

RECONsolidation of Traumatic Memories to Resolve Posttraumatic Stress Disorder Study (RECON)



Michael J. Roy, M.D., M.P.H.

Colonel (Retired), U.S. Army

Director, Division of Military Medicine

Professor of Medicine

Deputy Director, Center for Neuroscience & Regenerative Medicine

Deputy Director, Traumatic Brain Injury Research Center

Uniformed Services University

IRB Approved at Uniformed Services University,

Walter Reed National Military Medical Center,

& Madigan Army Medical Center;

Funded by the Center for Neuroscience and Regenerative Medicine

Disclaimers

- **No commercial relationships or conflicts of interest to disclose.**
- **The views expressed in this presentation are solely those of the presenter and do not necessarily represent those of the Uniformed Services University, Department of Defense, or the U.S. government and should not be construed as such.**

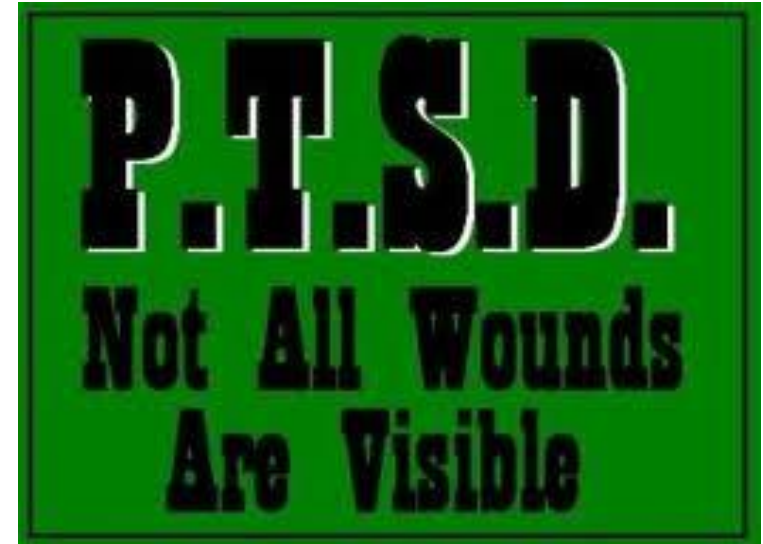


“In war, there are no unwounded soldiers.”

-Jose Narosky (Argentine author)

Post Traumatic Stress Disorder (PTSD)

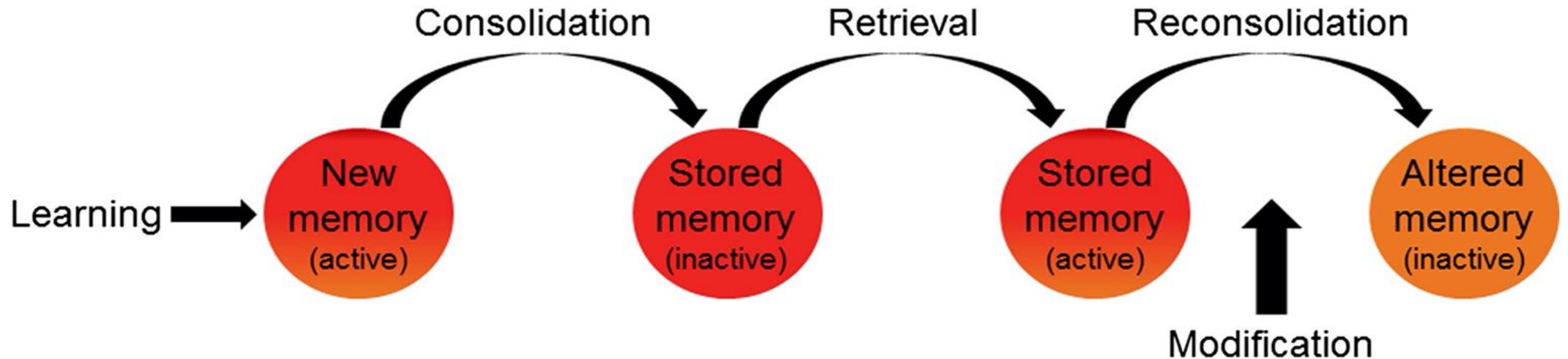
- Exposed to traumatic event
- Impaired function, duration > 1 month
- 4 categories of symptoms
 - Reexperiencing (nightmares, flashbacks)
 - Avoidance and numbing
 - Increased arousal (startle, hypervigilance)
 - Negative changes in mood and cognition



PTSD in U.S. Military Service Members

- Common: 10-20% of OEF/OIF-deployed service members (SMs)
- Associated with high rates of depression, suicide, and impairment in multiple domains
- Successful treatment achieved in less than half with current standard of care [Prolonged Exposure (PE), Cognitive Processing Therapy, and pharmacotherapy]
- Treatment Challenges: treatment ineffectiveness, low tolerability, poor compliance, high dropout rates, need for long-term therapy

RTM Mechanism



Study Objective

- to determine whether Reconsolidation of Traumatic Memories (RTM) achieves a greater and/or more rapid response than PE in the treatment of active duty and retired SMs with PTSD



Study Design

- Randomize 108 current and former military SMs with PTSD (CAPS-5) to up to ten 90-minute sessions of RTM or PE, in-person or via VTC
- Outcome Measures:
 - PTSD remission rates on CAPS-5 (primary measure)
 - Symptom reduction on CAPS-5 and PCL-5
 - PHQ-9 (depression), GAD-7 (anxiety),
NSI (post-concussive symptoms),
PSQI (sleep), WHOQOL-100 (functional status)
 - Rapidity of response
 - Durability of response

