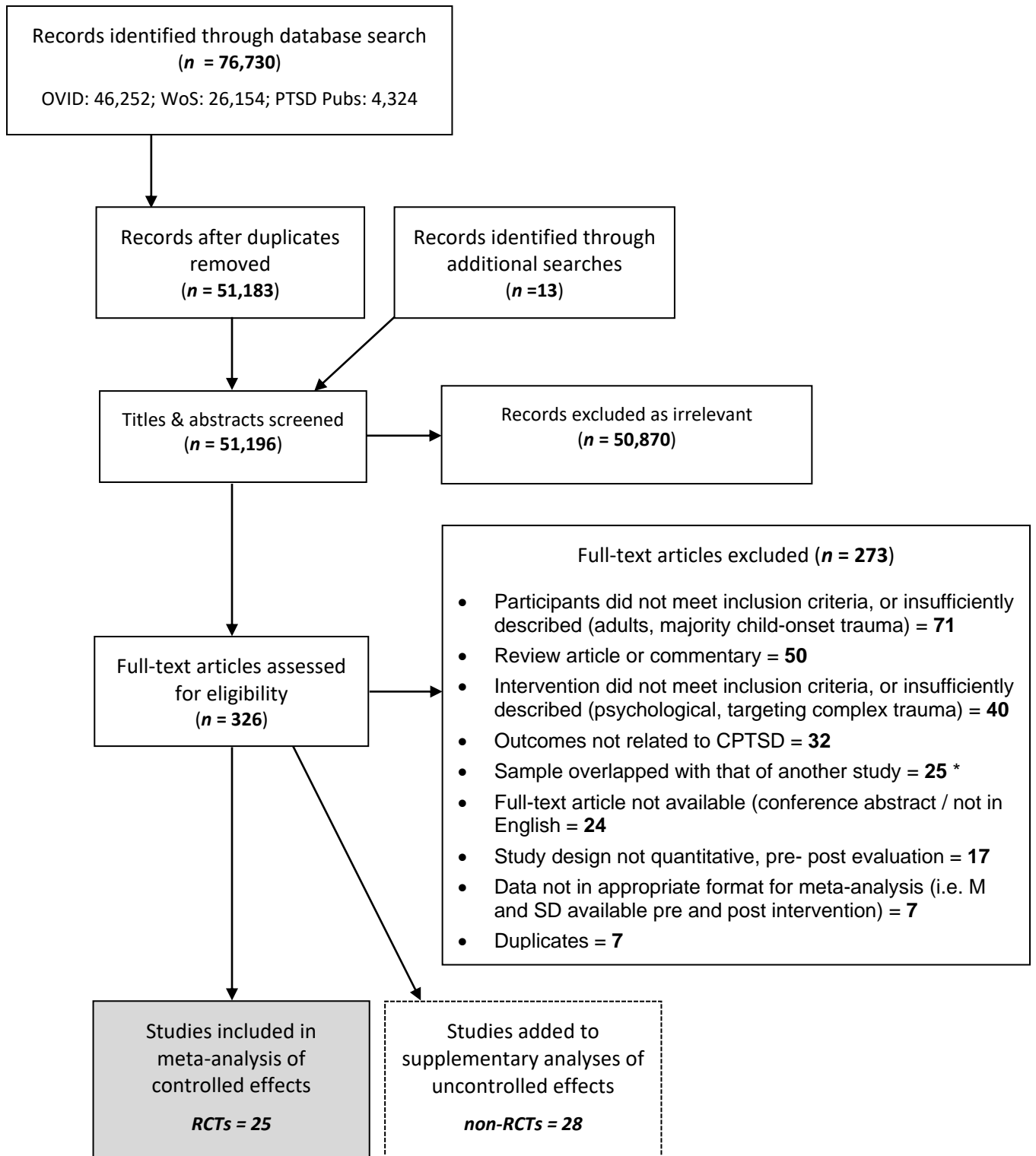


Figure 1.1

PRISMA diagram depicting study identification and selection (Moher, Liberati, Tetzlaff, & Altman, 2009). * 25 studies presented data from previously-published studies: in these cases, only the original study was retained for meta-analysis.

Table 1.1: Details of Studies Included in the Main Analysis (RCTs; $n = 25$)

Authors & Publication Year	Population	Setting	Sample Characteristics		Study Groups Treatment / Control	Category of Intervention / Control	N ITT (completer)	Mode of delivery	Number of sessions	Follow-Up Period (months)
			% women	Mean age (SD) yr						
Bohus et al. (2013)	Women with CSA-related PTSD (+ 50% BPD)	Residential	100	35.1 (10.6) ^a	DBT-PTSD	Phased	36 (29)	Combination	24	3
					TAU (any treatment)	Active control	38 (29)	-	-	
Bohus et al. (2020)	Women with CA-related PTSD (+ AD + BPD traits)	Community	100	36.3 (11.1)	DBT-PTSD	Phased	98 (73)	Combination	up to 45	3
					CPT	Bona-fide therapy	95 (58)	Individual	up to 45	
Boterhoven et al. (2020)	Adults with CA-related PTSD	Community	77	38.5 (11.2)	ImRs	TMP	74 (64)	Individual	12	2, 12
					EMDR	TMP	81 (67)	Individual	12	
					WL	Inactive control	92 (nr)	-	-	
Bradley & Follingstad (2003)	Incarcerated women with history of CA	Prison	100	36.7 (8.27)	DBT + writing	S&S	24 (13)	Group	18	-
					WL	Inactive control	25 (18)	-	-	
Chard et al. (2005)	Women with history of CSA + PTSD	Community	100	32.8 (8.9)	CPT-SA	TMP	36 (28)	Combination	27	12
					MA	Inactive control	35 (27)	-	-	
Classen et al. (2020)	Women with history of CA + PTSD (full or sub-threshold)	Community	100	43.5 (10.0)	TBG	S&S	18 (14)	Group	20	6
					WL	Inactive control	19 (18)	-	-	
Cloitre et al. (2002)	Women with CA-related PTSD	Community	100	34.0 (7.2)	STAIR + PE	Phased	31 (22)	Individual	16	3, 9
					WL	Inactive control	27 (24)	-	-	
Cloitre et al. (2010)	Women with CA-related PTSD	Community	100	36.3 (9.2) ^b	STAIR + PE	Phased	33 (28)	Individual	16	6
					STAIR + SC	S&S	38 (28)	Individual	16	
					SC + PE	Bona Fide Therapy	33 (20)	Individual	16	

Authors & Publication Year	Population	Setting	Sample Characteristics		Study Groups Treatment / Control	Category of Intervention / Control	N ITT (completer)	Mode of delivery	Number of sessions	Follow-Up Period (months)
Dorrepaal et al. (2012)	Women with history of CA + CPTSD + severe comorbidities	Community	100	40.3 (10.7) ^a	Supportive Group Therapy	S&S	38 (33)	Group	20	-
					TAU (therapy + meds)	Active Control	33 (28)	-	-	
Duberstein et al. (2018)	Women with history of CSA + depression + 93% PTSD	Community	100	36.3 (11.2) ^a	IPT-T	Other	83 (68)	Individual	16	8
					TAU (individual therapy)	Active Control	78 (68)	-	-	
Edmond et al. (1999)	Women with history of CSA (+ majority PTSD)	Community	100	35 (SD nr)	EMDR	TMP	20 (20)	Individual	6	3, 18
					TAU (individual therapy)	Active Control	20 (20)	Individual	nr	
					WL	Inactive control	19 (19)	-	-	
Hien et al. (2009)	Women with history of complex trauma + PTSD + SUD	Community	100	39.2 (9.3)	Seeking Safety	S&S	176 (140)	Group	12	3, 6, 12
					Women's Health Education	Active Control	177 (149)	Group	12	
Krakow et al. (2001)	Women with SA-related PTSD (90% childhood)	Community	100	36 (10.9) ^b	Imagery Rehearsal Therapy	TMP	88 (54)	Group	3	3, 6
					WL	Inactive control	80 (60)			
Krupnick et al. (2008)	Women with interpersonal-trauma-related PTSD (98%)	Community	100	32.0 (10.2)	Group IPT	Other	32 (20)	Group	16	4
					WL	Inactive Control	16 (7)	-	-	
Mahoney et al. (2020)	Incarcerated women with history of IP violence and trauma (77%+)	Prison	100	33.5 (10.3) ^a	Survive & Thrive	S&S	44 (35)	Group	10	1
					WL	Inactive control	42 (28)	-	-	
McDonagh et al. (2005)	Women with CSA-related PTSD	Community	100	40.5 (9.8) ^b	CBT	TMP	29 (17)	Individual	14	6
					PCT	S&S	22 (20)	Individual	14	
					WL	Inactive control	23 (20)	-	-	
Paivio et al. (2010)	Adults with history of CA	Community	53	45.6 (13.0)	EFTT + IC	Other	27 (20)	Individual	20	6
					EFTT + EE	Bona Fide Therapy	28 (25)	-	-	

Authors & Publication Year	Population	Setting	Sample Characteristics		Study Groups Treatment / Control	Category of Intervention / Control	N ITT (completer)	Mode of delivery	Number of sessions	Follow-Up Period (months)
Resick et al. (2008)	Women with interpersonal-trauma-related PTSD (78+%)	Community	100	35.4 (12.4)	CPT	TMP	53 (42)	Individual	12	6
					CPT-C	TMP	47 (37)	Individual	12	
					Writing only	Active control	50 (38)	Individual	7	
Schafer et al. (2019)	Women with PTSD + SUD (93% childhood)	Community	100	40.9 (11.4)	Seeking Safety + TAU	S&S	111 (67)	Group	16	6
					RPT + TAU	Active control	115 (69)	Group	16	
					TAU (any treatment)	Active control	117 (90)	-	-	
Scheck et al. (1998)	Women with history of trauma (90% childhood; 77% PTSD)	Community	100	20.9 (nr)	EMDR	TMP	30 (28)	Individual	2	-
						Active listening	Active control	30 (29)	Individual	
Sikkema et al. (2007)	Adults with history of CSA + HIV	Community	54	42.5 (6.9)	HIV+Trauma Coping Grp	S&S	96 (73)	Group	15	-
					HIV Support Grp	Active control	101 (77)	Group	15	
					WL	Inactive control	56 (48)	-	-	
Spidel et al. (2018)	Adults with history of CA + psychosis	Community	52	40.4 (nr)	ACT	S&S	30 (30)	Group	8	3
						TAU (any treatment)	Active control	20 (20)	-	
Talbot et al., (2011)	Women with history of CSA + depression	Community	100	36.0 (nr)	IPT	Other	37 (37)	Individual	16	-
						TAU (psychotherapy)	Active control	33 (33)	Individual	
Van der Kolk et al. (2007)	Adults with PTSD (child-onset trauma subgroup) ^c	Community	83	36.1 (13.4)	EMDR	TMP	15 (11) ^c	Individual	8	6
					Fluoxetine	Active control	13 (10)	Individual	-	
					Placebo	Active control	17 (14)	Individual	-	
Zlotnick et al. (1997)	Women with CSA-related PTSD (+ DESNOS)	Community	100	39.0 (9.6)	AMG + TAU	S&S	23 (17)	Group	15	-
						TAU (individual therapy)	Active control	23 (16)	-	

Abbreviations:

ACT = Acceptance and Commitment Therapy; **AD** = affect dysregulation; **AMG** = Affect Management Group; **BPD** = Borderline Personality Disorder; **CA** = childhood abuse; **CPT** = Cognitive Processing Therapy; **CPT-C** = Cognitive Therapy only; **CPT-SA** = cognitive processing therapy adapted for survivors of sexual abuse; **CSA** = childhood sexual abuse; **DBT** = Dialectical Behavior Therapy; **DBT-PTSD** = DBT adapted for PTSD; **EE** = empathic exploration; **EFTT** = Emotion-Focused Therapy for Trauma; **EMDR** = Eye Movement Desensitization and Reprocessing; **IC** = Imaginal Confrontation; **ImRs** = Imagery Rescripting; **IPT** = Interpersonal Psychotherapy; **IPT-T** = Interpersonal Psychotherapy adapted for Trauma; **MA** = minimal attention; **nr** = not reported; **PCT** = Present-Centred Therapy (problem-solving focus); **PE** = Prolonged Exposure; **PTSD** = Post-Traumatic Stress Disorder; **RPT** = Relapse Prevention Training (for SUD); **S&S** = safety and stabilization; **SA** = sexual abuse; **SD** = standard deviation; **STAIR** = Skills Training in Affective and Interpersonal Regulation; **SUD** = substance use disorder; **TAU** = treatment as usual; **TMP** = trauma memory processing; **TBG** = Trauma and the Body Group ; **WL** = wait list.

^a mean age for treatment group (overall sample mean not reported)

^b mean of subgroup group means (overall sample mean not reported)

^c mixed sample of child- and adult-onset trauma; results reported for child-onset trauma group only.

1.4.3 Assessment of Study Quality

Studies were assessed for risk of bias using Cochrane's Risk of Bias 2.0 tool (Sterne et al., 2019) by the first author (see Figure 1.2). Inter-rater reliability calculations for 25% of the studies yielded a Cohen's k of .47 (95% CIs .19 - .75), $p = 0.002$, indicating moderate agreement between the two raters (Landis & Koch, 1977). Discrepancies were discussed and agreement reached for each in turn. Learning points were applied to the remaining quality assessments to ensure consistency across trials.

Most studies (23 / 25) were deemed to be at high or medium risk of bias overall. Studies published prior to the revised CONSORT quality guidelines for the reporting of randomized trials (Moher et al., 2010) were less likely to report the methods by which participants were randomized into study groups, or to publish the trial protocol in advance of study recruitment, leading to more frequent ratings of "some concerns" in these earlier studies for RoB domains 1 (randomization) and 5 (selective reporting). Domain 3 (attrition bias) contained the highest proportion of "high" RoB ratings (9 / 25). Studies were deemed at high risk of attrition bias when dropout rates in the experimental group(s) were high (i.e. above 10%), and the authors did not sufficiently examine whether participants who dropped out of treatment were systematically different to those who remained in the study, or attempt to control for these factors.

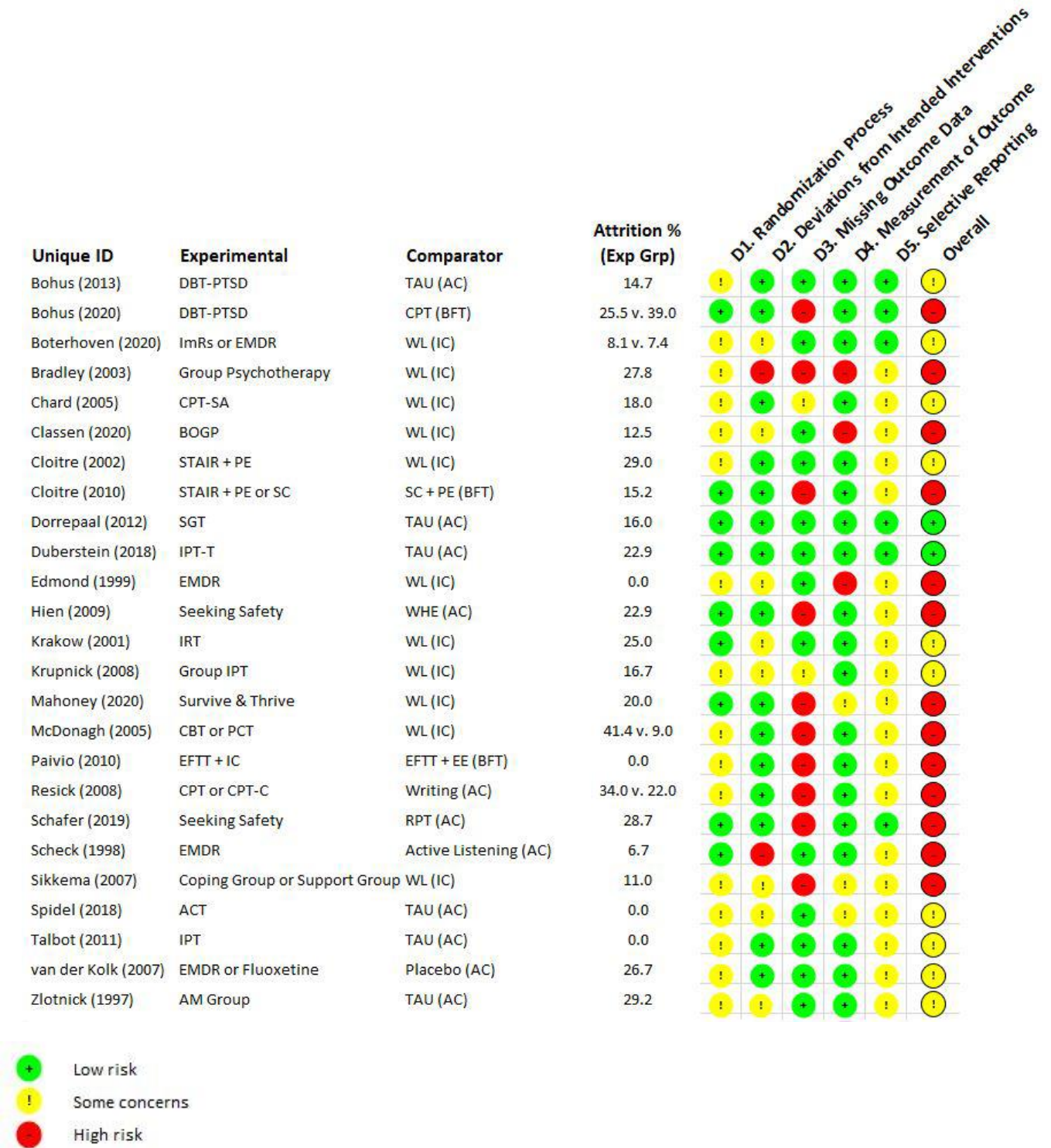


Figure 1.2: Summary of Attrition and Risk of Bias Assessments for included studies ($n = 25$).

