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Body therapy versus treatment as usual among Danish veterans with PTSD: Study protocol for a randomised controlled trial combined with a qualitative study

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ABSTRACT

Background: Many veterans suffer from Post-Traumatic Stress Disorder (PTSD) after returning from military missions. This implies complex physical and psychosocial problems for veterans and their families. Treatment options today are primarily medically and psychologically founded but treatment response is incomplete. Body therapy for PTSD is scarcely researched though subject of increased attention. In 2015, a Danish pilot study was conducted exploring body therapy for PTSD. The study showed positive results and formed basis for a randomised controlled trial. This paper outlines the protocol for this trial.

Methods: The intervention will be evaluated in a two-arm randomised controlled trial (1:1). The trial will include 42 veterans with PTSD recruited by the Danish Military Psychiatric Centre. The intervention group receives treatment as usual and weekly body therapy treatment as add-on. The control group receives treatment as usual (TAU). Participants will complete four questionnaires assessing PTSD, depression, quality of life, function level and body awareness: at baseline, and at 3 months, 6 months and 12 months post baseline. Linear regression models and mixed effects models will be used to assess intervention effects. Furthermore, an ethnographic study will examine how the participants experience the treatment and changes in their everyday life. The ethnographic study is based on in-depth interviews, participant observations and focus groups. A mixed method, convergent parallel design will be applied.

Discussion: This study examines the efficacy of body therapy for veterans with PTSD and how the treatment is experienced and affects daily life. The study will contribute with important knowledge on an alternative treatment for PTSD.

Trial registration: ClinicalTrials.gov Identifier: NCT03777800.

1. Introduction

To carry out military missions a soldier must rely on a well-trained autopilot that is able to react quickly. This ability is cultivated through military training that may involve compromising personal thoughts, feelings and bodily signals. However, the severity of real-life combat can pose a great threat to the mental and physical health of soldiers; consequently, some soldiers and veterans develop Post-Traumatic Stress Disorder (PTSD) [1].

PTSD is a persistent condition that may intensify over time [2]. Of all Danish veterans posted on missions between 1992 and 2009, 2.4% were registered with PTSD based on the Danish Health Register, however, the prevalence is estimated to be 5–10% [3]. A study found that 14% of Danish veterans deployed to Afghanistan in 2009 had a high PTSD symptom level 6.5 years after their return [4]. These numbers are comparable to US veterans deployed to Vietnam [5]. The exact number of veterans suffering from PTDS is difficult to determine; the symptoms fluctuate over time and not all cases are registered [3,5].

Symptoms of PTSD are typically classified within three sub-groups: 1) *Flashback/re-experience* of the trauma, often set off by stimuli on the senses. It often involves nightmares and sensitivity to high-volume sounds as well as physical excitement involving increased heart rate

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and sweating, 2) *Avoidance* characterised by withdrawal from social situations that resemble the traumatic events as they can push social anxiety, 3) *Hyperarousal*, often described as being stuck in battle-mind, involves increased attention towards potential dangers, leading to overstimulation of the sympathetic nervous system creating a downstream effect of disturbances in sleep, memory, appetite, sexual desire, social competences, temper and cognitive functions [1,4,6,7].

There is a complex interplay between the psychological and somatic expressions of the illness; the two are bound together in a reciprocal relation potentially maintaining and aggravating each other [8–10]. A major challenge for veterans with PTSD is emotional control and difficulty reading their own and others' emotional state [11]. They experience problems engaging with close social relations [12], which may lead to relatives also suffering from psychological distress [13]. The emotional and relational challenges may also lead to incapacity for work [11,12]. The complex pathology places special demands on treatment, which must integrate these mechanisms.

PTSD-treatment is primarily based on medical and psychological premises [14,15]. There is evidence of pharmacological treatment [16], individual and group trauma-focused cognitive–behavioral therapy (CBT), eye movement desensitization and reprocessing (EMDR) and stress management [17,18]. However, many do not benefit significantly [19]. Furthermore, limitations to these therapies include drop-out rates of 50% [19].

During the last decade, mind-body oriented treatments have come increasingly in focus and may be an important supplement to medical and psychological treatment [20–30]; and are deemed more relevant than a cognitive approach in some cases [12,28,31–35]. Despite the encouraging results, mind-body oriented approaches to the treatment of PTSD is still a new field that needs further exploration. In 2015, a Danish study evaluated preliminary effects of a body therapeutic treatment (called ManuVision) for veterans with PTSD. The study showed reductions on several participants' PTSD symptoms (not published). These results encouraged us to test the treatment in an RCT and investigate the veterans' experienced gains more in-depth.

