A Smartphone-Based Intervention for Anxiety and Depression in Racially and Ethnically Diverse Adults (EASE): Protocol for a Randomized Controlled Trial

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**Abstract**

**Background:** Clear health disparities have emerged in the rates of COVID-19 exposure, hospitalization, and death among Black, Hispanic, and American Indian (BHA) individuals, relative to non-Hispanic White (NHW) individuals. BHA populations have been disproportionately affected by lower behavioral health access and heightened negative mental health outcomes during the pandemic.

**Objective:** This project directly addresses health disparities in access to behavioral health care during the COVID-19 pandemic among BHA populations via an adaptation of the established, initially validated, low-cost, mobile app Easing Anxiety Sensitivity for Everyone (EASE) among individuals with symptoms of elevated anxiety or depression or both.

**Methods:** The EASE trial is a 2-arm, prospective, randomized, blinded-assessor study with intention-to-treat analysis. Participants (N=800; n=200, 25%, Black; n=200, 25%, Hispanic; n=200, 25%, American Indian; and n=200, 25%, NHW) are randomized to receive either EASE or an active comparison condition for anxiety and depression. Participants complete an online prescreener, an enrollment call to provide informed consent, a baseline survey, a 6-month intervention period, and 3- and 6-month postbaseline assessments. Select participants also complete a 3- and 6-month postbaseline qualitative interview via phone or an online platform (eg, Zoom). Participants complete 2 scheduled daily ecological momentary assessments (EMAs) during the 6-month study period. These twice-daily EMAs guide a just-in-time approach to immediate, personalized behavioral health care.

**Results:** Outcomes include reductions in anxiety and depressive symptoms and functional impairment at 3 and 6 months postrandomization. We also will examine putative mechanisms (eg, anxiety sensitivity [AS] and COVID-19–specific stress and...
fear) of the intervention effects. Further, as treatment effects may differ across sociocultural factors, perceived discrimination, social support, and socioeconomic status (SES) will be evaluated as potential moderators of treatment effects on the primary outcomes. Process evaluation using data collected during the study, as well as individual interviews with participants, will complement quantitative data.

**Conclusions:** Data from this efficacy trial will determine whether EASE successfully improves symptoms of anxiety and depression and whether these improvements outperform an active comparison control app. If successful, findings from this study have the potential to decrease anxiety and depression symptoms among vulnerable populations determined to be most at risk of exacerbated, long-lasting negative health sequelae. Data from this study may be used to support an implementation and dissemination trial of EASE within real-world behavioral health and social service settings.

**Trial Registration:** ClinicalTrials.gov NCT05074693; https://clinicaltrials.gov/ct2/show/NCT05074693

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**KEYWORDS**

COVID-19; just-in-time adaptive intervention; anxiety; depression; mHealth; minority populations; death; behavioral; care; mobile application; app; public health; symptoms; risk

**Introduction**

Significant racial/ethnic health disparities have been identified in the United States [1] related to COVID-19 [2]. Indeed, the rates of COVID-19 infection, hospitalizations, and death are disproportionately higher among Black, Hispanic, and American Indian (BHAIs) individuals relative to non-Hispanic White (NHW) persons [1,3-6]. BHAIs are also more likely to experience COVID-19–related stress relative to NHW persons [7]. Recent data from April 27 to May 9, 2022, indicate that 31.2% of Black and 34.7% of Hispanic individuals report current symptoms of an anxiety or depressive disorder [8]. These estimates are in stark contrast to the estimated 11.3% of Black and 10.3% of Hispanic individuals who reported symptoms of an anxiety or depressive disorder prior to the COVID-19 pandemic from January to July 2019 [8]. Although NHW individuals experience comparable, albeit slightly lower, rates of anxiety or depression (30.0% from April 27 to May 9, 2022) [8], the racial/ethnic disparity gap for mental health outcomes is widening. To illustrate, data from January to July 2019 found a 0.2%–1.2% difference in elevated anxiety or depression symptoms between NHW and Black and Hispanic persons, with NHW individuals evincing higher prevalence rates of these symptoms (11.5%) [8]. The inverse pattern is now prevalent, with Black and Hispanic persons reporting higher rates of these symptoms by 1.2%–4.7% [8,9]. Although postpandemic onset mental health data for American Indians in the United States is lacking, American Indian community leaders have expressed continued concern for the health of their constituents, given their propensity for worse physical and mental health outcomes related to COVID-19 [10,11]. Pre-existing inequities related to social determinants of health (eg, lower access to mental health care and therefore less treatment engagement [12,13]) and the effects of racism [14] have likely contributed to and exacerbated these disparities and may compound the severity of emerging COVID-19–related mental health disparities [7]. Emerging COVID-19–related disparities in mental health symptoms are likely to widen without proper early intervention tactics.