1.4.4 Effects of Psychological Interventions on Symptoms of Complex Trauma

1.4.4.1 Controlled Effect Sizes

PTSD

The standardized mean difference in PTSD symptoms between treatment and control groups at post-treatment was calculated across all RCTs ($k = 29$), yielding a moderate overall effect size of $g = 0.58$ (95% CIs = 0.40 – 0.75; $Z = 6.48$; $p < 0.05$) (see Table 1.2 and Figure 1.3). Heterogeneity tests yielded an I^2 of 79% ($p < 0.001$), indicating considerable heterogeneity across studies. Sensitivity analyses revealed that restricting the meta-analysis to studies in which all participants experienced childhood trauma, or were women only, or did not report severe additional difficulties (such as substance misuse, offending, or personality disorders), or reported childhood sexual abuse, only reduced heterogeneity by between 0 and 6%, indicating that none of these were likely significant sources of variability in treatment outcome.

A priori subgroup analyses of controlled post-treatment effect sizes were carried out to determine whether at least some of this heterogeneity could be attributed to variations between studies in variables believed to have an important effect on treatment outcomes in therapy, such as type of therapy (e.g. S&S vs. TMP) and mode of delivery (individual vs. group). Given the high degree of heterogeneity overall, we also carried out additional subgroup analyses on variables shown to have an effect in previous similar meta-analyses, such as type of control group (active vs. passive), type of outcome (clinician-rated vs. self-reported symptom measures), and treatment duration.

[Psychological interventions for complex PTSD]

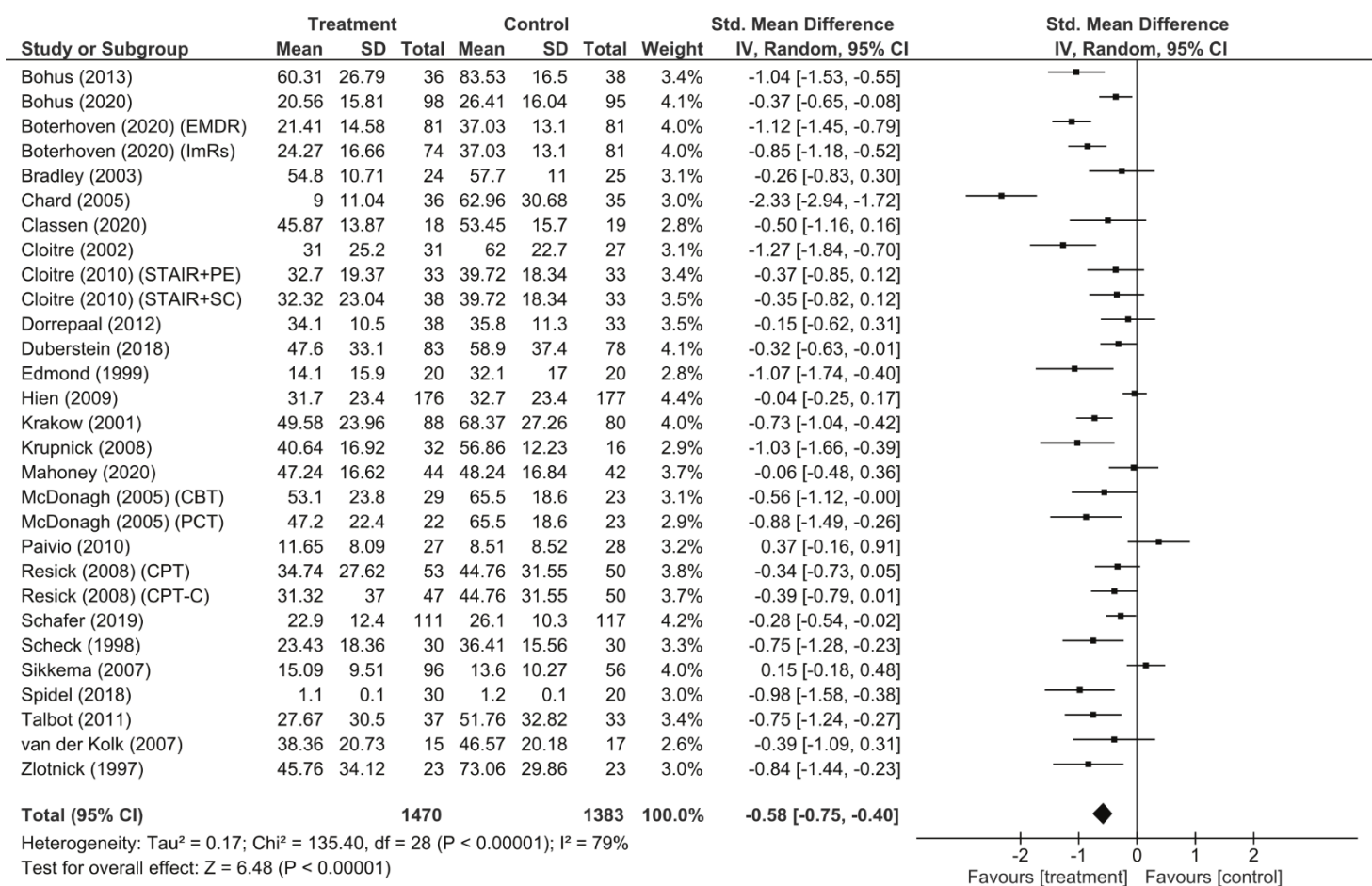


Figure 1.3: Forest plot of controlled post-treatment effects sizes for PTSD (n = 25)

Subgroup Analysis: Type of Therapy

Present-focused therapies (S&S) were associated with small controlled effect sizes at post-treatment ($g = 0.30$), while trauma-focused (TMP), phased, and interpersonal therapies demonstrated effect sizes in the medium range ($g = 0.73$, 0.73 , and $.63$, respectively (see figure 1.4). Heterogeneity was moderate among both the present-focused and interpersonal therapy groups, but remained high in the trauma-focused and phased therapy groups.

The small number of studies present in the “phased” and IPT arms meant that a subgroup analysis would have been underpowered to detect statistically-significant differences between groups in the small to medium range. A subgroup analysis limited to the two largest groups ($k = 11$ for both) revealed that trauma-focused therapies yielded significantly larger controlled effect sizes compared with present-focused interventions focused on safety and stabilization ($X^2 = 4.93$; $df = 1$; $p = 0.03$).

Subgroup Analysis: Mode of Delivery

The combined (I + G) treatment group yielded a very large effect size of $g = 1.22$. However, the number of arms in this group was small ($k = 3$) and the variance large, so was excluded from the subgroup analysis. Individual and group therapies were associated with medium and small effect sizes at post-treatment ($g = 0.60$ vs. 0.37), respectively. This difference was not statistically significant ($X^2 = 2.02$; $df = 1$; $p = 0.16$).

[Psychological interventions for complex PTSD]

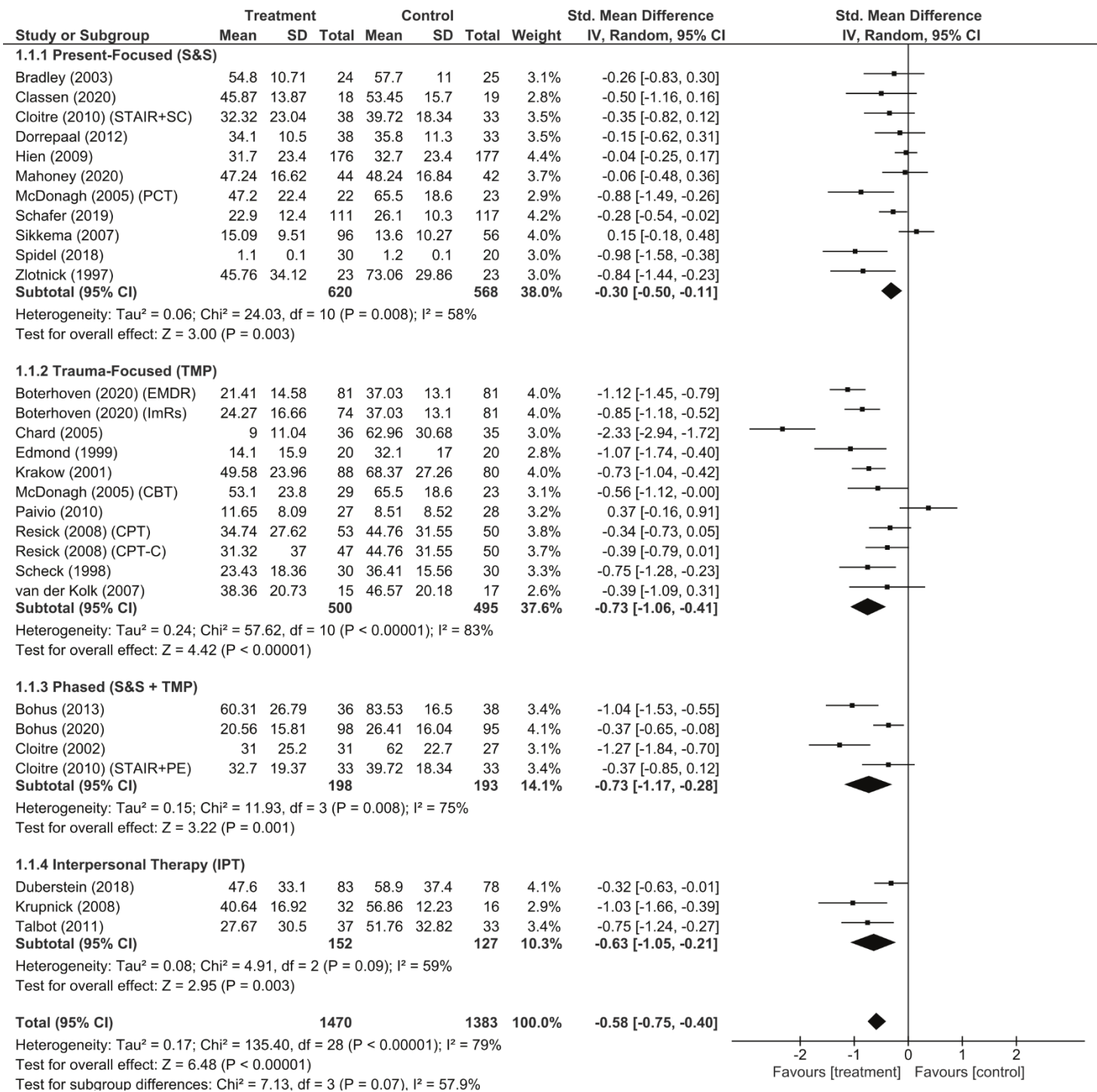


Figure 1.4: Forest plot of controlled post-treatment effects sizes for PTSD, by type of therapy ($n = 25$). S&S = safety and stabilization; TMP = trauma memory processing.

Subgroup Analysis: Type of Control

Interventions which had been compared with *bona-fide* therapies, active controls, and inactive or minimal attention controls at posttreatment yielded small, medium, and large effect sizes ($g = 0.21, 0.47, \text{ and } 0.79$), respectively. The difference between active and inactive controls was not significant ($X^2 = 2.77; df = 1; p = 0.10$).

Subgroup Analysis: Type of Outcome

Trials using clinician-rated measures of PTSD (such as the CAPS) yielded an overall controlled effect size of $g = 0.69$, in the medium range, while those using self-report measures demonstrated a small-to-medium effect size of $g = 0.40$. This difference did not reach statistical significance ($X^2 = 2.99; df = 1; p = 0.08$).

Subgroup Analysis: Treatment Duration

Treatment duration did not appear to have a significant impact on uncontrolled effect sizes for PTSD symptoms at post-treatment ($X^2 = 1.74; df = 1; p = 0.42$). Shorter-term (10 sessions or fewer) and longer-term (17 sessions or more) treatments were associated with medium effect sizes ($g = 0.64 \text{ and } 0.69$, respectively), while treatments lasting 11 – 16 sessions yielded a small-to-medium effect size of $g = 0.45$.

ADDITIONAL SYMPTOMS OF COMPLEX TRAUMA

Controlled effect sizes at post-treatment were also calculated for additional outcomes commonly associated with complex trauma, including dissociation and the disorders of self-organization (DSOs) associated with ICD-11 complex PTSD – namely, affect dysregulation, difficulties in relationships, and negative self-concept (see Table 1.2). Overall, psychological interventions yielded small-to-medium controlled effect sizes for dissociation ($g = 0.44$), affect dysregulation ($g = 0.54$), and disturbances in relationships ($g = 0.45$). The effect of treatment on negative self-concept appeared negligible ($g = 0.25$; $p = 0.21$), though only 3 trials reported any measure of NSC, so this result must be interpreted with caution. The sample sizes were too small to permit any meaningful subgroup analyses.

Table 1.2: Controlled Effect Sizes for Symptoms of Complex PTSD at Post-Treatment.

Outcome	Variable / Group	K	Hedge's g	95% CIs	Z	I ²	Subgroup analysis (Q _m)	
PTSD	All Active Treatments	29	0.58	0.4-0.75	6.5*	79***	-	
	Type of Therapy						4.93 ^a *	
	Present-Focused (S&S)	11	0.30	0.11-0.50	3.0**	58**		
	Trauma-Focused (TMP)	11	0.73	0.41-1.06	4.4***	83***		
	Phased (S&S + TMP)	4	0.73	0.28-1.17	3.2**	75**		
	Interpersonal Therapy (IPT)	3	0.63	0.21-1.05	3.0**	59		
	Mode of Delivery							2.02 ^b
	Individual (I)	15	0.60	0.39-0.80	5.6***	66***		
	Group (G)	11	0.37	0.15-0.60	3.2**	71***		
	Combined (I + G)	3	1.22	0.15-2.28	2.2*	94***		
	Type of Control							2.77 ^c
	Inactive / WL control (IC)	13	0.79	0.46-1.12	4.7***	85***		
	Active control (AC)	11	0.47	0.28-0.66	4.8***	62**		
	Bona-fide therapy control (BFT)	4	0.21	0.1-0.53	1.4	52		
	Type of Outcome Measure							2.99
Clinician-Rated	17	0.69	0.45-0.93	5.65***	83***			
Self-Report	12	0.40	0.16-0.75	6.48***	79***			
Number of Treatment Sessions							1.74	
10 or fewer	6	0.64	0.33-0.95	4.1***	55			
11 - 16	14	0.45	0.26-0.64	4.6***	68**			
17 or more	9	0.69	0.28-1.10	3.26**	88***			
DISS	All Active Treatments	12	0.44	0.26-.62	4.7***	48*	-	
AD	All Active Treatments	7	0.54	0.14-0.95	2.7**	86***	-	
DR	All Active Treatments	7	0.45	0.25-0.66	4.3***	0	-	
NSC	All Active Treatments	3	0.25	0.15-0.65	1.2	40	-	

AD = affect dysregulation
 DISS = dissociation
 DR = difficulties in relationships
 k = number of treatment arms
 NSC = negative self-concept
 S&S = safety and stabilization
 TMP = trauma memory processing
 * $p < 0.05$
 ** $p < 0.01$
 *** $p < 0.001$

^a subgroup analysis for S&S v. TMP only (number of observations in phased and IPT groups too low)

^b subgroup analysis for I v. G only (number of observations in Combined I + G group too low).

