Trauma-Informed Collaborative Care for African American Primary Care Patients in Federally Qualified Health Centers: A Pilot Randomized Trial

Study Protocol and Statistical Analysis Plan

Trial registration: (Clinicaltrials.gov NCT03591107)

September 15, 2017

METHODS

Design

ViStA-NOLA was a pragmatic pilot patient-level randomized controlled trial to compare the effectiveness of our adapted and tailored TICC intervention with enhanced usual care (EUC).[24] The RAND Institutional Review Board approved the study protocol.

Adaptation and Tailoring. We used a two-step approach in developing the study intervention to increase engagement in and adherence with collaborative care. First, we addressed both the challenges that the research team identified in implementing ViStA and the recommendations from selected patients and clinic staff interviewed at the end of that study to elicit practical feedback about how to make our collaborative care intervention more pragmatic, feasible, and acceptable. We hired and incentivized a CM from the clinic rather than hiring a CM from outside the clinic to better integrate into the clinic's flow. We also connected intervention patients with the CM on the same day or within two days using a warm handoff (e.g., in-person if available or using a handout with the CM's picture and contact information). To reduce patient burden and because a more frequent CM contact schedule was not feasible in the previous ViStA study, we shortened the duration of the intervention from 12 to nine months. Accordingly, we cut the number of CM contacts with patients from 15 to eight contacts. Because patients reported undue burden of being reassessed so often with many items, we used a briefer symptom assessment for measurement-based care. We provided 1.5 days of formal training on motivational interviewing (compared with just a brief 2-hour module previously). And we involved representatives from a local social

service organization to facilitate CM referrals to address social determinants of health needs rather than simply providing the patient with a list of resources.

We also used a community-partnered approach for tailoring the intervention to the local context and population. We formed a study workgroup comprised of multiple stakeholders (primary care providers (PCPs), behavioral health providers (BHPs), clinic managers, the CM, patient representatives, public health and community service representatives). Our goal was to target barriers that disproportionately impact African Americans, including financial hardship, chronic exposure to violence, negative beliefs about psychotropic medication,[4] trust in health care providers and institutions,[25-31] and the community-wide trauma experienced in this Hurricane ravaged area and associated flooding.[32]

Some of the suggestions from the community stakeholder workgroup were to use images reflective of the population, to gear intervention materials toward a 7th-grade reading level, and for the CM to use text messaging to communicate with providers. The group emphasized the importance of trust in providers and of providing hope and meaning given the suffering for many years since Hurricane Katrina. We incorporated all of these lessons and feedback to optimize the intervention protocol (training materials, guides, manuals, etc.) and to make it less burdensome.

Enhanced Usual Care (EUC). The EUC arm of the randomized study consisted of educating all primary care clinic staff about PTSD and trauma-informed care. Prior to implementing the intervention, we delivered a 2-hour training onsite at the FQHC. We also trained FQHC physicians on evidence-based medication for PTSD based on the National Institute for Clinical Excellence guidelines[33] and provided them with a

medication decision aid. In addition, we informed PCPs about patient's study eligibility and enrollment which indicated that the patient met criteria for having probable PTSD. We provided patients who were identified as having probable PTSD an information sheet adapted from patient education resources from the National Institute of Mental Health and the International Society for Traumatic Stress Studies.

Trauma-Informed collaborative care (TICC). The TICC intervention included all of the EUC components plus components facilitated by the study-trained CM, initially a medical assistant, replaced by a nurse care manager over the last several months of the study. These additional components involved active patient education and engagement using the PTSD handout and motivational interviewing techniques.[4] CMs also facilitated linkages to community resources with locally tailored information. CMs had structured cross-disciplinary communication with PCPs and mental health providers (if relevant), plus monthly meetings with the study behavioral health consultant to guide clinical care decisions. CMs facilitated measurement-based care (using the Short PTSD Rating Interview/SPRINT)[34, 35] through an initial in-person visit complemented by a series of seven follow-up contacts by telephone to monitor care over nine months. CMs also received ongoing phone supervision as needed (~once/month).

