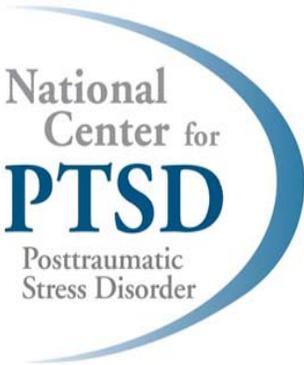


TeleMental Health Technology: Results from a Randomized Noninferiority Trial for PTSD Care

Leslie A. Morland, Psy.D. & Carolyn J. Greene, PhD



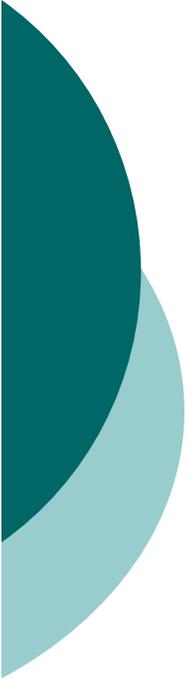
National
Center for
PTSD
Posttraumatic
Stress Disorder

**National Center for Posttraumatic Stress Disorder,
Pacific Islands Division
Department of Veterans Affairs,
Pacific Islands Health Care System**



Acknowledgements

This material is based upon work supported in part by the Office of Research and Development, Health Services R&D Service, Department of Veterans Affairs, VA Pacific Islands Health Care System, Spark M. Matsunaga Medical Center. Support was also provided by VA National Center for PTSD.



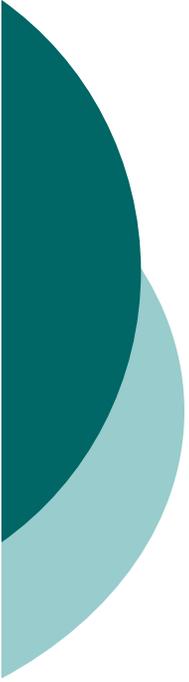
Questions for the Audience?

- How many listeners are currently involved with providing telemental health service delivery?
- How many listeners are currently providing mental health care in rural or remote areas?
- How many listeners currently encounter problems with access to care for veterans in rural or remote areas?



Objectives

- Why Telemental Health (TMH) is a Priority for VHA
- Current Evidence Base for TMH Technology - specifically videoteleconferencing (VTC)
- Results from a Recently Completed Noninferiority Telemental Health Randomized Control Trial
- Future Directions in Clinical Research for TMH Technology



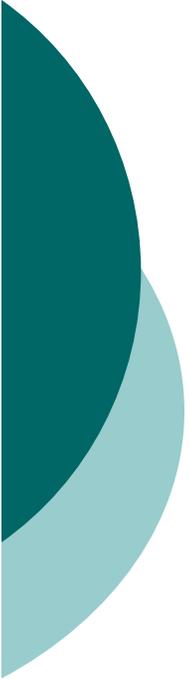
What is Telemental Health?

“The term telemental health services typically refers to behavioral health services that are provided using communication technology”

National Center for PTSD Fact Sheet “PTSD and Telemental Health”

What is Telemental Health?

