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Feasibility, Preliminary Efficacy, and Safety of a Randomized Clinical Trial for Asian Women's Action for Resilience and Empowerment (AWARE) Intervention

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Abstract

To our knowledge, Asian Women's Action for Resilience and Empowerment (AWARE) is the first gender- and culture-specific and trauma-informed group psychotherapy intervention designed for Asian-American young women with histories of interpersonal violence and trauma and/or Post-Traumatic Stress Disorder (PTSD) diagnosis. We employed a 2-arm randomized controlled trial. Sixty-three women who met clinical criteria for trauma were randomized to the intervention ($n = 32$) or waitlist control ($n = 31$) group. We documented retention rates, preliminary efficacy for sexual risk behaviors and depressive symptoms (overall and stratified by PTSD at baseline), and safety in terms of suicidality at baseline, post-intervention, and 3-month follow-up.

AWARE demonstrated high retention rates, in that 87.50% of those enrolled in the program completed at least 6 out of the 8 sessions. While there were no differences overall for sexual risk behaviors or depressive symptoms, among women with PTSD, significant reductions in depressive symptoms were observed in treatment compared to control, with an effect size of .84. Suicidal ideation and intent were reduced in both the treatment and control groups, with no attempts during the trial. AWARE is uniquely tailored to serve a pressing clinical need. These results support its feasibility and safety. A large-scale trial targeted at women with PTSD is recommended to further explore the efficacy of AWARE.

[ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT03370549) Identifier: NCT03370549

Keywords

Asian-Americans; Asian-American women; Mental Health; Depression; Suicide; RCT

Introduction

Recent epidemiological data document two emerging public health problems among Asian-American women in the United States: high suicide rates and a growing rate of HIV/AIDS diagnoses. Between 2004 and 2014, Asian-Pacific Islander (API) women between ages 15 and 34 experienced the second largest increase in suicide rates across all races (Centers for Disease Control and Prevention [CDC], 2015b). In 2014 alone, suicide accounted for 18% of all deaths among Asian-American women in this age group, a proportion higher than that of the overall U.S. female population (10.5%; CDC, 2015a, 2015b).

Depression is one of the leading predictors of suicide for Asian-American women (Wong & Maffini, 2011). Despite these mental health needs, Asian-American women are less likely to seek mental health treatment compared to women of other racial groups (Le Meyer, Zane, Cho, & Takeuchi, 2009; Leong & Lau, 2001). The National Latino Asian American Study (NLAAS) found that only 2.9% of Asian-American women sought specialist treatment in the past year compared to 8.8% of the general population (Appel et al., 2011; Spencer et al., 2010). Asian-Americans also have high rates of pre-intake attrition, such that one third of Asian-Americans who requested an intake appointment for a mental health program dropped out before the first intake assessment occurred (Akutsu, Tsuru, & Chu, 2004). In another study with young (ages 18–35) Asian-American women who presented with current depressive symptoms and had a history of suicidality, 60% of participants reported that they had not received mental health services in the past 12 months (Augsberger, Yeung, Dougher, & Hahm, 2015).

HIV/AIDS and sexual risk behavior are also areas of concern among Asian-American women. While the prevalence of HIV/AIDS among APIs is low compared to other races, the number of HIV diagnoses among Asian-Americans increased by nearly 70% between 2005 and 2014 (CDC, 2016). Among Asian-American women, 94% of HIV/AIDS diagnoses were attributed to heterosexual contact (Augsberger et al., 2015). A recent study found that sexually active, unmarried Asian-American women had similar levels of HIV risk compared to women of other racial groups, including lifetime rates of unprotected sex (63%), forced sex (18%), and anal sex (18%; CDC, 2016; Chin, Kang, Kim, Martinez, & Eckholdt, 2006).

Furthermore, having a history of interpersonal trauma, including child maltreatment and intimate partner violence, has been found to significantly increase the likelihood of poor mental health outcomes including PTSD and engagement in sexual risk behaviors among Asian-American young women (Hahm, Augsberger, Feranil, Jang, & Tagerman, 2016; Hahm, Gonyea, Chiao, & Koritsanszky, 2014). Compared to their White counterparts, Asian-American female college students who were victims of sexual assault reported higher levels of maladaptive beliefs about the assault (self-blame, shame, myths about rape) and consequently endorsed higher PTSD symptom severity (Koo et al., 2014). Stigma related to HIV/AIDS and the lack of culturally relevant HIV services have also contributed to the low

levels of preventive care-seeking, including HIV testing, in this population (Chin et al., 2006; Hahm, Song, Ozonoff, & Sassani, 2009).

To explain the underutilization of mental health services, maladaptive ways of coping, and risky behaviors among Asian American women, Augsberger and colleagues (2015) developed a cultural framework that includes shame and stigma related to the use of mental health services. With the belief that treatment for Asian-American females should effectively integrate cultural, familial, and racial factors, we developed Asian Women's Action for Resilience and Empowerment (AWARE; NIH: 1R34MH099943-01A1), a manualized intervention which uses existing theories and evidence from our previous research with this population to address the mental and sexual health needs of young Asian-American women with interpersonal trauma histories (Augsberger et al., 2015; Hahm, Chang, et al., 2014; Hahm, Augsberger, et al., 2016; Hahm, Gonyea, et al., 2014; Lee & Hahm, 2012; Le Meyer et al., 2009; Leong & Lau, 2001).

AWARE Intervention

The AWARE intervention consists of two components: an in-person 8-week gender- and culture-specific and trauma-informed group psychotherapy program, and a series of short, daily text messages called "AWARE stories." These text messages contain Asian-American women's personal stories related to their mental and sexual health; main takeaways of each session; and reminders of upcoming session times and locations.

AWARE is based on the Model of Healing, by Hahm and her colleagues (Hahm et. al., 2017). The Model of Healing is an empowerment-based model that incorporates gender- and culture-specific elements in the therapeutic process; such elements include enhancing participants' understandings of their self-identities as Asian-American women, navigating the family dynamics of immigrant families, discrimination, and gender issues from an Asian perspective. AWARE incorporates the context of Asian values and cultures and addresses the various issues that are central to young Asian-American women's identities, and well-being and yet are not openly discussed due to fear of stigma and shame. These topics include physical and sexual trauma caused by their families or intimate partners, mental health, and sexual risk behaviors (Hahm et al., 2017).

