An RCT of a Primary Care-Based PTSD Intervention: Clinician-Supported PTSD Coach

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Spotlight on Mental Health CoEs-HSR&D Cyber Seminar Partnership Series

April 8, 2019

CIH Center for Integrated Healthcare

VA HEALTH CARE Defining EXCELLENCE in the 21st Century

Presentation Overview

- Describe important aspects of addressing PTSD in primary care.
- Describe how Clinician-Supported PTSD Coach was developed and our early findings in testing this treatment.
- Describe how Clinician-Supported PTSD Coach is currently being tested in a multisite randomized clinical trial.

Poll Question #1

- What is your primary role in VA?
  - clinician
  - researcher
  - Administrator, manager or policy-maker
  - Other

Poll Question #2

- How do you use mobile applications in your VA role?

(select all that apply)

  - I recommend that my patients used them on their own
  - I incorporate apps as a part of the services I deliver
  - I conduct research with mobile apps
  - I do not used mobile apps in VA
  - I use mobile apps in another way in VA

The Problem of PTSD in Primary Care (PC) Patients

- PTSD in PC patients in common:
  - 12% University PC clinics
  - 12-20% VA PC clinics
  - 23% Urban PC clinics
  - 13.5% across all PC settings
- PTSD is associated with a variety of negative outcomes
  - Physical: cardiovascular disease, hypertension, diabetes, etc.
  - Highly co-morbid with depression, substance use, and anxiety
  - Functional: unemployment, poverty, and relationship difficulties

Spoont et al., 2015 *JAMA*

Why Address PTSD in PC?

- Individuals often seek PC services, when they don't engage in mental health services
  - De factor Mental Health System
    - 55-70% of visits related to MH concerns (Robinson & Rietier, 2007)
  - Treatment Barriers: negative beliefs about treatment, stigma, problems navigating to a new clinic.
- Physicians struggle to recognize and treat PTSD (Munro et al., 2004)
- Screening
  - PC-PTSD-5 (Prins et al., 2016, *JGIM*)
  - PCL-5 (Bovin et al., 2016, *Psych Assess*)

Behavioral Health Treatment in PC

- A behavioral health provider functions as a member of PC team
- Open access allows for warm-handoffs
- Population-based care
  - Brief: 30-minute appointments, 1-5 sessions
  - Stepped-care
- Treatment Focus
  - Patient's most pressing concern & provider's referral reason
- Present-focused and solution-oriented
- Self-management is emphasized
- Communication with PC team is key

Possemato et al. (2018) *General Hospital Psychiatry*

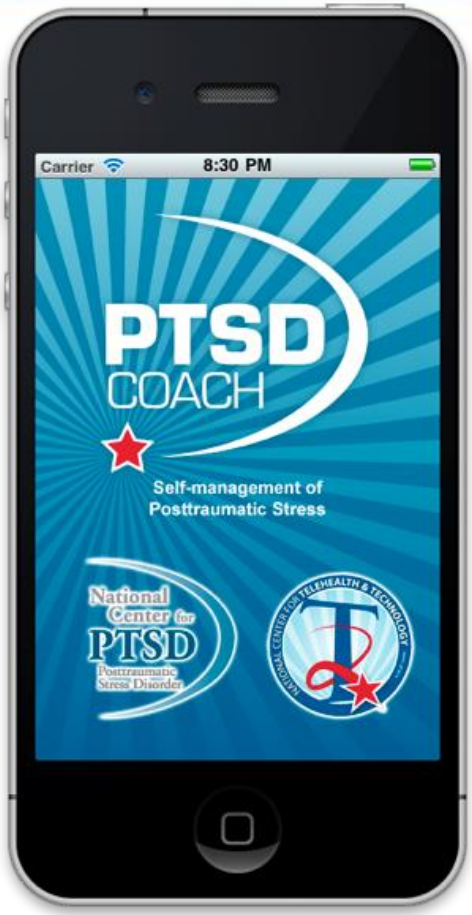
How to Address PTSD in PC?

