Reconsolidation of Traumatic Memories for PTSD: A Randomized Trial of 30 Females

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Abstract

Introduction: Reconsolidation of Traumatic Memories (RTM) is a cognitive intervention for PTSD with significant potential as a cost effective and empirically supported treatment. **Methods:** A randomized waitlist-controlled design (*n* = 30) examined the efficacy of RTM among female veterans with current-month flashbacks and nightmares. The most common index trauma was Military Sexual Trauma (MST; n = 16, with other sexual trauma as the next most frequently reported (n = 7). 30 female veterans were randomly assigned either to immediate treatment consisting of three 120 minute sessions of RTM, or to a three-week waiting condition before controls received the same treatment. Blind psychometricians evaluated symptoms at intake, two weeks, and six-weeks post. Wait-listed participants were re-evaluated before being treated. **Results:** Data analyses showed that RTM was superior to control. A between group comparison at study week five found significant decreases in symptom scores in the treatment group (p. < 0.001). Control scores were essentially unchanged. Of those treated, 96.5% lost DSM diagnosis for PTSD by one of the following definitions: 14% lost DSM diagnosis by standard means (PCL-M < 50 or PCL-M <50 and DSM criteria not met). 24 persons, 85.7%, were in complete remission (PCL-M <30). Within-group RTM effect sizes (Hedges' g) ranged from 6.64 to 8.79. Therapist competence and adherence to treatment protocols were both strong. Patient satisfaction with the intervention was high. Study limitations and implications for the assessment and treatment of veterans with PTSD are discussed.

Key Words: **Post-traumatic stress disorder (PTSD), randomized trials, reconsolidation, waiting list, Female subjects**

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PTSD is a continuing problem affecting between 13 and 24% of veterans returning from the Middle East and Afghanistan (Eftekhari, Ruzek, Crowley, Rosen, Greenbaum, & Karlin, 2013; Kok, Herrell, Thomas, & Hoge, 2012; Sripada, et al., 2013; Tanielian & Jaycox, 2008). A significant deficit in PTSD research among recent war veterans is the effect of military trauma on female veterans (Eftekhari, Ruzek, Crowley, Rosen, Greenbaum, & Karlin, 2013; Schnurr, & Lunney, 2015). Female veterans often report highly diverse types of trauma (Kintzle et al. 2015; Mouliso, Tuerk, Schnurr, & Rauch, 2015; Turchik & Wilson, 2010) along with high levels of MST (Holliday, Williams, Bird, Mullen, & Suris, 2015; Kintzle et al. 2015; Turchick & Wilson, 2010). Research suggests that the incidence of MST as attempted or completed rape against females ranges from 9.5 to 33% while up to 85% of women in the military experience MSTs ranging from harassment to rape (Kintzle et al. 2015; Turchik & Wilson, 2010). MST is associated with increases in depression and suicide rates (Turchik & Wilson, 2010).

In this study we review a 30 person RCT of a new cognitive behavioral treatment modality applied to a group of 30 female volunteers, 16 of whom suffered from MST and 7 from non-military sexual traumas. This is the third investigation of the Reconsolidation of Traumatic Memories protocol and the first devoted to the treatment of female volunteers.

Current Interventions for PTSD Have Limited Efficacy

Although the VA has identified several front line behavioral interventions which documented efficacy, the level to which they eliminate the diagnosis or are esteemed by patients to have been effective have been called into question. (Bisson, Roberts, Andrew, Cooper, & Lewis, 2013; Steenkamp & Litz, 2012; Steenkamp, Litz, Hoge, & Marmar, 2015). These

interventions include Prolonged exposure (PE), Cognitive Processing Therapy (CPT), and Eye Movement desensitization and reprocessing (EMDR; Bisson, Roberts, Andrew, Cooper, & Lewis, 2013; Fernández, Bavassi, Forcato, & Pedreira, 2016; Goetter, Bui, Ojserkis, Zakarian, Brendel, & Simon, 2015; Goodson, Helstrom et al. 2011; Resick, Williams, Suvak, Monson, & Gradus, 2012; Steenkamp & Litz, 2013, 2014; Steenkamp, Litz, Hoge, & Marmar, 2015). Many authors have called for the development of new approaches to the treatment of PTSD (Barrera, Mott, Hofstein, & Teng, 2013; Bisson, Roberts, Andrew, Cooper, & Lewis, 2013; Fernández, Bavassi, Forcato, & Pedreira, 2016; Goetter, Bui, Ojserkis, Zakarian, Brendel, & Simon, 2015; Goodson, Helstrom et al. 2011; Steenkamp & Litz, 2013, 2014; Steenkamp, Litz, Hoge, & Marmar, 2015). Others, pointing out the lack of research into female veterans' needs for treatment have called for a focus on the impact of treatment on this population (Eftekhari, Ruzek et al. 2013; Schnurr, & Lunney, 2015). Into this discussion we introduce an RCT of 30 Female veterans using a new approach to the treatment of PTSD.

The Reconsolidation of Traumatic Memories (RTM) intervention

RTM is presented as an alternative to current interventions (Gray & Bourke, 2015; Gray & Liotta, 2012). The intervention begins with a brief, controlled reminder of the target trauma. It is believed that, in accordance with the reconsolidation paradigm (Agren, 2014; Gray & Liotta, 2012; Forcato, Bourgos, et al., 2007; Kindt, Soeter & Vervliet, 2009; Lee, 2009; Schiller and Phelps, 2011; Schiller et al., 2013), this brief, incomplete, or unreinforced reminder renders the traumatic memory subject to change for a period of about six-hours (as established in pre-clinical research; Nader et al, 2000; Schiller, Monfils, et al., 2010). Insofar as RTM does not use a standard extinction protocol, a narrative of the index trauma is elicited, or a presentation of the trigger for flashbacks is presented. As soon as autonomic arousal is detected, the narrative or

nascent flashback is terminated. The client is then presented with dissociative experiences of the target event which are hypothesized to modify its remembered structure. As these changes provide relevant, new information about the target event and its current level of threat, it is believed that, in accordance with reconsolidation theory (Agren, 2014; Gray & Liotta, 2012; Fernández, Bavassi, Forcato, & Pedreira, 2016; Forcato, Bourgos, et al., 2007; Kindt, Soeter, & Vervliet, 2009; Lee, 2009; Schiller, & Phelps, 2011; Schiller et al., 2013), those changes are incorporated into the structure of the target memory. After treatment, the event becomes available to declarative memory without evoking the strong pathological emotion characteristic of PTSD (Gray & Bourke, 2015; Gray & Liotta, 2012; Kindt, Soeter, & Vervliet, 2009; Schiller & Phelps, 2011; Tylee, Gray, Glatt, & Bourke, 2016).

