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TITLE: Cell Phone-Based Expert Systems for Smoking Cessation

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14. ABSTRACT This project aims to enhance the emotional and physical well-being of veterans through the reduction of smoking by utilizing a web-based, computerized tailored intervention (CTI) with feedback messages delivered via cell phone. CTIs have shown increasing promise as useful behavior change programs for improved health behaviors. A variety of modalities are to deliver personalized CTI information and feedback; however, the ubiquity and sophistication of today's wireless mobile technologies represent new modes of delivery for empirically based smoking cessation and other behavioral health interventions. The CTI is based on the empirically-supported Transtheoretical Model of Behavior Change (TTM). A web-based CTI modified for a veteran population will be used to pilot test the effectiveness of the CTI alone and CTI plus individualized text messaging enhancements. The pilot study is a randomized controlled trial to assess the cell phone's feasibility as an intervention modality for changing smoking behaviors. This will be the first study to adapt a smoking cessation Internet based CTI to provide personalized feedback on a cell phone to reduce smoking behaviors in military veterans.					
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INTRODUCTION

Both the Department of Defense (DoD) and the Department of Veterans Affairs (VA) have made smoking cessation a priority for health promotion and disease prevention. The U.S. military includes 1.4 million active duty personnel stationed worldwide with a smoking prevalence higher (33.8%) than the civilian rate (23.6%) (Smith, Blackman & Malone, 2007). Many veterans began smoking while in the military, thus it is not surprising that like the military, the smoking rate among veterans exceeds that of the general population in the U.S. It contributes to the high morbidity and mortality rates among veterans (U.S. Department of Veterans Affairs, 2008), as well as to the nearly \$1 billion annually of lost productivity in the military (Conway, 1998).

This project aims to enhance the emotional and physical well-being of veterans, particularly Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF) veterans, through the reduction of smoking by utilizing a web-based, computerized tailored intervention (CTI) with additional individualized feedback delivered via cell phone. CTIs have shown increasing promise as useful behavior change programs for improved health behaviors (Neville, O'Hara, & Milat, 2009). A variety of modalities are used to deliver personalized CTI information and feedback such as printed materials (letters, reports, brochures), interactive applications (websites, email, CDs), and, more recently, portable devices (mobile phones, handheld computers). The ubiquity and sophistication of today's wireless mobile technologies represent new modes of delivery for empirically based smoking cessation and other behavioral health interventions. The CTI is based on the empirically-supported Transtheoretical Model of Behavior Change (TTM) (Prochaska & Velicer, 1997; Velicer, Prochaska, & Redding, 2006). A web-based CTI modified for a veteran population will be used to pilot test the effectiveness of smoking cessation system with veterans, as well as the text messaging enhancements to treatment. The pilot study design is two-group randomized controlled trial with a baseline assessment and one- and three-month follow-ups. This will be the first study to adapt a smoking cessation Internet-based CTI to provide personalized feedback on a cell phone to reduce smoking behaviors in military veterans.

Hypotheses and specific aims are as follows:

Hypothesis 1: The structure and content of the cell phone-based CTI for smoking cessation will be appropriate and relevant to veterans.

Specific Aim 1: Modify the existing web-based smoking cessation CTI feedback narratives for delivery on a cell phone using text messaging (160 characters) feedback.

Specific Aim 2: Conceptualize the cell phone-based CTI feedback approach, content, and design based on input from a diverse sample of military veterans.

Specific Aim 3: Conduct usability interviews with veterans to ensure that the target population can navigate through the cell phone-based CTI and understand the intervention content.

Specific Aim 4: Demonstrate participant acceptance and satisfaction with cell phone-based CTI

Hypothesis 2: Cell phone-based CTI will facilitate greater smoking cessation behavior change than assessment only on a web-based CTI.

Specific Aim 1: Conduct a 3-month randomized control pilot study to assess effectiveness of the cell phone-based CTI to facilitate greater progress through the stages of change, increase self-efficacy, improve decisional balance to reduce smoking behaviors, and increase use of processes of change compared to CTI assessment and feedback report only (control group) on a web-based CTI.

Specific Aim 2: Demonstrate reduced urge to smoke and greater abstinence from smoking between the cell phone-based CTI compared to the assessment and feedback report only on a web-based CTI.

BODY

During this second year of the project, all team members were hired, study Phases 1 and 2 were completed, and Phase 3 was commenced. A summary timeline is presented below.

