

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

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ABSTRACT

Posttraumatic stress disorder (PTSD) is a common problem in primary care. Although effective treatments are available, little is known about whether such treatments are effective within the context of Federally Qualified Health Centers (FQHCs) that serve as national “safety nets” for providing primary care for low income and underinsured patients. The Violence and Stress Assessment (ViStA) study is the first randomized controlled trial (RCT) to test the impact of a care management intervention for treating PTSD in FQHCs. To develop a PTSD management intervention appropriate for lower resource FQHCs and the predominantly Latino patients they serve, formative work was conducted through a collaborative effort between researchers and an FQHC practice-based research network. This article describes how FQHC stakeholders were convened to review, assess, and prioritize evidence-based strategies for addressing patient, clinician, and system-level barriers to care. This multi-component care management intervention incorporates diagnosis with feedback, patient education and activation; navigation and linkage to community resources; clinician education and medication guidance; and structured cross-disciplinary communication and continuity of care, all facilitated by care managers with FQHC experience. We also describe the evaluation design of this five-year RCT and the characteristics of the 404 English or Spanish speaking patients enrolled in the study and randomized to either the intervention or to usual care. Patients are assessed at baseline, six months, and 12 months to examine intervention effectiveness on PTSD, other mental health symptoms, health-related quality-of-life, health care service use; and perceived barriers to care and satisfaction with care.

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1. Introduction

Post-traumatic stress disorder (PTSD) is a common mental disorder associated with substantial psychological, physical and social consequences. PTSD affects over 10% of people in the

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United States [1,2] and its prevalence is high among patients seen in primary care settings, such as Federally Qualified Health Centers (FQHCs), with rates ranging from 9% to 23% [3–9]. PTSD often co-occurs with depression, substance abuse, other psychological problems [10–13], and medical conditions [14–20], and is associated with poor physical health functioning [21] and poor quality of life [14,18,21–23]. PTSD also heightens risk for marital instability [24], teenage childbearing [25], lower educational attainment [26,27], and unemployment [28]. Finally, PTSD and related impairment are associated with an annual loss of over \$3 billion in work productivity [29,30].

Better coordination between primary care and mental health services is an important priority for FQHCs, which serve as the national “safety net” for the poor and under- or uninsured. However, there are no models readily available for addressing PTSD in these settings. As with other mental health problems, individuals with PTSD visit primary care clinicians (PCCs) more often than mental health specialty clinicians for their initial treatment [31]. Because the identification and management of PTSD are not routine in primary care settings such as FQHCs, this mental illness may be underdiagnosed [32]. This is in part because physicians are reluctant to inquire about personal traumas [33–36]. Other general obstacles at the patient-, clinician-, and systems-levels impede care, such as patients’ low mental health literacy and perceived stigma about seeking mental health care; clinicians’ time constraints for dealing with psychological issues; gaps in clinician treatment knowledge about mental health and its treatment; and difficulty accessing mental health specialists.

Only a few studies have examined the effectiveness of primary care collaborative intervention for the improvement of anxiety disorders, including PTSD [37–42], and results are promising. Though these studies have yielded promising results, none have focused specifically on a substantial contribution to furthering knowledge of FQHCs and underserved patients. Therefore, it is unknown whether such approaches are feasible and effective in FQHCs that provide care for predominantly underserved populations, which often include a high proportion of Latino, uninsured, or publicly insured patients [43,44].

Some evidence suggests that collaborative care interventions for PTSD may be adapted and implemented to address the needs of this population [45]. However, it is necessary to contextualize that care to the type of trauma and cultural factors. For example, the literature shows that the types of traumatic events that immigrant Latina women experience are primarily domestic violence, community violence, and witnessing violence and these trauma experiences tend to be of amplified brutality if they occurred in their country of origin suggesting a greater adverse impact on mental health [11,46,84]. Querying Latinas about the intensity of the exposure and to fully understand their experiences is likely to facilitate assessment and treatment.

