Modular patient-centred CBT for Danish veterans with complex PTSD: A randomised controlled pilot study

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1. INTRODUCTION

Complex PTSD and Danish veterans

Complex PTSD is a new diagnosis in WHO's International Classification of Diseases ICD-11 (*the International Classification of Diseases and Related Health Problems*; World Health Organization, [WHO] 2018), which is expected to be put into use in Denmark in 2024. ICD-11 introduces a new way of diagnosing post-traumatic reactions, dividing them into two disorders rather than one: Post-traumatic stress disorder (PTSD) and complex post-traumatic stress disorder (CPTSD). To get the CPTSD diagnosis, the client must experience all symptoms of PTSD: 1) re-experiencing, 2) avoidance and 3) hyperarousal. In addition, the client must experience symptoms or exhibit problems in three areas described in ICD-11 as Disturbances in Self-Organisation (DSO). The three DSO symptom clusters are 1) affective dysregulation, 2) negative self-concept and 3) disturbed relationships. Thus, the diagnostic criteria for CPTSD contain a greater number of different symptoms than PTSD, and according to ICD-11, the disorder is most often the result of more and prolonged trauma exposure. This is supported by international research studies that have compared ICD-11 PTSD and CPTSD and consistently found that those who have the all symptoms of CPTSD have poorer functional outcomes, multiple comorbidities and poorer quality of life compared to those who have PTSD (Brewin et al., 2017; Cloitre et al., 2013; Karatzias et al., 2017).

A recently published study from the Danish Veteran Centre (Folke et al., 2019) has examined the prevalence of ICD-11 PTSD and CPTSD in 1,541 Danish veterans seeking treatment at the Military Psychology Department (MPD), the Danish Veteran Centre, from May 2014 to October 2018. Prior to starting treatment at the MPD, the Danish veterans completed questionnaires on PTSD and DSO symptoms, experienced traumatic life events as well as anamnestic data. Using the statistical method, latent profile analysis, it was found that several of the Danish veterans (about 17% of the sample) reported all symptoms of CPTSD, while slightly fewer (about 14%) reported PTSD symptoms alone (Folke et al., 2019). In line with comparable studies (Cloitre et al., 2013, 2014; Hyland et al., 2017; Karatzias et al., 2017; Knefel et al., 2015; Murphy et al., 2016), Danish veterans with symptoms of CPTSD also had lower psychosocial functioning (higher medication use, higher risk of living alone and higher risk of receiving sickness benefit) compared to those who only had symptoms of PTSD. In addition, childhood trauma was a statistically significant predictor for CPTSD rather than PTSD (Folke et al., 2019).

Thus, the study conducted by the Danish Veteran Centre together with comparable international empirical studies indicate that CPTSD is a more severe disorder than PTSD with more symptoms and lower psychosocial functioning. Recent meta-analyses that have examined the effect of existing PTSD treatments for clients with PTSD and CPTSD, respectively (Karatzias et al., 2019; Melton et al., 2019) have found that existing PTSD treatments do not yield the same positive treatment outcome for clients with CPTSD as for clients with PTSD. Therefore, the research literature has called for new treatments for clients with CPTSD. These treatments should be longer-lasting than existing PTSD treatments and should in addition to PTSD symptoms also directly address the DSO symptom clusters, i.e. problems with emotion regulation, persistent negative self-concept and interpersonal difficulties (Karatzias et al., 2019; Karatzias & Cloitre, 2019).

Modular patient-centred CBT (MPC) for complex PTSD

In collaboration with Professor Thanos Karatzias, Edinburgh Napier University, Scotland, the Danish Veteran Centre launched the development of a treatment programme for veterans with CPTSD in 2019. In short, the treatment programme is a psychotherapy manual with 32 individual therapy sessions, divided into an initial module (two therapy sessions) and five treatment modules (each consisting of six sessions) that can be combined in different ways to adapt to each client's most prominent symptoms, preferences and readiness (to work with exposure, for instance). The five modules address 1) Affect dysregulation, 2) Disturbed relationships, 3) Negative self-concept, 4) PTSD symptoms, and 5) Insomnia and trauma-related nightmares.

Modular treatment has been successfully tested for other disorders (e.g. depression and anxiety; Weisz et al., 2012), but not yet for adults with PTSD or CPTSD. Thus, this treatment programme is one of the first in the world to test a new, modular treatment approach for adults with CPTSD. A modular approach to treatment offers many potential benefits:

- First, the approach enables the treatment to be adapted to the individual client by providing treatment modules in the order that best matches the client's wishes, most prominent symptoms and state of readiness (to work with exposure, for instance). The approach thus emphasises flexibility in the selection of empirically supported interventions, which the field's leading clinicians and researchers have argued is particularly desirable for clients with CPTSD, partly because it is a very heterogeneous patient group (Karatzias & Cloitre, 2019), which is why treatment should be adapted to the individual client.

