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Computerized Tailored Intervention for Behavioral Sequelae of Post-Traumatic Stress Disorder in Veterans

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14. ABSTRACT

This project assessed the usability and feasibility of a multi-behavioral computerized, tailored intervention (CTI) delivered via the Internet for veterans with Post-Traumatic Stress symptoms. The project adapted and modified a CTI system based on the Transtheoretical Model of Behavior Change (TTM), utilizing methods that are characteristic of product development. Phase 1 focused on the review of current CTI programs on smoking cessation, stress management, and depression prevention with veteran focus groups, and integrating suggestions into a multi-behavioral program for application with veterans. Phase 2 was the adaptation of feedback messages and multimedia components. Usability testing of the modified CTI programs was done in Phase 3 and additional modifications to the behavioral modules were made based on the test results. Phase 4 was a feasibility test of the multi-behavioral CTI system with veterans who screened positive for mild to moderate PTSD (mean PCL-M score=55.6, SD=9.4) and depression (mean PHQ-8 score=12.0, SD=4.0). The CTI intervened at baseline, 1, and 3 months, and targeted smoking, depression, and stress. Participants selected a minimum of 2 behaviors and completed self-guided programs for 1-2 hours per month. Participants (n=57) had a mean age of 40.5 (SD=11.2), 74% were male, 70% White, and 56% married, with 86% reporting at least some college. Significant positive change was observed for behavioral and clinical outcomes. At 3-months, 27% of those who smoked cigarettes at baseline had quit ($\chi2(1)=23.5$, $p<.001$); 72% of those in pre-action stages for stress were practicing effective stress management at criteria ($\chi2(1)=6.2$, $p=.013$); and 67% of those "at risk" for depression reported they were in the action or maintenance stage of change ($\chi2(1)=8.8$, $p=.003$). At 3-months, scores for depression (PHQ-8) decreased 17% (mean=9.9, SD=5.8; $t(56)=2.5$, $p=0.15$), perceived stress (PSS) decreased 19% ($t(56)=3.7$, $p<.001$)), and quality of life (QOLS) increased 11% ($t(56)=-3.4$, $p<.001$). Finally, PTSD symptoms decreased by 12% (mean=48.8, SD=15.8; $t(56)=3.6$, $p<.001$). These findings were clinically meaningful; particularly, since the intervention was self-guided and required fewer than 1-2 hours of active participation per month.

15. SUBJECT TERMS
Behavior Change, Telemental Health, Post Traumatic Stress Disorder (PTSD), Computerized Tailored Intervention(CTI), Transtheoretical Model (TTM)

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INTRODUCTION

The overall aim of this project was to enhance the emotional and physical well-being of veterans with Post-Traumatic Stress symptoms through the reduction of smoking, depression, and stress with the use of an empirically based computerized tailored intervention (CTI) or expert systems. The more immediate objective of the project was to adapt and modify a successful CTI system for the general adult population to be relevant and applicable to military veterans with Post-Traumatic Stress symptoms, particularly those who have been deployed to Iraq and Afghanistan. Research with returning Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF) veterans suggests that there is a new generation of veterans with high levels of Post-traumatic Stress Disorder (PTSD) and depression (Hoge, Auchterlonie, & Milliken, 2006). Therefore, it is critical that we identify effective ways to increase access to efficacious treatments for combat-related PTSD and associated co-morbid behavioral health conditions. Further, due to the rapid development of Telemental health programs throughout the military, it is crucial that research address the effectiveness of this mode of service delivery for specialty services such as PTSD treatment.

This proof of concept project adapted and pilot tested a viable Internet-based intervention to assist veterans with Post-Traumatic Stress symptoms to progress toward changing negative health behaviors that are associated with PTSD and often difficult to change. Most commercially available CTIs and software applications have limited impact, because of the lack of theory-driven material and empiricism. The project's CTI is supported by more than 30 years of scientific evidence, and uses the Transtheoretical Model of Behavior Change (TTM) as the theoretical basis for generating personalized feedback (Prochaska & Velicer, 1997; Velicer,

Prochaska, & Redding, 2006). The TTM is ideally suited to those who are resistant to change and unlikely to take action in the near future, as well as those prone to relapse.

The intervention primarily targeted negative coping strategies that confound or exacerbate Post-Traumatic Stress symptoms and hinder progress toward remission. Progress in a TTM conceptual framework may be defined as movement from one TTM stage of change to the next level of the change process, rather than the elimination or significant reduction of smoking, depression, or stress per se. The CTI system modified during this project has been empirically tested and validated with a general population and has demonstrated significant outcomes for the three modules — smoking cessation, depression prevention, and stress management. The CTI system provided veterans with an intervention that emphasized advancement through the processes of change at one's own pace, rather than the typical linear progression through a structured behavior change program, to achieve changes in the undesired behaviors.

Hypothesis 1: *The structure and TTM-based content of the adapted Smoking Cessation, Depression Prevention, and Stress Management systems and consequent CTI will be appropriate for veterans.*

> **Primary Aim 1:** To modify TTM-based Smoking Cessation, Depression Prevention, and Stress Management behavioral intervention modules, originally developed for general adult populations, to be appropriate and relevant for veterans with PTSD symptoms.
>
> **Secondary Aim 1a:** To conceptualize the CTI program's approach, content, and design based on input from a diverse sample of military veterans and expert consultants.

Hypothesis 2: *A multi-behavioral CTI can be successfully implemented with veterans who have PTSD symptoms*

> **Primary Aim 2:** To demonstrate that a multi-behavioral CTI can be successfully implemented with veterans with PTSD symptoms.

Secondary Aim 2a: To conduct usability interviews with veterans to ensure that the target population can navigate through the computerized intervention and understand the intervention content.

Secondary Aim 2b: To demonstrate the feasibility of CTI by: a) recruiting veterans to the project and delivery of the proposed intervention; and b) assessing the acceptability and perceived usefulness of the intervention from the perspective of veterans with PTSD symptoms.

Secondary Aim 2c: To demonstrate feasibility of CTI to increase motivation to change targeted behaviors, i.e., smoking cessation, depression prevention, and stress management.

Secondary Aim 2d: To demonstrate positive change in assessment outcomes for PTSD symptoms, depression, quality of life, and perceived stress.

BODY

I. TASK COMPLETION

Task 1: IRB Protocol review and approval – 100% complete
- 1a. Local IRB – approved, continuing review approved
- 1b. 2nd level-USAMRMC -approved

Task 2: Project planning and coordination –100% complete

Task 3: Focus groups for 3 modules – 100% complete
- 3a. Recruit Veterans
- 3b. Conduct focus groups
- 3c. Analyze data & identify content changes

Task 4: Integrate modules into multi-behavioral CTI with single home page –100% complete

Task 5: Modify & tailor 3 modules to Veterans – 100% complete
- 5a. Modify content of feedback narratives for each module
- 5b. Modify CTI program

Task 6: Conduct beta test & usability interviews–100% complete
- 6a. Beta test CTI system
- 6b. Recruit Veterans & conduct usability interviews
- 6c. Modify CTI program

Task 7: Conduct feasibility study– 100% complete

7a. Recruit veterans & orient to CTI system
7b. Conduct baseline and post assessments
7c. Analyze data & interpret results

Task 8: Submit final report– 100% complete
8a. Prepare & submit final report
8b. Initiate manuscript preparation
8c. Prepare presentation for scientific meeting

II. METHODS

All procedures were approved by the VA Pacific Islands Health Care System (VAPIHCS), the U.S. Army Medical Research and Materiel Command's Human Research Protection Office (HRPO), and participating IRBs.

Recruitment

Focus Groups: Participants were recruited from the veteran community in Hawai'i with posters, flyers and by word of mouth. Interested veterans called to be screened for eligibility based on eligibility criteria. Ten qualified veterans were recruited for each focus group to evaluate a CTI program addressing one of the three PTSD-related behavioral risk factors, i.e., smoking, stress, and depression. Participants received a $25 gift card upon completion of the focus group to compensate them for their time and travel expense.

Usability Testing: Usability testing participants were recruited from the veteran community in Hawai'i with posters, flyers and by word of mouth. Interested veterans called to be screened for eligibility based on predetermined criteria. Qualified veterans scheduled an appointment to evaluate and test the CTI while being observed and recorded by research staff. Five tests were scheduled and conducted for each behavior module (smoking cessation, stress management, and depression prevention). Participants received a $50 gift card upon completion of the usability testing session to compensate them for their time and travel expense.

Feasibility Study: Participants were recruited through targeted mailings to VA patients at risk for PTSD (based on diagnostic codes); study flyers distributed by VA mental health providers; and national advertising on Web-based social media networks to target veterans of Operation Enduring Freedom (OEF)/Operation Iraqi Freedom (OIF). Interested veterans visited the study Web site to create a unique login and answer questions to determine eligibility. All participants had to confirm that they were veterans 18 years of age or older and had beginner level or greater computer literacy; eighth grade English literacy; and access to a computer with Internet connectivity. Initial screening excluded potential participants if they reported a history of mania, schizophrenia, or other psychoses; special medical conditions that may have prevented engagement with the CTI system, such as history of significant head injury; and/or suicidal ideation. In order to minimize participant risk, secondary screening excluded veterans who did not meet risk criteria for mild to moderate PTSD (score <25 or >73 on the PCL-M), or had severe depression (scoring ≥20 on the PHQ-8).

Veterans excluded by secondary screening were presented with an explanation that the current study could not meet their healthcare needs, and were provided with several referral options and an emergency help-line number on screen. Those meeting all study requirements and choosing to continue were consented and enrolled in the study. Participants were eligible to receive up to $125 in gift cards to reimburse them for their time and effort after completing the required activities for the study. They received electronic gift cards of $40 after completing the baseline assessment; $30 after the 1-month follow-up; and $55 after completing the final 3-month follow-up. In an attempt to improve retention, the amount was set higher for the final follow-up assessment.

Procedures

Focus Groups: Three focus groups were used to gather information on the acceptability of existing CTI program content for each behavior. Each group reviewed a behavior change module in order to match the expectations and needs of the target population. Each focus group (8-10 veterans; about 1.5 hours) was audio recorded with a note-taker present. Prior to the focus group meetings, participants provided informed consent, and completed stage of change and basic demographics measures. Participants were asked to provide feedback about the graphics, text and layout based on screen shots of the online system.

Adaptation and Beta-testing: CTI system content for the smoking cessation, stress management, and depression prevention behavioral modules were reviewed, adapted, and adjusted based on the theme-based focus group analyses. This included probes about veteran specific issues. The major focus of the revisions addressed adaptation of language, tone, and content to make it appropriate and relevant the veteran population. Iterative internal testing was done prior to usability testing with veterans.

Usability Testing: After the CTI program had been adapted and beta-tested, its acceptability and usability (National Cancer Institute, 1989) was examined as part of the system development process. Efforts were made to include veteran participants with varying levels of experience using interactive web-based multimedia programs (National Cancer Institute, 1989) and at various stages of change for the specific behaviors. Usability testing provided a scientific assessment of user errors, misunderstandings of content, navigation problems, and subjective satisfaction. This feedback was invaluable to the system design process and improved the acceptability and usability of the final system.

Participants were screened by telephone and scheduled for a testing session. Before beginning the session, the testing was described to them and they provided informed consent. During the usability testing, research assistants observed a participant as he or she navigated through the CTI system, resisting the temptation to offer help too soon to allow usability issues to be revealed. Participants were asked to think and make comments aloud as they worked through the various screens in the registration process, the introduction to the program, the assessment questions, the feedback messages, as well as the integration of the different behavior modules. The audio and video of screens visited and mouse movements were captured and recorded automatically for review and analysis. Participants were asked to interact with relevant sections of the integrated program, including the e-Workbook, and asked to comment on the options and content available. Participants provided qualitative and quantitative feedback on overall presentation and usability, as well as quality of the program, navigation, ease of use, attractiveness, etc. Feedback from individual interviews was then used to further modify the behavior modules and system integration before second round usability interviews were conducted. The comments from all interviews were used to modify the CTI system prototype prior to the feasibility study. At the conclusion of each usability interview, participants were asked to provide feedback on the module they interacted with using a measure adapted from existing acceptability measures (Cardinal, 1995; National Cancer Institute, 1989; Rimer et al., 1994) that has been used by Pro-Change in previous research.

Feasibility Study: Behavioral comorbidities of PTSD impact veterans' health and recovery. The three-month feasibility test was designed to assess acceptability and viability of the CTI system and the behavioral modules by veterans in the community, particularly recent

veterans returning from the Iraq or Afghanistan combat theaters. The CTI intervened at baseline, 1, and 3 months, and targeted smoking, depression, and stress. Participants selected a minimum of 2 behaviors and completed self-guided programs for 1-2 hours per month. In addition to behavioral and affective change, the study examined co-action effects associated with the intervention—whether interventions on targeted behaviors could improve PTSD and other behaviors such as sleep, alcohol use, exercise, and diet.

Participants provided informed consent and completed baseline, one- and three- month online questionnaires (see list of questionnaires in the Outcome Measures & Assessment Instruments section below). The project was approved for online screening and informed consent, allowing the registration, screening, and enrollment process to be automated for the feasibility testing. Veterans interested in participating in the feasibility study and meeting the basic criteria listed in the recruitment material visited the project webpage to complete the screening and consent process. After confirming that they were military veterans over the age of 18 and comfortable using a computer and the Internet, prospective participants had to meet inclusionary criteria by confirming that they have had a military experience so traumatic that in the past month they have had nightmares; been unable to stop thinking about it; were constantly on guard; and/or felt numb or detached because of it. Following this, they were asked to self-report whether they had any of the exclusionary criteria (history of schizophrenia, bipolarism; admitted as mental health inpatient in the past 2 years). If they passed the online prescreening questions, they were asked to view and print the informed consent fact sheet, which listed information about the study and their rights and responsibilities as participants. Next, they completed the PCL-M and PHQ-8 questionnaires and were enrolled in the study if the scores fell

within the allowable range for the study (exhibited mild to moderate PTSD >24 and <74 on the PCL-M; and were not severely depressed <20 on the PHQ-8) and they chose to enroll.

Participants were provided access to the Internet-based CTI system addressing smoking cessation, effective stress management, and depression prevention until they completed the final 3-month assessments. Participants who were non-smokers were not given access to the smoking cessation module. Participants were asked to participate in a minimum of three sessions for each module (at least once per month), and for at least two of the three modules. Enrollment included the consenting process and collecting demographics and an email address. The email address was used to provide system reminders to participants who had not accessed the system in 30 days. Participants completed assessments at baseline, 1- and 3-months.

Outcome Measures & Assessment Instruments:

Demographics Questionnaire Demographic data including race/ethnicity, age, gender, combat theater(s) served in, and total number of months in theater(s) were collected.

PTSD Symptom Checklist (PCL-M) (Weathers, Litz, Herman, Huska, & Keane, M., 1993). The PCL-M consists of 17 questions that map directly onto DSM-IV criteria for PTSD. Respondents are asked how often they have been bothered by each symptom in the past month on a 5-point Likert scale (1="not at all" to 5="extremely"). All items are summed to obtain a total severity score. A score of 44 is considered PTSD positive for the general population, while a score of 50 is considered PTSD positive in military populations.

Combat Trauma Exposure Survey (CTES) (Tanielian & Jaycox, 2008). The CTES is an 11-item, self-report survey that assesses the type of an individual's combat trauma experiences. It includes both direct (e.g., injury requiring hospitalization) and indirect trauma

exposure (e.g., witnessing a traumatic event) adapted from (Hoge et al., 2004)which requires only a yes or no response (Tanielian & Jaycox, 2008). The subset of 11 exposures used in the brief survey were found to be as predictive of PTSD as the full 24 items in veterans residing in NY (Farmer et al., 2011)

The Perceived Stress Scale (PSS) (Cohen, Kamarck, & Mermelstein, 1983). The PSS is a 10-item questionnaire assessing the degree to which situations in one's life are appraised as stressful. Items are designed to tap how unpredictable, uncontrollable, and overloaded respondents find their lives.

Patient Health Questionnaire (PHQ-8) (Kroenke & Spitzer, 2002; Kroenke, Spitzer, & Williams, 2001). The PHQ-8 is an eight item version lacking the ninth question regarding suicidal ideation of the PHQ-9, a tool for assisting clinicians in diagnosing depression as well as selecting and monitoring treatment. The PHQ-8 was selected for this study as responses were collected independently online and there was no personal interaction with the participants so any response by clinicians would be delayed. Also, the suicidal ideation question is rarely endorsed and most often reflects passive rather than active thoughts of suicide (Kroenke et al., 2010). The PHQ-8 is based directly on the diagnostic criteria for major depressive disorder in the DSM-IV, and includes items such as "Little interest or pleasure in doing things"; Feeling tired or having little energy." Respondents rate how often they have been "bothered by problems over the past 2 weeks" using a 4-point Likert scale (0= not at all; 3=nearly every day). Scores in the range of 5-9 indicate minimal symptoms; 10-14 minor depression or dysthymia; 15-19 major depression (moderate); and greater than 20 severe major depression.

Quality of Life Scale (QOLS)(Flanagan, 1978, 1982). The QOLS contains 16 items that represent five conceptual domains of quality of life. QOLS was developed with more consideration to cultural diversity and individual perspectives than other commonly used measures. It uses a unique 7-item Likert scale that allows responses regarding different aspects of life to range from "delightful" to "terrible". The original 15-item QOLS satisfaction scale was found to be internally consistent with alpha from .82 to .92 and showed high test-retest reliability over 3-weeks (r = 0.78 to r = 0 .84). Similar reliability was reported for the 16-item version used in this study (Burckhardt & Anderson, 2003).

Stage of Change for Depression (Levesque et al., 2011). This measure assesses readiness to engage in effective methods for preventing depression. The assessment includes a short description of depression prevention – Using effective methods to keep depression from occurring, or if it does occur, to keep it as mild and brief as possible. Respondents are asked, "Do you effectively practice depression prevention in your daily life?" A single item response category places individuals in one of the five stages of change.

Stage of Change for Stress Management (Evers et al., 2006). This measure assesses readiness to effectively their daily stress. The assessment includes a short description of stress management (stress management includes regular relaxation, physical activity, talking with others, and/or making time for social activities) and asks respondents, "Do you effectively practice stress management in your daily life?" A single item response category places individuals in one of the five stages of change.

Stage of Change for Smoking Cessation (DiClemente et al., 1991; Prochaska & Velicer, 1997). This measure assesses a readiness to quit smoking. Participants are asked if they

have quit smoking. A single item response category places individuals in one of the five stages of change.

Health Risk Intervention Survey (HRI) (Pro-Change, 2009). This is a brief customizable online questionnaire that was completed when a Feasibility Study participant first logs onto the CTI and at each assessment. The survey consists of questions to obtain user information about behaviors related to smoking cessation, stress management, and depression prevention. It also includes questions regarding other healthy behaviors, such as eating, sleep, alcohol, and exercise. The behavior information will be used to assess the participant's stage of change relative to the specific behavior being studied prior to engaging in the online behavior change facilitation modules for the specific behavior.

Evaluation of and Satisfaction with Intervention Materials (ESIM). This is a 16-item questionnaire intended to obtain user feedback about the CTI intervention materials and is typically used by Pro-Change during the program development process. Twelve items are rated on a 5-point Likert scale from 1 (Strongly Disagree) to 5 (Strongly Agree) and assess multiple dimensions of the intervention materials including ease of use, clarity of items and feedback, attractiveness, appropriateness of tailoring, degree of interest and enjoyment, ability to convey information, ability to change attitudes, helpfulness, ability to elicit appropriate action, and credibility. Total possible scores range from 12 to 60, with higher scores indicating higher user satisfaction with the intervention materials. The last four questionnaire items are open-ended questions requesting participants to provide suggestions and criticisms of the intervention materials. Usability Interview and Feasibility Study participants may be administered an online or paper-and-pencil version of this questionnaire after completing the interview or study.

System Usability Scale (SUS) © Digital Equipment Corporation, 1986, (Brooke, 1996). This is a 10-item questionnaire designed to assess the subjective usability of a computer software system. The SUS can be administered as a paper-and-pencil or an online questionnaire. Items are rated on a 5-point Likert scale from 1 (Strongly Disagree) to 5 (Strongly Agree). Total possible SUS scores range from 0 to 100, with higher scores indicating higher system usability. Early assessment indicated that the SUS demonstrated good reliability with a coefficient alpha value of 0.85 (Lucy, 1991; Kirakowski, 1994; as cited in (Lewis & Sauro, 2009) Usability Interview and Feasibility Study participants were administered an online or a paper-and-pencil version of the questionnaire after completing the interview or study.

Data Analysis Plan

Hypothesis 1:

Focus Groups: The primary aim of the study was to adapt and test the feasibility of a multiple behavior TTM-based CTI designed for the general adult population so that it would be appropriate for veterans with or at-risk for PTSD. Data analysis was conducted from qualitative data obtained from the smoking, depression, and stress focus groups. Data from the focus groups was coded and analyzed according to guidelines outlined by Miles and Huberman (1994) and Krueger (1998). Immediately after each focus group, the facilitator and research assistant (note-taker) debriefed about the group, noting common themes, unexpected items, and group dynamics. After all focus groups were conducted, the audio recordings from each group were transcribed and all identifiers removed to protect confidentiality. Transcripts were studied to identify common themes, and frequencies of responses noted. To be considered a theme, an idea had to be mentioned several times within a group or across groups. Similar responses were

grouped together, and categories identified and coded into descriptive headings based on the content of actual quotes. Matrices were used to organize quotes and paraphrases in a systematic data display (Miles & Huberman, 1994). Decisions made as to what headings and subheadings were used in each matrix were based on the questions posed. Common themes were identified, sorted, and compared. Analysis included systematic steps for identifying basic concepts and comparing results with other groups in order to find common patterns (Kreuger, 1998).

Development and Beta-Testing: Based on the results of the focus group data, the system was adapted to meet the needs of veterans and then beta-tested internally. The iterative testing and development process followed standard software development practices. Testing was done by machine following various sequences and after programming and content errors were eliminated, the research team staff followed a similar protocol to test and retest the system for omissions, errors and bugs prior to usability testing.

Usability Testing: Following the internal testing and adaptation of the system, 15 usability testing sessions were completed with volunteer veterans at risk for PTSD. The results of the first round of usability testing (3 sessions per behavior module) were reported for implementation to the system, and were completed as time and resources allowed before the second round tests were done. The usability testing provided a scientific assessment of user errors, navigation problems, and subjective satisfaction. This feedback was invaluable to the system design process and improved the acceptability and usability of the final system. Suggestions for additional adaptation of the CTI that could not be implemented will be completed in future rounds of improvements to the system.

Hypothesis 2:

Feasibility Study: The usability interviews and feasibility study with veterans at risk for PTSD provided data regarding the feasibility of implementing a multi-behavioral CTI with veterans who have Post-Traumatic Stress symptoms. The Usability Test data was derived from the assessment of multiple dimensions of the intervention materials including content, credibility, attractiveness, readability, helpfulness, ease of use, appropriateness of tailoring, ability to convey information, ability to change attitudes, and ability to elicit appropriate action, as well as an overall rating. The critique (suggestions and criticisms) of all aspects of the program, including appearance, navigation, usability, screen layouts, color and graphic selection, etc. was evaluated to identify common themes, and frequencies of responses. Similar responses were grouped together, and categories identified and coded to inform the adaptation and improvements made to the CTI before feasibility testing with veterans with PTSD.

All statistical analyses were conducted using IBM® SPSS® Version 20.0. Demographics were analyzed using descriptive statistics, frequencies, crosstabs, and t-tests. The following criteria was used to determine feasibility of the CTI for veterans with PTSD:

a) Completing the customization and testing of the baseline CTI;

b) Recruitment and delivery of the baseline intervention to approximately 50 veterans; and

c) Determination of the acceptability of the intervention, represented by an overall rating of 4 (good) or better by 75% of the participants on the ESIM. Acceptability is represented by a combined score of 68 or greater on the SUS using the standard scoring method and multiplying the resulting tally by 2.5. (Brooke, 1996).

Frequencies and means analysis were conducted to analyze and describe participant demographics. A univariate ANOVA was employed to examine whether any statistical

differences existed between those participants who were lost to attrition after baseline, and those who completed the study. Repeated measures ANOVA was used to examine longitudinal changes in behavioral assessments (PSS, PHQ-8, number of cigarettes per day) and outcomes measures (PCL-M, and QOLS).

Changes in stage of change distribution over time were examined in two ways. 1) Frequency distributions for each behavior at each timepoint; and 2) stage progression, maintenance, or regression was calculated by subtracting the stage score (i.e., PC=1, C=2, PR=3, A=4) of an earlier timepoint from that of a later timepoint. Negative valence scores indicate progress through the stages, positive valence scores indicate regression through the stages, and "0" indicated "no change." Plotting these frequencies allowed examination of within-subject change. Correlations between the frequency of use (the number of logins to the system) and outcome and usability measures were also examined.

III. RESULTS

Participants

Focus Groups: Thirty veterans were recruited and twenty-one veterans participated (70% participation rate); nine veterans in the smoking cessation group, six in the stress management group, and six in the depression prevention group. See Table 1 for demographics.

Usability Interviews: Twelve veterans participated in the usability testing. Fifteen sessions were completed, with five sessions for each of the three behavior modules. O ne participant was too stressed and could only complete the baseline assessments, not the behavior module. Assessment data was not collected as the participants were asked to try to take on a different persona for the purpose of answering assessment questions during usability testing.

One veteran was able to test three modules, and two had time to complete testing for two modules. The other nine veterans tested only one module. Those who had time after finishing the behavior module, also looked at the e-Workbook and other optional activities and gave feedback on usability. See Table 2 for demographics.

Feasibility Study: Of the 354 veterans who created logins and attempted to enter the feasibility study, 95 did not complete initial screening; 169 were screened out for not meeting inclusionary and/or possessing exclusionary criteria; and 25 completed only baseline assessments; 8 completed baseline and the 1-month assessments; and 57 completed assessments at all three timepoints. See Table 3 for demographics of 90 enrolled participants by completion status.

Focus Group Feedback

Content. In general, participants thought the content of the three programs was appropriate for veterans who were having difficulty quitting smoking, managing stress, or preventing depression. They found the concept of stages of change to be helpful for self-evaluating and stage-tailored feedback encouraging for progress. In terms of decisional balance feedback, participants identified with most pros and cons provided. Participants especially liked aspects of the system that acknowledged their autonomy as veterans. The individually tailored feedback on processes of change was also considered to help them adopt useful strategies or maintain effective strategies already employed. Many participants believed that the included goal-setting would be very useful in helping them move forward through the stages. In particular, small steps toward specific goals were especially appealing because it increased the manageability of behavior change. Scientific and user-friendly language each gained some

support, with a preference for a combination. They particularly preferred text that is clear, concise, specific, informative, and easy to understand. Most graphics in the programs were considered appropriate for the information presented in the corresponding text and helpful for users to better understand the content or feel more positive about changing. For example, pictures of the bright beach and grassland in the stress management program were thought to be relaxing and representative of a way to manage stress.

Although the majority of the content was appropriate, some was considered difficult or inappropriate. When reviewing the screenshots, participants had difficulty understanding a couple of professional terms without a definition or explanation, such as "transtheoretical" and "contemplation." They also had difficulty relating to the function of the "pros and cons" exercise. In addition, they indicated that some benefits (e.g., improvement in appearance) and certain activities (e.g., Tai Chi) in the CTI may not appeal to veterans. Furthermore, they did not like graphics that triggered combat memories or unhealthy behaviors, including the beach at sunset and cigarettes. They also suggested that helping relationships were a source of stress rather than support for veterans because of difficulty relating to non-veteran friends and family members.

Some suggestions for adaptation were proposed during the discussion. Inclusion of more scientific-based information in a user-friendly language was recommended; however, it should be noted that definitions for these terms are included in the CTI but were not reviewed during the focus group sessions. Providing more veteran-specific helping strategies was proposed, such as "couples counseling" for post-deployment relationship building and avoidance of isolation for

the depression prevention. Participants also suggested that the content of the graphics be consistently related to the written information.

Structure. Overall, participants thought the programs were well constructed and would be easy for users to navigate. In most parts, the text was considered clear, concise, and easy to understand. Most screenshots from the programs were perceived to provide a good balance between text and graphics. The color, size and layout of different components, i.e., text, graphics, and icons, were largely endorsed as appropriate in terms of usability and appearance. Especially, participants liked graphics that were engaging, pleasant, calming, and explicit. They believed that screenshots containing minimal text and appearing less compact were appealing to depressed users. Some graphics in the depression prevention program were thought to be too dark or depressing.

In spite of all the strengths reviewed above, some structural problems that might affect the applicability of the programs were identified. Some screenshots from the depression prevention program were thought to have too much text. Regarding the layout, the proportion of the text in some screenshots was visually overwhelming.