More intensive screening and intervention may also be needed for this population since both Latina women and Latino men, whom tend to experience political and community violence, do not readily disclose their traumatic experiences [47,48]. In addition, many Latinas, especially immigrants who lack strong social networks and therefore report being socially isolated even if their family is with them [48,49]. Moreover,

there is some evidence that battered women can be prevented from using needed services by male partners who may use physical or emotional methods to control their partner’s behavior [50]. Therefore, patient engagement strategies and readily accessible adjunctive non-medical community services (i.e., social, legal) are needed [49,51]. For example, interpersonal violence experiences are associated with a greater need for legal and social service support compared with those not reporting interpersonal violence.

Finally, health literacy obstacles combined with language discordance with health care providers for monolingual Spanish speakers and culture differences are common in this population [52]. Thus, it is crucial to create intervention materials that are at the appropriate language level and that are translated and culturally adapted and to employ bilingual and bicultural intervention staff who understand these needs.

This article describes the design and evaluation of a PTSD care management intervention for limited-resource settings serving low-income populations with complex health and social problems. Violence and Stress Assessment (ViStA) is the first large randomized controlled trial (RCT) to evaluate the effectiveness of a multi-faceted care manager (CM) based intervention for PTSD in FQHCs.

2. Method

2.1. Intervention development

The ViStA intervention was developed as part of an exploratory/developmental study that relied on an academic-community partnership between RAND and the Clinical Directors Network (CDN – www.CDNetwork.org), an established Practice-Based Research Network (PBRN) that works with FQHCs that provide comprehensive community-based primary care and preventive care to the underserved [53]. The intervention was tailored for FQHC settings and underserved populations based upon input from clinical staff at FQHC study sites; further details can be found elsewhere [48,54].

Briefly, through this formative work, we utilized group process methods [55] based on modified Delphi techniques [47,56,57] to identify key barriers to providing evidence-based PTSD care and strategies for addressing those barriers. We identified a panel of nine clinical staff from six FQHCs (5 physicians, 1 nurse, 1 social worker, and 2 non-clinical site administrators) to participate in the intervention design process. The panel was asked to: 1) review and prioritize the barriers that are most important to address for managing patients with PTSD in FQHCs, 2) discuss alternative evidence-based strategies for improving PTSD care, and 3) select the most promising approach for improving PTSD care that is feasible and appropriate for the setting and patients served.

To achieve these objectives, we asked the panel to provide ratings in two rounds of brief surveys and to participate in an in-person, half-day meeting that convened in November 2006. Specifically, we distributed a “pre-work” packet that included a 1-page survey to be returned in advance of the meeting. The survey asked participants to rank a set of common barriers and to identify a strategy for addressing each of the barriers. The top-rated barriers are shown in the first column of Table 1. Based on evidence (middle column of Table 1), we provided

Table 1
Barriers Identified, Proposed Evidence-Based Strategies for Addressing Barriers, and Intervention Components Adapted for the ViStA Study.

Barriers	Evidence-Based Strategies	ViStA Intervention Components
Patient-Level: 1. Perceived stigma 2. Low mental health literacy	1. Educating and activating/motivating patients about mental health problems [58–61] 2. Linking patients to non-medical services in the community [36,62–65]	1. CMs reviewed NIMH PTSD brochures (in English or Spanish) with patients during the initial visit prior to seeing the PCC and used motivational interviewing techniques to encourage self-care and problem-solving 2. CMs used locally-tailored resource guides to refer patients to non-medical community services
Clinician-Level: 3. Limited treatment knowledge and time 4. Difficulty finding MHSs	3. Providing PCCs feedback about patient diagnosis [66,67] 4. Educating clinicians on practice guidelines and evidence-based treatments [68]	3. Research team provided feedback about patients meeting PTSD diagnostic criteria placed in study chart 4. Research team provided on-site initial training and interim Webinar booster training to PCCs and MHSs about evidence-based treatments for PTSD and equipped PCCs with laminated medication guides
System-Level: 5. Poor care coordination with mental health 6. Unavailability of MHSs at the center or in the community	5. Coordinating primary and specialty care for persons with mental illness [69] 6. Enhancing continuity of patient care and planned follow-up care [70]	5. CMs provided structured communication about patients to PCCs and MHSs 6. CMs provided continuous care to patients over one year in up to 15 encounters