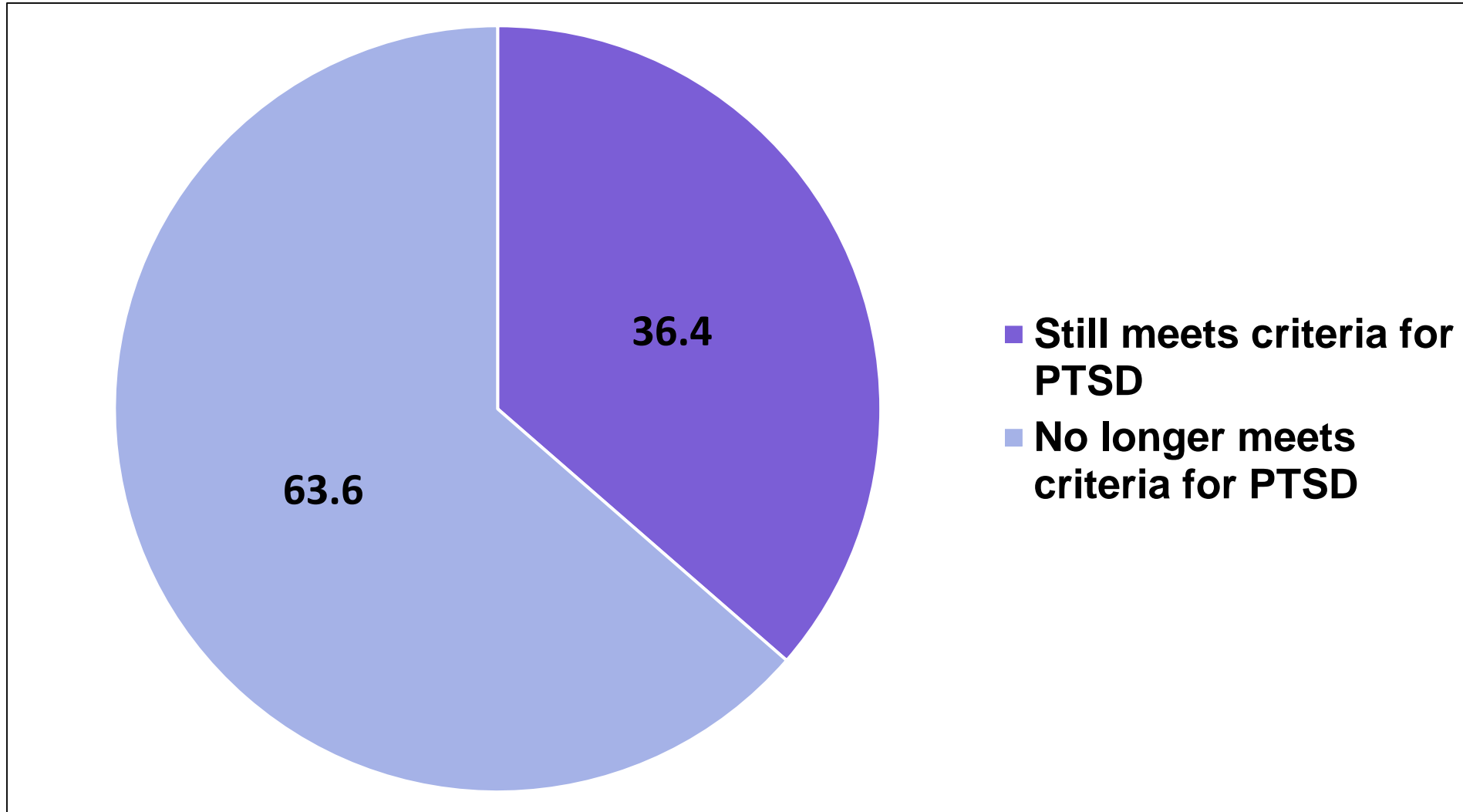
Study progress to date

- **63 participants enrolled**
- **42 participants completed intervention**
- **Average # of intervention sessions completed: 9**
- **Dropout rate 23%**
- **Assessors are still blinded to group assignment, results presented are for groups combined**

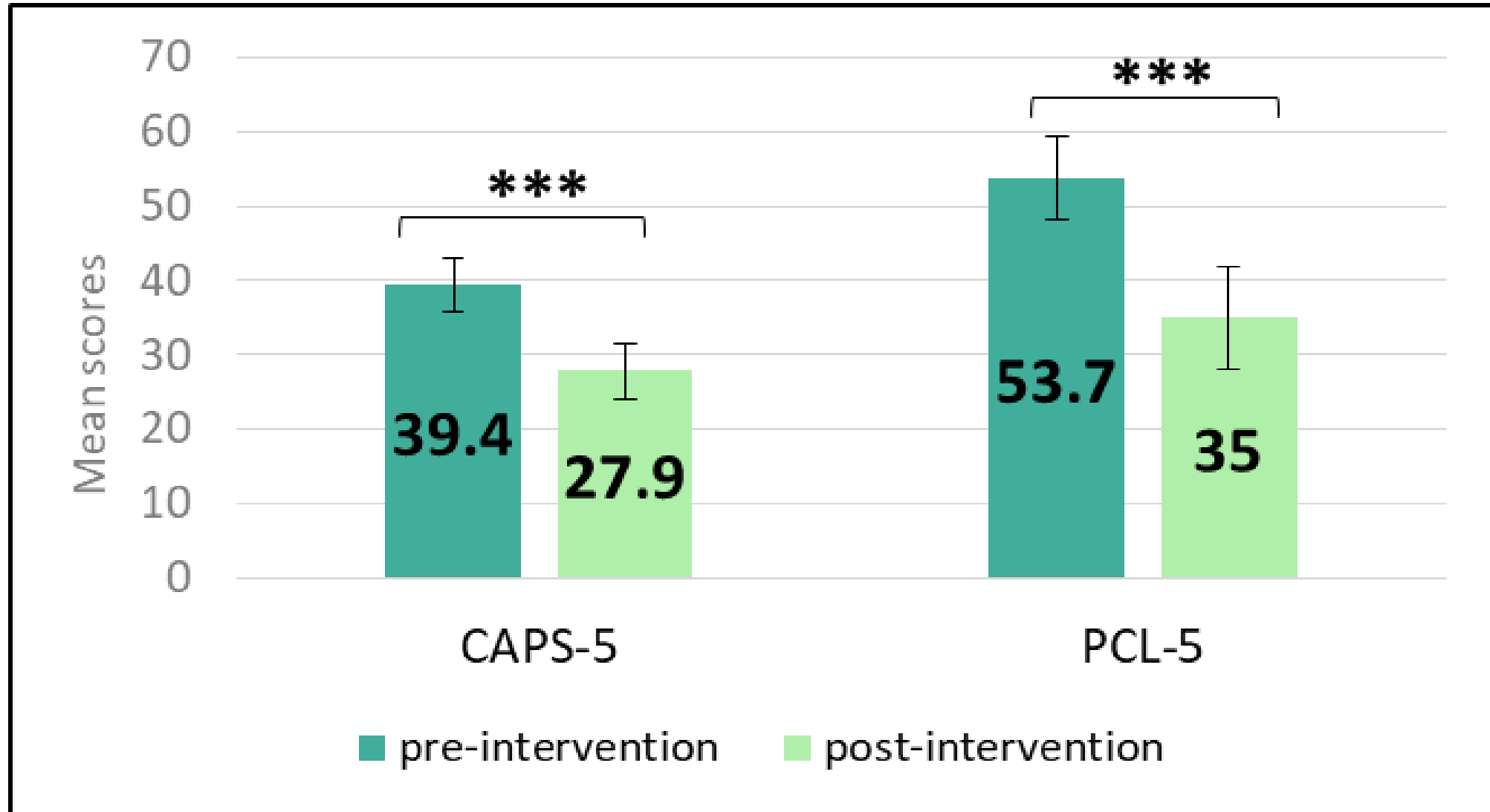
Demographics

	Mean or %
Age (Years)	45
Gender (Male)	66
Race/Ethnicity	
White	44.6
African American/Black	23.2
Other	32.1
Military Status	
Active Duty	39.3
Retired/Veteran	58.9
Military Spouse	1.8
Branch of Service	
Army	42.9
Navy	25
Reserves/National Guard	17.8
Other	14.3