2. Methods

The protocol follows the SPIRIT guidelines as provided in Additional file.

Our aim is to evaluate the efficacy of a 6-month ManuVision body therapy intervention as add-on to treatment as usual (TAU) among veterans suffering from PTSD and explore the veterans' perceptions and experienced gains of the intervention. More specifically, the study investigates:

- The effects of the intervention on PTSD symptoms (primary outcome), quality of life, function level, depression and body awareness (secondary outcomes)
- The dose-response relationship between body treatment session frequency and outcomes
- How is the treatment implemented, how do participants experience and respond to the treatment, including the interaction with the therapists?
- In which ways do the veterans experience transformation e.g. in terms of their body, feelings, social relations, everyday lives, quality of life, and PTSD symptoms? Furthermore, we include the perspectives of the relatives?

2.1. Study design

The design is a parallel two-arm randomised controlled trial (RCT) comparing the ManuVision body therapy treatment against a TAU control group. Moreover, we will use a mixed-methods approach [36] combining the RCT study with ethnographic fieldwork in order to gain insight into the multi-dimensional nature of PTSD and the participants' experiences with the intervention. Specifically, we will use a convergent parallel design concurrently conducting the quantitative and qualitative elements, weigh the methods equally, analyse the two components independently, and interpret the results together [37].

The project integrates research and practice in a collaboration between the National Institute of Public Health, University of Southern Denmark, the organization ManuVision, the Military Psychiatric Centre (in Danish: Militærpsykiatrisk Ambulatorium) of the Capital Region in Denmark, and the Patient Organization Denmark (in Danish: Patientforeningen Danmark). The project preparation period was 2018 and the implementation of the intervention will be running from 2019 to 2020.

2.2. Study setting

Eligible settings will be the Military Psychiatric Centre, Capital region of Denmark and at ManuVision body therapy centre in Copenhagen, the capital of Denmark. The veterans will be recruited, randomized and offered TAU at the Military Psychiatric Centre. The intervention group will receive the body therapy treatment at the ManuVision body therapy Centre.

2.3. Inclusion and exclusion criteria

Veterans will be included in the study based on the following criteria:

- Age ≥18
- Meet criteria for clinical PTSD assessed by The Structured Clinical Interview for DSM-5 (SCID-5)
- Demonstrate understanding of informed consent and normal cognitive skills.

Participants will be excluded if they have alcohol or drug dependence, severe mental disorders such as schizophrenia, bipolar disorder, or current psychiatric conditions such as psychosis, mania, dementia or cognitive impairment.

2.4. Recruitment

In total, 42 veterans are recruited and allocated to intervention or control group by randomization through the Military Psychiatric Center, which provides psychiatric support to veterans in the Eastern part of Denmark. Veterans are initially assessed as to whether they have PTSD based on a Structured Clinical Interview for Diagnosis (SCID) with a psychiatric specialist. Veterans who fulfil the inclusion criteria will be informed about the trial and invited to participate. The screening and the study information will be given by the psychiatric specialist at the Military Psychiatric Center. In order to include adequate participants, the psychiatric specialist will invite both newly arrived veterans and veterans who have been or still is in treatment at the Military psychiatric center.

2.5. Randomization

Veterans who accept to participate in the study and provide written informed consent are randomly assigned to either the intervention or the control group. The randomization is done through a computer-generated process prior to the intervention by a statistician, who is not involved in the trial. The randomization codes are held in sequentially numbered sealed envelopes placed at the Military Psychiatric Centre. Here, the envelopes will be distributed by the psychiatric specialist to whom the randomised order is unknown in consecutive or-

der at the time of each participant enrolment. The statistician and the effect evaluator will be held blind to the allocation of participants.

2.6. Intervention

ManuVision is a Danish developed body therapy. It is provided individually, and the therapist works with direct physical treatment of the body and with the client's psychosocial resources. Drawing on neurophysiological theory developed by Steven Porges [38], the treatment is based on the assumption that chock, trauma and stress is stored in the body thereby blocking muscles and breathing and affecting the nerve system. By working directly with those places of the body, the therapist seeks to release emotional stress as well as the breath. Involving the body through breathing techniques alone or in combination with focused attention training can be effective in the treatment of PTSD by stimulating the parasympathetic nervous system and thereby reducing the heart rate and stress hormone levels [24,25,39–43]. The body therapy sessions are based upon the therapeutic alliance which refers to the dynamic relation between the client and the therapist and their continuous negotiation of therapeutic goals. A positive alliance is a prerequisite for therapeutic change and improvement in symptoms [44–46].

