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PTSD in German Armed Forces service members – from diagnostics to therapy

PTBS bei Soldaten der deutschen Bundeswehr -
von der Diagnostik bis zur Therapie

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von der Diagnostik bis zur Therapie

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Widmung

Ich möchte diese Arbeit allen traumatisierten Angehörigen der deutschen Bundeswehr widmen.

"Viele Veteraninnen und Veteranen haben im Auslandseinsatz Dinge erlebt, die sie nicht mehr ohne Schwierigkeiten an ihren Alltag in Deutschland anknüpfen lassen. Es ist an der Zeit, diesen Menschen einen würdigen Platz in der gesellschaftlichen Mitte zu gewähren, denn es ist die gesellschaftliche Mitte, die sie in diese Einsätze schickt."

Johannes Clair

Allgemeine Erläuterungen

- Die vorliegende Arbeit wurde in englischer Sprache abgefasst, entsprechend der Vorgaben der Promotionsordnung der Humanwissenschaftlichen Fakultät der Universität zu Köln vom 18.12.2018, § 9 (3).

- Bei der vorliegenden Arbeit handelt es sich um drei bereits publizierte Arbeiten, die im Rahmen eines „Manteltext" zu einer kumulativen Dissertation zusammengefasst wurden. Die veröffentlichten Publikationen sind als solche gekennzeichnet und wurden original-getreu eingefügt entsprechend der Vorgaben der Promotionsordnung der Humanwissenschaftlichen Fakultät der Universität zu Köln vom 18.12.2018, § 9 (2c). Einzig die Tabellen und Grafiken sowie Anhänge wurden an den entsprechenden Stellen im Text eingefügt.

- Der individuelle Anteil des Autors an den genannten Publikationen, entsprechend der Vorgaben der Promotionsordnung der Humanwissenschaftlichen Fakultät der Universität zu Köln vom 18.12.2018, § 9 (2c) ist in der „Erklärung über den Eigenanteil an den Publikationen der als kumulative Dissertation eingereichten Schriften von Herrn Jan-Peter Spies" detailliert aufgelistet.

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List of abbreviations

AA – Acceptance an Action
AAQ – Acceptance and Action Questionnaire
BDI-II – Beck Depression Inventory – Revised
BIDR – Balanced Inventory of Desirable Responding
CAPS – Clinician-Administered PTSD Scale
CBT – Cognitive Behavioral Therapy
CISD – Critical Incident Stress Debriefing
CISM – Critical Incident Stress Management
cPTSD – complex Posttraumatic Stress Disorder
CSS – Crisis Support Scale
CTQ – Childhood Trauma Questionnaire
DERS – Difficulties in Emotion Regulation Scale
DES – Dissociative Experience Scale
DSM – Diagnostic and Statistical Manual of Mental Disorders
ER – Emotion Regulation
EMDR – Eye Movement desensitization and Reprocessing
FGG – Fragebogen zu Gedanken und Gefühlen
GAD-7 – Generalized Anxiety Disorder Scale
GAF – German Armed Forces
GSI – Global Severity Index
HTQ-5 – Harvard Trauma Questionnaire
IAQ –Interviewer Acceptance Questionnaire
ICD - International Classification of Diseases
IES-R – Impact of Event Scale – Revised
INT – Interpersonal sensitivity subscale of the Symptom-Checklist-90-Revised
IM – Impression management subscale of the Balanced Inventory of Desirable Responding
ITT – Intention to Treat
LC – Latent Change Score
LEC – Life Event Checklist
LMHAT – List of Mental Health Advisory Team
LOCF – Last Observation Carried Forward
MDN – Median
MIES – Moral Injury Event Scale
Mini-DIPS – Diagnostisches Kurzinterview bei psychischen Störungen
NICE – National Institute for Health and Care Excellence
OBS – Obsession-compulsion subscale of the Symptom-Checklist-90-Revised
PAQ –Patient Acceptance Questionnaire
PAR – Paranoid ideation subscale of the Symptom-Checklist-90-Revised
PCL-5 – PTSD Checklist for Diagnostic and Statistical Manual of Mental Disorders-Fifth Edition

PDS – Posttraumatic Diagnosis Scale

PTGI – Posttraumatic Growth Inventory

PHO – Phobic anxiety subscale of the Symptom-Checklist-90-Revised

PSWQ – Penn State Worry Questionnaire

PSY – Psychoticism subscale of the Symptom-Checklist-90-Revised

PTSD – Posttraumatic Stress Disorder

PTCI – Posttraumatic Cognitions Inventory

PTSD – Posttraumatic Stress Disorder

SAQ – Social Acknowledgment as a Victim or Survivor Questionnaire

STAI-S – State-Trait-Anxiety-Inventory State

SCL-90-R – Symptom-Checklist-90-Revised

SDE – Self deceptive enhancement subscale of the Balanced Inventory of Desirable Responding

SkPTBS – Screening zur komplexen Posttraumatischen Belastungsstörung

SOM – Somatization subscale of the Symptom-Checklist-90-Revised

SPSS – Statistical Program for Social Studies

SWLS – Satisfaction with Life Scale

TF-CBT – Trauma-Focused Cognitive Behavioral Therapy

US – United States of America

WBSI – White Bear Suppression Inventory

WL – Waiting List

1 Introduction

The history of Posttraumatic Stress Disorder (PTSD) and its conceptualization as a mental disorder is long. First reports go back to the ancient Sumerians (2000 BC). Later description of its symptoms focused, for example, on syndromes like irritable heart syndrome, railroad spine syndrome, soldiers heart, effort syndrome, transfer neurosis, or shell shock syndrome (1). Simultaneously, different etiological theories were suggested identifying different origins of the respective syndrome such as the malfunction of the heart or specific circumstances in the past of the afflicted individuals (1). In 1952, the first version of the Diagnostic and Statistical Manual of Mental Disorders (DSM) firstly contained Gross stress reaction as a diagnosis (2). In the second version of the DSM this diagnosis disappeared again, but reappeared in 1980 in the DSM-III as PTSD more or less as we know it today, with a time criterium added in the DSM-IIIR (3). In the newest version of the diagnostic manual, DSM-5, two major changes were adapted (4). Firstly, PTSD now is no longer part of the anxiety disorders. PTSD was regrouped with trauma- and stressor related disorders. Secondly, the cluster D "alliterations in cognitions and mood" was added to the symptom descriptors. The history of PTSD was always closely linked to the history of military conflicts. The listing of PTSD as a codable diagnosis in DSM-III in 1980 was a reaction to the consequences of the wars in the two centuries before (1). With PTSD as a codable diagnosis compensation and healthcare access for veterans suffering from posttraumatic symptoms was simplified. Today, PTSD after deployment remains a significant problem for service members and veterans worldwide. Prevalence numbers differ between nations and risk rises with the number of deployments and incidents (5, 6). For British service members a rate of 4 % was reported, whilst for US veterans rates vary between 9 and 20 % (7, 8). For service members of the German Armed Forces (GAF) rates vary between 2.8 % in deployed service members and 3.2 % for service members with combat exposure (9, 10). Alas, in the best known study reporting the comparably low rate of 2.9 % for deployed service members of the GAF authors estimated a high number of 45 % of unrecorded cases (10). Thus, members of the German Armed Forces clearly are also at risk to develop trauma related disorders and consequently, more research into the presentation of symptoms, etiological factors and treatment is needed.

2 Main section

2.1 Phenomenology and Symptomatology of PTSD

In the fifth version of the DSM, PTSD was relocated into the new section Trauma- and Stressor- Related Disorders (11, 12). In former versions it was located within the Anxiety Disorders. Additionally, the definition of a traumatic event, the A-criterium was sharpened and the former A2 criterium of peritraumatic fear, horror or helplessness was deleted (13, 14). The clusters were regrouped, new symptoms and the dissociative subtype were added (12, 13). These changes were made after a detailed methodological process involving various experts in theory and practice as well as in close consultation with the APA Committee (13).

Thus, the following criteria are now enlisted (the following list is based on the DSM-5 (11)):

Criterion A: stressor (one required) - The person was exposed to: death, threatened death, actual or threatened serious injury, or actual or threatened sexual violence, in the following way(s): Direct exposure, Witnessing the trauma, Learning that a relative or close friend was exposed to a trauma, Indirect exposure to aversive details of the trauma, usually in the course of professional duties (e.g., criminal investigators, first responders, medics, analysts)

Criterion B: intrusion symptoms (one required) - The traumatic event is persistently re-experienced in the following way(s): Unwanted upsetting memories, Nightmares, Flashbacks, Emotional distress after exposure to traumatic reminders, Physical reactivity after exposure to traumatic reminders

Criterion C: avoidance (one required) - Avoidance of trauma-related stimuli after the trauma, in the following way(s): Trauma-related thoughts or feelings, Trauma-related external reminders

Criterion D: negative alterations in cognitions and mood (two required) - Negative thoughts or feelings that began or worsened after the trauma, in the following way(s): Inability to recall key features of the trauma, Overly negative thoughts and

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assumptions about oneself or the world, Exaggerated blame of self or others for causing the trauma, Negative affect, Decreased interest in activities, Feeling isolated, Difficulty experiencing positive affect

Criterion E: alterations in arousal and reactivity (two required) - Trauma-related arousal and reactivity that began or worsened after the trauma, in the following way(s): Irritability or aggression, Risky or destructive behavior, Hypervigilance, Heightened startle reaction, Difficulty concentrating, Difficulty sleeping

Criterion F: duration (required), Symptoms last for more than 1 month.

Criterion G: functional significance (one required), Symptoms create distress or functional impairment (e.g., social, occupational).

Criterion H: exclusion (required), Symptoms are not due to medication, substance use, or other illness.

Two specifications: Dissociative Specification (one required for the subtype): In addition to meeting criteria for diagnosis, an individual experiences high levels of either of the following in reaction to trauma-related stimuli: Depersonalization. Experience of being an outside observer of or detached from oneself (e.g., feeling as if "this is not happening to me" or one were in a dream). Derealization. Experience of unreality, distance, or distortion (e.g., "things are not real").

Delayed Specification. Full diagnostic criteria are not met until at least six months after the trauma(s), although onset of symptoms may occur immediately.

Additionally, PTSD has a very high comorbidity rate with other mental disorders like generalized anxiety disorder, panic disorder, major depression, chronic dysthymia, substance use disorders, and somatoform disorders (15). In GAF service members the number of (deployment related) A-criteria and the number of comorbidities was a predictor for both short- and long term therapy success (16). Newer studies indicate a higher risk for autoimmune diseases in US veterans with PTSD in comparison with healthy fellow soldiers (17, 18).

2.2 Etiology of PTSD

Generally, it is possible to distinguish different approaches to PTSD models. A rough classification distinguishes learning theories, information processing theories, memory theories, and psychobiological theories. Nonetheless, dominating theories deducted

by systematic experience are cross-theoretical. The "fear-network" approach initially started in the learning field: a network of links is formed. This consists of information on the stimulus, verbal, physiological and behavioral reactions and interpretations of the meaning of the stimuli and the subsequent reactions (19-21). Usually, the network gets activated by an encounter with a threat stimulus. In individuals suffering from PTSD, the network is hypersensitive and overreacting. Two problems occur when PTSD has been established: first, the network's hypersensitivity is strongly resistant to reorganization. Indeed, long after the realistic threat present during the traumatic event is over, hypersensitivity endures (19, 20). The human longing for completeness of all memories is thought to be another reason for the long-lasting trouble with traumatic experiences (22). Due to the emotionally overwhelming nature of the experiences of a traumatic event, it is not possible to process the information related to this event adequately. Consequently, information stays active in memory. Apparently, the fear network theory combines ideas of the information processing approach and findings from memory research. Memory research with regard to traumatic memories mainly highlights the relevance of insufficiently processed memory content. There are currently two main approaches that try to explain the etiology of PTSD and include the notion of insufficiently processed memory content. According to the fear network model of PTSD (20), PTSD should be conceptualized as an anxiety disorders and its underlying mechanisms are based on learning theory. Accordingly, treatment manuals consist mainly of trauma exposure in sensu and in vivo to attain habituation and to promote emotional processing (i.e. adequate memory processing). The second model defines PTSD as a cognitive disorder (23). According to this model PTSD is mainly caused by negative appraisal of the traumatic event and a faulty formation of the trauma related autobiographical memory (23). Accordingly, therapy consists of cognitive interventions aiming directly towards reappraisal of trauma-associated cognitions and an integration of trauma memory into the autobiographical memory (24). Recently, both concepts have been combined, emphasizing the role of negative appraisal of traumatic events causing the formation, maintenance and severity of an individual´s PTSD (25).

2.2.1 Etiology of PTSD in GAF service members

For GAF service members the duration of deployment does not influence the development of PTSD, whereas a higher frequency of traumatic events increases the

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risk of PTSD in service members in general (6, 26). Previous studies have found several pre-traumatic factors in service members of the GAF that might have an influence on whether someone develops a PTSD after a critical incident or not. For example, a higher focus on the personal values, tradition, and universalism were linked to higher PTSD rates in GAF service members (27). Furthermore, one specific deployment related stressor called "Confrontation with hardship, suffering, and violence among the general population" was shown to have a direct influence on the development of PTSD in GAF service members (28). The construct Moral Injury (MI) describes the potential clash of a person's prior beliefs and values and morally ambiguous situations during deployment (29). MI was also found to be a mediator between events during deployment and the development of PTSD (28). Based on previous findings in civilians and military samples difficulties in Emotion Regulation (ER) are also closely associated with the development of PTSD in GAF service members (30-32). This theory driven hypothesis was tested in the following study. The study was accepted for publication in August 2020 in the international peer-reviewed open access journal "frontiers in psychiatry". The published manuscript is attached on the following pages after an introduction to Emotion Regulation (ER).

2.3   Emotion Regulation

"Emotion regulation" is a term generally used to describe a person's ability to effectively manage and respond to an emotional experience. In the following, I will describe the arguably most influential concept of emotion regulation as put forth by Gross (1998).

2.3.1   What are emotions

In a first step, Gross (1998) distinguished emotions from related constructs including the terms "affect" and "mood" (33). Affect was described more as a condition that might include emotions (33). Gross further distinguished emotion episodes and mood (33). Emotion episodes are wider in temporally and spatially terms, whereas emotions are quicker and shorter (33). Mood was also considered more durable and stable (33). Additionally, mood is more dispersed and importantly "moods bias cognition more than they bias action" in contrast to emotions that supposedly induce behavioral impulses (Gross, 1998, p. 273).

2.3.2 What is Emotion Regulation

According to Gross there are five categories of strategies relevant for emotion regulation: (1) situation selection, meaning to decide whether or not to get in contact with certain people, places or objects; (2) situation modification, meaning to modulate a situation at an early point; (3) attentional deployment which includes distraction, concentration, rumination; (4) cognitive change consists of conscious evaluation processes and cognitive processing as well as unconscious defense mechanisms; (5) response modulation is a late process that modulates "physiological, experiential, or behavioral responding" (Gross, 1998, p. 285), this includes self-medication attempts with drugs, food, or alcohol, relaxation techniques, or others (33).

Highlighting avoidance as a crucial ER strategy with respect to PTSD, Foa stated that external avoidance, such as avoiding trauma related external stimuli mainly on a behavioral level and internal avoidance such as avoiding thoughts, emotions, physical states, acts to prevent habituation processes. The habituation to unwanted feelings especially fear would be the instinctive reaction and thus commonly accompanying the natural course of recovery from a traumatic event (20, 21)

In a metanalytic review looking at emotion regulation strategies across different psychopathological conditions six strategies to regulate emotions were identified (32). Three of these strategies are described as destructive strategies (avoidance, rumination, and suppression), and the other three are described as constructive strategies (acceptance, problem solving, and reappraisal) (32). These strategies could be fitted to the listed theoretical categories Gross suggested. Maladaptive strategies have been linked with psychopathology in general, however, some maladaptive strategies such as rumination exhibit especially high effect sizes with regard to overall psychopathology (32). For specific disorders like depression, anxiety, eating, and substance use disorders, the effect sizes differed between the strategies. Notably, there is an indication that maladaptive ER strategies are more detrimental regarding mental health than a lack of adaptive ER strategies (32).

In a more recent meta-analysis focusing on ER and PTSD, the aforementioned six strategies were extended adding acceptance, experiential avoidance, expressive

suppression, general emotion dysregulation, reappraisal, rumination, thought suppression and worry. General emotion dysregulation showed the largest effect for PTSD, followed by rumination, thought suppression, and experiential avoidance (34). Interestingly, no significant effects were found for acceptance and reappraisal (34).

One interpretation of these findings with regard to more or less relevant emotion regulation strategies could be to focus on the maladaptive strategies over the adaptive strategies. This assumption is strengthened by a prospective investigation in military veterans by Boden et al. that found that "(…) change in expressive suppression, but not cognitive reappraisal, from treatment intake to discharge was significantly and incrementally predictive of PTSD symptom severity at treatment discharge after accounting for intake PTSD symptom severity, length of treatment stay, and participant age." (31).

Furthermore, not surprisingly, ER was found to be a powerful predictor of long-term psychopathology after child maltreatment (35).

2.3.3 Criticism concerning the Emotion Regulation concept

The definitions of ER constructs often overlap or do not allow to separate them clearly enough from one another. Indeed, overlapping confidence intervals in the meta-analyses might be indicative of this problem (32, 34). In other words, strategies labeled differentially might actually measure the same underlying strategies. Furthermore, usually only self-report assessments are used which might measure different emotions, different constructs and different time frames (34, 36).

2.4 PTSD Prevention

Based on the existing literature, a categorization of different mechanisms in different areas can be made. These mechanisms are candidates that may play a relevant role in the development of a PTSD or help to stay mentally healthy after a traumatic event. Feldner et al. (2007) suggested that these different areas are learning, information processing, memory and psychobiology. Nonetheless, the authors admit, that these fields also interact and overlap substantially (19). In a brief summary the authors conclude: "Survivors of traumatic events who do not recover from traumatization, compared to those who do, may (a) learn greater or less readily extinguished fear

responses to traumatic event-associated stimuli, (b) demonstrate problems in processing traumatic event-introduced information, (c) have disorganized traumatic event-related memory systems, and/or (d) have alterations in adrenergic, HPA, and other key psychobiological mechanisms"(19).

Several attempts were made to intervene between the traumatic event and the occurrence of full PTSD as a form of prevention. So far, only few of these approaches were shown to be effective (19). CBT and lowering the psychobiological reactions to a traumatic event either by medication, training or ER are promising (19). In contrast, providing self-help information had no influence as a prevention after an incident (37). The Critical Incident Stress Debriefing (CISD) was even shown to be harmful (19, 38). Note, however, that CISD is part of the more complete program called Critical Incident Stress Management (CISM), which if applied completely, has not been shown to be harmful (19). In addition, social support was demonstrated to act as a protective factor (39). Social support may be helpful by reducing negative affect, reducing avoidance behavior, and reducing avoidance of thoughts and feelings through personal disclosure about trauma-relevant contents (19).

Again, the role of ER in prevention interventions is noteworthy including aspects of learning, information processing, memory, or even psychobiological mechanisms.

2.5   Structure of this work

Against this background, the present dissertation presents three scientific publications focused on PTSD in GAF service members. The first publication takes a closer look on certain constructs associated with PTSD in general and service members in particular. The aim is to better understand underlying mechanisms that lead to PTSD. Those mechanisms or factors might be targeted accordingly to improve treatment of PTSD in GAF service members. The second publication focuses on diagnostic accuracy in service members suffering from PTSD. Different instruments to assess PTSD are described and categorized from a scientific practitioners' point of view. The gold standard in PTSD assessment is the Caps-5. The German version is currently being validated. The Caps-5 is further described and its advantages for a scientific and a practitioners' use is described. Finally, treatment methods for PTSD in service

members are described and the feasibility and the results of a novel online PTSD-treatment for GAF service members are presented. The final section of this dissertation provides specific reflections on these three publications and gives a general overview over potential further studies and observations made during the work with GAF service members suffering from PTSD in practice and research.

2.6 Publication I

Associations between difficulties in emotion regulation and post-traumatic stress disorder in deployed service members of the German Armed Forces

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2.6.1 Introduction

The diagnosis of posttraumatic stress disorder (PTSD) was firstly listed as a codable syndrome in the third version of the Diagnostic and Statistical Manual of Mental Disorders (DSM) (40). PTSD involves symptoms of re-experiencing, avoidance, and hyperarousal associated with a traumatic event. Since the introduction of the fifth edition of the DSM (DSM-5), symptoms of persisting negative cognitions and mood were added as a further cluster of symptoms (4). The symptoms of PTSD result in severe health restrictions and can seriously affect quality of life (41).

Even though experiencing a traumatic event can lead to PTSD, not every traumatized person develops PTSD (42). The lifetime prevalence of PTSD is 6.8% for civilians in the USA (43). For German civilians, the 12-month prevalence of PTSD is 2.3% (44). Compared with civilians, service members have a higher risk of developing PTSD, and deployed service members have a higher risk of developing it than undeployed service members (9).

Among deployed service members, it is possible to develop PTSD after one incident, yet there is growing evidence that various deployments or various incidents lead to a higher risk of developing it (5, 6). In general, PTSD remains a significant problem among service members after a foreign assignment (10). The prevalence rates range from 4% for British veterans to 9 - 20% for US veterans (7, 8). However, service members in the German Armed Forces (GAF) show lower prevalence rates, which range from 2.9% for deployed service members (10) to 3.2% for deployed service members with combat exposure (9). Yet presumably, nearly half of all GAF military personnel who suffer from PTSD after deployment are neither diagnosed nor reported (10). In the armed forces of other nations, it is also likely that the estimated number of unknown cases is higher than reported (45).

Risk factors have also been identified for the development of PTSD that do not apply exclusively to the military context. These factors comprise individual factors that are also reported in civilian samples, such as persisting psychological disorder (27, 46) or negative appraisals and cognition (47). Emotion regulation (ER) is one predictor that has repeatedly been identified as crucial for the development of PTSD (30-32). ER is defined as the deliberate or unintentional process of influencing the experience of emotions and their intensity (34). Thus, ER has to be distinguished from coping and other related constructs (33).

The profile of applied ER strategies of an individual coping with PTSD may even predict the overall symptom severity in PTSD and the severity of each cluster (30). Difficulties in ER are not only associated with the severity of PTSD symptoms in a civilian sample (36); they also seem to play an important role in the chronification of PTSD in civilians (48). Other studies have shown positive effects for acceptance and reappraisal in a sample of veterans (31), and an effective treatment of PTSD can also reduce ER difficulties (49).

Furthermore, difficulties in ER might hinder the recovery from PTSD, as shown in investigations with civilians, although this result concerns the treatment phase (50). ER has not been investigated specifically in the context of PTSD in GAF service members. Thus far, only a pilot study has investigated the effect of emotional ambivalence on the occurrence of PTSD after deployment among GAF service members, but not ER. The results showed that higher emotional ambivalence connected to neuroticism leads to higher symptom severity (51). However, based on the literature, we hypothesized that it could be possible to generalize the relationship between ER and PTSD and that there could be a relationship between ER and PTSD in our sample as well.

Recent results showed that experiential avoidance mediates the association between PTSD symptoms and social support in veterans after deployment (52, 53). Experiential avoidance was examined according to the construct of psychological flexibility and measured by the Acceptance and Avoidance Questionnaire, which measures avoidance, acceptance, cognitive defusion, and mindfulness. These results suggest that there is potential importance in acceptance and action (AA) as a mediator of PTSD and related factors among deployed service members. Since some studies regard AA as part of the difficulties in ER, there is particular interest in its role as a mediator in this study (34).

Furthermore, Moral Injury (MI) seems to play an important role in the development of PTSD in service members (29, 54-56). MI consists of shame and guilt resulting from a clash of prior beliefs and values with war experiences during deployment. Studies have reported on numerous situations that confront service members with ethically ambiguous situations created by modern warfare or deployment situations, such as shooting at enemies, being directly responsible for an enemy's death, or seeing women and children wounded and being unable to help (57). Such situations may lead to MI (29).

For the subgroup of deployed GAF service members, this specific factor could possibly play a key role in the development of PTSD after foreign assignment with traumatic experiences. One therapeutic approach to MI consists of a value-based cognitive behavioral group therapy concept, which has shown promising results in a sample of GAF service members who suffer from PTSD (58). Studies investigating predictors of the development of PTSD in deployed service members of nations other than Germany have confirmed the importance of the MI construct and a therapeutic focus on it (29).

The MI concept has been examined in several studies in Germany following the work of international colleagues and their findings (29, 59). Previous findings among GAF service members after deployment show that MI constitutes a differential mediator between stressors (such as confrontation with hardship, suffering, and violence among the population in a war zone) and post-traumatic stress. Furthermore, according to a qualitative data analysis of structured interviews with veterans, veterans judge MI as an important war-related risk factor (60).

Among deployed GAF service members, MI has been shown to be a moderator between deployment-related stressors and PTSD, depression, and alcohol abuse (28). However, in a more recent study, the MI Event Scale (MIES) showed no significant difference between GAF service members with PTSD and those without it (28). According to that study, there was a mediating effect of MI on the relationship between certain factors and PTSD, but there was no significant difference between service members with and without PTSD in the specific population of GAF service members. Thus, the mediating effect of MI and ER on PTSD is a present interest (28).