Several additional suggestions for adaptation were made to further improve the applicability to veterans. Bulleting points were recommended to simplify the narrative text. Light color schemes, such as lavender, sky blue, and pink, were suggested to make the programs appealing to both genders. In addition, a few participants proposed using a consistent layout throughout each program to make it easy for users to follow along.

Veteran-Specific Issues. In addition to the applicability of existing CTI programs to veterans, issues specific to veterans were elicited. Three major issues were identified from the

transcript (see Table 4). One noticeable issue to veterans was that their support systems were largely confined to the VA programs and peer veterans. They expressed a feeling of alienation from non-veterans after returning from combat and difficulty communicating with them. They admitted that it was especially stressful and challenging for them to communicate with and gain support from family members in changing unhealthy behaviors related to combat experience. They articulated a need for educating family members about combat experience and strategies for effective communication with non-veterans.

Another salient issue to veterans was the influence of the stigma and shame around mental health problems and their treatment. Although participants acknowledged the significant improvement in this area, they still reported difficulty admitting receiving counseling or therapy to a medical provider. In addition, some participants emphasized the importance of confidentiality promised by the CTI for disclosing their compliance to medication; in contrast, other participants did not have any concerns about the issue once they were out of the military.

Another significant challenge for veterans was avoiding unhealthy behaviors in high-risk situations. Some participants shared that it was extremely difficult to resist alcohol use if they were having trouble falling asleep. Some indicated difficulty avoiding smoking when they were drinking alcohol or coffee because they habitually engaged in these behaviors simultaneously. Others reported that they were more likely to resort to unhealthy behaviors once the healthy behavior failed to work. Lastly, frustration due to the lack of understanding and support from family members was also identified as a trigger for engaging in unhealthy behaviors.

See Appendix D for the Focus Group Analysis Report and Appendix G for a brief report that is pending publication in Military Behavioral Medicine.

Usability Testing Feedback

Usability testing delivered information on user errors, misunderstandings of content, navigation problems, and satisfaction. This feedback was invaluable to the system design process and improved the acceptability and usability of the final system. Analysis of the usability recording and user feedback yielded five major types of recorded usability events:(1) Navigation difficulties;(2) Semantic confusion; (3) Errors; (4) Suggestions; and (5)Positive Comments.

Navigation: Several participants had difficulty navigating the homepage. They could not find the link to go forward, or find the e-Workbook. They also had difficulty finding the link to continue in the study from the Study Fact Sheet during the consenting process. Often navigation errors were corrected by the user reading or re-reading instructions more carefully

Semantic confusion: An example of this is misinterpreting the meaning of symbols and text on the system. Some users were unable to understand that they needed to click the program in the list to start that program. To mitigate this type of confusion, the program links were enhanced to look like buttons, and small icons were incorporated that turned red when it was not time to do the program, and green when the participant was eligible to do the program and could then click the button to start. Several users were confused by pages that were educational and did not require something to be clicked. They would often try to click on bulleted items, thinking they were supposed to select an answer. Again style changes were made to clarify the educational slides that were to be read and were not interactive.

Errors: When a participant tried to set up a login and received an error indicating that he or she was not a returning user; the participant had not seen the “First Time Registering” link. The instructions to register and create a new user ID were moved to a different location, so that

participants could easily find them. Other error messages were similarly addressed by emphasizing the link or information that was missed that caused the error to occur.

Suggestions: Female participants were more sensitive to the color and graphics on the system. Two of the three female participants suggested having brighter colors and thought most of the screens were too boring. None of the male participants commented on this unless asked about the colors. They all said they were fine or they had not noticed them. Other suggestions for improvements included a preference for more graphics throughout the system, less text, confusion about how to answer pros and cons questions, and a recommendation to add drop down menus to some of the questionnaires. Suggestions that could be incorporated into the system without compromising the content or requiring a redesign of the GUI were incorporated when time and resources permitted it.

Finally, positive comments often reflected personal tastes, such as liking the color scheme, and liking certain photos. However, more often, positive comments were associated with the content of the system, such as the positive feedback and encouragement, the inclusion of the e-Workbook, the printable feedback report, and the relevance of the program to veterans. Users generally liked the system and thought it was easy to use and would be helpful for them. A copy of the deidentified user comments and summary analysis are attached as Appendix E.

The system evaluation (SUS) adjusted scores for the usability participants who completed all questions on the SUS and at least one program evaluation averaged 79.68, which is much higher than the cut-off of 68 for good usability. One of the participants was too stressed to complete the stress management program testing, so there is some evidence that highly impaired veterans may have difficulty using the CTI. The usability test participants mean score on the 12

Likert items in the ESIM evaluation was 48.75, which is an overall mean of 4 per item, indicating acceptability of the system. The qualitative responses were generally positive and similar to the responses and comments recorded during the testing sessions.

Feasiblity Study Results

Approximately 63% of enrolled participants completed all study follow-ups. See Table 5 for details on retention rates. The different demographics of the 90 participants who enrolled and the 57 who completed the study can be found in Tables 6, 7 and 8 by completion status. No statistically significant differences were found in demographics or baseline risk scores between those who were lost to attrition, and those who completed the study. As a result, the following analyses were conducted only on those for whom complete data are available (n=57). Participants (n=57) had a mean age of 40.5 (SD=11.2), 74% were male, 70% White, and 56% married, with 86% reporting at least some college. The participants showed mild to moderate PTSD (mean PCL-M score=55.6, SD=9.4) and depression (mean PHQ-8 score=12.0, SD=4.0).

Stage of Change

Significant positive change was observed for behavioral outcomes. At 3-months, 27% of those who smoked cigarettes at baseline had quit ($\chi 2(1)=23.5$, $p<.001$); 72% of those in pre-action stages for stress were practicing effective stress management at criteria ($\chi 2(1)=6.2$, $p=.013$); and 67% of those "at risk" for depression reported they were in the action or maintenance stage of change ($\chi 2(1)=8.8$, $p=.003$). Baseline frequency for the stages of change at baseline for Smoking Cessation, Stress Management and Depression Prevention are provided in Table 9. Since not all participants were smokers, sample sizes vary. Previous TTM-based research examining stage of change distributions report fairly consistent patterns across some

behaviors. For smoking cessation, several studies have replicated the 40% Precontemplation, 40% Contemplation, and 20% Preparation ratio (Laforge, Velicer, Richmond, & Owen, 1999; W F Velicer et al., 1995). Other TTM-based studies have found early-stage distribution patterns for stress management to be about 50% Precontemplation, 30% Contemplation, and 20% Preparation (Evers et al., 2006; Prochaska et al., 2011). One depression prevention study utilizing the TTM found a distribution pattern of 20% Precontemplation, 20% Contemplation, and 60% Preparation (Levesque et al., 2011). This sample of veterans demonstrated somewhat different distribution patterns among early-stage participants. For example, almost 60% of smokers were in the Contemplation stage for smoking cessation. More than 50% were in the Preparation stage for stress management, while just over 40% were in Contemplation or Preparation for depression prevention. Furthermore, approximately 40% of all participants reported being in Maintenance for the three behaviors.

When examining trends in stage progression, maintenance, or regression, the CTI helped a large proportion of individuals progress at least one stage of change from baseline to three months (see Table 10). For example, 22.8% of smokers progressed at least one stage of change. Approximately 47% and 39% of participants progressed one or more stages for stress management and depression prevention, respectively. Behavioral outcomes indicated that 27.5% of those who smoked cigarettes at baseline had quit at the three-month timepoint. For those in the pre-action stages for stress management, 72.4% were practicing effective stress management by the three-month timepoint; and 66.7% of those "at risk" for depression reported that were practicing effective depression prevention strategies at three months.

The number of participants was too low to analyze the groups by stage, so they were divided into Pre-Action and Action/Maintenance groups for analysis. See Table 9 for frequencies by exact stage of change at each time point. Co-action from learning behavior change was apparent, as 30-40% of veterans in pre-action at baseline moved to action for Exercise, Healthy Eating, Alcohol Use, and Sleep Management behaviors. Charts depicting the stage changes in both targeted and non-targeted behaviors from Pre-Action and Action/Maintenance are available in the International Society for Traumatic Stress Studies (ISTSS) 2012 presentation in Appendix H. These findings are noteworthy; particularly, since the intervention was self-guided, required minimal time commitment, and is highly scalable.

Behavioral Measures

Consistent with the stage of change distributions were the changes in number of cigarettes smoked daily, perceived stress, and depression. As expected, stress levels appeared much higher in this sample than those in the general population. According to Cohen (1988), PSS mean norms for men and women are 12.1 (*SD*=5.9) and 13.7 (*SD*=6.6), respectively. This sample's reported mean stress at baseline was 24.3 (*SD*=5.9), which was significantly higher than at three months (mean score=20.5, SD=7.3; Wilks' λ=0.81, p=.001, η^2=.19).

Participants also demonstrated symptoms of moderate depression (*M*=12.0, *SD*=4.1, range=3-19) that were significantly higher at baseline than at three months (mean score=9.9, SD=5.8; Wilks' λ=0.90, p=.015, η^2=.10). The PHQ-8 provides a 0-24 severity score. Scores in the range of 5–9 indicate mild symptoms, 10–14 moderate depression or dysthymia, 15–19 moderately severe depression, and greater than 20 severe depression.

Outcomes Measures

Although the CTI did not provide specific interventions for PTSD or quality of life, significant changes from baseline to three months were found in both. Participants reported mild to moderate PTSD symptoms at baseline, based on their PCL-M ratings (M=56.6, SD=10.0). It is generally accepted that scores of 17-33 indicate low posttraumatic stress (PTS); scores of 34-43 represent moderate PTS; and scores ranging from 44-85 suggest high PTS. Mean PCL-M scores at three months were 48.8 (SD=15.8; Wilks' λ=0.81, p=.001, η^2=.19).

QOLS scores can range from 16-112. Higher scores indicate higher quality of life. Average total score for healthy populations is about 90 (Burckhardt & Anderson, 2003). Our population reported much lower quality of life at baseline than average (M=62.4, SD=12.6). Quality of life at three months was significantly greater (M=69.5, SD=16.4; Wilks' λ=0.83, p=.001, η^2=.17). See Table 7 for symptoms and Table 8 for changes in outcome measures.

KEY RESEARCH ACCOMPLISHMENTS _____

1. Accomplished all required due diligence and administrative work to receive a highly unusual VA IRB approval to waive consent forms and HIPAA authorization for all phases of this study. This approval was sought to allow veterans to consent, screen, and enroll, and test the new program anonymously from the privacy of their own homes, without having to provide social security numbers or have their medical records accessed in order to add required progress notes regarding their participation in the study.

2. Completed all aspects of Phases 1-3 of the study to adapt and develop the CTI for feasibility testing.

3. Launched the revised STR2IVE Program on July 22, 2011 and began recruiting the target population through a mailings sent to veterans in the VAPIHCS database.

4. Manuscript on the study concept entitled "A Computerized, Tailored Intervention to Address Behaviors Associated with PTSD in Veterans: Rationale and Design of STR2IVE" was accepted for publication in *Translational Behavioral Medicine: Practice, Policy and Research.*

5. A no-cost extension was approved on January 13, 2012, making the new end of research on April 2, 2012 and the new POP on May 2, 2012.

6. Completed Phase 4 feasibility study, meeting and exceeding project recruitment and retention goals.

7. A final 5-month no-cost extension was approved on March 13, 2012 to allow more time to

complete additional data analysis, report and manuscript writing, and to submit presentations to additional conferences. The new POP ended on October 2, 2012.

8. Continuing review application was approved by VA IRB on August 21, 2012 and HRPO on September 24, 2012, and is valid through August 20, 2013.

REPORTABLE OUTCOMES

Publications:

1. Jordan, P., Evers, K., Burke, K., King, L., & Nigg, C. (2011). A Computerized, Tailored Intervention to Address Behaviors Associated with PTSD in Veterans: Rationale and Design of STR^{2}IVE. *Translational Behavioral Medicine*, Vol. 1, No. 4, 595-603. DOI: 10.1007/s13142-011-0088-1. (See Appendix F.)

2. Nigg, C. R., Jordan, P. J., Huang, Y., Burke, K., Kawasaki, M., Evers, Kerry E., K. E., King, L. & Spira, J. Identifying veteran-specific issues in adapting a computerized, tailored intervention to address behavioral risk factors associated with PTSD: A focus group approach. (Revised and resubmitted to *Military Behavioral Health*) (See Appendix G for resubmission.)

3. Jordan, P. J., Nigg, C. R., Evers, K. E., King, L. & Spira, J.L. Patterns of Behavioral Health Risk Factors Across Stages of Change Among Veterans with PTSD. (Preparing Manuscript)

4. Jordan, P. J., King, L., Evers, K. E., & Spira, J.L. A Computerized, Tailored Intervention to Reduce PTSD Symptoms in Veterans: Outcomes of the STR2IVE Study. (Preparing Manuscript)

Presentations:

1. Jordan, P. J., King, L., Lid, V. (2011). A web-based methodology for promoting health behavior change in veterans with PTSD-related comorbidities. Presentation to the National Center for PTSD, PTSD Research Group, 18-August-2011, via videoteleconference. (See Q9, Appendix B for slides.)

2. Jordan, P.J., King, L.A., Lid, V., Evers, K.E., & Nigg, C.R. (2012). Stage of change for multiple behaviors in veterans with and without PTSD. Poster presented at the 33rd Annual Meeting and Scientific Sessions of the Society of Behavioral Medicine, New Orleans, LA, April 11-14, 2012. (See Q11, Appendix E for presentation.)

3. King, L.A., Jordan, P.J., Evers, K.E., & Spira, J.L. (2012). A web-based multibehavioral change program for veterans with PTSD. Individual Oral Presentation at the 2012 American Telemedicine Association 17th Annual International Meeting and Exposition, San Jose, CA, April 29-May 1, 2012. (See Q11, Appendix F for presentation.)

4. Nigg, C**.,** Huang, Y., Jordan, P. J., Burke, K., Kawasaki, M., Evers, K., King, L., Daly, S., & Spira, J. (2012). Using focus groups with veterans to identify issues to adapt a computerized tailored intervention to Address PTSD related behavioral risk

factors. Paper presented at IADIS International Conference e-Society 2012, Berlin, Germany, March 10-13, 2012. (See Q10, Appendix C.)

5. King, L.A., Jordan, P.J., Whealin, J.M., Evers, K.E., & Spira, J.L. (2012). Tailored Online Multiple Behavior Intervention Reduces Symptoms of PTSD in Veterans Accepted for Oral Presentation on Nov. 3, 2012 at 9:00am at the International Society for Traumatic Stress Studies (ISTSS) meeting to be held in Los Angeles, CA, November 1-3, 2012. (See Q12, Appendix E.)

Grant Proposals Under Review:

1. VA HSR&D grant proposal for a randomized clinical trial entitled "A Computerized, Tailored Intervention to Manage Post-Deployment Stress" was resubmitted to the VA for consideration and is under review. (See Q12, Appendix B.)

2. CDMRP grant proposal for adding a new alcohol module and conducting a randomized clinical trial entitled "A Multibehavioral Program for Treating Behavioral Comorbidities Associated with Post-Deployment Stress" was submitted to PRMRP on June 25, 2012 and is under review. (See Q12, Appendix C.)

CONCLUSION

This highly successful project utilized four phases of CTI development and testing: 1) focus groups; 2) content adaptation and revision; 3) beta testing and usability interviews; culminating in a final feasibility study. The feasibility study (n=57) followed a pre-post design and assessed the effectiveness of the web-based CTI at baseline, 1- and 3-months. The study provided strong qualitative and quantitative evidence for the feasibility of the CTI for use with veterans at risk for PTSD. The 3-month post-study assessments showed significant trends toward: 1) progress through the stages of change; 2) improved coping skills for the target behaviors, and 3) reduction in PTSD symptoms. Participants also reported greater affective benefits, including improved quality of life.

Three focus groups with veterans were held in order to adapt the system to this population. Veterans preferred fact-based content, clear images that were relevant to the feedback and meaningful to veterans. These and other findings were used to adapt and integrate an existing CTI system for veterans. Further refinements were made to the system based on the results of usability testing with veterans. The final version of the CTI was launched in July 2011 for the feasibility study. Data collection and analysis were completed in 2012.

The Feasibility study results were very promising and retention was better than expected for this population. The 57 participants completing the study showed statistically significant improvements in all clinical and behavioral outcome measures. These improvements were based on 1-2 hours of time commitment over 3-4 months of intervention. The CTI appears to have been acceptable to the participants as retention at final 3-month follow-up was 75% (n=76) for participants who completed the baseline assessments and 63% (n=90) for those who met the

initial screening inclusion criteria and enrolled in the feasibility study. We are working to find funding for a randomized clinical trial and further testing of the CTI on veterans at risk for PTSD and other deployment related behavioral risk factors.

This research is particularly relevant in lieu of the current and anticipated demands on the VA mental health system with the return of OEF/OIF. The anticipated impact of intervening on veterans with PTSD with our intervention is that it may have very real implications on recovery, relapse prevention, and quality of life. This project may also have direct and indirect impact on patient care such as: 1) providing empirically based behavioral interventions as additional resources for health care providers who have increasingly limited time and resources; 2) providing support and intervention for individuals who have PTSD but are not yet ready to address these health risk behaviors by progressing them towards becoming ready; 3) providing support and relapse-prevention tools for individuals who are successfully coping with PTSD, but may be at risk for relapse; 4) improving the ability to reach individuals with PTSD at "teachable moments" through the Internet or disseminated technologies (e.g., computers, smart phones, cell phones). In other words, individuals can have access to the intervention when they are ready to receive the message.

The adapted CTI system is also flexible enough that additional modules targeted at other health risk behaviors or coping strategies can be added. These modules may include anger management, sleep disorders, pain management, domestic violence, war memories, and social support, among others. The system could be used to expand access to care at VA healthcare systems in the U.S. and Guam, to treat more veterans who are at risk for chronic diseases caused by smoking, stress, and depression.

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TABLES

Table 1. Focus Group Participant Demographics (n=21)

Table 2. Usability Test Participant Demographics (n=12)

Table 3. Comparison of Feasibility Study Participant Demographics (n=90)

Table 4. Feasibility Study Retention Rates

Table 5. Veteran-Specific Issues Raised by Participants

Table 6. Comparison of Military History (n=90)

Table 7. Comparison of Symptom Severity (n=90)

Table 8. Summary of Outcome Measures (n=57)

Table 9. Stage of Change Frequency for Smoking Cessation, Stress Management and Depression Prevention at Baseline (T0) and Study Completion (T3)

Table 10. Behavioral Results and Co-Action

Table 1. Focus Group Participant Demographics (n=21)

Total (N=21)	*Smoking (N=9)*	*Stress (N=6)*	*Depression (N=6)*
Mean Age (Range)	54.44 (45-68)	46.00 (24-62)	45.83 (30-55)
Sex (% Male)	100%	100%	100%
Branch	-----	-----	-----
Air Force	N = 3 (33.3%)	N = 1 (16.7%)	N = 0 (0%)
Army	N = 4 (44.4%)	N = 3 (50.0%)	N = 3 (50.0%)
Marines	N = 2 (22.2%)	N = 2 (33.3%)	N = 1 (16.7%)
Navy	N = 0 (0%)	N = 0 (0%)	N = 2 (33.3%)
Mean Months Served (Range)	66.11 (8-240)	39.0 (15-72)	69.67 (36-136)
Ethnicity	-----	-----	-----
African American	N = 1 (11.1%)	N = 1 (16.7%)	N = 1 (16.7%)
Hispanic/Latino	N = 0 (0%)	N = 0 (0%)	N = 1 (16.7%)
Pacific Islander	N = 5 (55.6%)	N = 0 (0%)	N = 0 (0%)
Caucasian	N = 3 (33.3%)	N = 3 (50.0%)	N = 2 (33.3%)
Other	N = 0 (0%)	N = 2 (33.3%)	N = 1 (16.7%)
No Response	N = 0 (0%)	N = 0 (0%)	N = 1 (16.7%)
Marital Status	-----	-----	-----
Never Married	N = 3 (33.3%)	N = 0 (0%)	N = 3 (50.0%)
Married	N = 1 (11.1%)	N = 1 (16.7%)	N = 1 (16.7%)
Separated	N = 2 (22.2%)	N = 1 (16.7%)	N = 1 (16.7%)
Divorced	N = 3 (33.3%)	N = 4 (66.7%)	N = 1 (16.7%)
Living with Partner - YES	N = 2 (22.2%)	N = 1 (16.7%)	N = 0 (0%)
At Least 1 Child	N = 3 (33.3%)	N = 3 (50.0%)	N = 3 (50.0%)
Education	-----	-----	-----
Some High School	N = 1 (11.1%)	N = 0 (0%)	N = 0 (0%)
High School/GED	N = 5 (55.6%)	N = 1 (16.7%)	N = 1 (16.7%)
Some College	N = 2 (22.2%)	N = 4 (66.7%)	N = 2 (33.3%)

Bachelor's Degree	N = 0 (0%)	N = 1 (16.7%)	N = 3 (50.0%)
Grad/Professional Degree	N = 1 (11.1%)	N = 0 (0%)	N = 0 (0%)
Stage of Change	-----	-----	-----
Pre-Contemplation	N = 1 (11.1%)	N = 1 (16.7%)	N = 0 (0%)
Contemplation	N = 5 (55.6%)	N = 1 (16.7%)	N = 2 (33.3%)
Preparation	N = 2 (22.2%)	N = 1 (16.7%)	N = 1 (16.7%)
Action	N = 1 (11.1%)	N = 0 (0%)	N = 0 (0%)
Maintenance	N = 0 (0%)	N = 2 (33.3%)	N = 2 (33.3%)
No Response	N = 0 (0%)	N = 1 (16.7%)	N = 1 (16.7%)

Table 2. Usability Test Participant Demographics (n=12)

	15 interviews
Mean Age (Range)	45.3 (29-63)
Sex (% Male)	75%
Branch	-----
Air Force	N = 1 (8%)
Army	N = 4 (33%)
Marines	N = 1 (8%)
National Guard	N=1 (8%)
Navy	N = 5 (42%)
Mean Years Served (Range)	7.2 (2 - 22.3)
Ethnicity	-----
African American	N = 2 (17%)
Asian	N = 1 (8%)
Caucasian	N = 4 (33%)
Multiracial	N = 3 (25%)
Other	N = 2 (17%)
Marital Status	
Never Married	N = 5 (42%)
Married	N = 2 (17%)
Separated	N = 1 (8%)
Divorced	N = 4 (33%)
Living with Partner - YES	N = 2 (17%)
At Least 1 Child	N =4 (33%)
Education	
High School/GED	N = 1 (8%)
Some College	N = 8 (67%)
Bachelor's Degree	N = 0 (0%)
Grad/Professional Degree	N =3 (25%)

Table 3. Comparison of Feasibility Study Participant Demographics (n=90)

		COMPLETION STATUS				***TOTAL***	
		Completed Baseline Only (n=33)		*Completed Study (n=57)*		*Baseline Total (n=90)*	
Gender*		N	%	N	%	N	%
	Male	26	78.8	42	73.7	68	75.6
	Female	7	21.2	15	26.3	22	24.4
Ethnicity							
	White, non-Hispanic	15	45.5	40	70.2	55	61.1
	Black, non-Hispanic	1	3	1	1.8	2	2.2
	Asian American	3	9.1	4	7	7	7.8
	Native Hawaiian, Other Pacific Islander	6	18.2	6	10.5	12	13.3
	American Indian, Alaska Native	1	3	-	-	1	1.1
	Hispanic	7	21.2	6	10.5	13	14.4
Marital Status							
	Single, never married	5	15.2	10	17.5	15	16.7
	Living with a partner	2	6.1	7	12.3	9	10
	Married	16	48.5	32	56.1	48	53.3
	Separated	1	3	1	1.8	2	2.2
	Divorced	7	21.2	7	12.3	14	15.6
	Widowed	2	6.1	-	-	2	2.2
Education							
	Less than HS	4	12.1	1	1.8	5	5.5
	High School	3	9.1	7	12.3	10	11.1
	Some College	16	48.5	31	54.4	47	52.2
	College Graduate	7	21.1	14	24.6	21	23.3
	Postgraduate	3	9.1	4	7	7	7.8
Age							
	M (SD)	42.4	-11.3	40.5	-11.2	41.2	-11.2
	Range	22.0-62.0		23.0-65.0		22.0-65.0	

Table 4. Veteran-Specific Issues Raised by Participants

Themes	*Sample Quotes*
Veterans' Support Systems (Helping Relationship—Process of Change)	"…directly to the VA [United States Department of Veterans Affairs], to the, uh, smoking cessation program." "I think with veterans, mostly you get more help from other vets than you do from anywhere else." "It's not like something to hide from her. It's a part our life and we really no like to share with our family." "Maybe there should be a program for their spouses so they can understand what the vets have been through…There's a lot of people who don't understand how we think. And that's a big issue dealing with when you come home and I see it as an issue."
Influence of Potentially Negative Stigmatization (Social Liberation—Process of Change)	"One thing that I've noticed, probably because of the Iraq /Afghanistan conflicts in the increasing amount of these problems…there are a lot more accessible means to find out how to go about dealing with these problems..." "I think there is a paradigm shift…That stigma or shame has been lifted so it's more socially acceptable to come to terms with these problems and deal with them in an effective manner." "We were told it was a confidential….then yes fine." "We're worried about what our doctor's gonna say"
Challenges in High-risk Situations (Temptations—Self Efficacy)	"Automatic…it's just a habit. I need my caffeine and my nicotine in the morning or I can't start." "It's automatic I just light up a cigarette or when I'm drinking alcohol. It goes hand in hand. Beer in one hand, cigarette in the other. Or coffee in one hand, cigarette in the other," "Maintenance I think is the hardest one you're going to come up to. For sure." "… like the substance abuse kind of thing, sometimes it's like you cannot resist it because you know the last time you used it, whatever it was, it really helped…it's so bad that whatever you're trying… isn't working… you think I just wasted all that time when I could have went out and grabbed me you know something, a 40 ounce…to help you break out of that phase…"

Table 5. Feasibility Study Retention Rates

	Completion Status				
	Registered on site	*HRI1 (Enrolled)*	*Baseline*	*30-day F/U*	*90-day F/U*
Number of Veterans	354	90	76	65	57
% retained from previous time point		25% (screen in)	84%	86%	88%
Overall retention from baseline (enrolled)				86% (72%)	76% (63%)

Table 6. Comparison of Military History (n=90)

Military History	*COMPLETION STATUS*				*Baseline Total (n=90)*	
	Completed Baseline Only (n=33)		*Completed Study (n=57)*			
Military Service Branch	**N**	**%**	**N**	**%**	**N**	**%**
Army	18	54.5	24	42.1	42	46.7
Marines	3	9.1	8	14.0	11	12.2
National Guard	3	9.1	3	5.3	6	6.7
Navy	3	9.1	7	12.3	10	11.1
Air Force	-	-	4	7.0	4	4.4
Coast Guard	1	3.0	-	-	1	1.1
Combination	5	15.2	10	17.5	15	16.7
Rank at Discharge						
Enlisted	15	45.5	27	47.4	42	46.7
Senior Enlisted	12	36.4	28	49.1	40	44.4
Officer	6	18.2	2	3.5	8	8.9
Time in Military (years)						
M (*SD*)	9.6	(7.3)	10.1	(8.2)	9.9(	7.9)
Range	1.58-32.5		0.5-34.3		0.5-34.3	
Time Deployed (months)						
M (*SD*)	20.4	(14.8)	24.5	(18.3)	23.0	(17.1)
Range	1.0-63.0		5.0-76.0		1.0-76.0	

Table 7. Comparison of Symptom Severity (*n*=90)

Measure	*COMPLETION STATUS*		*Baseline Total (n=90)*
	Completed Baseline Only (n=33)	*Completed Study (n=57)*	
PCL-M			
Mean (SD)	58.2 (11.2)	55.6 (9.5)	56.6 (10.0)
Range	31.0-73.0	30.0-70.0	30.0-73.0
PSS			
Mean (SD)	25.5 (4.4)	24.3 (5.9)	24.7 (5.4)
Range	15.0-33.0	7.0-36.0	7.0-36.0
PHQ-8			
Mean (SD)	13.5 (3.8)	12.0 (4.1)	12.6 (4.0)
Range	6.0-19.0	3.0-19.0	3.0-19.0
QOLS			
Mean (SD)	60.6 (10.7)	62.4 (12.6)	61.7 (11.9))
Range	44.0-86.0	35.0-98.0	35.0-98.0

Note. PCL-M = PTSD Checklist (Military version). PSS= Perceived Stress Scale. PHQ-8-Personal Health Questionnaire. QOLS=Quality of Life.