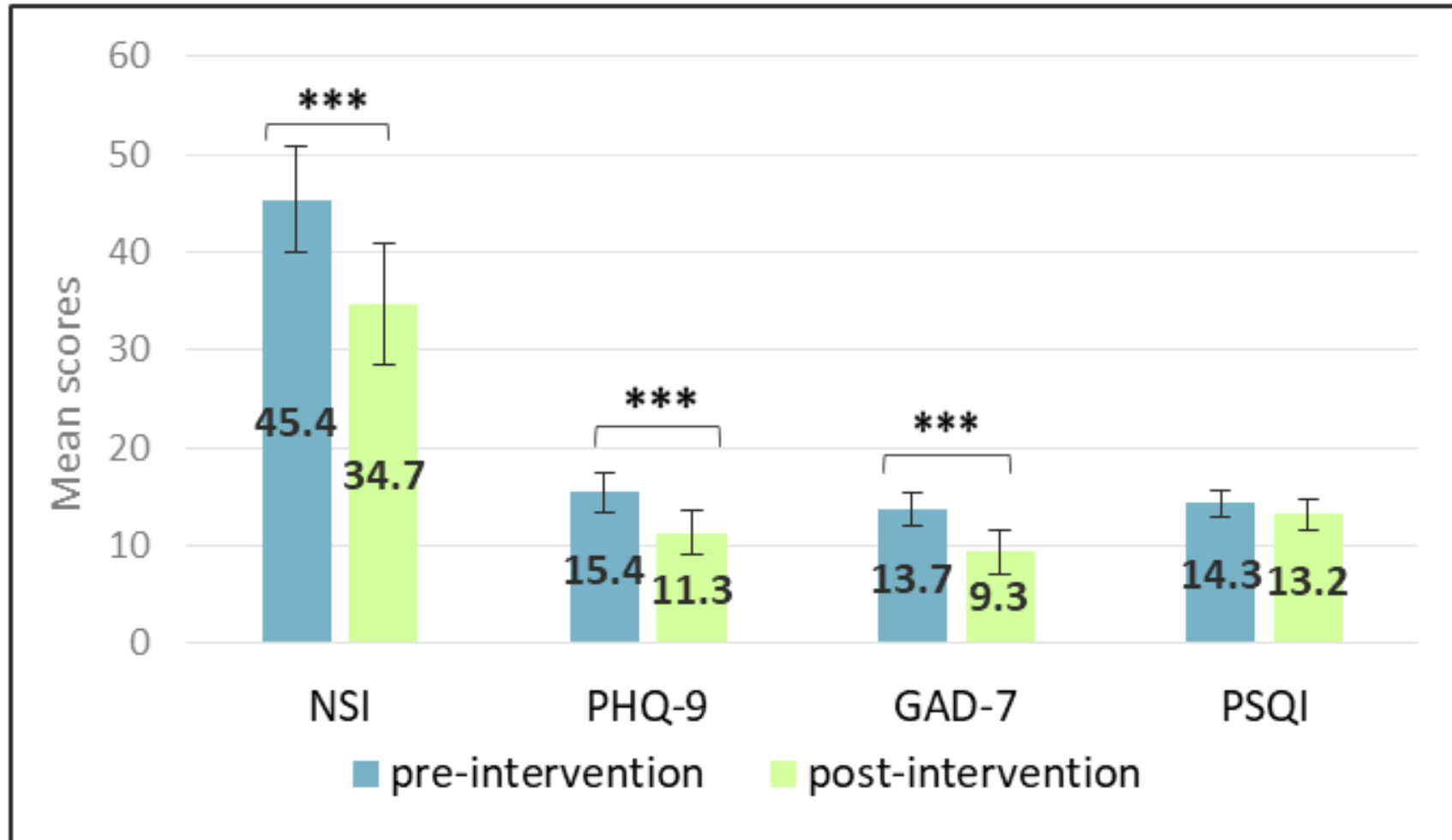
Remission rate by CAPS-5 post-intervention



Changes in CAPS-5 and PCL-5 Scores

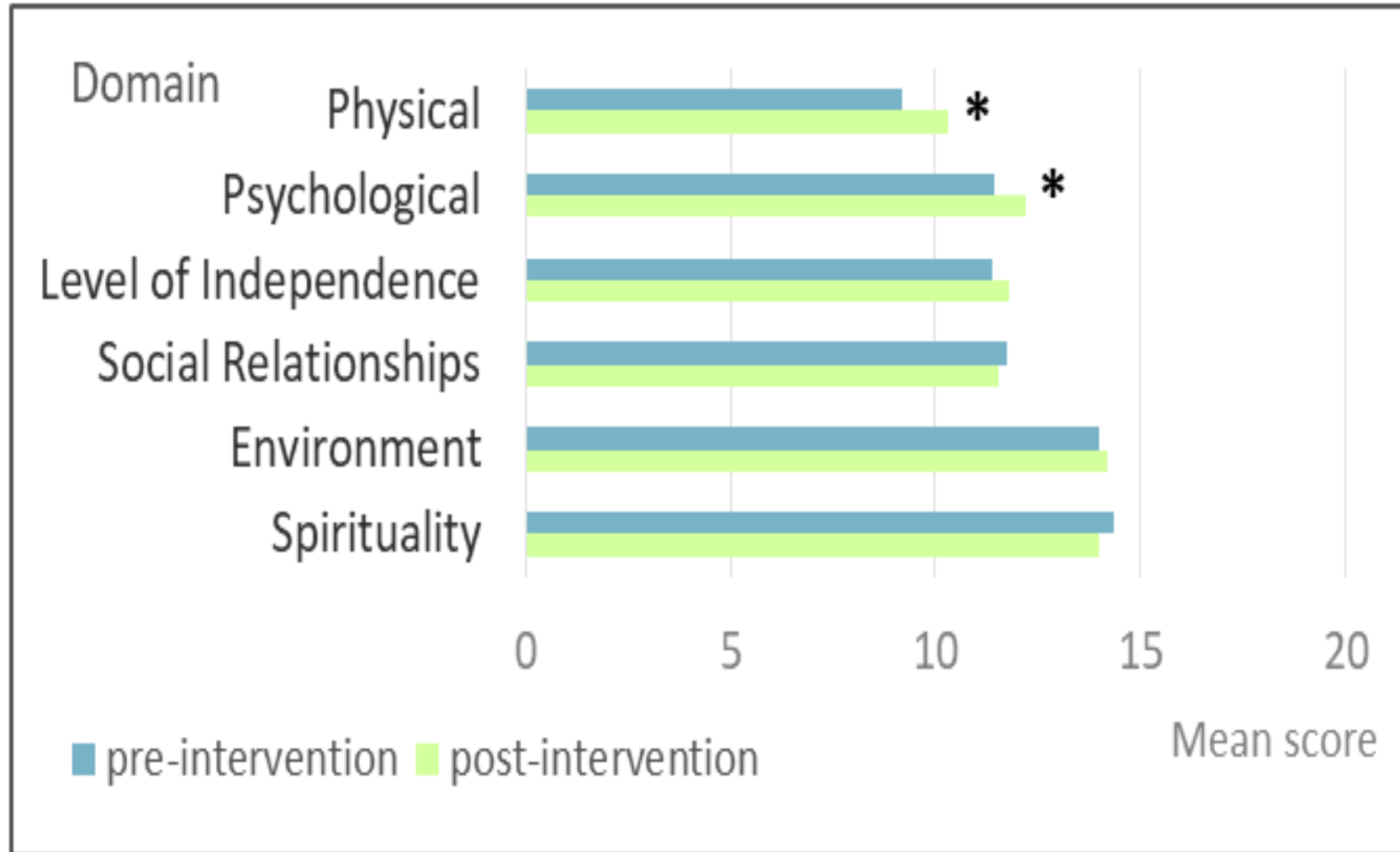


Changes in Secondary Measures (NSI, PHQ-9, GAD-7, PSQI)



***Significance is $p < .001$. Error bars indicate 95% confidence intervals.

Changes in Quality of Life (WHOQOL-100)



*Significance is $p < .05$. Confidence intervals are 95%. Higher scores indicate better function

Preliminary Conclusions

- **High rate of remission of PTSD diagnosis**
- **Clinically and statistically significant reductions in symptom severity on the CAPS-5 and PCL-5 for completers**
- **Significant improvements in post concussive symptoms, depression, anxiety, and multiple functional domains**
- **RTM well received by the military study participants**
- **Both RTM and PE can be successfully administered via VTC**
- **Data collection is ongoing and will determine the durability of the responses**

WRNMMC RECON Research Protocol Questions?

