Effects of hands-on mind-body therapy on posttraumatic stress disorder among Danish military veterans

A randomized clinical trial

Andersen, Susan; Andersen, Henrik Steen; Ahrensberg, Hannah; Lazar, Loana; Tjørnhøj-Thomsen, Tine; Ahlmark, Nanna Gram

Published in:
Mental Health Science

DOI:
10.1002/mhs2.52

Publication date:
2024

Document version:
Final published version

Received: 7 August 2023 | Revised: 22 December 2023 | Accepted: 2 January 2024

DOI: 10.1002/mhs2.52

RESEARCH ARTICLE

WILEY

Effects of hands-on mind-body therapy on posttraumatic stress disorder among Danish military veterans: A randomized clinical trial

Susan Andersen PhD[1] | Henrik Steen Andersen MedSc[2] | Hannah Ahrensberg MSc[1] | Ioana Lazar MSc[3] | Tine Tjørnhøj-Thomsen[1] | Nanna Gram Ahlmark PhD[1]

[1]National Institute of Public Health, University of Southern Denmark, Copenhagen, Denmark

[2]Military Psychiatric Outpatient Clinic, Psychiatric Center Copenhagen, Capital Region Psychiatry, Copenhagen, Denmark

[3]Institute of Digital healthcare, University of Warwick, Coventry, UK

Correspondence
Susan Andersen, PhD, National Institute of Public Health, University of Southern Denmark, Studiestræde 6, 1455 Copenhagen, Denmark.
Email: suan@sdu.dk

Funding information
Soldaterlegatet; Sundhedsstyrelsen; Styrelsen for Patientsikkerhed

Abstract

Posttraumatic stress disorder (PTSD) affects many military veterans. Given limited success of and barriers to conventional treatments, increasing interest is being paid to mind-body therapy approaches. However, little evidence exists on whether these have the potential to treat traumatic stress. The aim of this study was to compare 6 months of hands-on mind-body therapy as an add-on to treatment as usual (TAU) with TAU alone. Participants with PTSD resulting from active military service were randomly assigned to the intervention group or treatment-as-usual (TAU) group. The intervention group received 24 hands-on manipulative mind-body therapy sessions during 6 months as add-on to TAU. The primary outcome was the PTSD Checklist-Military version (PCL-M) at 6 months (postintervention). Outcome measurements were obtained at four time points; baseline, 3 months (midway), 6 months (postintervention), and 12 months (follow-up). Intention-to-treat analysis was done masked to allocation. A total of 42 participants were randomized (22 control, 20 intervention). In the intervention group, two discontinued the mind-body therapy. At postintervention, participants who had received mind-body treatment demonstrated greater reduction in PTSD severity (PCL-M scores between-group mean difference: −11.1, 95% CI −17.9 to −4.2, $p = 0.002$, effect size $d = 1.06$). At follow-up, PCL-M scores were not statistically significant between groups (between-group difference: −4.65, 95% CI −11.8 to 1.50). Post hoc analysis showed that number of participants remitting from PTSD from baseline to follow-up was 25% in the intervention group and 0% in the control group. Our study showed that hands-on mind-body therapy over 6 months produced clinically significant decrease in PTSD symptoms. The large reduction in symptoms was not maintained 6 months after the intervention period. Further research on mind-body therapy as adjunctive PTSD treatment is warranted.

KEYWORDS

complementary therapies, efficacy, military psychiatry, outpatient treatment, posttraumatic stress disorder, randomized controlled trial

1 | INTRODUCTION

Posttraumatic stress disorder (PTSD) occurs as a postreaction to one or more traumatic experiences and is characterized by re-experiencing the traumatic event, avoidance of reminders of the trauma, negative affect, distorted cognition, and altered arousal and reactivity (Bisson, 2007) Although the prevalence is inconsistent and depends on the diagnostic system among other, military personnel are at high risk of developing PTSD after returning from missions. In a meta-analysis of 32 studies, the incidence of PTSD among veterans was estimated to range from 1.1% to 34.8% (Xue et al., 2015). The prevalence of PTSD after returning from military service in Iraq and Afghanistan was 12.4% among combat deployed personnel and 4.9% among those in support roles (Hines et al., 2014). Among Danish soldiers deployed to Afghanistan, approximately 10% are estimated to suffer from PTSD 2.5 years after returning home (Madsen et al., 2016). Individuals diagnosed with PTSD are usually offered pharmacological and/or psychotherapeutic treatment. Despite evidence for positive treatment responses from first-line psychotherapies for PTSD among military populations such as Cognitive processing therapy (CPT) and Prolonged exposure therapy (PE), nonresponse and dropout rates are high, patients often remain symptomatic and the interventions show marginally superior results compared with active control conditions (Karlin et al., 2010; Steenkamp et al., 2015; Straud et al., 2019). A review of randomized controlled trials (RCTs) examining the effectiveness of psychotherapies for PTSD in military and veteran population found that there is a need for improvement in existing PTSD treatments as well as the development and testing of novel evidence-based treatment strategies, whether trauma-focused or nontrauma-focused (Steenkamp et al., 2015). Both CPT, which focuses on modifying dysfunctional thoughts, beliefs, and expectations by identifying, challenging, and replacing maladaptive cognitions and PE, which entails psychoeducation, imaginal or narrative exposure, in vivo exposure, and processing of thoughts and emotions, with the aim of confronting feared memories and stimuli, entails recalling traumatic events through cognitive processes (Steenkamp et al., 2015).

According to some trauma-oriented researchers, such as Bessel van der Kolk, this may prove difficult since the rational analyzing part of the brain shuts down, when traumatic incidents happen, and the emotional part of our brain, the limbic system, takes over, van der Kolk argues (Van der Kolk, 2006, 2014). Therefore, the traumatic event are recalled as disturbing bodily physical and emotional sensations, rather than a structured narrative, and hence, it might be difficult describe the traumatic experiences. Instead, there are potentials in trauma therapy which focuses on how the body responds to feelings of threat and fear, strengthens body awareness, and focus on feeling safe in one's body (Van der Kolk, 2006, 2014) In the literature an interest in such mind-body oriented approaches to PTSD is seen in the an increasing number of studies on, for example, mindfulness and meditation (Polusny et al., 2015), healing touch therapy (Jain et al., 2012), mindfulness-based stretching and deep breathing exercises (Kim et al., 2013), yoga (Cramer et al., 2018), osteopathic treatment (Urits et al., 2021), craniosacral therapy (Jäkel and von Hauenschild, 2012), emotional freedom technique (EFT), and Mindful Awareness in Body-oriented Therapy (McGreevy & Boland, 2022). A review of research on touch as treatment for the symptoms of PTSD showed that touch-based approaches can play an important role in emotional regulation and reduction of symptoms of PTSD (McGreevy & Boland, 2022). Despite these advances in mind-body oriented approaches to treating PTSD, there remains significant potential for further investigation in this research field.