This Model of Healing explains that Asian-American women face mental health risk factors which is conceptualized as "disempowerment traps" at four socioecological levels: individual ("inner voice trap"), interpersonal ("family trap"), community ("race trap"), and systemic or cultural ("suffering alone trap"). Specifically, the AWARE intervention targets these risk factors respectively: 1) reducing perfectionism and increasing emotional distress tolerance, 2) reducing conflict within families, 3) increasing a sense of belonging and connectedness to one's racial and ethnic group; and 4) reducing stigma related to mental health problems and help-seeking. With an understanding of the intersection among poor mental health, substance use, and trauma in Asian-American women, AWARE aims to promote a safe space and community for discussion, fostering hope, self-compassion, and empowerment. We introduce various coping skills such as deep breathing, grounding techniques, mindfulness, sensory stimulation, and positive distraction throughout these sessions. These skills originated from various theories and treatment models including

empowerment theory (Perkins & Zimmerman, 1995), Cognitive Behavioral Therapy (Beck, Emery, & Greenberg, 1985), the AIDS Risk Reduction Model (Catania, Kegeles, & Coates, 1990), and mindfulness-based treatment (Williams, Duggan, Crane, & Fennell, 2006).

For this RCT, the AWARE therapist is a bilingual/bicultural-licensed psychologist who identifies as an Asian-American woman herself and has over 10 years of experience working with Asian clients. In preparation for the trial, the PI met with the AWARE therapist for at least 2 hours for 16 weeks in order to discuss the therapy content and appropriate modification based on feedback from the participants and advisory board members as well as clinical issues. The titles of the eight sessions are as follows: Introduction to AWARE, ABCDG Parenting & Coping with Disempowerment, Catch-22: The Double Bind, Body Image, Stereotypes, & the Media, Romance, Violence, and Everything in Between, Sex & Substance Abuse, Giving Yourself Grace, and New Beginnings. Table 1 contains a summary of each session as well as examples of AWARE stories parallel to each session.

Current Study

We tested the feasibility, preliminary efficacy, and safety of AWARE among young Asian-American women with a history of interpersonal trauma in a two-armed randomized clinical trial ($M_{age} = 23.63$). We hypothesized that compared to women in the control group, those in the intervention group would demonstrate: (1) greater reduction in sexual risk behaviors (primary outcome) and (2) greater reduction in depressive symptoms (secondary outcome) at post-intervention and at 3-month follow-up. In addition, because our sample consisted of participants with varying levels of interpersonal trauma exposure, we tested whether the effect of the intervention differs by the severity of PTSD symptoms measured at baseline (pre-intervention). We hypothesized that AWARE would have a greater effect on the reduction of sexual risk behaviors and depressive symptoms for those who met criteria for a PTSD diagnosis compared to those who did not.

Method

Participant Recruitment, Screening, and Enrollment

The study was conducted at a private university in a large urban U.S. city in the northeast. All procedures were approved by Boston University IRB, Protocol # 3177, Asian Women's Action for Resilience and Empowerment (AWARE): A Stage IA and IB Intervention Development Study, prior to implementation. Participants were recruited using flyers, word-of-mouth, electronic newsletters of Asian-American organizations, group emails to previous study participants, and outreach at local Asian-American events.

Participants went through a two-stage screening process. As indicated in Figure 1, a total of 435 women completed an initial screening over the phone, face-to-face, or via an electronic survey between February 2014 and January 2016. Initial eligibility criteria included individuals who: self-identify as female; are unmarried; are between the ages 18 and 35; are of Chinese, Korean, and/or Vietnamese descent; are 1.5 (immigrated to the U.S. before the age of 18) or 2nd (U.S.-born children of 1st generation immigrants) generation; are fluent in English; have a mobile phone with text messaging; and have had penile-vaginal intercourse

in their lifetime. The three Asian ethnic groups (Chinese, Korean, Vietnamese) were selected for sampling because of their shared cultural roots in Confucian ideologies to focus generalizability of the results.

Women who met initial eligibility criteria ($n = 173$) were invited to the research lab for further clinical screening facilitated by a trained research assistant. Participants who gave informed consent completed computerized assessments on their trauma histories, depressive symptoms, sexual risk behavior, and PTSD symptoms following standardized batteries. To be clinically eligible for the AWARE intervention, participants had to have a history of exposure to at least one type of interpersonal trauma as assessed by select questions on the Traumatic Life Events Questionnaire (TLEQ; Kubany et al., 2000). Participants were excluded and immediately referred to appropriate services if they were at current significant risk of homicidal or suicidal behavior, intimate partner violence, and/or psychosis.

Following the baseline screening ($n = 435$), eligible participants ($n = 173$) were invited to participate and randomized ($n = 63$) to either the intervention ($n = 32$) or waitlist control ($n = 31$) group in a 1:1 ratio (14.3% inclusion rate). The primary reason for ineligibility after clinical screening was having no history of interpersonal trauma (87.04%). Other exclusion reasons included current significant risk of IPV or suicidality. There was no statistically significant difference in the demographic, trauma measured by PCL-C, or the outcome measures between individuals who were lost to follow up and were not enrolled ($n = 47$) and individuals who were randomized ($n = 63$).

We assessed the fidelity of the AWARE intervention using two methods. First, four trained research assistants who identify as Asian-American women each shadowed one of four intervention cohorts for all eight intervention sessions. These shadowers rated the therapist (A. Lee) for adherence to the manual and in her helpfulness for the participants on a 4-point Likert scale (0 = *poor*, 1 = *satisfactory*, 2 = *good*, or 3 = *excellent*). The adherence and helpfulness items were adapted from a scale used in the Seeking Safety intervention (Najavits, Kivlahan, & Kosten, 2011). Among the four intervention cohorts, the average rating for adherence to the manual was 2.72 and helpfulness for the participants was 2.73. Second, to validate the shadowers' ratings, the PI listened to approximately 80% of all the recorded sessions (26/32 sessions) and reviewed 100% of the therapist's post-session written progress notes (32 sessions). There were only two sessions over which the PI did not agree with the shadowers' scores for both adherence and helpfulness; hence the PI-rated concurrent validity was high.