Notes: CM: care manager; PCC: primary care clinician; MHS: mental health specialist.

potential strategies for ranking that might be effective in addressing these barriers. Participants were also given the opportunity to suggest additional strategies. Prior to the panel meeting, the research team tallied the pre-work survey results and prepared brief presentations to review the study aims and explain the meeting goals. The results provided a launching point for the working session, where the top three ranked barrier-strategy combinations were presented to the group. The remaining time was structured around three key questions for each combination: 1) What are the specific details of the strategy for addressing the barrier? 2) How receptive are you to an intervention for PTSD in the FQHC setting? And 3) How feasible and sustainable is the intervention? After the meeting, the research team summarized the discussions and shared them with the group.

The panel then recommended a potential intervention approach with promise for addressing the top barriers and improving the identification and management of PTSD. This approach included six components. The first is patient education (using National Institute of Mental Health PTSD brochures [58] placed in the waiting rooms and handed to each person screened) and training auxiliary staff to screen patients for PTSD before a PCC visit. Educating the clinicians and providing guidelines about evidence-based treatments for PTSD, particularly on appropriate prescribing practices, were additional strategies suggested to address clinician-level barriers. Other strategies included improving the feedback mechanism between primary care and mental health, and devising systems for improving continuity of patient treatment (e.g., medication refills). An Advisory Group consisting of the same stakeholders was formed subsequently, meeting via biweekly conference calls, to provide input to the ViStA team as we developed the intervention and the grant application (for the randomized trial) to insure its feasibility, compatibility for implementation, and cultural appropriateness with the patient population. Examples of cultural adaptations [52] include translating all study materials into Spanish at a low literacy level to ensure comprehension, employing bilingual Latinas in study recruitment and intervention delivery roles, and training CMs to rephrase technical terms to be more culturally meaningful. Specifically, because Latinos may be difficult to

engage in mental health treatment, they are using a 3-point engagement scale and strategies from motivational interviewing to encourage engagement. CMs also received training about how to present clinical information in the context of Latino cultural and religious contexts and how to use expressions common among the predominantly Dominican and Puerto Rican Latinos in our sample (e.g., “ataques de nervios” to describe uncontrollable shouting, crying attacks, shouting, and aggression). We also made adjustments to our study to enhance feasibility for clinical staff (e.g., training busy staff in hour-long modules at each FQHC to minimize disruption) and to tailoring CM communications to PCC preferences within the existing administrative system structures in FQHCs.

2.2. ViStA intervention

The resulting ViStA intervention design, based on the formative, partnered work, is a multi-faceted program that includes components and strategies implemented through a CM to overcome patient-, clinician-, and system-level barriers (column 1 of Table 1) that were operationalized based on the FQHC stakeholder input and evidence-based strategies (column 2 of Table 1). The ViStA PCM intervention has six key components (column 3 of Table 1). The first component, *patient education and activation* is facilitated through CMs' use of a National Institute of Mental Health PTSD brochure and motivational interviewing techniques [58–61]. We used these materials, in part, because they are available in both English and Spanish. The second component, *dissemination of non-medical community resources*, includes the provision of locally-tailored information based on previously established FQHC referral linkages and facilitating new linkages [62–65]. We researched and identified resources for both English-speaking and Spanish-speaking patients and our resource directory included service agencies that focused on Latinos' needs (i.e., immigration, English as a second language). This was a particularly important aspect of the intervention because of the need to make other community services accessible to a population that has broad service needs beyond those available from a medical setting. The third component involves patient screening and evaluation for PTSD diagnosis with *structured feedback* provided to PCCs

[66,67]. The fourth component, *clinician education* on practice guidelines, includes onsite and online continuing medical education (CME)-accredited sessions (available in the Webcast Library at www.CDNetwork.org) and a laminated medication guide [68]. The fifth component, *structured cross-disciplinary communication*, included regular meetings between CMs, PCCs, and specialty mental health providers, as well as CMs' participation in weekly supervision with the study psychiatrist [69]. This was important because we expected that PCCs would feel more confident about treating PTSD if they had relatively effortless access to mental health services and established relationships with adjunct services [48]. The sixth component, *continuity of patient care*, is facilitated by the CMs through an initial in-person visit in conjunction with a scheduled medical visit with the PCC and up to 14 additional follow-up contacts (by phone or in-person) over a year [69,70]. All of the intervention components are implemented through the CMs, except for the clinician education component, which was delivered by a physician-researcher (DE) and other members of the study team.