The ongoing COVID-19 pandemic has led to increases in stress, including stress related to unemployment, homelessness, food insecurity, and lack of adequate health care resources. The COVID-19 stress burden may have a particularly pernicious influence in persons already struggling with greater stress exposure and pre-existing psychopathology [15]. Theoretically, higher degrees of COVID-19 stress may influence patterns of social, emotional, and neurobiological development, facilitating the rapid detection of potential threats, and, by extension, increase the risk for multiple forms of psychopathology. A transdiagnostic approach to intervention development and deployment could serve as an effective treatment method. This approach relies on identifying the fundamental processes underlying multiple psychopathologies [16] and may be particularly effective and efficient at mitigating emerging mental health disparities arising from the pandemic.

Anxiety sensitivity (AS), defined as the fear of anxiety symptoms, including bodily sensations [17], has been identified as a key vulnerability factor for anxiety [17-20], depression [21-23], substance use [24-26], and other psychopathology symptoms [27-29]. Theoretical models posit that individuals with high AS are more likely to attend to bodily sensations that are associated with anxiety, such as respiratory symptoms, stomach distress, fatigue, and body aches, and to misinterpret these symptoms as dangerous or catastrophic [30,31]. These interpretations of bodily sensations can lead to increased anxiety and perpetuate a cycle of increased attention to and misinterpretation of bodily cues [31-33]. This process may eventually lead to avoidance and increased symptoms of anxiety, stress, and depression, with potential to exacerbate stress on the body systems, further compromising the immune system and placing certain individuals at greater risk for more severe psychopathology [34]. This maladaptive cycle may be particularly relevant to BHAIs during and following the pandemic, given their increased likelihood of COVID-19 exposure [5,35-39], challenges with enacting behaviors to reduce the likelihood of infection, concerns about the increased likelihood of worse outcomes if infected, and greater pandemic-related stressors (eg, job loss [40], income reduction [41-43], childcare needs [44,45], and discrimination). Further, because it has been shown previously that some minority groups experience higher levels of distress expressed somatically [46],
AS is particularly relevant because it could amplify the threat response to somatic perturbation.

Importantly, AS is malleable in response to psychosocial interventions [47], making it a prime mechanism to target in prevention/intervention programs. Reductions in AS improve clinical outcomes among clinical and nonclinical populations [47], reductions in AS have been shown to be associated with positive outcomes in smokers who are motivated to quit [48], and AS can be effectively engaged through in-person and digitally delivered methods [49,50]. This is a critical consideration, given the overwhelming stress that the pandemic has placed on the health care system and the current paradigm shift toward providing care remotely [51,52]. In the context of mental health, digital health (eg, mobile health [mHealth]), telemedicine/telehealth, and health IT (eg, mobile phones, wearable sensors) can be used to develop scalable interventions that offer mental health care that is personalized to meet the unique needs of patients [53-55] and thus reduce the burden on the health care system. Indeed, mHealth interventions have strong potential for a broad reach, high accessibility, and widespread dissemination and serve as a potential vehicle to provide access to evidence-based mental health treatments.

A recent meta-analytic review found that mHealth interventions for anxiety and depression reduction may lead to significant within-person reductions in anxiety and depression, and the reduction in anxiety was greater than what was reported by control participants [56]. The majority of the reviewed mHealth apps (67%), however, focused on strict cognitive behavioral therapy (CBT) and did not consider the potential of using a transdiagnostic approach to negative affective symptom reduction. Using an mHealth framework to deliver mHealth AS reduction treatment could address both individual- and system-level barriers to accessing effective mental health treatment during and after the pandemic and result in reduced anxiety and depressive symptoms by effectively engaging an underlying mechanism implicated in both conditions.

This study capitalizes on our expertise in mHealth interventions, mental health treatments, and health disparities research. We propose to test an accessible mHealth AS reduction treatment that incorporates a just-in-time treatment approach to address the mental health sequelae resulting from the COVID-19 pandemic. The primary aim of this study is to test the effects of a novel, smartphone-delivered intervention (Easing Anxiety Sensitivity for Everyone [EASE]) aimed at reducing mental health disparities across racial/ethnic minority groups that have been exacerbated by the COVID-19 pandemic in a large, racially/ethnically diverse sample of adults with clinically significant anxiety or depression. The comparison condition is a time-matched real-world treatment (mindfulness/relaxation-based therapy). Our primary outcomes are reductions in anxiety and depression symptoms and functional impairment at 3 and 6 months postrandomization. Recognizing the clinical importance of mechanistic research to optimize interventions [40], we will also examine putative mechanisms (eg, AS and COVID-19–specific stress and fear) of the intervention effects. Moreover, as treatment effects may differ across sociocultural factors, perceived discrimination, social support, and socioeconomic status (SES; indexed by monthly income) will be evaluated as potential moderators of treatment effects on the primary outcomes.