Unlike other Trauma Focused Cognitive Behavioral Therapies (TFCBTs), the RTM protocol does use the trauma memory as the central effector of treatment change. Here, the brief exposure to the index trauma serves to initiate a period during which the structure of the trauma memory is destabilized in such a manner that new information can be added to the structure of the target memory (Agren, 2014; Gray & Liotta, 2012; Fernández, Bavassi, Forcato, & Pedreira, 2016; Forcato, Bourgos, et al., 2007; Kindt, Soeter, & Vervliet, 2009; Lee, 2009; Schiller, & Phelps, 2011; Schiller et al., 2013); it is these changes in structure that effect the change in the memory.

RTM is targeted specifically at the intrusive symptoms of PTSD, especially when they are experienced as sudden, uncontrollable autonomic responses either to the trauma narrative, elements of the narrative, or stimuli known to evoke flashbacks and nightmares. This represents a relatively automatic and unconscious response style which some authors have identified as being particularly susceptible to modification through ‘reconsolidative modification’ (Kredlow,

Unger, & Otto, 2015). The centrality of flashbacks and nightmares and the automaticity of response are crucial indicators for the use of the protocol. If they are absent, the protocol is inappropriate. (Gray & Bourke, 2015; Gray & Liotta, 2012; Tylee, Gray, Glatt, & Bourke, 2016).

Studies of RTM efficacy.

There have been two previous studies of RTM. Both studies evaluated the protocol using the PSS-I as the major diagnostic for intake and two-week follow-ups and the PCL-M as the measure for all time points up to six weeks in the original study (Gray & Bourke, 2015) and two six months in a later study using a 15-person waitlist controlled evaluation (Tylee, Gray, Glatt, & Bourke). Both studies obtained high effect sizes and greater than 90% loss of diagnosis. Participants in both studies reported a complete absence of flashbacks and nightmares after the last treatment.

Gray and Bourke (2015) reported a mean reduction of 44.7 ±15.8 points, with a final mean PCL-M score of 28.8±7.5 at 6 weeks or the last measure reported. Hedges' g at 6-weeks post showed a 2.9 SD difference from intake to follow-up (CI 99% [26.05, 33.71]). An informal follow-up reaching approximately 75% of treatment completers indicated that those gains were maintained at six-months post (R. Gray, personal communication, August 5, 2016).

Tylee, Gray et al. (2016) reported a mean reduction of 39.8 points (cumulative intake mean = 66.5 ± 8.27) for all treatment completers, with a final mean PCL-M score of 26.8 ± 13.08 at 6 months. Hedges' g for all treatment completers at 6-months post indicated a 3.59 SD difference from intake to follow-up (CI 99% [22.06, 33.54]).

Clinical improvement in PTSD symptoms was determined using standard levels of change in PCL-M scores (Schnurr, et al., 2007; VA, 2016). Response to treatment was defined as improvements in PCL-M scores of greater than 20 points (clinically significant change; Monson,

Gradus et al., 2008). Loss of diagnosis was defined as a total PCL-M score of < 50 points and failure to endorse at least 1 re-experiencing, 3 avoidance/numbing, and 2 hyperarousal symptoms (APA, 1994). Full remission was defined as a total PCL-M score of less than 30 (Castillo, et al., 2016; VA 2016).

Purpose of the Study

The purpose of this study was to examine the effectiveness of the RTM protocol using PTSD treatment outcome measures in a population of female veterans. We examined immediate treatment outcomes and sustained treatment effects at 6 months among volunteers in immediate treatment, untreated waitlist and among patients who were treated after completing a 3-week waiting period. The economy, and relative permanence of the intervention and its outcomes is attributed to the effects of the reconsolidative mechanisms. These mechanisms appear to be conserved across species (Agren, 2014; Pedreira, Perez-Cuesta, & Maldonado, 2004; Schiller & Phelps, 2011) and have been observed in human subjects (Drexler, Merz, Hamacher-Dang, Marquardt, Fritsch, Otto, & Wolf, 2014; Forcato, Rodríguez, Pedreira, 2011; Forcato, Rodríguez, Pedreira Maldonado, 2010; Kindt & Emerik, 2016; Kindt, Soeter, & Vervliet, 2009; Oyarzún, Lopez-Barroso, Fuentemilla, Cucurell, Pedraza, Rodriguez-Fornells, & de Diego-Balaguer, 2012; Schiller, Monfils, Raio et al., 2010; Schiller & Phelps, 2011; Soeter & Kindt, 2015) Previous work has suggested that RTM can produce reductions in intrusive symptomatology that remain stable over a period of at least six months (Gray & Bourke, 2015; Gray & Liotta, 2012; Tylee, Gray et al., 2016). This led us to hypothesize that RTM would produce clinically significant symptom reductions using standard measures of PTSD symptoms (PCL-M, PSS-I), that these would remain stable over time, and that patients would report total or near total loss of

nightmares and flashbacks. We further hypothesized that loss of diagnostic-level symptom scores would persist over at least six months. Participants received only 3 sessions of RTM.

Methods

With the exception of its focus on female participants, the methods and study design follow the same parameters as those described in Gray & Bourke (2016), Gray and Liotta (2012) and Tylee, Gray, et al. (2016). They are repeated extensively below.

Study Design

The RTM Protocol for the treatment of PTSD was evaluated using a randomized, waitlist-controlled design (see Figure 1). Participants were admitted to the study in cohorts of ten and then randomly assigned to treatment and control groups. Random assignment to RTM and control groups were made in cohorts of ten, using a list of random numbers generated by the Microsoft Excel 2016 random number function. The numbers were generated by a researcher on the East Coast and transmitted by email to the treatment location in California. Clients were assigned to treatment conditions by the site manager, in accordance with the randomized list.