CMs manage their intervention patient panel using a secure, encrypted ACCESS database or patient registry. The registry includes multiple modules for documenting and tracking information obtained by the CM during the initial in-person intervention visit and follow-up contacts including PTSD symptoms, medications, PCC treatment plans, patient self-management goals, resource referrals and utilization, and appointment dates.

The one-year intervention has eight key steps (Fig. 1). The first step involves patient screening by the recruitment

coordinator (RC) using a brief 6-item screener [71] to identify those at risk for PTSD. For those with a positive brief screen, the RC assesses patients for exposure to traumatic events using the Stressful Life Events Screening Questionnaire (SLES-Q) [10,72] and administers the Clinician Administered PTSD Scale (CAPS) [73,74] to assess for a diagnosis of PTSD (Step 2). Patients who meet the criteria for PTSD are randomized to either the CM intervention or usual care and then complete the baseline evaluation assessment. Once the baseline assessment is completed, the CM imports screening data, trauma information, patient PTSD diagnosis, and contact information into the patient registry (Step 3).

Thereafter, the CM calls patients to arrange an initial Back-to-Back visit generally within two weeks of the baseline assessment (Step 4). During the visit the CM first meets with the patient in person for 45 minutes to collect information about PTSD symptom severity via the 17-item PTSD Checklist-civilian version (PCL-C) [75]; assessing suicide risk, stress, and resource needs; providing education about PTSD; engaging the patient to actively participate in their PTSD treatments; and using motivational interviewing techniques to encourage behavior change [59–61]. The CM also enters information about the patient into the registry and then transcribes relevant information for the patient to share with the PCC in the visit following the CM assessment (Step 5).

The PCC then meets with the patient and documents the management plan in the study visit worksheet (Step 6). Treatment may involve watching and waiting, starting the patient on a PTSD medication [68], referring the patient to a psychiatrist for medication evaluation and management,

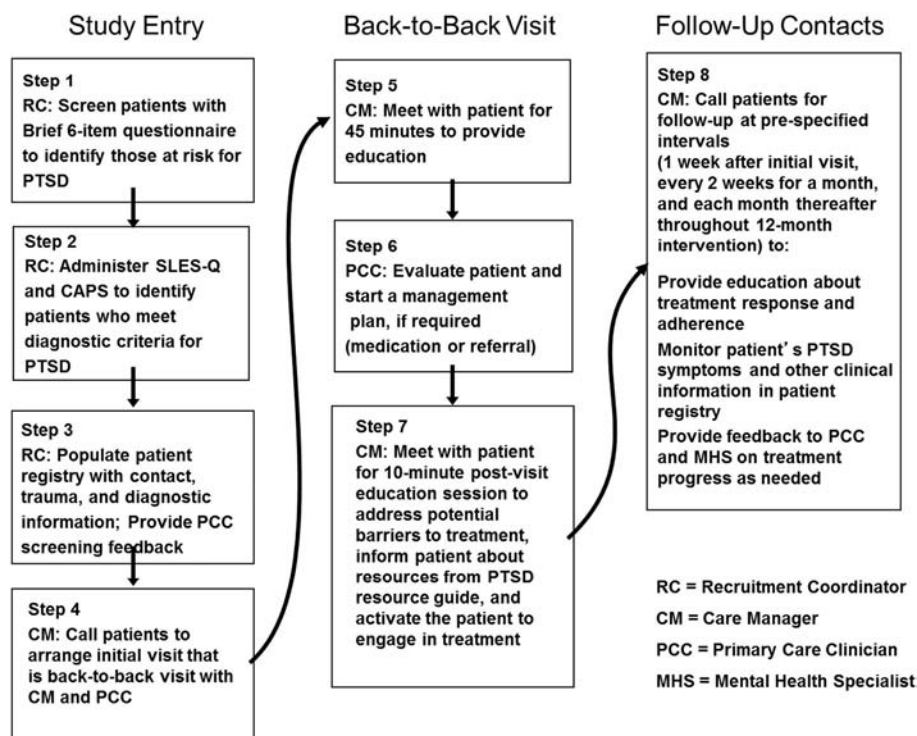


Fig. 1. Overview of ViStA intervention.

and/or referring the patient for psychotherapy with a mental health specialist.

