

Reconsolidation of Traumatic Memories for PTSD: A randomized controlled trial of 74 male veterans

Abstract

Design: A randomized waitlist-controlled design ($n = 74$) examined the efficacy of Reconsolidation of Traumatic Memories (RTM) among male veterans with current-month flashbacks and nightmares. Volunteers were randomly assigned to immediate treatment (three 120 minute sessions of RTM), or to a three-week waiting condition before receiving the same treatment. Blinded psychometricians evaluated symptoms at intake, two weeks, and six-weeks post. Wait-listed participants were re-evaluated then treated. 65 volunteers completed treatment. **Results:** Of those treated, 46 (71 %) lost DSM diagnosis for PTSD by one of the following definitions: 42 persons (65%) were in complete remission ($PSSI \leq 20$ and DSM criteria not met). Four others (6 %) lost DSM diagnosis or were otherwise subclinical by dichotomous criteria ($PSSI < 21$, and absence of flashbacks and nightmares) but non-ambiguous on PCL-M measures. Within-group RTM effect sizes (Hedges' g) for PSS-I score changes ranged from 1.5 to 2.2. The between group comparison between the treatment group and untreated controls was significant ($p < 0.001$) with an effect size equivalent to two standard deviations ($g = -2.121$; 95% CI [-4.693 - 0.453]). Patient satisfaction with the intervention was high. **Conclusions:** RTM shows promise as a brief, cost-effective intervention for PTSD characterized primarily by intrusive symptoms.

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

Current Interventions for PTSD

The United States Veterans Health Administration (VA) currently supports several psychotherapy interventions for PTSD at its medical centers. These include: Prolonged Exposure (PE) and Cognitive Processing Therapy (CPT (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; Steenkamp, Litz, Hoge, & Marmar, 2015). These treatments have well documented efficacy for both male and female veterans including combat, sexual and other traumas. Several other less well supported treatments are also provided in VA facilities (Eftekhari et al., 2013; Monson et al., 2006; Schnurr et al., 2007; Tuerk et al., 2011). Finlay, Garcia, et al. (2015) found that PE and CPT account for up to 50% of treatment hours for VA outpatient treatment providers in Veterans Affairs outpatient clinics. Nevertheless, lengthy treatment regimens and other difficulties, including negative expectations and perceptions of trauma focused cognitive behavioral treatments (TFCBTs) make completion difficult, resulting in high drop-out rates (Kim, Britt, Klocko, Riviere, & Adler, 2011; Najavits, 2015; Pietrzak et al., 2009; Steenkamp, Litz, Hoge & Marmar, 2015). Treatment efficacy in most studies is measured in modest reductions in symptoms scores and these treatments produce low rates of recovery from the PTSD diagnosis. In many studies, the number of persons who have lost or retained the diagnosis is not reported (Bisson, Roberts, Andrew, Cooper, & Lewis, 2013; Steenkamp & Litz, 2012; Steenkamp, Litz, Hoge, & Marmar, 2015). There is a continuing call for 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; Steenkamp, Litz, Hoge, & Marmar, 2015). Here, we report an RCT of 74 male veterans employing the Reconsolidation of Traumatic Memories protocol, a new treatment for PTSD.

The Reconsolidation of Traumatic Memories (RTM) intervention

RTM is a brief, systematic, non-traumatizing, trauma focused behavioral therapy (TFCBT) derived from Neuro-Linguistic Programming (NLP) techniques and is closely related to the Visual Kinetic Dissociation protocol (Gray & Liotta, 2012) and the Rewind Technique (Muss, 1991, 2002). It is distinct from them in its intentional reliance upon the syntax of reconsolidation to enhance outcomes (Gray & Bourke, 2015; Gray & Liotta, 2012; Tylee, Gray, Bourke and Glatt, 2017). RTM may represent an alternative to current cognitive and extinction-based interventions (Gray & Bourke, 2015; Gray & Liotta, 2012). RTM focuses upon PTSD symptoms that are expressed as immediate, phobic-like responses to triggering stimuli (flashbacks) and repeated nightmares or night terrors that repeatedly disrupt sleep and often make it impossible to return to sleep in a normal manner. Nightmares and flashbacks must be related to one or a few identifiable traumatic incidents. Patients without significant intrusive symptoms related to identifiable traumatic exposure are inappropriate to the intervention (see Methods for further explanation).

The RTM protocol initiates each treatment session with a brief, controlled retelling of the target trauma. That narrative is stopped as soon as signs of sympathetic arousal are observed (e.g.: changes in breathing position, muscular tone, lacrimation, flushing, voice tone, etc.). Besides ensuring that the patient is not re-traumatized by the exposure, this interrupted evocation is expected to initiate the reconsolidation mechanism (Agren, 2014; Gray & Liotta, 2012; Forcato, Bourgos, et al., 2007; Kindt, Soeter & Vervliet, 2009; Lee, 2009; Schiller and Phelps,

2011; Schiller et al., 2011; Schiller et al., 2013). In accordance with experimental frames developed in preclinical literature, this brief, incomplete, or unreinforced reminder is believed to render the traumatic memory subject to change for a period of from one to six-hours (Nader et al., 2000; Schiller, Monfils, et al., 2010). After termination of the narrative, and calming or reorienting the patient to present circumstances, those patients are then presented with healthy dissociative distancing experiences and exercises that de-reify the present experience of the target event. These exercises are hypothesized to modify the perceptual structure of the remembered traumatic event. 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. Partial memories are often restored to more complete narratives and the perspective within the memory typically shifts to a more-distant, third-person status. Except for the widening of scope, a change in perspective, and the addition of forgotten details, memory content remains unchanged (Gray & Bourke, 2015; Gray, Budden-Potts, & Bourke, 2016; Gray & Liotta, 2012; Kindt, Soeter, & Vervliet, 2009; Schiller & Phelps, 2011; Tylee, Gray, Glatt, & Bourke, 2017).