- Secondly, modular treatment may incorporate the use of interventions that have already been shown to have a good treatment effect[1] on the specific symptoms they target in the modular treatment programme.
- Thirdly, the approach is in agreement with patient-centred care, which emphasises the importance of client's autonomy in the selection of the problems to be targeted and which interventions to start with (Karatzias & Cloitre, 2019). The order of treatment modules is thus jointly decided by the client and therapist, based on the client's most prominent symptoms, preferences and state of readiness.

2. OBJECTIVE

ICD-11 CPTSD is a new diagnosis and up to this date, no effective treatment has been identified to help clients with this severe mental disorder. Therefore, it is very important that effective treatment methods for clients with CPTSD be identified.

According to recommendations of the British Medical Research Council (Craig et al., 2008), which explicitly recommend that feasibility studies be conducted prior to actual Phase III trials (which are randomised controlled trials comparing the effect of two (or more) interventions), this first trial of the MPC treatment programme is conducted as a pilot randomised controlled trial. The primary objective of this study is to increase chances of a future successful efficacy RCT (Phase III trial) comparing the efficacy (on symptoms of CPTSD and co-morbid disorders) of the patient-centred version of MPC (where the client actively participates in treatment decisions) with a control treatment, where the five treatment modules are delivered in a predefined order (further described in the section 'Control: MPC without co-decision' below).

The primary objective of the pilot study (after Thabane et al., 2010) is to:

1. Assess the implementation of the trial process in terms of inclusion, implementation and data collection

[1] Compassion-focused interventions have been found effective for severe cases of negative self-concept (Gilbert & Irons, 2004; Karatzias, Hyland, et al., 2019), Cognitive Behavioral Conjoint Therapy for PTSD has been shown to improve interpersonal difficulties and increase social engagement and relational satisfaction for veterans and their partners (Schumm et al., 2013), Classical Cognitive Behavioral Therapy (CBT) and psychoeducation have proven effective in increasing the ability to express and regulate emotions (Berking & Whitley, 2014), Trauma-Focused CBT has been proven effective in reducing PTSD symptoms (Ehlers et al., 2005; Ehlers & Wild, 2015) and Cognitive Behavioral Therapy for Insomnia + Exposure, Relaxation & Rescripting Therapy have been found to be effective in treating insomnia and nightmares (Pruiksma et al., 2018; Taylor & Pruiksma, 2014; Pruiksma et al., 2014; Taylor & Pruiksma, 2014).

2. Assess necessary resources, including the use of tablets for data collection, time spent on the project by participating therapists, assessing psychologists and secretaries

The secondary objective of the pilot study is to:

1. Assess changes in symptoms of complex PTSD, assessed with the International Trauma Questionnaire (ITQ; Cloitre et al., 2018) between the intervention and control group as well as within each group
2. Examine changes in levels of comorbidity associated with CPTSD, such as anxiety, depression, insomnia, somatic complaints, drugs and alcohol intake between the intervention and control group as well as within each group
3. Examine changes in well-being, functioning and attachment style between the intervention and control group as well as within each group
4. Examine developments in client motivation and working alliance between the intervention and control group as well as within each group

3. METHODS

Study design

The study is a randomised controlled pilot study that follows the guidelines of the *Consolidated Standards of Reporting Trials* (CONSORT; Boutron et al., 2017) and the SPIRIT guidelines (Chan et al., 2013).

Randomisation

We wish to recruit 60 clients who will be randomised for the modular patient-centred CBT (MPC) or a control treatment, where the order of the treatment modules is determined in advance (described in more detail below). A randomisation list will be prepared using R software (www.r-project.org). Participants will be randomised into an intervention group (MPC) or a control group (MPC without co-decision) with 30 participants in each group, stratified by recruitment/treatment site. A block size of six will be used to ensure an even balance. The randomisation list will be prepared by a data manager affiliated with the project, and only he will be able to see the randomisation list. First, the assessing psychologist will complete the informed consent procedure, and then the therapistwill perform the 2nd measurement ('Beginning of treatment', see Table 2 below) with the client (by having the client complete a questionnaire package on a small laptop with

pressure sensitive screen (tablet). The random allocation will then take place automatically on the tablet if the therapistdetermines that the client meets the inclusion criteria.

Intervention: Modular Patient Centred CBT for CPTSD

MPC (Folke, Friis, Thomsen & Roitmann, 2020) is a treatment programme consisting of up to 32 therapy sessions broken down by five treatment modules (each consisting of six sessions). Prior to the treatment modules, the client will complete an intro module (two sessions) focusing on psychoeducation on CPTSD, individual case formulation and introduction to the further treatment programme (including the content of the different modules). After the intro module (and after each treatment module), the client and therapist jointly decide which treatment module to proceed with based on 'co-decision', which is described in more detail in the manual. The order of the treatment modules is decided on the basis of a joint assessment of the client's most prominent symptoms, the client's preferences and wishes as well as the client's state of readiness to work with e.g. trauma processing.

The treatment modules (see overview in Table 1 below) directly address the symptoms of CPTSD: 1) Affect dysregulation, 2) Disturbed relationships, 3) Negative self-concept, 4) PTSD symptoms, and 5) Insomnia and trauma-related nightmares. Each treatment module is structured in such a way that it can be offered alone and independently of the other modules.

