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TITLE: Enhancing BATTLEMIND: Preventing PTSD by Coping with Intrusive Thoughts

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14. ABSTRACT This has been a very productive year for the study with a primary focus on data analyses and dissemination. We were able to continue our working relationship with Camber Corporation and are excited to report that our primary and secondary data analyses were completed during this period. We have continued to disseminate research findings via manuscripts and presentations, and have additional manuscripts in progress. Finally, we are looking very forward to the opportunity to complete additional exploratory data analyses and all remaining milestones in the coming year pending the approval to extend our period of performance for an additional no-cost year.					
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Introduction

Mandated post-deployment training currently instructs troops on maximizing mental health related to deployment. However, a critical element of successful adjustment is developing adaptive strategies for dealing with intrusive deployment-related thoughts. Intrusive thoughts are a common and upsetting symptom following deployment that are central to posttraumatic stress disorder (PTSD) and have historically been left unaddressed in post-deployment training. This project tests a new post-deployment module that translates evidence-based therapeutic strategies into a resilience-based training module (RESET). RESET specifically educates troops about intrusive thoughts and teaches adaptive skills for long-term coping with the thoughts. This is a two-phase project which tests an enhancement to mandated post-deployment training. **Phase 1**, which is complete, included the refinement of the training content of RESET and comparison condition CONTROL (short-term coping strategies). This was achieved with the investigation team and in focus groups with the target audience. **Phase 2** (currently in progress; data collection completed, primary and secondary data analyses completed, dissemination underway) assesses the immediate and short term effectiveness of RESET, CONTROL, and Psychoeducation about Intrusive Thoughts (PIT) as additional post-deployment modules. This was tested in a controlled trial with 4 conditions: RESET, CONTROL, PIT and Training as Usual (TAU).

Keywords

Mindfulness, training, post-deployment, intrusive thoughts

Body

This report details activities for this project during the time period of September 1, 2014—August 31, 2015 (no-cost extension of Award Period 4). During this period, we are pleased to report that significant progress on milestones outlined in the Statement of Work were made; a brief overview of major activities during the award period is summarized here, and more detailed accounts of activities over each quarter of the award period follow this summary.

We continued to utilize the services of Camber Corporation, with whom we have had an ongoing relationship (they were previously contracted to print study workbooks and scan collected data for this project), for Phase 2 data analyses. We are pleased to report that during the third Quarter of this period, Camber completed Phase 2 primary and secondary data analyses.

Also during this period, the research team has been engaged in ongoing dissemination efforts. Findings from primary analyses for this manuscript were presented to the DoD on September 8th, 2014; a Quad chart with study findings was developed for and provided to Mr. Lance Rahey for MEDCOM review on December 10, 2014; and Dr. Shipherd presented study findings to National Center for PTSD staff on February 19, 2015. Dr. Kristalyn Salters-Pedneault was contracted as statistical consultant during this period, and assisted with the development of the main Phase 2 manuscript, which was completed and submitted for publication during Quarter 4 of this period. A Phase 1 manuscript prepared by Drs. Shipherd and Fordiani

continues to be in progress, as does a qualitative manuscript by Drs. Shipherd, Matza, and Salters-Pedneault.

At the close of this award period, we also submitted for review a request for an additional 12-month no cost extension for this study. We projected the necessity of this additional time due to ongoing downstream effects of a previous delay in arrival of funding as well as prior delays in the hiring of the statistical staff. The additional requested time will allow for completion of exploratory analytical milestones, as well as provide continued time to complete ongoing manuscript preparation and other dissemination activities. In this request, we proposed to utilize remaining study funds to support additional exploratory data analytic work in order to broaden the scope and depth of study findings. We are currently awaiting approval of this request.

The quarterly milestones discussed below reflect the current SOW (included with this submission). For ease of reference and clarity, each task outlined in the Statement of Work will be discussed in chronological order. A copy of the proposed SOW associated with the pending no cost extension request is also attached.

No-cost extension of Award Period 4, Months 1-3

- **Statistical team compiles quantitative data codebook**

PROGRESS: This milestone (carried forward from previous quarters) continued to be in progress, as the development of the quantitative codebook continued as Camber Corporation progressed through the phases of data analysis.

- **Primary data analyses continue**

PROGRESS: Primary data analyses continued and we anticipated that these primary analyses would be completed during the next Quarter.

- **Manuscript preparation begins—Phase 1**

PROGRESS: This milestone (carried forward from the previous quarter) continued to be in progress; Drs. Shipherd and Fordiani continued to prepare a manuscript highlighting Phase 1 findings. Some delay in this progress occurred when Dr. Fordiani transferred to her new position in Biloxi, MS.

- **Secondary/exploratory data analyses begin**

PROGRESS: Camber Corporation began secondary/exploratory data analyses, and we anticipated that these analyses would be completed during the next Quarter.

- **Manuscript preparation continues—Phase 2**

PROGRESS: Findings from primary analyses for this manuscript were presented to the DoD on September 8th, 2014. We are attaching these slides for your review; preparation the main Phase 2 manuscript began.

- **Qualitative manuscript preparation begins**

PROGRESS: During this period, Dr. Matza began working with Camber Corporation on qualitative data analysis looking at negative thoughts and possible relationships with outcome variables. Dr. Matza and Dr. Shipherd also began outlining a qualitative manuscript, and qualitative analyses would continue in the next quarter.

- **Dissemination of findings to scientific community begins**

PROGRESS: Dissemination of findings to the scientific community was ongoing as statistical analyses and manuscripts are completed. We anticipated that this would continue into the next quarter.

- **Additional activity during this quarter:**

During the preparation of this Quarterly Report, a discrepancy was noted in the reported cumulative amount of expenditures for the study. Thus, an internal audit of all expenditures reported on all Quarterly Reports submitted for the study was conducted. The results of this audit confirmed the discrepancy found during preparation of this report, the source of the error was located, and the study team also found several additional minor errors. The cumulative expenditures reported were corrected on this Quarterly Report.

Additionally, we had several personnel changes during this quarter, as follows:

- Joanne Fordiani, Project Coordinator, took a new position with the Gulf Coast VA in Biloxi, MS. Her last paid day on this project was 8/8/14. Dr. Fordiani remained on the study protocol as a consultant at 10% donated effort.
- Andrew Curreri, B.A. was hired on 9/8/14 as a Research Technician for this study. IRB approval for the addition of Mr. Curreri was received on 10/8/14.
- Erik Lee, a new Camber Corporation employee, was added to the protocol. IRB approval for the addition of Mr. Lee was received on 8/25/14.
- Burak Ayden, former statistician at Camber Corporation, was removed from the protocol. IRB approval for the removal of Dr. Ayden was received on 10/8/14.
- Several Camber staff were removed from the protocol, as they were not actively involved in the data analysis phase of the project. These Camber employees included Sarah Morrissey, James Piersall, Aimee Reyes, and Elizabeth Sochar. IRB approval for removal of these Camber staff was received on 10/20/14.

No-cost Extension of Award Period 4, Months 4-6

- **Statistical team compiles quantitative data codebook**

PROGRESS: This milestone (carried forward from previous quarters) continued to be in progress, as the development of the quantitative codebook continued as Camber Corporation progressed through the phases of data analysis. In part, this milestone was delayed by staff turnover at Camber, but that issue was resolved and progress continued.

- **Primary data analyses continue**

PROGRESS: Primary data analyses continued and we anticipated that the primary analyses would be completed during the next Quarter.

- **Manuscript preparation begins—Phase 1**

PROGRESS: This milestone (carried forward from the previous quarter) continued to be in progress; Drs. Shipherd and Fordiani continued to prepare a manuscript highlighting Phase 1 findings.

- **Secondary/exploratory data analyses continue**

PROGRESS: Camber Corporation began secondary/exploratory data analyses, and we anticipated that these analyses would be completed during the next Quarter.

- **Manuscript preparation continues—Phase 2**

PROGRESS: The main Phase 2 manuscript continued to be in preparation, with assistance from Dr. Kristi Salters-Pedneault. We anticipated that Phase 2 manuscript preparation would continue in the next Quarter.

- **Qualitative manuscript preparation begins**

PROGRESS: During the previous quarter, Dr. Matza began working with Camber Corporation on qualitative data analysis looking at negative thoughts and possible relationships with outcome variables. Dr. Matza and Dr. Shipherd began outlining a qualitative manuscript. Analyses for this manuscript were ongoing during this quarter.

- **Dissemination of findings to scientific community begins**

PROGRESS: Dissemination of findings to the scientific community is ongoing as statistical analyses and manuscripts are completed. A Quad chart was provided to Mr. Lance Rahey summarizing the work to date on December 10, 2014 for internal MEDCOM review (attached for your review). We anticipated that dissemination would continue into the next quarter, as a talk to the National Center for PTSD community was planned for February 19, 2015.

- **Additional activity during this quarter:**

The following IRB activity was conducted during this quarter:

- Local continuing review documentation for the study was submitted to the VHABHS IRB during this quarter. Additionally, a request was made to convert the study to data analysis only. A one year approval (expiration 12/16/15) was received on 1/01/14.
- Documentation of approval of continuing review was sent to HRPO on 12/24/14.
- Several staff were removed from the protocol, as they were not actively involved in the data analysis phase of the project. These staff include Michael Suvak, Robyn Walser, and Cassidy Gutner. IRB approval for removal of these staff was received on 11/17/14.

No-cost Extension of Award Period 4, Months 7-9

- **Statistical team compiles quantitative data codebook**

PROGRESS: We received the quantitative data codebook from Camber Corporation during this quarter. This data codebook, which was reviewed for accuracy and completeness by study staff, was revised and finalized, and thus this milestone (carried forward from previous quarters) was completed.

- **Primary data analyses continue**

PROGRESS: Primary data analyses were completed during this quarter, thus this milestone was completed.

- **Manuscript preparation begins—Phase 1**

PROGRESS: This milestone (carried forward from the previous quarter) continued to be in progress; Drs. Shipherd and Fordiani continued to prepare a manuscript highlighting Phase 1 findings.

- **Secondary/exploratory data analyses continue**

PROGRESS: Camber Corporation completed exploratory analyses that were underway during the previous quarter and there were no additional exploratory analyses planned at this time, thus this milestone was completed.

- **Manuscript preparation continues—Phase 2**

PROGRESS: The main Phase 2 manuscript continued to be in preparation, and continued to be spearheaded by Drs. Shipherd and Salters-Pedneault. We anticipated that Phase 2 manuscript preparation would continue in the next Quarter.

- **Qualitative manuscript preparation begins**

PROGRESS: The qualitative manuscript spearheaded by Drs. Shipherd and Matza continued to be underway. We anticipated that during the next quarter, Camber Corporation would deliver a final dataset of qualitative data (intrusive thoughts), which would accelerate progress on this manuscript.

- **Dissemination of findings to scientific community begins**

PROGRESS: Dissemination of findings to the scientific community was ongoing as statistical analyses and manuscripts are completed; during this quarter, Dr. Shipherd presented study findings to the National Center for PTSD community on February 19, 2015. We anticipated that dissemination would continue into the next Quarter.

- **Additional activity during this quarter:**

The following IRB activity was conducted during this quarter:

- A required data inventory report form, detailing the location and disposition of both electronic and hard copy data related to this study was submitted to the VHABHS IRB during this quarter. We anticipated receiving approval/acknowledgment of this submission during the next quarter.

No-cost extension of Award Period 4, Months 10-12

- **Manuscript preparation begins—Phase 1**

PROGRESS: This milestone (carried forward from the previous quarter) continued to be in progress; Drs. Shipherd and Fordiani continued to prepare a manuscript highlighting Phase 1 findings. This milestone will be continued during the additional no-cost extension period, when approved.

- **Secondary/exploratory data analyses continue**

PROGRESS: Camber Corporation completed all planned secondary/exploratory analyses that were originally described under the contract with them for statistical support. There is additional exploratory data analytic work that will broaden the scope and depth of study findings (e.g.

exploring predictors of response to training type, influence of type of intrusive thought on training effectiveness, and effects of variables such as gender on outcomes). These analyses will be carried out under the direction of statistical consultant Dr. Kristi Salters-Pedneault during the additional no-cost extension period, when approved.

- **Manuscript preparation continues—Phase 2**

PROGRESS: The main Phase 2 manuscript for this study was submitted for publication on 29 JUL. Additional Phase 2 manuscripts are currently in planning stages and will include data analyses from exploratory analyses described in the milestone discussed above; preparation of these manuscripts would commence in the coming quarter of the requested no-cost extension period, when approved.

- **Qualitative manuscript preparation begins**

PROGRESS: The qualitative manuscript spearheaded by Drs. Shipherd, Matza, and Salters-Pedneault continues to be underway. The first draft has been completed, and we anticipate completion of this manuscript in the near future.

- **Dissemination of findings to scientific community begins**

PROGRESS: Dissemination of findings to the scientific community is ongoing as statistical analyses and manuscripts are completed. We anticipate that this will continue into the additional no-cost extension period, when approved.

- **Additional activity during this quarter:**

There were no IRB, staffing, or other additional activities during this quarter.

Key Research Accomplishments

During this Award Period, Phase 2 primary and secondary data analyses were completed. Dissemination continued, and included:

- Presentation of findings from primary analyses for this manuscript were presented to the DoD on September 8th, 2014. These slides are attached for your review.
- A Quad Chart was provided to Mr. Lance Rahey summarizing work to date on December 10, 2014 for internal MEDCOM review. This chart is attached for your review.
- Study findings were presented to the National Center for PTSD community by Dr. Shipherd on February 19, 2015. These slides are attached for your review.
- A Phase 1 manuscript prepared by Drs. Shipherd and Fordiani continues to be in progress.
- The first draft of a qualitative manuscript prepared by Drs. Shipherd, Matza, and Salters-Pedneault was completed.
- The main Phase 2 manuscript was completed and submitted for publication. This manuscript is attached for your review.

Reportable outcomes: See **Key Research Accomplishments**

Conclusion

We are pleased to report that this has been a very productive year for the study with a primary focus on data analyses and dissemination. We were able to continue our working relationship with Camber Corporation and are excited to report that our primary and secondary data analyses were completed during this period. We have continued to disseminate research findings via manuscripts and presentations, and have additional manuscripts in progress. Finally, we are looking very forward to the opportunity to complete additional exploratory data analyses and all remaining milestones in the coming year pending the approval to extend our period of performance for an additional no-cost year.

Publications, abstracts, and presentations: See **Key Research Accomplishments**

Inventions, patents and licenses: Nothing to report

Other achievements: Nothing to report

References: None

Appendices

A. Statements of Work (both current and projected)

B. Presentation slides of findings from primary analyses presented by Dr. Shipherd to the DoD on September 8th, 2014.

C. Quad chart provided to Mr. Lance Rahey on December 10, 2014 summarizing work to date (provided for internal MEDCOM review)

D. Presentation slides of study findings presented to the National Center for PTSD community by Dr. Shipherd on February 19, 2015.

E. Main Phase 2 manuscript "Evaluating Post-Deployment Training for Coping with Intrusive Thoughts: A Comparison of Acceptance-Based, Cognitive-Behavioral, and Psychoeducational Training Approaches to Training as Usual" (Shipherd, Salters-Pedneault, and Fordiani; currently under review)

STATEMENT OF WORK

For ease of review, completed milestones are shaded in grey below:

Period 1 Milestones: Administrative committee reviews including the VA Boston Healthcare System's IRB and R&D committees with Human Research Protection Office (HRPO) will provide Second Level Oversight IRB approval. Similarly, a Federal Certificate of Confidentiality will be obtained within the initial startup period. Hiring of staff through the not-for-profit organization (BVARI) typically takes 4 months. Preparation of the content of RESET and CONTROL will be finalized in regular meetings with the investigation team, with particular input from Dr. Walser on how to train acceptance of thoughts. Military perspective will be provided by Drs. Benham and Barry who are familiar with the target audience. DoD perspective optimizing the training feasibility and adherence to the Comprehensive Soldier Fitness format will be provided by Drs. Adler and McGurk. Focus group feedback about RESET and CONTROL content will take place with 4 small group sessions of 12-15 Soldiers (total n = 20) reviewing the material to assure user acceptability. Hiring of Fort Drum Trainer will occur.

Period 2 Milestones: Training of trainers will continue at VA Boston. VABHS IRB and HRPO approvals will be obtained for final versions RESET and CONTROL trainings. Scannable versions of questionnaire packets will be finalized and printed. Data collection will be initiated for Phase 2. All data collection will take place via groups at the Ramada Inn, Watertown NY. All waves of data collection will take place over 7-10 day periods where project staff will be on site. Follow up data collection via mailed questionnaires will occur 1 month post completion of RESET, CONTROL, PIT or TAU. At least once per month, 7-10 day data collection trips will occur in Periods 2 and 3, with participants being randomized and completing the RESET, CONTROL, PIT or TAU.

Period 3 Milestones: Conservatively, data collection will be completed with at least 700 primarily 10th Combat Aviation Brigade participants who complete the initial training by Months 1-4 of period 3. It is likely that only partial data (no follow-up data) will be available for roughly another 100 of these participants due to scheduling constraints and general attrition. A recruitment trip coordinated with the timing of PDHRA briefings for the 3rd BCT will occur in Month 4 of Period 3. Utilizing additional funding, scannable versions of questionnaire packets will be printed to enroll a maximum of an additional 800 participants. Data collection with the 3rd BCT will begin in Month 4 of Period 3 with the goal of randomizing 3rd BCT participants to RESET, CONTROL, PIT, or TAU groups. Baseline, pre-training, post-training, and follow up data collection for these participants will continue through months 9-12 of this period.