Setting and Participants

Researchers from RAND and the Louisiana Public Health Institute (LPHI) partnered with a large FQHC in New Orleans, Louisiana. Primary care patients participated in an intervention and interviews, and clinic staff in primary care participated in stakeholder meetings and exit interviews as described in the following sections.

Recruitment Procedures. We completed patient recruitment across 70 days over the course of nine months from October 12, 2018 to July 2, 2019. Patients were approached in the primary care waiting area and if they met inclusion criteria (age 18 or older, self-identified as African American, considered the clinic their usual source of care). They were asked to complete a brief PTSD symptom checklist (the PC-PTSD-5),[36] followed by a longer PTSD assessment with the PTSD checklist for version five of the Diagnostic Statistical Manual (PCL-5[37]). If patients were at-risk for PTSD, they were invited to enroll in the study and asked for informed consent. Study staff completed a baseline assessment either in the clinic or by telephone prior to randomization to study condition. A total of 42 adult patients were enrolled in the study.

Assessments. Patients were evaluated at baseline and nine months via in-person or telephone by interviewers blinded to the study assignment. Our primary outcome was PSTD symptoms based on the PCL-5.

We also examined three types of potential mediating variables to determine whether they might explain the relationship between the intervention and PTSD symptom reduction. We assessed outcome expectancy with a single question, “My PTSD symptoms can be successfully treated?” using a 5-point Likert rating scale.[38] We assessed coping efficacy with a single item also adapted from CALM – “I will be able to do what is necessary to make treatment of my PTSD symptoms successful?” using a 5-point Likert rating scale.[38] We assessed trust in health care provider with the 8-item trust subscale of the Primary Care Assessment Survey.[39] This measure uses a 5-point Likert scale to rate trust domains of integrity, agency, and competence and is correlated with measures of physician communication (r=.75) and interpersonal care (r=.73), and has

strong internal consistency reliability (α=.86). Sample items include, “I trust my doctor’s judgments about my medical care” and “I trust my doctor to tell me if a mistake was made about my treatment.”

Statistical Analysis. This pilot trial had planned a modest sample size of 40 and assumed a 20% attrition (n=32), which was powered to detect a large effect size of 1.0 standard deviation for a continuous outcome and about 45 percentage points difference in the mean of a binary outcome. The initial sample size at baseline was 42 when the recruitment was finished. However, one patient was double counted in both arms and subsequentially excluded from the analysis, and one patient dropped out before completing the baseline, leaving a sample size of 40 at baseline (21 in EUC and 19 in TICC). Attrition from study enrollment to baseline interview completion was 10%, yielding a sample of 36 completers at 9-month follow-up (20 in EUC and 16 in TICC).

Per the study protocol, we ran an intent-to-treat (ITT) analysis based on initial randomization and ignoring the actual treatment exposure. The primary outcome and all mediators were tested at both waves separately. We applied nonparametric Wilcoxon two-sample tests for numerical outcomes and Fisher’s exact test for categorical outcomes as our main approach. The usual two-sample t-tests and chi-square tests were also performed as sensitivity checks. Difference-in-differences analysis were performed for outcomes which had significant differences in the follow-up wave. Since no mediators showed a significant difference at follow-up, we did not perform further structural equation modeling analysis for potential moderation pathways. All analyses were performed in SAS 9.

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Table 1. Baseline Patient Demographic Characteristics and Primary Outcomes