PTSD is mostly associated with pathological aspects in civilians and service members, including chronic stress (61-63) or uncontrollable and recurring thoughts (64-66). In contrast, PTSD can be associated with positive psychological factors in civilians and military personnel, such as satisfaction with life (67-69) or post-traumatic growth as a coping strategy that helps people regain control by defining positive aspects of the traumatic experience (70). Recent studies have identified protective factors that are thematically independent from the military context and were found to be protective factors for the development of PTSD in civilians and deployed GAF service members. One example is psychological flexibility, which is the ability to remain focused on the present moment, even during a traumatic event. Psychological flexibility was shown to be a protective factor for the development of PTSD in both civilians and deployed GAF service members (71-73). Higher focus on hedonism and power (27) or hope and

religiosity (74) have been identified as other protective factors for the development of PTSD.

There is strong evidence for the effects of social support during and after a traumatic event (75-77) and social acknowledgement (SA) as a victim or survivor (70, 78-81), which have both been repeatedly illustrated as potential resilience factors in civilians and veterans. On the other hand, a lack of social acknowledgment as a victim or survivor has repeatedly been shown to be a risk factor in terms of higher PTSD rates among veterans (78, 82, 83). Additionally, findings in military and civilian samples have shown that negative social reactions have a higher influence on PTSD than positive social reactions (78).

Based on the various findings from previous studies, the aim of the present study was to test the following hypotheses. Firstly, it was hypothesized that there is a direct relationship between ER and PTSD in our sample of deployed GAF service members. The second hypothesis was that the relationship between ER and PTSD is fully or partly mediated by one or more of the following three factors: MI, SA, and AA.

2.6.2 Materials and Methods

Participants

The participants (N = 72) were German men who spoke German as their native language. The mean age of the participants was 38.24 years (SD = 8.75 years; range: 19 – 70 years). Table 1 provides demographic variables regarding their marital status, graduation, completion of training, employment status, and military branch, while Table 2 presents data about the diagnosed mental disorders among the sample.

Table 1: Demographic characteristics of participants.

	Frequencies		Statistics
	PTSD (n = 25)	Non-PTSD n = 47	
Treatment-seeking	- yes: n = 25 - no: n = 0	- yes: n = 14 - no: n = 33	X^2(1, 72) = 32.41; p < .001
Marital status	- single without relationship: n = 3 - single with relationship: n = 3 - married: n = 12 - divorced: n = 5 - n. a.: n = 2	- single without relationship: n = 1 - single with relationship: n = 13 - married: n = 26 - divorced: n = 6 - n. a.: n = 1	X^2(1, 69) = 5.44; p = .143
Graduation	- Primary school: n = 5 - Intermediate school leaving certificate: n = 14 - Vocational baccalaureate diploma: n = 3 - A-levels: n = 2 - n. a.: n = 1	- Primary school: n = 3 - Intermediate school leaving certificate: n = 22 - Vocational baccalaureate diploma: n = 10 - A-levels: n = 12	X^2(1, 71) = 8.84, p = .183
Completion of training	- No vocational qualification: n = 3 - In vocational training: n = 0 - Completed vocational training: n = 13 - Technical college degree: n = 4 - Bachelor degree: n = 0 - Master degree in technical college: n = 1 - Master degree from an university: n = 2 - n. a.: n = 2	- No vocational qualification: n = 3 - In vocational training: n = 2 - Completed vocational training: n = 21 - Technical college degree: n = 8 - Bachelor degree: n = 2 - Master degree in technical college: n = 3 - Master degree from am university: n = 6 - n. a.: n = 2	X^2(1, 70) = 4.52, p = .719
Employment status,	- Voluntary military service: n = 1 - Soldier for a fixed term: n = 13 - Professional soldier: n = 5 - Service status in special form: n = 1 - n. a.: n = 5	- Voluntary military service: n = 1 - Soldier for a fixed term: n = 18 - Professional soldier: n = 26 - Service status in special form: n = 2	X^2(1, 67) = 5.36, p = .148
Military branch	- Army: n = 11 - German Air Force: n = 4	- Army: n = 15 - German Air Force: n = 15	X^2(1, 70) = 3.57, p = .468

	- Navy: $n = 0$ - Medical Service: $n = 3$ - Joint support service: $n = 5$ - n. a.: $n = 2$	- Navy: $n = 2$ - Medical Service: $n = 4$ - Joint support service: $n = 11$	
Service grade	- Ratings: $n = 6$ - Non-commissioned officer: $n = 15$ - Officer: $n = 2$ - n. a.: $n = 2$	- Ratings: $n = 8$ - Non-commissioned officer: $n = 27$ - Officer: $n = 12$	$X^2(1, 70) = 2.98$, $p = .226$

Note: n. a. = not available.

Table 2: Clinical data of the PTSD ($n = 25$) and Non-PTSD group ($n = 47$).

	PTSD	Non-PTSD	Statistics
Current major depressive disorder	$n = 12$ (48.0%)	$n = 2$ (4.3%)	$X^2(1, 72) = 19.937$, $p < .001$
Current panic disorder	$n = 9$ (36.0%)	$n = 0$ (0.0%)	$X^2(1, 72) = 19.337$, $p < .001$
Current agoraphobia	$n = 17$ (68.0%)	$n = 4$ (8.5%)	$X^2(1, 72) = 27.955$, $p < .001$
Current social anxiety disorder	$n = 7$ (28.0%)	$n = 0$ (0.0%)	$X^2(1, 72) = 14.577$, $p < .001$
Current generalized anxiety disorder	$n = 5$ (20.0%)	$n = 1$ (2.1%)	$X^2(1, 72) = 6.824$, $p = .009$
Current suicidality	$n = 4$ (16.0%)	$n = 1$ (2.1%)	$X^2(1, 72) = 4.860$, $p = .029$
Lifetime suicide attempt	$n = 5$ (20.0%)	$n = 1$ (2.1%)	$X^2(1, 72) = 6.824$, $p = .009$
Current medical treatment	$n = 11$ (45.8%)	$n = 6$ (12.8%)	$X^2(1,71) = 9.539$, $p = .002$
Current psychiatric / psychotherapeutic treatment	$n = 8$ (33.3%)	$n = 2$ (4.3%)	$X^2(1,71) = 11.101$, $p = .001$
Current somatic disorder	$n = 7$ (29.2%)	$n = 10$ (21.3%)	$X^2(1,71) = .543$, $p = .559$
Regular use of medication	$n = 13$ (54.2%)	$n = 12$ (25.5%)	$X^2(1,71) = .5.710$, $p = .018$

Study design and sampling procedure

Data were collected between July 2016 and July 2018. Data from evaluation questionnaires administered upon entry into the study were subjected to a cross-sectional analysis. The inclusion criteria were status as an active or former service member of the GAF, male sex, and meeting criterion A according to DSM-5 for PTSD after having been deployed. The exclusion criteria were acute psychotic symptoms, an acute manic episode, current substance abuse or dependence, an acute high risk of suicide, neurological disorder, acute somatic disease, unstable psychotropic medication, or concurrent psychotherapeutic treatment.

In a quasi-experimental design, participants were separated into two groups according to the PTSD diagnosis based on the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5). Overall, $N = 89$ service members were screened. Participants without deployment and those with incomplete CAPS-5 scores were excluded. Accordingly, $n = 39$ treatment-seeking GAF service members and $n = 33$ GAF service members from the control group of the original RCT (84) were pooled ($n = 72$) and subsequently allocated to either the PTSD or the non-PTSD group according to their CAPS-5 PTSD diagnosis. Ultimately, a total of $n = 25$ participants fulfilled the PTSD criteria (PTSD group), while $n = 47$ participants experienced a traumatic event but did not fulfill the PTSD criteria (non-PTSD group).

Participating service members were deployed one or more times. More than half of the participants served in Afghanistan (58.9%), whereas 20.6% of the participants served in Kosovo, and 7.4% served in Mali. There were no significant differences between the missions ($\chi^2(40) = 38.358$, $p = 0.544$). The time since deployment varied between six weeks and 26 years ($M = 7.0$, $SD = 5.4$) and did not differ significantly between groups $U(N_{PTSD} = 20, N_{non-PTSD} = 45) = 320.0$, $z = -1.848$, $p = 0.065$). A detailed description of the procedure of the initial study is available elsewhere (84).The traumatic events experienced by both groups were measured with the Life Events Checklist for DSM-5

(85). As shown in Table 3, the frequencies of traumatic events did not differ significantly between groups.

Table 3: Frequencies of traumatic events according to the Life Events Checklist for DSM-5 for GAF service members with and without PTSD.

Traumatic event	PTSD	Non-PTSD	Statistics
Natural disaster	- directly experienced: $n = 4$ - witnessed: $n = 5$ - learned about it: $n = 1$ - part of job: $n = 2$ - not sure: $n = 0$ - doesn't apply: $n = 12$ - n. a.: $n = 1$	- directly experienced: $n = 8$ - witnessed: $n = 7$ - learned about it: $n = 7$ - part of job: $n = 8$ - not sure: $n = 1$ - doesn't apply: $n = 16$ - n. a.: $n = 0$	$X^2(5, 71) = 4.343$, $p = .501$
Fire or explosion	- directly experienced: $n = 9$ - witnessed: $n = 6$ - learned about it: $n = 3$ - part of job: $n = 3$ - not sure: $n = 0$ - doesn't apply: $n = 3$ - n. a.: $n = 1$	- directly experienced: $n = 10$ - witnessed: $n = 12$ - learned about it: $n = 5$ - part of job: $n = 9$ - not sure: $n = 0$ - doesn't apply: $n = 10$ - n. a.: $n = 1$	$X^2(5, 70) = 2.671$, $p = .614$
Transportation accident	- directly experienced: $n = 10$ - witnessed: $n = 6$ - learned about it: $n = 1$ - part of job: $n = 2$ - not sure: $n = 0$ - doesn't apply: $n = 5$ - n. a.: $n = 1$	- directly experienced: $n = 28$ - witnessed: $n = 10$ - learned about it: $n = 4$ - part of job: $n = 2$ - not sure: $n = 0$ - doesn't apply: $n = 3$ - n. a.: $n = 0$	$X^2(5, 71) = 4.889$, $p = .299$
Serious accident at work, home, or during recreational activity	- directly experienced: $n = 4$ - witnessed: $n = 4$ - learned about it: $n = 3$ - part of job: $n = 1$ - not sure: $n = 2$ - doesn't apply: $n = 10$ - n. a.: $n = 1$	- directly experienced: $n = 10$ - witnessed: $n = 10$ - learned about it: $n = 11$ - part of job: $n = 4$ - not sure: $n = 0$ - doesn't apply: $n = 12$ - n. a.: $n = 0$	$X^2(5, 71) = 6.978$, $p = .222$
Exposure to toxic substance	- directly experienced: $n = 2$ - witnessed: $n = 0$ - learned about it: $n = 0$ - part of job: $n = 3$ - not sure: $n = 2$ - doesn't apply: $n = 17$ - n. a.: $n = 1$	- directly experienced: $n = 7$ - witnessed: $n = 2$ - learned about it: $n = 3$ - part of job: $n = 7$ - not sure: $n = 2$ - doesn't apply: $n = 26$ - n. a.: $n = 0$	$X^2(5, 71) = 4.258$, $p = .513$

Physical assault	- directly experienced: $n = 8$ - witnessed: $n = 4$ - learned about it: $n = 2$ - part of job: $n = 0$ - not sure: $n = 1$ - doesn't apply: $n = 9$ - n. a.: $n = 1$	- directly experienced: $n = 18$ - witnessed: $n = 7$ - learned about it: $n = 7$ - part of job: $n = 0$ - not sure: $n = 1$ - doesn't apply: $n = 14$ - n. a.: $n = 0$	$X^2(5, 71) = 1.205$, $p = .877$
Assault with a weapon	- directly experienced: $n = 14$ - witnessed: $n = 2$ - learned about it: $n = 1$ - part of job: $n = 4$ - not sure: $n = 0$ - doesn't apply: $n = 3$ - n. a.: $n = 1$	- directly experienced: $n = 15$ - witnessed: $n = 3$ - learned about it: $n = 6$ - part of job: $n = 3$ - not sure: $n = 1$ - doesn't apply: $n = 19$ - n. a.: $n = 0$	$X^2(5, 71) = 10.205$, $p = .070$
Sexual assault	- directly experienced: $n = 0$ - witnessed: $n = 0$ - learned about it: $n = 1$ - part of job: $n = 1$ - not sure: $n = 0$ - doesn't apply: $n = 22$ - n. a.: $n = 1$	- directly experienced: $n = 1$ - witnessed: $n = 1$ - learned about it: $n = 7$ - part of job: $n = 0$ - not sure: $n = 0$ - doesn't apply: $n = 38$ - n. a.: $n = 0$	$X^2(5, 71) = 4.822$, $p = .306$
Other unwanted or uncomfortable sexual experience	- directly experienced: $n = 0$ - witnessed: $n = 0$ - learned about it: $n = 0$ - part of job: $n = 0$ - not sure: $n = 3$ - doesn't apply: $n = 21$ - n. a.: $n = 1$	- directly experienced: $n = 2$ - witnessed: $n = 0$ - learned about it: $n = 5$ - part of job: $n = 0$ - not sure: $n = 1$ - doesn't apply: $n = 39$ - n. a.: $n = 0$	$X^2(5, 71) = 6.647$, $p = .084$
Combat or exposure to a war-zone	- directly experienced: $n = 16$ - witnessed: $n = 1$ - learned about it: $n = 0$ - part of job: $n = 4$ - not sure: $n = 1$ - doesn't apply: $n = 2$ - n. a.: $n = 1$	- directly experienced: $n = 29$ - witnessed: $n = 1$ - learned about it: $n = 3$ - part of job: $n = 8$ - not sure: $n = 1$ - doesn't apply: $n = 5$ - n. a.: $n = 0$	$X^2(5, 71) = 2.149$, $p = .828$
Captivity	- directly experienced: $n = 0$ - witnessed: $n = 0$ - learned about it: $n = 1$ - part of job: $n = 1$ - not sure: $n = 0$ - doesn't apply: $n = 22$ - n. a.: $n = 1$	- directly experienced: $n = 0$ - witnessed: $n = 1$ - learned about it: $n = 4$ - part of job: $n = 0$ - not sure: $n = 1$ - doesn't apply: $n = 41$ - n. a.: $n = 0$	$X^2(5, 71) = 3.440$, $p = .487$

Life-threatening illness or injury	- directly experienced: $n = 2$ - witnessed: $n = 5$ - learned about it: $n = 2$ - part of job: $n = 1$ - not sure: $n = 2$ - doesn't apply: $n = 12$ - n. a.: $n = 1$	- directly experienced: $n = 2$ - witnessed: $n = 17$ - learned about it: $n = 9$ - part of job: $n = 0$ - not sure: $n = 0$ - doesn't apply: $n = 19$ - n. a.: $n = 0$	$X^2(5, 71) = 9.083$, $p = .106$
Severe human suffering	- directly experienced: $n = 3$ - witnessed: $n = 10$ - learned about it: 0 - part of job: $n = 4$ - not sure: $n = 2$ - doesn't apply: $n = 4$ - n. a.: $n = 2$	- directly experienced: $n = 6$ - witnessed: $n = 19$ - learned about it: $n = 3$ - part of job: $n = 10$ - not sure: $n = 2$ - doesn't apply: $n = 7$ - n. a.: $n = 0$	$X^2(5, 70) = 2.214$, $p = .819$
Sudden violent death	- directly experienced: $n = 3$ - witnessed: $n = 9$ - learned about it: $n = 2$ - part of job: $n = 2$ - not sure: $n = 1$ - doesn't apply: $n = 7$ - n. a.: $n = 1$	- directly experienced: $n = 4$ - witnessed: $n = 5$ - learned about it: $n = 16$ - part of job: $n = 2$ - not sure: $n = 2$ - doesn't apply: $n = 18$ - n. a.: $n = 0$	$X^2(5, 71) = 11.058$, $p = .050$
Sudden accidental death	- directly experienced: $n = 1$ - witnessed: $n = 3$ - learned about it: $n = 3$ - part of job: $n = 1$ - not sure: $n = 1$ - doesn't apply: $n = 15$ - n. a.: $n = 1$	- directly experienced: $n = 1$ - witnessed: $n = 7$ - learned about it: $n = 15$ - part of job: $n = 4$ - not sure: $n = 2$ - doesn't apply: $n = 18$ - n. a.: $n = 0$	$X^2(5, 71) = 5.089$, $p = .405$
Serious injury, harm, or death caused to someone else	- directly experienced: $n = 4$ - witnessed: $n = 0$ - learned about it: $n = 1$ - part of job: $n = 2$ - not sure: $n = 1$ - doesn't apply: $n = 16$ - n. a.: $n = 1$	- directly experienced: $n = 5$ - witnessed: $n = 0$ - learned about it: $n = 0$ - part of job: $n = 0$ - not sure: $n = 1$ - doesn't apply: $n = 41$ - n. a.: $n = 0$	$X^2(5, 71) = 7.402$, $p = .116$
Any other very stressful event or experience	- directly experienced: $n = 14$ - witnessed: $n = 0$ - learned about it: $n = 0$ - part of job: $n = 3$ - not sure: $n = 2$ - doesn't apply: $n = 4$ - n. a.: $n = 2$	- directly experienced: $n = 14$ - witnessed: $n = 2$ - learned about it: $n = 1$ - part of job: $n = 2$ - not sure: $n = 5$ - doesn't apply: $n = 21$ - n. a.: $n = 2$	$X^2(5, 68) = 9.972$, $p = .076$

Note: n. a. = not available.

The PTSD group showed a mean CAPS-5 sum score of 42.52 (SD = 11.62; range: 21 - 62), whereas that of the non-PTSD group was significantly lower at 7.79 (SD = 10.94; range: 0 – 42) ($U(N_{PTSD}$ = 25, $N_{non-PTSD}$ = 47) = 31.5, z = -6.650, p < 0.001). The groups did not significantly differ in age ($U(N_{PTSD}$ = 24, $N_{non-PTSD}$ = 47) = 496.5, z = -0.821, p = 0.411), number of people living in their households ($U(N_{PTSD}$ = 23, $N_{non-PTSD}$ = 45) = 478.0, z = -0.528, p = 0. 598), number of children ($U(N_{PTSD}$ = 24, $N_{non-PTSD}$ = 47) = 513.5, z = -0.639, p = 0.523), number of international assignments ($U(N_{PTSD}$ = 24, $N_{non-PTSD}$ = 47) = 505.0, z = -0.735, p = 0.462), or length of international assignments ($U(N_{PTSD}$ = 20, $N_{non-PTSD}$ = 45) = 432.5, z = -0.249, p = 0.803). However, net income was significantly lower in the PTSD group than the non-PTSD group (p = 0.003). As shown in Table 1, the groups did not differ significantly regarding other demographic variables. However, as illustrated in Table 2, the PTSD group showed significantly higher rates of mental disorders than the non-PTSD group.

Measures
CAPS-5
The PTSD diagnosis and symptom severity were assessed with the German translation of the CAPS-5 (86). The CAPS-5 is a structured clinical diagnostic interview for the assessment of PTSD based on the criteria of DSM-5 (4). The original version of CAPS-5 shows good psychometric properties with an internal consistency (Cronbach's α) of α = 0.88 and good convergent validity with the CAPS-4 severity score with r = 0.83. The CAPS-5 also shows high correlations with self-rated scales that measure PTSD symptoms according to DSM-5 (r = 0.66) (87). The German version is currently being validated (88).

Difficulties in Emotion Regulation Scale (DERS)
The DERS was used to evaluate the severity of deficits in ER (89). The scale has 36 items with a five-point Likert scale ranging from 1 = "almost never" to 5 = "almost always" (the total score ranges from 36 to 180, with higher scores indicating more difficulties in ER). This self-rated questionnaire assesses six factors of ER strategies: "nonacceptance", "goals", "impulse", "awareness", "strategies", and "clarity". The DERS shows high internal consistencies for the subscales with α = 0.82 - 0.92 and an overall internal consistency of α = 0.95 (89, 90).

Acceptance and Action Questionnaire – II (AAQ-II)
The AAQ-II (91) measures the construct of psychological flexibility. Psychological flexibility is defined as a superordinate construct consisting of avoidance, acceptance, cognitive defusion, and mindfulness. Items are rated on a seven-point scale from 0 = "never true" to 7 = "always true". A higher score reflects lower psychological flexibility (91). The original version has good internal consistency with α = 0.84 and test-retest reliability with r_{tt} between 0.81 (3 months) and 0.79 (12 months) (91). For the German version of the AAQ-II, excellent internal consistency of α = 0.97 was found in a student sample, and good internal consistency was found in a clinical sample with α = 0.84 (92).

Moral Injury Event Scale (MIES)
The MIES (28, 93) is a self-rated questionnaire that measures the burden of events that violate deeply rooted moral beliefs and values. Items are assessed on a six-point Likert scale (0 = "strongly agree" to 5 = "strongly disagree"). It has nine items in total, which are split between two factors: "perceived transgressions by self or others" (six

items) and "perceived betrayals by others, inside or outside the military" (three items) (93). The internal consistency of the German version was α = 0.82 for the first subscale and α = 0.78 for the second subscale (28).

The Post-traumatic Cognitions Inventory (PTCI)
The PTCI (94) is used to identify dysfunctional cognitions that play a key role in the development and persistence of PTSD. This self-rated questionnaire consists of 33 items that are answered on a seven-point Likert scale from 1= "totally disagree" to 7 = "totally agree" (range: 33 to 231). The three subscales are "negative cognitions about the world", "negative cognitions about oneself", and "self-blame", which show good internal consistency values of α = 0.86 - 0.97 and an overall consistency of α = 0.97 (94).

White Bear Suppression Inventory (WBSI)
The WBSI focuses on the experience of uncontrollable and recurring thoughts, as well as the desire and attempt to suppress these thoughts through avoidance and distraction. The original version has shown good internal consistency with Cronbach's α = 0.87 - 0.89 in five different samples (95). It also has high test-retest reliability (r_{tt} = 0.86; interval between 5 days and 5 weeks) (95). The German version has a good internal consistency of α = 0.88 and a satisfactory test-retest correlation of r_{tt} = 0.78 after 3-6 weeks (96).

Satisfaction with Life Scale (SWLS)
The SWLS consists of 5 items and measures global cognitive judgments of one's life satisfaction as a whole. Items are rated on a seven-point Likert scale from 1 = "strongly agree" to 7 = "strongly disagree" (range 5 to 35). A higher score reflects a lower satisfaction with life (97). The internal consistency varies between studies in the range of α = 0.86 – 0.89 (97, 98).

Post-Traumatic Growth Inventory (PTGI)
The PTGI assesses post-traumatic growth reported by people who have experienced traumatic events (99). Post-traumatic growth is defined as how successful individuals cope with the aftermath of trauma and reconstruct or strengthen their perceptions of themselves, others, and the meaning of events. The PTGI uses 21 items with five subscales: "relating to others", "new possibilities", "personal strength", "spiritual change", and "appreciation of life". The answers are rated from 0 = "I did not experience this change as a result of my crisis" to 5 = "I experienced this change to a very great degree as a result of my crisis" (range: 0 – 105). A higher total score means that more post-traumatic growth has occurred. The internal consistency of the total score of the PTGI is α = 0.94 (100).

Crisis Support Scale (CSS)
Social support was determined by using the CSS (101). This self-rated questionnaire has 14 items, which are each rated on a 7-point Likert scale ranging from 1 = "never" to 7 = "always". The first six items were asked twice to measure crisis support directly following a traumatic event (T1) and at the present time (T2). The seventh item measures the satisfaction with overall crisis support at T1 and T2. The total score varies between 6 and 42 for each subscale, and a higher score indicates a higher level of support. The internal consistencies of the subscales are α = 0.67 - 0.75 at T1, α = 0.67 - 0.69 at T2, and α = 0.82 for the entire scale (101, 102).

Social Acknowledgement as a Victim or Survivor Questionnaire (SAQ)

The SAQ is a self-rated questionnaire that assesses social acknowledgement as a victim or survivor. The SAQ asks for the degree to which people feel validated and supported by their social environment following a traumatic event. It comprises 16 items in three subscales that are rated on a six-point Likert scale from 0 = "denial" to 5 = "agreement". The SAQ measures three factors of social acknowledgment: "recognition as a victim", "general disapproval", and "family disapproval". The internal consistency is α = 65 for the recognition subscale, α = 0.79 for the general disapproval subscale, α = 0.80 for the family disapproval subscale, and α = 0.75 for the SAQ sum score (79).

Statistical analysis

The data were analyzed using SPSS version 25.0 for macOS (103). Descriptive data are presented as frequencies (%), mean scores, and standard deviations. The Shapiro-Wilk test results showed that the data of all variables were not normally distributed except for the SAQ (p = 0.246), so methods for the analysis of non-parametric data were used. In the first step, associations of the severity of PTSD symptoms and clusters of PTSD symptoms (intrusions, avoidance, negative alterations in cognitions and mood, and hyperarousal measured with CAPS-5) with clinical measures were analyzed with the Spearman score correlation coefficient (r_s) for the whole sample (N = 72).