1. September 2010: Viil Lid was hired as Research Project Manager.
2. October 2010: Subaward contract between Pro-Change and PHREI was signed.
3. October 2010: Contract for professional services to be provided by Dr. James Prochaska was completed.
4. October 21st – 22nd 2010: Kick-off Meeting for the study team was held at VAPIHCS. The meeting was attended by all local team members, as well as Dr. Kerry Evers and Dr. Jim Prochaska from Pro-Change in Rhode Island (see attachment to Quarterly Report 5).
5. November 2010: The project IT Coordinator position was eliminated as all IT needs for the project are handled by the Pro-Change subaward.
6. November 2010: Stacy Daly was hired as a Research Assistant.
7. November 2010: All team members completed VAPIHCS IRB Informed Consent training.
8. November 2010: Budget Reallocation was approved by the COR and CS.
9. December 2010: An internet domain with security certificates (www.txtresearch.org) was acquired to host the participant online interface to the web-based CTI system.
10. December 2010: A smart phone with telephone, text messaging, and internet subscription was purchased in order to use for focus group recording, cell phone-based system testing, and participant recruitment.
11. January 2011: A Focus Group with Veterans was conducted to gather information and feedback to inform adaptation and tailoring of the web-based CTI and integrated cell phone text messages.

12. January 2011: Study Phase 1 started. The web-based CTI was adapted to support text messaging, the system interface and language was tailored to Veterans, and the web-based feedback messages were modified to cell phone text messages.
13. February 2011: Several amendments to the protocol and other project documents were approved at a full IRB board meeting. These amendments allow us to move the informed consenting process online and automate the sending of cell phone text messages to participants (see attachments).

The process of developing and approving these amendments started in October 2010 and involved careful studying of VA policies and several meetings and coordination with VAPIHCS Privacy Officer, VAPIHCS Information Security Officer, VAPIHCS IRB Coordinator, and the Pro-Change technology design and development team to discuss options and solutions.

As far as we know the VA IRB approval of online informed consent is unprecedented in the nationwide VA system, and is a noteworthy accomplishment by our team. Through our effort we believe we improved human subject protection, data validity, and research practicability and effectively.

14. February 2011: A CRADA between Pro-Change and PHREI was signed.
15. March 2011: Study Phase 2 started. Beta and Usability Testing of the modified and tailored web- and cell phone-based CTI.
16. March/April 2011: Minor amendments to the protocol and other project documents were approved by the IRB (e.g., recruitment advertisements, etc. See Appendix).
17. April 2011: Study Phase 3 launched. The web- and cell phone-based CTI was launched on April 27th 2011, and from through August 2011 various initiatives were commenced in order to recruit study participants.
18. August 2011: Application for a six month No Cost Extension for the project was approved. The POP end date is March 31, 2012.
19. August 18th 2011: The PI and Project Manager were invited to present the project at a Video Conference for the National Center for PTSD (see Appendix).
20. August 2011: The project team was awarded an endowment gift from the Pacific Health Research and Education Institute to add a supplement study recruiting additional women participants to offset the gender imbalance in the Veteran population so that we can do a gender comparison with statistical power (see Appendix).

Progress this Period (See Gantt chart in Appendix):

Task 1.0 IRB Protocols Submission and Approval (100% complete)

1.1 Local IRB review and approval (100% complete)

1.2 Second-tier level review and approval (USAMRMC, HRPO) (100% complete)

Task 2.0 Adaptation of CTI Smoking Modules Based on Feedback from Focus Groups (100% complete)

2.1 Analyze data and identify content modifications (100% complete)

2.2 Modify the CTI Smoking Module based on analysis of feedback from Focus Groups (100% complete)

Task 3.0 Modify Web-based Feedback Message to Text Messages (100% complete)

3.1 Modify language, tone, and content of feedback narratives for smoking module (100% complete)

Task 4.0 Conduct Beta and Usability Testing on Cell Phone (100% complete)

4.1 Conduct beta testing of system (100% complete)

4.2 Conduct usability interviews with Veterans (100% complete)

Task 5.0 Conduct Pilot Study (70% complete)

5.1 Recruit participants and conduct baseline assessment (100% complete)

- Implemented recruitment plan
- Purchased additional Amazon.com Gift Cards for incentives and reimbursements for the increased number of enrolled study participants.
- Monitored pilot study participant online screening and informed consenting.
- Enrolled 313 study participants.
- Monitored online data collection.