^c subgroup analysis for IC v. AC only (number of observations in BFT group too low)

1.4.4.2 Uncontrolled Effect Sizes

PTSD

Uncontrolled, pre- to post-treatment effect sizes were calculated across all treatment arms (RCTs and non-RCTs; $k = 61$) to determine the overall effect of psychological interventions on PTSD symptoms (see Table 1.3; Figure 1.5). A large, statistically significant effect size was found ($g = 1.02$; 95% CIs = 0.88 – 1.16; $Z = 14.11$; $p < 0.001$), indicating that psychological interventions are likely to be clinically effective in reducing symptoms of PTSD among survivors of childhood trauma. Again, heterogeneity was very high ($I^2 = 86\%$; $p < 0.001$).

In order to examine what degree of change occurred following no intervention at all (as a result of spontaneous improvement), we calculated uncontrolled effect sizes for PTSD measures in waitlist control arms ($k = 16$). This revealed a small effect size of 0.22 ($Z = 3.41$; $p < 0.001$). Heterogeneity was very low ($I^2 = 0\%$).

Sub-group analyses revealed that all four types of therapy were associated with significant improvements in PTSD symptoms (see Table 1.3). Trauma-focused (TMP) therapies were associated with significantly larger effect sizes than present-focused (S&S) treatments ($g = 1.49$ vs. 0.70, respectively; $p < 0.001$: see Figure 1.6).

[Psychological interventions for complex PTSD]

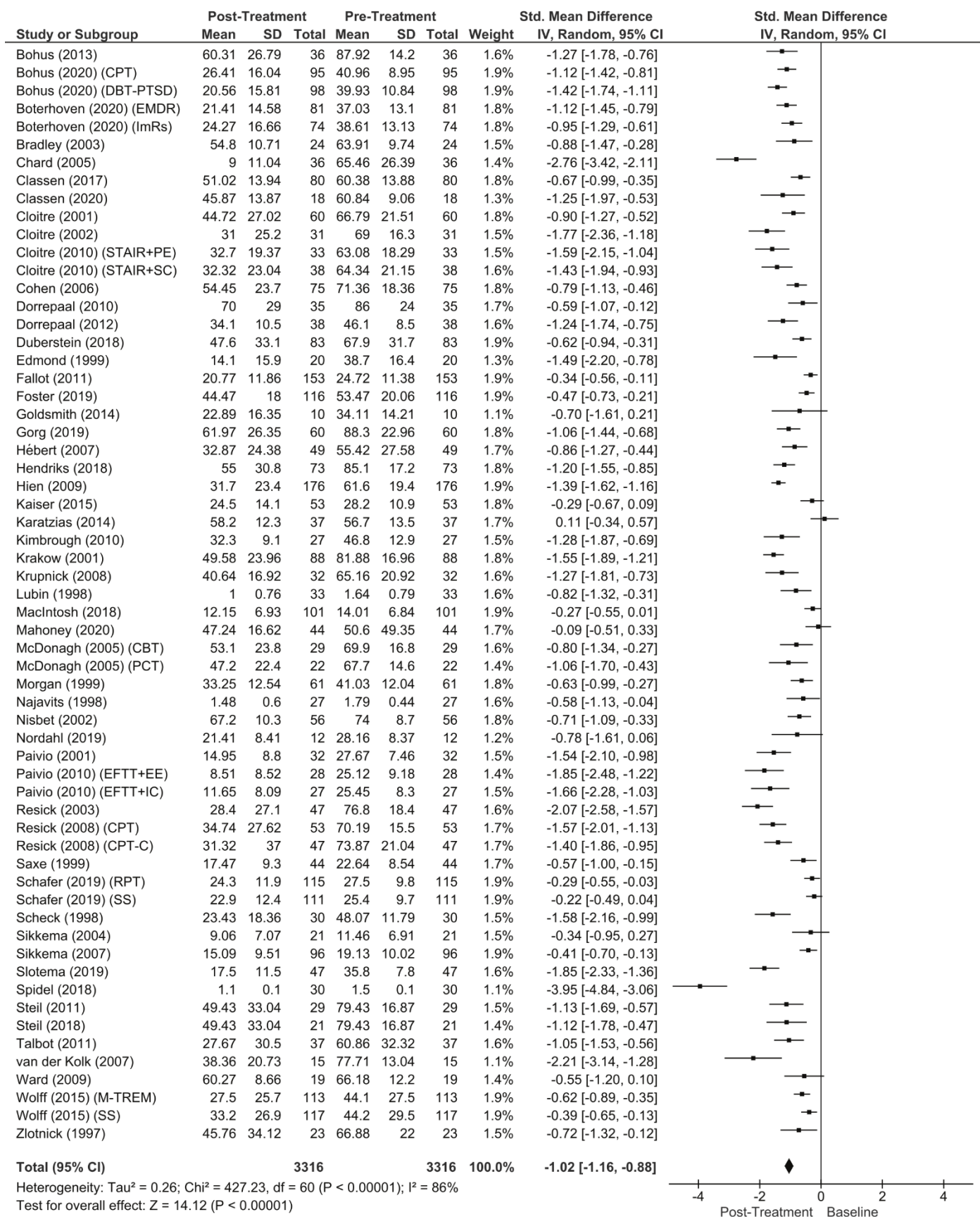


Figure 1.5: Forest plot of uncontrolled pre- to post-treatment effect sizes for PTSD (n = 58)

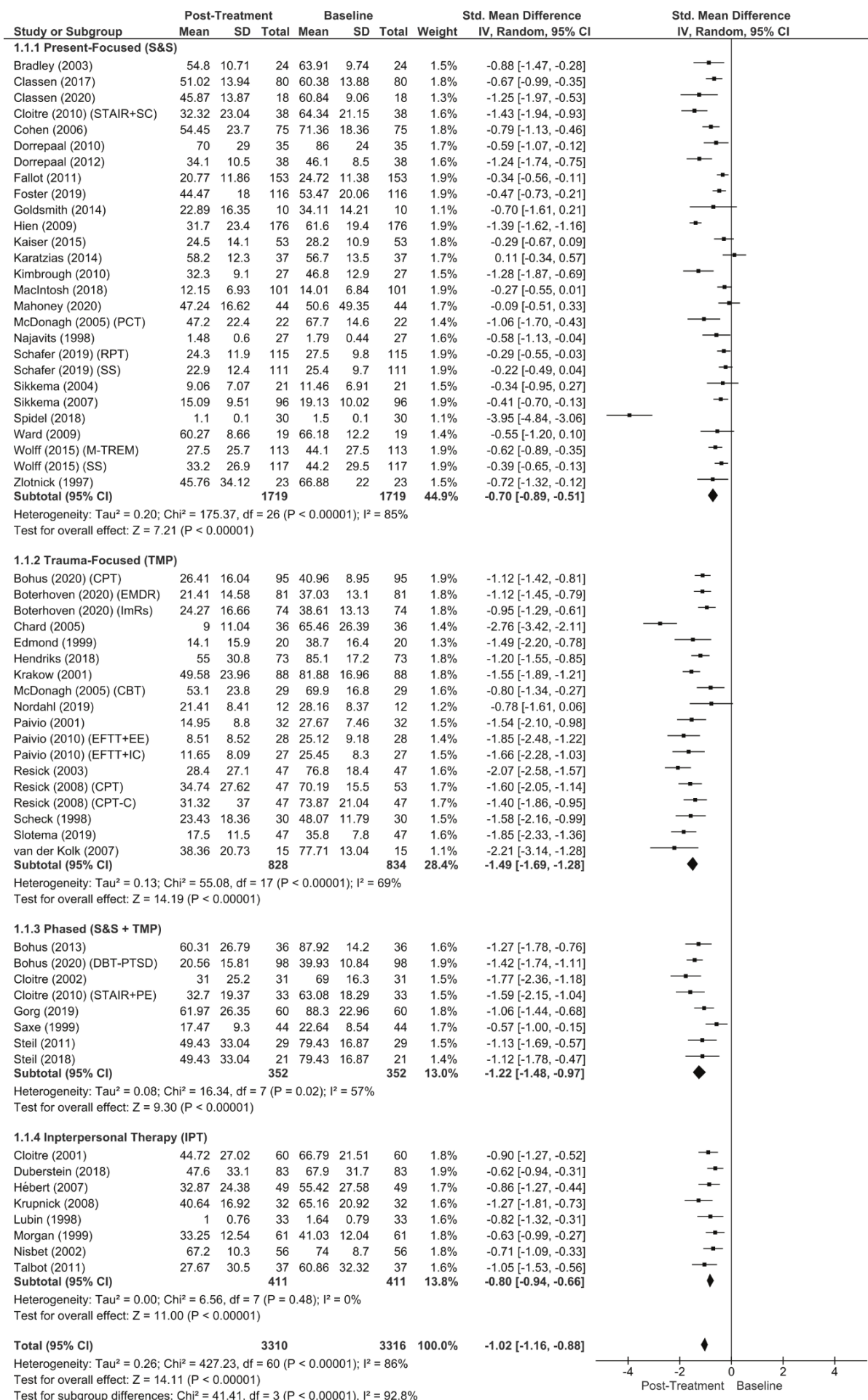


Figure 1.6: Forest plot of uncontrolled pre- to post-treatment effect sizes for PTSD, 33 by type of therapy (n = 58)

Sub-group analyses of mode of delivery indicated significantly greater effect sizes for treatments delivered in individual and combined compared with group formats ($g = 1.38$ and 1.30 vs. 0.72 , respectively; $p < 0.001$). Heterogeneity was high for combined and group formats (I^2 s of 83% and 85%) and moderate for individual treatments (I^2 of 66%). Finally, RCTs yielded significantly greater uncontrolled effect sizes than did non-RCTs and uncontrolled studies ($g = 1.25$ v. 0.77 , respectively; $p < 0.001$).

ADDITIONAL SYMPTOMS OF COMPLEX TRAUMA

Active treatments were associated with effect sizes in the “small” range for negative self-concept ($g = 0.38$) and dissociation ($g = 0.47$), medium-to-large for difficulties with relationships ($g = 0.78$) and “very large” for affect dysregulation ($g = 1.08$: see Table 1.3). A sub-group analysis of dissociation indicated no statistically significant differences between different types of therapy (present-focused, trauma-focused, or other); however it is likely the sample ($k = 24$) was underpowered to detect medium-sized differences between groups. Subgroup analyses could not be performed for any of the other DSO measures because the sample sizes were too small.

Out-come	Variable / Group	K	Hedge's g	95% CIs	Z	I ²	Subgroup analysis (Q _m)	
PTSD	No Treatment (WL)	16	0.22	0.09-0.35	3.4 ***	0%	-	
	All Active Treatments	61	1.02	0.88-1.12	14.1***	86%***	-	
	Type of Therapy							41.4 ***
	Present-Focused (S&S)	27	0.70	0.51-0.89	7.2***	85***		
	Trauma-Focused (TMP)	18	1.49	1.28-1.69	14.2***	69***		
	Phased (S&S + TMP)	8	1.22	0.97-1.48	9.3***	57***		
	Interpersonal Therapy (IPT)	8	0.80	0.66-0.94	11.0***	0%		
	Mode of Delivery							23.7 ***
	Individual (I)	22	1.30	1.12-1.48	14.4***	66***		
	Group (G)	31	0.72	0.54-0.90	7.9***	85***		
	Combination (I + G)							12.6 ***
	Combination (I + G)	8	1.38	1.01-1.76	7.3***	83***		
Type of Study Design								
RCTs	32	1.26	1.04-1.48	11.4***	88***	12.6 ***		
Non-RCTs and Uncontrolled Trials	29	0.77	0.61-0.93	9.5***	78***			
DISS	All Active Treatments	24	0.47	0.34-0.61	6.74***	64***	-	
	Type of Therapy							5.35
	Present-Focused (S&S)	13	0.32	0.17-0.47	4.2***	41***		
	Trauma-Focused (TMP)	6	0.59	0.30-0.88	3.9***	71***		
	Other (Phased + IPT)	5	0.70	0.35-1.05	3.9***	72***		
AD	All Active Treatments	10	1.08	0.64-1.53	4.76***	92***	-	
DR	All Active Treatments	14	0.78	0.56-1.00	6.92***	67***	-	
NSC	All Active Treatments	10	0.38	0.04-0.8	1.78	86***	-	

Table 1.3: Uncontrolled Effect Sizes for Symptoms of Complex PTSD: Pre- to Post- Treatment

AD = affect dysregulation
 DISS = dissociation
 DR = difficulties in relationships
 IPT = interpersonal therapy
 k = number of treatment arms
 NSC = negative self-concept
 RCT = randomized controlled trial
 S&S = safety and stabilization
 TMP = trauma memory processing
 WL = waiting list
 * $p < 0.05$
 ** $p < 0.01$
 *** $p < 0.001$

1.4.4.3 Maintenance of Treatment Gains at Follow-up

In order to examine whether improvements in PTSD symptoms were maintained beyond the immediate termination of treatment, we conducted a meta-analysis of uncontrolled, pre-treatment to follow-up effect sizes. A total of 30 studies ($k = 38$) reported follow-up data that could be used in this analysis. When studies reported more than one follow-up period, the longest one was used. Mean duration of follow-up was 6.9 months post treatment (SD 5.52; range 1 – 30 months). Results indicated that the overall pooled effect size increased slightly, from $g = 1.02$ at post-treatment, to $g = 1.25$ at follow up, and remained significant ($Z = 11.14$; $p < 0.00001$). Again, heterogeneity was very high ($I^2 = 88\%$).

1.4.5 Attrition

The mean attrition rate across all treatment arms for RCTs, non-RCTs and uncontrolled studies ($k = 55$) was 19.2% (SD = 11.29; range = 0 – 43.2%: see Table 1.4). There were no significant differences in attrition rate between RCTs and non-RCTs / uncontrolled studies ($t = .43$; $df = 53$; $p = 0.46$), or between different types of therapy ($F = 1.08$; $df = 2$; $p = 0.339$). However, attrition rates were significantly higher for group treatments compared with individual (21.2% vs. 13.91%; $t = 2.16$; $df = 45$; $p = 0.036$).

Variable / Group	<i>k</i>	Attrition (%)	SD	95% CIs	Between-Group Comparisons
Overall	55	19.2	11.29	16.2 – 22.2	-
Type of Therapy					$F = 1.10$ $df = 2$ $p = 0.349$
<i>Present-Focused (S&S)</i>	24	21.8	11.03	17.1 – 26.4	
<i>Trauma-Focused (TMP)</i>	15	17.6	14.72	9.45 – 25.7	
<i>Other^a</i>	16	17.0	7.20	13.2 – 20.8	
Mode of Delivery^b					$t = 2.16$ $df = 45$ $p = 0.036^*$
<i>Individual (I)</i>	17	13.9	12.94	7.26 – 20.6	
<i>Group (G)</i>	30	21.2	10.08	17.5 – 25.0	
Type of Study Design					$t = 0.74$ $df = 53$ $p = 0.461$
<i>RCTs</i>	28	18.1	11.79	13.7 – 22.5	
<i>Non-RCTs and Uncontrolled Trials</i>	27	20.4	10.85	16.3 – 24.5	

Table 1.4: Attrition Rates by type of therapy, mode of delivery, and type of study design.

^a All other therapies (including phase-based CBT, IPT, group psychotherapy)

^b Combined modes of delivery were not included in the between-group comparisons as the number of observations was too low ($k = 8$).