Table 8. Summary of Outcome Measures (*n*=57)

Measure	Baseline (*n*=57)	At 3 Months (*n*=57)	% change	Cohen's d	p
PCL-M					
Mean (SD)	55.6 (9.5)	48.8 (15.8)	-12%	.43	0.001
Range	30.0-70.0				
PSS					
Mean (SD)	24.3 (5.9)	20.5 (7.3)	-19%	.46	0.001
Range	7.0-36.0				
PHQ-8					
Mean (SD)	12.0 (4.1)	9.9 (5.8)	-17%	.36	0.015
Range	3.0-19.0				
QOLS					
Mean (SD)	62.4 (12.6)	69.5 (16.4)	+11%	.49	0.001
Range	35.0-98.0				

Note. PCL-M = PTSD Checklist (Military version). PSS= Perceived Stress Scale. PHQ-8-Personal Health Questionnaire. QOLS=Quality of Life.

Table 9. Stage of Change Frequency for Smoking Cessation, Stress Management and Depression Prevention at Baseline (T0) and Study Completion (T3)

		Percent Stage of Change				
Time	***Behavior***	***PC***	***C***	***PR***	***A***	***M***
T0	Smoking Cessation (n=*42*)	11.9	31.0	9.5	9.5	38.1
T3	(n=*45*)	1.8	14.0	12.3	15.8	35.1
T0	Stress Management (*n*=57)	8.8	15.8	26.3	10.5	38.6
T3	(*n*=57)	1.8	3.5	10.5	50.9	33.3
T0	Depression Prevention (*n*=56)	7.0	19.3	21.1	10.5	42.1
T3	(*n*=52)	0.0	7.0	10.5	42.1	31.6

Note. PC=precontemplation. C=contemplation. PR=preparation. A=action. M=maintenance.

Table 10. Behavioral Results and Co-Action

Behavior	***% Moving from Pre-Action Stages to Action at 3 Months***	***Statistical Significance Pre-Post***
Smoking	*27.5%*	*(χ2(1)=23.5, p<.001)*
Stress Management	*72.4%*	*χ2(1)=6.2, p=.013)*
Depression Prevention	*66.7%*	*(χ2(1)=8.8, p=.003)*
Exercise	*31%*	*(χ^2 (1)=12.9, p<.001)*
Healthy Eating	*30.2%*	*(χ^2 (1)=10.1, p=.001)*
Alcohol Use	*36.4%*	*(χ^2 (1)=8.4, p=.004)*
Sleep Management	*41.7%*	*(χ^2 (1)=4.0, p=.05)*

Note. * Pre-Action = PC, C or PR stage of change.

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APPENDIX A

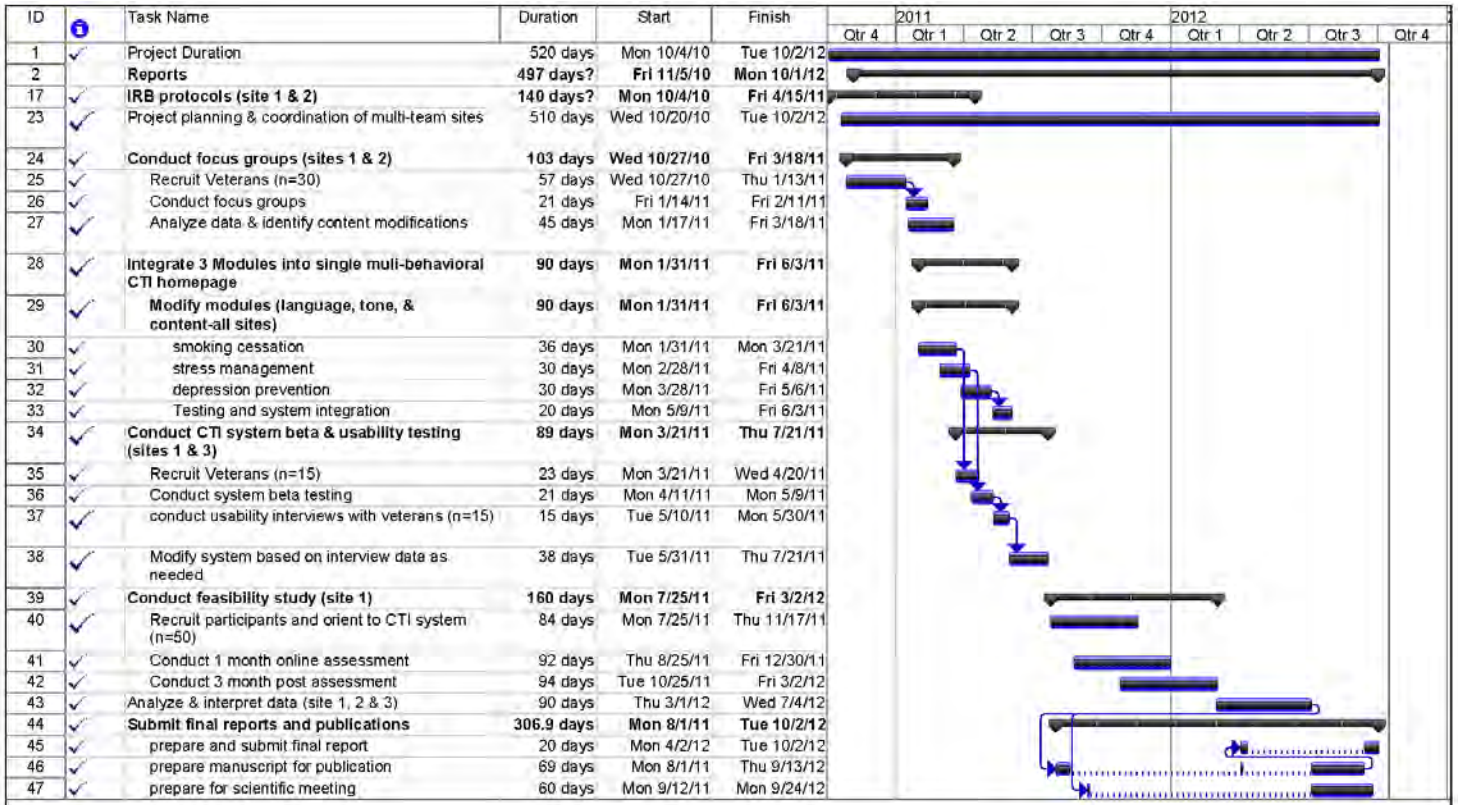
STUDY PERSONNEL

STAFF MEMBER	ROLE	% EFFORT
James Spira, Ph.D.	PI	15%
Julia Whealin, Ph.D.	Co-I	10%
Patricia J. Jordan, Ph.D.	Co-I/Consultant	15%
Claudio Nigg, Ph.D.	Co-I	5%
Kerry Evers, Ph.D.	Co-I	15%
Laurel King, Ph.D	Project Manager/IT	100%
Michelle Kawasaki, MA	Research Assistant	60%
Stacey Daley	Reseach Assistant	25%

APPENDIX B

TIMELINE

ID	Task Name	Duration	Start	Finish
1	Project Duration	520 days	Mon 10/4/10	Tue 10/2/12
2	**Reports**	**497 days?**	**Fri 11/5/10**	**Mon 10/1/12**
17	**IRB protocols (site 1 & 2)**	**140 days?**	**Mon 10/4/10**	**Fri 4/15/11**
23	Project planning & coordination of multi-team sites	510 days	Wed 10/20/10	Tue 10/2/12
24	**Conduct focus groups (sites 1 & 2)**	**103 days**	**Wed 10/27/10**	**Fri 3/18/11**
25	Recruit Veterans (n=30)	57 days	Wed 10/27/10	Thu 1/13/11
26	Conduct focus groups	21 days	Fri 1/14/11	Fri 2/11/11
27	Analyze data & identify content modifications	45 days	Mon 1/17/11	Fri 3/18/11
28	**Integrate 3 Modules into single muli-behavioral CTI homepage**	**90 days**	**Mon 1/31/11**	**Fri 6/3/11**
29	**Modify modules (language, tone, & content-all sites)**	**90 days**	**Mon 1/31/11**	**Fri 6/3/11**
30	smoking cessation	36 days	Mon 1/31/11	Mon 3/21/11
31	stress management	30 days	Mon 2/28/11	Fri 4/8/11
32	depression prevention	30 days	Mon 3/28/11	Fri 5/6/11
33	Testing and system integration	20 days	Mon 5/9/11	Fri 6/3/11
34	**Conduct CTI system beta & usability testing (sites 1 & 3)**	**89 days**	**Mon 3/21/11**	**Thu 7/21/11**
35	Recruit Veterans (n=15)	23 days	Mon 3/21/11	Wed 4/20/11
36	Conduct system beta testing	21 days	Mon 4/11/11	Mon 5/9/11
37	conduct usability interviews with veterans (n=15)	15 days	Tue 5/10/11	Mon 5/30/11
38	Modify system based on interview data as needed	38 days	Tue 5/31/11	Thu 7/21/11
39	**Conduct feasibility study (site 1)**	**160 days**	**Mon 7/25/11**	**Fri 3/2/12**
40	Recruit participants and orient to CTI system (n=50)	84 days	Mon 7/25/11	Thu 11/17/11
41	Conduct 1 month online assessment	92 days	Thu 8/25/11	Fri 12/30/11
42	Conduct 3 month post assessment	94 days	Tue 10/25/11	Fri 3/2/12
43	Analyze & interpret data (site 1, 2 & 3)	90 days	Thu 3/1/12	Wed 7/4/12
44	**Submit final reports and publications**	**306.9 days**	**Mon 8/1/11**	**Tue 10/2/12**
45	prepare and submit final report	20 days	Mon 4/2/12	Tue 10/2/12
46	prepare manuscript for publication	69 days	Mon 8/1/11	Thu 9/13/12
47	prepare for scientific meeting	60 days	Mon 9/12/11	Mon 9/24/12



APPENDIX C

STUDY PROGRESS

1. All protocol elements (design, informed consent, recruitment materials, assessments, etc.) were approved by the local VA and USAMRMC (ORP).

2. Accomplished all required due diligence and administrative work to receive a highly unusual VA IRB approval to waive documentation of consent and HIPAA authorization for all phases of this study. (This approval was sought to allow veterans to consent, screen, and enroll, and test the new program anonymously from the privacy of their own homes, without having to provide social security numbers or have their medical records accessed in order to add the required progress notes regarding their participation in the study.)

3. Phase 1 (Focus Groups):

    a. The Phase 1 focus group recruitment, data collection and analysis began in December 2010.

    b. The three focus group sessions were held on the evenings of January 14, January 28, and February 4, 2011.

    c. The data transcription, analysis, and reports were completed for all three sessions by the end of March 2011, marking the end of Phase 1.

    d. Summary report for all three focus groups was completed in April 2011.

4. Phases 2 and 3 (Adaptation and Usability Testing):

    a. The reports from Phase 1 Focus Groups were submitted to Pro-Change to complete the necessary system changes and adapt the smoking cessation, stress management, and depression prevention modules of the system for veterans.

    b. Beta-testing and bug reporting by the project team staff for the smoking module system was completed in April 2011.

    c. First round smoking usability tests were completed on smoking system in April 2011. Stress and depression module adaptation were completed so that beta-testing of the stress and depression modules by project team staff could begin in May.

    d. Phase 3 second round smoking module usability testing was completed and three of the first-round usability interviews with veterans were completed in May 2011.

e. The remaining usability and beta-testing was completed in June 2011.

f. Additional improvements were made based on the results of the second round of usability testing (e.g., changes to the language in the stress management program; implementing a user access code to prevent one person from creating multiple accounts; and improvements to the navigation and functionality of the online workbooks.)

5. Phase 4 (Feasibility Testing):

a. The completed STR2IVE Program was launched on the revised target date of July 21, 2011.

b. Eight-hundred invitations and flyers were mailed out to a targeted list of OEF/OIF veterans in the VA PIHCS catchment area on July 22, 2011.

c. Due to the low number of eligible veterans qualifying for the study, it was determined that the range of scores included in the screening was too narrow. Expedited amendments to expand the allowable range of the PCL-M and the PHQ-8 were approved by the IRB on August 2 and 11.

d. Recruitment recommenced on August 15, 2011 after this adjustment was implemented in the STR2IVE system. The overall screen-in rate improved from 13.6% to 23.4% after the change was made. Mailed 880 more recruitment letters on 8/26/12 and distributed 330 flyers to veteran organizations and PTSD service providers.

e. An online recruitment advertising campaign on FaceBook commenced on September 9, 2011. By the end of September, registration on the STR2IVE Program reached 62. Goal of recruitment for the feasibility study is to have 50 veterans complete the 3 data collection points.

f. After receiving IRB approval to enroll 100 participants in the feasibility study to ensure that a minimum of 50 would complete all follow ups, a final recruitment campaign commenced on October 17, 2011. Minimum recruitment needs were met in October, but recruitment was continued through November 30, 2011 to ensure that a minimum of 50 participants would complete all follow-ups.

6. The all-team meetings were held in Honolulu on February 27-28, 2012 (See Appendices B and C of Q11 report for agenda and presentations). The preliminary results on pre/post outcome data for a partial dataset were very promising. The final data set was not downloaded until March 5, 2012 in an attempt to encourage more participants to complete the final follow-up.

7. Recruitment and retention goals were met. The final dataset contained 90 enrolled participants; 76 completed baseline; 65 completed 30-day follow-up; and 57

completed the final 90-day follow-up. Final details of the recruitment and follow-ups for the study were as follows:

	Registered to be screened	Screened into study (enrolled)	Completed Full Baseline	Completed >30-day F/U	Completed >90-day F/U
Veteran Count	354	90	76 (14*)	65 (10*)	57(8*)

*Number of other participants who were eligible to complete that follow-up but did not. (One participant dropped out after completing baseline.)

8. The cleaning, coding, and analysis of the complete multi-behavioral data commenced in March 2012. The initial findings were very positive as can be seen in the ISTSS 2012 presentation attached. Several errors were discovered in the dataset in April causing a delay in the analysis. The problems were corrected and the revised dataset was carefully being checked for other possible coding errors to ensure the reliability of the results.

9. The 57 participants who completed all follow-ups showed statistically significant change in all behavioral measures (movement from pre-action to action stages of change) and all clinical outcome measures (PCL-M, PSS, PHQ-9, and QOLS) between baseline and 3 month assessments.

10. Manuscript on the study concept entitled "A Computerized, Tailored Intervention to Address Behaviors Associated with PTSD in Veterans: Rationale and Design of STR2IVE" was accepted for publication in *Translational Behavioral Medicine: Practice, Policy and Research.*

11. Completed all aspects of adaptation and development Phases 1-3 for the study.

12. Completed Phase 4 feasibility study and exceeded project recruitment and retention goals.

13. Continuing review application was approved by VA IRB on August 21, 2012 and HRPO on September 24, 2012, and is valid through August 20, 2013.

14. Completed all aspects of the study according to the revised timelines approved with no cost extensions.

15. The continuing review was approved on September 8, 2011 by the VA IRB.

16. The no-cost extension was approved on January 13, 2012, making the new end of research on April 2, 2012 and the new POP on May 2, 2012.

17. A final 5-month no-cost extension was approved on March 13, 2012 to allow more time

to complete additional data analysis, report and manuscript writing, and to submit presentations to additional conferences. The new POP ends on October 2, 2012. The IRB continuing review is valid through September 6, 2012. Continuing review application was approved by VA IRB on August 21, 2012 and HRPO on September 24, 2012, and is valid through August 20, 2013.

APPENDIX D

FOCUS GROUP ANALYSIS

STR_2IVE (CTI-PTSD): Focus Group Summary Analysis

Prepared by: Claudio Nigg and Katherine Burke

4/25/2011

Posttraumatic Stress Disorder in Veterans

PTSD rates range from 8% for those deployed to Somalia (Litz, Orsillo, Friedman, Ehlich, & Batres, 1997) to 16% for soldiers deployed during the Gulf War (Wolfe, Erickson, Sharkansky, King, & King, 1999). An estimated 19% of returning Operation Iraqi Freedom (OIF) Veterans reported a mental health problem with approximately half of these screening positive for PTSD (Hoge, Auchterlonie, & Milliken, 2006). Variability in the prevalence rates of symptoms may be due to factors unique to each conflict, such as length of deployment, which supports the assertion that the likelihood of developing PTSD is greater with longer duration of exposure to a stressor (American Psychiatric Association, 2000). Given that U.S. soldiers are currently deployed for 15-month tours of duty, exposure to potentially traumatic events is lengthy, and traumatic stress symptoms may be more likely (Lapierre et al., 2007). In fact, one study found that shortly after redeployment approximately 44% of service-members reported clinically significant depressive and/or posttraumatic stress symptoms (Lapierre et al., 2007).

Combat-related PTSD is a significant and long-lasting problem, e.g., up to 15% and 31% of male Vietnam Veterans meet current and lifetime PTSD diagnostic criteria, respectively, decades after the war (Cook et al., 2005). Examining the mental health effects in U.S. military personnel returning from current deployments to Iraq and Afghanistan has been of increasing importance. Research conducted following other military conflicts has shown that deployment to combat theaters and exposure to combat result in increased risk of PTSD, major depression, substance abuse, functional impairment in social and employment settings, and increased use of health care services (Hoge et al., 2006, 2007). Recent findings suggest a potentially large burden of co-occurring mental and behavioral health disorders associated with service in Iraq and Afghanistan (Seal et al., 2007). For example, a recent RAND study (Tanelian & Jaycox, 2008) found that an average of 18.5% of the warfighters who have returned from Afghanistan and Iraq meet criteria for either PTSD or depression — a prevalence nearly twice that observed among soldiers surveyed after other deployments (Hoge et al., 2006). Furthermore, when psychosocial problems were considered overall, nearly a third of Iraq and Afghanistan Veterans were classified as having either mental health diagnoses and/or psychosocial problems, including anxiety, depression, nightmares, anger, and inability to concentrate (Davidson, 2001; Greene-Shortridge et al., 2007; Seal et al., 2007).

PTSD symptoms seldom disappear completely, making it a continuing challenge for survivors of trauma to cope with PTSD symptoms and the problems they cause. Co-morbid conditions, including depression, other anxiety disorders and substance misuse, are common, along with relationship difficulties, excessive anger, and work problems (Forbes et al., 2007). In addition to affective disorders that are co-morbid with PTSD, concomitant changes in health include anxiety, anger, eating disorders, and substance abuse. Numerous studies have demonstrated a relationship between PTSD and negative health outcomes, including evidence that health behaviors have a significant impact on physical health, illness, and healthcare utilization (Jankowski, 2007). There is also evidence that negative changes in health behavior occur in response to post-traumatic psychiatric symptoms, contribute to the

development of these symptoms, and maintain symptoms once they have developed (Beckham et al., 1997; Chandler, 2002).

Focus Group Studies

This project aims to develop and test a computerized tailored intervention (CTI) targeted at behavioral sequelae (i.e., smoking, stress, depression) for populations impacted by PTSD. The theoretical framework upon which the CTI system is based is the Transtheoretical Model of Behavior Change (TTM) — one of the leading behavior change theories (Glanz, Rimer, & Lewis, 2002). The TTM (Prochaska, DiClemente, Velicer, & Rossi, 1993) is a comprehensive model of behavior change that integrates diverse psychological constructs (i.e., stage of change, decisional balance, process of change, and self-efficacy) to explain and predict how and when individuals change their health behaviors. The theoretically driven, individualized approach provided by the TTM assesses individuals' readiness and appropriately intervenes to facilitate forward stage movement that leads to effective and sustainable behavior change. A conflict ostensibly arises when the majority of an at risk population is not prepared to take action resulting in low recruitment and retention rates for action-oriented programs. TTM-based programs are suitable for individuals in all stages of change—those ready to change, those getting ready to change, and those not yet ready to change. As such TTM-based programs have an even greater impact partially, because these programs are likely to lead to higher participation rates.

This project will test three TTM-based computerized, tailored intervention (CTI) programs for application with a Veteran population with PTSD symptoms. The proposed intervention will leverage the empirically based, tailored communications for smoking cessation, depression prevention, and stress management previously developed and validated with a general adult population by Pro-Change, a research-based behavior change product development company. Educative information, narratives, examples, graphics, and feedback statements of the proposed CTI programs for smoking cessation, stress management, and depression reduction or prevention will be tested for relevance and appropriate for use with a Veteran population with PTSD symptoms. The theoretically driven, individualized approach provided by TTM will be used to assess individual readiness, and appropriately intervene to facilitate stage of change progress for effective and sustainable behavior change.

Three focus groups were conducted at the Veterans Administration Pacific Islands Health Care System (VAPIHCS) to gather information on the acceptability of the CTI program content and feedback reports developed by Pro-Change, Inc., for the smoking cessation, depression reduction and prevention, and stress management online CTI programs (for a detailed methods description see Appendix A). Suggestions for additional content, graphics, multimedia capabilities, and interactivity were also obtained for each program. Each group reviewed one of the behavior change programs to assess the extent to which the program matches the expectations and needs of Veterans, particularly those with PTSD symptoms. Feedback from the focus groups will be used to guide the adaptation of the current CTI programs for the target population.

Stages of Change

In terms of motivation to change, we were able to recruit a broad range of participants, see Table 1.

Table 1 *Stages of Change*

Stage of Change	Smoking (N=9)	Stress (N=6)	Depression (N=6)
Pre-Contemplation	N = 1 (11.1%)	N = 1 (16.7%)	N = 0 (0%)
Contemplation	N = 5 (55.6%)	N = 1 (16.7%)	N = 2 (33.3%)
Preparation	N = 2 (22.2%)	N = 1 (16.7%)	N = 1 (16.7%)
Action	N = 1 (11.1%)	N = 0 (0%)	N = 0 (0%)
Maintenance	N = 0 (0%)	N = 2 (33.3%)	N = 2 (33.3%)
No Response	N = 0 (0%)	N = 1 (16.7%)	N = 1 (16.7%)

In the general population, in a sample of 24,178 adult health maintenance (HMO) members ages 21-55 surveyed about multiple health behavior change, with respect to smoking cessation, 21.3% were in pre-contemplation, 19.3% were in contemplation, 9.3% were in preparation, 5.2% were in action and 45.0% were in maintenance (Nigg, Burbank, Padula, Dufresne, Rossi, Velicer, Laforge & Prochaska, 1999). With respect to reducing stress, 24.2% were in pre-contemplation, 6.1% were in contemplation, 5.0% were in preparation, 13.3% were in action and 51.4% were in maintenance (Nigg et al., 1999).

Among a group of 1,262 German college students surveyed about MHBC, with respect to smoking cessation, 36.0% were in pre-contemplation, 22.5% were in contemplation, 6.9% were in preparation, 12.4% were in action and 22.2% were in maintenance (Keller, Maddock, Hannöver, Thyrian & Basler, 2007).

In a sample of 205 participants, the stages of change for smoking cessation were 8% in precontemplation, 12% in contemplation, 8% in preparation, 8% in action, and 33% in maintenance, and 31% non-smokers (Acton, Prochaska, Kaplan, Small & Hall, 2001). In addition, 42% of non-smokers were depressed, and smoking was comorbid with depression among 53% of pre-contemplators, 60% of contemplators, 63% of those in preparation, 50% of those in action and 61% in maintenance (Acton et al., 2001).

Although our sample is not intended to be representative of motivational readiness in the general population, compared to the other samples, a broad representation was achieved.

Opening Questions: Health

Participants discussed the benefits of changing their behavior such as improving health, relationships with others, personal appearance and feeling better about yourself. In their discussions they were candid about the challenges of behavior change and spoke to the unique barriers for Veterans such as

relating to non-Veterans about deployment-related stressors. However, they acknowledged the VA as an important source of support.

As these are unique to each behavior the results are summarized separately in Tables 2-4.

Table 2 *Smoking*

Smoking Themes	**Number of Meaning Units**
Benefits of quitting	6
Smoking initiation	2
Support for quitting	15
Barriers to quitting	18

Participants discussed benefits of smoking abstinence including improved health, financial savings, social acceptance, personal hygiene, prolonging life and avoiding property damage. Participants also discussed avoiding the inconvenience of being in non-smoking situations.

Table 3 *Stress Management*

Stress Themes	**Number of Meaning Units**
Stress management	13
Benefit of stress management to self	13
Benefit of stress management to others	6
Support for stress management	28
Home-based stress management	5
Stress management for Veterans	6

Benefits of stress management included better health, feeling good about yourself, participating in group therapy, improved personal atmosphere, better attitude, better social interactions, and less anxiety. With respect to others, benefits of stress management to others included improved household morale and better role-modeling for younger family members and improved coping skills.

Table 4 *Preventing Depression*

Preventing Depression Themes	**Number of Meaning Units**
Benefits of preventing depression	5
Support for Veterans preventing depression	12
What can Veterans do to prevent depression	19
Who can Veterans turn to for support	19

Participants suggested that preventing depression might help reduce the economic impact of excess visits to the emergency room as a result of suicidal ideation, that it would help people feel better about themselves and improve their communication skills.

CTI System Usability (see Table 5)

Participants were asked questions regarding the usability of the system. For example:

- "Do these instructions make sense?"
- "Would you want the tone of the program to be friendly or more scientific and medical?"
- "Is this question clear and understandable? How would you indicate what your answer is?"
- "What would you do with the blank space [on this screen]?"

Sample screens are displayed in Figures 1-2.

Figure 1. Introduction to the LiveWell Stress Management System

Figure 2. Sample Feedback from the LifeStyle Depression Prevention System

Table 5 *CTI System Usability Feedback Frequency by Content Area*

Themes	**Number of Meaning Units: Smoking (N=9)**	**Number of Meaning Units: Stress (N=6)**	**Number of Meaning Units: Preventing Depression (N=6)**	**Number of Meaning Units: Total (N=21)**
Clear	14	12	19	45
Unclear	0	10	2	12
Like	10	10	38	58
Dislike	0	4	5	9
Neutral	1	2	0	3
Suggestion	3	20	16	39
Divided	0	8	5	13
Testimony	0	3	0	3

The concept of Stages of Change was clear to participants. Participants were generally able to follow the system's directions such as filling in blanks appropriately. The status bar, once explained, improved clarity.

Due to the nature of the focus group which relied on screenshots, some aspects of the system needed explanation such as the "Logout" link and the status bar. Participants wanted terms such as "stress management" to be clearly defined in the depression prevention system. Some participants thought the phrasing could be improved to add clarity in places.

Across focus groups, most participants preferred the LiveWell system's aesthetic and phrasing compared to that of the LifeStyle system. Participants generally preferred a mixture of friendly and scientific language, such as scientific facts presented in friendly language, such as in the screen shot in Figure 1. Participants found the system informative overall.

Participants who did not like the LifeStyle system found it too "book-like," "desolate" and "boring." Participants found the depression prevention system "too wordy."

Some participants suggested adding more scientific facts to the system. Some participants thought the system should be more personalized to the user's personal preferences. Participants would also like to have professional support available while using the system.

Some participants were divided between the two systems, seeing benefits of both and wanted to see a blend.

In some cases, the system provoked personal reactions to the system.

SUMMARY: *In general, participants preferred the LiveWell system over the LifeStyle system. Many participants stated they would benefit from having access to professional support while using the system. Participants stated they would prefer a mixture of scientific facts presented in friendly language.*

Layout (see Table 6)

Table 6 *Layout Feedback Frequency by Content Area*

Themes	**Number of Meaning Units: Smoking (N=9)**	**Number of Meaning Units: Stress (N=6)**	**Number of Meaning Units: Preventing Depression (N=6)**	**Number of Meaning Units: Total (N=21)**
Clear	0	9	3	12
Unclear	1	7	0	8
Like	1	8	5	14
Dislike	0	9	1	10
Neutral	1	4	1	6
Suggestion	7	13	5	25
Divided	0	6	0	6
Testimony	0	0	0	0

Participants found that the shading, headings and status bar made the system easy to follow.

The use of screenshots made the interactive quality of the system hard to follow.

Some participants preferred the layout of the LiveWell system while others preferred the color scheme of the LifeStyle system. One participant liked the overall consistency of the system.

Some participants thought that the LifeStyle system could be more colorful.

Some participants felt ambivalent about the color scheme of the systems.

Participants made suggestions for the color scheme of the systems such as lavender, aqua, pink, blue and green.

Some participants wanted to see a hybrid of the LifeStyle and LiveWell systems.

SUMMARY: *In general, participants found the layout of the system easy to follow. They preferred the layout of the LiveWell system and made color scheme suggestions for the LiveWell system.*

Text (see Table 7)

Table 7 *Text Feedback Frequency by Content Area*

Themes	**Number of Meaning Units: Smoking (N=9)**	**Number of Meaning Units: Stress (N=6)**	**Number of Meaning Units: Preventing Depression (N=6)**	**Number of Meaning Units: Total (N=21)**
Clear	36	63	58	157
Unclear	24	20	27	71
Like	26	23	46	95
Dislike	5	3	12	20
Neutral	0	0	6	6
Suggestion	11	30	54	95
Divided	0	6	11	17
Testimony	0	10	6	16

Overall, participants found the language and content of the text to be straightforward and relevant (see Figure 8, Appendix B).

