

Addressing the need for culturally-tailored telemental healthcare linkage for Indigenous populations: Protocol for a pilot evaluation of Shocktalk

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Submitted to: JMIR Research Protocols
on: October 20, 2024

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Addressing the need for culturally-tailored telemental healthcare linkage for Indigenous populations: Protocol for a pilot evaluation of Shocktalk

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Abstract

Background: Urban Indigenous populations face disproportionate mental health challenges, including high rates of PTSD, depression, and substance use disorders, yet they have limited access to health services, especially culturally relevant care. The mechanism for providing care to Indigenous people in the US, the Indian Health Service (IHS), is significantly underfunded, and only accessible to certain Indigenous people. With over 70% of Indigenous individuals in the U.S. living in urban settings, there is a growing need for innovative healthcare solutions.

Objective: This manuscript presents a protocol for evaluating ShockTalk, a culturally tailored telemental health linkage application designed to improve mental health care access for urban Indigenous populations. This study outlines the development and pilot study of ShockTalk.

Methods: The conceptual framework is based on the Behavioral Model of Health Care Utilization. ShockTalk uses AI to connect clients with Indigenous or culturally aligned therapists and facilitates access to care via Facebook Messenger. Using a pre/post waitlist design, 5 participant clients will be admitted to the study at first and 5 additional at 3 months. Data collection includes pre/post surveys on client attitudes towards mental health treatment and trust in the ShockTalk platform at baseline and 3 month follow up, followed by in-depth qualitative interviews at 3 months. A cost-effectiveness analysis will assess the impact of varying levels of treatment engagement on client outcomes.

Results: This pilot study will offer insights into optimizing technology-based, culturally relevant mental health care. By examining varying levels of engagement and associated costs, the research seeks to identify the most effective and cost-efficient strategies for improving mental health outcomes in urban Indigenous populations. ShockTalk has the potential to shape future healthcare innovations in this field.

Conclusions: Findings are expected to contribute significantly to Indigenous mental health care by offering insights into sustainable, accessible, and culturally appropriate telehealth interventions, guiding future policy and practice.

(JMIR Preprints 20/10/2024:67757)

DOI: <https://doi.org/10.2196/preprints.67757>

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Original Manuscript

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Abstract

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Keywords:

Native American, Indigenous, Telemental health, Linkage to care, Culturally tailored, Pilot protocol

INTRODUCTION

Urban-living Indigenous¹ people experience disproportionately higher rates of mental health disorders (*American Indian/Alaska Native Health | Office of Minority Health*, n.d.; Schein et al., 2021), which are often a result of forced isolation from homelands of origin, community, and a lack of adequate mental health care resources (Gracey & King, 2009; King et al., 2009). The most significant mental health concerns facing urban Indigenous communities include a high prevalence of substance use disorders (Soto et al., 2022), depression, suicide, anxiety (*American Indian/Alaska Native Health | Office of Minority Health*, n.d.), and PTSD (Schein et al., 2021). For example, estimates of rates of PTSD among Indigenous people range from 16% - 24% (Aronson et al., 2016; Beals et al., 2013; Brockie et al., 2015) which is three times the rate of the lifetime PTSD among the general population (*How Common Is PTSD in Adults? - PTSD: National Center for PTSD*, n.d.) and rivals the lifetime rate (29%) among US veterans returning from Iraq and Afghanistan (VA.Gov | *Veterans Affairs*, n.d.).

Access to Mental Health Services

Addressing the mental health disparities among Indigenous communities who reside in urban contexts comes with unique challenges. The Indian Health Service (IHS), created in 1955 through Public Law 568, The Transfer Act of 1954, exists to fulfill the US governments' treaty obligations and legal responsibilities to provide healthcare to Native American and Alaska Native tribes (The Transfer Act of 1954, 1954). The IHS is currently funded at less than half of its required budget (*New Indian Health Service Funding Provides Stability, but Long-Standing Issues Remain*, n.d.), faces significant challenges, including barriers to service, staffing shortages, extended wait times, and diminished access to quality care (Hartmann et al., 2019). Notably, the IHS dedicates only 1-2% of its line budget to Urban Indian Health Programs received only through contracts, and many of these programs have limited capacity ("Urban Indian Health Facts," n.d.). Due to colonial policies such as the termination boarding school and relocation era, many Indigenous community members

have been displaced from their original homelands into urban areas (Lomawaima & McCarty, n.d.). As a result, over 70% of Indigenous people, specifically those identified as American Indian/Alaska Native (AI/AN), in the US today live in urban areas (*Urban Indian Health Program | Fact Sheets*, n.d.) of which only 25% live within an IHS service area (“Urban Indian Health Facts,” n.d.). The discrepancy between the location of Indigenous medical services and the areas in which most Indigenous individuals in the U.S. live poses a significant challenge, highlighting the need for healthcare innovation.