For clarity of reporting, we refer to certain follow-up time points, during which symptoms were evaluated, based on the number of weeks elapsed since the completion of the treatment period. Intake evaluations were performed for all participants on study week 1. The

Figure 1. CONSORT Client Flow and Experimental Design

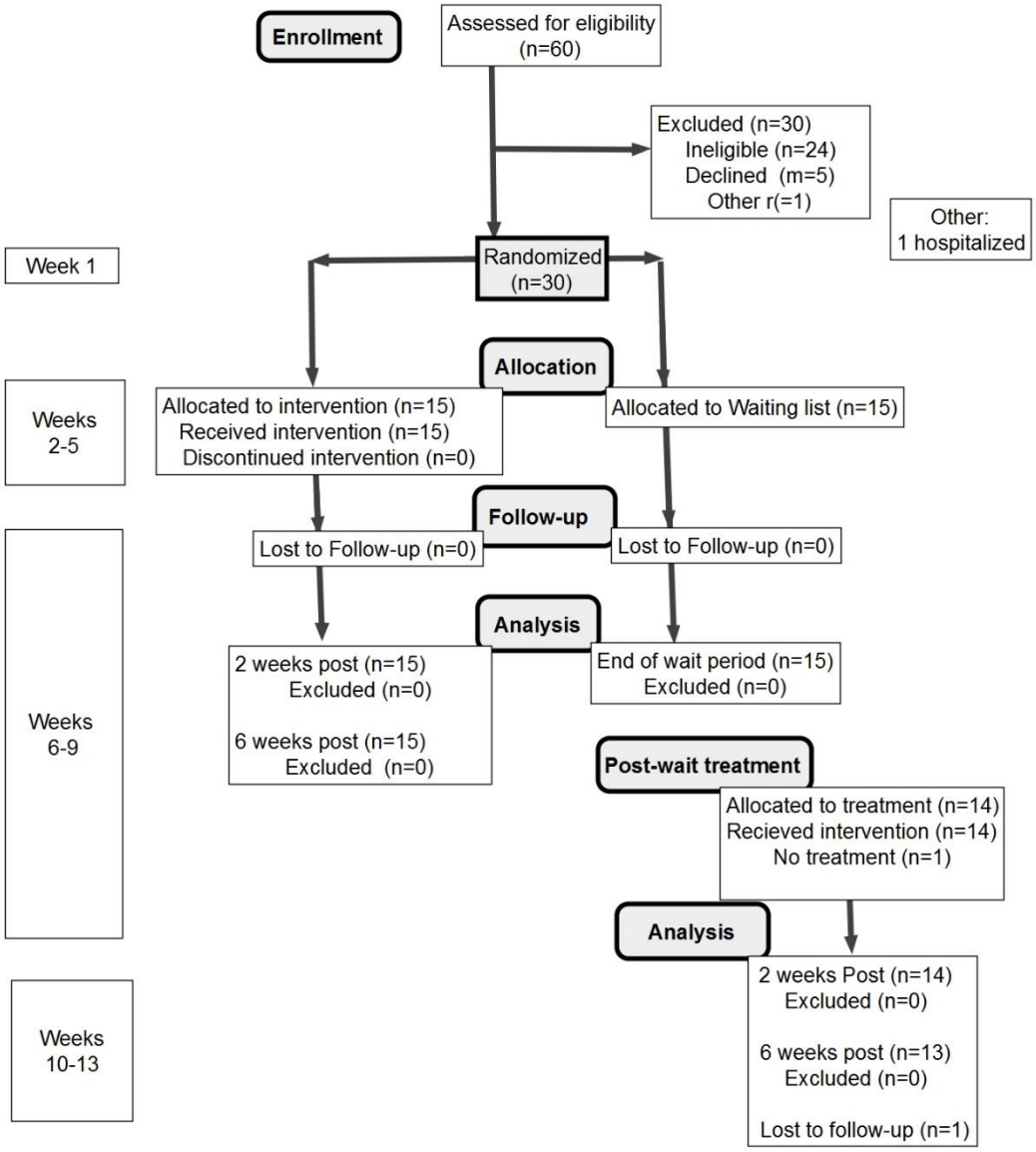

Figure 1. Participant flow chart following Consolidated Standards of Reporting Trials Guidelines. Subjects were pre-screened with a telephone interview and baseline symptoms were assessed using the PCL-M and PSS-I at study intake in week 1. Subjects were then randomized to RTM or waitlist control conditions. The RTM intervention was administered over the course of 3 weeks, during which time control subjects were informed that they would need to wait in order to receive treatment. On study week 6 (two weeks after the completion of treatment or the completion of the waiting period), symptoms were re-assessed using the PCL-M and PSS-I. Subsequently, for the RTM group, symptoms were re-assessed using the PCL-M on week 10 (six weeks after the completion of treatment) and again 6 months after treatment. Beginning on study week 6, subjects formerly in the control group received the RTM intervention over the course of 3 weeks and symptoms were assessed using the PCL-M and PSS-I on study week 10 (reflecting the two-week post-treatment time point) and with the PCL-M along on study week 16 reflecting the six-week post- treatment time point) and the 6-month follow-up time point.

treat

ment group began treatment on the same week. RTM was administered across a period of two-weeks**.** Participants received three 120-minute treatment sessions separated from each other by a minimum of 24 hours over the course of one to three weeks. Post-treatment evaluation of symptoms was performed two weeks after completion of treatment and four weeks later (reflecting the two and six-week follow-up time points). Control participants also had intake assessment during week 1 and were then informed they would wait several weeks before receiving treatment. On study week 5, control participants were re-evaluated using the same symptom scales. Control participants were then offered the same intervention schedule. and their symptom scores measured two and six-week post-treatment. All assessments were provided by psychometricians blinded to the study condition from which the subjects were drawn. All treatments and evaluations were performed in a private office suite dedicated to the study in a professional office complex in Vista, California, a suburban municipality in Northern San Diego County.

The RTM Protocol

The RTM Protocol is a brief cognitive intervention with a minimal, non-traumatizing exposure to the original trauma memory at the beginning of each session. It was administered in three sessions of up to 120 minutes each.

The intervention proceeds as follows in Table 1 (see Gray and Bourke; 2015; Gray & Li0tta, 2012: and Tylee, Gray, et al. (2016) for other descriptions.

Table 1. The RTM Process Outline

1. The client is asked to briefly recount the trauma.
2. Their narrative *is terminated as soon as autonomic arousal is observed*.
3. The subject is reoriented to the present time and circumstances.
4. SUDs ratings are elicited.
5. The clinician assists the client in choosing times before and after the event (bookends) as delimiters for the event: one before they knew the event would occur and another when they knew that the specific event was over and that they had survived.
6. The client is guided through the construction (or recall) of an imaginal movie theater in which the pre-trauma bookend is displayed in black and white on the screen.
7. The client is instructed in how to find a seat in the theater, remain dissociated from the content, and alter their perception of a black and white movie of the index event.
8. A black and white movie of the event is played and may be repeated with structural alterations as needed.
9. When the client is comfortable with the black and white representation, they are invited to step into a two-second, fully-associated, reversed movie of the episode beginning with the post-trauma resource and ending with the pre-trauma resource.