Characteristics	No. (%) of patients		
	Full Sample (N = 40)	EUC (N = 21)	TICC (N = 19)
Demographics			
Women	32 (80.0)	16 (76.2)	16 (84.2)
Education*			
< high school	12 (30.0)	10 (47.6)	2 (10.5)
High school graduate/ GED	17 (42.5)	9 (42.9)	8 (42.1)
College degree or graduate	11 (27.5)	2 (9.5)	9 (47.4)
Marital status			
Single	23 (57.5)	10 (47.6)	13 (68.4)
Married	3 (7.5)	2 (9.5)	1 (5.3)
Unmarried couple	1 (2.5)	1 (4.8)	0 (0)
Separated/divorced/ widowed	13 (32.5)	8 (38.1)	5 (26.3)
Type of medical insurance			
Medicaid	33 (82.5)	18 (85.7)	15 (78.9)
Medicare	3 (7.5)	1 (4.8)	2 (10.5)
Employer/private	2 (5.0)	1 (4.8)	1 (5.3)
Other (Medicaid and Medicare)	1 (2.5)	1 (4.8)	0 (0)
No insurance	1 (2.5)	0 (0)	1 (5.3)
Born in the US	39 (97.5)	21 (100)	18 (94.7)
Years lived in the US	42.75 (12.3)	45.38 (12.5)	39.84 (11.6)
Outcomes			
PCL-5 score, mean (SD) *(primary)*	73.12 (13.9)	72.95 (14.3)	73.32 (13.7)
PHQ-9 score, mean (SD) (*secondary)*	17.35 (4.8)	16.76 (5.0)	18.00 (4.7)

*p<.05

Table 2. Baseline Target Mechanisms, Health Comorbidity, and Health Care Characteristics

Characteristics	No. (%) of patients		
	Full Sample (N = 40)	EUC (N = 21)	TICC (N = 19)
Target Mechanisms			
Outcome expectancy, mean (SD)	3.83 (1.1)	3.86 (1.1)	3.79 (1.0)
Coping Efficacy, mean (SD)	4.42 (0.8)	4.29 (0.9)	4.58 (0.6)
Trust in health care provider, mean (SD)	19.12 (1.4)	19.24 (1.2)	19.00 (1.6)
Health Comorbidity*			
Depression	11 (26)	5 (24)	6 (29)
Psychoses*	4 (10)	4 (19)	0 (0)
Drug use	0 (0)	0 (0)	0 (0)
Alcohol use	1 (2)	1 (5)	0 (0)
Heart conditions	1 (2)	1 (5)	0 (0)
Diabetes	12 (29)	6 (29)	6 (29)
Hypertension	3 (7)	1 (5)	2 (10)
Cancer	0 (0)	0 (0)	0 (0)
Neurological disorders	1 (2)	0 (0)	0 (0)
Health Care			
Nervous, emotional, drug or alcohol problem in past 6 months	20 (50.0)	11 (52.4)	9 (47.4)
Think need to talk to professional about problems	33 (82.5)	17 (81.0)	16 (84.2)
Number of visits to general physician, mean (SD)	5.36 (4.5)	5.81 (4.7)	4.83 (4.3)
Number of visits mental health issues were discussed, mean (SD)	4.23 (4.0)	4.48 (3.7)	3.94 (4.5)
Received prescription medication for mental health	28 (71.8)	15 (71.4)	13 (72.2)
Received referral for mental health problem	28 (71.8)	16 (76.2)	12 (66.7)
Number of visits with mental health/substance use provider, mean (SD)	4.82 (8.0)	3.57 (4.8)	6.21 (10.5)
Number of visits where advice about medication, mean (SD)	2.88 (2.9)	3.69 (3.5)	1.91 (1.6)
Number of visits with counseling/ talk therapy, mean (SD)	7.42 (8.6)	5.15 (4.7)	10.09 (11.3)
Number of counseling visits, mean (SD)	7.40 (8.6)	5.15 (4.7)	10.09 (11.3)
Number of visits with psychiatrist, mean (SD)	3.12 (5.9)	3.23 (4.8)	3.00 (7.2)
Received prescription from psychiatrist	16 (69.6)	8 (61.5)	8 (80.0)
Attended self-help/ family support groups for mental health	4 (10.3)	2 (10.0)	2 (10.5)
Number of days in self-help/ family support group for mental health, mean (SD)	6.25 (9.2)	1.50 (0.7)	11 (12.73)

*p<.05; Comorbidity measures were derived from ICD-9 codes.

