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TITLE: Combat Stress and Substance Use Intervention

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14. ABSTRACT

The objective of the study is to evaluate the effectiveness of two Web-based brief interventions (BIs) for reducing stress and substance use among post-deployment active duty and National Guard military personnel. The interventions are designed to (1) educate personnel about the use of substances as a poor coping mechanism for combat and operational stress reactions (COSRs) and (2) boost resilience to COSRs, thereby reducing the tendency to self-medicate through substance use. These data are vital to understanding additional steps the military might take in addressing issues of behavioral health, such as developing new, more broadly focused treatment interventions, and starting additional prevention approaches and programs. Volunteers will complete a brief Web assessment for alcohol use and current stress reactions. Participants are randomly assigned to one of three intervention conditions: Wait-list control, Stress BI, or Stress plus Substance Use BI. A Web-based intervention provides a private and convenient approach and should facilitate access to care by reducing the stigma and common barriers associated with seeking treatment.

15. SUBJECT TERMS
Combat stress, substance abuse, alcohol, brief intervention, military personnel

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1. Introduction and Objectives

In today’s environment, decision makers who want to determine whether to adopt new health care interventions require evidence that the interventions make sense fiscally as well as medically. The estimated societal costs for returning veterans with PTSD or depression over the first 2 years after deployment are between $4 billion and $6.2 billion. The continued rise in health care costs could affect other Department of Defense (DoD) programs and could potentially affect areas related to military capability and readiness. Studies have examined the cost-effectiveness of brief interventions (BIs) in civilian settings with regard to many behaviors and the consequences of behavior and have found BIs to be cost-effective. The objective of the study is to evaluate the effectiveness of two Web-based BIs in reducing stress and substance use among post-deployment active duty and National Guard military personnel. One intervention will focus only on combat and operational stress reactions (COSRs), the other on COSRs plus substance use. The BIs will be compared to a wait-list control group. The overriding objective of this research is to reduce stress reactions and substance abuse. These data are vital to understanding additional steps the military might take in addressing issues of behavioral health, such as developing new, more broadly focused treatment interventions, and starting additional prevention approaches and programs. In addition to providing outcome data, the research will provide information on the cost, cost-effectiveness, and cost-benefit of the interventions. The proposed intervention shifts the locus of care from treatment of illness to promotion of psychological health and resilience. The intervention uses an emerging approach (the Web) that is also based on active and effective programs that enhance combat effectiveness, organizational health, and overall well-being of warriors and families. Finally, in an era of financial accountability, it is important that studies document the resources needed to build and maintain interventions. Thus, the information from the cost study will be available to decision makers to appropriately budget for setting up and implementing the interventions.
2. Keywords

Alcohol
Web-based intervention
Stress
Military
3. Overall Project Summary

This Web-based assessment, feedback, and educational intervention has the potential to assist military personnel who are dealing with issues related to alcohol and/or stress. The major challenge has been to enroll participants into the program. We have tried to be proactive in identifying avenues for participants but we continue to struggle with enrollment.
4. Key Research Accomplishments

Accomplishments during Year 3 include the following:

- Two armories and one active duty installation have been recruited to be in the study.
- Briefings have been conducted in Tennessee, Georgia, and Washington.
- Recruitment materials have been shipped to all participating locations.
- Recruitment began in January 2014.
- The Institutional Review Board (IRB) protocol has received final approval from both RTI and the Human Research Protections Office (HRPO).
- We worked with National Guard Bureau (NGB) and have received an endorsement letter for the project from NGB Surgeon (COL Ann Naclerio). This letter is used as we try to engage additional states.
- We followed up with Tennessee National Guard related to the materials distribution plan; they have received a shipment of materials; the Medical Command will distribute them beginning with January Post-Deployment Health Assessment (PDHA).
- Initial meeting and follow-up calls were held with the Georgia Army National Guard (GaARNG) Psychological Health Program (PHP) director (Dr. Barbara Latimore). They have received a shipment of materials. Materials will be distributed to units by Psychological Health Case Managers. Materials have been sent to the two Air Guard Air Wings’ Directors of Psychological Health for distribution.
- A meeting is scheduled for December 23 with Georgia Deputy State Surgeon to discuss additional distribution methods.
- We are communicating with Stephanie Lincoln, coordinator, Southeast Regional National Guard Psychological Health Programs, to explore contacting other states’ PHP directors.
- We are communicating with South Dakota Army National Guard (SDARNG) Chief of Staff on allowing distribution of SUSTAIN materials to South Dakota personnel.
- We provided a briefing to the Joint Base Commander (COL Hodges) at Joint Base Lewis-McChord (JBLM) who suggested that he send an introductory email to the Commanders at Fort Bragg and Fort Hood to tell them about the study and his enthusiasm for its benefits.
- We briefed the ASAP staff at JBLM (led by Dr. Jolee Darnell). ASAP staff members will make materials available at public locations in the ASAP offices and will distribute directly to patients.
- We briefed the Medical Command at Camp Murray, Washington Army National Guard (WaARNG) and met with Mr. Tom Riggs and Maj Brian Nelson. Also, Gary Lott, the Marketing Program Manager, has offered to publicize the study on the WaARNG Facebook page and in the quarterly newsletter for the WaARNG.
- We are working with MAJ Michael Hiett, USAMRMC, for additional study recruitment organizations.
- We conducted SUSTAIN briefings to the following GaARNG contacts:
  - Medical Command, GaARNG
- Joint Forces Headquarters, GaARNG
- 878 Engineer Battalion, GaARNG (Yellow Ribbon Event [post-deployment activity])
- 1/214 Field Artillery Battalion, GaARNG (Yellow Ribbon Event [post-deployment activity])
- Aviation Medical Group, 78th Troop Command, GaARNG
- Military Chaplain Conference, GaARNG

