

STUDY PROTOCOL

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A research programme to evaluate DBT-PTSD, a modular treatment approach for Complex PTSD after childhood abuse



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Abstract

Background: Posttraumatic stress disorder (PTSD) after childhood abuse (CA) is often related to severe co-occurring psychopathology, such as symptoms of borderline personality disorder (BPD). The ICD-11 has included Complex PTSD as a new diagnosis, which is defined by PTSD symptoms plus disturbances in emotion regulation, self-concept, and interpersonal relationships. Unfortunately, the empirical database on psychosocial treatments for survivors of CA is quite limited. Furthermore, the few existing studies often have either excluded subjects with self-harm behaviour and suicidal ideation — which is common behaviour in subjects suffering from Complex PTSD. Thus, researchers are still trying to identify efficacious treatment programmes for this group of patients.

We have designed DBT-PTSD to meet the specific needs of patients with Complex PTSD. The treatment programme is based on the rules and principles of dialectical behavioural therapy (DBT), and adds interventions derived from cognitive behavioural therapy, acceptance and commitment therapy and compassion-focused therapy. DBT-PTSD can be provided as a comprehensive residential programme or as an outpatient programme. The effects of the residential programme were evaluated in a randomised controlled trial. Data revealed significant reduction of posttraumatic symptoms, with large between-group effect sizes when compared to a treatment-as-usual wait list condition (Cohen's $d = 1.5$).

The first aim of this project on hand is to evaluate the efficacy of the outpatient DBT-PTSD programme. The second aim is to identify the major therapeutic variables mediating treatment efficacy. The third aim is to study neural mechanisms and treatment sensitivity of two frequent sequelae of PTSD after CA: intrusions and dissociation.

Methods: To address these questions, we include female patients who experienced CA and who fulfil DSM-5 criteria for PTSD plus borderline features, including criteria for severe emotion dysregulation. The study is funded by the German Federal Ministry of Education and Research, and started in 2014. Participants are randomised to outpatient psychotherapy with either DBT-PTSD or Cognitive Processing Therapy. Formal power analysis revealed a minimum of 180 patients to be recruited. The primary outcome is the change on the Clinician-Administered PTSD Scale for DSM-5.

Discussion: The expected results will be a major step forward in establishing empirically supported psychological treatments for survivors of CA suffering from Complex PTSD.

Trial registration: German Clinical Trials Register: registration number [DRKS00005578](https://www.clinicaltrialsregister.de/ct2/show/study/DRKS00005578), date of registration 19 December 2013.

Keywords: Childhood abuse, Complex posttraumatic stress disorder, Dialectical behavioural therapy, Randomised controlled trial

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Background

Sequelae of child abuse

Childhood abuse (CA) is a serious and pervasive problem worldwide, with childhood sexual abuse reported by 18% of women and 8% of men [1], and childhood physical abuse by 22 and 25%, respectively [2]. Adult survivors of CA often live with significant consequences, including psychiatric disorders. The World Mental Health Survey including representative surveys in 21 countries found that childhood adversities account for 30% of all mental disorders across countries [3]. Cohort studies [4–8] and epidemiological studies [3, 9, 10] revealed the highest odds ratios for affective disorders, substance related disorders, borderline personality disorder (BPD) and posttraumatic stress disorder (PTSD). The latter is often associated with emotion dysregulation, dissociative symptoms, aversive self-concepts, and interpersonal difficulties. This results in a relatively high comorbidity: Between 30 and 60% of patients with BPD suffer from co-occurring PTSD and between 17 and 30% of patients with PTSD meet the criteria for BPD [11–15]. These co-occurring symptoms have been described under the terms Complex PTSD (cPTSD) and Disorders of Extreme Stress Not Otherwise Specified (DESNOS). Both the DSM-5 [16] and the ICD-11 [17] have taken the symptoms of cPTSD into account. The DSM-5 added symptoms to the PTSD diagnosis that have frequently been viewed as symptoms of cPTSD, such as distorted beliefs about self and others, dissociation, and reckless behaviour. The ICD-11 [17] includes a distinct cPTSD diagnosis that comprises the three main symptom clusters of PTSD along with enduring disturbances in the domains of affect, self, and interpersonal relationships. Several studies support the ICD-11 distinction between PTSD and cPTSD, and have found that a history of CA is strongly associated with the latter [18, 19].

Economic costs of PTSD and co-occurring BPD

Apart from the individual suffering, economic costs for treatment and functional impairment (e.g., unemployment) are a heavy burden for the health care system. Data from our group on economic aspects of patients with PTSD and severe emotion dysregulation like BPD, in Germany indicate average direct and indirect costs of about €28,000 per patient (2/3 direct treatment costs) for a period of 1 year, and further indicate that within the German health system, co-morbidity as well as severity of PTSD is related to higher direct costs for healthcare [20, 21].

Psychosocial treatments

Cognitive-behavioural therapies have been shown to be efficacious in treating adults with PTSD in general [22, 23]. The recently revised Clinical Practice Guideline for the Management of PTSD [24] strongly recommends the use of individual, trauma-focused psychotherapies

that have a primary component of exposure and/or cognitive interventions. However, there has been little study of the efficacy of these therapies for PTSD related to CA in general and specifically in patients with co-occurring BPD-symptoms. Meta-analyses specifically studying psychological treatment effects in patients with PTSD related to CA yielded smaller effect sizes (medium effect size $d = 0.7$; [25]) and lower recovery rates in CA-related PTSD [26] than compared to those studies, that included all types of PTSD. Furthermore, studies on CA-related PTSD often excluded patients with substance abuse, dissociative disorders, BPD and suicidality [26].

There is a mixed data base on the impact of CA on PTSD treatment outcome. A randomised controlled trial (RCT) of eye movement desensitization and reprocessing (EMDR) found that PTSD related to a childhood trauma compared to PTSD related to an adulthood trauma was associated with less improvement and a lower remission rate [27]. Another study, which compared prolonged exposure (PE) with stress inoculation training, also found that patients with a childhood trauma showed less improvement [28]. However, several other studies found no evidence supporting a negative impact of CA on the treatment outcome after PE, EMDR and cognitive processing therapy (CPT) [29–33]. A most recent meta-regression-analysis included 51 RCTs and suggested that childhood trauma was associated with a poorer response to psychological therapy (Karatzias, Murphy, Cloitre, Bisson, Roberts, Shevlin: Psychological interventions for ICD-11 complex PTSD symptoms: systematic review and meta-analysis, submitted).

There is also a mixed data base regarding the impact of a co-occurring BPD. Five studies documented no significant effects of co-morbid BPD on treatment outcome [34–38]. Notably, three studies of these excluded patients with current self-injurious behaviour [34–36]. One study, which compared individual cognitive-behavioural therapy to individual present-centered therapy for female survivors of childhood sexual abuse (CSA) found that all patients with a co-occurring BPD diagnosis dropped out of cognitive-behavioural therapy [39].

Thus, researchers are still trying to identify treatment models for adult survivors of CA with concurrent severe emotional dyscontrol or severe dysfunctional behaviours. Currently, the American Psychological Association [24] and the US Department of Veterans Affairs and Department of Defense [40] considers four psychological treatments for PTSD to have strong research support. Among these empirically evaluated treatments, one of the currently most promising approaches is CPT [41, 42]. CPT was originally developed as a group treatment for rape victims. Originally it comprised two components: cognitive interventions and written trauma accounts [43]. Chard [44] adapted CPT for victims of CSA by combining

individual and group treatment. In an RCT comparing 17 weeks of this treatment to a wait-list control, the treatment was found to be highly efficacious [44]. However, this study did not report data for patients with BPD. Resick et al. [45] conducted an RCT to separate out the efficacy of the two components of CPT, and found that a treatment consisting of only the cognitive interventions was as successful in treating PTSD as was the combination of cognitive and exposure interventions, with lower dropout rates. Accordingly, the written trauma accounts constitute no standard intervention of CPT anymore [42].

However, since personality disorders were not assessed in the RCT by Resick et al. [45], and since only 38% of the participants defined CSA as their worst traumatic event it remains unclear whether these treatment results can be generalised to patients with cPTSD related to CA. Moreover, the data revealed only small effects on typical problems of patients with cPTSD, such as difficulties in anger control and re-victimisation [46].

The International Society of Traumatic Stress Studies (ISTSS) recommends in its guidelines for the treatment of cPTSD the use of phase-based, modular treatments including modules to improve emotion regulation and traumatic memory processing [47]. One of the empirically best supported treatment for emotion dysregulation is dialectical behavioural therapy (DBT). However, in the absence of a specific protocol for treating co-occurring PTSD, only a minority of BPD clients with co-occurring PTSD who underwent 1 year of DBT treatment achieved full remission from PTSD [48, 49]. Accordingly, several treatments combining DBT and trauma-focused methods have been developed. Harned et al. [49, 50] added a PE protocol after successful stage I standard DBT. In a first open-trial study by Harned et al. [50], 13 BPD patients with PTSD received a trauma-focused exposure-based treatment in addition to ongoing standard outpatient DBT once they had achieved control over so-called stage I treatment targets such as self-injurious behaviour. Intent-to-treat analyses revealed significant improvement in posttraumatic symptoms and in most secondary outcomes, with medium to large pre-post effect sizes. In a second pilot RCT, Harned et al. [49] compared standard DBT ($n = 9$) with DBT + PE ($n = 17$). Eight of the 17 patients randomised to the DBT-PE arm started the PE protocol and only six patients (35%) completed the treatment. The sample size was too small for a sound interpretation of differential treatment effects. Cloitre et al. [51] reported the benefits of DBT-derived skills training as a precursor to PE as compared to supportive counselling as a precursor to PE in adults with PTSD after CA. The study yielded first evidence that a phase-based treatment including emotion regulation training might be superior to PE. However, the lack of a PE alone condition in this study precludes drawing

conclusions about the relative benefits of the phased-treatment approach over state of the art PTSD treatment. Despite the promising results of these modified (phase-based) treatments, no treatment has yet been directly compared with a first-line PTSD treatment such as CPT.

