Experience with Enhanced Recruitment of Women Veterans to a CSP Trial

VA HSR&D CyberSeminar: Spotlight on Women’s Health Series
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Study Chair, CSP #591
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Poll Question

Are you considering submitting a research grant that oversamples women Veterans?

- Yes
- No
- Considering it
Acknowledgements

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CSP #591 (Schnurr, Chard, Ruzek)
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Alison Hamilton, PhD, MPH (Engagement Director)
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## Acknowledgements

### Local WERP Teams

### Hines
- **NODES Director:** David Leehey, MD
- **NODES Manager:** Conor McBurney, MPH
- **CSP #591 Local Site Investigator:** Kelly Phipps Maiersch, PhD
- **Study/WERP Coordinator:** Samantha Cymerman and Cheryl Odle
- **WH-PBRN Site Leads:** Sudha Bhoopalam, MD and Karen Saban, PhD, RN

### Minneapolis
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- **NODES Manager:** Debra Condon, MSN, RN, CCRP
- **CSP #591 Local Site Investigator:** Kyle Curry, PhD
- **Study/WERP Coordinator:** Courtney Sellberg and Jillian Wright
- **WH-PBRN Site Lead(s):** Erin Krebs, MD, MPH

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- **NODES Manager:** Emily Boeckman, MEd
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- **Study/WERP Coordinator:** Jade Heathman and Vanessa Posey
- **WH-PBRN Site Lead:** Rola El-Serag, MD

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- **NODES Manager:** Karen Bratcher, RN, MSN, CCRC
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- **Study/WERP Coordinator:** Kathryn Azevedo, PhD
- **WH-PBRN Site Lead(s):** Nicole Grant, MD and Jennifer Lee, MD, PhD

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- **NODES Manager:** Aliya Asghar, MPH
- **CSP #591 Local Site Investigator:** Michael Hollifield, MD
- **Study/WERP Coordinator:** Kala Harkin, MS and Linda Nguyen
- **WH-PBRN Site Lead(s):** Laurie Rudisill, RN, MSN and Amarpreet Bath, MD

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- **NODES Manager:** Kandi Velarde, MPH, CHES
- **CSP #591 Local Site Investigator:** Jennifer Romesser, PsyD
- **Study/WERP Coordinator:** Anthony Trumpy and Sheryl Campbell
- **WH-PBRN Site Lead(s):** Lori Gawron, MD, MPH
Why Do We Need to Increase Opportunities for Inclusion of Women Veterans in VA Research?

Susan Frayne, MD, MPH
The Need for Inclusion of Women in VA Research

- Like other federal agencies, VA requires inclusion of women in research
- Women historically under-represented in VA research → insufficient evidence base to guide their care
- Rapidly growing number of women Veterans
  - However, low # of women Veterans at any one VA
  - Single-site studies typically cannot recruit enough women to yield meaningful conclusions.

https://www.womenshealth.va.gov/WOMENSHEALTH/docs/WHS_Sourcebook_Vol-IV_508c.pdf
VA HSR&D Funded Infrastructure to Build Women’s Health Research Capacity
(for more detail, see HSR&D CyberSeminar 11/5/18)

Multilevel Stakeholder Engagement (Hamilton)

WH Research Consortium (Yano/Klap)
- Training, mentorship
- Methods support
- Research development
- Dissemination support

WH Practice Based Research Network (Frayne/Carney)
- ↑ recruitment of women
- ↑ multisite research
- Engage local clinicians, leaders
- ↑ implementation/impact

Accelerate implementation of research into practice and policy
VA Women’s Health PBRN: Overview

- National network of 60 VA facilities partnering to promote and support the conduct of multi-site research/QI
  - About WVs and/or their health care
  - Seeking to over-sample women to make gender analyses possible
- WH-PBRN Site Lead at each facility
  - Primed for PBRN research to improve health/health care of WVs
  - Connected with local clinicians, leaders, researchers
- National PBRN Coordinating Center
  - Promote local site development/grow the network
  - Support researchers conducting PBRN studies
  - Close collaboration with Consortium/Engagement arms
Opportunities for Synergies
with VA Cooperative
Studies Program (CSP)
Cooperative Studies Program (CSP)

- CSP is a division of VA ORD (since 1972)
  - Plans and supports VA investigator-initiated large multicenter clinical trials and epidemiology studies

- CSP tradition of enlisting under-represented groups in VA research
  - Example: the SELECT trial
SELECT Trial
Prior Initiative to Increase African American Accrual

