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TITLE: Combat Stress and Substance Use Intervention

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<b>13. SUPPLEMENTARY NOTES</b>					
<b>14. ABSTRACT</b>  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.					
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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 post-traumatic stress disorder 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 been very proactive in identifying avenues for participants and have significantly increased enrollment. We have recently added an active duty location and an additional National Guard organization.

## 4. Key Research Accomplishments

Accomplishments during Year 4 include the following:

- One armory and one active duty installation have been recruited to be in the study.
- Briefings have been conducted in Tennessee, Georgia, Washington, North Carolina, and California.
- 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). A number of amendments—streamlining recruitment materials, adding locations, including an incentive for National Guard participants—have been submitted and approved.
- We worked with National Guard Bureau (NGB) and have received an endorsement letter for the project from the NGB Surgeon (COL Ann Naclerio). This letter is being used as we try to engage additional states.
- 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.
- We are communicating with Stephanie Lincoln, Coordinator, Southeast Regional National Guard Psychological Health Programs, to explore contacting other states' PHP Directors.
- We briefed the ASAP staff at Joint Base Lewis-McChord (JBLM) led by Dr. Jolee Darnell. ASAP staff members will make materials available at public locations in the ASAP offices and will distribute materials directly to patients. Unfortunately, no personnel have been included from JBLM.
- 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. Likewise, no personnel have been recruited from WaARNG.
- We are working with MAJ Michael Hiatt, 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 requests for SUSTAIN brochures.
- We provided material to J-9 for an e-mail blast to all GaARNG personnel.
- We provided material for posting to the GaARNG DoD Facebook page.

## **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 points of contact at these sites. South Dakota and Tennessee National Guard organizations have not maintained contact with study personnel; we must assume that they are not interested in moving forward. However, we have recently added North Carolina Army National Guard (NCARNG) and anticipate briefings to personnel in late October. The study has rolled out at Twentynine Palms Marine Corps Base, and we are hopeful that Marines will enroll.

## **6. Publications, Abstracts, and Presentations**

There are no publications or abstracts at this time. A presentation was given at the annual IPR meeting in October 2015 (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. However, we do have some initial 1-month follow-up data as presented in Appendix B.

## 9. Other Achievements

None

## 10. References

Not applicable

## **11. Appendices**

Appendix A: Statement of Work

Appendix B: IPR Meeting Slides (October 2015)

## **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 review 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 6-24)**

We have received Institutional Review Board (IRB) approval from RTI and from the Human Research Protections Office (HRPO). We were delayed in submitting these materials until the Web site was fully operational in order that IRB members can see that to which participants will be exposed.

### **Activity 5. Develop Web Site (Months 6-18)**

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 Web site. All Web programming is complete.

### **Activity 6. Pilot Intervention (Months 20-22)**

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 27-51)**

Participant recruitment began in Month 27 and will continue through Month 51 of the project. Follow-up data collection will continue through Month 57.

### **Activity 8. Data Analysis (Months 51-60)**

Once collected, study data will be cleaned and prepared for analysis. We will test relevant models for examining hypotheses related to program efficacy, how effects were obtained (mediation), and differences in effectiveness (moderation). The primary analyses will center on recent expansions of longitudinal growth modeling (LGM), a technique that allows for the assessment of drinking trajectories over time and the factors that are associated with those changes in alcohol use (i.e., intervention condition). Interim data will be analyzed for presentation at national conferences.

### **Activity 9. Economic Evaluation (Months 51-60)**

We will gather data throughout the study period and conduct the cost, cost-effectiveness, and cost-benefit analyses for the economic evaluation. For the cost-effectiveness analysis, we will combine information on the efficacy of the intervention and the cost of each intervention. For the cost-benefit analysis, we will further combine information gathered on the economic outcomes.

### **Activity 10. Report and Manuscript Preparation (Months 12, 24, 36, 48, 56-60)**

A number of annual reports, conference presentations, installation briefings, and manuscripts will be prepared to ensure broad dissemination of the study findings.