Table 1. Overview of MPC treatment modules:

Module	Theme	Sessions per module	Total sessions	Duration of sessions
0	Introduction	2	2	60 min
1	Affective dysregulation	6	14	60 min
2	Disturbed relationships	6	20	60/75 min with a companion
3	Negative self-concept	6	8	60 min
4	PTSD symptoms (trauma processing)	6	26	60 min

5	Insomnia and trauma-related nightmares	6	32	60-90 min

The treatment manual has been developed by a working group at the MPD, the Danish Veteran Centre, consisting of three experienced trauma therapists: Katrine S. Friis, Ulrik Thomsen and Nikolai C. Roitmann as well as psychologist and researcher Sofie Folke. Professor Thanos Karatzias, Edinburgh Napier University, has been the clinical supervisor on the development of the treatment programme.

The MPC treatment manual (Folke, Friis, Thomsen & Roitmann, 2020) is established on cognitive methods including Compassion Focused Therapy (CFT), Cognitive Processing Therapy (CPT), Cognitive Behavioral Conjoint Therapy (CBCT), Trauma-Focused CBT (TF-CBT), Prolonged Exposure (PE), Classical Cognitive Behavioral Therapy (CBT) as well as mindfulness-based techniques. The insomnia and nightmare module is (as the only module) a direct translation of an existing treatment manual developed by Kristi E. Pruiksma, Daniel Taylor and colleagues[2] at the University of Texas Health Science Center in San Antonio and the University of Arizona, which combines Cognitive Behavioral Therapy for Insomnia and Exposure ('CBT-I'; Taylor et al., 2019), Relaxation and Rescripting Therapy ('ERRT'; Pruiksma et al., 2018). Kristi E. Pruiksma and Daniel Taylor have authorised the MPD to translate into Danish and use the combined CBT-I and ERRT treatment manual.

Control: Modular CBT for CPTSD (without co-decision)

Because the study investigates a potentially beneficial effect of including the client directly in treatment decisions (by having the client determine the order of treatment modules together with the therapist), the patient-centred version of the treatment is compared (as laid down in the treatment manual; Folke, Friis, Thomsen and Roitmann, 2020) with a control treatment, where the five treatment modules are delivered in a predefined order. The control treatment thus consists of the same treatment components as described above. It is only the aspect of co-decision that has been taken out. Instead, the therapist will just inform the client about the order of treatment modules in the programme. The order of treatment modules in the control treatment will be: 1) Affect dysregulation (6 sessions), 2) Disturbed relationships (6 sessions), 3) Negative self-concept (6

[2] The combined CBT-I and ERRT treatment manual and workbook were developed in 2019 by Pruiksma, K. E., Taylor, D. J., Davis, J., Dietch, J. R., Peterson, A. L., Balliett, N., Goodie, J. L., Miller, K., Grieser, E., Friedlander, J., Hryshko-Mullen, A. S., Rowan, A., Wilkerson, A., Hall-Clark, B., & Fina, B., Hummel, V., Casady, T., Tyler, H.

sessions), 4) PTSD symptoms (6 sessions) and 5) Insomnia and trauma-related nightmares (6 sessions).

Treatment modality

The treatment is offered as individual treatment, except the module on disturbed relationships, where the client is encouraged in the first session to complete the module with, for example, a partner or another important person in their life.

Treatment completion

As an integral part of the treatment, a short assessment is conducted after each treatment module by having the client complete the primary outcome measure, the International Trauma Questionnaire (ITQ; Cloitre et al., 2018), which is used as a measure for assessing ICD-11 PTSD and CPTSD. In practice, the client fills in the ITQ on a tablet in the beginning of the last session of each treatment module, after which the client and therapist receive an automatic response on the tablet, establishing whether the client (based on the ITQ) continues to meet the diagnostic criteria for PTSD or CPTSD. If the client has achieved sufficient symptom recovery and no longer meets the diagnostic criteria for CPTSD, the client is considered a treatment completer. However, the client and the therapist might decide to continue treatment until the client no longer meets the diagnostic criteria for PTSD. In this way, treatment can continue to up till 32 therapy sessions but client and therapist can end the treatment earlier if the client has a valid assessment and falls out of CPTSD criteria.

After completing the MPC treatment, the client cannot receive psychological treatment at the Danish Veteran Centre, until a three-month follow-up of the treatment effect has been completed. However, after a three-month follow-up, the client is welcome to seek psychological treatment again at the Danish Veteran Centre. If deemed relevant, the client is offered help and support from the Counselling and Rehabilitation Department as well as from the Family Unit under the Danish Veteran Centre, independently of the MPC treatment programme. If a client is assessed to require psychological treatment before the three-month follow-up, this will be initiated. As part of the three-month follow-up, all clients respond to whether they have received other help and support from the Danish Veteran Centre or others after ending their MPC treatment.