Following the visit with the PCC, the CM conducts a brief, 10-minute meeting with the patient (Step 7) to review the treatment plan, answer any questions, assess and address barriers to treatment adherence, provide relevant information from the PTSD resource directory (guided by the CM), and complete a personal plan for the patient. At the end of this session, the CM arranges for the next contact with the patient and enters information from the PCC into the patient registry. We chose to use this approach because it facilitates communication with both the PCC by providing synthesized information about the patient's condition and because it can help engage the patient in care by preparing the patient for the encounter with the PCC and in optimizing the productivity of that encounter [39]. In addition, the post-PCC visit session with the CM enhances care by reviewing the treatment plan with the patient to increase adherence and preparing them for the follow-up care.

After the visit (Step 8), the CM contacts the patient by phone for follow-up within one week of the visit, every two weeks for a month, and then subsequently once a month throughout the 12-month intervention period for a total of up to 15 contacts with a patient. During these scheduled follow-up calls, the CM reassess the patient for PTSD symptoms (using the PCL), provides information about treatment progress, answers patient questions, shares information on resources and community linkages, and schedules the next call. Throughout the intervention period, the CM provides feedback to the PCC and mental health specialist (if applicable) on the patient's progress, barriers the patient faces in adhering to the treatment plans, and changes in the patient's PTSD status. Due to a diversity of structures among the FQHCs, CMs use a range of strategies to communicate with the PCCs about CM cases (e.g., at monthly clinician meetings, between patient visits, and through email and notes placed in patient charts). The CMs compile monthly reports from aggregate patient data collected through the patient registries to track the number of patients with PTSD who are assessed, treated, and referred for care.

2.3. PTSD care managers

Because of resource constraints inherent in FQHCs, we hired non-clinical CMs from the community. The two bachelors-level half-time CMs were bilingual (in Spanish) Latinas with experience in community health service and

knowledge of cultural issues in this FQHC patient population. CMs were trained to provide care management for PTSD using the study protocol. Initial training consisted of 1.5 days of didactic instruction with role-plays followed by booster training mid-way throughout the intervention. Training covered all facets of the CM role, including contacting patients, using the patient registry, coordinating care with clinical staff (PCCs and mental health professionals), using psychiatric supervision, educating and activating patients (including basic principles of motivational interviewing), following-up and monitoring patients, assessing for PTSD symptoms using the PCL, and filing monthly reports. All patients at a given site see the same CM to avoid CM variation within site.

CMs meet weekly for one hour to review cases with the study psychiatrist. CMs share challenging patient cases and receive advice for how to best help those patients, as well as guidance and suggestions for modifying treatment plans. In addition, the weekly CM calls with the psychiatrist are used to share self-care strategies with the goal of preventing burnout among the CMs.

2.4. Evaluation design

The ViStA study is a patient-level randomized controlled trial currently evaluating the efficacy of a PTSD Care Management (PCM) intervention compared with usual care using differences in differences analysis of outcomes before and at six and 12 months after the intervention. In addition, ViStA is assessing the effects of the intervention implementation and examining the direct costs of the PCM program compared with usual care. Both Clinical Directors Network (CDN) and RAND Institutional Review Boards approved ViStA procedures before patient recruitment began.

2.5. Study measures

Our primary outcomes include mental health and functioning, health and mental health service use, patient satisfaction with care, and perceived barriers to care (Table 4). We will assess these outcomes at baseline, six, and 12 months. We also collected several secondary measures, which include process measures for assessing intervention fidelity (e.g., adjunctive support services, medications, CBT components). Secondary measures will be also be used as covariates in main analyses (e.g., functional impairment, intervention exposure, perceived need for treatment). Other secondary measures (e.g., resilience,

Table 2
Summary of Federally Qualified Community Health Center (FQHC) characteristics.