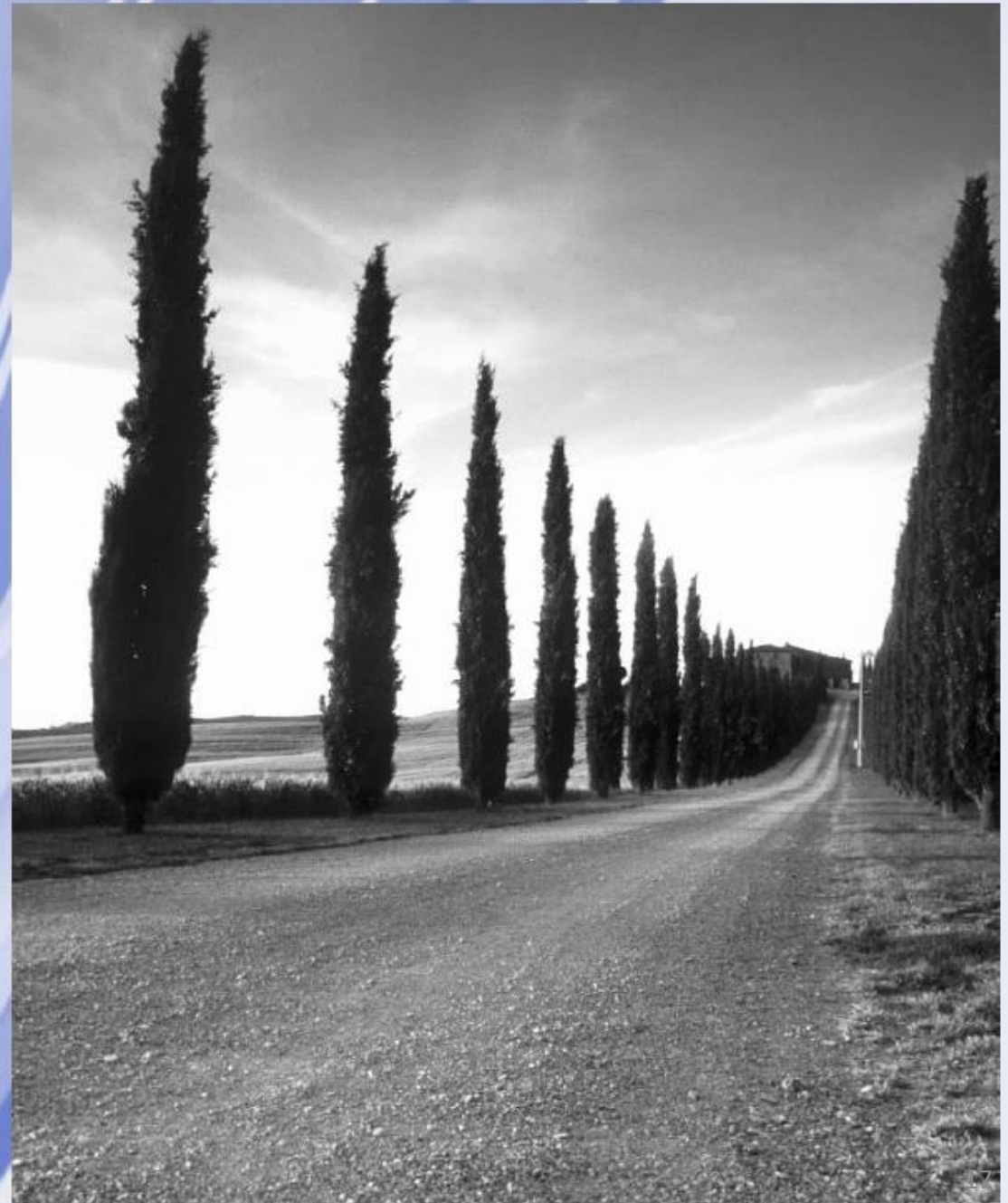
THE LONG ROAD HOME

“... I had no friends, I couldn't get out of bed, I was contemplating suicide. It seems like it is impossible to come back from that ... I finally realized 'this isn't getting any better' ... so I went and I did it ... for the first time in a long time I feel like my life has purpose and opportunity.”

Doug Baldwin

Army Veteran

Completed RTM treatment in 2016



Reconsolidation of Traumatic Memories (RTM) Protocol™ Training

March 21, 2023

J. Gregory Jolissaint, MD MS CPE

Colonel, US Army, Retired

Former VP, Military and Veterans Health Care Program

Holy Cross Health (MD) and Trinity Health (MI)

01

It is estimated that over 12 million people, 4.6% of the US population, suffer from PTSD in any given year. One in 11 people will be diagnosed with PTSD in their lifetime. This number is rising significantly due to the COVID-19 pandemic.

02

The annual US clinical and economic burden of PTSD exceeds \$232 billion, greater than that of depression and anxiety; this data may underrepresent the actual PTSD impact, due to misdiagnoses related to trauma symptoms masked by depression, anxiety, substance misuse & other comorbidities.

03

Current treatments are often retraumatizing to clients & clinicians, taking longer to complete therapy and achieving only 30-50% improvement in symptoms. The majority of patients still suffer from nightmares, flashbacks, hypervigilance, avoidance, etc., after treatment. Most also require medication management.

04

There are ~500,000 clinicians treating patients suffering trauma from accidents, combat, violence, domestic abuse, witnessing awful events, childhood abuse, etc. Annual continuing education courses are required to maintain licensure.

05

Individuals diagnosed with mild Traumatic Brain Injury (mTBI) also experience PTSD at a high rate, whether from combat trauma, sport concussion injuries, motor vehicle accidents or sexual assault. The importance of addressing both conditions simultaneously cannot be overstated.



THE URGENT CHALLENGE

01

A unique, brief, non-drug, non-traumatizing , highly effective and cost-efficient breakthrough treatment for PTSD is now available. It is called the Reconsolidation of Traumatic Memories Protocol™ (or RTM Protocol™ for short).

02

In four published clinical trials to date, the RTM Protocol™ has *eliminated PTSD symptoms in more than 90% of patients*. As a result, PTSD sufferers and their families are spared common co-occurring problems: alcohol and drug misuse, family and career disintegration, suicidal behaviors, etc.