Period 4 Milestones: Data collection (baseline and follow-up) and data scanning will continue through the award period until eligible and interested Soldiers in the targeted Brigades have been enrolled (1,533 Soldiers) and one-month follow-up data is complete. During Months 5-8, a final dataset will be received from Camber Corporation and hiring of the statistical team will begin. Once hired, statistical team will begin the compilation of the data codebook. The team will then begin preparation for analyses (writing of syntax, etc.) during this period. Also during this period, the qualitative team will transcribe the intrusive deployment thoughts. During months 9-12, data cleaning and checking by the statistical team will begin. Also during this time, primary quantitative data analyses will begin. The qualitative team will develop the coding scheme. During Months 13-16, primary qualitative data analyses will continue and manuscript preparation will begin. The qualitative team will code the intrusive thoughts. During months 17-20 and 21-24, data analyses and manuscript preparation continues and dissemination of findings to the scientific community begins. During months 25-28, the study team will also 1) report findings to Ft. Drum and debrief Ft. Drum leadership and 2) continue to disseminate findings to the scientific community.

PERIOD 1	Months 1-4	Months 5-8	Months 9-12
PHASE 1	- Hiring of staff, administrative work - Certificate of Confidentiality - VA IRB/R&D paperwork - Establish bi-weekly conference calls with all project personnel - Discuss content of trainings	- Finalization of IRB approval - Meetings with Fort Drum Leadership for feedback - Ongoing bi-weekly conference calls with all project personnel - Continued refinement of RESET and CONTROL content	- HRPO application - Finalization of RESET and CONTROL content for focus group - Hiring of the Fort Drum Trainer - Plan focus group recruitment - Training of trainers begins
	Months 13-16	Months 17-20	
PHASE 2	- Finalization of HRPO approval - Training of trainers continues - Recruitment of focus group participants via announcements and advertisements - Conduct 2 focus groups - Gather data from focus groups on content, utility and acceptability of RESET and CONTROL 1 month follow-up data collection	- Review qualitative and quantitative data gathered from first 2 focus groups - Conduct another 2 focus groups with feedback on RESET and CONTROL - Gather data from focus groups on content, utility and acceptability of RESET and CONTROL 1 month follow-up data collection - Review qualitative and quantitative data gathered from second 2 focus groups	
PERIOD 2	Months 1-4	Months 5-8	Months 9-12
PHASE 2	- Refine RESET and CONTROL content based on focus group feedback and data collection - Secure IRB/HRPO approval for final versions of RESET and CONTROL content - Randomize Companies to training condition: RESET, CONTROL, PIT, TAU - Recruitment efforts	- RESET, CONTROL, PIT and TAU provided, pre and post data gathered 1 month follow-up data collection - Recruitment efforts	- RESET, CONTROL, PIT and TAU provided, pre and post data gathered 1 month follow-up data collection - Continued recruitment efforts 800 additional scannable questionnaire workbooks printed
PERIOD 3	Months 1-4	Months 5-8	Months 9-12
PHASE 3	- RESET, CONTROL, PIT and TAU provided to already recruited participants, pre and post data gathered - Recruitment of 3rd BCT begins - Delivery of RESET, CONTROL, PIT and TAU to 3rd BCT participants begins, pre and post data gathered 1 month follow-up data collection continues for already recruited participants, begins for 3rd BCT - Scanning of collected data continues for already recruited participants, begins for 3rd BCT - Continued recruitment efforts	- RESET, CONTROL, PIT and TAU provided to 3rd BCT participants, pre and post data gathered 1 month follow-up data collection continues - Continued recruitment efforts - Scanning of collected data continues	- RESET, CONTROL, PIT and TAU provided to 3rd BCT participants, pre and post data gathered 1 month follow-up data collection continues - Scanning of collected data continues
PERIOD 4	Months 1-4	Months 5-8	Months 9-12
PHASE 3	- RESET, CONTROL, PIT and TAU provided to eligible Soldiers, pre and post data gathered until 1,533 participants enrolled 1 month follow-up data collection continues until complete - Scanning of collected data continues until complete	- Hiring of Statistician and Research Technician - Final dataset received from Camber Corporation - Statistical team compiles quantitative data codebook - Statistical team begins preparations for analyses - Qualitative team transcribes intrusive thoughts	- Data cleaning and checking - Primary data analyses begin - Qualitative team develops coding scheme
			Months 13-16 - Primary data analyses continue - Qualitative team codes data - Manuscript preparation begins—Phase 1

PERIOD 4	Months 17-20	Months 21-24	Months 25-28
PHASE 3	• Primary data analyses continue • Secondary/exploratory data analyses begin • Manuscript preparation continues-Phase II • Qualitative manuscript preparation begins • Dissemination of findings to scientific community begins	• Secondary/exploratory data analyses continue • Manuscript preparation continues-Phase II • Dissemination of findings to scientific community continues	• Manuscript preparation continues-Phase II • Dissemination of findings to scientific community continues • Report to Fort Drum with findings • Debriefing with Fort Drum leadership

STATEMENT OF WORK

For ease of review, completed milestones are shaded in grey below:

Period 1 Milestones: Administrative committee reviews including the VA Boston Healthcare System's IRB and R&D committees with Human Research Protection Office (HRPO) will provide Second Level Oversight IRB approval. Similarly, a Federal Certificate of Confidentiality will be obtained within the initial startup period. Hiring of staff through the not-for-profit organization (BVARI) typically takes 4 months. Preparation of the content of RESET and CONTROL will be finalized in regular meetings with the investigation team, with particular input from Dr. Walser on how to train acceptance of thoughts. Military perspective will be provided by Drs. Benham and Barry who are familiar with the target audience. DoD perspective optimizing the training feasibility and adherence to the Comprehensive Soldier Fitness format will be provided by Drs. Adler and McGurk. Focus group feedback about RESET and CONTROL content will take place with 4 small group sessions of 12-15 Soldiers (total n = 20) reviewing the material to assure user acceptability. Hiring of Fort Drum Trainer will occur.

Period 2 Milestones: Training of trainers will continue at VA Boston. VABHS IRB and HRPO approvals will be obtained for final versions RESET and CONTROL trainings. Scannable versions of questionnaire packets will be finalized and printed. Data collection will be initiated for Phase 2. All data collection will take place via groups at the Ramada Inn, Watertown NY. All waves of data collection will take place over 7-10 day periods where project staff will be on site. Follow up data collection via mailed questionnaires will occur 1 month post completion of RESET, CONTROL, PIT or TAU. At least once per month, 7-10 day data collection trips will occur in Periods 2 and 3, with participants being randomized and completing the RESET, CONTROL, PIT or TAU.

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PHASE 2	- Refine RESET and CONTROL content based on focus group feedback and data collection - Secure IRB/HRPO approval for final versions of RESET and CONTROL content - Randomize Companies to training condition: RESET, CONTROL, PIT, TAU - Recruitment efforts	- RESET, CONTROL, PIT and TAU provided, pre and post data gathered 1 month follow-up data collection - Recruitment efforts	- RESET, CONTROL, PIT and TAU provided, pre and post data gathered 1 month follow-up data collection - Continued recruitment efforts 800 additional scannable questionnaire workbooks printed
PERIOD 3	Months 1-4	Months 5-8	Months 9-12
PHASE 3	- RESET, CONTROL, PIT and TAU provided to already recruited participants, pre and post data gathered - Recruitment of 3rd BCT begins - Delivery of RESET, CONTROL, PIT and TAU to 3rd BCT participants begins, pre and post data gathered 1 month follow-up data collection continues for already recruited participants, begins for 3rd BCT - Scanning of collected data continues for already recruited participants, begins for 3rd BCT - Continued recruitment efforts	- RESET, CONTROL, PIT and TAU provided to 3rd BCT participants, pre and post data gathered 1 month follow-up data collection continues - Continued recruitment efforts - Scanning of collected data continues	- RESET, CONTROL, PIT and TAU provided to 3rd BCT participants, pre and post data gathered 1 month follow-up data collection continues - Scanning of collected data continues
PERIOD 4	Months 1-4	Months 5-8	Months 9-12
PHASE 3	- RESET, CONTROL, PIT and TAU provided to eligible Soldiers, pre and post data gathered until 1,533 participants enrolled 1 month follow-up data collection continues until complete - Scanning of collected data continues until complete	- Hiring of Statistician and Research Technician - Final dataset received from Camber Corporation - Statistical team compiles quantitative data codebook - Statistical team begins preparations for analyses - Qualitative team transcribes intrusive thoughts	- Data cleaning and checking - Primary data analyses begin - Qualitative team develops coding scheme
			Months 13-16 - Primary data analyses continue - Qualitative team codes data - Manuscript preparation begins—Phase 1

PERIOD 4	Months 17-20	Months 21-24	Months 25-28
PHASE 3	• Primary data analyses continue • Secondary/exploratory data analyses begin • Manuscript preparation continues- Phase II • Qualitative manuscript preparation begins • Dissemination of findings to scientific community begins	• Secondary/exploratory data analyses continue • Manuscript preparation continues- Phase II • Dissemination of findings to scientific community continues	• Secondary/exploratory data analyses continue • Manuscript preparation continues- Phase II • Dissemination of findings to scientific community continues
	Months 29-32`	Months 32-35	Months 36-40
PHASE 3	• Report to Fort Drum with findings • Debriefing with Fort Drum leadership • Secondary/exploratory data analyses continue • Manuscript preparation continues- Phase II • Dissemination of findings to scientific community continues	• Secondary/exploratory data analyses continue • Manuscript preparation continues- Phase II • Dissemination of findings to scientific community continues	• Manuscript preparation continues- Phase II • Dissemination of findings to scientific community continues

Enhancing Post-deployment Training: Preventing PTSD by Coping with Intrusive Thoughts

Findings, implementation, and translation discussion

Jillian C. Shipherd, Ph.D.
VA Boston Healthcare System
National Center for PTSD
Women's Health Sciences Division
Boston University School of Medicine

Introduction: Intrusive Thoughts

What are intrusive thoughts (IT)?

“Thoughts, memories, or images about any stressful experience, including deployment, that can pop into your mind repeatedly. Often these thoughts are annoying, and they might make it harder for you to concentrate or hard for you to get things done.”

Introduction: Intrusive Thoughts

- Why IT are important in general, and why are they especially important to the Army?
 - Following trauma, intrusive thoughts are expected
 - IT are associated with distress
 - Coping with IT can influence trajectory of recovery from trauma
 - 75% of a pilot sample of returning forces report IT about Iraq
 - Development of PTSD in returning Soldiers is a salient challenge for the Army; secondary prevention would be ideal (versus treatment)
 - Can Cognitive Behavioral Therapy (CBT) or Acceptance and Commitment Therapy (ACT) for PTSD be translated into skills?

Study Conceptualization/Rationale

- This project is a secondary prevention program designed to assist Soldiers with managing IT
- Intent was to develop a new module to be integrated into Comprehensive Soldier Fitness
- How to best manage IT raised several experimental questions...
 - Is psychoeducation enough?
 - Do Soldiers need skills to manage IT?
 - If skills are needed, what kinds of skills? (CBT, ACT)

Development of Trainings

- Three trainings were designed:
 - Psychoeducation about IT (PIT)
 - Mindfulness skills (RESET)
 - Cognitive-behavioral skills (CONTROL)
- These three modules were tested head-to-head in an RCT against a comparison training (TAU-CSF)
- There is no waitlist control condition. Active training comparisons- larger effects needed to find significant differences

Brief overview: TAU-CSF and PIT

- Training As Usual (TAU-CSF)
 - Comprehensive Soldier Fitness (CSF)
 - We ask about when CSF was given at baseline and 1-month follow-up
 - We provided only referral information
- Psychoeducation (PIT)
 - **15-20 minute** training by study staff
 - Educates Soldiers about IT are and normalizes them
 - Identifies when IT are a problem
 - Provides referral information

RESET and CONTROL skills – each 60 mins (also had TAU-CSF and PIT)

Common intrusive or unwanted thoughts affect almost everyone

Only you can learn to control them

New skills can help you

Thoughts can be stopped

Replace your thoughts with more pleasant ones

Other activities will help distract you

Learning comes with practice: Train your skills!

Remember it is normal to have intrusive or unwanted thoughts.

Ease up on control, it doesn't always work well with thoughts.

See & accept your thoughts: You are more than just your thoughts.

Experience thoughts as they happen: Don't judge them.

Train your skills: Practice is important!

RCT:

Sample Eligibility and Enrollment

- 1,524 Fort Drum Soldiers randomized to one of four conditions (TAU, PIT, CONTROL, RESET)
 - 10th Combat Aviation Brigade
 - 3rd Brigade Combat Team
 - Other Brigades
 - 3-12 months deployment (PDHRA recruitment)
- One in-person baseline visit (off post) with multiple assessments (baseline, pre-post each training)
- Mailed one month follow-up questionnaires
- Response rate ($707/1524 = 46\%$) or 1,480 with valid mail = 48%

RCT

IT identification

Soldiers wrote down their most intrusive thought from the most recent deployment. **Although Soldiers were asked to identify deployment thoughts, skills should translate to other types of thoughts .**

Injury or Combat experience

"The whistling of a mortar as well as the hum of a rocket flying over my head"

"Getting blown up by an IED"

"... images of my dead friends being wheeled to the Blackhawk that was taking their remains off the battlefield"

"Watching the death of 5 fellow Soldiers from my platoon"

Concerns about friends

"In my personal life one of my best friends was killed and I had no way of getting home to give my final respects;"

"I worry about losing connections with my friends."

Leadership concerns/concerns about job performance

"The careless attitude of my commander and first sergeant..."

"The thought of not being valuable to my unit"

Concerns about family

"That I would lose my son and/or my connection to him"

"Thoughts of my husband driving drunk with my daughter in the vehicle while I'm deployed"

[illegible]

RCT

Characteristics of Participant-Soldiers

- Soldiers in this study shared unique characteristics
 - No requirement to participate
 - Motivated to participate during off-duty hours
 - Information provided to study team kept (with exception of safety issues)
 - Soldiers were paid for their time (\$100 baseline/\$25 follow up)
 - Study was conducted off-post (Ramada Inn, Watertown NY)
 - Dates of participation were January 2012 through June 2013*
 - * May 2013 was last training session – June was last follow-up

Demographics

Demographic Characteristics	N = 1,524	
Sex		
Male	90.6%	
Female	9.4%	
Age (in years)	28.5 mean	(SD = 6.7; min/max = 19/56; mode = 26)
Rank		
Private (PV1, PV2, PFC), Corporal, Specialist	56.2%	
Sergeant/Staff Sergeant	28.3%	
Sergeant (1 st Class/Master/Major)	6.1%	
Officer (1LT, 2LT, CPT, MAJ)	6.5%	
Warrant Officer (W1—W5)	3.2%	
Race		
Black/AA	14.0%	
White/Caucasian	61.8%	
Hispanic	15.6%	
Other	8.6%	
Total number of deployments	Mean=1.95	(min/max = 1/14)

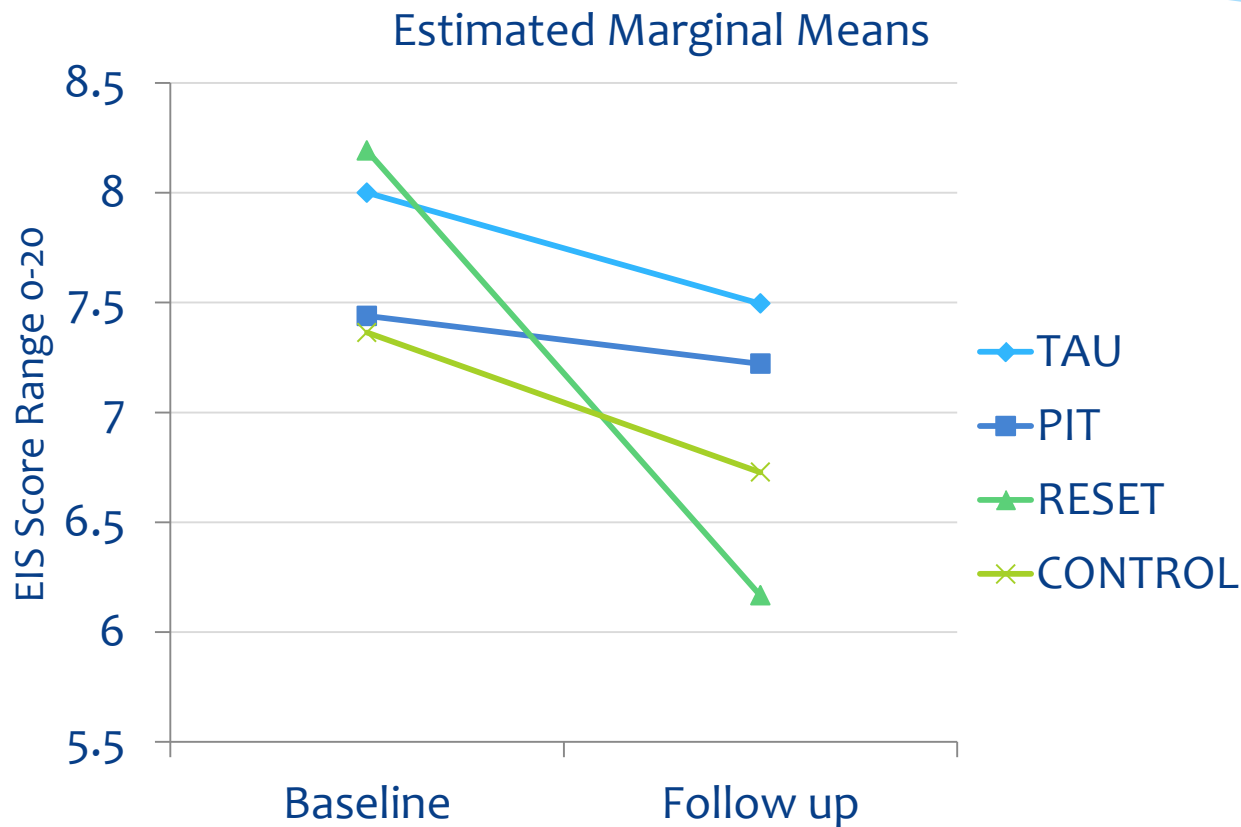
Results

General overall observations

- Psychoeducation (TAU-CSF + PIT) alone was not a helpful intervention
 - Without the addition of skills, providing Soldiers only with basic information and referral information did not change their ability to cope with IT
 - In some cases, receiving psychoeducation alone worsened outcomes
- Overall, the CONTROL skills group (TAU-CSF+PIT+CONTROL) performed well
 - Outcomes comparable to RESET skills on many measures
- RESET group (TAU-CSF+PIT+RESET) outperformed CONTROL in some important areas