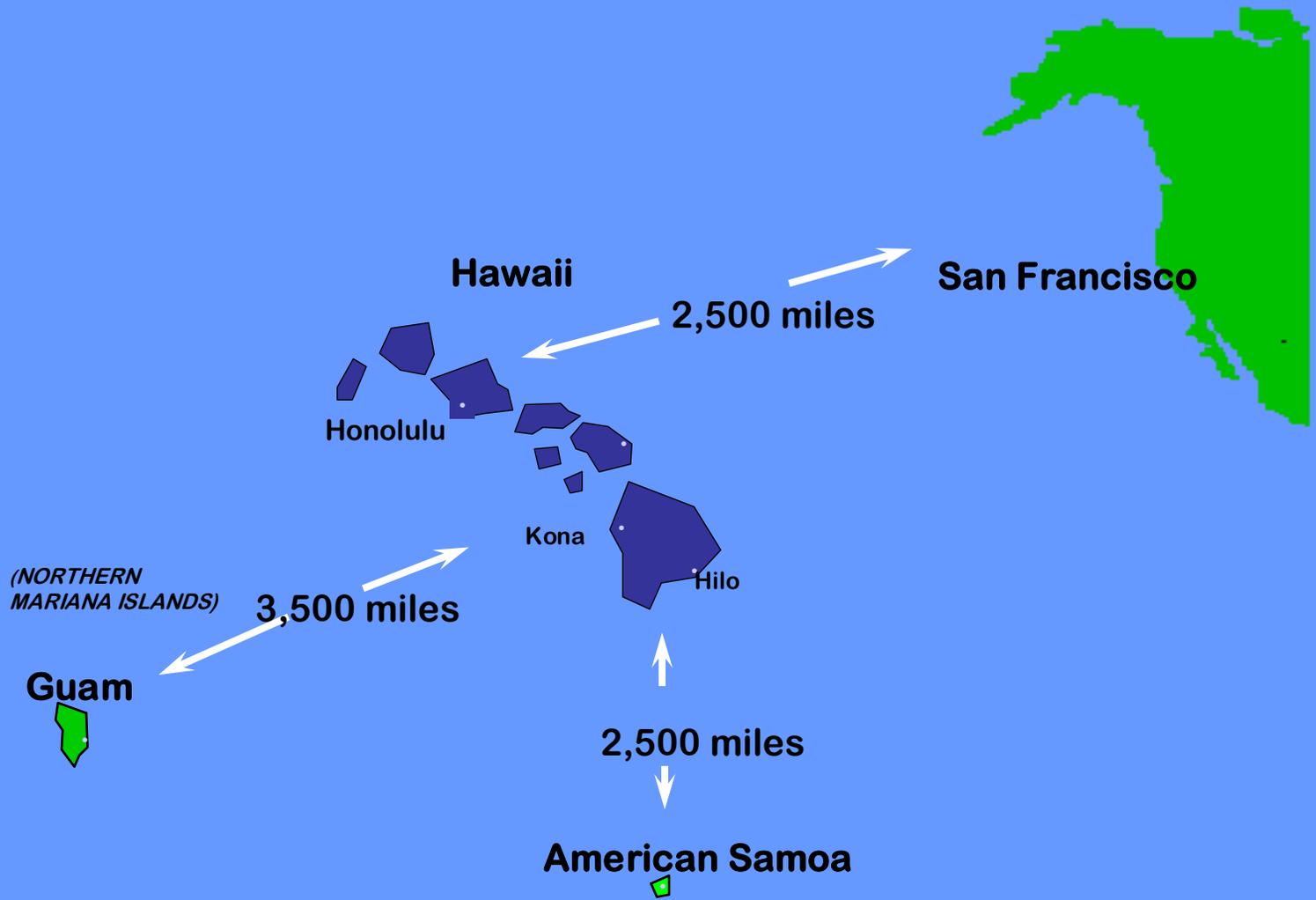




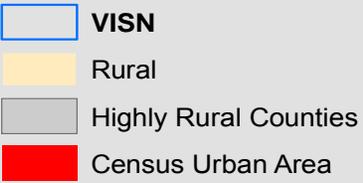
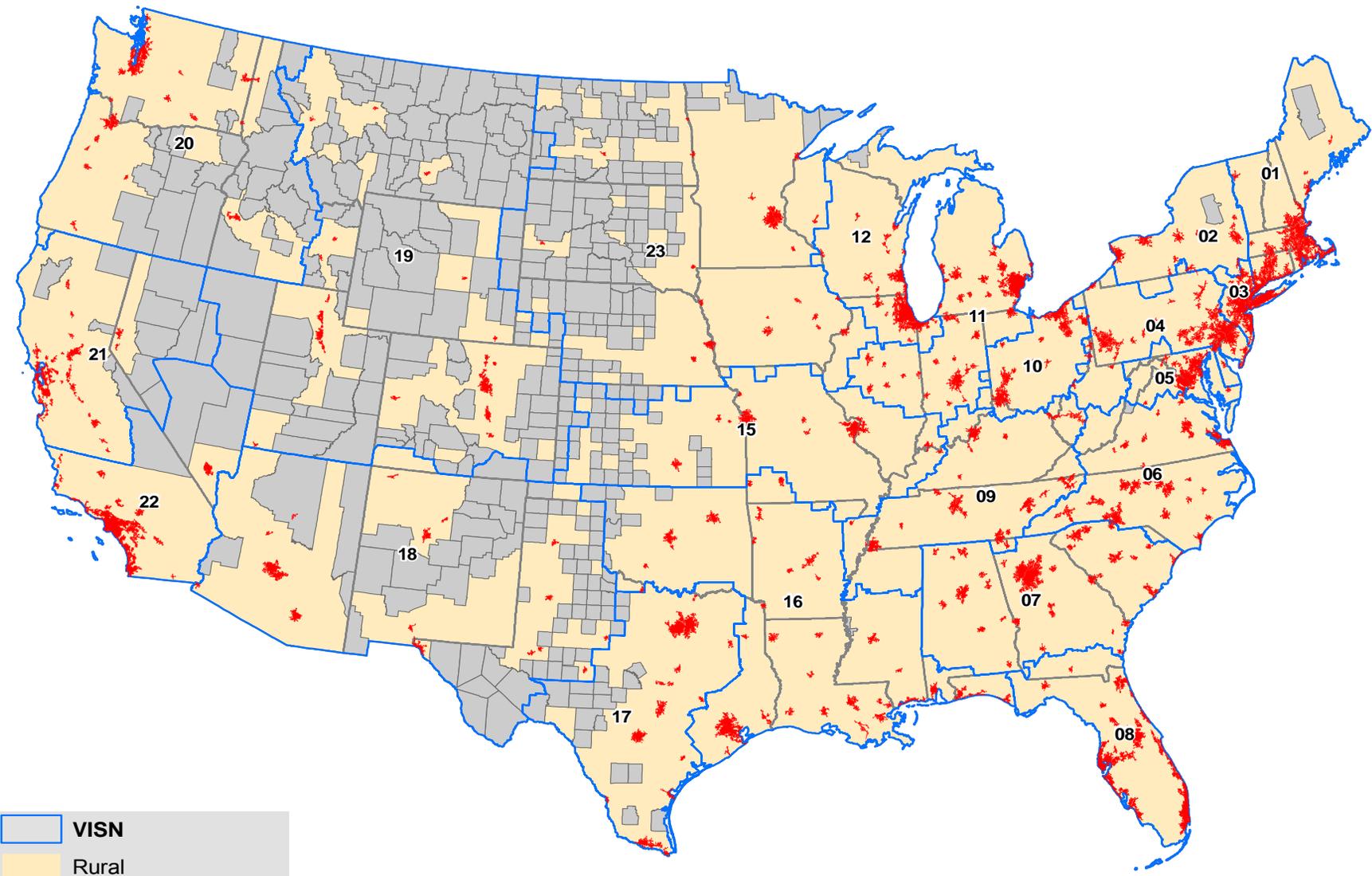
Why Use Telemental Health in the Veteran's Health Administration (VHA)?

- Geographic Dispersion of VHA
- Rural Health Needs
- Uniformed Services Package
- Access to PTSD Specialty Care

HAWAII VA SERVICE AREA



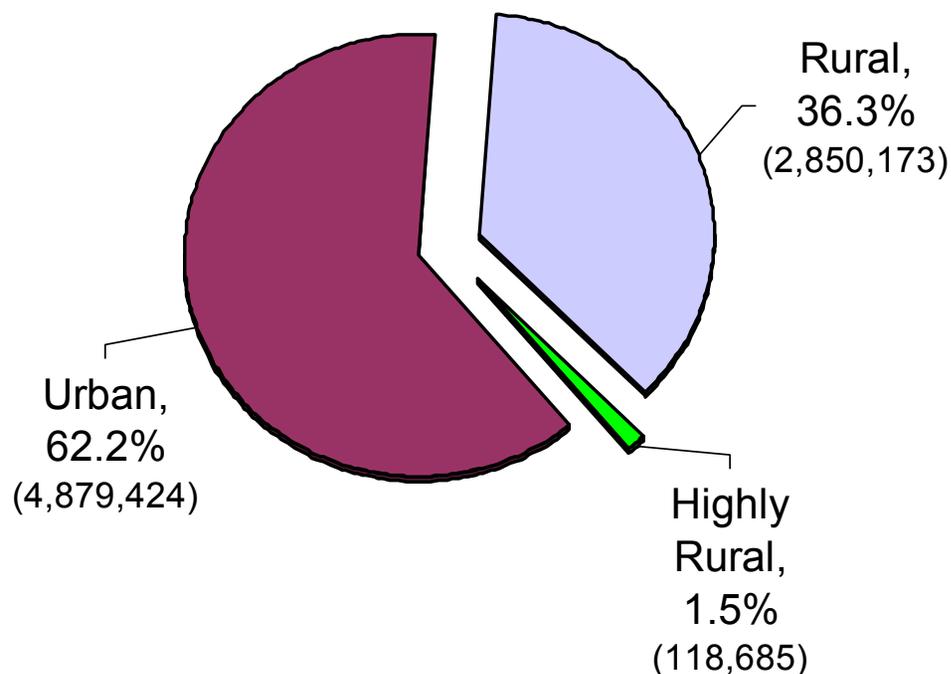
Highly Rural, Rural and Census Defined Urban Areas



Map generated by VHA Planning Systems Support Group, field unit for the VHA Office of Assistant Deputy Under Secretary for Health for Policy & Planning, April 6, 2007

Demographics and Definitions

Veteran Enrollees by U/R/H
End Of Year 06



Definition of U/R/H

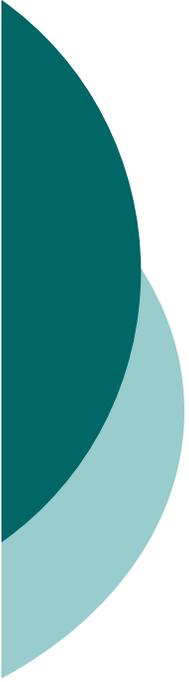
based on the Census' definition of rural.

Urban - Areas defined by U.S. Census as an *urbanized area** (excludes urban clusters)

Rural - All other areas excluded in U.S. Census defined urbanized areas

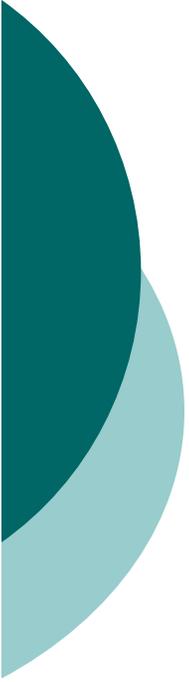
Highly Rural - Any rural area within a county with less than 7.0 civilians per square mile

* UA comprises one or more places ("central place") and the adjacent densely settled surrounding territory ("urban fringe") that together have a minimum of 50,000 persons.



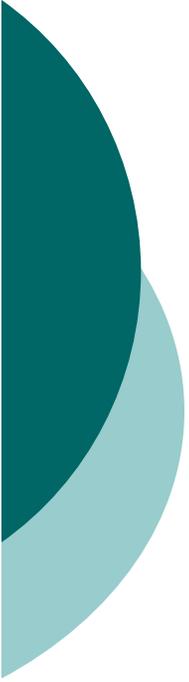
Uniformed Service Package

“This revised VHA Handbook defines minimum clinical requirements for VHA Mental Health Services. It delineates the essential components of the mental health program that is to be implemented nationally, to ensure that all veterans, *wherever they obtain care in VHA*, have access to needed mental health services” (VHA Handbook, 1160.01 p. 1)



Uniformed Service Package - PTSD

“(1) Evidence-based Psychotherapy for PTSD. All veterans with PTSD must have access to Cognitive Processing Therapy (CPT) or Prolonged Exposure (PE) Therapy. Medical Centers and very large CBOCs must provide adequate staff capacity to allow the delivery of evidence-based psychotherapy to their patients. Large and mid-sized CBOCs may provide these services through telemental health when necessary.” (VHA Handbook, 1160.01 p. 29)