Data Collection and Assessments

All randomized participants completed the computerized assessments at baseline (T0) and post-intervention (T1). The post-intervention assessment was conducted approximately 10 to 12 weeks after baseline. Participants in the intervention group completed an additional 3-month follow-up assessment (T2). We used a waitlist design where the control group was invited to receive the intervention following T1. Their post-intervention results are beyond the scope of this study and are not reported. This is with the exception of the safety measures, which are reported on everyone that eventually received the AWARE intervention ($n = 31$).

Measures and Outcomes

Intervention retention.—Study feasibility was evaluated by participant retention among those randomized to the intervention arm using the percentage of AWARE sessions attended. The “completers” of the intervention were defined as those who attended at least 75% of the sessions (6 out of 8 total sessions). Similar definitions have been used in other studies (e.g., Verhaeghe et al., 2013).

Sexual risk behaviors.—Engagement in sexual risk behaviors was the primary efficacy outcome and measured at T0, T1 in both groups, and at T2 for the intervention group only. Behaviors of interest included: engaging in unprotected sex, having multiple sex partners, and engaging in anal sex. Engagement in unprotected sex was assessed by asking participants, “Of those times that you had vaginal sex in the past three months, how often did you or your partner use condoms/latex protection?” Responses were dichotomized as 0 = “inconsistently” by collapsing response items, “never used a condom,” “some of the time,” “half of the time,” “more than half of the time” and 1 = “every time.” Having multiple sex partners was assessed by the question: “How many female/male sex partners have you had in the past three months?” Responses were dichotomized as 0 = “none or one sexual partner” and 1 = “more than one sexual partner.” Engagement in anal sex was assessed by the question, “How many times in the past three months did you have anal sex?” Responses were dichotomized as 0 = “never” and 1 = “one or more times.”

Depressive symptoms.—As a secondary outcome, depressive symptoms were measured at T0, T1 for both groups, and at T2 for the intervention group using the Center for Epidemiological Studies Depression Scale (CES-D), a 20-item self-report questionnaire designed to assess depressive symptomatology. For each item, participants reported their moods over the past two weeks using a Likert-type scale ranging from *rarely or never* (0) to *most days or always* (3). Responses were summed to create a total symptom score ranging from 0 to 60. The CES-D has demonstrated very high internal consistency, reliability and validity (Radloff, 1977). The internal consistency of our sample ranged from .86 to .92.

PTSD symptoms.—At T0, we collected trauma histories and related information including an assessment of PTSD, which we believed may be an effect modifier of the association between treatment and efficacy. The PTSD Checklist, Civilian version (PCL-C) is a 17-item self-report measure of PTSD symptom severity. Each item corresponds to a PTSD symptom outlined in the fourth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV). Participants reported both the frequency and intensity of their experiences of PTSD symptoms over the past 3 months on a 5-point scale ranging from *low* to *high*. Symptom severity was computed by summing the frequency and intensity scores. Total scores ranged from 17 to 85, with a score of 50 used as the cutoff to assess a diagnosis of PTSD (Conybeare, Behar, Solomon, Newman, & Borkovec, 2012).

Suicidal Ideation and Intent.—The Columbia-Suicide Severity Rating Scale (C-SSRS) was used to assess subject safety defined as suicidal ideation and suicidal intent (Posner et al., 2011). Participants who reported *yes* to either one of the following three questions were classified as having suicidal ideation: *wished to be dead, thought of killing yourself, and*

thought about how to do this. Suicidal intent was measured with answering *yes* to either *having intention of acting on thoughts of killing yourself* or *having worked out the details of how to do it*. Lifetime suicidal outcomes and suicidal outcomes of the past 30 days were measured at T0 and at post-intervention evaluations (T1, T2).

Statistical Analysis

Prior to analyses, descriptive statistics were generated to evaluate data distribution, plausibility, and missingness. To confirm that randomization had adequately balanced potential confounders between groups, we compared the demographic and clinical characteristics of the intervention and control groups at T0 using two-sided independent *t*-tests and Pearson's Chi-square (Fisher's exact tests where small cell sizes were observed). Any factors that significantly differed between groups were considered as potential confounders in the regression models.

In an omnibus test, we used a two-way repeated measure, ANOVA, to evaluate whether there was a difference in sexual risk behaviors and depressive symptom scores over time between the intervention and control groups. In the model, the random effect was defined as per subject and fixed effects were defined as group assignment, baseline score, and time point (T1 and T2). Multiple linear regression and a Chi-square test were used to test differences between groups.

Analyses were performed using both intention-to-treat (ITT) and per-protocol. For the intention-to-treat (ITT) analysis, all participants that were randomized were included in the analysis and values were imputed for all missing efficacy outcome measures using last observation carried forward (LOCF), assuming that the last measured outcome remained the same in time after the point of dropout. These results were compared to the per-protocol analysis where only those participants ($n = 56$) who completed all AWARE sessions were included and LOCF was again used for imputation. Values in the control group were carried over from T1, assumed to be unchanged, to compare to the intervention group evaluation at T2.

To examine effect modification by PTSD, that is, whether AWARE had a stronger impact on participants who met the criteria for a diagnosis of PTSD at baseline, we conducted a stratified analysis of the sexual risk behaviors and depression. We applied a two-way repeated measure, ANOVA, in both subgroups to evaluate the effect of the intervention.

All statistical tests used a significance level of $\alpha = 0.05$. All analyses were conducted using R (Version 3.2.2; R Core Team, 2015).