10. When the client signals that the rewind was comfortable, they are probed for responses to stimuli which had previously elicited the autonomic response.
11. SUDs ratings are elicited.
12. When the client is free from emotions in retelling, or sufficiently comfortable (SUDs ≤ 3), they are invited to walk through several alternate, non-traumatizing versions of the previously traumatizing event of their own design.
13. After the new scenarios have been practiced, the client is again asked to relate the trauma narrative and his previous triggers are probed.
14. SUDs ratings are elicited.
15. When the trauma cannot be evoked and the narrative can be told without significant autonomic arousal, the procedure is over.

Table note. Other versions of the outline can be found in:

Gray, R., & Liotta, R. (2012). PTSD: Extinction, Reconsolidation and the Visual-Kinesthetic Dissociation Protocol. *Traumatology*, 18(2), 3-16. DOI 10.1177/1534765611431835.

Tylee, D., Gray, R., Glatt, S., & Bourke, F. (2016). Evaluation of the reconsolidation of traumatic memories protocol for the treatment of PTSD: A randomized, wait list controlled trial. Submitted Manuscript.

Gray, R., & Bourke, F. (2015). Remediation of intrusive symptoms of PTSD in fewer than five sessions: A 30- person pre-pilot study of the RTM Protocol. *Journal of Military, Veteran and Family Health*, 1(2), 85-92. doi:10.3138/jmvfh.3119

Full details of the intervention are available from the corresponding author.

Inclusion and Exclusion Criteria

The following inclusion and exclusion criteria closely follow Gray and Bourke (2015) and Tylee, Gray, et al. (2016).

Inclusion criteria: Participants were only included if symptom assessments for PTSD were above commonly used diagnostic thresholds (PCL-M $\geq$ 50, PSS-I $\geq$ 23; VA, 2016) at intake. Reported PTSD symptoms must have included intrusive, instantaneous, phobic-type responses to triggering stimuli; and observable autonomic arousal either while recounting the index trauma or triggering of flashback-related stimuli. They must have reported at least one flashback or nightmare during the preceding month. Participants meeting intake criteria were reimbursed for travel expenses in the amount of $200. Reimbursements were disbursed on a per visit basis.

Exclusion criteria: possession of a comorbid DSM-IV Axis I or II disorder sufficiently severe as to intrude upon the participant's ability to cooperate with treatment; PTSD symptoms perceived as part of participant's identity structure. Prospects who were adjudged by the interviewer or clinician as being incapable of sustained attention were also excluded.

Insofar as the RTM protocol requires a significant capacity to focus upon imagined restructurings of the trauma memory, the inability to focus on the treatment tasks is a major disqualifying element. Excluded participants were referred to their ongoing treatment provider.

Client Flow

Of 60 original referrals, 10 were determined to be ineligible, based upon the inclusion/exclusion criteria, during telephone interviews. 14 others were excluded at intake.

Among the 36 remaining, 6 failed to report for intake (two had moved away, one decided to continue with her current therapist, another was hospitalized for a drug overdose). Four other persons originally assigned to the control condition, met inclusion criteria, completed the initial intake procedure, but never returned for the post-wait re-test at week 5. They were replaced. The thirty remaining volunteers were randomized to treatment and control conditions. All fifteen individuals in the RTM group completed treatment and follow-up. When waitlist control participants were later offered the RTM intervention, all opted to participate. Of the control subjects, 14 were retained for the follow-up assessments scheduled 2 and 6 weeks after they completed treatment. Post wait control treatments began on study week 6—after the end of the waitlist interval. One of the control subjects dropped out of treatment citing family problems. Participant flow, in compliance with CONSORT Guidelines, is illustrated in Figure 1.

Participants

Female US veterans were recruited from Veterans' groups and Mental Health Service providers in San Diego County, CA. The study employed a non-random convenience sample making use of referrals, fliers, and word-of-mouth recruitment. Recruiting began during December 2015 and was completed by mid- May 2016. All treatments were completed by June 27, 2016. Sample demographics are presented in Table 2.

Table 2. Demographic Data

Category		n (%)
Mean Age = 33.7 ± 14		
Ages	≤ 30	19 (63%)
	31-40	4 (13%)
	41-50	3 (10%)
	> 50	4 (13%)
Trauma type	MST only	7 (23 %)
	MST and other sexual trauma	2 (6.6 %)
	MST and other non-sexual trauma	7 (23 %)
	Non-MST only	1 (3 %)
	Non-MST and other sexual trauma	4 (13.3 %)
	Combat only	3 (10 %)
	Other military and non-military related	3 (10 %)
	Other non-military related	3 (10 %)
Service Type	USMC	17 (56.6%)
	USN	6 (20%)
	USAF	4 (13%)

	USA	2 (6.6%)
	Military spouses	1 (3.3%)
Ethnicity	Caucasian	23 (76%)
	African American	1 (3.3%)
	Native American	2 (6.6%)
	Hispanic non-white	1 (3.3%)
	Hispanic-white	2 (6.6%)
	Asian	1 (3.3%)
Location of trauma	Stateside	21 (73.6%)
	Iraq	1 (3.3%)
	Afghanistan	2 (6.6%)
	Stateside and any combat country	2 (6.6%)
	Stateside and any non-combat country	2 (6.6%)
	One or more non-combat country	2 (10%)

Note: MST = Military Sexual Trauma; Non-MST= Non-Military Sexual Trauma.

Percentages may not add to 100% due to rounding errors.

Twenty-three participants self-identified as Caucasian, two as Native American and two others as White Hispanics. One each identified as African American, Non-white Hispanic, and one as Asian. The treatment group had a mean age of 31 (±11.9) and controls, 36.4 (± 16.4) years. Seventeen participants served in the Marine Corps, six in the Navy, four in the Air Force and two in the Army. One other was a military spouse. Most traumas occurred stateside (22/30). Four participants were serving in Iraq or Afghanistan when traumatized, 2 were serving in non-combat foreign countries; 2 were traumatized both in the US and in some other non-combat location; two were traumatized in both combat and non-combat locations.