Moreover, group meetings where participants exchange experiences, facilitated by the therapists is included in the intervention. Research shows numerous benefits to peer support programs supplementing PTSD treatment [47,48], for example facilitating social support, purpose and meaning, normalization of symptoms and hope.

2.6.1. Intervention content

The intervention group receives 24 body therapeutic treatment sessions once or twice per week for a duration of maximum 6 months. The sessions are of 1-h durability and is delivered by an educated ManuVision therapist. Each veteran is assigned the same therapist throughout the trial. In-session time will include home practice in meditation with the aim of reducing stress, hyperarousal and other symptoms associated with PTSD [25,49]. The participants receive a digitally recorded meditation program, which they are encouraged to follow daily. In order to improve adherence to intervention protocols and ensure proper after-care, a coordinator or the relevant therapist will make phone calls to the veteran prior to and after each treatment session.

Fig. 1 outlines our logic model. We hypothesize that the intervention components will impact on physical, psychological, psychosocial and social domains. We hypothesize that the immediately and short-term outcomes are improvements in body awareness and the ability to engage in social relations. The reduction in PTSD and improvements of the secondary outcomes will result from strengthening the body awareness and enhancing the ability to engage in social relations.

2.6.2. Implementation resources and support

Treatment fidelity is ensured through the following mechanisms:

- Three full days training of all therapists in the project on how to work with veterans with PTSD (in addition to their ManuVision education and many years of experience as a ManuVision therapist).
- Exchange meetings/workshops (1.5 or 2 h) every fortnight among all therapists in the project in order to discuss practices, challenges and solutions working with the intervention group – and hence ensuring adherence to a common frame and approach across the individually tailored treatment.
- Voluntary exchange meeting among veterans throughout the project with participation of therapists. This contribute to therapists' insight into the various treatment processes and ensure support within the same overall frame and approach.
- Standardized journals filled by all therapists after each treatment. The ManuVision coordinator use the journals when following up with each of the veterans.
- Telephone calls to the veterans prior to and after every treatment by either the Manuvision coordinator or the veteran's personal therapist in order to ensure that veterans show up for their treatment and that each treatment is followed up by adequate support.
- A scheme with general data of the treatment process (day of randomization, days of attendance and absence in treatment) filled by the ManuVision coordinator and the psychiatrist as an overall monitoring tool.

2.7. Treatment as usual

Both the intervention and the control group receive TAU, which typically includes one or more of the following elements: medication, psychoeducation in the form of meetings with a psychiatrist approximately every 2–4 weeks, and psychological treatment via the Danish Defence's psychologists.

2.8. Data collection and measures

Questionnaire data will be collected at four time points: Baseline (T0, pre-treatment), midway (T1, 3 months post-baseline), post-

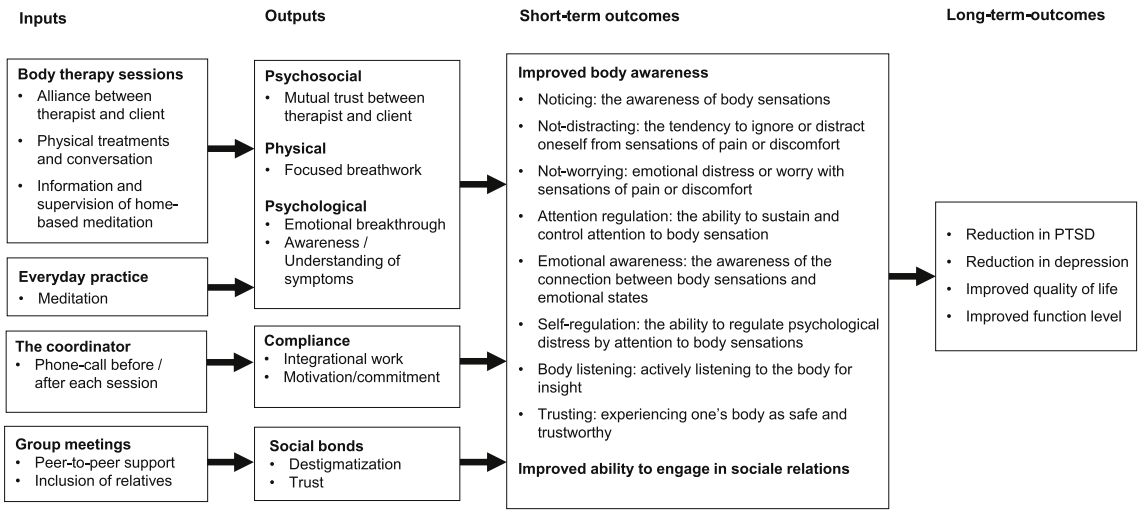

Fig. 1. Logic model of the Body therapy treatment program including inputs, outputs, short- and long-term outcomes.

treatment (T2, 6 months post-baseline) and at 6-month follow-up (T3, 12 months post-baseline.