5.2 Monitor participation at 1-month assessment point (80% complete)

- 156 study participants have completed the two first assessment points (more expected as more participants reach the 1-month milestone).
- Monitored online data collection (ongoing).
- Sent automated reminder messages to participants (ongoing).

5.3 Monitor 3-month assessment points (10% complete)

- 14 study participants have completed all three assessment points (more expected as more participants reach the 3-month milestone).
- Monitored online data collection (ongoing).
- Sent automated reminder messages to participants (ongoing).

Task 6.0 Analyze data and interpret results (2% complete)

6.1 Demographic statistics for enrolled study (see attachment to Quarterly Report 8).

Task 7.0 Submit Final Report (0% complete)

KEY RESEARCH ACCOMPLISHMENTS

1. Study team members hired.
2. Subaward and consultant contracts signed.
3. Study team kick off meeting conducted.
4. Approval of online participant informed consent process, unprecedented in the VA system.
5. Study Phase 1 successfully completed: adapting the web-based CTI to support text messaging, tailor the system interface and language to Veterans, and modify the web-based feedback messages to cell phone text messages.
6. Study Phase 2 successfully completed: Beta and Usability Testing of the modified and tailored web- and cell phone-based CTI.
7. Study Phase 3 successfully commenced: conducting pilot study.
 - a. Recruited and enrolled 313 study participants.
 - b. Achieving higher participant retention rates than what is normal for similar web-based CTIs.
8. Awarded 6 months No Cost Extension to compensate for the 11 months the project was delayed before the current study team was involved.
9. Study presented on invitation to the National Center for PTSD.
10. Endowment gift awarded from the Pacific Health Research and Education Institute to add a supplement study, recruiting additional female study participants.

REPORTABLE OUTCOMES

1. All quarterly reports have been submitted.
2. Research Assistant has been hired.
3. The study's public name is T.X.T, "Tobacco eXpertsystems Trial".
4. 313 participants have been enrolled in the study so far.

CONCLUSION

Significant advances in the study timeline have been made over the past year. The original 24-month timeline was reduced to 18 months, and the project work is currently well on schedule. Personnel changes compounded the delays caused by IRB and VA requirements during the first year of the project, but clear progress is evident in year two. Two of the three phases have been successfully completed. The PI change and efforts to protect the anonymity of veteran participants precipitated further amendments to the protocol and research documents. A new research project manager commenced work in September 2010 and in October 2010 the subaward agreement with Pro-Change Behavior Systems, Inc., and a consulting contract were executed. Kick-off meetings with PHREI and Pro-Change team members were held at VAPIHCS on October 21-22, 2010. The VA changed a previous decision and later required a CRADA to be drafted for one subaward, and this CRADA was finalized in February 2011.