1.4.6 Publication Bias

Visual inspection of the funnel plot of controlled effect sizes for PTSD indicated some asymmetry, indicating that larger studies tended to report smaller effect sizes. Egger's test for asymmetry was significant (intercept $\beta = -2.96$; $t = -6.41$; $p < 0.001$), and Duvall and Tweedie's Trim-and-Fill procedure reduced the estimated

combined effect size from $g = -0.58$ to $g = -0.11$ (95% CIs -0.14 to -0.08) on the basis of 14 imputed studies, suggesting that publication bias was likely significant.

1.4.7 Comparison with Previous Meta-Analyses

Pooled effect sizes fell within the range reported in previous meta-analyses examining survivors of trauma beginning in childhood, albeit towards the lower end (e.g. Dorrepaal et al., 2014; Ehring et al., 2014; Karatzias et al., 2019; Taylor & Henry, 2010). Both uncontrolled and controlled effect sizes were considerably smaller than those reported by previous meta-analyses examining chronic PTSD across wider populations (e.g. Bisson et al., 2007; 2013; Watts et al., 2013) (see Table 1.5), lending further weight to evidence that outcomes of psychological interventions are generally poorer for adult survivors of childhood, as opposed to adulthood, abuse.

Outcome	Study	Controlled ES (g)	Uncontrolled ES (g)
PTSD	Trauma beginning in childhood or adulthood		
	Bisson et al. (2007)	1.13	-
	Bisson et al. (2013)	1.62	-
	Watts et al. (2013)	1.14	-
	Karatzias et al. (2019): adult onset	0.85*	-
	Trauma beginning in childhood		
	Taylor & Harvey (2010)	0.72	0.77
	Ehring et al. (2014)	0.5 – 0.72	1.24
	Dorrepaal et al. (2014)	0.90	1.30
	Karatzias et al. (2019): childhood onset	0.50*	-
	Our meta-analysis	0.58	1.02
Affect Dysregulation	Karatzias et al. (2019) [childhood / adulthood]	0.82 – 1.42	-
	Our meta-analysis	0.54	1.08
Negative Self-Concept	Karatzias et al. (2019) [childhood / adulthood]	0.24 – 0.82	-
	Taylor & Henry (2010) [childhood]	0.56	0.58
	Our meta-analysis	0.25	0.38
Disturbances in Relationships	Karatzias et al. (2019) [childhood / adulthood]	0.32 – 0.66	-
	Taylor & Henry (2010) [childhood]	0.05	0.61
	Our meta-analysis	0.45	0.78
Dissociation	Ehring et al. (2014) [childhood]	0.67 – 1.05	0.76
	Our meta-analysis	0.44	0.47

Table 1.5: Pooled effect sizes from this study compared with those of previous meta-analyses.

* approximate (taken from figure)

1.5 DISCUSSION

1.5.1 Overall effectiveness of psychological interventions on symptoms of PTSD

The results of this meta-analysis indicate that psychological interventions are, on average, associated with significant reductions in symptoms of PTSD among adult survivors of childhood trauma, and that effects are generally maintained at follow-up durations of 3 months or more.

1.5.2 Comparative Effectiveness of Different Types of Therapy and Modes of Delivery

All four types of intervention categorized here (present-focused, trauma-focused, phase-based, and interpersonal) were associated with significant reductions in PTSD symptoms, with trauma-focused and phase-based interventions showing the largest effect sizes, and present-focused the smallest. These results are consistent with numerous previous studies indicating that trauma-focused interventions may be more effective than present-focused therapies in treating symptoms of PTSD (Bisson et al., 2007; Ehring et al., 2014). Of note, we did find that present-focused interventions, centred on enhancing safety and stabilization, and interpersonal therapy for trauma yielded medium-to-large uncontrolled effect sizes, suggesting that a significant proportion of individuals will have achieved clinically meaningful reductions in PTSD symptoms from these approaches. This is important because trauma memory processing procedures may be especially difficult for survivors of complex trauma, and the option of additional evidence-based therapies will only enhance client choice and empowerment.

Evidence for the relative efficacy of group vs individual therapy on symptoms of PTSD was more mixed. Interventions delivered individually were associated with larger effect sizes, on average, compared with group therapies, but these differences were only significant for uncontrolled, not controlled, comparisons.

These results are in contrast with several studies that report individual therapies are superior to those delivered in a group format (Ehring et al., 2014; Karatzias et al., 2019). Although the number of studies is still too small to permit any inferential statistical comparisons, it is interesting to note that combinations of individual and group therapy, generally employed by phase-based treatments such as STAIR + PE (Cloitre et al., 2010) and DBT-PTSD (Bohus et al., 2013; 2020), yielded the largest effect sizes of all.

It is important to acknowledge the potential impact of confounding in these findings; all of the present-focused interventions were delivered in groups, while most trauma-focused therapies were individual, making it difficult to attribute differences in one over another to either or both the focus of therapy or mode of delivery.

1.5.3 Overall effectiveness of psychological interventions on additional symptoms of complex PTSD

Relatively few studies reported outcomes relating to difficulties such as dissociation or the disorders of self-organization associated with complex PTSD, and only one study attempted to capture all these symptoms using a composite measure of complex trauma such as the SIDES (Dorrepal et al., 2012). As such, our understanding of which treatment approaches (e.g. present-focused vs. trauma-focused, or individual vs. group) may be most effective for these myriad, typically highly debilitating difficulties, remains poor. Our meta-analysis showed that overall effect sizes for improvements in affect dysregulation were similar in magnitude to those for symptoms of PTSD, less so for improvements in disturbances in relationships, and negligible for negative self-concept. Overall improvements in dissociative symptoms were in the small-to-moderate range.

Unfortunately, too few trials reported additional symptoms of complex PTSD in this meta-analysis, so it was not possible to test whether any therapeutic approach or mode of treatment delivery confers advantages over any other in terms of reducing

these distressing and typically highly debilitating difficulties in adult survivors of childhood trauma. Future research would do well to explore the effectiveness of interventions on the broader range of difficulties associated with ICD-11 complex PTSD, and which of these clients themselves prioritize for treatment.

1.5.4 Attrition

At 19%, the overall attrition rate across studies was in line with those of previous meta-analyses on the efficacy of psychological interventions for symptoms of PTSD (e.g. Ehring et al., 2014; Imel, Laska, Jakupcak, & Simpson, 2013), and not unlike those for cognitive-behavioural treatments for depression and anxiety (Fernandez, Salem, Swift, & Ramtahal, 2015). They did not differ significantly according to type of therapy (present-focused vs. trauma-focused) or study design (RCTs vs. non-RCTs or uncontrolled studies), but were significantly higher for group compared with individual modes of treatment delivery. Reasons for this are not clear, but likely to be complex, reflecting a combination of both internal and external factors (e.g. Yalom & Leszcz, 2005).

Attrition rates are often used as a crude metric of treatment acceptability, because of the assumption that most people drop out because they do not feel they are benefitting sufficiently from treatment. In this meta-analysis, almost one in five people dropped out of treatment overall, and more still would not have completed treatment as intended (*per protocol*), or have received an “adequate dose” of therapy. As such, it is likely that therapy as delivered did not meet the needs of a significant proportion of people referred for treatment.

1.5.5 Risks of Bias

Attrition rates above 5% are generally considered “high” in clinical trials (Higgins et al., 2011) and therefore a potential source of bias, especially if dropout is not random. Attrition bias in these studies was at least partially controlled for by

intention-to-treat protocols (used in all the trials included in our main analysis), but the methods used to impute missing values in ITT procedures are not uncontentious, and few studies attempted to control for factors such as baseline symptom severity which are believed to influence dropout. Over one-third of studies in this meta-analysis were deemed at high risk of attrition bias for these reasons, and therefore the potential for an inflation of overall treatment effect sizes is relatively high.

There was also some indication of publication bias in this meta-analysis, as evidenced by asymmetry in funnel plots of effect size vs. standard error, and the results of both trim-and-fill and Egger's regression procedures. However, several researchers have noted that when unexplained heterogeneity is high, as was the case in this study, asymmetry may arise for reasons unrelated to publication bias (Sterne et al., 2011), and trim-and-fill outcomes are less reliable (e.g. Song et al., 2009): as such, it is not possible to estimate with certainty the effects of any potential publication bias on the current results.

1.5.6 Potential Sources and Implications of Heterogeneity

We reasoned that the broad timing of complex trauma (whether beginning in child- or adult-hood) is likely a significant source of heterogeneity in previous meta-analyses of interventions for symptoms of chronic or complex PTSD. However, levels of heterogeneity remained very high in this study, despite restricting trials to survivors of childhood trauma. Between-study sensitivity and subgroup analyses generally did little to reduce heterogeneity, indicating that significant sources of variance must exist beyond gender mix, presence of severe comorbidity, therapy setting, focus of therapy, mode of treatment delivery, type of study design, nature of control group, or duration of treatment.

Our understanding of the within-study factors which may influence treatment engagement and outcome, and therefore what might account for the high degree of heterogeneity here, remains limited. Previous research has shown that symptom burden at pre-treatment, baseline levels of distress and ability to regulate emotions, levels of social support during treatment, and quality of the therapeutic alliance appear the more consistent moderators of treatment outcome in PTSD (e.g. Cloitre, Petkova, Su, & Weiss, 2016; Follette et al., 1991; Jaycox & Foa, 1996; van Minnen, Arntz, & Keijsers, 2002; Zlotnick et al., 1997), yet these are generally not reported in clinical trials of psychological interventions.

Of course, the variety and combinations of symptoms experienced by adult survivors of childhood trauma is also likely to vary both within and between studies, with important implications for which treatments may be most effective. Galatzer-Levy & Bryant, 2013 calculated that the revised DSM-5 criteria for PTSD yield a total of more than 630,000 unique combinations of symptoms that would qualify for a diagnosis of PTSD: if we were to further consider the additional disorders of self-organization associated with the ICD-11 conceptualization of complex PTSD, and the various comorbid difficulties which appear to be the norm rather than the exception in adult survivors of complex trauma (e.g. depression, substance misuse), this figure would increase still further. The utility of a purely diagnostic approach in guiding recommendations for treatment, therefore, appears especially limited in the case of complex PTSD.

It may be that different treatment approaches (e.g. present-focused, trauma-focused; individual, group) will be differentially effective for different clusters and severity of difficulties, and it is therefore likely that no single treatment approach will be effective for all clients presenting with complex PTSD. This is consistent with suggestions that psychological interventions for survivors of complex trauma should take a flexible, modular approach, based on the needs and preferences of each individual (e.g. Cloitre, 2015; Ford & Courtois, 2020; Karatzias & Cloitre,

2019). Future research would be most usefully directed at better understanding “what works for whom” in ameliorating the difficulties associated with repeated interpersonal trauma, taking into account different clusters of symptoms, individuals’ goals for treatment, and preferences for treatment approach.

1.5.7 Limitations of the Review & Directions for Future Research

We believe that this review had a number of strengths, including being the first to consider the efficacy of psychological interventions on symptoms of the latest conceptualization of complex PTSD among adult survivors of childhood trauma. In considering both controlled and uncontrolled effect sizes, we were able to explore sub-group differences in both. This was arguably the first meta-analysis to be sufficiently powered to detect statistically significant differences between subgroups according to the focus of therapy (present-focused versus trauma-focused) and mode of delivery (individual versus group).

There were of course a number of limitations, which restrict the conclusions that can be made on the basis of the findings. First, the degree of heterogeneity was very high, indicating that important sources of variability in treatment outcomes remain unknown and unexplored, and publication bias may have been evident, which raises further doubt about the reliability and validity of the pooled results. Second, this review focused on outcomes associated with the ICD-11 conceptualization of complex PTSD. None of the studies used an aggregate measure of ICD-11 complex PTSD such as the International Trauma Questionnaire (Cloitre et al., 2018), likely because the concept and measure have only recently been formalized. Instead, we looked at PTSD as the primary outcome measure, as well as the additional disorders of self-organization (DSOs). However, in doing so, this review excluded a number of intervention studies examining other relevant outcomes, such as depression or interpersonal functioning. Such treatments were more likely to be psychodynamic or relational in

their focus, which means these approaches were under-represented in this review. Finally, the review did not consider interventions that did not fit the narrow criteria of being “psychological” in nature. However, there is increasing evidence that “body-based” and other therapies may be particularly effective in reducing symptoms of CPTSD in survivors of childhood trauma, particularly those for whom somatic symptoms and dissociation are especially problematic (e.g. Classen et al., 2020; Rhodes, Spinazzola, & van der Kolk, 2016; Rogel et al., 2020; van der Kolk et al., 2016).

Despite these limitations, we found that psychological interventions are associated with clinically significant overall improvements in PTSD and emotion dysregulation among adult survivors of childhood trauma. Trauma-focused and phased treatments yielded the largest improvements in PTSD symptoms overall. However, the high degree of heterogeneity in both controlled and uncontrolled comparisons, even when between-study variables such as type of therapy and mode of delivery were taken into account, indicated that other factors likely contribute significantly to treatment outcomes. As such, the field would benefit from more research on “what works for whom” in the treatment of complex PTSD in order to provide survivors with individualized, evidence-based treatments that align with their difficulties, goals for therapy, and preferences for treatment.

Several researchers have suggested that the treatment of complex PTSD may be more effective and acceptable when applied within a more person-centred, modular approach to treatment, based on a shared individual formulation which highlights the client’s goals for intervention and an agreed roadmap for the order in which each of the key goals is targeted (T. Karatzias, December 2021, *pers. comm.*). Future research could therefore focus on examining the efficacy of these newer interventions for complex PTSD such as Enhanced STAIR (Cloitre, Karatzias, & McGlanaghy, 2019b) and DBT-PTSD (Bohus et al., 2013; Bohus et al., 2020), and the potential predictors of treatment engagement and outcome for

these therapies, such as type(s), duration, and onset of trauma and nature of symptoms (e.g. Cloitre et al., 2016). This information could be used by experienced clinicians to direct patients with different profiles of trauma, current life circumstances, and symptomatology to the intervention elements most likely to help, with the aim of improving the acceptability, effectiveness, and drop-out rates of psychological interventions for CPTSD across the population of survivors as a whole.

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Chapter 2 Empirical Study

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The effectiveness and acceptability of a phase-one psychological intervention (“Survive and Thrive”) for adult survivors of complex trauma in routine clinical care.

by

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2.1 ABSTRACT

Objective: Our understanding of how best to treat the difficulties associated with complex PTSD, and the extent to which the results of controlled research trials can be translated to “real-world” clinical practice, remain topics of considerable debate.

Methods: We used a retrospective, pre-post intervention design to investigate anonymised outcome and programme evaluation data from a single group of women ($n = 634$; mean age 39.0 yrs) who agreed to take part in the “Survive and Thrive” programme for complex trauma across NHS Lothian, Scotland, UK, as part of routine clinical care.

Results: 49% of participants completed the intervention (defined as attending at least 7 / 10 sessions). Significant pre- to post- treatment improvements were observed among programme completers on all outcomes, including psychological distress ($d = 0.58 - 0.71$; $p < 0.001$) and symptoms of PTSD ($d = 0.5 - 0.58$; $p < 0.001$), depression ($d = 0.62 - 0.81$; $p < 0.001$) and anxiety ($d = 0.59 - 0.76$; $p < 0.001$). 40% met criteria for clinically significant improvement in distress and symptoms of PTSD, and 99% reported high levels of satisfaction with the programme by the end of the programme.

Conclusions: These preliminary results suggest that “Survive and Thrive” may provide an acceptable, safe, and effective option for many women seeking help for symptoms of CPTSD in routine clinical practice. However, a significant proportion of women dropped out of treatment early without providing a reason, indicating that the acceptability and effectiveness of the programme for the population of treatment-seeking women as a whole requires further exploration. The lack of a control group further means that we cannot be certain that improvements in symptoms and wellbeing were causally related to taking part in the intervention.

2.2 INTRODUCTION

Traumatic events which are interpersonal in nature (such as physical, sexual, or emotional abuse) and occur repeatedly, during developmentally sensitive periods (such as childhood), are associated with significantly increased likelihood of severe and enduring mental health conditions (such as chronic post-traumatic stress disorder (PTSD), personality disorder, and psychosis), as well as pervasive and debilitating transdiagnostic difficulties such as emotional dysregulation and impaired intra- and inter-personal functioning (Finkelhor & Browne, 1985; Herman, 1992a; van der Kolk, Roth, Pelcovitz, Sunday, & Spinazzola, 2005).

