Examining the feasibility and acceptability of a tailored version of a Mindfulness-Based Intervention (MBI) among YEH aged 18-25 years old

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Refer to page 16, for the pilot study (Aim 3) registered as ClinicalTrials.gov record NCT04950816.

Protocol Title:	Examining the feasibility and acceptability of a tailored version of a Mindfulness-Based Intervention (MBI) among YEH aged 18-25 years old
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Study Coordinator:	Jennifer Jones
Population:	Homeless Youth Focus groups (n=56) Homeless Youth Working group (n=10) Pilot RCT with Youth Experiencing Homelessness ages 18-25 (n=90) Total of 156 Youth Experiencing Homelessness ages 18-25 in Houston, TX
Number of Sites:	Single site
Study Duration:	Three (3) years
Subject Duration:	Six (6) months for subjects in pilot RCT

General Information

This proposed development and pilot study will examine the feasibility and acceptability of a tailored version of a Mindfulness-Based Intervention (MBI), .b, among (Youth Experiencing Homelessness) YEH aged 18-25 years old. Building on our promising pilot research, we will work with YEH to tailor .b, including ensuring a trauma-informed approach. Using iterative beta testing with a (Homeless Youth Working Group) HYWG, we will tailor the intervention and determine appropriate methods and strategies for recruitment, adherence, and retention. Finally, we will conduct an attention control RCT pilot study of the tailored version of .b to determine feasibility and acceptability of conducting an adequately-powered RCT. We will test our recruitment/retention methods, enrollment criteria, randomization protocol, participant tracking and follow-up processes, and study measures. With the pilot, we will determine whether participants will adhere to the intervention protocol (i.e., attend sessions, complete study measures). We will determine whether the enrollment criteria appropriately identify and exclude youth who cannot safely participate in the study and if our tracking and follow-up protocol is feasible and acceptable. The results of the pilot will inform the sample size needed for a fully powered, attention control RCT of the tailored .b to provide robust and clinically useful data on intervention efficacy among YEH.

Background Information

Importance of Public Health Impact. On any given night in the U.S., 1.7 to 2.5 million youth under age 25 are homeless.[1-3] Youth experiencing homelessness (YEH), a hard-to-reach, underserved population, suffer a disparate burden of adverse health outcomes including death, suicide, substance use, overdose, pregnancy, HIV, and mental illness.[4,6,31-35] The tumultuous experiences of daily life on the streets are difficult for youth who become homeless. While surviving the dangers of the streets and meeting one's basic needs for food and shelter, youth face enormous difficulties in maintaining their health and well-being. YEH are transient and go to great lengths to stay hidden from the dangers of victimization.[36] Most YEH move frequently between housing situations.[37] When youth become homeless, they bring to the

streets a range of emotional and psychological challenges that negatively impact their well-being, risk decision making, emotion regulation, and coping skills. YEH often have lengthy histories of multiple traumas stemming from difficult family situations, poverty, and physical, sexual, and emotional abuse that significantly contribute to their risk for experiencing homelessness. Moreover, YEH have high rates of parental addiction, psychiatric disorders, and criminal involvement that compound the trauma and instability experienced during childhood.[38,39] To this end, interventions targeting YEH must use a trauma-informed model that addresses the state of vulnerability, high stress, unstable housing, trauma, and compromised executive functioning many youth experience to increase their resilience (i.e., capacity to cope successfully) and reduce life-threatening behaviors.[26] While the need for prevention and health promotion interventions tailored to the special considerations of YEH is undeniable, they continue to be understudied and underserved owing to prevailing sentiment that they are challenging to work with and a bleak and hopeless population.[40] Much to the contrary, YEH are eager for health promotion programs, able to be recruited and retained in intervention research,[41,42] and demonstrate improved outcomes when programs are tailored and relevant.[43]

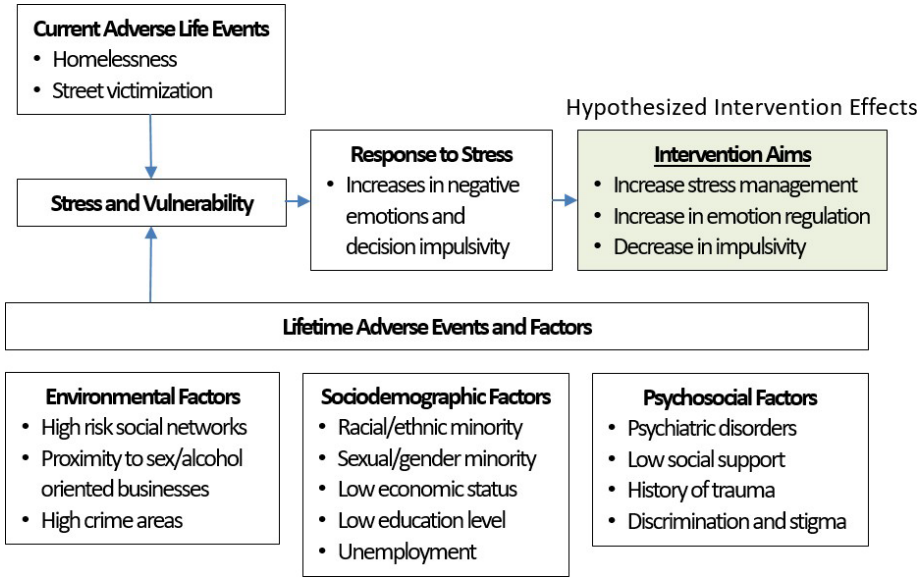
Psychological Symptoms and Mental Disorders among YEH. About 19% of YEH report being depressed,[46] compared with 11% of housed youth in a nationally representative sample.[47] Other studies have reported rates of 8%[48] to 61%[49] for depression and 5% to 48%[17,50,51] for post-traumatic stress disorder (PTSD) among YEH. Suicide is a leading cause of death among YEH[5] with suicide attempt rates ranging from 20% to 48%.[7,8] Houston data indicate that 42% of YEH are moderately to severely stressed with significant gender differences in reported stress (44% in females, 34% in males), 48% experience mental distress, 48% have a depression diagnosis, and 23% have a PTSD diagnosis.[52] Depression among YEH may be due to a disproportionate burden of lifetime adversity, including abuse, neglect, and housing instability.[53] One study found that 47% of YEH reported sexual abuse, 31% left home due to parental sexual abuse, 27% left home because of parental emotional abuse, and 20% left home because of parental physical abuse.[26] The chronic stress of homelessness related to meeting basic needs for food and shelter deflects attention from health promotion and disease prevention behaviors and is exacerbated by prevailing mood and anxiety disorders.[6] Stress and depression related to homelessness are crucial factors to consider when developing interventions to improve well-being and reduce health disparities.

Impact of Stress and Trauma on Impulsivity, Emotion Regulation, and Executive Function. Toxic stress is defined as an experience of strong, frequent, or prolonged stressful events.[20] Exposure to toxic stress is associated with a heightened risk of developmental or psychiatric disorders and health problems, including the development of chronic diseases,[66] and changes in brain structure and cognitive function, such as learning, working memory, and executive functioning tasks.[20] The chronic stress of being homeless can cause physiological changes that affect how an individual reacts to his/her environment. Acute stress also impairs executive functioning, working memory,[67] flexible task-goal implementation,[68,69] and impulse control.[70] Impaired executive functioning leads to poor decision-making ability[71] and lower inhibitory (i.e., impulse) control.[72] Interestingly, dispositional mindfulness has been found to be protective for exposure to the stress and trauma of early life adversity.[73] Additionally, the American Academy of Pediatrics has called for efforts to reduce toxic stress early in life to reduce the development of adult diseases and health disparities.[20]

Impact of Stress and Early Trauma on Substance Use and Sexual Risk Behaviors. Evidence is mounting on the impact of stress and trauma on engaging in risk behaviors. In a study among young adults (n=362), experiencing betrayal trauma prior to age 18 was associated with problematic substance use subsequent to PTSD and difficulty discerning or heeding risk ($\beta = 0.07$, $p < 0.01$) and self-destructiveness

(β = 0.12, p < 0.01).[74] PTSD has been associated with engaging in risky behavior while under the influence of substances.[60] Stress at age 19 was found to predict the development of a substance use disorder by age 22 among a sample of young males.[75] Stress also predicted inconsistent use of oral contraceptives,[25] condoms, and withdrawal.[56] In Black men, stress from discrimination has been suggested as a pathway to increased sexual risk behaviors.[76] Moderate to severe stress has been linked to increased sexual intercourse frequency.[23] In Black adolescent females, higher interpersonal stress was associated with lower, inconsistent, and non-use of a condom during the most recent sexual encounter.[78] High stress has also been associated with reduced condom and contraceptive use and increased frequency of sex. Among young men who have sex with men, having increased stress on the day of sex predicted inconsistent condom use.[11,79] Chronic stress related to homelessness impedes adoption of sexual risk reduction behaviors.[80] The most effective prevention interventions may be those that address stress as a root cause of risk behaviors.[59]

Figure 1. Theoretical Framework Guiding Intervention Development



Guiding Theoretical Framework. The tailoring of *.b* will be guided by a theoretical framework (see Figure 1) informed by the Risk Amplification Model (RAM) and the minority stress model (MSTM).[19,81] This framework demonstrates the trauma and stress resulting from minority status, socio-demographic, environmental, and psychosocial factors. Trauma and stress intersect with the vulnerabilities of homelessness, influencing the development of negative emotions, reactive stress responses, and impulsive decision making and leads to risk behaviors. The model takes into consideration the environmental, sociodemographic, and psychosocial factors contributing to the level of vulnerability and stress experienced by YEH. RAM explains many of the negative outcomes, experiences, and relationships prevalent among YEH.[82-87] A longitudinal study among 347 African American young adults, found a cascade effect from stress to risk behaviors.[88] In our similar model, stress leads to increases in negative emotions and risk behaviors; negative emotions have been shown to lead to affiliations with deviant companions.[88] MSTM posits that stigma, prejudice, and discrimination create stressful environments and affect one's stress responses and coping processes.[81] Prior to testing whether the intervention improves stress management, emotion regulation, and impulsivity, we must first optimize the program for YEH and conduct feasibility and acceptability testing.

Mindfulness-Based Interventions (MBIs). Before youth are primed for behavior change, underlying psychosocial factors must be addressed to improve stress management, increase emotion regulation, and decrease impulsivity. Yet, few interventions that target stress management, emotion regulation, impulsivity, and coping skills have been developed or tested. MBIs that incorporate somatic experiences may be particularly effective among populations with high stress and trauma. Somatic activities direct the person's attention to internal sensations: visceral (interception) and musculo-skeletal (proprioception and kinesthesis) as opposed to primarily cognitive or emotional experiences.[176] YEH often distrust and have low engagement in traditional mental health treatment. Thus, MBIs may not only be effective in reducing risk behaviors but, given it is trauma-informed and demonstrated acceptable, it may engage more young people than existing service and intervention models.[177]

MBI strategies enhance self-observation and self-regulation to produce a mindful state (e.g., meditation).[89] Mindfulness approaches build skills to increase non-judgmental attention and emotional reappraisal and improve present-focused states of experiencing cognitions and emotions[90] that lead to less reactivity, greater contemplation of behaviors, and improved interpersonal dynamics and relationships.[91] Evidence demonstrates the efficacy of MBIs across various populations to decrease frequency of unprotected sex[10] and to improve affect and executive functioning.[92-96] For example, a stress reduction intervention in HIV-positive adult men who have sex with men reported post-intervention decreases in condom less anal sex that were sustained over time.[97] Youth who received a mindfulness curriculum reported lower stress and have reduced salivary cortisol than controls.[98,94] Several studies have found that mindfulness reduces stress[99] and improves self-regulated behaviors,[100] executive function,[96,101,102] and resilience toward stress.[103]

While the effects of mindfulness approaches on stress and anxiety have been well documented in adults,[104] fewer studies have been conducted in youth and even fewer in homeless youth.[105,106] Even so, evidence of the effectiveness of mindfulness approaches in adolescents is mounting showing increased mindful attention and awareness and decreased reactivity in school-aged youth;[98] enhanced self-regulation and coping among youth;[107] improved mental health and emotional control, and reduced post-trauma stress symptoms in urban youth;[95] and reduced stress and anxiety in adolescent psychiatric patients.[108] Recent advances have led to the development of a neurodevelopmental framework that supports the potential for mindfulness as a self-regulation strategy particularly for groups with compromised self-regulation capacity, as is often the case with high-trauma groups such as YEH.[109] A systematic review of stress reduction interventions in adolescents revealed improved cognitive skills.[110] Reviews of youth-based mindfulness interventions[111] and meditation practices[112] suggest that these interventions may lead to improvements in depression and anxiety.[113] Despite the widespread dissemination of MBI strategies among homeless services providers, little evidence exists to support its efficacy and no MBIs have been tailored specifically for YEH despite their high need for stress management, emotion regulation, and impulse control. The proposed study is desperately needed to optimize and test the feasibility and acceptability of MBI among YEH. Building on this study, we can assess the efficacy of this intervention on stress management, emotion regulation, and impulse control that are so critical to the life-course of youth experiencing homelessness.