RESET Results

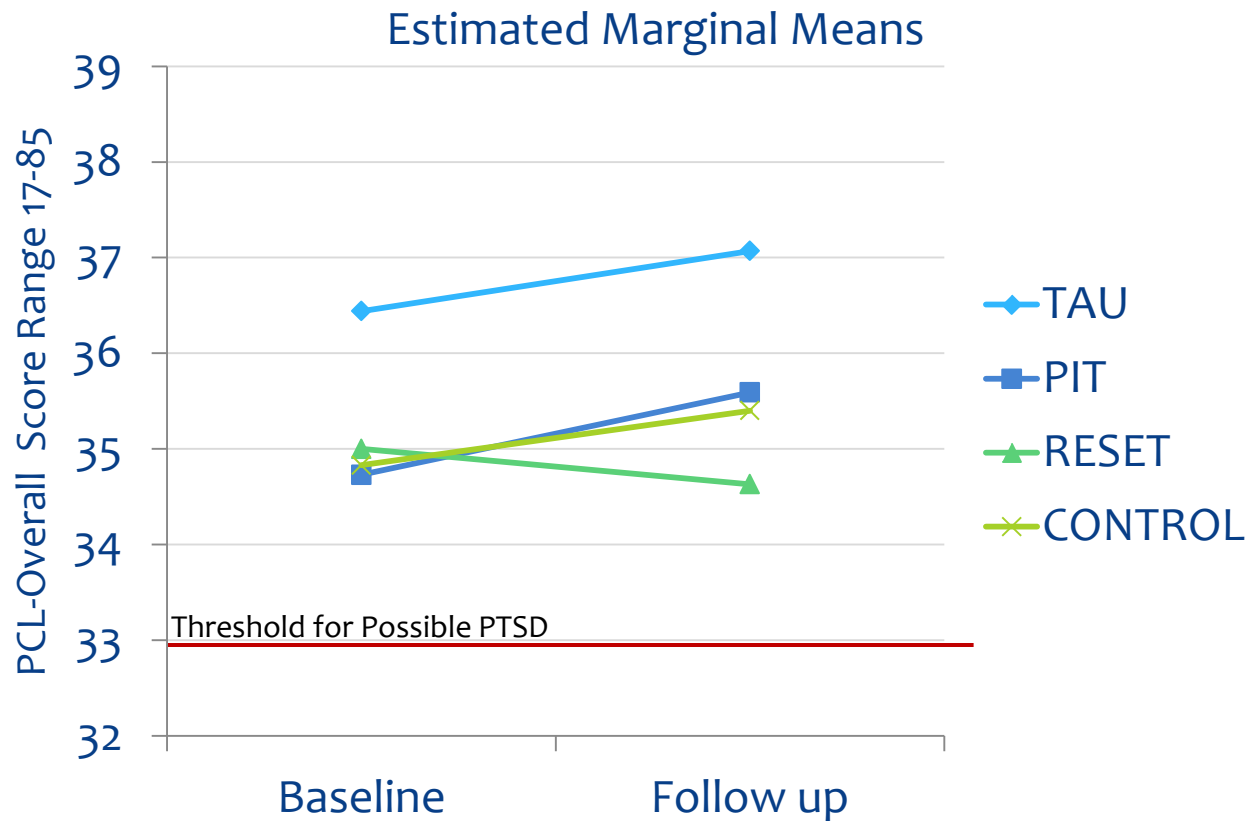
Experience of Intrusion Scale (EIS)



- A repeated measures ANOVA revealed that Soldiers' EIS scores changed significantly from baseline to follow-up [$F_{(1,697)} = 36.14, p < .01$] but the amount of change varied by training condition [$F_{(3,697)} = 8.49, p < .01$].
- While average EIS scores generally decreased over time for Soldiers in all four training conditions, those in RESET experienced the sharpest decrease from baseline to follow-up.

Results

PTSD Checklist (PCL)—Overall

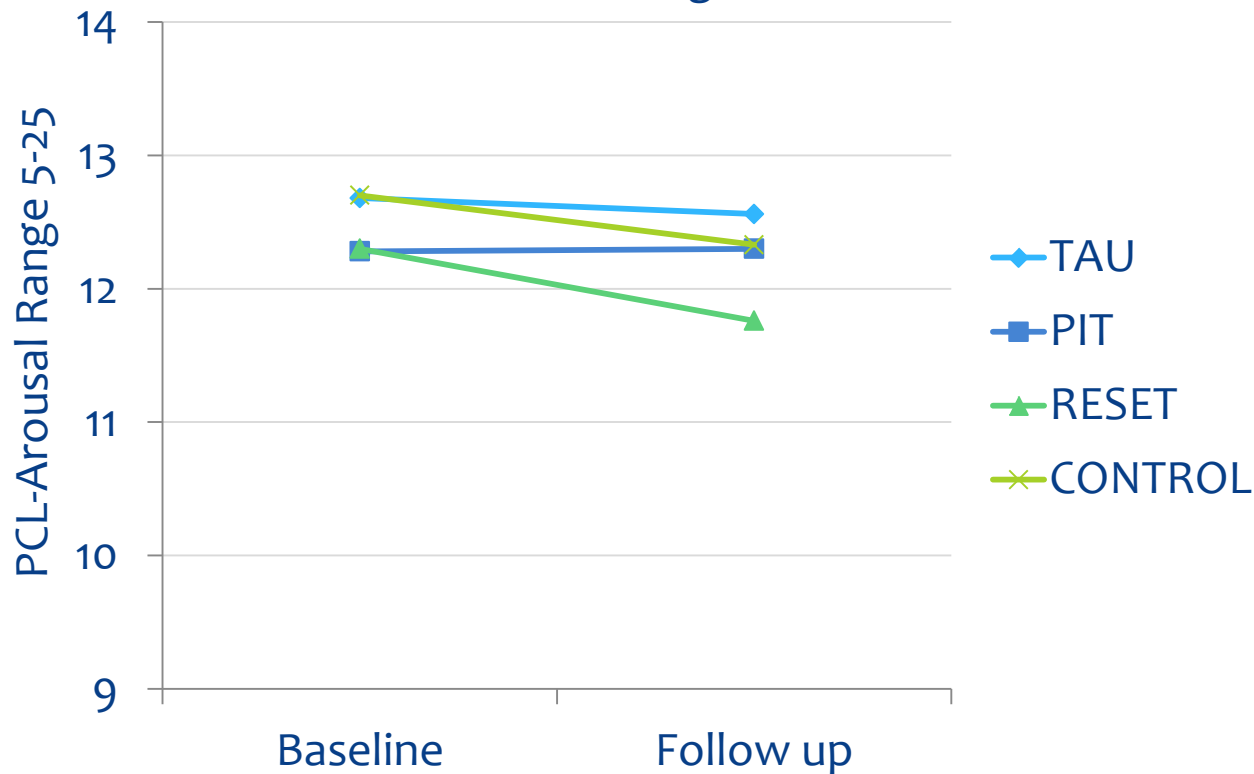


- Due to severe skewness, a multilevel model with a gamma distribution was used to test whether Soldiers in any group reported greater decreases in overall PCL scores than Soldiers in the TAU condition.
- Soldiers in RESET training showed a .37-point decrease in their overall PCL scores from baseline to follow-up, a marginally significant (1-point) improvement over Soldiers in TAU [$t = -1.68, p = .09$].

Results

PCL Arousal

Estimated Marginal Means

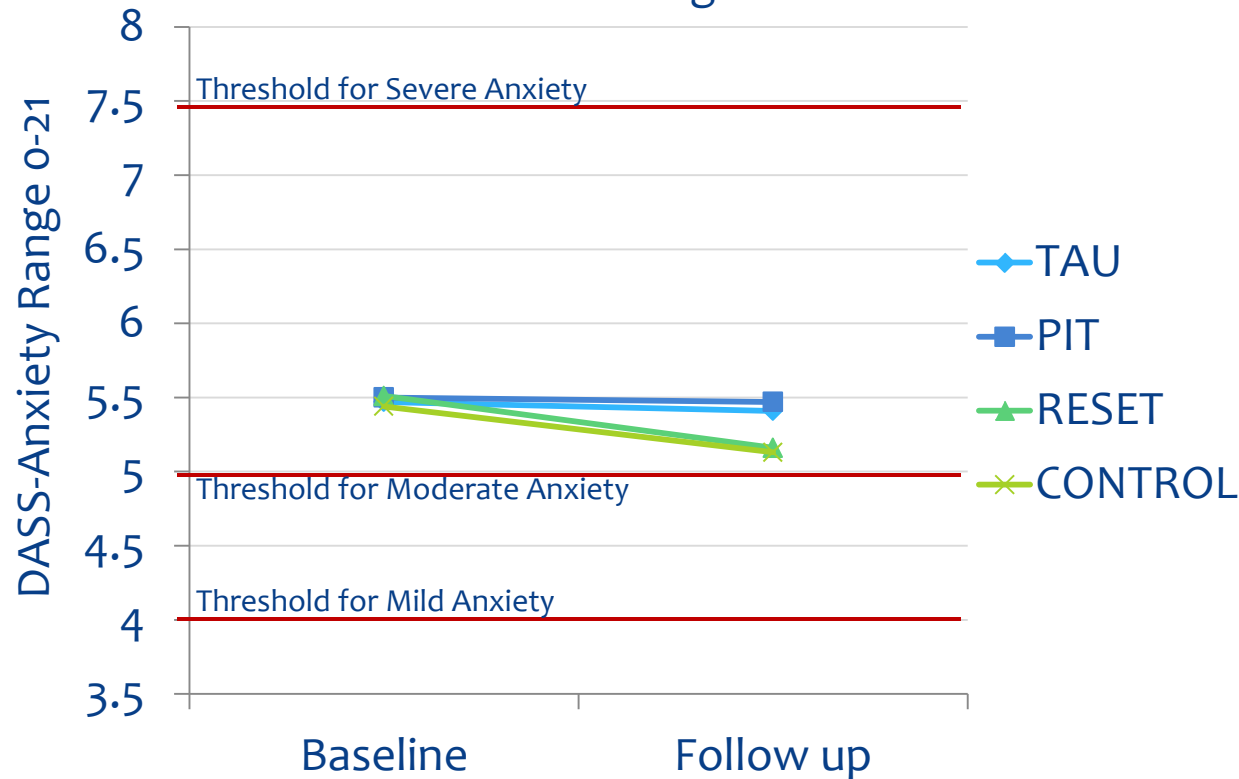


- A multilevel model with a gamma distribution was also used to test whether Soldiers in any group report greater decreases in arousal than Soldiers in the TAU condition.
- Soldiers in RESET showed a .54-point decrease in their PCL arousal scores from baseline to follow-up, a marginally significant improvement over Soldiers in the TAU condition [$t = -1.78, p = .07$].

Results

Depression, Anxiety, and Stress Scale (DASS) Anxiety Subscale

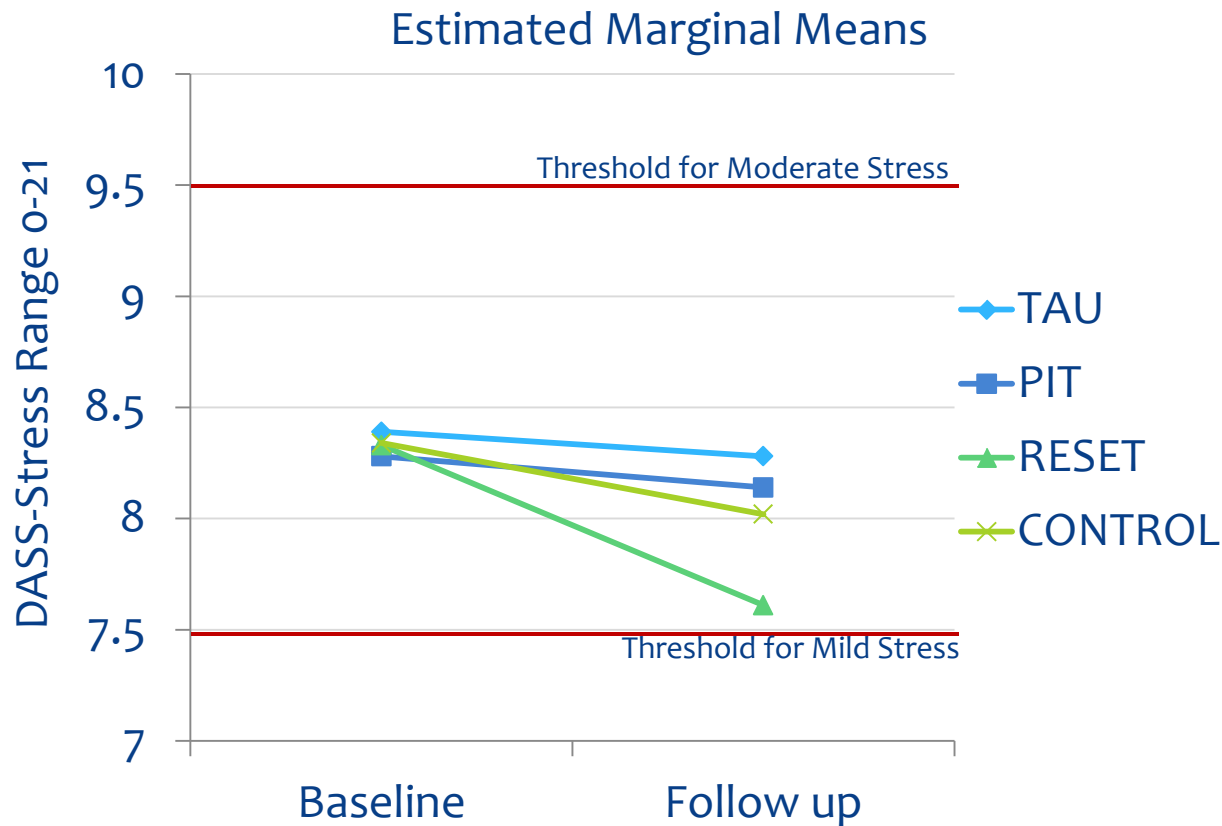
Estimated Marginal Means



- A multilevel model with a gamma distribution was also used to test whether Soldiers in any group experienced greater reductions in anxiety than Soldiers in the TAU condition.
- Soldiers in RESET showed a .35-point decrease in DASS anxiety scores from baseline to follow-up.
- Soldiers in CONTROL showed a .31-point decrease.
- Both are significant improvements over Soldiers in the TAU condition [$t = -2.15$, $p = .03$; $t = -1.93$, $p = .05$, respectively].

