



# ViStA

Violence and Stress  
Assessment Project

## Impact of Collaborative Care for Underserved Patients with PTSD in Primary Care: A Randomized Controlled Trial

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1 PM – 2 PM ET

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# Which of the following types of PTSD training or experience have you most recently completed?

- A. Accessed information or materials about PTSD on a web-site e.g., VA National Center for PTSD
- B. Participated in a self-administered training or workshop about PTSD e.g., online web-based training for CE/CME credit or STAIR training
- C. Participated in an in-person training about PTSD for a certificate e.g., Center for Deployment Psychology
- D. Attended the brief ViStA training on evidence-based treatment for PTSD *as a study site participant (in 2010)*
- E. None of the above, I have not received any training specifically about PTSD

# Why Address PTSD in Primary Care?

**PTSD is associated with**

- **A range of negative physical health outcomes (e.g., coronary heart disease, hypertension)**
- **Maladaptive behavior adaptations (e.g., substance use, tobacco use, risky sexual behaviors, passive suicidality, self-injurious behaviors)**
- **Decreased work functioning**
- **Impaired relationship functioning (e.g., divorce)**

# Comorbidity of PTSD

- Majority with PTSD have other diagnoses: ~80–90%
- Major depression
  - 1/3 of depressed patients in primary care also meet criteria for PTSD
- Alcohol abuse/dependence (mostly men)
- Phobias and generalized anxiety disorder
- Psychosis, personality disorders

Brown et al., *Journal of Abnormal Psychology*, 2001

Hamner et al., *Journal of Nervous and Mental Disease*, 2000

Kessler et al., *Archives of General Psychiatry*, 1995

# Primary Care Management Approach

1. Establish therapeutic alliance and trust
2. Assess for safety (suicidal ideation, homicidal ideation, domestic violence, weapons)
3. Begin psychoeducation
4. Treat PTSD-related symptoms
5. Coordinate care

# Treatment Choices: Medication, Psychotherapy, or Both

- Initial treatment can be either pharmacotherapy or psychotherapy
- Both approaches are efficacious, and each has advantages and disadvantages
  - Patient preference and/or special skills of the clinician may influence this choice.
  - Comorbidity may influence the type of medication or psychotherapy prescribed
  - Comorbidity may influence the choice of whether to use medication or psychotherapy

# Psychotherapy

- **Exposure Therapy (ET)**—Patients confront painful memories/feelings
- **Cognitive Therapy/Cognitive Processing Therapy (CPT)**—Patients process their thoughts
- **Eye Movement Desensitization and Reprocessing (EMDR)**
- **Interpersonal Therapy (IPT)/Anxiety Management**—Patients deal with the ways in which the traumatic event and memories affect their relationships and other parts of their lives
- **Group Therapy**—Reduces isolation and stigma and can allow affected family members and loved ones to participate

# Pharmacotherapy

- Feasible in primary care
- Co-occurs with other disorders that respond to medications
- Alterations in key neurobiological mechanisms, including dysregulation in adrenergic, serotonergic, GABAergic, dopaminergic, and other pathways
- SSRIs and SNRIs are generally the first-line treatment of choice



# SSRIs and SNRIs

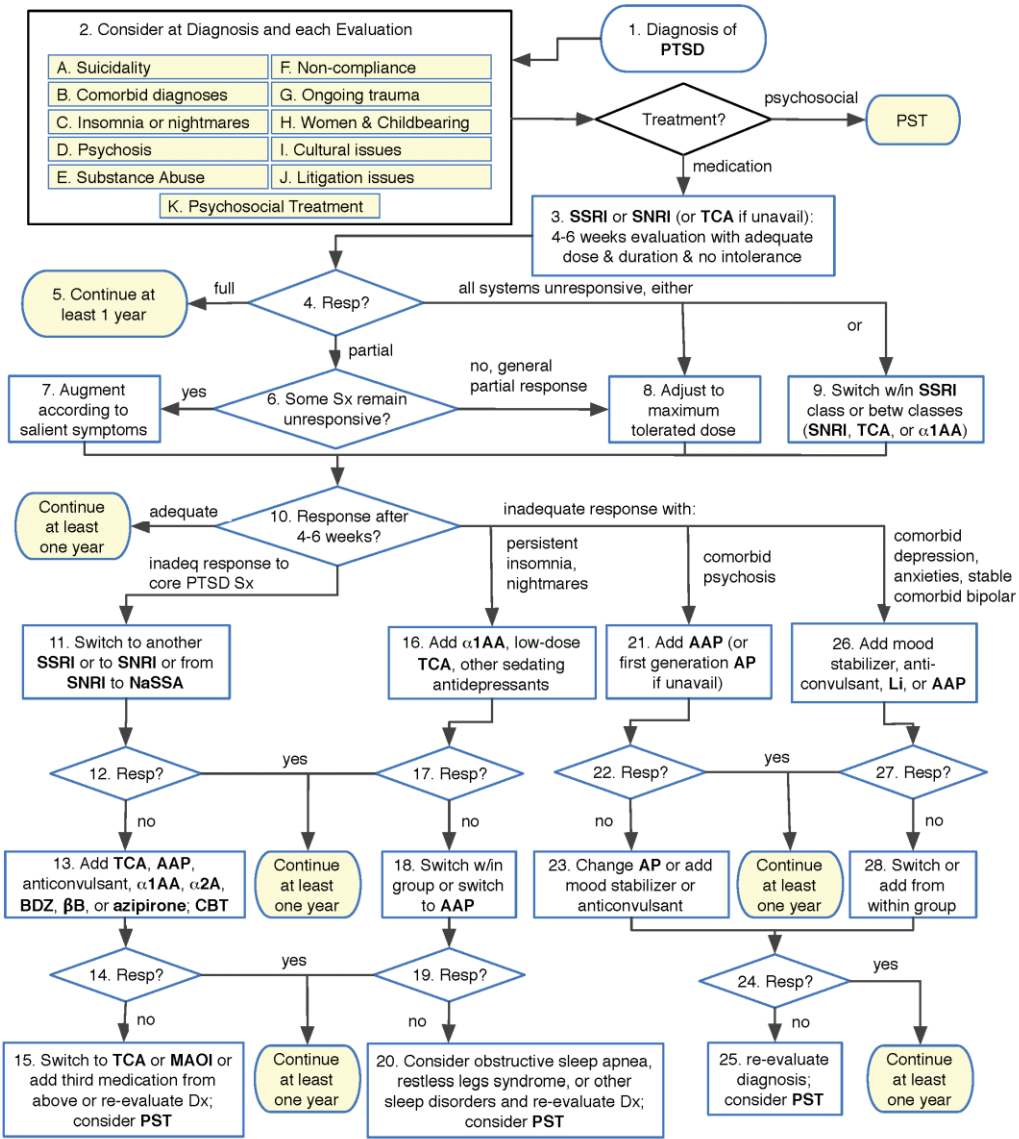
- **SSRIs**
  - Paroxetine (Paxil), fluoxetine (Prozac), sertraline (Zoloft), and citalopram (Celexa)
  - Relieves core PTSD symptoms, produces global improvement
  - Effective for comorbid depression, anxiety, insomnia, social phobias
- **SNRIs**
  - Venlafaxine
    - May exacerbate hypertension
  - Duloxetine