03

The RTM Protocol™ typically works in less than half the time of current therapies, averaging two to three sessions of 60-90 minutes. The RTM Protocol™ is non-traumatizing and has eliminated PTSD symptoms in 90% of patients in four published research studies, with more studies underway.

04

PTTI offers RTM Protocol™ training for clinicians across the US in an accessible live online format. In the past three years, despite the pandemic, over 300 US clinicians have been trained in using the RTM Protocol™; in 2022, 65 clinicians in Poland and Ukraine were trained and are using the protocol. RTM Protocol training institutes are currently being established in Asia and Europe.



**A PROMISING
BREAKTHROUGH**

WHY NOW?



PTSD, among other mental health illnesses, is on the rise, greatly exacerbated by the pandemic, incurring huge human costs, including preventable loss of life (30% increase in suicide since 2000), and undue economic burdens

40+ states have now adopted telemedicine parity laws; further, legislative achievements over the past several years are increasing access to care, including the establishment of mental health treatment as an essential health benefit

Mental health clinicians are reporting increased referrals for care, almost doubling pre-pandemic levels; more than 4 in 10 reported being unable to meet the treatment demand, and 46% said they felt burned out

Recognition of the impact of mental health issues on medical outcomes, lost productivity and human lives is driving payors and employers to find more effective and affordable solutions

RTM PROTOCOL™ DEVELOPMENT TIMELINE

The **RTM Protocol™** was developed by a team of experts at the Research & Recognition Project led by Frank Bourke, PhD, a clinical psychologist and former lecturer at Cornell University.

Dr. Bourke volunteered to help those suffering from PTSD after the 9/11 attacks for 10 months and *treated over 250 World Trade Center survivors suffering from PTSD.*

EXPANDING RTM PROTOCOL™ USE

2006 – Research & Recognition (R&R) Project founded as a 501(c)(3) nonprofit organization to accelerate research and advance adoption through licensing of the RTM Protocol™.

CLINICAL STUDIES

2014 – Four published clinical studies to date, with more underway.

CLINICIAN TRAINING

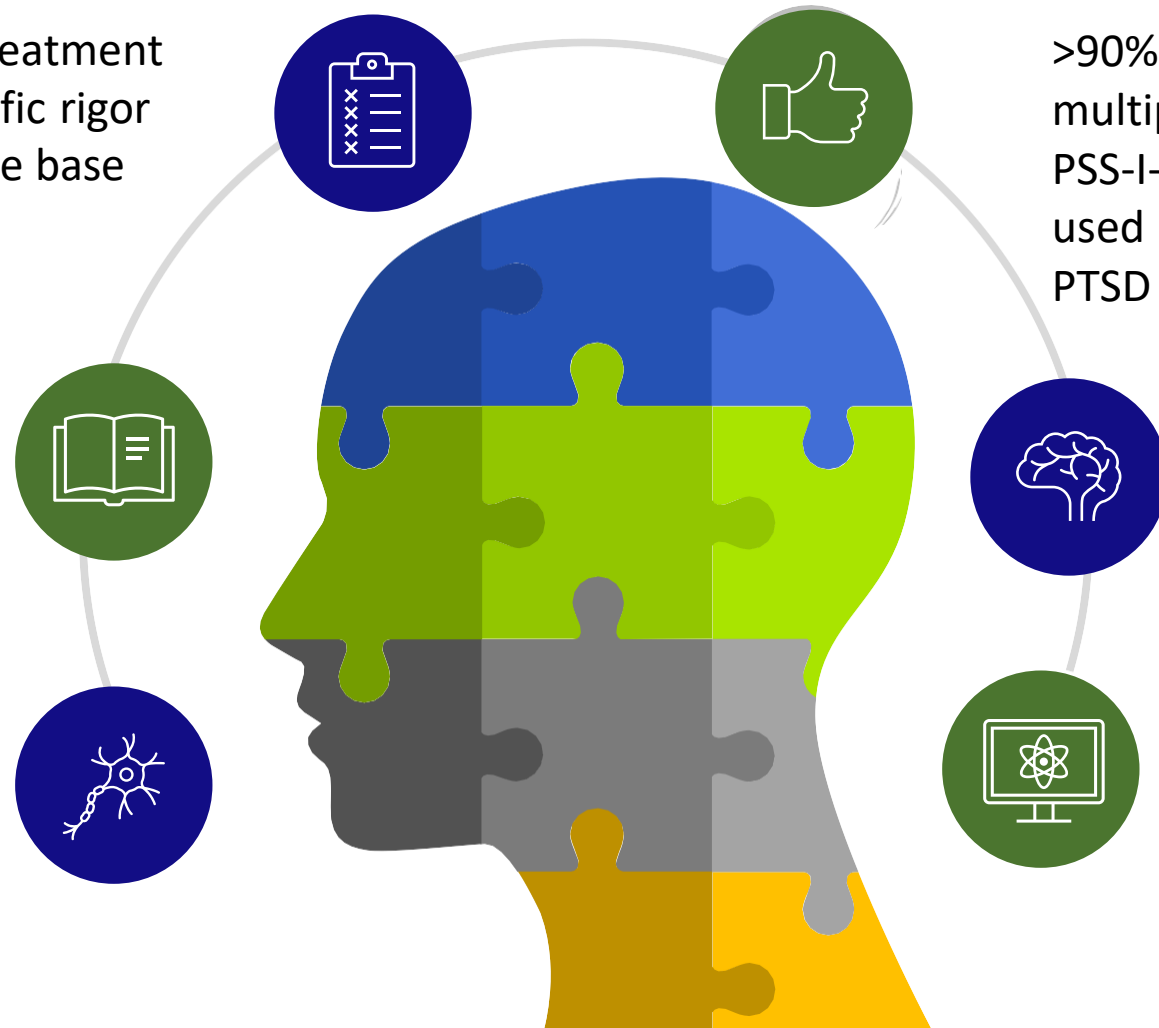
2020 – Post Traumatic Training Institute LLC (PTTI) began hosting US trainings; over 300 clinicians have been trained to date. Ukrainian and Polish clinicians trained in 2023.

RTM PROTOCOL™ EFFICACY

Breakthrough treatment protocol, scientific rigor building evidence base

Four clinical trials w/160 research subjects to date; more underway

RTM Protocol™ was designed as a leading neurobiological protocol to treat PTSD, to relieve suffering & restore lives



>90% remit symptoms in multiple clinical trials as per PSS-I-5, the most frequently used instrument to diagnose PTSD (Foa, et al.)

Brain scan imaging study (Lewine, et al., pending publication)

Specifically cited as effective in large meta-analysis study (Kitchiner, et al.)

Studies and Citations:

Foa EB, et al. (2016). Psychometric Properties of the Posttraumatic Stress Disorder Symptom Scale Interview for DSM-5 (PSSI-5). Psychol Assess. 2016 Oct; 28(10):1159-1165. doi: 10.1037/pas0000259.PMID: 26691507.

Lewine, JD et al. (2018). Quantitative EEG Markers of Post-Traumatic Stress Disorder: Baseline Observations and Impact of the Reconsolidation of Traumatic Memories (RTM) Protocol™ (submitted for publication)..

