Enhanced Skills Training in Affective and Interpersonal Regulation (ESTAIR)

vs.

Treatment as Usual (TAU) for ICD-11 Complex PTSD:

A pilot randomized controlled trial (The RESTORE trial)

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FOR VETERANS' MENTAL HEALTH

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Contents

Foreword

Whilst most Service personnel make a successful and positive transition to civilian life, we know that some veterans experience issues with their health that has a profound impact and requires specific support. Being able to better understand what these issues are and the support required enables us to ensure these needs are effectively addressed and their outcomes improved.

Forces in Mind Trust initially funded a study which identified that Complex PTSD is a more common problem in veterans than PTSD, yet no specific treatment exists and evidence suggests that the treatments for PTSD are less effective.

This new study has therefore been vital in providing key findings to inform the development of a new and specific treatment for Complex PTSD. The initial findings from the feasibility study indicate that the new approach is seeing positive effects and provides a positive start to the larger scale testing that would be required if veterans with Complex PTSD are to be able to access effective treatment, improving their and their families lives.

Michelle Alston

Chief Executive, Forces in Mind Trust

1. Institutions and acknowledgements

1.1 Institutions

Combat Stress

Combat Stress is a national veterans' charity in the UK that was established in 1919. It specialises in providing clinical mental health services for UK veterans with a history of trauma. Combat Stress receives approximately 2,500 new referrals per year. Clinical services are spread across the UK with 14 community teams and three residential treatment centres. Clinical services are delivered by a multi-disciplinary team of clinicians and are informed by NICE approved guidance for the treatment of PTSD. Further information about Combat Stress can be found at combatstress.org.uk.

1.2 Acknowledgements

The authors would like to take this opportunity to thank all participants who took part in this study, without whom it would not have been possible. Likewise, we would like to thank Forces in Mind Trust (FiMT) for funding the project and also for their support throughout the project, particularly from Michelle Alston (Chief Executive), and Kirsteen Waller (Health Programme Manager).

2.0 Glossary

Term	Definition
Complex Posttraumatic Stress Disorder	A psychological disorder caused by experiencing or witnessing a traumatic event or events. Symptoms include intrusive memories, avoidance, hyper-arousal with the addition of emotional dysregulation (i.e. emotional responses outside the accepted range), negative sense of self and disturbances in relationships.
Diagnostic and Statistical Manual of Mental Disorders (DSM-5)	Published in 2013 by the American Psychiatric Association, the DSM-5 is the principal authority for psychiatric diagnoses in the United States.
Disturbances in self-organisation	A set of symptoms (affective dysregulation, negative self-concept and disturbances in relationships) which identify CPTSD in combination with the diagnostic criteria of PTSD
International Classification of Diseases (ICD-11)	A diagnostic manual released by the World Health Organization. The most recent version was released in August 2018 and includes CPTSD as a standalone disorder.
Posttraumatic Stress Disorder	A psychological disorder caused by experiencing or witnessing a traumatic event. Symptoms include intrusive memories, avoidance and hyper-arousal.
Engagement rate	Refers to the level of active participation or involvement of trial participants in the activities or requirements of the trial.
Retention rate	Refers to the rate of participants who remain actively engaged in the trial over its duration, without dropping out or being lost to follow-up.
Completion rate	This indicates the proportion of participants who fulfill all the required tasks, assessments, or interventions within the trial protocol.
Dropout rate	Refers to the percentage of participants who discontinue their participation before the trial's completion.

3.0 Executive summary

Complex PTSD (CPTSD) is a relatively new condition in the international classification of diseases (ICD-11). Existing research suggests that CPTSD is more common than PTSD. Preliminary evidence also suggests that existing effective therapies for posttraumatic stress disorder (PTSD) such as Cognitive Behavioural Therapy or Eye Movement Desensitisation Therapy might be less effective for CPTSD, highlighting the need for developing and testing new interventions for this debilitating condition. We aimed to establish the feasibility of undertaking a definitive randomized controlled trial to determine the effectiveness of a new modular therapy namely Enhanced Skills in Affective and Interpersonal Regulation (ESTAIR) for CPTSD.

This pilot randomized controlled trial aimed to compare a four-module intervention developed to target all symptoms of ICD-11 CPTSD (i.e. ESTAIR) with treatment as usual (TAU) (i.e. psychoeducation and monitoring) in veterans in the UK.

ESTAIR is a treatment of cognitive-behavioural orientation that has been developed specifically for CPTSD. It theorises that trauma recovery involves processing memories of traumatic events from the past, but also covers the impact of trauma on the present as it affects current relationships, emotional distress in day-to-day life and quality of life. ESTAIR targets emotion regulation, interpersonal difficulties, negative self-concept, and PTSD symptoms.

Participants were eligible if they were UK armed forces veteran adults (18 years or older) in the caseload of a national UK charity, help-seeking for trauma related psychological distress, met diagnostic criteria for CPTSD as measured by the ITQ, and were proficient in the English language. The purpose of the study was to assess feasibility, safety, acceptability and preliminary outcomes at the end of treatment and 3-month follow-up. The International Trauma Questionnaire (ITQ) which measures CPTSD severity was the primary outcome. The trial was pre-registered with ClinicalTrials.Gov (NCT04752072).

A total of 56 eligible participants were randomized to either ESTAIR (28 veterans) or TAU (28 veterans). Achievement of enrolment and randomization targets was satisfactory, treatment dropout in both ESTAIR and TAU was low, and study retention was high, all of which supported the feasibility of the study. No serious adverse effects and very few adverse effects occurred, none of which were deemed related to the study. Interviews with the participants indicated that they viewed the treatment duration and structure as satisfactory and the treatment as having a positive impact on multiple dimensions of their lives. ESTAIR provided significantly greater reduction in CPTSD severity across time than the TAU comparator at post-treatment and follow-up. CPTSD pre-to-post effect sizes for ESTAIR were large. Remission[1] of probable CPTSD diagnosis at post-treatment was substantially greater in ESTAIR compared to TAU with only 18.2% retaining the diagnosis in ESTAIR versus 84% in TAU. That said, as noted previously, TAU in this instance was limited to psychoeducation and monitoring (as opposed to a therapeutic treatment alternative that would otherwise usually be offered). This may to some degree explain the large differences found between the two treatment arms in this study.

Overall, results indicate that ESTAIR is a feasible, safe and acceptable intervention for UK veterans. A further larger trial is required to establish the effectiveness of ESTAIR in veterans with CPTSD, compared to a usual therapeutic treatment alternative,

[1] Remission meaning a decrease in or disappearance of the signs or symptoms

such as Eye Movement Desensitisation Therapy (EMDR) or Cognitive Behavioural Therapy (CBT).

The following report describes the aims, background, methods and findings of the study, followed by a discussion of limitations and future directions.

4. Key findings

- Enrolment and randomization targets were satisfactorily achieved
- Treatment dropout was low
- No serious adverse effects and very few adverse effects occurred, none of which were related to the study
- Participants viewed ESTAIR positively, and that treatment structure and duration was satisfactory, and reported that treatment had a positive effect on multiple dimensions of their lives, indicating acceptability of the intervention by the intended beneficiaries
- ESTAIR resulted in a greater reduction in PTSD and CPTSD symptoms compared to TAU
- Remission of probable CPTSD diagnosis at post-treatment was substantially greater in ESTAIR, compared to TAU

5. Introduction

5.1 Background

The 11th version of the *International Classification of Diseases* (ICD-11) (WHO, 2018), the official diagnostic classification system in the UK, has included two trauma-based disorders: PTSD and Complex PTSD. ICD-11 PTSD includes six 'core' symptoms across three clusters, each of which is directly related to one's traumatic exposure. These include re-experiencing in the here and now, avoidance, and a sense of current threat. Diagnosis of ICD-11 PTSD requires the presence of one symptom per cluster, plus evidence of functional impairment. CPTSD is a broader diagnosis that includes the core PTSD symptoms plus an additional set of three symptoms that are collectively referred to as 'disturbances in self-organisation' (DSO). These symptoms are intended to capture pervasive psychological disturbances associated most typically with chronic and multiple types of traumatic exposures. The symptoms are distributed across three clusters including affective (hyper-activation and hypo-activation) dysregulation (AD), negative self-concept (NSC), and disturbances in relationships (DR). A CPTSD diagnosis requires that the PTSD criteria be met in addition to endorsement of DSO symptoms.

