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Authors

Biegler, Kelly
Mollica, Richard
Sim, Susan Elliott
et al.

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Rationale and Study Protocol for a Multi-component Health Information Technology (HIT) Screening Tool for Depression and Post-traumatic Stress Disorder in the Primary Care Setting

Kelly Biegler, PhD[a], **Richard Mollica, MD, MAR**[b], **Susan Elliott Sim, PhD**[c], **Elisa Nicholas, MD, MSPH**[d,e], **Maria Chandler, MD, MBA**[d,e], **Quyen Ngo-Metzger, MD, MPH**[f], **Kittya Paigne, MD**[g], **Sompia Paigne, LCSW, PhD**[g], **Danh V. Nguyen, PhD**[a,h], and **Dara H. Sorkin, PhD**[a]

[a]Department of Medicine, University of California, Irvine, Irvine, CA, United States

[b]Department of Psychiatry, Harvard Medical School, Boston, MA, United States

[c]Faculty of Information, University of Toronto, Toronto, Ontario, Canada

[d]Department of Pediatrics, University of California, Irvine, Irvine, CA, United States

[e]The Children's Clinic, *Serving Children and Their Families*, Long Beach, CA, United States

[f]US Preventive Services Task Force, Agency for Healthcare Research and Quality, Rockville, MD, Unites States

[g]The Community Medical Wellness Center, Long Beach, CA, United States

[h]Biostatistics, Epidemiology and Research Design, University of California, Irvine, Irvine, CA, United States

Abstract

The prevalence rate of depression in primary care is high. Primary care providers serve as the initial point of contact for the majority of patients with depression, yet, approximately 50% of cases remain unrecognized. The under-diagnosis of depression may be further exacerbated in limited English-language proficient (LEP) populations. Language barriers may result in less discussion of patients' mental health needs and fewer referrals to mental health services, particularly given competing priorities of other medical conditions and providers' time pressures. Recent advances in Health Information Technology (HIT) may facilitate novel ways to screen for depression in LEP populations. The purpose of this paper is to describe the rationale and protocol of a clustered-randomized controlled trial that will test the effectiveness of an HIT intervention that provides a multi-component approach to delivering culturally competent, mental health care in the primary care setting. The HIT intervention has four components: 1) web-based provider training, 2) multimedia electronic screening of depression and PTSD in the patients' primary language, 3) Computer generated risk assessment scores delivered directly to the provider, and 4)

Corresponding Author: Dara H. Sorkin, Ph.D.; Associate Professor; University of California, Irvine, 100 Theory, Suite 120, Irvine, CA 92697-5800; tel.: (949) 824-0149, dsorkin@uci.edu.

clinical decision support. The outcomes of the study include assessing the potential of the HIT intervention to improve screening rates, clinical detection, provider initiation of treatment, and patient outcomes for depression and PTSD among LEP Cambodian refugees who experienced war atrocities and trauma during the Khmer Rouge. This technology has the potential to be adapted to any LEP population in order to facilitate mental health screening and treatment in the primary care setting.

Keywords

Health Information Technology; Primary Care; Limited English Proficiency; Cambodian refugees; depression; PTSD

Introduction

The prevalence of depression in primary care is high,[1, 2] and primary care providers serve as the initial point of contact for most patients with depression.[3] Yet in usual care, providers recognize only about half of the depressed patients who present for care.[3–5] This lack of recognition may result from several factors, including the patient presentation limited to physical complaints, competing priorities of other medical conditions, and providers' time pressures.[5, 6]

Under-diagnosis and under-treatment of depression may be exacerbated among patients who encounter language barriers. Approximately 54 million people in the U.S. speak a language other than English, and over 21 million are considered to be limited English-proficient (LEP).[7] Language barriers affect the 2.5 million Southeast Asian refugees living in the U.S.,[8] many of whom have suffered war-related trauma and are at high risk for depression and post-traumatic stress disorder (PTSD).[9, 10] In particular, Cambodian refugees have the highest prevalence rates for depression and PTSD (51% and 62% respectively).[10] Experiences of war, genocide, cultural destruction, and starvation[10] have led many of these individuals to immigrate to the U.S. as political refugees. The mental health impact persists 30 years later,[10] possibly because many individuals have not been properly diagnosed and treated. Furthermore, the clinical presentation of mental disorders among Southeast Asians may be different from non-Hispanic whites, making detection of treatable illness more difficult.[11] For example, many Southeast Asian individuals may present with somatic complaints, such as headaches, musculoskeletal pain, abdominal pain, and fatigue, make diagnosis more difficult.[12, 13]

Research suggests that multi-component interventions directed toward improving depression outcomes in primary care settings may be more successful than single-component interventions.[14, 15] Advances in health information technology (HIT) make it possible to develop multi-faceted HIT interventions that include screening, provider training and notification, and clinical decision support, which may be more effective than any single intervention alone.[15, 16] In primary care, tailored interventions that give individualized patient data to providers are more effective than "generic, one-size-fits-all" interventions.[15, 16] Furthermore, this technology has the potential to be adapted and utilized for any group of LEP patients, regardless of language, and has the potential to be adapted for

providers to aid in the recognition and diagnosis of mental disorders in diverse primary care settings.

In this paper, we describe the rationale and protocol for a clustered randomized controlled trial to assess the potential of using HIT to improve the screening, diagnosis, treatment initiation, and outcomes for Depression and PTSD in a vulnerable, LEP Cambodian refugee population. In addition, we describe each of the four components of the HIT intervention. Finally, we provide baseline data describing the sociodemographic characteristics of the study sample.

Method

Intervention Rationale and Key Components

Although HIT holds the promise to improve the quality of care for some patients, it may *not* improve care for patients with limited English proficiency or low computer literacy. Individuals who are older, racial/ethnic minorities, foreign-born, or have limited English-language skills are more likely have low language and computer literacy.[17, 18] Thus, advances in HIT may not improve healthcare for these people unless such interventions are tailored to the user's language and computer literacy levels. The use of novel, culturally-competent HIT that enhances communication between patient and providers is particularly well-suited to overcoming these barriers. Thus, in the current study, we developed a multimedia risk assessment tool that addressed barriers at both patient and provider level (**see** Figure 1).

Patient—Language and cultural barriers can make it difficult for patients to communicate adequately with their English-speaking providers. Furthermore, fear of stigma may make patients unwilling to present their mental health symptoms to clinicians. Patients also may conceal or fail to acknowledge symptoms if they do not believe that depression/PTSD is a valid health problem requiring treatment.[19] Similarly, patients' lack of knowledge makes it less likely that they will recognize their own symptoms, thus presenting an unclear picture to the clinician.[6] Finally, there is evidence that depressed patients who present with a clear statement of their problem and a request for assistance are identified at a higher rate.[20] This implies that patients who are unaware of treatment options may not know how to request assistance and, thus, their mental health needs may be more likely to be overlooked by the primary care provider.

Compared to psychiatrists who care for a pre-screened group of individuals, primary care patients are not pre-screened for the presence of a mental health problem in most clinics. Thus, the first important step to improving the diagnosis of depression/PTSD in primary care settings involves screening patients in a way that overcomes the multiple barriers they face. In the current study, the HIT multi-media screening instrument was administered on a touch screen computer tablet (iPad) (Figure 1. ***Key Component of HIT, #2***). The touch screen modality allowed us to administer the screening in the patient's primary language, using both visual and auditory presentation to accommodate low language-and computer-literate patients. Because the computer immediately scores the screener, tailored information was

provided instantaneously, which normalized patients' experiences and encouraged them to discuss the symptoms with their primary care providers.

