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TITLE: Combat Stress and Substance Use Intervention

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CONTRACTING ORGANIZATION:

RTI International
Research Triangle Park, NC 27709-2194

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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 brief intervention, or Stress plus Substance Use brief intervention. 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 brief interventions (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. Body

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 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 have not been enrolled by Month 38.

3. Key Research Accomplishments

Accomplishments during Year 2 include the following:

- Finalized all survey assessments.
- Programmed and tested the survey.
- Finalized marketing materials.
- Finalized and programmed documents for frequently asked questions (FAQs) for both alcohol and stress.
- Finalized and programmed documents for myths and facts for both alcohol and stress.
- Recruited two armories and one active duty installation to be in the study.
- Initiated contact for approval at one additional state-level armory and one additional active duty site.
- Finalized and programmed feedback reports for alcohol and stress.
- Finalized and programmed brief interventions for alcohol and stress.
- Finalized and programmed all notifications for participants including: welcome message, ineligibility statements, group assignment statements, follow-up notifications, reminder emails, and holiday greetings.
- Submitted RTI IRB materials.
- Received RTI IRB approval.
- Submitted HRPO materials.
- Received HRPO approval – 10/4/13.

4. Reportable Outcomes

There are no reportable outcomes at this time because this study has not yet received all approvals and data collection has not begun.

5. Conclusions

At this time there are no conclusions that can be made because the main study has not been conducted.

6. References

Not applicable

Appendix A: IPR Meeting Slides

Combat Stress and Substance Abuse Intervention

Janice M. Brown, PhD
RTI International

Award Number(s): W81XWH-11-2-0197
Award Date(s): 9/15/11-9/14/15
Award Amount: $1,884,551
Contract Officer Representative: Dr. Jay Shore

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

- 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

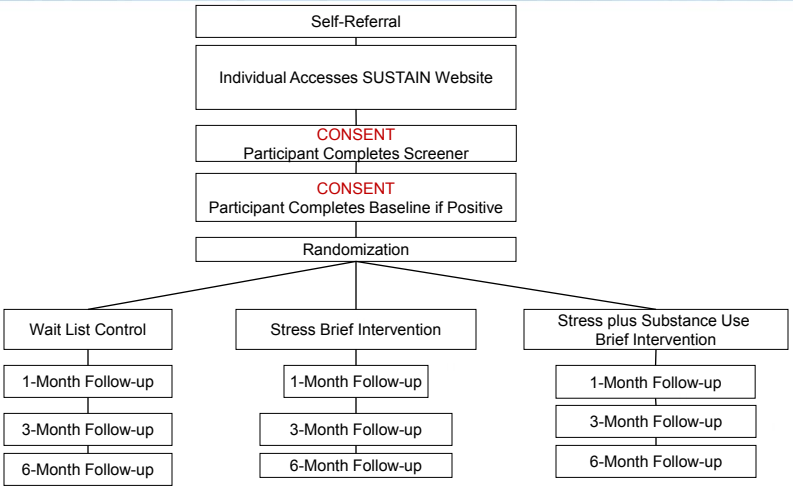
Substance Use and STress: An INtervention