# Medication Trial

- **Start low and go slow:** Begin with low doses with gradual dose increases in the first few weeks, since initial high doses can exacerbate anxiety/arousal symptoms
- **Week 3–4:** Increase the dose if excellent response is not achieved
- **If only partial response, push to maximal dose tolerated by patient**
  - E.g., sertraline: 25mg increase to 50mg in 1 week, then up by 25/50mg every 1–2 weeks to maximum 200mg
  - E.g., paroxetine: 10–20mg up by 10–20mg every 2 weeks to maximum 60mg (PTSD algorithm [IPAP])

IPAP Post-Traumatic Stress Disorder (PTSD) Algorithm v. 1.0 (June 2005)

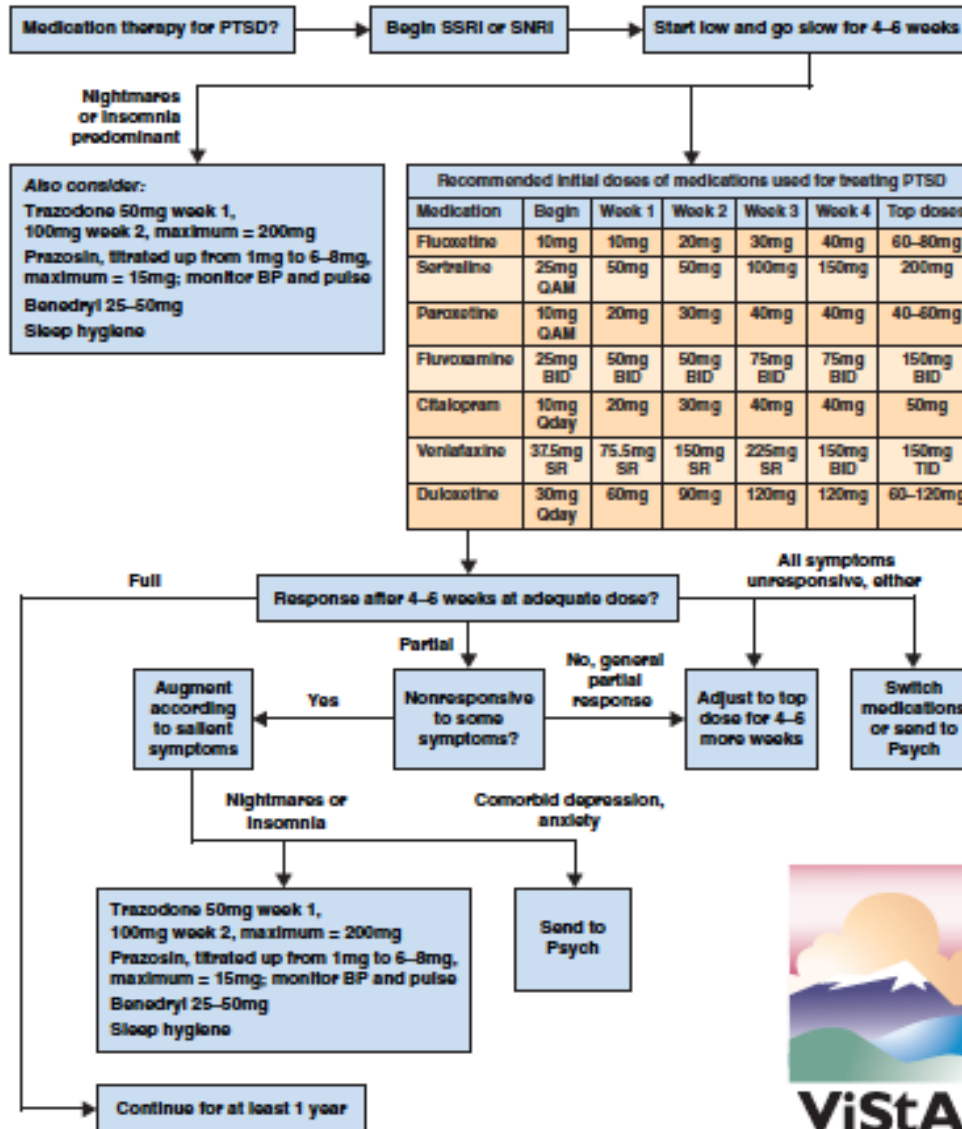
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**KEY:** α1AA=α<sub>1</sub>-adrenergic antagonist; α2A=α<sub>2</sub>-agonist; AP=antipsychotic; AAP=atypical antipsychotic; βB=beta-blocker; BDZ=benzodiazepine; CBT=cognitive behavioral therapy; Dx=Diagnosis; Li=Lithium; MAOI = monamine oxidase inhibitor; NaSSA = noradrenergic and selective serotonergic antidepressant; PST=Psychosocial Treatment; Resp=Response; SNRI = serotonin and noradrenaline reuptake inhibitor; SSRI = selective serotonin reuptake inhibitor; Sx=Symptoms; TCA = tricyclic antidepressant

# International Psychopharmacology Algorithm Project (IPAP) PTSD Algorithm

## Primary Care Clinician PTSD Prescribing Decision Aid



**ViSta**

Violence and Stress Assessment Project

# **PTSD is common in primary care but little is known about treating PTSD in safety-net primary care**

- **Primary care is common; prevalence = 9%-23% and often the first point of contact**
- **Effective treatments are available for PTSD, but many barriers to treatment especially in safety net settings**
  - **Patient-level (stigma, insurance)**
  - **Provider-level (under-detected, under-treated)**
  - **System-level (access to MH specialist)**
- **Trauma patients have added social and legal service needs (housing instability, homelessness, need for legal services (e.g., child custody) ...**
- **Collaborative care has been successful for depression in primary care and may be viable for PTSD**