The RTM protocol is distinct from other TFEBTs in that exposure to the trauma memory is not the central effector of treatment change. Here, the brief exposure narrative serves to initiate a period during which the structure of the trauma memory is destabilized and during which information can be incorporated into 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). RTM is not an exposure or extinction-based intervention.

RTM is targeted specifically at the intrusive symptoms of PTSD, especially when they are experienced as sudden, uncontrollable, sympathetic responses either to the trauma narrative, elements of the narrative, or stimuli known to elicit flashbacks and nightmares. This represents an 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, 2017).

Studies of RTM efficacy.

There have been two previous waitlist controlled studies of RTM and one pre-post pilot. Both RCTs evaluated the protocol using the PSS-I and PCL-M at intake and two-week follow-ups and the PCL-M either alone or with the PSS-I at six-weeks post and later follow-ups. The pilot study used PCL-M alone (Gray & Bourke, 2015; Tylee Gray & Bourke 2017; Gray, Budden-Potts, & Bourke, 2016). Two of the studies applied RTM to male veterans. The third study (Gray, Budden-Potts, & Bourke, 2016) examined thirty female veterans, 21 of whom suffered from some degree of Military Sexual Trauma (MST). All studies obtained high effect sizes and significant loss of diagnosis. Those who no longer met diagnostic criteria reported a complete absence of flashbacks and nightmares after the last treatment.

Gray and Bourke (2015), using a 50-point admission baseline score (PCL-M) for participation, reported a mean reduction of 44.7 ± 15.8 points in trauma severity, 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. (2017) 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 in effect from intake to follow-up (CI 99% [22.06, 33.54]). Further data from a one-year follow-up indicates that these improvements were maintained for a full year after treatment. Twelve-month mean PCL-M scores for treatment completers, with 81.5% reporting, were 20.9 (± 4.2).

In their study of thirty female subjects, Gray, Budden-Potts, & Bourke (2016) reported a mean reduction of 48.21 points (cumulative intake Mean = 71.06 ± 6.82) for all treatment completers, with a final mean PCL-M score of 22.85 (± 6.17) at 6 weeks. Hedges' g for all treatment completers at 6-weeks post indicated a 7.05 SD difference from intake to follow-up (CI 95% [19.95-8.046]).

Clinical improvement in PTSD symptoms was determined using standard levels of change in PCL-M scores (Schnurr, et al., 2007; VA, 2014). Response to treatment was regarded as clinically significant for improvements in PCL-M scores of greater than 20 points (Monson, Gradus et al., 2008). Loss of diagnosis (VA, 2014) was defined as a total PCL-M score of < 45 points. Full remission was defined as a total PCL-M score of less than 30 (Castillo, et al., 2016; VA, 2014)

For both RCT investigations, loss of diagnosis was determined based upon a combination of standard DSM criteria (scoring below threshold on symptom inventories while failing to endorse all three symptom clusters at the required levels). This accounted for 65% or more of the results in all three studies. A second criterion included scoring below the dichotomous clinical threshold for PTSD as defined for the primary measure ($PSS-I \leq 20$, $PCL-M \leq 45$) while showing no autonomic reactivity to relevant stimuli and reporting a total loss of nightmares and flashbacks. Using these combined measures, loss of diagnosis was above 90% for all three studies.

Purpose of the Study

The purpose of this study was to examine the effectiveness of the RTM protocol using PTSD outcome measures in a population of male US veterans. We examined immediate treatment outcomes and sustained treatment effects at 2 weeks and 6 weeks among volunteers in immediate treatment, untreated waitlist, and among patients who were treated after completing a 3-week waiting period. The economy of the intervention and the robust nature of its outcomes is attributed to the intentional evocation of the reconsolidative mechanism. 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 (Forcato, Rodríguez, Pedreira, 2011; Forcato, Rodríguez, Pedreira Maldonado, 2010; Kindt & Emmerik, 2016; Kindt, Soeter, & Vervliet, 2009; Meir Drexler, Merz, Hamacher-Dang, Marquardt, Fritsch, Otto, & Wolf, 2014; Oyarzún et al., 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, Budden-Potts & Bourke, 2016; Gray & Liotta, 2012; Tylee, Gray et al.,

2017). These earlier findings led us to hypothesize that RTM would produce clinically significant symptom reductions using standard measures of PTSD symptoms (PSS-I, PCL-M), and that these symptom reductions would remain stable over time. Participants received 3, 120 minute sessions of RTM.

Methods

The methods and study design here follow the same parameters as those described in Gray & Bourke (2016), Gray and Liotta (2012), Gray, Budden-Potts and Bourke (2016), and Tylee, Gray, et al. (2017). They differ from the methods reported by Gray and Bourke (2016) only in that the number of treatments is reduced from 5 to 3.

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 (5 each) using a list of random numbers generated using Microsoft Excel 2016. Clients were assigned to treatment conditions by site managers according to a randomized list generated by study personnel at another location.

For clarity of reporting, we refer to follow-up time points during which symptoms were evaluated, based on the number of weeks elapsed since the completion of the intake measures and the post-treatment period. Intake evaluations were performed for all participants on study week 1. The treatment 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 post-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 by psychometricians blinded to study condition. Control participants were then offered the same intervention schedule, and their symptom scores measured two and six-weeks 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 private office suites dedicated to the study.

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 shown in Table 1 (Reproduced with permission from Gray, Budden-Potts, and Bourke (2016).

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), Gray, Budden-Potts, and Bourke (2016), and Tylee, Gray et al. (2017).

Inclusion criteria: symptom assessments for PTSD above commonly used diagnostic thresholds (PCL-M \geq 45, PSS-I \geq 21; VA, 2014) at intake. A valid PSS-I-based diagnosis required that prospective participants endorse symptom clusters in accordance with DSM IV criteria (endorsing at least 1 question from the intrusive cluster, 3 from the avoidant cluster, and 2 from the hypervigilant cluster). Two ambiguous readings for scores greater than 20 but not endorsing all three symptom clusters were evaluated based upon concurrent PCL-M scores and

endorsements. Based on those criteria they were accepted. Subjects must have reported PTSD symptoms including intrusive, instantaneous, phobic-type responses to triggering stimuli; and observable sympathetic arousal either while recounting the index trauma or triggering flashback-related stimuli. Volunteers 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 (see definition below). Prospects adjudged by the interviewer or clinician as being incapable of sustained attention were 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.