2.8.1. Primary outcome

PTSD will be assessed by the PTSD checklist - military version (PCL-M). PCL is a validated measure that assesses symptoms of PTSD and has shown very good internal consistency and test-retest reliability [50,51]. It is comprised of 17 questions connected to the 17 diagnostic criteria for PTSD in the US psychiatric diagnosis system, DSM-IV. Past month symptom severity is indicated using a 5-point scale. The PCL yields a score from 17 to 85, with higher scores representing greater severity.

2.8.2. Secondary outcomes

Self-reported depression symptoms will be measured by the Major Depression Inventory (MDI) [52]. The MDI is a validated and widely used scale of self-reported depressive symptoms developed by World Health Organization (WHO). The severity of depression is measured over the last 2 weeks using a scale of 10 symptoms at which the frequency of each symptom can be indicated from 0 (at no time) to 5 (all the time). Score range is from 0 (no depression) to 50 (severe depression). The cut points for the total score of the MDI are no depression (≤20), mild depression (21–24), moderate depression (26–30), and severe depression (≥31) [53].

Self-reported quality of life will be measured using the WHO-5 Well-being index developed by WHO [54]. The questionnaire has five items reflecting mental well-being during the last two weeks rated on a six-point scale from 5 (all the time) to 0 (at no time). Raw scores, which range from 0 to 25, are multiplied by 4 to obtain a percentage score ranging from 0 (worst) to 100 (best).

SDS (Sheehan Disability Scale) [55] is a scale for the assessment of function level. Participants will rate the degree to which the PTSD symptoms affect work, social life, and family life using an 11-point Discan scale (0 = not at all and 10 = extremely). The three domains can be summarized to evaluate global functional impairment by adding the scores of each of the three domains, resulting in SDS score ranging from 0 (unimpaired) to 30 (highly impaired) [56].

Self-reported body awareness will be measured by the Multidimensional Assessment of Interceptive Awareness (MAIA) Questionnaire [57]. It comprises 32 items measured on a 6-point Likert scale (1 = never and 6 = always) with eight subscales measuring different dimensions of body awareness: (1) Noticing: the awareness of body sensations; (2) Not-Distracting: the tendency to ignore or distract oneself from sensations of pain or discomfort; (3) Not-Worrying: emotional distress or worry with sensations of pain or discomfort; (4) Attention Regulation: the ability to sustain and control attention to body sensation; (5) Emotional Awareness: the awareness of the connection between body sensations and emotional states; (6) Self-Regulation: the ability to regulate psychological distress by attention to body sensations; (7) Body Listening: actively listening to the body for insight; (8) Trusting: experiencing one's body as safe and trustworthy. Total scores are calculated for each subscale.

2.8.3. Participant characteristics

In the baseline questionnaire, the participants report their age, sex, living arrangement, children, number of military missions, and social support. The psychiatric specialist of the Military Psychiatric Centre report treatment history, medication, employment status, marital status, adverse childhood experiences, time since returning from military missions, Labor Market Insurance, military rang, event type, and service area/military deployment.

2.8.4. Process evaluation measures

The number and timing of completed body treatment sessions will be evaluated and systematically registered by the therapists. Process evaluation questions will explore which elements potentially made the veteran feel better or worse after the treatment period, including the body treatment, conversations with the therapist, home meditation, contact with the coordinator, exchange meetings with other veterans; to which degree the veteran felt safe and accepted by the therapist; how often the home meditation was done; to which degree the follow-up contact with the coordinator or therapist after a session had an impact.

2.9. Sample size

We have based the power calculation on the results of a pilot study (not published) and the assessment of the psychiatric specialist of the Military Psychiatric Centre. We calculated the necessary sample size using a power of 80%, and a significance level of 5%. Assuming a clinically relevant reduction of 5 points in PTSD symptoms scores in the intervention group compared to the control group and assuming a standard deviation (SD) of 5 in the changes in scores in both groups, the minimum number of participants needed to be included is 16 people for each group. However, we expect some drop-out. Therefore, the trial will include 42 veterans diagnosed with PTSD.