Evidence from clinical samples (Karatzias et al., 2017) as well as population-based samples (Cloitre et al., 2019; Karatzias et al., 2019) suggests that CPTSD is a more common condition than PTSD. Although comparisons between general populations and military populations are lacking, a recently completed cohort study (n=178) of a veteran help-seeking population found that 56% met diagnostic criteria for CPTSD versus 14% who met criteria for PTSD alone (Murphy et al., 2020). A larger study with n=599 veterans in Denmark found that 13.0% met probable ICD-11 criteria for PTSD and 31.4% for CPTSD (Folke et al., 2023). Considering how common CPTSD is in clinical and general population samples, it is now imperative to identify effective treatments to aid recovery from this debilitating condition.

5.2 CPTSD interventions

One recent review of the literature (Karatzias et al., 2019b) suggested that existing interventions that are commonly used for PTSD, such as Cognitive Behavioural Therapy (CBT) or Eye Movement Desensitisation and Reprocessing (EMDR), can provide less benefit for treating CPTSD symptoms if there is history of childhood trauma. However, more recent evidence (e.g. Voorendonk et al., 2020) suggests that exposure therapies can be useful for both PTSD and CPTSD. Emerging evidence highlighted that other interventions might also be effective for some CPTSD symptoms. In a pilot study exploring the effectiveness of on-line delivered mindfulness approaches in young adults with CPTSD, Dumarkaite and colleagues (2022) found that mindfulness therapy can reduce symptoms of negative self-concept and disturbed relationships but not PTSD and affect dysregulation symptoms. These studies have some limitations, for example they included people without the full CPTSD diagnosis and also people who did not have functional impairment.[2] Hence there is need for further work on the effectiveness of existing therapies for CPTSD.

Another recent meta-analysis (Coventry et al., 2020), reviewed studies specific to populations that had experienced complex trauma (e.g., military, childhood abuse,

[2] Some studies consider only diagnostic criteria without taking into consideration functional impairment

refugees). This work indicated that interventions with multiple therapeutic modules, which included both skills based and trauma-focused strategies were the most promising interventions for the affect dysregulation and disturbed relationships symptom clusters of CPTSD. **The use of a flexibly applied treatment approach that includes various therapeutic modules targeting different symptom clusters is new to the trauma field and therefore a treatment innovation, which has been proposed as a promising area of enquiry for CPTSD (Karatzias and Cloitre, 2019)**. Enhanced Skills Training in Affective and Interpersonal Regulation (ESTAIR) has been designed as a flexibly sequenced modular intervention, guided by measurement-based assessment of symptoms and patient identified needs and preferences (see Karatzias et al., 2023). ESTAIR involves 25 sessions; a formulation session, plus four modules each of which address all three symptom clusters of CPTSD (i.e. affective dysregulation (AD), disturbances in relationships (DR), negative self-concept (NSC)), PTSD symptoms and disturbances in self-organisation (DSO).

5.3 Evaluation of ESTAIR

A briefer multi-modular version of ESTAIR with a fixed sequence, STAIR-NT (Skills Training in Affective and Interpersonal Regulation coupled with Narrative Therapy) has been evaluated in three RCTs with good evidence of effect. Firstly, when compared with wait-list, significant improvement in affect regulation problems, interpersonal skills deficits, and DSM-PTSD symptoms were found to be maintained at 3 and 9 months (Cloitre et al., 2002). Secondly, in individuals with DSM PTSD related to childhood abuse, a component analysis trial showed that all three of full DSM PTSD remission, greater improvement in interpersonal problems, and lower attrition rates, were more likely to be achieved using STAIR-NT compared to using either of narrative therapy without skills training, or a skills-focused intervention without narrative therapy (Cloitre et al., 2010). Thirdly, STAIR-NT was equivalent to an extension (16 sessions) of Prolonged Exposure (PE) in PTSD related to childhood abuse (Oprel et al., 2021); however, it was also found that higher severity of childhood sexual abuse was a predictor of worse treatment outcome in both PE and intensified PE conditions, but not for STAIR-NT (Hoeboer et al., 2021) for DSM PTSD. STAIR-NT has also shown preliminary positive findings in non-western cultural contexts for ICD-11 CPTSD. In a recent open pilot investigation of STAIR-NT in Japan (n = 10), it was found that among the seven completers, six at post-treatment and all at follow-up no longer met CPTSD diagnosis (Niwa et al., 2022). While promising, STAIR-NT does not address the self-concept cluster of DSO, which is a core symptom of CPTSD that is associated with polytraumatisation[3] (Karatzias et al., 2020). As opposed to STAIR-NT, ESTAIR addresses all symptom clusters of CPTSD.

5.4 Aims and components of this study

No previous study has explored the feasibility of offering a modular therapy that targets all symptom clusters of CPTSD in veterans. The RESTORE trial aimed to address this gap in the literature. RESTORE was designed to assess the feasibility, safety and acceptability of a new treatment for CPTSD (i.e. ESTAIR) as well as preliminary outcomes for ESTAIR compared to treatment as usual (TAU) for a UK veteran sample.

Feasibility was assessed in terms of (a) satisfactory participant enrolment, (b) treatment dropout, and (c) study retention (data collection) through all phases of the study. Safety was assessed in terms of the occurrence of serious adverse events (SAEs) and adverse events (AEs). Acceptability was characterized as participant interest in the ESTAIR protocol and treatment targets (PTSD and DSO) as assessed by post-treatment

[3] Polytrauma is when a patient has sustained multiple injuries, some of which may cause significant disability and may be life-threatening

interviews. The primary treatment outcome was CPTSD severity defined by its two components: post-traumatic stress disorder (PTSD) and disturbances in self-organization (DSO) symptoms. Secondary outcomes included depression, anxiety, somatic symptoms, and alcohol misuse.

6. Method

6.1 Study design

This was a pilot randomised controlled trial of the ESTAIR intervention with 3-month follow-up. This study has been designed to provide information that will serve as the foundation for implementing a larger trial characterised by similar design parameters (e.g., allocation ratio, blind assessment, multiple sites and an active comparator). The planned randomised pilot study was a 28-month feasibility/pilot of a single site, single (rater) blind trial of ESTAIR (psychological intervention) vs. treatment as usual (TAU (i.e. psychoeducation and monitoring) alone for the treatment of CPTSD using ITQ as the primary outcome. At present, there are no recommended treatments for CPTSD and thus treatment as usual was chosen as a control condition as this provided a fair comparison with routine clinical practice.

6.2 Participants

Potential participants were drawn from those veterans referred to Combat Stress and who met criteria for probable CPTSD. For full study inclusion criteria and study procedures, please see Appendix 1. Consenting participants were randomized to receive either ESTAIR or TAU.