- VA Medical Record Review (Possemato et al., 2011 *Psychological Services*)
  - Supportive, not evidence based
  - Psychoeducation and normalizing
  - Relaxation
  - Manage related symptoms: insomnia, anger, and depression
  - Referral Management
- Medication with Care Management
    - Research indicates that this may be less effective for PTSD than it is for depression (Meredith et al., 2016 *JGIM*; Schnurr et al., 2012 *JGIM*).

Need for Brief Psychotherapies for PTSD in PC

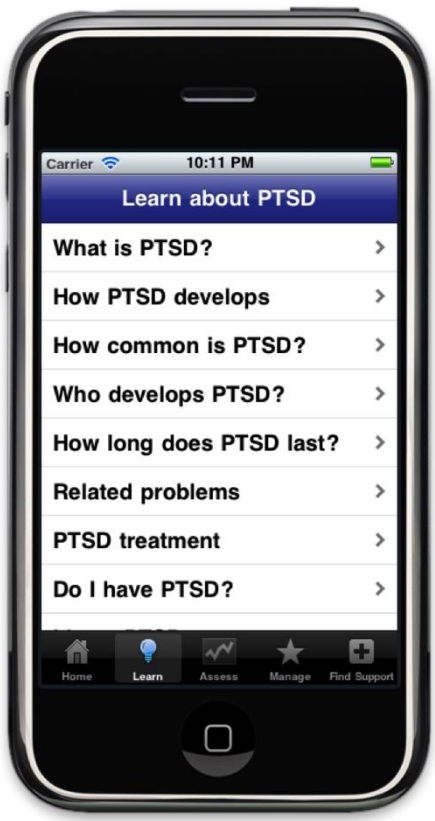
- PCMHI providers tend to want manuals and structured approaches
- Clinician-Supported PTSD Coach (CS PTSD Coach)
  - Support patients in learning about PTSD, treatment options, and using symptom management strategies
- Prolonged Exposure for PC
  - Four 30-minute appointments that include written, imaginal and in-vivo exposure
  - Good preliminary efficacy (Cigrang, et al., 2015 *J of Anx Dis*).