Mounting Evidence of Feasibility and Acceptability of Mindfulness Approaches. Many studies have suggested that MBIs have high levels of acceptability in urban, underserved youth[114] and YEH.[43,115] Recent meta-analyses found significant effects on mindfulness, executive function, attention, depression, anxiety/stress and risk behaviors when comparing youth receiving MBIs to those in control groups.[167-170] Among the most rigorous attention controlled randomized trials, significant benefits remained for mindfulness, depression, and anxiety/stress.[167,95] *.b* had high acceptability among a school-

based sample of 522 youth aged 12–16 years who reported lower stress, with amount of practice being associated with less stress.[98] A study in HIV-positive and at-risk youth showed that of those who attended any sessions, 79% participated in most sessions.[116] While mindfulness has been used with other high-risk, high-trauma youth populations, there is a dearth of published research on mindfulness among sheltered YEH. Our Co-I, Dr. Bender conducted a RCT with 97 with YEH, and found high intervention engagement, uptake of practices, and significant improvement in observational skills compared to control youth.[43] Many YEH-serving organizations are utilizing mindfulness strategies despite the lack of rigorous RCTs among sheltered YEH.

Despite promising findings, well-designed RCTs are needed to assess if methods are feasible and if interventions are acceptable.[111] In highly stressed populations, interventions need to address stress as an antecedent of risk behavior.[117-119] By recognizing that YEH often endure trauma, mindfulness approaches should align with trauma-informed care[124] and can help youth reframe their life narratives.[51] Therefore, we will build on the literature, our preliminary work, and the proposed study to lay the groundwork for developing and rigorously testing a tailored, trauma-informed MBI among YEH. To enhance the rigor of future intervention studies, we will use this R34 planning grant to optimize our YEH–informed MBI and conduct a pilot RCT to refine documentation and informed consent procedures, test data collection processes, establish regulatory reporting procedures and protocol monitoring, and inform recruitment, randomization, and retention protocols.

Innovation. This proposal will be the first to use participatory research strategies to tailor and pilot test an MBI for sheltered YEH. This study is based on a strong scientific premise supporting the high rates of stress and the positive impact of mindfulness strategies on stress management skills, emotion regulation, and impulsivity. This study is innovative because 1) we are engaging this vulnerable population in participatory, community-engaged research strategies to tailor an evidence based MBI (*.b*), 2) we are using cognitive interviewing to validate outcome measures, and 3) we will test the acceptability of commercially available mindfulness apps and determine the optimal measure of app use. Data usage information will be gathered from mediation app on participants' phone .The iterative pre-piloting approach we propose to use in this study will allow our team to quickly respond to user feedback to adjust intervention content, delivery methods, and outcome measures to assure a rigorous pilot. Our team of interprofessional experts in public health nursing, adolescent medicine, child development, social work science, and mindfulness instruction and research has worked extensively with YEH on observational, longitudinal, and intervention studies and among other at-risk youth and vulnerable young adult populations using MBIs (see biosketches). Our extensive preliminary work builds on findings from mindfulness experts and demonstrates promising outcomes of MBIs among YEH while highlighting the need for programs to be trauma-informed and tailored to enhance relevance and efficacy and scalability to a sheltered population of YEH.

Planning for a Randomized Trial. To conduct a rigorous RCT of an MBI for YEH, several essential aims need to be completed that this R34 will address. **First,** while evidence is mounting that MBIs may be effective, and MBIs have been tested among YEH, no MBIs has been specifically tailored for sheltered YEH. While *.b* has the main components that show promise, modifications are needed to assure cultural and situational relevance for YEH. **Second,** the control condition needs to be optimized to assure smooth trial implementation. **Third,** outcome measures and follow-up protocols need to be optimized. **Finally,** a test of feasibility for conducting a small RCT with longer participant follow-up is needed to inform the R01 protocol, measures, and sample size needed.

Objectives

Building on the promising results of our *.b* (pronounced dot-b) pilot study,[173] the goal of this R34 is to further tailor *.b* and conduct a feasibility pilot among sheltered homeless youth. Data from the proposed study will lay the groundwork for rigorous intervention testing in a real-world sheltered sample of YEH. Our strong partnerships with shelters will ensure that the intervention is tailored in a trauma-informed way in collaboration with service providers to approximate broad dissemination. A trauma-informed approach has three elements; realizing the prevalence of trauma, recognizing how trauma affects all individuals involved, and putting this knowledge into practice.[175] MBIs may address the root causes of risk behaviors in YEH by targeting stress management, emotion regulation, impulsivity, and executive function. [27,28-30]

The specific aims for this R34 exploratory clinical trial (PAR-18-417) are to:

1. Tailor *.b* and finalize the attention control condition using focus group discussions (n=56), key informant interviews (n=12), and iterative beta-testing with the Homeless Youth Working Group (HYWG; n=10)
2. Optimize RCT outcome measures using cognitive interviews with the HYWG (n=10)
3. Conduct an attention control randomized trial of the final tailored *.b* vs. attention control with 90 YEH 18-25 years old recruited from a shelter to test real-world feasibility and acceptability
    a. Evaluate recruitment, randomization, and follow-up strategies; adherence to intervention dose; retention benchmarks; and acceptability among YEH
    b. Evaluate the feasibility of outcome measures at 3- and 6-month follow-up

This study is ***significant*** as it lays the groundwork for a potentially beneficial program for YEH, a vulnerable, high risk, and growing population by tailoring and testing an intervention that targets the root causes of many health risk behaviors. If effective, the intervention has the potential to have far-reaching effects on youths' health and wellbeing. This scientific premise builds on the substantial body of literature that demonstrates the link between trauma, stress, maladaptive decision making, and risk behaviors and the promising effects of MBIs in high-risk youth. This ***innovative*** study capitalizes on established relationships with local providers and our access to this difficult-to-reach population to collaborate on tailoring of *.b* for a sheltered sample of YEH. This research aligns with NCCIH Priority Research Areas by developing and feasibility testing of a tailored MBI and evaluating its overall health and wellness impact. Data from this R34 will inform the development of an adequately-powered RCT, optimizing the recruitment and retention strategies, informing the final sample size for a larger randomized trial, and finalizing the outcome measures needed.

Study Design

This proposed study will fully develop and pilot test the feasibility and acceptability of a tailored mindfulness-based intervention among young adults experiencing homelessness ages 18-25 years old. The intervention targets stress management, emotion regulation, and impulsivity. A total of 56 homeless youth will participate in the focus group discussions (FGDs), 10 youth per session will participate and study team will consent up to 30 homeless youth for the Homeless Youth Working Group (HYWG) to account for participant drop off, 12 health and social services providers will participate in the key informant interviews, 8 service providers and 2 youth will participate on the Expert Advisory Panel (EAP), and 90 homeless youth will participate in the randomized attention control pilot study.

Expected duration of study and subject participation. Study duration is 3 years and subjects in the pilot RCT will be in the study for 6 months. Key informants and Homeless Youth Working Group will be part of the study for one year. The expert advisory panel will be in the study all three years.

Specific Aim 1. Tailor *.b* and finalize the attention control condition using focus group discussions (n=56), key informant interviews (n=12), and iterative beta-testing with the Homeless Youth Working Group (HYWG; n=10)

Specific Aim 2**.** Optimize RCT outcome measures using cognitive interviews with the HYWG (n=10)

Specific Aim 3**.** Conduct an attention control randomized trial of the final tailored *.b* vs. attention control with 90 YEH 18-25 years old recruited from a shelter to test real-world feasibility and acceptability.

Study Population

Youth participating in the FGDs, HYWG, EAP, and pilot study. YEH in Houston, TX (Total n = 156; HYWG = 10, FGDs = 56, Pilot study = 90) will be recruited from drop-in centers, shelters, local YEH service locations, clinics, federally qualified healthcare centers in locations with a high concentration of homelessness, magnet (e.g. hot meal) events, mobile clinics, and street outreach to increase representation from both connected and disconnected YEH and generalizability of the findings (see Letters of Support). These recruitment sites serve young men, women, families, and LGBTQ youth. We will use group-based study introduction sessions, flyers, and recruitment letters at the agencies, clinics, street outreach, and the website and Facebook pages of the agencies and the Homeless Youth Network (HYN), methods we successfully used in **Youth Count 2.0** to recruit 434 YEH in just 4 weeks.[44] The RC and RA will maintain a consistent presence at the recruitment sites throughout the study to facilitate both recruitment, follow-up, and retention efforts. The RA will approach youth to describe the study, screen for eligibility, and obtain informed consent (see Human Subjects section) in a quiet area (e.g., library or office space). Potential participants will be informed at each encounter that participation will have no effect on their ability to receive services such as housing, mental health, or healthcare. A nationally representative survey suggests that 3.5 million individual 18- to 25-year-olds experienced homelessness during the past year.[115] In 2016 in Houston, TX, local homeless youth service providers served over 5000 unduplicated YEH.[109] Given the aforementioned inclusion criteria and the high volume of YEH in Houston, we expect to have few challenges with enrolling 56 YEH to participate in FGDs or 90 YEH to participate in the pilot study.

Inclusion Criteria for Youth Participants**.** We will use a tiered eligibility screening method to assure that youth with a mental illness diagnosis, with non-severe symptoms who can perform activities of daily living and would otherwise be able to successfully complete the intervention, are not denied the opportunity to participate in the program. We will use the REALM health literacy assessment tool as a guide to see if the potential participant may require extra help with completing consent process and completing surveys. This will be done during the screening/consenting process and should take five minutes or less. This tiered screening method is an essential adaptation for reaching YEH who, by nature, have high rates of mental illness, stress, and emotion dysregulation. Inclusion criteria will be that potential participants are homeless youth receiving services at one of the recruitment sites in Houston, TX area at the time of enrollment, 18-25 years old, English speaking, and able to participate for the entire study period (i.e., not moving during the study). Homelessness will be defined as staying on the streets, in a place not meant for human habitation, a shelter, hotel/motel, or with someone temporarily in a location where they cannot stay for more than 30 days (i.e. couch surfing).

Exclusion Criteria for Youth Participants. Exclusion criteria include not meeting the inclusion criteria or are overtly exhibiting symptoms of severe, untreated mental illness criteria we used successfully in our previous studies with homeless youth. Youth will be excluded if they do not meet the criteria for age (18-25 years old) or are not staying at the shelter or currently experiencing homelessness or unstable housing. Experiencing homelessness will be defined as having slept on the streets, in a place not meant for habitation, in a shelter, in a hotel/motel, or with someone where they cannot stay for more than 30 days (e.g., couch surfing). YEH may stay in emergency shelters or on the streets (e.g., parks and tent cities), in abandoned or vacant buildings or apartments, temporarily with friends, family, or acquaintances (i.e. "couch surfing"), or in motels[101] and go to great lengths to stay hidden from the dangers of victimization.[10] This broader definition of homelessness aligns with the McKinney-Vento Homeless Assistance Act of 1987, allows us to account for the transiency and instability of housing experienced by YEH, and increases the generalizability of the study findings. If youth are overtly having severe, untreated mental illness symptoms, they will be asked to come back at a later date and still be eligible for subsequent screening for enrollment.

All participants will have ongoing access to mental healthcare services through the onsite health clinic located at the CHT shelter. Should study staff become aware of a participant experiencing significant symptoms during the study, they will be connected immediately to onsite mental health treatment resources and removed from the study. Based on our initial pilot of *.b,* where we had no incidences of significant symptoms, we do not anticipate this happening frequently.

Recruitment**.** Given the inclusion criteria and site volume for the pilot, we expect to recruit 15 youth per arm (intervention and attention control) session for a total of 3 cohorts of 15 in each arm or 6 total groups. Based on what we've learned from previous studies with YEH, we will recruit 90 youth to deliver the intervention or control to at least 60 youth. Youth will be recruited primarily from Covenant House Texas (CHT), and homeless shelters and drop-in centers if additional recruitment sites are needed, to participate in the pilot. Youth who are eligible and enroll in the pilot study will complete a baseline survey, attend 5 90 minute sessions, complete very brief pre-post session surveys, as well as follow-up surveys immediately post-intervention and at 3 months post-intervention. Approximately 22% (n=20) of the pilot study participants will be recruited to also participate in a post-intervention exit interview. Participants will have the phone for the duration of the study. The intervention is informed by the Risk Amplification Model (RAM) and the Minority Stress Model (MSTM) and will be fully developed in Years 1-2 using a systematic intervention development process; Plan, Do, Study, and Act. In order to ascertain the feasibility and acceptability of the intervention (Aim 3), we will obtain participant feedback via exit interviews as well as quantitative implementation indicators (e.g., refusal rate, completion rates, and survey measures).

Inclusion/Exclusion of Service Providers**.** Key Informant Interview participants (n=12) and Expert Advisory Panel service provider members (EAP, n=8) will be health and social service providers for YEH recruited from local shelters (i.e., resident advisors, in-take specialists), drop-in centers (i.e., social workers, case managers), homeless healthcare clinics (i.e., nurses, mental health counselors, patient navigators), and the Homeless Youth Network (a network of YEH providers, of which Dr. Santa Maria is an active member). Providers will be considered eligible if they are currently providing health or social services to YEH and are interested in participating in an interview or as a member of the Expert Advisory Panel. For those providers interested in the EAP, they will be considered eligible if they anticipate being able to meet for the regularly scheduled meetings at least 75% of the time.