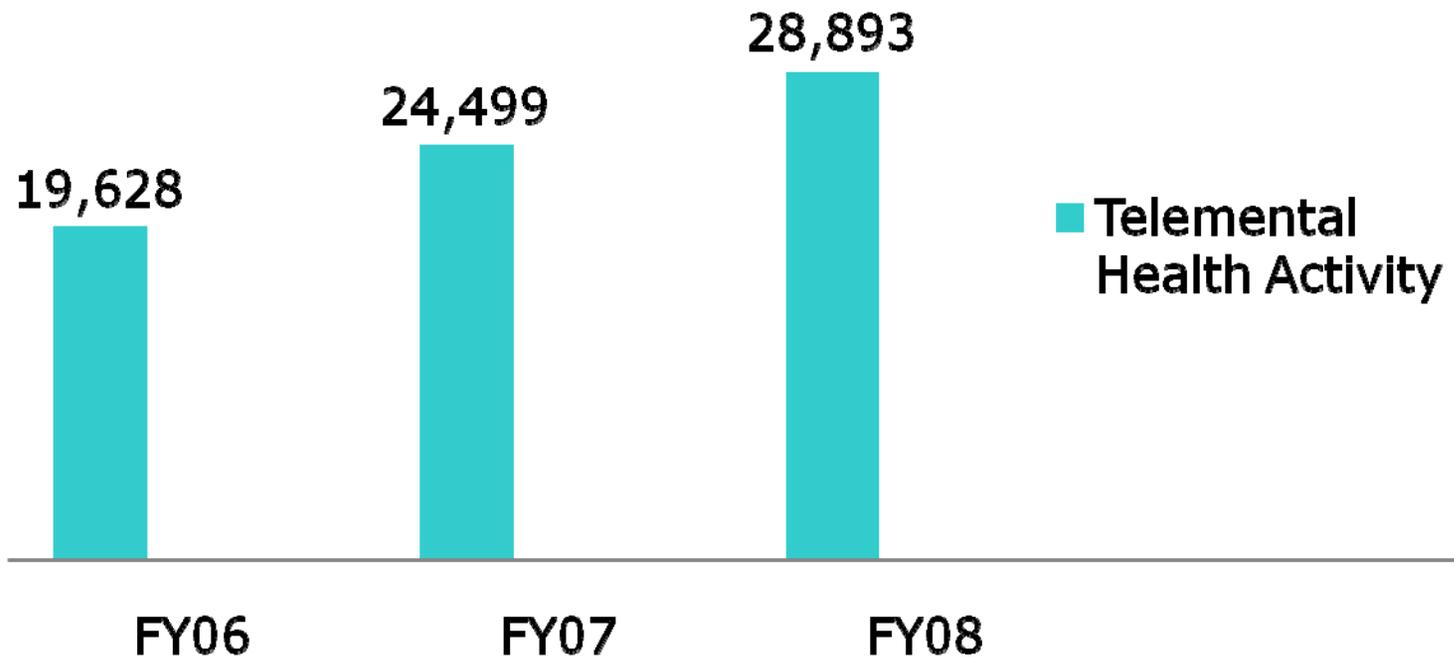
VHA TMH Initiatives

- In 2005 VA Office of Care Coordination developed several initiatives that prioritized the role of TMH for increasing access to care for veterans.
- In 2007 telemental health care services were identified as one of the first of five priority areas for future development by the VA.



VHA TMH Activity

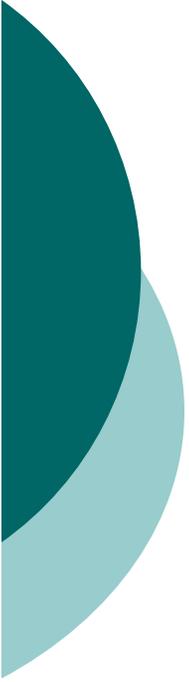
Unique Veterans Treated/Enrolled in Telemental Health Services





What Do We Know: Evidence Base for TMH Modality

- Feasibility
- Reliability
- Satisfaction

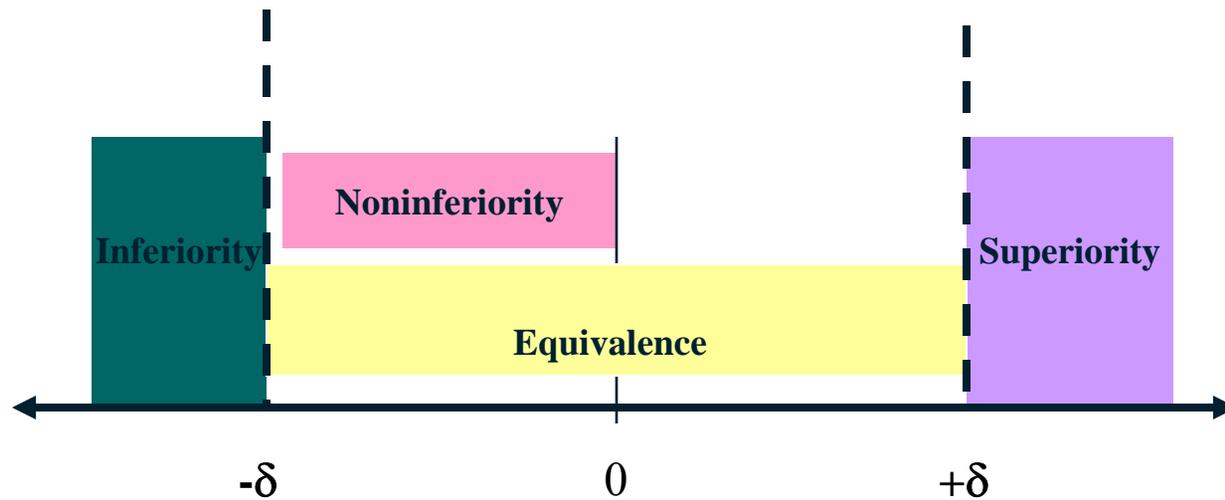


What Don't We Know: Evidence Base for TMH Modality

- Clinical Effectiveness
- Cost Effectiveness



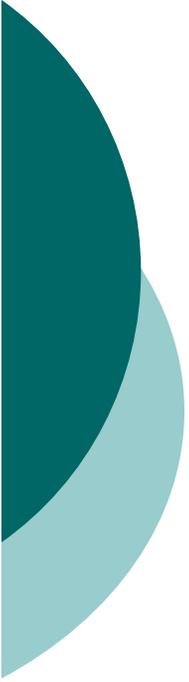
How do we determine if TMH
service delivery is “*as good as*”
traditional face-to-face care?



(Experimental Treatment vs. Standard Treatment)

δ = pre-specified margin of equivalence/noninferiority

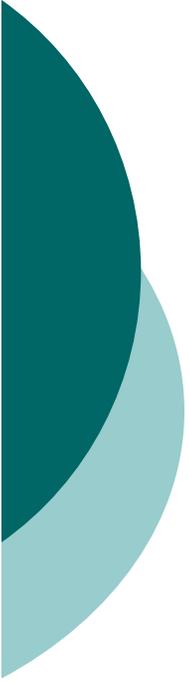
- The two-sided 95% confidence interval of the difference between treatments is less than the non-inferiority margin; fail to claim noninferiority of new treatment.
- The confidence interval is greater than the non-inferiority margin; claim noninferiority of new treatment.
- The confidence interval is greater than the non-inferiority margin and less than the non-superiority margin; claim equivalence of new treatment.
- The confidence interval is greater than the non-superiority margin; fail to claim equivalence.



When to Use this Design: Clinical Application

- Need to establish that a new treatment achieves clinical results similar to those of the standard therapy:

Example: Determine clinical equivalence or non-inferiority of innovative modalities of care (i.e., internet, video-teleconferencing, phone) for providing already established evidence-based PTSD services to remote populations.



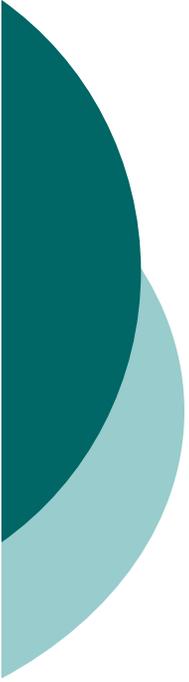
Why is this Design Important?