Increasing numbers of researchers argue that the diverse and debilitating set of difficulties experienced by many adult survivors of complex trauma are best considered as a single nosological entity, which has come to be termed complex post-traumatic stress disorder, or CPTSD (Briere & Runtz, 1987; Cloitre, Garvert, Brewin, Bryant, & Maercker, 2013; Courtois, 2004; Ford, 1999; Herman, 1992a; Roth, Newman, Pelcovitz, van der Kolk, & Mandel, 1997). CPTSD encompasses the three core symptoms of “classic” PTSD (re-experiencing of the traumatic event(s), hyperarousal, and avoidance), together with three additional sets of difficulties related to “disorders of self-organization” (DSOs) – namely, emotion dysregulation, negative self-concept, and interpersonal difficulties. CPTSD appeared for the first time in the most recent version of the International Classification of Diseases (ICD-11; World Health Organization, 2018), and as such, the evidence base for how best to treat it, remains in its infancy.

2.2.1 Which interventions are most effective for adult survivors of complex trauma?

The most effective way to treat the difficulties associated with complex PTSD remains a topic of considerable debate. Some researchers question the validity of CPTSD as a construct, arguing instead that its cluster of symptoms is better conceptualized as “classic” PTSD with additional comorbidities such as personality

disorder or chronic depression: as such, they argue it is best treated using one of the many evidence-based, trauma-focused treatments for PTSD, such as prolonged exposure therapy (PE: Foa, Hearst-Ikeda, & Perry, 1995), cognitive processing therapy (CPT: Resick & Schnicke, 1992), or cognitive therapy for PTSD (Ehlers et al., 2005) (de Jongh et al., 2016; Resick et al., 2012). These treatments differ in process, but share the aim of helping clients re-process trauma memories through repeated exposure and / or cognitive restructuring. These therapies have a sound evidence base and are “strongly recommended” for the treatment of PTSD by various national clinical practice guidelines (e.g. American Psychiatric Association, 2017; National Institute of Clinical Excellence (NICE), 2018; NHS Education for Scotland, 2015).

Proponents of the CPTSD construct argue that the disorders of self-organization which characterize CPTSD often present significant barriers to engaging with trauma-focused treatments, and are not appropriately addressed by them. They therefore recommend a stage-, or phase-based approach to treatment, incorporating an initial, *present-focused* “safety and stabilization” phase (aimed at developing emotion regulation and interpersonal skills in preparation for subsequent trauma processing), a second, *past-focused* trauma processing phase (for example, using trauma-focused treatments such as PE, CPT or CBT), and a third, *future-oriented*, “reconnection” phase, which aims to connect individuals with their values, aspirations, and wider social networks (Cloitre et al., 2011; Herman, 1992a). According to this model, treatment elements are individualised in collaboration with each client, recognizing that the three phases need not occur in the prescribed order, and that not all may need to be formally addressed in therapy (Cloitre, 2015; Karatzias & Cloitre, 2019).

Several recent meta-analyses of randomized, controlled trials (RCTs) indicate that psychological interventions are efficacious in reducing symptoms of PTSD in adult survivors of complex trauma (e.g. Coventry et al., 2020; Ehring et al., 2014; Karatzias et al., 2019b; Melton et al., 2020; Willis & O'Rourke, 2021). Although there are as yet too few studies to permit appropriately-powered statistical comparisons between trauma-focused and phase-based approaches to treatment,

preliminary findings indicate that phase-based interventions which incorporate both safety and stabilization and trauma memory processing elements are at least as effective in reducing symptoms of PTSD, and may be even more effective in ameliorating difficulties associated with negative self-concept, emotion dysregulation, and interpersonal difficulties (Coventry et al., 2020; Melton et al., 2020).

2.2.2 Are phase-one interventions useful in their own right?

Despite their demonstrated efficacy among a range of different populations, trauma-focused therapies are generally under-used in clinical practice (Becker, Zayfert, & Anderson, 2004), and are not the treatment of choice for many individuals seeking help for PTSD – typically because revisiting past trauma is often upsetting, at least at the beginning of treatment, and clients may consider they cannot, or choose not to, tolerate high levels of distress (Zayfert & Black, 2000). Additional disorders of self-organization among clients with complex PTSD (in particular, difficulties regulating emotions) likely make engaging with trauma-focused treatments more challenging still. For these reasons, the development and evaluation of “present-focused” or “phase-one” therapeutic approaches as alternatives to, or preparation for, trauma-focused work are essential.

Phase-one interventions aim to improve clients’ understanding of the impact of complex trauma, and develop their skills in emotion regulation and intra- and interpersonal relating. Delivery is usually in groups, which offer additional advantages over individual therapy in terms of reducing isolation and feelings of stigma and providing a safe space in which to practice developing emotion regulation and interpersonal skills (Ford, 2020; Knight, 2006; Yalom & Leszcz, 2005).

A number of present-focused, phase-one interventions for CPTSD have been developed in recent years and evaluated in clinical trials, including *Skills Training in Affective and Interpersonal Regulation* (STAIR: Cloitre, Koenen, Cohen, & Han, 2002); *Trauma Affect Regulation: Guide for Education and Therapy* (TARGET: Ford & Russo, 2006; Ford, Steinberg, & Zhang, 2011); the *Trauma Recovery and*

Empowerment Model (TREM: Falloot & Harris, 2002); and *Seeking Safety* (Najavits, Weiss, Shaw, & Muenz, 1998). In Scotland, the manualized group intervention *Survive and Thrive* (Ferguson, 2008; NHS Education for Scotland, 2016) has demonstrated potential effectiveness and acceptability in two uncontrolled pilot studies of community women (Ball, Karatzias, Mahoney, Ferguson, & Pate, 2013; Karatzias et al., 2014), and has since been rolled out across all health boards in Scotland as a first-line intervention offered to adult survivors of complex trauma.

Several recent meta-analyses indicate that phase-one interventions can be efficacious in reducing symptoms of PTSD, albeit to a lesser extent, on average, than trauma-focused treatments (Ehring et al., 2014; Karatzias et al., 2019b; Willis et al., 2021: but see also Dorrepaal et al., 2014). This is perhaps unsurprising, given that phase one interventions are generally not designed as standalone interventions, and their key focus is not on reducing PTSD symptoms *per se*: indeed, Mahoney et al. (2019) concluded, from their meta-analysis of group interventions for CPTSD, that phase-one treatments may be at least as good as trauma-focused interventions in improving wider difficulties such as general distress. Further research in this area is urgently needed.

2.2.3 Generalizability of findings from research trials to routine clinical care

Meta-analyses of clinical trials (in particular, randomised, controlled trials (RCTs)) provide important indications of the efficacy of interventions under tightly controlled conditions, and represent the pinnacle of the hierarchy of clinical evidence in Evidence-Based Practice. However, they also confer a number of limitations, and translating the results of RCTs and meta-analyses to “real-world” clinical practice, in a way that helps clinicians evaluate the likely effectiveness of a given treatment, and shape treatment decisions for individual clients, remains highly problematic (Roth & Fonagy, 2005).

Research trials of psychological interventions are generally more homogeneous in terms of client characteristics, treatment settings, therapist training and caseloads, and adherence to protocols compared with routine clinical practice, with the consequence that results may not be comparable with those obtained in “real-world” settings. One potential consequence of concern among clinicians has been that effect sizes may be significantly lower, and dropout rates higher in routine practice compared with research trials. Although these concerns have typically not been borne out for standardized interventions like CBT for common mental health disorders such as anxiety or depression (Shadish, Navarro, Matt, & Phillips, 2000; Stewart & Chambless, 2009), there is some evidence that drop-out rates are significantly higher (Najavits, 2015) and treatment effect sizes significantly lower (Willis & O'Rourke, 2021) in more clinically-representative studies of treatments for chronic or complex PTSD compared with those of RCTs.

In order to gauge whether a given client is likely to benefit from treatment, or, conversely, experience iatrogenic harm, clinicians must have some understanding of both: (1) the likelihood that clients will achieve clinically significant change in outcomes; and (2) the client factors that influence treatment engagement and outcome. However, meta-analyses generally report aggregate, between-group effect sizes of post-treatment outcomes, and rarely report overall pre- to post-treatment changes in outcome, or their clinical significance – i.e, the proportion of participants achieving statistically reliable or meaningful change (Jacobson & Truax, 1991). Further, the degree of heterogeneity in meta-analyses of clinical trials for chronic types of PTSD tends to be very high, even after between-study factors such as type of therapy and mode of delivery are taken into account (e.g. Karatzias et al., 2019b; Willis & O'Rourke, 2021). A great deal of variability in treatment outcomes is therefore likely attributable to within-study, between-participant factors. Unfortunately, studies examining individual predictors or moderators of treatment outcome in interventions for PTSD have yielded inconsistent results, with factors such as age, level of education, nature and timing of trauma, pre-treatment symptom severity and comorbidity, and levels of dissociation, influencing outcomes in some cases, and not others (Cloitre et al., 2016; Ehlers et al., 2013; Hembree, Street, Riggs, & Foa, 2004; van Minnen et al.,

2002). Our understanding of “what works for whom” in the treatment of complex PTSD therefore remains very limited.

In order to develop the evidence base for the effectiveness of interventions for adult survivors of complex trauma, then, future research would do well to evaluate the benefits and risks of a given treatment, focusing on a range of standardized metrics (e.g. pre- to post- treatment effect sizes, and proportions of clients achieving meaningful change), as implemented in both controlled research trials and real-world clinical practice (Najavits, 2015; Roth & Fonagy, 2005; Westbrook & Kirk, 2005).

2.2.4 Overview and Aims of the Study

The present study used a retrospective, uncontrolled (pre- post- intervention), cohort design to evaluate routine outcomes associated with *Survive and Thrive*, a phase-one group intervention for adult survivors of complex trauma, delivered as part of standard clinical care within a National Health Service board in Scotland, UK. Such approaches are increasingly recognized as an important means to determine the effectiveness of novel or under-researched psychological interventions in the published scientific literature, and the extent to which a treatment shown to be efficacious in RCTs is also effective in real-world clinical practice (e.g. Ehlers et al., 2013; Hayward, Edgecumbe, Jones, Berry, & Strauss, 2018; Johns et al., 2019; Jones et al., 2018; Patsopoulos, 2011).

The aims of this study were to assess: (1) the effectiveness of *Survive and Thrive* in reducing overall distress and symptoms of PTSD, depression, and anxiety, using metrics of (a) pre- to post- treatment change and associated effect size, and (b) proportions of participants achieving reliable change (improvement or deterioration) by the end of treatment; (2) drop-out rates at different stages of the programme, and baseline differences between treatment completers and non-completers; (3) the impact of client factors such as age and baseline symptom

severity on treatment completion and outcomes; and (4) participants' evaluations of the programme.

Research Questions

1. Is “*Survive and Thrive*” effective in reducing symptoms of PTSD, depression, anxiety, and improving psychological distress among female survivors of complex trauma?
 - a. Are there any significant changes in symptoms and psychological distress from pre- to post-intervention, and how does the magnitude of any changes compare with those of existing evidence-based interventions?
 - b. What proportion of women achieve clinically significant reductions in overall psychological distress, and symptoms of PTSD, depression, anxiety, by the end of the programme?
 - c. Is the intervention associated with improved understanding of the nature and impact of complex interpersonal trauma, and skills to better manage emotional dysregulation and interpersonal difficulties?

2. Is “*Survive and Thrive*” safe and acceptable for women who agree to take part in the programme?
 - a. What proportion of women complete treatment?
 - b. What proportion of women demonstrate significant deterioration in distress or symptoms by the end of the programme?
 - c. How do women evaluate the programme, and what recommendations do they make for improvement?

2.3 METHODS

2.3.1 Evaluation Approach

We have argued for the importance of “real-world” research to bolster the rudimentary evidence base for the effectiveness of psychological interventions for complex PTSD. Here, we use a practical program evaluation approach popular in social science research (e.g. McCall & Green, 2004; Rossi, Lipsey, & Freeman, 2004; Wholey, Hatry, & Newcomer, 2010), and the UK’s National Institute for Health Research guidelines for the development and evaluation of complex interventions (Skivington et al., 2021) to provide a robust framework for our approach.

At the heart of the program evaluation approach is the program theory, consisting of “*a set of statements that describe a particular program, explain why, how, and under what conditions the program effects occur, predict the outcomes of the program, and specify the requirements necessary to bring about the desired program effects*” (Sharpe, 2011, p. 72). Program theory is ideally considered contemporaneously with the development of the programme or intervention, to ensure they are developed in line with relevant theory and evidence, but they may be put into place subsequently in order to guide evaluation. Our program theory is outlined below and presented in graphic form in figure 2.1 (see McLaughlin & Jordan, 2010).

Programme Theory

IF help-seeking women survivors of complex trauma are offered a group intervention focused on “safety and stabilization” **THEN** they should experience improvements in psychological distress **BECAUSE** they will have a better understanding of the impacts of complex trauma (in particular, emotion dysregulation and interpersonal difficulties) and enhanced skills in dealing with these difficulties, which in turn are expected to reduce shame and stigma, and empower and support women to continue their recovery journey (Herman, 1992a. b, 2015; Cloitre et al., 2011).

Situation: Adults are presenting to mental health services seeking help for difficulties related to chronic and complex interpersonal trauma, a relatively new conceptualization for which the evidence base remains small.

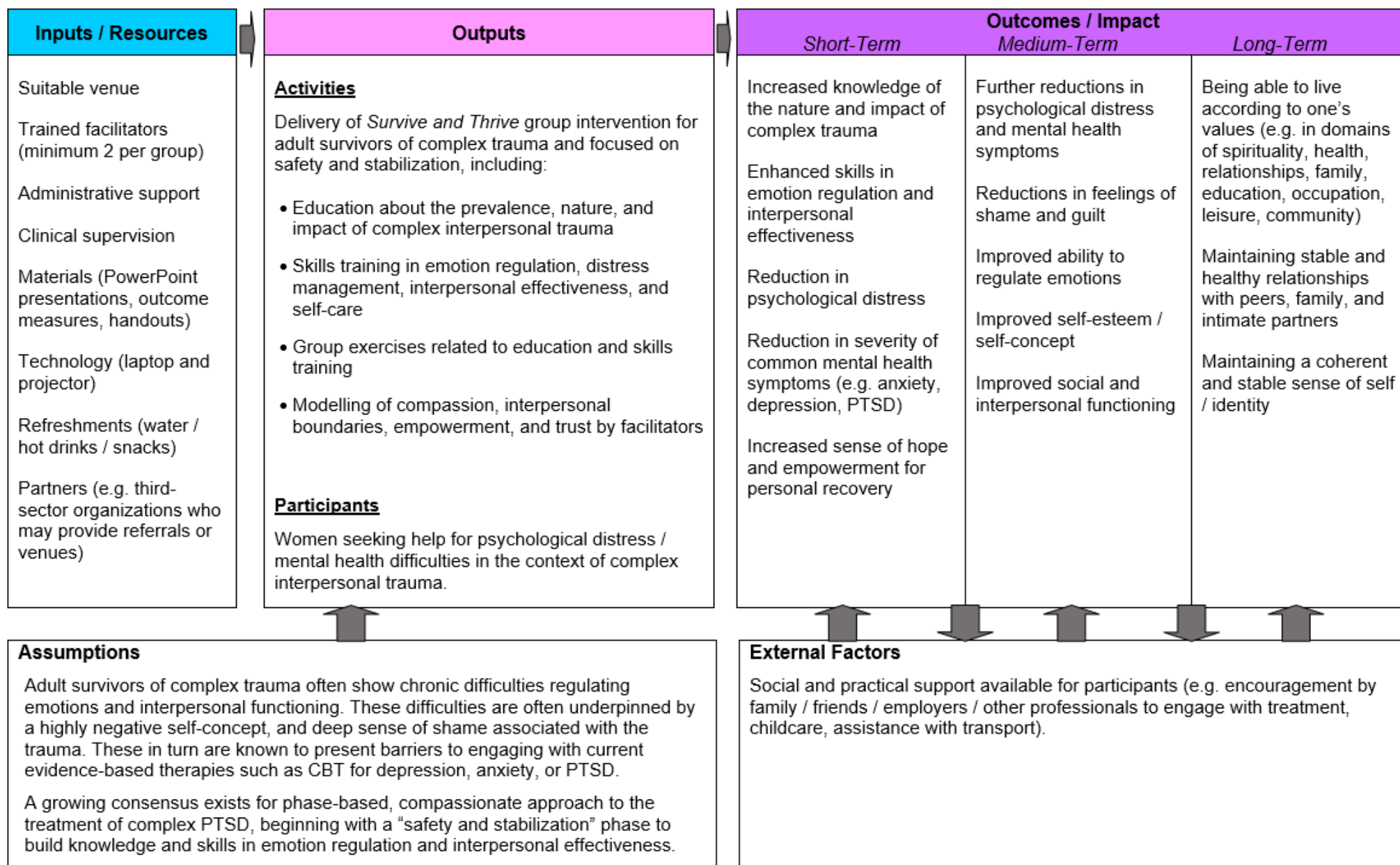


Figure 2.1 Logic Model depicting key inputs, outputs, and outcomes associated with implementing the *Survive and Thrive* intervention.