DBT-PTSD

As outlined above, none of established treatments met the requirements for a sufficient therapeutic approach for a population suffering from PTSD and co-occurring severe problems with emotion regulation, self-concept and social interaction. Accordingly, we developed DBT-PTSD to specifically address the needs of this group of patients. DBT-PTSD was designed to include severely sick patients, suffering from chronic CA-related cPTSD along with severe problems in emotion regulation, ongoing self-harm behaviour, suicidal ideations and dissociative symptoms, negative self-concepts with high levels of guilt, shame, self-contempt and interpersonal problems. DBT-PTSD has been developed as a disorder-specific multi-modular treatment concept with clear treatment algorithms. The backbone of DBT-PTSD, i.e. the principles, the rules, the majority of interventions and, in particular, the benevolent, challenging, “dialectical” attitude, are derived from DBT [52–54]. This concept, originally evaluated for chronic suicidal patients with BPD, includes clear structures and dynamic hierarchisation of treatment focuses. An additional significant element of DBT is the procurement of so-called “skills”. These are short and precise mental self-instructions and guidelines for action that aim to interrupt and modify automated, intrapsychic processing as well as behavioural patterns. The skills can be applied to manage extreme conditions of stress, tension and dissociation without problematic behaviour, to modulate maladaptive emotions and to modify automated cognitions. All of this plays a critical role in the successful treatment of cPTSD. Because trauma-specific interventions are not described in more detail in the standard DBT, we supplemented trauma-specific cognitive [55] and exposure-based techniques as described by Ehlers [55], and Foa et al. [56]. However, we had to consider, that within this group of patients, in-sensu exposure as described/applied in PE often goes with intense dissociative features, which hamper emotional learning [57–60] and therefore have negative impact on treatment outcome [61]. Accordingly, we modified the standard PE procedure [56] by adding anti-dissociative skills (skills-assisted exposure). Clinical experiences with patients with a history of CA have shown that early established cognitive-affective schemes often cannot be completely modified even by successful therapy. Therefore, it seems to be important that patients learn a better approach to these automated processes and implement a profound

meta-cognitive and meta-emotional awareness, which enables them to process these automatic thoughts and emotional patterns from a more distanced perspective, learn to control the emotion driven action tendencies and replace them by functional behaviour. Acceptance and commitment therapy [62] provides valuable interventions here. Furthermore, this treatment consists of many helpful interventions for the recognition and implementation of values and therewith the improvement of the quality of life. Precisely because the self-concept is often characterized by trauma-related emotions such as shame or guilt, disgust and self-hate, many patients have significant difficulties dealing with themselves in a sympathetic and self-valuing manner – which is also frequently reflected in problems relating to interpersonal issues. In addition to the DBT-concept of teaching self-validation, in compassion-focused therapy [63], these difficulties are addressed through the training of a compassionate perspective towards oneself and other people. Here, compassion is defined as sensitivity towards one's own suffering and that of other persons with a deep commitment to mitigate the suffering, and this thereby encompasses both an empathic, attentive and a purposeful, powerful component. All of these sources of DBT-PTSD are, in turn, anchored in the principles of mindfulness. Because many traumatized patients experience longer mindfulness meditations as unpleasant and encumbering at least at the beginning of the treatment, skills-based mindfulness is facilitated in DBT-PTSD. In this, the psychological active principles of mindfulness are portioned into individual skills suitable to a daily routine and shorter mindfulness exercises without relying on formal meditation as a necessary experience.

DBT-PTSD is divided into seven topical treatment phases (Fig. 1) which are spread out over 12 weeks in the inpatient setting and over 1 year with up to 45 individual therapy sessions in the outpatient setting. Every treatment phase includes mandatory and voluntary treatment modules. This modular approach allows to tailor the treatment to the diverse symptom constellations of individuals suffering from cPTSD. Manualized “if-then rules” help the therapists to decide which of the suitable modules is being used in the individual case.

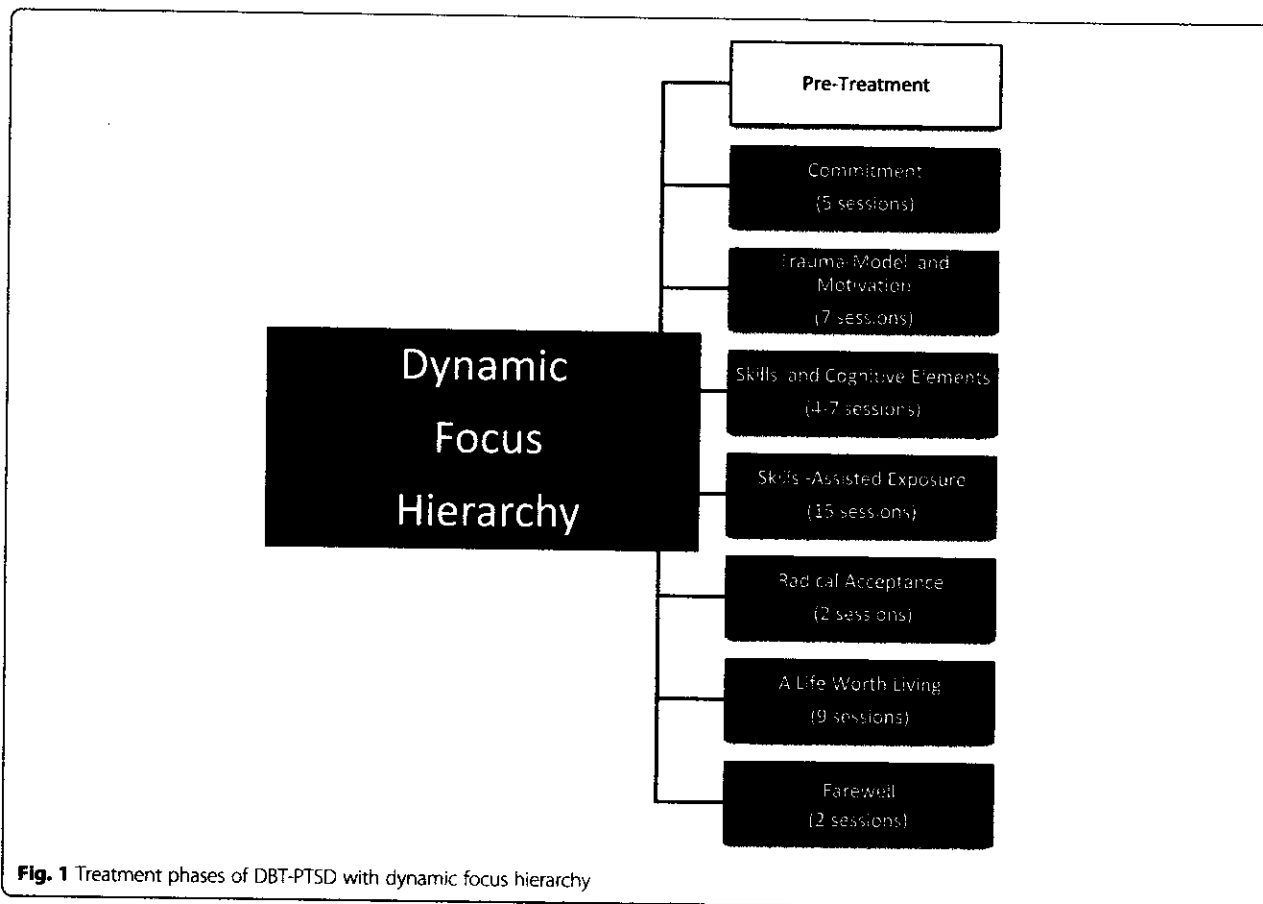
Independent of the distinct treatment phases, all individual session agendas are determined by hierarchically ordered treatment targets, as follows: 1) reduce imminent life-threatening behaviours, 2) reduce behaviours interfering with treatment maintenance or progress. Skills training is provided during the individual therapy: Skills have been modified for the specific needs of patients with cPTSD, and include: 1) mindfulness and compassion skills, 2) distress tolerance skills, 3) emotion regulation skills, and 4) regaining a life worth living skills. Phone consultations with the individual therapist focus on crisis intervention. Consultation team meetings

are aimed at maintaining treatment fidelity. These meetings are conducted by the therapists following guidelines in the treatment manual.

Diagnostics, indication of treatment, information on the treatment concept and the empirical database occur before the treatment begins (**Pre-Treatment Phase**). If the patient appears sufficiently motivated to start the treatment, a non-suicide contract will be concluded. In return, a crisis intervention telephone hotline is guaranteed to them.

In the **first phase (“Commitment”)**, a brief, structured interview records the active, dysfunctional behaviour pattern at the time. The therapist establishes a crisis and emergency plan. A short introduction to the skills concept also follows and, in this case in particular, an introduction to mindfulness. A special feature lies here in the development of a “compassionate-supporting self” (compassionate mindfulness). The patients develop this understanding by listening daily to imaginative self-instructions that have been recorded by their therapists. Specifically in this commitment phase, a rough orientation of time, manner and frequency of the traumatic experiences should be compiled, including the threats that the child was exposed to for reporting the trauma.

In the **second phase (“Trauma Model and Motivation”)**, the focus is on establishing a conclusive model of how PTSD develops, is preserved and can be treated. For this, the model of the “old path and the new path” with the trauma network and the mental and behaviour-related avoidance and escape strategies is generated. The patients should understand how strongly PTSD influences their lives and how trauma-related automatic thoughts and emotions prevent them from developing a meaningful life. The patients become acquainted with their typical avoidance and escape strategies and the related short- and long-term consequences. Moreover, they acquire a certain understanding for the mechanisms and effectiveness of exposure-based interventions (the brain must learn to differentiate between the past and the present). Based on this, therapist and patient develop operationalised, realistic and measurable treatment goals that are significant for the individual value system of the patient. Precisely because many patients with cPTSD have experienced severe disappointments from primary reference persons, we assume that these interpersonal experiences might repeat themselves in the therapeutic relationship in the context of transference processes and thereby hamper the cooperative work. In order to counteract this problem, we have taken up an idea from McCullough [64] and operate in advance an analysis of the experience with the most important formative significant others and their potential effect on the therapeutic relationship. The



second treatment phase is completed with an analysis of potential disorder-maintaining conditions and individual fears regarding the therapy.