# Combat Stress and Substance Abuse Intervention

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RTI International

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## Co-Investigators/Team

- Laura Strange, PhD – Co-Investigator
- Alex Cowell, PhD – Economist
- Richard Zemonek – Programmer
- Jason Williams – Statistician
- Carrie Borst – Project Manager

## Study Background/Rationale Statement of the Problem

- Combat and Operational Stress Reactions are 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.
- Randomized, controlled trial of two web-based interventions with active duty and National Guard personnel.
  - Stress Only Intervention
  - Stress plus Alcohol Intervention

# Solution – SUSTAIN

[Substance Use and STress: An INtervention]

## Military Relevance

- Intervention based on Motivational Interviewing (MI) principles
- 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
- Promotes readiness, health, and wellness through effective treatment of stress disorders and substance abuse
- Provides a skills development intervention while all reviewed web-based interventions primarily offer education

# Research Aims/Hypotheses

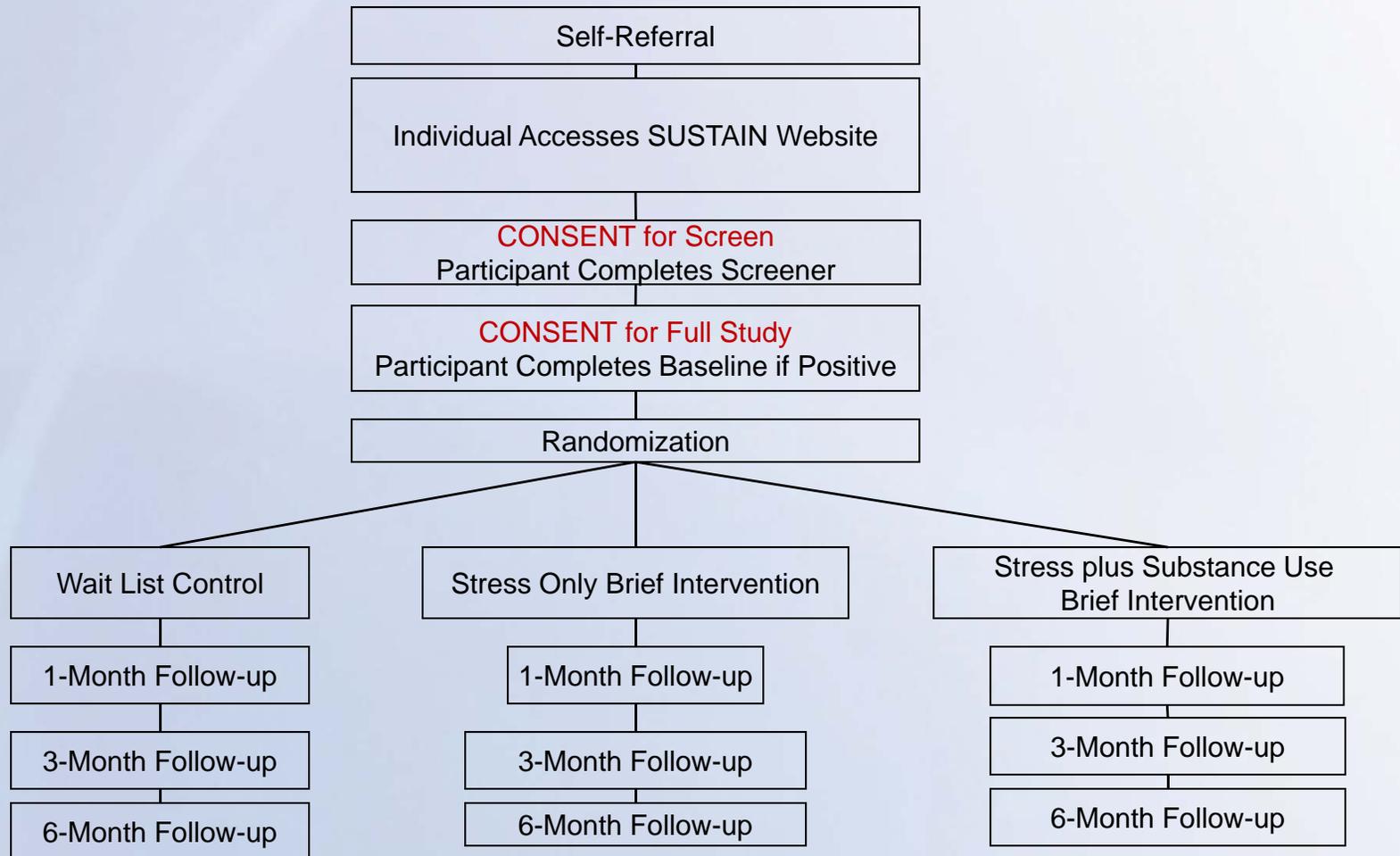
## AIMS

- **AIM 1:** To evaluate the effectiveness of two Web-based BIs for reducing stress reactions and substance abuse among two populations of post-deployment military personnel. One intervention will focus only on COSRs, the other on COSRs plus substance abuse. The interventions will be compared with a delayed feedback control group.
- **Aim 2:** To test factors that may mediate responses to the interventions. The assessment portion of the interventions will include measures of change factors to be tested as mediators of the interventions.
- **Aim 3:** To assess the cost and cost-effectiveness of the interventions. The cost analysis will describe what resources are needed to put the interventions in place and what it costs to maintain the interventions on an ongoing basis.

