

Development and Evaluation of a Brief, Modular, Cognitive-Behavioral Intervention for Anxiety in Primary Care

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Supporting, Evaluating, and Researching Veterans' Integrated Care Experience

Thanks to our SERVICE Lab Team!



The Problem



Anxiety Treatment in Primary Care

- Most often pharmacological^{1,2}



Anxiety Treatment in Primary Care

- Most common behavioral techniques used in PCMH¹:
 - Psychoeducation
 - Relaxation training
 - Supportive therapy
- Need effective brief behavioral anxiety interventions that are compatible with PCMH practice²



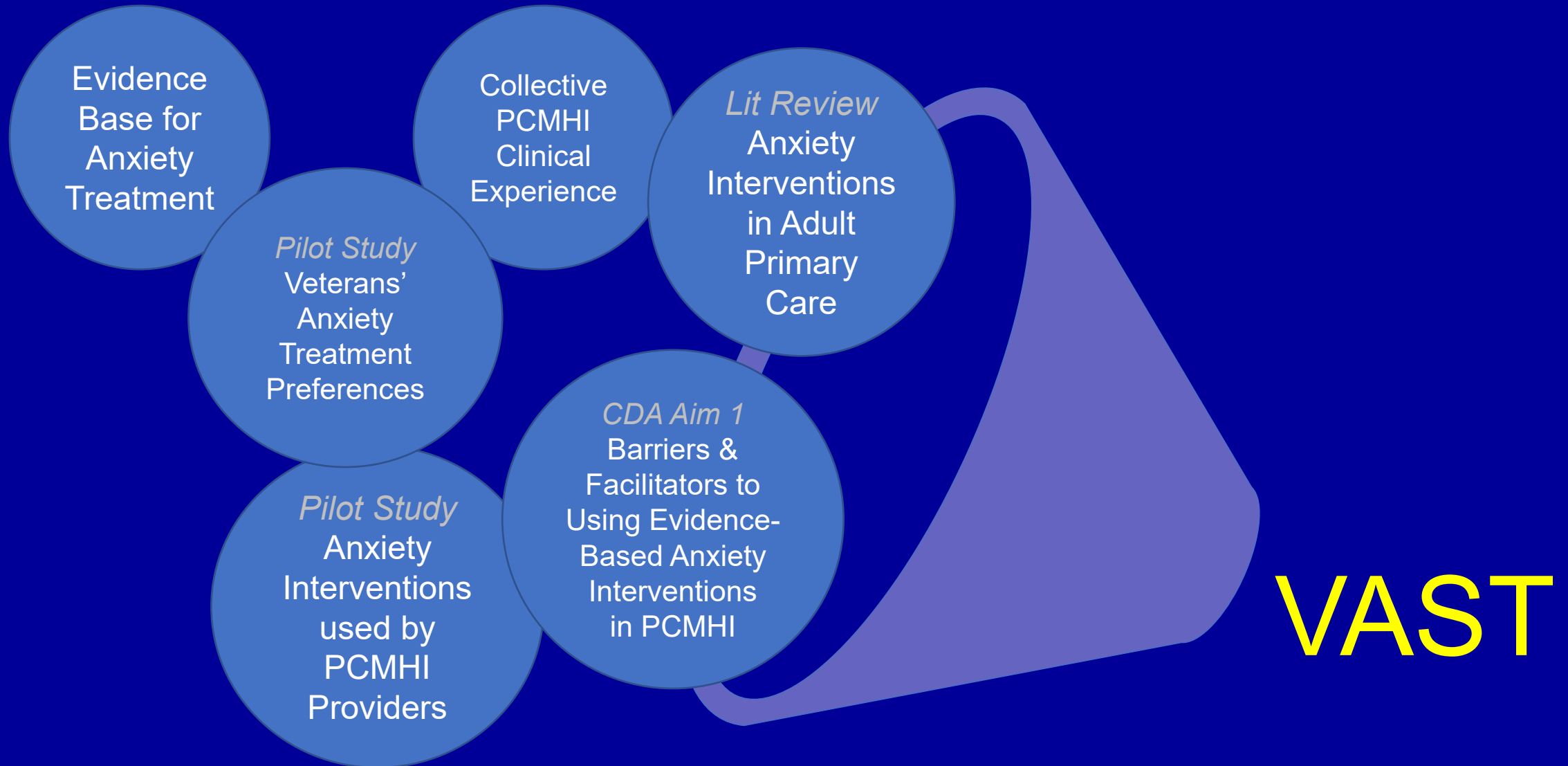
My CDA2 Research

- Goal: effective brief behavioral anxiety intervention for VA PCMH settings
 - Veteran-centered
 - Feasible for providers

HSR&D CDA2 Specific Aims

- **Aim 1:** Examine PCMHI providers' usual care practices in the behavioral treatment of anxiety
- **Aim 2:** Develop an (adapted) brief anxiety intervention for PCMHI, then use patient and provider feedback to refine the treatment manual
- **Aim 3:** Conduct a pilot RCT of the adapted anxiety intervention compared to PCMHI usual care