6.3 Treatment conditions

6.3.1 ESTAIR

ESTAIR was delivered by a CBT therapist (Masters' level). The therapist received a two-day workshop on ESTAIR followed by biweekly supervision by an experts in the treatment. A selection of treatment sessions was video-taped and assessed for treatment integrity and fidelity. A total of n = 12 randomly selected sessions (three per module) were scored for fidelity by an assessor independent to this trial and trained in adherence rating of ESTAIR by an experienced CBT therapist using a fidelity scale that was developed alongside the ESTAIR protocol. Session goals were assessed using a 4-point scale (not implemented, partially implemented, completely implemented, and not applicable / not implemented). Overall, it was concluded that ESTAIR was delivered to the protocol with all sessions being successfully delivered and all components fully implemented. Defined completers were those who attended at least 80% of treatment and received at least one session per module.

6.3.2 Treatment as Usual (TAU)

TAU typically consisted of receiving a mental health assessment by either a psychiatrist or psychologist followed by offering a treatment package that included psychoeducation, symptom-management and on-going monitoring. TAU interventions were provided by clinical psychologists, psychiatrists and occupational therapists. Of the n=28 randomized to TAU, n=23 received individual or group intervention and n=5 received no active trauma treatment but instead received on-going monitoring. Of the 23 who received individual or group therapy, one person received three Eye Movement and Desensitization and Reprocessing (EMDR) sessions. No other participant received trauma focused therapy and the comparison between the two groups was a trauma focused intervention (i.e. ESTAIR) vs non-trauma interventions (i.e. TAU). TAU interventions were recorded for all participants.

6.4 Data collection

Participants were asked to complete measures of CPTSD, alcohol misuse, depression, traumatic events in their lifetime, anxiety and somatic disorder symptoms as the primary and exploratory outcomes exploring efficacy of ESTAIR compared to TAU. Feasibility related to satisfactory participant enrolment was defined as achieving the target goal of randomizing n = 60 veterans over a two-year period. Treatment dropout for ESTAIR was defined as leaving treatment before all four modules were completed (about 24 weeks)

and for TAU leaving before 24 weeks of treatment had been completed. Study retention (data collection) was defined as the percent of randomized participants that completed post-treatment and follow-up assessments. Safety was defined as presence of serious adverse events (SAEs) and adverse events (AEs) as measured by the Adverse Events Questionnaire (AEQ: Hutton et al., 2017). Acceptability was characterized via post-treatment interviews using qualitative data analytic strategies described below regarding participant interest in the ESTAIR protocol and treatment targets (PTSD and DSO). The primary treatment outcome was CPTSD severity as assessed by its two components, post-traumatic stress disorder (PTSD) and disturbances in self-organization (DSO) symptoms.

See Appendix 1 for full inclusion and exclusion criteria, study measures, randomization details data collection and analysis.

7.0 Findings

7.1 Treatment Completion

During the treatment phase 18% (n= 6) dropped out of ESTAIR and 11% (n= 3) dropped out of TAU; this difference was not statistically significant. Reasons for drop-out in the ESTAIR treatment included changes in personal circumstances (n = 3), discontinuation because traumatic stress was no longer the primary cause of concern (n=2) and lack of interest in completing treatment (n=1). Reasons for those who dropped out of the TAU condition (n=3) were not known. There were no differences in retention rates between the two conditions.

7.2 Sociodemographic

Please see Appendix 2 for demographic findings.

7.3 CPTSD Symptoms

Table 2 (Appendix 3) shows that the two groups performed differently for both PTSD and DSO, and the means in Table 3 show that there was a greater decrease in scores in the ESTAIR group relative to the TAU group.

There were significant decreases in both mean PTSD and DSO scores for both TAU and ESTAIR, with the decreases larger for DSO, and the effect sizes for ESTAIR were larger than for TAU. Post hoc comparisons showed that there were significant differences between the groups on the PTSD scores at post-treatment ($t(111.4) = 5.343$, $p < .001$) and also at follow up ($t(126.0) = 3.729$, $p = 0.004$). There were also significant differences between the groups on the DSO scores at post-treatment ($t(113.7) = 6.98$, $p < .001$) and at follow up ($t(127.0) = 5.11$, $p < .001$). The effect size (i.e. comparison of the average difference between ESTAIR and TAU groups) for the differences in T1 and T3 PTSD and DSO scores were calculated using Cohen's d for paired samples. The effect sizes were large for both PTSD (d = 1.26, 95% CI .81, 1.71) and DSO (d = 1.42, 95% CI .94, 1.89).

7.4 Comorbid Symptoms

Table 4 (Appendix 3) shows that for anxiety and depression, both treatment conditions were associated with reductions in comorbid symptoms but there was a greater improvement in the ESTAIR group as compared to TAU. For somatic symptoms, the two arms did not differ on this outcome. There was no change in alcohol use during the study. Means for comorbid symptoms by condition and across time are provided in Table 5 (Appendix 3).

7.5 Diagnostic Status

There was a significant association between diagnostic status and treatment group ($\chi 2(1) = 23.31$, $p < .001$). Over 80% of the participants in the ESTAIR group did not meet the criteria for PTSD or CPTSD at post-treatment, compared to 16.0% for the TAU group. At post-treatment 84.0% of TAU participants met the criteria for PTSD/CPTSD versus only 18.2% of ESTAIR participants. Being in the ESTAIR group increased the likelihood of not meeting the criteria for PTSD/CPTSD compared to the TAU group (OR = 23.62: 95% CI = 5.15, 108.26).

Figure 3 (Appendix 3) shows that there was a consistent decrease in PTSD and DSO scores across all modules in the ESTAIR group.

7.6 Safety

There were no SAEs in either ESTAIR or TAU. Three AEs were recorded in ESTAIR and none in TAU; None of the AEs was associated with the study.

7.7 Qualitative findings on Acceptability

A total of 16 veterans who had received the ESTAIR intervention completed the qualitative survey (57% response rate) to further establish acceptability of the treatment. Two overarching themes were identified in the data: structure of treatment and impact of treatment.

7.7.1 Structure of treatment

The first theme encompasses perceptions on the length of treatment, the order of modules and patients' feelings about the content of the intervention. Many patients commented on not feeling rushed during the (90 minute) treatment sessions, for example: *"the time of each session, far superior to what I've experienced with any other service. There was time to explain things without worrying how long have I got left on my appointment".*

Contributing to this perception of having adequate time during sessions was the input of the therapist in terms of creating a dynamic where patients perceived they had the space to repeat any aspects of the session if needed, with one veteran commenting: "the way treatment was administered if unsure about anything it wasn't too much trouble to go over it again never felt pressured at any time was always on my terms". This was likely facilitated by the atypical treatment length of 25 weeks, as well as the length of individual sessions.

By contrast, patients commented on having a sense there was a lot of content to fit into each session: "I think there is more content in each session than time allows, as if it can only just be crammed in if the client doesn't have much to say. We sometimes had to skip parts due to this", with another patient commenting: "there wasn't enough time to be honest to finish". However, most patients felt that, by the end of treatment, most or all their difficulties had been addressed: "I believe we managed to cover everything some in more detail than others" and "I still have some difficulties…however I now have the tools to deal with this". Some veterans described having additional trauma memories that they didn't work on during treatment, although these patients either were offered subsequent treatment with the service, or felt equipped to cope with these memories with the skills practiced in treatment, e.g: "I do still have things I need to work on like other memories that I need to process, however I feel confident with the skills I have learnt to continue on and work on this under my own steam".

In this vein, most patients implied that the structure of ESTAIR worked for them, with skills-based modules before trauma work: "This memory affected me quite negatively during the week, but I managed to use the skills I had learnt to keep myself on track".

Some veterans commented on the "lengthy" build up to the narrative module as being something they had to endure before they could address them: "the long lead up to dealing with the events I understand why but the events haunt me on the lead up to dealing with them".