FQHC	Onsite BH	# Psychiatrists*	# Social Workers	# Adult users	# AM PCCs	Weekly patient volume	% Latino/a	% Women	% Uninsured	% Medicaid
A	Yes	1	2	8,000	9 [†]	330	56	59	37	50
B	No	0	1	20,000	4	400	65	60	20	50
C	No	1	1	9,000	5	450	60s	65	10	65
D	Yes	5	13	9,000	7	600	65	70	20	70
E	No	0	1	4,000	2	120	80	65	40	50
F	Yes	1	2	3,500	9	700	80	65	50	10
G	Yes	1	5	11,300	6	400	65	65	11	69

Notes. BH = behavioral health; AM = adult medicine; PCC = primary care clinician (adult medicine); *Indicates psychiatrist(s) except for site F which had a psychiatric nurse practitioner; psychiatrists were part-time at sites C and F. [†]4 of 9 are residents.

Table 3
Characteristics of ViStA participants (N = 355).

	N	Percent
Age (mean and standard deviation)	42.4	12.2
Women	286	80.6
Race/ethnicity		
Hispanic/Latino	183	51.8
Black	125	35.4
White	21	6.0
Other	24	6.8
Marital status ^a		
Single	201	57.6
Separated/divorced/widowed	76	21.8
Married	45	12.9
Member of unmarried couple	27	7.7
Has one child or more	279	79.7
Education		
<High school	137	38.9
12 years	116	33.0
>12 years	99	28.1
U.S. born ^b	276	81.4
Health insurance		
No insurance	26	7.4
Medicaid	286	81.2
Medicare	7	2.0
Other government insurance	20	5.7
Private insurance	13	3.7
No. of chronic medical conditions		
0	113	32.7
1	73	21.1
2	62	17.9
≥3	98	28.3
No. of lifetime traumas		
1	10	2.9
2	29	8.3
≥3	311	88.9
Probable major depression (PHQ-9 > 9)	181	48.4
Severe anxiety symptoms (GAD > 15)	160	45.2
Severe somatic symptoms (PHQ15 > 15)	116	33.2
Hazardous alcohol use (AUDIT > 8 men/>3 women)	65	18.4
Probable drug abuse/dependence (DAST-10 > 3)	31	8.8

Notes. Values are numbers and percentages except for age which is mean and standard deviation.

^a 6 patients did not disclose this information.

^b 16 patients did not disclose this information.

coping, and social support) will be employed as mediators and moderators in supplemental analyses.

3. Results

3.1. FQHC characteristics

The intervention is being implemented in seven different FQHCs in the New York/New Jersey Metropolitan area. These FQHCs span three of the five boroughs of NYC, Westchester, NY, and Northern NJ. Table 2 summarizes selected characteristics of these FQHCs. When the intervention was first implemented, four sites had onsite mental health care. However, two of the mental health components were independent mental health divisions accredited by the NY State Department of Health. These divisions served patients outside of primary care and were thus difficult to access. Additionally, one of the mental health divisions was closed during the study. Thus, mental health resources are more limited than anticipated. The study FQHCs vary in size and in ratio of clinicians to patients. The largest site, which has

20,000 adult users, initially had only four PCCs (which is a ratio of 5,000 patients per clinician), although three additional clinicians were hired after the study began. In contrast, the smallest FQHC, which has only 3,500 users, has nine PCCs (a ratio of 389 patients per clinician). Patient volume also varies from a low of 110 patients per week to as many as 700 patients per week. Between 59% and 75% of the patients seen in these centers are Latino and between 56% and 80% were women. Most of the patients have Medicaid insurance or are uninsured.

3.2. Sample size

Our study was designed with a targeted sample size of 400 (effective sample size = 320 after attrition). This will allow us to detect an effect size of .32 S.D. on primary outcomes using two-sample comparisons, and an effect size .19 S.D. using three-wave longitudinal data, both under the standard setting (significance level = .05, power = .8). These effect sizes are considered small in the standard power analysis in behavioral sciences. In addition, these effect sizes are plausible since they are smaller than the findings in the literature reported effect sizes .40 and .21 in cross-sectional and longitudinal analysis respectively.