- Need to increase access to care for rural or remote populations with PTSD
 - Geographic dispersion of VA Health Care System
 - 40% of Returning Operation Iraqi Freedom and Operation Enduring Freedom (OIF/OEF) population
 - Need to examine Innovative Ways to Reduce Travel and Increase Access to Care in order to provide the mandatory Care to All Veterans
- However it is important that we examine efficacy of TMH & utilize empirically supported modalities of care



Non-inferiority Trials Underway

- Anger Management Training (AMT) with veterans who have PTSD
- Cognitive Processing Therapy (CPT) with combat veterans who have PTSD

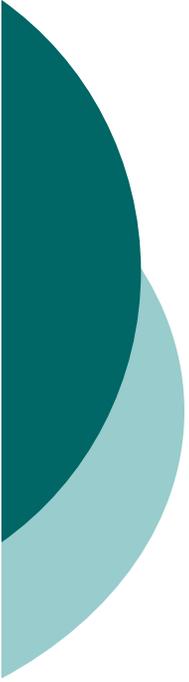


4 Year Clinical Trial

Telemedicine & Anger Management Groups
with PTSD Veterans in the Hawaiian Islands

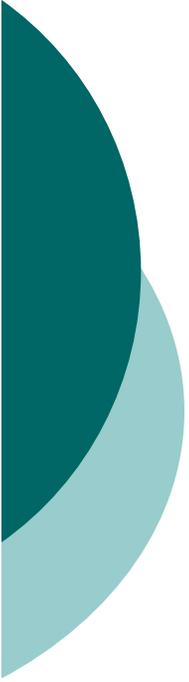
Principal Investigator: Leslie A. Morland, Psy.D.

Funded June 2005 by VA HSR&D



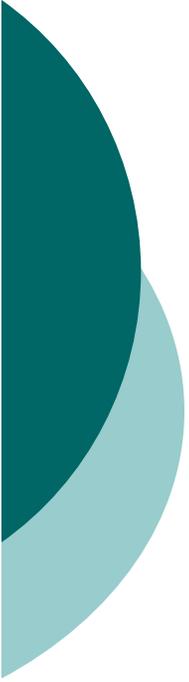
Contributors/Collaborators

- Carolyn Greene, Ph.D., Co-Investigator
- Craig Rosen, Ph.D., Co-Investigator
- Patrick Reilly, Ph.D., Co-Investigator
- B. Christopher Frueh, Ph.D., Co-Investigator
- Jay Shore, M.D., M.P.H., Co-Investigator
- David Foy, Ph.D., Project Consultant
- Dan King, Ph.D., Project Statistician



Research Goal

- Evaluate the efficacy of using Video Teleconferencing (VTC) modality as compared to the traditional face-to-face in-person (NP) modality for providing an evidence-based cognitive-behavioral group anger management intervention to veterans with PTSD.



Why Anger & PTSD?

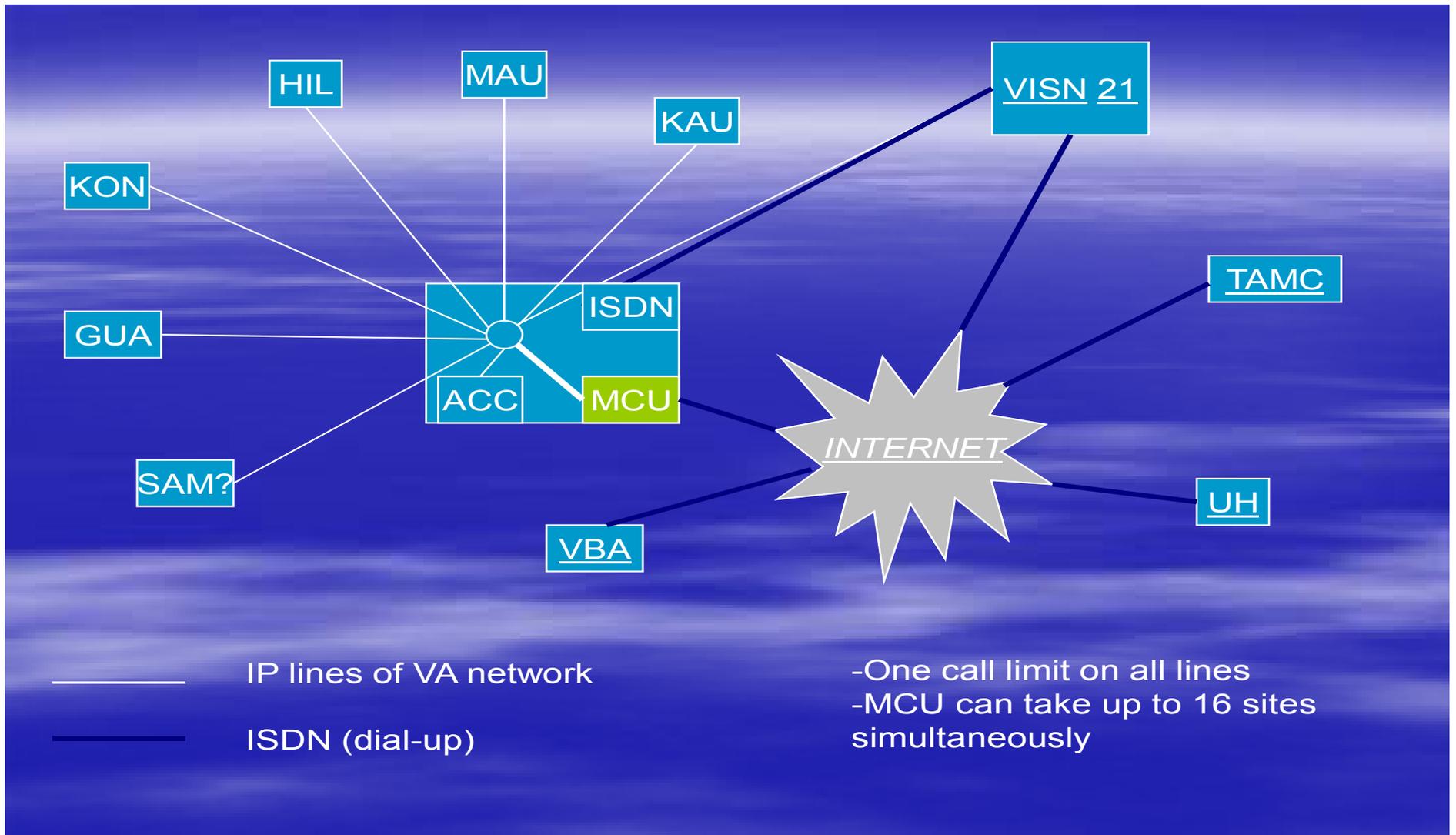
- Veterans with PTSD report more anger and interpersonal violence; This association between anger and combat-related PTSD has significant social and clinical implications for the veteran population including an impact on families, work settings, and society.
- The treatment of the anger component of PTSD is considered essential in the trauma recovery process.
- Anger during exposure treatment may block fear processing and thus interfere with the effects of exposure

Methods



- **Design:** Randomized Control Trial
- **Participants:** 125 veterans with PTSD from 3 VA sites; 10 cohorts (6-9 veterans per group)
- **Intervention:** 12 sessions of CBT Anger Management Training (AMT)
- **Assessments:** At baseline, mid, post, follow-up
 - Clinical Outcomes
 - Process Outcomes
- **Primary Analyses:** Noninferiority Analyses of VTC vs. face-to-face group therapy delivery

Video Teleconferencing (VTC) Technology - Tandberg 880s



Referrals VA & Vet Center

Personal or Demographic Variables
Age, Ethnicity, Educ, Service Era, SC Status, Military Branch, Employment, Marital Status, Distance to VA

Combat – Trauma
PTSD - Anger

NP
Anger Group

VTC
Anger Group

Process Outcomes
Therapeutic Alliance
Satisfaction
Trust/Comfort
Convenience
Compliance
Attrition

Clinical Outcomes
Anger Reduction
Disposition
Anger Control

Participants

Inclusion criteria:

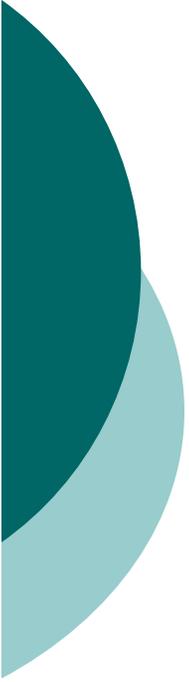


- **PTSD diagnosis (CAPS)**
- Significant level of anger (**STAXI**)
- Stable **medications regimen** for at least 2 months prior to study entry



Exclusion criteria:

- active **psychotic symptoms/disorder** as determined by the SCID for DSM-IV
- active **homicidal or suicidal ideation** as determined by the structured clinical interview
- any **significant cognitive impairment** or history of Organic Mental Disorder
- active (current) **substance dependence** as determined by the SCID
- **unwillingness to refrain from substance abuse** during treatment
- **female** veterans