In the next step, differences between groups were analyzed using X^2 tests for nominal data and Mann-Whitney U-tests for non-parametric data. Eta-squared (η^2) was calculated as an effect-size estimator of the differences between mean scores in the Mann-Whitney U-tests. $\eta^2 \geq 0.01$ indicates a small effect, $\eta^2 \geq 0.06$ indicates a medium effect, and $\eta^2 \geq 0.14$ indicates a large effect. Due to the exploratory nature of the data analysis, no corrections for multiple comparisons were conducted regarding the between-group analyses.

This study pooled treatment-seeking GAF service members and GAF service members in the control group of the original RCT who were not seeking treatment. Subsequently, all GAF service members were allocated to a PTSD and non-PTSD group, and n = 14 GAF service members who were seeking treatment were allocated to the non-PTSD group because they did not fulfill the PTSD criteria according to the CAPS-5 (see Table 1). Thus, a sensitivity analysis was conducted without these 14 GAF service members (PTSD group: n = 25; 100% treatment seeker; non-PTSD group: n = 33; 0% treatment seekers).

Finally, to test our hypotheses, a mediation analysis was chosen with an empirical approach, and variables were selected according to the literature (104). The mediation analyses were performed using the PROCESS macro by Hayes, which uses ordinary least squares regression and yields unstandardized path coefficients for total, direct, and indirect effects (105).

Bootstrapping with 5000 samples together with heteroscedasticity consistent standard errors were used to compute the confidence intervals and inferential statistics (106). Effects were deemed significant when the confidence interval did not include zero (105). The relationship of all variables involved in the mediation analysis was linear according to the visual inspection of scatterplots after LOESS smoothing, and the residuals were normally distributed (105).

2.6.3 Results

The non-parametric correlation analyses showed that the severity of PTSD symptoms (measured with the CAPS-5 sum score) and all clusters of PTSD symptoms (intrusions, avoidance, negative alterations in cognitions and mood, and hyperarousal) were significantly associated with most of the measured constructs. Only PTGI showed no significant associations with the severity of PTSD symptoms and clusters of PTSD. The results of the correlation analyses showed associations between constructs in expectable directions. The severity of PTSD symptoms and the symptoms themselves showed significant positive associations with constructs measuring psychopathology. However, the correlation analyses with constructs measuring resilience and positive psychological constructs showed significant negative associations with the symptoms and their severity (see Table 4).

Table 4: Spearman rank-correlations between CAPS-5 sum score (B+C+D+E), CAPS-5 subscale scores, and criteria measures

	DERS	AAQ-II	SAQ	MIES	SWLS	CSS	PTCI	PTGI	WBSI
CAPS sum score	.863*** (n = 68)	.877*** (n = 70)	-.798*** (n = 66)	.455*** (n = 66)	.778*** (n = 70)	-.794*** (n = 69)	.867*** (n = 68)	.022 (n = 67)	.834*** (n = 70)
CAPS-B	.799*** (n = 68)	.822*** (n = 70)	-.745*** (n = 66)	.400** (n = 66)	.719*** (n = 70)	-.736*** (n = 69)	.791*** (n = 68)	.033 (n = 67)	.756*** (n = 70)
CAPS-C	.822*** (n = 68)	.803*** (n = 70)	-.752*** (n = 66)	.389** (n = 66)	.756*** (n = 70)	-.733*** (n = 69)	.801*** (n = 68)	.005 (n = 67)	.834*** (n = 70)
CAPS-D	.836*** (n = 68)	.842*** (n = 70)	-.755*** (n = 66)	.474** (n = 66)	.793*** (n = 70)	-.759*** (n = 69)	.868*** (n = 68)	-.056 (n = 67)	.794*** (n = 70)
CAPS-E	.834*** (n = 68)	.853*** (n = 70)	-.753*** (n = 66)	.422** (n = 66)	.749*** (n = 70)	-.779*** (n = 69)	.812*** (n = 68)	-.003 (n = 67)	.799*** (n = 70)

Note: CAPS = Clinician-Administered PTSD scale; CAPS-B = intrusions scubscale of the CAPS; CAPS-C = avoidance scubscale of the CAPS; CAPS-D = negative alterations in cognitions and mood scubscale of the CAPS; CAPS-E = hyperarousal scubscale of the CAPS; CSS = crisis support scale; DERS = difficulties in emotion regulation scale; AAQ-II = acceptance and action questionnaire – II; PTCI = posttraumatic cognitions questionnaire; PTGI = posttraumatic growth inventory; SAQ = social acknowledgement as a victim or survivor questionnaire; MIES = moral injury event scale; SWLS = satisfaction with life scale; WBSI = white bear suppression inventory; ** = $p < 0.01$; *** = $p < 0.001$.

Next, differences in mean scores of the measures between groups were analyzed. As illustrated in Table 5, the PTSD group showed significantly higher mean scores on questionnaires measuring factors that have been associated with the psychopathology of PTSD. However, this group showed significantly lower mean scores in social support (CSS) and social acknowledgement as a victim or survivor questionnaire (SAQ) than the non-PTSD group. In accordance with the correlation analysis, the groups did not

differ significantly in the mean scores of the PTGI. These analyses were repeated after the exclusion of $n = 14$ treatment-seeking GAF service members, and the results were in a comparable range with slightly larger effect sizes (see Table 6).

Table 5: Results of Mann-Whitney-U-Tests regarding differences of mean ranks of measured questionnaires between service members with PTSD ($n = 25$) and service members without PTSD ($n = 47$; including treatment seekers).

	Mean Rank		
	PTSD	*Non-PTSD*	*Statistics*
CAPS sum score	*Mdn* = 58.74	*Mdn* = 24.67	$U(N_{PTSD} = 25, N_{Non-PTSD} = 47) = 31.5$, $z = -6.65$, $p < .001$; $\eta^2 = .601$
DERS	*Mdn* = 53.73	*Mdn* = 24.01	$U(N_{PTSD} = 24, N_{Non-PTSD} = 44) = 66.5$, $z = -5.92$, $p < .001$; $\eta^2 = .516$
AAQ-II	*Mdn* = 54.63	*Mdn* = 25.52	$U(N_{PTSD} = 24, N_{Non-PTSD} = 46) = 93.0$, $z = -5.69$, $p < .001$; $\eta^2 = .461$
SAQ	*Mdn* = 16.70	*Mdn* = 42.49	$U(N_{PTSD} = 23, N_{Non-PTSD} = 43) = 108.0$, $z = -5.21$, $p < .001$; $\eta^2 = .410$
MIES	*Mdn* = 40.61	*Mdn* = 29.94	$U(N_{PTSD} = 22, N_{Non-PTSD} = 44) = 327.5$, $z = -2.13$, $p = .033$; $\eta^2 = .069$
SWLS	*Mdn* = 53.63	*Mdn* = 26.04	$U(N_{PTSD} = 24, N_{Non-PTSD} = 46) = 117.0$, $z = -5.39$, $p < .001$; $\eta^2 = .414$
CSS	*Mdn* = 28.04	*Mdn* = 38.48	$U(N_{PTSD} = 23, N_{Non-PTSD} = 46) = 369.0$, $z = -2.08$, $p = .037$; $\eta^2 = .060$
PTCI	*Mdn* = 52.04	*Mdn* = 24.93	$U(N_{PTSD} = 24, N_{Non-PTSD} = 44) = 107.0$, $z = -5.40$, $p < .001$; $\eta^2 = .429$
PTGI	*Mdn* = 32.28	*Mdn* = 34.90	$U(N_{PTSD} = 23, N_{Non-PTSD} = 44) = 466.5$, $z = -.52$, $p = .602$; $\eta^2 = .004$
WBSI	*Mdn* = 54.48	*Mdn* = 25.60	$U(N_{PTSD} = 24, N_{Non-PTSD} = 46) = 96.5$, $z = -5.64$, $p < .001$; $\eta^2 = .454$

Note: *Mdn* = median; PTSD = posttraumatic stress disorder; CAPS = Clinician-Administered PTSD scale; CSS = crisis support scale; DERS = difficulties in emotion regulation scale; AAQ-II = acceptance and action questionnaire – II; PTCI = posttraumatic cognitions questionnaire; PTGI = posttraumatic growth inventory; SAQ = social acknowledgement as a victim or survivor questionnaire; MIES = moral injury event scale; SWLS = satisfaction with life scale; WBSI = white bear suppression inventory; ** = $p < 0.01$; *** = $p < 0.001$.

Table 6: Results of Mann-Whitney-U-Tests regarding differences of mean ranks of measured questionnaires between service members with PTSD (n = 25) and service members without PTSD (n = 33; excluding treatment seekers).

	Mean Rank		Statistics
	PTSD	Non-PTSD	
CAPS sum score	Mdn = 46.00	Mdn = 17.00	$U(N_{PTSD} = 25, N_{Non-PTSD} = 33) = 0.0$, z = -6.62, $p < .001$; $\eta^2 = .723$
DERS	Mdn = 42.42	Mdn = 15.57	$U(N_{PTSD} = 24, N_{Non-PTSD} = 30) = 2.0$, z = -6.23, $p < .001$; $\eta^2 = .719$
AAQ-II	Mdn = 44.77	Mdn = 17.53	$U(N_{PTSD} = 24, N_{Non-PTSD} = 33) = 17.5$, z = -6.14, $p < .001$; $\eta^2 = .657$
SAQ	Mdn = 13.22	Mdn = 37.57	$U(N_{PTSD} = 23, N_{Non-PTSD} = 30) = 28.0$, z = -5.70, $p < .001$; $\eta^2 = .611$
MIES	Mdn = 34.43	Mdn = 20.68	$U(N_{PTSD} = 22, N_{Non-PTSD} = 30) = 155.5$, z = -3.24, $p = .001$; $\eta^2 = .201$
SWLS	Mdn = 43.54	Mdn = 17.22	$U(N_{PTSD} = 24, N_{Non-PTSD} = 32) = 23.0$, z = -5.99, $p < .001$; $\eta^2 = .638$
CSS	Mdn = 20.48	Mdn = 33.41	$U(N_{PTSD} = 23, N_{Non-PTSD} = 32) = 195.0$, z = -3.03, $p = .002$; $\eta^2 = .158$
PTCI	Mdn = 41.38	Mdn = 16.40	$U(N_{PTSD} = 24, N_{Non-PTSD} = 30) = 27.0$, z = -5.80, $p < .001$; $\eta^2 = .622$
PTGI	Mdn = 26.52	Mdn = 28.23	$U(N_{PTSD} = 23, N_{Non-PTSD} = 31) = 334.0$, z = -.39, $p = .694$; $\eta^2 = .003$
WBSI	Mdn = 44.71	Mdn = 17.58	$U(N_{PTSD} = 24, N_{Non-PTSD} = 33) = 19.0$, z = -6.10, $p < .001$; $\eta^2 = .651$

Note: *Mdn* = median; PTSD = posttraumatic stress disorder; CAPS = Clinician-Administered PTSD scale; CSS = crisis support scale; DERS = difficulties in emotion regulation scale; AAQ-II = acceptance and action questionnaire – II; PTCI = posttraumatic cognitions questionnaire; PTGI = posttraumatic growth inventory; SAQ = social acknowledgement as a victim or survivor questionnaire; MIES = moral injury event scale; SWLS = satisfaction with life scale; WBSI = white bear suppression inventory; ** = $p < 0.01$; *** = $p < 0.001$.

Finally, a simple analysis for parallel mediation was performed to determine whether there is a relationship between ER and PTSD (measured with CAPS subtotal score) and whether the direct path is mediated by MI (measured with the MIES), AA (measured with AAQ-II), and SA (measured by the SAQ). A relationship between ER and PTSD was observed (B = 21.764, $p < 0.001$). After entering the three mediators into the model, there was a significant relationship between ER and the mediator MI (B = 3.833, $p < 0.05$), which in turn was not associated significantly with PTSD (B = 0.1844, $p = 0.184$).

In contrast, there was a significant relationship between ER and the mediator AA, $B = 14.687$, $p < 0.001$, which in turn was significantly associated with PTSD ($B = 0.697$, $p = 0.001$). Additionally, there was a significant relationship between ER and the mediator SA ($B = -7.264$, $p < 0.001$), which in turn was significantly associated with PTSD ($B = -0.397$, $p = 0.05$). Finally, the results showed that the relationship between ER and PTSD is partially mediated by AA (indirect effect $ab = 10.238$, 95% CI [4.973, 16.300]] and by SA ($ab = 2.880$, 95% CI [-0.178, 5.306]], but not by MI ($ab = 0.707$, 95% CI [-0.551, 2.742]], with an indirect effect total; $ab = 13.825$, 95% CI [7.592, 21.037]]).

Figure 1: Mediation model (N = 72), with standardized beta weights and significant level for the relationship between ER and PTSD, mediated by SA, AA, and MI.
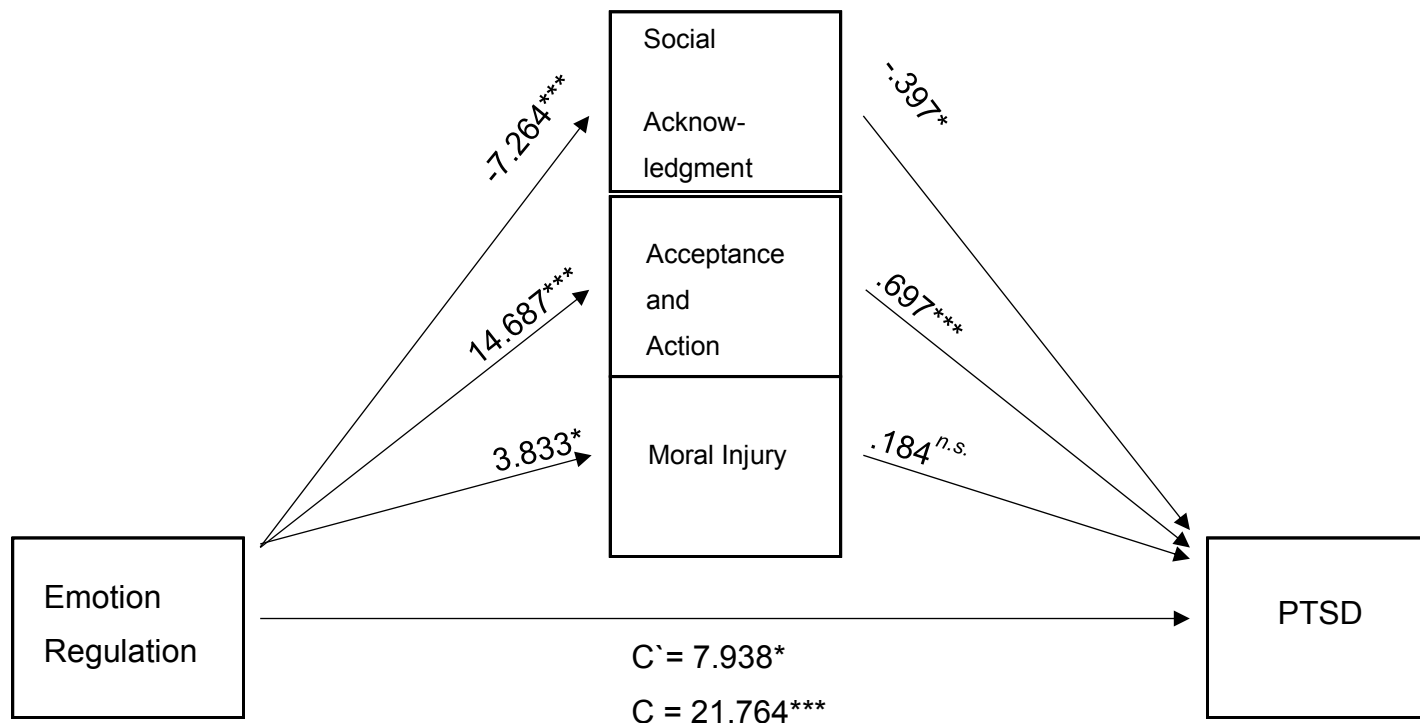
Note: 95 %-*CI* = 95 %-Confidence interval; Emotion Regulation measured by the DERS = Difficulties in Emotion Regulation Scale; Social Acknowledgment measured by the SAQ = Social Acknowledgement as a Victim or Survivor Questionnaire; Acceptance and Action measured by the AAQ-II = Acceptance and Action Questionnaire-II; Moral injury measured by the MIES = Moral Injury Event Scale; PTSD measured by the CAPS-5; *n.s.* = not significant; * = $p < .05$; ** = $p < 0.01$; *** = $p < 0.001$.

2.6.4 Discussion

The aim of the present study was to determine the relationship between ER and the severity of PTSD symptoms in GAF service members, as well as possible mediating factors. Firstly, nonparametric correlation analyses revealed significant associations of the severity of PTSD symptoms as well as PTSD symptoms themselves with most of the measured constructs. Given that dissociation and post-traumatic cognitions are part of the PTSD diagnosis, significant positive associations were expected between the PTCI with PTSD symptoms and their severity. The experience of reoccurring uncontrollable thoughts and attempts to suppress the trauma-associated thoughts as part of the PTSD symptomatology indicated a significant positive association between the WBSI and PTSD symptoms and their severity. Furthermore, the positive associations between PTSD symptoms and their severity were expectable due to the fact that PTSD has been repeatedly associated with hyperactivation of the hypothalamic-pituitary-adrenal axis (107, 108).

In line with previous research on veterans, MI (56, 60, 109) and difficulties with ER (34, 110, 111) also showed significant positive associations with PTSD symptoms and their severity in GAF service members. Furthermore, there were significant associations of PTSD symptoms and their severity in this sample with resilience factors that have repeatedly been associated with lower PTSD symptoms in veterans, such as higher social support (75, 76, 112), higher social acknowledgement as a victim or survivor (78-80), higher psychological flexibility (71, 113-115), and higher satisfaction with life (67, 68, 76). Interestingly, post-traumatic growth was significantly associated with neither PTSD symptoms nor their severity.

Studies show that younger age and higher extents of social support and SA are associated with higher scores of post-traumatic growth (116). Furthermore, social support was the best predictor for post-traumatic growth in a military sample (117). The current sample was middle-aged and reported a relatively low extent of SA. Furthermore, post-traumatic growth requires a traumatic event that is upsetting enough to cause a subsequent meaning-making of the event by the survivor (118). It is possible that this meaning-making process is absent in the current sample given the demographic variables, as well as the relatively low manifestation of social support and SA as a victim or survivor. This is also reflected by the relatively low manifestation of post-traumatic growth in the whole sample and subsamples. Thus, it is possible that the variability of post-traumatic growth was not pronounced enough to reveal significant associations.

In the next step, group differences between GAF service members with and without PTSD were investigated. The results of these analyses underpinned those of the correlation analyses, with the PTSD group showing significantly higher mean scores in all measures of psychopathology and significantly lower mean scores in all measures of resilience than the non-PTSD, except for post-traumatic growth. The PTSD and non-PTSD groups did not significantly differ in the mean score of post-traumatic growth. This analysis revealed that both groups had relatively low manifestations of post-traumatic growth.

Finally, a mediation analysis with multiple mediators was performed to analyze whether ER is associated with PTSD and whether MI, AA, and SA would mediate the direct path in parallel. The first step identified that difficulties in ER were significantly associated with the severity of PTSD symptoms. After entering the mediators into the model, the relationship between ER and PTSD was partially mediated by SA and AA,

but not by MI. The mediating effect of experimental avoidance is in line with previous findings, thus identifying it as an important target for therapeutic interventions and its potential closeness to ER (20, 53).

Of special interest is the mediating effect of SA because it is in line with previous findings in civilians and service members of other nations but conflicts with the findings of a longitudinal study on GAF service members deployed to Afghanistan within the ISAF mission (119). In this report, SA was shown not to have any effect on the occurrence of PTSD. Thus, the role of SA in GAF service members may be hidden in a mediation but still present. Additionally, the relationship between the mediators can be further investigated in this population, which would allow deeper insights since one previous longitudinal study found that experimental avoidance measured by the AAQ-II was a mediator between PTSD symptoms and social support (53).

The lack of mediation by MI might be explained by recent study results showing that MI and PTSD are two different pathologies that often occur together (29). MI and PTSD seem to differ in their underlying neurobiology (120). Additionally, MI appears definitely not to be fear-based in comparison to PTSD with different underlying theories (20, 23, 120). Research shows that difficulties in ER are generally associated with psychopathology (32, 50, 121-124). These results are in line with other studies on difficulties with ER in veteran samples. For instance, avoidance as a dysfunctional ER strategy was more often presented by veterans with PTSD than those without it (110). Veterans of operations Iraqi Freedom, Enduring Freedom, and New Dawn who were suffering from PTSD showed more use of expressive suppression and more difficulties with ER than veterans without PTSD (111). Furthermore, psychotherapeutic interventions focusing on ER in veterans were shown to be effective in reducing PTSD symptoms (125), and difficulties in ER were found to be a predictor of PTSD in veterans (31). Thus, the current results suggest that ER is also an important factor for further research and treatments of PTSD in GAF service members.

Implications

Considering the limitations of this study, the results should be interpreted with caution. However, keeping in mind the limited basis of research on GAF service members, the present results could be seen as an impetus for further research on the relationship between ER and PTSD. The demonstrated mediation of SA and AA allows for further hypothesis-driven research on the population of GAF soldiers. In particular, the role of MI in PTSD has to be investigated to determine whether it is a part of PTSD or whether both are distinct constructs. One recommended approach would be to assess all four constructs that were the focus of this study in further research to provide a broader basis of data.

Limitations and strengths

Several limitations of this study should be noted. First of all, the sample was relatively small, so it is possible that some results remained insignificant due to low power. Nonetheless, for testing mediation, the sample size ensured adequate power using the bootstrapping approach (126). Moreover, sum scores of the construct measurements were used due to the small sample size. Future studies should focus on subscales of measures, especially for ER, SA, AA, and MI. Finally, the sample comprised only males, so the results cannot be generalized to female GAF service members. Generally, the theory-driven approach of the mediation was necessary to check whether the idea of mediation is compatible with our data, but it does not necessarily mean that there is an actual mediation (127).

Nevertheless, the study also has some strengths. Constructs that have repeatedly been reported as having high interest for GAF service members were assessed and investigated in a mediation analysis. The theory-driven choice of constructs also enabled the assessment of a wide range of potential constructs that are associated with PTSD symptoms and their severity among GAF service members, thus leading to solid hypotheses. Finally, the examination of the symptoms and their severity was based on structured diagnostic interview data, whereas the PTSD diagnosis and symptom severity in other studies have often been based on self-rated questionnaires.

2.6.5 Conclusion

The results of the present study showed that difficulties in ER are associated with the severity of PTSD symptoms in GAF service members. This association is mediated by SA and AA, but not by MI. Thus, future studies should investigate these potentially crucial factors, including measures' subscales, for better understanding of the development and maintenance of PTSD in GAF service members after a deployment. Additionally, the role of MI as an individual construct in the association with PTSD should be further investigated in this population. The mediating effect between SA as a victim or survivor on the association of ER and PTSD is promising and requires further studies, especially for the population of GAF service members. The mediating effect of AA on the relationship between ER and PTSD is of special interest since it directly relates to already applied forms of therapy. Studies investigating an applicable use of therapy adaptions covering this effect are greatly encouraged.

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2.7 How to diagnose PTSD

An accurate diagnosis of PTSD is essential (128). Whether in the field of clinical work or in the field of clinical research or in other areas. This includes a precise determinability of the severity of the disorder (129). There are always different ways of diagnosing PTSD. Generally speaking, there are self-evaluating measures, interviews, and questionnaires. Measures can be used for screening or for accurate diagnosing or disorder-specific diagnosing. According to the German S3-guidelines for the treatment of PTSD the appropriate approach is to screen for potential diagnosis and then check further with self-report questionnaires and finally with a structured interview (130). This procedure is correspondent to the NICE guidelines (131). One example for a semi-structured screening interview is the Mini-DIPS, an example for semi-structured interview for the diagnosis of axis 1 disorders is the SKID-I (132-134). Specific PTSD self-evaluating instruments are e.g. the Post-traumatic Diagnosis scale (PDS), the PTSD Checklist (PCL-5) including the Life Event Checklist (LEC), providing a good overview, the Impact of Event Scale in the revised version (IES-R), the Harvard Trauma Questionnaire (HTQ-5), the Post-traumatic Cognitions Inventory (PTCI) and the Childhood Trauma Questionnaire (CTQ) ((85, 94, 135-138)). These measures are described in more detail in the following publication (88).

2.7.1 The Clinician Administered PTSD Scale

In the field of the structured interviews the Clinician Administered PTSD Scale (CAPS-5) is regarded as the gold standard for the diagnosis of PTSD (87, 139, 140). The CAPS was firstly designed in 1995 to assess PTSD thoroughly according to criteria of the DSM in the fourth version (141). The aim of the authors was to develop a structured interview for the diagnosis of PTSD as an aquivalent of the Hamilton Depression Scale for the diagnosis of depression (141, 142). Specifications for the new measure were the inclusion of a range of rating options in comparison to a dichotomy symptom presence, which allows the determination of severity both of a symptom and the diagnosis (141). Another specification for the emerging new PTSD measure was the possibility to describe frequency and intensity separately allowing a degree of detail not existent in PTSD evaluation (141, 143). Additionally, the new measurement should be comparable and conform with the existing diagnostic criteria and provide good psychometric properties (129). In the development of the further CAPS versions,

always adapted to the current DSM version, one aspect that changed, was the period of time measured, enabling to assess for a current status (CAPS-1) the previous week (CAPS-2), the previous month, a lifetime diagnosis, or the worst month, enabling a precise and distinguished application in clinical research and practice (141). Further advantages and strengths of the CAPS were and are the specification of basic questions and corresponding further questions, which allow an increasingly detailed answer and classification and a very differentiated gradation due to the 5-point Likert scales for each symptom (141, 143). Already in the first version the CAPS-1 showed very good psychometric properties (141). In a review focusing on the first ten years of CAPS research, Frank Weathers concluded:

> "The research evidence indicates that the CAPS has excellent reliability, yielding consistent scores across items, raters, and testing occasions. There is also strong evidence of validity: The CAPS has excellent convergent and discriminant validity, diagnostic utility, and sensitivity to clinical change" (Weathers et al., 2001, p. 1).