Results

Depression, Anxiety, and Stress Scale (DASS-21) Stress Subscale



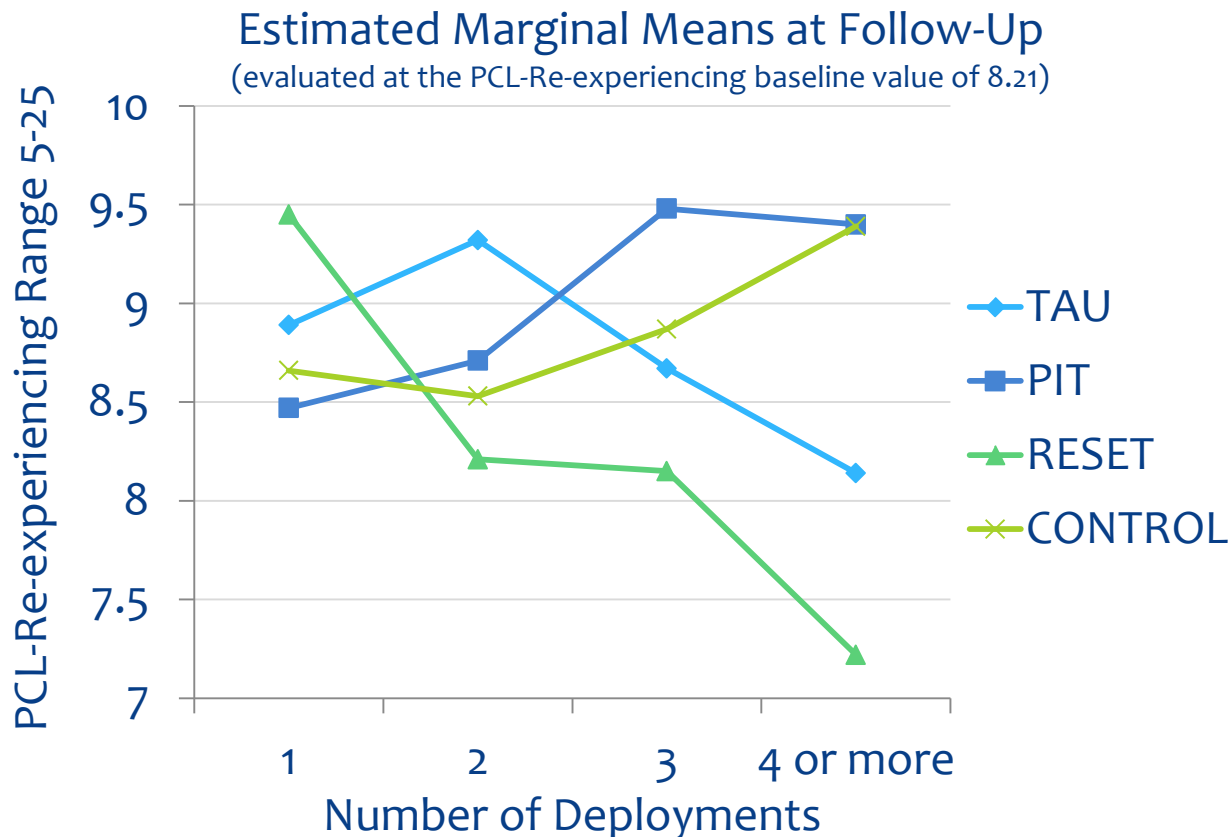
- A multilevel model with a gamma distribution was also used to test whether Soldiers in any group experienced greater reductions in stress than Soldiers in the TAU condition.
- Soldiers in RESET showed a .72-point decrease in their DASS stress scores from baseline to follow-up, a significant improvement over Soldiers in the TAU condition [$t = -2.98, p < .01$].
- The .32-point improvement for Soldiers in CONTROL was not statistically significant ($p = .27$).

Are there Soldiers who do better with certain trainings?

- * Do training effects differ based on individual difference factors (e.g., gender, number of deployments, types of experiences, etc) ?

Results

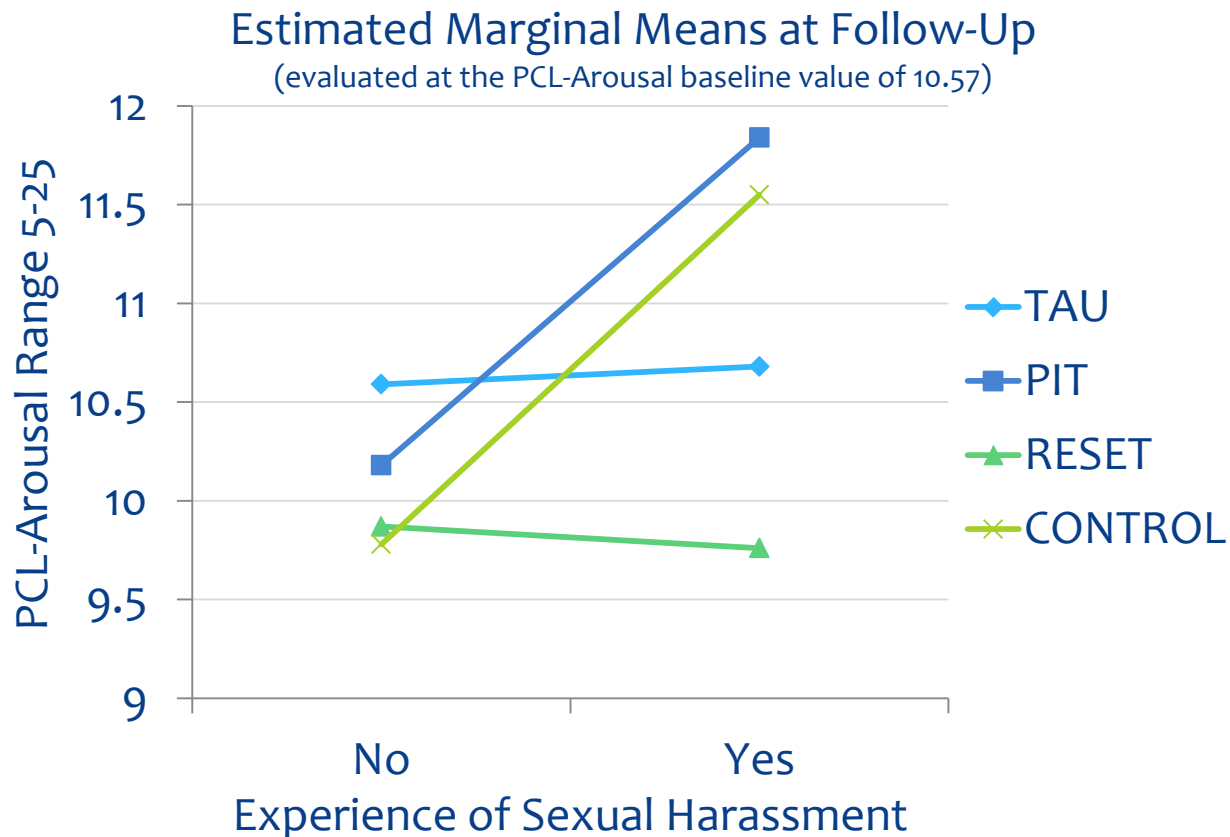
PCL Re-experiencing (Interaction of Training and Deployments)



- An ANCOVA revealed a significant interaction [$F_{(9,686)} = 1.94, p = .04$] between training condition and number of deployments for PCL – Re-experiencing scores.
- For Soldiers in the PIT and CONTROL conditions, follow-up PCL – Re-experiencing scores increased as number of deployments increased.
- The opposite was true for Soldiers in the TAU and RESET conditions, with Soldiers in RESET showing the greatest decrease across number of deployments.

Results

PCL Arousal Cluster (Interaction of Training and MST)



- An ANCOVA revealed a significant interaction [$F_{(3,691)} = 2.75, p = .04$] between training condition and a Soldier's experience with sexual harassment.
- For Soldiers in the PIT and CONTROL conditions, follow-up PCL – Arousal scores were higher for those who had experienced sexual harassment during deployment than those who had not.
- For Soldiers in the TAU and RESET conditions, follow-up PCL – Arousal scores were similar regardless their experience of sexual harassment during deployment.

Next Steps and Methodological Considerations

- Pilot testing of RESET in a military context
 - Slides, training manuals, certification of trainer checklists, and deliverables have been finalized
 - RTO to militarize training modules and for use with CSF2?
 - Combine PIT and RESET into one 60-75 min training?
 - Training and certification will be needed for MRTs or other trainers prior to any pilot test and/or implement with Soldiers
 - Experimental question: Is RESET as effective when delivered through the existing CSF2 program?

Trainers

- Four certified study trainers, all were female civilians
- Educational level:
 - Two doctoral level, licensed psychologists
 - One masters' level (MBA) spouse of a deployed Soldier
 - One master's level (psychology) research assistant
- Ethnic diversity:
 - Two Caucasian trainers
 - One African American trainer
 - One Hispanic trainer
- All trained using “Train the Trainer” methodology
- All certified via a formal certification process (see next slide)
- All monitored for fidelity by Dr. Shipherd (PI) throughout implementation
- Drs. Shipherd and Fordiani (PC) are currently willing and capable of engaging with certifying trainers

Train the trainer: Overview of method

- Certification process for PIT, CONTROL and RESET:
 - Average of two intensive, day-long educational and experiential workshops held per trainer. These intensive workshops included entire study team as well as ACT and mindfulness consultants
 - Workshops also included time for live practice, including audio and video taping of trainers' delivery of modules
 - One-on-one in person, Skype, and/or telephone coaching, 2-3x weekly for 4 to 6 weeks by PC
 - One-on-one sessions also included time for practice delivery of modules and additional audio/video taping
 - Culminated with a certification test in which trainer was rated on multiple domains and content areas by PI, PC, other certified trainers, as well as non-certified audience (e.g. research assistant).
 - 85% or higher to pass certification

Possible next steps

- * RTO translation of PIT and RESET materials into a sole 60-75 minute RESET-M for CSF2 - input from consultants (Shipherd & Fordiani).
- * Pilot test feasibility of training MRTs to deliver RESET – ideally at Fort Drum.
- * Video taped certification trials could be sent to consultants (Shipherd & Fordiani) for ratings and feedback to MRT trainers (strengths and weaknesses).
- * Evaluate efficacy of RESET-M with Soldiers learning from certified MRTs
- * Less useful is another civilian-led trial outside the existing training system. Does not offer translatability to the military.

PI: Jillian C Shipherd, Ph.D.

Org: VA Boston Healthcare System

Award Amount: \$1,220,277

Study Aims

- Develop three brief trainings consistent with current mandated deployment cycle mental health trainings
- The trainings will teach Soldiers to cope with intrusive thoughts via psychoeducation (PIT), CBT skills (CONTROL), or mindfulness-based skills (RESET).
- Phase 1: demonstrate the viability of these brief, easily implemented trainings to improve Soldiers' ability to cope with intrusive thoughts
- Phase 2: via a large RCT, demonstrate the superiority of the RESET training over Training as Usual (TAU), PIT only, and CONTROL skills training

Approach

- Phase 1: Focus Groups were held 2010-11. Soldiers were provided PIT, RESET, and CONTROL.
- These groups demonstrated feasibility and led to revisions and validation of the training materials.
- Phase 2: RCT with 1,524 Ft. Drum Soldiers randomized to 4 conditions (TAU, PIT, RESET, CONTROL).
- Results showed that PIT alone was not a helpful intervention and in some cases worsened outcomes.
- Overall, the CONTROL skills group performed well.
- RESET group outperformed CONTROL in important areas (PTSD, Depression, Anxiety).

Timeline and Cost

Activities	Award Period	1	2	3	4
Hiring of staff, regulatory approvals					
Completion of Phase 1 focus groups					
Completion of Phase 2 RCT					
Data analysis and dissemination					
Estimated Budget	\$1,399,667	\$368K	\$279K	\$573K	\$170K

Goals/Milestones

Hiring of staff, regulatory approvals, completion of protocol
Completed

Phase 1 Focus Groups: Recruitment and data collection
Completed—20 participants

Phase 2 RCT: Recruitment and data collection
Completed—1,524 participants
Quantitative and qualitative data collected

Analyses and Evaluation

Phase 1: Analyses complete, manuscripts in progress

Phase 2: Analyses in progress, manuscripts in progress

Budget Expenditure to date

Projected Expenditure: \$1,399,667 Actual Expenditure: \$1,218,393

Enhancing Post-deployment Training: Preventing PTSD by Coping with Intrusive Thoughts

Findings, implementation, and translation discussion

Jillian C. Shipherd, PhD

National Center for PTSD, Women's Health Sciences Division,
VA Boston Healthcare System, Boston, Massachusetts, and
Boston University School of Medicine, Boston, Massachusetts



ADVANCING SCIENCE AND PROMOTING UNDERSTANDING OF TRAUMATIC STRESS

RESET Study - Overview

- DoD funded project at Fort Drum
- Training enhancement (not treatment)
- Addressing intrusive thoughts (secondary prevention of PTSD?? decrease distress)
- Mindfulness based intervention
- Pilot/ development phase – not discussing here
- Randomized controlled trial – data presenting today



Introduction: Intrusive Thoughts

What are intrusive thoughts (IT)?

“Thoughts, memories, or images about any stressful experience, including deployment, that can pop into your mind repeatedly. Often these thoughts are annoying, and they might make it harder for you to concentrate or hard for you to get things done.”

Introduction: Intrusive Thoughts

- Why IT are important in general, and why are they especially important to the Army?
 - Following trauma, intrusive thoughts are expected
 - IT are associated with distress
 - Coping with IT can influence trajectory of recovery from trauma
 - 75% of a pilot sample of returning forces report IT about Iraq
 - Development of PTSD in returning Soldiers is a salient challenge for the Army; secondary prevention would be ideal (versus treatment)
 - Can Cognitive Behavioral Therapy (CBT) or Acceptance and Commitment Therapy (ACT) for PTSD be translated into skills?

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- This project is a secondary prevention program designed to assist Soldiers with managing IT
- Intent was to develop a new module to be integrated into Comprehensive Soldier Fitness
- How to best manage IT raised several experimental questions...
 - Is psychoeducation enough?
 - Do Soldiers need skills to manage IT?
 - If skills are needed, what kinds of skills? (CBT, ACT)

Development of Trainings

- Three trainings were designed:
 - Psychoeducation about Intrusive Thoughts (PIT)
 - Mindfulness skills (RESET)
 - Cognitive-behavioral skills (CONTROL)
- These three modules were tested head-to-head in an RCT against a comparison training (TAU-CSF)
- There is no waitlist control condition. Active training comparisons- larger effects needed to find significant differences
 - * 1st administration of CSF at Fort Drum

Brief overview: TAU-CSF and PIT

- Training As Usual (TAU-CSF)
 - Comprehensive Soldier Fitness (CSF)
 - We ask about when CSF was given at baseline and 1-month follow-up
 - We provided only referral information
- Psychoeducation (PIT)
 - **15-20 minute** training by study staff
 - Educates Soldiers about IT are and normalizes them
 - Identifies when IT are a problem
 - Provides referral information

RESET and CONTROL skills – each 60 mins (also had TAU-CSF and PIT)

Common intrusive or unwanted thoughts affect almost everyone
Only you can learn to control them
New skills can help you
Thoughts can be stopped
Replace your thoughts with more pleasant ones
Other activities will help distract you
Learning comes with practice: Train your skills!

Remember it is normal to have intrusive or unwanted thoughts.
Ease up on control, it doesn't always work well with thoughts.
See & accept your thoughts: You are more than just your thoughts.
Experience thoughts as they happen: Don't judge them.
Train your skills: Practice is important!

RCT: Sample

- 1,524 Fort Drum Soldiers randomized to one of four conditions (TAU, PIT, CONTROL, RESET)
 - 10th Combat Aviation Brigade
 - 3rd Brigade Combat Team
 - Other Brigades
 - 3-12 months deployment (PDHRA recruitment)
- One in-person baseline visit (off post) with multiple assessments (baseline, pre-post each training)
- Mailed one month follow-up questionnaires
- Response rate ($707/1524 = 46\%$) or 1,480 with valid mail = 48%

RCT: IT identification

Soldiers wrote down their most intrusive thought from the most recent deployment.
Although Soldiers were asked to identify deployment thoughts, skills should translate to other types of thoughts .

Injury or Combat experience

"The whistling of a mortar as well as the hum of a rocket flying over my head"

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"...images of my dead friends being wheeled to the Blackhawk that was taking their remains off the battlefield"

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"In my personal life one of my best friends was killed and I had no way of getting home to give my final respects;"

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Leadership concerns/concerns about job performance

"The careless attitude of my commander and first sergeant..."

"The thought of not being valuable to my unit"

Concerns about family

"That I would lose my son and/or my connection to him"

"Thoughts of my husband driving drunk with my daughter in the vehicle while I'm deployed"

A word cloud where the words are arranged to form the geographical shape of Afghanistan. The most prominent words, shown in larger fonts, include "deployments", "soldiers", "killing", "hit", "back", "family", "friend", "dying", "death", "attack", "mission", "worrying", "command", "platoon", "explosion", "rocket", "firing", "vehicle", "person", "incoming", "missing", "watching", "dead", "blown", "truck", "leadership", "injury", "loss", "bothersome", "bothers", "kids", "past", "experiences", "fight", "year", "leave", "good", "patrol", "troubling", "hurt", "enemies", "intrusive", "night", "sleep", "wounds", "helicopter", "combat", "helping", "legs", "severely", "new", "keep", "leader", "army", "mortars", "lost", "unit", "wife", "shot", "month", "life", "losing", "afghanistan", "guys", "buddies", "away", "injured", "blast", "felt", "knowing", "working", "caring", "badly", "team", "worried", "living", "rocket", "firing", "mission", "badly", "caring", "team", "worried". The colors used for the words are primarily shades of green, blue, yellow, and red, creating a vibrant and somewhat somber visual effect.