Smartphone. Study-issued phones will be provided to each of the participants to facilitate follow-up by phone call and or text message. Because youth often lack access to the resources and contact information for services, we will pre-program important locations and hotlines into the study-issued phone. Resources will include contact information for 1) the National Sexual Assault hotline to access local trained sexual assault service providers, 2) the National Human Trafficking Resource Center to speak with a trained specialist, 3) the National Runaway Safe Line for shelter resources, and 4) Sexual Assault Nurse Examiner locations. Participants will be shown how to access bedsider.org when they receive the phone to access local reproductive health services. Finally, the phone will be pre-programmed with contact information for local homeless youth service providers including youth- and LGBTQ-friendly shelters, healthcare clinics (e.g., medical care, HIV/STI testing and treatment, and mental health services), and social service providers (e.g., meals, housing, education, jobs, ID, and legal services). After completion of all sessions, participants in both pilot groups will receive the phone for the duration of the study. Basic cellular plans will offer limited data and cellular service to participants throughout the duration of the study to improve the likelihood we can maintain contact with phone calls and texts. Only the PI, RC, and RA will have access to the participant study phone numbers and be able to contact them to make follow-up appointments.

Screening for Literacy Level**.** Participants will be screened for literacy using the Rapid Estimate of Adult Literacy in Medicine (REALM) health literacy assessment at enrollment and should take five minutes or less.[8] Those who score < 4 (considered to be illiterate), will be read the consent forms, will verbalize understanding before providing written consent, and will access the survey using REDCap. We used this protocol for low literacy successfully in our previous studies with homeless youth.

Study Procedures

In YEAR 1, we will submit the final protocol including the informed consent forms for YEH and provider participants to the UTHealth IRB for review and approval. We will form and begin convening the Homeless Youth Working Group (HYWG; n = 10) and the Expert Advisory Panel (n = 12; 8 providers and 2 youth). We will also conduct approximately 7 focus group discussions with 56 YEH and 12 key informant interviews with health and social service providers. The analysis of the qualitative data will begin during the data collection to allow for iterative revisions to the focus group and interview guides. Finally, we will begin conducting the iterative beta testing of the intervention materials with the HYWG.

In YEAR 2, we will continue the iterative beta testing of the intervention materials with the HYWG. We will finalize the intervention and begin participant recruitment and implementation of the intervention and control conditions with YEH pilot participants (n=90). Follow-up of participants will begin immediately after enrollment to increase session attendance. We will conduct exit interviews (n=20) immediately following the final session of the intervention and control conditions. We will then analyze the exit interviews and quantitative survey data.

In YEAR 3, we will complete delivery of the intervention, participant follow-ups, and exit interviews. We will complete all data analyses of the exit interviews and quantitative survey data. Finally, we will prepare scientific presentations and manuscripts for dissemination.

Study Description: Study Setting**.** The project will take place at CHT, the largest YEH service provider in Texas, which assisted 7,303 YEH in 2018 including 4,890 overnight stays[45] and includes a crisis shelter, transitional living program, comprehensive case management and life skills, educational, and vocational training. Their onsite healthcare clinic provides comprehensive medical and mental health services for YEH. We chose CHT because of our ongoing 10-year partnership, and they are the largest provider of

shelter services for youth, with network of over 25 shelters in the U.S. CH are invested in disseminating evidence-based interventions across their sites. If the findings from this study suggest high feasibility and acceptability, we will partner with the national network of CH shelters to implement a large, multi-site randomized trial.

Recruitment**.** Approximately 56 YEH will be recruited to participate in focus group discussions (FGDs) (AIM 1), 10 health and social services providers to participate in key informant interviews (AIM 1), 10 YEH to serve on a Homeless Youth Working Group (HYWG) (AIM 2), two youth to serve on the Expert Advisory Panel (EAP), and 90 YEH to participate in the randomized, attention control pilot test of the tailored version of *.b* (AIM 3). Harris County has a high prevalence of homeless and unstably housed youth. However, it has the advantage of a well-integrated homeless youth service provider network. The Salvation Army, which runs the largest homeless youth drop-in center, served 1,745 unduplicated homeless youth 18-25 years old, and Covenant House Texas (CHT), the largest youth emergency shelter in Houston, TX, assisted 7,303 homeless youth aged 18-25 years in 2018.[45] The magnitude of the problem demonstrates the critical need for effective interventions and feasibility of recruiting eligible subjects.

Youth Participants will include YEH aged 18-25 years recruited from CHT by the trained Research Coordinator (RC) and Research Assistant (RA) via group sessions introducing the study and by word of mouth from CHT staff. Very few youth under 18 years of age access services in Houston, TX. Using the approach successfully employed in our pilot project, study staff will describe the program and review a study summary and consent documents with interested individuals. Participating youth will provide written consent, witnessed by study staff. Staff will follow the intervention protocol for assessing eligibility, recording basic demographic information (e.g., age, gender identity, race/ethnicity, and sexual orientation) to assess for refusal bias. Inclusion/Exclusion Criteria. Youth will be eligible if they are between the ages of 18-25 and are accessing resources at the shelter during the recruitment phase. We will use a tiered eligibility screening method which we used in the pilot study, to assure that youth with a mental illness diagnosis, with non-severe symptoms who can perform activities of daily living and would otherwise be able to successfully complete the intervention, are not denied the opportunity to participate in the program. This tiered screening method is an essential adaptation for reaching YEH who, by nature, have high rates of mental illness, stress, and emotion dysregulation. To assess symptom severity that warrants delay in enrollment or exclusion, we will implement several exclusion criteria. Youth will be excluded if they do not meet the criteria for age (18-25 years old) or are not staying at the shelter or currently experiencing homelessness or unstable housing. If youth are overtly having severe, untreated mental illness symptoms they will be asked to come back at a later date and still be eligible for subsequent screening for enrollment. All participants will have ongoing access to mental healthcare services through the onsite health clinic located at the CHT shelter. Should study staff become aware of a participant experiencing significant symptoms during the study, they will be connected immediately to onsite mental health treatment resources and we will consult with the DSMB to see if it is connected to the study. If a participant contacts someone from the study team, we will follow the same procedure. Based on our initial pilot of *.b,* where we had no incidences of significant symptoms, we do not anticipate this happening frequently. Key Informant Interview Participants (n=12) will be current YEH health and social service providers recruited from local shelters (i.e., resident advisors, in-take specialists), drop-in centers (i.e., social workers, case managers), homeless healthcare clinics (i.e., nurses, mental health counselors, navigators), and the Homeless Youth Network (a network of YEH providers, of which Dr. Santa Maria is a member). Expert Advisory Panel (n=10) will comprise 8 YEH service providers recruited from the Homeless Youth Network and 2 YEH between 18-25 years old. The group will meet by phone or in-person every other month for one hour during the study to provide input

on intervention development, implementation, evaluation, and study protocols. Meetings will coincide with scheduled Homeless Youth Network meetings. Homeless Youth Working Group (n=10) will comprise Dr. Santa Maria's existing group of YEH who meet monthly. For this project, the HYWG will meet up to 6 sessions prior to pilot RCT throughout YR-1 and as needed during YR-2 to refine the tailored version of *.b* components, duration, dose, and frequency and inform intervention procedures and interpretation of findings. HYWG members will participate in iterative beta testing of session content, delivery methods, and strategies based on user feedback. Sessions will take place at the shelter and last about 2 hours.

Study Overview. Tailoring *.b* will begin with a series of focus group discussions aimed at getting initial impressions from 56 youth staying at the shelter. Next, 12 service providers will participate in key informant interviews focused on assessing the tailored intervention to be trauma-informed, and practical within a shelter setting. Finally, after a draft of the tailored *.b* manual exists, it will be beta tested through iterative piloting with a small working group of 10 YEH which will fine tune the activites, language, and framing of the sessions.

Specific Aim 1. Tailor *.b* and finalize the attention control condition using focus group discussions (n=56), key informant interviews (n=12), and iterative beta-testing with the Homeless Youth Working Group (HYWG; n=10)

Proposed Intervention Description**.** The group-based tailored *.b* intervention will be finalized to meet the unique needs and circumstances of YEH. *.b* will be tailored with the assistance of the HYWG and EAP to meet the needs of YEH using iterative beta testing. The intervention will comprise approximately 5 90-minute sessions to introduce concepts such as paying attention, fostering curiosity, self-compassion, understanding rumination and catastrophizing, staying in the present, recognizing thoughts as separate from our minds/selves, responding instead of reacting, understanding stress and how it affects us, accepting negative and positive experiences, moving mindfully, and using mindfulness in our everyday lives (see Table 1).

MBI Cultural Modifications Needed**.** A recent pilot of *.b* conducted by the investigative team determined several modifications that may benefit YEH.[173] **1.** Participants expressed frustration that parts of the lessons did not always relate to their struggles and didn't take into account the circumstances surrounding homelessness. Therefore, we will tailor the lesson materials, narratives and delivery methods to the lived experience of YEH. **2.** The intervention was designed for a school-setting and not a shelter setting. Therefore tailoring needs to be made to adjust the spacing and length or session delivery to approximate the daily routines and length of stay of YEH in shelters. **3.** Youth wanted more time for discussions during the session. We will determine the optimal timing and format of additional discussion activities**. 4.** There was lower acceptance of some session topics. We will review these topics during the FGDs to determine how to improve acceptance and relevance in the delivered material. **5.** Youth suggested the need for ongoing mobile mindfulness tools. While attending an MBI itself is beneficial, maintaining practice outside of a course provides additional benefits.[98,136] Therefore, participants will be provided with a cell phone equipped with commercially available mindfulness apps (i.e. CALM, HEADSPACE). Data usage information will be gathered from mediation app on participants' phone .This R34 will allow us to work with YEH to further elucidate how to tailor the intervention to their needs, iteratively test the adapted intervention, and assess the feasibility and acceptability of the intervention, control condition, measures proposed, and RCT study procedures using a trauma-informed process.

Table 1. Description of *.b* Curriculum Sessions

Session Name	Session Description	**Example Activities**
Playing Attention: Training the Mind; Taming the Animal Mind: Cultivating Curiosity and Kindness	Introduction to attention; aiming and sustaining attention; attitudes for attention training (kindness, patience, repetition) Exploring the mind; nurturing an attitude of curiosity, kindness, acceptance, and openness to fluctuating mind-states; anchoring attention to find calm when the mind is reactive	Recognizing thoughts as separate from mind,[137] floating thought clouds
Recognizing Worry: Noticing Your Mind Tricks; Being Here. From Reacting to Responding	Understanding mind generated 'stories'; rumination and catastrophizing; effects of rumination on the body, mind, and emotions; switching from thinking to sensing mode. Exploring autopilot; appreciating and savoring the pleasant; learning to respond rather than react by turning your attention to the now; staying present	Body scan,[137] mindful movement,[137] drawing out areas of feelings and emotions
Moving Mindfully; Stepping Back: Watching the Mind's Thought Traffic	Expanding mindfulness from stillness to movement; Moving from autopilot movements to mindful movements. Recognizing your capacity to step back from your thoughts in your mind; responding vs. reacting to your thoughts	Mindfulness of the breath,[137] mountain meditation,[138] FOF-BOC
Befriending the Difficult; Taking in the Good: Being Present with Your Heart	Introduction to stress, what it is, how it works, how it affects your body; being present with difficult situations and thoughts; Appreciating the good in life; moving ordinary to good; turning good from idea to experience; Introduction to the CALM app	Well wishes (loving kindness),[139] loving ourselves/others
Putting It All Together	Applying mindfulness strategies to your life; reflecting on your new skills; Maintaining your skills	Narrow or broaden attention,[101] flashlight focus, reflection

Focus Group Discussions (FGDs). We will conduct up to seven FGDs with 6-8 YEH (n=56) recruited from CHT and drop-in centers to elicit feedback on the tailored *.b* and the attention control condition to inform and validate intervention objectives, dose, and delivery modality. FGDs will be planned around already scheduled events where 56 youth would be receiving meals or services at CHT. FGDs will be led by the RC who has experience conducting FGDs, key informant interviews, and exit interviews with YEH under the supervision of the PI. FGDs will be conducted with integrated age and gender groups using purposive sampling to assure representation of the entire age group and gender spectrum.[134] A sample size of greater than 20 youth will likely elucidate a saturation of themes.[174] Private rooms in CHT, such as

the library or conference room, will be used to minimize distractions. These areas are within CHT to ease accessibility to the youth and are sufficiently private to prevent nonparticipants from overhearing conversations. After providing written consent, each youth participant will complete a brief survey to assess the demographics of the FGD sample. FGDs will last approximately 1-1.5 hours with breaks as needed. Using a conversation style loosely structured focus group guide[135] with layered probes, we will elicit youths' reactions and feedback to the intervention session materials and control condition until no new themes emerge to inform the adaptation process. FGDs will be recorded and professionally transcribed verbatim. The RA will take field notes during the FGDs to be used in the analysis. Participants will receive a gift card for a local grocery store for participating in the FGDs.