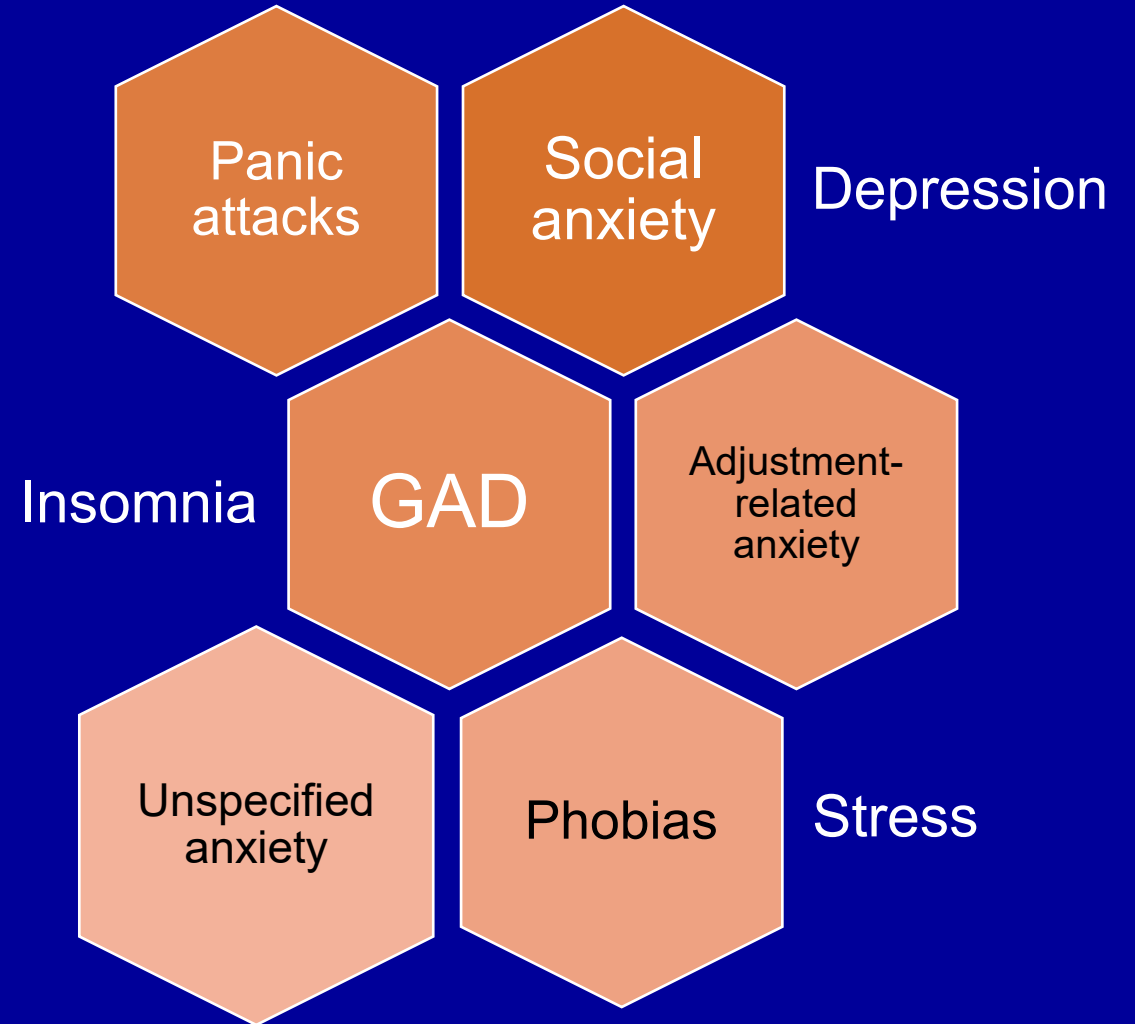
Developing the Intervention



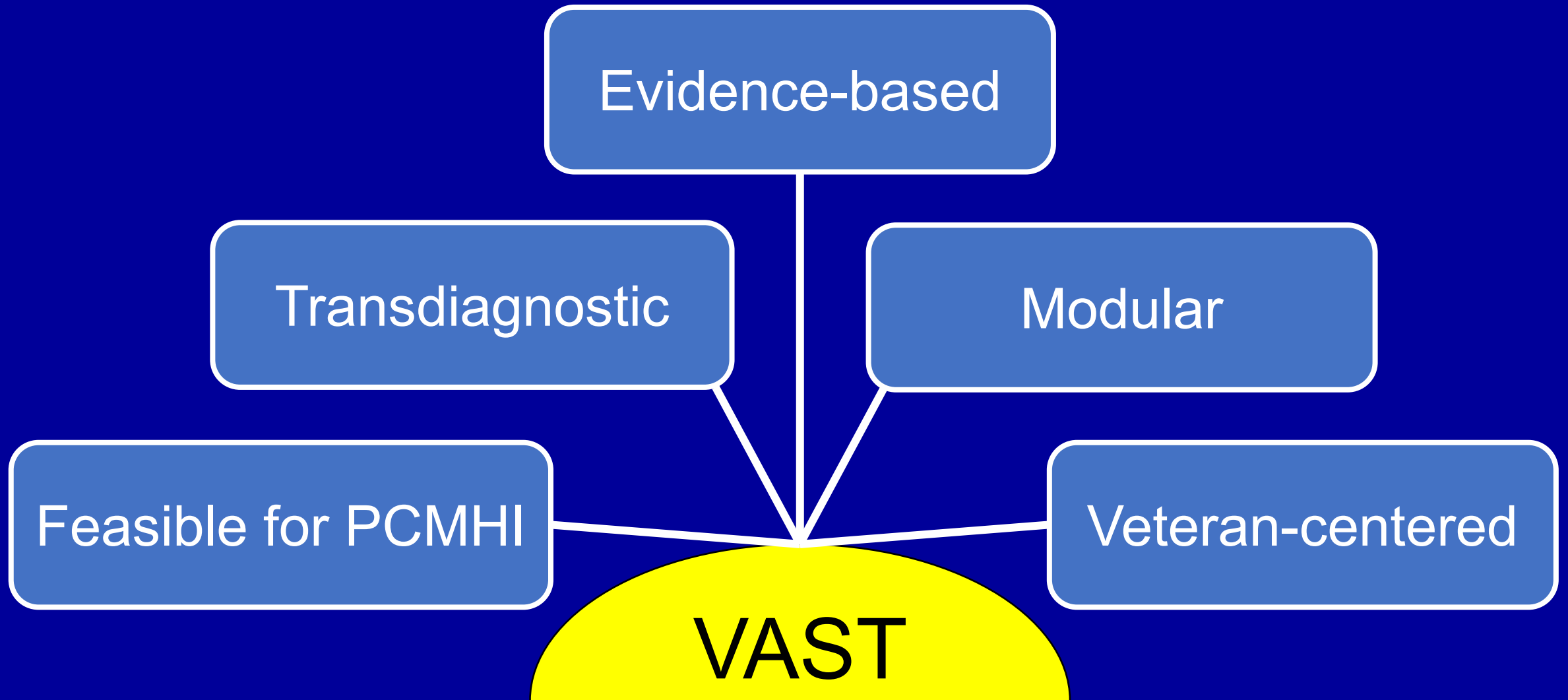
Who is VAST for?

Patients with

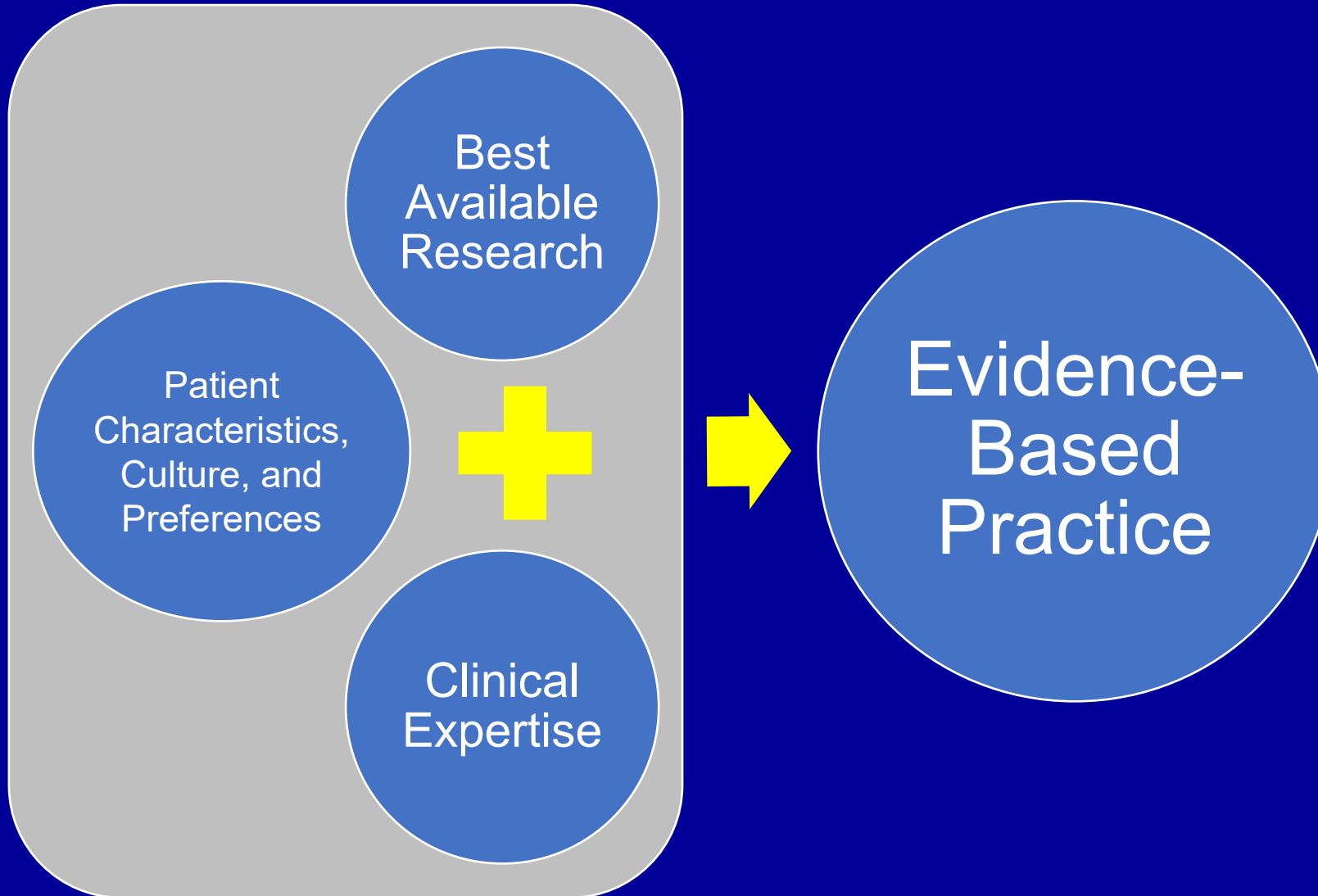
- Any anxiety presentation (other than PTSD or OCD)
- Subthreshold, mild, or moderate severity
- Comorbid symptoms/concerns