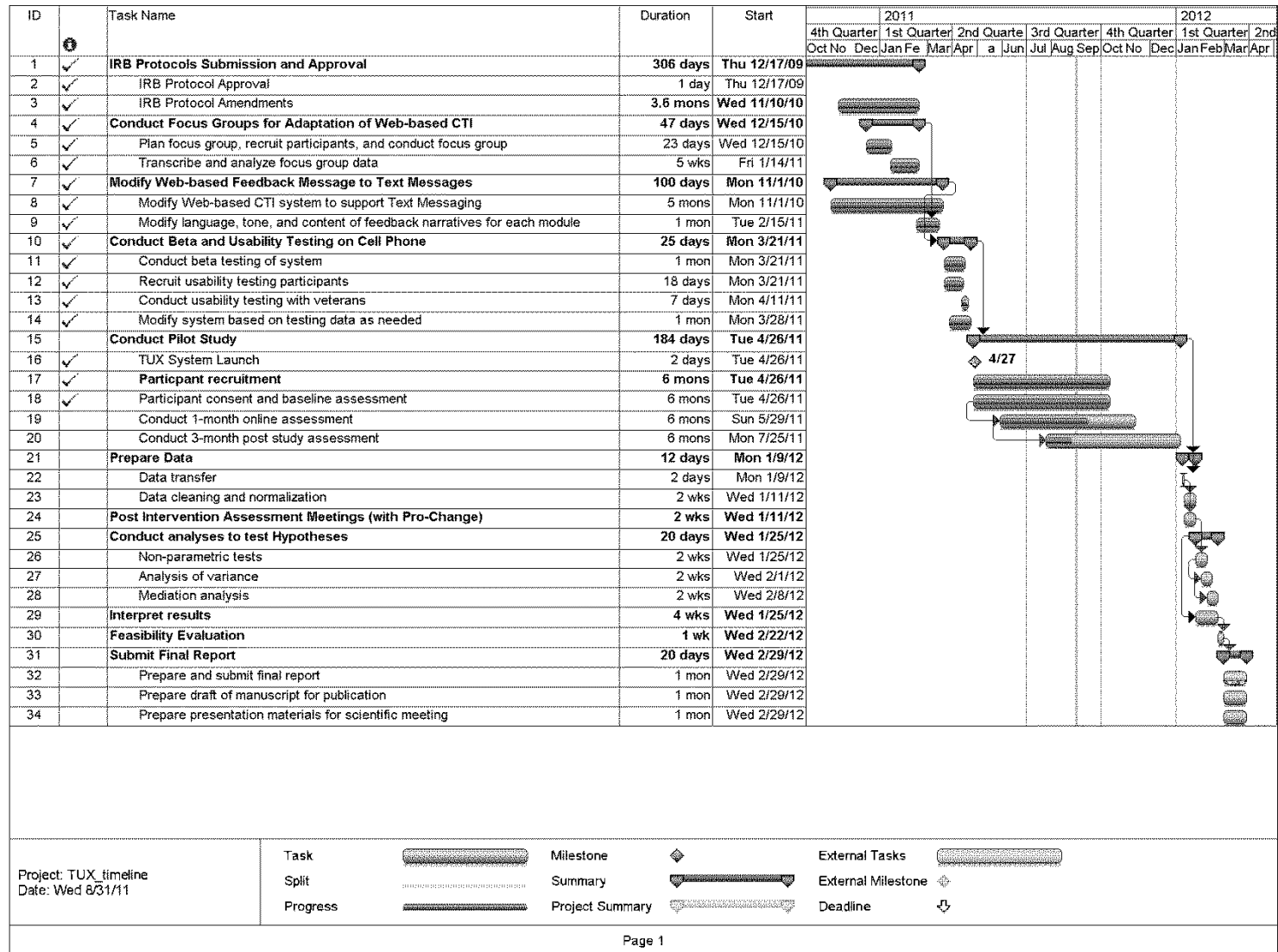
The Phase 1 web-based CTI system adaption and cell phone text message integration started in January 2011 and was completed in March 2011. In February 2011 changes to the protocol to allow for online consenting, screening, and enrollment in the study were approved by the VA IRB. The approved changes also included waivers of HIPAA authorization and documentation of informed consent. The Phase 2 beta-testing and usability testing and development were completed in March-April 2011. The finalized CTI system was launched for the Phase 3 pilot study on April 27th 2011. By the end of year two 313 of the approved 324 participants are enrolled in the study.

A 6-month no-cost extension was awarded August 2011 with a new POP end date of March 31st 2012.

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APPENDIX (Revised Timeline)



SMOKING VETERANS

WE NEED YOUR HELP TESTING A COMPUTER & CELL PHONE PROGRAM



Receive up to \$75 in online gift cards for your help testing a computer and cell phone program for health improvements in Veterans

ELIGIBILITY:

- ✓ male or female Veteran (preferably OIF/OEF service)
- ✓ current cigarette smoker
- ✓ over 18 years old
- ✓ comfortable using a computer & the internet
- ✓ have a cell phone with texting capabilities

START NOW

www.txtresearch.org

If you have any questions about this research study please contact the research team at (808) 781-4330.

Principal Investigator: Patricia J. Jordan, Ph.D., Pacific Health Research & Education Institute

Research study sponsored by the Department of the Army (Award Number W81XWH-09-2-0138).

t.x.t
Tobacco.eXpertsystems.Trial

APPROVED BY VAPIHCS IRB

APR 22 2011

Veteran Smoking Cessation



Help us test an online smoking cessation program designed for Veterans and get up to \$75 in online gift cards.

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JUL 05 2011

OEF/OIF Veteran? Smoker?



Help us test an online smoking cessation program designed for Veterans and get up to \$75 in online gift cards.