Participants thought that the question that identifies stage of change should clearly direct users to select one answer choice. Additionally they felt that the language could be more concise in places and provide definitions for words such as “contemplation,” “several,” “transtheoretical” and “stress management.”

Specifically for the stress system, some of the questions on slide 10 were difficult to answer in terms of importance instead of agree/disagree.

Participants liked language that was straightforward, positive, encouraging and promoted autonomy (e.g. "at your own pace"). They also liked content that provided scientific information (see Figure 9, Appendix B) and found the health strategies helpful.

Participants did not like text that was too limiting, prescriptive or "preachy." They did not like slides with a lot of text.

Participants wanted the text to be informative but succinct.

Participants made content suggestions about additional health strategies and phrasing that could improve clarity.

Some participants were divided between scientific and friendly language (see Figures 9-10, Appendix B). While some participants found the system "wordy," they also found it informative.

Some participants shared how they would process the answers to the questions by relating personal experiences.

SUMMARY: *Overall, participants liked the text of the systems and preferred language that was concise and friendly but based on scientific fact. They also preferred language that emphasized personal choice.*

Graphics (see Table 8)

Table 8 *Graphics Feedback Frequency by Content Area*

Themes	**Number of Meaning Units: Smoking (N=9)**	**Number of Meaning Units: Stress (N=6)**	**Number of Meaning Units: Preventing Depression (N=6)**	**Number of Meaning Units: Total (N=21)**
Clear	20	37	41	98
Unclear	24	7	5	36
Like	16	11	14	41
Dislike	24	17	12	53
Neutral	7	8	6	21
Suggestion	15	19	23	57
Divided	0	6	2	8
Testimony	0	17	7	24

In general, participants interpreted the graphics with accuracy, making appropriate connections to the associated text.

Participants found some of the graphics ambiguous or difficult to read, which made them distracting. In some places, the graphics did not fit the text.

Participants liked graphics that were calming and positive.

Participants had strong reactions to graphics that triggered negative emotions or unhealthy behavior such as smoking, stress or depressive thinking.

Some participants had no reaction to the graphics.

Participants made suggestions about making the pictures brighter, more positive and more clearly related to the text. Overall, they wanted the pictures to support the purpose of the system, to present information about smoking cessation, promote stress management and prevent depression.

Some participants found the graphics subjective.

Some participants made jokes and shared their personal reactions to the graphics, especially if they were reminiscent of being deployed.

SUMMARY: *Participants generally found the graphics clear and understandable but could be improved by avoiding provocative imagery and being more directly related to the text.*

Audience – Issues Specific to Veterans (see Table 9)

Participants were occasionally asked whether the CTI system would be appropriate for Veteran audiences. Participants were generally candid in offering their perspective as Veterans regarding specific content areas.

Table 9 *Audience Feedback Frequency by Content Area*

Themes	Number of Meaning Units: Smoking (N=9)	Number of Meaning Units: Stress (N=6)	Number of Meaning Units: Preventing Depression (N=6)	Number of Meaning Units: Total (N=21)
Clear	0	2	1	3
Unclear	0	0	0	0
Like	10	0	1	11
Dislike	4	1	1	6

Neutral	0	1	8	9
Suggestion	2	8	0	10
Divided	0	0	0	0
Testimony	0	4	8	12

Participants found the systems generally appropriate for Veteran audiences.

Participants thought Veterans would appreciate friendly language that promotes autonomy.

Some participants found that a couple of graphics would not be appropriate for Veteran audiences, such as the screenshot in Figure 3.

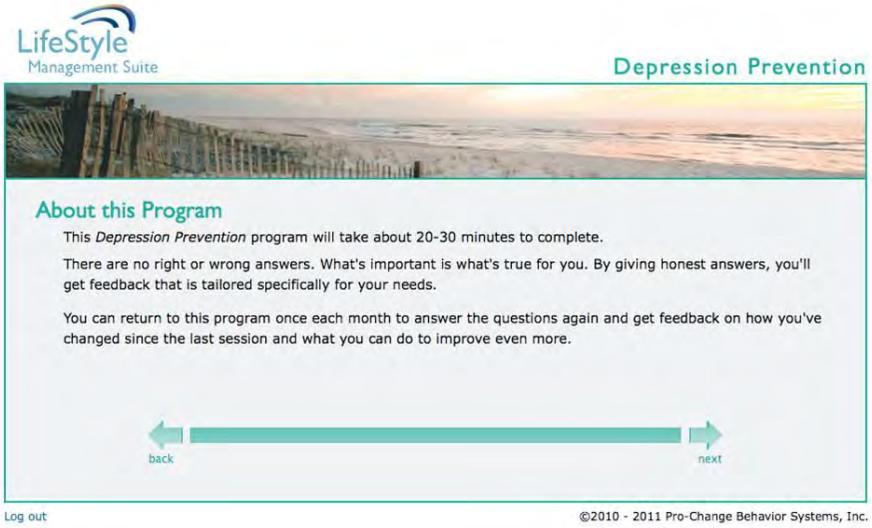
Figure 3. Sample Feedback from the LifeStyle Stress Management System

Some participants were ambivalent about the content if they did not experience the behavior targeted by the intervention. They did not feel Veterans would have difficultly answering questions honestly.

Some participants thought the system content could be made more relatable for Veteran audiences by adding "localized" images and addressing the tendency to use unhealthy strategies for stress management when healthy strategies are inadequate.

Participants found that some of the graphics, such as the screenshot in Figure 4, triggered memories of being deployed. Participants shared details about their challenges in avoiding unhealthy stress management strategies, such as alcohol use.

Figure 4. LifeStyle Depression Prevention System



SUMMARY: *Participants generally found the systems appropriate for Veteran audiences but had suggestions for improvement. In particular, participants wanted greater attention paid to avoiding unhealthy coping mechanisms, which is a challenge for Veterans. They also expressed concern about imagery that might trigger memories from deployment.*

Considerations for Veteran Issues

One of the primary challenges facing Veterans following deployment is restoring a sense of normalcy, particularly when faced with the behavioral sequelae of PTSD. This was reflected in the focus group feedback when participants discussed the challenges of relating to non-Veterans about their experiences. Some participants suggested couples' counseling, restricting their support network to other Veterans or using the CTI-PTSD system in a group setting with other Veterans. Alienation from previous support networks such as significant others, non-Veteran friends and family members may present a significant challenge to Veterans struggling to manage stress, prevent depression and abstain from smoking. Research shows that among Veterans with chronic PTSD, spouses were a source of support as well as stress (Laffaye, Cavella, Drescher & Rosen, 2008.) The CTI-PTSD system would be improved by addressing these unique stressors for Veterans.

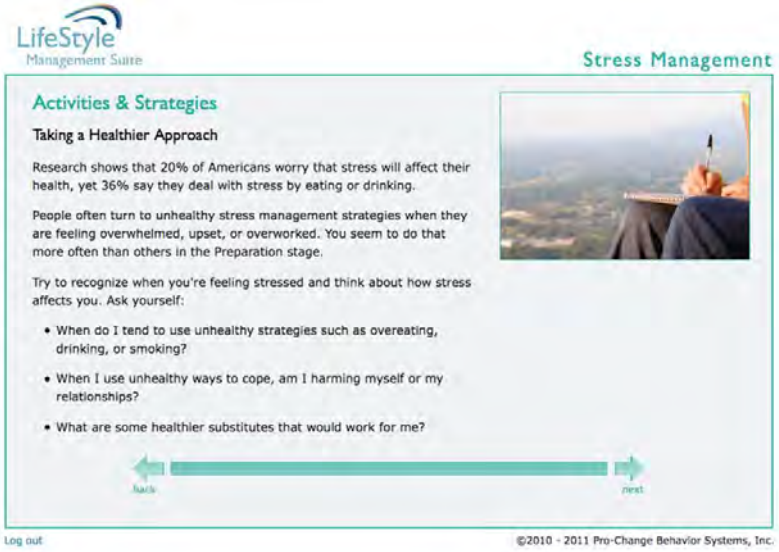
For example, slides such as Figure 5, could be adapted to represent the unique life situations confronting Veterans. For example, they could include case studies of survivors of combat stress

reactions (CSR), a precursor of PTSD (Solomon, 2001), which might alert CTI system users to the common symptoms of posttraumatic sequelae experienced resulting from combat exposure.

Figure 5. Stuart's Story from the LifeStyle Depression Prevention System

Similarly, feedback, in formats such as Figure 6, that specifically addresses how these symptoms trigger substance abuse and interpersonal conflict might be particularly helpful to Veteran survivors of CSR who are at increased risk for these behaviors (Solomon, 2001).

Figure 6. Suggestions from the LifeStyle Stress Management System



Finally, specifically referring Veterans to access support systems at the VA in formats such as Figure 7 and providing information about the potential for secondary traumatization among their non-Veteran support network (Solomon, 2001) might help Veterans avoid feelings of alienation.

Figure 7. Strategies for Change from the LifeStyle Smoking Cessation System

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APPENDIX A: Methods

Recruitment & Participants

The STR$_2$IVE study team recruited individuals with flyers, posters, and word of mouth. Interested participants were screened and if qualified, they were informed of the date and time of the focus group. Confirmation calls were made the morning of the focus group, however, there were some no shows (smoking N=1, stress N=1, depression N=3), cancellations (stress N=2) and participants who brought friends (depression N=1). Nine Veterans who smoke cigarettes, six Veterans who experience stress and six Veterans who experience symptoms of depression participated. Therefore, a total of twenty-one Veterans participated and all were male. The sample demographics are presented in Table 10.

Table 10 *Demographics*

Demographics	**Summary** (N=21)
Mean Age (Range)	49.57 (24-68)
Sex (% Male)	100%
Branch	-----
Air Force	N=4 (19.0%)
Army	N=10 (47.6%)
Marines	N=5 (23.8%)
Navy	N=2 (9.5%)
Mean Months Served (Range)	59.38 (8-240)
Ethnicity	-----
African American	N=3 (14.3%)
Hispanic/Latino	N=1 (4.8%)
Pacific Islander	N=5 (23.8%)
Caucasian	N=8 (38.1%)
Other	N=3 (14.3%)
No Response	N=1 (4.8%)
Marital Status	-----
Never Married	N=6 (28.6%)
Married	N=3 (14.3%)
Separated	N=4 (19.0%)
Divorced	N=8 (38.1%)
Living with Partner	N=3 (14.3%)
At Least 1 Child	N=9 (42.9%)
Education	-----
Some High School	N=1 (4.8%)
High School/GED	N=7 (33.3%)
Some College	N=8 (38.1%)
Bachelor's Degree	N=4 (19.0%)
Grad/Professional Degree	N=1 (4.8%)

Procedure

The focus group methodology was informed by Morgan (1998). Two practice sessions were conducted to familiarize staff with the procedures and to finalize the protocol. The focus groups began with the consenting of the participants; followed by introductory comments and questions; followed by the evaluation of the expert system using a pre-established focus group discussion guide developed for each topic. The focus groups were recorded on two tape recorders and a digital recorder placed strategically to ensure that all discussion points were captured. The focus groups were led by a trained moderator, an assistant moderator was present to take notes on poster paper for recap of points during the focus group, and two note takers were present.

The focus groups lasted approximately two hours each. Food and water were provided during the focus groups and participants received a $25 gift card at the end of the focus group as an incentive to participate and to compensate them for their time. Procedures were approved by the Veterans Administration Pacific Islands Health Care System (VAPIHCS) Institutional Review Board (IRB) and the University of Hawai‘i IRB.

Analysis

The focus group analysis followed the guidelines recommended by Krueger (1998). Immediately after the focus groups, the moderator, assistant moderator, and note takers discussed the groups, debriefing and noting group dynamics. Prior to transcribing, all identifiers were removed from the materials to protect confidentiality. All three audio recordings were used to develop the transcript, with the different recordings providing better sound from different parts of the room. The transcript was then compared with the notes taken to ensure completeness. Data from the focus groups were coded and analyzed according to published protocols—which summarize the major themes found from the group (Albright, Maddock, & Nigg, 2004; Lees, Clark, Nigg, & Newman, 2005; Padula et al., 2003; Pan & Nigg, 2011). This entailed breaking the transcriptions into meaning units, then grouping similar meaning units together to form themes. To be considered a theme, an idea had to be mentioned at least twice. Common themes were identified, sorted, and compared.

The results are presented by categories of feedback including *Opening Questions: Health,* and then addressing the expert system – *System, Layout, Text, Graphics, Audience – Issues Specific to Veterans* and *Gift Cards*. Each category has themes which are comprised of specific identified meaning units. The summary analysis was conducted by summarizing common themes across focus groups.

APPENDIX B: FOCUS GROUP FEEDBACK

Figure 8. NVivo9 Text Search Query: Clear Text

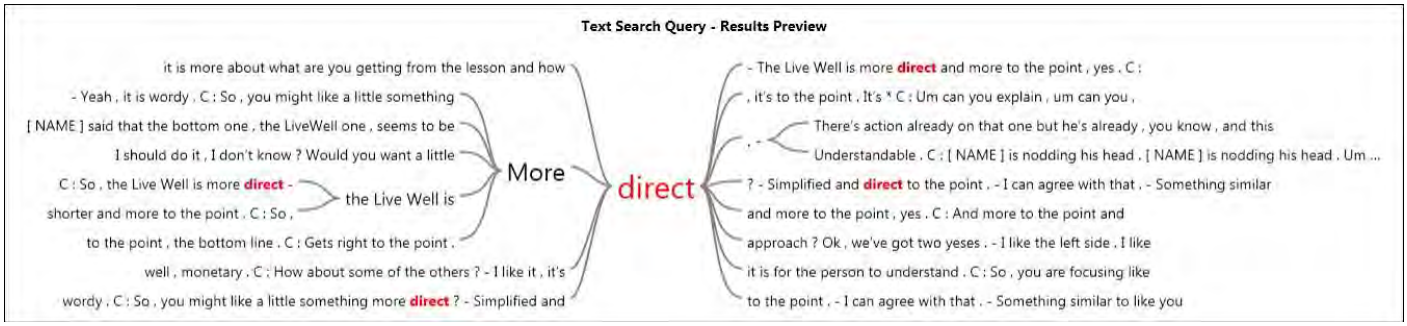


Figure 9. NVivo9 Text Search Query: Scientific Language

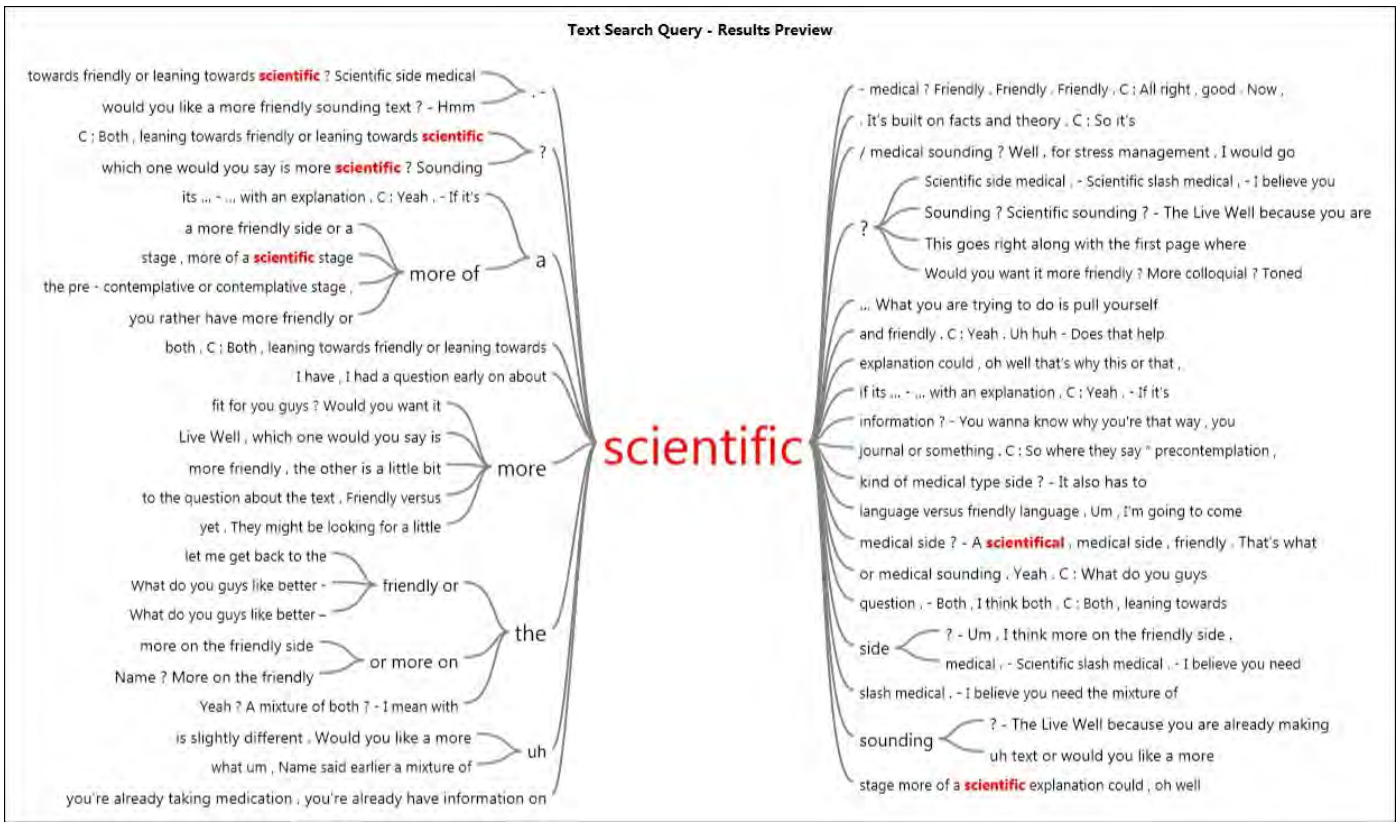
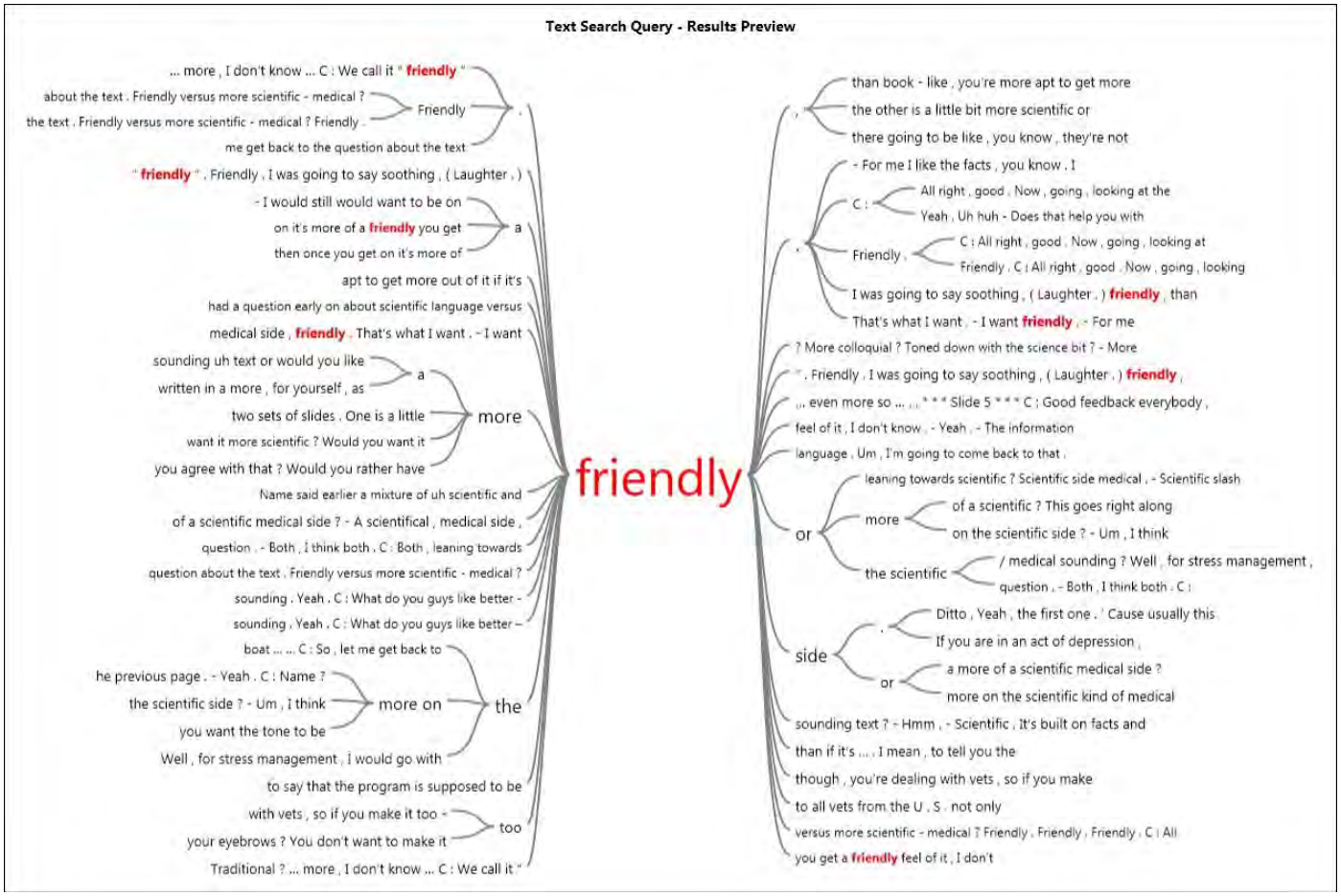


Figure 10. NVivo9 Text Search Query: Friendly Language



APPENDIX E

USABILITY TESTING SUMMARY REPORT

Time	Type	Pos/Neg	User Event	User Event Description	Screen Description
0:03:15	Observation		Structure - layout	Participant said she wasn't sure what to do here. Said "I don't know… register?" and clicked on Register without assistance.	Log-In
0:05:23	Observation			Participant said she doesn't like choosing log-ins, passwords, security questions because she has a bad memory and would have difficulty remembering them. Said this would stress her out but did not have any suggestions for alternatives.	Register
0:07:23	Observation		Content - language (instructions)	Participant asked if the question was asking specifically about "combat" experience or any truama while in the military. Said she would answer "yes" for the former and "no" for the latter. Thought it should say, for example, "combat or non-combat experience".	Screening Questions
0:09:49	Px prompted			Reminded participant to pretend the observers weren't there and that if the participant wouldn't normally read through the Study Fact Sheet then she should't feel obligated to. So participant went straight to "agree".	Study Fact Sheet
0:13:01	Px prompted		Content - language (questionnaire items)	Asked what the participant thought of the questions. Participant said that answering some of the questions were difficult because she really has to think about her feelings or think about the best fitting response based on the available options. She said some just have more complicated answers and has nothing to do with the system/program itself.	Military Experiences
0:17:03	Px prompted		Content - language (response options)	Asked participant what she was currently thinking. Participant said the reponse options could be improved. She suggested "not at all, rarely, sometimes, all the time" would make more sense to her than "not at all, several days, more than half the days, nearly every day." Said the current response options would probably be confusing to veterans.	General Questions (Depression)
0:26:40	Observation		Content - options	Participant said she didn't know which ONE race to choose since she is "half and half." Said it is "irritating" and it should be changed to "all that apply."	Demographic Questions

Time	Type	Pos/Neg	User Event	User Event Description	Screen Description
0:29:32	Px prompted		Content - language (response options)	Asked participant what she thought of this screen. Said that she didn't deploy so she thought there should be an "n/a" or "none" option. Didn't enter anything and went to Next button.	Military Background
0:30:15	Observation		Content - language (questionnaire items)	Participant wanted to know what was considered "dangerous duty" since she wasn't in combat, in order to respond to this item.	Combat Experience
0:31:49	Px prompted		Structure - layout/text.	Asked participant why she moved forward in her chair at this point. Participant said it was because she couldn't tell if the response option said "1 dash 3X" or "13X". When prompted, respondedthat she easily understoon that "X" meant times.	Combat Experience
0:33:55	Observation		Content - language (questionnaire items)	Participant said "rounds" is too specific since lots of other things can happen to veterans e.g., something could fall on them, be in an explosion,e tc. And it doesn't acurately reflect the experiences of veterans. Seems like she felt insulted that it didn't accurately capture other traumatic experiences.	Combat Experience
0:40:48	Error		Error	Participant pressed the Next button before answering any of the items on the screen and got an error message. When prompted, P said she hadn't noticed what she did or the error message. Said she noticed the "red" but not the message itse.f.	Perceived Stress
0:44:28	Px prompted		Content - language (instructions)	Asked participant what she thought about the instructions. Participant said it was confusing and she had to read it 3 times. Said she feels better after having re-read it and thinks it could be reworded. Then she read it several more times.	Quality of Life
0:49:14	Observation		Content - language (response options)	Participant asked "what's the difference between delighted and pleased?" regarding the response options. Said she would change it to "very pleased" and "pleased" or "0 to 5" to make it more clear. (Note: it took her 3 minutes to answer the 1st question.)	Quality of Life

Time	Type	Pos/Neg	User Event	User Event Description	Screen Description
0:53:06	Other - interviewer note		Content - language (questionnaire items)	Participant thought there should be an "n/a" option for "having and rearing children". Didn't connect the instructions to this item even though she read it 10+ times. She got frustrated and selected a random response to move on.	Quality of Life
0:56:40	Observation		Content - language	Participant thought the exercise definition might be too extreme (inaccurate). Said she only does light swimming twice a week which might add up to 2 hours and 30 minutes.	Exercise
0:57:59	Px prompted		Content - language	Asked participant what she thought the purpose of the exercise defition screen was and participant said she had no idea. Participant said she thought it might be trying to make people feel bad if they weren't exercising up to "regular exercise" defitions.	Exercise

Time	Type	Pos/Neg	User Event	User Event Description	Screen Description
0:02:24	Other - interviewer note		Structure - layout	Participant recognized that he was a New User immediately after being reminded to imagine he was doing this program at home alone. No difficulties going to the Register button (old login screen).	Log-In
0:04:09	Other - interviewer note		Technical	Participant enlarged the screen on his own.	Screening Questions
0:10:04	Observation		Content - language	Wasn't sure how to answer some questions as a former sailor. Thought some questions were geared toward soldiers in direct combat situations. He had similar experiences but not exactly like the questions.	Combat Experience
0:11:00	Observation		Content - language	Similar to above issue: he had difficulty responding to item "How often did you fire rounds at the enemy?" since he said he fired "warning shots." Felt it should be considered more than "never" but didn't feel like he was answering the question based on the wording so he ended up selecting "never."	Combat Experience
0:14:55	Other - interviewer note		Content - language	Participant quickly understood that the item about satisfaction with "having and rearing children" also included satisfaction with NOT having them and entered "delighted."	Quality of Life
0:17:15	Observation		Structure - layout; Content - language	Said "there's no answer box…" meaning that he was expecting to answer the Exercise definiton screen. Went to the next screen anyway and answered the question there.	Exercise
0:22:37	Px needed help		Structure - layout/text; Content - language	Looked for "next" button at the bottom of the screen so he wasn't sure what to do when there wasn't one. Thought that what he already did (HRI) was the Smoking Cessation program even though he read the instructions out loud that he was supposed to go to the programs to the left and that the numbers indicated how many times those programs were completed. Ended up to gift card information instead.	Home Page

Time	Type	Pos/Neg	User Event	User Event Description	Screen Description
0:38:31	Observation		Content - language	Wasn't clear what the question was asking regarding how many cigarettes he was willing to decrease each day. Thought it might mean if he selected "2 cigarettes" it would mean on day 2 he would have to decrease it by 4, etc.	Smoking Cessation - Small Steps
0:40:05	Other - interviewer note			Participant wasn't sure what to do next - probably since he thought we had an agenda for what he should work on during the usability testing. When asked, he said that he probably wouldn't have gone to the Report if he was home alone, but went to it anyway "because it's first" (before the Continue button).	Thank You
0:42:08	Other - interviewer note			Participant didn't have any specific comments regarding the Report.	Report
0:42:24	Px prompted		Structure - images/text	When asked, participant said he was primarily paying attention to the text and not the images so none of them stood out to him.	At Thank You
0:43:56	Px prompted		General	Asked participant if he thought this program could help him and he said "Yeah! Actually I'm stoked…" and asked if he could come back to use the program. Informed him that the feasibility study wouldn't be up and running for a few weeks but he could participate in the TUX study now.	At Thank You