Demographics

Demographic Characteristics	N = 1,524	
Sex		
Male	90.6%	
Female	9.4%	
Age (in years)	28.51 mean	(SD = 6.7; min/max = 19/56; mode = 26)
Rank		
Private (PV1, PV2, PFC), Corporal, Specialist	56%	
Sergeant/Staff Sergeant	28.3%	
Sergeant (1 st Class/Master/Major)	6.1%	
Officer (1LT, 2LT, CPT, MAJ)	6.5%	
Warrant Officer (W1—W5)	3.2%	
Race		
Black/AA	14.0%	
White/Caucasian	61.8%	
Hispanic	15.6%	
Other	8.6%	
Total number of deployments	Mean=1.95	(min/max = 1/14)

Results - Analytic Plan

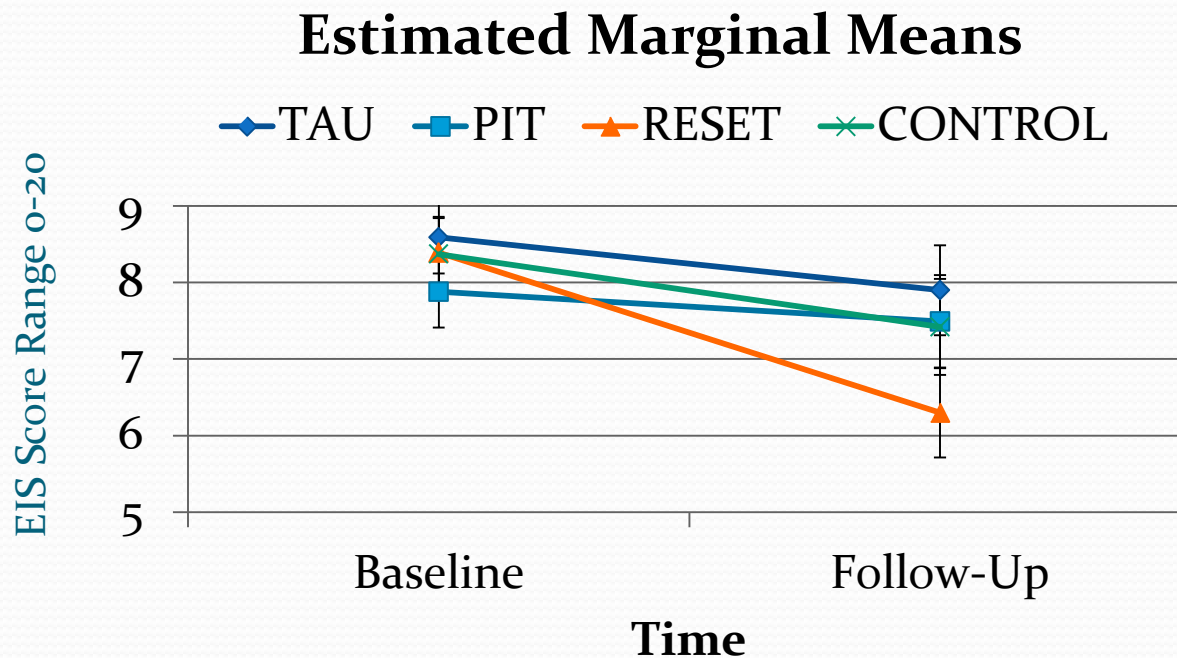
- Analyses were conducted in the intent-to-treat sample.
- First, multilevel models were used to test whether Soldiers in the RESET, CONTROL, or PIT conditions demonstrated greater changes in outcome scores from baseline to follow up compared to the TAU condition.
- Next, multiple comparisons within the multilevel model were performed to examine differences between the RESET, CONTROL, and PIT conditions on changes from baseline to follow up.

Results - overall observations

- Psychoeducation (TAU-CSF + PIT) alone does not appear to be a helpful intervention
 - Without the addition of skills, providing Soldiers only with basic information and referral information did not change their ability to cope with IT
 - In some cases, receiving psychoeducation alone appeared to have worsened outcomes
- RESET group (TAU-CSF+PIT+RESET) outperformed CONTROL in a number of important areas (EIS, PCL-Overall, PCL-Avoidance, DASS-Overall, DASS-Stress).

RESET Results

Experience of Intrusion Scale (EIS)¹

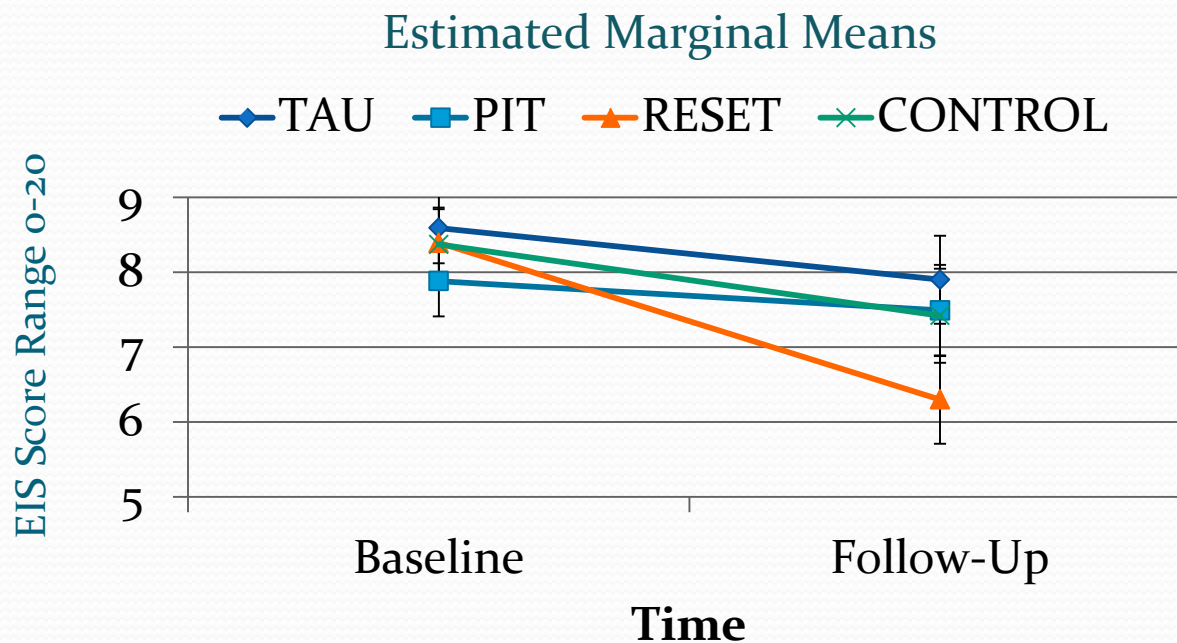


- A multilevel model revealed that Soldiers' EIS scores decreased significantly from baseline to follow-up in the TAU condition. [$t = -2.62$, $p = .009$, $d = 0.27$].
- Only Soldiers in the RESET condition had a significantly larger decrease in EIS scores from baseline to follow up when compared to TAU [$t = -3.74$, $p < .001$, $d = 0.43$].

1. Salters-Pedneault, Vine, Mills, Park, Litz, 2008

RESET Results - continued

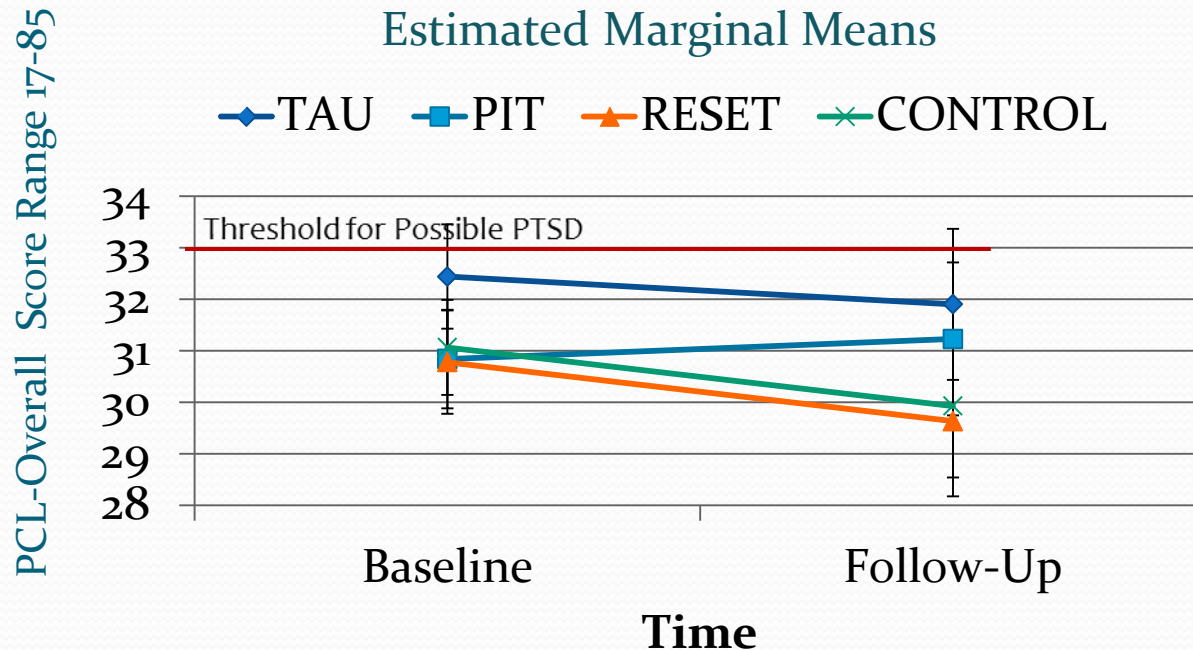
Experience of Intrusion Scale (EIS)



- Results of the multiple comparisons tests revealed that Soldiers in the RESET condition had greater decreases in EIS scores than both the PIT [$t = -4.48, p < .001, d = -0.46$] and the CONTROL [$t = -2.95, p = .002, d = -0.37$] conditions.
- The CONTROL condition did not perform significantly better than PIT [$t = -1.44, p = .08, d = -0.11$].

Results

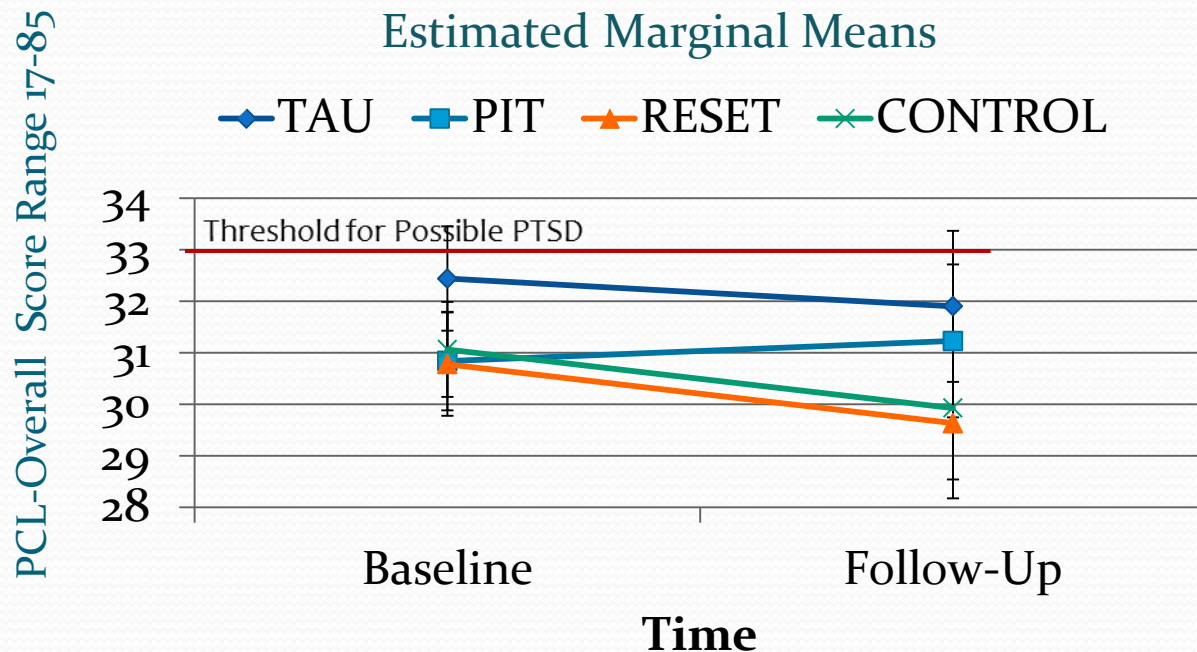
PTSD Checklist (PCL)—Overall



- Because all PCL outcomes were skewed, multilevel models with gamma distribution were used to test whether Soldiers in any group reported greater decreases in PCL outcome scores than Soldiers in the TAU condition.
- For PCL Overall, Soldiers in RESET training showed a trend toward improvement over Soldiers in TAU [$t = -1.67$, $p = .09$, $d = .09$].

Results

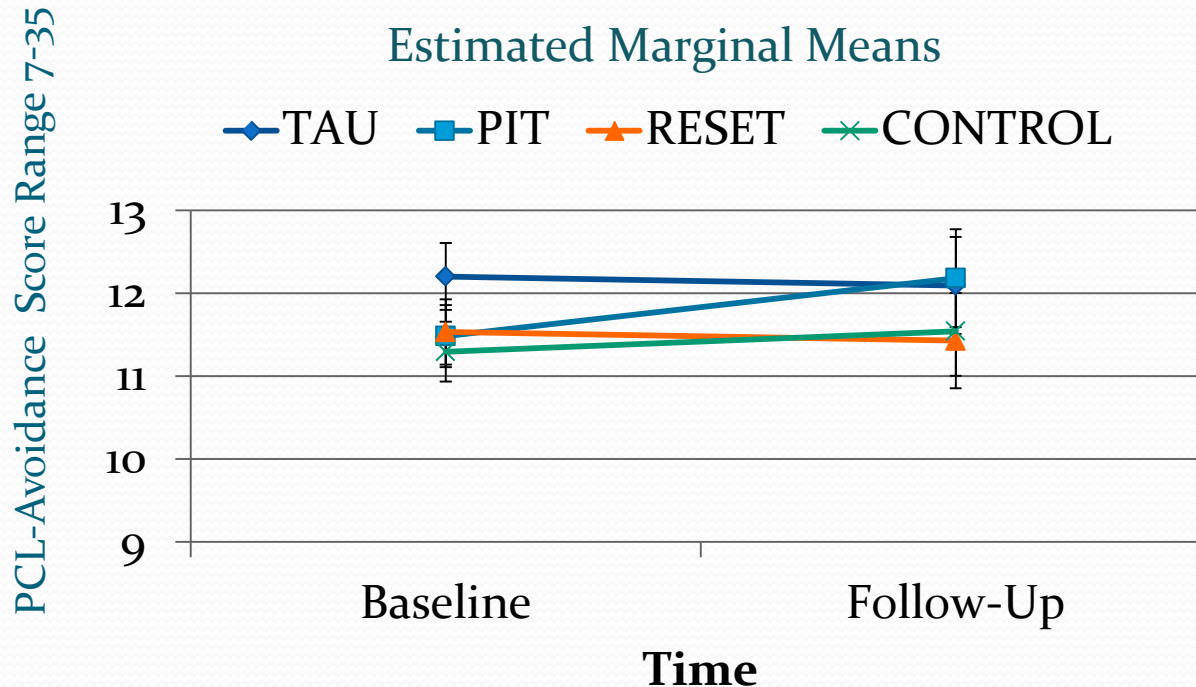
PTSD Checklist (PCL)—Overall



- Results of the multiple comparisons tests revealed that Soldiers in the RESET condition had a greater decrease in PCL Overall scores than the PIT condition [$z = -2.04$, $p = .02$, $d = -0.14$]; and a trend emerged compared to the CONTROL [$z = -1.56$, $p = .06$, $d = -0.16$] condition.
- Other comparisons were non-significant.

Results

PCL Avoidance

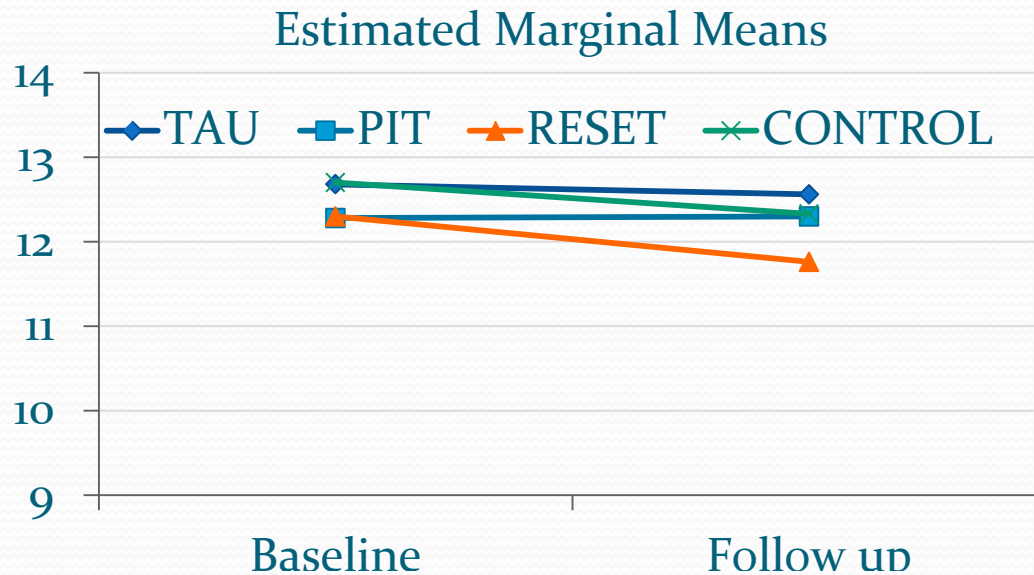


- Results of the multiple comparisons tests revealed that Soldiers in the RESET condition had a greater decrease in PCL Avoidance scores than the CONTROL condition [$z = -1.77, p = .04, d = -0.14$]; and a trend emerged compared to the PIT [$z = -1.37, p = .09, d = -0.09$] condition.
- Other comparisons were non-significant.