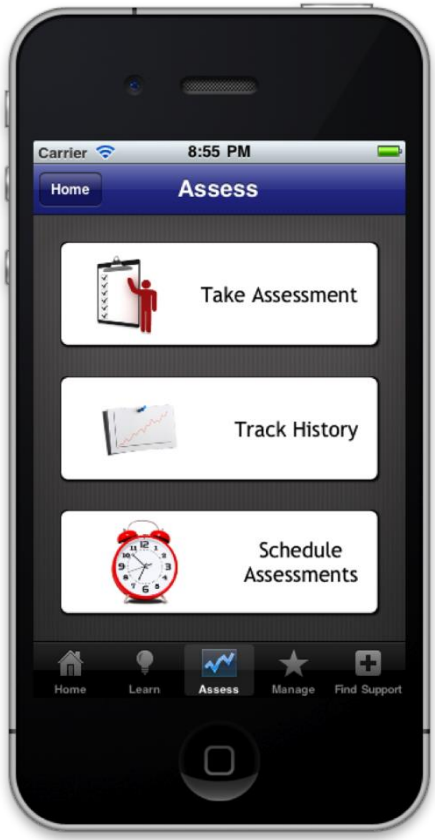
PTSD Coach

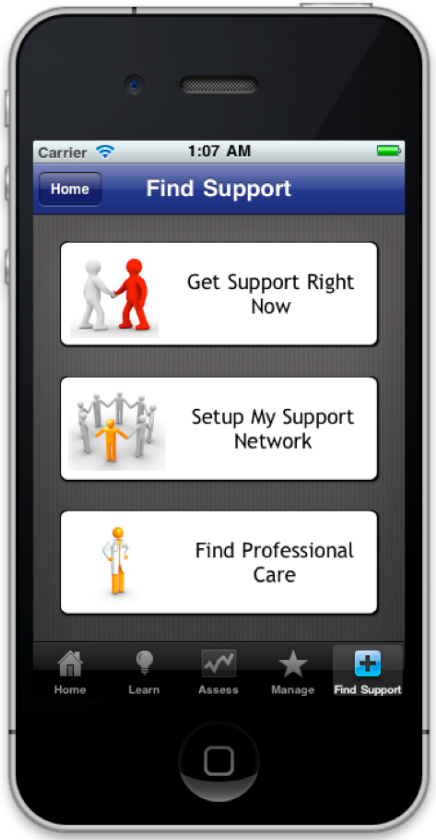


Hoffman, J. E., Wald, L. J., Kuhn, E., Greene, C., Ruzek, J .I., & Weingardt, K. (2011). PTSD Coach (Version 1.0). [Mobile application software]. Retrieved from http://itunes.apple.com.

Key Interventions







Tool Examples

Emerging Research on PTSD Coach

- Preliminary evaluation with Veterans (*N* = 45) showed that PTSD Coach is acceptable and perceived as helpful for PTSD symptoms (Kuhn, Greene, Hoffman, et al. 2014, *Military Medicine*)
- Pilot RCT (*N* = 49) with community trauma survivors showed that PTSD Coach is feasible, acceptable, and warrants further study to test its efficacy (Miner, Kuhn, et al., 2016, *Psych Trauma*)
- Full-scale RCT with community trauma survivors (*N* = 120) showed that PTSD Coach better than WL on PTSD (*d* = .41) and depression sxs (*d* = .45), and psychosocial functioning (*d* = .51) (Kuhn, et al., 2017, *JCCP*)
- Using novel data to understand PTSD Coach reach, reception, use, and impact in the wild (Owen, Jaworski, Kuhn, et al., 2015, *JMIR MH*)
  - Analyzed aggregate analytics data from 153,834 downloads in conjunction with qualitative analysis of 156 app store reviews
  - PTSD Coach has achieved substantial and sustained reach in the population, is being used as intended, results in decreased momentary distress, and has been favorably received

Clinician-Supported PTSD Coach

- Four 30-minute sessions focused on personalizing the symptom-management strategies for the participant's specific concerns.
  - Focus on one concern at a time and assigning the patients to use the app daily to manage that concern.
  - Focus on transitioning to other care if symptoms are still high at session 4.
- Early Studies:
  - Gathering stakeholder feedback on treatment development
  - Does the addition of clinician-support increase the efficacy of PTSD Coach?
  - Small pilot RCT (*N* = 20) that compares Clinician-Supported PTSD Coach to Self-Managed PTSD Coach

Study #1: Gathering Stakeholder Feedback

- Funded as an Local Initiated Project by Mental Health QUERI
- Aims:
  1. Gather preliminary feedback about the feasibility and acceptability of delivering CS PTSD Coach in PC,
  2. Gather information on factors that could support or hinder implementation of CS PTSD Coach in PC.
  3. Develop and refine a clinician manual for CS PTSD Coach that is responsive to VA provider and Veteran feedback.

Study #1: Methods

- VA PC providers and mental health leadership (*N* = 9) completed a survey and interview regarding implementation barriers and facilitators structured according to the Consolidated Framework for Implementation Research (CFIR).
- Clinicians who delivered CS PTSD Coach (*N* = 3) and patients (*N* = 9) who received it provided feedback on the intervention and implementation process.
- A structured, content-based, deductive coding system developed based on previous research with the CFIR model was used to code the data from the interviews

Study #1 Results: Facilitator Themes

PC and MH Leadership	CFIR Construct
CS PTSD Coach will help veterans overcome common barriers to receiving PTSD treatment	Patient needs & resources
CS PTSD Coach fits well into PC	Compatibility
CS PTSD Coach addresses a gap in current PC services	Tension for change
CS PTSD Coach will help PC patients transition to PTSD Specialty Care	Compatibility