- 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

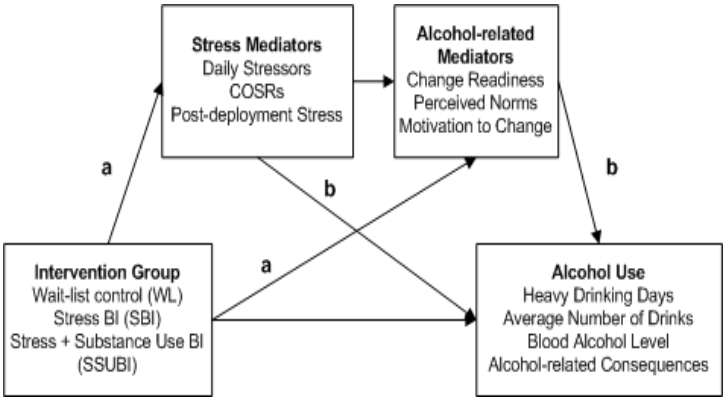
Research Questions/Hypotheses

- **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

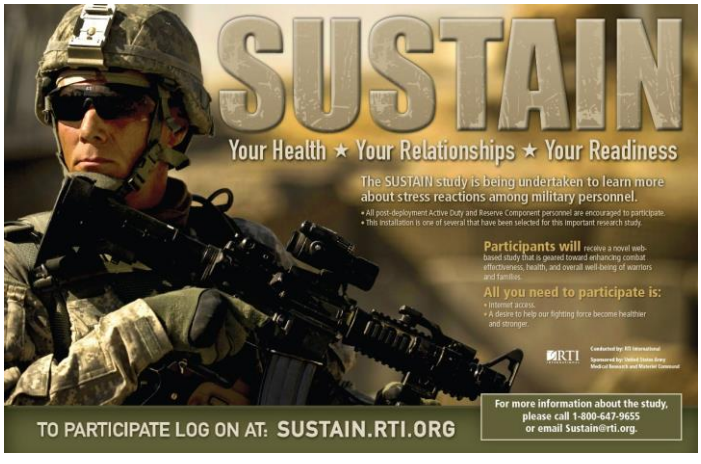


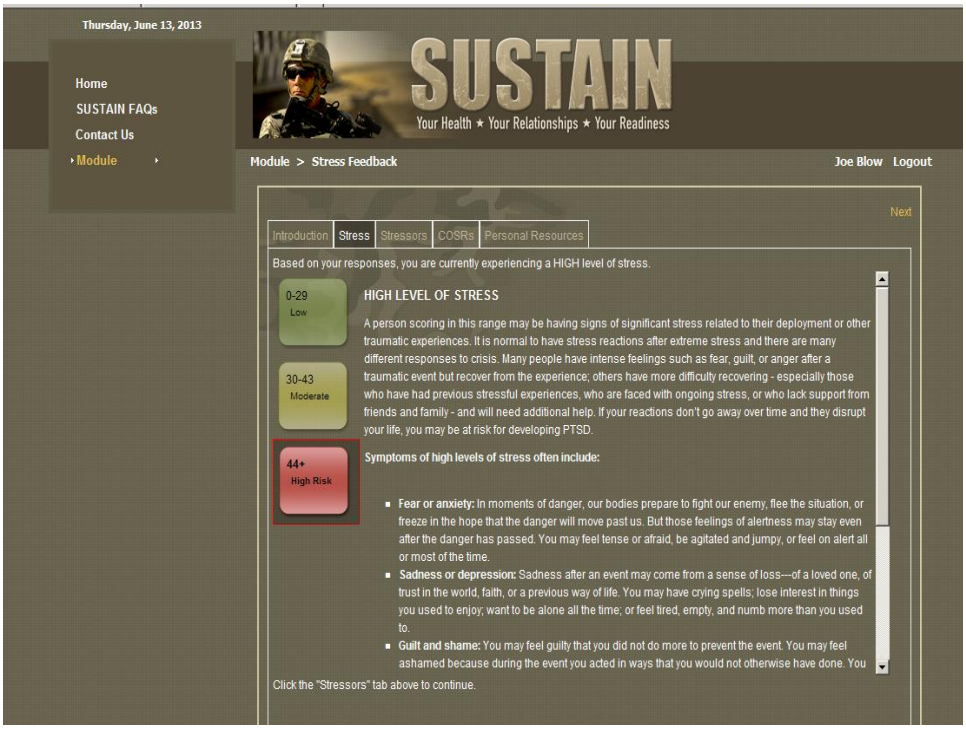
Mediation Model of Program Effects



Point estimates for individual mediated effects (the effect of the intervention on a single outcome through a single mediator) will be estimated as *ab*, the product of the path from program to mediator ("*a*") and the path from mediator to an outcome ("*b*"). Significance of mediated effects will be tested with confidence intervals around *ab* formed with the bias-corrected bootstrap.