• Multi-site prostate cancer prevention trial (SELECT)
• Enhance recruitment of African-Americans
  o Expanded eligibility criteria
  o Sought sites with prior success recruiting minorities
  o National infrastructure for minority recruitment
  o Minority Recruitment Enhancement Grants
    • Awarded to 15 sites
  o Impact
    • ↑ odds of African American recruitment vs. comparison sites
    • Boosted recruitment: 10% pre → 15% post

Source: Cook et al. Clin Trials 2010. SELECT (Selenium and Vit E Prostate Cancer prevention trial)
CSP Network of Dedicated Enrollment Sites (NODES)

- Consortium of VA medical centers (VAMCs) that have teams (Nodes) in place dedicated to conducting CSP studies to enhance the performance, compliance and management of CSP multi-site research.

- Expected outcomes:
  - Increasing study enrollment rates
  - Enhancing participant safety
  - Developing standardized procedures & best practices for conducting clinical trials
  - Providing local insights in the design and execution of studies
  - Improving the overall efficiency of CSP research

http://www.research.va.gov/programs/csp/nodes.cfm
CSP NODES ↔ WH-PBRN Collaboration
CSP NODES All Overlap with PBRN Sites: Opportunities for Synergies…!

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<th>Facility</th>
<th>WH-PBRN Site</th>
<th>CSP NODES Site</th>
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<td>Edward Hines Jr. VA Hospital <em>(Hines, IL)</em></td>
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<td>Minneapolis VA Health Care System <em>(Minneapolis, MN)</em></td>
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<td>Portland VA Medical Center <em>(Portland, OR)</em></td>
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<td>Michael E. DeBakey VA Medical Center <em>(Houston, TX)</em></td>
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<td>VA Salt Lake City Health Care System <em>(Salt Lake City, UT)</em></td>
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Women’s Enhanced Recruitment Process (WERP)

Goal: Develop and test a Women’s Enhanced Recruitment Process in the context of a specific study, CSP #591 (PIs: Schnurr, Chard, Ruzek)

Six CSP #591 sites co-located with NODES and WH-PBRN
CERV-PTSD (CSP #591): An Ideal Context to Test Women’s Enhanced Recruitment Processes

Paula Schnurr, PhD
CERV-PTSD (CSP #591)
Co-chairs: Paula P. Schnurr PhD, Kathleen M. Chard PhD, Josef I. Ruzek PhD
VA Cooperative Studies Program

- **Comparative Effectiveness trial comparing two effective treatments for PTSD:**
  - Prolonged Exposure (PE) vs Cognitive Processing Therapy (CPT)
  - PE and CPT both effective treatments for PTSD, and have been rolled out via VA-wide provider training programs

- **17 participating study sites**
  - 6 are NODES + WH-PBRN sites: Hines, Houston, Long Beach, Minneapolis, Palo Alto, Salt Lake City
  - 7 are WH-PBRN sites without a NODES
  - 4 have neither WH-PBRN nor NODES
Veterans in VHA with a diagnosis of PTSD, by year

![Graph showing the percentage of veterans with PTSD in VHA from 2002 to 2013, with an increase in percentage over time. The graph shows two lines: one for the total population and one for males, with a steady increase in percentage for both, with the total population reaching 13% in 2013, and males reaching 9.6% in 2013.](image-url)
Study Objectives

• **Primary:** Compare effectiveness of PE and CPT for reducing PTSD symptom severity

• **Secondary:** Compare effectiveness of PE and CPT for:
  - reducing comorbid mental health problems and service utilization
  - improving functioning and quality of life

• **Tertiary:** Examine whether discrepancy between preferred and assigned treatment reduces effectiveness

• **Exploratory:** Examine differential predictors of treatment outcome
Women’s Enhanced Recruitment Process (WERP)

Goals

1. Increase recruitment of women to CSP #591 at NODES sites
   - Maximize recruitment
   - Learn what is achievable
   - Secondarily seek to increase enrollment of women Veterans at non-WERP sites

2. Identify best practices for recruiting women Veterans, using CSP #591 as a “case study”
WERP:
Recruitment Rates
Women Veterans as a % of CSP #591 Participants, overall:

1 in 5
Women Veterans as a % of CSP #591 Participants, by site type

- **WERP Sites (N=6)**
  - Women: 67
  - Men: 257
  - Percentage: 21%
  - Range: 13%-36%