Providers—To address depression/PTSD in the primary care setting, providers need appropriate and specific knowledge in order to identify and treat these disorders correctly. Clinicians need a working knowledge of depression and PTSD that is specifically tailored to the ethnic/cultural groups they are most likely to treat for the most efficient and effective management possible in the primary care setting. HIT is well-suited to deliver this information. In this study, we used a web-based tutorial to train providers randomized to the intervention arm on the unique mental health needs of Southeast Asians, focusing on Cambodian refugees (Figure 1. ***Key Component of HIT, #1***). This training included how to recognize symptoms and how to discuss patients' mental health in a culturally-competent manner.

The fast pace of the primary care visit often creates additional barriers. Thus, the next key feature of the HIT system involves notifying providers of patients' results and, subsequently scanning the information into the patients' electronic health records (Figure 1. ***Key Component, #3***).

Finally, clinical uncertainty has been linked to management decisions in recent studies in primary care settings.[21] Specifically, clinicians who feel uncertain may be less likely to feel comfortable carrying out treatment guidelines. The final piece of the HIT system involves providing easily available, interactive, ongoing decision support in the form of a web-based mobile application that provides the latest information on dosing and links to local mental health service providers (Figure 1. ***Key Component of HIT, #4***). Thus, the current study tested the effectiveness of an integrated HIT system in improving rates of screening, diagnosis, and treatment initiation for depression/PTSD in primary care settings that serve limited English proficient, high-risk adults.

Detailed Description of the HIT Intervention Design and Procedures

The HIT intervention was delivered at the level of the provider, as the intent of this study was to examine whether providers could effectively incorporate the HIT intervention's clinical skills training and treatment guidelines into their existing patient practice in order to improve mental health diagnosis and treatment in Cambodian refugees. Because it is likely that providers would have difficulty systematically implementing two different types of care without cross-contaminating care methods across two patient groups,[22] we utilized a clustered randomization design in which providers were randomized in a 1:1 ratio into one of two study arms: Intervention and Minimal Intervention Control. Patients empaneled to participating providers were assigned to the study arm into which their provider was randomized. The greatest variability in terms of provider and patient characteristics is across clinics, not within clinics; thus, to minimize the effect of site variability on study outcomes, randomization of the provider occurred within the clinic when possible. The study design was a single-blind study in that only study patients were blinded to their study group assignment. Figure 2 outlines the study design and protocol that providers and patients received in the HIT Intervention and Minimal Intervention Control Arms.

Patient Enrollment and Study Procedures—Cambodian patients were identified through clinic patient registries and were recruited during regularly scheduled or walk-in appointments at both primary care clinics. Cambodian patients who were 18 years of age and older were eligible. Patients with severe visual/hearing impairments and/or life-threatening illness were excluded. At the time of the clinic visit or over the phone 1 – 2 weeks prior to a scheduled appointment, a bilingual Cambodian research assistant explained the study to eligible patients and asked if he/she was interested in participating in the study. On the day of the clinic visit, all participants completed an informed consent and a Health Insurance Portability and Accountability Act (HIPAA) waiver to allow the review of their medical chart in their preferred language (either Khmer or English). All study protocols were approved by the University of California, Irvine's Institutional Review Board.

After providing informed consent, all study patients completed the multi-media mental health screening instrument (in either Khmer or English) in the waiting room prior to their clinic visit. As discussed previously (see Figure 2), providers in the intervention group received a printed notification of computed depression and PTSD screening scores of their empaneled patients assigned to the intervention group (see 'Sources of Data' section for detailed description of the instruments and scoring; Figure 2). Conversely, providers in the control group did not receive depression and PTSD screening scores of their empaneled patients except if there was reasonable suspicion that the patient was likely to harm self or other or if there was a suspicion of child or elder abuse (see further details in the section below entitled '*Minimal Intervention Control Group*').

Within 1 – 2 weeks of enrollment, all study patients completed a baseline survey containing a wide range of assessments including: health status and health behaviors; medical care usage and experiences; relationships and personal experiences; and socio-demographic information. Twelve weeks after enrollment, all study patients completed a follow-up survey assessing potential changes in health behaviors; health care satisfaction; mental health care usage; and depression and PTSD status using the same multi-media mental health screening instruments conducted at baseline.

Providers—We designed the study to maximize our ability to examine the specific impact of the HIT mental health intervention on providers' medical practice (while limiting an effect of technology generally) by providing similar technology to the intervention and control groups. Specifically, providers in the control group received content focused on general health, while providers in the intervention group received content specific to mental health. All providers attended a brief orientation that introduced the project's general purpose of improving health in LEP patients and providing basic training on how to access the web-based clinical tutorials. Thus, providers participated in the study because of the desire to improve their care for these populations.

Intervention Group

1. Web-based tutorial for clinical skills training: The first component of the HIT intervention included training in providing culturally competent mental health care to the Southeast Asian population, particularly in individuals who have experienced extreme war

trauma. Mental health training was provided using web-based tutorials that included the following modules: 1) Assessment of depression in primary care; 2) Assessment of trauma and PTSD in primary care; 3) Simple ways of improving assessment of Southeast Asian patients; 4) Neuropsychological effects of head injury on survivors of trauma and torture; 5) Ethno-psychopharmacology for depression and PTSD that is specific to Southeast Asians (e.g., prescribing practices that are tailored to drug metabolism in this population); 6) Communicating with Southeast Asian patients about mental health; 7) Effective use of interpretation: a primer for clinicians and interpreters; 8) Helping patients cope and regain control; and 9) Resources and referrals for Southeast Asian and patients with mental health needs. This interactive, web-based tutorial was developed and adapted from a paper-based and CD-ROM "toolkit" previously developed by the Harvard Program in Refugee Trauma (HPRT). This toolkit has been introduced into the 30 treatment centers in the United States caring for survivors of torture funded by the Office of Refugee Resettlement, as well as into health clinics in Cambodia, Peru, Rwanda, Uganda, Iraq, Bosnia and Herzegovina. Estimated time of the self-study tutorials was three hours. Providers received three CME credits from the UC Irvine Office of Continuing Medical Education after completing the tutorial.

2. Multi-media mental health screening instrument: The second component of the HIT intervention featured a multi-media mental health screening instrument. All patients completed two culturally-adapted instruments screening for depression and PTSD (see Measures section for detailed description of the instruments and scoring), which were administered using a multimedia, interactive computer program on a touch-screen iPad (Figure 3). Each item of the depression and PTSD screening instruments was presented in a written format, while the research assistant read aloud each item as well. Participants' responses were recorded for each item on the iPad and composite scores for the depression and PTSD instruments were computed immediately after they were completed.