Marketing Poster




Thursday, June 13, 2013
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Module > Stress Feedback
Joe Blow Logout
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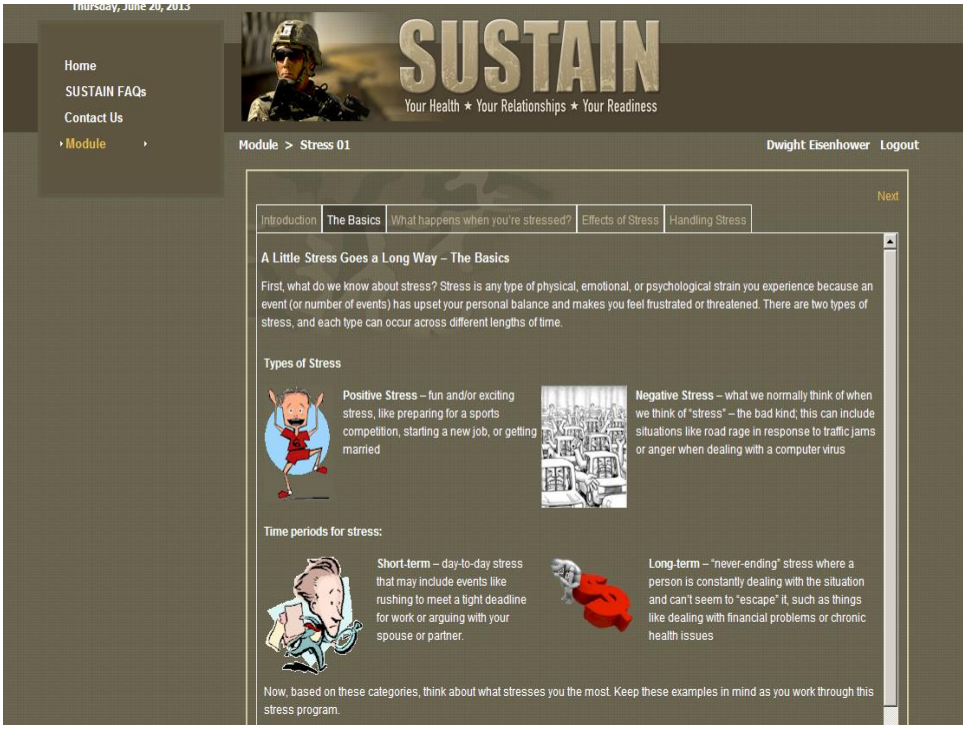
Introduction
Stress
Stressors
COSRs
Personal Resources
Based on your responses, you are currently experiencing a HIGH level of stress.
0-29
Low
30-43
Moderate
44+
High Risk
HIGH LEVEL OF STRESS
A person scoring in this range may be having signs of significant stress related to their deployment or other 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.


Thursday, June 20, 2013
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Dwight Eisenhower Logout
Next
Introduction
The Basics
What happens when you're stressed?
Effects of Stress
Handling Stress
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.


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Your Health ★ Your Relationships ★ Your Readiness
Module > Alcohol Feedback
Joe Blow Logout
Next
Introduction
Risks of Drinking
The Four Cs
Personal Strengths
Based on responses, your risk level is 17, which is considered Harmful Drinking.
0-4
Low Risk Drinking
5-15
Hazardous Drinking
16-19
Harmful Drinking
20+
Alcohol Dependence
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.
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.


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SUSTAIN
Your Health ★ Your Relationships ★ Your Readiness
Module > Alcohol 01
Janice Brown Logout
Next
How Do I Measure Up?
What type of drinker are you?
Standard Drinks
Staying Under the Limit
Determining BAL
Staying Under The Limit
It doesn't take much to put you over the safe blood alcohol level (BAL) of 0.05%. Drinking up to the safe level means:
Men of average size can drink up to two standard drinks in the first hour and no more than one standard drink per hour after.
Women of average size should drink no more than one standard drink an hour.
Your Drinking Compared to the Average Person's
Deciding whether you should cut down on drinking may not always be an easy decision. In addition to defining your personal drinking behavior and whether you are typically a low- or high-risk drinker, sometimes it helps to know how your drinking behavior compares to others to get an idea of where you measure up.
What you drink on average:
What you think others drink on average:
What others actually drink on average:
6
7
1
Are you surprised by this result? If so, it is important to remember that most people think others drink more than they actually do. On average, most people don't drink to get drunk.
With that in mind, your drinking appears to be significantly higher than others your age – lowering the number of drinks you have can lower your risk of experiencing alcohol-related problems.
Click the "Determining BAL" tab to continue.
10/2/2013

Current and Anticipated Challenges

- IRB Delays
  - Submission was contingent on a working website with full survey, feedback, and intervention components
  - Resubmission to address potential risks with increasing symptoms
  - Terminology concerns
- Engaging Sites
  - Currently in talks with Ft. Huachuca and WA ANG
  - IRB delays necessitate ongoing contact with recruited sites
- Next Steps
  - HRPO approval
  - Begin recruitment

Study Progress to Date

- Marketing materials completed
- Survey assessments programmed and testing completed
- Feedback reports completed, programmed, and tested
- Interventions completed, programmed, and tested
- Two NG sites committed, third site in progress
- One active duty site committed, one site in progress
- RTI IRB approval received
- Documents submitted to HRPO

Dissemination/Transition Plan

- Transition
  - Determine most effective intervention.
  - Encourage ARNG to use/adopt effective arm and work to support adoption of the program (i.e., host website, train personnel).
- Business
  - Seek funding to conduct larger trial across all active duty components.
  - Streamline interventions to focus on specific need.
  - Refine/modify design to highlight findings from ARNG.
- 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.