Key Informant Interviews**.** Using a loosely structured conversational interview guide,[135] we will conduct interviews with 12 YEH service providers to gain additional perspective on how the proposed session adaptations, materials, and activities meet the needs of YEH and elicit suggestions to assure the materials are trauma-informed and youth-friendly, during the first study year. Example inquiries include: what do you see as the major barriers and facilitators in conducting a multi-session intervention with YEH during their shelter stay? Interviews will last 30-45 minutes, be audio recorded, and transcribed verbatim for analysis. Participants will receive a $20 gift card.

Iterative Beta Testing. We will use an iterative Plan, Do, Study, and Act (PDSA) approach to test the minimally viable intervention materials produced in AIM 1. PDSA allows for iterative testing of modifications in the real world setting. PDSA calls for planning, testing, observing the results, and acting on the results to make further modifications that can be cycled through further testing. Interventions developed iteratively using the action-oriented learning from PDSA allow for adaptation to the target audience and context and are more responsive to unforeseen obstacles and unintended effects that can be addressed in subsequent pre-pilot testing.[140,141] The HYWG, an existing group of YEH, will participate in monthly intervention testing working sessions. HYWG members will be debriefed about the goals and objectives at the beginning of each session. Then the interventionist will conduct the session, including presentation of all proposed session activities, practices, and discussions. Following the sessions, we will ask participants to provide input about the materials, what resonated with them and what did not, and whether the delivery methods and strategies used to present the materials were effective in meeting the goals and objectives of the session. Findings from each round of iterative testing will inform modifications to the survey instruments, session materials, and delivery methods and strategies that will be further tested in subsequent rounds. We will conduct subsequent sessions if youth indicate that changes to content or delivery methods is needed. While the number of iterations will depend on feedback and adaptions needed, we anticipate that approximately 4 iterations will be needed to finalize the tailored *.b* intervention. The health education control program (Healthy Topics; HT) will be similarly adapted to match the tailored version of *.b* in session number, length, and relevant health education materials.

App Testing. We will ask youth participating in the iterative beta testing to assess the usability (System Usability Scale)[178] and preference for several commercially available mindfulness apps and a control condition app. Data from the youth will determine which apps to use in the RCT for the intervention and control conditions to address the youth desire for mobile access to mindfulness sessions during the intervention. Data usage information will be gathered from mediation app on participants' phone.

Expected Outcome**.** The result of Aim 1 activities will inform how to tailor *.b* to the lived experience and needs of sheltered YEH. The essence of .b will remain though we anticipate tailoring it to be 5-sessions

in order to approximate the average length of stay for YEH in the shelter. The tailored *.b* will retain common domains (i.e., analytical, somatic, grounding, visualization, and awareness) while tailoring the content and delivery to sheltered YEH. Subsequently, we will conduct iterative pre-pilot beta testing of sessions with the HYWG to finalize content and delivery methods and strategies based on user feedback.

Specific Aim 2**.** Optimize RCT outcome measures using cognitive interviews with the HYWG (n=10)

Cognitive Interviews**.** As part of the FGDs, we will field test the proposed outcome measures to assess understandability and participant burden allowing us to determine the optimal measures for the RCT. We will assess various ways to measure mindfulness app usage including self-report and app-based reports.

Proposed Measures**.** Baseline measures will include demographics (i.e., age, gender identity, race/ethnicity, sexual orientation, educational level, and employment). We will assess historical factors such as involvement in the foster care and juvenile justice systems, adverse childhood experiences,[142] victimization,[179] age at first homelessness, and length of current homelessness. We will include psychosocial wellbeing measures, including mindfulness; self-compassion; social connectedness; stress, anxiety, depression, psychological distress, affect, and vulnerability symptoms; and inhibition, impulsivity, and risk behaviors (see Table 2). Finally, we will test several ways of measuring mindfulness app use including self-report use and app use summary data obtained on the study phone such as the one from the CALM or Headspace app.

Table 2. Potential Outcome Intervention Measures for Pilot Testing

Construct	**Possible Scales to be Included**	**Psychometrics**
Emotion Regulation	Difficulties in Emotion Regulation Scale[143]	α = 0.72-0.87*
Mindfulness	Child and Adolescent Mindfulness Measure[144]; Cognitive and Affective Mindfulness Scale-Revised[145]; Mindful Attention Awareness Scale[146]	*α=0.82***
Self-Compassion	Self-Compassion Scale[147]	α=0.91**
Social Connectedness	Social Connectedness Scale; Interpersonal Support Evaluation (ISEL-12)[148]	α=0.91, *0.77**
Depression	Short Mood and Feelings Questionnaire[149]	α=0.87*
Anxiety	Spielberger State-Trait Anxiety Inventory[150]	α=0.82
Stress	Perceived Stress Scale[151,152]; Stress of the Streets Scale[30]	α=0.91**
Affect	Positive and Negative Affect Scale[153]	*α=0.*78**
Vulnerability	Vulnerability Scale[154]	*α=0.*86 & 0.81*
Distress	Kessler Psychological Distress Scale[155]	*α=0.*78**
Response Inhibition	Color Stroop Word Task[156,157]	*α=0.*71*
Impulsivity/Self Control	Delayed Discounting[158,159]	*α=0.*77*
Risk Seeking	Balloon Analogue Risk Task (BART)[160]	*α=0.*77*
Sexual activity and drug use	Youth Risk Behavior Survey Items on sexual activity, condom use, and substance use	*NA*

*tested among youth; ** tested among YEH

Feasibility and Acceptability Measures**.** While we will finalize measures with the HYWG and EAP, we anticipate including several valid measures that have been used with at-risk youth populations to assess the tailored version of *.b's* feasibility and acceptability (see Table 3). We will collect multiple process evaluation measures such as the number of eligible youth approached, participation refusal rate, number of sessions attended, and follow-up response rates. We will monitor recruitment rates and effort required (e.g., number of staff hours), number of screenings conducted and refusal rates,[161] and loss to follow-up, to inform the design of a subsequent fully powered RCT. To measure intervention acceptability, we will use a modified version of the credibility/expectancy questionnaire for measuring treatment expectancy and rationale credibility for use in clinical outcome studies (Cronbach's α = 0.85).[162] Treatment adherence benchmarks are set at 50% attendance (i.e., attending 3 of 5 sessions) based on our pilot data and data from a recent group-based intervention among YEH. In that study, only 52% of YEH participants attended >75% of a group-based motivational interviewing brief intervention to reduce substance use and sexual risk behavior and significant intervention effects were still found despite the less than prescribed session attendance.[163,108,164] Given the evidence that group interventions among YEH may be effective at low doses, we have set our attendance conservatively low. If the feasibility benchmark were set higher, we could inadvertently conclude that the intervention is not feasible if <50% of sessions are attended, preventing us from determining in future studies that 50% attendance may still be sufficient to lead to significant intervention effects (type 1 error). We will assess for a difference in between-group attendance/ retention with a benchmark set as <15% differential.

Specific Aim 3**.** Conduct an attention control randomized trial of the final tailored *.b* vs. attention control with 90 YEH 18-25 years old recruited from a shelter to test real-world feasibility and acceptability.

Purpose**.** The purpose of this pilot study is to examine intervention feasibility and acceptability and determine effective recruitment and retention strategies, randomization processes, participant tracking and follow-up procedures, retention benchmarks, and evaluate the feasibility of outcome measures. To this end, we will conduct this feasibility trial using a two-group randomized attention control trial design.

Intervention Delivery**.** Drs. Santa Maria and Cuccaro are certified teachers of existing youth-focused MBI curricula, *.b*[89] (Santa Maria, Cuccaro), and *MBSR-T*[108] (Cuccaro), and will work with the interventionist if issues arise during intervention delivery. Additionally a fidelity checklist will be made to assess the delivery of the tailored *.b*. While the session length, group size, and session spacing will be informed by the PDSA work with the HYWG and finalized in the formative phase, we describe our estimates below. We anticipate between 4 and 5 intervention sessions that will last between 60-90 minutes. Each cohort will include approximately 10-15 youth. Based on attendance at our recent pilot *.b* program, we plan to recruit 15 youth to have an average final group size of 10 youth depending on HYWG preferences and PDSA data. We anticipate having 6 cohorts of youth (3 intervention and 3 attention control). Each session will likely include brief didactic presentations, videos, and mindfulness practice followed by inquiry. We anticipate that sessions will take place twice a week. Sessions will be held on site at the CHT shelter in a quiet, designated learning space to ease access to sessions for the participants and to assure access to shelter staff (e.g., social workers and case managers) and services (e.g., food and shelter). CHT has onsite, weekday clinical and mental health care and established protocols for accessing needed resources 24/7. Selection criteria for the interventionist include maintaining a personal mindfulness

practice for at least two years, trained in *.b,* and prior experience working with high-risk youth. The interventionist will receive additional training in Trauma-Informed Care as well as study procedures.

Attention Control Condition**.** Working with the HYWG in YR-1, we will modify the health education program Healthy Topics (HT) adapted from the Glencoe Health Curriculum (McGraw Hill) from its current eight-session format to match the intervention condition and serve as an active control condition. Dr. Sibinga's (Co-I) previous RCTs have shown that HT is an effective control condition for MBI.[94,95,125,126] HT will be matched for session frequency and length, group size, location and timing, didactic instruction, and group discussion. HT is an appropriate attention control since it provides beneficial health information and is likely to attract youth interested in their health. Additionally, the active control condition controls for the effect of meeting with a positive adult instructor and peer group experience, learning new material, attention, and time. HT participants receive no training in MBI or meditation. Topics covered may include physical activity, nutrition, managing weight, understanding adolescence, personal care, avoiding tobacco, alcohol, and drugs though this will be finalized in YR-1 with the HYWG and advisory panel. The HT program will be led by a positive adult instructor with training in health education or a related field and experience working with YEH.

Participant Incentive**.** Participants in the pilot study will receive food, hygiene items, and a $10 gift card for attending each session and $15 for the baseline and immediate post-intervention surveys. To facilitate retention in the study, participants will receive $20 for the 3- and 6-month follow-up surveys. CHT has bus passes available for all YEH who are in need of public transportation. Rather than receiving compensation for attending the sessions, youth will receive food and toiletries as needed, current practice in the shelter for attending life skills courses.

Enrollment and Data Collection Procedures**.** The RC and RA will recruit and enroll all participants. Once consented, the youth will take the baseline survey and receive their group assignment from the RC. A computerized randomization generator will be used. The RA will be blinded to group assignment and will conduct all data collection. For the purpose of this study, enrollment will be defined as completing consent, baseline survey, and at least one lesson of the intervention or control condition. Surveys will be completed by participants on iPads using REDCap. Participants will enter response data directly into the tablet so their answers will be private. In the case of electronic device failure, we will use back-up iPads and paper surveys and the RA will enter the responses into REDCap within 24 hours. We will use unique study IDs in the place of names to protect participant confidentiality. ***Baseline and Follow-up Surveys.*** Participating youth will complete surveys at baseline, immediate post-intervention, and at 3- and 6-months post-intervention. Surveys will take approximately 30 minutes to complete and will include items to measure mindfulness, perceived stress, emotion regulation, impulsivity, and mental health symptoms (see Table 2 for example measures and psychometric properties) and youth risk behaviors. We will also pilot self-report and app use to determine the most effective way to measure use of commercially available mindfulness apps. Data usage information will be gathered from mediation app on participants' phone***. Pre- and Post-Session Surveys.*** Very brief pre- and post-session brief surveys will capture real-time stress, emotion regulation, positive and negative affect, mindfulness, impulsivity, and session feedback (post-session only) including likability of session content, delivery format, length, and delivery timeframe. These surveys will take approximately 5 minutes to complete prior to and immediately after each session. ***Exit Interviews.*** The RC will conduct individual or group exit interviews with 20 youth from the pilot study participants that will be audio-recorded and take about 30-45 minutes. We will randomly select participants from each of the 4-6 intervention cohorts to have equal representation by gender identity, age, and study group. We will elicit participant feedback on study procedures, intervention acceptability, delivery methods and strategies, barriers and facilitators of

session participation, mindfulness skills practice, measures completion, and overall experience with the intervention and the study. While the exit interview guide will be finalized during YR-1 with the assistance of the HYWG, we anticipate querying the participants about: 1) what the participant thought of the number and type of questions asked in the baseline, pre-post session, and initial follow-up survey, 2) thoughts on the intervention sessions (e.g., content, length, delivery mode, frequency/spacing, perceived impact), and 3) any other comments about the intervention or study procedures including a comparative analysis[180] of the commercially available mindfulness apps. Participants will receive an additional $10 gift card for a local restaurant or grocery store for completing the exit interview.