The purpose of this study was to examine the effect of a touched-based manipulative mind-body therapy as an adjunctive treatment to treatment as usual (TAU) on PTSD symptoms. The primary aim was to assess whether the intervention was effective immediately postintervention. We hypothesized that, compared with TAU, participants in the intervention group would experience fewer PTSD symptoms. The secondary aims were to assess (1) whether the intervention was effective at 6-month follow-up (maintenance), (2) whether change was observed midway during intervention, and (3) the impact of the intervention on symptom clusters.

2 | METHODS

2.1 | Study design

We did a single assessor-blinded, parallel group, RCT comparing mind-body therapy plus TAU with TAU only. The trial was conducted in eastern Denmark between January 2018 and August 2020. All participants were assessed at baseline (before randomization) and followed up after 3 months (or midway during the intervention), 6 months (or postintervention), and 12 months (i.e., 6 months after completion of the 6-month intervention period). We used self-administered, web-based questionnaires. The participants filled out the baseline questionnaire during the visit where information about the study was given (after written informed consent was given and before randomization). The follow-up questionnaires were sent out by e-mail. The study protocol is previously published (Ahlmark et al., 2020).

2.2 | Setting and participants

The study was conducted at the Military Psychiatric Center, a part of the Mental Health Services in the Capital Region of Denmark. Two trained clinicians, both psychiatric specialists, were responsible for evaluating the inclusion and exclusion criteria, which were determined clinically. All participants were well known by these two psychiatric specialists, having been patients at the clinic for a minimum of several months. Most patients at the Military Psychiatric Center are referred from the Danish Veteran Center under the Ministry of Defense due to severe mental health issues and associated problems that exceed the services provided by the Veteran Center. This indicates that the patients at the Military

Psychiatric Center represent the most mentally vulnerable segment among veterans dealing with PTSD. Consequently, a considerable number of them lack the stability needed to participate in and attend the frequent sessions that the intervention demands. The two experienced psychiatrists at the Military Psychiatric Center took this into consideration during their eligibility assessment. Moreover, inclusion criteria were veterans aged ≥18 years old, who met criteria for clinical PTSD as assessed by the Structured Clinical Interview for DSM-5 (SCID-5). Participants should also demonstrate normal cognitive skills. Exclusion criteria involved displaying active symptoms that could interfere with treatment progress and encountering challenges in attending regular consultations. This included alcohol or drug dependency/abuse, the presence of severe mental disorders such as schizophrenia, bipolar disorder, psychosis, current psychiatric conditions like mania, dementia, or cognitive impairment.

2.3 | Randomization and blinding

Randomization was conducted by an independent statistician who generated a computer-randomized list and assigned the participants to intervention and control groups. The randomization codes were held in sequentially numbered sealed envelopes placed at the Military Psychiatric Center and distributed to participants in due order by the psychiatric specialist to whom the randomized order was unknown. The evaluation team was blinded to trial arm status until the planned analyses had been completed, that is, during data management, analytic decisions, and performance of analysis. Participants and healthcare providers of the intervention and usual treatment were not blinded.

2.4 | Interventions

2.4.1 | TAU

In Denmark, the treatment approach for veterans with PTSD typically integrates the following elements:

- Medication: Patients may be prescribed antidepressants (SSRI or SNRI) and sedating antipsychotics, mainly quetiapine, to treat sleep disturbances.
- Psychoeducation: Monthly psychoeducational sessions, led by psychiatrists, aim to enhance patients' understanding of their condition, its symptoms, and effective coping strategies for managing PTSD.
- Psychological interventions: Psychologists primarily from the Danish Defense, delivers psychological interventions either in the form of CPT or PE depending on an individual assessment.

It should be noted that the treatment for individuals diagnosed with PTSD in Denmark is individually tailored. While some individuals may not participate in a treatment regimen, others undergo multifaceted therapeutic treatment according to needs, preferences, and possibilities.

2.4.2 | Hands-on mind-body therapy

Participants in the mind-body therapy group received hands-on manipulative mind-body therapy as add-on to TAU, that is, their regular treatment (if any). Hands-on mind-body therapy is a form of therapy where the therapist uses her hands to manipulate muscles and body parts to release tensions. In line with other mind-body oriented therapies such as yoga and mindfulness, a central element this therapy is improvement of body awareness, also called interoceptive awareness and training the ability to observe and stay present with painful sensations (Casals-Gutiérrez & Abbey, 2020; Weng et al., 2021). Several studies show that interoceptive awareness may builds skills in tolerating and regulating physiologic and affective states that have become dysregulated by the trauma exposure (Strigo & Craig, 2016; Van der Kolk, 2014). This is particularly relevant when suffering from PTSD where one's ability to regulate emotions is severely damaged. As opposed to, for example, mindfulness practices, this hands-on approach includes that a therapist uses her hands to provoke this awareness through massaging and pushing the client's body at the places where she feels the tensions.

The therapy was delivered by seven specially trained therapists educated through the Danish organization Manuvision (Jørgensen et al., 2023); an education that takes 2 years part-time. The participants received individual sessions lasting 60 min, once a week, amounting to 24 sessions in total that was delivered for 6 months. The sessions consisted of:

- Hands-on manipulatory techniques. The manipulatory techniques are specific hands-on touches, twists, and pressures on places of the client's body where the therapist senses painful bodily tensions, and guide the client to direct attention to these tensions without judging the discomfort. The client paying attention to and actively using her breath is central to the process.
- At the beginning and end of each session, the therapist actively prioritizes the establishment of a trusting relationship and atmosphere through body language and a pleasant tone of voice.
- Home meditation. The sessions included meditation practice with a focus on bringing awareness to different body parts. The participants received a digitally recorded meditation program aligned with the practice they were taught during the sessions, which they were encouraged to follow at home.
- The participants were given the opportunity to join group meetings with other veterans in the program two to three times during the 6-month intervention period, where they could exchange and compare their experiences with the treatment and its impact in their everyday life. These meetings were facilitated by a mind-body therapist.