# Meet a ViStA Patient: Lupe



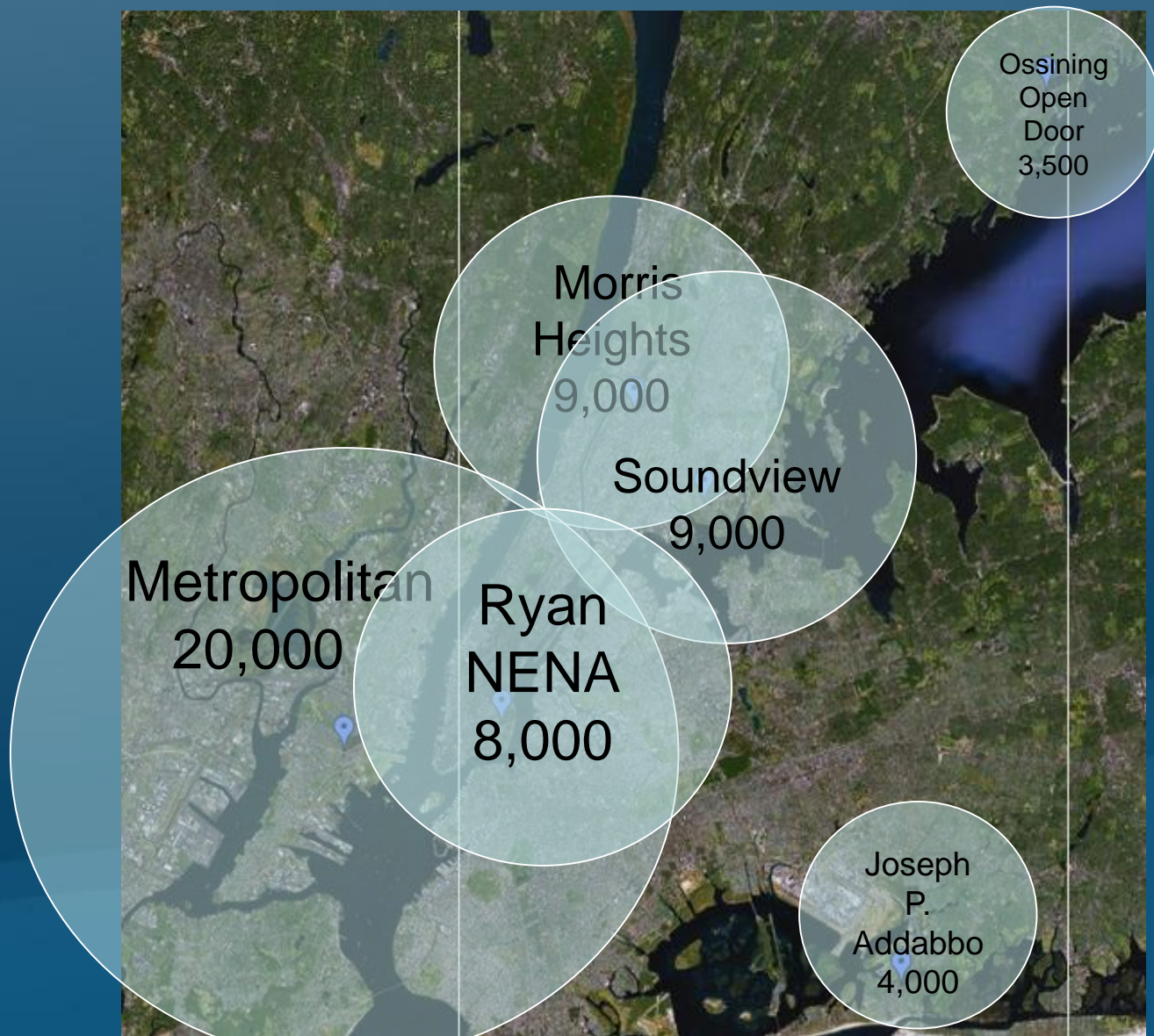
*Name and image has been changed to keep actual identities private.*

- Latina woman, late 20s, seven months pregnant with second child, attending community college
- “completely numb to everything,” insomnia, impaired concentration affects her school work
- Symptoms began at age 22 when she was held hostage with her 5-year old daughter and raped by two men
- Feelings of numbness increased after she entered an abusive relationship with the father of her current child; she fears he will return and hurt her or her child.
- Currently lives with four roommates who smoke and would like to move before the baby is born
- Has recurrent nightmares, resists referral for therapy because she does not want her mental health diagnoses recorded
- Ongoing legal issues between her and her ex-partner; fears she may lose child custody

# **ViStA is the first study to test the effectiveness of collaborative care for PTSD in FQHCs**

- **Multisite randomized controlled trial RCT**
- **Patients within 6 FQHCs in New York/New Jersey that are part of the Clinical Directors Network (CDN) Practice-Based Research Network (PBRN) were randomly assigned to either:**
  - **PTSD Care Management (PCM)**
  - **Minimally Enhanced Usual Care (MEU)**
- **Patients assessed at baseline, 6 months, and 12 months**
- **Intent-to-treat design**

# FQHCs vary in location and size





# ViStA Objectives

- Evaluate the effectiveness of the PTSD Care Management CM (PCM) program compared with Minimally Enhanced Usual Care (MEU)
- Assess the degree of implementation of the PCM program
- Examine the direct cost of the PCM program compared with MEU

# Study Measures

- Primary Outcomes as assessed with the Clinician-Administered PTSD Scale (CAPS)
  - % of patients with a current diagnosis of PTSD
  - Current symptoms of PTSD (sum of frequency and intensity ratings, range: 0-136)
- Secondary Outcomes Process of Care & HRQoL
  - % of patients:
    - Prescribed a medication for a mental health problem
    - With any mental health visit
    - With any visit involving counseling/talk therapy
  - Mental health functioning score MCS12 (0-100)
  - Physical functioning score PCS12 (0-100)

# Statistical Analysis

- **Powered to detect moderately small effect sizes**
  - **.19-.32 SD for numeric & 7-15% for binary outcomes with  $n=400$  & 20% attrition**
  - **Actual attrition was 12%; 355 baseline completers**
- **Sequential imputation method for 6 and 12 months**
- **Intent-to-treat analysis design per protocol**
  - **Jointly modeled outcomes at 3 waves by time, condition, and time x condition interaction**

# PCM Intervention Relative to MEU

For patients with PTSD	MEU	PCM
Patient education PTSD brochure	X	X
Patient screening and written feedback to Primary Care Clinicians PCCs	X	X
Clinician education on trauma, PTSD, E-B treatments, and medication guide	X	X
Structured assessment/feedback between PCCs and Mental Health Specialists with supervision*		X
Continuity of patient care*		X
Locally tailored resource guidance for community services*		X

\*These components are delivered through the Care Manager CM role.

## Study Entry

**Step 1**  
Data collector:  
Screen patients with brief 6-item questionnaire to identify those at risk for PTSD

**Step 2**  
Data collector:  
Administer SLES-Q and CAPS to identify patients who meet diagnostic criteria for PTSD

**Step 3**  
Data collector:  
Copies of patient screening feedback form go to patient and patient's chart for PCC

**Step 4**  
CM:  
Call patients to arrange initial visit that is back-to-back visit with CM and PCC

## Back-to-Back Visit

**Step 5**  
CM:  
Meet with patient for 45 minutes to provide education

**Step 6**  
PCC:  
Evaluate patient and start a management plan, if required (medication or referral)

**Step 7**  
CM:  
Meet with patient for 10-minute post-visit education session to address potential barriers to treatment, inform patient about resources from PTSD resource guide, and activate the patient to engage in treatment

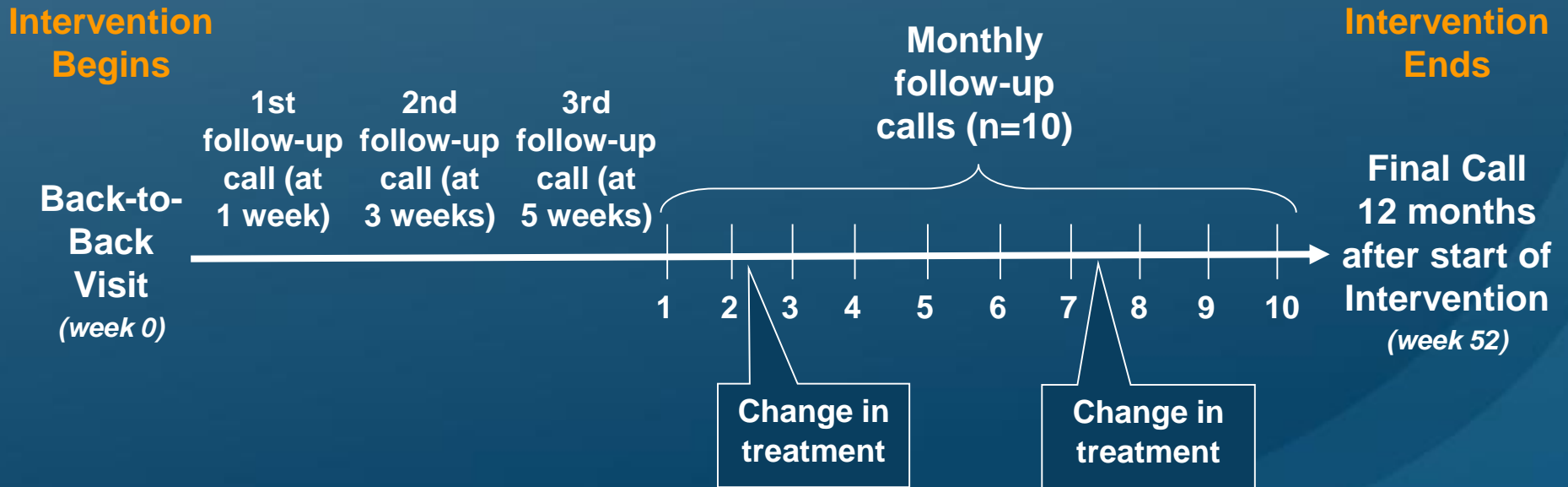
## Follow-Up Contacts

**Step 8**  
CM:  
Call patients for follow-up at prespecified intervals (1 week after initial visit, every 2 weeks for a month, and each month thereafter throughout 12-month intervention) to:

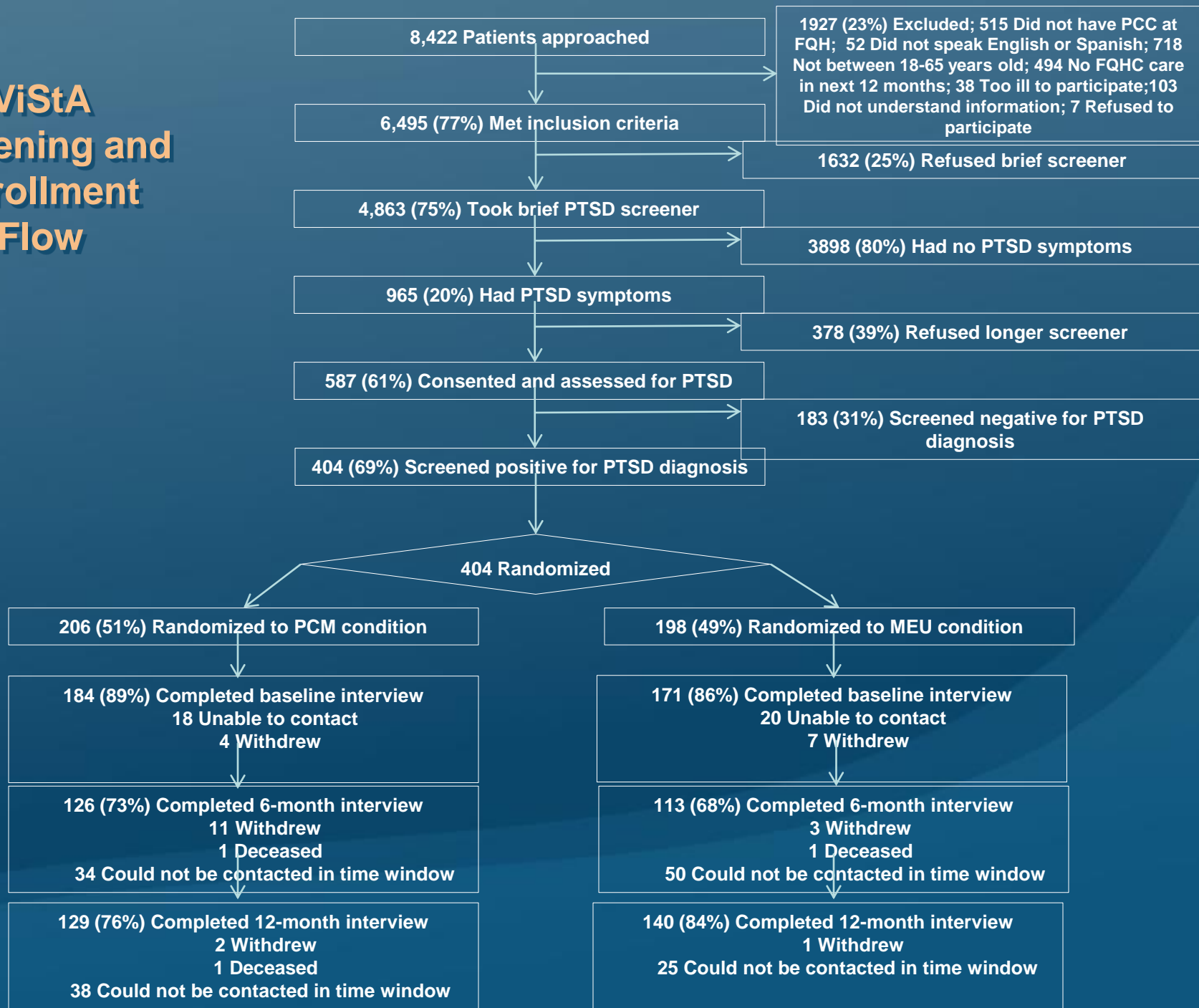
- Provide education about treatment response and adherence
- Monitor patient's PTSD symptoms and other clinical information in patient registry
- Provide feedback to PCC and MHS on treatment progress as needed

**NOTE:** Steps for CMs are in green boxes.

# CM Schedule for Contacting ViStA Patients



# ViStA Screening and Enrollment Flow



# How underserved are ViStA patients?

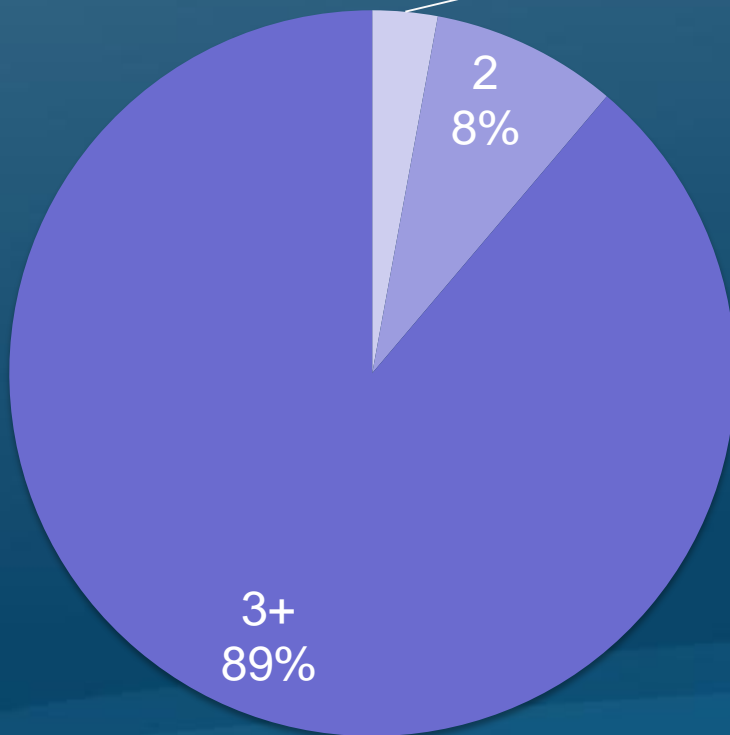
Characteristic, % at Baseline	MEU n=171	PCM n=184
Less than high school education	35.5	42.1
Born outside of the U.S.	17.7	19.4
<u>Race/Ethnicity</u>		
Hispanic	52.1	51.6
Black	35.5	35.3
White	4.1	7.6
Other	8.3	5.4
<u>Insurance Status</u> <i>unknown for 10 in each arm</i>		
No insurance	7.1	7.7
Medicaid	80.0	82.4
Medicare	2.4	1.6
Other government insurance	5.9	5.5
Private insurance	4.7	2.6

No significant differences by study arm.