Providers in the intervention group received a printed notification of patients' scores on all individual items, as well as composite scores, indicating positive and/or negative mental health screening results prior to the patient visit (see 'Sources of Data' section for detailed description of the instruments and scoring). In the event that results for depression and/or PTSD were positive, providers in the intervention group received recommendations to discuss the results with the patient and to follow practice guidelines for the initiation of follow-up care.[23, 24]

3. Clinical Decision Support: This component of the HIT intervention supported the health care provider in the diagnosis and initiation of treatment of depression or PTSD. Clinicians in the intervention group had access to evidence-based clinical algorithms and guidelines through the web-based mobile application. Clinical decision support was based upon an 11-point diagnosis and treatment approach summarized in Table 1. The 11-point action plan was derived from the *Harvard Program in Refugee Trauma Primary Care Provider Toolkit for the Identification, Diagnosis, and Treatment of Depression and PTSD*. Each action-oriented step in the 11-point plan provided easy navigation to access short, "bite-size" pieces of information.[25] Each of the 11 points was electronically linked to more evidenced-based

guidelines and algorithms. Research has shown that technology that provides *quick and easy access* to appropriate knowledge or protocols are more likely to be used by primary care providers.[16, 26]

An important link in the clinical decision support tool included information *to assist decision-making concerning drug dosages* (Table 2). Previous research has shown that this type of computer-assisted dosing is effective in improving clinicians' prescribing patterns for appropriate therapeutic drug levels and increased patient safety.[27] For example, our clinical experience among Southeast Asians has shown that primary care providers tend to start dosages that are not appropriate to the smaller body mass index (BMI) of Southeast Asian patients compared to non-Hispanic whites. Starting new psychiatric medications at high doses have led to a greater number of side effects, resulting in patients' non-adherence. We have found that Southeast Asian patients accept psychiatric medications when they are started at small doses and are increased incrementally. Such ethno-psychopharmacology information for prescribing medications at appropriate doses may result in increased patient adherence. Other ethno-pharmacology issues include patients' common use of folk remedies that may interfere or interact with psychiatric medications.[28] Clinical decision support provided clinicians with tools to facilitate discussion of these culture-specific issues with patients. Another important feature of the electronic clinical decision support was to aid and *facilitate communication between primary care providers and mental health specialists*. The "***Refer***" link on the 11-point action plan linked providers to local mental health providers. Poor communication between generalists and specialists has resulted in the lack of culturally competent referrals and continuity of care for patients. This feature provided referrals for local mental health services specializing in Southeast Asian refugee trauma that were trusted and well-established within their community.

Minimal Intervention Control Group—Providers randomized to the minimal intervention control group completed the online tutorial, "A physician's practical guide to culturally competent care," which was provided by The Office of Minority Health, US Department of Health and Human Services Website. Similar to providers in the intervention group, providers in the control group also received the following modules: 1) History of the migration of Southeast Asian to the U.S.; 2) Effective use of interpretation: a primer for clinicians and interpreters; and 3) General resources and websites for culturally-appropriate health education materials for Southeast Asian patients.

As noted above, patients empaneled to providers in the minimal intervention control group also were screened using the multi-media mental health screening instrument. Unlike the intervention group, however, computed depression and PTSD scores were not shared with the provider or the patient unless required by the safety net protocol. Specifically, one item in the depression measure assessed the extent to which patients had "Thoughts of ending your life" on a 4 point scale (1=Not at all, 2=A little, 3=Quite a bit, and 4=Extremely) (see 'Sources of Data' section for detailed description of the instruments and scoring). In the event that a patient scored a '3' or '4' on this particular item and/or in the event that a patient indicated that there was reasonable suspicion that the patient may present a danger of violence to self or others or if there was reasonable suspicion of child abuse or elder adult

physical abuse, the research assistant immediately notified the provider or the provider's medical assistant.

All Providers

All study providers (both HIT intervention and minimal intervention control) had access to behavioral health services, either on site or affiliated with the practice, as well as access to an outside mental health referral resource, Pacific Asian Counseling Services, both of which specialized in mental health issues related to extreme war trauma in Southeast Asian patients. Thus, upon notification, providers had the ability and the resources to intervene during the clinic visit, if necessary, based on his or her patient assessment and clinical judgment. Providers also received the recommendation to contact a Los Angeles County 24/7 psychiatric mobile response team or emergency services (911) if they suspect the patient is in imminent danger to his/herself or others. This kind of alert system has been found to be effective in previous research in reducing the time to appropriate treatment.[29, 30] If the results for either condition were negative, providers in the intervention group received the recommendation to consider re-screening the patient in six months.

Sources of Data

Patients

Multi-media mental health screening instrument: Depression and PTSD were assessed using the multi-media mental health screening instrument (Figure 3). Depression was assessed using the 15 item depression subscale of the Hopkins Symptom Checklist (HSC) [31] and PTSD was assessed using the Harvard Trauma Questionnaire (HTQ) [32]. The HSC and HTQ have been translated into Khmer (the Cambodian language) and validated in a Cambodian refugee population.[32–36] A bilingual Khmer research assistant conducted the HSC and HTQ instruments in patients' preferred language at baseline and follow-up assessments. Items in the 15 item depression subscale of the HSC included 'crying easily,' 'poor appetite,' and 'feeling everything is an effort'. Participants rated on a 4 point scale (1 = not at all, 4 = extremely) the extent to which they experienced the depression symptoms within the past week. Items were averaged to create a composite Depression score, ranging from 1 – 4. Based on previous research, scores greater than 1.75 indicated the presence of Major Depressive Disorder. In a recent study of 180 primary care patients who had experienced trauma, Mollica and colleagues reported a **sensitivity and specificity** for detecting major depressive disorder of **93.2%** and **91.2%**, respectively.[35]

The 40 item HTQ is a culturally-sensitive instrument designed to assess PTSD in trauma refugees. Items included 'Sudden emotional or physical reaction when reminded of traumatic event,' 'Recurrent nightmares,' 'Feeling jumpy or easily startled'. Participants rated on a 4 point scale (1 = not at all, 4 = extremely) the extent to which they experienced the PTSD symptoms within the past week. Items were averaged to create a composite PTSD score, ranging from 1 – 4. Based on previous research, scores greater than 2.5 indicated the presence of PTSD. The HTQ demonstrates good validity in screening for PTSD across languages and cultural contexts,[32–36] with a recent study reporting **sensitivity** at **100%** and **specificity** at **93.9%**.[35]

The HSC and HTQ instruments have been validated previously against the Structured Clinical Interview for Axis I diagnostic disorders (SCID), in which Receiver Operating Characteristic (ROC) Curves have demonstrated that the HSC and HTQ have good sensitivity and specificity. [33–36] In the current study, a bilingual Khmer licensed clinical social worker conducted the SCID to assess Depression and PTSD in a sub-sample of 75 study patients. Receiver Operating Characteristic (ROC) analysis will be conducted to assess the criterion validity of the HSC and HTQ. Although the sensitivity and specificity of the HSC and the HTQ (see above) is high in these well-validated measures,[33–36] this data will allow us to validate these measures when used in an electronic mode of delivery.

Baseline survey: After the screening and clinic visit were completed, participants completed a baseline survey that was administered by the bilingual Khmer research assistant. The survey assessed: self-reported physical and mental health status, relationships and personal experiences, medication adherence and utilization, chronic disease status and illness burden, patient-centered decision making and quality of care within the patient-provider relationship, satisfaction with health care clinic staff experiences, medical care usage that included frequency of inpatient and outpatient services, health behaviors, and socioeconomic and demographic characteristics.

12-week follow-up survey: We also conducted a survey at the 12 week post-index visit to assess patient self-reported outcomes. We assessed depression and PTSD status by re-administering the HSC and HTQ. To examine patients' satisfaction with the quality of their care, we adapted items from the CAPHS[37–40] to assess overall satisfaction with the quality of patients' mental health care, satisfaction with the primary care provider, and the degree of patient-centeredness[41] of their mental health care. In addition, we examined medication adherence and side effects,[42, 43] number of ER visits/ hospitalizations, and utilization of specialty mental health services.