Specific traumas:14 participants reported multiple sexual assaults. Six were treated for a single sexual assault event. Five of those 6 persons were treated for rape traumas and 1 for a molestation. One volunteer was treated for events that included combat trauma, sexual harassment, and physical assault. Three participants were treated exclusively for combat trauma. Six others reported non-sexual traumas including physical assault (3 persons) and accidents (3 persons). Eight victims of sexual assault were assigned to the experimental group and 12 to the waiting list control.

Ethical Approval and Safety Measures

The study protocol and informed consent were approved by the New England Independent Review Board (NEIRB). All personal identifying and Health Insurance Portability and Accountability Act (HIPAA)–sensitive information was held in strict confidence. Following NEIRB guidelines, the protocol and all aspects of participation were reviewed with participants and signed informed consents were obtained from each. If any participant had significant emotional difficulties during the study, an immediate intervention was administered by the

licensed clinician on staff. If necessary, the participant was referred to his psychiatrist or primary care physician or for emergency treatment. No need for such emergency treatment arose.

Definitions

Flashbacks and nightmares. For all clients, we required a minimum of one flashback or nightmare per month. These are defined as follows:

Flashbacks. involuntary re-association into the traumatic memory that: 1. involves a loss of orientation to the present time or context either in full or in part; 2. the traumatic event is experienced as a fully associated event: the client is 'in' the recalled event; 3. it is not only involuntary but it tends to persist as the client's current reality; 4. whether the dissociative event persists for a long period--many minutes--or doesn't persist for long, its emotional tone carries through past the end of the dissociative event (the re-association into the traumatic memory) so that it continues to color much of the following hours, the remainder of the day, or several days, afterwards.

Brief associations of current events with past traumas (the more common and cinematic use of the word *flashback*) that do not last long, that do not include a dissociation from the current context, and that do not have a continuing effect on the client are usually not, for our purposes, flashbacks. They are most often just normal memories.

Where there is difficulty in differentiating between a flashback and a brief memory of the trauma, the client must be questioned (as needed): How long did it last? Were you in the memory or watching from outside? How long did it take you to refocus on the present moment? How did the memory affect the rest of the day? If there was a bad effect, was it from the memory of the trauma or from the event itself? Etc.

Nightmares. Any dream or, more-especially, a night terror that whether consciously recalled or not: 1. Projects the client into the context of one or more index traumas and/or 2. results in hypnagogic imagery related to the index trauma sufficiently vivid as to result in confusion between waking and dream contexts; and/or 3. results in unconscious acting out as sleep walking, speaking, or violence that can be related by emotional tone or content to the index trauma or its context, that; 4. produces lingering emotional effects that may color the following hours or days, and that often makes it difficult or impossible to immediately return to sleep.

If a nightmare cannot be related by content, context or emotional tone to one or more of the index traumas, it is regarded as a simple nightmare and is not relevant to this context. It is reasonable for the client who has successfully overcome his or her PTSD to still have periodic nightmares about the index trauma, but the nature and the quality of the dreams will have changed: they will lack the intrusive and perseverative qualities of the definition above.

Psychometric Scales

The PTSD Checklist Military version (PCL-M) and PTSD Symptom Scale Interview (PSS-I) were used as primary measures of symptoms at various study time points (Figure 1). Both scales are regularly used by the military and the VA to assess PTSD symptoms. Both tests were administered at intake for both groups, the week five retest for controls, and the 2-week, six-week and six-month post-test for all participants. These were intended to document pre/post PTSD treatment changes as well as the consistency of change across time. In order to infer whether PTSD symptoms remitted below levels that might warrant a clinical diagnosis, commonly used thresholds were applied to these clinical scales (VA, 2016; PCL-M threshold $\geq$ 50; PSS-I threshold $\geq$ 20).

The PSS-I is highly regarded and second only to the CAPS in its accuracy (Foa, Riggs, Dancu, & Rothbaum, 1993; Foa & Tolin, 2000). The PSS-I has high concurrent validity and is regularly used by the military and the VA (Foa, Riggs, Dancu, & Rothbaum, 1993; VA, 2014; Weathers & Ford, 1996).

The PCL-M (Weathers, Litz et al. 1993) is a 17-item, self-report scale based upon DSM diagnostic criteria for PTSD (APA, 1994). The scale can be scored dichotomously based upon total score >50 or continuously following the DSM-IV symptom criteria. In the continuous model, participants must score three or higher on at least 1 item from the re-experiencing cluster, 3 items from the avoidance/numbing cluster, and 2 items from the hyperarousal symptom cluster. PCL-M evaluations are highly correlated to the CAPS (r = 0.93; Blanchard, E.B., Jones-Alexander, J., Buckley, T.C., Forneris, C.A, 1996; Castillo, Lacefield, C'De Baca, Blankenship, & Qualls, 2014).

Three types of loss of diagnosis are recognized in the study: 1, Complete remission. The client scores below 30 on PCL-M and does not meet DSM continuous diagnostic criteria; 2. DSM loss of diagnosis (Criterion A) by continuous scoring; 3 DSM loss of diagnosis (criterion B) by dichotomous scoring--score is below 50.

Treatment Fidelity

All screening and treatment sessions were video recorded on digital media for assessment of treatment fidelity. At the end of each day, video recordings were uploaded to a secure HIPAA-compliant server and archived for review. Three well-practiced experts, familiar with the RTM protocol (two Ph.D.-level psychologists and one licensed, masters-level social worker), reviewed the videos of treatment sessions. Evaluations were made based upon the following elements: (a) adherence to the RTM procedure (available from the corresponding author); (b) adherence to the

syntax of reconsolidation (as reflected in Gray & Bourke, 2015; Gray & Liotta, 2012; Schiller & Phelps; 2011); and (c) the calibration skills used by the clinician.

Data Analysis

All analyses were performed using Microsoft Excel 2016. To test for responses to treatment within groups, we performed six, individual, paired, one tailed Student's T-tests comparing baseline symptom scores at study week one to symptom score changes at two and six weeks post treatment. Separate analyses were performed for treatment and post-treatment control groups, and for the group of all protocol completers. To examine whether waitlisted controls changed either spontaneously or due to other treatments during the wait period, we compared waitlist control baselines at week one to their own post-wait baselines at study week five. Similarly, two-week follow-up results were compared against six-week follow-ups for all treatment completers to test for decay of results over time. A final one tailed T-test for groups of different variances was performed to test for expected differences between experimental and control groups at study week five, when the first post-treatment results from the experimental group could be compared to control subjects at their post wait re-evaluation. All data are reported as mean ± standard deviation.