Methods

Ethical Considerations

All participants provide written informed consent electronically after reviewing consent documents with research staff. To protect participant privacy and confidentiality, phone-based appointments are completed by research staff in a secure office at 1 of the 2 collaborating sites. Additionally, participants are assigned an ID number that is used to identify their data throughout the study. Only trained research staff have access to the key that can match participant data to the participant’s name. The key is password-protected on a secure server housed at the collaborating institutions. Participants are compensated up to US $410 for participating in the study and receive compensation via a GreenPihre [57] Mastercard gift card that is loaded by research staff. The Institutional Review Board (IRB) at the University of Houston approved the study (IRB approval no. STUDY00002802) and serves as the Relying IRB for all sites under the National Institutes of Health (NIH) Single IRB policy, and a Data Safety and Monitoring Board provides ongoing oversight.

Study Design

Adults who report clinically significant anxiety or depression (N=800; racial breakdown: n=200, 25%, Black/African American; n=200, 25%, Hispanic; n=200, 25%, American Indian; and n=200, 25%, NHW individuals) are being recruited American; n=200, 25%, Hispanic; n=200, 25%, American Indian; and n=200, 25%, NHW individuals) are being recruited to complete the baseline assessment. Participants who do not own a smartphone that is compatible with the Insight app [60] are mailed a study phone and contacted by study staff once the study phone arrives. Following completion of the baseline assessment, research staff contact participants to schedule their randomization phone call. During the randomization call, research staff randomly assign the participant to either the (1) EASE or the (2) mindfulness/relaxation-based comparison intervention for 6 months following randomization. Participants complete follow-up assessments at 3 and 6 months postrandomization, which includes self-report measures, and a randomly selected subset of the sample completes a qualitative interview focused on app use and experiences with the app. Additionally, participants are prompted to complete ecological
momentary assessments (EMAs) twice daily throughout the 6-month postrandomization period. See Figure 1 for the participant flow diagram.

Figure 1. Participant flow diagram.

Specific Aims and Hypotheses
This study has 2 specific aims:

- To use a randomized controlled trial (RCT) design to compare the effects of EASE to a mindfulness/relaxation-based comparison group on anxiety and depression symptoms, and functional impairment at 3-month and 6-month follow-up. We hypothesize that those assigned to EASE will show greater reductions from baseline to follow-ups in OASIS [58] and ODSIS [59] scores and also greater reductions in functional impairment in daily responsibilities (eg, work performance, household maintenance, social interactions, and relationships) [61] relative to the comparison group (hypothesis 1 [H1]). We also hypothesize that the effectiveness of EASE (as assessed by slope changes from baseline to follow-ups in outcomes listed in H1) will be similar across racial/ethnic groups (H2).

- To examine the mechanisms of action at 3- and 6-month follow-ups (H3) and moderators of treatment outcomes at 3- and 6-month follow-ups (H4). In testing the putative mechanisms of action, we hypothesize that the intervention effects on study outcomes will be mediated by reductions in AS and changes in COVID-19–related stress and fear. To determine possible moderators, we will test whether treatment effects vary as a function of perceived discrimination (worse intervention outcomes), social support (better intervention outcomes), or SES (lower SES associated with worse outcomes).

This study has 2 exploratory aims:

- To use daily EMAs to obtain a granular understanding of the course (eg, changes in anxiety/depression symptoms and fear of COVID-19) and sequelae (eg, employment status, daily activities, substance use) of the COVID-19 pandemic and health behaviors affected by COVID-19 (ie, physical activity, pain experience, sleep) among those who do and do not contract the virus

Participants
Participants will be 800 adults (n=200, 25%, Black/African American; n=200, 25%, Hispanic; n=200, 25%, American Indian; and n=200, 25%, NHW individuals) who report current clinically significant anxiety or depression. All participants must meet the following eligibility criteria: (1) have clinically significant anxiety or depression symptoms, as evinced by a score of 8 or higher on OASIS [58] or a score of 8 or higher on ODSIS [59]; (2) be aged 18 years or older; (3) self-identify as Black, Hispanic, American Indian, or NHW (singular or multiracial identification); (4) be willing to complete all study surveys/assessments; and (5) score 4 or more on the Rapid Estimate of Adult Literacy in Medicine-Short Form (REALM-SF) indicating an English literacy level higher than the sixth grade. Exclusion criteria include the following: (1) identifying with a race/ethnicity for which the corresponding study cell has been filled, (2) significant cognitive impairment evinced by a score of 8 or higher on the 6-Item Cognitive Impairment Test (6CIT) [62], and (3) inability to read or understand English at the sixth-grade or higher level.