2.3.2 Design

This study used a retrospective, single-group, pre-post intervention design to explore anonymised, routinely-collected data collected by participants' care teams as part of standard clinical care.

2.3.3 Setting

The sample comprised consecutive participants referred to the East Lothian, Midlothian, and City of Edinburgh sectors of NHS Lothian's Adult Mental Health service (NHS Scotland) between January 2015 and September 2020. These three sectors serve a combined population of 724,481 (National Records of Scotland, 2020), of whom 92 – 99% of residents identify as white, 1 – 5.5% Asian, and 0 – 2.8% black or “other” ethnicity (National Records of Scotland, 2011). Mean rates of poverty across these sectors are in line with the national average, though all contain areas classified as among the 5% most and least deprived in Scotland, according to the Scottish Index of Multiple Deprivation (Scottish Government, 2020). *Survive and Thrive* groups were held across a variety of locations across Lothian (such as NHS outpatient clinics, church halls, and premises operated by third-sector organizations).

2.3.4 Participants

Data from all women referred to *Survive and Thrive* during the study period and who met inclusion criteria to attend the group were included in the analyses. In order to take part in *Survive and Thrive*, participants must be 18 years or over and report a history of interpersonal trauma, and ongoing difficulties with emotion dysregulation and interpersonal functioning (NHS Education for Scotland, 2016; Shand, Duncan, Power, & Graham, 2018). Most will meet criteria for a diagnosis of complex PTSD, and likely additional difficulties such as depression, problematic

substance use, and / or personality disorder: however, the presence or absence of formal diagnoses are not required for participation.

All women referred to *Survive and Thrive* are invited to attend an initial screening and assessment appointment with a facilitator to discuss participation and agree whether the group will be appropriate. Women are not considered suitable for the group if their level of risk (to self and / or others) is considered acute or significant, if a group setting is likely to be difficult for themselves or other group members, or if another evidence-based treatment is likely to be more beneficial.

A total of 634 women were offered a place on the programme following referral and initial screening (see Figure 2.2 for flow diagram).

2.3.5 Survive and Thrive Programme

Survive and Thrive is a 10-session, closed-group, “phase one” intervention for adult survivors of complex trauma, focusing on safety and stabilization (Ferguson, 2008, 2016). The programme was developed by consultant clinical psychologist Sandra Ferguson (2008) according to Herman’s influential *phased intervention* model of complex PTSD (Cloitre et al., 2012; Herman, 1992a; Herman, 1992b), and in line with evidence-based principles of trauma-informed care (e.g. Harris & Fallot, 2001). Its current 10-session version has been offered throughout Scotland, UK, since 2013 as a first-line intervention for adult survivors of complex trauma reporting difficulties with emotion dysregulation and interpersonal functioning. The programme is available as a Resource Pack for Facilitators from NHS Education for Scotland and delivered according to robust national clinical governance standards and procedures. This stipulates that: (1) referrals are screened against defined referral criteria (self-reported history of complex trauma, difficulties with affect regulation and interpersonal functioning, and sufficiently low levels of risk to self and others); (2) venue is safe and confidential, preferably in a community (rather than hospital) setting, ideally with breakout space and access to facilities for tea and coffee making; (3) the programme is delivered by at least two trained

facilitators, with experience of working therapeutically with adult survivors of complex trauma; (4) clinical supervision is in place with an appropriately qualified and experienced supervisor, usually an applied psychologist. If possible, service users have a named link or contact person who can support them to attend sessions and engage with the materials.

The programme is present-focused and cognitive-behavioural in orientation, and focuses primarily on (1) psychoeducation about the nature and impact of interpersonal trauma, and (2) the development of helpful strategies to manage symptoms and distress (see Table 2.1 for details of week-by-week content). In order to promote a “safe space” for participation, groups are run in single-gender cohorts, and group members are asked not to disclose details of past abuse or trauma during sessions.

Sessions are scheduled for two hours, including a break, and run for 10 consecutive weeks at the same time and location. 12 – 14 participants are initially recruited for each group on the basis that the optimum group size is around 8, and that up to 50% may drop out by the end of treatment. Each group is led by at least two facilitators, experienced therapists who must have completed the 2.5-day training organized by NHS Education for Scotland. Sessions generally consist of a mixture of didactic presentations, group discussion, and experiential skills practice, and are supplemented by printed materials for participants to take home. Optional home practice is also suggested between sessions.

Survive and Thrive was not designed as a standalone intervention, but as part of a planned treatment approach for survivors of complex trauma, in line with national clinical guidelines (e.g. The Matrix, NHS Education for Scotland, 2015). On completion of the group, participants are supported to discuss next steps with their referrer, such as individual trauma-focused therapy (phase 2) or psychosocial approaches to enhance reconnection and reintegration with their wider community (phase 3).

Session	Focus
1	Orientation to the group; safety guidelines (including confidentiality and its limits, nondisclosure); nature and prevalence of interpersonal trauma; the “3 Ps” (preparation, practice, and patience).
2	The effects of abuse and trauma (including physical symptoms, emotion dysregulation, interpersonal difficulties, and negative beliefs about self and others); different ways of coping.
3	Getting safe and getting started: preparation for starting recovery; evaluating current safety and self-care (especially sleep); boundaries and healthy relationships.
4	Surviving the surviving: the impact of trauma on emotion regulation; the window of tolerance; discussion of “safe” and “unsafe” coping strategies (e.g. avoidance, using substances, self-harm) and their long-term impact.
5	Understanding and coping with anxiety: the effects of repeated trauma on the brain; relationship between thoughts, feelings, body sensations, and behaviours in anxiety; coping with anxiety and panic; making an anxiety management plan.
6	Understanding and coping with anger: anger as an important emotion; problems associated with “too much” or “too little” anger; importance of thoughts in anger; coping with anger.
7	Understanding and coping with depression: effects of trauma on mood; “vicious cycle” of depression; importance of valued activities and support networks; thinking and self-criticism in depression.
8	Understanding and coping with shame and guilt: shame and guilt as common reactions to abuse; fostering self-compassion; self-soothing.
9	Understanding and coping with flashbacks, nightmares, and dissociation: recognizing triggers; safe ways of coping, including grounding, positive self-talk, self-soothing, mindful orienting of attention to the present moment.
10	Effective communication and moving forward: understanding different communication styles; improving assertiveness skills; reflecting on the programme and planning next steps.

Table 2.1: week-by-week content of *Survive and Thrive* group sessions.

2.3.6 Procedures

Data were collected from all female *Survive and Thrive* groups delivered by NHS Lothian's Adult Mental Health service between January 2015 (when the programme was formally rolled out in the Midlothian service) and September 2020. No significant changes to the programme were made over this time. Three of the authors (A. Willis, P. Balfour, and A. Wells) were involved in facilitating some of the groups.

Data analysis procedures were designed in accordance with the Code of Ethics of the World Medical Association (World Medical Association, 2013), the UK Data Protection Act (2018), and approved by the University of Edinburgh's School of Health in Social Science Research Ethics Committee, and NHS Lothian's Caldicott Guardian. Participants had provided verbal informed consent for the following data to be used for the purposes of research and service evaluation, in anonymised form: age, attendance at sessions, self-reported outcome measures at pre- and post-treatment, and responses to the post-treatment evaluation questionnaire.

Data Management Procedures

A register was taken by group facilitators at the beginning of each session to monitor attendance. Group facilitators administered paper versions of the outcome measures at the beginning of group sessions in weeks 1 and 10, and programme evaluation questionnaires at the end of the final session in week 10. Participants were asked to write their initials on the outcome measures (but not the evaluation questionnaires) in order that data could be recorded accurately alongside their age and attendance. Women were further reminded that their participation in these exercises was entirely voluntary, and any data collected would be anonymised once collated and matched in a spreadsheet.

Details of participants' attendance and responses to outcome questionnaires were subsequently transferred from paper copies to a "master" spreadsheet by one of the group facilitators or assistant psychologists working in the service, and stored on a secure area of the NHS server. Prior to data analysis by the first author, an

assistant psychologist assigned to the service assigned each participant a unique ID in copy of the spreadsheet, and all identifying information of participants (names, initials, dates of birth) was removed. Group facilitators and assistant psychologists also input participants' anonymised responses to each item of the programme evaluation questionnaires into a separate spreadsheet for analysis by the first author.

Reflexivity Statement

Three of the authors of this paper were involved in delivering some of the *Survive and Thrive* groups included in this study, including the first author. All three are middle-aged, middle-class, female applied psychologists employed by the NHS and with a keen interest in the welfare of adult survivors of complex trauma. Although data were anonymised prior to analysis, and all authors adhered to the highest ethical and professional standards during the collection and analysis of data, the likelihood of any unconscious bias, particularly in the interpretation of open-ended questionnaire data therefore cannot be ruled out.

2.3.7 Outcomes

The *Survive and Thrive* practice guidelines recommend the routine collection of self-report measures of psychological distress and symptoms associated with complex trauma (PTSD, depression, and anxiety) before and after the intervention. The core mandatory outcome measures for the group in NHS Lothian's Adult Mental Health service comprise the following:

2.3.7.1 Psychological Distress

Psychological distress is a transdiagnostic construct that captures the impact of a wide range of symptoms on participants' overall wellbeing. Because the symptom profiles of survivors of interpersonal abuse are so heterogeneous, psychological distress was therefore considered the primary outcome measure of interest in this analysis. The CORE-10 is a 10-item, short version of the CORE-OM measure of

global psychological distress, appropriate for use with a range of different presentations (Connell & Barkham, 2007). Items are rated on a five-point Likert scale (from 0 to 4), with total possible scores ranging from 0 to 40. Scores of at least 11, 16, 21, and 26 indicate mild, moderate, moderate-to-severe, and severe levels of distress, respectively. The CORE-OM demonstrates high internal consistency and test-retest reliability, has been extensively validated across a range of clinical populations, and is highly sensitive to clinical change (Barkham et al., 2013; Evans, 2000).

2.3.7.2 PTSD

Severity of PTSD symptoms was assessed using the PTSD Checklist (Civilian Version) (PCL-C), a 17-item assessment and outcome measure designed to measure DSM-IV symptoms of PTSD among non-military populations (Weathers, 1993; Weathers, Litz, Huska, & Keane, 1994). Each item is rated on a five-point Likert scale scored from 1 – 5, such that the total possible score ranges from 17 – 85. The recommended clinical cutoff for a diagnosis of PTSD among community populations of women varies between 30 and 44 (Blanchard, Jones-Alexander, Buckley, & Forneris, 1996; Dobie et al., 2002; Harrington & Newman, 2007; National Centre for PTSD, 2012). The PCL-C has at least acceptable internal consistency, convergent validity, and test-retest reliability, though less is known about its sensitivity to treatment-related change (Blanchard et al., 1996; Wilkins, Lang, & Norman, 2011).

2.3.7.3 Depression

Severity of depression symptoms was measured using the nine-item Patient Health Questionnaire (PHQ-9; Kroenke, Spitzer, & Williams, 2001). Participants rate each item on a four-point Likert scale, from 0 to 3 (maximum score = 27). Scores of at least 5, 10, 15, and 20 represent mild, moderate, moderately-severe and severe depression, respectively. The PHQ-9 has been found to have high internal and test-retest reliability, good construct and criterion validity, high sensitivity and specificity, and is sensitive to clinical change (Kroenke et al., 2001; Lowe, Kroenke, Herzog, & Grafe, 2004).

2.3.7.4 Anxiety

Severity of generalized anxiety symptoms was assessed using the seven-item Generalized Anxiety Disorder Questionnaire (GAD-7: Spitzer, Kroenke, Williams, & Lowe, 2006). Each item is rated on a four-point Likert scale from 0 to 3 (maximum score = 21). Scores of at least 6, 11, and 16 represent mild, moderate, and severe anxiety, respectively. The GAD-7 has demonstrated good psychometric properties in both clinical and non-clinical samples and appears highly sensitive to clinical change (Johnson, Ulvenes, Økstedalen, & Hoffart, 2019; Lowe et al., 2008; Toussaint et al., 2020).

2.3.7.5 Programme Evaluation

Participants were asked to complete an evaluation questionnaire during the final session to elicit feedback about their experience of and satisfaction with the *Survive and Thrive* programme. Two versions of the questionnaire were used across East and Midlothian and the City of Edinburgh areas. Both contained a mixture of closed-ended items, to which they were asked to respond according to a four-point Likert scale, and several open-ended questions, to which they were free to respond as they liked. Two of the closed-ended items, and two open-ended questions were common to both versions of the questionnaire: these related to quality of the therapy and whether they would recommend the programme to others (closed-ended) and what they considered were the most helpful and least helpful aspects of the group (open-ended).

2.3.7.6 Data Analysis: Outcomes

The primary outcome was the change in self-reported distress between pre- and post-treatment. We also examined pre- to post-treatment changes in symptoms of PTSD, depression, and anxiety.

Statistical Analysis

All statistical analyses were carried out using SPSS® v. 25. Separate repeated-measures t-tests were carried out on programme completers to determine the statistical significance of any mean changes in distress, and symptoms of PTSD, depression, and anxiety, between pre- and post-treatment. In order to be comparable with the results of previous studies, only participants with at least “moderate” levels of severity were included in the analysis of each outcome. Binomial logistic regression was used to examine the extent to which age and baseline symptom severity predicted treatment completion and reliable improvement in distress.

Effect Size

Effect sizes associated with pre- to post-treatment changes in psychological distress and symptoms of PTSD, depression, and anxiety, were calculated using Cohen’s *d* for repeated measures using the statistical software package G*Power (Faul, Erdfelder, Lang, & Buchner, 2007):

Reliable Change

In order to examine the clinical effectiveness of the *Survive and Thrive* programme, we calculated the proportion of women who met criteria for reliable change (improvement or deterioration) from pre- to post-treatment (Jacobson & Truax, 1991), according to previously-calculated change indices for each outcome measure. Reliable change was defined by a difference of 6 or more points on the CORE-10 for psychological distress (Barkham et al., 2013), 10 points or more on the PCL-C for symptoms of PTSD (Monson et al., 2008), 9 points or more on the PHQ-9 for symptoms of depression (McMillan, Gilbody, & Richards, 2010), and 6 points or more on the GAD-7 for symptoms of anxiety (Bischoff, Anderson, Heafner, & Tambling, 2020).

2.3.7.7 Data Analysis: Participant Evaluation

Responses to participants' evaluation questionnaires were entered into an electronic spreadsheet for descriptive data analysis. Closed-ended items were analysed in terms of percentages of participants who selected each response option – typically 1 – 4 on a four-point Likert scale. Responses to open-ended questions were transcribed verbatim and subjected to a basic inductive content analysis by the first author to identify relevant themes elicited by participants, and the proportions of participants mentioning each one (Weber, 1990). This was considered the most appropriate method, given the brevity of responses and large number of respondents.

2.4 RESULTS

A flow chart depicting participants' journeys through recruitment and intervention is shown in Figure 2.2.