In 2013 the authors of the first version published the Caps-5 that was adapted to the DSM-5 (139). From DSM-IV to DSM-5 several changes were made regarding PTSD as described above. Consequently, the German version had to be adapted as well. Due to the diagnostic accuracy the CAPS-5 as its predecessor is regarded as the gold standard in PTSD diagnostic (87). The following publication focuses on the psychometric properties of the German CAPS-5 by looking at three subpopulations. In the following section the publication provides the details of the complete validation project.

2.8 Publication II

Psychometric properties of the German version of the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) in clinical routine settings: study design and protocol of a multitrait-multimethod study

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2.8.1 Strengths and limitations of this study

All diagnostic interviews will be conducted as face-to-face interviews with patients in their actual treatment settings

Interviewers will be blind to the results of former interviews, the results of the other assessments, and to a previously-assessed trauma index.

The study covers a broad range of psychometric properties such as test–retest and interrater reliability, convergent and divergent validity.

A sample encompassing both civilian and military participants will be included to ensure interpretability of the results in relation to both sample types and to allow generalization of the study's results.

Defining a trauma index as required by the CAPS-5 instruction can be very difficult for participants who have undergone multiple traumatic experiences

2.8.2 Background

The diagnosis of posttraumatic stress disorder (PTSD) was first introduced as a codable diagnosis in the third edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-III) (2), with extensive reporting during and after the Vietnam war a particularly strong driver for its inclusion. The inclusion of this diagnosis was intended to reduce the stigmatization of war-related psychological reactions, facilitate compensation claims, improve treatment, and to stimulate disorder-specific research (144-146). From DSM-III to DSM-IV (147), the PTSD diagnosis was classified as an anxiety disorder and consisted of a stressor criterion (criterion A) in addition to re-experiencing symptoms (criterion B), numbing and avoidance symptoms (criterion C), and hyperarousal symptoms (criterion D). A number of changes made in moving from DSM-IV to the fifth edition of the DSM (DSM-5) (11). First of all, PTSD is now part of the new category Trauma- and Stressor-Related Disorders. With regard to the stressor criteria, the experienced events must now be qualified as "traumatic", and the A2 criterion requiring a peritraumatic, subjective emotional response consisting of intense fear, helplessness, and/or horror was eliminated as a result of studies showing that such emotional reactions should be seen as risk factors rather than a diagnostic criterion (148-152). In DSM-5, sexual violence is now explicitly listed as potentially traumatic. Furthermore, besides directly experience of or witnessing an event, criterion A specifies that individuals can have been exposed to trauma via learning that it occurred to someone close to them or via repeated exposure to aversive details of a traumatic event. Additionally, in criterion A, a distinction between symptom onset and symptom exacerbation was added in order to highlight that the consequences of a trauma are not limited to symptom onset only (153).

Due to an increasing amount of research based on cognitive theories (21, 23, 154) and the fact that the DSM-IV three-factor model lacked robust empirical evidence, the symptom clusters were adapted and an additional cluster was added, reflecting the finding across the literature that four-factor models of PTSD symptoms consistently fit better and are unaffected by measure or sample type (12, 155). This four-factor structure was based on the four-factor emotional numbing model (156, 157), which was the first model to confirm the difference between avoidance and numbing. Consequently, the three symptom clusters of the DSM-IV entitled "re-experiencing", "avoidance and numbing", and "hyperarousal" were reformulated in the DSM-5 criteria into the clusters "re-experiencing" (criterion B), "avoidance" (criterion C), "negative alterations in cognitions and mood" (criterion D), and "alterations in arousal and reactivity" (criterion E). The DSM-IV cluster "avoidance and numbing" was split in DSM-5 into "avoidance" and "negative alterations in cognition and mood", and the former DSM-IV cluster "hyperarousal" was renamed "alterations in arousal and reactivity".

In addition to the changes and reformulations of the PTSD criteria, the total number of symptoms increased from of 17 in DSM-IV (153) to 20 in DSM-5 (158). Two new specific symptoms were added to the new criterion D ("negative alterations in cognitions and mood"): (1) "persistent distorted blame of self or others about the traumatic event(s)" and (2) "persistent negative emotional state". Following the redefinition of criterion E ("hyperarousal cluster") as "alterations in arousal and reactivity", one new item "reckless or self-destructive behavior" was added, and the focus of the anger criterion was exclusively shifted to behavioral aspects (11). Due to these changes in the diagnostic criteria, diagnostic instruments have had to be adapted accordingly.

Due to the changes made in PTSD diagnostic criteria from DSM-IV to DSM-5, several adaptions were made to the CAPS. First of all, the new DSM-5-based version of the CAPS (CAPS-5) (139) reflects all adaptions of diagnostic criteria from DSM-5 (i.e., omission of criterion A2, reformulations between and within criteria B–E, and inclusion of new symptoms) (159). Furthermore, the CAPS-5 scoring was simplified with regard to the intensity and frequency ratings. That is, both ratings can be converted into a severity scale. This severity scale is used as the basic scoring rule in CAPS-5 for each symptom (159). The CAPS has traditionally been translated into several languages (140). For each translated version, an investigation of psychometric properties is required, and the comparability of all versions should be tested to ensure robust CAPS-based clinical and scientific results.

Therefore, the aim of this study is to investigate the diagnostic accuracy, psychometric properties, and clinical applicability of the German version of CAPS-5 (160) under different routine clinical conditions. Furthermore, studies investigating the psychometric properties of the CAPS where often carried out in specific samples like veterans (159, 161, 162), or combined samples with different types of traumatic experience (163-165). However, investigations regarding the differentiation between specific traumatized samples are rare. Accordingly, this study also aims to investigate the diagnostic accuracy of the CAPS-5 between and within specific traumatized samples (persons with multiple-traumatization and PTSD, persons with mono-traumatization and PTSD, and traumatized persons without PTSD).

2.8.3 Methods and analysis
Participants, eligibility, and procedure
As this study aims to test the applicability of the CAPS-5 in a broad German sample, traumatized civilian participants in addition to traumatized active German Armed Forces (GAF) soldiers and veterans will be recruited in both inpatient and outpatient units and in daily clinical routine settings.

To be included in this study, (1) participants have to be adults (≥18 years; all genders), (2) who have experienced at least one traumatic event according to the DSM-5-A-criterion. This criterion requires experiencing an event that comprises threatened death, serious injury, or sexual violation. The traumatic situation can occur to the person herself/himself, can be witnessed by the person, can be occurred to a close family member or friend of the person, or can include a repeated or extreme exposure to aversive details of a traumatic event (for more details, see (11)). Furthermore, (3) the traumatic event(s) must have occurred more than a month before the application of the CAPS-5. There is only one exclusion criterion, i.e., an insufficient knowledge of the German language, in order to ensure both the feasibility of the interview and the validity of the patients' answers.

Participants will be interviewed at the very beginning of their treatment in order to reduce potential therapy-related effects on participants' answers. The results of the diagnostic assessment will be communicated to the participant's responsible therapist if the participant agrees to this.

Recruitment
Participants will be recruited from the outpatient therapy center of the Mental Health and Research Center (Forschungs- und Behandlungszentrum für psychische Gesundheit [FBZ]) at Ruhr-Universität Bochum, the inpatient and outpatient clinic of the Department of Psychosomatic Medicine and Psychotherapy of the LWL Universitaetsklinikum Bochum at the Ruhr-Universität Bochum, the outpatient therapy center of the university ambulance for psychotherapy at the University of Cologne (Hochschulambulanz für Psychotherapie Universität Köln [HAPUK]), and the inpatient and outpatient clinic of the German Armed Forces Center for Military Mental Health (Psychotraumazentrum Bundeswehrkrankenhaus Berlin). Advertisements for the study will be placed in all participating therapy facilities, and potential participants will also be identified by the clinicians at each facility. Patients who report traumatic events during admission to the respective in- or outpatient unit will be asked to participate in the study. Study participation is voluntary and participants will not receive any financial reimbursement.

Study design
This study is a non-interventional, multitrait-multimethod-design multicenter study. Participants will be categorized into one of three groups, depending on their traumatic experience(s) and posttraumatic symptomatology: (1) mono-traumatization (i.e. a single traumatic event) with PTSD; (2) multiple traumatization (i.e. multiple traumatic events) with PTSD; or (3) traumatization without PTSD.

After enrolling in the study, participants will take part in two additional assessments. During each assessment, participants will be asked to fill out a questionnaire battery and take part in a CAPS-5 interview. During the first assessment, a German diagnostic short interview (Diagnostisches Kurzinterview bei psychischen Störungen - Open Access (Mini-DIPS-OA); 133) will be administered in order to identify any potential comorbid diagnoses. For a detailed schedule of the study, see Figure 1.

All diagnostic interviews (CAPS-5 and Mini-DIPS-OA) will be audiotaped for post-hoc randomly-conducted quality checks of the interviews, and for the calculation of interrater reliability. The two interviews with each patient will be conducted by two different interviewers, and interviewers will be blind with respect to the results of the first interview and patient group. After completing all measurements, all patients will be reviewed in case conferences in order to check the quality of the interviews and the integrity of the ratings. All interviewers involved in the study and trained interviewers not involved in the study will participate in these case conferences. Potential errors regarding the application of the CAPS-5 interview and the scoring rules of the CAPS-5 will be documented on case conference sheets and will be subjected to internal discussion and correction if necessary. The final consensus ratings of all symptoms as well as PTSD overall symptom severity will be used for final analyses.

Figure 1: Study procedure of the inclusion and repeated measurement of participants.

T0 (subsequently to the admission to the care unit):
-   Identification
-   handing over study information
-   informed consent
-   inclusion

within the first week of treatment

T1:
•   Questionnaire battery
•   Life-Events-Checklist-5 (standard self-report)

Interviewer 1:
•   Mini-DIPS -OA

Interviewer 2:
•   CAPS-5 (last month version)

one week after T1

T2:
•   Questionnaire battery
•   Life-Events-Checklist-5 (standard self-report)

Interviewer 3:
•   CAPS-5 (last month version)

Assessment of traumatic life events and diagnostic interviews
Life Events Checklist (LEC)

For this study, the Life Events Checklist-5 (LEC-5; 85) has been translated into German (166). The LEC-5 is available in three different versions: (1) the standard self-report version; (2) the extended self-report version; and (3) the interview version. The standard self-report version lists 17 difficult or stressful life events (e.g., fire, assault with a weapon, sexual assault, or any other type of a highly distressing event or experience), and asks whether these events have ever happened to the participant, or if she/he witnessed, heard of them, or was exposed to them as part of her/his job. Furthermore, participants are also able to indicate if they are uncertain whether or not a specific event happened to them, or that the event definitely did not happen to them. The extended self-report version additionally includes a non-specific item, item no. 17 (any other very stressful event or experience), which asks for a brief description of the worst event and when it happened. Participants are able to name their traumatic experience in their own words. Further, the extended self-report version asks for more details of the worst event (e.g., whether someone's life was in danger or whether sexual violence was involved, and how many times similar events have occurred). In contrast to the other two versions, the LEC-5 interview version is conducted by an interviewer, who also asks for biographic information about the participant's family background, such as the participant's parents' educational principles and the parents' emotional handling of the participant. Afterwards, the 17 potential difficult or stressful events of the LEC-5 are assessed in an interview.

In the present study, the standard self-report version will be used to identify potentially traumatic events, because interviewers will be encouraged to explore the index trauma in more detail with the first question of the CAPS-5 interview and ensure that all interviewers are blind to the results of former interviews. However, all CAPS-5-interviewers will receive the LEC-5 for an overview of all experienced difficult or stressful events.

Clinician-Administered PTSD Scale for DSM-5 (CAPS-5)

Versions of the CAPS-5. The clinician-administered PTSD scale (CAPS-5) is available in three versions: (1) last month version; (2) last week version; and (3) worst month version (139). The last month version is the standard version that can be used to assess a current PTSD diagnosis in addition to PTSD symptom severity. The past week version assesses PTSD symptoms over a period of one week and can be used as a diagnostic tool in order to evaluate treatment progress. However, it cannot be used to establish a PTSD diagnosis. The worst month version can be used to establish a lifetime diagnosis of PTSD (159). In the present study, the last month version of the CAPS-5 will be used.

Administration of the interview. As a first step, the CAPS-5 assesses criterion A of the PTSD diagnosis according to the DSM-5. The traumatic events are then specified and categorized according to the kind of exposure (experienced, witnessed, learned about, exposed to aversive details) in CAPS-5. Here, patients are asked to report their experiences in their own words. Subsequently, each DSM-5 symptom of PTSD is evaluated separately and in the order of the DSM-5 section. The interview is then continued using the exact words of the CAPS-5 instructions with the following exceptions: (1) the interviewer should use the exact words of the patient to describe / speak of the traumatic event, the same is true for the description of specific symptoms; (2) questions can be reformulated if specific information is already known; (3) if the

questions do not produce sufficient information interviewers can use their own words to specify the questions; and (4) if necessary, examples can be obtained. Generally, there should be no comments made by interviewers that include suggestions for answers. In general, the interview should be conducted efficiently and smoothly using the minimal amount of questions in order to both keep the stress for the interviewee at a low level and to allow for a valid rating to be obtained. Also, note-taking should be reduced to obtaining only essential information in order to reduce delay, and the interviewer should remain respectful, yet purposeful, throughout the interview and focus on the traumatic events.

Scoring. As with the previous CAPS versions, the CAPS-5 scoring system is based on symptom frequency and intensity ratings. Intensity is rated on a four-point ordinal-scale. The rating scale should not be mentioned to the interviewee, as it is merely an orientation for the interviewer. For the frequency rating, either the frequency itself or the amount of time is used (e.g., "at least twice per month" or "some of the time (20-30%)"). For the CAPS-5, each item is rated with a single severity score in contrast to previous versions in which two ratings were combined into one severity rating (159). For the single severity rating, information about frequency and intensity is combined (e.g., moderate severity rating = "at least twice per month" and "distress clearly present, less than one hour sleep loss"). The severity rating scale consists of five points: (1) absent; (2) mild/subthreshold; (3) moderate/threshold; (4) severely/significantly elevated; and (5) extreme/incapacitating. There is a distinction between intensity and severity; nevertheless, both are related. Intensity is defined as the strength of a present symptom, whereas severity defines the total symptom load over a certain time period, and is a combination of intensity and frequency (159). Severity rating should only be made if both minimum frequency (e.g., "at least twice per month" or "some of the time (20-30%") and intensity (e.g., "distress clearly present…" or "reduction of positive emotional experience clearly present…") criteria are fulfilled. In cases of deviations in frequency and intensity, raters should use their clinical judgement. Each symptom needs to be related to the traumatic index event. For the remaining items, a trauma-related inquiry and rating scale is used, consisting of three ratings: (1) definite; (2) probable; (3) or unlikely, whereby a trauma-related rating of unlikely should not be used for the severity score or a PTSD diagnosis (159). For the CAPS-5 total symptom severity score, all item severity scores are summed after excluding the two dissociation severity scores. For the CAPS-5 symptom cluster severity scores, the severity score of each criterion is constructed by summing the corresponding items. Finally, the PTSD diagnostic status is defined by checking each DSM-5 criterion and dichotomizing the CAPS-5 criteria according to the scoring rules (absence: < 2; presence: $\geq$ 2).

After the interview section, interviewers have to make three global ratings regarding (1) the global validity, (2) the global severity, and (3) the global improvement. Each global rating is evaluated on a specific dimensional five-point Likert-scale.

Psychometric properties. In the first evaluation of CAPS-5 psychometrics in a military veteran sample, the CAPS-5 diagnosis showed strong inter-rater reliability (Cohen's kappa [K] = 0.78–1.00, depending on the scoring rule), strong test-retest reliability (K = 0.83), and high concordance with CAPS-IV (K = 0.84) (159). The CAPS-5 total severity score showed high internal consistency (α = 0.88) and inter-rater reliability (ICC = 0.91), good test-retest reliability (intraclass correlations [ICC] = 0.78), and high agreement with CAPS-IV severity score (r = 0.83) (159). Versions in other languages have also shown comparable indicators for very good psychometric properties (164,

165). In conclusion, CAPS-5 appears to be a solid measure for PTSD diagnosis and symptom severity (159).

Translation-backtranslation procedure. The CAPS-5 interview was translated into German following a translation–backtranslation procedure. One author translated the interview into German and the other author translated this German version back into English. This back-translated English version was checked by members of the National Center for Posttraumatic Stress Disorder. Potential translational inconsistencies or contradictions were then clarified via e-mail and adaptions were done if required. The finalized German version was then authorized by the National Center for Posttraumatic Stress Disorder (July 23, 2015).

Diagnostisches Kurzinterview bei psychischen Störungen Open Access (Mini-DIPS-OA).
The Mini-DIPS-OA (133, 134) is a short version of the Diagnostisches Interview bei psychischen Störungen Open Access (167). As a short semi-structured clinician-administered diagnostic interview, the Mini-DIPS-OA can be used to assess the most common disorders in daily clinical practice, such as anxiety disorders, depressive disorders, bipolar disorders, obsessive-compulsive disorders and related disorders. Furthermore, trauma- and stress-related disorders, eating disorders, somatic symptom and related disorders, substance-related and addictive disorders, and sleep-wake disorders can be diagnosed according to DSM-5, in addition to impulse-control problems, psychotic and sexual dysfunction symptoms, and suicidal tendencies.
Investigations of the psychometric properties of the DSM-IV version of the interview revealed good congruities between raters (on upper class levels of disorders [such as anxiety disorders]: 91%–100%; on the disorder level: 88%–100%), with moderate to perfect Cohen's kappa coefficients (0.76–1.0), and Yule's Y coefficient of colligation (–0.84–1.0) in upper class levels within disorders and on disorders level (Cohen's kappa: 0.67–1.0; Yule's Y: 0.73–1.0) (133). Additionally, the validity of the mini-DIPS has been confirmed by cross-validation with the validated long version of the interview (132-134, 167, 168).

Primary outcome measure
PTSD Checklist for DSM-5 (PCL-5).
The German version of the PTSD checklist (PCL-5) (161) will be used (169) as a primary outcome measure for the purpose of examining convergent validity. The PCL-5 is a self-report questionnaire to assess posttraumatic symptoms within the last month with respect to a traumatic event. It contains 20 item and each item reflects one of the 20 DSM-5 PTSD criteria. Participants report the intensity of each symptom on a five-point Likert-scale ranging from 0 (= "not at all") to 4 (= "extremely"). An overall PTSD symptom severity (ranging from 0 to 80) and a severity of each symptom cluster (ranges: intrusions = 0–20, avoidance = 0–8, negative alterations in cognition and mood = 0–28, hyperarousal = 0–24) can be generated. Scorings of ≥ 2 (= "moderately") indicate that a symptom is present according to the levels specified in the DSM-5. Studies investigating the psychometric properties of the English PCL-5 version have revealed strong convergent and discriminant validity, very good sensitivity and specificity, and high test–retest reliability (r_{tt} ≥ 0.82) (137, 161), an excellent internal consistency for PCL-5 total score (α ≥ 0.91) (137, 138, 161, 170), and acceptable to excellent internal consistencies for the symptom cluster scores (intrusions: α ≥ 0.80; avoidance: α ≥ 0.81, negative alterations in cognition and mood: α ≥ 0.82, hyperarousal: α ≥ 0.75) (138, 170). Furthermore, confirmatory factor analyses have

revealed a good model fit for the assumed DSM-5 model of PTSD, although a previously reported 7-factor hybrid model (171) revealed the best model fit (137, 138, 161, 170). Equivalently, good to excellent psychometric properties have also been reported for the French (170), German (169), Swedish (172), and Shona (173) versions. The overall PTSD symptom severity can be used to administer a cut-off score. The cut-off score for indicating clinically relevant PTSD symptom severity has consistently ranged between 31 and 33 for the PCL-5 scale (161, 169, 170, 172, 173), whereas for the German version a cut-off score of ≥ 33 is recommended (169).

Hypotheses. We expect significant positive associations between PCL-5 and both CAPS-5 total and symptom cluster scores. Additionally, we expect that patients who receive a PTSD diagnosis according to CAPS-5 will also exceed the cut-off score of ≥ 33 on the PCL-5 (area under the curve [AUC] ≥ 0.80). Furthermore, we expect significant differences in the mean PCL-5 sum score and subscales between the three groups (PCL-5 sum scores: multiple-traumatization > mono-traumatization > traumatized without PTSD).

Secondary outcome measures for assessing concurrent validity
Impact of Event Scale – revised (IES-R).
The German version of the Impact of Event Scale – Revised (IES-R) self-rating questionnaire (174, 175) will be used (176) as a secondary outcome measure to examine convergent validity. The IES-R is a well-established measure in the context of trauma that has been repeatedly used as an external criterion measure for PTSD-related measures. The IES-R is based on the DSM-IV PTSD criteria and consists of three subscales with a total of 2 items: (1) intrusions (eight items); (2) avoidance (eight items); and hyperarousal (six items), which show relatively high intercorrelations (136). The IES-R assesses the patient's distress per item within the past week on a five-point Likert-scale (0 = "not at all" to 4 = "extremely"). Studies with the English version revealed good scale construct validity (135, 136), adequate to excellent internal consistencies (total score: $\alpha \geq 0.90$; intrusions: $\alpha \geq 0.87$; avoidance: $\alpha \geq 0.84$; hyperarousal: $\alpha \geq 0.79$) (135, 136, 174, 177), and high test-retest reliability after six months ($r_{tt} \geq 0.89$) (174). As a cutoff score with good diagnostic accuracy, a score of 1.5 is recommended (136). However, some methodological issues also diminish the quality of the IES-R. Specificity and sensitivity are not within an optimal range for a diagnostic tool (135, 136). Furthermore, data concerning the factorial structure are inconsistent. On the one hand, mostly adequate model fit indices for a three-factor solution have been reported (135), but on the other hand, some studies report a questionable factorial structure of the three-factor solution and suggest one- or four-factor solutions (with an additional sleep factor) (136, 177). Another limitation is related to the invariance of the IES-R. Whereas its configural invariance has mostly been demonstrated, the metric invariance caused by variances in the intrusions factor over time has not been fully supported (177).
However, considering the comparability with results of other studies, we decided to include the IES-R as a secondary outcome measure. The German version of the IES-R has also revealed good construct validity and adequate to excellent internal consistencies with respect to two different samples (intrusions: $\alpha \geq 0.71$; avoidance: $\alpha \geq 0.79$; hyperarousal: $\alpha = 0.90$) (176). In addition to the original answering format related to distress, there is another format for the German version, asking about the frequency of symptoms in the past week (0 = "not at all", 1 = "infrequently", 3 "sometimes", 5 "frequently"). By using an evaluation formula (X = [–0.02 * intrusions] + [0.07 * avoidance] + [0.15 * hyperarousal] – 4.36), a cutoff score of > 0 indicates a

potential suspicion of PTSD (178). In the current study, both versions of the IES-R will be included.

Hypotheses. We expect significant positive associations between total scores from the IES-R and CAPS-5. Again, we expect that a significant proportion of patients diagnosed with PTSD according to CAPS-5 will also exceed the cut-off score of ≥ 1.5 (in the distress version) with the corresponding > 0 (in the frequency version) for the IES-R (AUC ≥ 0.80). Additionally, we expect significant differences of mean IES-R sum scores between groups (IES-R sum score: multiple-traumatization > mono-traumatization > traumatized without PTSD). Due to the questionable factor structure, the IES-R subscale scores will not be included in the analyses.

Beck Depression Inventory – revised (BDI-II)
In order to assess the severity of depressive symptoms, the German version of the Beck depression inventory (BDI-II) will be used [61.62]. The BDI-II consists of 21 items assessing depressive symptoms during the past two weeks. Anchors differ per items, however, for each item, patients are able to use a four-point Likert scale (0–3). BDI-II sum scores can be used to differ between no (0–8), minimal (9–13), mild (14–19), medium (20–28), and severe levels of depression (29–63). The English version of the BDI-II has shown good concurrent validity and diagnostic accuracy (179, 180) in addition to excellent internal consistency (α = 0.91) (181). The German version of the BDI-II has demonstrated good to excellent internal consistencies (α ≥ 0.84) in clinical and non-clinical samples and adequate concurrent validity (182, 183).