Table 3. Feasibility and Acceptability Benchmarks

Construct	Measure	Benchmarks
Recruitment feasibility	# screened & enrolled/mo; time delay from screening to enrollment; average time to enroll sufficient class size; appropriateness of exclusion criteria screening process	Enroll 50% of screened and eligible participants; <2-week delay from screening to enrollment; <2 weeks to enroll sufficient class size; <5% inappropriate exclusion/inclusion
Retention feasibility	3- and 6-mo follow-up survey completion; compare intervention vs. control group	At least 50% retained at 3 and 6-mo; <15% group retention differential
Treatment adherence	Attend all sessions; perform the intervention; complete study measures	At least 50% of participants in each cohort will attend at least 3 of 5 scheduled group sessions[108,164]
Treatment delivery fidelity	Session delivery fidelity checklist	At least 70% of each session content is completed
Completeness of assessment data	Data from surveys, focus groups, and key informant interview are complete and intact	Less than 50% data loss or incompleteness
Acceptability	Credibility/expectancy questionnaire[181]	Average score of >30

Data Management**.** The PI and Co-Is will be blinded to group assignment. The RA will download survey data from REDCap after each intervention session and store it directly onto a desktop computer encrypted master file. The RC will check data weekly for completeness. Survey and audio transcript data will be maintained in the Data Center Zone at UTHealth with data access limited to only necessary staff. Standard firewall and password protections will be implemented to limit access to and ensure confidentiality of data. To assure data security, we will make weekly backup copies of this master file onto an encrypted portable hard drive, which will be stored in the PI's office in a locked file cabinet. Unique logins will be assigned to each staff member. All data collected will be kept confidential and study IDs will be used in the place of participant names. A master list of study IDs linked to participant names will be maintained by the RC for the explicit purpose of linking participant data from baseline, follow-up, and pre- and post-intervention session surveys. This list will be stored in an encrypted, password-protected computer file. Only the RC and PI will have access to this file. Hard copy field notes, surveys, and participant contact information will be securely kept in a locked filing cabinet in a locked office by the PI. No personal identifying information will be recorded or labeled on field notes. All study-related forms, surveys, and data will be shredded after seven years. Confidentiality is a high priority and will be further protected with the Certificate of Confidentiality from NIH. A Data Safety and Monitoring Board (DSMB) will be included to manage the reporting and adjudication of unanticipated problems and serious adverse events to the IRB, NIH-NCCIH, and applicable regulatory agencies (See Form E. Human Subjects section). Results of this study will be reported in the aggregate.

Protection of Human Subjects**.** We understand that the vulnerable nature of the youth we will enroll in this study and will appoint a DSMB to assess participant safety throughout this study. Protection of human subjects procedures are outlined in Form E and summarized here. Our team is highly experienced in conducting intervention research among vulnerable populations, including YEH (see biosketches). Our experienced research staff are well trained in interview techniques related to sensitive material. In our extensive research with YEH, we have rarely encountered participant reactions more adverse than mild discomfort, transient awkwardness, or embarrassment. The intervention will take place within a shelter where youth have access to immediate care as needed including a medical clinic, psychologist, and procedures that study staff will follow if a participant were to have a mental health or medical crisis.

Staff Training**.** The research staff will receive 16 hours of training prior to initiating recruitment procedures for this study to assure that all protocols and procedures are followed. Research staff will have ongoing supervision on how to handle awkwardness, embarrassment, or discomfort and participate in bi-weekly meetings. Bi-monthly debriefing sessions with Micki Fine, the mindfulness expert consultant, will assist in processing challenges that arise during the study and to promote resilience in the study staff. It is possible that there may be occasions when study participants exhibit stronger and more serious signs of emotional distress. Research staff will be trained to identify signs of acute distress or suicidal ideation and how to respond. Staff training will also include UTHealth IRB certifications, protection of human subjects training, and a detailed review of the research protocols, strategies for interacting with YEH, collection of accurate data, feedback on how to interact in a non-judgmental manner, ethical issues, emergency protocols, participant recruitment, adolescent development, trauma-informed care, and maintaining appropriate boundaries (see Human Subjects section).The training will be conducted by Dr. Santa Maria (e.g., protocol, trauma-informed research methods), Dr. Cuccaro (e.g., adolescent development), and Micki Fine (e.g., mindfulness-based research strategies).

Potential Problems and Alternative Strategies**.** We do not anticipate recruitment issues based on our prior success in recruiting YEH from CHT. We have alternative sites eager to partner with us if needed. Dr. Santa Maria has current research studies in the community that will facilitate recruitment. Based on our multiple prior studies with YEH and experience recruiting from CHT, we anticipate enrolling 18 participants every 2 months to reach our total sample size of 90 youth within five months. While retention of YEH can be challenging, our team has extensive experience in retaining YEH in longitudinal RCTs. To reduce loss to follow-up, we will use a detailed tracking protocol and provide a study-issued phone to contact participants as needed. This thorough tracking protocol has been used by leaders in the field among hard-to-reach populations and in our previous longitudinal studies with YEH with high retention rates.[41,165] Participants who leave the shelter during the study will still be able to continue participation if they are a resident at the shelter when enrolled. If youth leave during the study, we will provide transportation vouchers for the sessions and follow-ups. Some participants will have a difficult time keeping follow-up appointments. Therefore, we will offer open-access walk-ins weekly at the shelter and drop-in center. Study staff will be able to meet youth at other locations (e.g., other shelters, libraries) for surveys and exit interviews if needed. We are very connected to the local network of service providers in Houston and can meet with youth at other highly frequented locations. We expect about 67% of participants to have a personal phone based on our prior studies. While study-issued phones will be available, we can use a participant's personal phone if preferred. Replacement phones will be available due to the heightened risk for phone damage or theft experienced by YEH. While there is an inherent risk for intervention contamination in any individually-randomized study design, our data

show that YEH in Houston are relatively disconnected from one another and function independently. The DMSB will adjudicate adverse events.

Next Steps. The proposed pilot study will establish the feasibility and acceptability of implementing a tailored trauma informed MBI. Subsequent trials will 1) assess feasibility of conducting a rigorously designed, multi-site RCT, 2) examine intervention dose to establish the minimal effective intervention dose, 3) assess the feasibility of longer term follow-up, and, 4) examine the efficacy of the intervention in a multi-site RCT. This research trajectory will ensure high rigor in establishing whether MBIs are a feasible and efficacious way of improving the health and well-being of a high-risk, vulnerable and underserved population of YEH. This study is critical and timely given the rapid adoption of mindfulness programs to serve this population without rigorous efficacy studies.

Recruitment and Retention Plan. Participant recruitment will begin after obtaining UTHealth IRB approval. Our team has received IRB approval for several studies involving interventions with vulnerable populations of young people including young adults and minors experiencing homelessness and mindfulness interventions. To recruit YEH, flyers describing the study will be posted in the common area of local shelters, drop-in centers, and clinics as homeless youth often access services from multiple service providers and locations. We will pass out study information during street outreach events hosted by the partnering agencies. Local healthcare for the homeless providers, The Homeless Youth Network, and the Coalition for the Homeless will be informed about the study and flyers will be posted at local clinics with permission as well as coordinated access housing first locations (where youth can access housing services). Project staff will also approach youth who receive services at the Salvation Army drop-in center and Covenant House Texas shelter to screen for eligibility. Additionally, participants can contact research staff after seeing the flyers at other shelters, drop-in centers, or healthcare for the homeless clinics. The research staff will work with the shelter staff to identify youth at the site each day who may be eligible. We will recruit participants three days a week during regular business hours at the shelter and drop-in centers and during street outreach until we have reached our final sample size. The research staff will maintain a consistent presence at the agencies and will approach young people who present. In the event that the common room in the shelter or drop-in center is crowded, they will ask to speak to identified youth in a private office. The research staff will explain the study and complete the informed consent process with interested youth. All prospective participants will be assured that study participation will in no way affect their health and social services. Informed consent and contact information will be obtained from participants.

YEH Recruitment. YEH in Houston, TX (Total n = 156; HYWG = 10, FGDs = 56, Pilot study = 90) will be recruited from drop-in centers, shelters, local YEH service locations, clinics, federally qualified healthcare centers in locations with a high concentration of homelessness, magnet (e.g. hot meal) events, mobile clinics, and street outreach to increase representation from both connected and disconnected YEH and generalizability of the findings (see Letters of Support). These recruitment sites serve young men, women, families, and LGBTQ youth. We will use group-based study introduction sessions, flyers, and recruitment letters at the agencies, clinics, street outreach, and the website and Facebook pages of the agencies and the Homeless Youth Network (HYN), methods we successfully used in **Youth Count 2.0** to recruit 434 YEH in just 4 weeks.[44] The RC and RA will maintain a consistent presence at the recruitment sites throughout the study to facilitate both recruitment, follow-up, and retention efforts. The RA will approach youth to describe the study, screen for eligibility, and obtain informed consent (see Human Subjects section) in a quiet area (e.g., library or office space). Potential participants will be informed at each encounter that participation will have no effect on their ability to receive services such as housing, mental health, or healthcare. A nationally representative survey suggests that 3.5 million individual 18-

to 25-year-olds experienced homelessness during the past year.[115] In 2018 in Houston, TX, local homeless youth service providers served over 7500 unduplicated YEH.[109] Given the aforementioned inclusion criteria and the high volume of YEH in Houston, we expect to have very few challenges with enrolling 56 YEH to participate in FGDs or 60 YEH to participate in the pilot study.

Homeless Youth Working Group (HYWG). Youth participants will be recruited in the same manner as above. Dr. Santa Maria has an established HYWG that she will recruit from for this study to include up to 10 youth 18- to 25-year-olds recruited to participate in up to 6 sessions lasting approximately two hours in YR-1 and as needed in YR-2.

YEH-serving Providers Recruitment**.** Key informant interview participants (n = 12) will be current health and social service providers for YEH recruited from local shelters, drop-in centers, homeless health care clinics, and the Homeless Youth Network. Providers will be invited through an email sent to them from the PI, announcements made at Homeless Youth Network meetings, or in person if needed. Participants will be informed that participation will in no way impact their employment or any services that they received from UTHealth. We do not anticipate any challenges recruiting eight service providers to participate in the key informant interviews. As we will be conducting only one interview with each key informant, we will not be conducting any participant tracking, retention, or follow-up with these individuals.

Expert Advisory Panel (EAP) Participants**.** An advisory panel comprising eight homeless youth service providers will be recruited from the Homeless Youth Network and two homeless youth between 18-25 years old will be recruited as mentioned above to assist in the project as members of the Expert Advisory Panel. Additionally, an advisor from the Mindfulness in Schools *.b* program will serve on the EAP. The group will be convened by phone/Webex or in-person every other month for one-hour during the course of the study to provide input on intervention development, implementation, evaluation, and study protocols.

Participant Tracking, Retention, and Follow-up for FGD and Interview Participants**.** No tracking will be done for the participants in the Focus Group Discussions or the Key Informant Interviews as those will be one-time data collection points.

Participant Tracking, Retention, and Follow-up for HYWG and Expert Panel Participants**.** No participants in the Homeless Youth Working Group (HYWG) and the Expert Advisory panel (EAP) will provide contact information in order to allow study staff to invite them to the sessions and meetings. HYWG and EAP participants will be asked to provide the best way to contact them for subsequent meetings and asked to provide one back-up way to contact them (i.e. phone number of a friend, email address, work number).

Pilot Participant Tracking, Retention, and Follow-up**.** Our team has a strong track record of retaining vulnerable urban and homeless youth in longitudinal studies.

All participants in the pilot study will complete an extensive tracking form at the time of enrollment to request participant's contact information including personal phone number, alternative phone number (e.g., parent, sibling, or peer phone number), case manager phone number and email address, and social media information (e.g., Instagram and Facebook names). This information is voluntary though youth will be instructed on the utility of providing this information to assist study staff in contacting youth for follow-up over the course of the study. These tracking procedures have been successful in our previous

homeless youth studies and are supported by the literature.[9-13] We have a strong participant tracking database in place using the REDCap data management system. To follow-up with participants, the RC will first send participants a text message reminder on their study-issued phone to schedule the in-person survey at immediate and 3 months. If the RC is unable to reach the participant by text, they will then call the study phone and other contacts listed on the contact form (e.g., friends, family, and case manager). If still unable to reach youth, the RC will reach out to participants using the private message features on Instagram and Facebook. RCs will also be on site at the drop-in center and shelter weekly and therefore be able to meet up with youth who are due for follow-up. The RC will also discuss the date of the next sessions and follow-up appointments and pre-program the calendar of the participant's study-issued phone with these dates. A smartphone calendar reminder will be set for 48 hours prior to the appointment to prompt the participant to call study staff to schedule the visit in the case the RC has not been successful in contacting the participant and scheduling the follow-up visit. The RC will stay engaged with the homeless youth population by being at the shelter sites weekly and attending agency events monthly.

Participant Incentives**.**
*Focus Group Discussion Participants***.** Participants will receive a $20 gift card for a local grocery store for participating in a FGD.
Homeless Youth Working Group participants. Participants will receive a $35 gift card for a local grocery store for participating in a working group sessions.
*Key Informant Interview Participants***.** Participants will receive a $20 gift card for a local grocery store for participating in the interview.
Pilot Study Participants. Participants will receive access to hygiene packs, food, and a $10 gift card for attending each session and $15 for the baseline and immediate post-intervention surveys. To facilitate retention in the study, participants will receive $20 for the 3- and 6-month follow-up survey. The shelter has bus passes available for all youth including the participants who are in need of public transportation.