Results

Participant Baseline Characteristics

There were no statistically significant differences in demographic characteristics between the intervention and waitlist control groups at baseline (Table 2). The mean age was 23.63 ($sd = 3.84$) years. Ethnically Chinese women made up the majority of the sample (57.15%), followed by Koreans (15.87%), and Vietnamese (15.87%). Eleven percent were multi-ethnic

within these three ethnicities. Nearly all participants (96.83%) were either attending college at the time of data collection or had a college degree. Forty-four percent identified as non-exclusively heterosexual. The intervention and control groups showed no statistically significant differences on most of the mental health and sexual risk behavior indicators at baseline (T0) except for the proportion of multiple sex partners ($p = .05$, 0.00% and 12.90% for the intervention and control groups, respectively). The intervention and control groups did not differ on mean CES-D scores ($p = .30$, 18.91 ± 13.04 and 15.97 ± 8.77 , respectively), on the prevalence of PTSD diagnoses ($p = .99$, 40.63% and 41.94%, respectively), or the proportion of the suicide ideation ($p = .99$, 68.75% and 70.97%, respectively) or suicide intent ($p = .99$, 21.88% and 19.35%, respectively). The proportion of unprotected sex (50.00% and 64.52%) and anal sex (25.00% and 35.48%) also did not significantly vary by group ($p = .97$ and $.67$, respectively).

Intervention and Study Retention

Of the 32 participants randomized to the intervention group, 4 dropped out before the start of the intervention. The remaining 28 (87.50%) participants completed at least 6 of the 8 sessions, meeting the definition of “completers,” and 25 (78.13%) participants completed at least 7 of the 8 sessions. No participants were removed from the study after the start of the intervention due to signs of homicidal or suicidal behavior.

In the intervention group, 87.50% and 81.13% of participants completed assessments at T1 and T2, respectively. In total, 26 of the 32 participants (81.13%) in the intervention group and 30 of 31 participants (96.77%) in the control group completed all eligible assessments. All the demographic and clinical measures at T0 were not significantly different among those who completed all assessments and those who did not, suggesting that the data were missing at random.

Primary outcome: Sexual Risk Behavior

The results from the ITT analysis are presented below in Tables 3 and 4.

Overall analysis.—At baseline (T0), more than half of the participants in both groups reported having engaged in unprotected sex in the past 3 months (50.00% vs. 64.52%, respectively). This proportion remained the same at T1 and T2 in the waitlist control group. The proportion increased to 53.13% at T1 and 56.25% at T2 in the intervention group, but it was not statistically significant. In the intervention group, there were no women who reported having multiple sex partners at T0, 9.38% at T1, and 3.13% at T2. In the control group, the proportion of multiple sex partners was 12.90% at T0 and 9.86% at T1. The proportions of women who had engaged in anal sex at T0 were comparable between the intervention and control groups (6.25% vs. 9.68%, respectively; $p = .67$). In the intervention group, this proportion remained the same at T1 and T2 while in the control group, the proportion increased to 6.45% at T1. However, no intervention effect was seen by group or time on changes in any of the three sexual risk behaviors (group*time effect $p = .99$, .16, and .99, respectively).

Stratified analysis.—There were $n = 13$ intervention, $n = 13$ controls who met criteria for PTSD at T0 and $n = 19$ intervention and $n = 18$ controls who did not meet criteria at T0. No significant changes in sexual risk behaviors over time were observed in either stratum. That is, among those with or without PTSD at baseline, no significant intervention effect was observed on any of the sexual risk behaviors (i.e., engaging in unprotected sex, having multiple sex partners, engaging in anal sex (group*time effect $p = .09$, $.89$, and $.33$, respectively, in those with PTSD, and $p = .14$, $.17$, and $.59$ in those without PTSD).

Secondary Outcomes: Depressive Symptoms

Overall analysis.—We used a linear mixed effect model to evaluate the effect of the intervention over time on depressive symptoms measured by the CES-D score. Participants in the intervention group experienced reductions in depressive symptoms over time, notably by 3 months post intervention (mean CES-D score 18.91 ± 13.04 [T0], 17.78 ± 10.80 [T1], 15.69 ± 11.57 [T2]); however, these reductions were not statistically significant at the tested significance level ($p = .71$). For the control group, the mean CES-D score was essentially unchanged ($p = .86$, 15.97 ± 8.77 [T0] and 15.58 ± 8.71 [T1]). The omnibus test showed no significant group*time effect ($p = .09$).

Stratified analysis.—Notable contrasts were found between the PTSD strata. Among those with PTSD at baseline, intervention group participants had higher depression scores at baseline (T0) than control group participants ($p = .004$, 30.15 and 17.85 , respectively). At post-intervention (T1), the mean CES-D score in the intervention group decreased by 5.07 compared to 2.16 in the control group. At T1, the mean CES-D scores of the two groups were no longer significantly different ($p = .41$), however, the effect size at T1 was higher in the intervention group compared to the control group ($.50$ vs. $.23$), indicating a greater reduction of depressive symptoms in the intervention group compared to the control group among those with PTSD at T0. Further, in the intervention group with PTSD, the effect size at T2 was $.84$ compared to $.50$ at T1, showing further reduction in depressive symptoms. The mixed effect analysis comparing the intervention and control groups showed a significant group effect ($p = .03$) among those with PTSD. There was also a significant group*time effect ($p = .05$), demonstrating significant group differences in treatment effect over time. Among participants without PTSD, there was no group*time interaction ($p = .66$) effect on depressive symptoms. The per-protocol analysis showed similar results.

Safety Outcomes

Among the 22 women in the intervention group who had reported lifetime suicidal ideation at baseline (T0), only 5 reported current suicidal ideation (defined as past 3 months) at T1 ($p < 0.0001$). At three months post-intervention, we observed further reduction to 4 ($p < .0001$, comparing T0 to T2). Suicidal intent also had a similar trend. Seven women randomized to treatment reported suicidal intent at the baseline (T0). However, at post-treatment (T1), none of the participants reported suicidal intent ($p = .02$) and the count remained zero at three months post-intervention (T2) ($p = .02$, comparing T0 to T2). Of the 22 women in the waitlist control group who initially reported any lifetime suicidal ideation at T0, 4 reported ideation in the past 3 months at T1 ($p < 0.0001$); of the 6 reporting suicidal intent at T0, none

reported it at T1 ($p = .03$). There was no further reduction in the waitlist control group upon completion of AWARE.