Figure 1. Study Flow Diagram

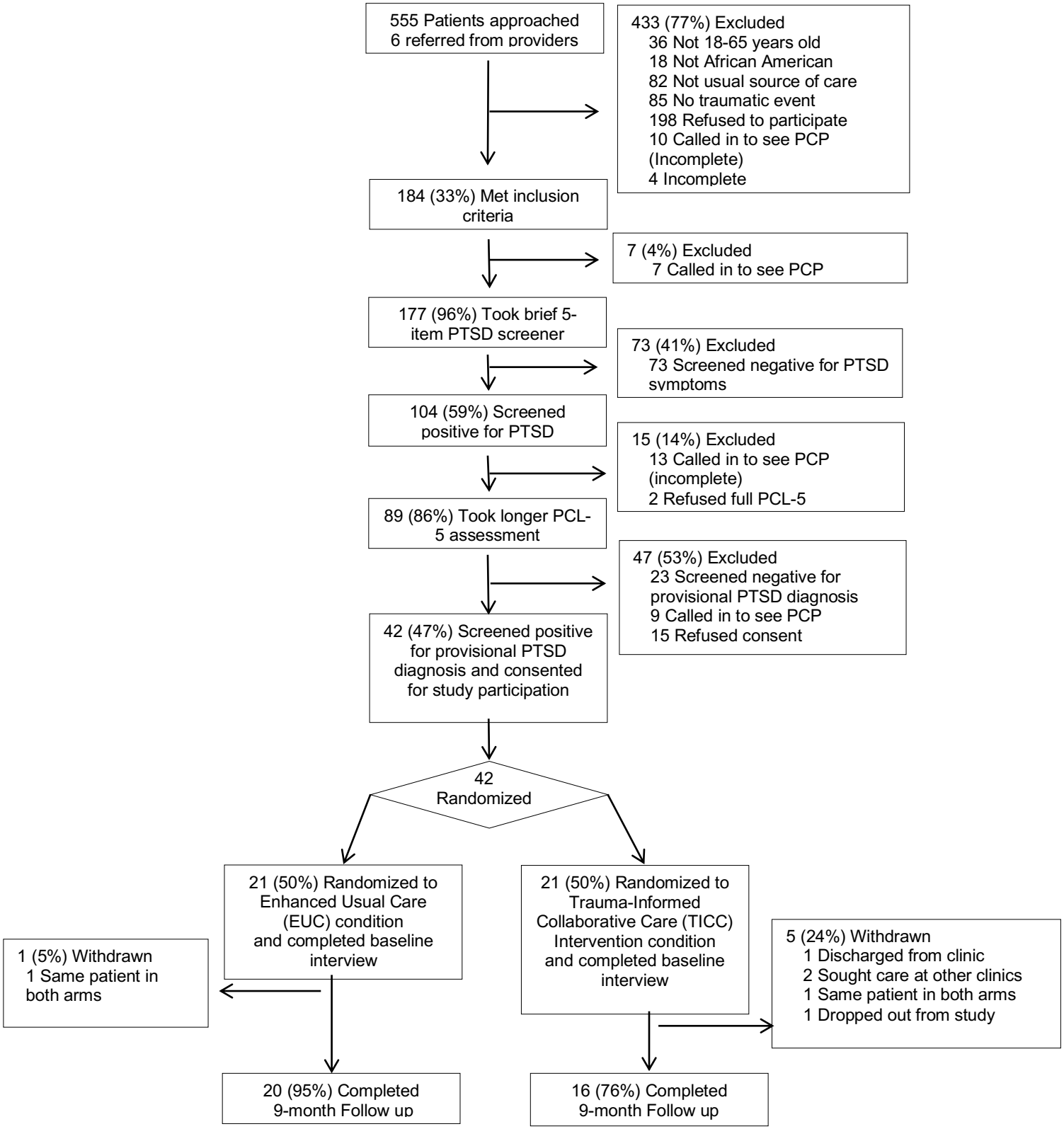

Figure 2. PCL-5 Scores at Baseline and 9-Month Follow-Up