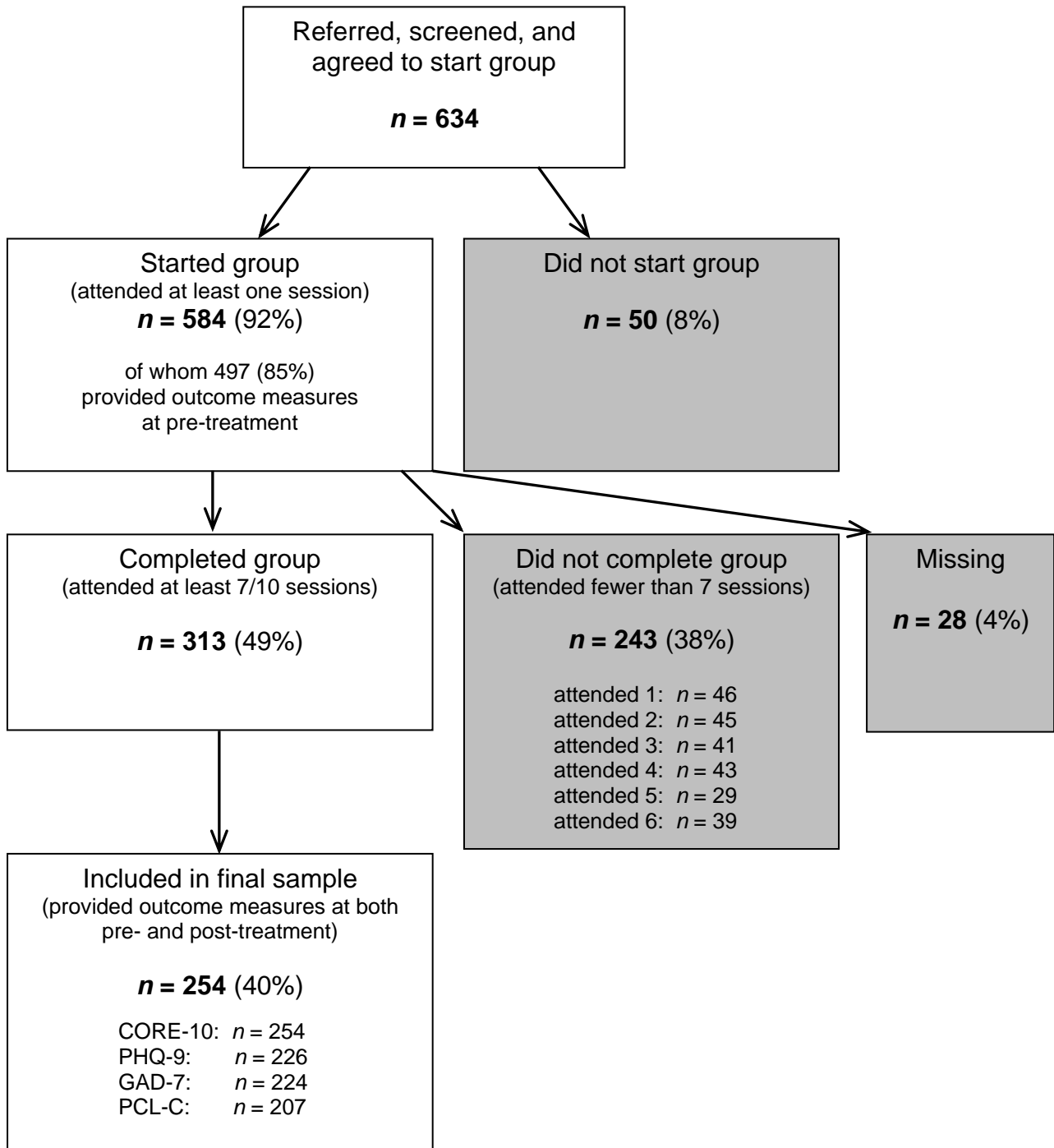


Figure 2.2: Flow chart depicting participants' journeys through the recruitment, treatment, and data analysis stages of the study.

Of the 634 women who initially agreed to take part in *Survive and Thrive*, 313 completed treatment, defined as attending at least 70% of sessions (49%), and 293 (46%) did not (see Figure 2.2). Reasons for not completing treatment were: illness, stress, or other commitments (10.4%, of whom half had requested to attend the next group instead as a “planned repeat”); course did not meet needs (7.5%); and unknown (stopped attending and did not respond to follow-up: 82%). Complete attendance data were not available for a further 28 participants (4%) and therefore coded as “missing”. Of the 313 who completed treatment, between 207 and 254 provided outcome measures at both pre- and post treatment (during sessions 1 and 10, respectively) and were included in the final paired comparisons.

2.4.1 Characteristics of Sample at Baseline

The mean age of women starting *Survive and Thrive* was 39.0 yrs (range 18 – 71 y; SD = 12.28; $n = 540$). 74% of participants were aged between 20 and 49 yrs. Baseline levels of distress and symptoms of PTSD, depression, and anxiety were generally high: 87% of participants reported moderate to severe levels of distress, and 82% and 90% of women reported moderate to severe symptoms of anxiety and depression, respectively. 86 - 90% of participants met criteria for a diagnosis of PTSD (using cutoff scores of ≥ 44 , or ≥ 30 on the PCL-C, respectively).

2.4.2 Differences Between Treatment Completers and Non-Completers at Baseline

Given the high noncompletion rate (46%), it was important to determine whether women who completed the group (i.e. attended at least 7/10 sessions) varied systematically from those who did not, in order to evaluate the potential effects of attrition bias. Independent-samples t-tests were carried out to determine whether variables such as age and baseline symptom severity were significantly different between the completer and non-completer groups (see Table 2.2).

Variable	Completer Mean (SD)	Completer n	Non-completer Mean (SD)	Non-completer n	Difference between completer and non-completer groups	
					Independent-samples t-test	Significance and effect size ^a
Age (years)	39.8 (12.58)	307	38.0 (11.82)	233	t (538) = 1.65; p = 0.10	ns
CORE-10	23.0 (6.72)	274	24.6 (7.07)	198	t (470) = 2.44; p = 0.015;	p < 0.05 d = 0.23
PCL-C	57.6 (13.12)	240	60.5 (15.0)	176	t (414) = 2.06; p = 0.04	p < 0.05 d = 0.21
PHQ-9	17.8 (5.78)	237	18.4 (6.02)	179	t (414) = 0.94; p = 0.35	ns
GAD-7	14.7 (4.82)	237	15.7 (5.19)	177	t (412) = 2.03; p = 0.043	p < 0.05 d = 0.20

Table 2.2: Baseline characteristics of completers (attended at least 7/10 sessions) and non-completers (attended < 7 sessions).

ns = not statistically significant ($p > 0.05$)

$$^a \text{Cohen's } d = \frac{|m_1 - m_2|}{\sqrt{\frac{s_1^2 + s_2^2}{2}}}$$

Women who completed *Survive and Thrive* were slightly older, on average, than those who did not (39.8 y vs. 38.0 y, respectively), but this difference was not significant. Treatment completers also tended to show slightly lower scores on measures of distress and symptoms of PTSD and anxiety (but not depression) at baseline compared with non-completers ($p < 0.05$), suggesting that women with more severe symptomatology at baseline may have been more likely not to start treatment, or drop out early: however, between-group differences were small ($d < 0.25$) and unlikely to be clinically meaningful (see Table 2.2). Further, a binomial logistic regression confirmed that none of the baseline variables (either separately or in combination) significantly predicted treatment completion (see section 2.4.5).

2.4.3 Treatment Effectiveness: Pre- to Post-Treatment Changes

Analyses of pre- to post-treatment changes in outcomes were conducted on treatment completers, defined as those who attended at least 7 of the 10 sessions. Change scores for each outcome were approximately normally distributed, as evidenced by visual inspection of Normal Q-Q Plots, and met all additional criteria for parametric testing. Results are summarized in Table 2.3.

The proportion of participants who met Jacobson-Truax criteria for clinically significant, reliable change at post-treatment was also calculated for each outcome (see Table 2.3). 38% of participants saw clinically significant improvements in distress, with 7 – 12% of participants showing significant improvements in symptoms of PTSD, depression, and / or anxiety. Only 2% of participants showed a reliable worsening of distress after treatment, and between 0.5 and 2% of participants demonstrated reliable deterioration in symptoms of PTSD, depression, and anxiety.

Outcome	<i>n</i>	Mean pre-group score (SD)	Mean post-group score (SD)	Cohen's <i>d</i>	% reliably improved	% reliably deteriorated
<i>Psychological Distress</i> CORE-10	254	22.8 (6.8)	18.8 (7.9)	0.58*	38	2
<i>PTSD</i> PCL-C	207	57.2 (13.0)	51.0 (16.0)	0.50*	12	2
<i>Depression</i> PHQ-9	226	17.8 (5.83)	14.3 (6.43)	0.62*	7	0.5
<i>Anxiety</i> GAD-7	224	14.6 (4.85)	11.9 (5.38)	0.59*	10	1

Table 2.3: statistical and clinical significance of pre- to post- treatment changes in outcomes for *Survive and Thrive* completers.

* $p < 0.001$, repeated-measures t-test, two-tailed.

2.4.4 Treatment Effectiveness among Participants who met Criteria for at least Moderate Distress or Symptoms at Pre-treatment.

Our study sample included all women referred to *Survive and Thrive* who self-reported a history of complex trauma and difficulties with emotion dysregulation and interpersonal functioning, irrespective of whether they met clinical criteria for PTSD, depression, or anxiety, or significant psychological distress. As such, our sample may not be representative of those of other services, or published trials, both of which may have more stringent criteria for inclusion. In order to permit more meaningful comparison of our findings with those of previously published trials and those collected routinely in mental health services, we re-analysed the data for women who met criteria for at least “moderate” psychological distress or symptoms at pre-treatment. Results are summarized in Table 2.4.

2.4.4.1 Psychological Distress (CORE-10)

34 participants (15.6%) were excluded from the analysis as their levels of distress at baseline were in the “healthy” or “mild” range. Mean scores on the CORE-10 were significantly lower at post-treatment compared with baseline ($t(183) = 9.65$; $p < 0.001$). The pre-post effect size was in the moderate-to-large range ($d = 0.71$).

2.4.4.2 PTSD Symptoms (PCL-C)

27 participants (14.9%) did not meet the higher threshold criterion for PTSD for community-dwelling women (≥ 44 on the PCL-C) and were excluded from the analysis. There was a significant reduction in PTSD symptoms between pre- and post-treatment ($t(153) = 7.19$; $p < 0.001$), with a moderate effect size ($d = 0.58$).

2.4.4.3 Depression (PHQ-9)

21 participants (10.7%) were excluded from the analysis because their baseline levels of depression were in the non-clinical or “mild” ranges. Depression scores were significantly lower at post-treatment compared with baseline ($t(174) = 10.54$; $p < 0.001$), with a corresponding large effect size ($d = 0.81$).

2.4.4.4 Anxiety (GAD-7)

33 women (17%) were excluded from the analysis because their pre-treatment levels of anxiety were in the nonclinical or “mild” ranges. GAD-7 scores improved significantly between pre- and post-treatment ($t(160) = 9.67$; $p < 0.001$); the associated effect size was in the moderate-to-large range ($d = 0.76$).

Outcome	<i>n</i>	Mean pre-group score (SD)	Mean post-group score (SD)	Cohen's <i>d</i>	% reliably improved	% reliably deteriorated
<i>Psychological Distress</i> CORE-10	184	25.0 (4.64)	20.3 (7.12)	0.71*	40	3
<i>PTSD</i> PCL-C	154	60.9 (10.0)	53.6 (15.2)	0.58*	40	5
<i>Depression</i> PHQ-9	175	19.4 (4.35)	15.0 (5.93)	0.81*	23	0
<i>Anxiety</i> GAD-7	161	16.5 (3.01)	13.0 (4.87)	0.76*	29	1

Table 2.4: statistical and clinical significance of pre- to post- treatment changes in outcomes for *Survive and Thrive* completers meeting criteria for at least moderate levels of distress or symptom severity at baseline.

* $p < 0.001$, repeated-measures t-test, two-tailed.

2.4.5 Predictors of Treatment Completion and Reliable Improvement in Distress

A binomial logistic regression analysis was carried out to determine the extent to which participants' age and pre-treatment scores of distress, PTSD, depression, and anxiety, predicted the likelihood they would complete therapy. The regression model accounted for only 2.7% of the variance (Nagelkerke R^2) and was not statistically significant ($\chi^2 (5) = 6.58; p = .25$).

A second logistic regression analysis indicated that a model with the same five predictor variables was able to predict reliable improvements in distress ($\chi^2 (5) = 11.54; p = 0.042$). The model provided a good fit to the data (Hosmer and Lemeshow $\chi^2 (8) = 3.99; p = .858$), explained 9.6% of the variance in reliable improvement overall (Nagelkerke R^2), and correctly classified 67% of cases. Sensitivity was 31.7% and specificity was 88.7%. None of the predictor variables were statistically significant when considered individually (see Table 2.5).

Variable	<i>B</i>	SE	Wald	<i>df</i>	<i>p</i>	Odds Ratio	95% CI for OR	
							Lower	Upper
Age (yrs)	.013	.013	.941	1	.332	1.01	.987	1.04
Baseline distress (CORE-10)	.060	.043	1.95	1	.163	1.06	.976	1.16
Baseline symptoms of PTSD (PCL-C)	-.029	.017	3.11	1	.078	.971	.940	1.00
Baseline symptoms of depression (PHQ-9)	-.008	.053	.024	1	.877	.992	.893	1.10
Baseline symptoms of anxiety (GAD-7)	.097	.054	3.15	1	.076	1.10	.990	1.23
Constant		1.03	3.93	1	.047	.130		

Table 2.5 Logistic regression predicting likelihood of reliable improvement in distress from pre- to post- treatment (CORE-10 score reduced by ≥ 6).

2.4.6 Programme Evaluation: Questionnaire Results

2.4.6.1 Closed-Ended Items

230 women across the City of Edinburgh, East Lothian, and Midlothian sectors completed a programme evaluation questionnaire during the final session of *Survive and Thrive*. Of these, 72% and 26% of participants rated the quality of treatment as “excellent” or “good”, respectively: 2% rated the quality as “fair” and none considered it “poor”. 96% of participants stated they would recommend the programme to others with similar difficulties, while 4% stated they were not sure or did not provide a response.

Participants’ responses to each of the four-option, closed-ended items on the evaluation questionnaires are summarized in Table 2.5. Responses were generally very positive. 99% of participants stated they were satisfied with the programme overall. The large majority (> 93%) agreed that the venue was suitable, course materials were relevant, the structure of the programme and support they received was satisfactory, and the programme helped them understand their problems and deal with them more effectively. Most women (> 87%) agreed that the programme helped them learn new coping strategies, they got the kind of input they wanted, and there was sufficient time for discussion.

Of the 101 participants who completed version 2 of the questionnaire (all from the City of Edinburgh), 50% believed their presentation had improved as a result of the programme, while 45% believed they had stayed the same, and 5% considered they felt worse. None reported that they felt “completely better”.

Questionnaire Item	Rating (% of participants)				n
	- -	-	+	++	
Venue was suitable ¹	1	5	36	58	128
Course pack (handbook, handouts) was relevant ¹	0	2	32	65	128
Course helped me understand my problems ¹	0	5	33	62	128
Course helped me learn new coping strategies ¹	1	13	41	46	128
Got the kind of input / support I wanted ²	1	13	54	31	101
Satisfied with amount of support I received ²	0	3	42	56	101
Enabled me to deal more effectively with my problems ²	1	6	73	20	101
Satisfied with the structure of the course ²	0	3	38	53	101
Sufficient time given for general discussion ²	1	8	44	43	101
Overall satisfaction with the course ²	1	1	50	44	101

Table 2.5: Participant responses to closed-ended items on post-group evaluation questionnaire: values show proportions of participants rating item as strongly negative (- -), negative (-), positive (+), or strongly positive (++).