2.5 | Primary outcome

PTSD symptoms was measured using the PTSD checklist-military version (PCL-M) (Weathers et al., 1993). PCL-M is a validated measure that assesses symptoms of PTSD (Wilkins et al., 2011). It comprises 17 questions corresponding to the 17 diagnostic criteria for PTSD in the US psychiatric diagnosis system DSM-IV. Past month symptom severity is indicated using a five-point scale. The PCL-M yields a score from 17 to 85, with higher scores representing greater severity. In the present study sample, PCL-M showed good internal consistency with a Cronbach's α of 0.89.

2.6 | Secondary outcome

While PTSD symptoms are often conceptualized as a univariate construct, factor analytic evidence suggests that PTSD symptoms represent at least four underlying constructs (Armour et al., 2016; Elhai & Palmieri, 2011; King et al., 1998; Lancaster et al., 2016). To explore potential differential treatment responses, we incorporated subscales of the PCL-M. Based on substantial support in the DSM-IV literature (Armour et al., 2016; Elhai & Palmieri, 2011; King et al., 1998; Lancaster et al., 2016), we opted for a four-factor model, encompassing re-experiencing, avoidance, numbing or negative change in mood and emotional detachment from others, and hyperarousal (such as heightened state of anxiety, irritability, anger and hypervigilance, and difficulty in concentrating).

In the intervention group, attendance of mind-body therapy sessions was documented by the therapists.

2.7 | Covariates

Information on baseline characteristics were obtained from the baseline questionnaire at study entry and included age, sex, employment status, living arrangement, social support, military rank, number of deployments, years since last military mission, countries they have been deployed in, and current psychoactive medication and psychotherapy. Information about depression symptoms was measured by the Major Depression Inventory (MDI); a brief self-rating scale based on the DSM-IV symptoms of major depression and the ICD-10 category of moderate to severe depression (Bech et al., 2001). The total score range is from 0 to 50, where higher scores indicate higher level of depression and cut-off score for depression is set to 26.

2.8 | Statistical methods

We estimated the sample size using unpublished data from a pilot study and by assessment of a psychiatric specialist of the Military Psychiatric Center in Copenhagen, Denmark. A conservative sample size calculation based on a two-sample *t* test was used. Specifically, to detect an effect size of 1, corresponding to a reduction of 5 points in PTSD symptom scores as measured by the PCL-M in the intervention group compared with the control group and assuming a standard deviation of 5, with 80% power and a 5% significance level, 16 participants were required per arm. Assuming a loss to follow-up of 20%, 21 participants were needed per arm, resulting in a total sample size of 42.

We carried out the statistical analyses according to a statistical analysis plan outlined before the trial was initiated. For all PTSD symptoms score outcomes ANCOVA-type linear mixed models were fitted to the entire longitudinal data with three time points at 3, 6, and 12 months. These models included group-by-time interaction terms as well as the following covariates: the baseline outcome, age, current treatment, and perceived level of social support as fixed effects. Participant-specific random intercepts were also included. Estimated mean differences between groups at 3, 6, and 12 months were reported with corresponding 95% confidence intervals. Where relevant relative effect sizes (Cohen's *d*) were reported. Model assumptions were assessed by means of histograms, residual plots, and normal probability plots. Intention-to-treat analyses were based on all participants that were randomized. Missing data were imputed using the "last observation carried forward" approach. As a supplement to the PTSD symptom outcome, the proportion of participants who demonstrated a reliable change was calculated. Clinically significant response to treatment was defined as 10-points decrease in PCL-M score (Monson et al., 2008), and remission was defined as PCL-M score <34 (Weathers et al., 1993). Numbers of responders and remitters were summarized by means of proportions and compared between groups using a chi-square test.

All statistical analyses were conducted using statistical software SAS, version 9.4 (SAS Institute, Inc.). A significance level of 0.05 was applied.

3 | RESULTS

Of those who were eligible, 84% (42/50) participated in the study (Figure 1). Completions of follow-up assessments were 98% at 3 months, 95% at 6 months, and 88% at 12 months. No adverse events such as suicide risk were reported.

Participants were predominantly men (39/42) with an average age of 41 years (Table 1). There were no differences in the proportions of participants regarding number of deployments, years since last military mission and depression. The majority (85.7%) had PCL-M scores ≥50. The intervention group had slightly lower mean PCL-M total score (59.65) than the control group (64.95); the "Re-experiencing" subscale exhibited the most pronounced difference between the two conditions (Table 2).

3.1 | Treatment completion

Out of 20 mind-body therapy participants, 17 (85%) attended at least 21 of the 24 sessions. Two participants dropped out, one finding the sessions too difficult (after attending 7 sessions), the other concluding that his