Further, rates of health insurance coverage are also markedly lower for Indigenous people compared to non-Hispanic white² individuals, compounding this health disparity. As of 2019, just over half (51.9%) of Indigenous individuals alone or in combination had private health insurance coverage (*American Indian/Alaska Native Health | Office of Minority Health*, n.d.). The percentage of Indigenous people who were enrolled in Medicaid or other public health insurance coverage was 42.9%, and 14.9% of Indigenous individuals did not have health insurance coverage; comparative rates for non-Hispanic white individuals were 74.7%, 34.3%, and 6.3%, respectively (*American Indian/Alaska Native Health | Office of Minority Health*, n.d.). Resultantly, there exists a profound need to improve and expand systems of care for urban Indigenous individuals seeking affordable mental health treatment.

Telehealth and Indigenous Populations

Telehealth, or telemedicine, uses two-way, real-time telecommunication audio and video technologies such as a computer, tablet, or smartphone, to deliver health care services and public health (*Telehealth Resource Center*, 2024). Telehealth interventions allows a health care provider to meet with a patient remotely to diagnose, consult, treat, educate, manage care, and it allows the patient to manage their care as well (Services, n.d.). Implementing care and interventions among underserved populations through telehealth has been shown to be feasible, cost effective (Kvedar et

al., 2014), with the ability to be culturally tailored to meet the needs of Indigenous populations (Moecke et al., 2024). In a recent scoping review regarding telehealth use by Indigenous populations from Australia, Canada, New Zealand, and the United States (Moecke et al., 2024), 47% of the 321 studies identified used mobile health (mHealth) and 26% focused on mental health. Indigenous communities expressed concerns regarding privacy and confidentiality concerns, limited broadband internet, uncertainty in their ability to use the technology, and lack of trust of the therapeutic relationship. However, collaboration with Indigenous communities to develop and implement the intervention and offering an Indigenous healthcare provider or cultural liaisons (13%) in its delivery indicated some increase in cultural safety. Notably, none of the identified studies discussed interventions that served solely as a linkage to mental health care, or facilitated a way for Indigenous clients to identify mental health support.

With these goals in mind, this manuscript provides a detailed protocol for the evaluation of the first telemental health linkage-to-care application tailored specifically for Indigenous communities, named *ShockTalk*. The purpose of the application is to improve access to culturally relevant mental health care for Indigenous individuals. The following section outlines the conceptual framework, the process of development for the mobile application, and identifies the needs of community members.

Conceptual Framework

The proposed research is informed by the Behavioral Model of Health Care Utilization (Andersen, 1995) which aims to understand how health care utilization and health-related outcomes are influenced by predisposing, enabling (inhibiting), and need factors at both the individual and contextual (e.g. community and policy level) characteristics levels. Individual and contextual factors also influence personal health practices and processes of care. In an iterative cycle, outcomes then affect subsequent predisposing and enabling factors, perceived need for health services, and health behavior.

Figure 1 depicts the conceptual framework for the study. The variables shown in black font will be included in our pre and post use survey. Guided by these findings, primary data collection and analysis of in-depth interviews will seek to better understand the components of the conceptual model in gray font (e.g. process of medical care). This study focuses on the relationship of *Individual Characteristics* and subsequent *Health Behaviors*.

[Insert Figure 1]

Preliminary ShockTalk application development

ShockTalk was conceptualized by three NYC-based Indigenous individuals with experience in social work, public health, technology, and research. To better understand the barriers to and facilitators of culturally responsive mental health service access in urban areas for Indigenous individuals, 70 in-depth interviews were conducted by the community-based partner team who originally conceptualized this application with community members and mental health clinicians in Lenapehoking. The findings of this assessment are presented in Table 1. Finances, lack of insurance, and lack of systems to help Indigenous clients identify culturally appropriate service providers were identified as the most prominent barriers through qualitative analyses. Facilitators of care included sliding-scale service offerings, and connections to Indigenous service providers, or providers that match the client on other statuses and/or identities.