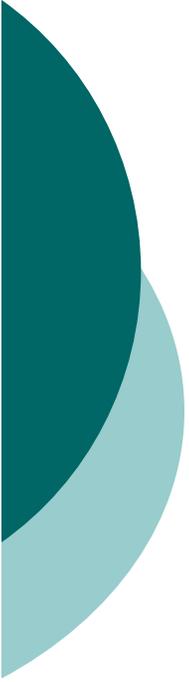
Recruitment & Retention

○ Recruitment

- Selection of sites with limited services
- Site visits and site liaisons
- Flyers

○ Retention

- Initial group meeting with Primary Investigator
- Weekly phone calls
- Travel reimbursement per session (\$10)



Measures



- Clinical Outcome
 - Anger (STAXI & NAS)
 - Violence (ABS)
 - PTSD (CAPS & PCL)
 - Quality of Life (Frisch)

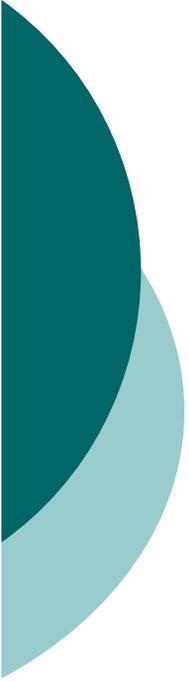
- Process Outcome
 - Attrition (Attendance)
 - Treatment Compliance (Homework)
 - Treatment Expectancy (Borkovec)
 - Group Therapy Alliance (GTAS)
 - Satisfaction (Frueh)

Anger Management Intervention

Each 90-minute group session consists of two components:

- A **didactic presentation** of the cognitive-behavioral material
- A **check-in procedure** involving group interaction and discussion

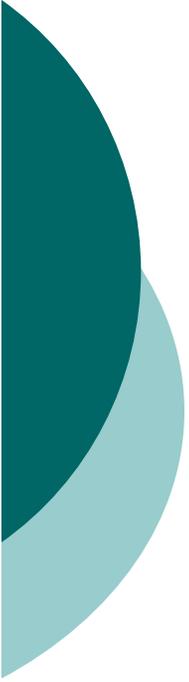




Primary Analyses

- Noninferiority Analyses
 - Clinical variables

- Analysis of Variance (ANOVA)
 - Process outcomes



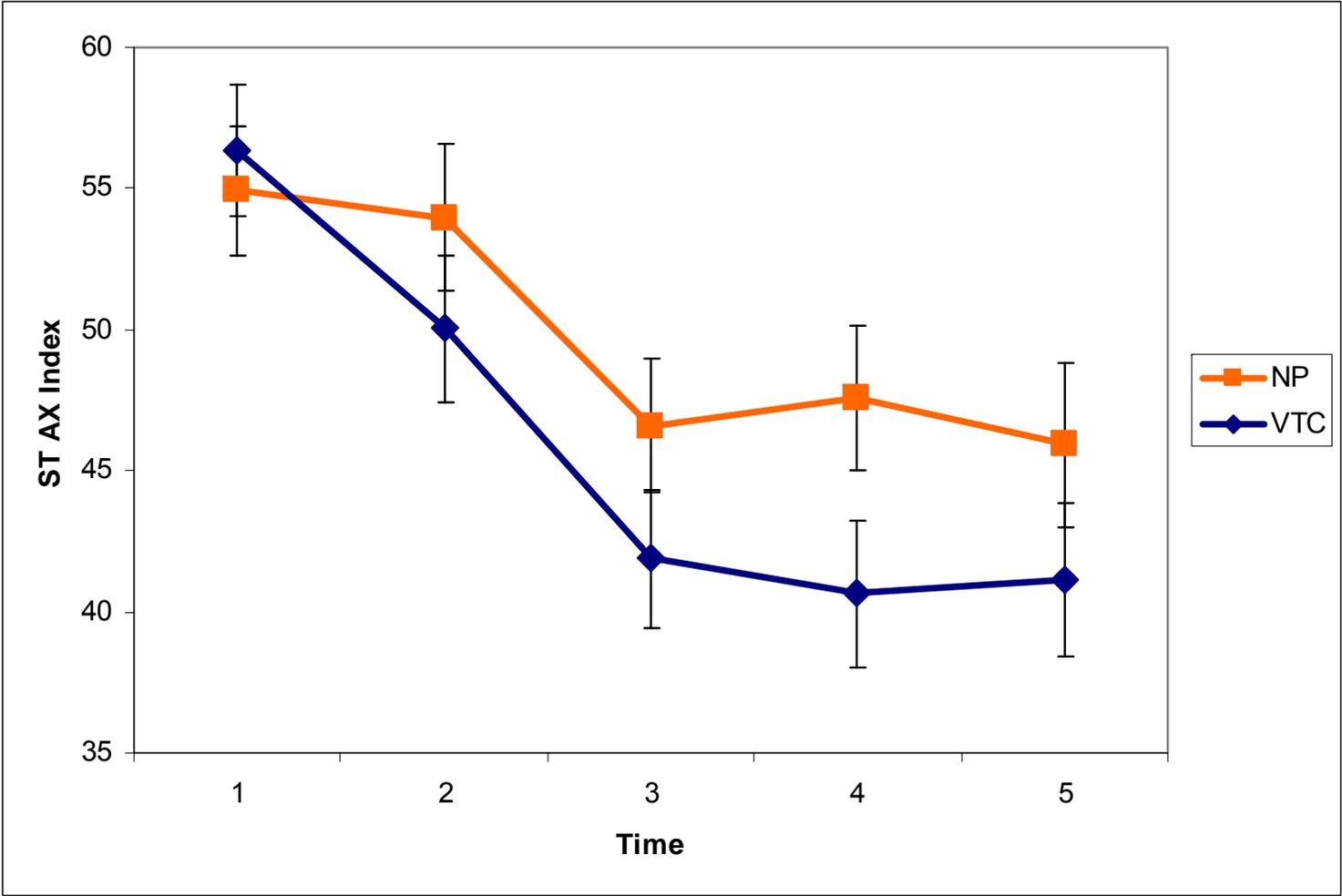
Preliminary Results



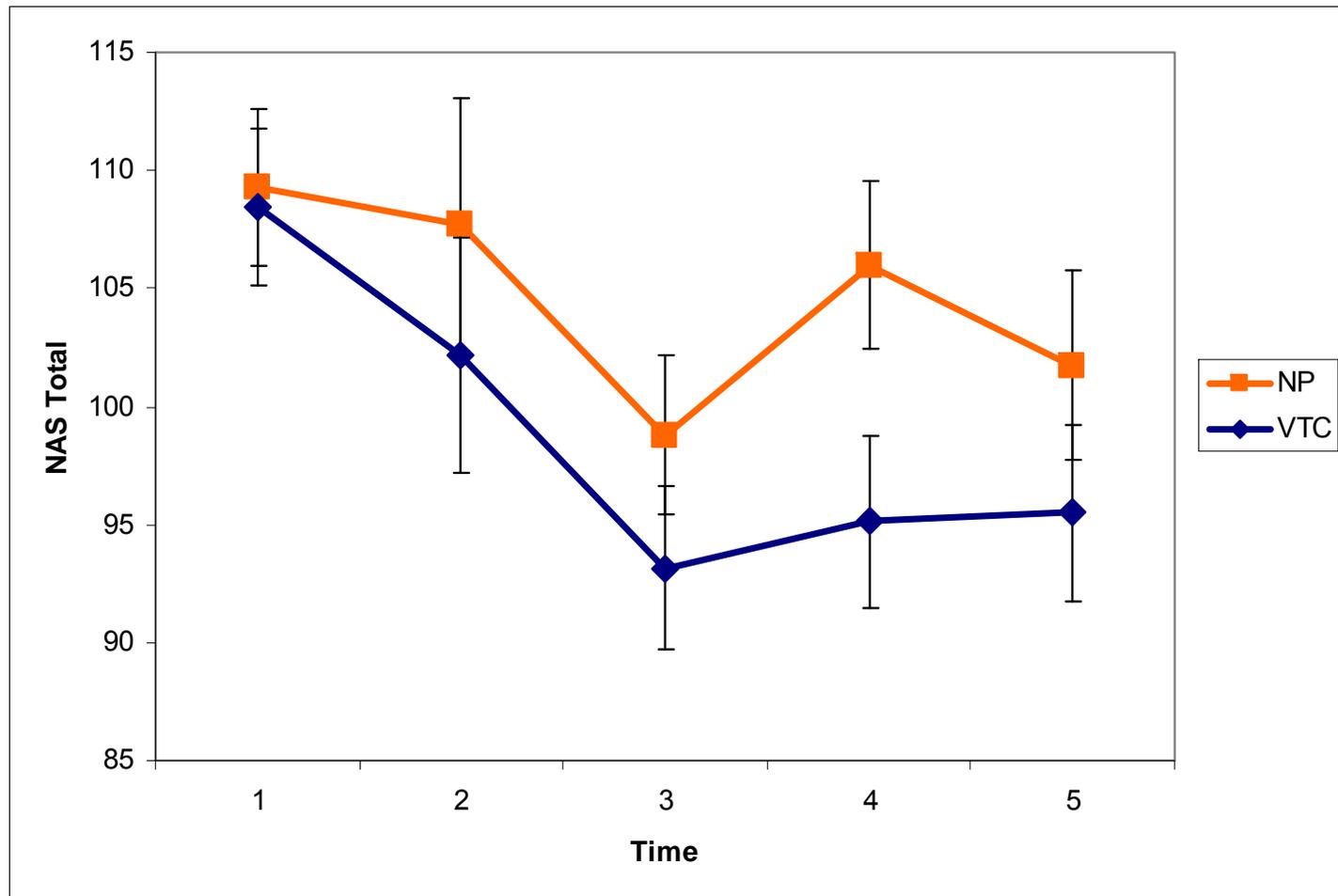
Mean anger scores at baseline, post-treatment, 3 & 6 month follow-up by treatment group