Data and Safety Monitoring

Trial Type/Level of Review**.** This study does not involve the testing of pharmacologic agents or any therapeutic treatments. Rather we are assessing the feasibility and acceptability of a mindfulness-based stress reduction intervention among homeless youth. Thus, this pilot study is classified as a Phase II of the Prevention Intervention Continuum – Methods Development, a moderate risk level study that dictates annual review by the IRB. To add additional safety measures for this study, we will convene a Data Safety and Monitoring Board.

Adverse Event Reporting**.** Study participants will be encouraged to report any "emergencies or events" by calling the study contact number. These instructions will be included on all cover letters that are sent to participants, programmed into the study issued cell phones, and on the consent forms. The study team will record all reported events in the adverse event log (including the subject's name, date, and event description). All members of the study team will inform the principal investigator, Dr. Diane Santa Maria immediately, who will consult with co-investigators and the monitoring board on the action that should be taken and report the incident to the UTHealth IRB. The action and date of implementation will also be recorded in the adverse event log. The entire investigative team and monitoring board will participate in classifying events as "serious" or "non-serious" (see list below), as well as "non-attributable," "possibly attributable" or "attributable" to the intervention (unlike a pharmaceutical trial

where known side effects exist, the classification of “expected” vs. “unexpected” is inappropriate for this behavioral intervention). Should study staff become aware of a participant experiencing significant symptoms during the study, they will be connected immediately to onsite mental health treatment resources and we will consult with the DSMB to see if it is connected to the study. If a participant contacts someone from the study team, we will follow the same procedure.

1. Serious events include any event or condition that is life threatening, results in a hospitalization, cancer or a physical or cardiac event serious enough to require medical attention. These events may be:
    a. Fatal
    b. Life threatening
    c. Permanently disabling
    d. Required or prolonged hospitalization (Admission—not ER visit)
    e. Overdose
    f. Significant hazard to patient
2. Non-Serious events includes all other events.

In addition, follow-up face-to-face visits at 3 and 6 months will include a query of subjects on whether they had “any serious health events that caused them to seek medical attention within the past 3 months,” and if any of these resulted in “hospitalizations overnight.” Details of these events will be recorded. All adverse reactions noted by any of the team members will be immediately reported to the principal investigator, the UTHealth IRB, Data Safety and Monitoring Board, and NCCIH All adverse events will be reviewed monthly by the research team and annually by the monitoring board. Also, in keeping with NIH guidelines, minority status and gender will be included in these reports to allow for detection of differential effects.

Data and Safety Monitoring Plan**.** This study is considered to constitute minimal psychological and physical risk and no legal or social risks. The risks are minimal since educational interventions generally promote good health, not endanger it. Our eligibility criteria are established to exclude individuals for whom the study procedures are not appropriate. We also will screen subjects directly using validated and reliable items for collecting information on co-morbidities such as unresolved serious mental illnesses or low literacy. Using this multi-gated approach, we should be able to effectively screen out any individuals for whom this intervention is contraindicated. All health-related occurrences will be recorded and regularly reviewed by the research staff.

A few potential minimal risks to subjects exist: breach of confidentiality or normal risks associated with having a phone. Breach of confidentiality is not believed to present any significant risk given the data protections described above. However, to mitigate this risk we have outlined steps we will take to protect confidentiality in the Human Subjects sections

Safeguarding Confidentiality and Certificate of Confidentiality. Our team will obtain a Certificate of Confidentiality from NIH to protect participants from the mandated release of study data. In the consent form, all participants will be informed that this certificate has been obtained, and what protections it affords them during the informed consent process. Participant data will not be released to any party outside the research team.

During data collection, participants may refuse to answer any questions that make them feel uncomfortable. Participants may discontinue participation in the study at any time. We anticipate that

the types of adverse experiences that may occur, if any, may be associated with issues arising during data collection. None of these risks are considered significant. Having a study phone poses no more risk than having a personal phone.

Role of the PI and Investigative Team**.** Dr. Santa Maria will have primary responsibility for monitoring study research staff, who will receive training on the study design, recruitment, and protocol prior to study initiation. Research staff will receive formal training on the study protocol by Drs. Santa Maria and Cuccaro, which will entail a one-day intensive training session followed by additional training sessions as needed. They will attend bi-weekly team meetings during data collection with the principal and co-investigators to discuss any study issues regarding recruitment and follow-up data collection. These meetings will be used to discuss experiences with the intervention participants, provide consultation, ascertain whether the research staff are following study protocols, evaluate and reinforce cultural competence, and identify any potential adverse reactions. Stan Cron, study statistician, will coordinate data management and analysis. He will oversee development of data entry screens and the database development, supervise data entry verification, and work with the investigators in conducting all data analyses.

Drs. Santa Maria, Cuccaro, Sibinga, and Bender will meet every 2-4 weeks (by phone and/or in person) to monitor study progress. Any adverse reactions noted by any of the team members will be immediately reported to the principal investigator, the UTHealth IRB, Data Safety and Monitoring Board, and NCCIH. One focus of investigator meetings will be on developing strategies to prevent adverse reactions and to better monitor the research staff and data integrity. Accrual data will be reviewed by the UTHealth IRB. The study team will make amendments to the protocol should accrual fall below 25% of the target, or should drop-outs exceed the projected 15-20%.

Role of the Data Safety Monitoring Board. A monitoring board will review the data monitoring and safety procedures annually. This group will comprise 3 members with expertise in risk prevention, health communication, and/or homeless youth intervention research. Dr. Elizabeth Baumler at the University of Texas Medical Branch; Dr. Cherrie Boyer at the University of California San Francisco Center for AIDS Prevention Studies; and Dr. Vanessa Schick at the UTHeath School of Public Health will be the monitoring board members. Monitoring board meetings will be conducted annually, beginning after the first 6 months of data collection. In addition, should any adverse reaction occur, the monitoring board will be informed immediately, and a special session will be scheduled to discuss strategies to deal with the problems. The meeting will include a synopsis of protocol and design, discussion of the status of interventions and data collection procedures, a summary of subject contacts, discussion of any adverse reactions or potential adverse reactions, status of data entry and verification, and a summary of any descriptive and inferential statistics to date. However, data analyses will be conducted on each time point of data collection (baseline, immediate, 3- and 6-months post-intervention) as it is completed. In addition, the monitoring board will be given time to meet in closed session without the investigators to discuss the need for additional procedures to prevent adverse reactions or ensure data integrity or the unlikely case that the study may need an early termination due to unexpected adverse reactions or inadequate conduct of the study. Recommendations from the monitoring board meetings will be shared with the UTHealth IRB and NIH during annual reports and immediately if the monitoring board identifies adverse reactions not previously reported or recommends early termination of the study.

Role of the IRB**.** This study will be approved by the UTHealth IRB. The UTHealth IRB will be the primary oversight IRB for the study and the study PI (Dr. Santa Maria) will be responsible for reporting to the IRB about the status of the study. Annual progress reports and renewals will be completed for the IRBs and

will include a summary of the recommendations of the monitoring board. If adverse reactions related to study procedures are noted, they will be immediately reported to UTH IRB by Dr. Santa Maria so that the IRB is aware of any risks involved with the study.

Role of NIH**.** Summaries of the protocol and design, status of intervention group, and data collection procedures, summary of subject contacts, discussion of any adverse reactions or any potential adverse reactions, status of data entry and verification, a summary of any descriptive statistics to date, and the recommendations of the monitoring board will be included in each annual report to NIH. In addition, should any adverse reaction occur or should the monitoring board recommend early termination of the study, the information will be immediately reported to the program officer at NCCIH.

Statistics

Fifty six YEH will participate in the focus groups during the first 2 years of the study to Tailor *.b* and finalize the attention control condition. Sixty YEH will participate in the pilot RCT.

Sample Size for Pilot RCT. We will recruit 90 YEH with equal randomization into the intervention and attention control arms to reach the target of 60 YEH completing the intervention and control conditions. The sample size is based on practical considerations regarding the number of participants needed to assess feasibility and acceptability outcomes and not on the performance of inferential statistical analyses. However, a final sample size of 60 youth completing the pilot will have 80% power to detect a medium effect size of 0.74 for stress response.[182]

Data Management and Statistical Analysis Plan. To align with the R34, we will not conduct inferential statistical analyses. The analyses goal is to examine study feasibility and acceptability, determine effectiveness of recruitment and randomization strategies, follow-up and retention protocols, and preliminary assessment of outcome measures using both quantitative and qualitative methods (See Table 3). In summary, for the quantitative analyses, frequencies and percentages will be calculated to determine the recruitment, retention, attendance, and data collection rates (See Table 3). While we do not anticipate missing data based on the low rate of missingness in our previous work using similar surveys and data collection methods, we will assess for and calculate the rates of missing and incomplete data to inform future studies. Means and standard deviations will be used to summarize changes in the outcome variables over the three time points (e.g., baseline, immediate post-intervention, and at 3- and 6-months). Estimation of effect sizes due to the intervention will involve the use of one-way repeated measures analysis of variance to provide the effect size R^2 for each proposed outcome variable.

For the qualitative analyses, we will analyze the data from FGDs, key informant, and exit interviews using thematic content analysis.[174,183] Audio files will be transcribed and validated against the written transcriptions. For the initial set of 2 FGDs and 5 interviews, the qualitatively trained RA will review the text for content and identify 5-10 themes. Next, we will develop a codebook through preliminary discussions of themes and team coding among the study team and refine the codebook iteratively with the HYWG and EAP to form a final set of codes. Then, two investigative team raters (Drs. Santa Maria and Cuccaro) will independently categorize passages until excellent interrater reliability (Cohen's kappa (*k*) = .85) is achieved. A thematic content analysis will be conducted to look for common themes present across the entire sample. The investigative team will discuss emerging themes and subthemes with the HYWG and EAP to generate the final results. ATLAS.ti will be used to manage the data, organize codes, and exemplar quotes. The team will meet to review coded data and discuss the meaning of the themes

that emerge in person and through phone/Webex. Using investigator consensus building strategies,[174,183] differing interpretations of texts will be merged. Confirmability of data will be verified among the team using peer debriefing of coding, thematic analysis, exemplars, and supportive quotes for the cohesion of descriptive interpretations. Participant quotes will be labeled by the participants' age and gender identity to demonstrate the distribution of themes across the sample.

Ethics

Protection of Human Subjects from Research Risks. This Human Subjects Research meets the definition of a clinical trial. IRB approval will be sought from UTHealth IRB.

Risk to Human Subjects**.** While mindfulness strategies have been shown to have positive impacts on participants and have minimal associated risk, there is the possibility of risk. There are no physical risks associated with participation. The possible risk of psychological distress is related to the types of study questions asked in the surveys concerning past events, current circumstances, thoughts and feelings, sexual behaviors, and sexually transmitted infections. As well, the practices of mindfulness may add risk of distress as youth experience thoughts and feelings that arise during the process. For data collection, participants may find thinking about thoughts and feelings that arise or answering questions about these issues upsetting; these questions will be asked in as sensitive a manner as possible. We use ACASI computer-based surveys to allow participants to read and answer the questions privately and not have to hear them aloud or tell another person, which may reduce any possible distress associated with answering the questions. While participants will be assured that their participation will not affect health and social services being provided at any location, some participants may feel concerned about or pressured to be part of the study. We will assure participants at the beginning of each session that their participation is voluntary and that they can participate in all, part of, or none of the session and can withdraw from the study at any time for any reason without penalty. Another potential risk is the loss of confidentiality or disclosure of information or data about the participant. We have detailed below extensive measures to ensure confidentiality and decrease the risk for disclosure of private information. While there were no reported adverse reactions to participating in mindfulness interventions in the team's previous work, there is the potential of stress and negative reactions from the self-reflection that the practices may evoke.

Consent and Protection of Human Subjects**.** Once finalized, and prior to recruitment of any participants, consent forms will be thoroughly reviewed before approval by the UTHealth Committee for the Protection of Human Subjects (CPHS) from the University of Texas Health Science Center at Houston (UTHealth). CPHS is the Institutional Review Board (IRB) for UTHealth. All research staff will complete the Protection of Human Subjects training at UTHealth prior to contact with potential participants. Research staff will also participate in project-specific training on project goals, procedures for recruitment, informed consent, data collection, and tracking, at which point they will have the opportunity to practice the recruitment and informed consent process. Research staff will also be shadowed during their first 3 recruitment sessions to assure that they are following the recruitment and informed consent process correctly.

Written informed consent will be received by all participants for the focus groups, key informant interviews, and the pilot study. Consent will be completed prior to data collection. The consent form will thoroughly describe risk assessment, data collection, and intervention procedures, as well as benefits and risks of study participation. The consent form will fulfill the requirements set out by the UTHealth CPHS. Participants will be given the opportunity to refuse participation in the study and will be told that

nonparticipation in the study will not affect services being provided by any health and social service providers.