Procedures
Enrollment to the RCT began in December 2021 and, as of this writing, is in the recruitment phase. Enrollment, randomization, intervention delivery, and assessments (EMAs and follow-ups) are completed remotely via a smartphone or phone call with
trained research staff. Both study conditions receive the same set of questionnaires at each assessment (see Tables 1 and 2 for a full list and timeline of study measures). These questionnaires assess anxiety or depression symptoms, functional impairment, general and COVID-19–specific affect constructs, and sociocultural factors.

Interested individuals complete an initial 5-minute online screener via Research Electronic Data Capture (REDCap; Vanderbilt University) to assess age, racial/ethnic identity, clinical anxiety and depression, state of residence, and willingness to complete study assessments. Those deemed eligible at the online screener complete an enrollment call with research staff that lasts approximately 30 minutes. During the enrollment call, participants provide informed consent and are informed of the purpose, goals, and procedures of the study. Participants are also further assessed for eligibility (ie, English literacy and fluency, and cognitive impairment). Those found eligible are instructed on how to download the smartphone-based app that will administer assessment and intervention content (ie, Insight app) during the enrollment call. Eligible participants who do not have a smartphone that is compatible with the study app are mailed a study smartphone to use during study participation and are contacted by study staff once the phone is received. After participants download the study app to their personal or study-provided phone, they are oriented on how to use the app to complete the baseline assessment and instructed to complete it within the next 7 days. The smartphone-based baseline assessment takes approximately 20 minutes to complete. Participants who have not completed the baseline assessment within 48 hours are contacted by study staff via text, phone, or email to remind them to complete the assessment.

Table 1. List and timeline of study measures.

| Measure                                                      | Screener | Enrollment | Baseline | Follow-ups |
|--------------------------------------------------------------|----------|------------|----------|------------|
| Demographic Questionnaire                                    | X^a      | N/A^b      | X        | N/A        |
| 6CIT^c [62]                                                  | N/A      | X          | N/A      | N/A        |
| REALM-SF^d [63]                                              | N/A      | X          | N/A      | N/A        |
| Demographic/Background Information Questionnaire             | X        | N/A        | N/A      | N/A        |
| Functional Impairment Related to Anxiety and Depression      | N/A      | N/A        | X        | X          |
| EDS^e [64]                                                   | N/A      | N/A        | X        | X          |
| CRBS^f [65]                                                  | N/A      | N/A        | X        | X          |
| F-SozU K-6^g [66]                                            | N/A      | N/A        | X        | X          |
| OASIS^h [58]                                                 | X        | N/A        | X        | X          |
| ODSIS^i [59]                                                 | X        | N/A        | X        | X          |
| SSASI^j [67]                                                 | N/A      | N/A        | X        | X          |
| Fear of COVID-19 [68]                                         | N/A      | N/A        | X        | X          |
| COVID-19 Psychological Impact Survey                         | N/A      | N/A        | X        | X          |

^aX: applicable.
^bN/A: not applicable.
^c6CIT: 6-Item Cognitive Impairment Test.
^dREALM-SF: Rapid Estimate of Adult Literacy in Medicine-Short Form.
^eEDS: Everyday Discrimination Scale.
^fCRBS: Coronavirus Racial Bias Scale.
^gF-SozU K-6: 6-Item Perceived Social Support Questionnaire.
^hOASIS: Overall Anxiety Severity and Impairment Scale.
^iODSIS: Overall Depression Severity and Impairment Scale.
^jSSASI: Short-Scale Anxiety Sensitivity Index.
Table 2. List and timeline of EMAs\(^a\).