Definitions

PTSD and identity structure. PTSD is assumed to be part of the client's identity structure when the client's expression of his relation to the diagnosis moves from a thing that he or she possesses, has or is battling, to something that describes their essence: this is part of me, I will never be done with it, it is who I am. It now defines and will always define what I can do and who I can be.

Flashbacks and nightmares. These definitions come into play especially during intake and follow-up. Their application in those circumstances is discussed below. For all clients, we

required a minimum of one flashback or nightmare per month. These are defined (following Gray, Budden-Potts, & Bourke, 2016) as follows:

Flashbacks. involuntary re-association into the traumatic memory that includes all of the following elements: 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 presence or absence of intrusive autonomic responses will normally be determinative.

Nightmares. Any dream or, more-especially, a night terror that, whether consciously recalled or not may be indicated by any of the following: 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.

Client Flow

Clients were referred based upon fliers, personal referrals and recommendations by local clinicians. All referrals and public solicitations included the restriction that prospects have current month flashbacks and nightmares. This had the effect of prescreening many of the referrals. Recommendations by persons having experienced the intervention may have introduced a positive expectation bias.

Of 98 original referrals, 9 were determined to be ineligible, based upon the absence of present month flashbacks and nightmares as reported during telephone interviews. Fifteen others were excluded at intake. Rejections were based upon client failure to meet DSM diagnostic criteria, the lack of observable autonomic reactivity, or the inability to identify one or more discrete traumatic events (DSM IV Criterion A). The 74 remaining volunteers were randomly assigned to treatment and waitlist control conditions: 37 to each condition. Among the 37 control group participants, 4 persons, having met inclusion criteria, and completed the initial intake procedure never returned for the post-wait re-test (Baseline 2) at week 5 leaving 33 control subjects. In order to maintain the statistical validity of the study, results for these four persons, for whom only baseline data was available, we used the baseline observation carried forward (BOCF) method to fill out all subsequent measures. This was justified in light of our expectation that treatment would improve these scores. Thus, this conservative measure had the

effect of including these participants as hypothetical treatment failures (European Medicines Agency, 2010; National Research Council, 2010; White, Carpenter & Horton, 2012).

One treatment group participant dropped out after intake. Like the control drop-outs, his scores were represented by the BOCF method. Thereafter, all 36 of the remaining treatment group members completed treatment and two-week follow-up. When waitlist control participants were offered the RTM intervention, all opted to participate. One of the control subjects dropped out of treatment citing family problems. Of the control subjects, 32 were retained for the follow-up assessments. Post wait control treatments began on study week 6—after the end of the waitlist interval.

When persons from either group, after completing the two-week follow-up testing, failed to report for subsequent observations, the last valid observation was carried forward (LOCF) to represent the missing data. This was justified by our expectation that scores would either remain the same or improve for treatment completers. Insofar as all measures were simple scores or means, and the same kind of allocation was provided for those who had or had not improved, the measure was deemed acceptable (European Medicines Agency, 2010; National Research Council, 2010; White, Carpenter & Horton, 2012). Participant flow, in compliance with CONSORT Guidelines, is illustrated in Figure 1.

Participants

The study employed a non-random convenience sample using referrals, fliers, and word-of-mouth to recruit male US veterans. Recruiting began during December 2015 and was completed by mid-August 2016. All treatments were completed by September, 2016. Sample demographics are presented in Table 2.

Thirty-nine volunteers self-identified as Caucasian, 18 as African American, 3 as Hispanic, and, 1 as Native American. Two others claimed multiple ethnicities. Participants had a mean age of 48.67 (± 13.33) and a median age of 51.5. Thirty-nine participants served in the Army, 24 in the Marine Corps, 12 in the Navy, and 4 in the Air Force. Most traumas occurred in combat situations. Traumas reported included a mix of active duty, pre-enlistment, and post-service events.

Nine participants were treated for 1 trauma, 25 for 2, 21 for 3, and 13 for 4 or more. Specific traumas included 78 combat related incidents, 13 non-combat related deaths, 10 military and non-military sexual traumas, 6 accidents, 9 criminal victimizations, 5 terrorist attacks, 2 legal incidents, 9 incidents of family violence and other domestic issues, and 3 miscellaneous traumas. A more complete enumeration of events treated and trauma contexts is provided in Table 3.

In the past, as reported in other RTM studies (Gray & Bourke, 2012; Gray, Budden-Potts, & Bourke, 2016; Tylee, Gray, Budden Potts, Bourke and Glatt, 2017), volunteer populations recruited from similar communities using similar referral sources have been found unresponsive to pharmacological interventions (beyond their palliative effects) and treatment refractory. Many had tried and failed or tried and had been dissatisfied with other interventions.

Although we did not collect information on comorbid diagnoses, we did collect data on current medication regimens. Among those treated, 36 persons reported the use of antipsychotics, anti-depressants or anxiolytics before and during the study. Thirteen persons reported using prescription sleep aids alone. Two were unable to specify their medications. Ten persons reported using non-psychotropic prescription drugs for the treatment of pain and other conditions, and 12 reported using no prescription medications. One person reported using

medicinal marijuana alone. The use of prescription psychotropics appeared to be evenly distributed between control and treatment conditions.

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.

Psychometric Scales

The PTSD Symptom Scale Interview (PSS-I) and PTSD Checklist Military version (PCL-M) were used as primary measures of symptoms at various study time points. 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 and 6-week, post-tests 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, 2014; PCL-M threshold ≥ 45 ; PSS-I threshold ≥ 20).