Study #1 Results: Facilitator Themes

Veterans	CFIR Construct
1. CS PTSD Coach has an effective design (e.g., amount of information, tools, session number and format).	Design Quality and Packaging
2. Clinician support was important to engaging with the app.	Patient Engagement
3. Flexibility with session format and spacing between sessions facilitated completion.	Patient Needs & Resources
Clinicians	
1. Flexibility with the protocol is important.	Patient Needs & Resources

Study #1 Results: Barrier Themes

Leadership	**CFIR Construct**
Strong leadership support/ clinic champions needed.	Leadership engagement
PC staff need education about how to talk to their patients about PTSD.	Knowledge and beliefs about the intervention
Clinicians	
Manual lacked detail on collaborative goal setting.	Patient Engagement
Homework was complicated.	Complexity of the intervention
Phone sessions were difficult but modality was important to patients.	Patient needs & resources

Study #2: Pilot RCT in VA PC

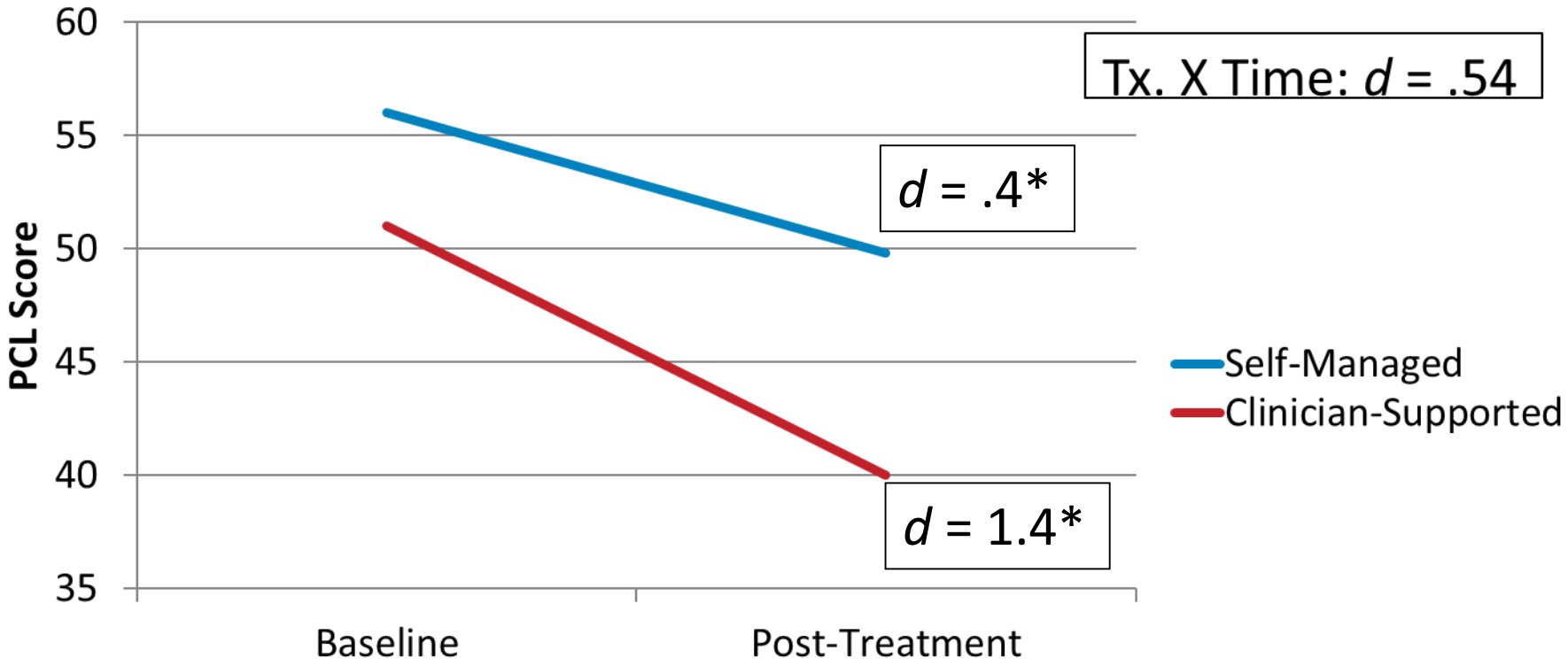
- Participants:
  - VA PC patients who scored ≥44 on the PTSD Checklist-Specific (PCL).
    - Excluded: receiving or interested in receiving specialty mental health care.
- Conditions:
  - Clinician-Supported: 4 brief (20-30 min.) manualized sessions with PC-MHI provider over 8 weeks
  - Self-Management: 1 in-person, 10-minute session on how to use the app.
- Hypotheses:
  - Both conditions would lead to improvements in PTSD sxs
  - CS PTSD Coach would lead to greater reductions in PTSD sxs and increases in mental healthcare initiation compared to SM PTSD Coach.