| Assessment                                | Daily diary | Sunday morning diary | Report distress | COVID-19 symptoms |
|-------------------------------------------|-------------|----------------------|-----------------|-------------------|
| Sleep                                     | X\(^b\)     | N/A\(^c\)            | N/A             | N/A               |
| Alcohol consumption                       | N/A         | N/A                  | N/A             | N/A               |
| Cigarette consumption                     | X           | N/A                  | N/A             | N/A               |
| Marijuana use                             | X           | N/A                  | N/A             | N/A               |
| Fast-food consumption                     | X           | N/A                  | N/A             | N/A               |
| Other substance use                       | X           | N/A                  | N/A             | N/A               |
| SSASI\(^d\)                               | X           | N/A                  | N/A             | N/A               |
| Prescription medication consumption       | X           | N/A                  | N/A             | N/A               |

**Discrimination experience**

|                                |            |                     |                 |                  |
|--------------------------------|------------|---------------------|-----------------|------------------|
| Affect                         | X          | N/A                 | X               | N/A              |
| Pain level                     | X          | N/A                 | X               | N/A              |
| Ability to cope with stress   | X          | N/A                 | X               | N/A              |
| Social support                | X          | N/A                 | N/A             | N/A              |
| Physical activity             | X          | N/A                 | N/A             | N/A              |
| Location                      | N/A        | N/A                 | X               | N/A              |
| Self-rated health questionnaire| N/A        | X                   | N/A             | N/A              |
| OASIS\(^e\)                   | N/A        | X                   | N/A             | N/A              |
| SSASI                         | N/A        | X                   | N/A             | N/A              |
| Current COVID-19 symptoms     | N/A        | N/A                 | N/A             | X                |
| Exposure to someone with COVID-19| N/A       | N/A                 | N/A             | X                |

\(^a\) EMA: ecological momentary assessment.
\(^b\) X: applicable.
\(^c\) N/A: not applicable.
\(^d\) SSASI: Short-Scale Anxiety Sensitivity Index.
\(^e\) OASIS: Overall Anxiety Severity and Impairment Scale.

Research staff are automatically notified via an encrypted email once a participant completes the baseline assessment. Once notified, research staff call the participant and complete the randomization process with the participant. During the randomization call, participants are randomly assigned to an intervention condition: (1) EASE or (2) mindfulness-based comparison; see Table 3 for a comparison of treatment components. Specifically, participants are randomized using permuted block randomization to allocate them to a treatment condition within each racial/ethnic category (EASE=100, 12.5%, per racial/ethnic group; mindfulness/relaxation-based comparison=100, 12.5%, per racial/ethnic group). The study statistician (author MWG) set up the randomization schema tables (stratified by racial/ethnic identity and sex assigned at birth) in REDCap and has no contact with participants, thereby preventing experimenter bias in randomization. Only the study project manager can see and access the tables once uploaded to REDCap; all other study team members use the REDCap randomization module, which hides the allocation until randomization is prompted.

Following randomization, research staff provide participants with a code that enables them to access condition-specific intervention materials. Next, trained research staff provide a brief app orientation to the participant on how to use the app and its components, and answer any questions the participant may have. Research staff also provide a brief orientation on how to report distress and COVID-19 symptoms via the app (both groups). The day after the randomization call, all participants begin to receive 2 prompts to complete daily EMAs, one 30 minutes after waking and one 75 minutes before bedtime. Daily EMAs take approximately 2 minutes to complete. Research staff monitor participant EMA completion rates weekly. When a participant’s completion rate significantly decreases, a staff member contacts the participant via text, phone, or email to remind them of the importance of completing the daily EMAs. Participants are informed that they can contact study staff at any point during the trial by pressing the “Call Staff TX” button at the top of the app home screen if they experience technical difficulties (see Figure 2). Participants are encouraged to use the app daily for 6 months, particularly when they are experiencing distress.

Participants complete follow-up smartphone-based, self-report assessments at 3 and 6 months postrandomization. Additionally, research staff contact participants selected through a modified
quota sampling strategy \cite{69} at 3 and 6 months postrandomization to complete a brief qualitative interview to assess their experience with the app and to solicit suggestions on ways to improve the app content, delivery, or reach potential. The qualitative interview uses a semistructured interview guide and is audio-recorded for transcription. The 3- and 6-month self-report assessments each require approximately 20 minutes to complete, and the 3- and 6-month qualitative interviews take approximately 30 minutes to complete. Data gathered through the qualitative interviews will be used to identify opportunities to improve the efficacy, reach, and adoption of the EASE app.