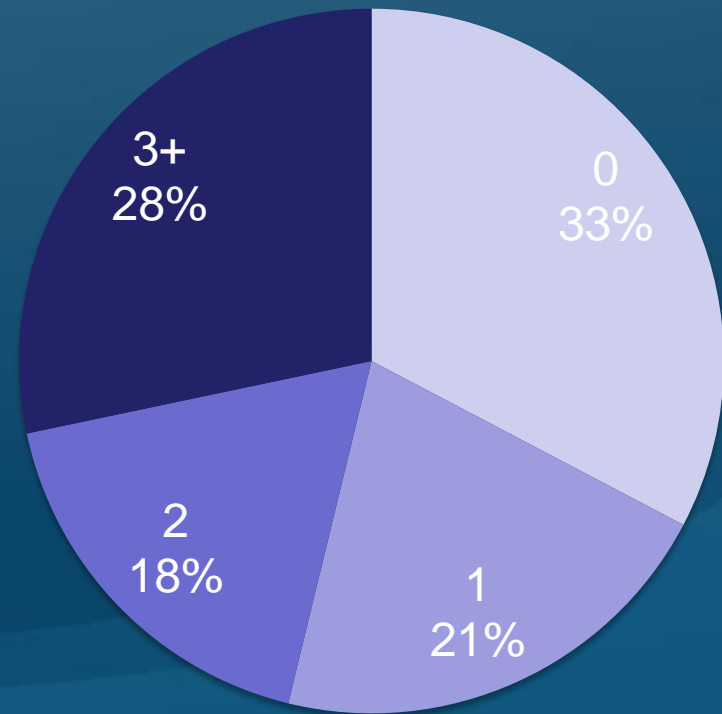


# ViStA patients have multiple problems

# of Traumatic Events



# of Chronic Medical Conditions



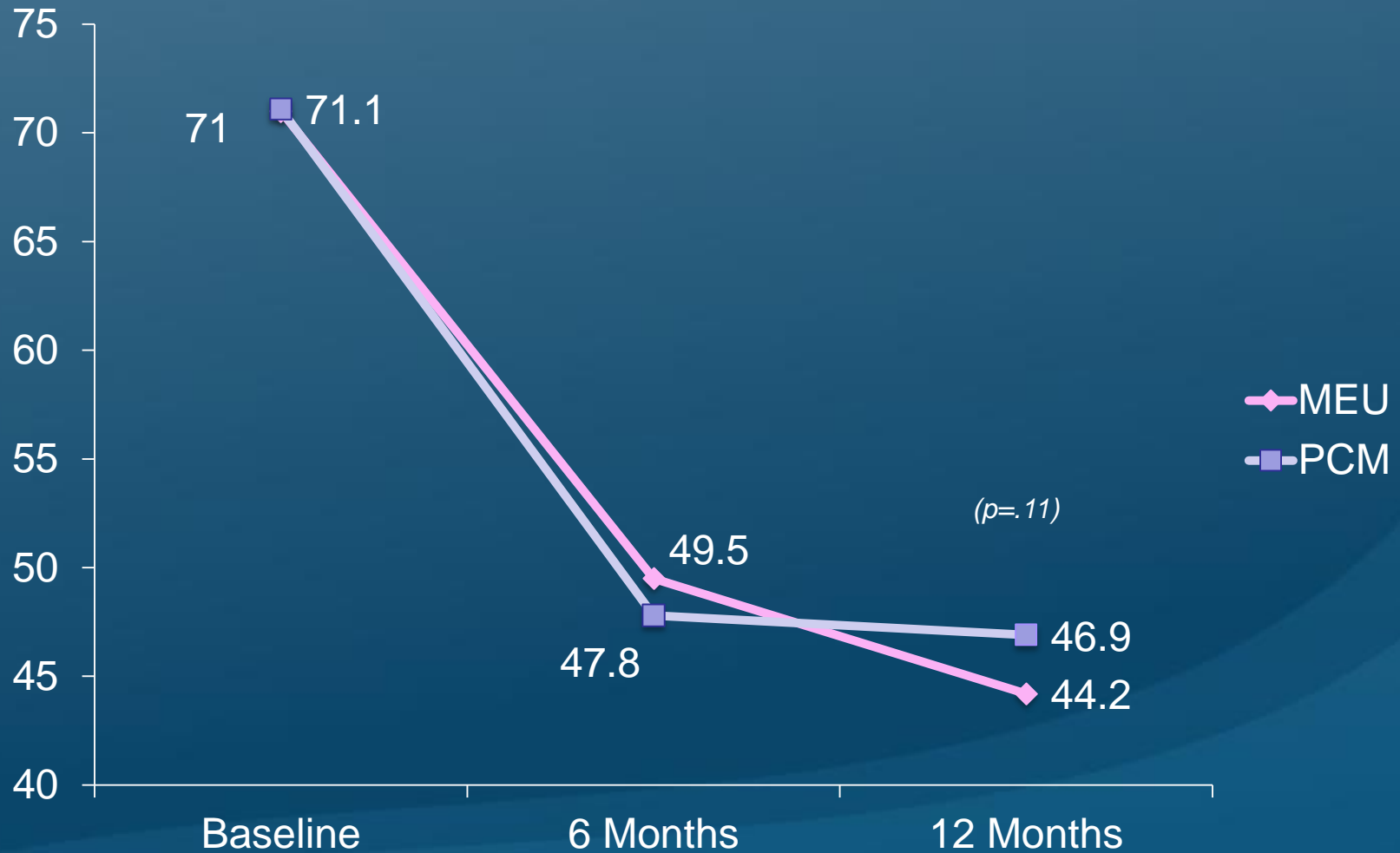
No significant differences by study arm at Baseline.