¹ East and Midlothian evaluation questionnaire; City of Edinburgh questionnaire v.1

² City of Edinburgh questionnaire v. 2

2.4.6.2 Open-Ended Items

Most Helpful Aspects of Programme

252 women across the City of Edinburgh, East Lothian, and Midlothian sectors replied to the question “*what did you find most helpful about the course?*” A basic content analysis of responses revealed a number of important themes:

1. **Improved understanding of the impacts of abuse and trauma**

The most commonly identified helpful aspect of the course, identified by 39% of women, was an improved understanding of the impacts of past abuse and trauma on their own thinking, emotions, and behaviours, with some stating that this felt like a “revelation”:

“Understanding why I think and feel this way, and where it comes from.”

“Making connections between now and the past.”

“The week about shame and guilt really resonated with me and gave me the 'light bulb' moment to help me begin to move forward with my feelings.”

2. **Normalising responses to trauma; reducing feelings of isolation, guilt or shame**

25% of women identified that the most helpful aspect of *Survive and Thrive* was in normalizing their responses to abuse and trauma, and consequently reducing their sense of stigma, isolation, and feelings of guilt or shame associated with their traumatic experiences:

“Realising it wasn’t just me going through this.”

“Understanding that it wasn’t my fault.”

“Just hearing that we’re all normal. We have coped, which is amazing.”

“I thought my own thoughts, feelings and mood were abnormal or wrong, but this course has taught me they are completely normal.”

Some women specifically reflected that a better understanding of the impact of trauma on their lives, and its normalizing effects, had allowed them to begin to think differently about themselves and others:

“... seeing something for the first time through an adult’s eyes: I got to see that I am not worthless...”

“Helping me realise it is not my fault, and to look at things differently in life.”

Several women reflected that this learning allowed them to feel more hopeful that recovery was possible:

“I found with each session I was more informed about why I “feel, think, react” the ways I have in the past, and then ways that I can make changes to heal.”

“Even though I cannot change what happened, I can accept it, learn from it, and still be happy.”

“[I learned] that I’m not alone with my thoughts and feelings, and that I can work on myself to learn to heal after all the suffering.”

3. Developing helpful coping skills

25% of participants stated that they particularly valued learning more helpful ways of coping with distress, such as rhythmic breathing, mindfulness meditation, grounding techniques, positive self-talk, and keeping diaries:

“Being able to put together a wee toolkit of actions and ideas to talk myself through when things get tough.”

“I have learned about many tools / techniques to help stay in the green zone.”

“Mindfulness and belly breathing was very useful. Instructions on how to counter anxiety attacks and grounding techniques [too].”

4. Shared experiences

13% of women found the group nature of the programme especially helpful, in terms of being with and hearing from other women who reported similar experiences:

“The revelation that I shared many similar thoughts and feelings with others in the group... not feeling so alone or “abnormal.”

“Hearing from the other women that although our traumas varied, our symptoms were very similar.”

“Listening to others, I understood that there are some people that understand exactly what I feel.”

For some women, just “being with” likeminded people in the same room was validating and normalizing. Some said they appreciated just turning up to

sessions, and valued being with others, without necessarily having to talk if they didn't feel like it.

“Having people around, and meeting people with similar issues.”

“Being able to listen and understand rather than talking”

“Encouraged me to start new routine. Got me out into a safe space with no touchy feely people in my face.”

5. Skilled therapists

13% of participants considered that the most helpful aspect of the programme was the therapists' effectiveness in providing a safe and supportive space to share experiences, explaining concepts clearly, and encouraging new ways of coping with distress. Many mentioned therapists' skills in making them feel respected and understood, and in acknowledging the difficulties they had experienced with compassion:

“Feeling in a safe space, being allowed to address my feelings without judgement... probably for the first time ever.”

“The therapists were really amazing in how they explained, their empathy, their humour, and respect for everyone.”

“How friendly and understanding all the therapists were. They never made you feel bad or stupid about anything you said.”

6. Programme content and delivery

10% of women reported that they found the overall content and delivery of the programme to be the most helpful; these women said they found the information on the slides and handouts useful, enjoyed the interactive exercises, and valued not being “made” to speak out if they did not want to.

Least Helpful Aspects of Programme

148 women responded to this item on the questionnaire. Almost half (43%) said they could not identify anything unhelpful about the course, for example:

“Nothing was unhelpful. I found a missing piece of the puzzle I have been looking for for a long time about how I am and my view of the world.”

“Thank you so much. I feel as though I've made more progress than I have done for years - I feel well prepared for any setbacks too.”

A few women stated that although they could not identify any unhelpful elements of the group, they did not feel they had achieved the degree of improvement they had been hoping for as a result of taking part:

“I think Survive and Thrive is really worthwhile but I found it hard not having someone to talk to about the thoughts it brought up.”

“I hoped to gain confidence through the group but haven't found this.”

“I enjoyed attending but I didn't feel it has helped my thoughts and self or memories...”

A content analysis of the remaining responses revealed two key themes relating to the least helpful aspect of the programme:

1. Programme content

14% of women commented that some aspects of the programme content were not relevant to them (e.g. anger or domestic abuse), but most of these qualified this by stating they felt that they were likely useful to others in the group. Others said they would have liked more on the topics most relevant to them.

“The anger session... but only because anger is not a problem for me anymore.”

“I felt like it didn’t go into trauma relating to bullying / mental abuse.”

2. Distress associated with discussing trauma

9% of women claimed that the content could be distressing or upsetting at times. Some said that the content could be triggering, and that discussing some topics brought back painful memories, or felt like “opening a can of worms”. Some participants found this especially difficult if they felt they could not discuss this afterwards:

“Brought back a lot of memories... upsetting and painful to remember things that had been forgotten.”

“Feelings brought up and no outlet to discuss them after the group.”

3. Other

A smaller proportion of women commented that the location of the group was not always ideal (for example, too noisy, too hot, or in a hospital setting which was anxiety-provoking), or that accessing the group could be difficult by walking or public transport. Four women (2.5%) reported that they found it unsettling and / or stressful when sessions were cancelled or there was a change of therapist at the last minute, though most said they understood this was not always possible to avoid.

Recommendations for Improvement

Several women suggested changes they felt may enhance the experience of *Survive and Thrive* for participants in the future, including greater flexibility and choice around the timing and location of sessions, and easier access to resources such as guided meditations, visualization scripts, mobile apps, and links to relevant organizations. Some women reported that they would value the opportunity to make up sessions they had missed in a coexisting rolling or open group. Others suggested that input from other survivors and hearing their “success stories” could further foster hope for recovery from trauma, and one woman suggested that a separate psychoeducational group for friends and families of survivors could be helpful in supporting their recovery. Finally, some participants indicated that a more joined-up pathway to subsequent services (e.g. individual, phase-two, trauma-focused interventions, or referrals to other agencies for further support) with shorter waiting times would be welcome on finishing the *Survive and Thrive* programme.

2.5 DISCUSSION

The development of a practical program theory and associated logic model in this study provided a useful framework for evaluating the *Survive and Thrive* intervention, and highlighting gaps in our understanding of how the programme works, how it could be improved, and how it may be evaluated more effectively in the future.

2.5.1 Treatment Acceptability

Preliminary positive feedback from the post-treatment evaluation questionnaire suggested that *Survive and Thrive* was acceptable to the large majority of women who completed treatment. 99% of respondents stated that they were satisfied with the programme overall, 98% rated the quality of the treatment as “good” or “excellent”, and 96% stated they would recommend the programme to others with similar difficulties. However, 46% of women who agreed to take part in *Survive and Thrive* did not meet criteria for completing treatment (attending at least 7 of the 10 sessions), suggesting that the intervention may not have been acceptable to a significant minority of women. Evaluation questionnaires were only administered to participants who attended the final session, which would certainly have biased the sample towards those who had completed the programme and were more positive about the intervention. The attrition rate was higher than the mean of 19 – 22% reported in recent meta-analyses of research trials (e.g. Ehring et al., 2014; Willis & O'Rourke, 2021): however, the proportion of women who completed therapy in our study (54%) was higher than that reported by the handful of studies of trauma-focused treatments for chronic PTSD in “real-world” clinical practice, some of which report “adequate dose” completer rates of as low as 2% (see Najavits, 2015; Zayfert et al., 2005).

2.5.2 Treatment Safety

Our results suggest that *Survive and Thrive* is a safe intervention overall. Only 2 – 5% of treatment completers met criteria for reliable deterioration in PTSD symptoms by the end of treatment, which compares favourably with rates of between 7% and 15% reported by clinical trials of phase-one interventions for complex PTSD (Classen, Muller, Field, Clark, & Stern, 2017; Foster & DeCamp, 2019; Sikkema et al., 2004; Sikkema et al., 2007). Rates of significant deterioration were lower still for overall psychological distress (2 – 3%), anxiety (1%) and depression (0 – 0.5%). Again, these findings must be interpreted with caution as the relatively high attrition rate further biases the outcomes to those who persevered with treatment and therefore likely felt more positive about the programme. Of note, however, 9% of respondents who completed the post-treatment questionnaire reported finding the content distressing at times, and did not consider that they had a safe outlet for discussing this within sessions.

2.5.3 Treatment Effectiveness

Our program theory identified five key short-term outcomes relating to the overall effectiveness of the *Survive and Thrive* intervention (see figure 2.1). Each is considered in turn below.

Increased Knowledge of the Nature and Impact of Complex Trauma

The large majority of women who completed the post-treatment evaluation questionnaire (95%) agreed that *Survive and Thrive* had “helped me understand my problems”. When asked to identify what they found most helpful about the programme, an increased understanding of how past traumatic experiences may have impacted their emotions, thinking, and behaviours was the most-cited theme, mentioned by 39% of respondents. Many women went on to report that this knowledge in turn helped them feel more “normal” and noted the importance of this in reducing feelings of shame, guilt, and stigma in the longer term.

Enhanced Skills in Emotion Regulation and Interpersonal Effectiveness

The large majority of women who completed the programme (87%) agreed that *Survive and Thrive* helped them “learn new coping strategies” to manage distressing emotions, typically associated with difficult interpersonal relationships. When asked what they found most helpful, one quarter of women identified that learning helpful ways of coping with distress, such as relaxation and grounding techniques, positive self-talk and journaling, was of particular benefit. Some women articulated that these skills had led to increased sense of empowerment and hope that recovery was possible, just as our model predicted.

Reductions in Psychological Distress and Severity of Common Mental Health Symptoms

The moderate reduction in psychological distress between pre- and post-treatment ($d = 0.58 - 0.71$) was in line with those reported by several previous studies of phase-one interventions for complex trauma, between 0.1 (ITT sample: Karatzias et al., 2014) and 0.77 – 1.12 (completer samples: Kaiser et al., 2015; Foster & DeCamp, 2019).

Improvements in PTSD symptoms were moderate ($d = 0.5 - 0.58$), but compared satisfactorily to aggregated effect size estimates of phase-one group treatments from our recent meta-analysis ($d = 0.70$ overall; 0.43 for subgroup of uncontrolled or non-randomized, controlled trials: see Willis & O'Rourke, 2021). The overall pre- to post-treatment effect size for depression symptoms ($d = 0.62 - 0.81$) compared favourably to those of more established phase-one interventions such as TREM and Seeking Safety ($d = 0.21 - 0.61$: Kaiser et al., 2015; Masin-Moyer, Kim, Engstrom, & Solomon, 2020; Sikkema et al., 2004): the same was true for anxiety symptoms ($d = 0.59 - 0.76$, compared with 0.1 – 0.61 for Seeking Safety and TREM, respectively: Sikkema et al., 2004; Masin-Moyer et al., 2020).

Of all the women who completed *Survive and Thrive*, up to 40% demonstrated reliable improvements in either or both distress and symptoms of PTSD by the end of the programme. These rates are within the range of those reported for PTSD

symptoms in clinical trials of phase one, group interventions for survivors of complex trauma (22.5 – 55%; Classen et al., 2017; Dorrepaal et al., 2012; Foster & DeCamp, 2019; Sikkema et al., 2004; Sikkema et al., 2007), and in line with the 50% reported in a large-scale study of the effectiveness of CBT for anxiety in routine clinical practice (Westbrook & Kirk, 2005).

2.5.4 Recommendations

Our evaluation has yielded a number of recommendations for future research and evaluation. First, it may be useful to consider alternative outcome measures in future efforts to evaluate the effectiveness of *Survive and Thrive* that more closely align with Herman’s phased intervention model of complex PTSD – especially now this conceptualization has been recognized for the first time in the International Classification of Diseases (ICD-11: WHO, 2018). In particular, self-report instruments that address the “disorders of self-organization” that characterise this condition (namely, emotion dysregulation, interpersonal difficulties, and negative self-concept) would yield important insights into the extent to which phased interventions work as the theory predicts.

Our framework also highlights the importance of longer-term follow up in evaluating the extent to which any treatment gains are maintained in the medium and longer term, and highlighting the potential causal mechanisms that drive therapeutic change. Improvements in following up and recording women’s reasons for dropping out of treatment (including monitoring of any adverse effects) should prove helpful in elucidating the participant, intervention, and external factors that contribute to drop-out, and yielding suggestions for how to address common barriers to engagement.

Finally, in order to shed light on “what works for whom” in interventions for adult survivors of complex trauma, future research and evaluation would do well to

examine the roles of some of the many participant, intervention, and external factors believed to predict, moderate, or mediate treatment engagement and outcomes, including, for example: the nature, chronicity and complexity of trauma experiences; overall symptom burden, distress, levels of functioning, and availability of social support at baseline; socioeconomic status / degree of deprivation; clients' goals for therapy; therapist warmth and competence; and treatment fidelity.

2.5.5 Study Strengths and Limitations

We consider that the key strengths of this study were its high external validity and relevance to real-world, routine clinical practice. Treatment outcomes and acceptability were evaluated using a number of different metrics (such as standardized pre- to post-treatment effect sizes and indices of reliable change, as well as feedback from participants at the end of treatment), using standardized methods which we hope will permit useful comparison with other, similar studies.

We acknowledge that the study has several important limitations. First, it did not contain a control group, so we cannot be certain that pre- to- post- treatment changes in outcomes occurred as a result of taking part in the intervention. Effect sizes in the moderate to large range for all the outcomes suggested that the improvements observed were unlikely to be attributable to spontaneous changes alone: however, the lack of an active control group means that we cannot establish the extent to which any changes arose as a result of the specific attributes of *Survive and Thrive*, or other, nonspecific effects of therapy such as therapists' ability to convey warmth and empathy, peer support, and clients' expectations of change (e.g. Wampold, 2015).

Second, outcome measures were only completed at two time points – one before treatment began, and the second immediately after – which raises concerns about both regression to the mean (for baseline scores that were very high), and lack of

any follow-up to determine whether treatment outcomes were maintained beyond the end of treatment.

Finally, the non-completion rate (46%), and therefore the proportion of missing data, was high, and reasons for attrition largely unknown, indicating that overall treatment effects may have been affected by attrition bias if data were not missing at random. There were few differences at pre-treatment between completers and non-completers in terms of age, and baseline levels of distress, PTSD, depression, or anxiety, and a logistic regression indicated that neither age nor baseline symptom severity, either individually or in combination, predicted treatment dropout. However, we did not have information about a number of factors that some studies have shown may influence treatment engagement, such as nature, number, and timing of traumatic events, baseline emotional regulation skills, and degree of social support. In only considering data from the 49% of participants who completed therapy *per protocol* (defined as those who attended at least 7 out of 10 sessions), it is likely that effect sizes, proportions of people achieving reliable change, and participant evaluations reported here are positively biased and should be interpreted with caution.

2.5.6 Conclusions

We have shown that, although not designed as a standalone intervention in its own right, the phase-one complex trauma intervention *Survive and Thrive* may be effective in reducing psychological distress and symptoms of PTSD, depression, and anxiety for a significant proportion of women who complete the programme in routine clinical care. Our results also indicate that the programme is safe for and acceptable to the large majority of women completing treatment. However, the high drop-out rate means we cannot be sure of the effectiveness and acceptability of the programme for the population of treatment-seeking women as a whole. Further research could be directed at exploring why women do not complete treatment, and which individuals are likely to benefit most and least from the programme, by evaluating in more detail the factors which influence treatment

dropout and outcomes, and seeking a better understanding of individuals' goals for and expectations of treatment. We hope this study will contribute to the emerging evidence base on effective interventions for adult survivors of complex interpersonal trauma, thereby increasing the options available to individual clients in planning their unique recovery journey.

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