Hypotheses. Due to the inclusion of the new PTSD cluster "negative alterations in cognition and mood" and considering high comorbidity between PTSD and depression (184-188), we expect high correlations between the CAPS-5 total and the BDI-II sum score. In particular, we expect high correlations between the CAPS-5 score of the cluster "negative alterations in cognition and mood" and the BDI-II. Furthermore, significant differences in mean BDI-II sum scores between groups are expected (BDI-II sum score: multiple-traumatization > mono-traumatization > traumatized without PTSD).

State-Trait Anxiety Inventory (STAI)
The state-trait anxiety inventory (STAI) (189) is a self-report questionnaire that consists of two distinct scales measuring state and trait anxiety (STAI-S and STAI-T, respectively), with 20-items per scale. For both scales, participants are asked to rate each item on a four-point Likert-scale (STAI-S: 1 = "not at all" to 4 = "very much so"; STAI-T: 1 = "almost never" to 4 = "almost always"). The STAI-S asks for currently experienced anxiety, and the STAI-T asks how patients feel in general. The sum score of each scale lies between 20 to 80. For the present study, the German version of STAI-S and STAI-T will be used (190). The STAI-S shows excellent (α ≥ 0.90) and the STAI-T good to excellent (α ≥ 0.88) internal consistencies. Furthermore, both scales have shown good convergent and divergent validity, and norms for both sexes for different age classes based on German data have been reported.

Hypotheses. For the present study, we expect high correlations between the total CAPS-5 sum score and the STAI-S and STAI-T sum scores as well as significantly higher STAI-S and STAI-T sum scores for patients with PTSD compared to traumatized persons without PTSD (STAI-S/T sum score: multiple-traumatization = mono-traumatization > traumatized without PTSD).

Dissociative Experiences Scale – 20 items short version (DES-20)
The dissociative experiences scale (DES) is a 44-item questionnaire (191, 192) that was constructed to measure dissociative symptoms according to the DSM-IV and ICD-10 scales. Each item measures how often a dissociative situation occurred on a scale from 0% (= "never") to 100% (= "always"). The DES has shown very good psychometric properties: high test-retest-reliability ($r_{tt} \geq 0.79$) and split half reliability ($r \geq 0.83$), excellent internal consistency ($\alpha \geq 0.93$), and good construct validity (193). However, the factor structure and temporal stability of the DES have been reported as problematic. Thus, a short version with 20 items (DES-20) was constructed to address these problems. In the present study, the German version of the DES-20 (193) will be used. This version presents excellent internal consistency ($\alpha = 0.93$), relatively high temporal stability, and good divergent and convergent validity. Additionally, the DES-20 significantly discriminates between patients with borderline personality disorder and patients with PTSD from patients with other mental disorders (193). However, it cannot be used to differentiate patients with borderline personality disorder from patients with PTSD (193).

Hypotheses. For the present study, we expect significantly higher DES-20 sum scores for patients with PTSD as compared to traumatized persons without PTSD (DES-20 sum score: multiple-traumatization = mono-traumatization > traumatized without PTSD). Additionally, we expect higher DES-20 sum scores amongst patients with PTSD with a dissociative subtype according to DSM-5 compared to patients with PTSD without a dissociative subtype (DES-20 sum score: PTSD with dissociation > PTSD without dissociation).

Questionnaire of Thoughts and Feelings (QTF)
The questionnaire of thoughts and feelings (QTF) is a German questionnaire "Fragebogen zu Gefühlen und Gedanken" (FGG) that was developed on the basis of the cognitive concepts of personality disorders, and especially the bio-social model of borderline personality disorder (194, 195). The QTF is a self-rating questionnaire and consists of 34 items that describe typical borderline-specific statements regarding thoughts and feelings. Items are rated on a five-point Likert-scale (1 = "do not agree at all" to 5 = "I agree completely"). Item analysis has revealed overall satisfactory to good values, and analyses of psychometric properties have revealed good sensitivity to change, good internal consistency ($\alpha = 0.89$), and good test-retest reliability ($r_{tt} = 0.81$) in addition to good construct validity measured via self-rating questionnaires and a semi-structured diagnostic interview (194, 195). In the present CAPS-5 study, the short version of the QTF (14 items) will be used, which also has good to excellent psychometric properties (195).

Hypotheses. With respect to results of the present study, we expect significantly higher sum scores on the QTF for participants with multiple-traumatization compared to both other groups, but no significant differences between mono-traumatized PTSD patients and traumatized participants without PTSD (QTF sum score: multiple-traumatization > mono-traumatization = traumatized without PTSD).

Screening zur komplexen Posttraumatischen Belastungsstörung (SkPTBS).
The "screening zur komplexen Posttraumatischen Belastungsstörung" (SkPTBS) (196) is a German self-rating questionnaire for the screening of complex PTSD (cPTSD) according to the eleventh edition of the International Classification of Diseases (ICD-

11) (197, 198). The questionnaire consists of three parts (199). In part one, patients are asked if they have ever personally experienced or witnessed one of the eleven listed potentially traumatizing events. The list is divided into two parts; on the left side, six non-interpersonal traumatic events are listed (such as a serious accident, natural disaster, or a work-related traumatic event), whereas the right side lists five interpersonal traumatic events (such as emotional abuse, sexual assault, or torture). Additionally, patients are able to name another event in case it is not listed, or to state that they have not experienced any of the listed events. Subsequently, patients who have experienced more than one event are instructed to circle the most distressing event. Part two assesses risk and resilience factors regarding the selected event. First, the age of patients when experiencing the event, the frequency of the experience (once, twice, three times, 4–5 times, or more often), the duration of the event (not prolonged, over _ months, over _ years), and who caused the event (a stranger, a family member or better known person, force majeure, or illness) are asked. Next, patients are asked to rate on a seven-point Likert-scale (0 = "not at all" to 6 "fully correct") several sets of symptoms: whether (1) they were afraid for their life; (2) they received posttraumatic social support; and (3) the event now seems unreal, such as in a dream or a movie. Finally, part three uses 14 items on a seven-point Likert-scale (0 = "not at all" to 6 "fully correct") to assess the rate of personal experiences in everyday life as a consequence of the traumatic event (such as difficulty in trusting people, uncomfortable feelings when physically touched, or feeling ashamed of the events that happened).

The psychometric properties of the SkPTBS are good to excellent with item difficulties and discriminatory power within the requested range, good convergent, divergent and predictive validity, and an excellent internal consistency (α = 0.91) (199, 200). However, the questionnaire can only be used to assess the risk of having a CPTSD diagnosis, not to diagnose the disorder (200).

The evaluation of the SkPTBS will be carried out in four steps (199, 200). For the first step, for each interpersonal traumatic event (right side of the first part) a score of 10 (except for sexual violence, which is scored with 50) is given, regardless of whether the event happened to the patient or the patient witnessed the event. All scores are then summed up to a sum score A, which can range from 0 to 90. Next, the sum score B is determined by summing up the answers of items 4 to 14 of part three of the questionnaire, in which personal experiences in everyday life are assessed. The sum score B is calculated independently of missing values within these items. Thus, a possible sum score B could range from 0 to 66. Finally, the SkPTBS sum score is calculated using the following formula: sum score SkPTBS = sum score A + 2 * sum score B.

For the evaluation and interpretation of the questionnaire, the authors will provide an sheet that automatically evaluates the raw data, supports the interpretation, and provides norms (201). A SkPTBS score can be interpreted: (1) very low risk of CPTSD: SkPTBS score = 0–2.20; (2) low risk of CPTSD: SkPTBS score = 2.21–5.07; (3) high risk of CPTSD: 5.08–28.18; and (4) very high risk of CPTSD: SkPTBS score ≥ 28.19.

Hypotheses. For the present study, we expect a significantly higher SkPTBS score for PTSD patients with multiple-traumatization compared to mono-traumatized PTSD patients and traumatized controls and a significantly higher SkPTBS score for PTSD patients with mono-traumatization compared to traumatized controls (SkPTBS score: multiple-traumatization > mono-traumatization > traumatized without PTSD).

Symptom-Checklist-90-Revised (SCL-90-R) – Global Severity Index (GSI). The symptom-checklist-90-revised (SCL-90-R) – global severity index (SCL-90-R) (202) is a self-report questionnaire assessing various psychological symptoms. In this study, the German version (203) will be used. In order to determine the concurrent validity of the CAPS-5, the GSI score will be used. The GSI reflects the overall distress caused by psychological symptoms during the past week and is calculated by summing up the scores of all 90 items of the SCL-90-R and dividing them by 90. Items are coded on a five-point Likert scale (0 = "not at all" to 4 = "extremely"). The internal consistency of the GSI is good to excellent ($\alpha \geq 0.89$) for the original version (204, 205) and excellent ($\alpha \geq 0.96$) for the German version of the SCL-90-R (203).

Hypotheses. Based on study results regarding associations between the GSI and trauma-associated symptoms, which show that complex traumatized patients present the highest GSI scores (200), we expect high correlations between the total CAPS-5 sum score and the GSI and significant differences of mean GSI scores between groups (SCL-90-R GSI: multiple-traumatization > mono-traumatization > traumatized without PTSD).

Secondary outcome measures for assessing for testing divergent validity
Symptom-Checklist-90-Revised (SCL-90-R) – subscales
Six of the nine subscales of the SCL-90-R (202, 203) will be used to determine the divergent validity: (1) somatization (SOM); (2) obsession-compulsion (OBS); (3) interpersonal sensitivity (INT); (4) phobic anxiety (PHO); (5) paranoid ideation (PAR); and (6) psychoticism (PSY). Due to former study results regarding the identification of PTSD patients by using SCL-90-R items, several items will be excluded for the calculation of the sum scores of the subscales and the analyses for the divergent validity of CAPS-5: (1) item 3 (OBS); (2) item 43 (PAR); (3) item 50 (PHO); (4) item 55 (OBS); (5) item 70 (PHOB); and (6) item 90 (PSY). However, the number of excluded items lies under the threshold of the maximally tolerated missing items for each subscale (203). Internal consistencies for the subscales range from questionable for the PSY subscale ($\alpha \geq 0.69$), acceptable for the PAR subscale ($\alpha \geq 0.72$), and good for the subscales SOM, OBS, INT, and PHO ($\alpha \geq 0.81$) (204, 205). The test–retest reliability of the SCL-90-R is high after one week of therapy ($r_{tt} \geq 0.80$), and the construct validity is good (205). The German version of the SCL-90-R has shown acceptable to good internal consistencies with respect to the six selected subscales in clinical samples ($\alpha \geq 0.75$) and also good parameters regarding its construct validity (203).

Hypotheses. We expect no or at most small correlations between the CAPS-5 total sum score and the six subscales of the SCL-90-R, and no significant differences in mean scores of the six subscales between groups (SCL-90-R sum scores: multiple-traumatization = mono-traumatization = traumatized without PTSD).

Patient Acceptance Questionnaire (PAQ)
The patient acceptance questionnaire (PAQ) is a questionnaire that was developed to assess the satisfaction of patients when undergoing a structured diagnostic interview (206). PAQ items were constructed based on theories and research concerning factors that are of high importance for the therapeutic relationship (206). The questionnaire consists of two factors measuring the mental effort of patients during the interview, and emotional reactions during the interview. For the present study, the PAQ was slightly modified. The overall satisfaction rating scale was dropped, and patients will be able

to make their response to the ten items (see 206) on a five-point Likert scale (0 = "completely disagree" to 4 = "completely agree"). Furthermore, three items were added to assess patients' evaluation of the therapeutic relationship during prior therapeutic settings (1. "I did not feel taken seriously", 2. "I had the feeling of receiving too little attention", and 3. "I had the feeling that no doctor/therapist is interested in me as a human being"). For the present study, the PAQ will be used to investigate the feasibility of the CAPS-5.

Hypotheses. We expect a medium to high satisfaction of patients with the CAPS-5 interview, yet no significant differences in satisfaction between groups are expected (PAQ sum scores: multiple-traumatization = mono-traumatization = traumatized without PTSD).

Interviewer Acceptance Questionnaire (IAQ)
The interviewer acceptance questionnaire (IAQ) was developed to assess the interviewers' satisfaction with the structured diagnostic interview in the interview situation itself. The IAC consist of four items and assess whether interviewers (1) rate the interview as helpful, (2) the interview can be useful to organize patient's problems, (3) the questions of the interview are useful to justice to the patient's problems, and (4) the interview pushed the patient to the limits of her/his resilience (reversed coded). Each item is rated on a five-point Likert scale (0 = "completely disagree" to 4 = "completely agree").

Hypotheses. We expect a medium to high satisfaction of the interviewers with the CAPS-5 interview. However, we expect a significantly higher IAQ score when assessing mono-traumatized PTSD patients and traumatized controls, compared with PTSD patients with multiple-traumatizations (IAQ score: mono-traumatization = traumatized without PTSD > multiple-traumatization)."

Balanced Inventory of Desirable Responding (BIDR)
The balanced inventory of desirable responding (BIDR) is a questionnaire for assessing socially desirable responses (207, 208). It assesses two factors of socially desirable responses: (1) self-deceptive enhancement and (2) impression management. For the present study, the German version of the BIDR, which has shown to be a valid questionnaire with acceptable psychometric properties, will be used (209).

Hypotheses. For the present study, we assume that there is no significantly increased tendency for socially desirable response for none of the groups (BIDR sum scores: multiple-traumatization = mono-traumatization = traumatized without PTSD).

Training of interviewers
Similar to the training procedure for the DIPS interviews (133, 134, 167), all interviewers will have to undergo a standardized training procedure. This training procedure consists of six phases: (1) The diagnostic-phase: In this phase, interviewers are trained in the correct administration of the DSM-5 criteria of the PTSD and PTSD subtypes. This step includes a theoretical introduction and illustrations based on case reports; (2) The introduction-phase: interviewers are trained in the correct administration and evaluation of the CAPS-5 interview. Additionally, they are trained how to deal with typical problematic situations that can arise during the CAPS-5 interview; (3) The monitoring-phase: In this phase, interviewers take part in at least two

interviews that are conducted by a trained interviewer; (4) The exercise-phase: interviewers train to conduct the interview with familiar, non-diagnosed persons; (5) The coding-phase: At least two audiotaped CAPS-5 interviews, which were conducted by a trained interviewer, are rated by the trainees. The conclusions of these ratings have to be in accordance with the rating of the trained interviewer. Ratings are in accordance if they agree with respect to the primary diagnosis (including subtypes), and if the symptom ratings do not significantly differ ($\pm$1 on the rating scale); and (6) The certification-phase: In this last phase, interviewers have to conduct at least two interviews with patients and their ratings have to be in accordance with a trained interviewer as defined in the coding-phase. Additionally, the interviewers have to conduct interviews without making severe administrative errors. Administrative errors consist of the several violations: (1) inadequately introducing the interview to the patient; (2) marked aberration from the questions of the interview; (3) inadequate requests to clarify the diagnosis; (4) describing the numeric severity ratings for describing symptoms to the patients; and (5) excessive comments or questions unrelated to the interview.

Interviewers applying the CAPS should be graduated clinical psychologists, or should have completed their training as a psychiatrist, or should be in the last phase of their master's degree in clinical psychology.

Patient and public involvement
No patient involvement.

Statistical analyses
Characteristics of the study sample will be described separately for all three groups using frequencies, means, and standard deviations. Potential group differences will be tested by using X^2 tests for categorical variables, Mann-Whitney-U-tests for ordinally and not normally-distributed data, and t-tests for normally distributed data.

The aim of the present study is to investigate the psychometric properties of the German CAPS-5 and its diagnostic accuracy in daily clinical routine. First of all, an item analyses (*M*, *SD*, skewness, kurtosis, range) for all CAPS-5 items will be applied to all three groups. The test–retest reliability will be assessed by conducting intraclass correlations analyses between the CAPS-5 interviews at T1 and T2 (one week after T1). The interrater reliability will be analyzed by calculating Cohen's kappa coefficients between the actual assessment of CAPS-5 at T1 and the independent rating of the audio record of the interview at T1. In order to test the internal consistency of the CAPS-5 and its subscales, SEM-based internal consistency (McDonald's omega: 93–95) will be calculated. Construct validity, consisting of divergent and convergent validity, will be measured with Spearman's rank correlation analyses and a multivariate analyses of variance (MANOVA) with Holm-Bonferroni corrected post-hoc ANOVAs with *a priori* contrasts. In order to test the diagnostic accuracy (true-positive [TP], true-negative [TN], false-positive [FP], and false-negative [FN]) of the German CAPS-5, the PCL-5 score will be used as external criterion. Based on these results of the diagnostic accuracy, the sensitivity and specificity in addition to the receiver operating characteristics (ROC) and the sensitivity, specificity, *AUC*, positive likelihood ratio (the ratio of TP versus FP test results), and negative likelihood ratio (the ratio of TN to FN test results) will also be calculated. The CAPS-5 was constructed as a structured diagnostic interview to assess whether patients fulfill the DSM-5 criteria of PTSD. Accordingly, each item represents a specific PTSD criterion. Thus, by using a confirmatory factor analysis with Satorra-Bentler correction (210, 211), the convergent validity of the German CAPS-5 can and will be analyzed. Finally, network analyses will

be used to investigate the associative strength between the different PTSD symptoms as assessed with the CAPS-5.

Power calculation
G*Power (version 3.1.9.3 for MacOS) (212-214) was used to determine a sufficient sample size for a multivariate analysis of variance (MANOVA) with three groups: (1) PTSD patients with mono-traumatization; (2) PTSD patients with multiple-traumatization; and (3) traumatized controls without PTSD and 23 dependent variables (primary and secondary outcome measures) by using an α of 0.05, a power of 0.80, and a small effect size (f = 0.10) (212). This calculation resulted in a total sample size of at least n = 168. However, due to dropouts (e.g., due to incomplete interviews) and missing data, a rate of 30% of uncompleted data sets is expected, implying that an additional n = 51 participants will be tested in order to ensure a minimal sample size of n = 73 participants per group with a total sample size of N = 219 participants.

2.8.4 Discussion
The present study protocol describes the methods and the design of a non-interventional, multitrait-multimethods design multicenter study that aims to investigate the diagnostic accuracy, psychometric properties, and feasibility of the German version of the CAPS-5 interview. The study will be carried out under routine clinical conditions and will include participants with different types and numbers of traumatic experiences to examine the feasibility of the CAPS-5 for diagnosing PTSD and PTSD symptom severity (215). In clinical research and daily practice, the use of structured diagnostic interviews is highly recommended for the assessment of mental disorders, because they ensure a systematic assessment of symptoms combined with clinicians' expert knowledge (216-223). For the assessment of PTSD, the Clinician-Administered PTSD Scale (CAPS) (141) is considered the diagnostic gold-standard (161, 173, 224, 225), and its use is recommended by PTSD guidelines (226). The CAPS was designed to represent a standard in terms of an interview-based diagnostic measure of PTSD (140, 141). It was created as a structured diagnostic interview based on the DSM criteria of PTSD, and given its excellent psychometric properties it became universally accepted for PTSD diagnosis in both research and practice (153). Further, CAPS users are able to evaluate the interview according to different scoring rules, enabling more liberal evaluations for daily clinical practice or more conservative evaluations for research (162). The DSM-IV version of the CAPS consistently exhibited good to excellent psychometric properties (140, 141, 143, 156, 227), with good diagnostic utility and good sensitivity to clinical change (140). Given the importance of the CAPS-5 for research and treatment, it is essential to scrutinize its diagnostic accuracy, psychometric properties, and clinical utility under clinical routine conditions using a broad and heterogeneous sample. Based on these results, the German CAPS-5 can contribute to individualized planning of treatments and adequate evaluation of therapy efficacy. However, studies such as the current one have several strengths and limitations.

Strengths of the study
One strength of the study is that all interviews will be conducted as face-to-face interviews with patients in their actual treatment settings. Additionally, the detailed training and ongoing supervision of interviewers in this study should be highlighted. Thus, high quality of the interviews will be ensured. Another important strength of this study is that all interviewers will be blind to the results of former interviews, the results of the other assessments, and to a previously-assessed trauma index. This helps to

strengthen the results of this study. Furthermore, the study covers a broad range of psychometric properties such as test–retest and interrater reliability, convergent and divergent validity. Additionally, a sample encompassing both civilian and military participants will be included to ensure interpretability of the results in relation to both sample types and to allow generalization of the study's results. Patients' acceptance of the CAPS-5 interview will be evaluated. Inclusion of participants who experienced mono- and multiple traumatization in addition to participants who experienced different kinds of traumatic events (such as motor accident, sexual abuse, or combat actions) is another strength of the study and allows us to compare our samples with other samples and to generalize the results. Former studies have mostly focused on homogeneous study samples (e.g., veterans or motor accident victims), and thus it is questionable whether the results of these studies can be generalized to other samples (e.g., sexual assault victims). Finally, this study will also investigate aspects such as socially desirable response patterns in the form of self-deceptive enhancement and impression management, which are rarely investigated in relation to diagnostic interviews.

Challenges and limitations
However, in addition to its strengths, this study also has several potential limitations and challenges. First, defining a trauma index as required by the CAPS-5 instruction can be very difficult for participants who have undergone multiple traumatic experiences. Especially when these events occurred several years or decades ago, the answers' validity could be affected by a variety of influencing factors (such as former treatment, avoidance behavior, or time factors). Furthermore, results of previous studies have shown that summarizing several traumatic events as one trauma index leads to significantly higher symptom severity ratings (228) . This, in turn could potentially bias the results in relation to the validity of the interview. Additionally, the fact that participants will have to report stressful, stigmatizing, and shameful events to strangers could potentially lead to an increased dropout rate. This could be worsened by the fact that three different interviewers will interview each participant and thus, events have to be reported three times. Another challenge might be the different arrangements of interviewer teams with different genders. It could potentially be difficult for some participants to talk to either male interviewers (such as women after a sexual assault) or female interviewers (such as men with abasement experiences). These difficulties could potentially have an influence on the answers' validity. Furthermore, given the naturalistic design of the study, participants will show different types of comorbidity. Thus, it might be possible that the results regarding psychometric properties may be affected by symptoms of other disorders (such as personality disorders or severe major depressive disorders). Finally, it may be possible that the final composition of the sample could lead to issues regarding some of the planned statistical analyses (such as network analyses) due to high heterogeneity or high rates of dropouts.

Ethics and dissemination
Ethical considerations
The study received ethical approval by the Ethics Committees of the Faculty of Psychology at the Ruhr-Universität Bochum (reference numbers: 331 and 358). The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008. Furthermore, this study will follow the principles of good scientific practice. The study

participation is entirely voluntary. All participants will be informed about the aims, the procedure, the data collection, and the dissemination plans of the study and will be asked to give their written informed consent. Participants may withdraw the participation at any moment without any negative consequences.

Dissemination plan
The results of the study will be presented nationally and internationally at scientific conferences and will be published in scientific journals.

Availability of data and material
The datasets used and/or analyzed during the current study will be available from the corresponding author on request.

List of abbreviations
BDI-II – Beck Depression Inventory – Revised
BIDR – Balanced Inventory of Desirable Responding
CAPS – Clinician-Administered PTSD Scale
cPTSD – complex Posttraumatic Stress Disorder
DES – Dissociative Experience Scale
DSM – Diagnostic and Statistical Manual of mental disorders
FGG – Fragebogen zu Gedanken und Gefühlen
GSI – Global Severity Index
IAQ –Interviewer Acceptance Questionnaire
ICD - International Classification of Diseases
IES-R – Impact of Event Scale – Revised
INT – Interpersonal sensitivity subscale of the Symptom-Checklist-90-Revised
IM – Impression management subscale of the Balanced Inventory of Desirable Responding
Mini-DIPS-OA – Diagnostisches Kurzinterview bei psychischen Störungen – Open Access
OBS – Obsession-compulsion subscale of the Symptom-Checklist-90-Revised
PAQ –Patient Acceptance Questionnaire
PAR – Paranoid ideation subscale of the Symptom-Checklist-90-Revised
PCL-5 – PTSD Checklist for Diagnostic and Statistical Manual of Mental Disorders-Fifth Edition
PHO – Phobic anxiety subscale of the Symptom-Checklist-90-Revised
PSWQ – Penn State Worry Questionnaire
PSY – Psychoticism subscale of the Symptom-Checklist-90-Revised
PTSD – Posttraumatic Stress Disorder
SCL-90-R – Symptom-Checklist-90-Revised
SDE – Self deceptive enhancement subscale of the Balanced Inventory of Desirable Responding
SkPTBS – Screening zur komplexen Posttraumatischen Belastungsstörung
SOM – Somatization subscale of the Symptom-Checklist-90-Revised
STAI-S – State-Trait-Anxiety-Inventory State
STAI-T – State-Trait-Anxiety-Inventory Trait

Declarations
Consent for publication. All authors have agreed to authorship. All participants agreed to the publication of pseudonymized data.
Competing interests. The authors declare that they have no competing interests.

Planning and conceptualization of this study started in March 2015, and the recruitment of participants began in December 2016. Shortly before the planned enrolment of the first civil study patient, the authors decided to additionally involve a military subsample. Due to the already implemented recruitment procedures in the in- and outpatient units and to avoid a delayed recruitment, the study started with civil participants before the ethics agreement of the military units was given. This resulted in a retrospective study registration and delayed formulation of this study protocol.