7.7.2 Impact of treatment

The second theme incorporates veterans' perceptions about the impact of treatment on their lives, including their emotions, self-esteem and how this positively affected their relationships and everyday functioning, all of which are DSO symptoms targeted by the ESTAIR modules. Many veterans described positive changes to their perceptions of themselves: "I used to hate myself and think I was a bad person who deserved this life, I no longer feel that way" and "I feel better about myself…I'm more confident too", as well as "my ability to handle emotions is much better now. I trust myself much more". Veterans commented on how these changes had supported positive shifts in their relationships, for example: "my relationship with my wife is a lot better" and "my relationships both personal and work have improved as I can now regulate my issues and fears", as well as their everyday functioning: "I am much kinder to myself [which] helps my everyday life".

These changes seemed to have also been noticed by patients' friends and family e.g., "even [my wife] said I have changed, whereas before I would have flown off the handle at stuff, she says I'm totally different now". One veteran commented "friends and family noticed a huge difference in me more alert not so miserable more approachable", while another described how they "see lots of changes and improvements, which has also been echoed by my loved ones and friends". This reflects the wider impact of treatment across patients' networks.

7.8 Power Analysis for an adequately powered trial

See Appendix 3 for Power analysis for RESTORE 2.

8. Discussion

To our knowledge, this is first RCT evaluating ESTAIR for veterans with ICD-11 CPTSD. Results indicate that ESTAIR is feasible, safe and a potentially efficacious treatment. CPTSD symptoms and CPTSD diagnoses as well as comorbid symptoms of depression and anxiety were significantly reduced compared to TAU. Comorbid somatic symptoms improved in both treatments and alcohol use, which was relatively low at baseline, did not change in either treatment. There were no serious adverse events and a small number of adverse events during the study which were not related to the study. Overall, participants found the treatment acceptable and highlighted the benefits of the treatment particularly as related to social and interpersonal relationships.

Feasibility assessment yielded encouraging results. Enrolment was satisfactory with 72 individuals screened and 56 randomized during over a two-year period. While the target randomization number was n = 60, the attrition rate from screening to randomization was low (22%), compared to many veteran studies where attrition tends be about 50% in community settings (e.g., Schnurr et al., 2020).

Dropout in both treatment conditions was low (19% and 11% for ESTAIR and TAU respectively). These results compare well to the average dropout rate of 24% reported in a recent meta-analysis of dropout rates for PTSD treatments among military and veteran populations (Edwards-Stewart et al., 2021). Consistent with other reviews (Kitchiner et al., 2019; Lewis et al., 2022), the authors found that dropout was higher in trauma-focused treatments than treatments that were not (27.1% versus 16.1%, respectively). Given that ESTAIR is a trauma-focused treatment, the dropout rate of 19% is particularly encouraging.

Retention rates for the sample across the entirely of the study were good with data availability ranging between 54% and 89% across measures at post-treatment and 3-month follow-up. Taken together, these results provide support for the feasibility, recruitment, and follow-up of service user participants with CPTSD in a future trial. Engagement with ESTAIR was high and completion rate was good. Qualitative feedback for the intervention was positive overall in terms of format (i.e. modular delivery) and content for ESTAIR.

A few areas for improvement have been identified including content and sequencing of modules, which should be addressed in a future trial. ESTAIR has been safe with no adverse events attributed to the intervention itself being recorded.

The trial also included findings for several exploratory clinical outcomes that should be further explored in a fully powered clinical trial. There were significant reductions in CPTSD symptoms at post-treatment and follow-up. Over 80% of the participants in the ESTAIR group did not meet the criteria for PTSD or CPTSD at post-treatment, compared to 16.0% for the TAU group. There were significant reductions in depression and anxiety scores for the ESTAIR group in comparison to TAU, but not for somatic problems and alcohol use. Overall, preliminary results indicate that ESTAIR can produce superior to TAU results in CPTSD symptoms and other comorbidities such as depression and anxiety that are commonly presented in those with CPTSD. These results require replication in an adequately powered trial.

ESTAIR is a treatment of cognitive-behavioural orientation that has been developed specifically for CPTSD. It theorises that trauma recovery involves processing memories of traumatic events from the past, but also covers the impact of trauma on the present as it affects current relationships, emotional distress in day-to-day life and quality of life. Thus, it includes traditional cognitive - behavioural interventions related to the processing of the trauma memories (e.g., reappraisal of their meaning) as well as practical skills, training, and related interventions to improve

relationships, sense of self, emotion regulation, and mood management (Karatzias et al., 2023). A CPTSD specific intervention has never been tested in a population with CPTSD before and therefore it is not possible to compare the present findings with those of previous research. However, earlier variants of ESTAIR have been effective to treat traumatic stress symptoms in adult survivors of childhood abuse (Cloitre et al., 2002; Cloitre et al., 2010), indicating that modular therapies (Karatzias and Cloitre, 2019) can adequately treat complex traumatic stress symptoms.

ESTAIR was not superior to TAU in regard to two secondary outcomes including somatic symptoms and alcohol use. Somatic symptoms improved significantly across time and inspection of the means seems to suggest that overall change was attributable to the ESTAIR. Greater focus and follow-through on body-based interventions in module 1, particularly as related to pain, might improve outcomes. Neither treatment indicated any improvement in alcohol use. This might be the result of floor effects: a score of 5 on the AUDIT is typically the cut-off for risk of an alcohol use disorder among men and the average score at baseline for ESTAIR and TAU were 2.82 (SD = 0.50) and 3.82 (SD = 0.50), indicating relative low use in this study sample with little room for improvement. This might be because alcohol use and substance use disorders (AUD and SUD) were exclusions to this study and the programme triages veterans with AUD and SUD to programming that addresses these problems as a primary concern (Bradley et al., 2003).

8.1 Limitations

There are a number of limitations of this work to discuss. Firstly, and although in line with the aims of the study, the sample size is quite small to generalise any findings to the wider CPTSD population. Secondly, we have only recruited help-seeking veterans with CPTSD and we do appreciate that there is need for further work with other trauma treatment seeking groups. Thirdly, because of limited resources, we were only able to follow-up participants 3-months post-treatment. There is clearly a need for trials with longer follow-ups to confirm that benefits are maintained over a period of at least a year or more. Fourthly, the sample size prohibited sub-group analysis on predictors of outcome, such as the role of gender, to identify groups that would most likely benefit from an intervention such as ESTAIR. Fifthly, and with regard to acceptability, we were only able to recruit completers of the programme for participation and feedback. Nevertheless, evidence suggests that patients are more likely to report negative rather than positive feedback about psychological treatment (Crawford et al., 2018). As such, it is likely that the sample of respondents quite likely captured negative feedback about ESTAIR. Another limitation regarding acceptability is that the free-text responses may have led to a smaller dataset than qualitative interviews, although a decision was made when designing the protocol that the feedback survey would allow more participants the opportunity to provide their views on treatment. Finally, careful consideration should be given as to whether people with AUD/SUD and CPTSD should be included in future ESTAIR trials although there is evidence to suggest that targeting these symptoms separately might result in better outcomes in those with traumatic stress (Simpson et al., 2021).

8.2 Recommendations and next steps

Notwithstanding its limitations, this is the first ever study to report on the feasibility of delivering a new intervention specifically designed to target the symptoms of ICD-11 CPTSD. RESTORE 1 has shown that ESTAIR is a feasible and safe intervention to be used in a clinical setting. A few areas for improvement have been identified including content and sequencing of modules in ESTAIR, which should be addressed in a future trial. Also taken into account the lessons learned from this trial, there is now a need to conduct a larger trial of ESTAIR in order to allow implementation in relevant services in the UK and beyond. With

reference to the framework for the development and testing of psychological interventions, we recommend further testing of ESTAIR vs other trauma focused therapies or routine care to establish its effectiveness for different trauma samples as well its cost effectiveness. RESTORE 1 has shown the provisional superiority of ESTAIR against TAU but not against other trauma-focused treatments. It is now essential to compare the effectiveness and efficiency of ESTAIR against other psychotherapies routinely used in clinical practice for those with CPTSD. It is important to highlight that there is no evidence for the effectiveness of these interventions (i.e. Cognitive Processing Therapy - CPT or Eye movement Desensitisation and Reprocessing - EMDR) for CPTSD. We are now planning RESTORE 2, an adequately powered trial of testing the effectiveness of ESTAIR against CPT. We anticipate that ESTAIR would be at least as effective as CPT.