Clinical detection and treatment initiation data obtained from medical record abstraction: At 12 weeks following patients' initial screening visits, patients' electronic medical records were abstracted to determine the extent to which providers in both study groups made diagnostic decisions that corresponded with the HSC depression and HTQ PTSD screening scores. That is, the presence or absence of a depression and/or PTSD diagnosis for each patient was compared with each patient's computed depression and PTSD screening score (positive or negative) to determine whether there was a match, thereby determining the extent to which the HIT intervention impacted providers' clinical detection of depression and/or PTSD.

In addition, we examined the extent to which providers followed guideline care for the initiation of treatment.[23, 24] Providers received credit for having initiated one or more the following treatment indicators were in the patient's medical record: 1) pharmacotherapy discussion and prescription, 2) watchful waiting, with supportive psychological counseling, and/or 3) referral to a mental health specialist.[23, 44, 45] The initiation of guideline care was coded as present (1) or absent (0).

As the intervention was designed to train providers in administering appropriate care to address experiences of war and trauma among Cambodian refugees, we also examined the extent to which providers initiated trauma-informed care. The initiation of trauma-informed care was defined as the presence of one or more of the following indicators in the patient's medical record: 1) conducted a risk assessment of patients' depression or PTSD status (e.g., HSC and HTQ scores), 2) discussed the trauma story with the patient, 3) asked patients if they wanted to improve their well-being, and/or 4) assessed psychiatric symptoms. The initiation of trauma-informed care was coded as present (1) or absent (0).

Outcome Assessments

The primary objective of the study was to assess the impact of the HIT intervention on improving depression and PTSD in LEP Cambodian patients in the primary care setting. To that end, we will test the following hypotheses in future work:

> H1: The appropriate clinical detection of depression and/or PTSD, as documented by the provider's diagnosis, in the patient electronic health record for LEP patients in primary care will be improved by using the interactive, multi-media electronic risk assessment tool.

> H2A: Provider initiation of guideline mental health treatment and trauma-informed care will be improved by the HIT intervention.

> H2B: Patient outcomes (at 12 weeks post-index visit) for depression and/or PTSD will be improved by the HIT intervention.

Secondary outcomes included evaluating the usability and acceptability of the technology among providers and patients and identifying potential facilitators and barriers to widespread implementation of the HIT intervention in the primary care setting. We obtained feedback from providers in the intervention group about the usefulness and effectiveness of the three components of the HIT intervention: web-based tutorial, multimedia screening instrument, and clinical decision support (11-point tool kit). For the web-based tutorial, we asked providers in both intervention and control groups to comment on the extent to which they found their respective tutorials useful in: 1) developing their Cambodian patients' treatment plan, 2) improving their ability to provide culturally competent care, and 3) developing their plan to address their Cambodian patients' mental health problems.

To obtain feedback on the usefulness and effectiveness of the screening instrument and clinical decision support tools we asked providers in the intervention group to comment on 1) the extent to which they found the screening instrument helpful in developing their mental health treatment plan for their Cambodian patients, 2) the frequency in which they discussed the screening scores with their patients, 3) the frequency in which providers accessed the clinical decision tools and incorporated the information into their patient practice both generally and when specifically treating Cambodian patients with mental health issues.

In addition, we obtained organization- and provider-level feedback regarding the feasibility and acceptability of the implementation of the HIT study components, particularly focusing on the multimedia screening instrument, given its real-time usage in the clinic setting on a day-to-day basis.

Sample Size Determination

We examined the sample size and power for a cluster-randomized design with binary outcome to assess the efficacy of HIT intervention to detection of depression/PTSD. The number of providers (clusters) in both the control and HIT intervention is fixed to be 7. To examine the fidelity of study power, we considered the average number of patients per provider in the HIT intervention to 38 and the average number of patents per provider in the control group is about half of that in the intervention arm. Based on randomized controlled studies that screen for depression in primary care, the proportion of diagnosis under the control group of no active screening regimen range from 29–40% with active screening intervention improving the rate of diagnosis between 10–50%.[46, 47] Thus, Table 3 provides the power of a two-sided z-test (pooled) at level $\alpha = 0.05$ to detect 30–40% differences (improvement) in the proportion of depression/PTSD diagnosis due to HIT intervention and conservatively assuming that detection rate in control arm is 40%. Furthermore, we examined the fidelity of the study power for intracluster correlation (ICC) ranging from 0.1 to 0.2, typical empirical ICC estimates.[48] Thus, the current study has >80% power to detect a difference of 30% in the proportion of diagnosis between study arms when ICC is   0.13; for 40% improvement, the study has >90% power across all ICC (0.2).

Results

Patients

As shown in Figure 4, 531 Cambodian patients were assessed for eligibility. Forty-one patients refused to participate in the study. Twelve patients were scheduled to see providers who were not enrolled in the study, and were therefore ineligible to participate. Eighty-five patients no-showed, rescheduled, or cancelled their appointments, and three patients were unable to complete the HIT mental health screener due to technical difficulties, thereby precluding their enrollment into the study. Thus, the total analytic patient sample consisted of 390 patients, with 272 patients randomized to the intervention group and 118 patients randomized to the control group. All enrolled patients completed the HIT mental health screening. Medical chart data, which included provider mental health diagnosis and treatment documentation, were abstracted for 389 patients. Three-hundred thirty-eight patients completed the baseline survey assessment and 331 patients completed the end of study 12-week follow-up assessment.

Patient demographic characteristics are presented in Table 4. All patient participants self-identified as being Cambodian/Khmer (i.e. Southeast Asian). At the time of enrollment, study participants' average age was 56 years of age [range 19–89 years old]. More than 43% of study participants did not complete grade school, and nearly all participants (83.9%) had a high school degree or less. Most (93.4%) of the study sample was born outside of the United States. The majority of the sample (86.4%) reported having a public insurance plan for low income individuals (i.e., Medicaid/Medi-Cal, Dual Medi-Cal/Medicare, Medical Services Initiative (MSI), and Healthy Families), with only 3.3% of the sample reporting having Medicare only and 1.5% having employer-based insurance. Approximately 79.5% of the sample fell below the 2015 Federal Poverty Level threshold of $20,090 for a family of three, which was the average family size for study participants.

In general, the study participants reported relatively poor health (**see** Figure 5), with nearly 87.1% of the sample rating his or her health as fair or poor, in contrast to Healthy People 2020[49] which found that only 26.8% of people over the age of 65 who rate their health as fair or poor. Similarly, this sample reported high levels of limitations in their activities of daily living, with approximately 88.1% (mean=1.7, SD=0.52) reporting at least one limitation of daily activity compared with 32.6% of noninstitutionalized adults age 65 and older. Interestingly, only 5.6% of respondents indicated that they were lonely (as measured by a score of 44 or higher on the UCLA Loneliness Scale) compared to 35% of respondents aged 45 and older.[50]

Providers

Providers who participated were recruited from two primary care community clinics in Long Beach: 1) The Children's Clinic, *Serving Children and Their Families* (TCC), which is a Federally Qualified Health Center (FQHC) with 11 different clinic locations and 2) The Community Medical Wellness Center (CMWC), a single provider site. All providers whose patient panel included adult Cambodian patients were invited to participate. After providing informed consent, providers were randomized to the HIT intervention group or the Minimal Intervention Control Group. Eighteen providers consented to participate in the study; ten providers were randomized to the Intervention group (TCC: 9; CMWC: 1) and the remaining eight providers (TCC) were randomized to the control group.