Measure	Baseline		Post-Treatment		3-month		6-month	
	NP	VTC	NP	VTC	NP	VTC	NP	VTC
Anger Expression (AX)	55.0 (10.3)	56.7 (12.0)	46.6 (12.2)	42.4 (16.2)	47.0 (13.4)	41.8 (15.3)	46.6 (15.3)	42.0 (15.6)
Trait Anger (T-ANG)	27.8 (5.6)	28.0 (6.0)	23.3 (6.0)	22.1 (6.2)	25.0 (7.1)	22.4 (7.5)	25.6 (8.2)	22.4 (7.3)
Novaco (NAS-T)	109.8 (14.0)	109.3 (16.1)	99.2 (17.1)	94.2 (19.1)	105.2 (19.2)	96.4 (18.4)	101.0 (22.5)	97.7 (20.2)

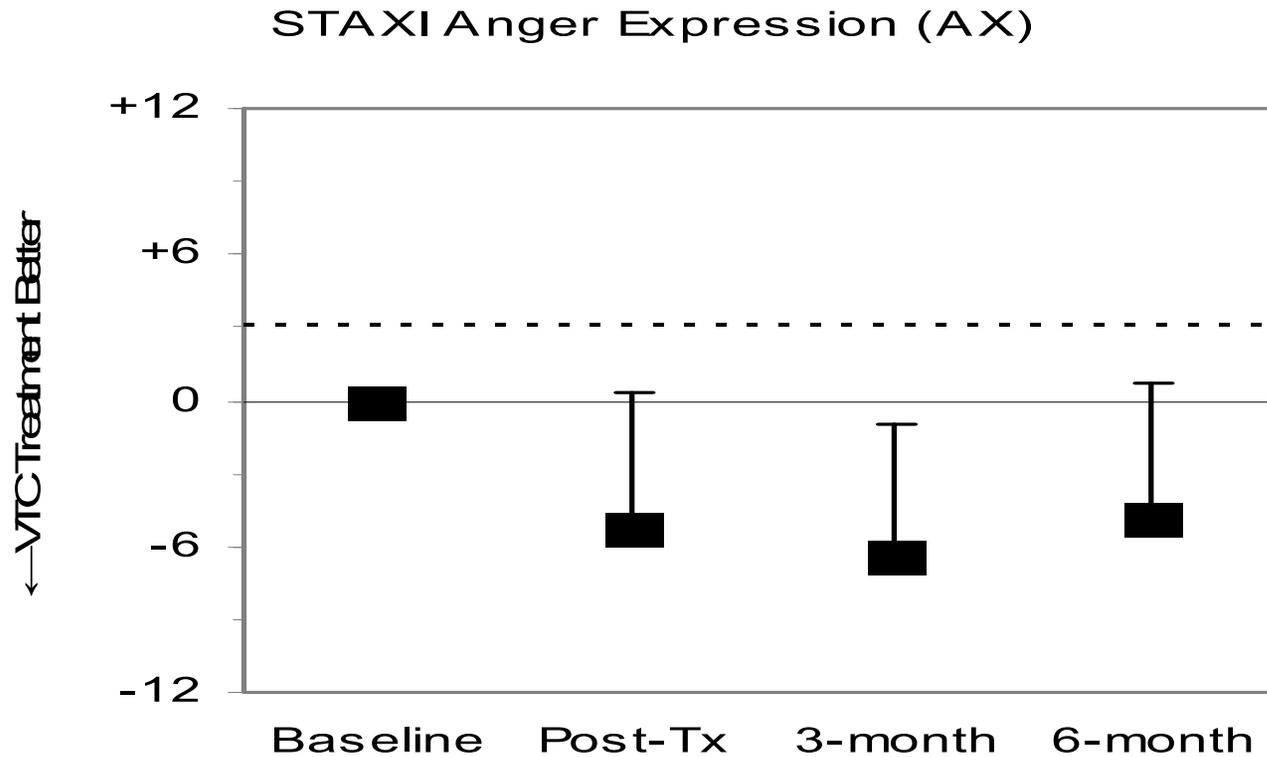
Results: STAXI Anger Expression



Results: Novaco Anger Scale (NAS)



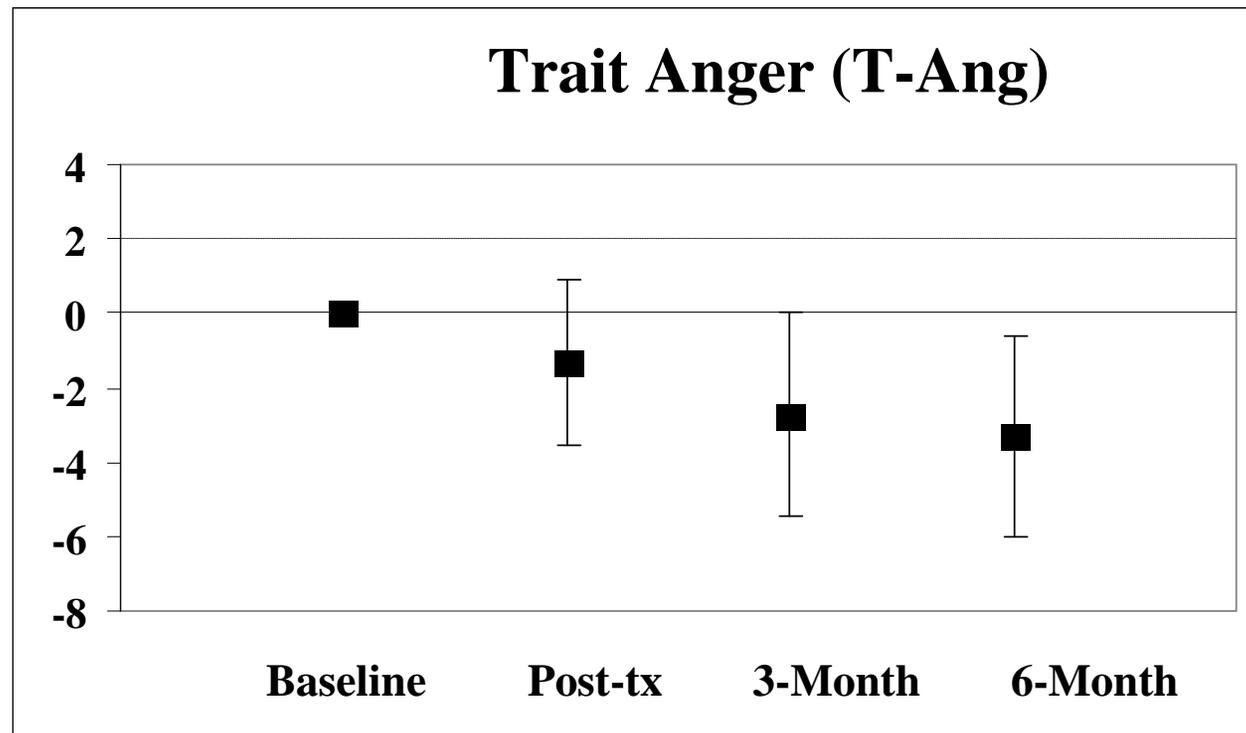
Results: Non-inferiority Analyses



Non-inferiority 95% Confidence Intervals at Baseline, Post-Treatment, 3-month, and 6-month Follow-up

Notes. The total ITT sample ($N= 125$) was used for these analyses. Missing values were multiply imputed using the Markov Chain Monte Carlo method. All confidence intervals are two-sided (95%). The dotted lines show the minimum clinically meaningful difference ($\Delta=2$) for all except NAS-T ($\Delta=4$).