3.3. Study sample and patient characteristics

Approximately 8,300 patients were approached for participation in the study and 4,815 met the initial inclusion criteria (have a scheduled or walk-in appointment with a PCC, no physical or cognitive disabilities, 18–65 years of age, and plans to continue receiving care at that FQHC for the next year) and completed the brief screener for PTSD symptoms. Of those, 30% were at-risk for PTSD (defined as a cut-off of 14). Most patients at-risk consented to the study (72%) and had a DSM-IV PTSD diagnosis (69%) according to the CAPS. The overall rate of PTSD was 8% in the total eligible sample. A total of 404 patients were enrolled into the trial. Patients within the participating FQHCs were randomized to each of the two study conditions. The baseline sample includes 206 patients randomized to the ViStA intervention and 198 randomized to usual care; 184 (89%) and 171 (86%) patients completed the baseline interview, respectively. The six and 12-month follow-up data collection are in progress.

The majority of ViStA participants who have completed baseline interviews (N = 355) are women (Table 3). Half of the sample is Hispanic/Latino (51.8%) and over a third is Black (35.4%). A high proportion of the ViStA participants have not finished high school and is either uninsured (7.4%) or on subsidized insurance (81.2%). Nearly all of the ViStA participants reported having experienced three or more traumatic events. A large proportion of these patients also have one or more chronic medical conditions. Comorbid mental health and substance use symptoms are common, with nearly half meeting criteria for probable major depression (48.4%) and severe anxiety (45.2%). A third of the patients have probable somatization disorder (33.2%) according to the PHQ, and 27.2% of the participants meet criteria for either hazardous alcohol use (18.4%) or drug abuse/dependence (8.8%).

Table 4
ViStA baseline measures.

Measure	Source(s)
Mental health and functioning	
Brief 6-item PTSD screener	Lang & Stein, 2005 [71]
Trauma exposure	SLES-Q, Goodman et al., 1998; Green et al., 2006 [10,72]
PTSD diagnosis and symptoms	Clinician Administered PTSD scale (CAPS), Blake et al., 1995; Weathers et al., 2001 [73,74]
Health-related quality of life	SF12/MH15, Ware Jr. et al., 1995; Ware Jr. & Sherbourne, 1992 [77,78]
Functional impairment	Sheehan Disability Scale, Leon et al., 1997 [79]
Health and mental health service use	
Physical/mental health service use	Partners in Care (PIC), Wells et al., 2000 [80]
CBT components	PIC, Jaycox et al., 2003 [81]
Awareness of intervention Exposure	PIC, Rubenstein, et al., 1999 [82]
Medications	PIC, Ünützer et al., 2001 [83]
Adjunctive support services	Community Partners in Care (CPIC), unpublished
Problem recognition	National Comorbidity Study-Revised (NCS-R), Koenen et al., 2003; Alegria et al., 2004 [84,85]
Perceived need for treatment	NCS-R, Koenen et al., 2003; Mojtabai et al., 2002 [85,86]
Patient satisfaction with care	Hays et al., 1999 [87]
Perceived barriers to care	PIC, unpublished
Comorbidity	
Medical conditions	Charlson Comorbidity Index, Charlson et al., 1987; Charlson et al., 1984 [88,89]
Somatization	Patient Health Questionnaire (PHQ), Spitzer et al., 1999 [90]
Depression symptom severity	PRIME-MD PHQ-9; Spitzer et al., 1999 [90]
Anxiety symptom severity	GAD-7, Spitzer et al., 2006 [91]
Alcohol and drug use	AUDIT, Babor et al., 2001 [92]
Substance disorder	Drug Abuse Screening Test (DAST-10), Skinner, 1982; Yudko et al., 2007 [93,94]
Stressful life experiences	Perceived Stress Scale, Cohen et al., 1983 [95]
Resilience	CD-RISC, short form, Connor & Davidson, 2003; Campbell-Sills & Stein, 2007 [96,97]
General coping	PIC; Sherbourne et al., 2004 [98]
Religious coping	Tepper et al., 2001 [99]
Social support	PIC; Sherbourne et al., 2004 [98]
Relationship satisfaction	General Social Survey
Chronic pain	PEG, Krebs et al., 2009 [100]
Demographics	Standard items