Kitchiner NJ, et al. (2019). Active duty and ex-serving military personnel with post-traumatic stress disorder treated with psychological therapies: systematic review and meta -analysis, European Journal of Psychotraumatology, 10:1, 1684226, DOI: 10.1080/20008198.2019.1684226.

COMPARATIVE ADVANTAGES OF THE RTM PROTOCOL™

CLINICALLY-EFFECTIVE

The **RTM Protocol™** has demonstrated remarkable effectiveness in four clinical studies with 90%+ remission compared to an average of 35% improvement with other treatments.

LOWER COST

<\$1,000 = average treatment cost using the **RTM Protocol™** ; more affordable AND effective as compared with **\$8300** (the average VA PTSD annual treatment cost for one US Veteran)

NON-TRAUMATIZING

Minimal distress when treated with the **RTM Protocol™** compared with moderate to extreme discomfort with other treatments (resulting in high rates of treatment dropout).

“There are many hundreds of thousands suffering from PTSD. Their families suffer along with them. Over 20 each day die by suicide. I can only hope that the Veterans Administration and others will totally embrace this successful RTM Protocol™.”

-VADM David Buss, US Navy (Ret.)

CLINICIANS and the RTM PROTOCOL™ TRAINING

Clinicians are searching for more effective treatments for their clients' trauma; current methods are falling short.

Clinicians are susceptible to secondary trauma and burnout, which increases the need for an effective protocol which is safe for clients & clinicians alike.

Over 500,000 licensed mental health professionals currently practice in the US.

Clinicians are required to earn annual Continuing Education (CEs) to maintain current clinical licensure; RTM Protocol™ training offers up to 21 CEs.

Client No.	Age	Branch	Pre-Treatment PCL-M Score (PTSD CheckList-Military)	Type of Traumas Treated	Post-Treatment PCL-M Score	Point Change	Post-Treatment Flashbacks, Trauma-related Nightmares
3216	39	Army	73	Military ,Childhood	18	55	0
3217	25	Marines	64	MST	17	47	0
3218	44	Army	68	Combat, Childhood	18	51	0
3219	37	Navy	73	Childhood Sex Trauma, Other	17	56	0
3220	55	Army	68	Childhood	19	49	0

3/1/2018

To the Blue Angels Foundation,

I am a United States Army Veteran. Since my discharge from the military in 2001, I have endured and suffered from service-related trauma. For close to 18 years, I have been a prisoner to my nightmares, to the hypervigilance, to my emotions, and the overwhelming guilt of the events that took place during my military service. Over these years, I have been incarcerated, hospitalized at numerous mental health institutions, and have experienced frequent, yet lengthy, periods of homelessness.

I am not alone in my suffering. My family has endured in watching me go through my twisted cycle of mental and emotional torture, suicide attempt after attempt, hospital after hospital, and jail after jail. Endlessly I struggled to fight those demons within that fed on my soul. I had come to terms that this was my reality and that this would be my life of continuous darkness. I express this to you in hopes that it will help you understand the hopeless circumstances in which I once lived.

Through the guidance, knowledge, and dedication of Dr. Denise , I am forever thankful. The depth of my gratitude, my respect, and that of my entire being is within these words, "Thank you." I thank you, first and foremost, for this opportunity. I thank you for Dr. Denise and the Reconsolidation of Traumatic Memories method. I thank you for helping me release myself from the bondage of my past and my guilt. I thank you for now I can see the beauty around me. I thank you for the light that I now stand in. I thank you for the opportunity to be present in the moment with my family, but most of all, my son. I thank you for the gift of my life. Mostly, I thank you for allowing me the resources to learn how to finally love myself.

Sincerely,

Thursday March 8, 2018.

Dear Blue Angels Foundation:

I want to start off by saying this method, RTM Protocol, "it works." I would refer any vet or active duty who is dealing with PTSD or going through a stressful situation. It not only took care of the flashbacks and nightmares I was weighted down by for years, I am now doing things I was not doing before like hobbies. I have more concentration and feel better about myself. After working with Dr. Denise and the RTM Protocol I have more hope for myself than I had before, which is one of the biggest changes for me.

After doing this work I no longer have demeaning feelings related to how I was terrorized by my father during childhood. The fear, anger and frustration that haunted me for years are now gone. I am able to talk about these earlier situations with family members and not worry about having flashbacks later that night. I no longer have to worry about the father situation anymore. I was able to go to Universal studios where my father worked, and we would go to as kids, and enjoy myself without recalling bad memories for the first time. Growing up as a kid I listened to music daily. I can now hear songs that used to trigger upset and bad memories and no longer feel helpless or fearful. I have perspective on the abuse I suffered and am no longer re-living it. Most importantly I no longer waking up sweating from the nightmares I was having which was affecting my marriage and relationships with my kids due to sleep deprivation and feeling powerless.

Much thanks for helping Dr. Denise and the Research and Recognition Project work with us vets and sharing this fine method which can help so many.

Gratefully,

RTM Protocol Endorsements

The Blue Angels Foundation



New York State Division of Veterans Affairs



New York State American Legion



New York State Rotary



New York State Department of Correction



New York State Council of Veterans Organizations



ONE HUNDRED AND SECOND NATIONAL CONVENTION
OF
THE AMERICAN LEGION
Phoenix, Arizona
August 31, September 1, 2, 2021

Resolution No. 25: Reconciliation of Traumatic Memories Protocol for Treatment of
Post-Traumatic Stress Disorder
Origin: New York
Submitted by: Convention Committee on Veterans Affairs & Rehabilitation

WHEREAS, Post-traumatic Stress Disorder (PTSD) is a significant contributor to suicide ideation throughout the United States; and

WHEREAS, Suicide of our military servicemembers is the highest on record and military veterans are committing suicide upwards of 20 per day; and

WHEREAS, The stress of multiple deployments, combat injuries, deaths, illnesses, and guilt challenge the healthiest of families both active duty and veteran; and

WHEREAS, Clinicians managing patients with PTSD have the following goals: establish a therapeutic alliance, provide ongoing assessment of safety and psychiatric status, address comorbid disorders, increase the patient's understanding of and coping with the effects of exposure to the traumatic event through implementing specific treatments (e.g. psychoeducation, psychotherapy and psychopharmacology) for PTSD; and

WHEREAS, It is time to face the fact that the currently accepted evidence-based protocols and drugs used in the private and government healthcare sectors aren't providing the care and relief PTSD patients need and require; and

WHEREAS, The Research and Recognition Project Inc., a New York based 501(c)3 non-profit, was formed for the express purpose of performing the comprehensive research necessary to validate the effectiveness of a treatment for PTSD; and

WHEREAS, Reconsolidation of Traumatic Memories (RTM) is a non-traumatizing, drug-free, reimagining process which removes nightmares, flashbacks, and the directly related emotional problems associated with PTSD stress in less than five hours; and

WHEREAS, 96% of the individuals completing the RTM pilot program had a total cessation of nightmares, flashbacks and directly related emotional problems; and

WHEREAS, These results were confirmed in a follow-up check conducted six months after treatment signifying the permanence of the relief; and

WHEREAS, The pilot was followed by three replication studies: first replication-30 male veterans-93% effectiveness-results maintained 12 months after treatment, second replication-30 female veterans-96% effectiveness, third replication-75 male veterans-90% effectiveness; and