Appendix 1: Data collection, randomization and analysis

Study procedures

The ITQ was used to identify those with a probable diagnosis of ICD-11 CPTSD. All new referrals were discussed at a weekly case management meeting. The following procedure was implemented to recruit participants for the study. Firstly, the research assistant attended the case management meeting to screen veterans for eligibility for the study. If eligible, potential participants were then approached to take part by the research assistant by letter and were sent a Participant Information Sheet (PIS) and consent form. This invitation was followed up by a telephone call by the research assistant to discuss any questions about the study and participants' willingness to participate. Those willing to participate were then asked to attend a one to one or online meeting with the research assistant. At this meeting, they were asked again if they had any questions about the study, sign the consent form and completed pre-treatment measures. All forms could also be returned via mail. Following this step, participants were randomized to one of the two treatment conditions. The ITQ was administered at the end of every module for those in the ESTAIR condition; if the person was CPTSD diagnosis free then they were offered a full post-treatment assessment. Subsequent input from the service following completion of trial was offered as required and as per normal service standards. Those randomized to the TAU group or who were opted out were offered the standard treatment and they completed the ITQ at pre-, post-treatment and 3-month follow-up.

Participants in both groups were asked to complete these outcome measures at baseline (week 0), at post-treatment (week 25) and then again after a 12-week follow-up (week 37). The International Trauma Questionnaire (ITQ: Cloitre et al., 2018) was also completed by the ESTAIR group at the end of every module. In addition, data were recorded on retention and rates of non - attendance. The research assistant was masked to group allocation to demonstrate to future funders this is achievable in a future trial.

Participants were free to withdraw from the study at any point, without giving any reason and without their legal rights or usual care being affected. Investigators were also able to withdraw participants if they deemed their continuation to be harmful. The trial management group reviewed all instances of adverse events, whether or not they were judged to be attributable to the trial or interventions, and, based on this information, determine whether the participant should have been withdrawn. Non-identifiable data from participants who have been withdrawn were used to assess the feasibility of the study.

Study inclusion and exclusion criteria

Inclusion criteria

Adults (18 years or older) in the caseload of a national UK charity, armed forces veteran, help-seeking for trauma related psychological distress, meeting diagnostic criteria for CPTSD as measured by the ITQ, proficiency in English language and signed informed consent provided.

Exclusion criteria

Presence of severe psychotic disorder (defined by previous clinical diagnosis), current alcohol or drug use disorder, serious cognitive impairment or planned concurrent additional treatment.

Randomisation and masking

Block randomisation was used to ensure balanced assignment to the intervention and comparison group. Randomly permuted blocks (based on 12 blocks with 4 subjects per block) were used to reduce the risk of predicting group assignment and ensure equal groups sizes.

Randomized lists were generated using an online, closed-source, web service (http://www.randomization.com/). Randomisation was completed by a team member who was not otherwise involved in the implementation of the study.

Life Events Checklist (LEC; Gray, Litz, Hsu, & Lombardo, 2004): The LEC is a 17-item self-report measure for potentially traumatic events in the respondent's lifetime. The LEC assesses exposure to 16 events plus one item assessing any other extraordinarily stressful event. The respondent checks whether they (a) directly experienced, (b) witnessed, (c) learned about, (d) are not sure, and (e) does not apply to them. The LEC has demonstrated adequate reliability and validity.

International Trauma Questionnaire (ITQ; Cloitre et al., 2018). The ITQ includes 6 items that measure the 3 symptom clusters of PTSD (Re-experiencing, Avoidance, and Sense of Threat) and six that measure the 3 symptom clusters of Disturbances in Self-Organisation (Affective Dysregulation, Negative Self-Concept, and Disturbances in Relationships). There are also 3 questions that assess functional impairment related to PTSD and DSO. The items are scored on a 5-point Likert scale ranging from 0 (not at all) to 4 (extremely), indicating how much a symptom has bothered the respondent in the past month. The PTSD and DSO items are summed to reflect symptom severity with a range of possible scores from 0 - 24. The Likert scores can be also recoded into binary variables with scores greater than 2 representing endorsement. A diagnosis of PTSD requires endorsing at least one symptom in each of the three clusters as well as functional impairment. A diagnosis of CPTSD requires PTSD and endorsement of at least one of the three DSO clusters plus functional impairment.

Patient Health Questionnaire-9 (PHQ-9: Kroenke et al., 2001). Respondents indicate how often they have been bothered by each symptom over the last two weeks using a four-point Likert scale ranging from 0 (*Not at all*) to 3 (*Nearly every day*). Possible scores range from 0 to 27, with higher scores indicative of higher levels of depression. To identify participants likely to meet the criteria for depressive disorder, a cut-off score of 15 was used as it has been reported that this score produces specificity of .96 (Kroenke et al., 2001). The psychometric properties of the PHQ-9 scores have been widely supported.

Generalized Anxiety Disorder 7-item Scale (GAD-7) (Spitzer et al., 2006). Respondents indicate how often they have been bothered by each symptom over the last two weeks on a four-point Likert scale (0 = *Not at all*, to 3 = *Nearly every day*). Possible scores range from 0 to 21, with higher scores indicative of higher levels of anxiety. The GAD-7 has been shown to be a reliable and valid measure in multiple studies. To identify participants likely to meet the criteria for generalised anxiety a cut-off score ore of 15 was used as it has been reported that this score produces specificity of .96 (Spitzer et al., 2006).

*Alcohol Use Disorder (AUD) (*Saunders et al., 1993). Probable AUD was measured using the AUDIT-C, a brief self-report measure comprised of the first three questions of the *Alcohol Use Disorders Identification Test*. The clinical utility of the AUDIT-C has been demonstrated in multiple samples including the general population, military veterans, and hospitalised patients. Scores on the AUDIT-C range from 0-12, and based on a nationally representative sample of adults from the United States, scores ≥ 4 effectively capture a DSM-5 diagnosis of AUD.

Patient Health Questionnaire-15 (PHQ-15) (Kroenke et al., 2002). The scale includes the most prevalent DSM-IV somatization disorder somatic symptoms. Participants were required to rate the severity of 13 symptoms as 0 (“not bothered at all”), 1 (“bothered a little”), or 2 (“bothered a lot”). Responses are coded as 0 (“not at all”), 1 (“several days”), or 2 (“more than half the days” or “nearly every day”) to produce total scores ranging from 0 to 30 and scores of ≥5, ≥10, ≥15

represent mild, moderate and severe levels of somatization. The reliability and validity of the PHQ-15 are acceptable.

Adverse Events Questionnaire (AEQ: Hutton et al., 2017). Serious adverse events (SAEs) were defined as (i) death by suicide; (ii) suicide attempt; (iii) suicidal crisis without attempt; (iv) severe symptom exacerbation (increase of 2 standard deviations or more on the patient or researcher-rated ITQ. Adverse events (AEs) were defined as a score of ≥3 (agree 'quite a lot' or 'a lot') on any relevant item (e.g., subjectively worsening mental state, heightened stigma, increased medication use, increased conflict). AEQ was completed by clinicians during the intervention at the end of every module (6 sessions) or upon the report of an SAE or AE by the participant in or out of session. The clinician was instructed to report all adverse events to the trial management group. The trial management group was asked to review this form and determine whether the event could reasonably be attributed to the intervention or participation in the trial. The trial management group reviewed all instances of adverse events, whether or not they are judged to be attributable to the trial or interventions, and, based on this information, determine whether the participant should be withdrawn and/or whether the trial should be suspended, stopped or continued.