The PSS-I is a highly regarded structured clinical interview, on par with other structured interviews such as the CAPS (Foa, Riggs, Dancu, & Rothbaum, 1993; Foa & Tolin, 2000). It is

sufficiently accurate to be used as a primary diagnostic tool in the assessment of PTSD (Foa, Riggs, Dancu, & Rothbaum, 1993; VA, 2014; Weathers & Ford, 1996).

We note that the PSS-I may be analyzed using the presence or absence of specific symptom clusters or as a continuous score. Foa and Tolin (2000) indicate that the PSS-I is highly correlated with other gold standard measures. In both the initial diagnosis and post treatment diagnosis we have used a 20-point cut off for PSS-I scores in combination with the presence or absence of DSM criteria (cluster endorsements). According to this measure any score ≥ 20 indicates the presence of PTSD with an optimal diagnosis for veterans and active military at 45 points. We used a total score of ≤ 20 with concurrent failure to meet DSM IV Criteria (failure to endorse all of the following: 1 item from the intrusive symptoms cluster, 3 items from the avoidant cluster, and 2 from the hypervigilant cluster) as indicating the loss of diagnosis.

The PCL-M (Weathers, Litz et al. 1993) is a 17-item, self-report scale based upon DSM diagnostic criteria for PTSD (APA, 1994; Weathers, Litz et al., 1993). The scale can be scored dichotomously based upon total score >50 or continuously following the DSM-IV symptom criteria. 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). Scores ≤ 30 points on PCL-M which likewise failed to meet DSM criteria were also regarded as being in in full remission.. In cases where PSS-I diagnoses were ambiguous the PSS-I was used to determine the final diagnosis. At intake, a PSS-I score might have more than met threshold requirements but only endorsed two DSM categories (or a similar case) were endorsed for study entry if PCL-M data were unambiguous. Two such cases were described earlier. Likewise, for the determination of loss of diagnosis, ambiguous PSS-I ratings were compared with PCL-M materials for a final decision.

All post-treatment evaluations were completed by independently contracted psychometricians who were not informed of the arm of the study from which the client was referred.

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 arbitrary and targeted 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); (c) the calibration skills used by the clinician; and (d) whether the client had been properly screened.

Data Analysis

Following the method described in Gray, Budden-Potts, and Bourke (2016), all analyses were performed using Microsoft Excel 2016. We performed a one tailed student's t-test for groups of different variances to test for expected differences between experimental and control groups at the point when the first post-treatment results from the experimental group could be compared to control subjects at their post wait re-evaluation. To test for responses to treatment within groups, we performed six 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. Hedge's g was used to assess effect size for all comparisons.

As previously noted, in accordance with intent to treat practice, when persons from either group, after completing the two-week follow-up testing, failed to report for subsequent observations, the last valid observation was carried forward (LOCF) to represent the missing data. This was justified by our expectation that scores would either remain the same or improve for treatment completers. (European Medicines Agency, 2010; National Research Council, 2010; White, Carpenter & Horton, 2012). Similarly, for any person for whom only baseline data was available, their baseline scores were carried forward (BOCF) through all follow-up measures. This was justified in light of our expectation, in light of research reporting a poor prognosis for untreated PTSD (Deville & McFarlane, 2009), that treatment would improve these scores (European Medicines Agency, 2010; National Research Council, 2010; White, Carpenter & Horton, 2012). All data are reported as means \pm standard deviation.

RESULTS

We have already noted the results from previous studies of the RTM protocol (Gray & Bourke, 2015; Gray, Budden-Potts, and Bourke (2016); and Tylee, Gray, Glatt, & Bourke, 2017). Here we predicted that RTM would reduce PSS-I and PCL-M scores as effectively as it had in the previous studies.

Using the PSS-I as the primary diagnostic instrument, we found the following:

Sixty-five persons completed treatment. Of those, 44 were in total remission (44/65 or 67%; PSS-I \leq 20 and DSM criteria not met). Another 4 persons provided ambiguous responses to

the last PSS-I measure. In each of those 4 cases the total score was at or below 20, and each person had lost 23 or more symptom score points at the last follow-up recorded (mean score decrease = 32.75). When the PCL-M responses for each of these cases was examined, it was found that each had scored below 30 on the PCL-M and that they had not met DSM IV diagnostic criteria after treatment. These four were therefore considered to have lost the diagnosis as well. Including these four, the number of successful cases, ending treatment diagnosis-free rises to 48 of 65 cases, or 73%. None of those designated as cleared of the diagnosis reported post-treatment flashbacks or nightmares related to the treated traumas and none showed autonomic reactivity in response to relevant probes or stimuli at follow-up. Inconsistencies between scores on the PSS-I and PCL-M inventories were minor and not unexpected. All scores are reported in Table 4.

Experimental Comparison. We compared PSS-I scores for the treatment group at week 4 (their two-week post-treatment follow-up) to the untreated wait listed control group at week 5 (their untreated re-evaluation at the end of the wait period). As expected, the untreated waitlist participants at the end of the wait period (Mean = 37.11 ± 9.387) and treatment subjects at two-weeks post (Mean = 12.9 ± 12.9), were significantly different in the expected direction ($p < 0.001$; Table 4, comparison 7). The effect of treatment as compared to the untreated post-wait sample was equivalent to two standard deviations above the post wait control mean ($g = -2.1$; 95% CI [-4.69 – 0.453]).

Within group comparisons. Symptom scores for experimental subjects were significantly reduced ($p < 0.001$) from baseline (PSS-I Mean = 37.32 ± 6.678 , $n = 37$) to two-weeks post (Mean = 12.9 ± 12.9 ; $n = 36$) and six-weeks post (Mean = 17.4 ± 14.3 ; $n = 37$; Table 4, comparison 1-2). Hedges g was computed for both comparisons and showed the effect to be

meaningful at the equivalent of 2.3 standard deviations from baseline at two weeks ($g = 2.348$; 95% CI = [0.005 - 4.69] and to 1.5 standard deviations at six weeks ($g = 1.550$; 95% CI [-1.282 - 4.383]).