Provider demographics are presented in Table 5. The majority of the providers were women (66.7%), non-Hispanic white (55.6%), and spoke English as their first language (77.8%). Notably, almost a third of the providers were Asian or Pacific Islander (27.8%), and two of the providers were fluent in Khmer (Table 5). The providers had been practicing medicine for approximately 15 years and practiced either Family Medicine (88.9%) or General Internal Medicine (11.1%). Two of the providers were Nurse Practitioners, who indicated that their area of specialty was Family Medicine.

Discussion

We describe the rationale and study protocol of an HIT intervention that was designed to improve the screening, diagnosis, and initiation of mental health treatment in a Cambodian refugee population who survived the Khmer Rouge genocide. Despite this population's documented use of mental health services for mental health conditions that are highly prevalent in this population, high rates of depression and PTSD persist.[51, 52] As such, novel, culturally competent, trauma-informed approaches to identifying and treating depression and PTSD in Cambodian refugees are warranted.[52]

It is important to consider various characteristics of the Cambodian refugee population including low literacy, low socioeconomic status, historical migration and immigration experiences, and subsequent difficulty in assimilating into U.S. society, which contribute to the overall vulnerability in this population. Like many other patient populations who have experienced war atrocities, the long-term, combined effects of severe head trauma, starvation, rape, and torture pose a multi-faceted patient presentation that requires the recognition and management of a variety of factors other than symptoms of depression and

PTSD alone, thus requiring a more holistic approach.[53] The HIT Depression and PTSD screening tool, together with the evidence-based 11 point tool kit, have the capacity to provide a synergistic approach to delivering trauma-informed, culturally competent care to any patient population who has experienced war trauma within the busy practice and patient flow of a primary care clinic.

The beneficial effects of different types of HIT on the quality, efficiency, and cost of health care have been well documented.[27, 54] A majority of HIT studies up until this point have focused on how technologies such as telemedicine, electronic health records, and e-prescribing influence patient outcomes in primary care settings.[27, 54] Although some studies have examined the diagnostic utility of computerized tools,[55] evidence is mixed with regard to the utility of these same tools for mental health screening.

Research suggests that *multi-component* interventions directed toward improving depression outcomes in primary care settings may be more successful than single-component interventions.[14, 15] Multi-faceted interventions that include screening, provider training and notification, and clinical decision support may be more effective than any single intervention alone.[15, 16] Furthermore, in primary care, tailored interventions that give individualized patient data to providers are more effective than "generic, one-size-fits-all" interventions.[15, 16] To our knowledge, this is the first study to employ an innovative, multi-dimensional, culturally competent HIT intervention that was designed to reduce the high rates of depression and PTSD in a vulnerable, underserved patient population.

Since the inception of the Affordable Care Act, improvement and integration of both HIT and behavioral health have been at the forefront of government recommendations and mandates within the primary care system. The use of HIT in the primary care setting is increasing exponentially because of federal mandates and funding. Since 2011, Congressionally-mandated HIT grants, distributed by Health Resources and Services Administration (HRSA), provided $1.5 billion in federal funds for community health centers to acquire and use innovative HIT, with the goal of having widespread use for every U.S. citizen by 2014.

Recent US Preventive Services Task Force Recommendations include screening for depression in non-white, undereducated, and unemployed adults with adequate procedures in place to provide effective treatment and follow-up care.[56] In addition, Agency for Healthcare Research and Quality (AHRQ) guidelines for improving primary care practice have recommended the integration and delivery of behavioral health in the primary care setting based on growing evidence that the provision of mental health services in primary care is associated with improved care and reduced costs.[57] Furthermore, The Affordable Care Act allocated $54.6 million to 221 Federally Qualified Health Centers across the country in an effort to broadly and systematically expand behavioral health services in primary care. Thus, the implementation of both HIT and behavioral health services in the primary care setting is a high priority. However, the integration of HIT and behavioral health services within community clinics is lacking. Importantly, the HIT intervention tool described herein closes this gap in the primary care system by innovatively merging

screening, provider training and notification, and clinical decision support within the HIT environment.

There are some limitations to this study. We used a clustered randomized trial design in which randomization occurred at the level of the provider in order to most effectively examine whether the HIT intervention could be feasibly and effectively incorporated into primary care patient practice. However, in randomizing at the level of the provider, we encountered some limitations. While providers were randomized using a 1:1 ratio, the intervention group included a single provider site, resulting in an imbalance in the number clinic sites and empaneled patients assigned to the intervention and control groups.[58, 59] While not ideal, the study group composition was the result of pragmatic issues in conducting research with patients and health care providers in the Cambodian community. We approached several community-based primary care clinics and primary care providers who provide medical care to the Cambodian community in an attempt to recruit them into the study. However, the clinics and providers expressed fear and skepticism both in participating in a clinical trial and in addressing patients' mental health issues, particularly since mental health is associated with great stigma in the Cambodian community. Nevertheless, the work we accomplished in conducting this study with this high-risk, high-need, under-resourced and vulnerable community far outweighs the practical limitations of the study design, particularly given that less than 5% of participants in clinical trials to date are of a non-white racial/ethnic group.[60]

In addition, we were unable to transmit the screening scores from study iPads into the electronic medical record directly. However, we were able to connect to the clinics' wireless networks to print the screening scores and hand out paper copies directly to intervention group providers (or their MAs) before the patient appointment. The paper copies were subsequently scanned into the patient electronic medical record within 10 days of the clinic visit. In addition, the patient follow up period was 12 weeks; thus, one limitation was that we were unable to examine whether the HIT intervention had an impact on mental health care and management, and patient outcomes over a longer time period, such as 6 months to a year. Future studies are needed to assess whether HIT is able to be adopted into long term, ongoing provider practice behavior. Furthermore, this study only focused on delivering the HIT intervention in the Cambodian population. While this population is particularly in need of mental health services to reduce high rates of depression and PTSD, future studies should adapt the HIT intervention to examine its effectiveness in the screening and treatment of mental health conditions in other ethnic groups. Finally, because this was a mental health treatment study conducted in a vulnerable population with high rates of depression and PTSD, all providers were notified if there was concern of patient harm to self or other. In doing so, providers had the opportunity to further assess the patient's suicidal risk status and initiate a course of action if the provider's assessment and clinical judgment deemed such action necessary. We recognize that the utilization of the safety net protocol and provision of mental health treatment may result in an underestimation of the effect of the HIT intervention on the study's primary and secondary outcomes. Nevertheless, the study design limitations associated with this safety net protocol are eclipsed by the ethical obligation to address severe mental health problems in a poor and underserved population that has a severe, protracted, and widespread prevalence of depression and PTSD.

To our knowledge, this is the first study to use HIT to integrate both mental health screening *and* care management, through provider training and clinical decision support, in primary care. Thus, should the HIT intervention be successful, it has the capacity to revolutionize the delivery and management of behavioral health services across various patient populations in the primary care setting.