WHEREAS, The 90%-96% clinical effectiveness results using the RTM Protocol compared to the 35% clinical effectiveness results for veterans treated with Department of Veterans Affairs accepted therapies makes the RTM Protocol a genuine breakthrough in PTSD treatment with national ramifications; and

WHEREAS, PTSD symptoms have lasted far too long, and the goal is not to manage symptoms, it is time to eliminate the nightmares, flashbacks and directly related emotional problems thereby reducing suicide ideation; and

WHEREAS, The RTM Protocol has been included in the International Society for Traumatic Stress Studies' 2019 book "Effective Treatments for PTSD," the gold standard of evidence-based PTSD; and

WHEREAS, The American Legion, Department of New York enthusiastically supports and strongly recommends the RTM Protocol and has donated \$25,000 to the Research and Recognition Project; now, therefore, be it

RESOLVED, By The American Legion in National Convention assembled in Phoenix, Arizona, August 31, September 1, 2, 2021, That The American Legion urge the Secretary of Veterans Affairs and the Secretary of Defense to offer the Reconsolidation of Traumatic Memories (RTM) Protocol as a treatment option for veterans and active-duty military suffering from Post-traumatic Stress Disorder (PTSD); and, be it finally

RESOLVED, That The American Legion urge Congress to provide oversight and funding to the Department of Veterans Affairs, Department of Defense, and the Research and Recognition Project for innovative PTSD research and clinical training in the RTM Treatment Protocol aimed at the national need.

PTTI conducted Virtual Training for New York State and WRNMMC Mental Health Therapists March 10-12, 2023. All received "scholarships" for the training from the New York American Legion.

Dr. J. Gregory Jolissaint, Family Physician and former Army Operational Medicine and Veterans Affairs Physician, also completed the RTM Protocol training with the New York Mental Health Therapists.

WRNMMC Bethesda Clinical Research

Dr. Michael Roy is leading a clinical research team actively using the RTM Protocol for military service Members *and Veterans*.

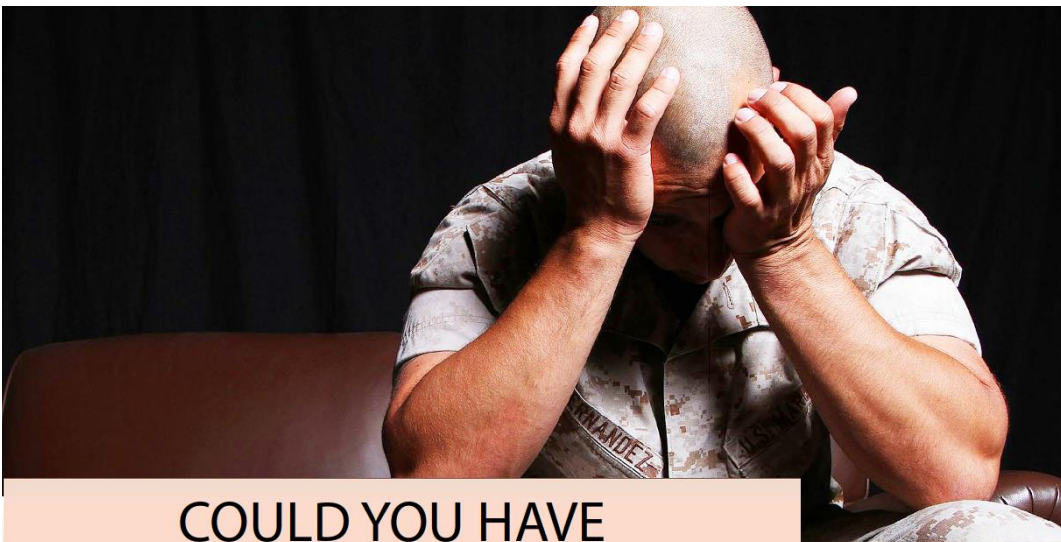
Research Protocol Title is “**Reconsolidation of Traumatic Memories to Resolve Posttraumatic Stress Disorder (RECON)**”

Since the RTM Protocol can be administered virtually, access to the WRNMMC-Bethesda base is not required. ***Veterans can participate virtually!***

Research Team Contact Information:

Email recontrol@usuhs.edu

Phone 301.412.8187



COULD YOU HAVE POST-TRAUMATIC STRESS?

Are you a veteran, active duty or retired service member experiencing:

nightmares or flashbacks? difficulty sleeping?
difficulty concentrating? feeling easily irritated or angered?

PLEASE JOIN OUR STUDY TO ASSESS A THERAPEUTIC RESEARCH INTERVENTION THAT MAY HELP SYMPTOMS OF PTSD

PARTICIPATION KEPT CONFIDENTIAL &
NOW APPROVED FOR REMOTE ACCESS
DOESN'T NEED TO BE IN PERSON

YOU MAY BE COMPENSATED FOR YOUR PARTICIPATION

Principal Investigator:
Michael J. Roy, MD, MPH

✉ recontrol@usuhs.edu

☎ 301.412.8187

10 90-minute sessions
+
2 Pre/Post Assessments
+
3 follow up sessions
at 2, 6 and 12 months

Location: Walter Reed

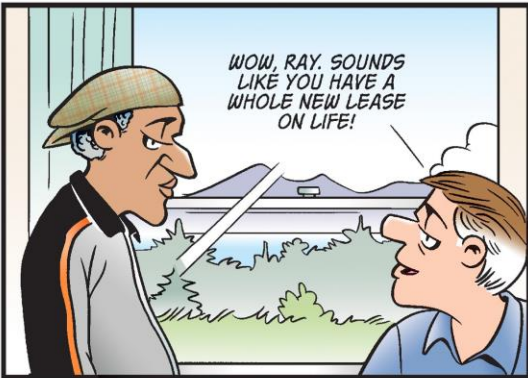
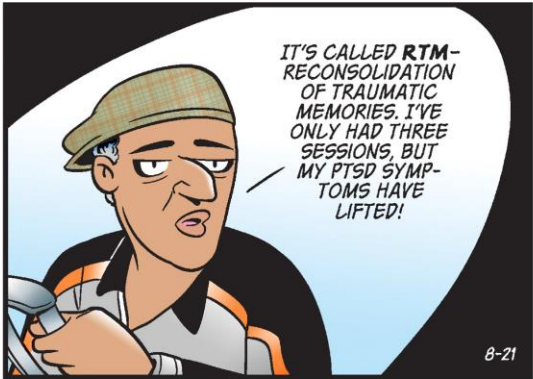
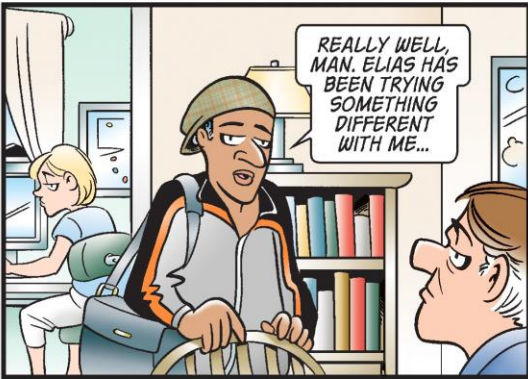
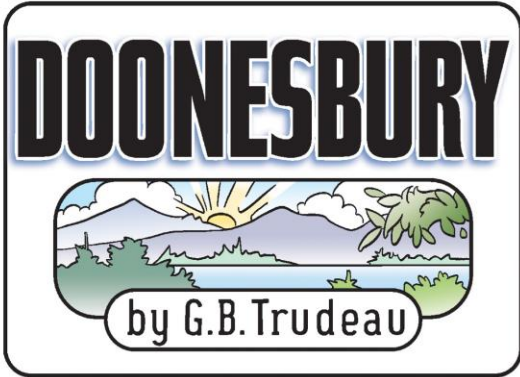
Protocol Title:
Reconsolidation of
Traumatic Memories to
Resolve Posttraumatic
Stress Disorder
(RECONTROL)