Similarly, when we tested the previously waitlisted controls, who also received treatment, we found significant ($p < 0.001$) reductions in two-week (Mean = 18.46 ± 15.48 ; $n = 37$) and six-week (Mean = 17.84 ± 16.26 ; $n = 37$) post treatment scores as compared to (initial) baseline (Mean = 36.67 ± 6.936 ; $p < 0.001$; $n = 37$; Table 4, comparisons 3-4). Here too, effect sizes indicated that these changes were meaningful with hedge's g pointing to very large effects ($g = 1.750$; 95% CI [-0.983 - 4.83 and $g = 1.728$; 95% CI [-1/121 - 4.577], respectively).

Cumulative within group comparisons. Following the pattern of earlier studies, when we pooled results for all treatment completers we compared baseline PSS-I (Mean = 38.5 ± 6.783 ; $n=74$) against two-week (Mean = 17.93 ± 14.7 ; $n = 74$) and six-week (Mean = 15.38 ± 15.23 ; $n = 74$) post-treatment follow-ups, those differences were also significant in the expected direction ($p < 0.001$; Table 4, comparisons 5-6). Both measures provided very large effect sizes when compared to the pooled mean baseline ($g = 1.787$; 95% CI [.059 - 2.632]; and $g = 1.951$; 95% CI [0.052 - 3.850], respectively).

Control group stability. The experimental comparison (Week 4 treatment group vs week 5 post-wait control) raised the question whether the untreated waitlist control group had made significant improvements or declines during the waiting period. We therefore compared the waitlist PSS-I results from baseline at study week 1, (Mean = 38.5 ± 6.78) to the untreated retest at study week five (Mean = 37.11 ± 9.156), and found the differences to be significant at the .05 level ($p = 0.048$; Table 4., comparison 8). This result falsified our assumption of group equivalence. However, analysis of the effect of the difference, suggests that it did not have a

great impact ($g = 0.181$; 95% CI [-1.242 – 1.603]). These differences and their implications are discussed below.

Stability of results over time. As other PTSD treatments have been shown to be unstable over time (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= 17.93 ± 14.7 , $n=74$) with their six-week post-treatment scores (Mean = 15.38 ± 15.226 , $n=74$). The differences were significant ($p = 0.0134$; Table 4., comparison 9), however, the actual increase in mean scores (2.45) did not reach a meaningful level (≥ 5) and had a minimal effect ($g = 0.173$; 95% CI [-2.293 - 2.585.]).

Similar comparisons were made using the PCL-M. All results are reported in Table 4.

Rebounding treatment scores.

Several clients, over the course of several evaluations, made dramatic changes in symptom scores, either improving dramatically or suddenly declining and then rebounding. Interviews with these clients found that their life situations had changed dramatically at one of the evaluation points and that those circumstances had affected their responses. This suggests the importance of framing of follow-up questions to ensure that the target trauma is the focus of their concern.

Screening failures.

Despite high levels of remission, we note that some treatment responses varied from what was expected. RTM is expected to have some positive impact on symptom scores, even when the client does not lose the diagnosis. Three cases in the current study began with high PCL-M scores that failed to vary after treatment. When we reviewed video records of intake and

treatment, all three appeared to be screening failures. They were nevertheless included in the present analysis. One person could not identify an appropriate DSM Criterion 1 event. He had no flashbacks within the noted definition and no nightmares. He was just angry.

A second client experienced his trauma dissociatively. He dreamed about it as if through a tunnel and his “flashbacks” were experienced third person. The completely dissociative nature of his symptoms marked him as ineligible for the RTM intervention.

A third client complained of multiple traumas but as the narratives proceeded, the events tended to merge into a broad all-encompassing anxiety. Although no direct measure was applied, the reviewer recognized the symptoms of Generalized Anxiety Disorder (GAD), without separate specific symptomatology that could he could identify as PTSD.

These cases reflect the need for a high level of expertise in the screening process. We recommend that, in the future, prospective clients be evaluated for GAD, that screeners be trained to differentiate clearly between PTSD and intense but otherwise normal anger, and to differentiate between the dissociative subtype and the intrusive variety of PTSD for which RTM is best suited. Target traumas must be distinct events that can be differentiated from a broad emotional background. Experience suggests that targeting the trauma that is most closely associated by content or feeling tone to nightmares and flashbacks is often valuable in targeting the most relevant incident. In some cases, traumas appear to be linked as part of a complex memory system so that targeting one particularly salient trauma, in terms of its autonomic characteristics, can affect many associated traumas and comorbidities.

DISCUSSION

These results indicate that the RTM protocol is an effective treatment for PTSD. Based simply on the mean symptom scores, effect sizes indicate that, as compared to no treatment,

these results surpass other treatments as reviewed by Steenkamp and Litz (2013) and Steenkamp, Litz, Hoge, and colleagues (2016).

Symptom Inventories

PSS-I was used as the primary diagnostic at intake and at both post-treatment measures. Although CAPS is generally regarded as the better measure, there is an extensive literature documenting the accuracy and utility of the PSS-I (Blanchard, Jones-Alexander, et al., 1996; Foa and Tolin, 2000; Castillo, et al., 2016). In the interest of available time, the possibility of overtaxing the client, and similar considerations, we opted to use the briefer PSS-I.

Consistency of RTM Over Time

Variations in the present study. We noted above that whereas we had expected little or no change for control participants between untreated baseline scores at the initial and post-wait baselines, the 1.4-point decline in mean PSS-I score, significant at the .05 level ($p = 0.048$) and 3.28 -point decline in mean PCL-M scores, significant at the .03 level ($p = 0.024$), was somewhat surprising. Insofar as many of the clients were receiving other care and many of them were on medication, it is perhaps not surprising that there should have been changes. There is also some likelihood of a placebo effect in that just being seen or cared for, impacted many of the waiting list controls. It is also important to note that this investigation took place using outpatient volunteers so that all clients were living in the community or nearby shelters and all were exposed to the vagaries of everyday life. This leads the study to the border between the classical experiment and efficacy research where such changes are much more likely.