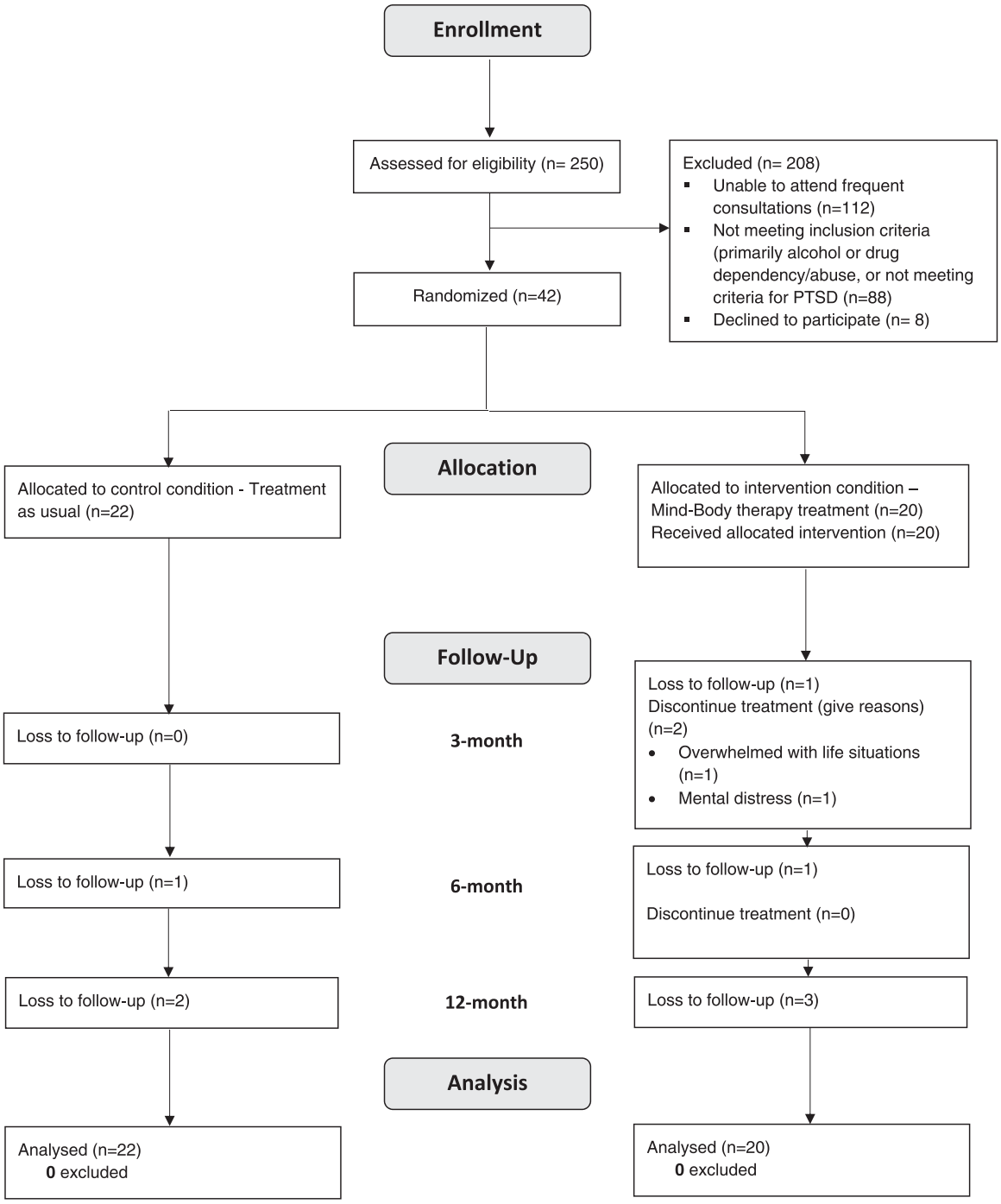

FIGURE 1 Consolidated Standards of Reporting Trials (CONSORT) flow diagram.

mental state did not allow him to continue (after attending 6 sessions). Concerning meditation practice, at the postintervention assessment, approximately 40% reported engaging in home meditation several times a week, whereas 45% reported seldom or never.

3.2 | Changes in PTSD symptoms

The mean values of PTSD scores in both groups improved from baseline to postintervention (Table 2). In the control group, the PCL-M scores declined from 65.0 at baseline to 62.0 and 60.6, respectively, at midway and postintervention. Within the intervention group, the PCL-M scores declined from 59.7 at baseline to 47.5 and 45.5 at midway and postintervention. In the intention-to-treat linear mixed model analysis, the adjusted mean differences were −10.39 (95% CI −14.39 to 6.38, $p < 0.0001$; $d = 1.00$) at midway and −11.07 (95% CI −17.92 to −4.21, $p = 0.002$; $d = 1.06$) at the end of the mind-body therapy, in favor of the intervention (Table 3). The analysis of subscales showed that participants in the intervention group scored lower on each of the four symptom clusters when

TABLE 1 Baseline characteristics, by trial arm and in total.

	Total (*n* = 42)	Intervention group (*n* = 20)	Control group (*n* = 22)
Age, years, mean ± SD	41.3 (±9.0)	42.5 (±8.7)	40.3 (±9.3)
Men, *n* (%)	39 (92.9)	19 (95.0)	20 (90.9)
Employment status, *n* (%)			
Unemployed/early retirement	27 (64.3)	11 (55.0)	16 (72.7)
Employed/education	15 (35.7)	9 (45.0)	6 (27.3)
Living arrangement, *n* (%)			
With partner or spouse	22 (52.4)	12 (60.0)	10 (45.5)
Live alone	14 (33.3)	7 (35.0)	7 (31.8)
Other (e.g., veteran homes)	6 (14.3)	<5[a]	5 (22.7)
High level of perceived social support after deployment, *n* (%)			
Family	21 (50.0)	12 (60.0)	9 (40.9)
Friends/acquaintances	19 (45.2)	8 (40.0)	11 (50.0)
Veteran organizations	13 (31.0)	5 (25.0)	8 (36.4)
Other support	11 (26.2)	7 (35.0)	4 (18.2)
Military rang, *n* (%)			
Private	33 (78.6)	17 (85.0)	16 (72.7)
Officer/Sergeant	9 (21.4)	<5[a]	6 (27.3)
Number of deployments, *n* (%)			
1	16 (38.1)	7 (35.0)	9 (40.9)
2	12 (28.6)	6 (30.0)	6 (27.3)
>3	14 (33.3)	7 (35.0)	7 (31.8)
Years since last military mission, *n* (%)			
>5 years	40 (95.2)	19 (95.0)	21 (95.5)
Countries, deployment,[a] *n* (%)			
Balkan	17 (40.5)	10 (50.0)	7 (31.8)
Afghanistan	21 (50.0)	9 (45.0)	12 (54.5)
Other (e.g., Iraq)	9 (21.4)	<5[a]	5 (22.7)
Current psychoactive medication, *n* (%)	28 (66.7)	11 (55.0)	17 (77.3)
Current psychotherapy, *n* (%)	19 (45.2)	6 (30.0)	13 (59.1)
PCL-M cut-off scores, *n* (%)			
≥50	36 (85.7)	17 (85.0)	19 (86.4)
34–49	6 (14.3)	3 (15.0)	3 (13.6)
<34	0	0	0
MDI score, mean (SD)	32.02 (8.58)	32.82 (9.21)	31.15 (7.97)
MDI score ≥26, *n* (%)	36 (85.7)	17 (85.0)	19 (86.4)

Abbreviations: MDI, major depressive inventory; PCL-M, PTSD Checklist-Military version.