At the end of this second treatment phase, the patients and their therapists present the treatment plan together to the consultation team, mutually discuss the prospects of success as well as possible required support and obtain the permission to enter the third therapy phase – and, with it, permission to begin the preparation for the exposure phase.

In the **third phase** (“**Skills and Cognitive Elements**”), the therapists analyse behaviour-related (e.g., self-harm) and emotional (e.g., guilt, shame, dissociation) escape strategies and convey the appropriate functional skills. The patients learn to recognise and rate the level of internal tension and learn to identify early signals of beginning dissociative states and to reduce them with strong sensory stimuli or physiological distraction (ice packs, ammonia, chili, juggling, eye-movement, and balancing). They also become familiar with the fundamental evolutionary significance of emotions such as guilt, shame, contempt and disgust and learn to recognise and modulate them.

The exposure-based processing of trauma-associated memories and emotions are at the core of the **fourth phase** (“**Skills-Assisted Exposure**”). To maintain the level of aversive arousal within a tolerable range and to prevent dissociative symptoms, the exposure occurs in accordance with the principle of the skills-assisted exposure. In doing so, the application of skills helps establishing a balance between activation of trauma-associated emotions and awareness of the present moment. The primary objective of this intervention is the exposure to the trauma-associated primary emotions such as powerlessness, disgust, anxiety and pain. In conformity with the theory of inhibitory learning, the intervention results in a reduction of these feelings which are not adequate for the present moment and in the correction of unrealistic fears in terms of a behaviour experiment (e.g., “I will go crazy if I allow this memory.”). Methodically, DBT-PTSD proceeds as follows: First the therapists and patients establish the so-called index trauma together. It has proved reasonable to select the incident here that is currently bound to the most frequent and most distressing intrusions and nightmares. During the later course of the phase, additional stressful

memories can then be the focus. In the second step, the most critical fears and concerns are processed with respect to exposure: "I will go crazy.", "I won't survive it". These fears are first substantiated and questioned in Socratic dialogue. The actual exposure phase begins when the patients first write down the incident including thoughts and feelings that occurred during the event. This script is first read aloud in the therapy session. Then the repeated in-sensu exposure follows. In this, the therapists essentially strive to achieve a high emotional activation and to actively interrupt dissociative symptoms. Prototypically, the patient relates the traumatic experience during the exposure in the first person, in the present, with closed eyes. Intermittently, the exposure is interrupted by the therapists to create the sensory reference to reality: "What is the difference between then and now? How do you see this, how do you feel this?". In the therapy session, the memory should be imagined at least two times. To ensure this, "hot spots" are selected and imagined. It is also helpful to ask at the end of the "hot spots" if the patient has reported anybody to this event and, if not, what prevented them from doing so. Often non-validating rejection by close caregivers is experienced as highly traumatic and should also be exposed. Between the therapy sessions, the patients listen to the audio recordings of the exposure every day at home. We have developed and evaluated an app that can easily impede dissociate symptoms during the exposure and can also monitor the processes of the emotions (decline in guilt, shame, disgust, etc.) (<https://morpheus-deuschel-schueller.de>). In most of the cases, a significant reduction in symptoms (decline in the frequency and distress from intrusions and flashbacks; revision of guilt and shame) sets in within 5 to 6 exposure sessions. Then the focus can be adjusted to other incidents in which the handling of generally requires less time and energy.

The **fifth phase ("Radical Acceptance")** is linked to the exposure phase with exercises in acceptance and embracing what has been experienced. The majority of patients are still at odds with their past after the exposure phase and have marked difficulties in accepting this as unalterable and as an incident that happened. Patients often show concerns that acceptance could signify that the incidents were not so bad or that they have to forgive the perpetrators. Moreover, they show emotional difficulties in parting from old illusions: "If I had only behaved appropriately, this would not have happened and I would have achieved an attentive, loving relationship with my father / mother". This phase is also about ending the illusory relationship with primary caregivers and making room for a mature, revised and realistic consideration. Embracing what has been experienced opens up space for grief which needs its own time.

In the **sixth phase ("A Life Worth Living")**, the patients explore new areas of life or actively seek improvements to those factors which stand in the way of a meaningful life worth living. For patients with a history of CA, topics such as partnership and relationships, physical experience and sexuality as well as changes in the professional life are almost always significant. Precisely because not only the trauma-associated experience and behaviour but also the entire self-concept is to be accounted for in this therapy programme with very intense changes, the patients need structured support in this phase to develop a new living concept. Methodically, we rely on the model of the "old and new path" in this phase.

The **seventh and final phase ("Farewell")** follows some predefined rules, since fear of abandonment is an intrinsic problem of patients with cPTSD. However, ending a therapeutic relationship after such an intense phase of cooperation naturally is a bit painful (for both, therapist and patient).

In summary, DBT-PTSD aims to help patients i) reduce their avoidance of trauma-associated primary emotions such as fear, disgust, pain, and powerlessness, ii) question non-justified trauma-related emotions such as guilt, shame, and self-contempt, and iii) radically accept trauma-related biographic facts. To successfully reduce avoidance of trauma-associated emotions, exposure-based techniques including control of escape strategies are required. Accordingly, patients learn to identify their typical cognitive, emotional, and behavioural escape strategies in response to trauma-related stimuli, and to use DBT skills to control these. The exposure protocol allows the patient to control the intensity of memory activation, and balances the vividness of trauma memories with the awareness of being in the (non-dangerous) present, by using skills during exposure sessions and exposure homework (skills-assisted exposure). Finally, the treatment focuses on relevant psychosocial aspects including work and partnership.

The empirical base of DBT-PTSD

Following the usual process of evaluating a new treatment, as a first step, we carried out a non-controlled clinical pilot trial on residential DBT-PTSD treatment on 29 women who suffered from PTSD after CA and at least one other co-occurring diagnosis [65]. An effect size of Cohen's $d = 1.22$ on the Posttraumatic Diagnostic Scale (PDS; [66]) was found between baseline and the follow-up 6 weeks after the end of the 12-week programme. Effect sizes for secondary outcomes ranged from medium to large. The results suggested that DBT-PTSD is a very promising treatment for reducing severe PTSD after CA.

Next, we conducted a RCT in which women ($N = 74$) diagnosed with PTSD after CA plus at least one of the following additional diagnoses/symptoms: at least 4 DSM-IV criteria of BPD, current major depressive disorder, eating disorder, or alcohol and drug abuse were randomised to either the 12-week residential DBT-PTSD programme or a treatment-as-usual waiting list (TAU-WL) [67]. The two primary outcomes were scores on the Clinician-Administered PTSD Scale (CAPS; [68]) and on the PDS [66]. All measurements were done by blind raters. Only 6% of the DBT-PTSD group (2 out of 36) discontinued the treatment prematurely. Hierarchical linear models yielded statistically significant group*time effects, indicating a more pronounced improvement in the DBT-PTSD group compared to the TAU-WL, with large effect sizes. Between-group effect sizes were large for the CAPS (Hedges's $g = 1.57$), PDS ($g = 1.27$), Global Assessment of Functioning (GAF, [69]; $g = 1.31$), and Beck Depression Inventory-II (BDI-II, [70]; $g = 1.13$). No patient in the DBT-PTSD group showed worsening of posttraumatic symptoms or exaggerated dysfunctional behaviour [67, 71]. Neither BPD symptom severity, the number of BPD criteria, nor self-harm behaviour had a significant influence on treatment outcome. Our findings provided clear evidence for the efficacy, high tolerability, and safety of the newly developed DBT-PTSD under residential conditions.

In preparation for the trial on hand, we have adapted the DBT-PTSD manual to outpatient conditions. DBT-PTSD now consists of a 1 year multi-component treatment providing up to 45 sessions à 50 min (37.5 h hours in total) of individual therapy (and telephone consultation as needed) plus up to 3 additional booster sessions during the following 3 months. These booster sessions mainly focus on implementation of relevant treatment aspects in daily live. We have tested the manual in a pre-post pilot study that enrolled 20 patients with PTSD after CA plus at least 4 BPD criteria, and found similar results to those obtained under residential conditions (effect size CAPS: Cohen's $d = 1.5$) [72].

Unlike current state-of-the-art treatments for PTSD, which typically consist of 12 to 16 sessions, we decided on a longer treatment duration and more treatment sessions as justified by the following:

- a) The included patients suffer not only from PTSD but also from severe emotional dysregulation and serious dysfunctional behavioural patterns including self-harm behaviour. Standard DBT programmes that do not focus on PTSD usually last at least 1 year [73–75];
- b) The successful residential programme consists of twice-weekly 45-min sessions of individual

treatment (a total of 23 sessions over the 12 weeks) plus the following weekly group treatments: 90 min of skills training (11 sessions in total), 60 min of group intervention focusing on self-esteem (8 sessions in total), three 25 min mindfulness sessions (35 sessions in total), as well as 60 min of PTSD-specific psychoeducation (11 sessions in total) and three 90-min non-specific weekly group interventions (music therapy, art therapy).

In the trial on residential DBT-PTSD, we found an average reduction of PTSD symptoms as assessed by the CAPS from 88 at admission to 55 at discharge [67]. Despite this clinically significant reduction in the primary outcome, many of the patients needed further psychotherapy after discharge. Taken together, 45 sessions of outpatient treatment is a minimum, and is justified for scientific and ethical reasons. Furthermore, the German health care system in general covers the costs for up to 80 sessions of behaviour therapy. Designing a short-term therapy for this group of severely disturbed patients would be unrealistic and would not fit into the frame of the German health care system. To facilitate transfer into routine conditions, we further decided to provide all psychotherapeutic sessions in an individual format. This allows to disseminating these treatments to rural regions which have little access to psychotherapeutic supply.