Practical implementation

Treatment sites and participating therapists (will be updated regularly)

The treatment is carried out at five local veteran centres in Denmark by six clinical psychologists employed by the MPD, Danish Veteran Centre:

1. Svanemøllen Kaserne, Ryvangs Allé 1, 2100 Copenhagen Ø. Clinical psychologists: Katrine Friis and Ulrik Thomsen.
2. Ringsted Kaserne, Garnisonen 1, 4100 Ringsted. Clinical psychologist: Elias Kristjánsson
3. Garderkasernen, Høveltevej 111-117, 3460 Birkerød. Clinical psychologist: Mette A. Rimmen
4. Aalborg Kaserner, Gl. Høvej 34, 9400 Nørresundby. Clinical psychologist: Nikolaj Tøffner-Clausen
5. Ryes Kaserne, Treldevej 110, 7000 Fredericia. Clinical psychologist: Carl A. Albertsen

The treatment is carried out by clinical psychologists who have either helped develop the treatment programme or have received training and regular method-specific supervision in the MPC treatment programme. The six participating psychologists have different levels of experience. The four of them are authorised and specialists in psychotraumatology or psychotherapy for adults, one is authorised and one is about to be authorised.

Referral procedure

For veterans who are seeking psychological treatment at the MPD, the Danish Veteran Centre, and who are potentially offered to participate in the research project, the referral procedure is as follows:

1. ***1st measurement, 'Baseline'.*** When a veteran seeking treatment contacts the MPD for psychological treatment, they are invited to a visitation interview as part of the regular procedure. Prior to the interview, the veteran receives a package of questionnaires in their digital mailbox (e-Boks) as part of the regular procedure at the MPD. The questionnaires of the 1st measurement ('Baseline') are presented in Table 2 and are described in more detail below ('Evaluation and Effect Analysis').
2. ***Visitation interview.*** Prior to the visitation interview, the assessing psychologist receives a short report that provides an inventory of most questionnaires from the 1st measurement. Among other things, the assessing psychologist receives an inventory of the client's response

to the ITQ. If the veteran meets the diagnostic criteria for CPTSD, based on the results of the ITQ, and if the assessing psychologist deems MPC to be a relevant treatment offer, the assessing psychologist will inform the veteran of the research project. If the client is interested in hearing more about the project, they are invited to an initial interview with the treating psychologist.

3. ***2nd measurement ('Beginning of treatment') and randomisation.*** During the initial interview, the treating psychologist provides oral information about the research project and hands over further written participant information and a consent form. The treating psychologist points out that the client has one week to decide whether S/he wishes to participate in the research project and that s/he can withdraw his/her consent at any time. The client is informed that s/he will be offered other relevant treatment by the MPD, if s/he does not wish to participate in the research project. If the client wishes to participate in the research project and the therapist assesses that, based on the initial interview, the client meets the inclusion criteria, the psychologist initiates the 2nd measurement ('Beginning of treatment'), involving a questionnaire package that the client is to fill in on a tablet. The questionnaires of the 2nd measurement are presented in Table 2 and are further described in the section 'Evaluation and Effect Analysis'. To complete the client's response to the 2nd measurement, the random allocation of the client for either intervention (MPC) or control treatment (MPC without co-decision) is automatically carried out on the tablet, as described in the 'Randomisation' section.
4. After that, either intervention (MPC) or control treatment (MPC without co-decision) is carried out as prescribed in the treatment manual.
5. ***3rd measurement ('Continuous process and effect evaluation').*** After each treatment module including the intro module (see detailed description of the MPC treatment programme below), a brief assessment is conducted. This includes four questionnaires as shown in Table 2. The client completes these questionnaires on the tablet, and the client and therapist automatically receive a response as to whether the client still suffers from C/PTSD, based on the ITQ (primary outcome measure). When the therapist and client decide to end the treatment, the therapist asks the client to complete the final questionnaires (4th measurement) on the tablet.
6. ***4th measurement ('End of treatment').*** At the end of treatment (se description below) the 4th measurement ('End of treatment') is completed on the tablet.
7. ***5th measurement ('3-month follow-up').*** Three months after completing the 'End of treatment' assessment, the client will receive a questionnaire package in their e-Boks as a three-month follow-up assessment.

Record keeping

The treatment is registered in COSMIC (the record keeping system used at the MPD). Treatment record is used for treatment sessions, and the treatment ends with a concluding record.

Supervision

The participating therapists receive method-specific supervision in MPC every 14 days by supervisors Katrine Friis and Ulrik Thomsen, who have been involved in the development of the treatment programme. In addition, all therapists receive supervision in Trauma-Focused Cognitive Behavioral Therapy on a monthly basis, as part of the regular routine at the MPD.

Evaluation of treatment effects

A thorough effect evaluation of the MPC treatment programme will be carried out with questionnaires completed by the clients before, during and after the treatment. In addition, the therapeutic process will be evaluated with questionnaires completed by the client after each treatment module.

Table 2 provides an overview of all measurement times and questionnaires used for the process and outcome assessment of the MPC treatment programme.