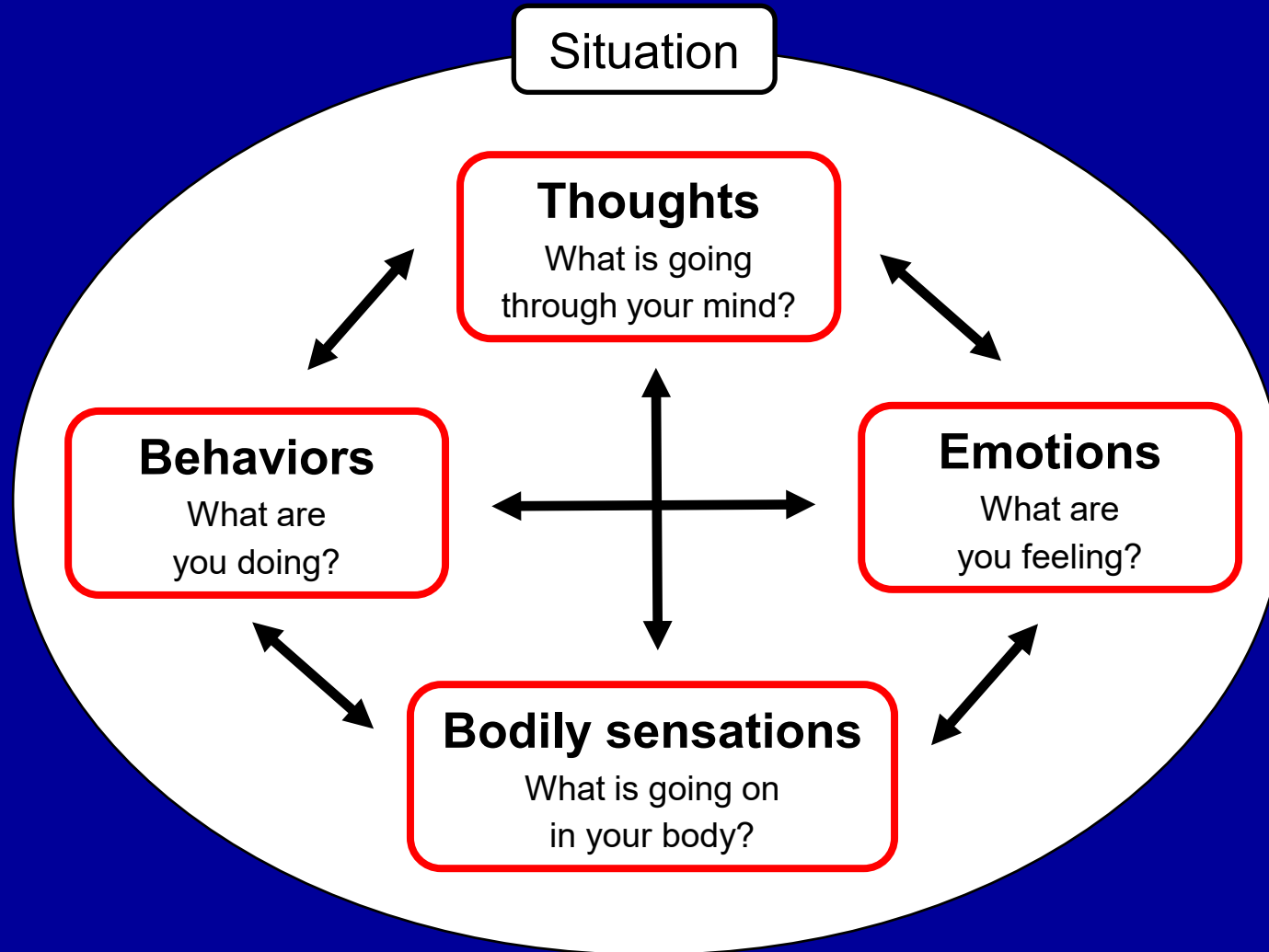
Key Characteristics of VAST



VAST is Evidence-Based



VAST is Grounded in the CBT Model

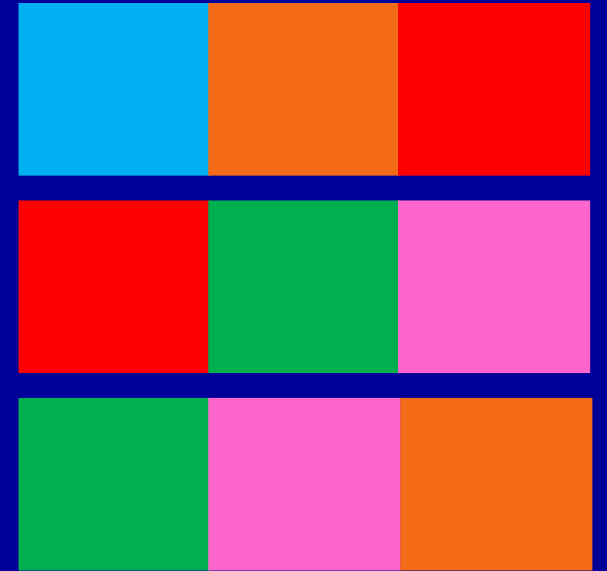


VAST is Transdiagnostic

- Targets underlying mechanisms across similar disorders
- Theoretical reasons
- Pragmatic reasons

VAST is Modular

- Different combinations of treatment components delivered in different orders¹
- Permits flexibility in clinical decision-making and tailoring to individual patients²
- Many advantages over standard intervention designs^{3,4,5}



VAST Modules

Name	Essence
Understand Anxiety	Assessment & psychoeducation
Identify Anxious Thinking	Cognitive restructuring
Relax Your Body	Relaxation training
Face Your Fears	Exposure
Live in the Here & Now	Mindfulness meditation
Improve Your Mood	Behavioral activation
Improve Your Sleep	Stimulus control for sleep
Manage Your Stress	Healthy stress management
Maintain Your Progress	Relapse prevention planning

VAST is Feasible for PCMH

Education & Skills to Improve Functioning¹

5 A's Approach^{2,3}

Focused Functional
Assessment^{4,5}

Measurement-Based
Care^{6,7}

F2F or
Telehealth

SMART Goals

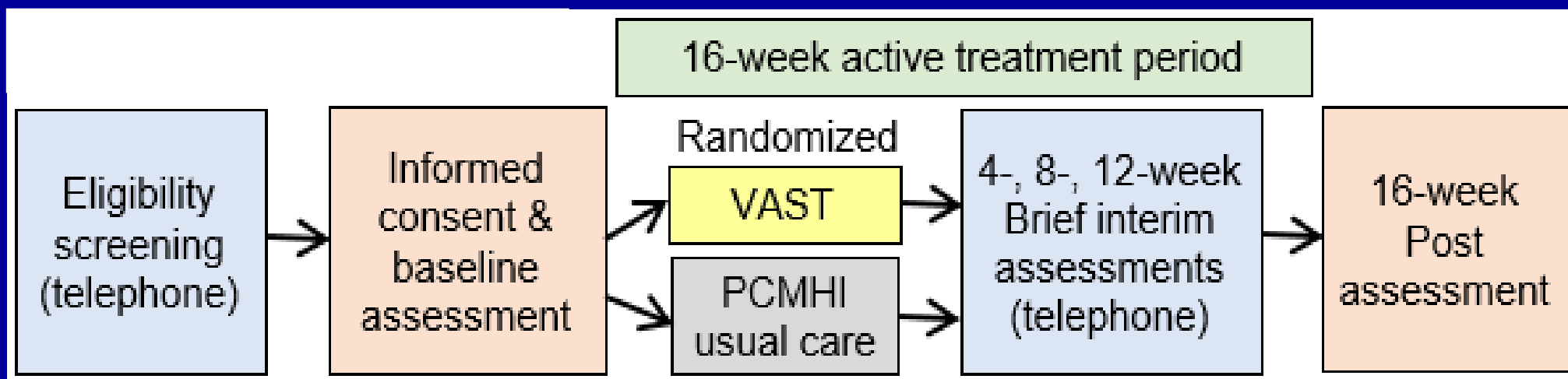
Collaborative Therapeutic Style⁸

VAST is Veteran-Centered

- Tailored to the Veteran population
 - Responsive to Veterans' anxiety treatment preferences^{1,2}
 - Military/Veteran terminology, examples, graphics, etc.³
- Personalized to the individual patient^{4,5}
 - Personalize didactic material
 - Collaboratively select modules of interest

Pilot RCT Methods

- Hybrid I RCT¹: VAST vs. PCMHI usual care
- Case finding & direct referrals



Eligibility Criteria

- Inclusion criteria
 - Veteran
 - Age \geq 18 years
 - Seen in primary care at SYR VAMC in past 12 months
 - Screen + for current anxiety symptoms¹ (\geq 8 on GAD-7²)