- We met with Commander and Surgeon, Warrior Transition Battalion, Ft. Gordon.
- We met with Supervisor, Family Support Program, GaARNG.
- We met with Georgia Consultant, Military One Source.
- We responded to individual units with request for SUSTAIN brochures.
- We provided material to J-9 for email blast to all GaARNG personnel.
- We provided material for posting to Ga DoD Facebook Page.
- We followed up with request to SDARNG Vice Chief of Staff.
- We followed up on recruitment material status with Behavioral Health staff, TNARNG.
- Information about SUSTAIN was posted on the Facebook page of the WaARNG (with IRB approval).
- We currently have an amendment before HRPO (approved by RTI IRB) to provide compensation to participants for their off-duty involvement. Payment of $15 per assessment, for a total of $60, is proposed.
- We are currently in talks with the Director for Behavioral Health in the Marine Corps to determine feasibility and interest in offering SUSTAIN to the Marine Corps. RTI IRB and HRPO approval will be sought prior to distributing materials.
5. Conclusion

Enrollment in the study has been surprisingly slow. We are doing everything possible to increase enrollment. JBLM and WaARNG have not enrolled any participants and we are having difficulty reaching the POCs at these sites. SDARNG and TNARNG have not maintained contact with study personnel – we must assume they are not interested in moving forward.

There are no publications or abstracts at this time. A presentation was given at the annual IPR meeting in September 2014 (see Appendix B).
7. Inventions, Patents, and Licenses

None
8. Reportable Outcomes

There are no reportable outcomes at this time because study enrollment is ongoing.
9. Other Achievements

None
10. References

Not applicable
11. Appendices

Appendix A: Statement of Work

Appendix B: IPR Meeting Slides (September 2014)
Appendix A: Statement of Work

Activity 1. Develop Web-Based Assessment Materials (Months 1–3)
We have finalized all assessment materials including the baseline and follow-up surveys and programmed the Web-based assessment instruments. We have also written text for all participant messaging through the Web-based system.

Activity 2. Prepare Recruitment and Marketing Materials (Months 1–3)
We have developed recruitment and marketing materials for the study including a poster and tri-fold brochure. We have had the materials reviewed by our points of contact (POCs) and made revisions based on their feedback.

Activity 3. Prepare Intervention Materials (Months 1–5)
The Web-based intervention application has been adapted to include military-specific content (e.g., graphics, feedback on military-specific drinking norms based on our previous research), a military-oriented interface, graphics of younger adults, and an interactive goal-setting component. The full intervention consists of modules for assessment, individualized feedback, intervention materials, and goal setting. All intervention materials have been finalized.

Activity 4. Obtain Study Approvals (Months 1–12)
We have received Institutional Review Board (IRB) approval from RTI. The human subjects packet has been submitted to the Human Research Protections Office (HRPO). We were delayed in submitting these materials until the Website was fully operational in order that IRB members can see that to which participants will be exposed.

Activity 5. Develop Web Site (Months 1–11)
We have developed a project Web site that includes the baseline and follow-up surveys, feedback documents, intervention materials, and also information on the nature of the program, including sponsorship, purpose, time requirements, benefits of participation, frequently asked questions, and myths and facts. We have also developed a schematic of the study flow for the project including event codes for each significant path along the model in order to track participants’ progress as they go through the Website. All Web programming is complete.