Cognitive processing therapy (CPT)

We chose CPT as an adequate active control condition. In close cooperation with P. Resick (Duke University, Durham, USA), the developer of this treatment, we have adapted the established protocol for CPT (cognitive only version) to a 1 year outpatient individual therapy programme comprising up to 45 sessions plus up to 3 additional booster sessions during the following 3 months. Thus, dosage and frequency of both treatments are equal.

The protocol has been translated and has been approved by Dr. Resick, who serves as a cooperation partner and supervisor. We have further translated and adapted the rating for therapeutic adherence for CPT on the basis of the ones used by Resick et al. [45, 76].

To ensure treatment fidelity therapists receive 1.5 h per week team consultation with local supervisors. In addition, the local supervisors have monthly case-consultations with the treatment developer Dr. Resick.

Individual sessions follow a session-by-session protocol. In addition to building an effective therapeutic alliance, the first 4 sessions aim to obtain a detailed case history, patient's specific problem behaviour, and emergency plans. The next 12 sessions contain the original 12 CPT core sessions, starting with psychoeducation about

PTSD and the treatment rationale. After the patient has written an impact statement as to why the trauma has happened and how it affected her beliefs, cognitive restructuring is applied with regard to guilt and denial. Then, worksheets are introduced step by step which are intended to support the patient in identifying and changing other dysfunctional trauma-related beliefs (the so-called stuck-points) regarding safety, trust, control and power, self-esteem, and intimacy. From session 17 onwards, the content of the sessions is derived from the patient's individual stuck point log. After working on the index trauma, and writing a second impact statement, other traumatic incidents can be the treatment focus. Towards the end of the treatment, other goals of the patient (positive activities, social relationships, vocational training or work issues) can be addressed using the already established cognitive techniques.

Design

Work plan

The three goals of this collaborative research group are:

- 1) To evaluate the efficacy and effectiveness of a newly developed outpatient psychotherapy programme tailored specifically for patients suffering from cPTSD after childhood physical and sexual abuse (Main project)
- 2) To assess the role of treatment integrity (therapeutic adherence and competence) for treatment outcome of DBT-PTSD and CPT (Adjunct project I)
- 3) To study the impact of successful treatments on the neurophysiological underpinnings of dissociation and intrusions (Adjunct project II)

Main project

Hypotheses

- 1) Improvement of PTSD symptoms will be superior in DBT-PTSD as compared to CPT.
- 2) The superiority of DBT-PTSD over CPT is related to the severity of BPD symptoms at baseline.

Additional analyses

The collected data will enable us to additionally test potential moderator variables for both, general and differentiated treatment response: a) Client variables including severity of CA, age at the onset and duration of CA, pre-treatment severity of PTSD and dissociation, co-occurring depressive disorder, current age, and educational level; b) Therapist variables including length of experience and gender.

Health care costs

As cPTSD is related to very high health care costs, we will also address this aspect. Direct and indirect costs will be compared across treatments and will be further compared with costs related to other epidemiologically relevant mental disorders. The reference time frames will be 1 year before the start of the treatments, at the end of treatments, and at 1 year follow-up. State of the art methodology will be applied (e.g., [77–80]), including a questionnaire and a structured interview to assess health care costs.

Inclusion criteria

We include female subjects between the ages of 18 and 65 who have a primary diagnosis of DSM-5–defined PTSD related to childhood sexual abuse or childhood physical violence before the age of 18. In addition, the patients have to meet at least 3 DSM-5 criteria for BPD (including criterion 6, affective instability). Furthermore, the patients have to be available for 1 year of outpatient treatment with no scheduled absence of more than 4 weeks, have to understand the implications related to the participation in a clinical trial, and have to give their written informed consent prior to randomisation.

Exclusion criteria

Exclusion Criteria are a lifetime diagnosis of schizophrenia or bipolar I disorder, mental retardation, severe psychopathology requiring immediate treatment in a different setting (such as acute alcohol withdrawal syndrome, or BMI < 16.5), current substance dependence without abstinence within the last 2 month, life-threatening suicide attempts as assessed by the Severe Behaviour Dyscontrol Interview (SBDI, [81]) within the last 2 months, medical conditions contradicting exposure protocol (e.g., severe cardiovascular disorder), pregnancy, currently severe instable life situations (e.g., homelessness, or ongoing victimisation by the perpetrator), or treatment with CPT or DBT-PTSD within the last year. Patients with ongoing self-harm or high-risk behaviours are accepted in the study.

Randomisation and blinding procedures

Before the start of the study, patients who meet the eligibility criteria are randomised in 1:1 ratio to either DBT-PTSD or CPT. Concealed assignment to the treatment groups is assured by using an external, web-based randomisation service (<http://randomizer.at>, University of Graz, Austria). All persons involved in the diagnostics and ratings are blinded with respect to the group assignment.

Crisis management

Both interventions develop safety plans at treatment start, and employ active crisis intervention when needed. Similar to standards of care, therapists provide on-call after-hours service via area crisis services. Patients in both groups have access to emergency services when viewed as necessary by therapists in the respective conditions. Inpatient services are readily available across conditions and across sites.

Hospitalisation policy

Because of the nature of the population, some patients may require treatment in a psychiatric hospital, either at their own request or due to the concerns of care providers (usually due to high acute suicide risk). No outpatient therapist will serve in a responsible position for any patient (e.g., attending) during inpatient treatment. Study treatment will be terminated when patients are hospitalised for more than 2 weeks.

Psychotropic medication protocol

There is no established pharmacological treatment protocol for PTSD after CA. On the other hand, tapering patients off medication would restrict recruitment to a small number of patients with less severe pathology and would be at the cost of external validity. We decided to track week-by-week medications and medication changes in order to document any difference in medication management across conditions. The purpose of the study is not to evaluate the efficacy of a combination of psychotherapy and a psychopharmacologic algorithm, but rather to evaluate psychotherapy interventions under conditions similar to those encountered in the community.

Dropout policy

Besides patients prematurely terminating therapy, any patient who misses 6 consecutively scheduled weeks of individual therapy or stays longer than 2 weeks in a psychiatric hospital will be considered a drop-out from treatment. This rule was instituted because it can be very difficult to know exactly when an emotionally dysregulated patient has actually dropped out of therapy. Often, patients miss sessions because of mood swings, discouragement, or interfering day-to-day hassles, but they do not mean to drop out of treatment and they often change their minds within a short period of time. This drop-out rule will be explained to patients during the first session of individual therapy. It is conceivable that some patients achieve the treatment goals (full symptomatic remission) and want to terminate the treatment prior to 1 year of treatment. The study protocol foresees the possibility of an early remission: No longer fulfilling the diagnostic criteria of PTSD, as assessed by

the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5; [82, 83]), as well as the approval by the patient, the therapist and the supervisor. Patients who have achieved an early remission are not considered having dropped out of the study.

Protocols to prevent cross-contamination between DBT-PTSD and CPT conditions

To reduce contamination, CPT and DBT-PTSD are not provided by the same therapists. Treatment fidelity will be supported by regular team consultation, including video-based real-time supervision in both treatments. Protocol violations will be reported to the therapists immediately. Therapeutic training and experience of the therapists will be balanced across treatment groups.

Therapists, training, and treatment adherence

At each of the three sites, therapists have been either trained in DBT-PTSD or in CPT. DBT-PTSD therapists at each site have been trained by the treatment developers, CPT therapists at each site have been trained by Dr. Resick. Therapists were asked to videotape every session. A randomly selected 2 of the 45 sessions of each therapy are being evaluated with regard to treatment integrity. DBT-PTSD treatment adherence is evaluated by using the DBT-PTSD Adherence Rating Scale, which generates a global rating of DBT adherence as well as sub-scale strategy ratings for various DBT-PTSD strategy domains. CPT treatment adherence is evaluated using the CPT Adherence Ratings Scale, which is based on the adapted CPT treatment manual and orientated on the original CPT Therapists' Adherence Protocol – Revised [84] and has been adapted to the present CPT manual by R. Steil's workgroup [76].

Assessments

Assessments will be conducted by blind raters at intake and at months 3, 6, 9, 12, 15 (end of the treatment phase) and at 1 year follow up. In addition to these assessments, in DBT-PTSD weekly measurements will be completed in the form of a daily diary card, rating of suicidal ideation, non-suicidal self-injury, therapist notes, and pre- and post-session ratings for each individual session.

Screening measures

Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I; [85]); CAPS-5 [82, 83]; International Personality Disorder Examination – Borderline section (IPDE; [86]); SBIDI [81]; Childhood Trauma Questionnaire (CTQ; [87]), Maltreatment and Abuse Chronology of Exposure Scale (MACE; [88]), Mehrfachwahl-Wortschatz-Intelligenztest (MWT; [89]).

Primary and secondary endpoints

The CAPS-5 [82, 83] will be used as the primary endpoint for testing hypotheses 1 and 2. In the first place testing will be based on the dimensional CAPS-scores assessed in the intent-to-treat sample. Secondary endpoints will include the Posttraumatic Stress Disorder Checklist for DSM-5 (PCL-5; [90]) to assess self-rated symptomatology of PTSD, the Dissociation Tension Scale (DSS-7, [91]), the short version of the Borderline Symptom List (BSL-23; [92]), the behavioural items of the Borderline Symptom List [93] including suicide attempts and non-suicidal self-injury, the BDI-II [70], and the GAF [69].