[a]Exact number not shown due to data confidentiality issues.

TABLE 2 Means and standard deviation of outcome measures by condition and time points ($n = 42$).

PCL-M total score	Group	Baseline Mean	Midway Mean	Postintervention Mean	Follow-up Mean
	Intervention	59.65 (10.81)	47.45 (10.86)	45.45 (14.85)	49.55 (14.62)
	Control	64.95 (10.05)	61.95 (9.74)	60.64 (11.35)	58.32 (10.12)
PCL-M subscale score	**Group**	**Mean**	**Mean**	**Mean**	**Mean**
Re-experiencing	Intervention	16.10 (4.82)	13.55 (3.83)	12.30 (3.96)	13.35 (4.11)
	Control	18.68 (3.47)	17.59 (4.08)	16.59 (4.31)	16.59 (4.03)
Avoidance	Intervention	7.05 (2.04)	5.60 (1.96)	5.45 (2.46)	5.65 (2.50)
	Control	7.27 (1.45)	7.00 (1.51)	6.95 (1.53)	6.55 (1.63)
Numbing	Intervention	17.25 (3.34)	12.95 (4.12)	13.00 (4.97)	14.05 (4.73)
	Control	18.59	18.63	18.09	16.68
Hyperarousal	Intervention	19.25 (3.14)	15.35 (3.63)	14.70 (4.78)	16.50 (4.47)
	Control	20.41 (3.61)	18.73 (3.24)	19.00 (4.33)	18.50 (3.94)

Note: T0 = Baseline; T1 = after 3 months (midway); T2 = after 6 months (postintervention); T3 = after 12 months (follow-up).
Abbreviation: PCL-M, PTSD Checklist-Military version.

TABLE 3 Linear mixed model analyses of the association between the intervention (vs. treatment as usual) and PTSD midway during intervention, at postintervention, and at follow-up.[a]

	Midway (3-months)		Postintervention (6-months)		Follow-up (12-months)	
	Mean (95% CI)	*p* Value	Mean (95% CI)	*p* value	Mean (95% CI)	*p* Value
Intention-to-treat						
Primary outcome: PCL-M total score (17–85)	−10.39 (−14.39, −6.38)	<0.0001	−11.07 (−17.92, −4.21)	0.002	−4.65 (−10.80, 1.50)	0.13
Secondary outcomes: PCL-M subscores						
Re-experiencing (5–25)	−2.23 (−4.17, −0.28)	0.023	−2.48 (−4.71, −0.24)	0.031	−1.43 (−3.65, 0.80)	0.20
Avoidance (2–10)	−1.22 (−2.16, −0.28)	0.013	−1.32 (−2.45, −0.20)	0.022	−0.71 (−1.90, 0.48)	0.23
Numbing (5–25)	−4.63 (−6.33, −2.93)	<0.0001	−4.03 (−6.51, −1.55)	0.002	−1.57 (−3.65, 0.51)	0.13
Hyperarousal (5–25)	−2.68 (−4.40, −0.95)	0.003	−3.60 (−5.93, −1.27)	0.003	−1.30 (−3.32, 0.72)	0.20
Available cases						
Primary outcome: PCL-M score (17–85)	−10.64 (−14.51, −6.77)	<0.0001	−11.38 (−18.35, −4.41)	0.002	−5.42 (−11.85, 1.00)	0.095
Secondary outcomes: Subscales						
Re-experiencing (5–25)	−2.33 (−4.26, −0.39)	0.020	−2.73 (−4.96, −0.49)	0.018	−1.60 (−3.91, −0.71)	0.17
Avoidance (2–10)	−1.25 (−2.20, −0.30)	0.011	−1.37 (−2.52, −0.22)	0.021	−0.87 (−2.13, 0.39)	0.17
Numbing (5–25)	−4.73 (−6.40, −3.05)	<0.0001	−4.11 (−6.65, −1. 57)	0.002	−1.89 (−4.11, 0.33)	0.092
Hyperarousal (5–25)	−2.68 (−4.43, −0.93)	0.004	−3.65 (−6.03, −1.28)	0.004	−1.24 (−3.29, 0.81)	0.23

Abbreviation: PCL-M, PTSD Checklist-Military version.
[a]Adjusted for baseline score of outcome, age, current treatment (medication or psychotherapy), support from family, friends/acquaintances, or veteran organizations.

compared with the control group, with the largest between-group difference on the "Numbing" subscale. Symptom reduction did not differ between groups at 6-month follow-up (adjusted mean PCL-M total score −4.65, 95% CI −10.80 to 1.50, $p = 0.13$; $d = 0.45$), suggesting that the intervention effect was not maintained after the end of treatment.

The analysis of complete cases (Table 3) and models incorporating additional potential confounders, namely occupational status,

military rank, number of deployments, and living arrangement, in conjunction with age, treatment regimen, and social support, resulted in similar results (Supporting Information: Table S1). Among the various potential confounding variables examined, only "living arrangement" emerged as a statistically significant predictor of PTSD symptoms, with a mean PCL-M score of 9.17 (95% CI 1.97, 16.37) for individuals living alone compared with those living with a partner.

3.3 | Dose-specific postintervention effects

Additional analysis comparing PCL-M scores after low completers (≤16 sessions), medium completers (17–22 sessions), and high completers (23–24 sessions) to control group showed that reductions in PTSD symptoms from baseline to postintervention were large for both medium and high completers (differences −12.31, 95% CI −21.03 to −3.58; and −13.84, 95% CI −21.39 to −6.28) while no reductions were found for low completers (Supporting Information: Table S2).

3.4 | Response and remission (post hoc analysis)

At the end of the trial, the proportion with clinically significant response (≥10-point decrease in PCL-M score) was higher in the mind-body therapy group as compared with the control group (65% vs. 27%, $p = 0.014$) (Table 4). The proportion of mind-body therapy participants who achieved remission from PTSD symptoms was 5% (vs. 0% for control group, $p = 0.48$) at mid-intervention, 35% (vs. 4.5% for control group, $p = 0.018$) at postintervention and 25% (vs. 0% for control group, $p = 0.018$) at 6-months follow-up.