RESULTS

We have already briefly discussed the positive results from previous studies of the RTM protocol (Gray & Bourke, 2015; Tylee, Gray, Glatt, & Bourke, 2016). Nevertheless, both of the previous studies were limited to male veterans. Following from these results, we wanted to see if the treatment was equally effective with female volunteers. This led to the prediction that RTM should reduce PCL-M scores as effectively in women as in men. Students T-tests (paired, 1 tailed) found that symptom scores for experimental subjects were significantly reduced ($p. <$

0.001) from Baseline (Mean = 73.47±5.83) to two-weeks post (Mean = 28.27±13.46) and six-weeks post (Mean =25.33±13.97; Table 3, comparison 1-2). Similarly, when we tested the previously waitlisted controls, who also received treatment, we found significant reductions in two-week (Mean = 22.21±4.53) and six-week (Mean =22.85±6.17) post treatment scores as compared to baseline (Mean = 68.67±7.31; p. < 0.001; Table 3, comparisons 3-4). Unsurprisingly, when we pooled results for all treatment completers and compared baseline PCL-M (Mean = 71.06 ± 6.82) against two-week (Mean = 25.33 ± 10.82) and six-week (Mean = 24 ± 10.63) post-treatment follow-ups, those differences were also significant in the expected direction ($p < 0.001$; Table 3, comparisons 5-6). The intervention appears to work across time points.

The heart of a waitlist design is the comparison of control condition scores at the end of the wait period with time-matched experimental results. Thus, in order to test the RTM against a valid control condition, we compared the treatment group at week 4 (their two-week post-treatment follow-up) to the untreated wait listed control group at week 5, their re-evaluation at the end of the wait period. As expected, the untreated waitlist participants at the end of the wait period (Mean = 67.13 ±8.46) and treatment subjects at two-weeks post (Mean = 25.43 ± 8.06), were significantly different in the expected direction ($p < 0.001$). The intervention appears to work as compared to a control group (Table 3, comparison 7).

This between group comparison (Week 4 treatment vs week 5 control) raised the question as to whether the supposedly untreated waitlist control group had made significant improvements or declines during the waiting period. Had they declined significantly, our treatment results would have been artificially inflated. Had they improved, our results would have lessened in significance. We therefore compared the waitlist PCL-M results from baseline at study week 1;

(Mean = 68.67 ± 7.31) to the retest at study week five (Mean = 67.13 ±8.46), and found the differences to be non-significant (P = 0.22; Table 3., comparison 8). There were few changes in the PTSD scores of the waitlisted control group from baseline one to baseline two and those changes were non-significant.

As other PTSD treatments have been shown to be unstable over time, independent of the number of treatments (Steenkamp & Litz, 2013; Steenkamp, Litz, Hoge, & Marmar, 2016,), we wanted to know whether our treatment results were stable. We therefore compared the two-week post-treatment scores for all subjects (Mean= 25.33 ± 10.82) with their six-week post-treatment scores (mean= 24 ± 10.63). The differences were non-significant (p = .47; Table T3., comparison 9). It would appear that the effects of the RTM protocol are stable over time.). All results are reported in Table 3.

	Table 3. PCL-M T-test Comparisons at All Time Points					
	Comparison	Type	Tails	*df*	T-statistic	p
1	Treatment group Baseline x 2-weeks Post	Paired	1 tail	13	16.08188	< 0.001
2	Treatment Group Baseline x 6-weeks post	Paired	1 tail	13	15.94214	< 0.001
3	Post waitlist controls week 1 Baseline x 2-weeks post (study week 1 x study week 9)	Paired	1 tail	13	10.29424	< 0.001
4	Post waitlist controls week 1 Baseline x 6-weeks post (study week 1 x study week 13)	Paired	1 tail	13	1.795108	< 0.001
5	All treated subjects baseline x all treated subjects 2 weeks-post	Paired	1 tail	27	28.1706	< 0.001
6	All treated subjects baseline x all treated subjects 6 weeks-post	Paired	1 tail	27	28.1706	< 0.001
7	Treatment group at study week-4 x wait-listed controls) at study week 5 (	Unequal variance	1 tail	13	3.604012	< 0.001
8	Waitlist baseline 1 (week 1) X week 5 waitlist retest	Paired	1 tail	13	0.7924607	NS
9	2-Week post treatment follow-up for	Paired	1 tail	27	1.461916	NS

	all completers x 6-Week post treatment follow-up for all completers					
	Note: One subject was moved from the treatment group as receiving no benefit. A second subject was removed from the control group having provided no data after baseline.					

Beyond statistical validation of the studies themselves, we also sought to assess the efficacy of the intervention across time points. We used Hedges' g as the more conservative instrument among effect sizes and the one most appropriate for small-group studies. Here we found that in all comparisons, the RTM performed the equivalent of 6 standard cores or more above the no treatment condition (See Table 4.). These results far exceed Cohen's relatively arbitrary definitions of significance levels (low, med, high; Sun, Pan, & Wang, 2010; Devilly & McFarlane (2010).

Table 4. PCL-M Effect sizes for RTM treatment completers

	Baseline	**RTM 2 weeks post and untreated controls study week 5**	2 weeks post treatment	6 weeks (post treatment)	95% CI	ES
	Mean (SD) n	**Mean (SD) n**	Mean (SD) n	Mean (SD) n		
RTM group	73.47 (5.83) 15	**25.43 (8.06) 15**	25.43 (8.06) 15	22 (5.53) 15	7.736 (14.26-29.7)	8.79
Control group	68.67 (7.31) 15	**67.13 (8.46)15[a]**	22.21 (4.53) 14	22.85 (6.17) 14	3.56 (19.29-26.41)	6.83
All Treated	71.06 (6.82) 28		25.33 (10.82) 29	24 (10.63) 29	4.046 (19.95-8.046)	7.05

Note: CI = Confidence Interval.

ES=effect size: Hedges' g

[a] After completion of the waiting period, control subjects began treatment on study week 7. They were tested at two weeks post treatment on study week 9 and at six-weeks post on study week 13.