Table 1. Themes from preliminary ShockTalk development

Theme	Findings
Structural Barriers to Accessing Therapy	<ul style="list-style-type: none">○ Perceived stigma of accessing therapy○ Need for variety of therapeutic settings, online, in person, “meet the client where they are”○ Lack of availability of Indigenous therapists○ Access to therapy, including telehealth○ Limited scheduling and availability and a cumbersome process
Interpersonal Barriers to Accessing Therapy	<ul style="list-style-type: none">○ Lack of comfort with therapist○ Uncertainty about online therapy○ Fear of not having a cultural connection○ Cost○ Lack of spiritual component in Western dominant therapy

Characteristics of an Ideal Therapist	<ul style="list-style-type: none"> ○ Ability to connect deeply with someone “beyond the surface” who is “down to earth” ○ Relational (compassionate and lets the person talk) vs advice giving ○ Can assure privacy and trust, especially in a small community ○ Someone with shared characteristics/understanding of experience ○ Shared understanding of trauma, colonization ○ Understanding of Indigenous culture, experiences, and ways of knowing ○ Share Native or Indigenous Identity who better understand the “everyday struggle” connected with Indigenous identity ○ History of working with Indigenous people “in a good way” ○ Feel connected ○ Can offer cultural and/or spiritual coping mechanisms and tools
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Findings from the community needs assessment informed the development of *ShockTalk* application. *ShockTalk* leverages Facebook Messenger as the point of entry for clients to interface with *ShockTalk* artificial intelligence (AI), which autonomously communicates with clients. Specifically, the AI gathers basic contact information, syncs relevant dates to clients’ calendars, and allows them to schedule an introductory 15-minute intake session with one of therapists from the vetted *ShockTalk* directory. It also sends a reminder message to prompt clients before their first session. After the intake session is complete, the client and therapist decide if the therapeutic fit is appropriate, and either begin a therapeutic relationship or the therapist refers the client to other services.

Current Study

The *ShockTalk* team has partnered with a researcher at the Columbia University to evaluate the pilot program of this application, which will involve interviews with ten Indigenous mental health treatment seekers in the urban area of Lenapehoking (specifically in what is now known as New York City) and three practitioners. The aims of this research are as follows: 1) assess changes in client attitudes related to telemental health treatment value and trust in *ShockTalk* technology; 2) assess the accessibility, experience, and value of *ShockTalk* for practitioners and clients interested in providing or receiving culturally responsive mental health treatment; and 3) estimate the potential benefit of the culturally responsive mental health treatment facilitated by *ShockTalk*. The ultimate

evaluation of this pilot program will assess the prospective benefits of telemental health care linkage for Indigenous individuals living in urban settings.

AIMS

Long term Goal: Increase access to culturally appropriate mental health care among urban Indigenous people in the US

Aim 1: Assess changes in client attitudes related to telemental health treatment value and trust in *ShockTalk* technology

Aim 2: Assess the accessibility, experience, and value of *ShockTalk* for practitioners and clients interested in providing or receiving culturally responsive mental health treatment

METHODS

To test the efficacy of the application and to determine the potential benefits of *ShockTalk* to Indigenous clients, a pilot study will be conducted using ten Indigenous therapy seekers (clients) and three Indigenous mental health therapists (practitioners) in Lenapehoking. Employing a pre/post wait-list control design with baseline and 3-month follow up surveys. We will randomize 5 clients to the control condition and half to treatment condition. At three months, 5 waitlisted clients will be accepted into the linkage to care. Open-ended interviews, which will last approximately 1-hour, with participants and practitioners will be conducted at 3 months. Interviews Finally, a cost analysis will be conducted to achieve the three separate aims of the study.

Study sample recruitment

Ten Indigenous clients and three Indigenous practitioners will be recruited to assess the efficacy and effect of *ShockTalk* on care linkage for therapists and clients. Therapists will be contacted directly via email from a listserv that was previously compiled through the *ShockTalk* company website. Therapists who signed up with name and email address and consented to being contacted at a later date will be contacted by our team about their continued interest in *ShockTalk*, and whether they would participate in the pilot program of the application. Indigenous therapy-seeking participants

will be recruited via the *ShockTalk* internal listserv and social media posts on Facebook, Instagram, and Twitter, which will include brief information about the study, compensation, and participant expectations.