Results

PCL Arousal

PCL-Arousal Score Range 5-25

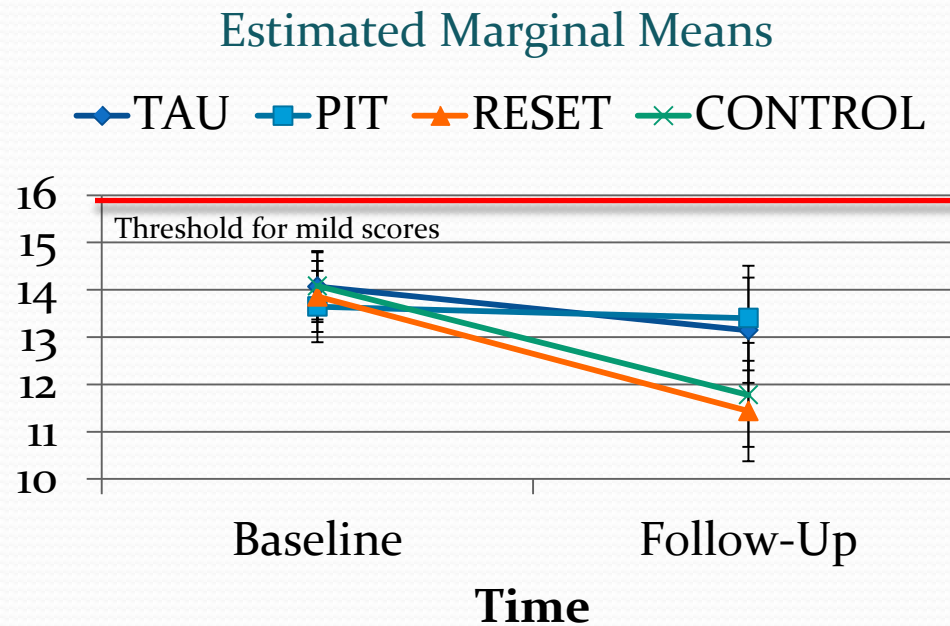


- Soldiers in RESET showed a marginally significant improvement over Soldiers in the TAU condition [$t = -1.78$, $p = .08$, $d = 0.18$].
- Soldiers in the RESET condition had a greater decrease in PCL Arousal scores than the PIT condition [$z = -2.41$, $p = .008$, $d = -0.21$]; and a trend emerged for CONTROL compared to PIT [$z = -1.57$, $p = .06$, $d = -0.08$] condition.

Results

Depression, Anxiety, and Stress Scale (DASS) Overall Scores

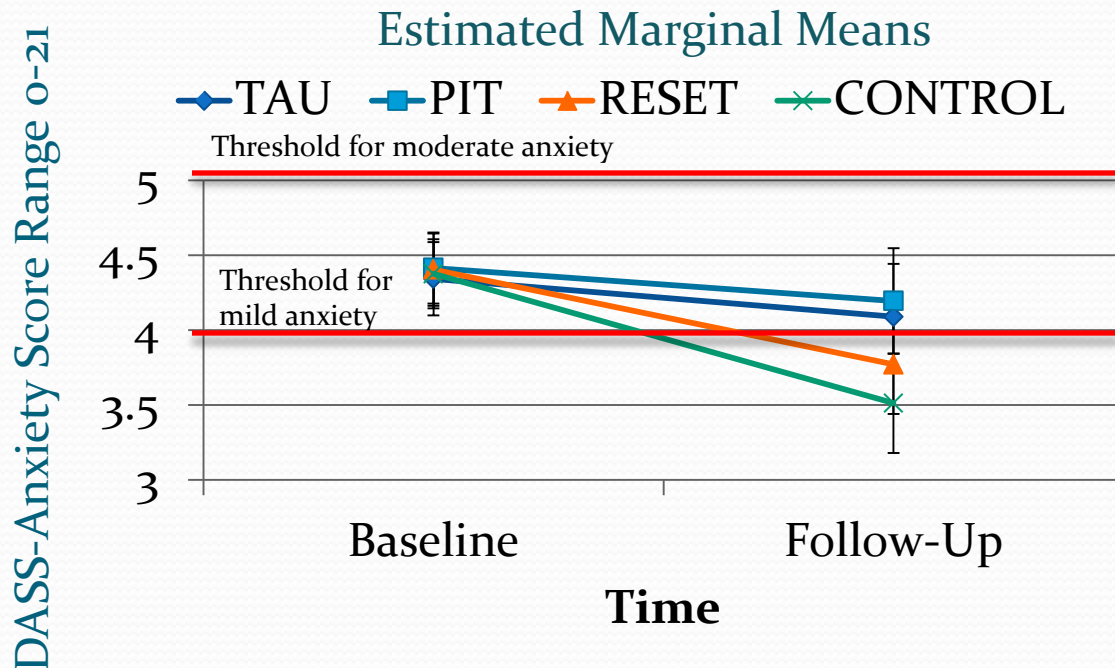
DASS-Overall Score Range 0-63



- Only RESET showed significant improvements over Soldiers in the TAU condition [$t = -4.1$, $p < .001$, $d = 0.17$].
- RESET demonstrated significantly greater reductions in DASS Overall scores than PIT [$z = -4.32$, $p < .001$, $d = -0.17$], and CONTROL [$z = -2.15$, $p = .02$, $d = -0.17$].
- In addition, CONTROL outperformed PIT [$z = -1.71$, $p = .04$, $d = -0.01$], although the effect was very small.

Results

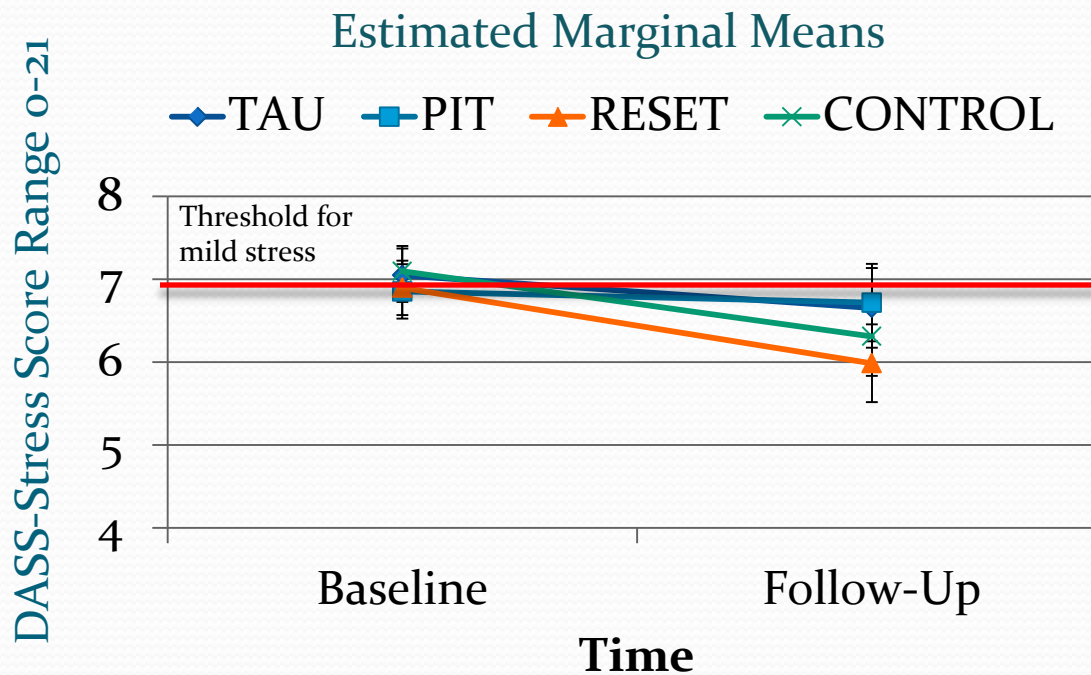
DASS Anxiety



- For the DASS Anxiety subscale, Soldiers in both the RESET and CONTROL conditions demonstrated greater improvements than Soldiers in the TAU condition [$t = -2.15, p = .03, d = 0.16$; $t = -1.93, p = .05, d = 0.06$ respectively].
- Multiple comparisons revealed that both RESET and CONTROL outperformed PIT [$z = -2.36, p = .009, d = -0.08$], and CONTROL [$z = -2.16, p = .02, d = -0.07$] on reductions in the DASS Anxiety subscale.

Results

DASS Stress



- Only Soldiers in RESET showed a significant improvement over Soldiers in the TAU condition [$t = -2.98, p = .003, d = 0.26$].
- Soldiers in the RESET condition demonstrated significantly greater reductions in symptoms than Soldiers in the PIT [$z = -2.77, p = .003, d = -0.27$], and CONTROL [$z = -1.87, p = .03, d = -0.28$] conditions.

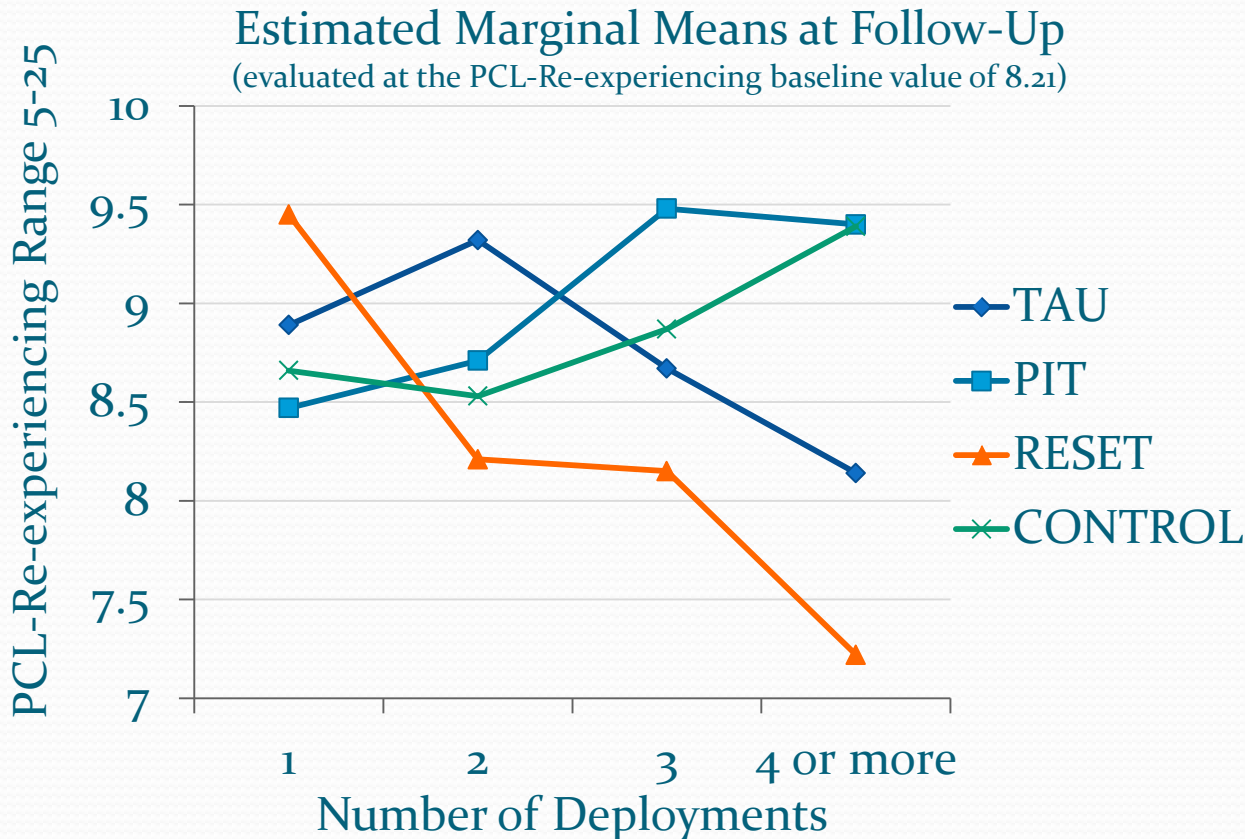
Are there Soldiers who do better with certain trainings?

- Do training effects differ based on individual difference factors (e.g., gender, number of deployments, types of experiences, etc.) ?

Results

PCL Re-experiencing

(Interaction of Training and Deployments)

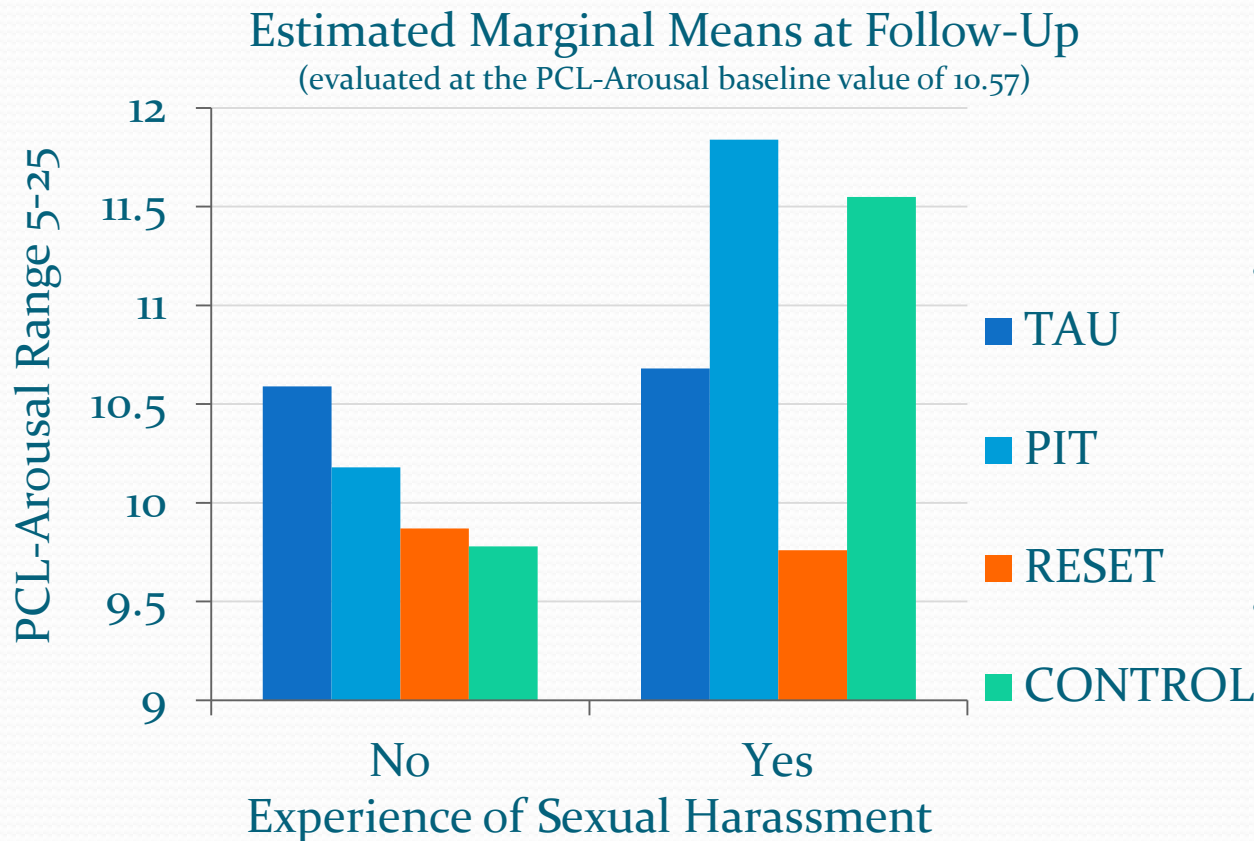


- An ANCOVA revealed a significant interaction [$F_{(9,686)} = 1.94, p = .04$] between training condition and number of deployments for PCL – Re-experiencing scores.
- For Soldiers in the PIT and CONTROL conditions, follow-up PCL – Re-experiencing scores increased as number of deployments increased.
- The opposite was true for Soldiers in the TAU and RESET conditions, with Soldiers in RESET showing the greatest decrease across number of deployments.

Results

PCL Arousal Cluster

(Interaction of Training and MST)



- An ANCOVA revealed a significant interaction [$F_{(3,691)} = 2.75, p = .04$] between training condition and a Soldier's experience with sexual harassment.
- For Soldiers in the PIT and CONTROL conditions, follow-up PCL – Arousal scores were higher for those who had experienced sexual harassment during deployment than those who had not.
- For Soldiers in the TAU and RESET conditions, follow-up PCL – Arousal scores were similar regardless their experience of sexual harassment during deployment.

RCT: Participant-Soldiers

- Soldiers in this study shared unique characteristics
 - No requirement to participate
 - Motivated to participate during off-duty hours
 - Information provided to study team kept with exception of safety issues)
 - Soldiers were paid for their time (\$100 baseline/\$25 follow up)
 - Study was conducted off-post (Ramada Inn, Watertown NY)
 - Dates of participation were January 2012 through June 2013*
 - * May 2013 was last training session – June was last follow-up

Next Steps

- September 8, 2014 Briefing to WRAIR, Education
- Translation of research to training
- Pilot testing of RESET in a military context
- Train the Trainer model
 - Combine PIT and RESET into one 60-75 min training
 - Training and certification will be needed for trainers for CSF, then test if Resilience Trainers can train to competency, and pilot test with Soldiers
 - Experimental question: Is RESET as effective when delivered through the existing CSF2 program?