Eligibility Criteria

- Exclusion criteria
 - Unable to communicate in English or provide informed consent¹
 - Hearing impairment precluding telephone screening
 - Diagnosis of OCD or SMI in Problem List
 - Encounter Dx of PTSD in past 2 years or + PC-PTSD-5 screen²
 - Current psychotherapy/counseling for anxiety/depression
 - Severe depressive symptoms (≥ 20 on PHQ-9)³
 - Imminent risk of suicide
 - Started anx/dep med or had dosage change in past 30 days⁴

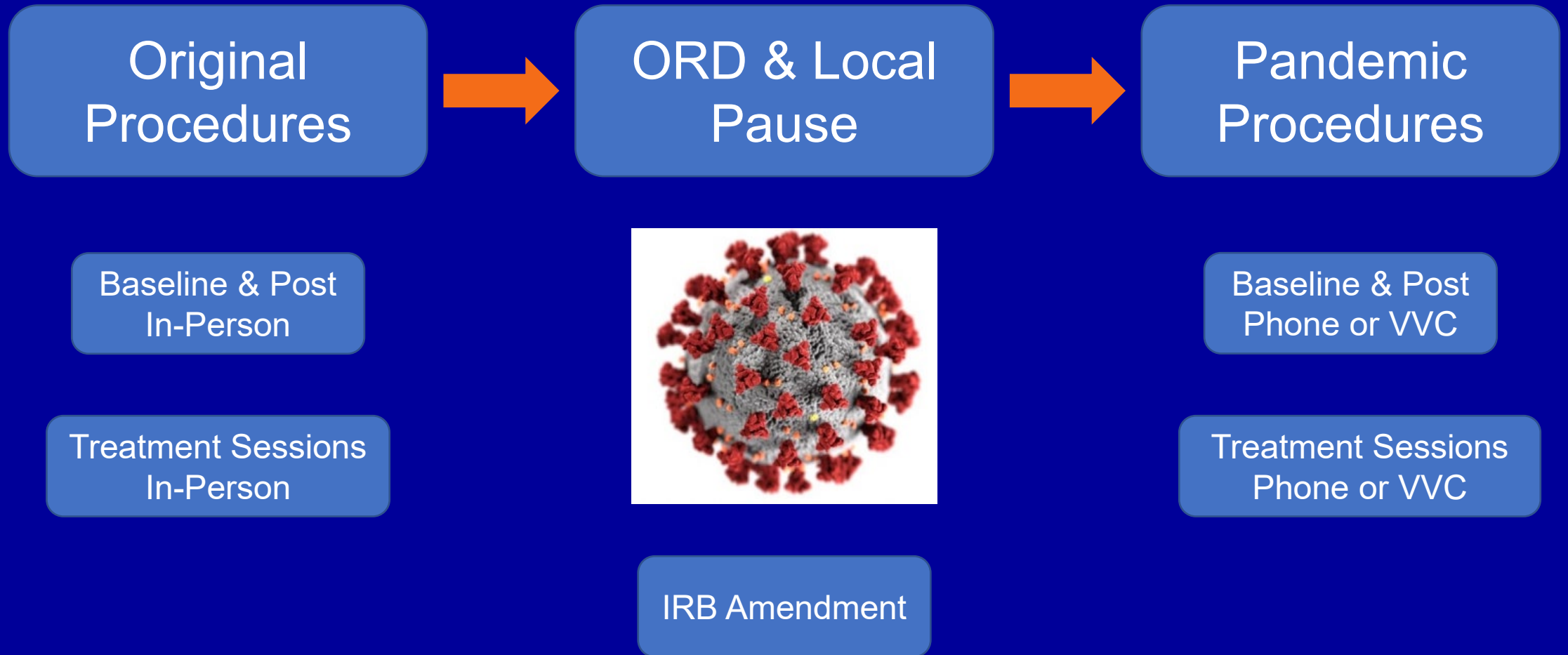
Participants

- $N = 35$
 - 18 PCMH Usual Care
 - 17 VAST Intervention
 - 86% men
 - 82% White, 14% Black, 11% Hispanic/Latino/a
 - M age = 47 (16) years, range 23-77
- GAD-7** $M = 12.3$ (3.7)
PHQ-9 $M = 11.0$ (4.8)

Study Therapists

- 3 men, 2 women
- 5 psychology interns & fellows
- Current or prior PCMHl experience
- Training: 5 hours of didactics + role play
- Group supervision

COVID-19 Pandemic



Study Retention

Condition		Baseline	4 weeks	8 weeks	12 weeks	Post 16 weeks
PCMHI Usual Care	<i>n</i>	18	18	18	17	17
	%		100	100	94	94
VAST	<i>n</i>	17	16	14	13	11
	%		94	82	76	65
Overall	<i>n</i>	35	34	32	30	28
	%		97	91	86	80

Measures – Feasibility

- Patients

- Engagement in VAST (attend ≥ 1 session)
- Retention in VAST (complete ≥ 4 sessions)
- Comprehension, engagement, and resistance to session material*
- Homework completion*

- Therapists

- Session data – number, frequency, duration
- Feasibility of delivering module in 30-minute PCMHI sessions*
- Overall feasibility of VAST for PCMHI¹
- Fidelity of VAST delivery: adherence & competence
- Implementation barriers & facilitators

Measures – Acceptability

- Patients

- Expectancy Rating Scale¹
- Working Alliance Inventory-Short Form Revised²
- Client Satisfaction Questionnaire-8³
- Satisfaction with VAST format
- Acceptability interview

- Therapists

- Satisfaction with session material*
- Appropriateness of session material for PCMH¹*
- Appropriateness of VAST for PCMH⁴
- Acceptability of VAST in PCMH⁴

Measures – Effectiveness

- Baseline to post
 - Generalized Anxiety Disorder-7 (GAD-7)¹
 - Patient Health Questionnaire-9 (PHQ-9)²
- All 5 timepoints
 - Depression Anxiety Stress Scales-21 (DASS-21)³
 - Overall Anxiety Severity and Impairment Scale (OASIS)⁴

Analyses

- Feasibility & acceptability
 - Descriptive statistics
 - Independent samples *t*-tests
 - Rapid qualitative analysis¹
- Effectiveness
 - ANCOVA for GAD-7 & PHQ-9 $\alpha = .05$
 - Multi-level modeling (intent to treat) for DASS-21 & OASIS

PCMHI Usual Care

- 6 providers delivered 33 sessions to 13 patients
 - 27 audio recordings, 3 self-report forms, 3 missed
 - $M = 34$ (11) minutes

- Elements of VAST used infrequently and at low dosage:

Intervention Technique	Present in Session	Dose (Minutes)
Exposure	0	-
Cognitive therapy	40%	2
Relaxation training	40%	3
Mindfulness meditation	17%	1
Behavioral activation for mood	33%	2
Stimulus control for sleep	13%	1

Feasibility

Condition	Engagement in Treatment (≥ 1 session)	# of Sessions Overall ($N=35$)	# of Sessions Engaged ($N=28$)
VAST Intervention	88%	4.7 (2.2)	5.3 (1.4)
PCMHI Usual Care	72%	1.8 (1.6)	2.5 (1.3)
	<i>ns</i>	$p < .001$	$p < .001$

- Retention in VAST
 - 87% completed ≥ 4 sessions
 - 80% completed max of 6 sessions

Feasibility

- VAST Session data
 - Number: $M = 5.3$ (1.4) sessions (range: 2-6)
 - Frequency: $M =$ every 1.8 (0.6) weeks (range: 1-3.5)
 - Duration: $M = 42$ (6.9) minutes (range: 30-60)
- Feasibility of module delivery in 30-minute PCMHI sessions*
 - $M = 4.2$ (0.7) out of 5 ($N = 80$ sessions)
- Overall feasibility¹ of VAST for PCMHI
 - $M = 4.7$ (0.4) out of 5

**Therapists completed ratings after each session
Scale: 1 (extremely low) to 5 (extremely high)*

Feasibility

Module usage
& duration
(minutes)

VAST Module	<i>n</i>	<i>M</i>	<i>SD</i>	Range
Understand Anxiety	15	47	6.8	35-60
Identify Anxious Thinking	13	39	6.3	30-48
Relax Your Body	9	46	4.2	40-52
Face Your Fears	5	42	7.0	33-50
Live in the Here & Now	8	44	4.8	34-49
Improve Your Mood	9	46	5.3	36-55
Improve Your Sleep	5	43	5.1	35-48
Manage Your Stress	3	35	4.5	30-39
Maintain Your Progress	13	37	6.8	30-55
Overall	80	42	6.9	30-60