- **PBRN-only Site (N=7)**
  - Women: 77
  - Men: 297
  - Percentage: 21%
  - Range: 7%-46%

- **Neither (N=4)**
  - Women: 42
  - Men: 176
  - Percentage: 19%
  - Range: 10%-29%

Preliminary Results
Women Veterans as a % of CSP #591 Participants, 
WERP Sites Only, pre/post WERP

Group 1
Group 2
Group 3

Pre-WERP  Post-WERP

Preliminary Results
WERP: Design and Activities

Alyssa Pomernacki, MPH
Roles / Coordination at Local Site
Capitalizes on Synergies: CSP/NODES + WH-PBRN + CSP #591 Study Team

- **WERP Site Coordinator (SC)** ~ 1 day per week of time
- **NODES Director**
- **Local Site Investigator (LSI)**
- **WH-PBRN Site Lead**
Women’s Enhanced Recruitment Process (WERP) Activities

- Development of enhanced recruitment procedures for CSP 591

- WERP site activities
  - Monthly meetings, local presentations, mailings, recruitment

- Program evaluation
  - Veteran Feedback Form (VFF)
  - Qualitative Interviews with research study staff

- Toolkit development:
  - Synthesize lessons learned around recruitment of women
  - Amass resources relevant to inclusion of women
WERP: Lessons Learned So Far
Best practices for recruiting women Veterans

*The Veteran’s Voice*

- Veteran Feedback Form (VFF) Goals
  - Provide study participants with an opportunity to explain:
    - Why they participated in the study
    - Reflect upon their perspectives about the recruitment process
Veteran Feedback Form (VFF) Methods

- 2-page survey included in packet of instruments completed by study participant
- Some items adapted from Ohio State University instrument
- Examined gender differences in Veterans’ preferences around participation in a clinical trial

Best practices for recruiting women Veterans

The Veteran’s Voice

Parts of the VFFs were adopted from the Participant Satisfaction Survey of The Ohio State University Center for Clinical and Translational Science, which is supported by Award Number Grant UL1TR001070 from the National Center For Advancing Translational Sciences.
Best practices for recruiting women Veterans

The Veteran’s Voice

Veteran Feedback Form

N= 40 women; N=144 men

• Where did you first hear about this study?

Preliminary Results
Best practices for recruiting women Veterans

The Veteran’s Voice

Veteran Feedback Form
N= 40 women; N=144 men

- Why did you decide to take part in this study?

![Preliminary Results](diagram.png)
Best practices for recruiting women Veterans

*The Veteran’s Voice*

Veteran Feedback Form

N= 40 women; N=144 men

- Satisfaction with how you were approached to be in study?
  - 100% women were satisfied or very satisfied
  - 88% men were satisfied or very satisfied

Preliminary Results
Best practices for recruiting women Veterans

The Veteran’s Voice
Veteran Feedback Form
N= 40 women; N=144 men

• What did you like about the way your were approached?
  o “I felt pleased to be asked for my input”
  o “I liked how it was emphasized that I would be able to help other veterans or people [with] the condition that I have”

• What could we have done better?
  o “I think it would be beneficial to give flyers out in some of the groups where women veterans are attending.”
  o “The word is not getting out that [this] research is available to the average vet.....”
Program Evaluation: Qualitative Interviews

Goals

• Understand experiences around recruitment and retention of women Veterans
  o Recruitment/retention strategies
  o Challenges enrolling women into research
  o Suggestions for improvement
Program Evaluation: Qualitative Interviews

**Methods**

**Data collection**
- 42 participants (out of 54 contacted) from Jan-May 2018
- Semi-structured telephone interviews
- ~30-60 minutes
- Audio recorded and transcribed

**Analysis**
- Rapid analysis of interview transcripts
- Summarized in a matrix
- Consensus based coding
Program Evaluation: Qualitative Interviews

**Sample**

- **Site-Level:**
  - Across 15 of 17 CSP #591 Sites
    - NODES (WERP) sites (n=6)
    - WH-PBRN only (n=7)
    - Neither: (n=2)
    - National CSP#591 Study Staff

![Pie chart showing the distribution of interviewees by role.](image-url)
What STRATEGIES have worked well recruiting women Veterans?

Qualitative Interviews

- **Finding “Champions,” nurturing relationships to facilitate buy-in, integrating into clinic “flow”**
  - “The best referrals came when there was clinician buy-in and the clinician gave the participant a heads up and actively encouraged the participant to participate.”
  - “We had a built-in kind of referral system through the MST coordinator. She was a huge help in sending us referrals.”