A separate effect size (Hedges' g) was computed for the comparison between untreated, wait-listed controls and the RTM treatment group (at their first two-week follow-up). The effect was equivalent to a nearly 5 standard score difference (g= 4.91; 95% CI [21.03-29.89].

DISCUSSION

The current results indicate that the RTM protocol is an effective treatment for PTSD. As noted, based simply on the mean PCL-M scores, the resultant effect sizes indicate that, as compared to no treatment, these results surpass other treatments (as reviewed by Steenkamp and Litz (2013) and Steen Kamp, Litz, Hoge, and colleagues (2016). Here we review the results in more depth with an examination of the loss of diagnosis via treatment inventories, the severity of traumas suffered by our volunteer population, and the consistency of RTM results over three separate studies.

Symptom Inventories

PSS-I was used as the primary diagnostic at intake and two weeks post treatment. The PSS-I, although designed to be scored dichotomously (Score below diagnostic criterion, in this case 30), may be scored in two ways, dichotomously, and continuously. Continuous scoring (criterion a) defines clearance of the diagnosis by a symptom score ≤ 13 and non-endorsement of the three symptom clusters at the following levels—one intrusive symptom, at least three avoidant questions, and at least two hypervigilant questions--with a response of at least 1 (Once per week or less/little) or higher (VA, 2016). Dichotomous scoring (criterion b) defines a symptom score of 30 as the diagnostic threshold for Military PTSD. We have defined a class of total remission as a total symptom score of 13 or below.

29 persons completed PTSD treatment, and one dropped out 1/30 or 3%). Among those 29 completing the treatment protocol 28 (28/29 or 96.5%) lost the PTSD diagnosis. Of those 28 participants, 23 were in total remission (23/28 or 82 %), with scores ≤ 13; 4 were cleared of diagnosis by criterion a (4/28 or 14 %); 1 by criterion b (2/28 or 7%), while one retained the diagnosis by all criteria (PSS-I = 45 at six weeks).

Among the 23 participants who were determined to be in complete remission by PSS-I, only one participant endorsed any of the three diagnostic criteria (hypervigilance). Among the four criterion a participants, one endorsed hypervigilance alone, while one other endorsed both Intrusive and hypervigilant symptoms. The lone criterion b participant endorsed all three symptom clusters but lost 23 score points and ended with a final PSS-I symptom score of 23. She also reported a complete absence of nightmares and flashbacks.

The PCL-M may be scored in two ways, dichotomously, and continuously. Continuous scoring (criterion a) defines clearance of the diagnosis by a symptom score below fifty and non-endorsement of the three symptom clusters at the following levels-- one intrusive symptom, at least three avoidant questions, and at least two hypervigilant questions--with a response of at least 3 (Moderately) or higher (VA, 2016). Dichotomous scoring (criterion b) defines a symptom score of 50 as the diagnostic threshold for Military PTSD. Following Castillo et al. (2016), we have defined total remission as a total symptom score of 30 or below.

29 persons completed PTSD treatment, and one dropped out 1/30 or 3%). Among those 29 completing the treatment protocol 28 (28/29 or 96.5%) lost the PTSD diagnosis. Of those 28 participants, 25 were in total remission (25/28 or 89 %), with scores below 30; 2 were cleared of diagnosis by criterion a (1/28 or 3.5 %); 1 by criterion b (1/25 or 3.5%), while one retained the diagnosis by all criteria (PCL-M = 72 at six weeks; see table CMP).

Among the 25 participants who were determined to be in complete remission (PCL-M), 2 (8%) endorsed hypervigilance, but none of the other diagnostic clusters.

These results, in which the majority of those deemed to be in total remission (PSS-I, 23 of 29; PCL-M, 24 of 28) failed to endorse the presence of any of the three major symptom clusters of PTSD on PSS-I at two weeks and PCL-M at six-weeks post-treatment, supports the hypothesis that the RTM Protocol effectively treats PTSD in all dimensions for more than 80% of those treated. Insofar as RTM targets the intrusive symptoms specifically, it is striking that only one of those losing the diagnosis by any criterion endorsed the Intrusive elements. Among those designated as cleared of the diagnosis by any criterion, none reported flashbacks or nightmares related to the treated traumas.

Effect Sizes

Sun and colleagues (2010) with other researchers, have indicated that effect sizes are only truly useful when they represent direct comparisons with other, similar results. Steenkamp & Litz' 2013 review of treatments for PTSD reports 22 effect sizes for completers of various PTSD treatments (As our study reported only treatment completers, we have left out ITT reports). Among those 22, the lowest effect size was a g of .58 in an 11-person open trial of Behavioral Activation and the largest reported a d of 4.25, in a 47-person open trial of in-person Prolonged Exposure. The median effect size lay between ds of 1.141 and 1.7. We believe that these results will be informative in the interpretation of the effect sizes, presented in Table 4.

The Severity of Trauma in the Female Experience

The female veterans participating in this study, although limited in ethnicity, service affiliation and location of trauma, match the trauma profiles of other female veterans who often report highly diverse types of trauma, with a longer history of traumatizing events than male

patients (Kintzle et al. 2015; Mouliso, Tuerk, Schnurr, & Rauch, 2015; Turchik & Wilson, 2010) including high levels of MST (Holliday, Williams, Bird, Mullen, & Suris, 2015; Kintzle et al. 2015; Turchick & Wilson, 2010). Kintzle and colleagues (2015) have reported the incidence of MST as attempted or completed rape ranging from 9.5 to 33%. among women in the military.

This third examination of the RTM protocol treated a population of severely traumatized female veterans, a majority of whom (21 or 70%) had suffered sexual traumas. Some of these events occurred while they were in the service (16) and others outside of a military context (5). Among those treated, 7 were treated for multiple (2) rapes, 14 others were treated for at least one rape or unwanted sexual contact along with other non-sexual traumas. Seven participants were treated for multiple non sexual traumatic events and 2 were treated for single, non sexual traumas. In all cases, save one, treatment completers reported loss of nightmares and flashbacks with 96% having lost the diagnosis.

Consistency of RTM Over Time

The RTM protocol has been subjected to one pilot with minimal controls and two waitlist controlled studies. Each of the investigations has sought out clients with high levels of symptomatology and current month reports of flashbacks and nightmares. In the last two studies, (Gray & Bourke, 2015; Tylee, Gray, et al., 2016) diagnoses and remissions have been confirmed using PSS-I and PCL-M. In Table 5, we present those results as percentages of cases who responded or failed to respond in terms of the three positive criteria for the interpretation of PCL-M described above.