Acknowledgments

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Figure 1.
Key Components of the HIT Intervention

PROVIDER ORIENTATION

PROVIDER RANDOMIZATION

INTERVENTION ARM	**MINIMAL INTERVENTION CONTROL ARM**
PROVIDERS (N = 10)	**PROVIDERS (N= 8)**
EMPANELED PATIENTS (N = 272)	**EMPANELED PATIENTS (N = 118)**

3 HOUR CME	**3 HOUR CME**
• Providers receive web-based tutorial on providing culturally competent mental health care to Cambodian war trauma refugees	• Providers receive web-based tutorial on providing culturally competent care generally in primary care practice

MULTI-MEDIA MENTAL HEALTH SCREENING INSTRUMENT	**MULTI-MEDIA MENTAL HEALTH SCREENING INSTRUMENT**
• Patients complete screening instrument on iPad	• Patients complete the screening instrument on iPad

SCREENING SCORE NOTIFICATION	**SCREENING SCORE NOTIFICATION**
• Hopkins Screening Checklist: Composite score $\geq$ 1.75 indicates the presence of Major Depression • Harvard Trauma Questionnaire: Composite score $\geq$ 2.5 indicates the presence of PTSD	• NONE • Providers notified **ONLY IF** one screening item on the Hopkins Screening Checklist indicates that patient has thoughts of suicide

CLINICAL DECISION SUPPORT

• 11 point tool kit in mobile application format
• Evidence-based guidelines on diagnosing and treating depression and PTSD
• Ethno-psychopharmacology support tool recommending medications and dosages for Southeast Asian (Cambodian) refugees who experienced extreme war trauma

PATIENT VISIT	**PATIENT VISIT**
WITH PROVIDER	**WITH PROVIDER**

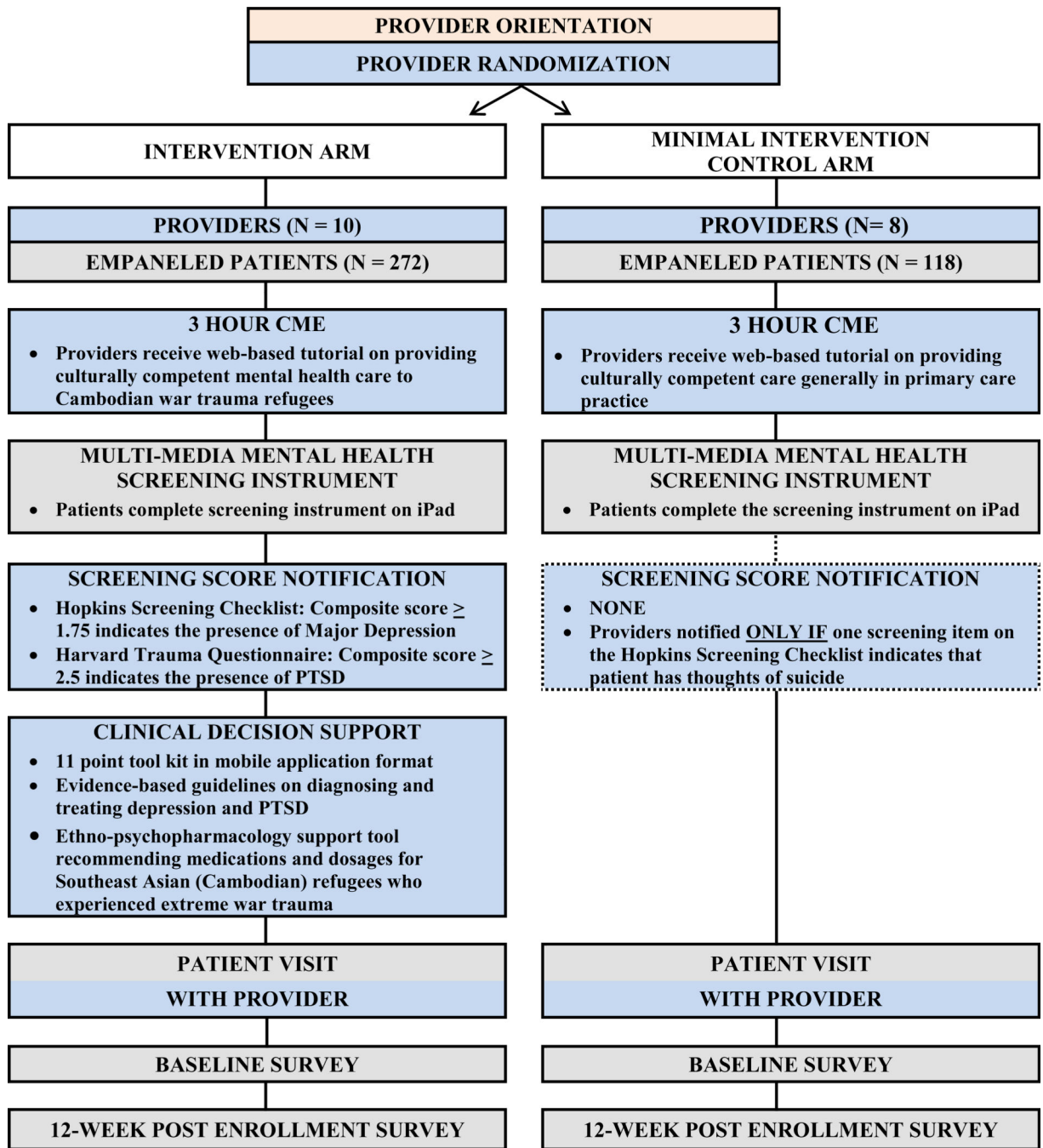| **BASELINE SURVEY**	**BASELINE SURVEY**
12-WEEK POST ENROLLMENT SURVEY	**12-WEEK POST ENROLLMENT SURVEY**

Figure 2.
Research Design and Randomization Protocol
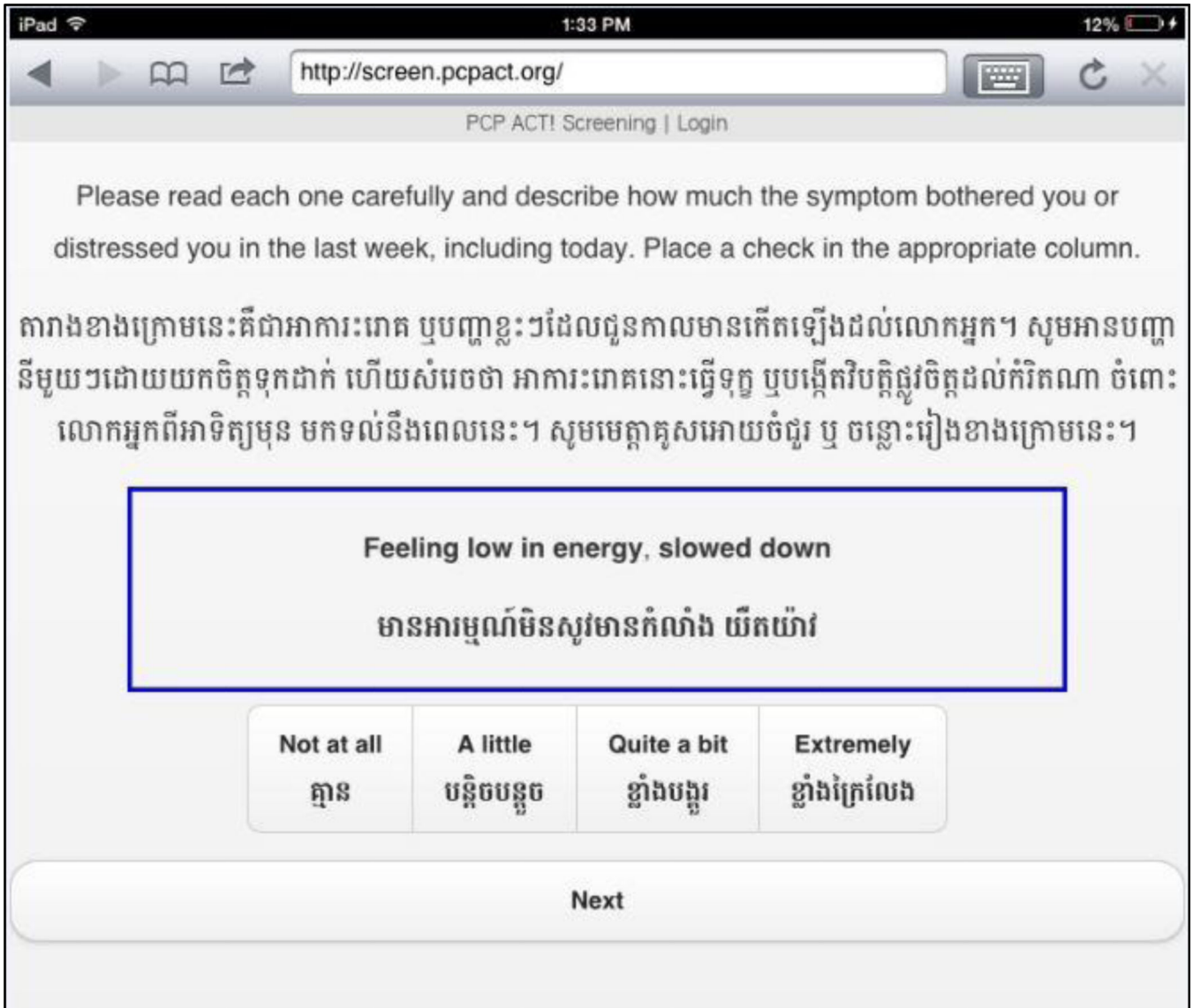
Figure 3.
Screenshot of Khmer/English Mental Health Screening Instrument