Feasibility

Therapist ratings completed after each session
Scale: 1 (extremely low) to 5 (extremely high)

		Comprehension			Engagement			Resistance			Homework		
	<i>n</i>	<i>M</i>	<i>SD</i>	Range	<i>M</i>	<i>SD</i>	Range	<i>M</i>	<i>SD</i>	Range	<i>M</i>	<i>SD</i>	Range
Understand Anxiety	15	4.5	0.5	4-5	4.6	0.6	3-5	1.3	0.5	1-2	.	.	.
Identify Anxious Thinking	13	4.5	0.5	4-5	4.9	0.4	4-5	1.3	0.9	1-4	3.9	1.4	1-5
Relax Your Body	9	4.9	0.3	4-5	4.9	0.3	4-5	1.1	0.3	1-2	4.2	0.8	3-5
Face Your Fears	5	4.8	0.4	4-5	4.8	0.4	4-5	1.6	1.3	1-4	4.0	1.4	2-5
Live in the Here & Now	8	4.6	0.5	4-5	4.9	0.4	4-5	1.3	0.7	1-3	4.0	0.9	3-5
Improve Your Mood	9	4.4	0.7	3-5	4.6	0.7	3-5	1.7	1.0	1-4	3.9	1.1	2-5
Improve Your Sleep	5	4.4	0.5	4-5	4.6	0.5	4-5	1.0	0.0	1-1	4.0	1.7	1-5
Manage Your Stress	3	5.0	0.0	5-5	5.0	0.0	5-5	1.0	0.0	1-1	4.3	0.6	4-5
Maintain Your Progress	13	4.9	0.3	4-5	5.0	0.0	5-5	1.0	0.0	1-1	4.3	0.8	3-5
Overall	80	4.6	0.5	3-5	4.8	0.5	3-5	1.3	0.7	1-4	4.1	1.1	1-5

Feasibility

- Fidelity of VAST delivery

- 3 raters rated $N = 79$ sessions

- 29 double rated to assess inter-rater reliability

- Adherence Kappa = .66 (substantial agreement)¹

- Competence ICC = .63 (moderate agreement)²

- Adherence

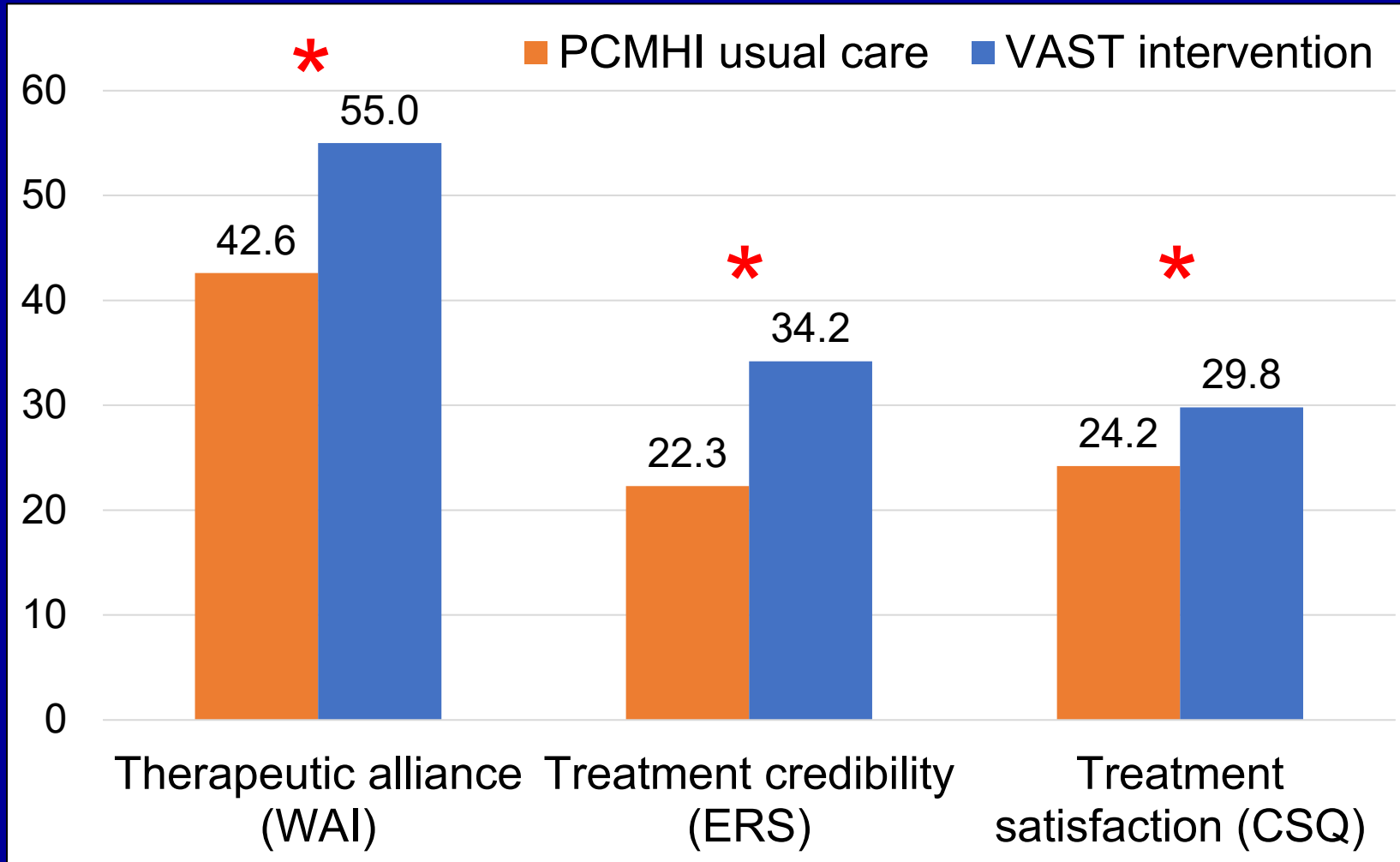
- $M = 86\%$ (12%) of essential components delivered