The study coordinator will contact client and practitioner participants to determine eligibility and to discuss the study purpose, risks, benefits, and compensation. During this meeting, the study coordinator will also provide informed consent. Participants will be provided an electronic version of the consent form and will be asked to sign and return the form at the end of the call.

Eligibility Criteria

Participants will be screened for the following eligibility criteria: 1) are at least 18 years old, 2) self-identify as Indigenous to North, South, Central Americas or the Caribbean, 3) live in New York state. Individuals will be excluded from the analysis if they live outside of New York state, do not self-identify as Indigenous, or are less than 18 years of age. Practitioners will be screened for the following eligibility criteria: 1) are a mental health professional licensed to practice in the state of New York, 2) self-identify as Indigenous to North, South, Central Americas or the Caribbean.

Compensation

Participants (therapy seekers) will be compensated \$10 for completing each survey, one at baseline and one at 3 month follow up. Participants (therapy seekers) will receive \$30 for completing an in-depth interview. In total, participants are eligible to receive a total of \$50 for completing both surveys and the in-depth interview. Additionally, as a part of participating in this study, participant clients will have the cost of their therapeutic sessions covered, up to five (5) sessions and no more than \$600. Therapist participants will be compensated \$40 for completing an interview.

Data Safety and Monitoring

The study facilitator, under the supervision of the principal investigator, will monitor data. Data will be securely stored on a password-protected computer and laptop, and on a password-protected Google Drive associated with the study facilitator's University administered email address. Hard

copy data will be stored in a securely locked filing cabinet in the study coordinator's offices, to which only the study facilitator will have access. All data collection is entirely anonymous; no identifiers will be associated with the ID number labeled on the data.

Potential Risks

Despite best efforts to protect privacy and confidentiality, participants face a risk of potential loss of confidentiality. During an in-depth interview, there may be risks associated with discussing potentially stressful subjects. There is no more than a minimal risk of any harm to participants.

Potential Benefits

Participants may benefit from increased access to a culturally relevant mental health therapist. Some participants may find the in-depth interview process empowering and therapeutic in experience. Additionally, the information collected from this research may help others in the future.

Dissemination

Initial findings will be disseminated first with participants to obtain their feedback and to assure that the themes that are developed from qualitative interviews align with their experience and represent their views well. Additionally, results from this study will be disseminated in culturally relevant and accessible ways such as community meetings, social media posts, and a community-facing report that is developed with Shocktalk. Findings will be used to improve the current *ShockTalk* application and linkage-to-care process. The results will also be used to facilitate the search for additional sources of funding to implement broader assessments.

Ethics Approval

This study has been approved by the Columbia University Institutional Review Board (IRB # AAAU0850).

MEASURES

Quantitative

The first survey instrument will examine changes in attitudes related to telemental health treatment

value for clients before and after treatment facilitated by *ShockTalk*. One month before treatment and three months post treatment, clients will be given the Attitudes Toward Seeking Professional Psychological Help - Short Form survey (ATSPH-SF) (Fischer & Farina, 1995). This survey measures participants' openness to seeking professional help for emotional problems and the value and need in seeking professional help. Clients are asked whether they disagree, partly disagree, partly agree, or agree with an item, including questions such as, "The idea of talking about problems with a psychologist strikes me as a poor way to get rid of emotional conflicts," "A person with an emotional problem is not likely to solve it alone; he or she is likely to solve it with professional help," and "A person with an emotional problem is not likely to solve it alone; he or she is likely to solve it with professional help." Their attitudes toward seeking professional help are scored based on the sum of all responses. The short version of the scale demonstrates internal consistency ranging between 0.82 and 0.84, and high test-retest reliability ($\alpha = 0.80$). Once pre- and post-surveys are collected, the study team will examine differences in openness to treatment before and after *ShockTalk*. A positive difference between pre-treatment and post-treatment ATSPH-SF score will indicate an increase in client valuation of mental healthcare treatment. T-tests will evaluate whether differences are statistically significant.³