## Hypotheses

- **Hypothesis 1:** Both intervention groups will show reduction in COSRs over time compared with the delayed feedback control group.
- **Hypothesis 2:** The stress plus substance use group will show lower use of alcohol over time compared with the stress only group. Both groups will demonstrate lower substance use outcomes compared with the delayed feedback control group.
- **Hypothesis 3:** The stress plus substance use group will be cost-effective relative to stress only and delayed feedback groups.

# Study Design



# 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.

**RTI INTERNATIONAL**  
Conducted by: RTI International  
Sponsored by: United States Army  
Medical Research and Materiel Command

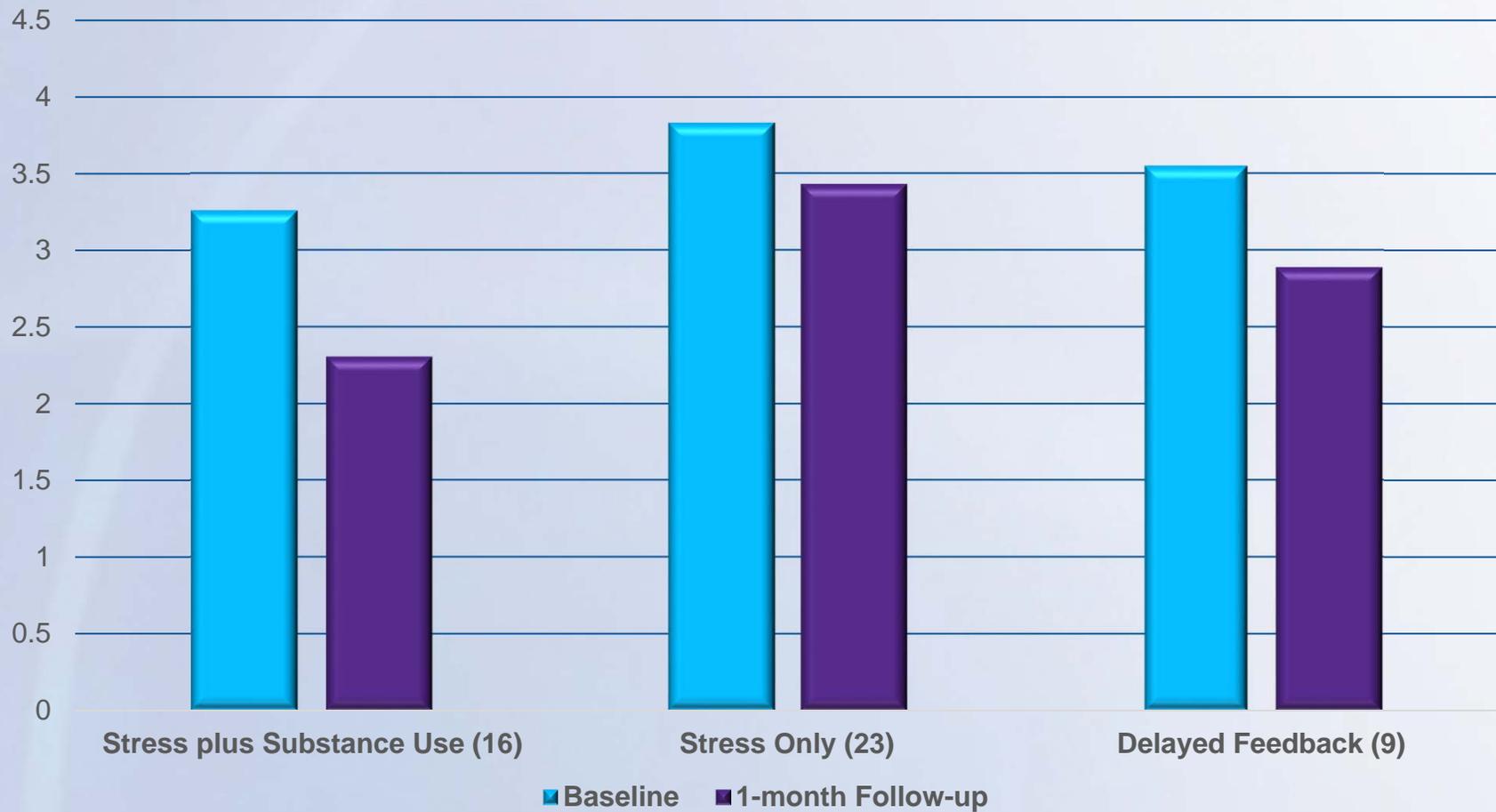
**TO PARTICIPATE LOG ON AT: [SUSTAIN.RTI.ORG](http://SUSTAIN.RTI.ORG)**