- Competence

- $M = 3.2$ (0.4) out of 4

- 1 Inadequate skills
- 2 Some deficiencies
- 3 Capable skills
- 4 Proficient

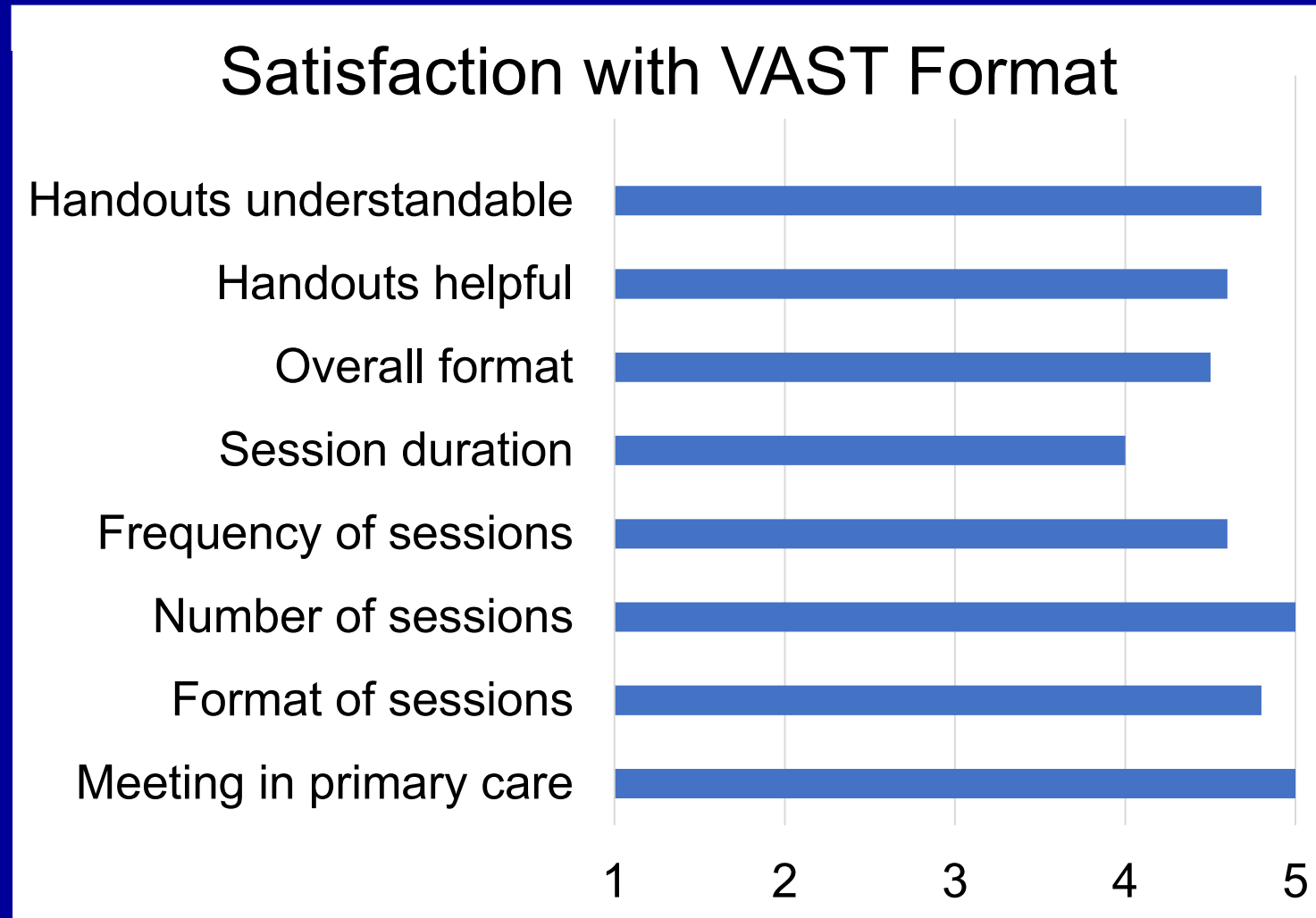
Acceptability – Patients



* $p < .01$

Acceptability – Patients

Scale: 1 (not at all helpful / satisfied)
to 5 (extremely helpful / satisfied)



Acceptability – Patient Interview

General impressions

“It was self-paced. I worked on things that I wanted to work on. I was able to practice things in session, then work on for two weeks between sessions. It didn’t feel rushed or like too much was crammed in. It was focused on me and didn’t feel rushed.”

“It was good, informative. Makes you think about how you react to stuff.”

“It’s helpful, knowledgeable, something you have to apply – you can’t just leave it at the session.”

Module choice

“I liked it. I was guided in the right direction of what to pick but still given the choice. Options are great, helps you feel in control.”

“Yes, it definitely is beneficial. I think as a whole if you’re interested in something, you’ll be more engaged, so choice is important.”

“It shouldn’t be up to me. This should all be done by the therapist.”

Acceptability – Providers

- Therapist ($n = 5$) ratings of 80 sessions with 15 Veterans
 - Satisfaction* with material: $M = 4.9$ (0.3), range: 4-5
 - Appropriateness* of material for PCMHI: $M = 5$ (0.2), range: 4-5
- Overall Appropriateness¹ of VAST for PCMHI
 - $M = 4.7$ (0.4) out of 5
- Overall Acceptability¹ of VAST in PCMHI
 - $M = 4.8$ (0.4) out of 5

**Therapists completed ratings after each session
Scale: 1 (extremely low) to 5 (extremely high)*

Therapist Comments

“**The modular approach**, which offers patients and providers a chance to tailor the intervention to a patient's unique experience of anxiety. I like the focus on evidence-based, skills-focused interventions. The manual is also comprehensive and detailed, which **makes delivering the intervention very straightforward and easy.**”

“Patients like it and grasp the material. **It is nice to have the structure while still allowing patients to have their say in treatment by choosing their own modules.**”

“The manual is easy to use after some practice, and **the modular format seems to be really appealing to Veterans...** I appreciate that it's anchored in CBT, but seems to be easy to cast with more of an ACT bent... Overall it just feels like a really good fit for PCMHI.”

“It is easy to utilize, being well organized and providing concise yet thorough guidance for administering each module. **It allows for teaching of a wide variety of skills to Veterans and makes it clear how to tailor specific modules to the needs and capabilities of specific Veterans.**”

“**I love the modular approach and the balance** between patient input and provider recommendations. **I also really like the structure of the manual,** interventions included, link to CBT model in every session, and the handouts.”

Implementation Barriers & Facilitators

Barriers

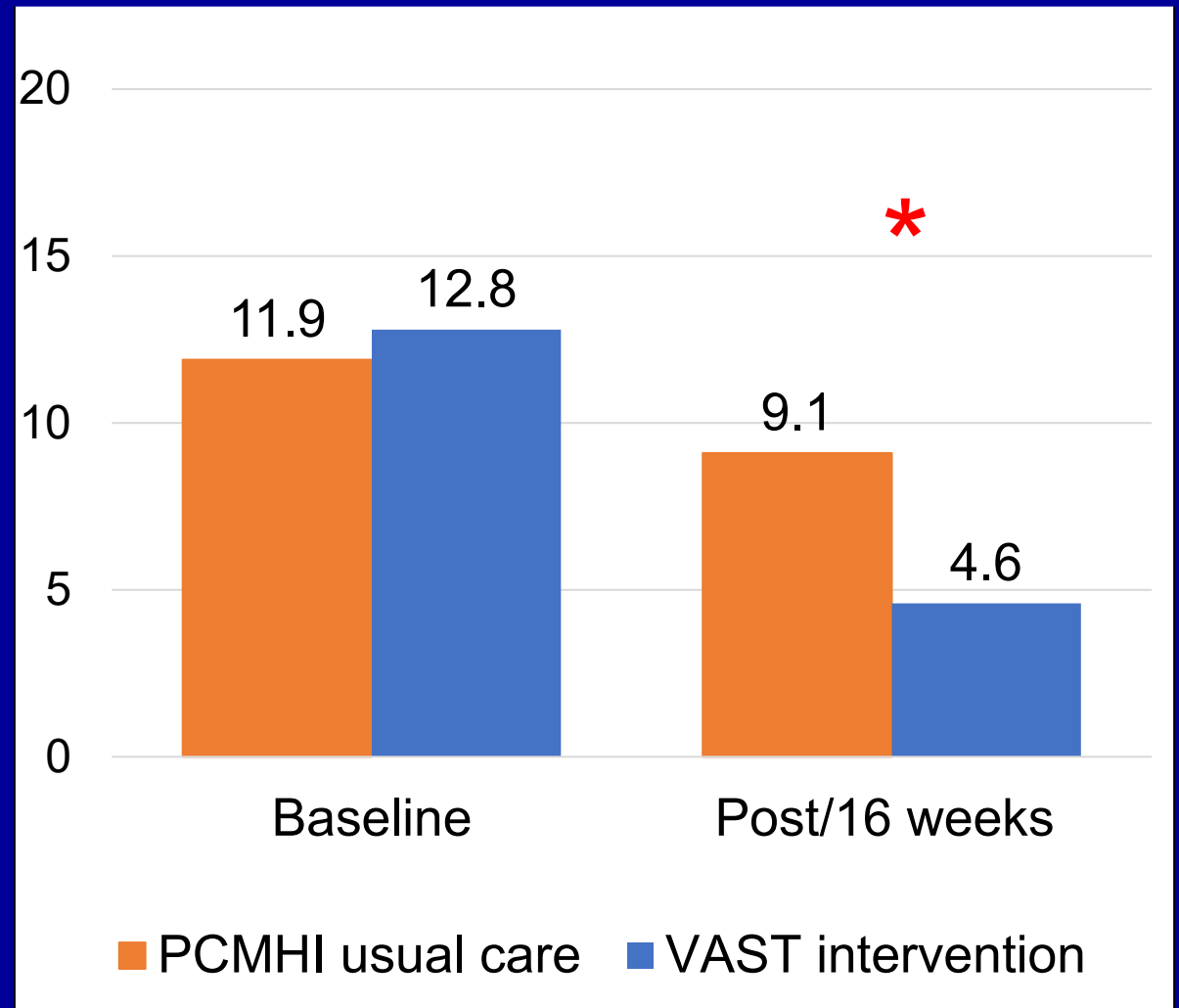
- 30-minute sessions
- Lack of referrals