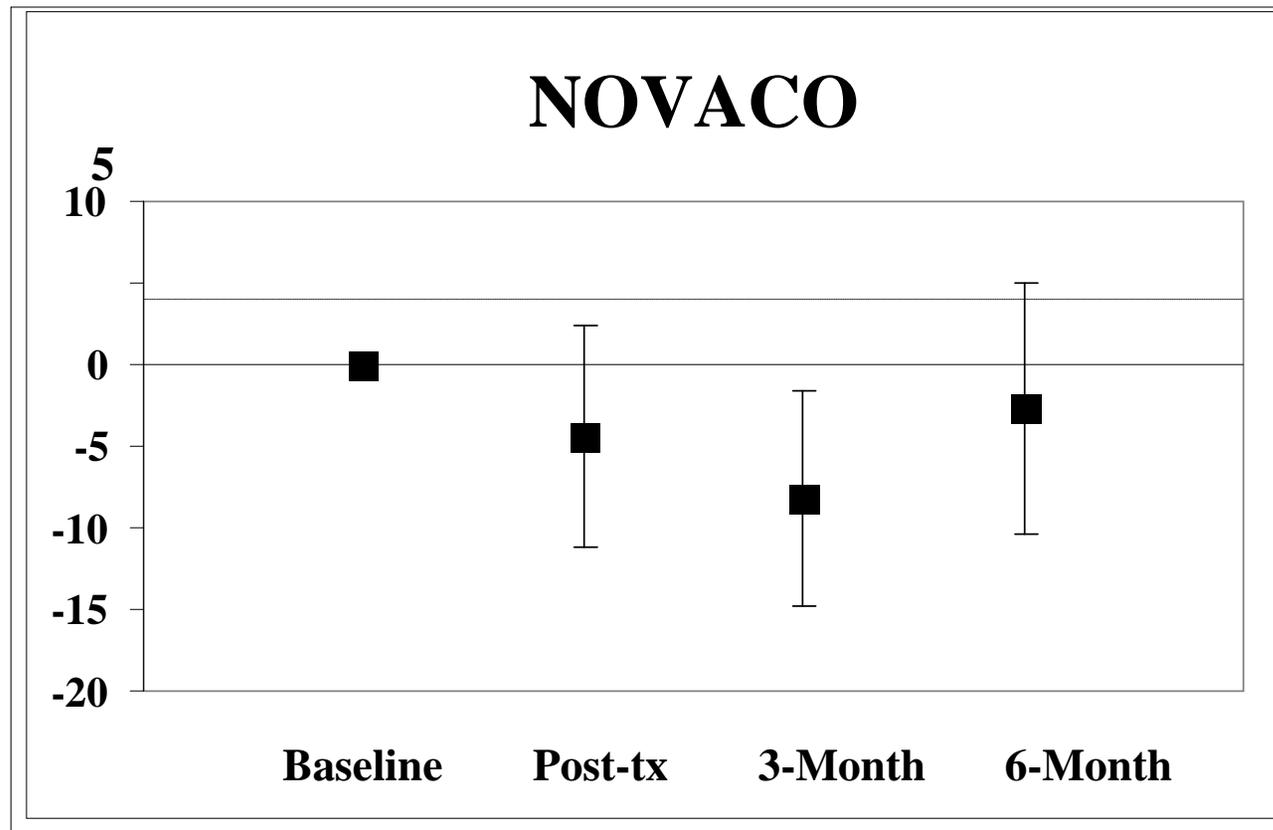
Results: Non-inferiority Analyses



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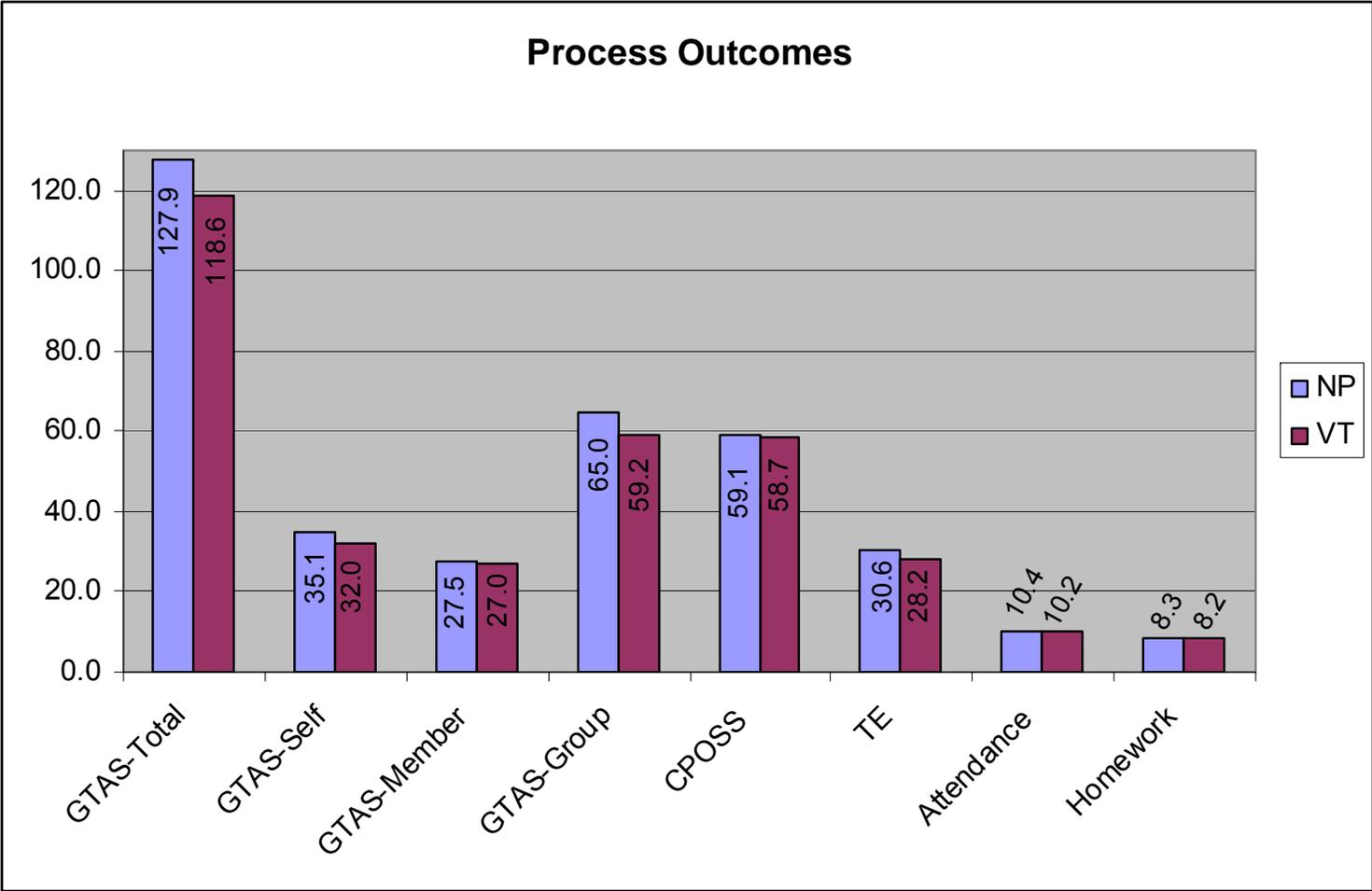
Results: Non-inferiority Analyses