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Iraq/Afghanistan Veteran?



Help us test an online smoking cessation program designed for Veterans and get up to \$75 in online gift cards.

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Help us test an online smoking cessation program designed for Veterans and get up to \$75 in online gift cards.

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JUL 05 2011

APPENDIX A

"A Web-based Methodology for Promoting Health Behavior Change in Veterans with PTSD-related Comorbidities."

National Center for PTSD
Pacific Islands Division, VAPIHCS
and the
Pacific Health Research and Education Institute
(W81XWH-09-2-0106 / W81XWH-09-2-0138)



Background

- ▶ Prevalence of mental health disorders in OEF/OIF Veterans continues to rise.
- ▶ Recent statistics on this population suggest that prevalence rates of PTSD and depression are between 23% and 31%.
- ▶ Co-occurring mental and behavioral health disorders associated with the OEF/OIF service.
- ▶ Two TATRC-funded projects address negative coping behaviors using computerized, tailored interventions (CTIs).
- ▶ Combines sophisticated technologies and evidence-based approaches to behavior change.



Corporate and Academic Partners

- ▶ **Pro-Change Behavior Systems, Inc.**
 - Founded by James O. Prochaska, Ph.D.
 - Focused on Transtheoretical Model-based interventions
- ▶ **University of Hawai'i at Mānoa**
 - Department of Public Health Sciences & Epidemiology
 - TTM expertise at public health level



Transtheoretical Model of Behavior Change

- ▶ Framework incorporating 15 disparate psychological constructs.
- ▶ Can describe, promote, predict, maintain volitional behavior change.
- ▶ **Stage of Change:**
 - Temporal construct across 5 stages of change
 - precontemplation, contemplation, preparation, action, maintenance
- ▶ **Decisional Balance** (pros and cons)
- ▶ **Situational Self-efficacy** (confidence or temptations)
- ▶ **Processes of Change** (5 experiential; 5 behavioral)



Project Aims

- ▶ Combine the advantages of a clinic approach (individualized interactions) with the goals of a public health approach (targeting large population segments).
- 1. Combine multiple behavior approach to address OEF/OIF Veterans at risk for PTSD, particularly those ambivalent to change.
- 2. Utilize text messaging to engage Veterans who may be resistant to quit smoking.



Barriers to Care

- ▶ Clinicians acknowledge that thousands of OEF/OIF veterans are reluctant to seek help.
- ▶ Concern about stigma is disproportionately greatest among those most in need.
- ▶ Ambivalence to treatment may result from patients' perceptions that their unhealthy coping strategies are actually functional approaches to dealing with their symptoms.
- ▶ Mental health providers are not sufficiently accessible to all service members (e.g., rural areas).



APPENDIX A

Computerized, Tailored Interventions (CTIs)

- ▶ Adaptive interventions that offer multiple contacts in which messages are dynamically tailored are more effective than traditional one-size-fits all interventions.
- ▶ Interact directly with users.
- ▶ Can be easily adapted as empirical findings are updated.
- ▶ Yield equally effective treatment outcomes compared to self-help interventions delivered via other methods.



Advantages of CTI's

- ▶ Reach a large population at relatively low cost and can be accessed wherever computers are available.
- ▶ They can be accessed privately from individuals' homes and completed at users' own pace.
- ▶ Tailored to the needs of a diverse group of participants.
- ▶ Readily collect precise user data (e.g., reduces time burden on users).
- ▶ Individuals with substance use problems tend to report more information to computers than to human clinicians.



TTM-Based CTIs

- ▶ Deliver anonymous and confidential access to behavioral health modules, based on readiness to change framework.
- ▶ Effective with multiple target behaviors without reducing the efficacy of treating just one behavior at a time.
- ▶ Builds on the concept of co-action.
- ▶ Can produce healthier coping strategies.



Target Behaviors

- ▶ **Smoking.**
 - A frequent co-morbid condition with PTSD
 - Has an indirect impact on cardiovascular health
 - Veterans with PTSD who smoke report higher levels of PTSD symptoms, trait anxiety, and depression
- ▶ **Depression.**
 - OEF/OIF postwar rates of depression range from 7.1% to 7.9%
 - Symptoms of PTSD and depression can have a delayed onset
- ▶ **Stress.**
 - Interventions needed to reduce the physiological arousal, anxiety, depression, and other comorbidities that accompany PTSD



The Two Studies

- ▶ The **STR²IVE** project adapts a multi-behavioral computerized tailored intervention (CTI) delivered via the Internet to Veterans, and assesses the program usability and feasibility with Veterans at risk for PTSD.
- ▶ The **t.x.t.** project assesses the effectiveness of a smoking cessation CTI with random-assignment to receive cell phone text messages. The text messages are tailored to the participant's stage of change.