Power analyses

The sample size was determined from a formal power analysis. The study was designed to have sufficient statistical power ($1-\beta \geq 0.80$) to detect a supposed medium-size superiority of DBT-PTSD over CPT for the time*treatment interaction. A no more than medium between-group effect-size ($d = 0.5$, which corresponds to an effect-size $f(V)$ of 0.354 for the time*treatment contrast for DBT-PTSD vs. CPT within a repeated measures design) was assumed since CPT was supposed to be substantially more efficacious than the TAU-WL condition to which DBT-PTSD has been previously compared. Under these assumptions, data from 70 participants per group are required to achieve sufficient statistical power ($1-\beta \geq 0.80$) for Hypothesis 1. For Hypothesis 2 ("the superiority of DBT-PTSD is related to the severity of BPD-symptoms at baseline") the power analysis indicated that a sample-size of at least 90 per group is needed to achieve sufficient statistical power to detect a clinically meaningful incremental R^2 of at least 0.1 within a regression model. Accordingly, the recruitment target was set at a minimum of 180 participants (90 per group) to be randomised. In order to recruit and treat a minimum of 180 patients within 2 years, the study is conducted at three large German centres: the Central Institute of Mental Health in Mannheim, the Institute of Psychology, Goethe University in Frankfurt, and the Institute of Psychology, Humboldt University in Berlin.

Statistical analysis

The CAPS-5 and the assessments pertaining to the secondary hypotheses are obtained at baseline (=T1); at month 3 (=T2); month 6 (=T3); month 9 (=T4); month 12 (=T5, end of high frequency phase); and month 15 (=T6, end low frequency phase = post assessment). Mixed linear models including these assessment points will be used as the primary analytic strategy to analyse and compare the changes in the two groups. Parameters will be estimated using restricted maximum likelihood estimates (REML) and without imposing predefined

assumptions such as compound symmetry on the covariance matrix. Analyses are based on the intent-to-treat sample of patients who were randomised and fulfilled all inclusion criteria. To provide a more complete picture these primary analyses are complemented by analyses comprising those participants who completed the study according to protocol (ATP). To allow for a more comprehensive evaluation of the data, the results from the mixed linear models are supplemented by clinically meaningful indices including remission rates, response rates and effect sizes.

Adjunct project I: Identifying key therapeutic components and competence as predictors of outcome in DBT-PTSD and CPT

Background

Treatment integrity, defined as the extent to which treatment is implemented as intended, is not only required in order to draw valid conclusions from clinical trials, but is also implicated as a key ingredient of treatment success [94, 95]. Treatment integrity includes 3 components: 1) treatment adherence, which refers to the degree of utilization of techniques as specified in a manual, 2) treatment differentiation, which implies that treatments in a study differ on relevant dimensions; and 3) therapeutic competence, which is defined as how well these techniques are delivered and adapted to the specific therapeutic context [96].

In controlled clinical trials, it is currently standard practice to control for treatment integrity by using adherence ratings, but there are considerably fewer studies assessing therapeutic competence and its relationship to outcome [95, 97, 98]. With respect to established treatments of PTSD, there are no published studies investigating adherence and competence as predictors of outcomes. One study investigated these variables in gestalt-derived treatment for survivors of CA, but only 54% of the sample met PTSD DSM-IV criteria [99]. Competence here was not significantly related to changes in interpersonal stress and emotional resolution; it should be noted, however, that ratings were delivered by non-expert raters. In contrast, previous trials with other disorders [100, 101] indicate that competence is a significant predictor of outcome and a better predictor than adherence. In both studies, improved methods to assess competence were used, which also covered specific treatment components.

Based on the finding that therapeutic alliance has been more consistently found to correlate with treatment outcome than competence correlates with treatment outcome [102, 103], it has often been argued that common factors may be more important than competences related to the specific treatment. However, findings from a meta-analysis [98] suggest that therapeutic alliance may

be considered as a moderator of the relationship between competence and outcome, as indicated by larger effect sizes in studies that did not control for the influence of therapeutic alliance.

The present study aims at identifying therapeutic competencies that are predictive for effective treatment of PTSD, as well as its associations with adherence and alliance. In addition, the present study provides the possibility to compare two treatments, DBT-PTSD and CPT, with respect to general aspects of competence common to cognitive-behavioural treatments. Finally, the contribution of particular components of general and specific therapeutic competence to treatment response in both treatments, will be subject to secondary, exploratory analyses.

Hypotheses

- 1) Therapists' general therapeutic competencies will significantly predict treatment response (pre-post-changes of CAPS) in both treatments.
- 2a) Therapists' DBT-PTSD-specific competencies will significantly predict treatment response at post-treatment in DBT-PTSD.
- 2b) Therapists' CPT-specific competencies will significantly predict treatment response at post-treatment in CPT.

We expect that both general (hypothesis 1) and specific competencies (hypotheses 2a and 2b) will contribute significantly to the prediction of treatment response at post-treatment when controlling for pre-treatment severity of PTSD (pre-treatment scores of the CAPS) and BPD (pre-treatment scores of the BSL) as well as adherence and therapeutic alliance. To test hypotheses 2a and 2b, general competencies will also be controlled for.

Method

Assessments: Primary outcome measure will be the CAPS-5 [83]. Therapeutic competence will be assessed by two independent and extensively trained clinician raters who are blind to treatment outcome, using rating scales that have been specifically developed on the basis of the manuals applied in this trial (i.e. [104]).

Observer ratings of competence and adherence will be obtained from two randomly selected videotaped sessions per patient, covering two different treatment phases. The level of ratings averaged over the two phases will enter the path analyses. To assess general competencies, the Cognitive Therapy Scale [105] will be applied. This scale comprises 15 items (e.g., homework, guided discovery, efficient use of time, etc.). Items are rated on a scale ranging from 0 to 6, referring to the quality of

implementation of interventions. The DBT-PTSD Competence Rating Scale [106] comprises 6 items referring to components specific for DBT-PTSD, such as appropriate implementation of skills. The CPT Competence Rating Scale [104] comprises 4 items reflecting competencies specific for CPT, such as identification of stuck points and optimal application of worksheets. For both treatment specific competence scales, items are rated on a scale from 0 to 6, and according to a detailed raters' manual referring to the quality of implementation of interventions.

Adherence ratings will be assessed using the DBT-PTSD Adherence Rating Scale and the CPT Adherence Rating Scale, respectively, which both have been developed by our workgroup (i.e. [76]). To rate competence and adherence for one treatment session, on average 2 h are required.

All rating scales which have been developed to assess treatment integrity of DBT-PTSD and CPT as used in the present RCT have been evaluated for their psychometric properties e.g., with respect to inter-rater reliability (i.e., [76, 104]).

Therapeutic alliance will be assessed using the Helping Alliance Questionnaire [107]. This rating scale is an 11-item questionnaire that assess therapeutic alliance from both the patient's and the therapist's perspective. For example the patients' version consists of 11 subtypes of patients' helping alliances (e.g., the patient feels optimism and confidence that the therapist can help; the patient shares with the therapist similar conceptions of the aetiology of the problems). These components are rated on a 6-point Likert scale.

Data analyses: Path analyses will be carried out to determine the effects of the predictor variables listed above. For all hypotheses, differences in CAPS-5-scores at pre- vs. post (T6) will be specified as the criterion variable. For hypothesis 1, path analyses models with general competencies as predictor variables will be specified. For hypotheses 2a and 2b, path analyses models with the specific therapeutic competencies as predictor variables will be specified. For all hypotheses, path analyses models with pre-treatment severity of PTSD and BPD (pre-treatment scores in the CAPS-5, pre-treatment scores in the BSL) as well as therapeutic adherence and therapeutic alliance as additional predictor variables will be carried out. For hypotheses 2a and 2b, general competence will also be included into the path analysis. For hypothesis 1, a multi-sample path analysis with the grouping variable treatment condition (DBT-PTSD vs. CPT) will be performed. Path analyses allow us to specify correlations between predictor variables, and will be carried out using Mplus version 7 [108]. Mplus offers several advantages for data analysis, such as effective ways of missing value imputation (FIML) and dealing with multi-level (nested) data.

Adjunct project II: Experimental validation of therapy response

Background

Besides psychometric measures, behavioural and neurobiological data can be used to validate treatment effects. Several studies have shown that functional (and in part also structural) alterations in PTSD are amenable to change by psychotherapy [109]. While intrusions are characterized by increased traumatic memory processing, dissociation is related to reduced memory processing up to amnesia [110]. Clinically, intrusions are accompanied by physiological hyperarousal, while dissociation is characterized by reduced arousal and, in extreme cases, a shut-down of sensory and motor processes. Dissociative responses have been shown to be stress-related [111] and reduced startle responses during dissociative states have been demonstrated [112]. The interaction of dissociation and learning processes has been investigated: Pavlovian conditioning was disturbed during dissociation in patients with BPD [57], and dissociation predicted poor outcome of standard DBT and of DBT-PTSD [61, 113]. Recently, a neurobiological model of PTSD has been proposed, differentiating processing of intrusive hyperarousal as opposed to dissociation with emotional overmodulation [114]. Intrusive responses are characterized by increased sympathetic activity (elevated heart rate and blood pressure), whereas dissociative responses are characterized by no change or a decrease in heart rate [115]. On the neural level, several studies have demonstrated amygdala hyperactivity together with medial prefrontal hypoactivity [116–118] to be associated with intrusive hyperarousal. On the other hand, dissociative responses are characterized by an increase in medial prefrontal and insular activity [115, 119, 120]. Amygdala activity was negatively correlated with dissociation levels during an Emotional Working Memory Task (EWMT; [121]). As intrusions and dissociation interfere with attention, the Stroop task has been widely used in PTSD. PTSD patients demonstrated increased interference to trauma-related material in the Emotional Stroop Task (EST; e.g., [122–124]). Imaging studies have demonstrated over-activation in the dorsal anterior cingulate cortex (dACC) as well as the insula in PTSD related to sexual abuse [125, 126]. Psychotherapy response was found to be related to a decrease of this over-activation in sexual abuse-related PTSD [127].