Appendix B: Study Marketing Materials

SUSTAIN

Your Health ★ Your Relationships ★ Your Readiness

The SUSTAIN study is being undertaken to learn how to help military personnel deal with stress

- Active Duty and Reserve Component personnel are encouraged to participate

Participants will receive a web-based education program that will be tailored to their specific stresses

All you need to participate:

- 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

READY? VISIT **SUSTAIN.RTI.ORG** TO GET STARTED

For more information about the study, please call 1-800-647-9655 or e-mail sustain@rti.org

Information

If you have questions about the study, participation, or your rights as a participant, please contact one of the following:

About the study:

Dr. Janice Brown, Principal Investigator
1-800-647-9655
jmbrown@rti.org

About how to participate:

Russ Peeler
SUSTAIN Site Coordinator
1-800-647-9655
rvp@rti.org

About your rights as a participant:

RTI Office of Research Protection,
1-866-214-2043 (toll free)

Visit
sustain.rti.org
to get started

SUSTAIN

Your Health
★
Your Relationships
★
Your Readiness

RTI INTERNATIONAL

Conducted by: RTI International

Sponsored by: United States Army Medical Research and Materiel Command

SUSTAIN

Your Health ★ Your Relationships ★ Your Readiness

The goal of the SUSTAIN program is to determine ways to better help members of the military deal with the effects of combat and operational stress

About SUSTAIN

The purpose of the SUSTAIN study is to test the effectiveness of two web-based programs in reducing combat and operational stress reactions in Active Duty and Reserve Component personnel.

SUSTAIN Study Objectives

- to test the effectiveness of web-based education programs in reducing combat and operational stress reactions and other stresses among military service members
- to determine individual factors that may influence the effectiveness of these web-based programs
- to determine if these web-based education programs are a cost-effective way to help service members manage stress

Frequently Asked Questions

What does the SUSTAIN study involve?

Participating in the SUSTAIN education program will involve completing a series of questionnaires several times during the study. In addition, you will learn ways to manage your stress by setting realistic goals for yourself. YOUR ANSWERS TO ALL QUESTIONS ARE CONFIDENTIAL.

The SUSTAIN program is designed to determine if web-based stress management educational programs can help Active Duty and Reserve Component personnel reduce the various types of stress they experience. When you join the study, you may be assigned to one of the two groups that receives the web-based stress management education program immediately or to a group that receives the education program later when you complete the 6-month follow-up questionnaire.

YOUR PARTICIPATION IN SUSTAIN IS COMPLETELY CONFIDENTIAL. No one in your command will know that you are a participant. No identifying information will be published or reported about those who participate in the study.

How will SUSTAIN help Active Duty and Reserve Component personnel?

If successful, SUSTAIN may offer a number of benefits to those participating in the study. Potential benefits include:

- reduction of stress
- reduction in problems that can result from combat and operational stress and other stresses
- improved readiness, health, and wellness through the effective reduction of unhealthy behaviors

How long will the study take?

Once you are enrolled in the study, you will be randomly assigned to one of three groups. All groups will complete an initial questionnaire, which takes about 30 minutes, and three follow-up questionnaires, at 1, 3, and 6 months, each of which takes about 15 minutes. Two of the groups will also complete a 30-minute education program. If you are randomly assigned to one of the education groups, reviewing this material will take an additional 30 minutes. So your total time commitment will be no more than 2 and a half hours over 6 months.

Are there any risks?

There are no physical risks to taking part in the study. However, because the surveys will ask you questions about your military experiences and how you manage stress, you may find this emotionally uncomfortable at times. Participants who are made uncomfortable by any part of the program will receive a list of resources that can provide assistance.

Am I required to participate?

Your participation is voluntary. However, the input you and others provide is critical in determining if the program is effective. Hopefully the SUSTAIN program will help military members improve the ways they manage stress.

Will my information be kept confidential?

Identifying information about you or knowledge of your participation in the study will not be available to anyone outside of the research team, including your command. The answers we collect from you will be combined with answers from other participants so that it is impossible to identify any single participant. We will not publish any names or other identifying information in any reports or presentations.

Ready? Visit
sustain.rti.org
to get started.

What will I receive for participating?

You will receive a web-based education program that may help you better manage stresses—those related to your military service and those related to your relationships.

Who is conducting the SUSTAIN study?

The SUSTAIN program is funded by the United States Army Medical Research and Materiel Command. RTI International (RTI) is conducting this study. Headquartered in Research Triangle Park, NC, RTI is a leading independent, nonprofit institute that provides innovative scientific research and technical solutions for government, military, and business clients worldwide.