Possemato, K., Kuhn, E., et al. (2015). *General Hospital Psychiatry, 38,* 94-98.

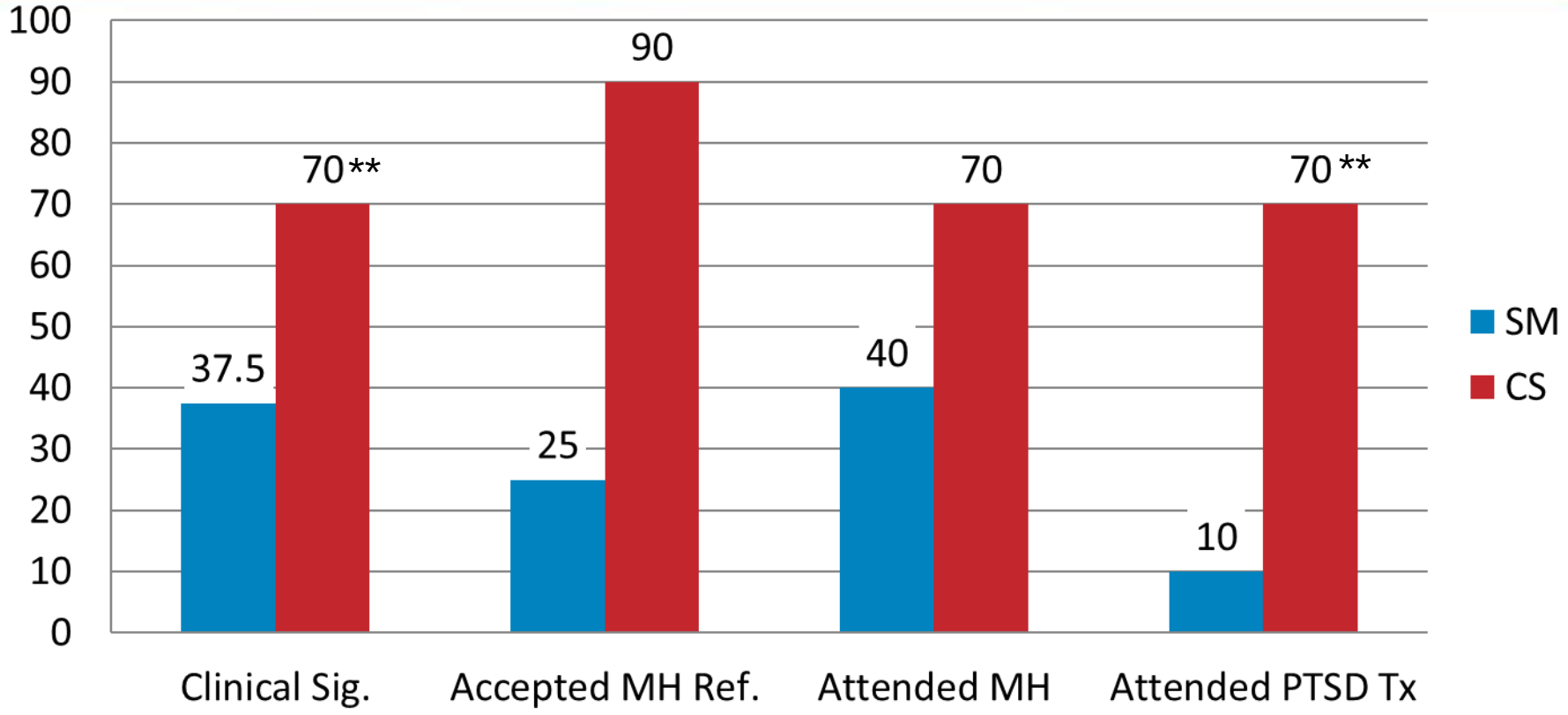
Participants (N = 20)