Inclusion criteria of homeless youth for the focus groups and the pilot study will be the same. Potential participants are homeless youth receiving services at CHT or one of the recruitment sites in Houston, TX at the time of enrollment, 18-25 years old, English speaking, and able to participate for the 6-month study period (i.e., not moving out of the county during the study). Homelessness will be defined as staying on the streets, in a place not meant for human habitation, a shelter, hotel/motel, or with someone temporarily in a location where they cannot stay for more than 30 days (i.e., couch surfing). Exclusion criteria are not meeting the inclusion criteria or having a severe, untreated mental illness as determined by the Behavioral Symptom Index,[10] criteria we have used successfully in our previous studies with homeless youth. If participants are excluded based on the Behavioral Symptom Index, they are still eligible for screening for later enrollment as a high proportion of homeless youth have a mental illness diagnosis. We are only screening for exclusion of those with current unmanaged symptoms. We understand that with subsequent treatment and stabilization, youth may present at a later date within the enrollment period with resolved symptoms and therefore be eligible for enrollment at that time. Inclusion criteria for the health and social service providers will be persons currently providing health or social services to homeless youth ages 18-25 years old who are able and interested in participating in a key informant interview.

Participant recruitment will begin after obtaining UTHealth IRB approval. Our team has successfully been approved to conduct similar studies among YEH recruited and followed-up in the same fashion. Flyers describing the study will be posted in the common area of CHT, local drop-in centers, and shelters as homeless youth often access services from multiple service providers and locations. Local Healthcare for the Homeless providers and the Coalition for the Homeless will be informed about the study and flyers will be posted at local clinics with permission. Project staff will approach youth who receive services at CHT to screen for eligibility. Additionally, participants can contact research staff after seeing the flyers at other shelters, drop-in centers, or Healthcare for the Homeless clinics. The research staff will work with the shelter case managers to identify youth at the site each day who may be eligible. We will recruit participants three days a week during regular business hours at the shelter and drop-in centers for two weeks prior to the beginning of each group session and the research staff will maintain a consistent presence at the recruitment sites. The research staff will approach young people present at the recruitment sites. In the event that the common room in the shelter or drop-in center is crowded, the research staff will ask to speak to identified youth in a private office or the library meeting area. The research staff will explain the study and complete the informed consent process with interested youth. As part of the consenting procedures, each youth will be asked to provide a separate signature of consent if they are interested in being contacted for an exit interview. All prospective participants will be assured that study participation will in no way affect their health and social services. Informed consent and contact information will be obtained from participants. These procedures for recruitment were developed and proved successful in our prior qualitative, cross-sectional, and mindfulness pilot studies with homeless youth and have been used at the same sites we will use in this study to recruit participants.

Pilot Participant Tracking**.** We will issue study phones to facilitate participant follow-up. In the case that we are unable to contact youth using the study-issued phone, we will use an extensive participant tracking form to collect contact information from those youth who agree to enroll in the study. Our team has experience in successfully retaining homeless and at-risk youth in longitudinal and intervention studies. To reduce the risk of loss to follow-up, we will utilize an extensive tracking protocol. We will use

a detailed participant tracking form to collect contact information from those youth who agree to enroll in the study. The tracking form asks participants to provide information on various ways to reach them including their personal phone numbers, phone numbers of those who would be able to contact them, and their social media contact information such as Facebook name. This thorough tracking form has been used by leaders in the field for tracking hard-to-reach populations and in our previous longitudinal studies with homeless youth and facilitated high retention rates.[11]

Protection Against Risks. We are taking steps to minimize other potential risks as described below.

Participant Discomfort. Mindfulness practices, survey questions, and exit interviews might create awkwardness or discomfort. A potential risk in participating in the proposed research is becoming more aware of and/or reporting past events, current circumstances, thoughts and feelings, and risk behaviors that may make participants feel uneasy. Our experienced research staff will receive an additional 16 hours of training before initiating recruitment for this study to assure that all protocols and procedures are followed. Our staff have worked on several studies with homeless youth under the supervision of Dr. Santa Maria. If new staff are hired during the study, they would receive a minimum of 40 hours of project training in addition to the university-level and Human Subjects training. Research staff will have ongoing supervision in how to handle awkwardness, embarrassment, or discomfort. Participants can choose whether to be in the study or not. They may withdraw at any time without consequences of any kind. They may also refuse to answer any questions they do not wish to answer and still remain in the study. It is possible that there may be occasions when study participants exhibit stronger and more serious signs of emotional distress; we may encounter individuals who express suicide intent, have psychiatric emergencies, or exhibit other indicators of acute distress. Research staff will be trained to identify signs of acute distress or suicidal ideation and trained how to respond to them. With respect to the assessments, we will emphasize to research staff that if a participant becomes upset, they should be offered the option of discontinuing without penalty (i.e., still receiving payment) or continuing at a later time after a break. Further, the computer-assisted survey administration limits participant exposure to potentially sensitive items. For example, participants who have not engaged in a certain risk behavior, such as substance use, are not exposed to more detailed questions about use. Participants will also be informed that they may skip any item that makes them feel uncomfortable. In the event of any acute emotional distress, research staff will remain with the participant until s/he is no longer distressed.

The CHT shelter where the intervention sessions will be conducted has 24-hour staff trained in managing acute episodes of distress or even psychosis. We will follow the protocols of the shelter, who have over 30 years of experience with homeless youth. Additionally, the shelter has a fully functional Federally Qualified Healthcare Center on the premises with clinical psychologists and a psychiatrist on staff. Individuals who wish to pursue follow-up care will also be given a referral list specifically tailored to the individual's request. We will have prepared referral lists for perpetrators and victims of abuse as well as for other psychological problems. At the end of each assessment, all participants will be offered a list of relevant, local referrals. We will not be asking about suicidal ideation, so it is unlikely that we will have to deal with acute suicidal ideation. However, anyone having direct involvement with the participants will be fully trained by the PI in procedures for assessment and intervention in cases where suicidal ideation is expressed. Research staff will be instructed to immediately contact shelter staff to implement shelter protocols on suicidal ideation and to contact the PI and take appropriate clinical action in these circumstances to assure participant and staff safety including referral to another level of clinical care. As well, recruitment will take place in shelters and drop-in centers staffed by trained clinical social workers, case managers, and healthcare providers. RAs will be able to notify recruitment site staff and facilitate implementation of protocols for care in cases of acute distress. Experienced supervisors

and Dr. Santa Maria will be available for immediate consultation in the event of encountering an unexpected acute psychological problem; and as part of their training, research staff will be made familiar with referral resources and procedures for local psychological, social service, and other emergency care needs.

In order to minimize such risks that we may encounter in this study, extensive research staff training, and supervision will be developed. In the case of staff turnover, hiring of research staff will favor applicants with experience working with homeless youth or other vulnerable populations. UTHealth has staff and researchers highly experienced in research in vulnerable populations,[11] adolescent and young adult risk behavior, and mental health assessment interviewing. In our extensive research with homeless youth with our current RA and RC who are experienced and well trained in interview techniques related to sensitive material, we have rarely encountered participant reactions more adverse than mild discomfort, transient awkwardness, or embarrassment. Research staff will be trained initially with ongoing supervision in how to handle such participants' transient discomfort. The training will also include UTHealth IRB certifications, protection of human subjects training, and a detailed review of the research protocols, strategies for interacting with homeless youth, collection of accurate data, feedback on how to interact in a non-judgmental manner, ethical issues, emergency protocols, train-the-trainer on participant recruitment, adolescent development, trauma-informed care, maintaining appropriate boundaries, and general risk prevention information. A minimum of bi-weekly supervision meetings will be conducted with the entire research team.

Reducing the Risk for Coercion**.** To ensure that potential participants do not feel coerced to enter or remain in the study, research staff recruiting participants will follow a standardized script to ensure that all ethical issues are reviewed and that the study procedures are reviewed. All protocols will be reviewed and approved by the UTHealth IRB prior to implementation. It will be made explicit in the consent document—both verbally and in writing—that their study participation is voluntary, that it is unrelated to their entitlement for health and social services, and that they can drop out of the research at any time for any reason. In addition, research staff reviewing the consent will be trained to probe for comprehension of the consent form and study procedures. Through our prior experience with homeless youth, the IRB, and youth advisory board, we have also set the incentive levels at a modest amount that is commensurate with the amount of time youth will spend in the research study.

Safeguarding Confidentiality**.** Data confidentiality is a high priority of the PI and research staff. All research staff will complete extensive training focused on each of the following topics: 1) project rationale and objectives, 2) the informed consent process, and 3) general data collection procedures (e.g., data collection, privacy). To assure participant confidentiality and accuracy of information, research staff will be extensively trained in standardized data collection procedures using a data collection manual of procedures. Unique passwords will be assigned to data management and data analysis team members, tracking staff, project coordinators, and investigators. Unique participant identifiers will be rigorously protected by all research staff. Each participant will be assigned an ID number that will be utilized in place of names in all electronic and print data files. The file containing the links between participant names and identifiers will be kept in a separate password-protected file, which will be destroyed 12 months after the completion of the study. Informed consent will be stored in a locked filing cabinet in the Principal Investigator's office. No information that would disclose the participant's identity will be contained on any interview or survey research database. During the consent process, youth will be informed that there are two instances in which project staff will voluntarily make a report to authorities. First, if they disclose that they want to harm themselves. Second, if they tell us they want to harm someone else. At the beginning of the intervention, the research staff will inform

participants about restrictions on his/her ability to keep certain information confidential, i.e., by law, if the participant discloses intentions to hurt themselves or others. In such a case, the facilitator will report this information to shelter staff and the police when the risk for harm is immediate. This situation has never occurred in any of our past studies with homeless youth. Any adverse event will also be reported to the UTHealth IRB.

Data Archiving and Preservation**.** We will archive all data collected through the research project for 10 years. Paper documents, including signed informed consents and paper surveys (if needed), will be securely stored in locked filing cabinets. All electronic data will be stored on password-protected computers. While surveys will be administered using an online survey platform called REDCap, we understand there may be circumstances that would require the need for a paper survey.

Responsibility**.** The PI and Co-Is will maintain joint responsibility for the data management plan and its oversight and monitor compliance over the lifespan of the project.

Certificate of Confidentiality**.** Participants will be asked to answer questions about private information that may have legal consequences if it were disclosed because homeless youth tend to interact with law enforcement more frequently and risk behaviors may be illegal. Therefore, before data collection is initiated, researchers will obtain a Certificate of Confidentiality from NIH to protect participants from the mandated release of study data. All participants will be informed in the consent form and verbally during the consent process that this certificate has been obtained and what protections it affords them during the informed consent process. Participant data will not be released to any party outside the research team. We have received a Certificate of Confidentiality from NIH-NIDA on our previous longitudinal study with homeless youth.

Potential Benefits of the Proposed Research to Human Subjects and Others. Potential benefits to study participation, which will be outlined in the consent forms, are that the participants may become more aware of how thoughts and feelings can affect one's behaviors and stress. Previous experience indicates that young adults usually do not mind answering questions about their risk-taking behavior and knowledge, attitudes, and beliefs. In addition, research staff are provided with lists of resources available to participants and will be trained to offer referrals to appropriate resources at the end of the assessment if a participant indicates that s/he needs services they are not otherwise receiving. Finally, participants will have access to resources and contact information for services that will be pre-programmed into the study-issued smartphones provided to participants for the duration of the study.

Data handling and record keeping

Data Security**.** Unique passwords will be assigned to data management and data analysis team members, tracking staff, project coordinators, and investigators. Unique participant identifiers will be rigorously protected by team members. No names will be used in data analysis files or in reports. No names will be kept on the computer where the study data is collected or stored. Results of this study will be reported in the aggregate. Data collected in the study will be kept confidential except in cases when the research staff are provided with information that raises suspicion for abuse, neglect, harm to oneself, or harm to another. Participants will be made aware of the confidentiality of the data except in cases of safety concerns during the consent and assent process. In order to minimize risk and ensure the quality of the data, research staff will receive extensive training. Research staff will attend biweekly supervision meetings where any problem will be discussed and solutions developed. Any breaches of protocol will be immediately reported to the PI, and in the case of breach of confidentiality or other event that would constitute a potential adverse event, they will be reported to the UTHealth IRB within

5 days. This would include situations where interviewers need to break confidentiality in cases of suspected concern for suicide or homicide. As stated above, research staff are extensively trained on handling such sensitive situations. No such events have happened in our previous studies with homeless youth. Such events are immediately reported to the PI, the appropriate authorities, and an adverse event report filed with the UTHealth IRB.

Data at pre- and post-surveys will be collected on tablets using surveys programmed in REDCap. Computerized assessments are transferred electronically to UTHealth on a weekly basis. We have used similar protocols with our previous homeless youth studies with success. REDCap is a well-tested computerized survey program, our staff is trained in REDCap surveys, and our extensive experience should reduce implementation, data management, and design problems. Participants entering data will be able to interrupt and resume sections in mid-course, review previously entered data, and back up to change prior entries. The quality of the data on these programs is enhanced, as REDCap will provide immediate feedback to the participant if unexpected data are entered. Only data analysis personnel connected with the study will have access to data files. Those files will be de-identified and not contain any identifying information.

Paper Study Documents**.** A hard copy of the participant consent and tracking forms will be saved in a secured and locked filing cabinet at the UTHealth School of Nursing for seven years. All study related forms, surveys, and data will be destroyed by shredding after seven years. In order to assure security of the data, we will make weekly backup copies of the REDCap data set. These copies will be stored in a secure area physically separate from the data management and analysis sections of the main project site.