Perhaps more importantly, the observed differences were not at the 5-point level generally regarded as being meaningful (Monson, et al., 2008), and the effect of the difference

was minimal to non-significant ($g=0.307$; 95% CI [-1.701 -2.009]; and $g = 0.295$; 95% CI [-2.191-2.780]

Similarly, and also contrary to expectation, the two-and six-week post treatment comparisons for all participants were significantly different for the PSS-I ($p = 0.013$), but not for the PCL-M ($p. = 0.48$). Nevertheless, as with the pretreatment control comparisons, the actual effect of this 2.45-point difference in PSS-I means was negligible ($g = 0.198$; 95% CI [-2.820-2.245.]).

We noted earlier that contrary to expectations both the pre- and post-wait waitlist comparisons of the control group and the two and six-week follow-up comparisons for all subjects showed significant differences from time point to time point. Earlier studies did not fully follow ITT protocols. Here we included 5 BOCF and 37 LOCF scores for the six week follow-ups which have inevitably biased the later observation in an unfavorable direction. As noted, neither change had a material impact on the result, as both changes were less than 5 points—the downward limit of meaningful change—and neither had a significant effect size.

Previous research. The RTM protocol has been examined in three other studies. Each of the investigations used clients drawn from similar populations, using similar means, who all displayed high levels of symptomatology and current month reports of flashbacks and nightmares. In all three studies, (Gray & Bourke, 2015; Gray, Budden-Potts, & Bourke, 2016; Tylee, Gray, et al., 2017) participants were required to have pre-existing diagnoses of PTSD. Their diagnoses and remissions were confirmed using PSS-I and PCL-M. Consistent with findings reported here, total remissions using standard criteria in previous studies have hovered above the 60% mark. Total clearance of diagnosis in those other studies report a consistent loss of diagnosis above 90% but differ from the current study in its adherence to more conservative

outcome measures. Prior studies included participants who scored below cutoff on the relevant symptom inventory with secession of nightmares, flashbacks and autonomic reactivity to relevant stimuli as being free of diagnosis. When examined from the perspective of standard outcome measures, all four studies are consistent in their reporting of > 65% clearance of diagnosis. Other differences in outcomes may be related to the use of the PCL-M as the main measure for follow-up observations in the other studies.

Identification of RTM with the reconsolidation mechanism

Other researchers have suggested that the enhanced efficacy and robust changes related to the RTM approach lies in its proposed mechanism of action. This has been discussed previously by Gray and Liotta (2015) and Tylee, Gray, Bourke and Glatt (2017). This discussion follows their argument closely.

We have previously noted that the RTM protocol relies upon structural modifications of the trauma memory that change its immediacy and salience and that the intervention as a whole takes advantage of the so-called labilization window associated with the reconsolidation phenomenon so that changes made to the perceptual structure of the recalled trauma experience become a stable part of the original memory. We have identified the following elements as crucial to the association of reconsolidation blockade with the RTM intervention. 1. The syntax of RTM (Gray & Bourke, 2015; Gray & Liotta, 2012) matches the syntax of reconsolidation; 2. Our studies indicate, that the results of the intervention tend to be long lasting and robust (Agren, 2014; Björkstrand, Agren, Frick et al., 2015; Clem & Schiller, 2016; Fernandez, Bavassi, Forcato & Pedreira, 2016; Gray & Bourke, 2015; Schiller, Kanen et al., 2013; Schiller, Monfils, & Rao, 2010; Tylee, Gray, Bourke, & Glatt, 2017); they do not appear to be characterized by clinical relapse as is reflected in extinction memories which are characterized by spontaneous recovery,

contextual renewal, reinstatement, and rapid reacquisition (Björkstrand, et al., 2015; Bouton, 2004; Kindt & Soeter, 2013; Kredlow & Unger, 2016); 3. RTM uses an abbreviated reminder stimulus that is too short and lacking in intensity to support extinction (Almeida-Correa & Amaral, 2015; Gray & Bourke, 2016; Gray & Liotta, 2012; Lee, 2009; Merlo, Milton, Goosee, et al., 2014; Nader, 2003; Perez-Cuesta & Maldonado, 2009; Suzuki, Josselyn, Frankland, et al., 2004); 5. Like the RTM protocol, the initiation of labilization in reconsolidation requires a novel presentation of the fear stimulus rather than a repeated or extended exposure (Almeida-Correa & Amaral, 2014; Fernandez, Bavassi, Forcato, & Pedreira, 2016; Lee, 2009; Kindt & Soeter, 2013; Pedreira, Perez-Cuesta, & Maldonado, 2004). Novelty may be represented by non-reinforcement (Agren, 2014; Perez-Cuesta, 2009; Schwabe, Nader, & Pruessner, 2014), changes in the duration of re-exposure (Almeida-Correa & Amaral, 2014), the presentation of safety information (Clem & Schiller, 2016), or retelling the trauma narrative in a safe clinical setting (Agren, 2014).

Limitations of the study

The current study is limited by several factors. These are enumerated as follows:

Sampling Technique. The sampling technique targeted a specific subpopulation of male veterans. It used a combination of referrals and word-of-mouth recruitment, resulting in a non-random distribution of veterans which may limit the external validity of the results. That many of the referrals were made by others who reported good results from intervention raises the possibility of expectation bias and placebo effects.

We note, however, that expectancies may have been overcome in part by the non-intuitive nature of the intervention. The imaginal nature of the intervention and its radical commitment to providing a non-traumatizing context for and experience of treatment have often

been greeted with outright disbelief on the part of our participants (Gray & Bourke, 2015; Gray, Budden-Potts, & Bourke, 2016; Tylee, Gray, et al., 2017).