Questionnaires	**Number of items**	**Time of administration (minutes)**	**Measurement times**				
			Before treatment		**During treatment**	**After treatment**	**3-month follow-up**
			1st measurement 'Baseline' (package of questionnaire is sent to the client's e-Boks as part of the regular procedure at the MPD)	**2nd measurement 'Beginning of treatment'** Questionnaire package is completed on tablet before randomisation and first therapy session	**3rd measurement 'Continuous process and effect evaluation'**[a] Four questionnaires are completed after each treatment module	**4th measurement 'End of treatment'** Questionnaire package is completed on tablet after last therapy session	**5th measurement '3-month follow-up'** (questionnaire package is sent to the client's e-Boks)
Demographic information	5	2:23	X			X	X
Suicidal thoughts and behaviour	4	0:35	X			X	X
Prior treatment	7	0:52	X				
Medicine	2	0:22				X	X
TLEQ	23	7:33	X			X	X
DASS-42	42	2:50	X			X	X
ITQ	20	2:49	X	X	X	X	X
PCL-C	17	1:49	X			X	X
ADRS	6	0:48	X				
Alcohol intake	3	1:02	X			X	X
Drugs	7	0:49	X			X	X
WHO-5	5	1:02	X	X		X	X
SDS	3	1:01	X	X		X	X
ACE	25	5:40		X			
ISI	7	1:40		X	X	X	X
CMDQ	12	2:58		X		X	X
ECR-S	12	2:24		X		X	X
Social support	12	2:20		X		X	X
Other help and support	10	2:00				X	X
CMTS	24	2:38			X		
SAI	6	0:44		X	X		

Number of items	142	106	57	237	184
Estimated use of time (minutes)	24	20	7	30	34

Table 2. Overview of measurement times and questionnaires

Note: [a] Note that measurement 3 occurs after each treatment module (including the intro module) and is thus carried out several times (depending on the length of the client's course of treatment).

TLEQ = Traumatic Life Events Questionnaire; Dass-42 = Depression Anxiety Stress Scales; ITQ: International Trauma Questionnaire (primary outcome measure); PCL-C = Posttraumatic Stress Disorder Checklist - Civilian Version; ADRS = ADHD Symptom Checklist for Children - The Adult Self Report Symptoms of Childhood Scale; WHO-5 = WHO-Five Well-being Index; SDS = Sheehan Disability Scale; ACE = The Adverse Childhood Experiences questionnaire; ISI = The Insomnia Severity Index; CMDQ = item 1-12 from the Common Mental Disorders Questionnaire; ECR-S = The Experiences in Close Relationships - Short Form; CMTS: Client Motivation for Therapy Scale; SAI = Session Alliance Inventory

Measures

See Table 2 for an overview of measurement times.

Demographic information. Five questions examine the client's gender, age, marital status, job position and children.

Suicidal thoughts and behaviour are assessed with four questions regarding suicidal thoughts, plans and previous suicide attempts. Two questions are to be answered on a 5-point scale from 'Never' to 'Very Often', examining suicidal thoughts and plans in the last six months. Two others are to be answered with 'Yes/No', examining suicide attempts in the last year and before that. The four questions have been used in EPSIS, the WHO study ('Euro Multicentre Study of Suicidal Behavior') as well as national surveys (SuSY, the National Institute of Public Health, University of Southern Denmark) and in studies by the Danish Centre for Suicide Research.

Previous treatment and medication. Previous treatment is assessed with five questions that examine whether the client has received treatment in the past due to psychological or psychiatric problems, whether the client has been diagnosed and whether the client is still in treatment. Medication is assessed with two questions, asking whether the client has received any prescription or nonprescription medicines in the last 14 days, and if so, what the medicine is called.

Traumatic events. The Traumatic Life Events Questionnaire (TLEQ; Kubany et al., 2000) asks the client about 20 types of potentially traumatic events including natural disaster, traffic accident, military service in a war zone, life-threatening illness, and so on. The questionnaire has been adapted to a population of Danish soldiers (see Berntsen et al., 2012). For each event, the client indicates the number of times the event has occurred (ranking from 'Never' to 'More than 5 times'), and whether the client experienced anxiety, helplessness or horror when it happened ('Yes/No'). The last question asks the client to identify the one event that causes the client 'the most pain today', as well as specify what date this event occurred and how much pain it causes today (ranking from 'Nothing happened to me' to 'Extreme pain').

Attention problems in childhood are measured with six items that ask about attention problems between the ages of 5 and 12. The items derive from the Adult Self Report Symptoms of Childhood Scale (ADRS v1. 1, ADHD Symptom Checklist for Children; Barkley & Murphy, 2006). If the client answers 'Yes' to four out of six items, it indicates possible ADHD in childhood.

Adverse childhood experiences. The Adverse Childhood Experiences questionnaire (ACE; Felitti et al., 1998) is a 25-item self-reporting scale that measures exposure to 13 categories of adverse childhood experiences ('ACES') during the first 18 years of life. The questionnaire covers physical and sexual assault, emotional abuse, physical neglect, emotional neglect, domestic violence, an adult in the home with mental illness, an adult in the home with an alcohol or drug addiction, an adult in the home who is in prison, parental divorce or death, bullying and exposure to community violence, and exposure to collective violence. The items are answered either with 'Yes' or 'No' on a 5-point Likert scale from 'Never' to 'Very Often'. A Danish translation of Røhder, Lind & Harder (2007) from the University of Copenhagen is applied in the study.