The second survey addresses trust and accessibility in telemental health care services and linkage services for clients. Clients will be asked five items each from the Trust in Technology and Trust in Telemedicine Service scales from the Patient Trust Assessment Tool (PATAT) (Velsen, Tabak, & Hermens, 2017). The PATAT is a trust benchmarking survey and, currently, the only instrument that provides a comprehensive measurement of trust in an eHealth service and the underlying trust concepts. Clients will respond to questions related to their trust in technology and telemedicine surveys using responses on a Likert scale, which range from totally disagree (1) to totally agree (5). Questions from the Trust in Technology subset include items such as "Everything done on *ShockTalk* remains private" and "The personal information that is stored at *ShockTalk* will not get lost." Items

from the Trust in Telemedicine Service include questions like, “I trust *ShockTalk* less than other online services.” In conjunction, these two quantitative surveys will assess practitioner and client trust in the *ShockTalk* application and changes in client valuation of treatment as a result of culturally appropriate telehealth care linkage.

Qualitative

To identify potential service gaps or accessibility concerns in the *ShockTalk* application we will conduct in-depth interviews with practitioners and clients three months after treatment participation. Practitioners will be interviewed in a talking circle, a technique consistent with Indigenous methodologies (Kovach, 2007). In the talking circle, practitioners will be asked a series of open-ended questions related to past experiences with telehealth care linkage systems and how *ShockTalk* compares in its accessibility, organization, and usability to other systems. They will also be asked about their favorite elements of the application, any problems they experienced, and potential improvements that might benefit both the client and the practitioner. The qualitative interview consists of six base questions with several probing questions. The talking circle is expected to take one to two hours.

Clients will also engage in one-on-one in-depth interviews. Though talking circles may be preferable to facilitate discussions, the sensitive nature of the client interviews prevents the study team from conducting discussions of this type. Clients will be asked about previous experiences in therapeutic contexts, how their experience in therapy resulting from *ShockTalk* is similar or different from those experiences, and what could be done to make the application more accessible. Clients are asked to walk through the process of accessing *ShockTalk*, and discuss points at which the application was not intuitive or problematic. After discussing the process and experience of using the application, clients will be asked about their process in choosing and retaining a therapist—what therapist attributes were most important in deciding on a therapist, what factors influenced a therapeutic fit, and what influenced their likelihood of rescheduling with the therapist they saw. Finally, clients are asked

about any potential changes or improvements they would make to improve their experience. Each client interview is expected to take thirty minutes to one hour.

Qualitative Analysis

To analyze the qualitative data, this research will utilize an exploratory approach within an applied thematic analysis framework to code practitioner and client responses. In an exploratory analysis, the content of responses drives the development of codes and the identification of themes (Guest et al., 2011). Thus, themes will be derived inductively after iterative readings of the transcribed interviews. Codebooks were constructed separately for clients and practitioners to define the presence of themes related to: 1) the accessibility of *ShockTalk* for clients and practitioners, 2) the experience of using *ShockTalk* for clients and practitioners, and 3) the value of *ShockTalk* for clients and practitioners. Once codebooks are constructed, the data will be systematically coded in steps to improve accuracy (Guest et al., 2011). To establish reliability, interview transcripts will be independently coded by two researchers, and Cohen's kappa will be calculated and assessed (Cohen, 1960).

Cost analysis

To comprehensively evaluate the impact of different intensities of culturally responsive mental health treatment provided through the *ShockTalk* application, we will integrate a cost analysis using a dose-response study. This approach will not only measure the effectiveness of varying treatment doses, but also assess the economic implications associated with varying degrees of engagement in the intervention. The objective is to determine how different "doses" of treatment—defined by session frequency and total duration—affect both the well-being of Indigenous clients in urban settings and the associated costs of providing these services.

In this context, "dose" refers to the varying levels of engagement in culturally responsive treatment, specifically, the number of sessions per week (e.g., once, twice, or three times) and the overall period of treatment. We hypothesize that higher doses of treatment, characterized by more frequent sessions

over a more extended period, will result in greater improvements in trust towards mental health treatment. However, we also anticipate that these higher doses will incur greater costs. Participants will include ten Indigenous clients, stratified into different groups based on the dose they receive, and three Indigenous practitioners administering the treatments according to the varied dosages.

To measure outcomes, we will focus on the measures of trust described in previous sections. Namely, primary outcomes will focus on changes in trust towards mental health treatment, using the Attitudes Toward Seeking Professional Psychological Help - Short Form (ATSPH-SF) and the Patient Trust Assessment Tool (PATAT). Secondary outcomes will include engagement levels, tracked via app usage and session attendance. For cost measurement, we will evaluate the direct costs associated with each dose of treatment, including therapist time, platform usage fees, and administrative expenses. This will enable us to perform a cost-effectiveness analysis, where the costs of different treatment doses are compared against their respective outcomes.