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Enrollment                    ┌─────────────────────────┐
                              │  Assessed for eligibility │
                              │      (N = 531 )           │
                              └─────────────────────────┘
                                         │
                              ┌─────────────────────────┐
                              │        Refused           │
                              │       (N = 41)           │
                              └─────────────────────────┘
                                         │
                              ┌─────────────────────────┐
                              │       Ineligible         │
                              │ (Provider did not participate │
                              │       in study)          │
                              │       (N = 12)           │
                              └─────────────────────────┘
                                         │
                              ┌─────────────────────────┐
                              │  No show/rescheduled/    │
                              │      cancelled           │
                              │       (N = 85)           │
                              └─────────────────────────┘
                                         │
                              ┌─────────────────────────┐
                              │ Unable to complete enrollment │
                              │  due to technical difficulties │
                              │   with iPad Screening    │
                              │       Instrument         │
                              │        (N = 3)           │
                              └─────────────────────────┘
                                         │
                              ┌─────────────────────────┐
                              │     Study Sample         │
                              │      (N = 390 )          │
                              └─────────────────────────┘
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	Intervention	Control
Randomized	N = 272	N = 118
Depression/PTSD Screening	N = 272	N = 118
Medical Chart Data	N = 271	N = 118
Baseline Assessment*	N = 233	N = 105
12-Week Follow-up Assessment*	N = 235	N = 96

❖ **Not all patients completed both Baseline and 12-week follow-up assessments; 310 patients completed longitudinal assessment data (Intervention N=218; Control N=92)**
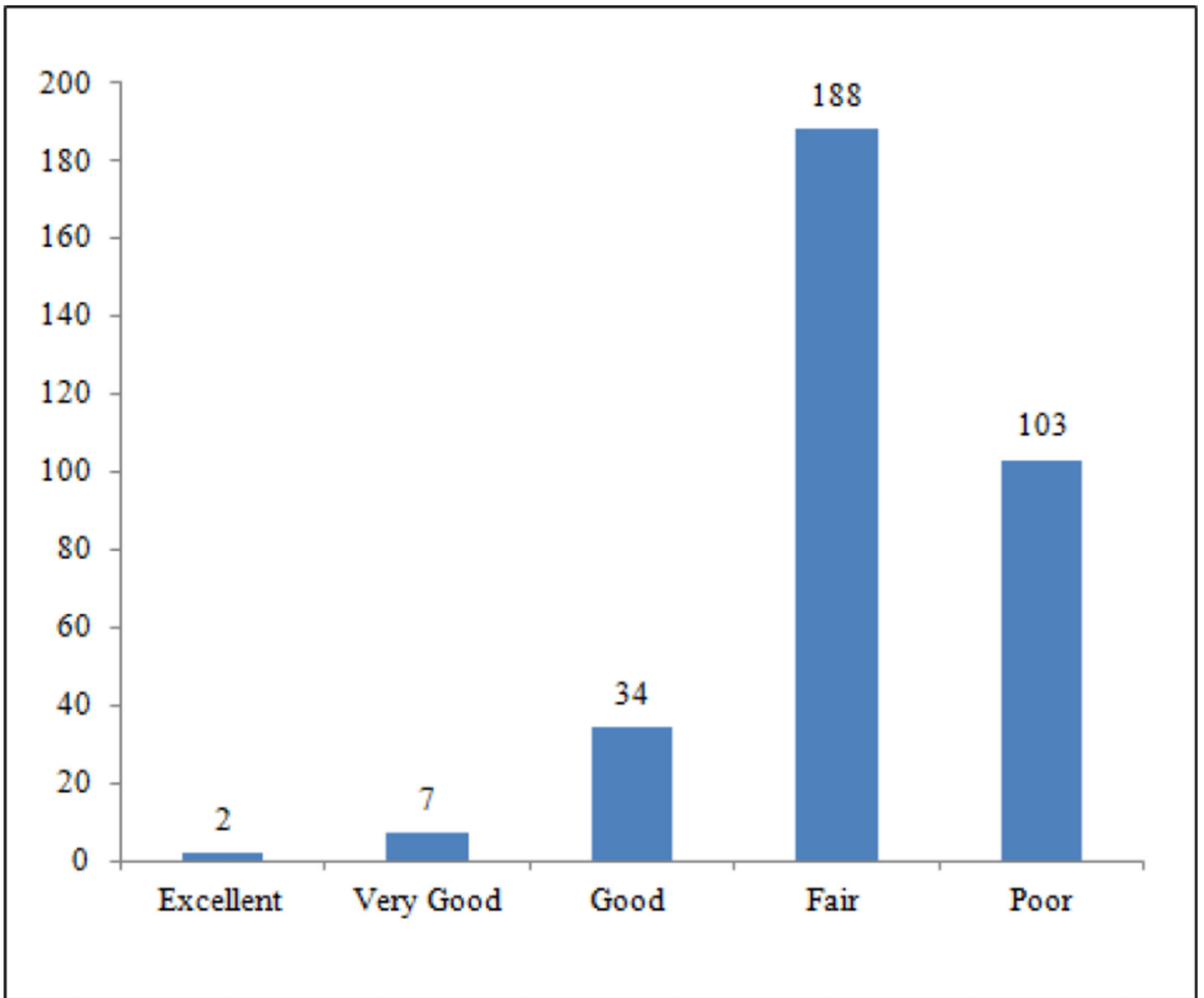
Figure 4.
Consort Diagram of Patient Sample

Figure 5.
Self-rated Health (# of patients)