For more information about the study, please call 1-800-647-9655 or email [Sustain@rti.org](mailto:Sustain@rti.org).

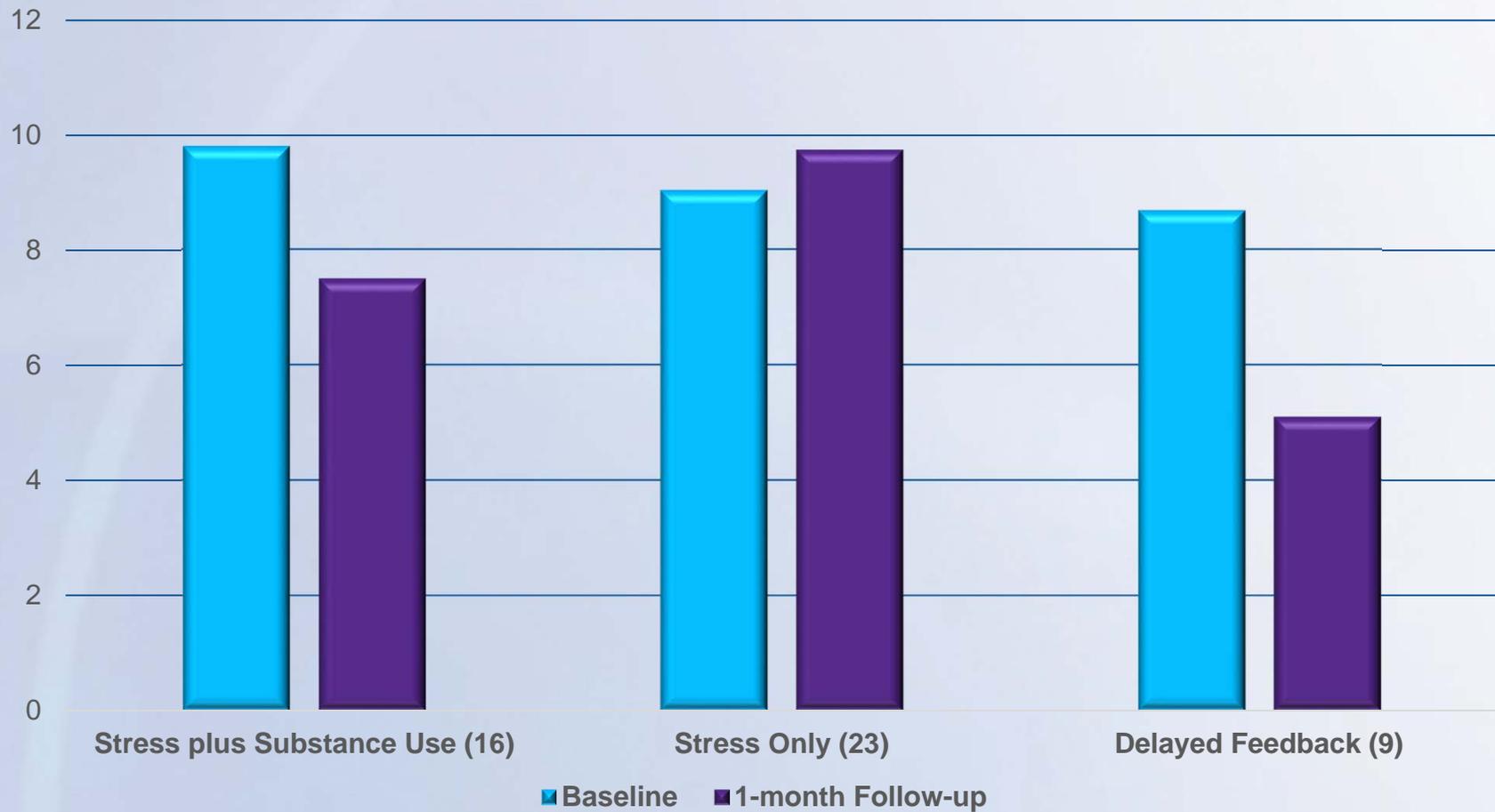
# Demographics and Baseline Characteristics

	All (92)	Stress Plus (34)	Stress Only (36)	Delayed FB (22)
Male	68.5	61.8	72.2	72.7
Female	31.5	38.2	27.8	27.3
E1-E3	13.5	12.1	11.4	19.0
E4=E6	60.7	60.6	60.0	61.9
E7-E9	9.0	9.1	14.3	
O1-O3	12.3	12.1	11.4	14.3
O4-O6	4.5	6.1	2.9	4.8
Married	45.1	44.1	44.4	47.6
PCL (17-81)	28.1	29.7	26.9	27.4
AUDIT (0-19)	4.63	3.91	5.19	4.82
COSR (0-20)	9.2	9.8	9.0	8.7