Socio-demographic	*n* (%)	Mean (SD)
Male	19 (95)	
Age		42 (12)
White Race	13 (65)	
Employed	9 (45)	
OEF/OIF/OND Veterans	18 (90)	
PCL Total		53.5 (11.5)

Potential Efficacy



Clinical Significance and MH Initiation



Conclusions

- PTSD Coach in PC is feasible and possibly helpful.
- Adding clinician support may improve outcomes and initiation of mental health services.
- CS PTSD Coach may strike a good balance between the convenience and self-autonomy offered by mobile interventions and the support and guidance offered through brief PC-based treatment.
- Results offer promise for enhanced delivery of PTSD services in PC and warrant a larger-scale RCT.

VA HSR&D Merit (IIR-14-288)
PIs: Kuhn & Possemato

Study Overview:

- Conduct a two-site, two-arm pragmatic RCT (*N* = 260) in VA PC
- Include Veterans with significant PTSD symptoms
- Randomized to
  - PC-MHI Treatment as Usual (PC-MHI TAU) or
  - Clinician-Supported PTSD Coach (CS PTSD Coach).
- Assessments will occur at baseline, post-treatment (week 8), and 16- and 24-week follow-ups.

Duration of Project: 4 years (2017-2020)

Total Budget: $1.1 million

Participants

Inclusion Criteria:

•Enrolled in PC at VA Syracuse or Palo Alto healthcare systems

•Traumatic event on the Criterion A screener + ≥33 on the PCL-5

Exclusion Criteria

•Gross cognitive impairment

•Current symptoms of mania or psychosis

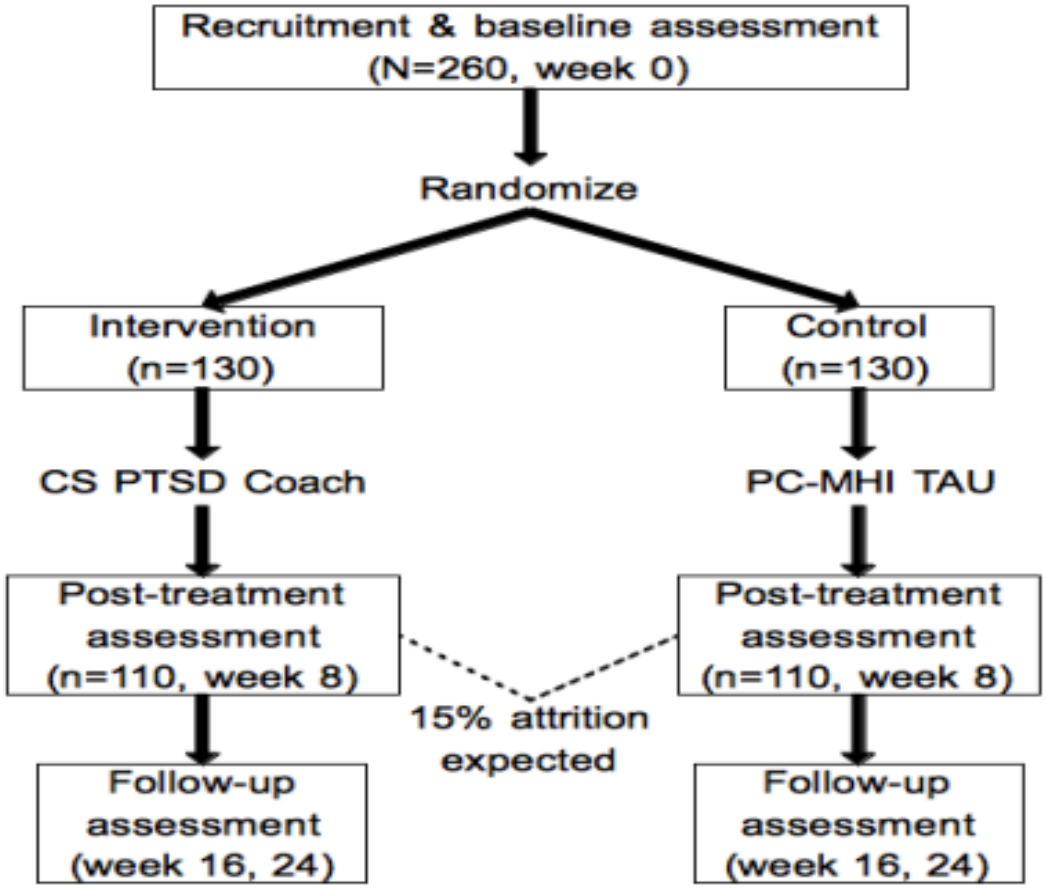
•More pressing concerns that need to be addressed first (i.e., suicide attempt in the last two months or current intent to commit suicide)