Sample diversity. While the sample is fairly diverse (see tables 2 & 3), it is notable for its lack of female participants. Further, and as already noted in light of the sampling method, it is not unlikely that the study attracted participants who were predisposed to respond well. As noted, although the study focused on a target population (intrusive symptoms primary with current month flashbacks and nightmares), and thus has limited generalizability to PTSD more generally, its targeting is based upon clinical experience with older variants of the model that suggest that the intervention will not work for the excluded types (Gray & Liotta, 2012). We believe that it is not unimportant that the intervention potentially applies to 50-75% of all afflicted by the disorder (Lanius, Vermetten, Loewenstein, et al., 2010; Wolf, 2013). Further experiments with access to larger pools of veterans will be able to test RTM's generalizability beyond our target group and in the process further clarify the boundaries of the larger subpopulation which this intervention appears to serve.

The waiting list control. Waiting list comparisons indicate, basically, that these results are better than nothing. Nevertheless, observed effect sizes (often greater than two standard measures), symptom reductions (>20 points on average), loss of diagnosis (for more than 73% of those treated) and maintenance of treatment gains over at least six months, argue for its value as compared to interventions using similar waiting-list controls for more main line treatments (Bisson, Roberts, et al., 2013; Devilly & McFarlane, 2009; Foa & Meadows, 1997; Steenkamp & Litz, 2013; Steenkamp, Litz, Hoge, & Marmar, 2015). An active comparison condition would have provided more generalizable results and a more valid comparison for

RTM. As we have previously reported (Tylee, Gray, et al., 2017) that the agencies who have helped by referring clients have a great deal of difficulty finding volunteers for placebo, possibly less effective, or more noxious comparison conditions. It is with these limitations in mind that we chose the waiting list design. We invite other researchers to create the required comparison trials.

Length of the waitlist control period. It is important to note that our 3-week waitlist protocol, runs far short of more standard waitlist designs. Devilly and McFarlane's (2009) meta-analysis of 20 waiting list studies of PTSD interventions showed a mean wait of 9.6 weeks with a 6-week median. Our short wait period may have allowed for the effects of other treatments and the normal progress of the disorder to have been expressed inaccurately and so have affected our measures. Further studies, if based on waitlist designs, should look to extend the waiting period to at least six weeks.

Conclusion

These results, in line with other investigations of the RTM Protocol (Gray & Bourke, 2015; Gray, Budden-Potts, & Bourke, 2016; Tylee, Gray, et al., 2017), 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 larger sample of male veterans suggests that the intervention should be subjected to further evaluations using larger populations, and more rigorous investigative designs.

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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. Table is reproduced from Gray, R., Budden-Potts, D., & Bourke, F. (2016). The Reconsolidation of Traumatic Protocol (RTM) for the treatment of PTSD: A randomized waitlist study of 30 female veterans. Submitted manuscript. It is used with the permission of the authors.

Table 2. <i>Demographic Data</i>		
Category		n (%)
Age	Mean Age = 48.671 (\pm 13.3)	
	Median Age = 51.5	
Service Type	US Army	30 (57%)
	US Marines	22(35%)
	US Navy	12 (17.5 %)
	US Air Force	3 (6%)
Ethnicity	Caucasian	32 (28%)
	African American	19 (26%)
	Hispanic	9 (4%)
	Native American	3 (1.5%)
	Asian	2
	Other/multiple	2 (3%)
<p>Note: MST = Military Sexual Trauma; Non-MST= Non-Military Sexual Trauma.</p> <p>Traumas per location reflect multiple traumas per location per person.</p> <p>Percentages may not add to 100% due to rounding errors.</p>		

Table 3. Trauma Types and contexts

Table 3a. Trauma Categories Treated		
Combat general	Discrete combat incidents	65
	Sets of combat traumas related to one incident	13
Non-combat deaths	Non-combat deaths or murders of non-family members	7
	Non-combat deaths of family members	6
Sexual Assault	MST	5
	Non-MST	5
Accidents	Combat related	2
	Non-combat related	4
Crimes	Non-military assaults	4
	Gang related assaults	4
Terrorist attacks	Terrorist attacks	5
Non-Military legal Encounters	Legal situations	2
Family related	Family violence	4
	Other domestic incidents	5
Miscellaneous	OTHER (panic attack, weather related)	3

Table 3b. Locus of incidents

	Location	Number of incidents (approx.)
	USA	49
	Kuwait, Iraq, Afghanistan	47
	Vietnam	16
	Europe	4
	Korea	2
	Somalia	2
	Other	2

Table note: Clients regularly reported multiple traumas spanning multiple contexts.

Table 4. Effect sizes for all comparisons at 95% CI

Comparison & Terms	Measure	Term a	Term b	Hedges g	95% CI		
		Mean \pm sd	Mean \pm sd		Lower	Higher	
1	RTM group	PSS-I					
	a. Baseline	PSS-I	37.32 \pm 6.678	12.92 \pm 12.9 ⁺⁺⁺	2.348	0.005	4.691
	b. 2-weeks Post	PCL-M	62.92 \pm 10.94	31.46 \pm 15.1 ⁺⁺⁺	2.361	-0.643	5.382
	2	RTM group	PSS-I				
a. Baseline	PSS-I	37.32 \pm 6.678	17.41 \pm 14.3 ⁺⁺⁺	1.550	-1.282	4.383	
b. 6-weeks post	PCL-M	62.91 \pm 10.94	32.40 \pm 15.735 ⁺⁺⁺	2.228	-0.860	5.315	
3	Post waitlist controls	PSS-I					
	a. week 1 Baseline	PSS-I	36.67 \pm 6.936	18.46 \pm 15.48 ⁺⁺⁺	1.750	-0.983	4.83
b. 2-weeks post	PCL-M	66.216 \pm 9.51	37.19 \pm 18.10 ⁺⁺⁺	1.987	-1.308	5.282	
4	Post waitlist controls	PSS-I					
	a. week 1 Baseline	PSS-I	36.67 \pm 6.936	17.84 \pm 16.26 ⁺⁺⁺	1.728	-1.121	4.577
b. 6-weeks post	PCL-M	66.216 \pm 9.51	36.08 \pm 19.59 ^a	1.957	-1.572	5.446	
5	All treated subjects	PSS-I	38.5 \pm 6.783	17.93 \pm 14.7 ⁺⁺⁺	1.787	0.059	3.632
	a. baseline	PCL-M	64.567 \pm 10.25	37.18 \pm 17.79 ⁺⁺⁺	1.876	-0.463	4.251
b. 2 weeks-post							
6	All treated subjects	PSS-I	38.5 \pm 6.783	15.38 \pm 15.23 ⁺⁺⁺	1.951	0.052	3.850