Regarding compensation, all participants who enroll in the study receive a GreenPhire \cite{57} Mastercard gift card to facilitate paying them for completing study surveys. GreenPhire offers an auditable mechanism for all study payments. Participants receive US $20 for completing the baseline assessment and US $50 for completing each of the 3- and 6-month follow-ups. Additionally, participants are compensated for completion of EMAs (2 per day × 30 days = 60 monthly EMAs). Specifically, those who complete 50%-74% of prompted EMAs each month receive US $20, those who complete 75%-89% of assessments receive US $30, and those who complete 90% or more of their EMAs receive a total of US $40 for that month. Participants can click the “Payment” button on the app home screen at any time for an up-to-the-moment summary of EMAs presented and completion rate (see Figure 2). Payments for completing EMAs are loaded onto GreenPhire cards each month. Participants are not compensated for accessing on-demand app features or completing treatment components. Following completion of study participation, participants who borrowed a study smartphone are mailed a prepaid envelope and instructed to return the phone.

| Table 3. Comparison of treatment components. |
|---------------------------------------------|
| **App components**                          |
| EMA\(^b\)                                   |
| Distress reporting                          |
| App instructions                            |
| AS\(^d\) psychoeducation                    |
| Interoceptive exposure exercises            |
| **On-demand tips and exercises**            |
| General relaxation tips                     |
| Coping with mood                            |
| Coping with stress and anxiety              |
| Coping with COVID-19                        |
| Coping with loss and grief                  |
| Coping with discrimination                  |
| Videos for distraction                      |
| Interoceptive exposure                      |
| Guided relaxation exercises                  |
| Inspirational messages                      |
| Challenge unhelpful thoughts                |
| Tailored treatment messages in real time    |
| State and national resources for needs      |
| Compensation earned                         |
| **EASE\(^a\)**                             |
| X                                           |
| X                                           |
| X                                           |
| X                                           |
| X                                           |
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\(^a\)EASE: Easing Anxiety Sensitivity for Everyone.
\(^b\)EMA: ecological momentary assessment.
\(^c\)X: applicable.
\(^d\)AS: anxiety sensitivity.
\(^e\)N/A: not applicable.
Event-sampling EMAs are self-initiated by the participant. Specifically, all participants are instructed to self-initiate an event-sampling EMA to record distress and new COVID-19 symptoms. Participants are instructed to answer questions based on immediate thoughts/feelings when they initiate an event-sampling EMA. EASE participants receive unique intervention content when they report elevated depression or anxiety symptoms. Further, our previously developed COVID-19 risk assessment and detection algorithm [70] automatically advises participants in both conditions to get a test for COVID-19 when elevated risk is detected. In addition, the app immediately triggers an automated and encrypted email to study staff to call the participant and assist with obtaining a COVID-19 test (if desired by the participant). All EMAs are date-, time-, and location-stamped for future analyses.

Study Conditions

Easing Anxiety Sensitivity for Everyone

EASE integrates standard CBT with AS reduction. EASE provides (1) standard treatment on a schedule, (2) scheduled and cued interoceptive exposure sessions, (3) on-demand intervention content (ie, ways to cope with symptoms of anxiety and depression, cognitive restructuring exercises, guided relaxation videos), (4) tailored treatment messages based on responses to EMA items, and (5) additional resources. All interactions with the app are date-, time-, and location-stamped for future analyses.

Treatment on a Schedule

EASE includes 18 four- to six-minute intervention videos (adapted from our previous interventions [71-75] and recorded by racially/ethnically diverse actors) that are delivered via a smartphone over the first 3 months of the intervention period. Specifically, new videos become available during the morning daily EMAs on Mondays and Thursdays. Participants have the option to watch the videos immediately or later by clicking the “Treatment Videos” button (see Figure 2). Videos can be watched as many times as desired, and the app records the date/time/location when each video is watched (both initiation and completion).

The videos cover topics including the role of AS in interoceptive stress, the CBT model of anxiety/depression and interoceptive stress, procedures for each intervention module, coping mechanisms for negative emotions (eg, chronic stress due to sociocultural stressors), fear avoidance hierarchy for specific stressors (eg, bodily stress or stress burden due to experiences of racism or discrimination), interoceptive exposure techniques, the relationship between COVID-19 and anxiety/depression, and use of AS reduction strategies to mitigate the impact of COVID-19–related stress on mental health. Videos also present known disparities regarding COVID-19 and the potential impact on mental health disparities. Finally, several videos focus on relaxation training to help mitigate the impact of stress related to discrimination, general life events, and COVID-19–specific stressors on heightened symptoms of anxiety and depression. See Table 4 for a list of video titles.
Table 4. List of video titles.