Facilitators

- VAST manual & handouts
- Offering consultation

Effectiveness

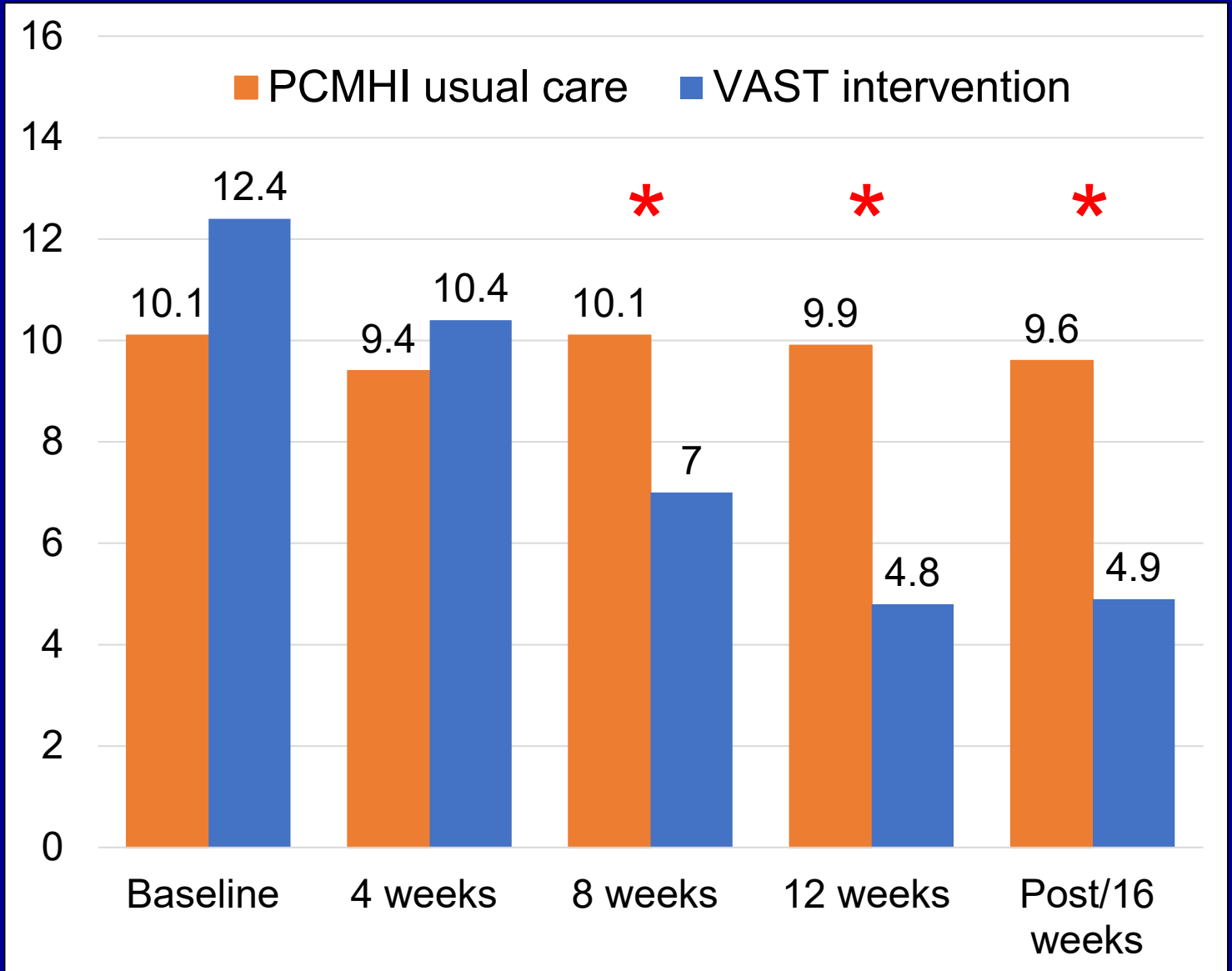
- GAD-7
- Anxiety symptoms
- ANCOVA controlling for baseline score
- $p = .035$