Activity 6. Pilot Intervention (Months 11–13)
We have conducted a series of tests on the intervention to ensure smooth operation of all systems. Testing individuals were drawn from health care staff at our participating National Guard armories and multiple RTI staff. Data from the pilot testing will not be maintained or used for any analyses.

Activity 7. Participant Recruitment (Months 13–36)
Participant recruitment will begin as soon as all approvals are obtained (estimated as Month 25) and will continue through Month 38 of the project. Follow-up data collection will continue through Month 44. We have been significantly delayed in initiating participant recruitment and will likely request a one-year no-cost extension if the required number of participants has not been enrolled by Month 36.
Combat Stress and Substance Abuse Intervention

PI: Janice M. Brown, PhD
Co-PI: Laura B. Strange, PhD

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www.rti.org
Co-Investigators/Team

- Alex Cowell, PhD – Economist
- Richard Zemonek – Programmer
- Jason Williams – Statistician
- Carrie Borst – Project Manager
Study Background/Rationale

- Combat and Operational Stress Reactions - expected and predictable emotional, intellectual, physical, and/or behavioral reactions.

- Estimated 20% to 30% of US military personnel returning from combat operations report significant psychological symptoms (including COSRs).

- Studies with soldiers have found that symptoms increase 3 to 6 months after returning home.

- Perceived stigma often keeps personnel from seeking help.
Solution – SUSTAIN

Substance Use and STress: An INtervention

- Intervention based on Motivational Interviewing (MI)
- Randomized, controlled trial of two web-based interventions with active duty and National Guard personnel
  - Stress Only Intervention
  - Stress plus Alcohol Intervention
- Intervention groups compared to a Delayed Feedback control group (intervention provided at 6-month follow-up)
- Cost analysis
  - Resources needed to put the interventions in place
  - Costs to maintain the interventions
  - Cost-benefit of the two interventions (Bang for your buck)
- Adjunct to those currently receiving help
- Supports those who do not seek help because of perceived stigma
Research Questions/Hypotheses

- **Hypothesis 1**: Both intervention groups will show reduction in COSRs over time compared with the wait list (WL) control group.

- **Hypothesis 2**: The stress plus substance use group (SSUBI) will show lower use of alcohol over time compared with the stress only group (SBI). Both groups will demonstrate lower substance use outcomes compared with the WL control group.

- **Hypothesis 3**: The SSUBI group will be cost-effective relative to SBI and WL groups.

- **Additional Analyses**: A number of individual-level factors (e.g., combat experiences, deployment history, unit cohesion) may interact with the interventions to attenuate responses to the interventions. These factors will be tested as moderators of the interventions’ effectiveness. Factors that moderate effectiveness will help to identify for whom the interventions work.
Study Design

Self-Referral

Individual Accesses SUSTAIN Website

CONSENT
Participant Completes Screener

CONSENT
Participant Completes Baseline if Positive

Randomization

Wait List Control
- 1-Month Follow-up
- 3-Month Follow-up
- 6-Month Follow-up

Stress Brief Intervention
- 1-Month Follow-up
- 3-Month Follow-up
- 6-Month Follow-up

Stress plus Substance Use Brief Intervention
- 1-Month Follow-up
- 3-Month Follow-up
- 6-Month Follow-up
Marketing Poster

SUSTAIN
Your Health ★ Your Relationships ★ Your Readiness

The SUSTAIN study is being undertaken to learn more about stress reactions among military personnel.
- All post-deployment Active Duty and Reserve Component personnel are encouraged to participate.
- This installation is one of several that have been selected for this important research study.

Participants will receive a novel web-based study that is geared toward enhancing combat effectiveness, health, and overall well-being of warriors and families.

All you need to participate is:
- Internet access
- A desire to help our fighting force become healthier and stronger.

For more information about the study, please call 1-800-647-9655 or email Sustain@rti.org.
Based on your responses, you are currently experiencing a HIGH level of stress.

HIGH LEVEL OF STRESS

A person scoring in this range may be having signs of significant stress related to their deployment or other traumatic experiences. It is normal to have stress reactions after extreme stress and there are many different responses to crisis. Many people have intense feelings such as fear, guilt, or anger after a traumatic event but recover from the experience; others have more difficulty recovering - especially those who have had previous stressful experiences, who are faced with ongoing stress, or who lack support from friends and family - and will need additional help. If your reactions don't go away over time and they disrupt your life, you may be at risk for developing PTSD.