| EASEa group | Title                           | Active comparison group | Title                            |
|-------------|--------------------------------|-------------------------|----------------------------------|
| Video number| Title                          | Video number            | Title                            |
| 1           | Introduction to the Program    | 1                       | What Is Mindfulness              |
| 2           | CBTb Model & Example           | 2                       | Mindfulness vs Meditation        |
| 3a          | General Stressors              | 3                       | Levels of Mindfulness            |
| 3b          | Race/Discrimination Stressors  | 4                       | The WHAT Skills                  |
| 4           | ASic & Interoceptive Stress    | 5                       | The HOW Skills                   |
| 5           | Interoceptive Exercises        | 6                       | Living Mindfully                 |
| 6           | Present-Focused Exercise       | 7                       | Mindfulness and Acceptance       |
| 7           | Interoceptive Exercises (CON’TD)| 8                       | Diaphragmatic Breathing Exercise |
| 8           | Unhelpful Thinking             | 9                       | Body Scan Exercise               |
| 9           | Thinking Flexibly              | 10                      | Walking Mindfully Exercise       |
| 10          | Avoidance & Exposure           | 11                      | Eating Mindfully Exercise        |
| 11          | Opposite Action                | 12                      | Sleep and Mindfulness Exercise   |
| 12          | Diaphragmatic Breathing        | 13                      | Science of Mindfulness           |
| 13          | Values                         | 14                      | 5-4-3-2-1                       |
| 14          | Grief/Loss and Control         | 15                      | STOP Practice                    |
| 15          | Grounding                      | 16                      | Leaves on a Stream               |
| 16          | Self-Care & Compassion         | N/A                     | N/A                              |
| 17          | Review Video                   | N/A                     | N/A                              |
| 18          | Next Steps                     | N/A                     | N/A                              |

aEASE: Easing Anxiety Sensitivity for Everyone.
bCBT: cognitive behavioral therapy.
cAS: anxiety sensitivity.
dN/A: not applicable.

Exposure Exercises

To target AS, graduated exposure to anxiety and distress-provoking situations and response prevention is introduced, reviewed, and practiced via EASE videos and the “Stress Management Trainings” button. Participants learn to manage negative affect, stress, and uncomfortable physiological symptoms during exposure exercises without acting on acute motivation to suppress distress. These exposure exercises were created and pilot-tested as part of our previous work on smartphone-delivered AS reduction [72]. The exercises include overbreathing, straw breathing, running in place, chair spinning, and head rush. EASE participants are reminded to practice the interoceptive exercises during treatment videos and are asked whether they would like to practice stress management training 2 times per day (during morning and evening EMAs). Participants can access the exposures by clicking the “Stress Management Trainings” button on the app home screen (see Figure 2). When this button is clicked, the app explains the purpose of the exercise and assesses the current level of distress (0-100 scale) and physical sensations (1-7 scale). Next, the app randomly selects 1 of the 5 exercises and explains how to complete it. A 1-minute countdown timer is initiated, and the participant completes the exercise. Following the exercise, the app reassesses the level of distress and physical sensations. The app suggests repeating the exercise up to 3 additional times if the current reported distress is greater than 50 on a 1-100 scale. This strategy aims to increase habituation to feared sensations. Participants are encouraged to continue practicing these exposures daily.

On-Demand Features

Participants have access to a “Coping Toolkit” menu of on-demand intervention content (see Figure 3). Specifically, participants can access (1) suggestions on ways to cope with stress and anxiety, (2) guided relaxation exercise videos, (3) exercises focused on challenging automatic thoughts, (4) suggestions for coping with COVID-19–related stress, (5) coping with loss and grief, (6) coping with discrimination, and (7) coping with sadness and depression. In addition, participants are instructed to click the “I’m Bored, Distract Me” button to gain access to brief funny or cute videos. Further, participants are prompted to press the “Report Distress” button when they experience elevated stress, anxiety, or depression (see Figure 2). The Report Distress assessment includes questions about mood and feelings, and the app provides tailored content based...
on current anxiety, depression, and self-reported ability to cope with current emotions. The “Report COVID-19 Symptoms” button assesses symptoms that are consistent with COVID-19. When symptom clusters that are consistent with COVID-19 are reported, participants are informed that they should get tested and asked whether they would like help with finding a testing center. An encrypted email is sent to study staff in real time when participants report symptoms consistent with COVID-19. The “Additional Resources” button contains links to state and federal resources focused on COVID-19, housing, food, and job placement.

Figure 3. “Coping Toolkit” menu of on-demand intervention content.
self-report, with the exception of the REALM-SF [63] and the 6CIT [62], which are administered via interviews during the enrollment phone call. See Tables 1 and 2 for a schedule of study measures.