Primary outcome measure

Symptoms of ICD-11 PTSD and Complex PTSD are assessed with the questionnaire, the International Trauma Questionnaire (ITQ; Cloitre et al., 2018), which is a 20-item self-report scale that assesses the diagnostic criteria for PTSD and CPTSD according to ICD-11. Six items represent the three PTSD symptom clusters; ongoing re-experiencing, avoidance and hyperarousal. In addition to PTSD, CPTSD includes three symptom clusters describing Disturbances in Self-Organisation; DSO: Affective Dysregulation; AD, Negative Self-Concept; NSC and Disturbed relationships; DR. All symptoms are scored on a 5-point Likert scale, which ranges from 0 (Not At All) to 4 (Very Much), reflecting how much the given symptom has affected the respondent within the last month. AD is assessed on the basis of two questions: C1) 'When I'm upset, it takes me a long time to calm down' and C2) 'I feel numb or emotionally shut down'. NSC is assessed on the basis of the questions C3) 'I feel like a failure' and C4) 'I feel like I am not worth anything', and DR on the basis of the questions C5) 'I feel distant or cut off from other people' and C6) 'It is difficult for me to remain emotionally close to others'. Scores can be recoded into six binary variables, which together assess whether the criteria for ICD-11 PTSD or CPTSD are met. A PTSD diagnosis requires that at least one symptom for each of the three PTSD symptom clusters be scored to a minimum of 2, and that PTSD symptoms have affected the respondent's social life, ability to work or parenting/schoolwork/other important activities within the past month. A CPTSD diagnosis requires PTSD and that the DSO criteria are met by at least one symptom for each of the three DSO symptom clusters being scored to a minimum of 2, and that DSO symptoms have negatively affected the respondent's psychosocial functioning within the past month. A Danish translation of Hansen and colleagues (2018) is applied in the study.

Secondary outcome measures

Symptoms of depression, anxiety and stress are assessed with the Depression Anxiety Stress Scales (DASS-42; Lovibond & Lovibond, 1995), which is a 42-item self-reporting instrument designed to measure three related negative emotional stages of depression, anxiety and tension/stress. Symptoms are measured with 14 questions for each symptom category, which measure the degree of depression, anxiety and stress on a 4-point Likert scale from 0 ('I have not experienced that at all') to 3 ('I have experienced this many times or all the time'). Based on the responses, a total score can be calculated by dividing symptoms into five severity levels.

Symptoms of DSM-IV PTSD are assessed with the Posttraumatic Stress Disorder Checklist-Civilian Version IV (PCL-C; Weathers et al., 1993). PCL-C is a 17-item self-reporting screening tool developed to measure PTSD symptoms as described in the DSM-IV (the American Psychiatric Association, 1994). A score of 44 is recommended as a cut-off score for possible PTSD (validated against the Structured Clinical Interview for the DSM-IV; see Karstoft et al., 2014) with a specificity of 0.96/sensitivity 0.72.

Alcohol intake is assessed with three questions about alcohol consumption; 1) how often the client consumes alcohol; 2) how many items the client consumes on a typical day, and 3) whether the client has been treated for alcohol abuse. The questions are modified questions from the questionnaire, the Alcohol Use Disorders Identification Test (AUDIT; Saunders et al., 1993).

Drugs are measured with seven questions on cannabis and other forms of drugs, respectively: Have you ever... How often... What drugs... Including information about treatment for cannabis abuse or other forms of abuse. The questions have previously been used in surveys by the Danish Veteran Centre and the National Institute of Public Health, the University of Southern Denmark.

Well-being is measured with the 5-item World Health Organization Well-being Index (WHO-5), which is a short and generic rating scale. WHO-5 measures subjective psychological well-being with five questions asking the respondent to assess whether they have 1) been happy and in good spirits in the past two weeks, 2) been feeling calm and relaxed, 3) been feeling active and energetic, 4) woken up fresh and rested, and 5) had a daily life filled with things that interested them. All questions are assessed on a 6-point Likert scale from 'Not at any time' (= 0) to 'All the time' (= 5). Raw scores range from 0-25 and are multiplied by 4 to give a total score from 0 (representing the worst case) to 100 (representing the best possible well-being). A score ≤50 indicates the

risk zone for stress and depression. *WHO-5* has been translated into Danish by the Psychiatric Research Unit, Hillerød, 1999 (Beck, 2004).

Functioning is assessed with the Sheehan Disability Scale (SDS; Leon et al., 1997), which consists of three questions that examine occupational, social and family functioning. The three questions are scored on a Likert scale from 0 ('Not at all) to 10 ('Very Strong'). Reduced functioning is present if the score is ≤ 5 in one of the three domains.

Insomnia is assessed with the 7-item self-report scale, the Insomnia Severity Index (ISI; Bastien et al., 2001). Total scores range from 0 to 28, with a higher total score indicating severe insomnia. ISI is considered to be a valid and reliable measurement tool that has proven sensitive to changes in treatment studies (Morin et al., 2011). A cut-off of 10 is assessed to be optimal for detecting insomnia (Morin et al., 2011; Zachariae et al., 2018). A Danish translation of Zachariae and colleagues (2012) is applied in the study.