•Already receiving psychotherapy or MH counseling for PTSD outside of PC

•Started or changed dose of a psychotropic medication for PTSD in the last two months that was prescribed outside of VA PC

•Voice a preference to be directly referred to MH specialty care

Flow Through Study



Specific Aims

Aim 1: Investigate the impact of CS PTSD Coach on PTSD severity.

Aim 2: Investigate the impact of CS PTSD Coach on engagement in specialty mental health care.

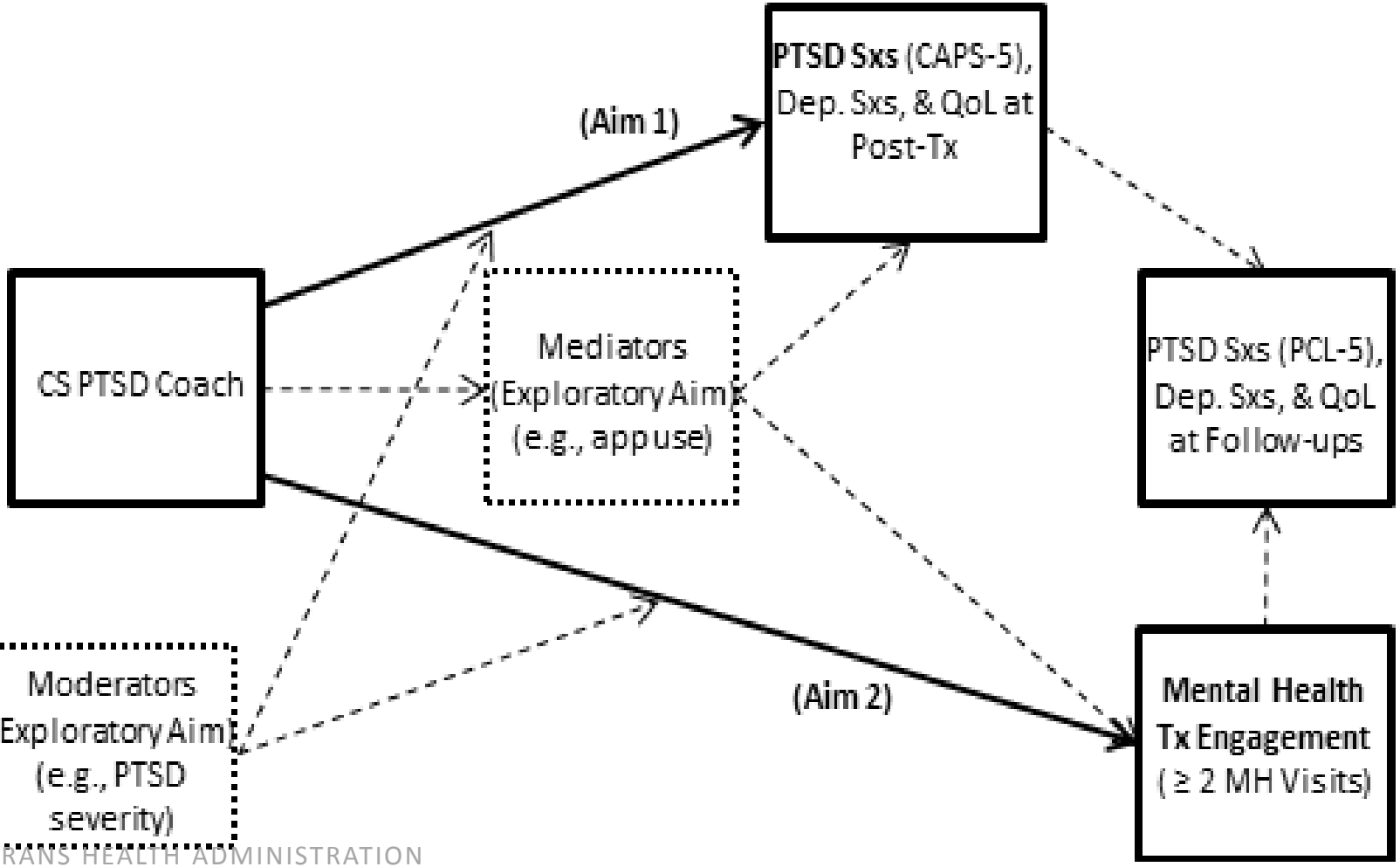
Aim 3: Investigate patient and provider satisfaction with CS PTSD Coach.