- **Helping other women Veterans**
  - “The women that signed up were very invested because of the way we presented it: ‘We can’t look at what’s going to be helpful and effective for female Veterans if you don’t participate in research. So your participation is not only going to help hopefully you, but really to help [what] we can do for other female Veterans as well.’ I found that to be very effective as a rationale that the female Veterans really attach to.”
Preliminary Results

What CHALLENGES has your site experienced trying to recruit women?

**Qualitative Interviews**

- **Multiple studies recruiting from a small pool**
  - “There were too many ...programs that were competing for that same population base.”
  - “I think the [women’s health] stakeholders are burdened with many requests for their women”

- **Recruiting women Veterans is complex**
  - “I think they have a lot of comorbidities, so I think ...that they just need a lot of attention with a lot various health issues.”

- **Women are busy!**
  - “Younger Veterans certainly had more logistical barriers consistent with what we see in other studies in the research, either working, child care“
  - “…if there was a sick child they were the one that had to take off work”
What CHALLENGES has your site experienced trying to recruit women?

Qualitative Interviews

- Local cultural issues around treatment for women
  - “I did find that a few of the providers were – I don’t want to say overprotective of the women in their programs, but I will say they were a little more cautious about referring them to us ....”

- Unwelcoming setting for women Veterans
  - “I’d have to go to a clinic area which, there’s like five men’s bathrooms and one women’s bathroom.”
  - Color: the clinic is [a depressing color]. The men in the waiting room need to behave. There are women who have babies and the bathrooms do not have accommodations to change a diaper...”
What CHALLENGES has your site experienced trying to recruit women?

Qualitative Interviews

• Not always able to accommodate female provider preference

• Identifying where the women Veterans receive care

• More flexibility to recruit outside the mainstream
  o “I wish we could be more flexible with how we communicate, I wish we could do research using online surveys... I think if we improve or technologic interfaces, giving people more options... Just trying to make it easier and more time efficient for busy people.”
What SUGGESTIONS do you have to improve recruitment?

Qualitative Interviews

• Increase awareness about women Veterans’ recruitment
  o “...we definitely could’ve talked about it more and gotten people excited about looking for women who were good candidates for the study.”
  o “when I told [women] that this study was a part of an initiative to increase women enrollment, they were surprised, but pleasantly surprised, that there was a research [study] that even cared that much to try and increase female enrollment.”

• Address participant’s logistical barriers
  o “If you’re thinking about competing demands and how little time you have, to add something else to your plate can be a big challenge and so I think trying to identify those aspects of studies where patients really can see, “Oh, this would be good for me.”
What SUGGESTIONS do you have to improve recruitment? Qualitative Interviews

- **Building relationships with clinicians and staff**
  - “Getting to know staff and explaining to them why we’re recruiting and getting them on board, like medical assistants and nurses can be really helpful because that’s kind of like the warm handoff where they can encourage patients who they know to participate.”
  
  - “Presenting at provider team meetings is always important... so that the provider can actually explain that to the patient. And also, we do a lot of myth-busting and dispelling rumors about research.”
  
  - “You can’t just kind of like pop in; you have to reside, you have to be a presence.”
Putting it All Together

**WERP Toolkit**

- **National WERP Toolkit:** *available for dissemination soon!*
  - Sample gender-tailored recruitment materials (e.g.: letter, opt-in/opt-out form, brochure, flyers, telephone script)
  - Guidance on finding and selecting pictures of diverse women Veterans
  - IRB approach to incorporate focus on recruitment of women Veterans

- **Local WERP sites have also developed local toolkits**
  - Local tips, resources, contacts for local women’s health stakeholders
Thank you for your efforts to ensure that women Veterans are represented in VA Research!
Resources

- HSR&D Women’s Health Research
  - Includes searchable women’s health literature database and searchable women’s health research portfolio
    http://www.hsrd.research.va.gov/for_researchers/womens_health/

- Women’s Health Evidence Synthesis Reports
  http://www.hsrd.research.va.gov/publications/esp/women.cfm
  http://www.hsrd.research.va.gov/publications/esp/women-vets.cfm

- Women’s Health Issues Supplement
  http://www.whijournal.com/content/supplements

- Women Veterans Sourcebook Volume 4
  https://www.womenshealth.va.gov/latestinformation/publications.asp

- CyberSeminar series
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