RUNNING HEAD: INTRUSIVE THOUGHT TRAINING

Evaluating Post-Deployment Training for Coping with Intrusive Thoughts

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Abstract

Objective: While intrusive thoughts (ITs) are common in Soldiers post-deployment, and successful coping with ITs may predict better long-term psychological health, few elements of current programmatic post-deployment trainings have directly addressed adaptive strategies for managing intrusive thoughts. The current study explored the efficacy of a brief acceptance-based training for coping with ITs relative to a traditional cognitive-behavioral training, a psychoeducation-only training, or training as usual.

Method: Participants were 1,524 (1,372 men and 143 women) active duty U.S. Army Soldiers stationed at Fort Drum who were 3 to 12 months post-deployment.

Results: Soldiers who received acceptance-based training demonstrated larger reductions in distress and impairment related to ITs about deployment, and larger reductions in symptoms of PTSD and general psychopathology, relative to other training conditions. Participants in the change-oriented cognitive behavioral skills training also showed benefits but relatively fewer improvements than those in the acceptance-based training. Soldiers who received the psychoeducation-only training showed no benefits relative to training as usual.

Conclusions: Results suggest that very brief skills-based trainings focused on common post-deployment psychological experiences (such as ITs) may have modest benefits for Soldiers up to one month later. Findings also indicate that an acceptance-based training approach may be more beneficial than a traditional change-oriented cognitive behavioral approach for helping Soldiers manage ITs, and that training as usual and psychoeducation alone may be insufficient for helping Soldiers manage these thoughts.

This trial is registered in the Defense Technical Information Database (DTIC), Accession # 579178.

Intrusive thoughts (ITs), or the experience of unwanted, often uncued, distressing thoughts, are common in community samples, (1, 2) and particularly in individuals who have been exposed to potentially traumatic or stressful events. (3) Clinically relevant ITs occur unintentionally and recurrently, and impair functioning. (4) Posttraumatic re-experiencing of this kind via ITs is one of the hallmark features of posttraumatic stress disorder (PTSD). (5)

Exposure to potentially traumatic events is a nearly universal experience for Soldiers deployed to the Global War on Terror. (6-8) While an estimated 9-13% of GWOT Veterans have persistent PTSD symptoms, (6-8) ITs are very common among even resilient combat veterans. One recent study (9) found that GWOT Veterans reported equivalent rates of ITs of combat, irrespective of PTSD diagnostic status.

While the presence of ITs is common, they are not widely discussed and people often fear that they might be “going crazy.” (10) Negative individual responses to ITs predict poorer long term mental health and functional consequences (11) and predict chronic symptoms in Veterans. (12) However, Aikins et al. (9) determined that while the vast majority of returning Soldiers had combat related ITs, those who developed effective ways of managing distress related to ITs were less likely to be diagnosed with PTSD.

Given the ubiquity of ITs among Soldiers post-deployment, and that ITs predict poorer outcomes in individuals who have not developed effective management strategies, this study sought to assess the most effective method for reducing distress associated with ITs. Thus, this study assessed if normalization of intrusive thoughts through psychoeducation only was sufficient to reduce distress, or if targeted skills training was needed. Moreover, two separate skills-based approaches to coping with ITs were tested: short term change-based skills that

comprise the foundation of traditional cognitive behavioral therapy (CBT), and acceptance-based long term coping skills which are central to Acceptance and Commitment Therapy (ACT) (13) and other acceptance-based behavior therapies. Thus, this study examined whether psychoeducation only, psychoeducation plus CBT skills training, or psychoeducation plus acceptance-based training about ITs could benefit Soldiers both in terms of the perceived experience of ITs, and/or in terms of broader mental health consequences (i.e., PTSD and general psychological symptoms) one month later.

Coping with Intrusive Thoughts: Which Strategies are Adaptive?

The experimental and clinical research literatures have addressed various strategies for managing intrusive thoughts. One approach that has been central to cognitive-behavioral interventions is a focus on change-based strategies for coping with distressing thoughts. Traditionally these strategies have aimed at altering, controlling, or directly reducing the frequency of distressing thoughts. These skills are typically easy to teach and are consistent with an individual's innate desire to modulate negative experiences and focus attention on other activities. (14) Further, change-oriented CBT interventions have been used to manage distress across a wide spectrum of intrusive thinking. (15-17) However, it should be noted that the literature is somewhat mixed in terms of the specific skills that are most adaptive for managing these thoughts. (18) The use of some control-oriented strategies, such as thought suppression, in the wake of stressful experiences has been found to predict psychological distress. (19-22)

Given that suppression is problematic, researchers have explored the utility of the converse; acceptance-based strategies. The coping literature suggests that approach-based coping is more helpful to trauma survivors' long term functioning as compared with avoidance-based coping. (23-25) Approach-based coping is an important aspect of empirically supported

treatments for PTSD. (26) By not avoiding or suppressing thoughts and memories, it is possible to integrate these isolated and disturbing thoughts, images, and sensations into a cohesive narrative account of the event. Thus, acceptance-focused coping (rather than change-focused coping) with ITs may be particularly adaptive. Finally, at the heart of both CBT and acceptance-based interventions is psychoeducation and it is possible that this alone may be sufficient.

Study Overview and Hypotheses

This study examined how to best assist Soldiers in coping with ITs following deployment. We examined if psychoeducation about intrusive thoughts was sufficient, or if skills were also needed to improve outcomes, relative to training as usual. In addition, two types of skills were compared. Thus, four training conditions were compared: Training as Usual (TAU), Psychoeducation (PIT), Psychoeducation plus change-based CBT skills (CONTROL), and Psychoeducation plus acceptance-based skills (RESET).

We hypothesized that RESET would outperform other conditions in deployment-related IT distress, PTSD symptoms, and general psychopathology. We also hypothesized that CONTROL would outperform the PIT and TAU conditions, and that the PIT condition would outperform TAU, on all outcome measures.

Method

Participants

Participants were 1,524 (1,372 men) active duty U.S. Army Soldiers recruited from Fort Drum, in New York, USA. Inclusion criteria were: 1) age 18 years or older, 2) at least one GWOT deployment in the past 3-12 months, and 3) ability to speak and read English. See Supplemental Materials for the CONSORT diagram of participant enrollment and disposition throughout the study. Participant characteristics by condition are reported in Table 1.

Training Conditions

With the exception of the TAU condition, the trainings were presented in the form of a brief workshop. A civilian trainer presented training material assisted by a slide presentation illustrating key points. Trainings were conducted at an off post location during non-duty hours. The trainer also engaged Soldiers in experiential exercises as relevant to each of the skills-based trainings.

Participants randomized to the TAU condition completed baseline and one-month follow up assessments, but were not offered additional trainings beyond the Army's mandatory deployment cycle resilience trainings. The PIT training was 20-30 minutes focused on education about the nature of intrusive thoughts. CONTROL was a 50-60 minutes teaching traditional CBT skills to manage intrusive thoughts in the short-term. Traditional skills (e.g., thought-stopping, distraction) used in empirically supported treatments were selected for the CONTROL skills training. (15-17) RESET was 50- 60 minutes focused on promoting skills of acceptance and non-judgment for coping with ITs, and is aligned with other acceptance-based behavioral therapies (i.e., ACT; Dialectical Behavior Therapy). (13, 27)

The full manuals for each of the active trainings are available from the first author by request.

Measures

Dependent measures described below were administered to participants in all four conditions at baseline and at one-month post-training. Additional self-reports were administered at various intervals that are not included in the current report.

Intrusive Thoughts of Combat. The primary outcome measure for this study is the Experience of Intrusions Scale (EIS). (28) The EIS is a 5-item self-report measure used to assess

the frequency of intrusive thoughts as well as intensity (e.g., distress, unpredictability, unwantedness and interference) caused by the intrusions. The EIS has demonstrated good internal consistency and excellent test-retest reliability, as well as convergent validity with existing measures of intrusion. (28) For the purposes of this study, participants were asked to identify their most distressing deployment-related IT and the EIS items referred specifically to that thought.

PTSD Symptoms. The PTSD Checklist (PCL) (29) is a 17-item self-report measure of PTSD, with each item corresponding to a DSM-IV-TR symptom for PTSD. (30) Participants were asked to complete this measure in relation to the event that is “troubling you the most from your last deployment.” Responses were summed for total score and for each cluster of symptoms (reexperiencing, avoidance, and arousal). The PCL has excellent psychometric properties (29, 31) and good concordance with standardized interviewing for PTSD. (32)

General Psychological Symptoms. The Depression Anxiety Stress Scales-21 (DASS-21) (33) is a 21-item measure that distinguishes between features of depression, physiological anxiety, and psychological stress. Three subscales (depression, anxiety, and stress) were calculated by summing items in the category. This measure has strong psychometric properties and performs very well with clinical and non-clinical samples. (34-36)

Perceived Success and Credibility of Training and Skills Practice. The Expectancy of Therapeutic Outcome Questionnaire (ETO) (37) is a 4-item questionnaire that is used to assess beliefs about the perceived success and credibility of a therapeutic outcome, and is a measure that is considered the gold standard in the field. In addition to the four original questions, we augmented ETO with an additional item designed to measure the degree to which participants were likely to, or did, practice skills taught during the RESET and CONTROL trainings. This

measure was given only to the participants in the RESET and CONTROL conditions, both immediately after the training and at one month follow up.

Combat Exposure. Exposure to potentially traumatic events during Soldiers' most recent deployment was assessed using The Deployment Risk and Resilience Inventory (DRRI). (38) The DRRI is a suite of scales that can be used to assess 14 key deployment-related risk and resilience factors. The DRRI has been shown to have good internal consistency, test-retest reliability, and criterion-related validity. (38) The DRRI was administered at baseline; only the combat exposure subscale was analyzed to establish equivalence between conditions on exposure to combat.

Protocol Training and Intervention Integrity Checks

Certification checklists for each training condition were developed by the study team, with each checklist utilizing a 0-100% rating, comprised of markers of the salient elements of each training module. Formal certification in a training module required a rating of 85% or better adherence by the study staff. The Project Coordinator (PC) was certified and subsequently trained three additional trainers (a doctoral level counseling psychologist, and two master's level trainers) to certification. Each live training was supervised by a second certified trainer, and the PI traveled to the delivery site to observe and supervise live trainings on a quarterly basis in order to maintain quality and fidelity across trainers.

Procedures

This study was conducted in compliance with the institutional review boards of the VA Boston Healthcare System, US Army Medical Research and Material Command (USAMRMC), Office of Research Protections (ORP), and Human Research Protection Office (HRPO). Data were collected between January 2012 and June 2013.

Recruitment of participants was coordinated with the Fort Drum Behavioral Health team and staff at the Fort Drum Soldier Readiness Center. Study staff responded to interested Soldiers and administered a brief phone screen. Eligible Soldiers were scheduled for the in-person study visit which took place off-post during off-duty hours. Upon arrival, those consenting to participate after full study description were randomized to one of the four training conditions using a randomization table balanced for condition.

Following baseline measurement, participants in the TAU group were released. Remaining participants stayed through completion of their assigned trainings (PIT, RESET or CONTROL) and completed additional measures. Follow up questionnaires were mailed to participants one month following this initial study visit. The response rate was 707 of 1524 (46%) or 1,480 with a valid mailing address (48%). This response rate is on par with other studies in military populations post-deployment. (39)

Results

Analytic Plan

To test the hypotheses, multi-level regression models on intent-to-train samples were computed in SPSS. The restricted maximum likelihood estimator (REML) was used to calculate the parameters. Item-level missing data was imputed with the mean if the Soldier had responses for 75% or more of the other items. Significance levels were computed based on a one-tailed p value in the direction of the hypotheses. Effect size was calculated using Cohen's d .

Preliminary Analyses

Variables were examined for violation of assumptions of normality. PCL Overall scores, PCL subscale scores (Arousal, Avoidance, and Re-experiencing), DASS Overall scores, and DASS subscale scores (Anxiety, Stress, and Depression) demonstrated significant positive

skewness. We used gamma distribution to address skewness in the PCL and DASS models. The multilevel models with gamma distribution were conducted with `glmer` function in `lme4` package in R. (40) The R package `lme4` does not provide degrees of freedom; for these analyses, a Wald z-test was performed to calculate p values.

Participants did not differ significantly on any of the participant characteristic variables (results reported in Table 1). For key study variables, none of the conditions differed significantly at baseline ($F_s < 1.65$, $p_s \geq .174$, $\eta_p^2 \leq .003$), although a non-significant trend of very small effect for PCL avoidance emerged ($F(3,1521) 2.31$, $p = .07$, $\eta_p^2 = .005$).

Primary Outcome

The raw means and standard deviations for the key study variables for the full sample and by condition at baseline and follow-up are reported in Table 2.

EIS. A graph depicting EIS scores by condition at baseline and follow up (based on estimated marginal means derived from the multi-level model) is found in Figure 1. Results of the multi-level regression comparisons between conditions across time are found in Table 3. Soldiers in the RESET condition experienced a significantly larger decrease in EIS scores from baseline to follow up compared to TAU. Soldiers in the PIT and CONTROL conditions did not differ significantly across time from TAU. In addition, Soldiers in the RESET condition showed significantly greater decreases on the EIS from baseline to follow up than both the PIT and CONTROL conditions.

Secondary Outcomes

PCL. Multi-level models were computed comparing the conditions on PCL Overall scores as well as the PCL Re-experiencing, PCL Avoidance, and PCL Arousal subscales. Results

of the multi-level regression comparisons between conditions across time are found in Table 3.

No significant differences emerged between conditions on PCL Re-experiencing.

Participants in the RESET condition demonstrated a significantly larger decrease in PCL Overall scores compared to those in the TAU and PIT conditions, and a non-significant trend emerged in the comparison between the RESET and CONTROL condition ($p = .06$), with RESET outperforming CONTROL.

No condition differed significantly from TAU for PCL Avoidance, however, participants in the RESET condition showed significantly larger reductions in PCL Avoidance than those in the CONTROL condition, and a non-significant trend emerged for the comparison between RESET and PIT, with greater reductions in the RESET condition participants ($p = .085$).

For PTSD Arousal, participants in the RESET condition showed greater reductions in PCL arousal than those in the TAU and PIT conditions. In addition, a non-significant trend emerged for the comparison between CONTROL and PIT, with CONTROL participants demonstrating larger decreases than those in the PIT condition ($p = .059$).

DASS. Multi-level models were computed comparing the conditions on DASS Overall scores as well as the DASS Depression, DASS Anxiety, and DASS Stress subscales. Results of the multi-level regression comparisons between conditions across time are found in Table 3. No significant differences emerged between conditions on DASS Depression.

Participants in the RESET condition demonstrated a significantly larger decrease DASS Overall scores relative to participants in the TAU, PIT, and CONTROL conditions. In addition, participants in the CONTROL condition showed a significantly greater reduction in DASS Overall scores than those in the PIT condition, and a non-significant trend emerged for the comparison between the CONTROL and TAU conditions ($p = .068$). For DASS Anxiety,

participants in the both the RESET and CONTROL conditions had significantly larger reductions in scores from baseline to follow up relative to the TAU and PIT conditions. For DASS Stress, participants in the RESET condition showed greater reductions in scores than those in the TAU, PIT, and CONTROL conditions.

Therapeutic Expectancy and Skills Practice

To test whether observed differences between the RESET and CONTROL conditions could be attributed to differences in therapeutic expectancy and satisfaction, we conducted a one-way ANOVA comparing ETO scores at post-training. Results revealed no significant differences between conditions on ETO scores ($F(1,752) 0.88, p = .35$).

We also examined whether observed differences between the RESET and CONTROL conditions may be attributed to differences in frequency of practicing skills. We explored differences between these two conditions on responses to the practice item of the ETO. A chi square analysis revealed no significant difference in practice between the two conditions at follow-up $\chi^2 = 4.71, p = .45$.

Discussion

The findings supported that both skills-based trainings (CONTROL and RESET) were beneficial to Soldiers, whereas psychoeducation alone did not improve outcomes over Training as Usual. RESET in particular offered promising results as a brief, targeted acceptance-based behavioral training program for helping Soldiers manage ITs post-deployment. Soldiers who received RESET training experienced a significantly greater reduction in the frequency, intensity, and impairment associated with their ITs (measured via EIS scores) than those in the three comparison conditions.

The benefits of RESET may extend beyond a direct impact on distress associated with ITs. RESET also outperformed the comparison conditions with modest reductions in both PTSD and general psychopathology symptoms. RESET outperformed the TAU and PIT conditions on overall PTSD symptoms. The impact of RESET was most evident for PTSD arousal symptoms. Participants in the RESET condition also showed greater reductions in DASS Overall scores than participants in the three comparison conditions. This advantage was most evident for DASS Stress scores.

As predicted, RESET demonstrated benefits relative to the active skills-based comparison condition (CONTROL) on several outcomes (EIS scores, DASS Overall and Stress scores, and a trend for PTSD Overall score). These findings cannot be explained by differences in participants' expectancies about the usefulness of the trainings or by differences in skills practice between training and follow up. It may be that, in terms of managing intrusive thoughts and coping with general stress and PTSD symptoms, acceptance-based strategies are particularly useful relative to more traditional CBT change-oriented skills.