Quantitative analysis will involve linear mixed-effects models to understand the impact of different doses on mental health outcomes, accounting for repeated measures and potential intra-group correlations. Analysis of Variance (ANOVA)³ will be used to compare mean outcomes across dose groups. Additionally, cost-effectiveness ratios will be calculated to determine the economic efficiency of each treatment intensity. This comprehensive analysis will provide insights into the optimal balance between treatment effectiveness and cost, guiding resource allocation and decision-making for culturally responsive mental health services delivered through the ShockTalk application.

DISCUSSION

Given the limitations of the service provisions of IHS to service Indigenous communities in the United States, there exists a pressing need to connect urban-living Native people to mental health services. The purpose of this work is to assess the potential of *ShockTalk*, the first telemental healthcare linkage application created for Indigenous treatment seekers, to improve the landscape of treatment. This research is novel as there is no current assessment of this kind, and salient given the

significant mental health concerns of this population. Overall, the contributions of this work are expected to facilitate improved mental health care provisions for a population of exceptional need.

Limitations and Future Research

Due to the nature of the pilot project and funding limitations, the outcomes of this work will be limited by sample size. Specifically, it is difficult to establish statistically significant differences in outcomes pre- and post-treatment with only ten participants. Further, this research focuses on an assessment of the application using a small subset of the urban Indigenous population in the United States- Indigenous mental health care seekers in urban Lenapehoking. The results of this pilot program will be used to seek additional funding opportunities, which will be used to fund additional sites of research across the United States. Additional data collection will be used to 1) increase statistical power for quantitative analysis and 2) improve generalizability of results.

Conclusions

The disproportionate burden of mental health disorders among urban Indigenous community members highlights a critical need for innovative and culturally responsive healthcare delivery systems. *ShockTalk*, as the first telemental healthcare linkage application designed specifically for Indigenous individuals, represents a promising intervention to bridge this gap. This pilot study's comprehensive evaluation of *ShockTalk* will provide valuable insights into how culturally responsive, technology-mediated mental health treatments can be optimized and tailored to meet the unique needs of Indigenous clients in urban settings. Through assessing different intensities of engagement and their associated costs, this research aims to identify the most effective and economically viable treatment strategies.

The findings from this study are poised to significantly contribute to the field of Indigenous telemental health care by demonstrating the potential benefits of integrating culturally relevant telehealth services into broader mental health support frameworks. By examining variations in treatment "doses" and their impact on client trust, engagement, and overall satisfaction, we aim to

delineate the most effective approaches for delivering mental health care that is both culturally appropriate and accessible. The integration of a cost-effectiveness analysis further ensures that the solutions proposed are sustainable and scalable. Future expansions of this research, supported by additional funding, will extend these insights to a larger and more diverse subset of the urban Indigenous population, ultimately guiding policy and practice towards more equitable mental health care provisions.

Notes

1. We use the word Indigenous, a term that does not center arbitrary geo-political lines, to describe American Indian, Native American, and Alaskan Native populations in what is now known as the United States of America.
2. As part of the ongoing project of reclamation for Indigenous people, we lowercase the word “white” when referring to racial, ethnic, or cultural terms related to this population because white people do not have a similar experience of being discriminated against because of skin color.
3. Because of sample size limitations, we acknowledge that t-tests and ANOVA may be underpowered measurements of the true impact of the intervention on changes in attitudes surrounding therapy.

Conflicts of Interest

SK and AS are founding members of Shocktalk and hold shares in the company. AR and ALR declare no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Abbreviations

ATSPH-SF –Attitudes Toward Seeking Professional Psychological Help - Short Form

NYC – New York City

PATAT – Patient Trust Assessment Tool

PTSD – Post Traumatic Stress Disorder

Data availability

Data from this study will not be made public to maintain the privacy of participants.

Ethical considerations

This study has been approved by the Columbia Institutional Review Board (IRB # AAAU0850).

Consent to participate

Written, informed consent will be obtained by any participants enrolled in this study.

Funding statement

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This work was supported by a seed grant from the Columbia University School of Social Work.

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Supplementary Files

Figures

Conceptual Framework.