Table 1

Excerpt from the 11-point tool-kit

HPRT 11-Point Primary Provider Toolkit Model for Identification, Diagnosis, and Treatment of Depression and PTSD In Primary Health Care	
1. Ask about the patient's "trauma story" and current symptoms of mental distress	"Many of my patients have felt that experiences of trauma have had a big effect on their health and well-being. Has this been the case for you?" Listen to the answer and acknowledge the patient's trauma story.
2. Identify concrete physical and mental effects	By identifying the concrete physical and psychological effects of mass violence, PCPs can reassure patients that these effects and symptoms are normal.
3. Diagnose & Treat depression and PTSD	Screen for depression and PTSD using the HSC and HTQ (see www.hprt-cambridge.org). Patients will benefit from counseling on the nature of their symptoms and coping techniques.
4. Refer screened cases of serious mental illness	Consider referral to a mental health professional in the following circumstances: danger to self or others, complicated grief, severe forms of PTSD and/or depression, physical and social disability
5. Reinforce & Teach positive coping behaviors	Recommend coping strategies beginning with self-care; remind the patient to build physical, spiritual, and mental strength.
6. Recommend altruism, work, & spiritual activities	Scientific studies of survivors of mass violence have repeatedly revealed increased resilience associated with altruism, work and spiritual activities.
7. Reduce high-risk behaviors	Patients often increase their use of cigarettes, drugs, and alcohol, or become involved in risky sexual behavior during times of crisis. PCPs must be alert for these unhealthy activities.
8. Be Culturally Attuned in communicating & prescribing	Different cultures have different views of trauma and different ideas about the cause of illness, as well as different reactions to doses and side effects.
9. Prescribe psychotropic drugs if necessary	Use HPRT's ethno-psychopharmacology module for culturally appropriate guides about drugs most commonly used to treat depression, PTSD, and insomnia.
10. Close & Schedule follow-up visits	Make a plan with that includes follow-up visits and further discussions; additional conversations at a later date can do wonders for a patient's mental strength.
11. Prevent Burnout by discussing with colleagues	You can prevent the state of chronic stress and fatigue known as "burnout" by regularly discussing cases and your reactions with at least one colleague.

Table 2

Excerpt from Ethno-psychopharmacology decision support tool: "*SSRI antidepressants, proposed therapeutic dose range, and adjustments for different populations that require lower doses than suggested in the Physicians' Desk Reference (PDR) or medication inserts.*"

Medication (generic name)	Therapeutic Dose Range for Adult Caucasians (mg)	Recommended Therapeutic Dose Range for Other Ethnic Groups (mg)	Comments
Escitalopram	10–20; initially 10, may increase up to 20 after one week	5–10; initially 5 for four weeks, reevaluate and may increase up to 10. Liquid available for doses <5	Fewer reported sexual side effects; faster onset of action. Do not use with history of seizure, hepatic, or renal disease. At least 14 days must elapse between discontinuation of Lexapro and initiation of an MAOI
Citalopram	20 once daily initially morning or night, with or without food; wait 1 week before increasing dose; max: 60; 40 recommended	10–20 daily initially; reevaluate; increase in 1 or more weeks; mas: 20–40	Same as Lexapro
Paroxetine	25–62.5; initially 25 in the morning, adjust by 12.5/day at one week intervals; max. 62.5 in the morning	12.5–25; initially 12.5 in the morning for four weeks, adjust as needed in one week intervals; max. 25 in the morning	Excellent for anxious depression and PTSD; may cause night sweats, sexual problems, more severe with withdrawal symptoms
Sertraline	25–200 one day dosing, mornings or night, initially 50/day; may increase in one week intervals; max. 200	12.5–200; 12.5 for several weeks, slowly increase to 25; max. 200; one day dosing in the morning	Excellent choice for anxiety and PTSD; may achieve clinical dose at lower dose
Fluoxetine	10–80; initially 5–10 in the morning; increase needed after several weeks; may give >20 in divided doses morning and noon; max. 80/day	10–40; initially 10 for two-four weeks, then may increase to 20; max. 40	Longer onset of action; safer to discontinue due to long half-life; not as effective with African-Americans. May cause insomnia, drowsiness, anxiety, anorexia, night sweats, nervousness
Fluvoxamine	100–300; initially 50–100 once daily, night, with or without food; >150 twice daily or more. Max 300/day	50–150; initially 50–100, max 150	Also effective in OCD; may contribute to sedation and fatigue in some patients through its sigma1 antagonism

Table 3

Power to detect 30%-40% improvement in depression/PTSD diagnosis at level $\alpha = 0.05$ for a clustered-randomized design with 7 providers per arm with an average of 38/19 patients per provider in the HIT/control arms

Difference in proportion (P_1-P_2)	Power	ICC
30%	0.88	0.10
30%	0.81	0.13
30%	0.74	0.16
30%	0.66	0.20
40%	0.99	0.10
40%	0.98	0.13
40%	0.95	0.16
40%	0.91	0.20

ICC: Intracluster correlation

Table 4

Patient Demographics

	(N), mean [SD] or %
Age	56.3 [13.4]
Gender	
Male, (N) %	(139) 35.6%
Female, (N) %	(251) 64.4%
Education	
No formal education	(67) 20.2%
Some grade school	(76) 22.9%
Completed grade school	(11) 3.3%
Some high school	(66) 19.8%
Completed high school	(59) 17.7%
Some college	(36) 10.9%
Completed college	(10) 3.1%
Completed graduate/professional school	(7) 2.1%
Born in the United States	
Yes	(22) 6.6%
No	(312) 93.4%
Health Insurance Status	
No health insurance	(12) 3.6%
Medi-Cal	(224) 66.3%
Medicare	(11) 3.3%
Medi-Cal/Medicare	(68) 20.1%
Insurance provided by job/employer	(5) 1.5%
Other	(18) 5.2%
Marital Status	
Married	(139) 41.9%
Divorced/separated	(84) 25.3%
Widowed	(60) 18.1%
Never married, single	(42) 12.7%
Other	(7) 2.1%
Income	
Less than $9,999	(88) 28.1%
$10,000-$19,999	(161) 51.4%
$20,000-$29,999	(35) 11.2%
Greater than $30,000	(29) 9.3%
Limitations in Activities of Daily Living[1]	1.7 [0.52]
Loneliness[2]	28.5 [8.6]

Baseline demographics based on the number of participants who completed the baseline survey (N = 338).

[1] Ware JE Jr, & Sherbourne CD (1992). The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Medical Care, 30, 473–483

[2]Russell, D , Peplau, L. A.. & Ferguson, M. L. (1978). Developing a measure of loneliness. Journal of Personality Assessment, 42, 290–294.

Table 5

Provider Demographics

	Mean [SD] or (N) %
Years in Practice	14.8 [10.6]
Age	
30 and under	(2) 10.5
31 – 40	(6) 31.6
41 – 50	(3) 15.8
51 – 60	(7) 36.8
61+	(1) 5.3
Gender	
Male, (N) %	(6) 33.3
Female, (N) %	(12) 66.7
Race/Ethnicity	
Non-Hispanic White	(9) 50.0
Asian/Pacific Islander	(5) 27.8
Hispanic mixed racial background	(3) 16.6
Hispanic White	(1) 5.6
Primary Language	
English	(14) 77.8
Second languages	
Spanish	(15) 83.3
Chinese	(1) 5.6
Vietnamese	(1) 5.6
Khmer (Cambodian language)	(2) 11.2
Medical Specialty	
Family Medicine	(16) 88.8
General Internal Medicine	(2) 11.2