Discussion

This article describes the feasibility, preliminary efficacy, and safety results of an RCT of the first and only culturally informed group psychotherapy intervention for Asian American women with a history of interpersonal trauma and/or with a PTSD diagnosis. AWARE demonstrated high retention rates, in that 87.50% of those enrolled in the program completed at least six out of the eight sessions. This high retention rate is similar to our previous pilot test of AWARE with a smaller sample ($n = 9$; Hahm et al., 2017). Certain characteristics of the program design may explain the high retention rates in this RCT trial. The group psychotherapy treatment setting, culturally informed psychoeducational content, and shared cultural background between participants and the therapist may have collectively contributed to a therapeutic alliance and rapport among participants (Hahm et al., 2017). Specifically, the topics covered in each session created a natural space for participants to have open discussions about issues that have impacted their mental and sexual health, including Asian gender roles, parent-child relationships, intergenerational cultural conflict, trauma, racial discrimination, and other forms of systemic oppression, intimate partner violence, and resilience. Another important element that may have contributed to the high retention rate is the text messaging feature of the intervention. Consistent reminders about upcoming sessions and “AWARE Stories” sent to participants’ mobile phones may have been an effective tool to increase their engagement with treatment.

The study demonstrated positive safety outcomes with respect to suicidal ideation and intention. Reductions were seen in both the intervention and waitlist control groups over time. Like retention, these results may be tied to the design and intent behind the AWARE program. We suspect that AWARE provided inspiration, validation, and strength in a safe therapeutic environment to all participants. This may have allowed women to develop the sense of empowerment that is vital in coping with suicidal ideation or intent. The reduction of suicidal ideation and intent for the women assigned to the waitlist control group could be explained by the effect of the anticipation of participating in a novel intervention tailored to a group of their peers of API women of similar age with similar sexual experiences, prior trauma, and depression profiles. This anticipation may have manifested as a placebo-like effect, reducing suicidal thoughts and tendencies in the control group in our data. Our safety data suggest that, while the intervention as designed may not have been effective in reducing sexual risk behaviors for the participants, it may be effective in reducing suicidal outcomes. Reductions in suicidality may be a better marker of its potential efficacy in future applications of AWARE.

In terms of preliminary efficacy, no statistically significant differences were observed between the waitlist control group and the intervention group on sexual risk behaviors or depressive symptoms at post-intervention (T1) or at 3-month follow-up (T2) after controlling for baseline levels of sexual risk behaviors and depressive symptoms. However, the statistical tests were underpowered to detect small differences due to the limited sample size in each arm. Further, stratified analyses demonstrated that among those with PTSD

measured at baseline, the intervention significantly reduced depression scores for those in the intervention group, after controlling for baseline levels of depression. Moreover, we saw a large, continued decrease in depressive symptoms from baseline to 3-month follow-up for the intervention group participants with PTSD. Since the waitlist control group was not evaluated at 3 months post treatment, it is difficult to infer whether the continued decrease is attributed to AWARE; however, given the differences between groups directly post-intervention, it seems plausible. This effect size ($d = .84$) was larger compared to similar studies that aimed to decrease depressive symptoms in individuals with PTSD (Cary & McMillen, 2012). In addition, since the intervention group participants with PTSD had higher baseline depression scores, one may argue if the reduction of depression scores should be considered as a regression toward the mean. In fact, regression toward the mean is a phenomenon of measurement error. We have no reason to believe that mismeasurement would be greater in either (treatment/control) group at baseline. If regression toward the mean was explaining the observed reduction in the treatment group at T1, by the same logic we should expect the control group (which was slightly though not significantly lower at baseline compared to the treatment group) to shift upwards from T0 to T1, to also “regress toward the mean.” However, we do not see such a phenomenon; rather the control group is essentially unchanged. We believe that it is highly unlikely that all depression measurements in the treatment group would be extreme the first time around and all simultaneously regress downward toward the second time around. It seems more likely to us that the observations are due to a systematic shift explained by the effect of the treatment rather than measurement error and the correlation between these errors at T0 and T1.

One of the most critical inclusion criteria was having a history of interpersonal violence. All 63 women had at least one history of interpersonal violence. Our evaluation at baseline showed that 40.63% of the intervention group and 41.90% of the control group also met criteria for the DSM-IV PTSD diagnosis at baseline. For women with PTSD, depressive symptoms or emotional dysregulation have been shown to be common mental health issues (Brown et al., 2016). However, despite the fact that many of them were suffering from PTSD, our analysis found that on average, RCT participants had attended only 3.3 sessions at outpatient mental health settings in the past year (before they received AWARE). AWARE may have provided the participants the needed psychoeducation and support for them to cope and better manage their depressive symptoms and challenges associated with PTSD. Thus, AWARE may provide a promising outlet for depression reduction particularly for the Asian-American women who are suffering alone from PTSD.

AWARE provided new coping skills to deal with common symptoms of depression and/or PTSD such as guilt, hopelessness, and helplessness over the course of eight sessions. Specifically, the coping skills and empowerment exercise such as *STOP* (Stop, Take a deep breath, Observe, and Proceed with caution) taught participants how to manage their PTSD symptoms. In addition, participants were given the “AWARE Coping Skills Cards” key chain, a set of index cards consisting of coping skills to use in various circumstances (e.g., when feeling suicidal or feeling like harming themselves, when feeling unsafe in an unhealthy or abusive relationship, when tempted to abuse alcohol or drugs), as well as a list of emergency contacts. AWARE’s emphasis on skills training around interpersonal relationships, particularly around trust building, safety, and empowerment, also promoted

discussions related to stigma toward mental health service utilization in the context of interpersonal violence. These aspects of the intervention might have allowed the participants to try out new ways of coping and develop an increased sense of control over their mental health. All these factors might have restored hope and thus led to the reduction of depressive symptoms among those who met criteria for PTSD. Further analysis is needed to understand the mechanism of why AWARE had more impact on depression reduction for women with PTSD. However, a separate study using qualitative data collected from AWARE participants in the intervention group found that the majority reported experiencing increased hopefulness, sense of empowerment, and quality of life whether or not they met the criteria of PTSD (Hahm et al., 2018). A future larger RCT for AWARE should incorporate measures of these psychosocial constructs in its evaluation.