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2.9 Treatment of PTSD

According to the German S3-guidelines (130), as well as in the NICE guidelines (131) for the treatment of PTSD, the recommendation is clear. Each patient should be informed about the effectiveness of the trauma-confrontational procedures and each patient should be offered treatment with some form of trauma-confrontational procedure. This includes all described procedures in the sections above, since all approaches share as basis some form of confrontation with the traumatic event and a focus on either avoidance or appraisal, etc. Current methods for which evidence is sufficiently or fully confirmed include prolonged exposure according to Foa, trauma-confrontational cognitive therapy according to Ehlers and Clark, EMDR according to Shapiro, CPT, IRRT, IRT and NET. Due to the low level of evidence for their efficacy, medications should only be prescribed at the explicit request of the patient after informed consent (130). According to the available evidence, there is only one contraindication for trauma-confrontative treatment. In the case of dissociative identity disorder, integration of the dissociation-induced identities is indicated before confrontation (130, 229). In all other comorbid disorders, trauma confrontation is the first step of treatment. If patients are prone to increased use of avoidance strategies or it proves necessary due to the complexity of PTSD, it may be necessary to teach and practice emotion regulation strategies before trauma confrontation (229). However, teaching emotion regulation strategies must not be confused with the application of stabilization, a technique which has been suggested repeatedly in the German-speaking countries (230). However, there is no evidence for the necessity of stabilization therapy before or even replacing trauma-confrontational treatment (229, 230). Indeed, the evidence is unambiguous and even suicidal patients show no increase with regard to their suicidal impulses and cognitions when trauma confrontation is applied lege artis (229). In other countries, such as the United Kingdom, Australia or the United States, stabilization therapy is not implemented (231-233).

2.10 Treatment availability and Online-Therapy

As is the case in the treatment of other mental disorders, treatment of PTSD may have to face certain hurdles in terms of treatment availability in an outpatient setting (234).

First, a person needs to realize that they suffer from a condition in need of treatment, followed by finding a professional able to give the correct diagnosis of PTSD. In addition, a qualified and available therapist has to be found. In Germany and other countries, not all licensed therapists offer PTSD treatment. Even fewer have participated in additional PTSD treatment training which comes with a special qualification[1]. Having found a therapist, that is capable, qualified, and likeable, this therapist has to offer appointments in the spare time of the client, i.e., not during working hours or during care time for children or other duties. If the traumatic event happened during working hours, it may count as a work-related accident. In this case the employer should be informed and the special employees' insurance may cover the costs in favor of the personal insurance responsible for events happening in the spare-time. In other nations the costs of a therapy come on top due to different insurance systems. In many cases trauma-confrontative therapy challenges client's commitment.

2.10.1 Online treatment of PTSD

Online therapy is on the rise. Gradually, evidence is published for the efficacy and effectiveness of different online treatment concepts targeting several disorders. Especially for online treatment of major depression efficacy has been shown (235, 236). However, evidence for the efficacy of online treatment for PTSD remains unclear and ambiguous (234). Internet-based Cognitive Behavioral Therapy (i-CBT) and Expressive Writing (EW) both were shown to be superior to passive control conditions but neither of them was equal to or superior to active control conditions (237). Especially more details have to be investigated, such as a specification of interventions and techniques (at this point one has to keep in mind the necessity of a traumaconfrontative approach), the possible side effects, the therapeutic relationship, the advantages and disadvantages, shortly, all details that allow a reliable judgement (234).

2.10.2 PTSD treatment for German Armed Forces service members

For GAF service members and former service members there is a standard procedure in case a member is afflicted by PTSD. For former service members the origins of the

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[1] This additional qualification is specific for the German speaking countries (Spezielle Psychotraumatologie für Erwachsene der Deutschen Gesellschaft für Psychotraumatologie)

disorder must be deemed a service related injury. The first person to see for GAF service members is the military physician in case of any kind of health problem. The military physician screens for major problems and refers accordingly to specialists if necessary. As soon as a case is reported by a military physician, an inpatient admission in a GAF hospital is scheduled. (238). During this stay of several weeks, a comprehensive diagnosis is carried out. In the GAF hospital In Berlin the CAPS-5 is part of the standard procedure providing a reliable PTSD diagnosis. In the case of a PTSD diagnosis, further action is planned together with the affected person. This usually includes a block-by-block inpatient treatment targeting the disorder as well as supportive or curative outpatient psychotherapy, which can be performed by a civilian state-licensed psychotherapist. The costs of the outpatient psychotherapy are covered by the GAF on the basis of a contract between the German Ministry of Defense and the Federal Chamber of Psychotherapists. A major advantage for the service members is, that this contract also applies to private practices and thus the affected persons may find an outpatient therapist faster than if only insured through statutory health insurance. One potential disadvantage is that some civillian psychotherapists prefer to not treat soldiers or war traumas, either because they do not have experience in this field or fear being confronted themselves with narratives of war atrocities. Others may have political reasons or ethical convictions not to provide psychotherapy to soldiers. Finally, some psychotherapists principally opt to not offer trauma therapy. On the other hand, service members report that they prefer psychotherapists with at least basal knowledge of the GAF and of deployment situations and are familiar with service member vocabulary. Also, sometimes service members prefer male psychotherapists and only about 30% of Psychotherapists in Germany are men (239).

2.10.3 Potential treatment barriers in international service members

An often-reported finding is potential stigmatization related to impaired mental health by the unit or superiors in case of psychotherapeutic needs (240, 241). Stigmatization would be accompanied by various negative consequences, such as a worse standing in the unit or even negative effects on career opportunities. However, one Canadian study found that risk of stigma related to mental health had no influence on self-reported psychotherapy seeking intentions (242). Nonetheless, negative attitudes about mental health treatment, the mental health care system or psychotherapy in

particular predicts aversion and less utilization of mental health treatment (241-244). Structural problems, in contrast, such as living in isolation, result in the use of mental health treatment being more likely (242).

Regarding these barriers and obstacles to treatment, one can assume, that online therapy could potentially overcome some of them. Structural problems like living in isolation or the need for treatment during working hours or on duty could also be overcome by the flexibility of online treatment. Stigmatization could be overcome by anonymous online treatments.

Based on these considerations, the following study, looking at the feasibility and evaluation of an internet-based intervention for GAF service members with deployment-related posttraumatic stress symptoms was conducted.

2.11 Publication III

Evaluation of an internet-based intervention for service members of the German armed forces with deployment-related posttraumatic stress symptoms

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2.11.1 Background

Posttraumatic stress disorder in military personnel

Posttraumatic stress disorder (PTSD) is a common dis- order, with a 12-month prevalence rate of 3.7% in the US general population [1] and 2.3% in the German general population, with the latter being in line with PTSD prevalence rates in other European countries [2]. Military personnel have an elevated risk of experiencing or being exposed to traumatic stressors such as threat to one's own person or colleagues [3] and witnessing suffering and death [4–7]. Point prevalence rates vary be- tween 2 and 17% for US veterans and 3 to 6% for British veterans after deployment, according to a systematic re- view [8]. A 12-month prevalence rate of 2.9% was found for combat-experienced service members of the German Armed Forces (Bundeswehr [9]). These varying prevalence rates might be explained by factors such as frequency and duration of deployments, but also by cross-national differences in military structures or in the openness to disclose sensitive information about PTSD symptoms [10–13]. Within the German Armed Forces, the risk of developing PTSD is increased in combat-experienced military personnel as compared to never-deployed military personnel [14], and only one in two service members with PTSD are diagnosed or treated [9]. Deployment-related PTSD is often accompanied by depression, anxiety, and substance misuse [4, 15], functional impairments [16], relationship difficulties [8], and poor quality of life [17]. If left untreated, it often follows a chronic course [6]. Moreover, military personnel with subthreshold PTSD are also at risk of worsening psycho- logical distress [18, 19].

Psychotherapeutic treatment for service members with PTSD

Given the significant impairment associated with subclinical and clinical levels of PTSD, access to efficacious interventions is important. International evidence-based guidelines recommend trauma-focused cognitive behavioral therapy (TF-CBT) and eye movement desensitization and reprocessing (EMDR) for the treatment of PTSD [20, 21]. For face- to-face TF-CBT compared to control groups a standardised mean difference of 1.62 was found in a comprehensive meta- analysis [22]. However, also according to meta-analytic evidence, military samples benefit less from such interventions than civilians, although TF-CBT still shows stronger effects than other psychotherapeutic approaches, with symptom re- ductions from pre- to post-test of g = 1.06 [23–28]. Moreover, between 60 and 75% of veterans with PTSD do not seek treatment [29–33], and among those who do, the number of attended sessions is usually low. Studies indicate that only 2–10% of veterans suffering from PTSD complete the treatment as intended [30, 34]. Reasons for not seeking treatment, dropping out, or not optimally benefitting include stigma, confidentiality concerns and perceived treatment inefficacy [10, 35–37]. Logistical and access barriers and concerns about potential negative effects of treatment-seeking on one's military career also influence treatment-seeking behavior [37, 38]. Face-to-face treatments require appointments in an outpatient clinic or a hospital for which patients often need to take time off from work. Studies demonstrated that fear of judgment and exclusion by comrades and the leadership as well as fear of negative consequences for the career due to psychotherapeutic treatment and psychiatric diagnoses are widespread among military personnel, and that confidentiality concerns play an important role in not seeking treatment or dropping out of it [10, 37, 39–42].

Taken together, low rates of treatment utilization, high dropout rates and lower efficacy of treatments in veterans highlight the need to optimize treatment for PTSD in military service members [26]. Service members might benefit from more flexible treatment options that protect their privacy. The low threshold and visual anonymity of internet-based treatments have the potential to reach specific populations that otherwise might not seek treatment, e. g. individuals with fear of judgment or stigmatization. Distance delivery approaches such as internet-based interventions provide access to evidence-based treatments such as TF-CBT [26], minimize treatment barriers and increase client confidentiality [43, 44], especially when participants do not have to meet a mental health care professional in person before starting an internet-based intervention. Participants can access the treatment in their own time and while staying in their personal environment, e.g. while being at home. In internet-based CBT (iCBT), evidence-based treatment protocols are delivered online, generally based on asynchronous written communication [45]. The content is usually not altered, deviating from face-to-face CBT only in the method of delivery [46]. Most notably, Lange and colleagues [47] developed a pioneering iCBT for trauma victims by combining a manual-based cognitive- behavioral writing therapy with the Internet (Interapy), but also other internet-based programs have taken a trauma-focused CBT approach. ICBT is easily accessible and privacy sensitive. It also aims at reducing healthcare expenditures [46]. Moreover, iCBT has been found to be acceptable and compatible with the establishment of a good therapeutic relationship in civilians [48, 49]. Therefore, iCBT can fill an important gap [32].

Efficacy of iCBT in military personnel

US veterans appear to be receptive to the use of mental health technologies [50, 51]. A preliminary study of a CBT-based online workshop (afterdeployment.org) supplemented with weekly telephone calls reported an effect size of d = 1.04 [52]. A study evaluating a mobile app intervention (PTSD coach) was perceived as helpful [53]. A meta-analysis revealed that iCBT for PTSD was more efficacious than waitlist (d = 0.95), although it was not found to be superior to active comparison interventions [54]. However, only one study included in the meta-analysis has been based on a military sample (DES- TRESS [55]). DESTRESS comprised six writing assignments focusing on cognitive restructuring and trauma exposure. Compared to an active control group, a small effect size of d = 0.41 at post-treatment emerged. The effect disappeared at the 3-month follow-up (d = 0.10) but was large at the 6-month follow-up (d = 0.95). The drop- out rate lay at 30% [55]. In a more recent trial, a modified version of DESTRESS without writing assessments but with homework and telephone support was compared to treatment as usual. Of the 491 primary care patients approached for study participation, about half (49%) refused [56]. Thirty-five percent of the participants completed the treatment. The effect size at post-treatment (d = 0.23) and at 12-week follow-up (d = 0.47) was small, and dis- appeared after 18 weeks (d = 0.08 [56]). Another recent study compared an iCBT program for veterans with PTSD, named "Vets Prevail", with treatment as usual [57]. Vets Prevail did not include trauma exposure and no writing assignments, but psychoeducation, media elements, individualized storylines, serious gaming principles and real-time chats with other veterans. It resulted in a small effect size at post-test, and the dropout rate lay at 20% (d = 0.42 [57]). To the best of our knowledge, these are all Randomized Controlled Trials (RCTs) on the efficacy of iCBT in military personnel that have been published to date.

To sum up, all studies compared iCBT to active control conditions, and the writing-based version of DES- TRESS as well as Vets Prevail yielded at least small effects. All studies were conducted in the US. As military structures and prevalence rates of PTSD differ cross- nationally, it is worthwhile to investigate the efficacy of iCBT for service members in military structures other than the US.

Treatment of PTSD in the German armed forces

The German Armed Forces provide treatment in military hospitals, and civilian psychotherapists are also involved in delivering treatment to military personnel [58]. However, treatment utilization rates are lower than the prevalence and incidence rates for German military personnel with PTSD, with less than 50% of traumatized service members seeking treatment within 12 months after deployment [9]. A number of treatments for PTSD offered by the German Armed Forces have demonstrated good efficacy. Non-trauma-focused inpatient group CBT showed medium efficacy from pre- to post-treatment (d = 0.68) and high efficacy to follow-up (d = 0.95 [59]). For in- patient EMDR, a medium pre-post effect size of d = 0.77 was found [60]. However, there is a need for comprehensive and low-threshold treatment within the German Armed Forces.

Objectives

The current study was a RCT designed to investigate the feasibility, acceptability and efficacy of iCBT in service members of the German Armed Forces. In view of the findings demonstrating the efficacy of iCBT, we adapted a trauma-focused, therapist-guided iCBT [61, 62] that was based on the treatment protocol of Interapy [47] and Integrative Testimonial Therapy (ITT [63]). Service members experiencing mild to severe posttraumatic dis- tress, but also with chronic courses, were suitable for inclusion. The iCBT was compared to a waitlist (WL) condition, and we expected a moderate reduction of posttraumatic stress symptoms. Anxiety was assessed as the secondary psychopathological outcome. We hypothesized that treatment effects would be sustained during the 3-month follow-up period. In accordance with previous findings, it was expected that participation rates would be lower than in civilian samples.

2.11.2 Methods

Sample   and   measures
Participants were deemed eligible for the current study if they met all of the following criteria: 1) male members of the German Armed Forces with clinical PTSD according to Diagnostic and Statistical Manual of Mental Disorders-5 (DSM-5) [64], or with subclinical symptoms, that is symptoms on one or more subscales of the CAPS without the overall number of symptoms for the clinical diagnosis. In addition, the person had to report suffering from these symptoms and report to be in need of treatment. 2) Minimum age of 18years (no restrictions on maximum age); 3) active or out-of-duty service members; 4) fluency in reading and writing in the German language; 5) ability to use computers without assistance and 6) regular access to the internet for the duration of the iCBT. Exclusion criteria were acute psychosis, acute manic episode, current substance abuse or dependence, current suicidal ideation, neurological disorder, acute somatic disease, concurrent psychotherapeutic treatment, or un- stable psychotropic medication. An eligibility telephone screening comprised the assessment

of the PTSD A criterion (traumatic event) and the PTSD Checklist for DSM-5 (PCL-5) [65], followed by the Mini International Neuropsychiatric Interview (M.I.N.I) sections for alcohol and substance abuse, psychotic symptoms, depressive and manic episode [66]. Suicidality was assessed with the respective Beck Depressions-Inventar-II (BDI-II) item (item 9 [67]). Finally, we asked whether the participant was in current psychotherapeutic or pharmacological treatment. At each diagnostic face- to-face assessment, symptom severity (primary outcome) and the presence of a diagnosis of PTSD were assessed by applying the German translation of the Clinician-Administered PTSD Scale for DSM-5, which has very good psychometric properties (CAPS-5 [68]). The CAPS-5 is an interview-based assessment of all PTSD domains. Each item is rated by a clinician on a 5-point scale ranging from 0 = not present to 4 = extreme, representing the severity of PTSD symptoms during the last month. The CAPS yields an overall score (range: 0 to 80) as well as subscale scores reflecting symptom severity in the PTSD core domains (Criterion B: Re-experiencing symptoms, max. Twenty points; Criterion C: Avoidance symptoms, max. Eight points; Criterion D: Negative alterations in cognitions and mood, max. Twenty-eight points; Criterion E: Alterations in arousal and reactivity, max. twenty-four points). Comorbid diagnoses were assessed with the Mini-International Neuropsychiatric Interview German Version 5.0, a structured clinician-administered diagnostic interview according to DSM-IV and ICD-10 (M.I.N.I [69]). Traumatic events were assessed at the first assessment with the Life Events Checklist for DSM-5 (LEC-5 [70, 71];), which assesses exposure to 16 selected types of potentially traumatic events (e.g., severe accident, severe physical injury) and provides the additional option to report any other potentially traumatic event. The List of the Mental Health Advisory Team (LMHAT [72]) was also used at the first assessment to assess 33 military- and deployment-related traumatic events. Sociodemographic information was also collected (e.g., age, relationship status, education, length of duty in the armed forces) at the first assessment, and medical re-cords and previous psychotherapeutic, pharmacological, and medical treatments were documented. The secondary outcome anxiety was measured at each assessment using the 7-item Generalized Anxiety Disorder scale (GAD-7, [73]). It assesses anxiety symptoms during the past 2 weeks and has good psychometric properties [74]. Moreover, participants completed a number of self-report questionnaires (e.g. about post- traumatic cognitions, posttraumatic growth, moral in- jury) at each assessment. The risk of suicide (measured by the BDI-II item number 9 [67]) was repeatedly assessed, that is before the first writing assignment as well as during the course of treatment, i.e. after the third (biography), seventh (exposure) and tenth (cognitive restructuring) writing session. After the treatment, patients were also asked about potential adverse events during the course of treatment. Adverse effects were assessed with the Negative Effects Questionnaire [75].

Procedure
The sample was recruited via advertisements in military journals, on websites and in online chat rooms for service members. Printed flyers and posters were distributed in health service centers and military hospitals of the German Armed Forces. Service members were also recruited by coordinating with unit commanders, who distributed flyers in post-deployment seminars. The study was presented at mental health conferences of the German Armed Forces to military psychologists and psychiatrists. Service members could contact the study team via email or telephone. An appointment was scheduled for a pre-consent eligibility screening in a telephone call by a licensed therapist (BM, JS). The telephone screening took about 45 min. If a participant was

found to be eligible in the screening, he was invited to the German Armed Forces Hospital Berlin for a full diagnostic assessment.

Participants were randomly assigned to the immediate treatment group (IT) or the waitlist control group (WL) before the first diagnostic assessment. Randomization was based on a computer-generated randomization list in excel. Written consent was obtained. Participation was voluntary and strictly confidential. Patients received no financial reward for their participation. All eligible active service members were released from their routine duty for the assessments, without knowledge of their seniors about participation in a treatment study. The diagnostic assessment was conducted by clinical psychologists (AK, SB, BM) or graduate Master's-level psychology students (HK, CKE, DW) who were especially trained in administering the CAPS-5 (CAPS-5 [68]) and the M.I.N.I. (M.I.N.I [69]). The assessors were not blinded. After the diagnostic interviews had been conducted the trauma event checklists were provided, which were administered on a computer screen. The pre-treatment assessment also included an introduction to the web- site's structure, and participants were provided with a login code and set a personal password. Post-treatment self-report questionnaires were assessed partly online and partly during the face-to-face post-assessment in the hospital 1 week after the end of the intervention. Assessments in the German Armed Forces Hospital Berlin were completed three (IT) to four (WL) times (pre-treatment, post-treatment, 3-month follow-up). The WL control group attended an additional pre-wait time assessment, followed 6 weeks later by the pre-treatment assessment. This waiting interval was chosen because of the treatment duration, which was 5 weeks, plus 1 week to consider also the days between the pre-treatment assessment and the start of the treatment as well as be- tween the end of the treatment and the post-treatment assessment. The assessments took 1 day and required overnight stays of participants with a longer travelling time to the German Armed Forces Hospital in Berlin. Therefore, the assessments were scheduled for either 1 or 2 days, depending on the arrival times of the participants on the first day. For a description of the comprehensive study design see Supplement 1. All participants received treatment within 1 week after the pre-treatment assessment. The post-treatment assessment was completed within 1 week after the final session of the iCBT. The WL group received the same treatment after the waiting period. Details of participant flow are shown in Fig. 1. Of 89 service members who were screened, 41 met all inclusion criteria and were randomized to either the IT (n = 20, 48.8%) or WL (n = 21, 51.2%) group. Two of the WL participants did not attend the pre-wait time assess- ment, and another two withdrew during the waiting period. Altogether, 37 participants started the intervention. Six (16.2%) participants were classified as no-shows. Ten (32.3%) participants who began the treatment dropped out (n = 21 completers). Data were collected between July 2016 and July 2018. The study was approved by the Freie Universität Berlin Institutional Review Board [reference number: 85/2014].

Intervention

The iCBT lasted for 5 weeks, and participants were instructed to write twice a week (10 essays in total). Each writing assignment required approximately 45 min of writing time. The therapists conducting the treatment were female postdoctoral-level psychologists licensed in cognitive-behavioral psychotherapy (HN, SSch) who had received special training in therapeutic writing via the internet. They provided written feedback after one working day and were available on demand in case of questions about the interventions or for technical support via phone calls. The iCBT consisted of

three treatment phases: 1) bio- graphical reconstruction, 2) exposure, and 3) cognitive restructuring. In the first treatment phase of the bio- graphical reconstruction, in three writing assignments, the patient described his childhood, youth and adult- hood up to the time shortly before the most debilitating traumatic event. Previous studies demonstrated the relevance of reflecting on positive life experiences, but also on negative experiences which patients have already successfully overcome in life [63]. The second treatment phase comprised repeated exposure to the most debilitating traumatic event in four writing assignments. Participants received psychoeducation about the mechanisms of exposure and were instructed to describe the traumatic event in the first person and present tense. The therapists helped the patients to focus on the most painful aspects and the emotions, thoughts and sensory perceptions that they experienced during the traumatic event. The third phase comprised three sessions of cognitive restructuring. In order to develop a new perspective on the traumatic event, patients wrote supportive letters to their former self at the time shortly after they had experienced the traumatic event. They were instructed to reflect on feelings of guilt and shame, to challenge dysfunctional automatic thinking and behavior patterns and to correct unrealistic assumptions. Patients were also encouraged to consider potentially positive consequences of the traumatic event and lessons learned from it, and to reflect on how they plan to cope with it in the future. The participants were instructed not to concentrate on style, grammar or spelling in their writing assignments, and were assured of the confidentiality of their writing. Written feedback by the therapist was provided after one working day for all writing tasks except for session 2 (biographical reconstruction) and session 5 (exposure). Feedback for these sessions was combined with the feed- back for the following session and thus provided after sessions 3 and 6, respectively. All feedback was based on standardized templates from the treatment manual, which were tailored within the boundaries of the proto- col to patients' specific needs. Important aspects of this feedback were recognition and reinforcement of the patients' work, positive feedback and motivation, as well as help and directions if the biographical reconstruction, the exposure or the cognitive restructuring had not been performed as intended. To address the needs of German service members, we tailored the treatment to their specific situation and provided the treatment in the German language. Reminders were sent if assignments were overdue. Contact on demand was possible to clarify questions about the intervention or in the case of technical problems. Any patient who did not respond to the reminder or who reported suicidal ideation during the iCBT was contacted by one of the study coordinators (BM, JS). The study's safety protocol included a timeline for contacting the patient and instructions on how to assess the risk of suicidality and to take appropriate action if necessary. The intervention was provided via an encrypted communication platform.
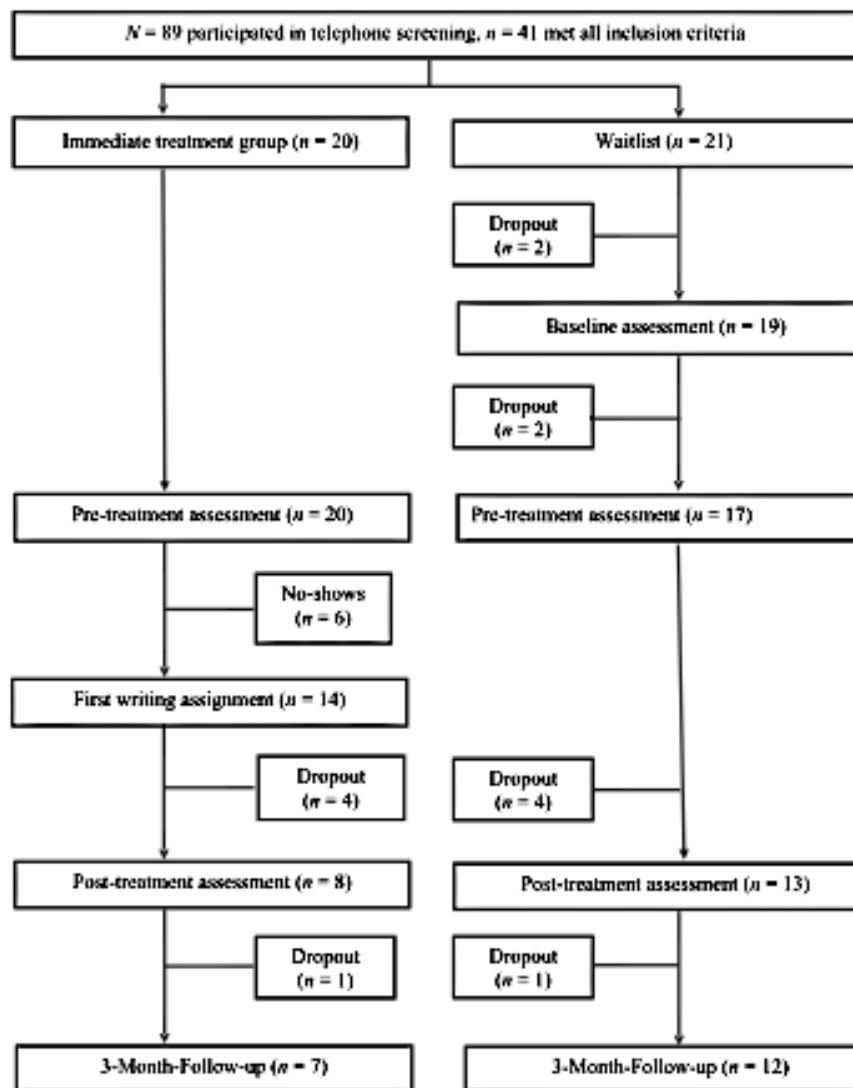
Fig. 1 Participants flow chart. Descriptive data on the patient flow through the study, that is the number of participants and drop-outs. Provides all details of the participant flow from the telephone screening to the follow-up assessment, which comprises also the detailed numbers of drop- outs per group and time-point (that is, according to the intervals between the assessments)

Statistical analyses

An a priori power analysis (power = 95%, alpha = 5%, two-tailed) indicated that at least 100 participants are needed to estimate a moderate between-group difference of d = 0.7, based on results of previous meta-analyses. Due to recruitment issues, only n = 37 persons started the intervention (WL = 17, IT = 20), and a relatively large proportion of non-completion (43%) occurred. There- fore, we decided to collapse the two groups to investigate symptom change during the intervention period. Even though this results in uncontrolled effect-estimates we deem this to give a better idea of how individuals change than a between group-comparison based on two very small group with large rates of attrition. We compared no-shows (individuals who did not start the treatment)

with treatment-starters (individuals who completed at least the first writing assignment) and dropouts (individuals who started but did not complete the treatment) with completers using Fisher's exact tests for categorical variables and Welch-tests for continuous variables. Change in PTSD symptoms and in anxiety over the course of treatment was estimated using latent change score (LC) models [76–78] using Mplus 8.0, which is comparable to computing a t-test for repeated measures [79]. We favored this approach due to the ease of using multiple imputation to deal with a large proportion of missing values. An intention-to-treat (ITT) analysis was performed, that is, all participants randomized and available immediately prior to the start of the intervention were included. Given the large proportion of missing values, we used different approaches for dealing with missing data. First, we used last observation carried forward (LOCF). Since no between-group comparisons are made, this approach can be considered as conservative, under the assumption that individuals who drop out do not deteriorate. Second, we used multiple imputation as implemented in the R package MICE on the level of subscale scores (50 data- sets, 50 iterations, [80]. Two different imputation methods were used: predictive mean matching (MI-PMM) and norm (MI-norm), since the best practice to impute large proportions of missing values in small data sets is still a matter of debate. Finally, a completer analysis was performed including only those individuals who completed all 10 treatment modules. The different approaches used to deal with missing data help to gain an impression of how estimated effects change under various assumptions (sensitivity analysis). We report un- standardized mean changes, which are better comparable across measurement occasions because they are unaffected by differences in the variability of change. In addition, we computed standardized effect size by dividing the mean change score by its standard deviation (d). We also assessed clinically meaningful changes from pre- to post-test as well as from pre-test to follow-up. Changes in the CAPS-5 score of > / = 10 were considered as clinically meaningful and percentages of improvement, non-improvement, and worsening were calculated [81]. All analyses were two-sided and p < .050 indicated statistical significance. Figures were created in R using ggplot [82].