Methods

- ▶ **Development**
 - **Phase 1:** Focus groups of Veterans assess programs
 - **Phase 2:** Programs revised and adapted into integrated multi-behavioral program for Veterans
 - **Phase 3:** Beta testing and usability interviews to inform further adaptations and improvements
- ▶ **Feasibility Study (n=50)**
 - Assess feasibility of the program as a web-based intervention for Veterans with PTSD symptoms.
 - Baseline, 1-, and 3-month assessments



APPENDIX A

Recruitment



- ▶ **Development Phases**
 - Flyers and posters at VA clinics and centers.
 - Email to student veteran organizations
 - Word of mouth
- ▶ **Feasibility Study**
 - Targeted mailing to OEF/OIF Veterans
 - VA providers distribute invitations to patients and clients
 - Veteran organizations distribute flyers to members
 - Interested vets visit study URL to anonymously be screened and enroll in the study.



Online Consenting and Screening



Lessons Learned



- ▶ Discuss issues with IRB, Privacy Officer, and Information Security Officer to better understand their concerns with new methods of consenting and screening.
- ▶ Anticipate requirements of automating parts of the study and how to meet IRB rules during the proposal phase.
- ▶ Implement ways to verify and remind participants automatically without collecting identifiers (e.g., codes, separate reminder systems, etc.).
- ▶ Monitor the site and process daily to make sure it is working as planned and address any problems immediately.



Methods



- ▶ **Development**
 - Used focus group data from STR²IVE study to adapt smoking program.
 - **Phase 1:** CTI program adapted for Veterans and enhanced with tailored cell phone text messaging feedback.
 - **Phase 2:** Beta testing and usability testing with Veterans.
- ▶ **Phase 3: Pilot study (n=324)**
 - Randomized control trial where Tx group receives tailored cell phone text message feedback.
 - Baseline, 1-, and 3-month assessments.



Recruitment



- ▶ Study participant recruitment through Veterans' organizations, websites, newsletters, and social media.
- ▶ The potential reach of electronic mailing lists and websites is not the same as actual reach.
- ▶ Participant incentives
 - electronic gift cards



Response Data

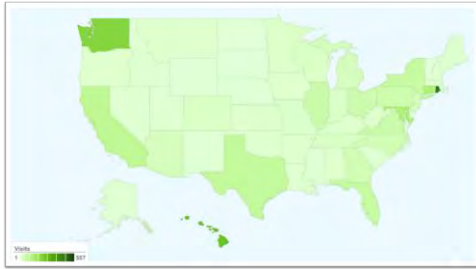


- ▶ Over the past 3 months:
 - 1555 unique visitors to study website
 - 602 registered interested individuals
 - 291 enrolled study participants (goal $n=324$)



APPENDIX A

Reach



Lessons Learned



- ▶ VA IRB research policies are designed for clinical research on VA patients, not non-consultation research on Veterans.
VA information security requirements are not always compatible with current information and communication technologies that are part of Veterans' lives.
- ▶ Anonymous participation opens up for potential fraud.



IRB Considerations

- ▶ Each phase required different recruiting, consenting, and screening processes.
- ▶ Preferred not to collect personal information, which could increase participant risk and reduce privacy.
- ▶ Online consenting, screening and assessments ensured anonymity.
- ▶ Development phases were done in person.
- ▶ Received waiver of documentation of informed consent, waiver of HIPAA authorization, and waiver of Master List.



Recommendations

- ▶ Discuss issues with IRB, Privacy Officer, and Information Security Officer to better understand their concerns with new methods of consenting and screening.
- ▶ Implement automated security to reduce multiple accounts being created by single users.
- ▶ When using an external technology provider make sure that technology decisions are properly informed by the research design.



Future Work

- ▶ 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 non-veterans with variety of negative health risks.
- ▶ Enhance the system by developing additional modules
 - sleep, pain management, alcohol use, anger management
- ▶ Collaborations with other VA Health Centers or National Center for PTSD.