# Change in PTSD Diagnosis Over 1 Year



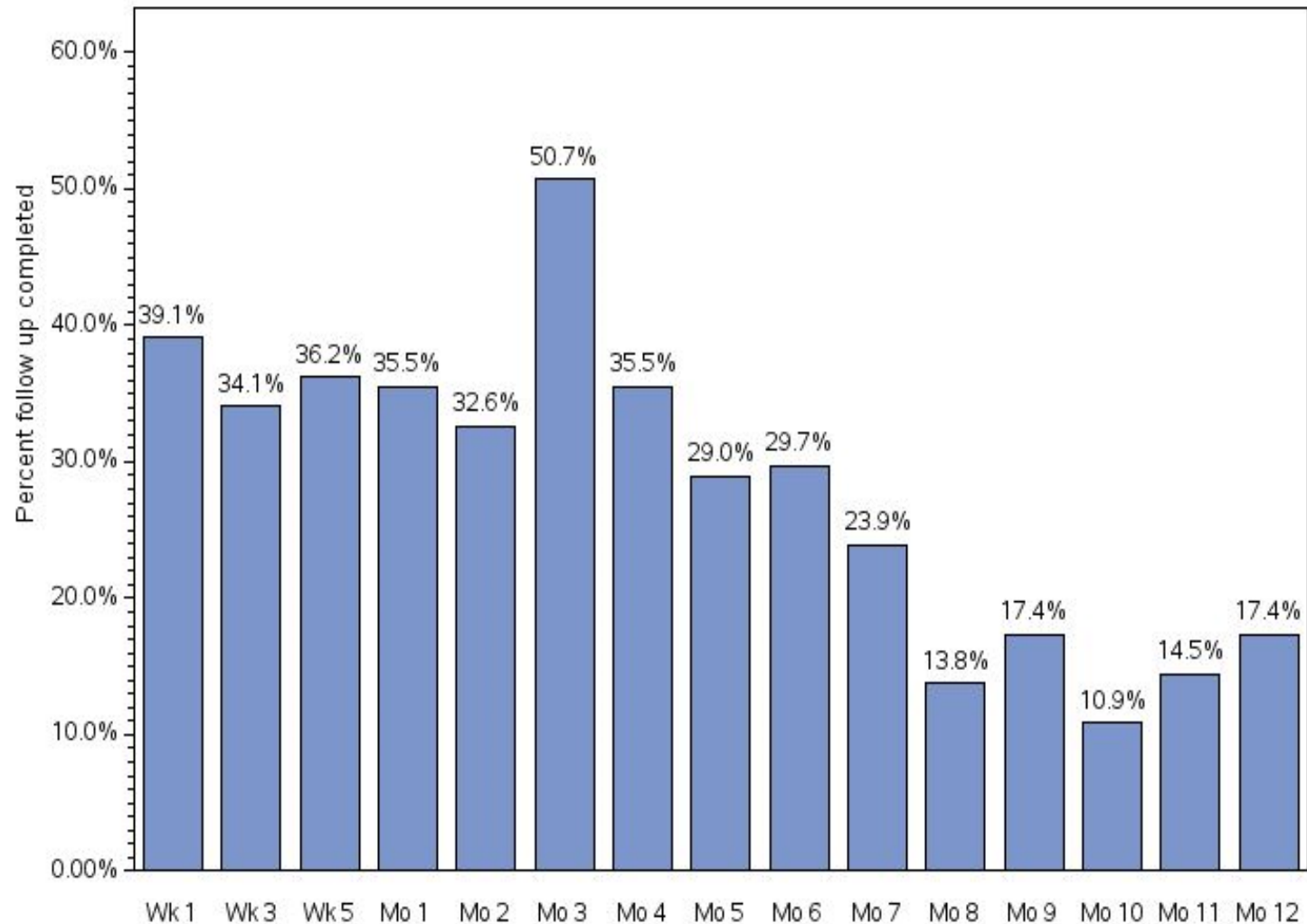
reduction of 60.6% for MEU vs. 56.7% for PCM

# Change in PTSD Severity Over 1 Year



reduction of 24.2 points for MEU vs. 26.8 points for PCM on the CAPS total score range = 0-136

# Intervention dose delivered less than planned

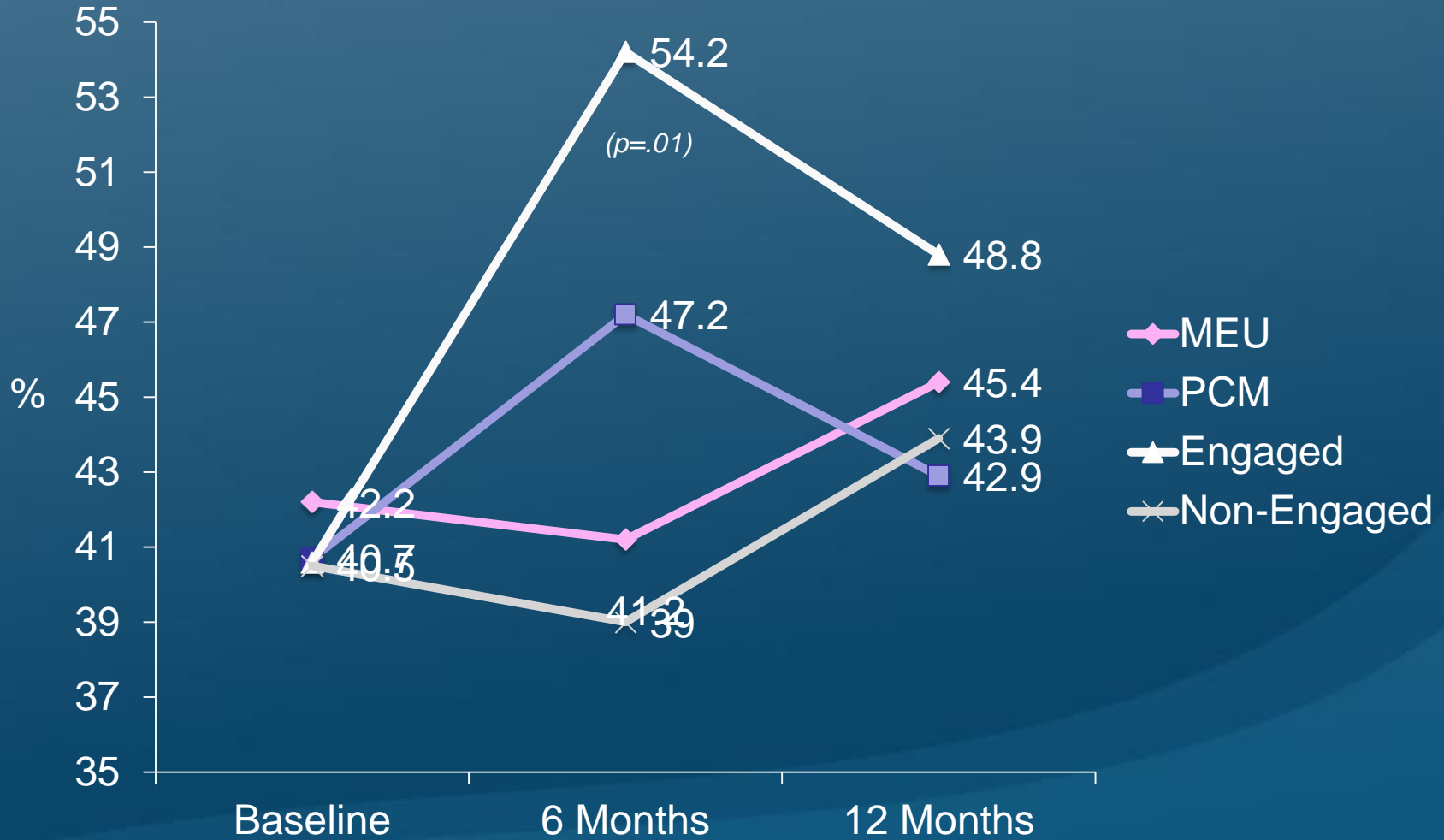


73% (134/184) completed initial B2B visit  
Mean follow-ups: 4.2 of intended 14 (28% dose)