Time	Type	Pos/Neg	User Event	User Event Description	Screen Description
0:13:14	Observation		Content - spelling error	Noticed a spelling error. Says "fried" instead of "friend."	Your Level of Confidence (SM)
0:21:21	Observation		Content - language	Said "it's encouraging!" regarding increasing stress management goals (increasing time spent managing your stress in the next month)	Small Steps
0:21:47	Observation		Content - language	Same issue as in SC program - unsure what the question is asking him regarding how many minutes he is willing to increase each day managing stress. (He put the lowest option (i.e., 5 min) because he's interpretting it as he has to increase stress management by 10 min on day 2, 15 min on day 3, etc.)	Small Steps
0:22:52	Px prompted		Content - language	Asked what P thought of the SM recommendations. He said it was good.	At Thank You
0:23:02	Px prompted		Content - language	Laurel asked about adding minutes of SM each day. Participant said it sounded like he had to keep increasing the number of minutes by that number each day and joked that by October he'd have to quit his job because he's be managing his stress all day.	At Thank You
0:38:22	Other - interviewer note		Content - language; Structure - text box	P had a little difficulty with the fill-in-the blank that asked him to "type one thing you've been doing to prevent depression that deserves credit. Then type in how you can reward yourself" and commented that there's only one box so he had to re-read the question a few times.	Your Own Experiences - Reward Yourself
0:42:20	Px prompted		Content - language	Asked P if he thought the DP program would help someone at his SoC (Maintenance). He said "yes" because he thought it was interactive without being judgmental or telling him what to do like a counselor might. He said, as a veteran/out of the military, he doesn't want to be told what to do.	At Thank You

Time	Type	Pos/Neg	User Event	User Event Description	Screen Description
0:02:24	Observation			Wasn't sure if he should register or log-in. Took him about 40 seconds of talking through it until he went to Register without help.	Log-In
0:03:17	Other - interviewer note		Content - language	Participant asked if there was a "demo" for assistance in selecting a log-in, passowrd, etc. (Note: maybe could provide parameters e.g., not case-sensitive, must be at least four characters, etc.)	Register
0:05:07	Observation		Technical	Commented that he had to scroll down to see the last security question.	Register
0:05:56	Error		Error	Read the 1st screening question as "are you in the military" instead of "military veteran" so he selected "no". Asked him how he read that question and then he saw his error. Would have screened out for this.	Screening Questions
0:08:10	Observation			Wasn't sure if he was answering each of the four PTSD criteria separately or together even though there was only one "yes/no" option. He said he would say "yes" to 2 items and "no" to the other 2 items.	Screening Questions
0:09:01	Other - interviewer note		Technical	Experiencing difficulty with Internet - slow to respond and "Internet Explorer cannot display the webpage."	At Screening Questions
0:10:16	Other - interviewer note			Answered "yes" to SMI screening question. Said he didn't know what Bipolar Disorder. Not sure what he was endorsing but he would've screened out here as well.	Screening Questions
0:12:59	Other - interviewer note		Structure - format; Content - language	Looked for way to "answer" the exercise definition screen. Decided to click next without assistance.	Exercise
0:17:42	Other - interviewer note		Technical	Realized that we told Pro-Change the appointment was cancelled and forgot to tell them when we filled the openning at the last minute. Might be the cause of the technical difficulties if Pro-Change was working on the system at the same time.	At Healthy Eating

Time	Type	Pos/Neg	User Event	User Event Description	Screen Description
0:35:42	Other - interviewer note		Structure - images; Technical	Images did not show up on the majority of the screens due to technical issues so participant didn't/couldn't comment on them.	General

Time	Type	Pos/Neg	User Event	User Event Description	Screen Description
0:01:39	Observation	Negative	Structure - Color	Doesn't like the colors	Log-In
0:02:32	Error - resolved by participant		Structure - Layout	Logged in to Returning User then got error message saying previously not registered. So went to New User to register without assistance.	Log-In
0:03:30	Observation		Content? - Unexpected	Security questions are different from those normally asked	Security Questions
0:04:51	Observation		Structure - Text	I would just skim this	Study Fact Sheet
0:06:14	Observation	Positive	Content? - Informative	Likes that Fact Sheet provides contact info if participant needs help	Study Fact Sheet
0:11:17	Observation		Content - Instructions	Confused about instructions for satisfaction but continues	Quality of Life Questionnaire
0:15:32	Observation		Structure - Layout	Wishes the screen/font was bigger (not used to laptop-size). Told her she could maximize the screen.	Healthy Eating
0:17:07	Observation	Negative	Content - Language	Prefer if these (types of) questions were asked in a different way. Thinks they "put [her] on the spot" or are "finger pointing."	Healthy Eating & Responsible Drinking
0:18:56	Observation	Negative	Structure - Text	A lot of words on the screen which may be difficult for older Veterans or those with severe depression/PTSD. Said she likes to read & is in school now & she thinks the screens are "wordy" & she feels "edgy."	Preventing Depression
0:20:00	Observation		Content - Response Options	Thinks response options are too narrow. But then says maybe we wanted to categorize responses in this way.	Preventing Depression
0:20:43	Observation		Structure - Image	Not sure what image is (next to the word "wellness").	Thank You
0:24:44	Observation	Positive	Structure - Image	Liked the picture of person sitting on a lounge chair; wished it was bigger; already makes her feel calm.	SM Program Homepage
0:28:59	Error - resolved by participant			Missed an item/radio button & got an error message. Read the message, answered the item & moved on.	SM Activities Questionnaire
0:30:43	Observation	Positive	Structure - Image	Likes pictures with people in them	Activities & Strategies: Taking a Healthier Approach

Time	Type	Pos/Neg	User Event	User Event Description	Screen Description
0:30:48	Px Prompted	Negative	Content - Feedback	Px was asked what she thought of the feedback since she hadn't made any comments on the last few screens. Reported that they seemed too "general." She suggested using examples but was unable to provide specific suggestions.	Activities & Strategies: Taking a Healthier Approach
0:31:29	Observation	Positive	Structure - Image	Said she "definitely" likes the picture of the ladybug on the yellow flower.	Pros & Cons
0:32:34	User needs help	Negative	Content - Instructions	Confused about how to answer the questions. Siad if she were by herself, she would just "muddle through it."	Pros & Cons Questionnaire
0:34:26	User needs help	Negative	Content - Instructions	Doesn't understand what the screen means by "what is your most important Pro for managing stress?"	Weigh the Pros & Cons
0:35:46	Observation	Negative	Content - Language	Thinks feedback is poorly worded. Said she would "laugh at that."	Your Level of Confidence
0:36:31	Observation	Negative	Content - Language	Thinks feedback is inappropriate based on her responses to the questionnaire items. Thinks asking someone who IS confident what they do (feedback provided by program) is not the first thing she would do & that she wouldn't even be able to recognize if someone was confident in order to ask them.	Your Level of Confidence
0:37:17	Observation	Negative	Content - Language	Thinks feedback could be worded differently to be "more empathetic" and less "you, you , you." But she liked the suggestions.	Your Level of Confidence feedback
0:38:13	Observation	Positive	Content - Instructions	Said she likes to answer these types of questionnaires because she understands what they're asking of her and she can answer them quickly (e.g., as opposed to the other questionnaires that ask how important was blank in your decision to…)	Your Own Experience Questionnaire
0:41:00	Observation	Negative	Content - Language	Said that feedback could be elaborated on with more specific examples (similar to her other comment on the feedback screens).	Your Strategies for Change feedback

Time	Type	Pos/Neg	User Event	User Event Description	Screen Description
0:41:38	Observation	Negative	Content - Language	Again, participant thinks feedback could be reworded, using less "you" and "your" type feedback so it sounds less blaming.	Your Strategies for Change feedback
0:42:33	Observation	Positive	Content - Language	Likes the exercise of writing things down (3 fill-in-the-blank boxes) because it reminds her of exercises that her e.g.,	Your Strategies for Change: Use
0:43:15	Observation		Content - Language	Said there was not enough elaboration on feedback but it was still overall because she likes using calendars to remind her.	Your Strategies for Change: Make a Commitment
0:43:59	Observation	Positive	Content - Language	Likes that it gives websites. Said she would go to the site to get ideas.	Your Strategies for Change: Get Support
0:45:19	Observation	Positive	Content - Language	Likes when the program gives positive feedback/encouragement, for ex., "Way to go!" Thinks it would make most people feel good.	Small Steps
0:46:43	Observation		Content - Language	Said she would read the whole report and when asked, said she thinks she would print it out as well.	Report
0:48:48	Observation		Content - Language	Said she doesn't use Amazon much, but getting a gift card is nice.	Report
0:50:14	Observation	Positive	Content - Language	Likes that it's tailored (SoC) to where the person is in their management of stress.	E-Workbook Homepage
0:52:14	Observation	Positive	Structure	Likes that it's like a workbook - can work on it a little bit, save, and come back to it later.	E-Workbook
0:52:25	Observation		Structure - Layout	Sees that the pull-down menu is on the right and she can pick which topic she wants to look at in more detail.	E-Workbook
0:53:15	Observation			Thought the program would give her more info/skills but then thinks that that's probably what the e-workbook will provide.	E-Workbook
0:54:23	Observation	Negative	Content - Instructions	Doesn't understand what she's supposed to do. She said she would have to read it again. (53:44-56:20)	E-Workbook: 50 Benefits of Managing Your Stress.

Time	Type	Pos/Neg	User Event	User Event Description	Screen Description
0:02:02	Other		Structure - Layout/Text	**Initially appears like participant will go to Returning User but catches that he needs to register as a New User**	Log-In
0:02:13	Participant prompted			Prompted participant to register	Log-in
0:09:44	Other			Note: Would have screened "out" of secondary screening questions	Screening Questions
0:14:37	Observation	Positive	Content - Language	Apologized he wasn't commenting on the program. Said the questions were easy to understand and answer so he forgot to comment as he went along.	Perceived Stress
0:16:32	User needs help		Content - Language	**Asked participant what a question (QOL - Having and Rearing Children) meant. Asked him what he thought it meant. Said that he just didn't read it carefully enough & now he understands it. Asked him to explain why he selected his response. His justification seemed like he understood the question to me.**	Quality of Life
0:17:57	Error		Structute - Layout	**Clicked on "next" button before completing questionnaire items on second screen of questionnaire. (Seemed like he thought he already answered the items since screen looked the same as the previous one). Got error message, read it, and completed the items without assistance.**	Quality of Life
0:19:42	Error		Structure - Layout/Text	**Participant didn't catch that the previous screen asked if he currently smoked (which was "never" for him) so when he got to this screen (how long ago he quit), he didn't know how to respond. Suggested participant return to the previous screen and he noticed his error.**	Current Smoking Habits
0:21:02	Observation		Structure - Text	Suggested that this definition screen of exercise activity levels could be shortened/simplified.	Exercise
0:21:57	Observation		Structure - Text	Suggested that this definition screen of healthy eating could be more detailed.	Healthy Eating
0:22:19	Observation		Content - Language	Thought "sometimes" should be an additional response option on this screen.	Healthy Eating - eating number of calories to reach and maintain healthy weight

Time	Type	Pos/Neg	User Event	User Event Description	Screen Description
0:23:30	Observation		Content - Language	Commented that this definition screen should be combined with the question screen (as well as other similar definition/question screens) so you don't have to remember the definition or click "previous" button.	Responsible Drinking
0:27:59	Participant prompted	Positive	Content - Language	Asked participant if the program made sense so far. Said it did.	Program Home Screen
0:31:32	User needs help		Structure - Layout/Text	**Said he was "lost" when he gets to the program welcome screen. Reported that he didn't read the screen thoroughly because it seemed like the information on the screen was presented earlier so thought he could skip/skim. Said he wasn't sure what to do next and initially, thought he was done and wouldn't need to return for a month. Then he read the screen and realized he needed to continue and selected the DP program.**	Program Home Screen
0:39:50	Observation	Negative	Structure - Text	Said that some screens are a little wordy. Said that the information is good but might not be good keeping someone's attention.	Advantages and Disadvantages
0:44:05	Observation		Content - Language	Said for clarity, he would prefer "sometimes" instead of "occasionally" as a response option.	Your Own Experiences
0:45:12	Other		System	**Went "back" 2 screens and the system cleared his answers to the first screen. Confused because he thought he was on a new screen but the questions were repetitive.**	Your Own Experiences
0:46:43	Observation		Content - Language	Said that one of the questionnaire items were similar to another. He said it made him concerned about how he answered a previous item because he wanted to be consistent.	Your Own Experiences
0:53:33	Participant prompted	Both	Content - Language/Text	Asked participant what he thought of the feedback. Said he thought it was kind of basic (e.g., go for a walk) especially for people who have had previous counseling. But he likes the fill-in-the-blank options because they helped him think about options.	Your Own Experiences
0:57:35	Observation	Positive	System	Commented that being able to print out a copy of his report was good because he could see how he's doing and what he could work on.	Your Summary
1:00:26	Observation		Structure - Layout	Commented that the DP and SM programs look similar.	Stress Management Activities

Time	Type	Pos/Neg	User Event	User Event Description	Screen Description
1:00:44	Observation		Structure/Content	Commented that real program users wouldn't have to do the two programs back-to-back (implying it was a lot to do at once). Told it would be up to the user but that they could return or do them at once depending on preference.	Stress Management Activities
1:24:59	Participant prompted	Both	General	Asked what he thought of the programs in general. Said he thought they were good, especially the fill-in items because they make you think. When prompted, he said there was nothing he saw that wasn't appropriate for Veterans. When prompted if program would be helpful, said that for him, it was a lot of text on each screen.	Program Home Screen
				BOLDED user event descriptions indicate times participant may have had difficulty with program because he didn't read the text thoroughly. Also perhaps an issue with how the text is presented.	

Time	Type	Pos/Neg	User Event	User Event Description	Screen Description
0:02:06	Other			Note: Initially looked like participant was going to try to log-in as a Returning User. But before he entered anything, he saw that he needed to register first and he did without any difficulty.	Log-In
0:05:17	User needs help		Content - Instructions	Confused about screening criteria (inpatient treatment); would've screened out	Screening Questions
0:10:07	Participant prompted	Positive	Structure - Color/Layout; Content - Language	Asked participant if he understood everything because he hadn't been making any comments. Said he understands the questions. Commented that he likes the colors because they're soothing. Also said it was easy to navigate the program.	General Questions
0:23:05	Observation	Negative	Content - Specific Item	Didn't connect with an item (i.e., if he was less depressed others would expect more from him). Said he felt the opposite way (i.e., excells when others expect more - drill sargeant, coach).	Advantages & Disadvantages Questionnaire
0:27:34	Observation	Negative	Content - Questionnaire Items	Said that being in the military, being male, and raised in the culture he was raised in, he wasn't encouraged to express things so some items didn't resonate with him.	Your Own Experiences
0:30:38	Other	Negative	Technical Difficulties	Program didn't respond if the "Next" button was clicked more than once. Had to close out screen and go back to Home Screen. Previously happened when Pro-Change was not informed we would be doing usability testing. However, they had been informed of testing this time.	Your Own Experiences
0:40:28	Observation	Positive	Structure - Image	Liked picture of a man relaxing in a hammock.	Your Summary
0:44:01	Observation	Positive	Content - Informative	Said learning about how to use disputing statements would be a good idea	E-workbook - Use the ABCDs

Time	Type	Pos/Neg	User Event	User Event Description	Screen Description
0:46:04	Participant prompted	Both	Structure - Layout	Asked participant if he would've felt he needed to/filled in all 7 text box examples if he was at home. Said he might not have even gone to the e-workbook at all. But he enjoys "mental stimulation" so it would depend on if he had the time. Said some links sounded interesting.	E-Workbook - Increase Positive Thinking
0:49:11	Observation	Positive	Content - Links	Said he would click on certain e-workbook links out of curiousity.	E-Workbook - Thought Stopping
0:50:07	Participant prompted	Both	Structure - Color/Layout/Text	Asked participant what he thought of the program in general. Said he liked the colors. Suggested adding drop-down menus at the top of the screens so options are easier to see. Also suggested not putting too much information on each screen since that can be off-putting & encourages skimming. Suggested only putting summaries of the important information and have links/drop-downs as an option for those that want more detailed information.	(Program Home Screen)
0:52:03	Participant prompted	Positive	Content	Asked participant if he would use this program. Said he would because he is trying to better himself after experiencing post-deployment issues.	(Program Home Screen)
0:52:49	Other		Confidentiality	NOTE: Participant says his name	(Program Home Screen)

Time	Type	Pos/Neg	User Event	User Event Description	Screen Description
0:01:56	Other - interviewer note		Structure - layout	No difficutly (other than Internet) understanding that he was "not a Returning User" and needed to register first. (Side-by-Side New User/Returning User)	Log-In
0:05:28	Observation		Structure - text	Initially thought he was supposed to click on which of the trauma criteria applied to him but then he noticed the "Yes/No" options and radio buttons at the bottom of the screen.	Screening Questions (Trauma)
0:11:32	Other - interviewer note		Structure - font size	Text may be easier to read if the font size is increased; however, this may affect the alignment of the text. For example, the questionnaire items may take up too much room on the screen so the participant had to keep scrolling up to see the response	e.g., Military Experiences
0:14:52	Observation		Content - language (response options)	Had difficulty deciding between "never" and "several days" response options. Said there should be a middle option such as "1-2 days".	General Questions
0:15:21	Observation		Structure - font size	Said it kind of bothered him that the "p" in the word "problems" was cut-off. (Likely because the font size was increased.)	General Questions
0:16:28	Observation		Content - language (response options)	Said the questionnaire items sounded like they should have "Yes/No" response options rather than "not at all" etc. (Even though the question asked "How often…".) Agreed that response options could be more specific like "1-2 days a week", etc.	General Questions
0:19:49	User needs help		Content - language	Assumed the questions had to do with combat since the heading was "Combat Experience". Wasn't sure how to answer items if he wasn't in combat. Assisted participant to think of items as pertaining to his military service (as the instructions indicate) rather than during combat. Participant suggested changing the heading to "Combat or Military Experience."	Combat Experience
0:23:23	Observation		Structure - font size	(Related to increased font size) said that response options could be repeated on the side, etc. so participants don't have to keep scrolling up. (Didn't notice that response options appeared if cursor was over the radio button.)	Quality of Life

Time	Type	Pos/Neg	User Event	User Event Description	Screen Description
0:31:40	Participant Prompted		Content - language	Asked participant if he understood what he needed to do if he was in the feasibility study. Said he thought participants should log-in MORE than once a month since their status may change. Thought that the Thank You screen seemed like a class syllabus and that it might deter participants because it looks like a lot of work. Said he thought the word "compensation" sounded like he was goingt o be "sold" something and it put his guard up.	Thank You
0:35:12	Other - interviewer note	Positive	Content - language; Structure - layout	Understood he was supposed to click on a program (i.e., Stress Management) and did not have to be prompted to continue.	Program Homepage
0:37:21	Observation	Positive	Content - language	Said he liked that the program said "the stress management program can help" on the first screen. Siad it was "a good pitch."	About This Program (SM)
0:37:41	Observation		Content - language in links; Structure - text	Clicked on the link to the TTM to find out the definition. Said the pop-up box had more information that what he was looking for and initially said it didn't provide the definition. Later, he said that he had heard of the stages before and called it "PCPM" (as an acronym) and was able to describe the stages.	About This Program
0:39:45	Observation	Positive	Structure - image	Said he liked the image of his stage of change.	Your Stage of Change
0:41:35	Error		Structure - error message	Missed a questionnaire item and received an error message. Saw which item he missed (thought he answered it but realized he accidentally answered the wrong item) and answered it without assistance/prompting.	Stress Management Activites
0:43:56	Other - interviewer note		Content - language	Prior to usability testing, participant completed a hard copy stress management questionnaire and didn't know what the term "poke fun" meant. He noticed that the same item appeared at this point in the program. Had he not be explained the meaning of the term earlier, he might not have known how to answer it or would have guessed.	Stress Management Activites
0:45:32	Observation	Negative	Content - language	Said it wasn't clear that the feedback screens were giving him suggestions based on his previous responses. Said the headings (e.g., Activities & Strategies - Being Prepared and Planning Ahead) didn't described that it was tailored feedback.	Activities & Strategies
0:50:09	User needs help		Content - instructions	Initially started answering the questionnaire items without reading the instruction question at the top of the screen & therefore said the items didn't make sense. Suggested participant read the instruction question and then he said he understood the items.	Pros & Cons

Time	Type	Pos/Neg	User Event	User Event Description	Screen Description
0:50:35	Observation		Structure - font size	(Font size finally changed to small.) Said he could read the smaller font because he had his glasses on and liked that he could see all of the items on the screen without having to scroll down.	Pros & Cons
0:52:40	Observation		Content - language (response options)	(Again) said the wording is unclear on the questionnaire items (importance of the items to effectively manage stress). Said he thought they sounded more like "Yes/No" items.	Pros & Cons
1:03:17	Observation		Structure - image	Image - said the picture (man with zen garden) was distracting because he couldn't tell what it was. He said it kept drawing his attention away from the text because he wanted to know what the man was doing.	Your Strategies for Change
1:05:52	Observation	Negative	Content - language (unclear)	Thought that when the previous screen said that it's time to "pick a start date", it meant that this screen would give him a date or have him select a start date, etc. He was confused and disappointed that he didn't see what he expected. He said actually picking a start date within the system would increase his commitment to change.	Thank You
1:08:33	Participant Prompted			Asked if he would do both programs back-to-back or return later if he were in the feasibility study doing this at home. He said he would most likely do the programs back-to-back.	Program Homepage

Time	Type	Pos/Neg	User Event	User Event Description	Screen Description
0:05:58	Other - interviewer note		Computer literacy	Realized that participant was not screened and he was not comfortable using the computer/Internet (would have been ineligible for usability interview). Decided to let him continue and test the system as a non-computer literate user with our technical assistance. Had difficulty entering information and needed a lot of assistance.	Log-in
0:14:16	Error		Content - language	Answered "yes" to screening question and would have incorrectly screened out (of feasibility study). Said it was because he has "depression" and didn't understand what "manic-depression" was. (Perhaps there could be a link to a definition of less familiar terms like these.)	Screening Questions
0:18:49	User needs help		Structure - layout	Tried to click on a bullet to respond on an instruction screen (no questions).	Healthy Eating
0:29:16	User needs help		Content - language	Confused about the staging screen. Thought it was asking how long he's been depressed versus when he was planning on starting depression prevention strategies.	About this Program (DP)
0:29:47	Observation		Structure - layout	Again, tried to click on a bullet to respond on an instruction screen (no questions).	About this Program
0:37:16	User needs help		Structure - layout	Again, thinks he needs to click on the bulleted items to respond even though the screen was only informational.	Depression Prevention Activities
0:38:51	User needs help		Structure - layout/text; Content - questionnaire items	Asked for clarification regarding the questionnaire items. Suggested he read the main question/instructions. He did, and was then able to answer the items.	Advantages & Disadvantages
0:40:03	Participant prompted		Structure - progress bar	Laurel asked if he understood what the bar was at the bottom of the screen. Participant guessed it gave a message of how depressed he was. Laurel told him it was a progress bar and then he understood.	Advantages & Disadvantages

Time	Type	Pos/Neg	User Event	User Event Description	Screen Description
0:54:04	User needs help		Content - language	He wasn't sure what he needed to do on this screen. Thought the "report" button might be asking him to report "on" something. Was told to click on it to get his personalized report.	Thank You
0:55:05	Other - interviewer note		Technical issue	Wasn't able to enlarge screen so had to adjust to 100% so could see all the text in the screen.	Personal Health Report
0:58:24	Participant prompted		Both	Asked participant if he thought this program would be helpful to him. Responded that he wasn't sure if he would turn to this program because of his particular situation, but he thought it did have some helpful suggestions which might be more helpful to others. Thought information could be more specific and include other areas of depression (e.g., hopelessness, living situation).	Personal Health Report

Time	Type	Pos/Neg	User Event	User Event Description	Screen
0:03:07	Other - interviewer note		Structure - layout	Said she needed a Log-In Name but then went to More Information about the program.	Log-In
0:04:32	Other - interviewer note		Structure - layout	After participant closed the Study Fact Sheet/More Information, she said she would register as a New User. Prompted her that she could enter any information here.	Log-In
0:05:33	User needs help		Structure - layout	Selected the three Security Questions from the drop-down boxes but did not provide any answers. Received an Error Message and didn't know how to resolve the error. Was prompted that she didn't answer the security questions and needed to register again.	Log-In
0:08:23	Other - interviewer note			Would have screened out at Trauma Criteria.	Screening Questions
0:10:47	Participant prompted		Structure - layout/images	Asked participant what she thought of the "new" homepage (revised recently by Pro-Change). Said she would have suggested adding pictures, but then she said she scrolled down and saw the pictures at the bottom of the screen. Said she would make the pictures more prominent (e.g., on the sides or top of the screen) and make them more relevant to the programs (e.g., someone putting out a cigarette).	New Homepage
0:14:15	Participant prompted		Content - language	Asked participant to verbalize what the homepage was instructing her to do. Said she thought it should say, "Now that you've completed your assessment/looked at your personalized report, the next step is…" so the participant knows exactly what to do next. Said she would also add go to programs "to the left of the screen" so the participant knows where they need to go to select their programs.	New Homepage
0:17:19	Participant prompted		Content - language	Asked participant what she thought of the "old" homepage. Said she thought it explained what to do more thoroughly and was easier to understand than the revised/new homepage.	Old Homepage

Time	Type	Pos/Neg	User Event	User Event Description	Screen
0:18:04	Participant prompted		Structure - image	Asked participant what she thought of the image and she provided several suggestions. She said the colors could be more vibrant, could include different images, and the images could be moved to the top or sides of the screen. She said in general this screen is very "sterile" and uninteresting.	Old (and New) Homepage
0:20:11	Observation		Structure - image	Said she would add an image of a really stressed out person (like hair's being electrocuted) on one side of the screen and a really relaxed person on the other side - like a before and after program.	Stress Management Homepage
0:21:09	Observation		Structure - image	Would use pictures along with the text.	About This Program
0:22:26	Observation		Content - language	Initially she thought the Stages of Change screen was about the different types of stress. Clicked on the TTM link to find out more information. Said the information could be simplified but was understandable.	About This Program
0:24:35	Observation	Positive	Content - language	Said this screen was explained well.	About This Program (3rd screen)
0:28:41	Participant prompted		Content - language	Asked participant if she knew what the term "poke fun" meant. She accurately replied that it meant to laugh at sources of stress in your life.	Stress Management Activities
0:29:32	Observation		Content - language	Said the information on this screen seemed repetitive & said last question could be reworded to "to see more progress…" instead of "to make even more progress."	Activities and Strategies
0:31:23	Observation		Content - language	Said "Taking a Healthier Approach" screen should provide some positive examples. Said the screen could say "in order to avoid (this category)" and then provide some options.	Activities and Strategies - Taking a Healthier Approach

Time	Type	Pos/Neg	User Event	User Event Description	Screen
0:33:41	Observation		Content - language	Thought this screen focused too much on stress and the negative instead of taking your mind off of the stress. Said should have positive ideas (e.g. go for a walk, take a bath, drink a cup of tea, etc.).	Activities and Strategies - Focusing on Your Response to Stressful Events
0:35:36	Observation		Content - language	Thought some questionnaire items could use skip patterns since she thought if she agreed to one item, it would make others irrelevant.	Pros & Cons
0:38:17	Observation		Content	Thought the program was appeal to more people if it was tailored to participants in other areas (e.g., weight management).	Weigh the Pros & Cons
0:40:31	Observation	Positive	Content - language	Thought the insturctions and questionnaire screens made sense.	How Confident Are You
0:46:38	Observation		Content - language	Thought the questionnaire items were "sterile" and didn't reflect what she considered stressful experiences.	Your Own Experiences

APPENDIX F_____

TRANSLATIONAL BEHAVIORAL MEDICINE ARTICLE

A computerized, tailored intervention to address behaviors associated with PTSD in veterans: rationale and design of STR²IVE

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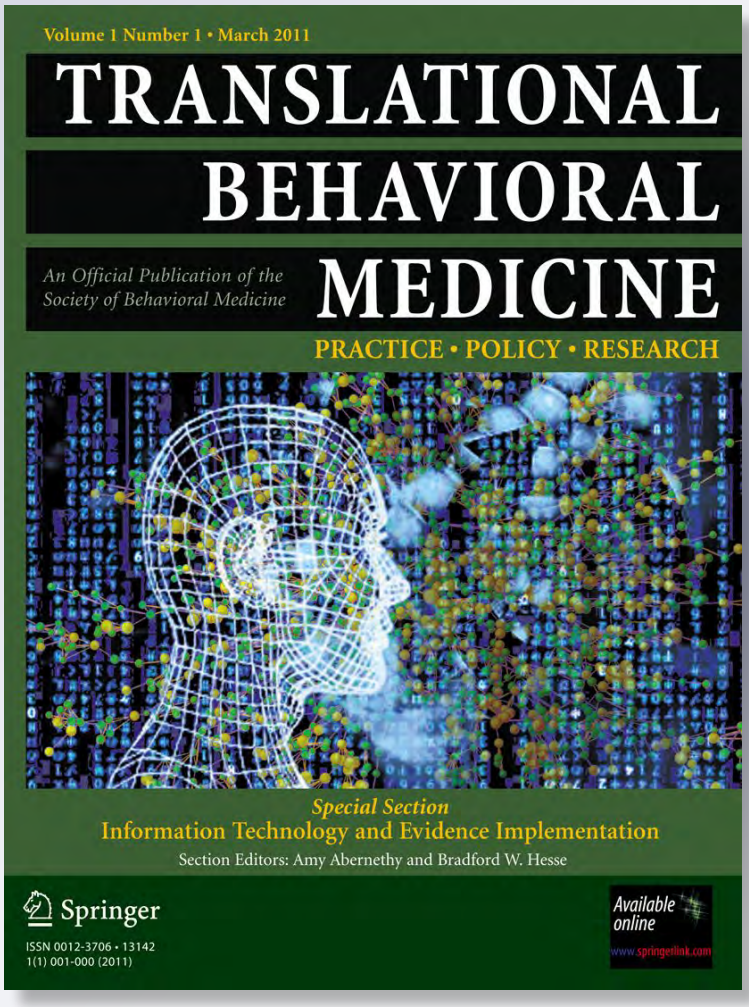

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TBM

A computerized, tailored intervention to address behaviors associated with PTSD in veterans: rationale and design of STR^{2}IVE

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ABSTRACT

Combat exposure among military personnel results in increased risk of posttraumatic stress disorder (PTSD), major depression, substance use, and related health risks. PTSD symptoms require innovative approaches to promote effective coping postdeployment. PTSD's nature and scope requires an approach capable of integrating multiple health risks while reaching large populations. This article provides the rationale and approach to adapt and evaluate a Pro-Change computerized tailored intervention (CTI) targeted at behavioral sequelae (i.e., smoking, stress, and depression) for veterans with or at risk for PTSD. The three-phase approach includes: 1) focus groups to review and, subsequently, adapt content of the existing CTI programs; 2) usability testing; and 3) feasibility testing using a three-month pre–postdesign. Effective, theory-based, real-time, multiple behavior interventions targeting veterans' readiness to quit smoking, manage stress, and depression are warranted to provide potential health impact, opportunities for learning veteran-specific issues, and advance multiple health behavior change knowledge.