MoCo Veterans Commission Opportunities

- *Refer Veterans with symptomatic PTSD to Dr. Roy's Research Team for potential inclusion in the WRNMMC RECON Study*
- Encourage Mental Health Therapists to complete the RTM Protocol Training for the treatment of PTSD (Vet Centers, Stephen A. Cohen Clinic, Hospital LCSWs, etc.), then request they utilize this therapeutic “Tool” in their practices for the treatment of PTSD.
- Encourage Primary Care Physicians to complete the RTM Protocol Training for the treatment of PTSD (Family Medicine, Internal Medicine, Family and Adult Nurse Practitioners, etc.), then utilize this therapeutic “Tool” in their practices for the treatment of PTSD.
- Maryland County Veterans Commissions collaborate with their county American Legion Posts to create statewide American Legion RTM Protocol scholarships similar to New York State (Montgomery County Veterans Commission; Howard County Commission for Veterans and Military Families; etc.).
- MD's County Veterans Commissions collaborate to petition the Maryland Department of Veterans Affairs to petition the MD Assembly, Governor's Office for RTM Protocol funding

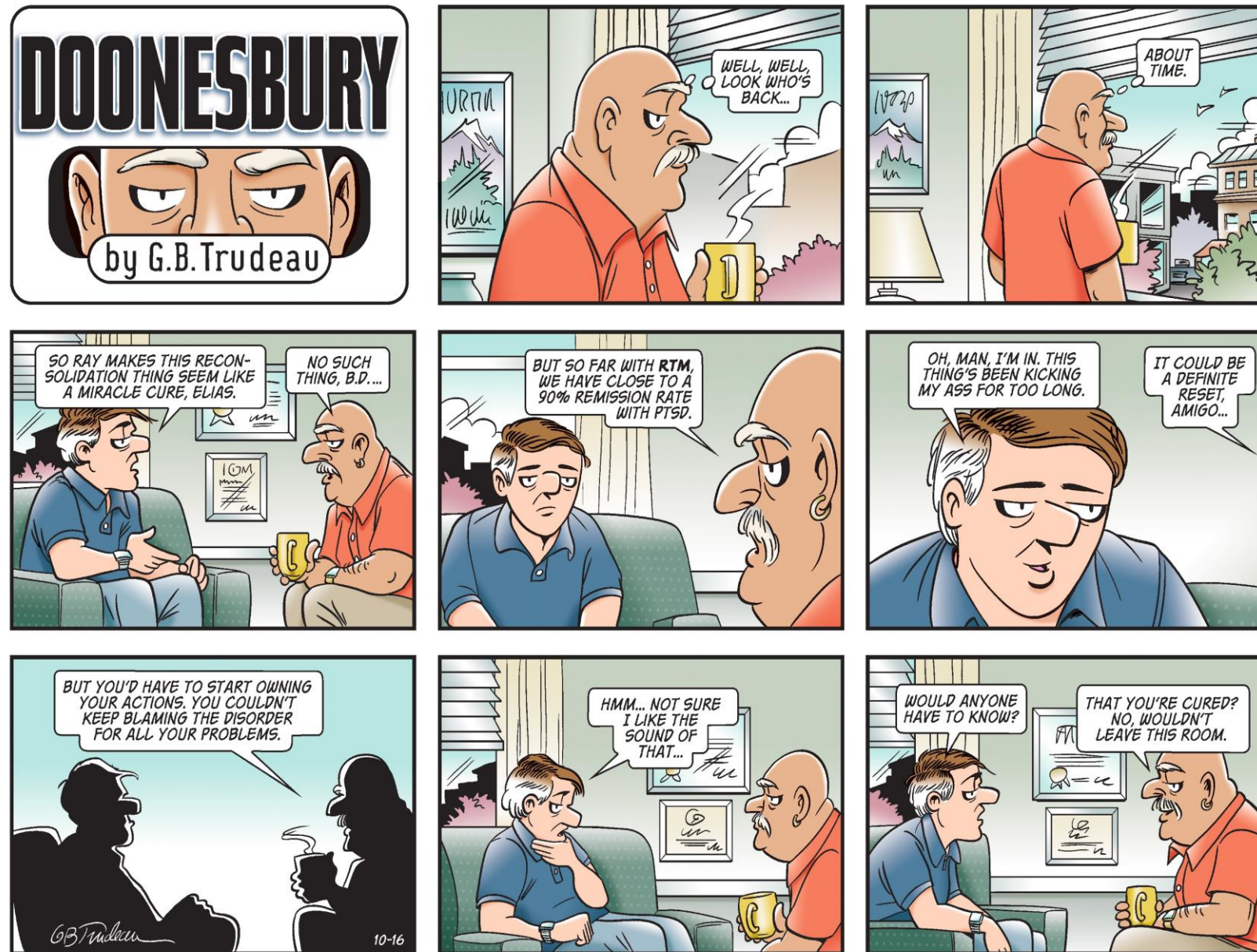
THE RTM PROTOCOL™ IN DOONESBURY

August 21, 2022



THE RTM PROTOCOL™ IN DOONESBURY

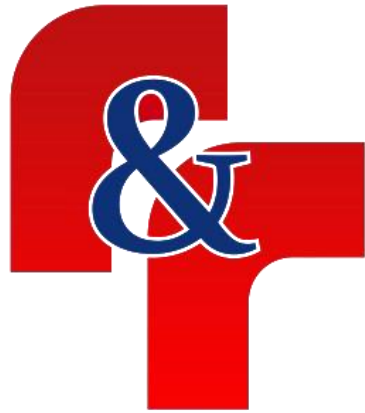
October 16, 2022



“Garry Trudeau provides millions of Americans with a gut-level appreciation of the impact of PTSD on soldiers and their families ... In so doing he is helping to raise awareness about the importance of PTSD as a national challenge, where investment in treatment and research could have an important and lasting impact.”

John Krystal, MD

Chair, Yale Department of Psychiatry



The Research and
Recognition Project



CONTACT

The R&R Project

Mark Ackermann
Chief Operating Officer
917-847-6796
randrproject.org

PTTI, LLC

Loree Sutton, MD
President and Board Chair
917-280-3331
pttinow.com

Comments?

Questions?

Dr. J. Gregory Jolissaint, MD Email gjollysaint@hotmail.com

Dr. Michael Roy, MD Email michael.roy@usuhs.edu