AWARE did not show a significant overall group time effect or subgroup effect on sexual risk behaviors. There are several possible explanations for this finding. First, the proportions of participants who had multiple sex partners and those who had engaged in anal sex in the past three months at baseline (T0) were very low. Thus, the low observation counts of these variables made it difficult to detect the reduction of these behaviors over time. Second, while AWARE was originally designed to target sexual risk behaviors among women who are in heterosexual relationships, 44% of the participants identified as non-exclusively heterosexual. The high proportion of sexual minority individuals in our study sample is consistent with findings from one of our previous studies where Chinese-, Korean-, and Vietnamese-American women who are sexual minorities were more likely to have worse mental health status and use higher level of substances compared to their heterosexual counterparts (Lee & Hahm, 2012). Sexual minority Asian-American women were also nearly twice as likely to access any mental health care in the past year than heterosexual Asian-American women, controlling for covariates (Hahm, Lee, Chiao, Valentine, & Lê Cook, 2016). During the intervention, the AWARE therapist was cognizant about the diversity of sexual orientation among the participants, therefore, she adapted the sexual behavior topics to be more inclusive of all sexual orientations; however, the lack of content and activities specifically applicable to non-heterosexual individuals may have contributed to these non-significant findings. Third, the approximately 6-month time frame of the assessments conducted in this study may not have been long enough to measure changes in sexual risk behaviors of the participants. A longer follow-up period (e.g., 12 months post-intervention) to measure sexual risk behaviors has shown significant improvement in other RCT studies (Shain et al., 1999; O'Leary, Jemmott, & Jemmott, 2008). Thus, it is unclear whether the lack of a treatment effect on sexual risk behaviors is related to the efficacy of the intervention, or is reflective of a sampling or other element of the study design. Nonetheless, a more comprehensive psychoeducation around sexual risk behaviors and risk reduction counseling that is inclusive of all sexual orientations would potentially increase AWARE's effect on sexual risk behaviors.

Limitations

Results of the present study must be interpreted considering the following limitations. Although 435 women expressed an interest in participating in AWARE, only 14.30% were included due to our stringent inclusion criteria which includes specific ages (18–35),

ethnicities (Chinese-, Korean-, Vietnamese-Americans only), single status, and women who were sexually experienced. While these stringent criteria were necessary to test our study hypothesis, the majority of participants were those who were in higher education, limiting the generalizability of our findings. In contrast, we believe that the content of the AWARE sessions focuses on racial/gender identity, relationships, risk behaviors, coping, and resilience, which transcend one's age, SES, or educational background. Thus, future research should include experimentation with different inclusion criteria including different lifespan of women, diverse marital status and SES, as well as different ethnic groups.

Despite these limitations, our study showed promising results for the feasibility of a mental and sexual health intervention designed for a population who has historically underutilized mental health services. The high intervention retention rates among participants offer evidence that AWARE was well-accepted by our sample. In addition, stratified analyses demonstrated that AWARE may be an effective treatment option for depression among Asian-American women with PTSD. Future studies should explore the mechanisms of action explaining why AWARE was more efficacious for women with PTSD vs. women without PTSD. For instance, mediators such as increasing distress tolerance and reducing negative mood, and the role of increased empowerment should be tested to understand the path of efficacy of AWARE for those with PTSD.

Conclusion

This study demonstrates that a culturally specific group therapy intervention is feasible and efficacious in reducing depressive symptoms among Chinese-, Korean-, and Vietnamese-American young women with PTSD. Aspects of the intervention may need to be modified to observe change in sexual risk behaviors of these women. The results highlight that providing culturally-relevant mental and sexual health psychoeducation and therapy in a group format is a valid and acceptable tool for Asian-American women who lack the support and space to openly discuss issues that impact their mental and physical well-being. The intervention should be tested in a large-scale RCT for further validation.

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Public Policy Relevance

AWARE showed promise in reducing depression levels among young Chinese-, Korean-, and Vietnamese-American women with Post-Traumatic Stress Disorder. Our results highlight the importance of assessing for PTSD in Asian-American women who seek mental health treatment and providing a gender- and culture-specific intervention to address the systemic barriers, which negatively impact the mental and sexual well-being of these women.

Figure 1:
Consort chart of AWARE intervention

Table 1.

AWARE intervention group psychotherapy session descriptions and AWARE stories (complimentary dairy text message intervention) examples.