KEYWORDS

Computerized tailored interventions, Posttraumatic stress disorder, Transtheoretical model, Veterans

Implications

For researchers: A process including qualitative content evaluation, usability and feasibility testing is recommended to adapt existing effective computer tailored interventions addressing multiple PTSD risk factors for veteran populations.

For practitioners: Although there may be common underlying principles addressing multiple behavior change targeting PTSD risk factors such as smoking, depression and stress, it is important to identify population-specific issues prior to intervening to maximize acceptability and effectiveness.

For policy-makers: Evidence of effectiveness in veterans should be required prior to implementing and disseminating PTSD prevention programs for this population.

Combat-related posttraumatic stress disorder (PTSD) is a significant and long-lasting problem with up to 15% of veterans meeting current and 31% meeting lifetime PTSD diagnostic criteria (1). Examining the mental health effects in U.S. military personnel returning from current deployments to Iraq and Afghanistan is of increasing importance, particularly since research conducted following other military conflicts and Operation Enduring Freedom (OEF) or Operation Iraqi Freedom (OIF) has shown that deployment and exposure to combat result in increased risk of PTSD, major depression, substance abuse, functional impairment in social and employment settings, and the increased use of health care services (2–7).

The majority of OEF/OIF veterans have been involved in combat situations, and approximately 10–17% of veterans in combat infantry units have reported symptom levels consistent with a diagnosis of PTSD (8). Given that U.S. soldiers are currently deployed for 15-month rotations, exposure to potentially traumatic events is lengthy, and traumatic stress symptoms may be more likely (9). Shortly after redeployment, approximately 44% of service members reported clinically significant depressive and/or posttraumatic stress symptoms (9). Because PTSD symptoms seldom disappear completely, it is usually a continuing challenge for survivors of trauma to cope with PTSD symptoms and the problems they cause. Comorbid conditions, including depression, other anxiety disorders, and substance misuse, are common along with relationship difficulties, excessive anger, work problems, physical health, illness, and healthcare utilization (10, 11).

According to a 2007 report from the Defense Health Board Task Force on Mental Health, the military's mental health system does not have adequate resources, funding or personnel to support the psychological health of service members and their families (12). In response to anticipated need, the Veterans Affairs (VA) health care system has

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increased the number of psychologists since 2005 by 478, but at least 330 more are needed (13) indicating potential gaps in service provision. Such gaps in service come at a significant cost to the military. PTSD and depression in returning service members cost up to $6.2 billion in the 2 years following deployment (5). However, evidence-based treatment for PTSD and depression would pay for itself within 2 years; thus, there is a need to develop and evaluate effective interventions. The ultimate impact of successfully intervening on young veterans is that it has very real implications on recovery, relapse prevention, and quality of life. This will ultimately allow affected individuals to return to their task, occupations, and family life.

BEHAVIORAL HEALTH RISK FACTORS AND TREATMENT FOR PTSD

Research with returning OEF/OIF service members suggests that there is a new generation of veterans with high levels of PTSD and depression (2). Treatment options for PTSD include cognitive–behavioral therapy (CBT), group psychotherapy, and pharmacotherapy to ease depressive symptoms and promote sleep (13, 14); however, most efficacy trials using randomized controlled designs have focused on CBT (15). In general, CBT methods have been effective in producing significant reductions in PTSD symptoms in civilian populations, but the degree of remission has been somewhat less in veterans with chronic combat-related PTSD (16, 17).

It is, therefore, imperative to identify effective ways of increasing access to efficacious treatments for combat-related PTSD and associated comorbid behavioral health conditions. Moreover, given the rapid development of telemedicine programs within the military, it is vital that research address the effectiveness of this mode of service delivery for specialty services such as PTSD treatment. Research that investigates prospective, randomized evaluations of clinical and process outcomes for specialized PTSD interventions is imperative (18). This paper describes the development of a computerized, tailored intervention (CTI) that will target health behaviors associated with PTSD in veterans (specifically, smoking, depression and stress). Ultimately, the goal of the CTI program is to teach users healthy coping skills that will promote effective management of the psychological impact of traumatic events.

Smoking

PTSD is associated with a high prevalence of smoking, heavy cigarette consumption and low cessation rates (19), and for some, becomes a way of coping with chronic symptoms (20, 21). Smokers report a higher frequency of smoking in response to military memories (19, 22); however, stopping smoking is not associated with worsening PTSD or depression (23). Because PTSD is associated with elevated rates of nicotine use, it has an indirect impact on cardiovascular health (24). Further, compared to Vietnam veterans with PTSD who do not smoke, Vietnam veterans with PTSD who do smoke have reported higher levels of PTSD symptoms, trait anxiety, and depression (25).

Stress

The PTSD impact extends beyond trauma victims by disrupting their intimate relationships and families (26). In combating anger regulation problems, stress management interventions are critical to reduce the heightened physiological arousal, anxiety, depression, other comorbid problems, and maladaptive coping strategies accompanying PTSD (27, 28).

Depression

A recent study of combat troops following return from deployment to Afghanistan or Iraq found postwar rates of depression from 7.1% to 7.9% (29). More importantly, the majority of soldiers with PTSD or depression at 7 months did not meet criteria for either condition at 1 month (29). The RAND study (5) also found that symptoms of PTSD and depression can have a delayed onset–appearing months after exposure to stress.

COMPUTERIZED, TAILORED INTERVENTIONS (CTIs) FOR PTSD

PTSD interventions can vary considerably in content, timing, intensity, and delivery method; research on the efficacy of self-help protocols for behavior change has been promising. The proposed intervention will deliver empirically-based, tailored communications for smoking cessation, depression, and stress management on a personal computer. Compared to nontailored materials, tailored materials are better remembered, perceived as more relevant and credible, and are more effective in changing health behavior (30, 31). Advances in behavioral science, communications, and computer technology have contributed to the development of behavioral health interventions that effectively motivate behavior change (32, 33) with minimal or no clinician contact. Computer/Internet-based interventions yield equally effective treatment outcomes compared to self-help interventions delivered via other methods (34).

Computerized interventions have several potential advantages over noncomputerized protocols (32). First, computer-based interventions allow for personalization of recommendations including tailoring over time with minimal burden of superfluous material. Second, the application of precise user data (e.g., time burden on users, answers to knowledge questions) collected via interactive computerized interventions present a unique advantage relative to noncomputerized self-help methods such as bibliotherapy or videotape protocols. Third,

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where Internet is available, Internet-based interventions can reach a large population at a relatively low cost. Fourth, they can be accessed privately from individuals' homes and completed at each user's own pace. Finally, they can be easily adapted and updated to reflect emerging empirical findings to ensure the highest quality of care.

Web-based computer tailored interventions (CTIs) are particularly beneficial for intervening with some mental health issues because they offer anonymity (35, 36), reduce fear of stigma (35, 36), and increase self-disclosure (37, 38). CTIs can be more engaging, allowing participants to control their learning environment, move at their own pace, and allow access to sensitive information (39–41). They can also potentially increase retention rates by increasing convenience and allowing doses of interventions as needed (42). Additionally, advanced CTIs employ empirical databases consisting of data collected from thousands of participants and heuristics. These databases provide the basis for decision rules that guide the development of individualized interventions tailored according to behavior change theory variables (33, 43).

The Transtheoretical Model of Behavior Change (TTM), one of the leading behavior change theories (43), has been frequently employed as a framework for this type of tailoring. The TTM (44) is a comprehensive model of behavior change that integrates diverse psychological constructs (i.e., stage of change, decisional balance, process of change, and self-efficacy) to explain and predict how and when individuals change their health behaviors (for a full description of the TTM see Ref. (45)). Several clinical trials have documented the ability of TTM interventions to recruit, retain, and effect change across a number of health behaviors including smoking (46, 47), stress (48), depression prevention (49), and multiple health behaviors (50–52), and has also shown impacts on readiness to change, perceived treatment relevance, attendance at group treatment sessions, and attrition in Vietnam veterans with PTSD (53).

TTM-BASED TAILORED APPROACHES FOR TREATMENT-RESISTANT POPULATIONS

Resistance to treatment can be expressed in several major ways, e.g., not seeking treatment or dropping out of treatment. TTM has been found to predict and reduce both of these treatment-resistant behaviors (49, 54). In the active duty military, there are unique factors that contribute to resistance to seeking mental health care, particularly the concern about how a soldier will be perceived by peers and by leadership (55). Concern about stigma is disproportionately greatest among those most in need of help from mental health services (55). Soldiers often report more discomfort in discussing potential psychological problems than medical problems, especially when they are returning to their units. In addition, soldiers report a lesser likelihood of following through with a psychological referral than a medical referral (7). Moreover, war fighters may have legitimate incentives to minimize their distress such as hastening discharge, to accelerate return to their family, or to avoid compromising their military career or retirement (56).

Clinicians also acknowledge that thousands of OEF/OIF veterans are reluctant to seek help even those experiencing distressing psychiatric symptoms (17). For example, of those soldiers and Marines returning from Iraq who reported experiencing a mental health problem, only 38 to 45% indicated an interest in receiving help, and only 23 to 40% reported actually receiving professional help (7).

Premature termination or dropout from treatments for PTSD is typically in the 50% range. This occurrence is common across treatments for a broad range of mental health problems (57). In their metaanalysis of 125 studies on dropout, Wierzbicki and Pekarik (57) found poor ability to predict dropout with the only variables being minority status, lower education and addiction behaviors. In contrast, Brogan et al. (54) found that TTM variables were able to predict over 90% of premature terminators from therapy for a broad range of mental health problems with premature terminators being similar to people in precontemplation.

RATIONALE FOR A MULTIPLE BEHAVIOR APPROACH

Conventional wisdom on disease management has been that it is not possible to treat multiple behaviors simultaneously because it places too many demands on a person's inherent ability to change (58). In fact, one of the limitations of much of the published research is that it has been based primarily on an action paradigm limiting application to the majority of individuals. Using a TTM-based approach allows multiple behaviors to be addressed without overburdening participants. The TTM posits reduced resistance and greater behavior change occurence when interventions are tailored to the individual's stage of change, rather than “one size fits all.” The TTM provides a framework for intervening when individuals are not ready or ambivalent to change unhealthy behaviors or adhere to traditional treatments such as CBT used in the treatment of PTSD. Multiple behavior change interventions based on TTM for a common health objective, e.g., cancer prevention, diabetes self-management, and weight management, have been shown to have significant impact on entire populations (50, 51, 59–63). For example, smokers treated for two or three behaviors were as effective in being abstinent at long-term follow-up as those treated for only smoking (52).

TTM-based CTI's tend to generate much higher rates of participation (e.g., 65% to 85%) for problems like smoking, stress, and obesity than the 2% to 20% rates commonly found with action-oriented clinic-based

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treatments (46, 48, 60, 64). Further, participants who are traditionally at the greatest risk for dropping out in the precontemplation stage completed CTIs at the same high rate as those ready to take action (65). This project builds on this recent evidence that treating multiple behaviors with a TTM-based CTI is effective with each of the target behaviors without reducing the efficacy of treating one behavior at a time. It also builds on the covariation/coaction concepts that individuals taking effective action on one target behavior are much more likely to take effective action on a second behavior and that individuals are likely to take effective action on untreated behaviors that are related to the treated behaviors.

THE STR^{2}IVE PROJECT (STRESS REDUCTION STRATEGIES TO IMPROVE VETERAN'S HEALTH)

Currently, there are no multiple behavior CTI programs for veterans. Utilizing a CTI approach can produce healthier coping strategies to reduce stress, depression, and smoking. It is anticipated that this effort will lead to a fully integrated, scalable, multibehavioral system that can be easily disseminated online to serve veterans and nonveterans with a number of negative health risks. The STR^{2}IVE program has been fully conceptualized and is now being developed and tested. This paper addresses the concept and approach; thus, the purpose and methodology is presented below. This allows the detailing of rationale and methodology that are not otherwise possible in typical data-based publications.

The primary aims of STR^{2}IVE are:

1. To adapt and test the feasibility of a multiple behavior TTM-based CTI designed for the general adult population to be appropriate for veterans with or at-risk for PTSD.
2. To demonstrate preliminary behavior change in each of the three behaviors targeted by the CTI–smoking, depression, and stress–as well as reductions in PTSD-related symptoms and improved quality of life.

Research will be completed in three phases. Phase 1 focus groups obtain feedback from combat veterans on three TTM-based CTI programs previously developed and validated by Pro-Change Behavior Systems, a research-based behavior change product development company. The focus group data will be used to guide veteran-specific adaptation or revisions. Phase 2 usability testing uses Morae® software, the Think Aloud Protocol (66, 67) and the Wizard of OZ method (68, 69). Phase 3 includes pre–post feasibility testing of the adapted system.

Participants

A total of 95 male and female veterans aged 18 or older, preferably with former military service in Iraq or Afghanistan, are being recruited to participate in three phases of this project: 1) focus groups (n=30); 2) usability study (n=15); and 3) a feasibility study (n=50). Participants are being recruited from the veteran community residing in Hawai'i through posters and flyers at VA clinics, referrals from VA mental health providers, and targeted mailings to VA patients at risk (exhibiting associated psychological symptoms) for PTSD.

Inclusion criteria for all phases are: veterans aged 18 years or older, OEF/OIF service preferred, computer literacy at the beginner level, eighth grade English literacy level, and access to a computer with Internet connectivity. Exclusion criteria for all phases are: history of mania, schizophrenia, or other psychoses; special medical conditions that may prevent engagement with the CTI system such as history of significant head injury; and suicidal ideation.

Description of the CTI system

Initially, the participants are prompted to access any or all behavior modules within 7 days and as often as desired thereafter. Subsequently, participants will be required to access the system a minimum of once a month over a three-month period. Users can update their assessments every 30 days with access to their most recent report and the interactive e-Workbook during the interim. Participants who fail to return as often as recommended will receive proactive email prompts as reminders to revisit the program.

The entry point into the CTI system assesses readiness to change the key health behaviors addressed. The participant's homepage provides information and access to the three individualized modules that are available to the individual based on risk (being in a preaction stage). During each session for a behavior module, individuals are assessed on all relevant TTM variables (i.e., stage of change, decisional balance, processes and self-efficacy) in addition to relevant constructs for a particular behavior and receive feedback based on the assessment. The Stress Management module, for example, includes all appropriate constructs of the TTM as well as tailored feedback on positive coping strategies and behaviors. In the baseline session for each behavior (e.g., smoking), the CTI system compares a participant's responses to a large comparative sample of other individuals in that stage (normative comparisons) and provides individualized, real-time onscreen feedback on which principles of change they are underutilizing, overutilizing or appropriately utilizing to facilitate forward stage movement.

All subsequent follow-up sessions are based on normative comparisons and ipsative comparisons. Ipsative feedback, which involves access to a database of results of previous contacts, reinforces progress individuals have made since their last

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assessment. The CTI system for one behavior can generate over 150 unique feedback sessions at baseline and more than 20,000 unique sessions at follow-up; this ensures uniqueness of feedback each time they interact with the system. The CTI sessions employ statistical decision-making to guide individuals through the intricacies of each stage, encouraging the use of the most appropriate change processes. Without this kind of expert and individualized feedback, participants cannot assess how much progress they are making, what processes and principles they are applying most effectively and which ones they need to emphasize the most in order to change successfully. This level of feedback is particularly helpful to those who may not yet have progressed to the next stage, despite substantive gains in appropriate use of change processes. The personal feedback report provided at the end of the session typically is two to three full color pages. From the report, the user can link to an interactive e-Workbook, in addition to the other behavior modules. The e-Workbook contains interactive exercises that are designed to engage the participant in using one or more processes or principles of the TTM that are most appropriate for that stage. The e-Workbook also includes links to external resources, assessments, tracking tools (e.g., logs and diaries to record temptations to engage in unhealthy stress management behavior), testimonials (e.g., how people develop new habits), and activities (e.g., rate the benefits; calculate the cost of unhealthy stress management behavior, True/False quiz). Users may choose to go through a particular stage or the entire e-Workbook. Participants have unlimited access, which can be used to progress between expert system sessions.

Procedures

All procedures have been approved by the VA Pacific Islands Health Care System (VAPIHCS), the U.S. Army Medical Research and Materiel Command's Human Research Protection Office (HRPO), and participating IRBs.

Phase I: focus groups

Three focus groups will gather information on the acceptability of existing CTI program content for each behavior. Each group reviews a behavior change module in order to match the expectations and needs of the target population. Each focus group (8–10 veterans; about 1.5 h) will be audio recorded with a note-taker present. Prior to the focus group meetings, participants provide informed consent and complete stage of change and basic demographics measures.

CTI system content for the smoking cessation, stress management, and depression prevention behavioral modules are reviewed, adapted, and adjusted based on the theme-based focus group analyses. Participants will be asked to provide feedback about the graphics, text and layout based on screen shots of the online system. This will include probes about veteran-specific issues. The major focus of the revisions will address adaptation of language, tone, and content to be appropriate and relevant the veteran population.

Phase II: usability study

After the CTI program has been adapted and beta-tested, its acceptability and usability (70) will be examined as part of the system development process. Efforts will be made to include veteran participants with varying levels of experience using interactive web-based multimedia programs (70) and at various stages of change for the different behaviors. Usability testing provides a scientific assessment of user errors, misunderstandings of content, navigation problems, and subjective satisfaction. This feedback is invaluable to the system design process and will improve the acceptability and usability of the final system.

During the usability testing, a research assistant observes a participant as he or she navigates through the CTI system, resisting the temptation to offer help too soon so that usability issues will be revealed. Participants are asked to think and make comments aloud as they work through the various screens in the registration process, the introduction to the program, the assessment questions, the feedback messages as well as the integration of the different behavior modules. Their audio and video of screens visited and mouse movements are captured and recorded automatically for review and analysis. Participants are asked to interact with relevant sections of the integrated program including the e-Workbook and asked to comment on the options and content available. Participants are asked to provide qualitative and quantitative feedback on overall presentation and usability as well as quality of the program, navigation, ease of use, attractiveness, etc. Feedback from individual interviews is then used to modify the behavior modules before additional usability interviews are conducted. The comments from all interviews are used to modify the CTI system prototype prior to the feasibility study. At the conclusion of each usability interview, participants are asked to provide feedback on the module they interacted with using a measure adapted from existing acceptability measures (70–72) that has been used by Pro-Change in previous research.

Phase III: feasibility

A three-month feasibility test is designed to assess acceptability and viability of the CTI system and the behavioral modules by veterans in the community, particularly recent veterans returning from the Iraq or Afghanistan combat theaters. Participants will

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provide informed consent and complete baseline, one- and three-month online questionnaires (see entire content of the questionnaires in "Outcome measures and assessment instruments" below).

The project has been approved for online screening and informed consent, allowing the registration and enrollment process to be automated for the feasibility testing. Veterans interested in participating in the feasibility study and meeting the basic criteria listed in the recruitment material can visit the project webpage to complete the screening and consent process. After confirming that they are military veterans over the age of 18 and comfortable using a computer and the Internet, prospective participants must meet inclusionary criteria by confirming that they have had a military experience so traumatic that in the past month they have had nightmares, been unable to stop thinking about it, were constantly on guard, and/or felt numb or detached because of it. Following this, they are asked to self-report whether they have any of the exclusionary criteria. If they pass the online prescreening questions, they are asked to view and print the informed consent fact sheet, which lists information about the study and their rights and responsibilities as participants. Next, they complete the PCL-M and PHQ-8 questionnaires and are enrolled in the study if the scores fall within the allowable range for the study (exhibit mild to moderate PTSD >24 and <74 on the PCL-M and are not severely depressed <20 on the PHQ-8) and they choose to enroll.

Participants will be provided access for 3 months to the Internet-based CTI system addressing smoking cessation, effective stress management, and depression prevention. Participants who are nonsmokers will not be given access to the smoking cessation module. Participants are asked to participate in a minimum of three sessions for each module (at least once per month) and for at least two of the three modules. Enrollment includes the consenting process and collecting demographics and an email address. The email address will then be used to provide reminders to participants who have not accessed the system in 30 days.

Outcome measures and assessment instruments

Demographics questionnaire–Demographic data including race/ethnicity, age, gender, combat theater(s) served in, and total number of months in theater(s) will be collected.

PTSD Symptom Checklist (PCL-M) (73)–The PCL-M consists of 17 questions that map directly onto DSM-IV criteria for PTSD. Respondents are asked how often they have been bothered by each symptom in the past month on a five-point Likert scale (1="not at all" to 5="extremely"). All items are summed to obtain a total severity score. A score of 44 is considered PTSD-positive for the general population, while a score of 50 is considered PTSD-positive in military populations.

Combat Trauma Exposure Survey (CTES) (5)–The CTES is an 11-item, self-report survey that assesses the type of an individual's combat trauma experiences. It includes both direct (e.g., injury requiring hospitalization) and indirect trauma exposure (e.g., witnessing a traumatic event) adapted from Ref. (55) that requires only a yes or no response (5). The subset of 11 exposures used in the brief survey was found to be as predictive of PTSD as the full 24 items in veterans residing in NY (74).

The Perceived Stress Scale (PSS) (75)–The PSS is a 10-item questionnaire assessing the degree to which situations in one's life are appraised as stressful. Items are designed to tap how unpredictable, uncontrollable, and overloaded respondents find their lives to be.

Patient Health Questionnaire (PHQ-8) (76, 77)–The PHQ-8 is an eight-item version lacking the ninth question regarding suicidal ideation of the PHQ-9, a tool for assisting clinicians in diagnosing depression as well as selecting and monitoring treatment. The PHQ-8 is selected for this study as responses are collected independently online and there is no personal interaction with the participants so any response by clinicians would be delayed. Also, the suicidal ideation question is rarely endorsed and most often reflects passive rather than active thoughts of suicide (78). The PHQ-8 is based directly on the diagnostic criteria for major depressive disorder in the DSM-IV and includes items such as "Little interest or pleasure in doing things" and "Feeling tired or having little energy." Respondents rate how often they have been "bothered by problems over the past 2 weeks" using a four-point Likert scale (0=not at all, 3=nearly every day). Scores in the range of 5–9 indicate minimal symptoms, 10–14 minor depression or dysthymia, 15–19 major depression (moderate), and greater than 20 severe major depression.

Quality of Life Scale ([QOLS]) (79, 80): (feasibility study)–The QOLS contains 16 items that represent five conceptual domains of quality of life. QOLS was developed with more consideration to cultural diversity and individual perspectives than other commonly used measures. It uses a unique seven-item Likert scale that allows responses regarding different aspects of life to range from "delightful" to "terrible". The original 15-item QOLS satisfaction scale was found to be internally consistent with alpha from 0.82 to 0.92 and showed high test–retest reliability over 3 weeks (r=0.78 to r=0.84). Similar reliability was reported for the 16-item version used in this study (81).

Stage of Change for Depression (49)–This measure assesses readiness to engage in effective methods for preventing depression. The assessment includes a short description of depression prevention–using effective methods to keep depression from occurring, or if it does occur, to keep it as mild and brief

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as possible. Respondents are asked, "Do you effectively practice depression prevention in your daily life?" A single item response category places individuals in one of the five stages of change.

Stage of Change for Stress Management (48)–This measure assesses readiness to effectively manage their daily stress. The assessment includes a short description of stress management (stress management includes regular relaxation, physical activity, talking with others, and/or making time for social activities) and asks respondents, "Do you effectively practice stress management in your daily life?" A single item response category places individuals in one of the five stages of change.

Stage of Change for Smoking Cessation (82)–This measure assesses a readiness to quit smoking. Participants are asked if they have quit smoking. A single item response category places individuals in one of the five stages of change.

Data analysis

Primary aim 1–Primary aim 1 is to adapt and test the feasibility of a multiple behavior TTM-based CTI designed for the general adult population to be appropriate for veterans with or at-risk for PTSD. In order to determine successful outcomes for Aim 1, data analysis will be conducted from qualitative data obtained from the smoking, depression, and stress focus groups. Data from the focus groups will be coded and analyzed according to guidelines (83, 84). Analysis will include systematic steps for identifying basic concepts and comparing results with other groups in order to find common patterns (84).

Primary aim 2–Primary aim 2 is to demonstrate preliminary behavior change in each of the three behaviors targeted by the CTI–smoking, depression, and stress–as well as reductions in PTSD-related symptoms and improved quality of life. Data analysis for Aim 2 will be focused on the self-report measures described above to provide estimates of effect size for the intervention on PTSD symptoms (PCL-M), perceived stress (PSS), depression (PHQ-8), quality of life (QOLS), status on TTM variables including stage of change, and ratings of acceptability and satisfaction with intervention (ESIM, SUS). Given that this is a feasibility study, the analyses are not adequately powered to detect statistically significant differences across all three time points; therefore, differences in effect sizes (i.e., Cohen's *d* and odds ratios) and visual trends will be examined. More specifically, repeated measures Analysis of Variance (ANOVA) and logistic regression will be used to examine differences in continuous (e.g., decisional balance, confidence, number of cigarettes, and satisfaction) and categorical measures (e.g., progressing to Action or Maintenance and willing to recommend program to friends). Frequency of use and acceptability ratings will also be compared across the stages of change. Finally, how utilization relates to stage progress and changes in other TTM constructs will be examined. Measures such as number of log ins and interactions and satisfaction ratings will be compared using repeated measures ANOVAs.

Assessment of feasibility–The following criteria will be used to determine feasibility: a) completing the customization and testing of the baseline CTI; b) recruitment and delivery of the baseline intervention to 40–50 veterans; and c) determination of the acceptability of the intervention, represented by an overall rating of 4 (good) or better by 75% of the participants. The feasibility study analysis will include the completion of the beta tests, the delivery of the complete intervention to 40–50 participants, and the determination of the acceptability of the intervention represented by an overall rating of 4 (good) or better on the ESIM and SUS by 75% of the participants.

DISCUSSION AND CONSIDERATIONS

The largest integrated health care system in the United States is the network of facilities operated for veterans of military service by the Department of Veterans Affairs (VA). The proposed research is particularly relevant in lieu of the current and anticipated demands on the VA mental health system with the return of OEF/OIF. The anticipated impact of intervening on veterans with PTSD with our intervention is that it may have very real implications on recovery, relapse prevention, and quality of life. This project may also have direct and indirect impacts on patient care such as: 1) providing empirically based behavioral interventions, as additional resources, for health care providers who have increasingly limited time and resources; 2) providing support and intervention for individuals who have PTSD but are not yet ready to address these health risk behaviors by progressing them towards becoming ready; 3) providing support and relapse prevention tools for individuals who are successfully coping with PTSD, but may be at risk for relapse; and 4) improving the ability to reach individuals with PTSD at "teachable moments" through the Internet or disseminated technologies (e.g., computers, smart phones, and cell phones). In other words, individuals will have access to the intervention when they are ready to receive the message.

The proposed CTI system is also flexible enough that additional modules targeted at other health risk behaviors or coping strategies can be added. These modules may include anger management, sleep disorders, pain management, domestic violence, war memories, and social support, among others. Ideally, access to the system should be expanded through other VA healthcare systems in the U.S. and Guam and veterans who are at risk for chronic diseases caused by smoking, stress, and depression should be included.