4. Discussion

Only a few studies have explored the application and translation of primary care collaborative care models to improve anxiety disorders, including PTSD. Roy-Byrne et al. [40] examined the effectiveness of collaborative care for panic disorder in primary care and found significant improvement in patient quality of care, as well as clinical and functional outcomes, relative to usual care. The Coordinated Anxiety Learning and Management (CALM) study [42] found that the intervention was significantly associated with reduced anxiety and depression symptoms; decreased disability; improved quality of care [37,39]; and more anxiety-free days; with modest increases in healthcare expenditures over 18 months compared with usual care [38]. Furthermore, it was feasible to implement and acceptable by clinic staff [76]. There was no significant effect on PTSD symptoms, although this could have been due to the small number of patients with PTSD in the study. A recent study of collaborative care for PTSD in veterans (RESPECT-PTSD) did not find significant differences in symptoms or functioning, but did find that the intervention increased quality of care relative to usual care [41].

These studies have made a substantial contribution to furthering knowledge about the management of anxiety disorders in “real world” primary care settings. However, these settings, which are relatively well-resourced, academically-affiliated clinics, with patient populations who mostly have insurance and are predominantly White or veterans, are quite different from FQHCs and their underinsured and low resource patients including those whom are undocumented

and have no legal access to some services. It is not known whether such approaches are feasible for community-based FQHCs that serve as the main system of care for these populations, which include a high proportion of minorities, including Latinos, other non-English speaking populations, and high levels of uninsured or publicly insured patients [43,44]. Collaborative care interventions may be adapted and implemented to address the needs of those with PTSD in cost-effective ways [62] and may include psycho-education, hybrid treatments, psycho-pharmacology, and systems-level interventions that integrate mental health treatment into primary care settings [45].

ViStA was designed using an academic-community research-PBRN collaboration that considered formative data and evidence-based practices to improve PTSD care. The data collection and analysis are currently underway to assess the impact of this intervention [39,40]. ViStA will be the first randomized controlled study of a care management intervention for PTSD in low-resource FQHCs that provide primary care to many low-income, non-English speaking minority patients. The ViStA approach is grounded in previous work, and innovative in its application to this FQHC population. We chose to implement and adapt the components of the intervention that were previously tested and shown to be effective in higher resource environments to FQHC settings and patients.

The delivery of effective collaborative care intervention within FQHC settings can be challenging given that the patient population includes many low-income, uninsured patients from diverse backgrounds and with high rates of

chronic trauma and multiple clinical co-morbidities. Some of the unique barriers identified in our formative work, include limited access to and affordability for specialty mental health care, make it even more challenging to engage and retain patients in treatment. Many of the patients seen in this study's FQHCs are immigrants and may return to their home countries for extended periods of time, contributing to discontinuity of care and medication non-adherence. Additionally, several FQHCs were shut down permanently or temporarily during the study period for reasons ranging from legal situations culminating in the incarceration of the FQHC Chief Executive Officer, to a catastrophic natural disaster (i.e., Super storm Sandy).

Despite the many challenges inherent in implementing a care management intervention in these types of settings and patient populations, ViStA was successful in engaging seven different FQHCs. ViStA has recruited over 400 patients with clinical diagnoses of PTSD. The ViStA study will test the effects of the intervention on the management of PTSD, further adding to the science of care improvement. In addition, ViStA will examine the implementation fidelity as well as its cost and cost-effectiveness.

5. Conclusion

This study will fill a gap in our knowledge of how to intervene with PTSD patients in low-resourced community-based primary care settings where most patients prefer to be treated [48]. Additionally, we will learn whether the intervention can be implemented in FQHCs, and whether it is clinically effective in settings where many patients may not have realistic referral options for specialty care and where the PCC may also serve as the primary mental health clinician. The longer-term goal of ViStA is to disseminate more broadly an effective model tailored to these populations and settings to improve the quality of care, quality of life, and clinical outcomes for those who are exposed to trauma and suffer from PTSD.

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