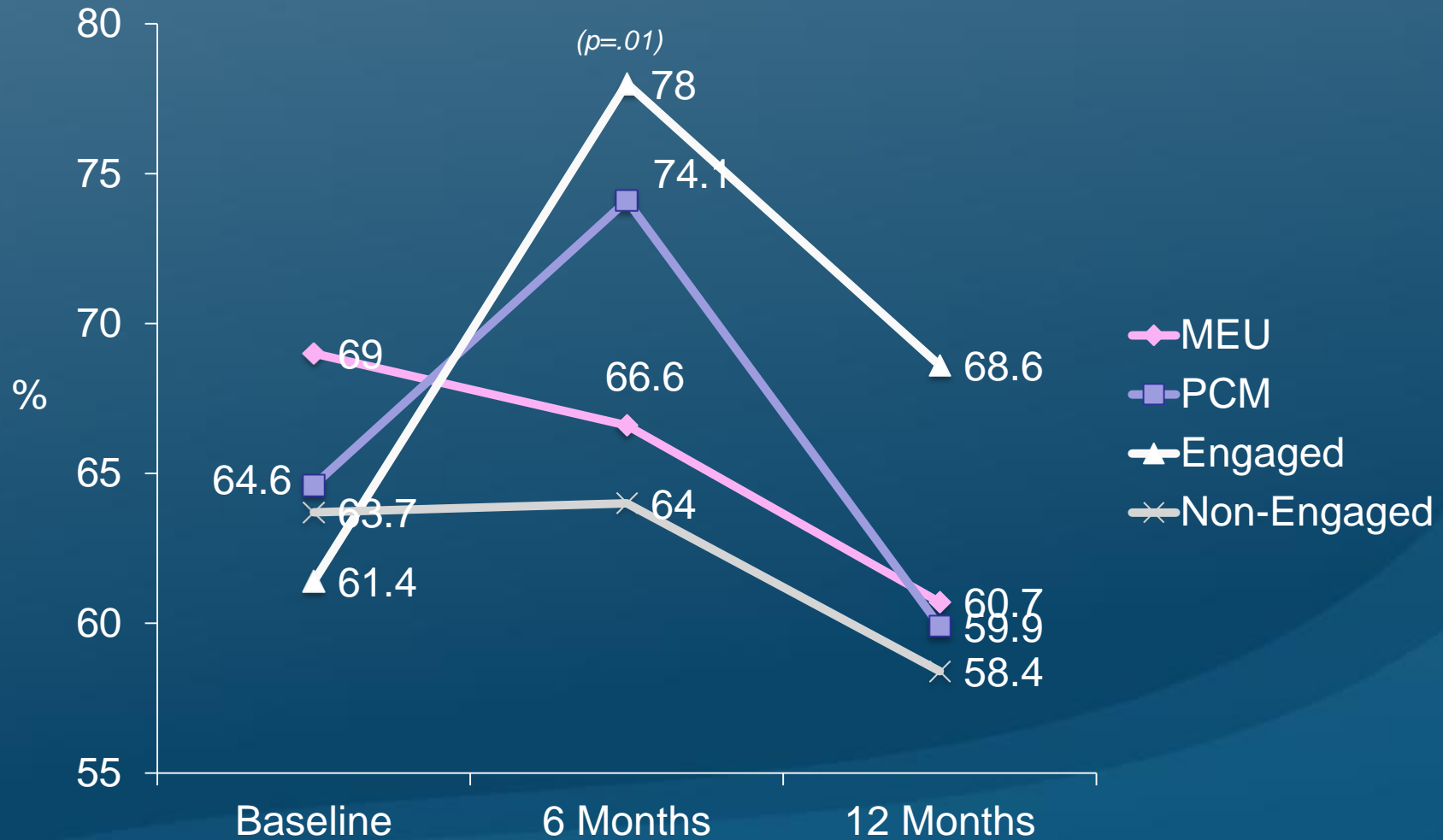
# As-Treated Statistical Analysis

- **Post-hoc as-treated analysis**
  - Only 73% engaged in the intervention
  - Inverse compliance propensity score
  - Controlling for covariates