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APPENDIX G_____

MILITARY BEHAVIORAL MEDICINE SUBMISSION

IDENTIFYING VETERAN-SPECIFIC ISSUES IN ADAPTING A COMPUTERIZED TAILORED INTERVENTION TO ADDRESS BEHAVIORAL RISK FACTORS ASSOCIATED WITH PTSD: A FOCUS GROUP APPROACH

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Abstract

The increasing prevalence of posttraumatic stress disorder (PTSD) and associated behavioral risk factors among veterans necessitates examining evidence-based interventions in this population. This study evaluated the relevance of an evidence-based computerized tailored intervention (CTI) addressing PTSD-related behavioral risk factors to veterans. Three focus groups with 21 male veterans were conducted. Themes were generated using qualitative methods. Participants thought the CTI was largely applicable to veterans although they identified a few issues to be adapted.

They also had population-specific suggestions. This evidence-based CTI is largely applicable and can be successfully adapted to be relevant for veterans.

Keywords: computerized tailored intervention, posttraumatic stress disorder, veterans, behavioral risk factors, transtheoretical model, motivation to change, focus group, applicability, veteran-specific issues, adaptation

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Identifying Veteran-specific Issues in Adapting a Computerized Tailored Intervention to Address Behavioral Risk Factors Associated with PTSD:

A Focus Group Approach

U.S. veterans Posttraumatic Stress Disorder (PTSD) prevalence ranges from 2%-31%, two to four times that of U.S. civilians (Richardson, Frueh, & Acierno, 2010). Studies of Iraq and Afghanistan veterans report slightly higher PTSD rates, up to 48.7% (Helmer et al., 2007). The Department of Veterans Affairs (VA) recognizes issues in disseminating traditional PTSD therapies for veterans (Karlin, et al., 2010), such as veterans' interest, treatment motivation, and access to care. Finding effective, stigma-free, easily-accessed, prevention-oriented, and cost-efficient alternatives may help bridge the gap between increased need and limited resources.

Computerized Tailored Interventions (CTIs) may help reduce barriers to military mental health care (Greene-Shortridge, Britt & Castro, 2007), addressing the above issues, along with broad reach, individualized treatment, and confidential data collection (Ruggiero, et al., 2006). CTIs appear to be as effective as self-help and clinician intervention (Hamel, Robbins, & Wilbur, 2011; Hirai & Clum, 2006; Klein, et al., 2010; Nguyen, Kornman, & Baur, 2011).

Transtheoretical Model (TTM) based CTIs may offer additional advantages, such as motivational enhancement (Prochaska & Velicer, 1997), and are efficacious for various health risk behaviors, including smoking cessation, stress management, and depression prevention (Evers, et al., 2006; Levesque, et al., 2011; Prochaska, Velicer, Fava, Rossi, & Tsoh, 2001). TTM-based CTIs evaluate users' stage and TTM constructs to provide specific tailored feedback. No TTM-based CTIs have been developed specifically for, or tailored to, veterans. This focus group study, part of the STR^{2}IVE project (Jordan, Evers, Burke, King, & Nigg, 2011), evaluated

the applicability of an evidence-based CTI to smoking cessation, stress management, and depression prevention in veterans.

Method

Participants

Participants were recruited from Hawai‘i’s veteran community. Inclusion criteria included smokers with mild to moderate stress and/or depression, some computer literacy, Iraq or Afghanistan service preferred. Ten qualified veterans were recruited for each focus group evaluating a CTI program addressing one of the three PTSD-related risk factors. Twenty-one veterans participated (70% participation rate; mean age = 49.6, range = 24-68 years; mean military service duration = 59.4 months; n = 9 smoking cessation; n = 6 stress management; n = 6 depression prevention; see Table 1).

Procedures

Two local IRBs and the Office of Research Protections approved the protocol. Each focus group began with informed consent and a survey, followed by introductory questions and evaluation of CTI screenshots using a program-specific discussion guide. Discussion was led by trained facilitators and recorded, which lasted approximately two hours with refreshments and a $25 gift card provided. Analyses followed accepted methods (Krueger, 1998).

Results

Participants considered content and structure of the CTI generally applicable to veterans (see Table 2).

Content

The program content was considered generally appropriate by veterans, who indicated that the stage concept was helpful for self-evaluation, and stage-tailored feedback encouraged progress. Participants identified with most pros and cons, and especially liked that the system acknowledged their autonomy as veterans. The individually tailored feedback was also considered helpful for adopting or maintaining change. The goal-setting was deemed very useful in stage progression. The small steps toward specific goals were appealing because of increased manageability. Participants preferred a combination of scientific and user-friendly language with clear, concise, specific, and informative text. Most graphics were considered appropriate and improved understanding of the content or feel more positive about changing. For example, beaches and meadows were relaxing and helped manage stress.

However, participants had difficulty understanding professional terms ("transtheoretical" and "contemplation") and relating to the "pros and cons" exercise. Some benefits (e.g., improvement in appearance) and certain activities (e.g., Tai Chi) may not appeal to veterans. They disliked graphics that triggered traumatic memories or unhealthy behaviors (e.g., a beach sunset, cigarettes). They also regarded helping relationships as stressors rather than support for veterans because of difficulty relating to non-veteran friends and family. Adaptation suggestions included more scientific information in user-friendly language (term definitions provided in programs were not reviewed) and more veteran-specific helping strategies (e.g., "couples counseling" for post-deployment relationship building and avoidance of isolation for depression prevention).

Structure

The programs were considered to be well constructed, easy to navigate, the text was considered clear, concise, and simple, and most screenshots provided a good text/graphic balance. The color, size and layout of different components (e.g., text, graphics, and icons) were appropriate for usability and appearance. Participants particularly liked engaging, pleasant, calming, and explicit graphics. Screenshots containing minimal text and appearing less compact appealed to depressed participants.

A few structural problems affecting applicability were identified. Some screenshots from the depression prevention program had too much text, and some colors were too dark or depressing. The proportion of the text in some screenshots was visually overwhelming. Additional suggestions for adaptation included bulleted text, gender-neutral colors, and a consistent layout.

Veteran-Specific Issues

The focus groups elicited veteran-specific issues (see Table 2). Veterans' support systems are largely confined to the VA programs and peer veterans. They experience alienation and communication difficulties with non-veterans after deployment. Especially stressful and challenging was communicating with and gaining support from family members to change deployment-related unhealthy behaviors. They articulated a need for educating family members about deployment experience and effective strategies for communication with non-veterans.

Another salient issue to veterans was the stigma and shame around mental health problems and treatment. Although participants acknowledged significant improvement in this area, they still reported having difficulty disclosing receiving mental health care to medical providers. In addition, some participants emphasized the importance of confidentiality promised

by the CTI for disclosing their medical compliance; however, others did not have such concerns once out of the military.

Another challenge for veterans was avoiding unhealthy behaviors in high-risk situations including resisting alcohol use when having trouble sleeping, avoiding smoking while drinking alcohol or coffee, and resorting to unhealthy behaviors once healthy ones failed to work. The lack of understanding and support from family was also identified as a trigger for engaging in unhealthy behaviors.

Discussion

This evidence-based CTI addressing PTSD-related behavioral risk factors is largely applicable to recent veterans from Iraq and Afghanistan, with few veteran-specific changes proposed.

Program Content

The TTM-based concepts and strategies helped veterans enhance motivation to change, take action toward goals, improve self-efficacy, and maintain change over time. Only minor revisions were suggested, including removing pictures triggering traumatic memories or unhealthy behaviors and adding strategies for handling relationships or avoiding isolation.

The general content applicability may be due to previous successful applications of the TTM to multiple health risk behaviors across populations (Driskell, Dyment, Mauriello, Castle, & Sherman, 2008; Evers, et al., 2006; Levesque, et al., 2011; Prochaska, et al., 2001). Also, veterans may not differ from the general population in their motivation and process of change when targeted behaviors are the same.

The content adaptations reflect some general and veteran-specific issues. For example, participants' difficulty selecting one stage answer may imply ambiguity about their change process. Participants' strong reaction to pictures reminding them of Iraq may suggest risk of post-deployment stress. Comments on managing relationship stress and avoiding isolation may indicate veterans' feelings of isolation and difficulties with relationship.

Program Structure

Participants found the CTI screenshots easy to navigate and providing a good text/graphic balance, requiring no systematic structure changes. Only a few suggestions were made to reduce the proportion of text and to use a calming, pleasant color scheme appealing to both genders. Concise text and simple layout preference may be related to military training and experience. The proposed gender-neutral color scheme may reflect a perceived increase in women in the military.

Veteran-Specific Issues

The perception of insufficient family support, concerns about stigma of seeking mental health care, and problems with resisting health risk behaviors in high-risk situations, are consistent with previous veteran studies (Durai, et al., 2011; Hoge, et al., 2004; Wheeler, 2007).

Strategies for effective communication with non-veterans could be added to the existing CTI, or new programs, to help family members understand veterans' deployment experience and support their behavior change. Provision of confidential CTIs may allow veterans to seek help without feeling stigmatized. Programs addressing multiple comorbid problems in veterans, like the CTI examined here, should be developed to help veterans cope with high-risk situations.

Limitations

As there are increasingly more female veterans (Franklin, 2009), it is important to learn female veterans' opinions about this CTI. The high proportion of separated or divorced participants (57.1%) may bias participants' responses, although family dysfunction was documented among veterans (Wheeler, 2007). Although all participants lived in Hawai‘i, many haled from various US states. Participants viewed static screenshots without experiencing the interactive program aspects, which may have limited understanding of certain components.

Conclusion and Implications

This is a solid first step to adapt an evidence-based intervention to address PTSD-related behavioral risk factors in veterans. For veterans not ready for in-person psychotherapy, having access to care issues, or fearing stigma for seeking mental health care, this veteran-tailored CTI may provide unique benefits. In addition, veterans with mild PTSD symptoms and comorbid behavioral risk factors may find this CTI sufficient to resolve their problems. In this sense, the adapted CTI will make evidence-based mental health care more accessible to veterans in need.

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Table 1

Participants' Demographics and Stage of Change

Category	Ethnicity						Branch			
	C	AA	H/L	PI	O	NR	AF	A	M	N
Number of Participants	8	3	1	5	3	1	4	10	5	2

Category	Education Level					Marital Status				Social Support	
	SHS	HS/ GED	SC	BD	G/P D	NM	M	S	D	LWP	HOC
Number of Participants	1	7	8	4	1	6	3	4	8	3	9

Category	Stage of Change					
	Behavior	PC	C	P	A	M	NR
Number of Participants	Smoking Cessation (n = 9)	1	5	2	1	0	0
	Stress Management (n = 6)	1	1	1	0	2	1
	Depression Prevention (n = 6)	0	2	1	0	2	1

Note: C=Caucasian, AA=African American, H/L=Hispanic/Latino, PI=Pacific Islander, O=Other, NR=No Response;
AF=Air Force, A=Army, M=Marines, N=Navy;
SHS=Some High School, HS/GED=High School/General Education Degree, SC=Some College, BD= Bachelor's Degree, G/PD=Graduate/Professional Degree;
NM=Never Married, M=Married, S=Separated, D=Divorced;
LWP=Living with a Partner, HOC=Having at least One Child;
PC = Pre-Contemplation, C = Contemplation, P = Preparation, A = Action, M = Maintenance, NR = No Response

Table 2

Themes and Sample Quotes on the Applicability of the CTI to Veterans

Category	Themes	Sample Quotes
Content	Positive Comments	"Well, it shows where I'm at… going up hopefully I'll be at the maintenance stage." "It's choice. Anything that comes with choice is positive…as a veteran you have choice..." "I like the idea of smaller steps. Big steps can also end in not only just frustration but just end in a total discontinuation of the whole process."
	Negative Comments	"There's more than one answer. Mine would be number two or number three." "… you see a lot of the people doing the Tai Chi…As it relates to veterans, it doesn't…it's not appropriate, it's not something that I as a veteran…Too old." "It's been too many tours in Iraq or Afghanistan. And when you came up on water…Sometimes spontaneous recall is excited by that…"
Structure	Positive Comments	"Letting you know how far you've gone [in the program]." "… it gives you a status of where you stopped and where you can come back to." "I like it, it's direct, it's to the point…it's very clear and understandable." "It's just more calming…more at ease. It's not as tight as the other one…I like it." "I think the color scheme is fine." "I think there is a balance between the images and the text, from what I've seen."
	Negative Comments	"I can't even pronounce this word and I don't comprehend it…Transtheoretical? Yeah, you gotta break it down to our level…" "It could be a little more condensed to make it more a little simpler because if someone was depressed the last thing they want." "It should be brighter, the sun shining, a little bit and more color." "Fit too much in the small space."
Veteran-Specific Issues	Veterans' Support Systems (Helping Relationship—Process of Change)	"I think with veterans, mostly you get more help from other vets than you do from anywhere else." "It's not like something to hide from her. It's a part our life and we really no like to share with our family." "Maybe there should be a program for their spouses so they can understand what the vets have been through…There's a lot of people who don't understand how we think. And that's a big issue dealing with when you come home and I see it as an issue."
	Influence of Potentially Negative Stigmatization (Social	"One thing that I've noticed, probably because of the Iraq /Afghanistan conflicts in the increasing amount of these problems…there are a lot more accessible means to find out how to go about dealing with these problems..." "I think there is a paradigm shift…That stigma or shame has been

Liberation—Process of Change)	lifted so it's more socially acceptable to come to terms with these problems and deal with them in an effective manner." "We were told it was a confidential….then yes fine." "We're worried about what our doctor's gonna say"
Challenges in High-risk Situations (Temptations—Self Efficacy)	"It's automatic I just light up a cigarette or when I'm drinking alcohol. It goes hand in hand. Beer in one hand, cigarette in the other. Or coffee in one hand, cigarette in the other," "…like the substance abuse…sometimes it's like you cannot resist it because…it really helped…it's so bad that whatever you're trying…isn't working…you think I just wasted all that time when I could have went out and grabbed me…a 40 ounce…to help you break out of that phase…"

APPENDIX H_____

INTERNATIONAL SOCIETY OF TRAUMATIC STRESS STUDIES (ISTSS) 2012 PRESENTATION

Tailored Online Multiple Behavior Intervention Reduces Symptoms of PTSD in Veterans

ISTSS 28th Annual Meeting, Los Angeles, CA – Nov.3, 2012

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Team Members

- James L. Spira, Ph.D. (Principal Investigator)
- Laurel King, Ph.D. (Project Manager)
- Patricia J. Jordan, Ph.D. (Co-Investigator)
- Julia Whealin, Ph.D. (Co-Investigator)
- Kerry E. Evers, Ph.D. (Co-Investigator, Pro-Change Behavior Systems)
- Claudio R. Nigg, Ph.D. (Co-Investigator, University of Hawai`i)
- Michelle Kawasaki, M.A. (Research Assistant)
- Stacy Daly (Research Assistant)

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Disclaimer: *The contents of this presentation do not represent the views of the Department of Veterans Affairs or the United States Government.*

Study Objectives

- To adapt and assess a behavioral TTM-based Computer Tailored Intervention for use in a veteran population at risk for PTSD

- To demonstrate:
  - behavior change in each of the three behaviors targeted by the CTI: **smoking, depression, and stress**
  - reductions in PTSD and depression related symptoms
  - Improved lifestyle and quality of life.

Transtheoretical Model of Behavior Change (TTM) – James Prochaska

- Framework:
  - Intended to describe, promote, predict, and maintain volitional behavior change
  - Incorporates15 different psychological constructs
- Stages of Change
  - Precontemplation/contemplation/preparation/action/maintenance
- Decisional Balance (pros & cons)
- Situational Self-efficacy (confidence & temptations)
- Processes of Change (5 experiential & 5 behavioral)

Computerized Tailored Interventions

Advantages of a Self-Help CTI:

- Adaptive interventions that offer multiple contacts with individualized dynamically-tailored messages:
  - Content area of interest/need
  - Stage of change/readiness
- Reducing Stigma:
  - Reach a large population at relatively low cost
  - Can be accessed privately from individuals' homes and completed at users' own pace.
  - Individuals often report more information to computers than to human clinicians due to less stigma and social compliance

Project Overview

- Development Process
  - 1. Focus groups with Veterans to assess programs (3 groups, total n=21)
  - 2. Programs revised and adapted for multi-behavior change program for Veterans
  - 3. Beta testing/usability interviews to inform further adaptations and improvements (15 interviews)
- Feasibility Study
  - Assessed feasibility of Web-based intervention for Veterans with PTSD symptoms.
  - Baseline-, 1-, and 3-month assessments
  - (90 enrolled, 57 completed)

Feasibility Study Recruitment

- Recruiting Methods
  - Targeted mailings to Veterans
  - VA providers distributed invitations to patients and clients
  - Veteran organizations distributed flyers to members
  - Ads on social media groups for veterans
- Inclusion & Exclusion Criteria
  - Veterans over 18, Computer & Internet access
  - PCL-M (25-73 range)
  - PHQ measure (<20)
  - No Hx of psychosis, recent inpatient MH treatment, suicidal ideation

STR2IVE
Stress Reduction Strategies to Improve Veterans' Health

National Center for PTSD
Posttraumatic Stress Disorder

Most Popular Online Ads

1.

Veteran? Got Trauma?

Help us test an online program for stress, depression and smoking. Receive up to $125. See if you qualify at www.str2ive.org.

2.

Veteran? Feeling Stress?

Help us test an online program for stress, depression and smoking. Receive up to $125. See if you qualify at www.str2ive.org.

Campaign Stats

- 2,879,301 Impressions
- 2,096 Clicks
- 0.073% CTR
- $2,000.00 Spent
- $0.69 CPM
- $0.95 CPC

CTR – click thru rate
CPM – cost per 1000 impressions
CPC – cost per click

Online Screening and Consenting

Interested veterans visited the study URL for:

- Recruiting
- Screening
- Consenting
- Assessments
- Interventions
- Incentives

Gift card incentives were paid for completions: $40 for baseline, $30 for 1-month, and $55 for completing the 3-month assessment

Feasibility Study

STR²IVE
Stress Reduction Strategies to Improve Veterans' Health

Pilot Study (1 group)

- Health Risk Intervention (HRI) completed at baseline, 1 & 3 months
- 3 Possible behavior programs available:
  - smoking cessation
  - stress management
  - depression prevention
- Definition of Complete:
  - Completed 3 HRI Assessments
  - Completed 3 sessions for at least 2 behaviors

Main Hypotheses

- 3-month pre-post study assessments to measure:
  - Progress through stages of behavior change
  - Improved coping skills in targeted behaviors
  - Reduction in PTSD symptoms
  - Improved behavioral and affective benefits
- Statistical Analysis:
  - Descriptive
  - Cross-sectional
  - Longitudinal analyses on trends in behavior change

Demographics (N=90)

- General
  - 75.6% male
  - Mean Age 41.2 (SD=11.22)
    - Range 22-65
  - 61.1% white, non-Hispanic
    - 13.33 % Native Hawaiian, Other Pacific Islander
    - 14.44 Hispanic
    - 7.78% Asian American
  - 53.3% married
  - 52.2% attended "some college"
- Military Service: M(SD)
  - Years in Military =9.9 (7.9)
  - Months Deployed =23 (17.1)
  - Army: 46.7%
  - Navy: 11.1%
  - Marines: 12.2%
  - National Guard : 6.7%
  - Air Force: 4.4%
  - Coast Guard: 1.1%
  - Combination: 16.7%
  - Enlisted = 46.7%
  - Senior Enlisted = 44.4%
  - Officer = 8.9%

Retention

- 76% of baseline completers completed all follow-ups
- Each time-point required completing HRI and at least 2 of 3 behavior programs

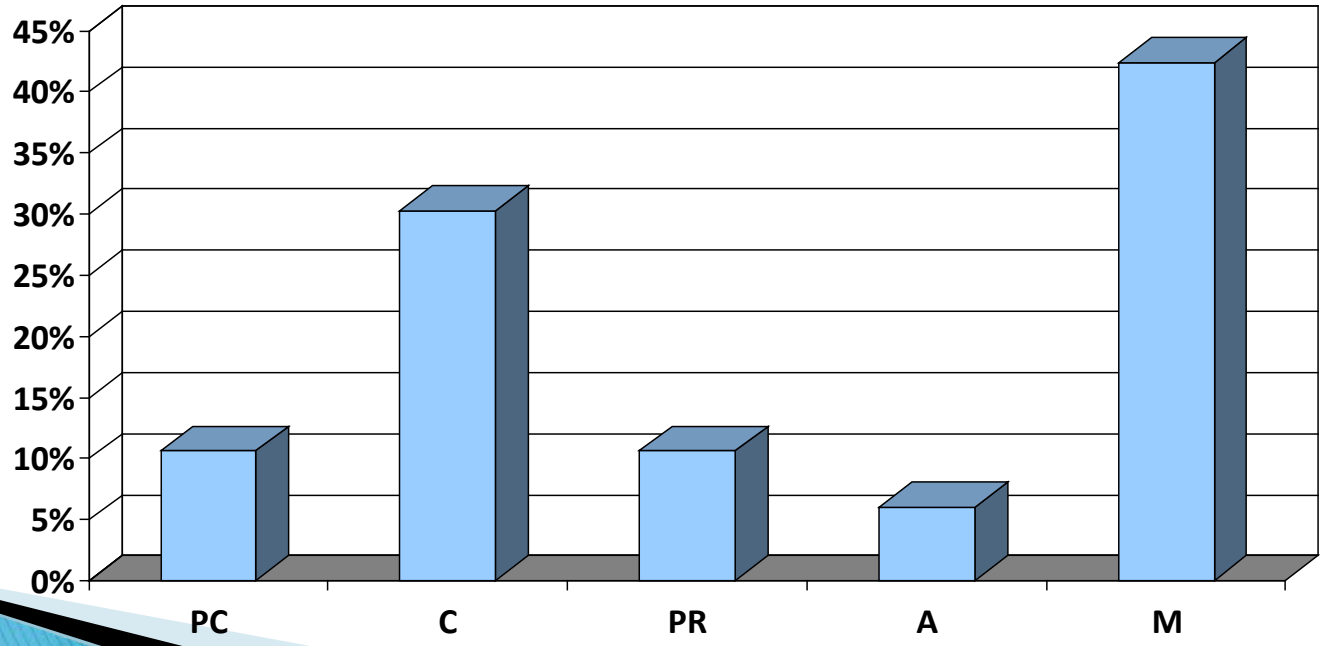
Registered on site	Completed HRI1 (Enrolled)	Full Baseline	30-day F/U	90-day F/U
354	90	76	65	57
% retained from previous time point	25% (screen in)	84%	86%	88%
Overall retention from baseline (enrolled)			86% (72%)	76% (63%)

Assessing Stage of Change – Smoking Cessation

- Have you quit smoking cigarettes?
  - "I was never a cigarette smoker";
  - "No, and I do not intend to quit in the next 6 months" [Pre-contemplation(PC)];
  - "No, but I intend to quit in the next 6 months" [Contemplation(C)];
  - "No, but I intend to quit in the next 30 days" [Preparation(PR)];
  - "Yes, I quit less than 6 months ago" [Action(A)];
  - "Yes, I quit more than 6 months ago, but less than 5 years ago" [Maintenance(M)].
  - "Yes, I quit more than 5 years ago" [Maintenance(M)].

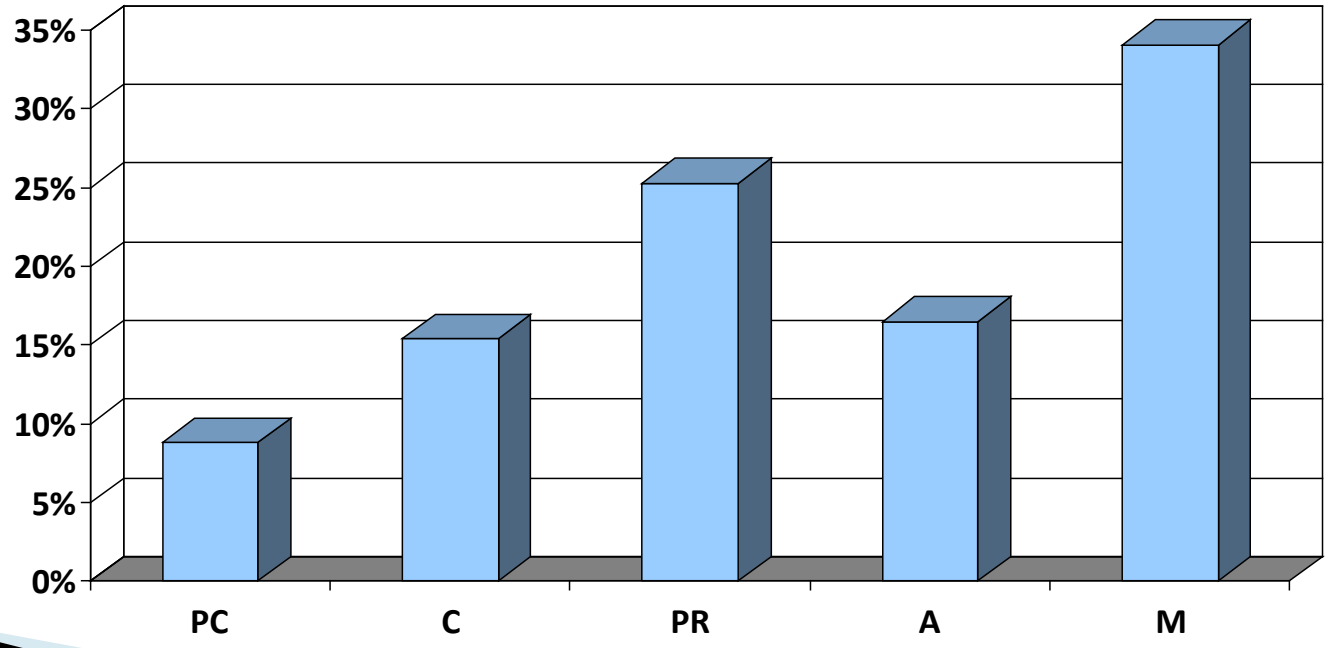
Baseline Stage of Change for Smoking Cessation

- Pre-Action Stages: Pre-contemplation(PC); Contemplation(C); Preparation(PR)
- Action(A); Maintenance(M)
- Very high % in maintenance at baseline



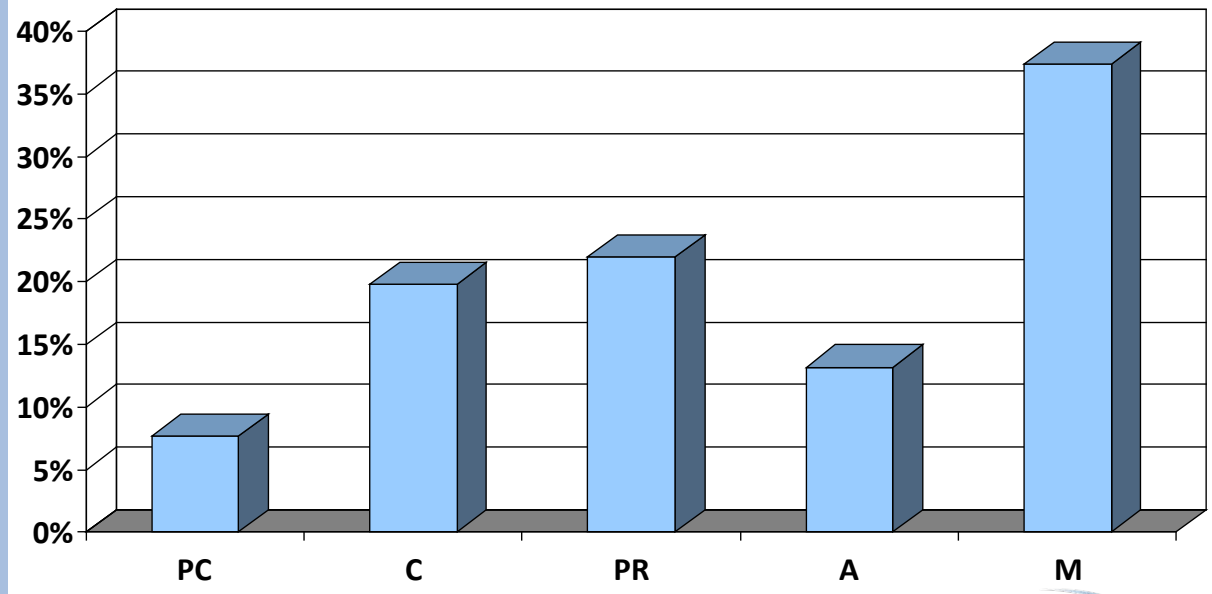
Baseline Stage of Change –Stress Management

- **Stress management** includes regular relaxation, physical activity, talking with others, and/or making time for social activities.