Acceptability of materials and intervention (qualitative data), Every participant who completed treatment in the ESTAIR arm (n = 22) was emailed a link to the qualitative questionnaire hosted on Survey Monkey once they had completed the end of treatment quantitative measures at 25 weeks. Non-completers were also invited to participate. Instructions included that completion of the qualitative survey was voluntary, that all responses would be anonymous and that their therapist would not have access to the feedback. The survey included seven questions asking participants about their positive and negative experiences during treatment (e.g. What, if anything, have you found particularly positive about the treatment? Please give examples). All responses were free-text.

Data analysis

Recruitment, treatment completion and study retention rates at all stages of the trial were recorded and summarised. Any comments regarding acceptability of the intervention and the outcomes were recorded and summarised.

Analyses on clinical measures was conducted in 4 linked phases. First, the longitudinal changes in the summed scores across the treatment conditions were tested using linear mixed models based on the *GAMLj package (*Gallucci, 2019) in the jamovi software (jamovi project, 2022). Time (baseline, post-treatment and follow up) and Treatment (TAU or ESTAIR) were fixed effects and participants were random effects. Main effects and the interaction were estimated for each dependent variable separately based on Restricted Maximum Likelihood estimation that uses all available data and does not require listwise deletion which made this an intention to treat analysis. Efficacy of treatment would be indicated by a significant time by treatment interaction. Estimated marginal means were reported and plotted. Second, the same form of analyses were conducted on all secondary outcomes. The third phase involved cross tabulating probable PTSD/CPTSD diagnostic status at post-treatment to determine if there were differences in change in status: all participants screened positive for CPTSD at baseline so any differences can be interpreted in light of this. A significant chi-square statistic would indicate differences in diagnostic status across TAU and ESTAIR, and standardised residuals greater than 2 were used to understand the overall effect. Finally, the mean PTSD and DSO scores from the ITQ were estimated and reported for each module for the ESTAIR group only to explore the effects of individual modules. Quantitative analyses were performed by MS.

For qualitative data all responses were collated and analysed using Thematic Analysis in order to provide a rich description of meaningful patterns contained in the data (Braun & Clarke, 2006) via QDA Miner Lite (2016). Due to the pre-defined topic area of treatment experiences and pre-set questions in the survey, a deductive Thematic Analysis approach was used. Namely, we anticipated participants would comment on the structure and content of sessions, as well as the therapeutic relationship. The data was repeatedly read, and preliminary codes were applied to sentences and paragraphs where patterns of meaning were identified. It was possible for multiple codes to be applied to segments of text. Codes which hung together were then grouped into themes. Qualitative analysis was performed by NB, although debriefing was used to establish great consistency in interpreting the data (Morrow, 2005). This is a reflexive, rather than a coding reliability approach. Whilst both approaches have their advantages, we felt the latter more suited to an inductive Thematic Analysis (O'Connor & Joffe, 2020).

Appendix 2: Detailed results

Enrolment

As shown in the CONSORT chart (See Figure 1), a total of 92 people were screened for eligibility; n=36 were excluded and of those, n = 11 (12%) declined participation with a total of 58 (63% of those initially approached) participants randomized to either the ESTAIR (n=28) or the TAU (n=28) treatment conditions group.

Sociodemographics

The responses to the LEC indicated very high levels of trauma exposure; the most frequently reported events were "Exposure to combat or exposure to a war-zone" (92.9%), "Any other very stressful event or experience" (89.3%), "Assault with a weapon" (87.5%), "Fire or explosion" (85.7%), and "Sudden violent death" (83.9%). Multiple trauma exposure was common, ranging from 1 to 17, with the mean number of LEC endorsements of 11.48 (SD = 3.75: Mdn = 11.50).

At baseline there were no significant differences in gender ($\chi 2$ (1) = 1.08, p = .299) and age between the ESTAIR (M =47.14, SD= 12.24) and the TAU Group (M = 46.32, SD=10.48: t (54) = 0.27, p=.748). Mean scores on PTSD did not differ between the TAU (M = 20.21, SD = 2.69) and ESTAIR (M = 19.57, SD = 2.88) group (t(54) = .86, p = .393) nor did the DSO scores (TAU M = 20.75, SD = 2.44; ESTAIR M = 19.78, SD = 2.67; t(54) = 1.41, p = .082).

Table 1 shows the demographic and service-related variables. There are no significant differences between the two groups across all variables.

Power analysis for RESTORE 2

A power analysis was conducted to calculate the sample size for RESTORE 2. This analysis was based on a 2-armed trial with ESTAIR being compared to another active evidence-based Trauma-focused CBT treatment (i.e. Cognitive Processing Therapy – CPT). The intention to treat analysis will be based on testing the mean differences from pre to post for the PTSD and DSO subscale scores. The determination of effect size was informed by previous research. In this trial, the between group effect sizes, in terms of Cohen's f 2 (Cohen, 1988), are for PTSD (f 2 = 1.85) and DSO (f 2 = 2.35) with ESTAIR being compared to treatment as usual. However much smaller effect sizes are reported for comparisons of competing active treatments; an effect size of 0.85 was reported for the difference in PCL scores between CPT and PCT for the treatment of PTSD (Schnurr et all., 2022). With CPTSD being associated with additional symptoms and greater levels of impairment it might be prudent to assume a smaller effect size when comparing treatments of CPTSD. An effect size of 0.65 was chosen, along with required power of .80 and alpha of .05. With these parameters a sample size of 78 is required to reliably detect the difference between-group mean differences on the ITQ for a trial comparing ESTAIR vs. CPT.