2.11.3 Results

The mean age of the combined sample was 37.7years (SD = 9.8; range: 19–70). 80.6% of the participants were in full-time employment while participating in the treatment and had served in the German Armed Forces for an average of 17 years (SD = 9.9; range: 1–52). On aver- age, they had participated in 2.8 foreign missions (SD = 3.1; 0–15), mostly in Afghanistan (73.5%). Table 1 gives a summary of the sample characteristics. Overall, 94.4% of the participants reported combat or war zone exposure, followed by witnessing severe human suffering (88.6%), as assessed with the LEC-5. The most debilitating traumatic event had occurred on average 9.4 years ago (SD = 5.8; range 2.0–25.0). Furthermore, ac- cording to the LMHAT scale, service members were frequently exposed to several traumatic events (mean: 33.4, SD = 17.2, range 8.0–74.0; see also Supplement 2). The mean CAPS-5 score was 33.5 (SD = 14.9). Twenty-two participants (59.5%) had a PTSD diagnosis. Comorbid mood and anxiety disorders were common: 13 patients (31.5%) suffered from comorbid major de- pression and n = 7 (18.9%) reported dysthymia. Two patients (5.41%) had experienced a lifetime manic episode and n = 1 (2.7%) a lifetime hypomanic episode, but re- ported no current symptoms. Nine patients (33.3%) suffered from panic disorder, n = 19 (51.4%) from agoraphobia, n = 7 (18.9%) from social phobia and n = 5 patients (13.5%) from generalized anxiety disorder. There were no differences in

comorbid diagnoses be- tween the former IT and WL group. The majority of the sample had previously received psychotherapeutic or pharmacological treatment (58.3%; see Table 2).

No-shows and dropout

While no-shows did not differ from participants who began treatment on any clinical or sociodemographic characteristic, all no-shows were randomized to the IT condition. There were no significant differences between dropouts and completers (see Supplement 3). Reasons re- ported for dropout comprised difficulties with internet connection (n = 1), lack of motivation for treatment (n = 1), preferring face-to-face over online settings (n = 4), feeling no improvement (n = 2), and hospital admission (n = 1). One participant did not report a reason for dropout. Adverse effects during the iCBT where assessed in the completer sample and 9.5% reported severe resistance against the writing assignments, whereas another 23.8% experienced intense negative feelings while they were writing.

Pre-treatment to post-treatment changes

Within-group effect size estimates revealed no significant changes for any of the measured outcome variables from pre- to post-assessment (see Table 3). The estimated average changes as measured with the CAPS-5 total score ranged between − 1.0 (LOCF) and − 2.35 (MI- PMM), depending on the method that was applied to handle missing data. Overall, the CAPS-5 total score was missing for 43% (n = 16) at post-assessment and for 49% (n = 18) at follow-up-assessment. Figure 2 shows the individual trajectories and the estimated mean changes in the CAPS-5 total and subscale-scores. The percentage of clinical meaningful change from pre- to post-test as well as from pre-test to follow-up is described in Table 4. The majority of participants did not change (about two thirds), and more participants improved than deteriorated.

Table 1. Sociodemographic Characteristics

Variables		Total (*n* = 37)	Waiting List (*n* = 17)	Treatment Group (*n* = 20)	Test statistics *t* (*df*)	*p*
			Comparison of groups			
Sociodemographic characteristics						
Age	*M*	37.7	37.8	37.7 (6.86)	0.01 (21.79)	.989
	(*SD*)	(8.8)	(12.8)			
Marital status‡						.786
Single	*n*	4	1 (6.2)	3 (15)		
	(%)	(11.1)				
Relationship	*n*	5	2 (12.5)	3 (15)		
	(%)	(13.9)				
Married	*n*	19	10	9 (45)		
	(%)	(52.8)	(62.5)			
Education‡						.680
Secondary school qualification	*n*	6	3 (18.8)	3 (15.0)		
	(%)	(16.7)				

Variable		Total	Group 1	Group 2	Test	p
Secondary school certificate	n (%)	24 (66.7)	11 (68.8)	13 (65)		
High school diploma	n (%)	6 (16.7)	2 (12.4)	4 (20)		
Employment status‡						.894
Fulltime	n (%)	29 (80.6)	13 (81.2)	16 (80)		
Part-time	n (%)	1 (2.8)	0 (0)	1 (5)		
Training/Apprenticeship	n (%)	1 (2.8)	0 (0)	1 (5)		
Unemployed	n (%)	5 (13.9)	3 (18.8)	2 (10)		
Joined the military	Year (SD)	2001 (9.9)	2000 (12.5)	2001 (7.6)	-0.06 (21.87)	.950
Work status‡						.593
Voluntary service	n (%)	2 (6.1)	2 (12.5)	0 (0)		
Temporary	n (%)	20 (60.6)	10 (62.5)	10 (58.8)		
Professional	n (%)	8 (24.2)	3 (18.8)	5 (29.4)		
Military unit‡						.145
Army	n (%)	18 (51.4)	10 (62.5)	8 (42.1)		
Air Force	n (%)	5 (14.3)	0 (0.0)	5 (26.3)		
Navy	n (%)	1 (2.9)	1 (6.2)	0 (0)		
Medical service	n (%)	3 (8.6)	1 (6.2)	2 (10.5)		
Joint support service	n (%)	8 (22.9)	4 (25.0)	4 (21.1)		
Military ranks						
Enlisted ranks	n (%)	10 (28.6)	5 (31.2)	5 (26.3)		
Non-commissioned	n (%)	20 (57.1)	10 (62.5)	10 (52.6)		
Commissioned officer	n (%)	5 (14.3)	1 (6.2)	4 (21.1)		
Number of deployments	M (SD)	2.78 (3.12)	1.75 (1.18)	3.60 (3.9)	-2.01 (23.24)	.056
Country‡						.634
Afghanistan	n (%)	25 (73.5)	9 (60.0)	16 (83.2)		
Bosnia	n (%)	2 (5.9)	1 (6.7)	1 (5.3)		
Kosovo	n (%)	5 (14.7)	3 (20.0)	2 (10.5)		
Mali	n (%)	1 (2.9)	1 (6.7)	0 (0)		

Somalia	*n*	1	1 (6.7)	0 (0)
	(%)	(2.9)		

Note. ‡Fisherʹs exact test was used to test the significance of independence in categorical variable. The category "secondary school qualification" (Realschule) also includes "subject-restricted higher education entrance qualification" (Fachhochschulreife). df = degrees of freedom; M = mean; N = sample size; PTSD = posttraumatic stress disorder; SD = standard deviation.

Table 2. PTSD psychopathology and treatment

Variables		Total (*n* = 37)	Waiting List (*n* = 17)	Treatment Group (*n* = 20)	Test statistics *t* (*df*)	p
Clinical PTSD (CAPS)						1.000
No	*n (%)*	15 (40.5)	7 (41.2)	8 (40)		
Yes	*n (%)*	22 (59.5)	10 (58.8)	12 (60)		
CAPS sum score	*M (SD)*	33.54 (14.88)	33.6 (15.3)	33.3 (1)	0.06 (33.76)	.954
Previous treatment						0.320
Yes	*n (%)*	21 (58.3)	11 (68.8)	10 (50)		
No	*n (%)*	15 (41.7)	5 (31.2)	10 (50)		
Current pharmacological treatment						1.000
Yes	*n (%)*	9 (25)	4 (25)	5 (25)		
No	*n (%)*	27 (75)	12 (75)	15 (75)		

Note. Previous treatment was psychotherapeutic or psychiatric treatment. df = degrees of freedom; M = mean. N = sample size; PTSD = posttraumatic stress disorder; SD = standard deviation.

Pre-treatment to 3-month follow-up changes

Depending of the approach to deal with missing data, the estimated average improvements as measured with the CAPS-5 total score ranged between 2.11 (LOCF) and Regarding the CAPS-5 scores, the different methods mainly indicated that the changes between pre-treatment and 3-month follow-up were not significant. 5.42 (MI-PMM) points. All methods indicated a significant symptom reduction regarding the secondary outcome GAD-7 ranging from − 2.20 (LOCF) to − 3.04 (MI-PMM) points. Table 3 summarizes all estimates.

Table 3. Changes in Outcome Measures Across the Intervention

Outcome	Analysis	*n*	Pre	Pre-to-Post				Pre-to-Follow-Up			
				D	[95% CI]	*p*	*d*	D	[95% CI]	*p*	*d*
CAPS Total	Completer	21	32.71	-1.76	[-5.71, 2.19]	.388	-0.19	-3.71	[-7.48, 0.92]	.086	-0.38
	LOCF	37	33.54	-1.00	[-3.35, 1.27]	.394	-0.14	-2.11	[-4.54, 0.38]	.096	-0.27
	MI PMM	37	33.54	-2.35	[-6.55, 1.84]	.272	-0.21	-5.42	[-10.51, -0.33]	.037	-0.42
	MI NORM	37	33.54	-1.68	[-5.11, 1.75]	.337	-0.19	-3.28	[-7.01, 0.45]	.085	-0.36
CAPS - B	Completer	21	9.29	-0.48	[-1.95, 1.00]	.525	-0.14	-1.29	[-2.63, 0.00]	.053	-0.44
	LOCF	37	9.32	-0.27	[-1.11, 0.60]	.532	-0.10	-0.73	[-1.54, 0.03]	.066	-0.30
	MI PMM	37	9.32	-0.54	[-2.17, 1.10]	.520	-0.13	-0.93	[-2.48, 0.62]	.239	-0.26
	MI NORM	37	9.32	-0.41	[-1.92, 1.10]	.596	-0.11	-1.21	[-2.54, 0.13]	.076	-0.39
CAPS - C	Completer	21	3.43	-0.24	[-0.86, 0.52]	.513	-0.14	-0.03	[-0.78, 0.70]	.930	-0.02
	LOCF	37	3.73	-0.14	[-0.54, 0.27]	.515	-0.11	-0.05	[-0.49, 0.35]	.798	-0.04
	MI PMM	37	3.73	-0.42	[-1.32, 0.48]	.357	-0.20	-0.36	[-1.52, 0.79]	.538	-0.13
	MI NORM	37	3.73	-0.28	[-1.01, 0.45]	.448	-0.16	-0.04	[-0.80, 0.72]	.924	-0.02
CAPS - D	Completer	21	10.05	0.19	[-1.43, 2.14]	.833	0.05	-1.25	[-3.50, 1.21]	.299	-0.24
	LOCF	37	10.24	0.11	[-0.84, 1.19]	.833	0.04	-0.65	[-1.84, 0.65]	.311	-0.17
	MI PMM	37	10.24	0.08	[-1.89, 2.05]	.937	0.08	-2.27	[-5.23, 0.69]	.132	0.32
	MI NORM	37	10.24	0.20	[-1.62, 2.01]	.834	0.05	-0.91	[-3.41, 1.59]	.475	-0.18
CAPS - E	Completer	21	9.95	-1.24	[-2.57, 0.14]	.070	-0.39	-1.17	[-2.43, 0.12]	.076	-0.40
	LOCF	37	10.24	-0.70	[-1.49, 0.05]	.081	-0.28	-0.68	[-1.46, 0.05]	.078	-0.29
	MI PMM	37	10.24	-1.47	[-3.03, 0.09]	.065	-0.37	-1.85	[-3.59, -0.11]	.037	-0.44
	MI NORM	37	10.24	-1.18	[-2.63, 0.26]	.109	-0.35	-1.13	[-2.54, 0.28]	.116	-0.36
GAD-7	Completer	21	11.76	-1.53	[-3.81, 0.29]	.147	-0.35	-2.79	[-5.66, -0.75]	.022	-0.62
	LOCF	30	12.30	-1.23	[-2.67, -0.03]	.065	-0.33	-2.20	[-3.87, -0.83]	.005	-0.51
	MI PMM	37	11.87	-1.66	[-4.15, 0.83]	.191	-0.27	-3.04	[-5.59, -0.48]	.020	-0.58

MI NORM	37	11.96	-1.34	[-3.62, 0.93]	.247	-0.28	-2.22	[-4.35, -0.09]	.041	-0.54

Note. Completer = Analysis of working with all 10 treatment modules. LOCF = Missing data dealt using Last Observation Carried Forward. MI NORM = ITT with multiple imputed data using norm. MI PMM = ITT with multiple imputed data using predictive mean matching. D = Average change in metric of the questionnaire.

Figure 2. Individual trajectories

Fig. 2 Individual trajectories. Individual trajectories of the change in PTSD symptoms over the course of the treatment. Shows the individual trajectories and the estimated mean changes in the CAPS-5 total and subscale-scores. The results for completers, the results from the last observation carried forward (LOCF) approach, and the results from the full information maximum likelihood (FIML) are displayed

Table 4.
Rates of individuals showing clinical meaningful change (Change in CAPS overall score >= 10)

Outcome	Analysis	Post			Follow-up		
		% improved	*% unchanged*	*% deteriorated*	*% improved*	*% unchanged*	*% deteriorated*
CAPS Total	Completer	28.6	61.9	9.5	26.3	63.2	10.5
	LOCF	16.2	78.4	5.4	16.2	78.4	5.4
	MI PMM	31.1	55.5	13.4	36.7	51.2	12.1
	MI NORM	22.9	67.8	9.2	24.9	66.0	9.1

[a] Please note that the rates for LOCF are equal for both measurement occasions. This is because LOCF assumes no change for cases with missing data per definition.

2.11.4 Discussion

The present study aimed to investigate the acceptability and efficacy of iCBT in a German military sample with subclinical or clinical levels of PTSD. Only 37 service members completed the pre-treatment assessment. Six individuals did not begin the treatment and 10 individuals dropped out during the course of treatment. Investigating the change occurring during the intervention period resulted in small and non-significant changes as assessed with the CAPS-5. This is also true for individuals who completed the intervention, and changes from pre-treatment to 3-month follow-up were

also non-significant. Small, significant improvements from pre- to follow-up assessment emerged for anxiety. Overall, only n=89 of individuals could be screened for eligibility. The most frequently reported reasons for dropout were preferring face-to-face over online settings and lack of improvement. When assessing adverse effects, we found that up to 25% of the completers re- ported intense negative feelings during the iCBT. It should be emphasized that trauma-focused, exposure-based interventions are often experienced as aversive, and thorough psychoeducation as well as cognitive restructuring of dysfunctional thoughts about trauma exposure are necessary to convince patients about the treatment [83]. In particular, service members might need an individual discussion of potential fears about facing memories of traumatic events. In the current iCBT, such in-depth psychoeducation was probably not possible to the required extent. Notably, many participants in the current study had difficulties writing the trauma-exposure assignments in the present tense, and in focusing on their emotions in detail, which might hint at trauma avoidance. Potential reasons discussed in the literature influencing treatment-seeking behavior and dropout in military personnel in face-to-face interventions include trauma avoidance and comorbidity [84, 85, 86, 87–90]. The first meta-analysis on predictors of treatment efficacy found that the number of trauma- focused therapy sessions predicted effectiveness and that both high and low pre-treatment PTSD severity levels predicted lower treatment gains [25].

In the current study, some participants also had difficulties connecting to the internet and accessing the web page, which in some cases required repeated personal instruction (telephone consultations) to resolve. The patients mainly used the contact on demand option for technical support. Questions about the assignments were usually resolved in the written feedback. Reading and writing skills, interest in writing, as well as computer skills may have hampered the motivation to begin and complete the iCBT. Additionally, the rather effortful assessment days required participants to travel to the German Armed Forces Hospital, in some cases with overnight stays, and the home sampling of psycho-physiological markers (see Supplement 2) demanded time and preparation. Moreover, despite the fact that confidentiality was protected the assessments in the military hospital might have elicited subjective concerns in some participants. Therefore, the advantages of iCBT were probably less accessible for the current sample. Future studies on the acceptability and efficacy of iCBT might benefit from phone-based instead of face-to-face diagnostic assessments. An evaluation of how iCBT can be successfully promoted in military systems could be helpful, as policies concerning confidentiality remain an ongoing issue. An additional reason might include disability compensation incentives. Furthermore, many participants in the current study had received psychotherapeutic treatment before and presented rather chronic symptoms, and might have developed low expectations about the efficacy of treatment in general. Our findings are in line with the low utilization and high dropout rates reported for military personnel in psychotherapeutic treatment in general and partly consistent with the previous studies on iCBT in military personnel with PTSD. Treatment efficacy was comparably higher for the written-based DESTRESS version and for Vets Prevail than in our trial. However, due to a number of differences between the interventions and the study designs, the results are not directly comparable. The intervention in the current study was text-intensive, while Vets Prevail, in contrast, included sophisticated media elements. Vets Prevail was investigated in non- active-duty veterans with mild to moderate symptoms, including also females [57]. The majority of the male participants in the current study had been confronted with several army-associated traumatic events, many were particularly burdened, and a considerable number were still in active duty. Furthermore, all previous stud- ies on

iCBT were conducted in the US, which has different military structures and higher PTSD prevalence rates. Broadening the perspective beyond military personnel, a recent meta-analysis investigating the efficacy of iCBT for PTSD in both non-military and military samples [46] found lower effect estimates compared to previous meta-analyses. This demonstrates the need for future studies to identify patient and treatment characteristics that modify treatment success. In order to improve iCBT, high quality clinical trials that systematically dis- entangle the role of different program components and patient characteristics for the acceptance and efficacy of iCBT are necessary. With respect to the identification of patient characteristics that modify treatment acceptance and success, sociodemographic and psychopathological characteristics, such as clinical status, symptom severity and traumatic events, should be investigated systematic- ally. Moreover, examining the impact of specific variations of program components such as the duration of treatment, therapeutic support, and technical components such as multimedia components or reminders, as well as additional modules such as stress management, for example, can help to identify who benefits most from which iCBT concept (see also [54]). Another promising way to improve iCBT are blended approaches, such as combining face-to-face treatment with iCBT or iCBT with mobile applications. Blended approaches may be particularly indicated for patients with deficits in emotion regulation or stress management. The practice of new skills can be prompted in everyday life, for example to help to cope with negative emotions, and the higher treatment intensity and support in the application of therapeutic strategies might enhance the acceptability and efficacy. However, more research in general and especially in military samples is necessary. Moreover, utilization is likely determined by a com- plex interaction between patient, treatment, and system factors, and embedding new approaches such as iCBT within an already given care setting is also crucial. An evaluation how new modes of delivery such as iCBT can successfully be promoted especially in military systems could be helpful.

Limitations

We employed a randomized controlled design, but col- lapsed the groups and reported uncontrolled estimates even though we were aware that it is important to follow the study plan [88]. The interpretability of the results is still compromised by the small sample size and the missing data. Further analysis of potentially relevant predictors of treatment efficacy or dropout was not possible due to the small sample size.

Future studies

Our results highlight priorities for future studies. Considering that iCBT is cost-efficient and easily accessible, possibilities to promote the advantages as well as lever- age strategies, such as motivational interviewing, should be investigated. If iCBT is to be helpful, it must be acceptable. Future research should focus on identifying participant and intervention features that are relevant for treatment efficacy.

2.11.5 Conclusion

Military members present unique challenges in the treatment of PTSD. This study represents a call to action to validate interventions to improve treatment engagement and retention. Progress in the field is unlikely to occur without a better understanding of patient preferences and factors influencing treatment engagement and retention.

Fostering engagement and willingness to remain in psychotherapeutic treatment is essential to ensure the provision of evidence- based treatment to military personnel. Future research in this regard is eagerly encouraged.

Supplementary information

Additional file 1. Comprehensive study design including psychophysiological and experimental assessments.

Comprehensive study design including psychophysiological and experimental assessments

The investigation of treatment efficacy was embedded in a comprehensive study design to investigate mechanisms of change and dysregulations in various psychophysiological systems.

As secondary outcomes, biological markers reflecting the regulation of the hypothalamic-pituitary-adrenal (HPA) axis, markers of the autonomic nervous and immune system, dehydroepiandrosterone, oxytocin and vasopressin were assessed. Additionally, at each diagnostic face-to-face appointment, eye-tracking assessments were conducted to measure attentional bias, and heart rate variability was assessed.

In an additional cross-sectional study arm, the PTSD patients were compared at baseline to never-traumatized (NE) as well as trauma-exposed (TE) healthy controls with respect to potential dysregulations in the psychophysiological systems, attentional bias and heart rate. Inclusion criteria for the healthy participants were male adult German-speaking service members of the German Armed Forces who had either experienced a potentially traumatic event (TE) or had never experienced a potentially traumatic event (NE), but did not fulfill the criteria for PTSD or any other mental disorder. Exclusion criteria were neurological disorders and acute physical illness. The results of these secondary outcomes will be reported elsewhere.

Additional file 2. Supplement 2. Traumatic events.