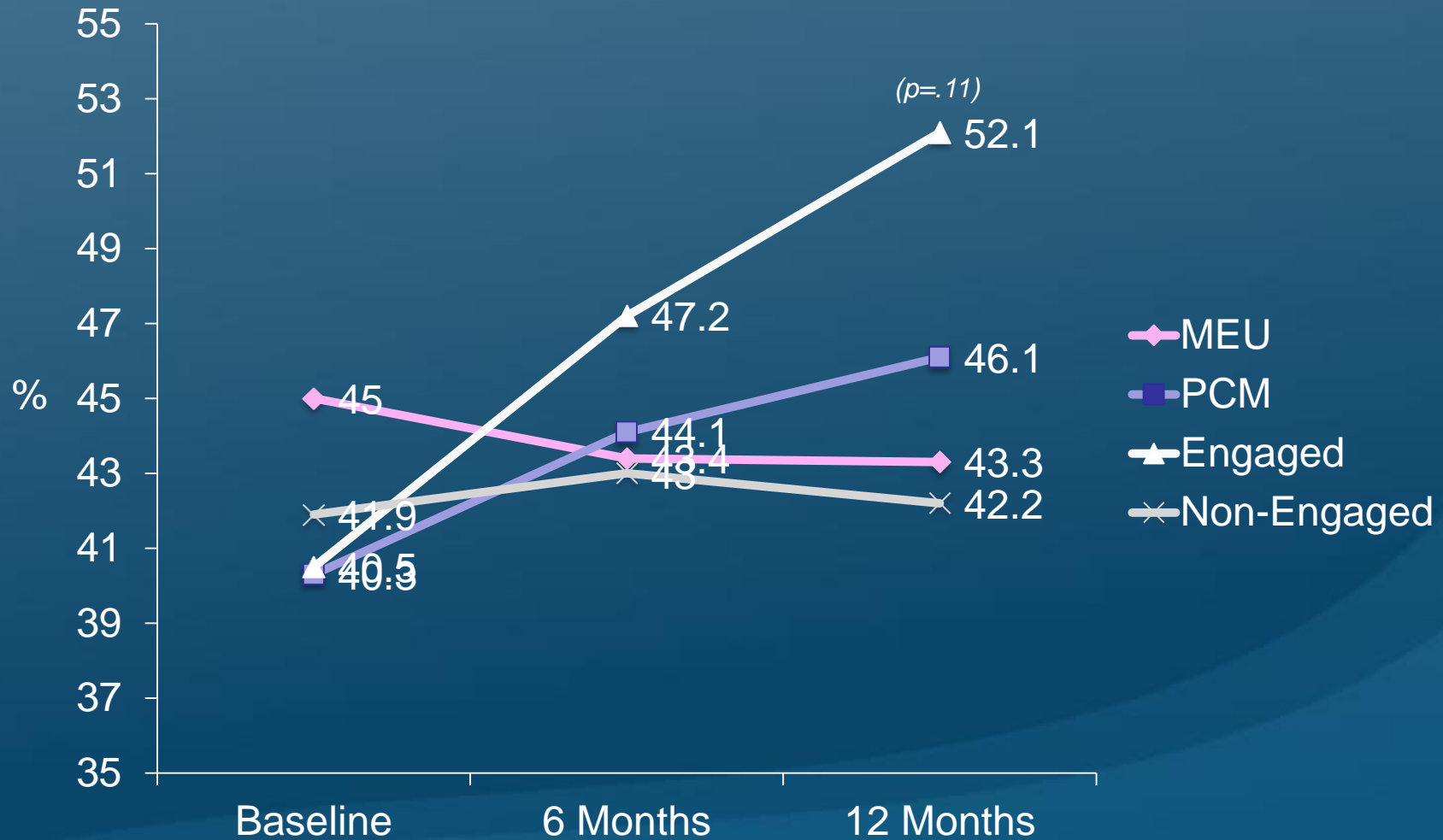
# PCM patients received more MH Rx



# PCM patients received more MH visits

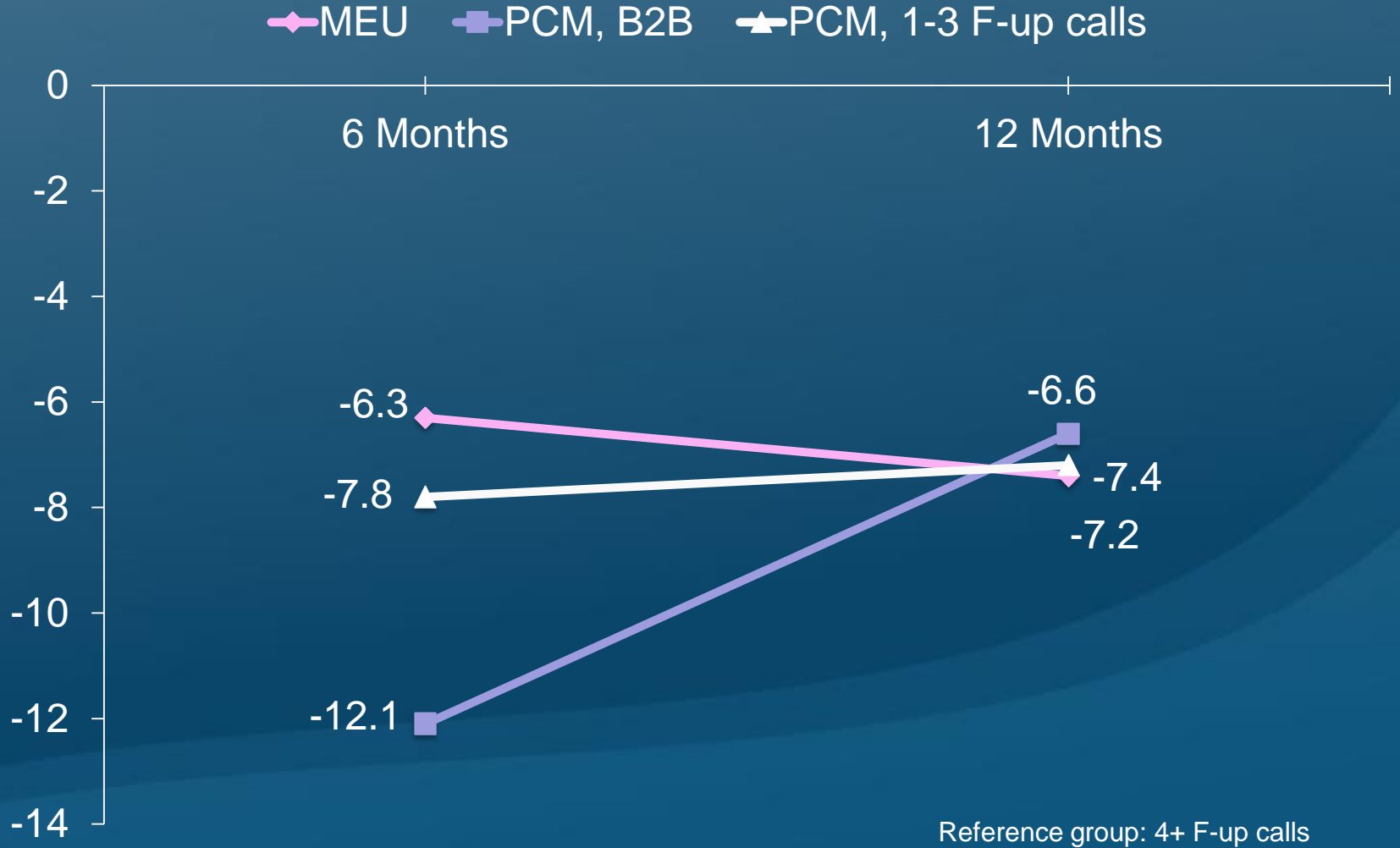


# PCM patients received more MH counseling visits





# No dose response effect for PTSD Dx



# Resource referrals provided

	Percent of patients receiving community service referrals
<b>Any referral provided</b>	<b>63%</b>
<b>1 referral</b>	<b>37%</b>
<b>2-4 referrals</b>	<b>19%</b>
<b>5+ referrals</b>	<b>8%</b>
<b>Resource used</b>	<b>23%</b>

# Resources referrals provided

- **Employment**
- **Housing**
- **Training & education**
- **Legal**
- **Immigration**
- **Transportation assistance**
- **Family support & childcare**
- **IPV and support groups**
- **Charities, food, utilities, debt, cash assistance**

# ViStA Costs

- An average of 6.3 hours per day was spent in clinical time at the study site to administer the intervention
- Average direct cost of the PCM intervention for person-date-site observation was \$509. CMs spent:
  - 1.25 hours on each back-to-back visit
  - 9 minutes on each follow-up contact
  - 30 minutes on each other activity (e.g., communication with clinic staff, supervision calls with the study psychiatrist, etc.)
- Difference in differences analyses showed no significant differences between the two study arms in cost and utilization measures except for:
  - group counseling ( $p < .05$ ) which decreased across time for the PCM but increased for the MEU group

# Conclusions

- Patients in both PCM and MEU groups improved substantially over the 1-year evaluation period but no added benefit of PCM intervention
  - Remission rates as high as 56.7% (PCM) and 60.6% (MEU)
  - Symptom reductions of 24.2 (PCM) and 26.8 (MEU) points
- PCM effect was less than expected, but improvement is clinically significant with large effects
  - Relative decreases in PTSD diagnoses above 50%
  - Relative PTSD symptom reduction above 30%
- In the as-implemented analysis, the PCM vs. ECE intervention increased rates of
  - Visits for MH specialty services +14%,  $p < .01$
  - Prescriptions for psych meds +15.2%,  $p < .01$

# Possible Explanations

- Regression to the mean? Enrolled patients in both groups may have had less severe PTSD and more favorable prognoses (but large improvement in both arms)
- Exemplar sites? These 6 FQHCs may have been better able to implement care improvements (but wide variation)
- Low dose is sufficient? MEU was more than typical care in these settings (73% adherence is not atypical)
- Non-clinical CMs? CMs with clinical background have better results in collaborative care (but less practical)
- Better linkage to social services? Referral alone was insufficient; we need a warmer hand-off

# If you build it, they may not come...

Need to retool, reassess, and find what works better

- Consider simpler, briefer, less burdensome interventions to better **engage** this population
- Equip CMs with resources to increase intervention **reach and efficiency**:
  - Formalize MI training
  - Add stepped care
  - Establish partnerships with social service agencies to facilitate referrals to community resources and services
- Train MH providers on manualized E-B therapy



# ViStATeam



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# Questions?

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Meredith, L. S., Eisenman, D. P., Green, B. L., Kaltman, S., Wong, E. C., Han, B., Cassells, A., Tobin, J. N. (2014). Design of the violence and stress assessment (ViStA) study: A randomized controlled trial of care management for PTSD among predominantly Latino patients in safety net health centers. Contemporary Clinical Trials, 38, 163-172.

Meredith, L. S., Eisenman, D. P., Han, B., Green, B. L., Kaltman, S., Wong, E. C., Sorbero, M., Vaughan, C., Cassells, A., Zatzick, D., Diaz, C., Hickey, S., Kurz, J., & Tobin, J. N. (2016). Impact of the Violence and Stress Assessment (ViStA) program to improve PTSD management in primary care: A randomized controlled trial. Journal of General Internal Medicine, 31, 509-517.



# ViStA

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