There was less support for our hypothesis that participants in the CONTROL condition would receive greater benefits than those in the PIT and TAU conditions. While CONTROL outperformed PIT and TAU on three of the secondary outcomes (PTSD Overall scores, PTSD Arousal, and DASS Overall), no other significant differences between CONTROL, PIT and TAU emerged. CONTROL was developed from a set of cognitive-behavioral techniques for managing intrusive thoughts that make up aspects of several empirically-supported cognitive behavioral treatments. (15-17) Our findings suggest that traditional cognitive-behavioral skills training with strong change or control-oriented components may not convey significant benefits in terms of helping Soldiers manage ITs post-deployment beyond current Army training.

No support was found for the hypothesis that PIT would outperform the TAU condition. In fact, Soldiers receiving psychoeducation about ITs did not receive benefits relative to TAU on any of the outcome measures. This finding is surprising and interesting, and has implications for the trainings we provide to Soldiers post-combat. Very few studies have isolated psychoeducation as a component of post-deployment training (or as a component of treatments in general), but it has long been assumed within the cognitive-behavioral tradition that psychoeducation is a necessary component of intervention that may convey benefits alone. More work on the necessity/sufficiency of psychoeducation in prevention is warranted given these results.

Only modest controlled effect sizes were observed. The largest effects (approaching medium effect sizes) were for our primary outcome measure, the EIS, which directly measured the impact of the training on the Soldiers' experience of ITs. That said, the trainings provided to our participants were extremely brief, and effects were measured a full month later (with no reminders to practice or support from a trainer in between). Additionally, all cases were comparisons of active trainings (including TAU, as Soldiers in this condition received other mandatory post-deployment trainings). In light of these parameters, small to medium effects were expected, and demonstrate that even a very brief training can provide modest but lasting benefits to participants.

While efforts were made to balance the active trainings (RESET and CONTROL) for time, content of training, number of skills taught, etc., comparisons between RESET and CONTROL and the other two conditions (PIT and TAU) do not control for factors such as face-to-face time spent with study trainers and expectancy. That said, the RESET and CONTROL

interventions were equivalent in contact time but RESET outperformed CONTROL on several outcomes, suggesting that contact time does not fully explain the results.

There are limitations in terms of the external validity of this study because volunteer Soldiers participated off-post during after duty hours. Thus, this sample may not be comparable to outcomes found in programmatic trainings which are mandatory (i.e., provided to Soldiers regardless of interest, by Army personnel, on duty hours, and on post). The participants had relatively low levels of distress at baseline. Average PTSD and psychopathology scores for participants in this study were subclinical, consistent with the literature on resiliency of Soldiers post-combat. (7) Further work is needed to explore whether brief trainings like RESET may convey benefits to individuals with clinical PTSD or other sequelae of trauma.

Despite these limitations, this study has several potential implications for the use of brief, targeted post-deployment trainings with Soldiers returning from combat. First, even brief trainings may provide lasting benefits to Soldiers in terms of managing normative post-traumatic psychological experiences (e.g., ITs). In addition, acceptance-based approaches may have the broadest benefits to Soldiers for managing intrusive thoughts. Results also call into question the sufficiency of providing Soldiers with psychoeducation without also conveying skills for managing distressing post-deployment experiences. Future work is needed to understand whether similar brief, targeted trainings can provide benefits for other common post-deployment problems, and whether such trainings will be effective if provided on a programmatic basis or to individuals with clinical levels of symptoms.

Table 1.

Participant Characteristics by Condition

Variable	Condition								Statistic (χ^2) or F	p	
	TAU (N = 385)		PIT (N = 384)		CONTROL (N = 377		RESET (N = 378)				
	N or M	% or SD	N or M	% or SD	N or M	% or SD	N or M	% or SD			
Gender											
Women	32	8.4	34	8.9	40	10.6	37	9.9	1.31	.727	
Men	350	91.6	347	91.1	337	89.4	338	90.1			
Age	28.39	6.45	28.23	6.82	29.00	7.02	28.48	6.58	0.844	.470	
Race/Ethnic											
Hispanic/ African Am.	23	6.0	20	5.2	12	3.2	22	5.8	20.2	.685	
Hispanic/ White	41	10.6	45	11.8	38	10.2	36	9.5			
Native Am.	7	1.8	4	1.0	5	1.3	2	0.5			
Asian	11	2.9	12	3.1	11	2.9	9	2.4			
Black/AA	44	11.4	63	16.5	52	13.9	54	14.3			

Intrusive thought training 16										
Pacific Is.	6	1.6	3	0.8	7	1.9	5	1.3		
Mid. East	0	0	0	0	2	0.5	1	0.3		
Multi-Ethnic	15	3.9	8	2.1	13	3.5	9	2.4		
White	238	61.8	227	59.4	234	62.6	239	63.4		
Rank										
Enlisted (E1-E9)	340	88.5	355	92.4	344	92.0	331	88.5	6.8	.335
Warrant	15	3.9	8	2.1	12	3.2	14	3.7		
Officer	29	7.6	21	5.5	18	4.8	29	7.8		
Combat Exposure	9.65	6.97	8.63	6.78	9.41	6.69	9.39	7.22	1.57	.196
# Deploy	1.92	1.30	1.97	1.42	1.99	1.38	1.93	1.20	0.191	.902
Education										
Some high school	1	0.3	0	0.0	1	0.3	1	0.3	7.90	.980
High school graduate	126	32.7	129	33.6	111	29.4	114	30.5		
Vocational training	13	3.4	11	2.9	13	3.4	15	4.0		
Some college	189	49.1	189	49.2	203	53.8	186	49.7		

College graduate	37	9.6	38	9.9	31	8.2	38	10.2
Some graduate school	7	1.8	7	1.8	11	2.9	9	2.4
Graduate degree	12	3.1	10	2.6	7	1.9	11	2.9

Note. Hispanic/African Am. = Hispanic or Latino and African American, Hispanic/White = Hispanic/Latino and Caucasian, Native Am. = American Indian or Alaskan Native, Asian = Asian or Asian American or East Indian, Black/AA = Black or African American, Pacific Is. = Hawaiian or Other Pacific Islander, Mid. East = Middle Eastern, White = White/Caucasian, Warrant = Warrant Officer, High school graduate = high school graduate or GED, Vocational training = vocational or technical training, Some college = some college or associate's degree, college graduate = four-year college graduate, some graduate school = some graduate or professional school, Graduate degree = graduate or professional degree, Combat Exposure = Scores on Deployment Risk and Resiliency Inventory WRAIR Combat Exposure Scale.

Table 2. Raw Means and SDs for Key Study Variables by Condition for Each Time Point and Results of ANOVA Comparing Differences by Condition at Baseline.

Variable	Condition								F	p
	TAU (N = 385)		PIT (N = 384)		CONTROL (N = 377)		RESET (N = 378)			
	Baseline M(SD)	1-month M(SD)	Baseline M(SD)	1-month M(SD)	Baseline M(SD)	1-month M(SD)	Baseline M(SD)	1-month M(SD)		
EIS	7.99 (4.70)	7.50 (4.48)	7.51 (4.66)	7.27 (4.27)	7.25 (4.43)	6.64 (4.23)	8.13 (4.77)	6.08 (4.67)	1.43	.233
PCL										
Overall	31.70 (13.85)	32.44 (14.39)	30.62 (13.40)	32.15 (14.05)	28.69 (11.28)	30.11 (12.53)	30.32 (13.82)	29.97 (14.03)	1.65	.175
Arousal	11.05 (4.86)	10.92 (4.94)	10.45 (4.72)	10.55 (4.99)	10.29 (4.52)	10.07 (4.71)	10.51 (5.07)	9.75 (5.00)	1.34	.259
Avoid	12.15 (5.92)	12.43 (6.23)	11.92 (5.80)	12.71 (6.08)	10.76 (4.82)	11.67 (5.01)	11.48 (5.89)	11.66 (5.98)	2.34	.072
Re-exper	8.50 (4.35)	9.09 (4.64)	8.25 (4.21)	8.89 (4.11)	7.64 (3.30)	8.37 (3.79)	8.33 (4.36)	8.56 (4.01)	1.66	.174
DASS										
Overall	14.04 (12.56)	13.71 (12.72)	14.20 (11.53)	13.95 (11.86)	12.18 (10.65)	11.88 (11.03)	13.65 (11.57)	11.79 (12.26)	0.17	.916
Depression	4.11 (4.79)	4.07 (4.83)	4.21 (4.31)	4.17 (4.48)	3.43 (4.24)	3.54 (4.35)	3.79 (4.40)	3.49 (4.49)	0.56	.641

Anxiety	3.62 (4.17)	3.60 (4.35)	3.58 (3.91)	3.65 (3.88)	2.94 (3.35)	2.75 (3.36)	3.41 (3.65)	3.19 (4.13)	0.02	.996
Stress	6.31 (5.00)	6.04 (4.93)	6.41 (4.59)	6.13 (4.74)	5.81 (4.36)	5.60 (4.64)	6.45 (5.06)	5.11 (4.66)	0.13	.944

Note. EIS = Experience of Intrusions Scale, PCL = Posttraumatic Stress Disorder Checklist, DASS = Depression, Anxiety, Stress Scales – 21 Item Version.

Table 3. Multilevel Regression Effects of Condition by Time for Primary and Secondary Outcomes

	<i>B</i>	<i>t or z*</i>	<i>Cohen's d</i>	<i>p</i>	<i>Power</i>
Experience of Intrusions Scale					
PIT vs. TAU	0.30	0.80	0.08	.788	0.00
CONTROL vs. TAU	-0.26	-0.67	-0.04	.251	0.02
RESET vs. TAU	-1.39	-3.74	-0.42	<.001	0.95
CONTROL vs. PIT	-0.56	-1.44	-0.11	.075	0.08
RESET vs. PIT	-1.70	-4.48	-0.46	<.001	0.97
RESET vs. CONTROL	-1.14	-2.95	-0.37	.002	0.84
PTSD Checklist Overall					
PIT vs. TAU	0.23	0.36	0.06	.642	<0.01
CONTROL vs. TAU	-0.06	-0.10	0.07	.462	<0.01
RESET vs. TAU	-1.00	-1.67	-0.09	.047	0.06
CONTROL vs. PIT	-0.28	-0.45	<0.01	.325	0.01
RESET vs. PIT	-1.23	-2.04	-0.14	.021	0.14
RESET vs. CONTROL	-0.94	-1.56	-0.16	.06	0.19

PTSD Checklist Avoidance

PIT vs. TAU	0.32	1.15	0.09	.876	<0.01
CONTROL vs. TAU	0.43	1.55	0.14	.939	<0.01
RESET vs. TAU	-0.05	-0.20	<0.01	.421	0.01
CONTROL vs. PIT	0.11	0.38	0.04	.647	<0.01
RESET vs. PIT	-0.38	-1.37	-0.09	.085	0.06
RESET vs. CONTROL	-0.48	-1.77	-0.14	.038	0.13

PTSD Checklist Arousal

PIT vs. TAU	0.14	0.56	0.05	.712	<0.01
CONTROL vs. TAU	-0.25	-0.99	-0.03	.162	0.02
RESET vs. TAU	-0.42	-1.78	-0.17	.037	0.23
CONTROL vs. PIT	-0.38	-1.57	-0.08	.059	0.04
RESET vs. PIT	-0.56	-2.41	-0.21	.008	0.34
RESET vs. CONTROL	-0.18	-0.75	-0.14	.228	0.14

PTSD Checklist Re-experiencing

PIT vs. TAU	0.08	0.43	<0.01	.665	0.01
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DASS Overall	CONTROL vs. TAU	0.02	0.10	0.06	.539	<0.01
	RESET vs. TAU	-0.06	-0.32	-0.08	.373	0.05
	CONTROL vs. PIT	-0.06	-0.32	0.05	.375	<0.01
	RESET vs. PIT	-0.15	-0.74	-0.07	.229	0.04
	RESET vs. CONTROL	-0.08	-0.41	-0.13	.340	0.12
DASS Depression	PIT vs. TAU	0.09	0.30	<0.01	.620	0.01
	CONTROL vs. TAU	-0.59	-1.49	-0.01	.068	0.01
	RESET vs. TAU	-1.62	-4.11	-0.17	<.001	0.20
	CONTROL vs. PIT	-0.67	-1.71	-0.01	.044	0.01
	RESET vs. PIT	-1.71	-4.32	-0.17	<.001	0.20
	RESET vs. CONTROL	-1.03	-2.15	-0.17	.016	0.21
DASS Depression						
	PIT vs. TAU	-0.05	-0.38	-0.01	.353	0.01
	CONTROL vs. TAU	-0.13	-1.03	0.02	.152	<0.01
	RESET vs. TAU	-0.13	-1.07	-0.07	.143	0.05

DASS Anxiety	CONTROL vs. PIT	-0.08	-0.65	0.03	.259	<0.01
	RESET vs. PIT	-0.08	-0.67	-0.06	.251	0.03
	RESET vs. CONTROL	-0.00	-0.01	-0.10	.497	0.07
	PIT vs. TAU	0.03	0.27	0.01	.605	0.01
	CONTROL vs. TAU	-0.25	-1.93	-0.06	.027	0.03
	RESET vs. TAU	-0.29	-2.14	-0.07	.016	0.04
	CONTROL vs. PIT	-0.29	-2.16	-0.07	.015	0.04
	RESET vs. PIT	-0.32	-2.36	-0.08	.009	0.05
	RESET vs. CONTROL	-0.03	-0.23	-0.01	.409	0.01
	PIT vs. TAU	-0.03	-0.18	0.00	.427	0.01
DASS Stress	CONTROL vs. TAU	-0.21	-1.11	0.01	.133	0.01
	RESET vs. TAU	-0.61	-2.98	-0.26	.001	0.54
	CONTROL vs. PIT	-0.17	-0.92	0.01	.179	0.01
	RESET vs. PIT	-0.57	-2.77	-0.27	.003	0.54

RESET vs. CONTROL	-0.40	-1.87	-0.28	.031	0.57
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Note. TAU = Treatment as Usual, PIT = Psychoeducation on Intrusive Thoughts, CONTROL = CBT Training, RESET = Acceptance-Based Training. DASS = Depression, Anxiety, Stress Scales – 21-item Version. *All PCL and DASS models were conducted with gamma regression to address skewness; these analyses produce a z rather than a t score.

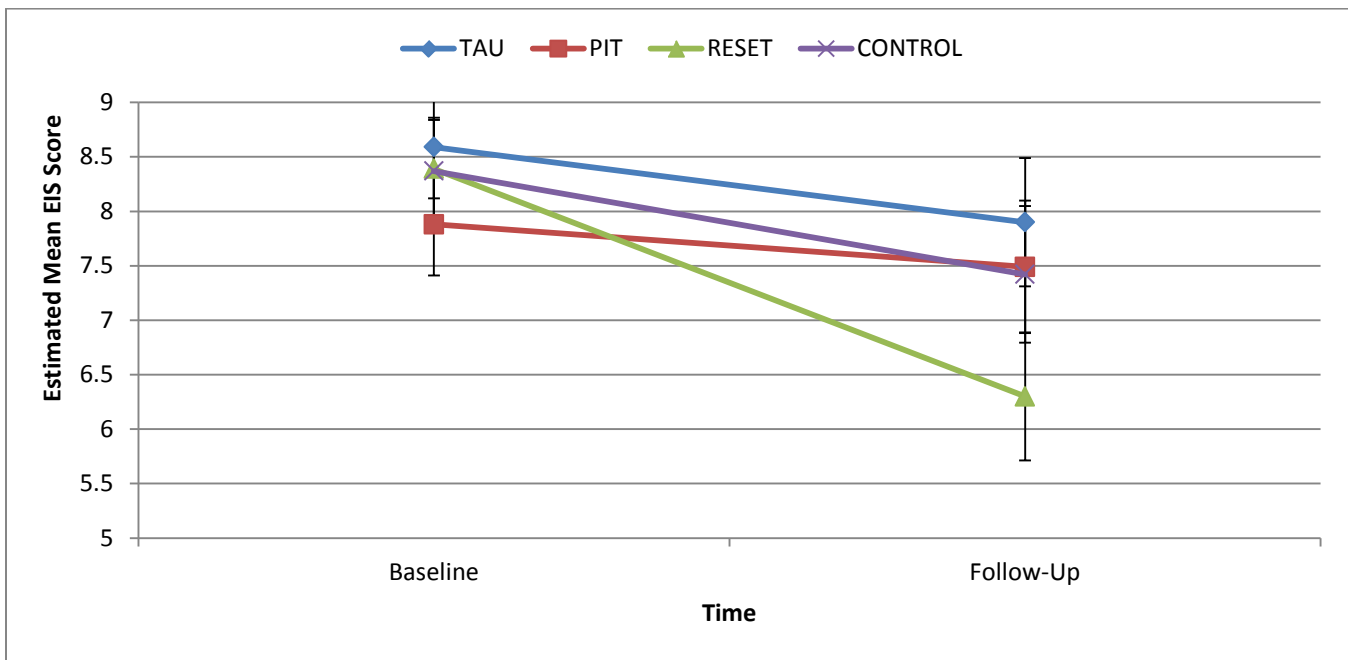


Figure 1. Change in Experience of Intrusions Scale (EIS) Estimated Marginal Means by Training Group from Baseline to Follow-Up with 95% Confidence Intervals.

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