Appendix 3: Results tables

Fig. 1 RESTORE CONSORT

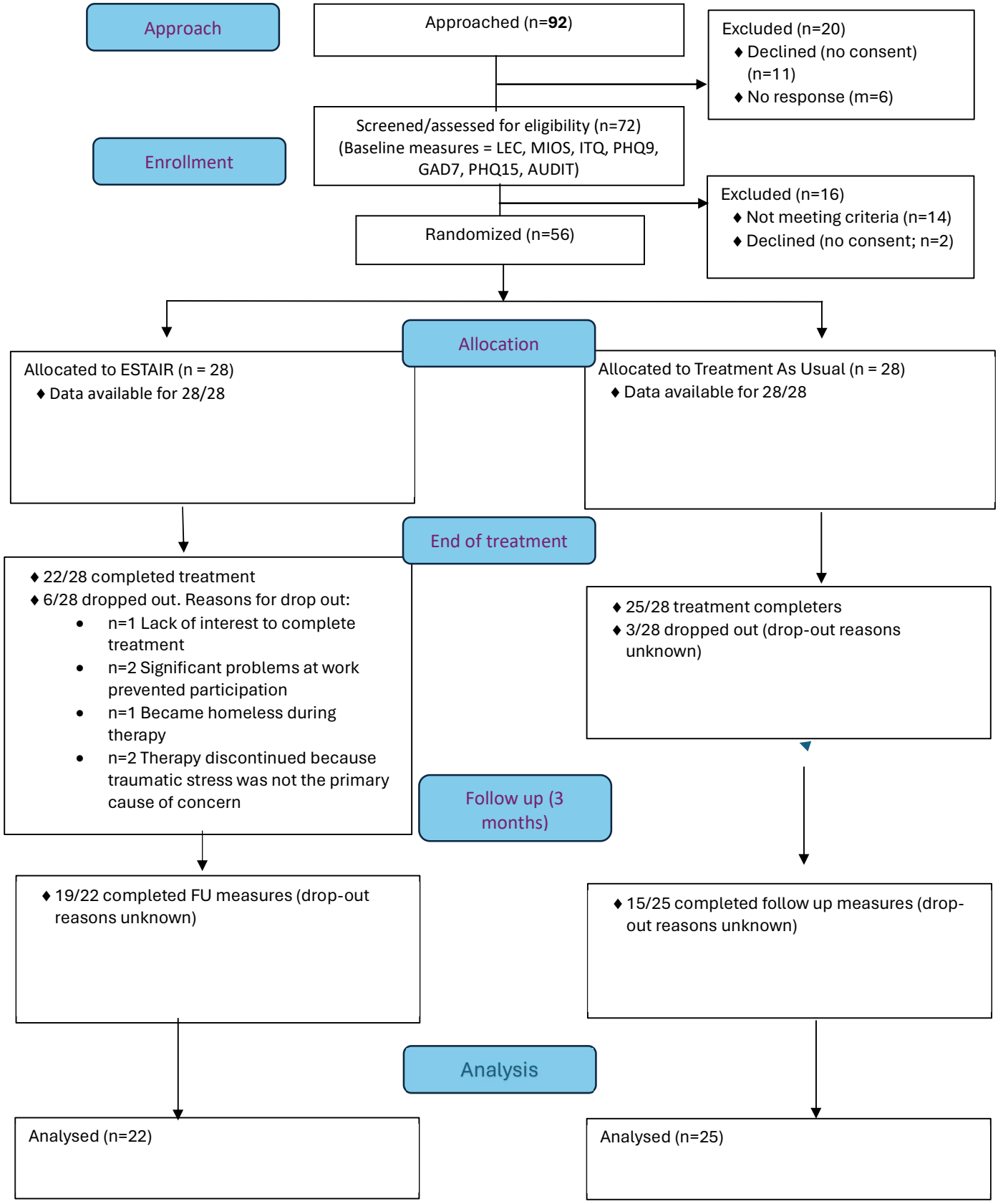

Table 1. Demographic and medical characteristics at baseline

	TAU N=28	ESTAIR N=28	Total N=56	[a]t, (df), p [b]χ^2, (df), p		
Age (years)	46.32 (10.47)	47.14 (12.24)	46.73 (11.23)	-.270	54	.788
Gender (male)	25 (89.3%)	27 (96.4%)	52 (92.9%)	1.07	1	.299
Relationship status						
Single	1 (3.6%)	3 (10.7%)	4 (7.1%)	4.50	4	.342
In a relationship	3 (10.7%)	4 (14.3%)	7 (12.5%)			
Married/cohabitating	19 (67.9%)	20 (71.4%)	39 (69.6%)			
Separated	2 (7.1%)	1 (3.6%)	3 (5.4%)			
Divorced	3 (10.7%)	0 (0.0%)	3 (5.4%)			
Employment						
FT/PT employment	13 (46.4%)	14 (50.0%)	27 (48.2%)	3.09	4	.542
Stay at home parent/caregiver	0 (0.0%)	2 (7.1%)	2 (3.6%)			
Not working	3 (10.7%)	1 (3.6%)	4 (7.1%)			
Not working due to ill health	9 (32.1%)	8 (28.6%)	17 (30.4%)			
Retired	3 (10.7%)	3 (10.7%)	6 (10.7%)			
Service						
Royal navy	1 (3.6%)	0 (0.0%)	1 (1.8%)	2.18	2	.337
Army	24 (85.7%)	27 (96.4%)	51 (91.1%)			
Royal air force	3 (10.7%)	1 (3.6%)	4 (7.1%)			
Enlistment						
Regular	26 (92.9%)	22 (78.6%)	48 (85.7%)	2.61	2	.270
Reservist	0 (0.0%)	1 (3.6%)	1 (1.8%)			
Both	2 (7.1%)	5 (17.9%)	7 (12.5%)			

	TAU N=28	ESTAIR N=28	Total N=56	[a]t, (df), p [b]χ^2, (df), p		
Time						
<4 years/esl	2 (7.1%)	3 (10.7%)	5 (8.9%)	1.24	2	.539
4-14 years	13 (46.4%)	16 (57.1%)	29 (51.8%)			
15+ years	13 (46.4%)	9 (32.1%)	22 (39.3%)			
Service role						
Combat	21 (75.0%)	20 (71.4%)	41 (73.2%)	1.02	2	.599
Non combat	7 (25.0%)	7 (25.0%)	14 (25.0%)			
Combat support	0 (0.0%)	1 (3.6%)	1 (1.8%)			
Deployments						
0	1 (3.6%)	3 (10.7%)	4 (7.1%)	2.34	3	.503
1	4 (14.3%)	6 (21.4%)	10 (17.9%)			
2	6 (21.4%)	7 (25.0%)	13 (23.2%)			
3 or more	17 (60.7%)	12 (42.9%)	29 (51.8%)			
Last rank						
Officer	3 (10.7%)	0 (0.0%)	3 (5.4%)	3.17	1	.075
Other	25 (89.3%)	28 (100.0%)	53 (94.6%)			
Time to support						
< 5 years	10 (35.7%)	8 (28.6%)	18 (32.1%)	.33	1	.567
> 5 years	18 (64.3%)	20 (71.4%)	38 (67.9%)			

Table 2. Fixed effect omnibus tests for primary outcome variables

	PTSD			**DSO**		
	F	df	p	F	df	p
Treatment	18.9	(1, 59.4)	< .001	35.3	(1, 59.8)	< .001
Time	54.9	(2, 89.3)	< .001	72.3	(2, 90.1)	< .001
Treatment x Time	11.3	(2, 89.3)	< .001	18.3	(2, 90.1)	< .001

Table 3. Mean PTSD and DSO scores by treatment and time

Treatment		**Time**	**N**	**Mean (se)**	
				PTSD	DSO
TAU		1	28	20.21 (0.87)	20.75 (0.84)
TAU		2	25	16.99 (0.92)	17.58 (0.88)
TAU		3	15	15.84 (1.13)	16.14 (1.09)
ESTAIR		1	28	19.57 (0.87)	19.79 (0.84)
ESTAIR		2	22	9.83 (0.97)	8.58 (0.93)
ESTAIR		3	19	10.12 (1.030)	8.55 (0.99)

Table 4. Fixed effect omnibus tests for secondary outcome variables

	Depression			**Anxiety**			**Somatic**			**Alcohol**		
	F	df	p	F	df	p	F	df	p	F	df	p
Time	62.05	(2, 82.9)	< .001	54.06	(2, 83.3)	< .001	18.660	(2, 78.2)	< .001	0.188	(2, 79.0)	0.829
Treatment	16.25	(1, 58.0)	< .001	13.25	(1, 59.0)	< .001	0.136	(1, 55.4)	0.714	2.357	(1, 56.2)	0.130
Time x Treatment	6.80	(2, 82.9)	0.002	8.93	(2, 83.3)	< .001	2.017	(2, 78.2)	0.140	0.554	(2, 79.0)	0.577

Table 5. Mean secondary outcome scores by treatment and time

Treatment		**Time**	**N**	**Mean (se)**			
				Depression	Anxiety	Somatic	Alcohol
TAU		1	28	21.14 (1.09)	17.32 (0.92)	13.9 (1.10)	2.82 (0.50)
TAU		2	25	16.62 (1.13)	13.76 (0.96)	10.7 (1.14)	2.87 (0.52)
TAU		3	15	15.16 (1.33)	13.60 (1.13)	12.3 (1.30)	2.42 (0.59)
ESTAIR		1	28	18.39 (1.09)	16.32 (0.92)	14.9 (1.10)	3.82 (0.50)
ESTAIR		2	20	8.37 (1.21)	7.57 (1.03)	10.0 (1.21)	3.51 (0.55)
ESTAIR		3	19	9.41 (1.23)	8.09 (1.07)	10.4 (1.24)	3.82 (0.56)