Hypotheses

- 1a) Improvement of PTSD symptoms from pre to the end of the high frequency phase of treatment (Δ CAPS T1-T5) is correlated with the reduction of dorsal ACC and anterior insula activity (Δ BOLD-

signal T1-T5) during trauma-related words in the Emotional Stroop Task (EST).

- 1b) Improvement of PTSD symptoms from pre to the end of the high frequency phase of treatment (Δ CAPS T1-T5) is correlated with reduction of amygdala activity and heart rate increase (Δ BOLD-signal T1-T5) during negative pictures in the Emotional Working Memory Task (EWMT).
- 2) Exploratively, we will investigate potential differences regarding neural activation patterns between DBT-PTSD responders and CPT responders. As DBT-PTSD includes skills-assisted exposure, we assume that DBT-PTSD will have a stronger effect on intrusions than will CPT. At the neural level, we would therefore expect a stronger reduction of the neural activation patterns of intrusions in DBT-PTSD responders as compared to CPT responders.

Power analyses for the hypotheses, i.e., that “Improvement of PTSD symptoms is correlated with the reduction of i) dorsal ACC activity, ii) anterior insula activity, iii) amygdala activity, iv) heart rate increase” are all tested at the Bonferroni-adjusted level of $\alpha_1 = 0.0125$. A large effect ($r = 0.5$) is assumed for the hypotheses. The assumption of a large effect is in line with the results on Emotional Stroop interference published by Thomaes et al. [127] who found large correlations ranging from 0.64 and 0.74 between improvements on the CAPS and decreased activation of several regions including the dorsal ACC and the anterior insula. Under these assumptions, the sub-sample recruited at the Mannheim and Frankfurt sites will be sufficient to achieve sufficient statistical power of $1 - \beta = 0.86$ for rejecting each of the hypotheses at the adjusted α -level of 0.0125 (two-tailed).

Method

Patients from both the DBT-PTSD and CPT arms who have been recruited at Mannheim and Frankfurt will be included in Adjunct project II, in which fMRI and laboratory measurements will be done before and after the high frequency phase of the treatment. During fMRI, the EST (20 words per valence; valence types: neutral, negative, trauma-related, colour words; each word presented in four colours) will be conducted first. Following the EST, the EWMT will be conducted, a working memory task with neutral and negative distractors. Activity of brain regions as assessed by the BOLD-responses as well as sympathetic (heart rate) and parasympathetic activity (heart rate variability) will be measured. Acute dissociation will be assessed with the Dissociation Tension Scale (DSS-4; [128]) intrusions will be assessed with the subscale “Intrusions” of the Impact of Event Scale-Revised (IES-R; [129]). Imaging data will be acquired using

a 3 Tesla MRI Scanner (TRIO, Siemens Medical Systems, Erlangen, Germany). Neural activation patterns will be correlated with dissociation and intrusion scores within a multiple regression analysis using SPM 8 (<http://www.fil.ion.ucl.ac.uk/spm/>).

Discussion

We have designed DBT-PTSD as the first treatment programme specifically designed for cPTSD related to childhood abuse. A first RCT revealed large between group effect sizes as compared to treatment-as-usual under residential conditions. The study on hand is aimed to compare the newly designed treatment with an established evidence based state of the art programme – CPT. In addition to treatment effectiveness and efficacy, this study will provide a large data set of including 200 patients with 6 assessment points plus follow up. This will open the opportunity to enlarge our knowledge about the complexity and interrelatedness of psychopathology, neurocognitive patterns and neuroimaging. Considering the fact, that cPTSD is a new ICD-11 diagnosis, there is not only a strong need to understand predictors, moderators and mediators of treatment response, but to create hypotheses of differential treatment response to exposure based or pure cognitive treatments.

Abbreviations

ATP: According to Protocol; BDI: Beck Depression Inventory; BMI: Body Mass Index; BPD: Borderline Personality Disorder; BSL-23: Borderline Symptom List – short version; CA: Childhood Abuse; CAPS: Clinician-Administered PTSD Scale; CAPS-5: Clinician-Administered PTSD Scale for DSM-5; CPT: Cognitive Processing Therapy; cPTSD: Complex Posttraumatic Stress Disorder; CSA: Childhood Sexual Abuse; CTQ: Childhood Trauma Questionnaire; dACC: Dorsal Anterior Cingulate Cortex; DBT: Dialectical Behavioural Therapy; DBT-PE: Dialectical Behavioural Therapy plus Prolonged Exposure; DBT-PTSD: Dialectical Behavioural Therapy for Complex PTSD; DESNOS: Disorders of Extreme Stress Not Otherwise Specified; DSM-5: Diagnostic and Statistical Manual of Mental Disorders -5th revision; DSS-7: Dissociation Tension Scale; EMDR: Eye Movement Desensitization and Reprocessing; EST: Emotional Stroop Task; EWMT: Emotional Working Memory Task; GAF: Global Assessment of Functioning; ICD-11: International Statistical Classification of Diseases and Related Health Problems 10th Revision; IES-R: Impact of Event Scale – Revised; IPDE: International Personality Disorder Examination – Borderline section; MACE: Maltreatment and Abuse Chronology of Exposure Scale; MWT: Mehrfachwahl-Wortschatz-Intelligenztest; PCL-5: Posttraumatic Stress Disorder Checklist for DSM-5; PDS: Posttraumatic Diagnostic Scale; PE: Prolonged Exposure; PTSD: Posttraumatic Stress Disorder; RCT: Randomised Controlled Trial; REML: Restricted Maximum Likelihood Estimates; SBDI: Severe Behaviour Dyscontrol Interview; SCID-I: Structured Clinical Interview for DSM-IV Axis I Disorders

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Availability of data and materials

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Authors' contributions

MB, KP, NK, TF and PL developed the main project RCT concept and design. RS and MME designed adjunct project I, CS and JH designed adjunct project

II. MB, KP and NK drafted the manuscript and all others provided critical revision. All authors read and approved the final manuscript.

Ethics approval and consent to participate

This study approval was obtained from the independent Ethics Committee of the Medical Faculty Mannheim at Heidelberg University (Reference number: 2013–635 N-MA). The study was also approved by the ethics committee of Goethe-University and Humboldt University.

Consent for publication

Not applicable.

Competing interests

On behalf of all the authors, the corresponding author states that he has no competing interests.

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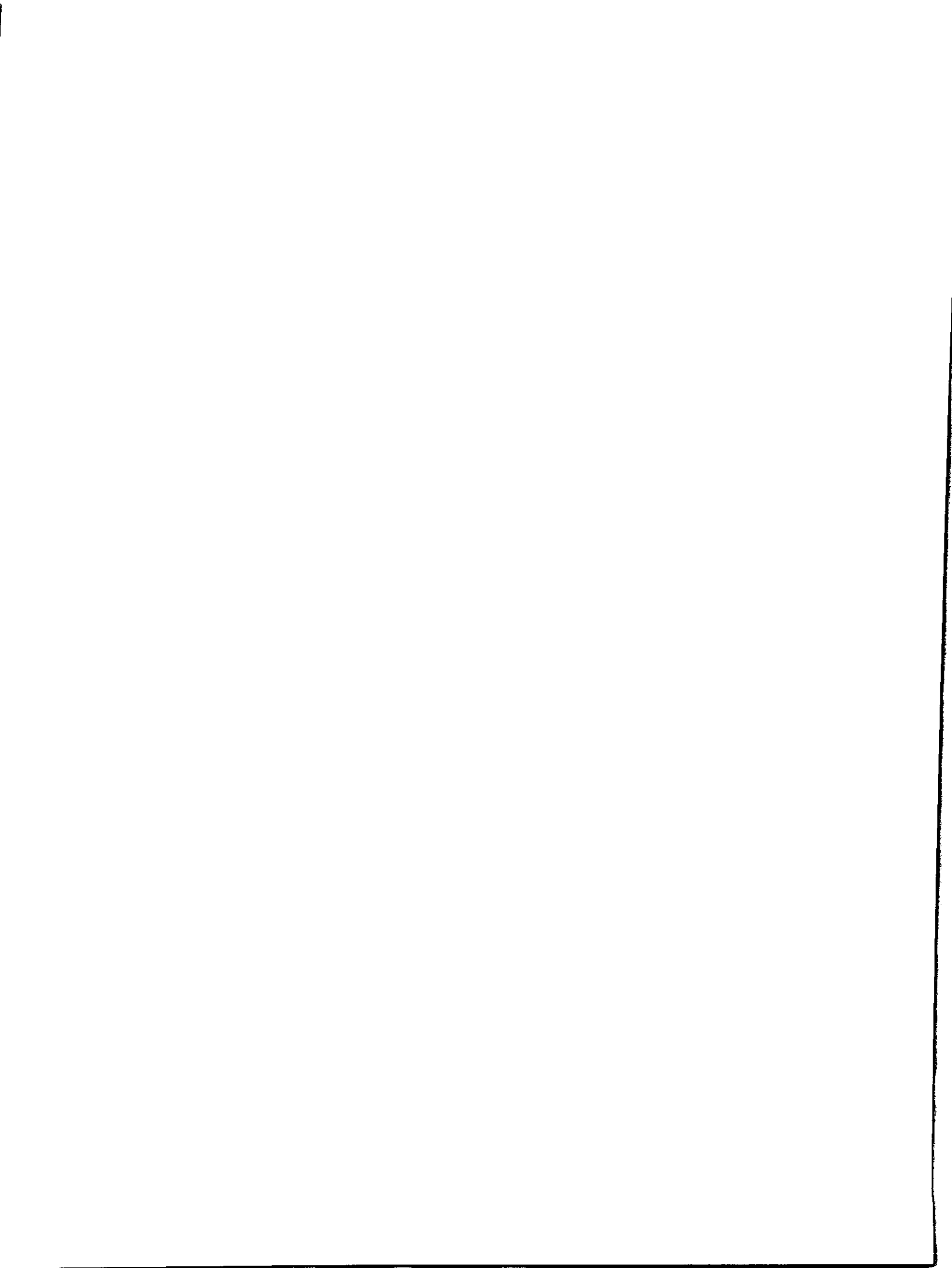
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ORIGINAL ARTICLE

Mental health in prisons: A public health agenda

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Abstract

Mental illness affects the majority of prisoners. Mental health issues are beginning to take a central position in the development of prison health services, reflecting this burden of disease. This change in focus is not before time. But prison mental health services cannot exist in isolation. Public health systems should lead provision of care for patients with acute and severe illness. A whole prison approach to health and, specifically, mental health will offer the greatest likelihood that offenders will thrive, benefit from imprisonment, and lead law-abiding lives after release. Public awareness of the scale and commitment of prisons to mental health and illness, and understanding of prisons' role in society, are necessary developments that would protect and enhance public mental health, as well as creating a healthier and safer society. This article draws on recent reviews, information and statements to set out a public health agenda for mental health in prisons.