Table 5. Percentage loss of diagnosis by PCL-M from all RTM studies

	NY 2014 [a]	SD 2015[b]	SD 2016[c]
n	26	27	30
Last measure	6 weeks†	6 months††	6 weeks
Non-response n (%)	1 (4%)	1 (4%)	1 (3.4 %)
Reduction >10 points only n (%)	0	1 (4%)	0
Loss of Dx Criterion A n (%)	4 (15.3%)	1 (4%)	2 (6.8 %)
Loss of Dx Criterion B n (%)	4 (15.3 %)	1 (4%)	1 (3.5 %)
Full remission n (%)	20 (77%)	23 (85%)	25 (89%)
Total loss of Dx (all Criteria) n (%)	25/26 (96%)	25/27 (93%)	28/29 (96.5%)

Note: Data from the below cited studies was provided to the authors by Richard Gray in a personal communication and is used with his permission. Percent estimates may not sum to 100% due to rounding errors.

Dx=Diagnosis;

Non response = PCL-M ≥ 50 and all DSM criteria still met;

Reduction >10 points only = all Dx criteria still met but there is a clinically significant reduction in

score;

Loss of Dx (criterion A) = score < 50 and failure to endorse DSM Dx criteria;

Loss of Dx (criterion B) = total score < 50 but DSM criterion A still may be met;

Full remission = Total PCL-M score < 30 and DSM criteria no longer met.

† Six-week data was not available for 12 subjects; their two-week results are reported.

†† Six-month data was not available for 4 subjects; their six-week results are reported.

[a] Gray, R., & Bourke, F. (2015). Remediation of intrusive symptoms of PTSD in fewer than five sessions: A 30- person pre-pilot study of the RTM Protocol. Journal of Military, Veteran and Family Health, 1(2), 85-92. doi:10.3138/jmvfh.3119

[b] Tylee, D., Gray, R., Glatt, S. & Bourke, F. (2016). Evaluation of the reconsolidation of traumatic memories protocol for the treatment of PTSD: A randomized, waitlist controlled trial. Submitted manuscript.

[C] Current results.

The Proposed Mechanism of Change and Two Targets for Further Research

RTM takes advantage of two significant processes. The first is a cognitive intervention that transforms the perceptual structure of remembered event in such a way as to allow the client to dissociate from the traumatic memory. The second is the use of the reconsolidation mechanism, as mentioned above to make those perceptual changes an integral part of the memory.

The cognitive elements of the intervention have been known for some time. Although here derived from the discipline of Neuro-Linguistic Programming (Andreas, & Andreas, 1987; Bandler, 1985), the removal of color, the distancing, dissociation from the memory, as well as the cognitive restructuring of the memory, are all standard elements of cognitive/perceptual psychology. Flattening the picture, removing the color and dissociation were observed by Moore, Mischel, and Zeiss (1976) in their famous marshmallow experiment. Dissociation and the addition of distancing was reported by Adyuk & Kross (2010; see also Kross & Adyuk, 2011). Codispoti and De Caesari (2007; De Caesari & Codispoti, 2006, 2008, 2010) reported on the subjective modification of the size and perceived distance of remembered images. Restructuring the trauma-related imagery is a fairly common cognitive intervention (Arntz & Weertman, 1999, Germain, Shear, Hall, & Buysse,2007; Lu, Wagner, Van Male, Whitehead, & Boehnlein, 2009), first designed for the treatment of PTSD but more recently used to treat PTSD related nightmares.

The crucial element here, is the use of the cognitive elements of the intervention during the labilization window, which is for our purposes, the core of the reconsolidation phenomenon.

During this period, thought to last approximately 6 hours (Nader, 2003; Nader et al, 2000; Schiller, Monfils, et al., 2010), information about the target memory that is new, or novel, that provides safety information, or information that changes the status of the threat, may be introduced into the structure of the memory (Agren, 2014; Fernández, Bavassi, Forcato, & Pedreira, 2016; Forcato, Bourgos, et al., 2007; Kindt, Soeter, & Vervliet, 2009; Lee, 2009; Schiller, & Phelps, 2011; Schiller et al., 2013). It can then be quickly integrated into the structure of the original memory in short order. This leads to a fast, largely permanent change in the index memory.

Further research must explore the empirical relationship between RTM and the reconsolidation phenomenon. This might be done by comparing the full RTM protocol to a set of its cognitive elements (the black and white movie, the rewind, and the memory restructuring) outside of the reconsolidation environment as suggested by Tylee, Gray and Bourke (2016). While these elements are expected to have some impact in three sessions, we would predict that outside of the labilization window, their observed speed and efficacy would be significantly lessened.

Limitations of the study

As noted previously (Tylee, Gray, et al., 2016) this study, as were those before it, is limited by the nature of the sample in all aspects including, sampling method, sample size, and sample diversity. It is also limited by its focus on a specific subpopulation of PTSD afflicted veterans and its design as a waitlist controlled study without an active comparison treatment.

The study used a convenience sample comprising a combination of referrals and word-of-mouth recruitment. The resulting non-random distribution of veterans and active duty service members, and their relatively high expectations, may limit the external validity of the results.

The sample is plainly biased in that all of those treated were female, the majority were white, and slightly more than half had served or were serving in the USMC. Despite the larger problems with generalizability, these demographics do focus the study on the severity of PTSD in the female population targeted by the study,

The size of the sample is problematic. Were it not for the size of the effects measured, their stability over time, and the consistency of RTM results between experiments, the small sample sizes would make further generalization difficult. This is, nonetheless, the third experimental test of the protocol, and the measured effect sizes compare well against the results of other treatments (Steenkamp & Litz, 2013; Steenkamp, Litz et al. ,2015; Bisson, Roberts et al., 2013).

The limitations on generalizability imposed by our focus on a specific type of PTSD, the lack of a comparison treatment, the problematic nature of waitlist controls and the, as yet unconfirmed nature of the association with reconsolidation blockade, have all been addressed in detail by Tylee, Gray et al. (2016).

Conclusion

These results and those of two previous evaluations (Gray & Bourke, 2015; Tylee, Gray et al., 2016) suggest that the RTM protocol is viable treatment modality for PTSD-related symptoms in a military population challenged by high levels of intrusive symptoms. Here, its application to a population of female subjects, the majority of whom have suffered sexual traumas in civilian and military circumstances, suggest that the intervention is effective for the most severe PTSD cases.

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