Sessions	Session Themes	Example of AWARE Story (Text message intervention)
1	Getting to know participants Cultivating a zone free of judgment and criticism to foster a sense of safety Developing awareness of risky or unsafe behaviors & unhealthy coping skills Building a sense of resiliency through replacing unsafe coping behaviors with empowering coping skills	“Being empowered means choosing how we want to act in the face of adversity. However, this is easier said than done. When someone faces an emotionally challenging obstacle, we can often act in ways that we feel aren’t in our control. Recognizing our emotions and how we react to them is a key step in discovering how we can empower ourselves.”
2	Learning about immigrant parenting and its impact on Asian American women In-depth discussion on the kind of parenting styles that participants have experienced growing up Recognizing how these parenting styles may have contributed to one’s identity development and mental health Learning to better understand the large contexts in which immigrant parents suffer Developing empowering coping skills for when one encounters negative parenting styles	“We are often are our own harshest critic. When we face failure, we often blame ourselves and engage in negative self-talk. It is important to counter this talk by using healthy coping skills, such as empowering self-talk. Instead of blaming yourself when you make a mistake you should say mistakes are normal and it is how you learn from them that matters. Treat yourself with the respect you deserve.”
3	Identifying one’s priorities and the values that are important to them and how these align with the priorities and values of their parents as well as societal expectations Learning to recognize that the double bind may bring emotional paralysis Breaking through the double bind in order to achieve a healthy, integrated sense of identity	“It isn’t easy to deal with the push and pull deciding between what you want, what your parents want, and what other people want. We can’t necessarily give you the right answer because ultimately only you will be able to decide what works best. What we can teach you however is how to handle the emotions that can arise from these situations.”
4	Understanding the role played by one’s family, the media and society in perpetuating negative stereotypes on Asian American women Examining the way one views their own body and how this impacts overall self-image Sharing stories on body image, stereotypes, racism, and the media as Asian American young women Guided mindfulness exercises to foster self-compassion and healthy self-image	“How we feel about how we look has a deep impact in our lives. Sometimes we feel deeply troubled that we will be judged on our appearances and not for who we are, so we often focus obsessively on our looks in an unhealthy manner. Think about your own life. Are there times when you feel like you’ve obsessed about your appearance? Have you ever done anything extreme for the sake of how you look? Try to recognize these moments in your life. This is the first step in getting a healthy body image.”
5	Understanding characteristics of healthy, unhealthy, or abusive relationships Recognizing whether one’s own relationships exhibit the characteristics of healthy or unhealthy relationships Learning to build healthy relationships Advice on how to seek help if participants are experiencing abuse and/or sexual assault, including safety planning, learning about sexual rights and practicing communication skills for negotiation with sexual partners	“Sometimes, we can feel trapped in a relationship. Sometimes, we lack confidence that we can receive more love than what we have, or frankly that don’t we even deserve love at all. However, if you feel unsafe in a relationship, if you partner is hurting you and harming you, we need to be willing to take that jump and leave a relationship. It may seem difficult, but you’re not alone so don’t be afraid to reach out for help; there are many people who understand what you’re going through and want to help.”
6	Identifying the types of behaviors linked to increased risk of contracting HIV and STI or developing a substance abuse disorder Determining if one has a substance use problem, and if one has engaged in behavior that puts one at risk of contracting STIs or HIV. Working through reasons people engage in unsafe sex. Developing a sense of empowerment to increase one’s safety in sexual practices and substance abuse	“Using alcohol or drugs during times of distress is tempting. It can provide strong feelings of pleasure or relief. Unfortunately, substances only offer temporary relief and they often exacerbate a problem. If you are feeling down or angry, try to find other places for help. Reach out to friends. Talk to a counselor. Alcohol or drugs can numb pain, but they can’t cure it.”
7	Identifying cultural forces that result in the propensity to develop self-blame and self-hatred Learning how to forgive oneself and self-compassion exercises. Understanding self-care	“We frequently will talk to ourselves in a very harsh manner after we make a mistake. We often think this is a way for us to take responsibility for our actions and will help change us. We think that if we yell at ourselves that we will eventually learn. In reality, these thoughts prevent us from changing. Self-

Sessions	Session Themes	Example of AWARE Story (Text message intervention)
	Affirming one's intrinsic worth by virtue of being human	hated is a defensive reaction that stunts our emotional growth. Taking a look at our own actions in an open, compassionate, and nonjudgmental manner is what promotes our personal growth."
8	Overview of the topics and themes covered in AWARE Reflecting upon one's own journey through AWARE Developing concrete and specific after-care & safety care plans	"Take care of yourself and view yourself with grace. Yes, you may have flaws, but you also have your strengths. Love and be proud of yourself."

Table 2.**Baseline Characteristics of Participants by Randomized Group Assignment**

	Intervention (<i>n</i> =32)	Control (<i>n</i> =31)	p-value
	Mean (SD) or No. (%)	Mean (SD) or No. (%)	
Age	23.63 (3.84)	24.00 (3.00)	0.67
Years of education			0.63
High school/GED	2 (6.25%)	0 (0.00%)	
Currently in college	9 (28.12%)	9 (29.03%)	
College degree and above	21 (65.63%)	22 (70.97%)	
Race			0.52
Chinese	19 (59.38%)	17 (54.84%)	
Korean	3 (9.37%)	7 (22.58%)	
Vietnamese	6 (18.75%)	4 (12.90%)	
Mixed and other	4 (12.5%)	3 (9.68%)	
Raised Location			0.67
Asia Only	0 (0.00%)	0 (0.00%)	
Mostly Asia	0 (0.00%)	0 (0.00%)	
Equally	1 (3.12%)	2 (6.45%)	
Mostly US	10 (31.25%)	7 (22.58%)	
US Only	21 (65.63%)	22 (70.97%)	
Self-assessed Physical Health			0.54
Poor	0 (0.00%)	0 (0.00%)	
Fair	2 (6.25%)	5 (16.13%)	
Good	19 (59.38%)	14 (45.16%)	
Very Good	9 (28.12%)	9 (29.03%)	
Excellent	2 (6.25%)	3 (9.68%)	
Self-assessed Mental Health			0.23
Poor	3 (9.37%)	0 (0.00%)	
Fair	8 (25.00%)	10 (32.26%)	
Good	14 (43.75%)	15 (48.39%)	
Very Good	7 (21.88%)	4 (12.90%)	
Excellent	0 (0.00%)	2 (6.45%)	
Sexual Orientation			0.38
Exclusively Heterosexual	20 (67.67%)	15 (50.00%)	
Mostly Heterosexual	5 (15.67%)	11 (36.67%)	
Bisexual	3 (10.00%)	3 (10.00%)	
Mostly Homosexual	1 (3.33%)	1 (3.33%)	
Homosexual	1 (3.33%)	1 (3.33%)	
Nativity			0.52
1.5 generation	8 (25.00%)	10 (32.26%)	

	Intervention (n=32)	Control (n=31)	p-value
	Mean (SD) or No. (%)	Mean (SD) or No. (%)	
2 nd generation	24 (75.00%)	21 (67.74%)	
Clinical and behaviour indicators			
Suicide Ideation	22 (68.75%)	22 (70.97%)	0.99
Suicide Intent	7 (21.88%)	6 (19.35%)	0.99
Sexual Risk Behaviors			
Any unprotected sex in past 3 months	16 (50.00%)	20 (64.52%)	0.97
	Intervention (n=32)	Control (n=31)	p-value
	Mean (SD) or No. (%)	Mean (SD) or No. (%)	
Sexual Risk Behaviors			
Multiple sex partners in past 3 months	0 (0.00%)	4 (12.90%)	0.05*
Any anal sex in the past 3 months	2 (6.25%)	3 (9.68%)	0.67
CES-D Score	18.91 (13.04)	16.00 (8.77)	0.30
PTSD Diagnosis ^I	13 (40.63%)	13 (41.94%)	0.99

^I. PTSD Diagnosis was determined by the PTSD Checklist, Civilian version (PCL-C) with a score of 50 as the cutoff to assess a diagnosis of PTSD.