Keywords: *mental health, public health*

Context

The mental health agenda in prisons is an under-recognised problem and challenge for prison systems everywhere. Mental illness lurks in the shadows of a seemingly overwhelming burden of need for prison health care through addiction to drugs, and dependence on alcohol (WHO, 2007). In developed societies, their prison systems have mental illness and mental health problems next on their list of burdens for health care. Communicable disease eclipses mental health in less developed countries – HIV, TB, other blood-borne viruses and sexually transmitted infections. Until present times, tackling mental illness for prison systems has meant the containment and treatment of people with severe and enduring mental illness – so-called Mentally Disordered Offenders. While their prevalence is significantly higher than in the general population and they present challenges for custody and care, these people are relatively uncommon within the prison system. Prison systems have a range of relationships with the judicial and public health systems of the country in devising arrangements to look after such people and address their needs, with prisons often shouldering much of the responsibility for secure mental health care (Edgar & Rickford, 2009).

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However, the agenda has now broadened in the following ways:

- (1) A building and clear consensus that people with acute and severe mental illness should not be in prison: they should be entitled to health care in a secure hospital setting, designed for the purpose of expert treatment and acute management.
- (2) Prison systems have begun to recognise the burden of lesser degrees of mental illness, or conditions of 'sadness'. Anxiety, depression and associated stress affect the majority of prisoners (Graham, 2007; WHO, 2007). It is neither possible nor practically relevant, subject to subsequent study, to determine whether the effect of imprisonment induces mental health in a population already pre-disposed to poor mental well-being. There is little doubt, nonetheless, that the experience of incarceration in many present-day prisons can only make mental health the poorer.
- (3) Publications such as this journal, and the work of WHO in drawing attention to this agenda, bringing together leading thinkers and practitioners in mental health care, has started to create an agenda for mental health in prison. Work has highlighted good practice as well as issuing a challenge through the Trecin Statement of the WHO Health in Prisons Project (WHO European Office, 2008).
- (4) The Trecin Statement aims to shape an agenda that promotes mental health as an integral part of a prison's ethos, tackling mental illness of every severity, highlighting the need to reduce further harm to mental well-being from the experience of prison while reducing the risk to the public, through crime or acts made more likely by mental disorder. Mental health promotion, unlikely as it sounds, is possible in prison, and is an essential component towards rehabilitation and the core purpose of prison as a place to reduce the likelihood of re-offending. The contribution which a good primary care service can provide for mental health in prisons has been outlined (SCMH, 2007).
- (5) With the rising global interest in health inequalities, the potential for health in prisons to help reduce inequalities is of some importance. This especially applies to mental health, which has recently been described as 'a fundamental element of the resilience, health assets, capabilities and positive adaptation that enable people both to cope with adversity, and to reach their full potential and humanity' (Friedli, 2009). This is an area deserving of greater research and development as part of coping better with mental health and prisons.
- (6) Some work and knowledge is still speculative – for instance, the emerging debate on trans-institutionalisation, whose underlying theory is that the closure of mental health institutions, inadequate capability and alternatives of supervision and care for people with mental disorders in the community, has driven them to crime and imprisonment. While tragic, this debate highlights the interplay between the mental health agenda in prison, and that of public mental health and provision of an adequate blend of mental health services and positive public mental health for the entire population.

Facts and figures

The work of Blaauw and von Marle, set out in the WHO Guide to the Essentials in Prison Health (WHO, 2007) (see Box below) makes clear the burden of mental illness in prisons internationally. The presence of psychosis is at least twice as common as the general population. The presence of all severities of depression and other conditions is even higher

among women prisoners than men. The presence of depressive symptoms as a sentinel indicator of the stress-anxiety-depression complex is near to universal among prisoners – 89% recording ‘depressive symptoms’. Meantime, there is a background of personality disorder of varying types affecting the majority.

Mental health in prisons – prevalence of illness, disorder, symptoms

- Psychosis – ~4%
- Major depression – 10%*m.*; 12%*f.*
- Personality disorder – >50%
- Depressive symptoms – 89%
- Stress-Related symptoms – 74%

‘A WHO Guide’; Blaauw and von Marle; 2007

Mental health symptoms and conditions should also be seen against the backdrop of at least 70% of most prisoner populations with problems with drug addiction and alcohol dependency. It is readily apparent, therefore, that prisoners present with multiple co-occurring problems, often at their most acute on first reception into prison. Their overall burden or need for health care is disproportionately much higher than that of communities from which they come. Within the prisoner population, there is evidence that not only women, but also undocumented migrants and any other minorities have an even higher risk of developing mental illness. The rising age structure within prisons is introducing to the population new challenges such as depression and dementia among older people (Edgar & Rickford, 2009). In addition, there is early evidence through small studies (Brooker, Fox, Barrett, & Syson-Nibbs, 2008) that offender populations in the community have similarly poor levels of health more akin to the prison than the background community mental health experience.

Blaauw and von Marle’s work turns then to the burden of care. Again, drawing together published experience internationally, they estimate that between 6% and 12% require mental hospital care owing to the severity of their illness and a staggering 30–50% require ‘some assistance from mental health care services’.

Until now, few prison systems have been aware of such high levels of morbidity, let alone find themselves in a position to respond through realistic endeavours to invest to levels that would approximate the need for health care (Edgar & Rickford, 2009). However, it is also clear that with levels of illness and need for care as high as those stated, public health systems must be in a better position to respond to mental illness through hosting the care of people with particularly severe ailments, and offering in-reach services to prisons with high burdens of care need. The second general implication of such high levels of need is that prison systems in their entirety require, as communities, to support people with mental illness and poor mental well-being as a central characteristic of their role.

The Trencin Statement

In response to these statistics, the WHO's Health in Prisons Project has focused on mental health and mental illness in two annual conferences within the 14 years of its existence. The production of a consensus Statement on Mental Health Promotion in Prisons 1998 was, in many senses, ahead of its time. Since then, there has been considerable work on mental health promotion (see WHO, 2005) but little of it in the prison environment. Prison and health is often seen as an oxy-moron when the words are placed together. Indeed, prison and the promotion of mental health seem entirely contradictory. Nonetheless, the Trencin Statement puts forward forcefully the case for prison systems, and wider public health systems, to take prisons and mental health much more seriously.

In its opening passages, it states that '*prisons (are) becoming 21st Century asylums for the mentally ill (and are) unsuitable places with limited help and treatment available*'.

Most prison systems manage the burden of severe and enduring mental illness among mentally disordered offenders – those for whom crime is a prominent part of their behaviour and major life events. The Trencin Statement advocates that, while recognising the concentration of people with severe and enduring mental illness in prisons, the treatment of acute illness is inappropriate for prison. The ethos of prison is wrong. Resources, facilities and clinical skills are usually inadequate; the institutions are not geared to therapeutic environments. People with very high needs fail to thrive. Responding to the needs of people with severe and enduring mental illness who are acutely unwell is a complex matter – it is expensive for whichever system responds to their needs. It is often bound up with mental health legislation of the country and closely allied with human rights and entitlements. Development of suitable systems that meet the needs require collaboration between health, judicial and legislative interests, and merit resources. But the Trencin Statement's assertion is unavoidable as a challenge to public health systems, given the experience and knowledge available from Member States within the WHO European region.

The Statement goes on to state, '*it is in the best interests of society, that a prisoner's health needs are met, (they are) prepared for re-settlement (and) causes of re-offending are addressed*'. This part of the Statement effectively places the prisons and mental health agenda in the context of broader health needs, the rehabilitative element of prison, and the purpose of modern penitentiaries which do not expect to incarcerate their inhabitants until the end of their lives. Prisoners, whether or not they are also patients with mental health problems, need to be ready to face and, where possible, thrive in the world outside on completion of their sentence.

It is instructive also to underline that doctors and nurses do not determine when a prisoner with a mental health problem leaves prison. For the minority who commit serious crimes and whose sentences are reviewed, health evidence is placed alongside other considerations of a criminological, social, psychological and resource nature in determining future risk and prospects for release and subsequent support. For the vast majority, however, who are serving short sentences for often minor crimes, release dates are a function of punishment tariffs set earlier and are very unlikely to take into account the likely course of mental illness or deteriorating general health subsequent to serving a prison term. The transition of release from prison often means that prisoners are lost to community-based mental health services, even if they have the capacity to absorb the workload (Edgar & Rickford, 2009; SCM, 2008). Therefore, in addition to the effects of imprisonment, supervision of mental health care is likely to take a further step back. Throughcare is perhaps the greatest challenge to the development of mental health services in Western countries (SCM, 2008).

Offenders, mental health and illness

Historically, the core agenda for mental illness in prison has been recognition and treatment of people with severe and enduring mental illness, together with the emerging realisation that, to a greater or lesser degree, a majority of prisoners have mental health problems of every degree of severity. However, the mental health agenda does not stop there. It is possible, and also attractive, to prevent illness or the worsening of illness among prisoners on coming into prison. A further extension of this approach would be the protection among prisoners of any existing sense of mental health and well-being. Finally, is it possible to imagine prison as a place to aspire for the promotion of mental health as a positive state, as set out in the WHO's principles of the 'attainment of the highest possible standard of health and wellbeing'?