Symptoms of high levels of stress often include:

- **Fear or anxiety**: In moments of danger, our bodies prepare to fight our enemy, flee the situation, or freeze in the hope that the danger will move past us. But those feelings of alertness may stay even after the danger has passed. You may feel tense or afraid, be agitated and jumpy, or feel on alert all or most of the time.
- **Sadness or depression**: Sadness after an event may come from a sense of loss—of a loved one, of trust in the world, faith, or a previous way of life. You may have crying spells; lose interest in things you used to enjoy; want to be alone all the time; or feel tired, empty, and numb more than you used to.
- **Guilt and shame**: You may feel guilty that you did not do more to prevent the event. You may feel ashamed because during the event you acted in ways that you would not otherwise have done. You

Click the "Stressors" tab above to continue.
A Little Stress Goes a Long Way – The Basics

First, what do we know about stress? Stress is any type of physical, emotional, or psychological strain you experience because an event (or number of events) has upset your personal balance and makes you feel frustrated or threatened. There are two types of stress, and each type can occur across different lengths of time.

Types of Stress

Positive Stress – fun and/or exciting stress, like preparing for a sports competition, starting a new job, or getting married

Negative Stress – what we normally think of when we think of “stress” – the bad kind, this can include situations like road rage in response to traffic jams or anger when dealing with a computer virus

Time periods for stress:

Short term – day-to-day stress that may include events like rushing to meet a tight deadline for work or arguing with your spouse or partner.

Long term – “never-ending” stress where a person is constantly dealing with the situation and can’t seem to “escape” it, such as things like dealing with financial problems or chronic health issues

Now, based on these categories, think about what stresses you the most. Keep these examples in mind as you work through this stress program.
Based on responses, your risk level is 17, which is considered **Harmful Drinking**.

**Harmful Drinking**

A person scoring in this range will already be experiencing significant alcohol-related harm. The harmful drinking category applies to people drinking over medically recommended levels, probably at somewhat higher levels than in hazardous drinking. It suggests that you are at higher risk of harming your health because of drinking.

- 0-4 Low Risk Drinking
- 5-15 Hazardous Drinking
- 16-19 Harmful Drinking
- 20+ Alcohol Dependence

The problems that are being detected by you at this stage may be acute, such as an alcohol-related accident, acute pancreatitis or acute blood poisoning. You are also likely to have experienced feeling tired or depressed, gaining weight or having periods of memory loss when drinking. You may be sleeping poorly or having sexual difficulties. You may find it difficult to reduce or limit your drinking but there are useful strategies you can try. We will provide some of these tips later in this session.

If you are in this category, the amount you are drinking is likely to be causing you harm— in fact, it might even be having bad effects on your body that you are not aware of. You have a difficult decision to make: should I cut down on my drinking?

Click the "The Four C's" tab above to continue.
Study Progress to Date

- HRPO approval received - October 2013
- Recruitment materials to the field (TN, WA, GA) - November/December 2013
- National Guard Bureau (NGB) endorsement – December 2013
- Intensive recruitment activities – Jan 2014 - present
- Current sample 9
Recruitment Activities

- Tennessee Army National Guard
  - Recruitment materials at PDHAs, Medical Command, with Behavioral Health Staff

- Georgia National Guard
  - Fragmentary order (FRAGO) - supporting program and directing recruitment materials in units
  - Briefings/brochure distribution – unit level, Yellow Ribbon, Chaplains, Behavioral Health Staff, Medical Command, Flight Surgeons, Soldier Readiness Processing (SRPs), Public Affairs Office (PAO)

- Warrior Transition Unit (WTU)/ Ft Gordon - Commander/Surgeon briefing/brochure distribution
Current Challenges

- **Recruitment**
  - Addition of incentive
  - RTI IRB approved
  - HRPO approval request in process
  - Distribution of revised recruitment materials
  - Repeat briefings
  - Facebook/email blasts

- **Engage Additional Sites**
Dissemination/Transition Plan

- **Transition**
  - Determine most effective intervention.
  - Encourage military services to use/adopt effective interventions and work to support adoption of the program (i.e., host website, train personnel).

- **Business**
  - Seek funding to conduct larger trial across all components.
  - Streamline interventions to focus on specific need.

- **Dissemination**
  - Publish results in peer reviewed journals.
  - Present findings at professional association meetings.
  - Prepare briefing reports for sites to gauge ongoing interest.
  - Present briefings to DoD committees concerned with these issues.