Somatic symptom disorder is assessed with item 1-12 from the Common Mental Disorders Questionnaire (CMDQ), which measures somatic symptoms. CMDQ has been validated in a Danish context (Christensen et al., 2005). The respondent should indicate 'Within the last 4 weeks, how much have you been bothered by': headaches, dizziness, heart or chest pain, low-fitting back pain, nausea or stomach discomfort, muscle pain, difficulty breathing, hot or cold sensations, numbness or tingling sensations in the body, a lump in the throat, a feeling of weakness in the body, heavy feeling in the legs or arms. For all 12 questions there is a five-point Likert scale answer category from 'Not at all' to 'A lot'. If the overall score is above 10, somatic symptom disorder should be considered.

Adult attachment style is assessed with a 12-item version of the Experiences in Close Relationships - Short form (ECR-S; Wei et al., 2007). ECR-S consists of two continuous scales that measure fear and avoidance of attachment. A Danish translation of O'Connor and colleagues (2009) is applied in the study.

Process measures

Client motivation is assessed with the questionnaire, the Client Motivation for Therapy Scale (CMTS; Pelletier et al., 1997), which measures the client's motivation to go to therapy. With 24 items, the questionnaire measures six different types of motivation: Intrinsic motivation (four items), integrated regulation (four items), identified regulation (four items), introjected regulation

(four items), external regulation (four items) and amotivation (four items). The client assesses their motivation for therapy within these six motivational aspects on a five-point Likert scale ranking from Strongly disagree (1) to Strongly agree (5).

The working alliance is assessed with the Session Alliance Inventory (SAI; Falkenström et al., 2015), a 6-item measure of the working alliance, based on items from the Working Alliance Inventory (WAI; Hatcher & Gillaspy, 2006; Horvath & Greenberg, 1989). Like WAI, SAI contains items that reflect the three theoretical aspects of the alliance; agreement on therapeutic goals and tasks, and a positive emotional bond between client and therapist.

4. STATISTICAL CONSIDERATIONS

Number of subjects

Strength calculation is not required for pilot studies for Phase III trials and is in some cases even advised against (Billingham et al., 2013; Thabane et al., 2010). Based on comparable feasibility studies on testing new treatment methods for clients with PTSD (Mahoney et al., 2020; Scharff et al., 2020), we have estimated that 30 participants in the intervention and 30 in the control group are required for a representative sample.

Statistical analysis

Data from this pilot study will help provide information for a future efficacy RCT (Phase III trial) by testing the trial procedures. Therefore, no formal statistical analysis of data from the pilot study will be carried out. A description of the participants and a simple compiling of pilot data will be presented. Exploratory analyses will be conducted to compare means (and 95% confidence intervals) of the ITQ and the other secondary outcome measures between intervention and control group at the end of the treatment using a t-test. Furthermore, repeated measurements within the same group will be analysed using variance analysis (ANOVA). All randomised participants will be included in the analyses. The statistical analyses of pilot data will only be exploratory since the sample size does not allow for definitive analyses.

We will consider the study as complete if the following success criteria are met:

1. > 70% of potential participants accept and be included in the study

2. Completion rate of 70%, that is, we expect to have complete data (Measurement 4, completed at the final therapy session) of at least 70% of all participants included
3. Complete three-month follow-up (Measurement 5, obtained via e-Box) of at least 50% of all participants included

5. TARGET GROUP/PARTICIPANTS

During the recruitment period, all veterans who turn to the MPD with CPTSD will be invited to participate in the study. Clients are selected to participate on the following in- and exclusion criteria:

Inclusion criteria

- Meets the diagnostic criteria for CPTSD, assessed with the ITQ
- Danish veteran (cf. the Veteran Policy of Denmark[3])
- Seeks help for deployment-related psychological issues

Exclusion criteria

- Severely suicidal[4]
- Current alcohol or drug abuse that prevents treatment[5]
- Blast injuries or current severe attention disorder
- Has received psychotherapeutic treatment in the past three months
- Is participating in another research project[6] that interferes with this research project

6. RISKS, SIDE EFFECTS AND SHORT- AND LONG-TERM DISADVANTAGES

No side effects are expected in the short or long term by participating in the psychotherapeutic MPC treatment programme, and no known side effects of similar psychotherapeutic interventions are described in the literature. In the case of side effects that do not go away within 1-2 therapy

[3] According to the Veteran Policy of Denmark of 5 September 2016, a veteran is defined as 'a person who has been deployed in international operations at least once, on the grounds of a decision made by Folketinget, the Danish Government or a minister' regardless of whether they still serve in the military (https://fmn.dk/temaer/veteraner/Documents/the-veteran-policy-of-denmark-2016.pdf)
[4] To a degree that will make it difficult to complete the manualised treatment programme
[5] E.g. if the client shows up under the influence of intoxicants
[6] For example, the client cannot simultaneously participate in other research projects in the Danish Veteran Centre, such as evaluation of body therapy with BBAT for PTSD.

sessions, the client will be offered other relevant treatment at the MPD. Any side effects are registered by the therapist. The client may always withdraw from the MPC treatment if they do not wish to continue, and the client is informed that this will not affect their possibilities of receiving other relevant psychological treatment at the MPD.