It is broadly agreed that severe and enduring mental illness is, for the most part, not preventable. However, it is possible to devise ways of lessening the risk of deterioration of mental illness of this type through close support, high-quality care, and creating an environment in which that person, to an extent, can thrive. The mass of other types of mental illness is preventable – or, at least, possible to prevent from deterioration. It is possible for a prison system to exert substantial positive influence on levels of mental well-being across the prison population. This could extend, even, to prison as a community, with a positive effect on staff, visitors and especially the families of prisoners and the wider community to which prisoners will return. This approach and agenda is not only desirable, but important, possible and strategically achievable without necessarily incurring great expense. A basic level of mental health understanding and skilled health professional care is necessary, especially for those who are most severely affected with illness. However, the entire environment of prison is a matter for the whole institution and service, and can fundamentally change the prospects of individuals and large groups within prison for the better.

Prison as a setting for mental health and illness

The chapter by Blaauw and von Marle makes this broader approach the centre of its recommendations to raise the prospects for people with poor mental well-being, and mental illness in prison. Its checklist, published on pages 141–144 of the *Prison Health Guide* (WHO, 2007), is an agenda that threads right through the prisoner's experience. A prisoner's first experience is crucial on coming into prison, or returning, as so many do. The physical and social environment in which they live, and the quality of interaction with staff, are key to consistent and positive relationships. Relative freedom from boredom and engagement in activity is a further theme, while the respect for individuals and their basic human rights completes the 'checklist' profile.

Prison, therefore, rather than solely prison health services, can be a setting for positive mental health, as well as the treatment of illness and the protection of mental health problems from getting worse.

The challenge of mental health in prison

It is already clear that the burden of illness is substantial, the need for health care is, for most systems, well in excess of most estimates, and health care alone is insufficient to protect, preserve and treat mental illness and promote mental health. Mental health in prison is a whole-prison concern. In many respects, it is not a matter of mental health – rather, a humane and decent regime that is properly resourced and whose ethos is couched

within a society that understands the role of prisons and its potential for benefit to communities.

Therefore, explaining the work of prison to the public is a necessary element in the overall challenge.

A further challenge is to appreciate that mental health does not exist in isolation – not at the individual level, and certainly not in groups and across prisons. A majority of prisoners have complex problems that are multi-layered and do not stop with labels such as mental illness and addiction. Problems with housing and homelessness, family relationships, the total experience of poverty, basic life skills and prospects for making a positive contribution to the community on release, operate as influences and, often, severe brakes on progress on mental health and well-being. Mental health in prison, therefore, has to be seen in the context of society, and the total experience of crime, punishment and poverty.

A further challenge is for prison not only to explain its function to wider society, but also to set out its limitations. Prison is not a place to receive people for whom society has no other answers. It is not a place to go if you are acutely mentally ill, or if your offending is driven primarily by the state of your mind. It is not a place to go as a 'pre-paid' public service that is easier, less awkward and less visible to the public eye and public finances than other, more appropriate, alternatives. However, the rise in prison populations, and the concomitant fall in capacity for institutional mental health care, along with rising public expectations of public protection by state means and falling tolerance of people who exhibit anti-social or other abhorrent behaviour means that pressure on prisons to receive, without condition and waiting times, people with mental health problems is self-evident and rising. The role of prison, therefore, as a chief alternative to 'look after' people who might have other labels for their behaviour and problems, but conveniently could be classed as 'criminal' means that prison is the consequence of 'trans-institutionalisation'. It is in the process of becoming, as the Trencin Statement says, the '21st Century asylum for the mentally ill'.

Can a prison be good for your mental health?

Prison systems are not primarily designed to sustain mental health or treat mental illness. Nonetheless, statistics, reports and statements show that prison is an important provider of mental health care (Graham, 2007), a crucial setting that influences the mental well-being of those who work and live in it, and an influencer of mental health and well-being for, at least, the community of staff and offenders. Primarily, prison removes the freedom of offenders and places them in custody. It therefore removes a fundamental human right and, of itself, endangers mental well-being. It also, however, endeavours to keep the community safe from people who endanger the security and well-being of others and therefore performs a function that underpins the assurance of the community in the face of threats of offenders who have committed serious crimes and for which society has deemed prison as the necessary sanction. In order to work, however, prison also is a community of prisoners, and staff, who look to the system to keep them safe from those who might harm them. Prison is a community where, to function properly, staff and prisoners must feel safe. It therefore must have an ethos which is fundamentally good for the basic mental well-being of all who are inside it.

This basic regime – that of structure, rules, clearly understood relationships within a closed institution – offers a level of assurance that constitutes better mental well-being for some prisoners. These prisoners may be the small minority, but they benefit through

underlying vulnerability or their lack of a better experience in the community, from the structure and function of a well-running prison. Therefore, if prison is good for a person's mental health, then their alternative circumstances are of such a low quality that prison is an attractive alternative. That is a challenge for wider society.

Second, prison is a setting that can minimise further harm to mental health and well-being through those who are already ill and who gain access to services and support, including regular food, a change of clothing and warmth that would not be available elsewhere. They also take advantage of access to a level of health and other services that may not be available to them in the community.

Third, a prison can be good for an individual's mental health if it is skilled in the detection and management of mental illness and can contribute to mental well-being as part of a combined and integrated rehabilitative process. A good prison system, therefore, can be good for an individual's mental health and has the most chance of excelling in the presence of very poor circumstances in the community that 'make it look good'; a regime of decency; and adequate, integrated health and other services that support the rehabilitative process.

Can prison be good for public mental health?

On the face of it, prison has something to offer public mental health, but it does not take much examination to question the firmness of this assertion (Edgar & Rickford, 2009). In the UK, as in other communities, there is a persistent trend of increased imprisonment, a decline in several important classes of severe offending and, yet, a steady decline in the feeling of personal safety for those in the community. It must be true, though, that the imprisonment of a small number of dangerous criminals supports public mental health through the sense of safety that such measures offer to the community. However, modern prison systems in Western countries now imprison at levels well above this apparently basic level of imprisonment, and no amount of increased imprisonment seems to bring the perception of greater public safety and therefore, mental well-being and assurance. Prisons therefore do not perform this function for the public, by inference of these trends. However, prison may offer an improvement to public mental health through other more specific means, not least the mental health care of those in prison; suitable management of people with severe and enduring mental illness, in collaboration with health services and secure hospitals; and wider commitment to good care of those within the prison system who, through rehabilitation, return to the community in a better state than that in which they arrived.

This is largely a theoretical argument that would require justification at a small area level in order to gain credence. Therefore, prison can act, at basic levels, as an assurance for public mental health through its prime function not to punish, but to keep dangerous criminals out of the community and render the community safe for law-abiding citizens. But, at levels of current imprisonment, this trend appears not to be apparent, and we must rely on the rehabilitative and service commitment of prisons to return offenders to the community in a better state than that in which they arrived in order to contribute to the overall well-being of the communities to which they return.

The future

The issue of mental health and prisons is now a matter of record in specialist circles, and it is now time to broaden professional and public awareness of this reality.

For politicians and policy makers committed to better health and better justice, there is a need to send out a message that good prisons can be good for public health; and that good prison practice that promotes mental health makes the country safer because people in prison who have problems that were addressed are less likely to commit more crime after they leave. There are both empirical and evidence-based reasons why this is so.

For health services, the case of mental illness in prison is a reminder that the balance of care needs to shift towards the support of people with complex problems, and people in the community who have mental health problems of all severities, some of whom are involved with the criminal justice system. Prison is just one setting where health services are likely to find people who are normally hard to reach, and where there is enormous capacity for benefit.

For prison policy makers, there is still a challenge to help them, within very constrained resources, appreciate the burden of mental illness within their population, and the importance of addressing these needs and integrating responses to people with mental health problems within the general rehabilitative environment of a prison. Prison leaders need to be persuaded, and engaged with, the argument that the potential for benefit through good prison practice has benefits to the good mental health of the individual, and the overall running of the institution, its staff and prisoners, visitors and families, and the surrounding community. The converse is that harm to mental health is an important consequence of a struggling prison where the opposite qualities hold sway. Nonetheless, prison management are all too aware that prisoners face challenges other than mental health in their often complex and difficult lives, not least from problems of addiction, intellectual and physical disability, as well as their social, economic and spiritual aspects of well-being.

There is much to do in related research in order to explain and highlight need, to investigate good practice and enhance knowledge and understanding. Prime targets for research investment include cohort studies of offenders coming into and leaving prison, the best styles of care for people with severe and enduring mental illness, the use of and compliance with best practice that lacks a firm evidence base, and continued attention to critical incidents that are related to mental illness and poor mental well-being, such as self-harm and suicide.

Finally, the public, justice and health practitioners need to know that prison should not be a dumping ground for people with mental illness. The misuse of prison to address apparent public safety by incarcerating people with significant mental illness in prison is an abuse of power, and an infringement of human rights. The converse is that we should uphold human rights; find, celebrate, understand and apply good practice – ranging from individual acts of kindness to wholesale changes in prison and mental health practice, and societal attitude. Any transformation of whatever scale should involve a voice for prisoners who have mental health problems, with their advocates, stretching from Parliament to the prison gate.

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5

Care Versus Custody: Challenges in the Provision of Prison Mental Health Care

Introduction

In the early 2000s, mental health in-reach teams were introduced into prisons in England and Wales. Initially, these multi-disciplinary teams of community-employed mental health professionals were intended to provide the same range and quality of services to prisoners as is available to the general population (the principle of 'equivalence of care'). However, little thought was given to how such teams might operate in the closed prison environment where security and control take precedence over more therapeutic goals and where cultural clashes and differences in working practices between prison and National Health Service (NHS) healthcare staff may affect the delivery and extent

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