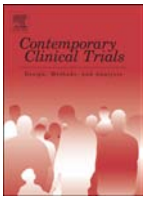
Contemporary Clinical Trials 38 (2014) 163–172

Contents lists available at ScienceDirect

Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclintrial



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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ARTICLE INFO

Article history:
Received 28 January 2014
Received in revised form 6 April 2014
Accepted 9 April 2014
Available online 18 April 2014

Keywords:
Post-traumatic stress disorder
Care management
Safety net Federally Qualified Health Centers (FQHCs)
Hispanic/Latino
Primary care
Integrating primary care and mental health

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.

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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http://dx.doi.org/10.1016/j.cct.2014.04.005
1551-7144/

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