4 | DISCUSSION

This RCT study is one of the first randomized trials of mind-body therapy with therapists using hands-on mind-body therapy for treating PTSD symptoms in military veterans. The study showed that mind-body therapy as add-on to usual treatment reduced postintervention PTSD symptoms among Danish military veterans as compared with participants offered TAU only. The study demonstrated that the postintervention reduction was not maintained to follow-up. However, we found that 25% of mind-body therapy participants remitted from PTSD symptoms at follow-up while none achieved this in the control group.

The results in reducing the severity of PTSD symptoms among veterans are consistent with results from studies of interventions based on meditation and mindfulness, although some studies showed less robust changes than our study (Bormann et al., 2013; Kearney et al., 2013; Nidich et al., 2018; Polusny et al., 2015). For example, a RCT among US combat veterans by Polusny et al. (2015) reported greater improvement in PTSD through mindfulness-based stress reduction group therapy, with between-group difference in PTSD Checklist scores of 4.95; 95% CI, 1.92–7.99 (Polusny et al., 2015). Research suggests that integrating mindfulness with manual touch can be beneficial (Casals-Gutiérrez & Abbey, 2020). One approach, known as healing touch, involves therapists using their hands to release blocked or congested energy. This method has been studied in both active duty US military personnel (Jain et al., 2012) and veterans (Reeve et al., 2020), with results showing reduction in severity of PTSD symptoms. The intervention techniques used in our mind-body therapy treatment share similarities with the osteopathic treatment approach described by Liem and Neuhuber (2020), whereby the treatment effect is based on patient-therapist interactions, aiming to establish trust and a sense of security for the patient followed by exercises in stress arousal and reduction and a confrontation phase with palpation, regulation, and anchoring of resources (Liem & Neuhuber, 2020). The emphasis on the trusted alliance in the mind-body therapy treatment may contribute to the observed positive outcome. This aligns with the common factors model, as proposed by Wampold (2015), suggesting that the effectiveness of therapeutic interventions is influenced by elements such as the therapeutic alliance and the expectations of improvement for individuals in the treatment group. While this dynamic is relevant to those in the mind-body treatment group, in the same vein it might apply to the impact on individuals undergoing psychotherapy in the TAU condition. Additionally, there may have been a positive impact of social support arising from the voluntary group meetings (offered up to three times only during the 6-month period). It is essential to view these meetings as a supplementary rather than a central component, designed to accommodate individual preferences (Steenkamp et al., 2015, 2020).

The number of received mind-body therapy treatment sessions was positively associated with reduction in PTSD symptoms, which is consistent with previous findings (Straud et al., 2019). However,

TABLE 4 PTSD improvement and remission over time by condition, *n* (%).

	Midway			Postintervention			6-month follow-up		
	Intervention	Control	*p*	Intervention	Control	*p*	Intervention	Control	*p*
PTSD improvement[a]	15/20 (75%)	2/22 (9.1%)	>0.0001	13/20 (65%)	6/22 (27%)	0.014	11/20 (55%)	8/22 (36%)	0.23
PTSD remission[b]	1/20 (5%)	0/22 (0%)	0.48	7/20 (35%)	1/22 (4.5%)	0.018	5/20 (25%)	0/22 (0%)	0.018

Abbreviation: PCL-M, PTSD Checklist-Military version.

[a]Improvement was defined as ≥10 point decrease in PCL-M score.

[b]Remission was defined as PCL-M score <34.

specific dose–response effects are unclear and not possible to investigate given the small sample size. Only two intervention participants dropped out of the treatment, and the attendance rate among the remaining participants was high. This is definitely a positive finding because adherence to standard PTSD treatments is low (Steenkamp et al., 2015, 2020).

4.1 | Strengths and limitations

The strengths of this study are that it followed a randomized controlled design protocol, with a study population randomly allocated to intervention and control groups; it had a high response rate with four assessments over 12 months, a high retention rate, high protocol adherence, and blinding of the data analysts. There are limitations to this study that need to be considered in interpreting the findings. First, our study is constrained by a low sample size recruited from a single center. The determination of the sample size was initially based on a *t* test, and since we used a linear mixed model that requires greater statistical power, there is a potential risk of introducing type II error. Consequently, our results should be considered preliminary, and a future large-scale effectiveness study is warranted, including the recruitment of participants from several centers, such as the Danish Veteran Center, where veterans with less severe comorbidities and disturbances may be represented. Second, we recruited only few women, and the results may not reflect this category of veterans. Third, the small sample size may have led to some baseline differences between the intervention and control group. However, we controlled for baseline differences between the intervention and control group, and adjusting for the covariates did not impact on the obtained results. Still, there may remain residual confounding regarding TAU because we were unable to precisely quantify the extent of TAU. Fourth, the lack of participants blinding may have influenced the reported outcomes or introduced substitution bias. Achieving blinding is challenging in nonpharmacological trials, but we could have designed a placebo-controlled trial that mimics the active treatment, such as the use of light touch interventions as demonstrated in the Osteopathic Manipulative Treatment trial of Nguen et al. (2021). However, before implementing this approach, it is essential to investigate how a light touch treatment should be designed in a way to avoid diminishing the effect of the mind-body therapy. As discussed in two systematic reviews about placebos (sham methods) for manual or osteopathic clinical trials, different touch strategies could influence clinical outcomes (Cerritelli et al., 2016; Lavazza et al., 2021). For example, light touch itself could have a positive mental health effect as it activates low-threshold mechanoreceptors which modify the autonomic nervous system functions and may play an important role in emotional regulation (Cerritelli et al., 2016). A final point to address is that we chose the PCL-M over the PCL-5 due to study timeline and practical reasons. While tailored for military personnel, this decision may limit alignment with the latest diagnostic criteria and advancements present in the PCL-5. Also, the assessment of PTSD symptoms utilized self-reported, web-based questionnaires rather than a standardized interview, although there have been positive reports regarding the reliability and validity of the PCL (McDonald & Calhoun, 2010).