Effectiveness

- DASS Anxiety
- Anxiety symptoms

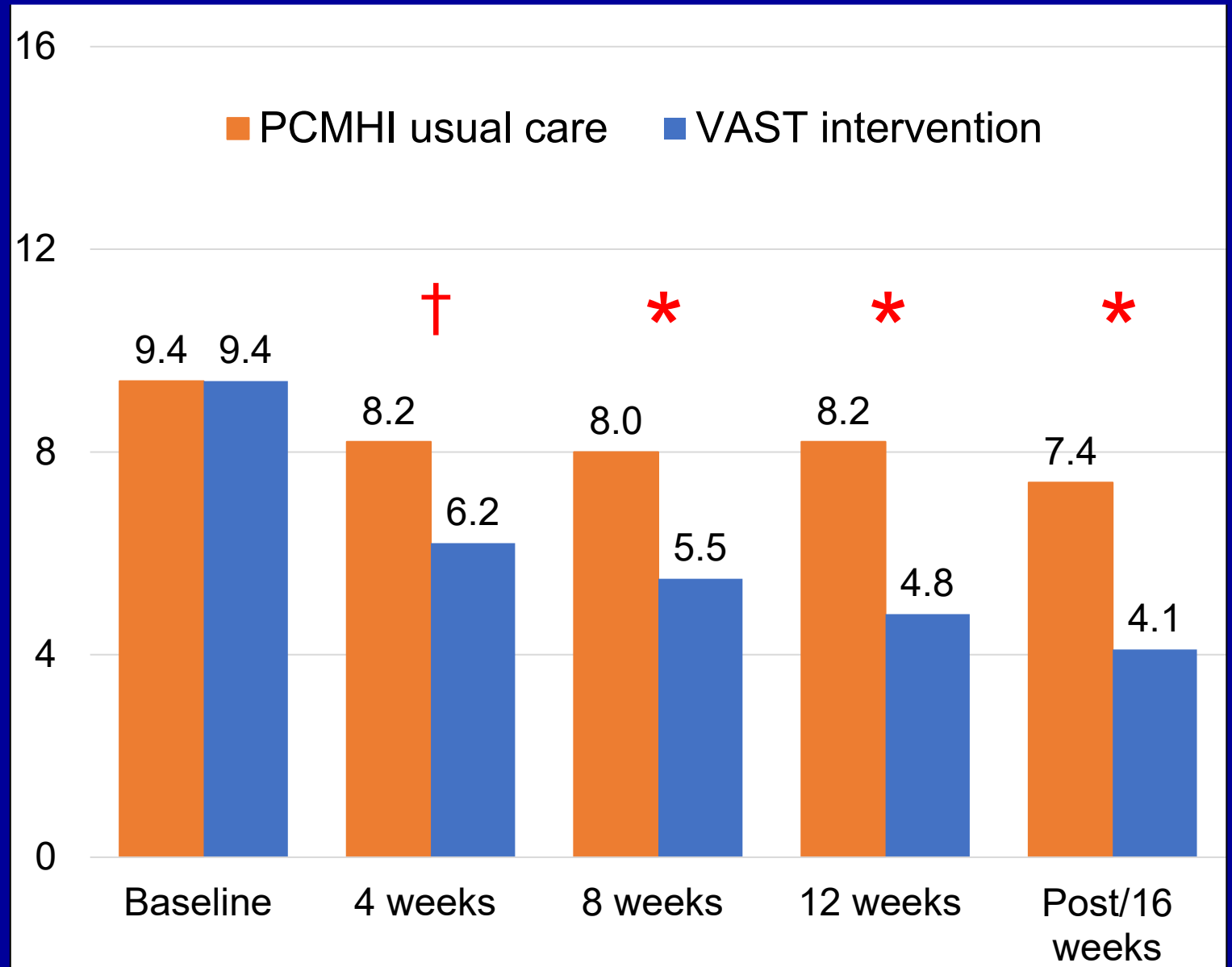
* $p < .05$



Effectiveness

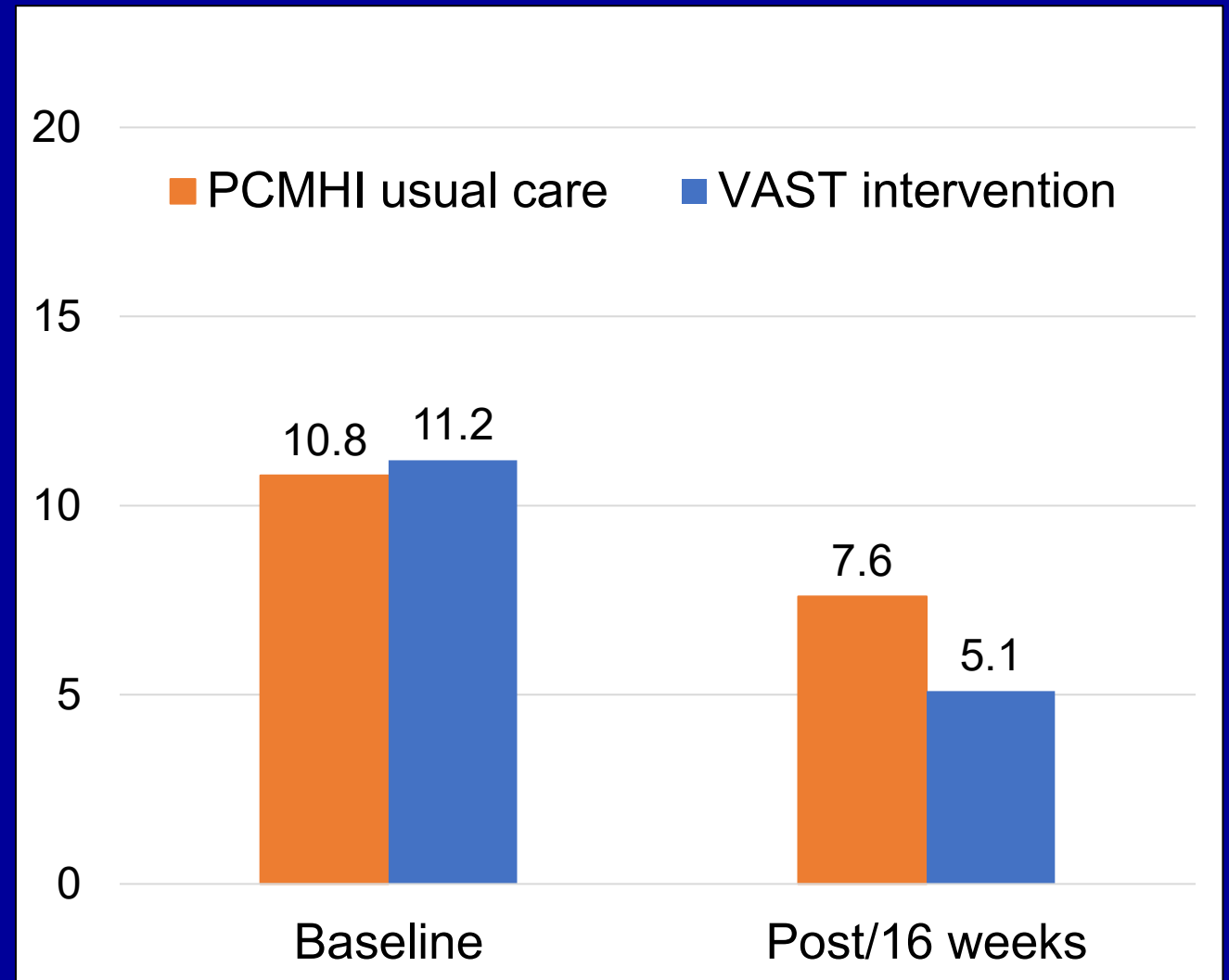
- OASIS
- Functional impairment due to anxiety

† $p = .059$; * $p < .05$



Effectiveness

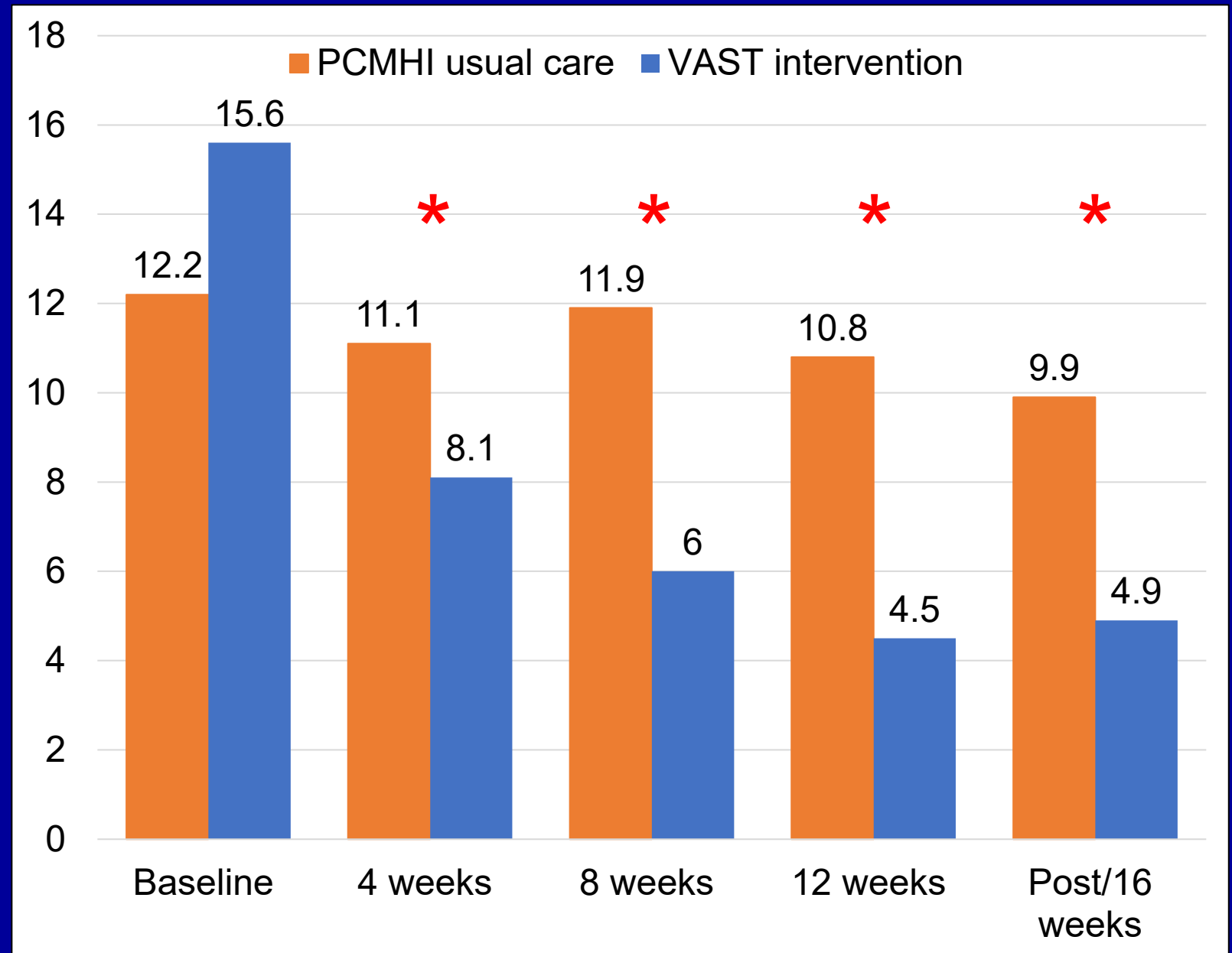
- PHQ-9
- Depressive symptoms
- ANCOVA controlling for baseline score
- *ns*



Effectiveness

- DASS Depression
- Depressive symptoms

* $p < .05$



Conclusions

- VAST was feasible
 - Patients had high engagement & retention in treatment
 - Patients seemed to have good comprehension & skills practice
 - Therapists delivered with high fidelity
 - Revised manual to decrease session duration to ~30 minutes
- VAST was acceptable
 - Patients reported high treatment satisfaction & credibility
 - Patients perceived strong therapeutic alliance
 - Providers found it acceptable & appropriate for PCMH
 - Providers appreciated modular design – allows flexibility

Conclusions

- VAST was more effective than PCMH usual care
 - Greater decrease in anxiety symptoms & functional impairment
 - Effects emerging by ~8 weeks (~3 sessions)

Limitations

- Single site
- Small sample size ($N=35$)
- More attrition in VAST condition
- Some patient-related indicators based on therapist ratings
- No follow-up assessments
- Study therapists experienced with PCMHI & CBT

Next Step

- Full-scale study ($N = 178$)
 - HSR&D Merit Grant # 20-146
 - Just started recruitment!
- Addressing limitations of pilot RCT
 - 2 VAMCs
 - Adding 3-month follow-up
 - PCMHI clinicians randomly assigned to VAST or usual care

CDA2 Research Challenges

- Treatment development took longer than anticipated
- Recruitment & retention
- COVID-19 pandemic
- Balancing research & writing & everything else

Questions: Robyn.Shepardson@va.gov

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