Table 6. Post-Treatment diagnostic status stratified by treatment condition

		Post Treatment			Total
		CPTSD	PTSD	No Diagnosis	
TAU	Count	21	0	4	25
	Expected Count	12.8	.5	11.7	25.0
	%	84.0%	0.0%	16.0%	100.0%
	Adjusted Residual	4.8	-1.1	-4.5	
ESTAIR	Count	3	1	18	22
	Expected Count	11.2	.5	10.3	22.0
	%	13.6%	4.5%	81.8%	100.0%
	Adjusted Residual	-4.8	1.1	4.5	
Total	Count	24	1	22	47

Fig. 2. Pre, post-treatment and follow-up mean plot of PTSD and DSO scores

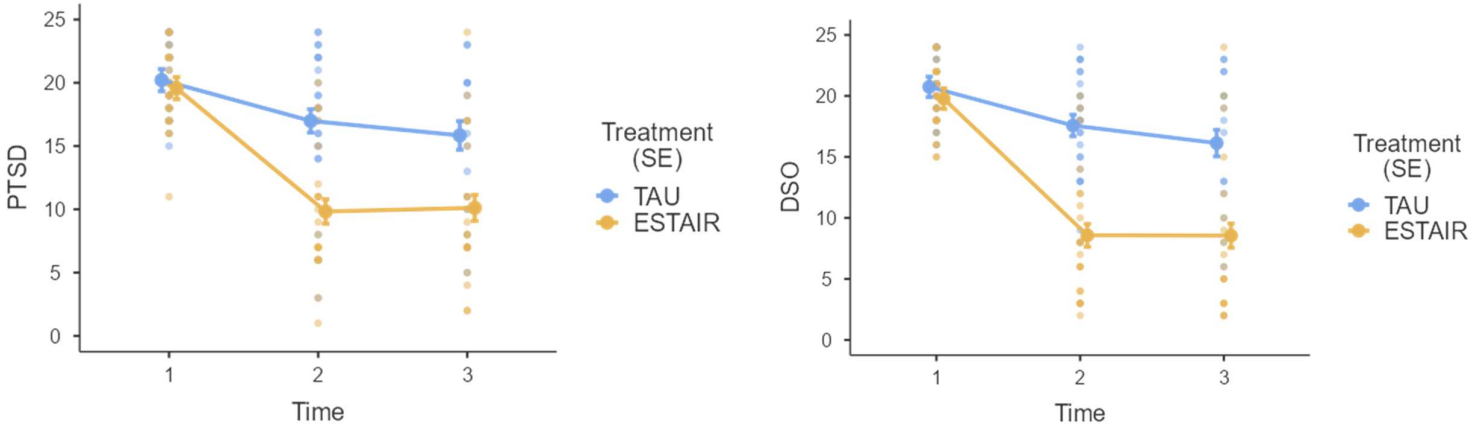

Fig. 3. Pre, post-treatment and follow-up mean plot of secondary outcome scores

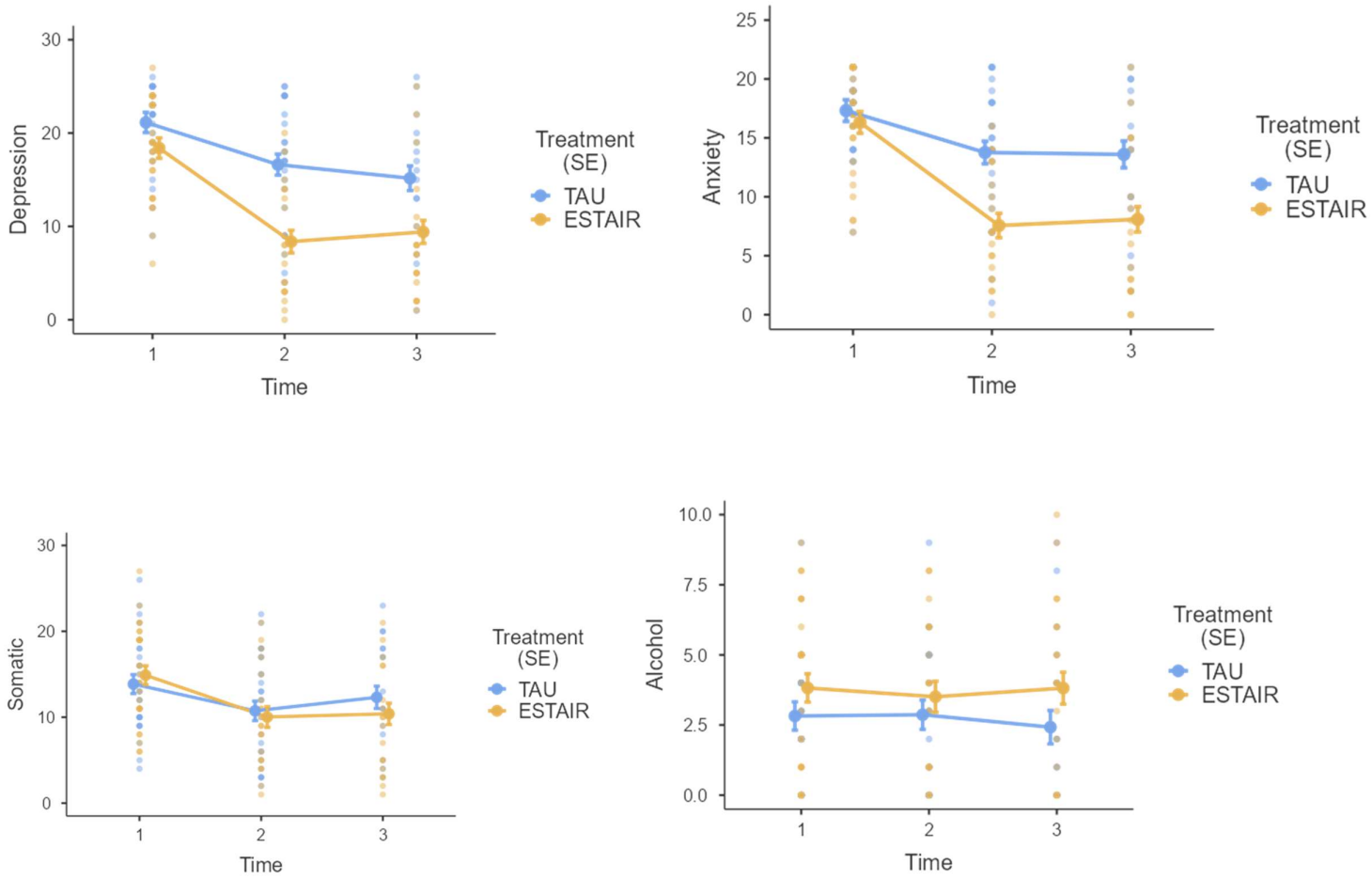

Table 7. Means for PTSD and DSO per module

	Baseline	Module 1 Emotion Regulation	Module 2 Relationships	Module 3 Self-concept	Module 4 PTSD
PTSD	19.57 (2.88)	15.09 (4.13)	11.90 (3.95)	12.18 (4.07)	7.63 (3.78)
DSO	19.78 (2.67)	12.95 (5.13)	11.27 (4.76)	9.77 (4.76)	6.81 (4.54)

Fig. 4. Mean PTSD and DSO scores by module