7	a. Baseline	PCL-M	64.567 ± 10.25	34.24 ± 17.62 ⁺⁺⁺	2.093	0.230	4.415
	b. 6 weeks-post						
	a. Treatment group at 2-weeks post	PSS-I			-2.120	-4.693	0.453
	b. wait-listed controls at baseline 2	PCL-M	12.92 ± 12.9	37.11 ± 9.387 ⁺⁺⁺	2.276	-5.398	0.846
8	a. All waitlist baseline1	PSS-I	38.5 ± 6.78	37.11 ± 9.156 ^b	0.307	-1.701	2.009
	b. All waitlist baseline 2	PCL-M	66.21 ± 9.52	62.973 ± 12.14 ^c	0.295	-2.191	2.780
9	All Completers	PSS-I			0.173	-2.293	2.585
	a. 2-Week post treatment	PCL-M	17.93 ± 14.7	15.38 ± 15.226 ^d	0.165	-3.869	4.199
	b. 6-Week post treatment		37.18 ± 17.79	34.24 ± 17.62 ^e			

Table note: All computations based upon ITT analysis where incomplete values were replaced using the last observation carried forward (LOCF). Post randomization drop-outs were replaced using the baseline observation carried forward (BOCF; European Medicines Agency, 2010; National Research Council, 2010; White, Carpenter & Horton, 2012).

⁺⁺⁺ p , 0.002

^a p = 0.16

^b p = 0.048

^c p = 0.024

^d p = 0.0135

^e p.= 0.48

Figure 1. CONSORT Client Flow and Experimental Design

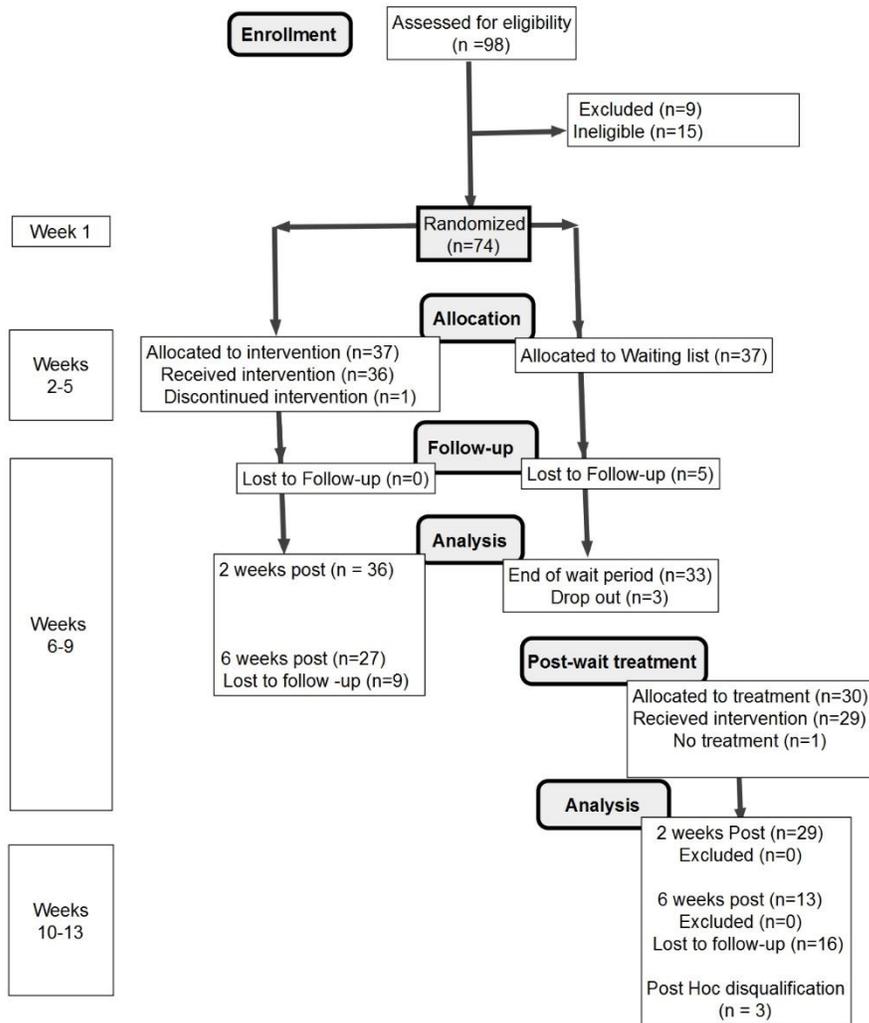


Figure 1. Participant flow chart following Consolidated Standards of Reporting Trials Guidelines.

Note: Subjects were pre-screened with a telephone interview. Baseline symptoms were later assessed using the PCL-M and PSS-I at study week 1. Subjects were then randomized to RTM or waitlist control conditions. The RTM intervention was administered to the treatment group over the course of 3 weeks, during which time control subjects remained untreated. After the completion of the waiting period, control group symptoms were re-assessed using the PCL-M and PSS-I. For the RTM group, symptoms were re-assessed using the PCL-M two weeks and six weeks after the completion of 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 on study weeks 9 and 13. In order to preserve statistical integrity, data from missing clients was replaced using BOCF for clients only reporting intake measures and LOCF for clients who dropped out after the two week follow-up measure.