Phone Data Loss Prevention**.** Participants will be provided with a study-issued smart phone to facilitate participant follow-up and access to pre-programmed homeless youth resources. In our previous study, we had a phone loss or damage rate of 12%. If a phone is lost, it will be remotely wiped. One replacement phone will be provided to each participant in the event of a lost, stolen, or damaged phone. No data will be collected or stored on the phones. Phones will only be used to contact participants to schedule follow-up appointments.

Data Protection during Data Sharing. The privacy and confidentiality of research participants will be protected at all times, including qualitative (audio files) and quantitative (surveys) data collection, analysis, storage, and preparing public-use data sets. Therefore, data to be released will be de-identified, which will ensure that linkages to individual research participants cannot be made. Data will be de-identified per HIPAA definitions; all Personal Health Information (PHI) will be removed. All data will be formatted to allow for maximum accessibility using non-proprietary, unencrypted, uncompressed software. Whenever possible, we will use standard, widely used file formats for storing the data produced through study activities, e.g., PDF for text, Excel, SAS or ASCII format for electronic data.

Focus Group Discussion Data. A total of 56 homeless youth 18-25 years old will be recruited to participate in focus group discussions (FGDs). FGDs will be planned around already scheduled events where youth would be receiving meals or services at CHT. Private rooms such as the library or conference room will be used to minimize distractions. These areas are within CHT to ease accessibility to the youth and are sufficiently private to prevent nonparticipants from overhearing the conversations. After providing written consent, each youth will complete a brief survey to assess the demographics of the focus group sample. Focus groups will comprise 6-8 youth each and last approximately 1-1.5 hours. FGDs will be recorded and professionally transcribed verbatim. The research assistant (RA) will take

copious field notes during all of the FGDs to be used in the data analysis. Participants will receive a $20 gift card for a local grocery store for participating in the FGDs.

Example Focus Group Guide**.** While the focus group guide will be finalized during YR-1 with the assistance of the HYWG and expert advisory panel, we anticipate to query the participants about: 1) what they know or have heard about mindfulness and other contemplative practices, 2) lived experiences while homeless, 3) sources of stress, 4) stress management strategies, 5) emotion regulation strategies, and 6) barriers and facilitators to session attendance. We also anticipate asking general open ended questions about 6) what they propose as session content, delivery methods, session length and spacing, activities, and group discussion topics, 7) number and types of questions to include in the baseline, pre-post session, and initial follow-up survey, and 8) thoughts on the intervention sessions including content, length, delivery mode, frequency/spacing, perceived impact.

Homeless Youth Working Group Session**.** In these working sessions we will present session materials and delivery modality examples and query participants about 1) session content, delivery methods, session length and spacing, activities, and group discussion topics, 2) number and types of questions asked in the baseline, pre-post session, and initial follow-up survey, 3) what they thought of draft intervention session materials (e.g., content, length, delivery mode, frequency/spacing, perceived impact) when demonstrated, 4) usefulness of the practice tools (e.g., if they used it and for what), 5) utilization of the study-issued phone to facilitate communication and follow-up planning, and 6) any other comments the participant has about the intervention or study procedures.

Key Informant Interviews**.** Using a loosely structured conversational style interview guide,[122] we will conduct key informant interviews with 12 YEH service providers to gain additional perspective on how the proposed adaptations, materials, and activities in the sessions meet the needs of YEH and elicit suggestions to assure the materials are trauma-informed and youth-friendly. Interviews will last approximately 30-45 minutes, be audio recorded, and transcribed verbatim for analysis. Participants will receive a $20 gift card for a local grocery store for participating in the interview.

Example Key Informant Interview Guide**.** While the key information interview guide will be finalized during YR-1 with the assistance of the HYWG and advisory panel, we anticipate to query participants about: 1) what they propose as session content, delivery methods, session length and spacing, activities, and group discussion topics, 2) number and types of questions asked in the baseline, pre-post session, and initial follow-up survey, 3) thoughts on the intervention sessions (e.g., content, length, delivery mode, frequency/spacing, perceived impact) when demonstrated, 4) usefulness of the practice tools proposed (e.g., if they used it and for what), 5) utilization of the study-issued phone to facilitate communication and follow-up planning, and 6) any other comments the participant has about the intervention or study procedures.

Expert Advisory Panel**.** This group comprises 8 YEH service providers recruited from the Homeless Youth Network and 2 YEH. The group will be convened by phone or in-person every other month for 1-hour during the course of the study to provide input on intervention development, implementation, evaluation, and study protocols.

Plan, Do, Study, Act Field Notes**.** A Homeless Youth Working Group (HYWG) comprising up to 10 participants will be asked to participate in iterative intervention pre-pilot sessions. Multiple iterative sessions will be conducted to finalize *CALM* session content (materials and activities) with homeless youth (n=10) using pre-post surveys, exit interviews, and instant feedback processes. During this phase

of development, participants will debrief after each activity (e.g., didactic session, practice, video) using open-ended qualitative (e.g., Tell us what you thought of this activity) and quantitative (e.g., On a scale of 1-10, how helpful was the last activity?) responses to assess perceived acceptability, relatability, and perception of the impact the activity would have. At the end of each session, there will be a group interview style debriefing to assess general impressions of the activities and suggested modifications. This iterative Plan, Do, Study, and Act[9] process will allow the team to determine session content preferences including approach, method, length, tone, and verbiage. Message modifications will be made using iterative field testing with the HYWG until session material and activities are rated as acceptable and relatable with high perceived post-session behavioral action.

Baseline and Follow-up Survey Data**.** During the pilot phase, a baseline and follow-up survey will be administered at immediate post and 3 months post intervention and will take approximately 45 minutes each to complete. We will finalize the pre- and post-surveys during the development phase with the assistance of the Homeless Youth Working Group (HYWG) feedback. We anticipate including items to assess demographics (e.g., homelessness, historical factors, race/ethnicity, sexual orientation, gender identity) and behavioral outcomes. Additionally, the post-surveys will contain items measuring usability, mediating factors, and risk behaviors. To assess feasibility, we will calculate the number of eligible youth approached, participation refusal rate with reason for refusal, the number of sessions attended, follow-up survey response rates, and successful tracking methods. We will also monitor rates of recruitment and effort required (e.g., number of staff hours), number of screenings conducted and refusal rates,[2] and participant lost to follow up, to inform the design of a subsequent Phased Innovation Award to Optimize Mind and Body Interventions. For refusal rate, we will ask each youth we approach their age, race/ethnicity, gender identity, and sexual orientation to allow for demographic comparisons by participation status to monitor potential sample bias. Participants will be notified that no survey data will be shared with shelter and drop-in center staff or their case workers. Data will be collected on encrypted iPads using a secured REDCap system for the baseline, follow-ups, and pre-post session surveys. This data will be collected using REDCap offline at the shelter and drop-in center in order to minimize concern over data integrity in locations with weak Wi-Fi systems. Data is stored on the hard drive of the encrypted iPad and uploaded to REDCap nightly at the UTHealth office. No data from REDCap is accessible from the iPads. The tablet will be encrypted and password protected so that no one except research staff is able to gain access to the information on the tablet and the tablet is rendered useless if stolen. Only research staff will have the passwords for the REDCap database and computer. Survey data cannot be accessed from the encrypted iPad tablet and is only accessible on the REDCap secure server. Data will be downloaded from REDCap on a weekly basis and saved on secure, firewall protected hard drives.

Pre-Post Session Survey Data**.** The brief pre-post session surveys will be finalized in YR-1. We anticipate measuring 'right now' measures of affect, stress, emotion regulation, and impulsivity, mindfulness, and mind wandering in the pre- and post-session surveys. We have used these items in our brief pilot of *.b* (manuscript under review). These brief surveys will take approximately five minutes to complete.

To assess the feasibility of proposed outcome measures we will pilot test them in the baseline and post-intervention surveys. While the surveys will be finalized during the development phase with the help of the HYWG and the Expert Advisory Panel, items will include those outlined in Table 2 and 3 in the Research Strategy.

Exit Interview**.** A subsample of approximately 20 participants will be asked to participate in a brief, semi-structured private or group exit interview to provide insight about the intervention and study

experience within two weeks of completing the pilot. We will randomly select and contact participants from each of the study arms ensuring that equal numbers of participants by group are selected. This will allow us to assess feasibility and acceptability of the intervention and the control condition and study procedures for all participants. The research staff, who will be trained in human subjects research methods, and trauma-informed qualitative research methods, will conduct the exit interviews using an open casual conversation style.

Example Exit Interview Guide**.** While the exit interview guide will be finalized during YR-1, we anticipate the RA will query the participants about: 1) what the participant thought of the number and types of questions asked in the baseline, pre-post session, and initial follow-up survey, 2) what they thought of the intervention sessions (e.g., content, length, delivery mode, frequency/spacing, perceived impact), 3) how useful the pre-programmed smartphone resource materials were (e.g., if they used it and for what), 4) utilization of smartphone apps to facilitate mindfulness practices, and 5) any other comments the participant has about the intervention or study procedures. Participants will receive a $10 gift card for a local restaurant or grocery store for completing the exit interview.

Quality control and assurance

Data Management. The Research Coordinator will monitor study data for completeness and accuracy weekly and report to the investigative team. Ongoing training and weekly quality assurance checks will be performed to ensure adherence to confidentiality protocols. Data from the REDCap surveys will be stored on hard drives of encrypted tablets and then uploaded to a desktop microcomputer master file daily. Individual data files are automatically merged with the master data set. Weekly backups of the REDCap data set will be stored as an encrypted file and in a secure area physically remote from the data management area. All study related forms, surveys, and data will be destroyed by shredding after seven years. All necessary firewall and password protections will be implemented to restrict access and ensure data confidentiality.

Role of the Data Safety Monitoring Board. A monitoring board will review the data monitoring and safety procedures annually. This group will comprise 3 members with expertise in risk prevention, health communication, and/or homeless youth intervention research. Dr. Elizabeth Baumler at the University of Texas Medical Branch; Dr. Cherrie Boyer at the University of California San Francisco Center for AIDS Prevention Studies; and Dr. Vanessa Schick at the UTHeath School of Public Health will be the monitoring board members. Monitoring board meetings will be conducted annually, beginning after the first 6 months of data collection. In addition, should any adverse reaction occur, the monitoring board will be informed immediately, and a special session will be scheduled to discuss strategies to deal with the problems. The meeting will include a synopsis of protocol and design, discussion of the status of interventions and data collection procedures, a summary of subject contacts, discussion of any adverse reactions or potential adverse reactions, status of data entry and verification, and a summary of any descriptive and inferential statistics to date. However, data analyses will be conducted on each time point of data collection (baseline, immediate, 3- and 6-months post-intervention) as it is completed. In addition, the monitoring board will be given time to meet in closed session without the investigators to discuss the need for additional procedures to prevent adverse reactions or ensure data integrity or the unlikely case that the study may need an early termination due to unexpected adverse reactions or inadequate conduct of the study. Recommendations from the monitoring board meetings will be shared with the UTHealth IRB and NIH during annual reports and immediately if the monitoring board identifies adverse reactions not previously reported or recommends early termination of the study.

Publication Plan

Drs. Santa Maria (PI), Paula Cuccaro, Erica Siblinga, and Kimberly Bender are committed to the timely dissemination of the research findings. During the first biweekly meeting with the co-investigators, we will create a plan regarding the dissemination of the protocol and preliminary and final results of this study. Included in this list of abstracts and papers will be potential journals and conferences these results will be disseminated to, and when. We will also include in the list the potential first authors of these abstracts and papers. The data generated from this study will be presented at national or international conferences and indexed journals in a timely manner. We will submit all final peer reviewed manuscripts from the data generated by this clinical trial to the digital archive PubMed Central. Aggregated results in lay person terms will be shared with the participants, partnering agencies, and the larger community in addition to the scientific presentations and publications.

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ATTACHMENTS

Proposed Study Timeline

Project Aims		Year 1						Year 2						Year 3					
	Finalize study procedures and receive IRB approval																		
	Convene monthly HYWG and EAP meetings																		
	Convene DSMB meetings																		
Aim 1	Conduct focus group discussions		28	28															
Aim 1	Conduct key informant interviews		6	6															
Aim 1	Transcribe focus group and key informant interview audio recordings		34	34															
Aim 1	Analyze focus group and key informant interview data																		
Aim 2	Conduct iterative beta-testing sessions rounds 1-4 with HYWG					1	2	3	4										
Aim 2	Iteratively tailor *.b* intervention from beta-test results																		
Aim 2	Finalize intervention for pilot testing																		
Aim 3	Recruit 90 pilot participants										30	30	30						
Aim 3	Conduct RCT pilot of intervention											15	15	15	15				
Aim 3	Conduct exit interviews											5	5	5	5				
Aim 3	Transcribe exit interview audio recordings											5	5	5	5				
Aim 3	Participant tracking and follow-up																		
Aim 3	Analyze pilot test results																		
Aim 3	Report findings and apply for optimization funding																		