Table 5. Supplement 2. Traumatic events

Variables	*Sample* n_{total}	N event†	%	Variables	n_{total}	n	%
LEC5				Seeing dead or seriously injured comrades	34	21	61.76
Natural disaster	36	20	55.56	Knowing someone seriously injured/killed	34	29	85.29
Fire or explosion	36	30	83.33	Participating in demining operations	34	15	44.12
Transportation accident	36	31	86.11	Improvised explosive device/booby trap exploded nearby	33	20	60.61
Serious accident	36	21	58.33	Working in mined areas	34	22	64.71
Exposure to toxic substance	36	9	25	Having hostile reactions from civilians	34	27	79.41
Physical assault	36	21	58.33	Disarming civilians	34	14	41.18
Assault with a weapon	36	30	83.33	Shooting/directing fire at enemy	34	20	58.82
Sexual assault	36	4	11.11	Calling in fire on the enemy	34	8	23.53
Other unwanted sexual experience	36	2	5.56	Engaging in hand-to-hand combat	34	6	17.65
Combat/exposure to a war-zone	36	34	94.44	Clearing/searching homes/buildings	34	13	38.24
Captivity	36	3	8.33	Clearing/searching caves/bunkers	34	6	17.65
Life-threatening illness/injury	36	21	58.33	Witness of mistreatment of uninvolved persons	34	12	35.29
Severe human suffering	35	31	88.57	Being wounded/injured	34	7	20.59
Sudden violent death	36	27	75	Seeing injured women or children, but unable to help	34	18	52.94
Sudden accidental death	36	20	55.56	Receiving incoming artillery/rocket/mortar fire	34	21	61.76
Serious injury/harm/death caused to someone	36	8	22.22	Being responsible for enemy combatant's death	32	5	15.63
Any other very stressful event/experience	32	21	65.63	Observing abuse of Geneva Convention	33	6	18.18
LMHAT				Being responsible for a comrade's death/injury	33	2	6.06
Be attacked/ambushed	34	25	73.53	Had a comrade nearby shot/killed	34	13	38.24
Sighted destroyed homes and villages	33	33	100	Had a close call, dud landed nearby	34	14	41.18
Receiving small arms fire	34	27	79.41	Had a close call, equipment shot off body	33	0	0
Seeing dead bodies/human remains	33	25	75.76	Had a close call, was shot/hit but protective gear saved you	34	1	2.94
Handling human remains	33	17	51.52	Having a member of your own unit become a casualty	34	4	11.76
Witnessing an accident which resulted in injury/death	34	21	61.76	Being in threatening situations, unable to respond because of RoE	34	15	44.12
Witnessing violence within the local population	33	27	81.81	Informed others of comrade´s death	33	7	21.21

Note. †For the LEC5 the categories 'happened to me', 'witnessed it', 'learned about it', 'part of my job' were combined and coded with 1, and the categories 'not sure' and 'doesn't apply' were combined and coded as 0. For the LMHAT the 5-point scale asks how often an event was experienced ('never', 'once', '2-4 times', '5-9 times', 'more than 10 times'). To keep results comparable with LEC5, we coded never with 0 and combined all other categories coded as 1, so the results display having experienced the respective event at least once. LEC5 = Life Events Checklist for DSM-5; LMHAT = List of the Mental Health Advisory Team; RoE = Rules of engagement.

Additional file 3. Supplement 3. Sociodemographic Characteristics for No-shows vs. ITT sample and Dropouts vs. Completers.

Table 6. Supplement 3. Sociodemographic Characteristics for No-shows vs. ITT sample and Dropouts vs. Completers

Variables		Noshows (n = 6)	Shows (n = 31)	Test statistics t (df)	p	Dropouts (n = 10)	Completers (n = 21)	Test statistics t (df)	p
Sociodemographic characteristics									
Age	M (SD)	37.8 (7.2)	37.7 (10.3)	-0.04 (9.68)	.970	35.5 (8.5)	38.8 (11.2)	0.90 (23.12)	.377
Education‡					1.000				.960
Secondary school qualification	n (%)	1 (16.7)	5 (16.7)			2 (20)	3 (15)		
Secondary school certificate	n (%)	4 (66.7)	20 (66.7)			7 (70)	13 (65)		
High school diploma	n (%)	1 (16.7)	5 (16.6)			1 (10)	4 (20.0)		
Joined military	Year (SD)	1998 (8.47)	2001 (10.2)	0.59 (6.20)	.577	2005 (7.47)	1999 (11)	-1.72 (25.03)	.097
Number of deployments	M (SD)	4.67 (5.4)	2.4 (2.4)	-1.01 (5.41)	.356	2.5 (3.95)	2.35 (1.2)	-0.12 (9.88)	.909
Years abroad	M (SD)	9 (5.8)	8.36 (5.2)	-0.25 (6.8)	.810	7.62 (3.81)	8.65 (5.7)	0.55 (19.38)	.587
Clinical PTSD (CAPS)					.368				.280
No	n (%)	1 (16.7)	14 (45.2)			3 (30)	11 (52.4)		
Yes	n (%)	5 (83.3)	17 (54.8)			7 (70)	10 (47.6)		
CAPS sum score	M (SD)	31 (11.2)	33.9 (15.7)	0.54 (9.27)	.602	36.4 (15.4)	32.7 (16)	0.62 (18.47)	.546

Note. Not all subjects have answered all items, so the number on each item may differ from total. The category "secondary school qualification" (Realschule) also includes "subject-restricted higher education entrance qualification" (Fachhochschulreife). ‡The Fisher′s exact test was used to test the significance of independence in categorical variable. CAPS = Clinician Administered PTSD Scale for DSM-5; df = degrees of freedom; ITT = intention to treat; M = mean; N = sample size; PTSD = posttraumatic stress disorder; SD = standard deviation.

Availability of data and materials
The data that support the findings of this study are available upon reasonable request from the German Federal Ministry of Defence (BMVg FüSK III 5).

Ethics approval and consent to participate
The study was approved by the Ethics committee of Freie Universität Berlin

(85/2014), after internal approval from the German Armed Forces. All participants gave informed written consent.

Consent for publication
Not applicable.

Competing interests
HR and GDW are employed by the German Armed Forces. Their employment had no influence on the study design or the collection, analysis and interpretation of data. All other authors declare that they have no conflict of interest.

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3 Summary, implications and reflections

3.1 Summary of the main findings of the three studies

3.1.1 Etiology of PTSD against the background of the findings of the presented studies

Experiencing a traumatic event can lead to post-traumatic stress disorder (PTSD), but not every traumatized person develops PTSD. Several protective and risk factors have been identified in civilians and veterans to explain why some individuals develop PTSD and others do not. However, no research has confirmed the relationship between emotion regulation and PTSD in deployed German Armed Forces service members after a foreign assignment. Previous studies have identified some protective factors, such as social support, social acknowledgment, specific personal values, and posttraumatic growth, as well as risk factors, like moral injury and emotion regulation. Thus, the aim of the presented study was to confirm the relationship between emotion regulation and PTSD and to test for factors that are associated with higher severity of PTSD symptoms in such a sample.

A post-hoc secondary analysis was conducted on data collected in a randomized controlled trial. Participants (N = 72) were male active and former military service members that have returned from deployment and were recruited from the German Armed Forces. These participants were separated into two groups according to PTSD diagnosis based on the results of a structured diagnostic interview. Data from evaluation questionnaires administered upon entry into the study were subjected to a cross-sectional analysis. The measures included the severity of PTSD symptoms, clusters of PTSD symptoms, clinical measures, and several measures assessing PTSD-related constructs. Analyses included the Spearman rank correlation coefficient, X^2 tests for nominal data, Mann-Whitney U-tests for non-parametric data, and a mediation analysis.

The results of the mediation analysis revealed that difficulties in emotion regulation were significantly associated with the severity of PTSD symptoms, which was mediated by social acknowledgment and experimental avoidance but not by moral injury. The analyses showed that the severity of PTSD symptoms and all clusters of PTSD symptoms were significantly associated with most of the measured constructs in expectable directions. Participants in the PTSD group showed significantly higher

mean scores on questionnaires measuring constructs that have been associated with PTSD, like emotion regulation and moral injury. They also showed lower mean scores in questionnaires for social support and social acknowledgment as a victim or survivor than participants in the non-PTSD group.

The present results show that difficulties in emotion regulation are directly associated with the severity of PTSD symptoms in service members of the German Armed Forces. This association is mediated by social acknowledgment and experimental avoidance, but not by moral injury. Thus, future studies should investigate these potentially crucial factors for better understanding of the development and maintenance of PTSD in service members of the German Armed Forces after deployment to create possible treatment adaptions.

The well-investigated influence of ER on the development of PTSD was confirmed for service members of the GAF also. Additionally, the mediating effect of three important constructs on the relation of ER and PTSD could be shown. Herein the role of moral Injury cannot completely be explained based on our findings. The mediating effect of SA is interesting as it is inconsistent with prior findings in GAF service members. It is of special interest as our finding is in contrast consistent with findings in other nations service members and this bears also a basis for discussion in a broader socio-political perspective. In comparison to e. g. the U.S., GAF service members do not have a wide popular support and appreciation. As for the influence of AA as found in our investigation, further work is required, since AA might be seen as an important part of ER.

3.1.2 How to diagnose PTSD in the light of this work

The aim of the second study was to investigate the diagnostic accuracy, psychometric properties, and clinical utility of the German version of the clinician-administered post-traumatic stress disorder scale for DSM-5 (CAPS-5) in routine clinical settings. This study is a non-interventional, multitrait-multimethod design, multicenter study that will be carried out at German civil and military inpatient and outpatient clinics. A total sample size of $N = 219$ participants who have experienced at least one traumatic event according to criteria as defined in the DSM-5 will be recruited. For the investigation of the diagnostic accuracy and clinical utility of the CAPS-5, participants will be categorized into one of three groups, depending on their traumatic experiences and

posttraumatic symptomatology: (1) mono-traumatization with PTSD; (2) multiple traumatization with PTSD; and (3) traumatization without PTSD. Interviews will be conducted face-to-face by interviewers in routine clinical settings. All participants will also be asked to complete a comprehensive set of questionnaires in order to investigate different facets of construct validity and clinical utility. First, differences between all three groups in CAPS-5 sum and subscale scores will be investigated. Test–retest reliability and inter-rater reliability will be determined. Internal consistency will be calculated using SEM-based internal consistency coefficients. Construct validity will be measured with Spearman's rank correlation analyses and multivariate analyses of variance with Holm-Bonferroni corrected post-hoc ANOVAs. In order to test diagnostic accuracy, receiver operating characteristics and sensitivity and specificity analyses will be conducted. The model structure of the German CAPS-5 will be analyzed using confirmatory factor analyses.

In the validation project of the CAPS-5, we aimed to maintain the high diagnostic standard of previous CAPS versions. Analogous to the psychometric evaluation of the original version, this process was conducted with the German version of the CAPS-5 under routine clinical conditions (159, 160). Therefore, three categories of participants can be distinguished, namely mono traumatization with PTSD, multiple traumatization with PTSD and traumatization without PTSD. Additionally, participants either had a civilian or a service background. This allowed a comparison of the three respectively two groups on the CAPS-5 overall score and the respective subscales. In addition, the Test–retest reliability and interrater reliability, the internal consistency, the construct validity, the diagnostic accuracy and the model structure were investigated and analyzed. Other hypothesis were also investigated, such as questions regarding social desirability or patient acceptance. By conducting this study to detect the psychometric properties of the German version of CAPS-5 an important gap in the existing diagnostic instruments was closed.

3.1.3 Treatment of PTSD in the light of this work

The third study was designed to evaluate the efficacy of a therapist-guided internet-based cognitive-behavioral therapy (iCBT) intervention for service members of the German Armed Forces with posttraumatic stress disorder (PTSD). The iCBT was adapted from Interapy, a trauma-focused evidence-based treatment based on

prolonged exposure and cognitive restructuring. It lasted for 5 weeks and included 10 writing assignments (twice a week). The program included a reminder function if assignments were overdue, but no multimedia elements. Therapeutic written feedback was provided asynchronously within one working day.

Male active and former military service members were recruited from the German Armed Forces. Diagnoses were assessed with the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) and the Mini-International Neuropsychiatric Interview. Psychopathology was assessed at pre-treatment, post-treatment, and 3-month follow-up. Severity of PTSD was the primary outcome and anxiety was the secondary outcome. Participants were randomly allocated to a treatment group that received iCBT immediately or to a waitlist group that received iCBT after 6 weeks. Due to the overall small sample size (n = 37), the two groups were collapsed for the statistical analyses. Change during the intervention period was investigated using latent-change score models.

Improvements in the CAPS-5 were small and not statistically significant. For anxiety, small significant improvements were observed from pre- to follow-up assessment. The dropout rate was 32.3%.

The low treatment utilization and the high dropout rate are in line with previous findings on treatment of service members. The interpretation of the current null results for the efficacy of iCBT is limited due to the small sample size, however for military samples effect estimates were also smaller in other recent studies. Our results demonstrate the need to identify factors influencing treatment engagement and efficacy in veterans.

Due to the small sample size the results of this study have to be interpreted with caution. However, no significant improvements were found on the CAPS-5 after completion of the online-based writing therapy. In addition, there was a particularly high dropout rate of about one third of all participants. On the one hand, these results align well with some previous findings with regard to treatment of military personnel. On the other hand, these are the first results for GAF service members. Various factors, such as the exact factors of efficacy or treatment compliance urgently need to be further investigated in order to not miss out on the potential benefits of online treatments.

3.2 General overview and discussion

PTSD remains a significant problem among GAF service members. Nonetheless, research uncovers more and more helpful details, enabling us to specify etiology and to specialize the diagnostic process and treatment forms for service members and veterans. Some aspects are similar in civilians and service members and many aspects are similar between service members of different nations and the GAF service members. In the previous sections the field of PTSD was subdivided in the three topics etiology, diagnosis and treatment. In the etiology section findings encourage further studies regarding underlying mechanisms in GAF service members PTSD, such as ER, MI and social acknowledgment. The main finding of the study is the confirmation that there is a relationship between ER and PTSD in GAF service members after deployment. Furthermore, the mediating effect of social acknowledgement is remarkable because it is inconsistent with a previous finding (119). The mediating effect of acceptance and action leads to hypotheses regarding novel treatment options. One could argue that this is not a surprising result because the constructs explored with the Acceptance and Action Questionnaire are closely related or even part of the ER construct. Nevertheless, approaches with more specified targets in prevention and treatment should be explored with a focus on ER and Acceptance and, as already practiced, a focus on reducing avoidance in behavior and thinking. Other aspects might be different due to special circumstances of the traumatic index event. Due to these differences the construct of MI deserves further attention (29). Our finding, that there was no mediating effect of MI on the relationship of ER and PTSD might cautiously be interpreted in combination with previous findings that MI and PTSD are different constructs (120). Moral injury plays a special role in the field of PTSD in the military field. Due to the circumstances of military operations, soldiers have a significantly higher risk of getting into morally questionable situations (29). Therefore, they seem to be particularly vulnerable to the consequences of moral injury. Several studies have confirmed the meditating role of MI (28). Focusing on MI might as well be an opportunity in treatment (59). Further studies in the GAF hospital in Berlin are in preparation to investigate MI in GAF service members to better understand the underlying mechanisms and to eventually use the findings to improve psychotherapeutic treatment. In the treatment section the high prevalence of MI in the military sample and in GAF service members as our target group might explain that a mismatch between therapeutic approach and the type of index trauma might lead to

worse treatment outcomes compared to civilian population with less MI related feelings and cognitions (245). Certainly, the findings of this study propose multiple approaches regarding an improvement and a specialization in the treatment of PTSD in service members of the GAF.

Diagnostic tools developed to assess PTSD, especially the CAPS-5, seem to do the job for civilians as good as for service members. Nonetheless, our ongoing study to investigate the psychometric properties of the German version of Caps-5 will eventually point out potential starting points for further improvements regarding PTSD diagnosis and treatment in GAF service members. This concerns diagnostic procedures as well as treatment, since it might be an opportunity to use the comprehensive information provided by a thorough conduction of CAPS-5 regarding treatment approaches.

Online therapy is promising in principle, especially since it is possible to overcome several barriers of standard health care approaches (compare above). However, there clearly is a need for optimization in execution. Especially more specific mechanisms of action need to be identified, allowing to better target subpopulations such as service members. Due to the treatment implemented in our online therapy program, some individual participants improved considerably. Dividing participants into meaningful groups at the beginning, resulting in a clear categorization of a group of individuals with a CAPS score above cut-off and being treatment-seeking and a group of individuals with a CAPS score below cut-off and not seeking treatment would have been helpful and might have resulted in clearer results. This was only possible in the post-hoc analyses as described in the publication due to the design.

Furthermore, the inclusion of chronically traumatized soldiers in the study who have been in the system for a long time and have often had unsuccessful attempts at therapy, should be critically analyzed in the light of a stepped care approach. Possibly, the optimal target group for the online treatment might be newly and only slightly traumatized soldiers, because individuals belonging to that group often profited well. Furthermore, in case of a re-implementation, attention should also be paid to other aspects, i.e. personal contacts with the therapists, including, for example regular telephone contacts or video-telephony, since this aspect was often mentioned by the study participants.

3.3   Outlook and further research

For a better understanding of the underlying mechanisms in the process of developing a PTSD different design approaches may enlarge insights. To check post-hoc for factors relevant in service members with PTSD that are not relevant in service members without PTSD is a useful approach as showcased above. Alternatively, different prevention or treatment programs can be checked for efficacy in RCTs. Another very promising approach seems to be the field of peritraumatic experimental designs, which may be widened to a field investigation during deployment (25, 246, 247).

Regarding PTSD diagnostic instruments for the subgroup of GAF service members a few points are of special interest. For the CAPS-5 certain evaluation rules for this specific subgroup might be found in our evaluation project. Additionally, the participants acceptance of applied diagnostic instruments is interesting and important to evaluate as it is planned for CAPS-5 in the evaluation study. An important point in diagnosing PTSD in GAF service members may also be the secondary health gain, since a PTSD diagnosis usually has financial and legal consequences. Overall, the validation of diagnostic instruments for the subgroup of GAF soldiers is highly encouraged to guarantee progress in the diagnostic and treatment process wherever possible.

Online therapy for PTSD in GAF service members is promising despite our disappointing first findings. Overcoming barriers like the fear of stigma or limited local availability to specialized treatment seems to be an important advantage. Some adjustments to the conducted online treatment program could improve both efficacy as well as the high dropout rates. The high dropout rates are in line with the results of a recent RCT offering tele-therapy in US veterans. However, the treatment outcome in this study was at least numerically higher indicating that there might be room for improvement in a new investigation in GAF service members (d = 1.08 vs. d = -0.19)(248). The reliance on the internal health care system of the military and the reliance on psychotherapy as use- and helpful when suffering from PTSD as a service member has to be carefully evaluated for GAF service members to eliminate potential obstacles.

3.4 Critical reflection

Experiences from research practice

The challenges and difficulties that arose in these projects were on the one hand the typical ones in applied (psychotherapy) research. On the other hand, some problems were very specific for the population of GAF service members. For example, the iCBT study encountered various study specific problems due to planning errors as outlined in the paper. Major recruitment difficulties were also common. On the positive side, the recruitment problems can be interpreted in the way, that the GAF service members are already very well cared for, arguably the reason why there is only limited demand for this kind of therapy. However, service members must meet particularly high demands at their workplace and professional internet-based treatment offered anonymously for service members would probably be welcomed. The quality of execution of such treatments, however, is enormously important and particularly the two factors "therapeutic relationship" and "adaptability" of the treatment should be of excellent quality. These two factors were probably not provided with sufficiently high quality in the conducted iCBT-study. First, there was no individual therapeutic relationship and, secondly, due to the need to strictly follow the manual of the research trial no adaptability was possible. PTSD treatment of GAF service members is not entirely comparable to the PTSD treatment of civilians as discussed above. The effectiveness of therapeutic approaches lies both in the trauma-confrontative rational and the quick adaption of methods with a constant close therapeutic relationship with a great importance of a trustful and personal therapeutic alliance to avoid therapy dropouts for whatever reasons. This has to be kept in mind when a concept for a PTSD therapy study is planned as well as when new therapeutic approaches are created or adapted.

Other difficulties are that criteria are not always clear when they are to be transferred from the civilian sector to soldiers. Thus, for example, our classification into mono-traumatized and multiple traumatization in soldiers is often not clearly assessable. Several events have often occurred during one deployment and possibly the sum of these traumas has led to the formation of PTSD in an individual. Sometimes one service member has completed several deployments with several potentially traumatic events, but only one event is trauma-inducing as a A-criterion and only this event is experienced intrusively again. Is such a person accordingly mono-traumatized or multiple traumatized?

Another aspect we noticed was because of a comment from a Reviewer as part of the peer-review process. In iCBT data screening, the planned classification of treatment seeking and PTSD diagnosis according to Caps-5, and non-treatment seeking and no PTSD diagnosis after Caps-5, was unfortunately not as uniform as expected. Therefore, we redistributed the groups according to Caps-5 PTSD diagnosis. However, there was an allocation of non-treatment seeking soldiers to the PTSD group and treatment seeking soldiers to the non-PTSD group. Scientifically, this problem was solved neatly in the paper using a sensitivity analysis. In practice, however, one has to take a closer look at these subjects. Here, too, the above-mentioned constructs of social recognition, MI and ER can play an important role. For example, in the sense, that service members do not meet the CAPS-5 PTSD criteria, but are highly burdened in MI and therefore have a high level of suffering and need for therapy. For a treatment this may be resolved by an alternative diagnosis like depression or adjustment disorder. In a scientific treatment evaluation, these circumstances have to be kept in mind though. Thus, different diagnosis can occur in the course of the development of a PTSD in practice. For example, a common detected course in practice is, that there is often a first phase, when service members suffer from first PTSD symptoms but are not able to admit that there is something wrong or do not detect symptoms due to a lack of knowledge. A first symptom in service members suffering from PTSD often observed is a deterioration of sleep quality. This leads to a deterioration of concentration and might as well gradually strain the partner relationship of the affected person. The relationship although is an important factor to stabilize the individual (249-251). If there is further hyperarousal and possibly strong feelings such as anger (in order to be able to deal with the hyperarousal and the fear that arises in the nightmares and through the occurring memories), the partner may separate or divorce finally. This process may be accompanied by an attempt of self-medication with alcohol or other substances. In this entire time, the patient is probably not yet treatment-seeking and without a good knowledge of the patients background different diagnosis apart from PTSD could be given. This exemplary course could e.g. be fought by an even wider spreading of specific information and a tighter net of post-deployment screening.

Overall, PTSD remains a significant problem within the group of GAF service members, although there are plenty promising approaches to reduce the impact of this disorder and its burden. These approaches aim at different stages of the development

of PTSD, allowing a better understanding of the disorder and thereby making it more controllable.

The presented studies show, that research in the field of deployment related posttraumatic stress disorder for GAF service members is necessary and rewarding. This research allows to identify specific risk and maintaining factors, to identify diagnostic characteristics, and to identify possibilities and challenges in the treatment of this subgroup. In the hope of contributing to this important undertaking, I thank all participants and patients of the presented and future studies, who make this research possible.

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5 Erklärung über den Eigenanteil

Erklärung über den Eigenanteil an den Publikationen der als kumulative Dissertation eingereichten Schriften von Herrn Jan-Peter Spies

Peer Review publiziert

Spies, J.-P., Cwik J.C., Willmund G.-D., Knaevelsrud C., Schumacher S., Niemeyer H., Engel S., Küster A., Muschalla B., Köhler K., Weiss D. & Rau H. (2020). Associations Between Difficulties in Emotion Regulation and Post-Traumatic Stress Disorder in Deployed Service Members of the German Armed Forces. DOI: 10.3389/fpsyt.2020.576553

- **Studienkoordinator, dies beinhaltete folgende Tätigkeiten:**
- Rekrutierung der Probanden, dies beinhaltete Information und Kontakt zu allen Bundeswehrkrankenhäusern, entsprechenden Verbänden und Informations- und Pressestellen.
- Ansprechpartner für alle Interessenten und Fach-Kollegen.
- Das Screening potenzieller Probanden auf Teilnahmeeignung.
- Koordinierung und Planung der Testtermine.
- Zuordnung der Probanden zu Studientherapeuten
- Ansprechpartner für alle Studienteilnehmer
- Supervisionstätigkeit für die Studienassessorinnen
- Koordinierung mit den Verwaltungen der Bundeswehr und der Freien Universität
- Koordinierung der Datenverarbeitung und -Aufbereitung
- Erstellen der Projektberichte
- **Für diese Publikation spezifisch:**
- Mitverantwortlich für die Datenverarbeitung und die Datenaufarbeitung
- Mitverantwortlich für Planung und Durchführung der statistischen Auswertung
- Hauptverantwortlich für die Manuskripterstellung

Spies, J.-P., Woud, M. L., Kessler, H., Rau, H., Willmund, G.-D., Köhler, K., Herpertz, S., Blackwell, S. E., Bovin, M. J., Marx, B., & Cwik, J. C. (2020). Psychometric properties of the German version of the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) in clinical routine settings: study design and protocol of a multi-trait-multi-method study. DOI: 10.1136/bmjopen-2019-036078

- Mitverantwortlich für das Studiendesign
- Mitverantwortlich für die Studienplanung

- o Mitverantwortlich für die Entwicklung der Studienerweiterung auf die Subpopulation der Angehörigen der Bundeswehr
- o Entwicklung der Methodik am Standort Berlin (Planung der Testvorgabe, Durchführung der Testungen)
- o Hauptverantwortlich für die Manuskripterstellung

Niemeyer H., Knaevelsrud C., Schumacher S., Engel S., Küster A., Burchert, S., Muschalla B., Weiss D., Spies, J.-P., Rau, H. & Willmund, G.-D. (2020). Evaluation of an internet-based intervention for service members of the German armed forces with deployment-related posttraumatic stress symptoms.
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- o Mitverantwortlich für die Datenverarbeitung und die Datenaufarbeitung
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- o Mitgestaltung des Manuskripts
- o Teilverantwortlich für die Endredaktion des Manuskripts