Exploratory Aims:

Explore potential mediators *(*i.e., objective app use, coping self-efficacy) *and* moderators (e.g., baseline PTSD severity and co-morbid psychiatric symptoms) of outcomes.

Explore trajectories of change over the follow-up period to examine if specialty mental health treatment engagement or continued app use interacts with symptom change.

Conceptual Model of CS PTSD Coach Effects



Progress to Date: Baseline Comparisons Between Conditions

	TAU (*n* = 50)			CS PTSD Coach (*n* = 50)			
	N	Mean	%/SD	*N*	Mean	%/SD	p-value
PCL-5	50	46.22	10.64	50	47.62	10.11	0.502
Age	50	50.73	15.53	50	50.83	15.79	0.975
Women	6		12.2%	7		14.3%	1.000
Minority	23		44.9%		20	37.5%	0.961
By site							
Palo Alto	17		51.52%	16		48.48%	
Syracuse	33		49.25%	34		50.75%	

Progress to Date: Aggregated Outcomes at Each Time Point

	Baseline			Post-Treatment (8 Weeks)			Follow-Up 1 (16 Weeks)			Follow Up 2 (24 Weeks)		
	N	Mean	*SD*	*N*	Mean	*SD*	*N*	Mean	*SD*	*N*	Mean	*SD*
CAPS-5	100	28.44	11.13	79	23.91	11.28						
PCL-5	100	46.92	10.35	85	38.77	14.83	67	35.49	15.24	63	34.49	14.68

Challenges

- Recruitment
  - Opening recruitment in new clinics (Palo Alto)
  - Maintaining enrollment rates in established clinics (Syracuse)
  - Solution: We have spread to 5 CBOCs
- Keeping consistency among research staff at multiple sites
  - Weekly joint meetings
  - PIs determine when flexibility is needed to meet site needs
- Maintaining staffing across a 4-year study
  - Especially challenging because we use interns and practicum students as clinicians and assessors.
- Maintaining blinded assessors within a small study team
  - Blinding all materials for joint meeting

Questions/ Comments

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National Center for PTSD

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