4.2 | Implications

This study showed that mind-body therapy for PTSD among military veterans may be effective compared with usual treatment, but most noteworthy on numbing and hyperarousal symptoms. This long-lasting improvement is noteworthy given the fact that the mind-body treatment in particular aimed at providing veterans with methods to handle recurring everyday situations where they felt challenged by high arousal or emotional distress. However, the specific mechanisms that contributed to the intervention effects cannot be established from this study and will be investigated in a qualitative process evaluation. The data demonstrated that intervention effect was already visible after 3 months. This underlines the importance of future research to investigate in more detail the relationship between mind-body therapy, including how and under which circumstances mind-body therapy works, and calls for similar studies with a shorter intervention period to test whether similar effects might be obtained with half the intervention period. The findings also show that effect was maintained 6 months after the intervention ended for some subareas, though not for all. This also calls for future research to understand why this might be the case, and possibly to test whether booster sessions would support veterans with PTSD in integrating and maintaining positive progress in their everyday lives.

In conclusion, the findings suggest that considerable benefit might derive from pursuing research on supplementing usual treatment with mind-body therapeutic approaches to relieve the symptoms of PTSD among veterans who do not adequately respond to established treatments.

ACKNOWLEDGMENTS

Thanks to Camilla Øst Cloos for contributing to conducting the study and to Nina Stefansdottir for pilot testing the questionnaire. This work was supported by the Danish Health Authorities, the Danish Patient Safety Authorities, and the Soldier's fund (in Danish: Soldaterlegatet).

CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author on reasonable request.

ETHICS STATEMENT

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the

Helsinki Declaration of 1975, as revised in 2008. Before recruiting participants, all procedures were approved by the National Committee on Health Research Ethics (Denmark) (record number H-18052238). Written informed consent was obtained from all participants before study entry. Each participant was given oral and written information about the project and had 30 min or more if needed to sit alone and read the document. They were also offered a further meeting within 3–4 days if more time was needed and were given the opportunity to have a personal assessor to join them. ClinicalTrials.gov, Identifier: NCT03777800.

ORCID

Susan Andersen http://orcid.org/0000-0002-2741-0742

PEER REVIEW

The peer review history for this article is available at https://www.webofscience.com/api/gateway/wos/peer-review/10.1002/mhs2.52.

REFERENCES

Ahlmark, N. G., Dahl, A., Andersen, H. S., Tjørnhøj-Thomsen, T., & Andersen, S. (2020). Body therapy versus treatment as usual among Danish veterans with PTSD: Study protocol for a randomised controlled trial combined with a qualitative study. *Contemporary Clinical Trials Communications*, *19*, 100596.

Armour, C., Műllerová, J., & Elhai, J. D. (2016). A systematic literature review of PTSD's latent structure in the Diagnostic and Statistical Manual of Mental Disorders: DSM-IV to DSM-5. *Clinical Psychology Review*, *44*, 60–74.

Bech, P., Rasmussen, N. A., Olsen, L. R., Noerholm, V., & Abildgaard, W. (2001). The sensitivity and specificity of the Major Depression Inventory, using the Present State Examination as the index of diagnostic validity. *Journal of Affective Disorders*, *66*(2–3), 159–164.

Bisson, J. I. (2007). Post-traumatic stress disorder. *BMJ*, *334*(7597), 789–793.

Bormann, J. E., Thorp, S. R., Wetherell, J. L., Golshan, S., & Lang, A. J. (2013). Meditation-based mantram intervention for veterans with posttraumatic stress disorder: A randomized trial. *Psychological Trauma: Theory, Research, Practice, and Policy*, *5*(3), 259.

Casals-Gutiérrez, S., & Abbey, H. (2020). Interoception, mindfulness and touch: A meta-review of functional MRI studies. *International Journal of Osteopathic Medicine*, *35*, 22–33.

Cerritelli, F., Verzella, M., Cicchitti, L., D'Alessandro, G., & Vanacore, N. (2016). The paradox of sham therapy and placebo effect in osteopathy: A systematic review. *Medicine*, *95*(35), e4728.

Cramer, H., Anheyer, D., Saha, F. J., & Dobos, G. (2018). Yoga for posttraumatic stress disorder—A systematic review and meta-analysis. *BMC Psychiatry*, *18*, 72.

Elhai, J. D., & Palmieri, P. A. (2011). The factor structure of posttraumatic stress disorder: A literature update, critique of methodology, and agenda for future research. *Journal of Anxiety Disorders*, *25*(6), 849–854.

Hines, L. A., Sundin, J., Rona, R. J., Wessely, S., & Fear, N. T. (2014). Posttraumatic stress disorder post Iraq and Afghanistan: Prevalence among military subgroups. *The Canadian Journal of Psychiatry*, *59*(9), 468–479.

Jain, S., McMahon, G. F., Hasen, P., Kozub, M. P., Porter, V., King, R., & Guarneri, E. M. (2012). Healing touch with guided imagery for PTSD in returning active duty military: A randomized controlled trial. *Military Medicine*, *177*(9), 1015–1021.

Jäkel, A., & von Hauenschild, P. (2012). A systematic review to evaluate the clinical benefits of craniosacral therapy. *Complementary Therapies in Medicine*, *20*(6), 456–465.

Jørgensen, A., Meisling, I., & Rankenberg, F. (2023). Når kroppen er i krig - Manuvisions kropsterapeutiske behandling af traumer. [When the body is at war. Manuvision body therapeutic treatment of trauma]. Manuvision, Copenhagen. Manuvision homepage in UK 2023; https://manuvision.co.uk/

Karlin, B. E., Ruzek, J. I., Chard, K. M., Eftekhari, A., Monson, C. M., Hembree, E. A., Resick, P. A., & Foa, E. B. (2010). Dissemination of evidence-based psychological treatments for posttraumatic stress disorder in the Veterans Health Administration. *Journal of Traumatic Stress*, *23*(6), 663–673.

Kearney, D. J., McDermott, K., Malte, C., Martinez, M., & Simpson, T. L. (2013). Effects of participation in a mindfulness program for veterans with posttraumatic stress disorder: A randomized controlled pilot study. *Journal of Clinical Psychology*, *69*(1), 14–27.

Kim, S. H., Schneider, S. M., Bevans, M., Kravitz, L., Mermier, C., Qualls, C., & Burge, M. R. (2013). PTSD symptom reduction with mindfulness-based stretching and deep breathing exercise: Randomized controlled clinical trial of efficacy. *The Journal of Clinical Endocrinology & Metabolism*, *98*(7), 2984–2992.

King, D. W., Leskin, G. A., King, L. A., & Weathers, F. W. (1998). Confirmatory factor analysis of the Clinician-Administered PTSD Scale: Evidence for the dimensionality of posttraumatic stress disorder. *Psychological Assessment*, *10*, 90–96.