Table 3.

Sexual Risk Behaviors among Participants with PTSD vs. without PTSD over Time

Proportion of Any Unprotected Sex (%)				Proportion of having multiple sex partner (%)				Proportion of having anal sex (%)				
Intervention	Waitlist Control	P-value ¹	Omnibus Test ² P-value	Intervention	Waitlist Control	P-value	Omnibus Test P-value	Intervention	Waitlist Control	P-value	Omnibus Test P-value	
All participants(n=63)												
T0	50.00	64.52	0.97	$P_{group*time}=.99$ $P_{time}=.99$	0.00	12.90	0.05*	$P_{group*time}=.16$ $P_{time}=.15$	6.25	9.68	0.67	$P_{group*time}=.99$ $P_{time}=.99$
T1	53.13	64.52	0.99	$P_{group}=.94$	9.38	9.68	0.99	$P_{group}=.56$	6.25	6.45	0.99	$P_{group}=.95$
T2	56.25	64.52 [†]	0.99		3.13	9.68 [†]	0.35		6.25	6.45 [†]	0.99	
High level of PTSD ³ participants(n=26)												
T0	30.77	76.92	0.16	$P_{group*time}=.09$ $P_{time}=.14$	0.00	23.08	0.48	$P_{group*time}=.89$ $P_{time}=.41$	7.69	7.69	0.99	$P_{group*time}=.33$ $P_{time}=.33$
T1	38.46	61.54	0.41	$P_{group}=.61$	0.00	15.38	0.22	$P_{group}=.15$	0.00	7.69	0.99	$P_{group}=.18$
T2	53.85	61.54 [†]	0.99		0.00	15.38 [†]	0.22		7.69	7.69 [†]	0.99	
Lower level of PTSD participants(n=37)												
T0	63.16	55.56	0.39	$P_{group*time}=.14$ $P_{time}=.15$	0.00	5.56	0.49	$P_{group*time}=.17$ $P_{time}=.16$	5.26	11.11	0.60	$P_{group*time}=.59$ $P_{time}=.58$
T1	63.16	66.67	0.41	$P_{group}=.66$	15.79	5.56	0.60	$P_{group}=.44$	10.53	5.56	0.99	$P_{group}=.67$
T2	57.89	66.67 [†]	0.99		5.26	5.56 [†]	0.99		5.26	5.56 [†]	0.99	

¹. P-value is derived from chi-square test (fisher's exact test is applied when chi-square is not appropriate) to test the difference between two groups.

². Omnibus test is a two-way repeated measures anova, equation: Any Unprotected sex = baseline + group +time +group*time +(1|subject); while $P_{group*time}$ represents the group condition * time effect, P_{time} represent the within group time effect, P_{group} represents the within subject group effect.

³. PTSD symptoms stratified using a PTSD cut-off at 50.

[†]. Control group did not receive 3 months follow-up, and we assumed that the score did not change for waitlist control group in T1 and T2.

Table 4.

Depression Severity among Participants with PTSD vs. no PTSD over Time

	Mean(SD)/CES-D Score		Group Difference (95% CI)	p-value ¹	Omnibus Test ² p-value
	Intervention	Control			
All participants (n=63)					
Baseline (T0)	18.91 (13.04)	15.97 (8.77)	2.84 (-2.68,8.56)	0.30	$P_{group*time}=.09$
Post-intervention (T1)	17.78 (10.80)	15.58 (8.71)	2.20 (-2.75,7.15)	0.72	$P_{time}=.09$
Effect size	Cohen's $d=0.09$		Cohen's $d=0.04$		$P_{group}=.52$
3-month follow-up (T2)	15.69 (11.57)	15.58 (8.71) [‡]	0.11 (-5.69,5.28)	0.22	
Effect size	Cohen's $d=0.26$		Cohen's $d=0.04$		
Participants with PTSD ³ (n=26)					
Baseline (T0)	30.15 (10.19)	17.85 (9.16)	12.30 (4.46,20.16)	0.004**	$P_{group*time}=.05^*$
Post-intervention (T1)	25.08 (10.29)	15.69 (9.30)	9.39 (1.44,17.32)	0.41	$P_{time}=.05^*$
Effect size	Cohen's $d=0.50$		Cohen's $d=0.23$		$P_{group}=.03^*$
3-month follow-up (T2)	20.92 (11.78)	15.69 (9.30) [‡]	5.23 (-3.36,13.82)	0.06	
Effect size	Cohen's $d=0.84$		Cohen's $d=0.23$		
Participants without PTSD (n=37)					
Baseline (T0)	11.21 (8.34)	14.61 (8.48)	-3.40 (-9.01,2.21)	0.23	$P_{group*time}=.66$
Post-intervention (T1)	12.79 (8.09)	15.50 (8.54)	-2.71 (-8.26,2.84)	0.77	$P_{time}=.65$
Effect size	Cohen's $d=-0.19$		Cohen's $d=-0.10$		$P_{group}=.18$
3-month follow-up (T2)a	12.11 (10.23)	15.50 (8.54) [‡]	-3.39 (-9.70,2.91)	0.99	
Effect size	Cohen's $d=-0.10$		Cohen's $d=-0.10$		

¹ P-value is derived from the linear regression model adjusted for baseline to test the difference between two groups.

² Omnibus test is a two-way repeated measures ANOVA, equation: CES-D score = baseline CES-D score + group + time + group*time + (1|subject); while $P_{group*time}$ represents the group condition * time effect, P_{time} represents the within group time effect, and P_{group} represents the within subject group effect.

³ PTSD symptoms stratified using a PTSD cut-off at 50.

[‡] Control group did not receive 3-month follow-up, and we assumed that the score did not change for waitlist control group in T1 and T2.