7. COLLECTION OF NEW BIOLOGICAL MATERIAL OR BIOLOGICAL MATERIAL FROM EXISTING BIOBANK

The project neither collects new biological material nor biological material from existing biobanks. The project is based on questionnaire data.

8. DATA FROM PATIENT RECORDS

The project will not use data from patient records.

9. PROCESSING OF PERSONAL DATA IN THE PROJECT

The Data Protection Regulation and the Data Protection Act are complied with. The veteran will be informed that all data is processed in a confidential manner and that the data collected will be de-identified via a serial number when used in analyses including all participants' responses. All data is stored securely on a secured drive and on an encrypted USB drive and/or in a double locked room.

The project will be notified to the Regional Research Ethics Committee, Region Zealand, Denmark.

Since the Danish Veteran Centre is already covered by the joint notification to the Danish Data Protection Agency (Case No 2015-57-0097), the MPC project does not need to be notified and the project will therefore be registered as a study under the joint notification of the Danish Veteran Centre.

10. FINANCING

The principal investigator has initiated the trial, and the research project is completed entirely within the existing operating budget of the Danish Veteran Centre.

11. REMUNERATION OR OTHER BENEFITS FOR THE PARTICIPANTS

The research participants are not granted remuneration or other benefits.

12. RECRUITMENT OF PARTICIPANTS AND INFORMED CONSENT

All clients from the MPD contact the Danish Veteran Centre for treatment on their own initiative. When they contact the Danish Veteran Centre, they are invited to a visitation interview with a psychologist to assess whether their problems are deployment-related. If the assessing psychologist deems MPC to be a relevant offer for the client, the assessing psychologist informs the client of the research project. If the client expresses an interest in hearing more about the treatment and the research project, s/he is invited to an initial interview. The client is informed that they can bring a companion to the interview.

The initial interview takes place in a treatment room where only the treating psychologist, the potential participant and any companion are present. During this interview, oral information about the treatment and the research project is provided and further written participant information and a consent form are handed out. In the written material, the client can find contact information on the principal investigator and project manager, who can be contacted if the client requires further information about the project. The psychologist stresses that the client has a week to decide whether they wish to participate in the project and that their consent can be withdrawn at any time. The client is informed that they will receive other relevant treatment at the MPD, if they do not wish to participate in the pilot trial.

If the client wishes to participate in the pilot trial, further diagnostic investigation is initiated. If the inclusion criteria are met, randomisation is initiated for further treatment. If the client has a more severe diagnosis requiring treatment, in addition to CPTSD, the client will be offered other relevant treatment.

13. PUBLICATION OF RESULTS

All the results of the project - whether positive, negative or inconclusive - will be published, e.g. via www.pilotfeasibilitystudies.biomedcentral.com. The publication will follow the CONSORT guidelines (Boutron et al., 2017) and the SPIRIT checklist (Chan et al., 2013). The purpose and results of the project will be regularly available in Danish on the Danish Veteran Centre's website

(www.veteran.forsvaret.dk). They will also be presented at international conferences, such as annual meetings of the International Society for Traumatic Stress Studies and the Veterans' Mental Health Conference, as well as at national conferences such asthe Danish Veteran Centre's annual meeting of external partners, as well as for relevant patient associations such as the Danish National Association for PTSD and other relevant associations and actors with an interest in the area.

14. RESEARCH ETHICS

The psychotherapeutic MPC treatment programme is not considered to involve risks per se and will not cause participants any disadvantages or unnecessary side effects. In the case of side effects that do not go away within 1-2 therapy sessions, the client will be offered other relevant treatment at the MPD. The client may always withdraw from the MPC treatment programme if they do not wish to continue, and the client is informed that this will not affect their possibilities of receiving other relevant psychological treatment at the MPD.

The Danish Veteran Centre of the Danish Ministry of Defence Personnel Agency is working to improve the conditions for Danish veterans. One of the focus points is veterans with CPTSD. Existing psychotherapeutic treatment programmes have all been developed for PTSD, and international research studies indicate that these treatment programmes may be less effective for clients with CPTSD (Karatzias et al., 2019; Melton et al., 2019). Therefore, there is a need to develop and test new treatment methods for this severely troubled client group. The MPC treatment programme has been developed specifically for Danish veterans with CPTSD, and could thus potentially help a client group for which there are currently no proven treatment services.

15. INFORMATION ON FINANCIAL COMPENSATION SCHEME

The pilot trial is conducted under the auspices of the Danish Veteran Centre under the Military Psychology Department of the Danish Ministry of Defence Personnel Agency. As the treatment is carried out by authorised healthcare professionals (psychologists), the trial is covered by the Patient Compensation Association, as referred to in Law No 314 of 25 April 2018 of the Danish Act on the Right to Complain and Receive Compensation.

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