Van der Kolk, B. A. (2006). Clinical implications of neuroscience research in PTSD. *Annals of the New York Academy of Sciences*, *1071*(1), 277–293.

Van der Kolk, B. A. (2014). *The body keeps the score: Brain, mind, and body in the healing of trauma*. Viking Press.

Lancaster, C., Teeters, J., Gros, D., & Back, S. (2016). Posttraumatic stress disorder: Overview of evidence-based assessment and treatment. *Journal of Clinical Medicine*, *5*(11), 105.

Lavazza, C., Galli, M., Abenavoli, A., & Maggiani, A. (2021). Sham treatment effects in manual therapy trials on back pain patients: A systematic review and pairwise meta-analysis. *BMJ Open*, *11*, e045106.

Liem, T., & Neuhuber, W. (2020). Osteopathic treatment approach to psychoemotional trauma by means of bifocal integration. *Journal of Osteopathic Medicine*, *120*(3), 180–189.

Madsen, T., Andersen, S., & Karstoft, K.-I. (2016). Are posttraumatic stress symptoms related to mental health service use? A prospective study of Danish soldiers deployed to Afghanistan. *The Journal of Clinical Psychiatry*, *77*, 1299.

McDonald, S. D., & Calhoun, P. S. (2010). The diagnostic accuracy of the PTSD checklist: A critical review. *Clinical Psychology Review*, *30*, 976–987.

McGreevy, S., & Boland, P. (2022). Touch: An integrative review of a somatosensory approach to the treatment of adults with symptoms of post-traumatic stress disorder. *European Journal of Integrative Medicine*, *54*, 102168.

Monson, C. M., Gradus, J. L., Young-Xu, Y., Schnurr, P. P., Price, J. L., & Schumm, J. A. (2008). Change in posttraumatic stress disorder symptoms: Do clinicians and patients agree? *Psychological Assessment*, *20*(2), 131–138.

Nguyen, C., Boutron, I., Zegarra-Parodi, R., Baron, G., Alami, S., Sanchez, K., Daste, C., Boisson, M., Fabre, L., Krief, P., Krief, G., Lefèvre-Colau, M. M., & Rannou, F. (2021). Effect of osteopathic manipulative treatment vs sham treatment on activity limitations in patients with nonspecific subacute and chronic low back pain: A randomized clinical trial. *JAMA Internal Medicine*, *181*(5), 620–630.

Nidich, S., Mills, P. J., Rainforth, M., Heppner, P., Schneider, R. H., Rosenthal, N. E., Salerno, J., Gaylord-King, C., & Rutledge, T. (2018). Non-trauma-focused meditation versus exposure therapy in

veterans with post-traumatic stress disorder: A randomised controlled trial. *The Lancet Psychiatry*, *5*(12), 975–986.

Polusny, M. A., Erbes, C. R., Thuras, P., Moran, A., Lamberty, G. J., Collins, R. C., Rodman, J. L., & Lim, K. O. (2015). Mindfulness-based stress reduction for posttraumatic stress disorder among veterans: A randomized clinical trial. *Journal of the American Medical Association*, *314*(5), 456–465.

Reeve, K., Black, P. A., & Huang, J. (2020). Examining the impact of a Healing Touch intervention to reduce posttraumatic stress disorder symptoms in combat veterans. *Psychological Trauma: Theory, Research, Practice and Policy*, *12*(8), 897–903.

Steenkamp, M. M., Litz, B. T., Hoge, C. W., & Marmar, C. R. (2015). Psychotherapy for military-related PTSD: A review of randomized clinical trials. *Journal of the American Medical Association*, *314*(5), 489–500.

Steenkamp, M. M., Litz, B. T., & Marmar, C. R. (2020). First-line psychotherapies for military-related PTSD. *Journal of the American Medical Association*, *323*(7), 656–657.

Straud, C. L., Siev, J., Messer, S., & Zalta, A. K. (2019). Examining military population and trauma type as moderators of treatment outcome for first-line psychotherapies for PTSD: A meta-analysis. *Journal of Anxiety Disorders*, *67*, 102133.

Strigo, I. A., & Craig, A. D. (2016). Interoception, homeostatic emotions and sympathovagal balance. *Philosophical Transactions of the Royal Society, B: Biological Sciences*, *371*(1708), 20160010.

Urits, I., Schwartz, R. H., Orhurhu, V., Maganty, N. V., Reilly, B. T., Patel, P. M., Wie, C., Kaye, A. D., Mancuso, K. F., Kaye, A. J., & Viswanath, O. (2021). A comprehensive review of alternative therapies for the management of chronic pain patients: Acupuncture, tai chi, osteopathic manipulative medicine, and chiropractic care. *Advances in Therapy*, *38*(1), 76–89.

Wampold, B. E. (2015). How important are the common factors in psychotherapy? An update. *World Psychiatry*, *14*, 270–277.

Weathers, F. W., Litz, B., Herman, D., Huska, H. A., & Keane, T. (1993). The PTSD check list (PCL): Reliability, validity, and diagnostic utility. *Proceedings of the 9th Annual Meeting of International Society for Traumatic Stress Studies (ISTSS)*.

Weng, H. Y., Feldman, J. L., Leggio, L., Napadow, V., Park, J., & Price, C. J. (2021). Interventions and manipulations of interoception. *Trends in Neurosciences*, *44*(1), 52–62.

Wilkins, K. C., Lang, A. J., & Norman, S. B. (2011). Synthesis of the psychometric properties of the PTSD checklist (PCL) military, civilian, and specific versions. *Depression and Anxiety*, *28*(7), 596–606.

Xue, C., Ge, Y., Tang, B., Liu, Y., Kang, P., Wang, M., & Zhang, L. (2015). A meta-analysis of risk factors for combat-related PTSD among military personnel and veterans. *PLoS One*, *10*(3), e0120270.

SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Andersen, S., Andersen, H. S., Ahrensberg, H., Lazar, I., Tjørnhøj-Thomsen, T., & Ahlmark, N. G. (2024). Effects of hands-on mind-body therapy on posttraumatic stress disorder among Danish military veterans: A randomized clinical trial. *Mental Health Science*, *2*, e52. https://doi.org/10.1002/mhs2.52