STR²IVE Research Team

- ▶ 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)
- ▶ Michelle Kawasaki, M.A. (Research Assistant)
- ▶ Kerry E. Evers, Ph.D. (Pro-Change Behavior Systems)
- ▶ Claudio R. Nigg, Ph.D. (University of Hawai'i)



APPENDIX A

t.x.t. Research Team

- ▶ Patricia J. Jordan, Ph.D. (Principal Investigator)
- ▶ Viil Lid, M.S. (Project Manager)
- ▶ James L. Spira, Ph.D. (co-Investigator)
- ▶ Julia Whealin, Ph.D. (co-Investigator)
- ▶ Stacy Daly, M.A. (Research Assistant)
- ▶ Kerry E. Evers, Ph.D. (Pro-Change Behavior Systems)



Questions?

**An Examination of Gender Differences in Veterans Who Smoke:
A Pilot Study Using a Computerized, Tailored Intervention**

Patricia J. Jordan, Ph.D. (Principal Investigator)

Viil, Lid, M.S. (Co-investigator)

BACKGROUND

Recent studies suggest that the prevalence of smoking among active duty military women is higher than that of active duty military men or civilians of either gender¹. It is a particular problem for women using the Veterans Health Administration (VA), where the prevalence of smoking among women is 30%². Ironically, published literature in the area of Veterans health includes nothing substantive on smoking cessation or treatment for women Veterans³. A 2006 review of published literature found that female Veterans represented only 7% of the all study populations included in smoking cessation studies³. To date, most research on VA women's health is descriptive in nature and has concerned PTSD, sexual harassment and assault, the utilization and organization of care, and various psychiatric conditions³.

Despite substantial progress in observational research in the past several years, interventional studies that seek to address women veteran's health care needs are lacking. A recent systematic review of the literature found that fewer than 3% of women's health studies conducted from 2004 to 2008 were clinical trial^{3,4}.

Of added importance are findings that female Veterans may receive less effective treatment recommendations than men² and that female Veterans are less satisfied and have lower perceptions of VA facilities and staff³. These observations may increase barriers or female Veterans to seek mental health or behavioral health treatment from the VA. In fact, Batuman and colleagues³ found that younger women Veterans are less likely than young male Veterans to use mental health services, a pattern that also held for those with substance abuse or mood/anxiety disorders.

OBJECTIVES

This research project proposes to utilize a parent study, currently funded by USAMRMC, as a basis for collecting data from an additional sample of female veterans who smoke ($n=200$).

In partnership with Pro-Change Behavior Systems, our research team is currently conducting a randomized pilot study that examines the effectiveness of a CTI with a mobile health enhancement. The Tobacco Expert System Trial (t.x.t.) utilizes a version of Pro-Change's CTI for smoking cessation, which we have adapted for Veterans, and adds regular text messaging to those in the treatment arm to examine the benefits of mobile health enhancements in interventions for Veterans. Veterans ($n=324$) are being recruited through Facebook communities and other online veterans' organizations for the t.x.t. study.

By oversampling female Veterans, we can include gender comparisons as part of our overall analysis, and include the following questions:

1. Do women veterans progress through the stages of change at different rates than men?
2. Do women veterans perceive their self-efficacy greater or less than men at each stage of change?
3. Are women veterans more likely to change other negative health behaviors as a result of quitting smoking (i.e., co-action hypothesis)?
4. Does gender moderate engagement with the CTI system (e.g., user statistics, time spent, system evaluation scores)?

METHODS

The proposed supplemental study will recruit approximately 200 women veterans, in addition to those already in the parent study. Currently women represent approximately 14% of the Veteran population, which makes it difficult for researchers to effectively examine gender differences in randomized trials. By oversampling women, we can include gender comparisons in our analysis. This would represent the first time that this type of study has been done.

DATA ANALYSIS

In addition to the data analyses already proposed in the parent study, we will include an overlay of gender differentiation at all levels. Both chi-square and repeated measures analysis of variance (ANOVA) will be used to determine our findings.

RELEVANCE

Differential effects of military service by gender have been clearly demonstrated, though the volume and quality of the literature is as yet modest. We believe that our work can contribute to the emerging literature on the health OEF/OIF women Veterans, and begin to fill the gaps that exist in the areas of experimental studies and behavioral health.