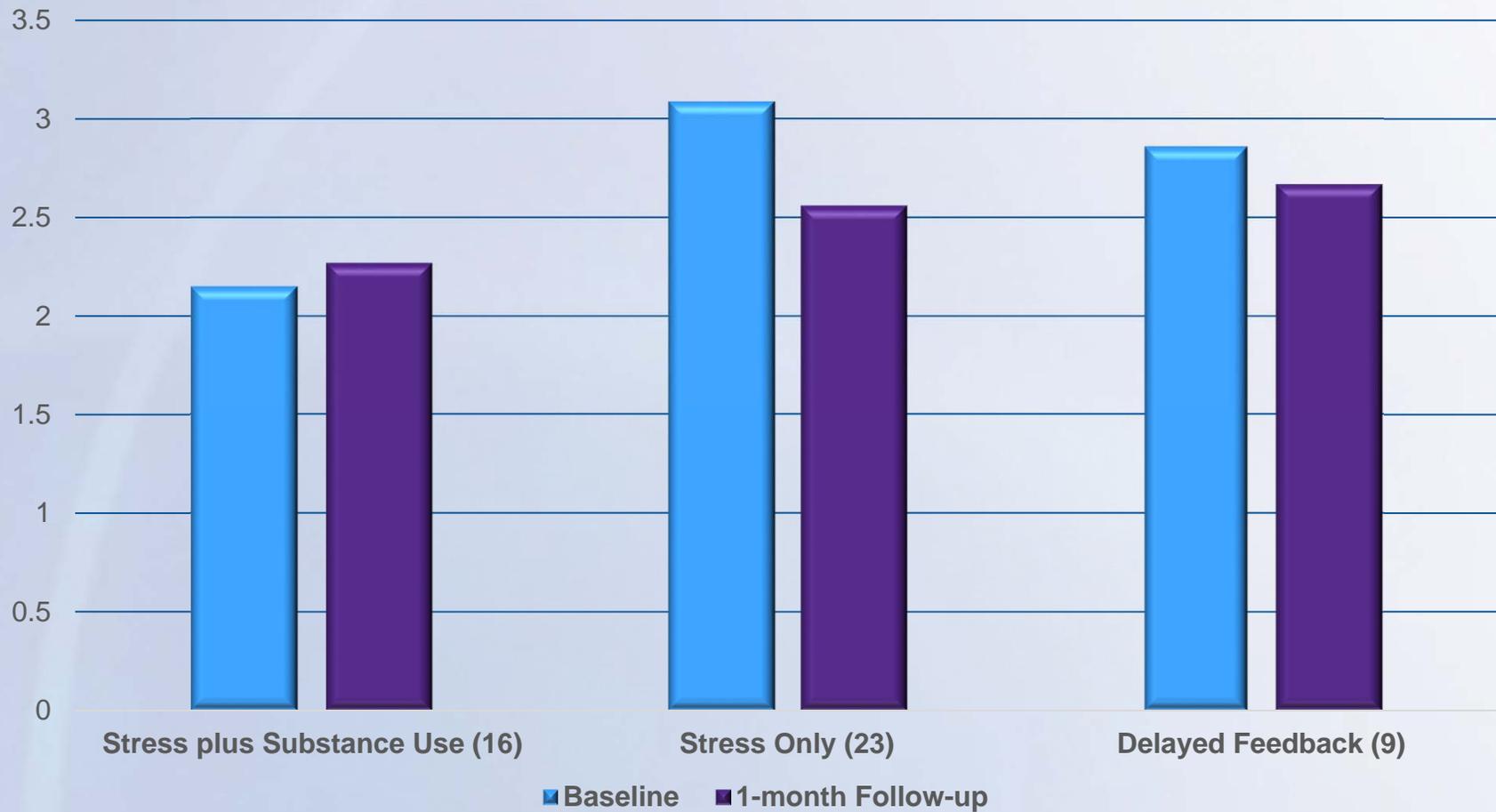
## Change in AUDIT-C Scores at 1 Month



## Change in COSR Scores at 1 Month



## Change in Average Number of Drinks at 1 Month



## Current Challenges

- **Recruitment**
  - Addition of incentive for National Guard participants
  - Distribution of revised recruitment materials
  - Repeat briefings
  - Recently added Marine Corps base
  - Recently added North Carolina National Guard
  - Working with Arizona National Guard
  
- **Follow-up Rate**
  - 60% at 1 month
    - 39% prior to incentive
    - 74% following incentive
  - 47% at 3 months (42% vs. 52%)

## Study Progress to Date

- HRPO approval received - October 2013
- Recruitment materials to the field (TN, WA, GA, JBLM) - November/December 2013
- National Guard Bureau (NGB) endorsement –December 2013
- Intensive recruitment activities – Jan 2014 - present
- Current sample 96 (all from Georgia National Guard)
- Enrollment

202		Accessed the website	
96		Enrolled	23-WL; 37-SA;36-S
25		BL not complete	
10		Anomalies	Screen only/Bad email
34		Ineligible	Low scores – no alcohol
37		Did not complete screener	

## Recruitment Activities

- 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
- Twentynine Palms Marine Corps Base
  - Posters/brochure distribution in Behavioral Health, Family Advocacy, Community Counseling Center, Substance Abuse Counseling Center
- North Carolina National Guard
  - Briefing scheduled for October 5, 2015

## 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 military 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.