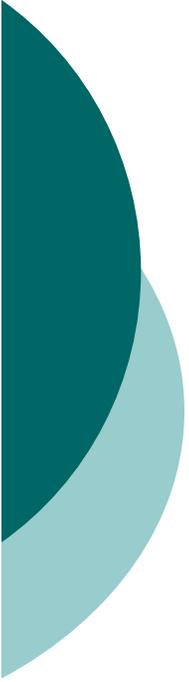


Non-inferiority 95% Confidence Intervals at Baseline, Post-Treatment, 3-month, and 6-month Follow-up

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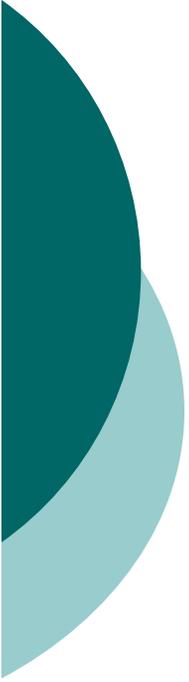
Process Outcome Measures by Treatment Condition





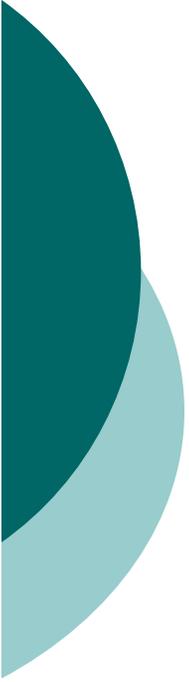
Results Summary

- Both conditions showed significant and clinically meaningful improvement on relevant anger symptoms outcomes post treatment and out to 6-months post-treatment.
- Participants in both conditions tolerated & benefitted from Anger Management Therapy making this one of the few large RCTs to show meaningful treatment effects for veterans with anger difficulties and PTSD.



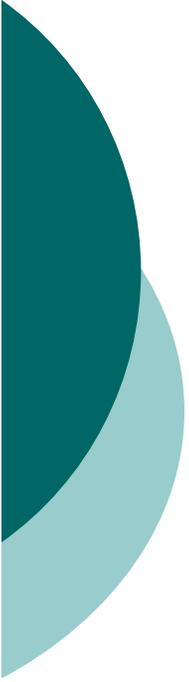
Discussion

- Results from this randomized clinical trial provide strong support that providing evidence-based psychotherapy groups over a video teleconferencing modality can be *as effective as* the in-person delivery of the same treatment for rural veterans with PTSD.



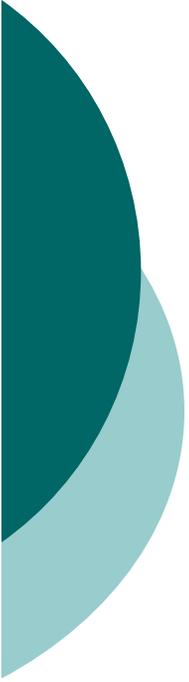
Discussion

- Our process outcomes confirm the feasibility of implementing TMH for rural veterans with PTSD.
- Participants in both conditions reported high levels of treatment credibility, satisfaction with care and homework adherence.



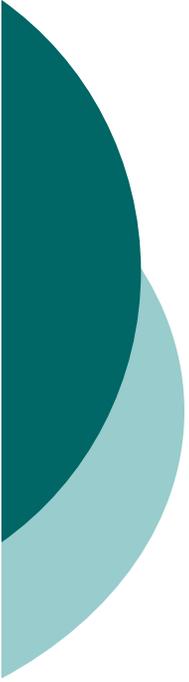
Discussion

- Participants in both conditions reported high therapeutic alliance with the therapist and group members; however the NP condition reported slightly more alliance with the therapist.
- Together, these data indicate that TMH intervention is both acceptable to and effective for this population.



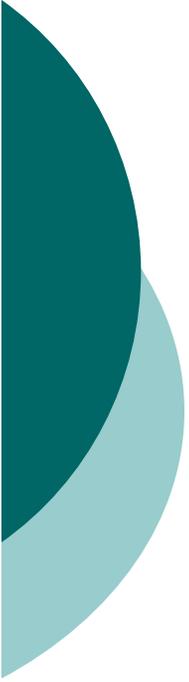
Discussion: Study Strengths

- One of the **first** methodologically rigorous non-inferiority designed RCTs of TMH interventions and the first with a PTSD veteran population.
- Retention rates were high in the complex, difficult to treat clinical sample.
- Ability to tolerate and manage strong affect over video teleconferencing modality was demonstrated.



Discussion: Limitations

- PTSD was not specifically evaluated or directly treated.
- It is unknown how easily patients who are accustomed to face-to-face group therapy would accept the transition to a VTC modality.

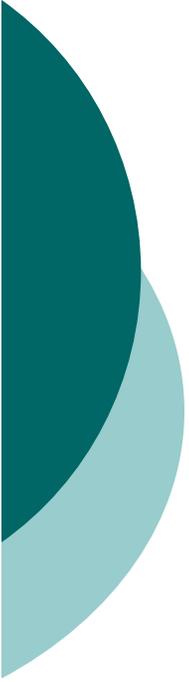


4 Year Clinical Trial

Telemedicine & Cognitive Processing Groups
with PTSD Veterans in the Hawaiian Islands

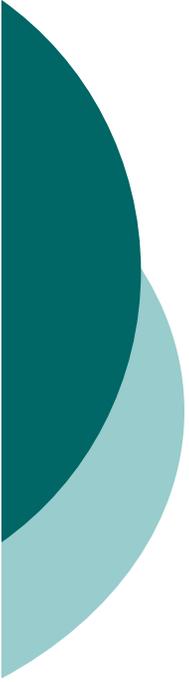
Principal Investigator: Leslie A. Morland, Psy.D.

Funded June 2008 by DOD & VA HSR&D



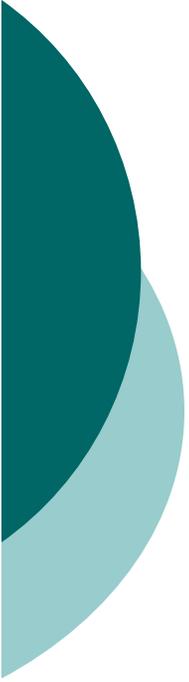
Cognitive Processing Therapy (CPT)

- A well-validated therapy for PTSD:
 - Cognitive components
 - Exposure components
 - Effective and palatable to clinicians and patients
 - The benefits of CPT can be generalized to co-morbid mental health conditions and day-to-day problems
 - CPT is well suited and efficacious for veteran populations and VA treatment settings



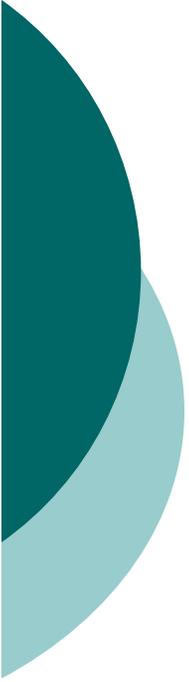
Methods:

- **Design:** Randomized Control Trial
- **Participants:** ~125 veterans with PTSD from 3 VA sites; 10 cohorts (6-9 veterans per treatment group, 2 groups per cohort)
- **Intervention:** 12 Sessions of CPT
- **Assessments:** At baseline, mid, post, follow-up
- **Primary Analysis:** Equivalence analysis of VTC vs. in-person mental health service delivery.
 - **Clinical Outcomes**
 - **Process Outcomes**
 - **Cost Outcomes**



Progress to Date:

- Completed 2 treatment Cohorts
 - 26 enrolled and 20 completed 12 session CPT group therapy
 - Thus far overall attrition rates have ranged from 15-30%
- Cohort 3 is currently underway
- Early feasibility/tolerability has been established for providing CPT group therapy over videoteleconferencing.



Clinical Implications

- Data supports that using a video teleconferencing modality for providing an evidence-based anger group therapy treatment is *as good as* providing this treatment in a traditional face-to-face modality. Clinical efficacy for this modality was established.
- Preliminary data support *feasibility* of using video teleconferencing for a CPT group intervention to treat PTSD directly.
- Veterans reported an acceptance and willingness to use these services in the future & reported satisfaction & comfort this modality.

Future Directions



- More Clinical Applications
- More Randomized Clinical Trials (RCTs)
 - Examine Clinical, Process and Economic Outcomes
- Differential Cost & Clinical Effectiveness Studies
- Application in Ethnically and Culturally Diverse Populations
- Examine different modalities of care (i.e., phone, palm pilot)



QUESTIONS??