2.10. Statistical analysis

In accordance with the Consolidated Standards of reporting Trials (CONSORT) recommendations, the participant flow will be reported. Primary analysis is of intention to treat type [58]. Missing data might be handled with multiple imputation [59]. General linear models will be used to analyse the differences in means between the intervention and the control group based on PTSD symptoms, quality of life, daily function level, depression and body awareness measured at post-intervention. Independent general linear models will be fitted for each of the continuous outcome variables. We will adjust for baseline score of the outcome, age, current treatment, time since returning from military missions and social support. Assumptions of normality will be evaluated; normalizing transformations or generalized linear models using appropriate link functions will be used if warranted. Moreover, linear mixed effects models [60] will be used to analyse the effectiveness of the intervention at all three follow-up time points. In a supplementary analysis, number of registered treatment sessions will be included in the regression models to examine how number of body therapy sessions affect the outcome.

2.11. Qualitative methods

In order to investigate veterans' perceptions and experienced gains of the intervention, we use qualitative methods, including participant observations, qualitative interviews, and focus group interview with veterans, their family members and with the therapists. Participant observation is well-suited for studying how social processes and interactions play out [61]. We will participate in joint exchange meetings with veterans and therapists and talk informally with participants before and after treatments. Individual in-depth interviews are useful when interested in participants' experiences, perspectives, and own ways of talking about their condition [62]. In total, we will carry out 10–15 in-depth semi-structured interviews with veterans just before, during and after the course of their treatment, including 6 months after. Focus group interviews are useful to investigate peoples' reactions to each other's statements on a given topic [63]. It forces the participants to be discursively explicit in their negotiation with each other, and the researchers gain an understanding of what the participants can agree or disagree with. We will carry out one focus group with therapists about the treatment process and one with the veterans' relatives. We envisage that a focus group among the veterans' family members will provide insight into common or different types of frus-

trations as well as reliefs, and that listening to the stories of others in the same situation may encourage sharing such experiences.

Qualitative data will be analysed as a thematic analysis [64], guided by the research questions, but we will also pay attention to themes based on the informants' perspectives and experiences. Initially, all the material is read and discussed in the research group, an open coding process takes place, and central themes are defined. In consecutive rounds of analysis, themes and subthemes are refined. This is followed by a collaborative analysis [65], where researchers share perspectives on the same material and aimed at ensuring that different analytical perspectives come to light. We will use the programme Nvivo to organise the data and analysis.

2.12. Ethics

The project has been approved by the National Committee on Health research Ethics, record number.

H-18052238. All participants will provide written informed consent prior to participation. Information can be obtained with the consent of the participants, and it will be noted in the participants' journal which information has been passed on (in accordance with Danish legislation). The project is approved by The Personal Data Protection Act. During the process with informed content, the participants are given oral and written information and have 30 min to sit alone and read the text if desired. They are also offered a new meeting if they want more time for considering participation (3–4 days) or want to have a companion attend the meeting.

Being aware that some veterans are mentally exhausted from preparing for an interview, interviews will last a maximum of 1 h unless the veteran have a lot to tell and explicitly wants to stay longer. In planning the interviews, we strive to adjust the place and form of the interview to the individual veteran's preferences, e.g. life situation and symptoms. This may entail considerations about the position in the interview room as some veterans prefer sitting with the back against the wall (facing the door) to avoid a vulnerable position. If the veteran is uncomfortable with eye contact, we will suggest carrying out a walking-interview. Finally, we try to minimize noise e.g. from adjoining rooms during interviews to avoid causing unease. If veterans display suicidality or experience adverse effects from the intervention, they will be referred to the psychiatric specialist at the Military Psychiatric Center.

3. Conclusions

The primary aim of this study is to investigate the impact of body therapy delivered approximately once a week during a 6-month period on veterans diagnosed with PTSD. The protocol describes the primary aims of the trial, including the effect of the intervention on depression, quality of life, function level and body awareness. Furthermore, an ethnographic study will examine how the participants experience the body therapy and changes in their everyday life. Evaluation data from a pilot study indicated that body therapy improves the veterans' symptoms and life circumstances; the current study seeks to investigate this. This step, involving a randomized controlled trial is critical for testing the effectiveness of the intervention. The findings will provide important information for researchers and practitioners to consider when developing interventions to help veterans. If the intervention proves effective and acceptable, our next goal will be to examine how to disseminate the intervention into the treatment offered to Danish veterans.

3.1. Trial status

Recruitment of participants is completed; the intervention delivery and data collection is underway.

Contributors

NGA led the design of the study. SA and HSA contributed to the quantitative trial design and TTT to the qualitative design. AD contributed to the literature research. SA will lead the quantitative data collection and analyses, NGA will lead the qualitative data collection and analyses, supported by AD and TTT. The article was drafted by NGA with contributions from AD, SA, HSA and TTT.

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Declaration of competing interest

None declared.

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