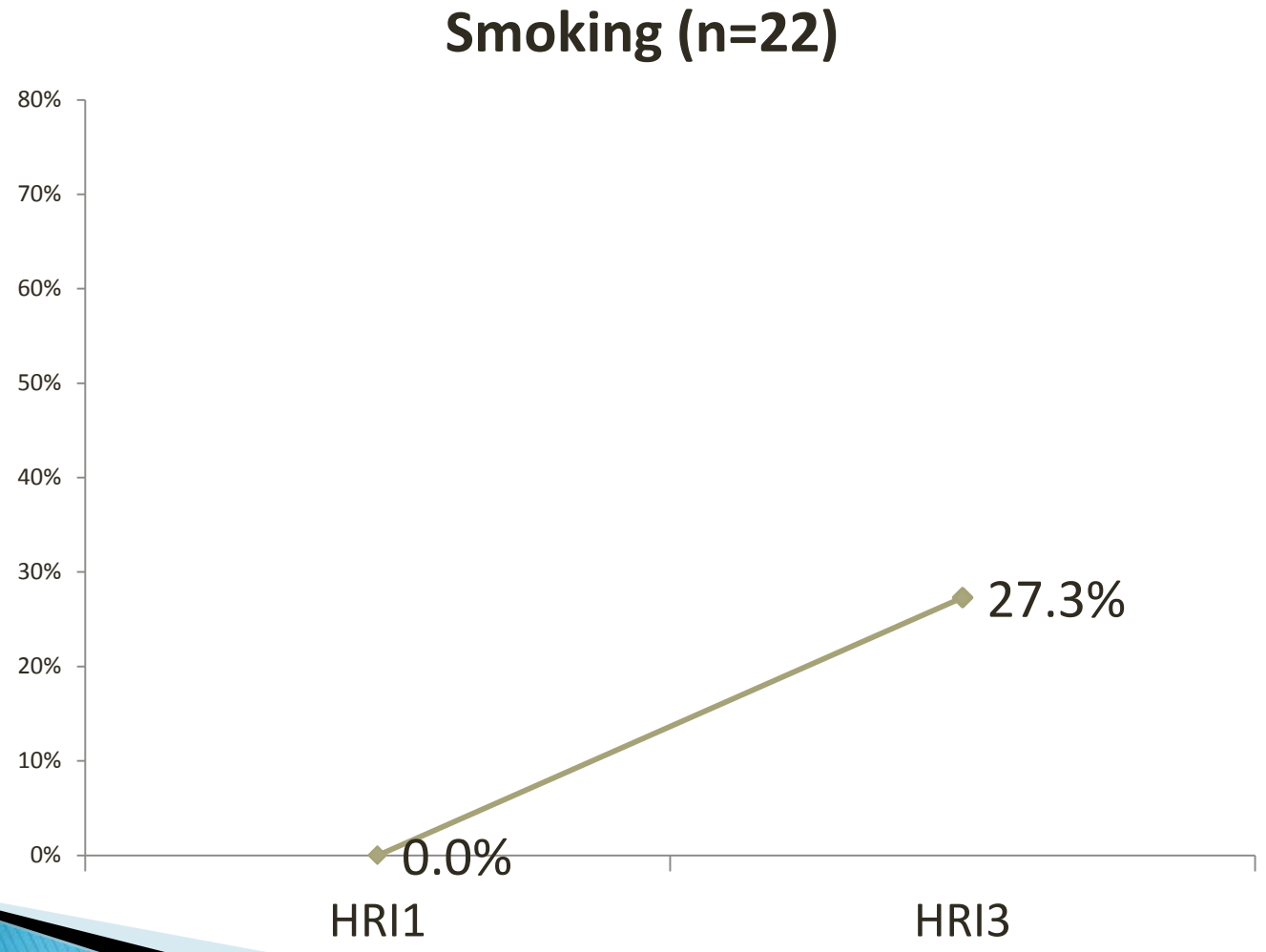


Baseline Stage of Change –Depression Prevention

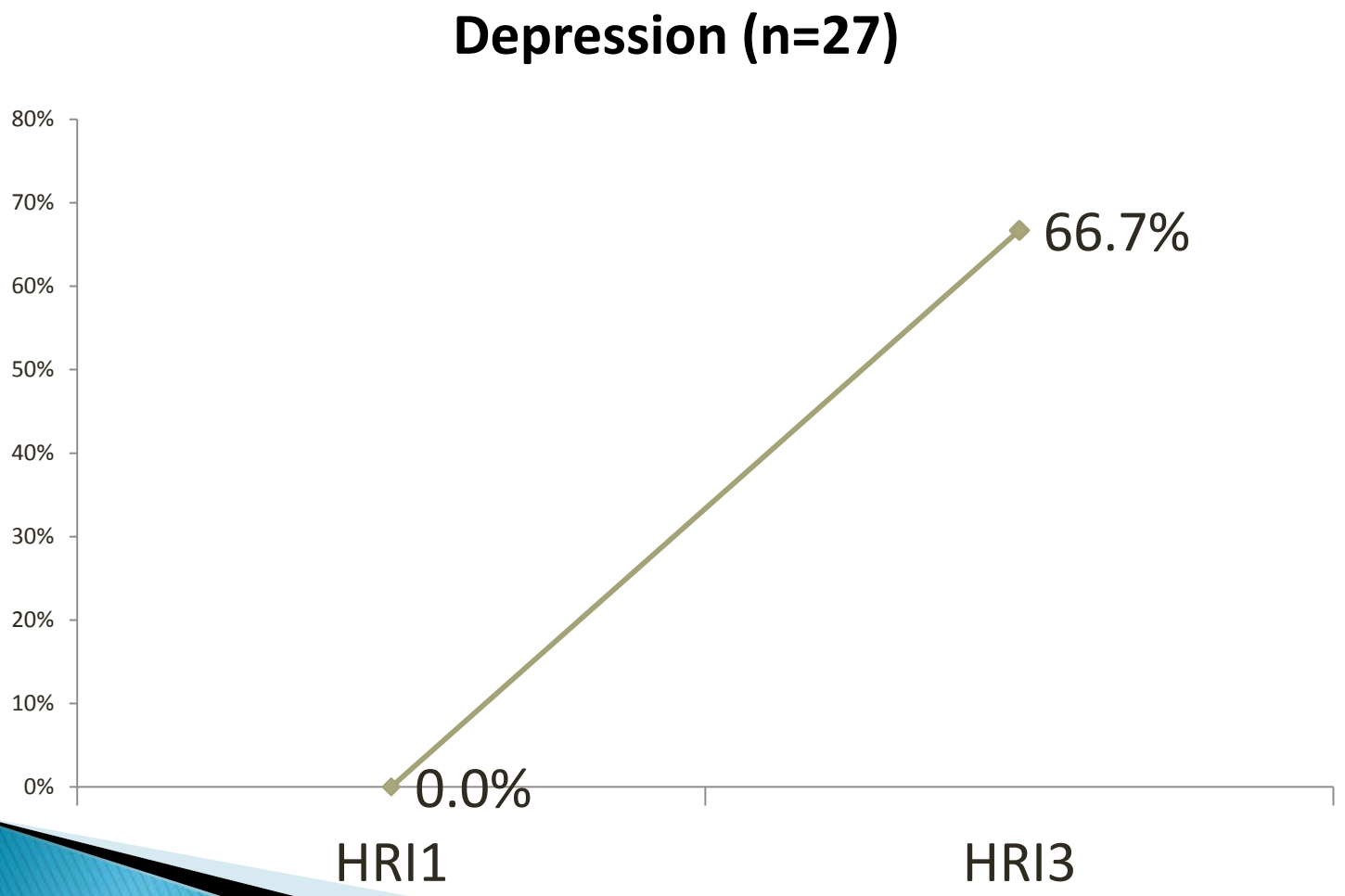
- **Depression prevention** means using effective methods to keep depression from occurring, or if it does occur, to keep it as mild and brief as possible.



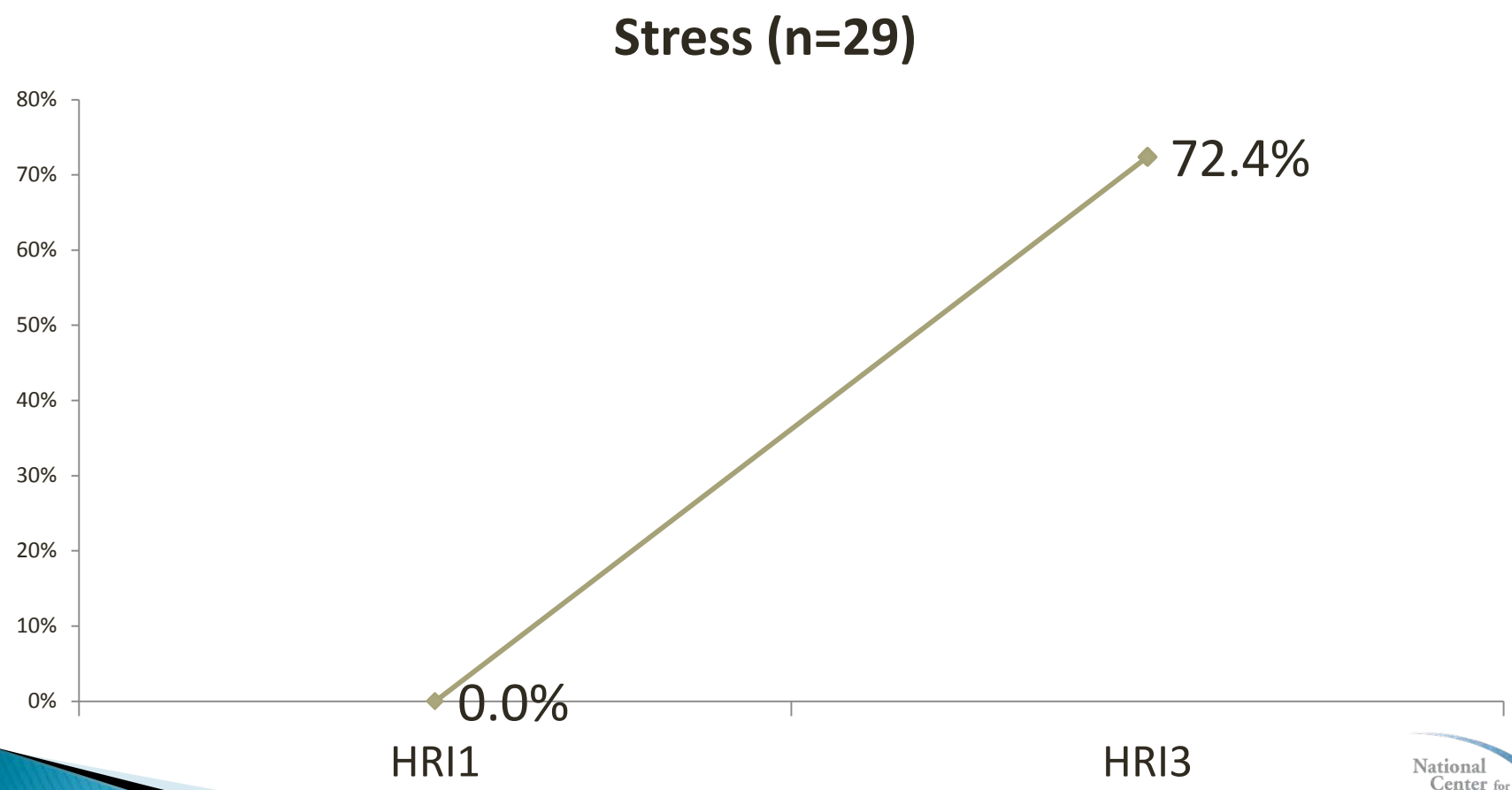
Movement to Action/Maintenance of targeted behaviors



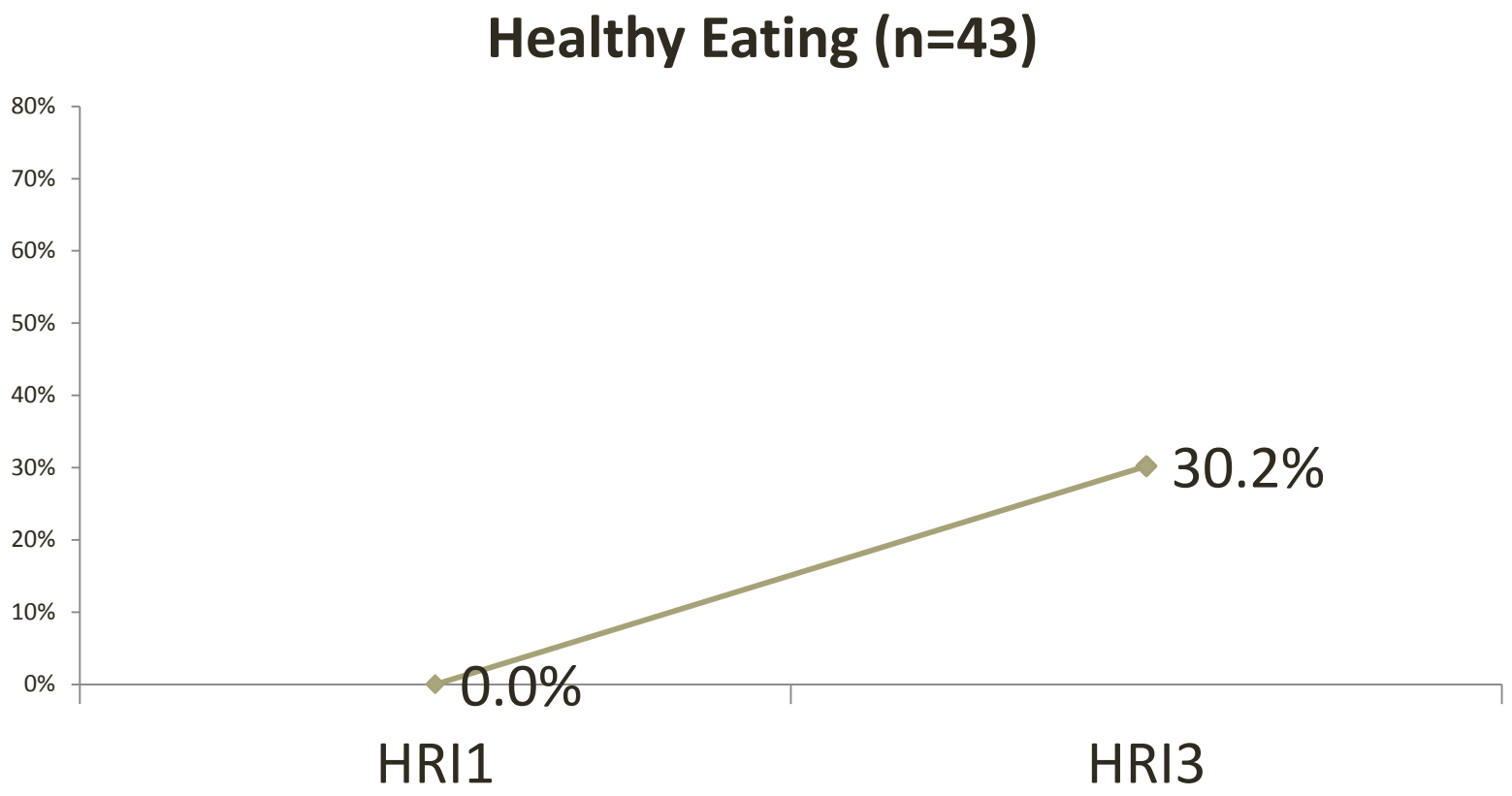
Movement to Action/Maintenance of targeted behaviors



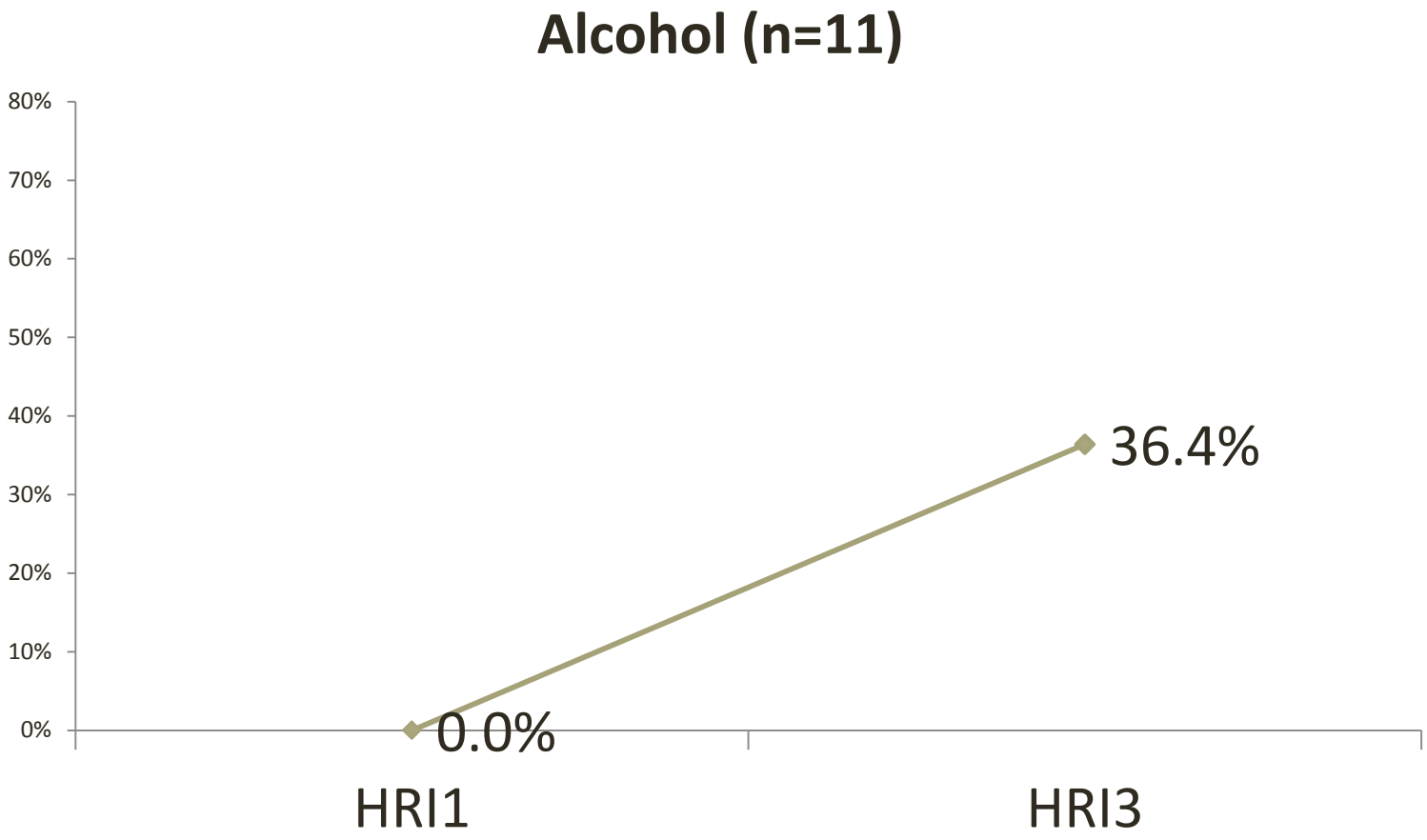
Movement to Action/Maintenance of targeted behaviors



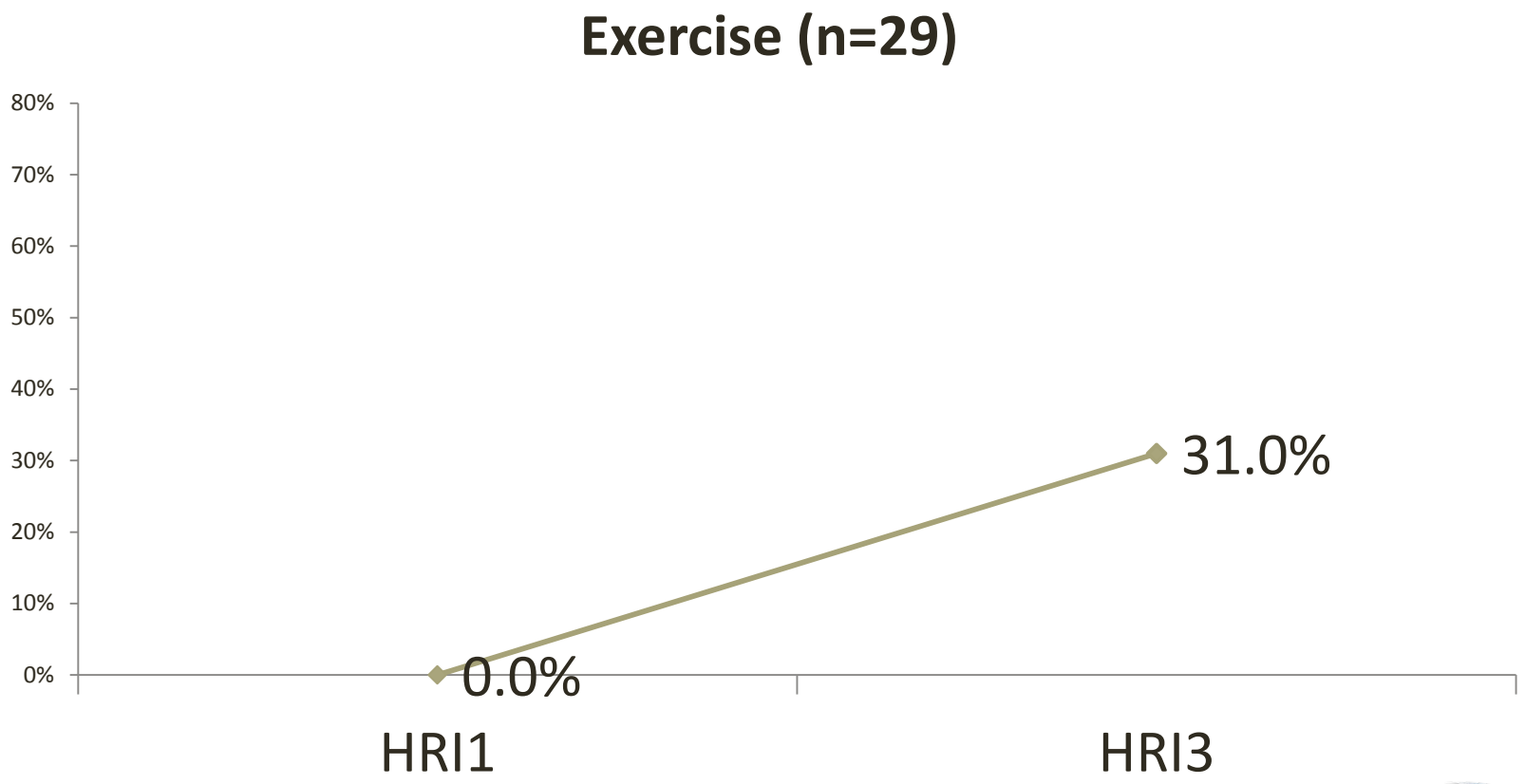
Movement to Action/Maintenance of ancillary behaviors



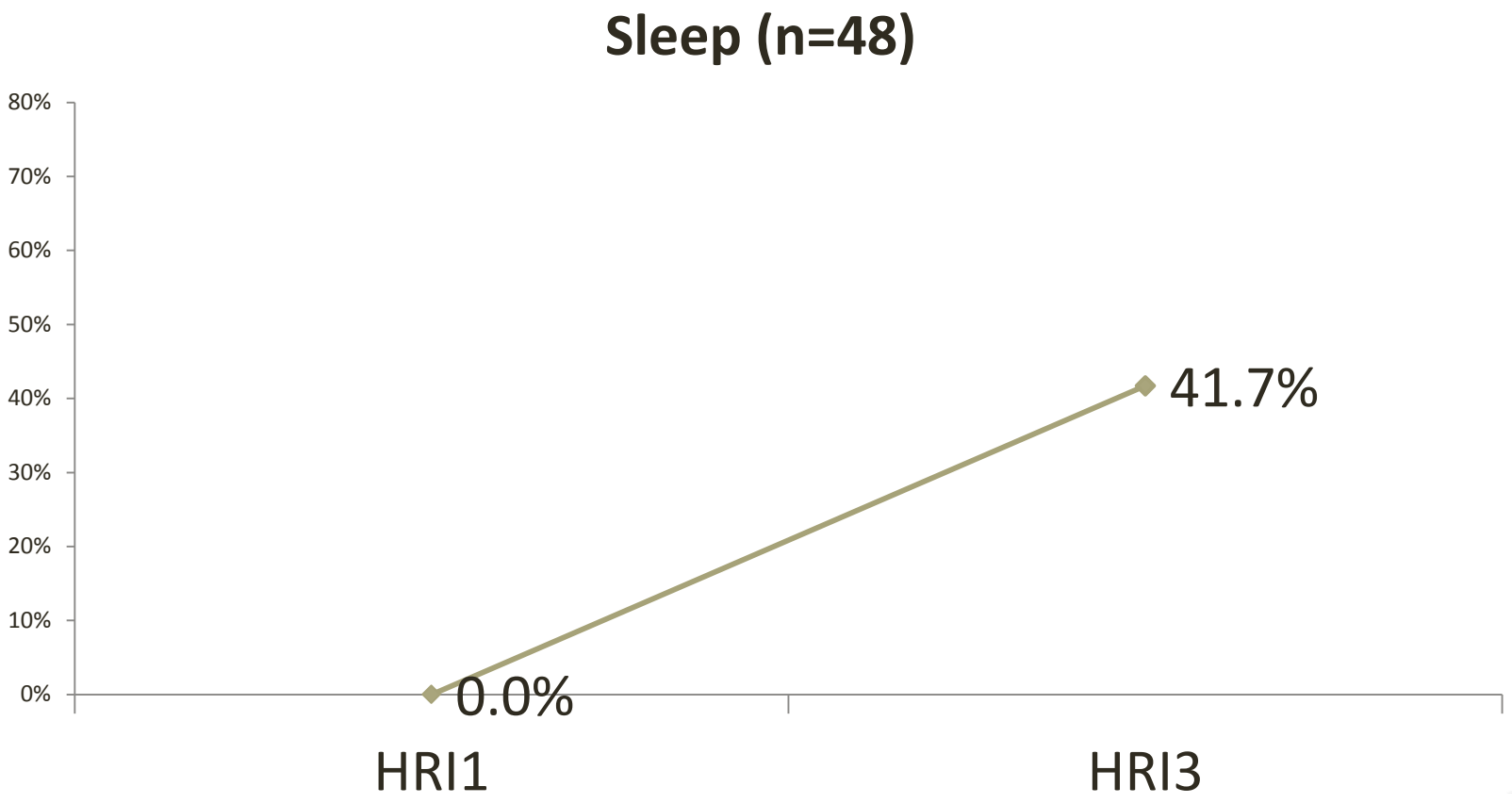
Movement to Action/Maintenance of ancillary behaviors



Movement to Action/Maintenance of ancillary behaviors



Movement to Action/Maintenance of ancillary behaviors



Behavioral Outcomes

Behavior	% Moving from Pre-Action Stages to Action at 3 Months	Statistical Significance Pre-Post
Smoking	27.5%	($\chi 2(1)=23.5$, $p<.001$)
Stress Management	72.4%	$\chi 2(1)=6.2$, $p=.013$)
Depression Prevention	66.7%	($\chi 2(1)=8.8$, $p=.003$)
Exercise	31%	($\chi^2(1)=12.9$, $p<.001$)
Healthy Eating	30.2%	($\chi^2(1)=10.1$, $p=.001$)
Alcohol Use	36.4%	($\chi^2(1)=8.4$, $p=.004$)
Sleep Management	41.7%	($\chi^2(1)=4.0$, $p=.05$)

Clinical Outcomes

Measure	Baseline (*n*=57)	At 3 Months (*n*=57)	% change	Cohen's d	p
PCL-M (Range=30-70)					
Mean (SD)	55.6 (9.5)	48.8 (15.8)	**-12%**	.43	0.001
PSS (Range=7-36)					
Mean (SD)	24.3 (5.9)	20.5 (7.3)	**-19%**	.46	0.001
PHQ-8 (Range=3-19)					
Mean (SD)	12.0 (4.1)	9.9 (5.8)	**-17%**	.36	0.015
QOLS (Range=35-98)					
Mean (SD)	62.4 (12.6)	69.5 (16.4)	**+11%**	.49	0.001

PCL >48: n=44 at baseline, n=32 at 3-month assessment

Conclusions and Future Research

- CTI appears to be feasible as a cost effective self-help intervention for veterans at risk for PTSD to:
  - Move them into the action stage of seeking treatment
  - Reduce symptoms
  - Improve lifestyle
- Next steps:
  - Confirm results with a randomized clinical trial
  - Lengthen follow-ups to measure sustainability
  - Adapt and test additional behavior programs with veteran population (alcohol misuse, pain, sleep, etc)

QUESTIONS?