Demographics and Screener Questions

Participants are asked to provide standard demographic information (ie, name, contact information, age, sex, race/ethnicity, monthly income used as a measure of the SES [79-83], level of education), current state of residence, comfort with the English language, information about the type of phone they have, and whether they would like to download the app to their personal phone or be provided with a phone with the app predownloaded to it.

English Literacy

The REALM-SF [63] is an interviewer-administered checklist in which individuals are asked to read and pronounce 9 common medical terms. Individuals who pronounce ≤4 words correctly are considered to be reading at a reading level higher than the sixth grade (an English literacy level higher than the sixth grade is required to complete EMAs). The REALM-SF is administered by trained research staff during the enrollment call.

Cognitive Functioning

The 6CIT is a brief cognitive function test that takes less than 5 minutes to complete and is widely used in primary care settings [62]. The scale uses an inverse score, and questions are weighted to produce a total out of 28. Participants with scores in the normal range (ie, 0-7) are eligible for study participation. Individuals with scores of 8 or higher (ie, mild-to-severe impairment) are excluded from participating in this study.

Anxiety

OASIS [58] is a 5-item measure that has demonstrated strong psychometric properties to identify those with clinically significant anxiety symptoms [58]. A score of 8 or higher is indicative of clinically significant anxiety. OASIS is administered during the REDCap prescreen (to screen for eligibility), baseline assessment, and 3- and 6-month postrandomization assessments.

Depression

ODSIS [59] is a 5-item measure that has demonstrated strong psychometric properties to identify those with clinically significant depression symptoms [59]. A score of 8 or higher is indicative of clinically significant depression. ODSIS is administered during the REDCap prescreen (to screen for eligibility), baseline assessment, and 3- and 6-month postrandomization follow-up assessments.

Functional Impairment

The research team developed items to assess functional impairment related to experiencing anxiety and depression. These items assess the extent to which a person’s relationships, work performance, household maintenance, and social interactions have been negatively affected by depression and anxiety. These items are administered at baseline and 3- and 6-month postrandomization follow-up assessments.

Anxiety Sensitivity

The Short-Scale Anxiety Sensitivity Index (SSASI) [67] is a 5-item brief measure of AS derived from the Anxiety Sensitivity Index-3 (ASI-3) that has demonstrated excellent psychometric properties. The SSASI is administered at baseline and 3- and 6-month postrandomization follow-up assessments.

COVID-19–Related Stress and Fear

The Fear of COVID-19 [68] scale is a 6-item validated measure to assess emotional fear and the somatic expression of fear related to COVID-19. The COVID-19 Psychological Impact Survey is a 4-item self-report measure of the psychological impacts of COVID-19 and associated risk factors [84]. The survey asks (1) the extent to which participants agree with the statement “I worry about the coronavirus all of the time” (1=strongly disagree to 7=strongly agree), (2) how sad participants feel when they think about coronavirus (0=not at all to 100=extremely), (3) how stressed participants feel when they think about coronavirus (0=not at all to 100=extremely), and (4) the degree to which the participant is stressed due to the COVID-19 pandemic (0=no stress to 100=extreme stress). The Fear of COVID-19 and COVID-19 Psychological Impact Survey measures are administered at baseline and 3- and 6-month postrandomization follow-up assessments.

Perceived Discrimination

The Everyday Discrimination Scale (EDS) [64] is a 6-item validated measure of discrimination. The Coronavirus Racial Bias Scale (CRBS) [65] is a 9-item Likert-type scale designed to assess disparities in COVID-19, including the likelihood of contracting COVID-19, lack of appropriate health care, and viewing negative social media posts against certain racial groups. Both measures are administered at baseline and 3- and 6-month postrandomization follow-up assessments.

Social Support

The 6-Item Perceived Social Support Questionnaire (F-SozU K-6) [66] is a self-report measure of the perceived availability of social support [66]. This measure is administered at baseline and 3- and 6-month postrandomization follow-up assessments.

Ecological Momentary Assessments

The EMA methodology used for this study is similar to that used in our previous studies and by other researchers [74,75,85-95]. Each EMA asks about current emotional, physical, and behavioral symptoms and takes approximately 2 minutes to complete. Two types of EMAs are used: time-based sampling (ie, daily diary) and event sampling. Time-based EMAs are prompted and initiated by the smartphone 2 times per day during the 6-month study period (ie, morning daily diary 30 minutes after the participant’s preset wake time, end-of-day daily diary 75 minutes before the participant’s preset bedtime). The phone rings and vibrates to cue these EMAs for 5 minutes (ie, alternating between 30-second alerting and silence periods). If the participant does not respond to the daily diary prompts, the EMA is automatically rescheduled (up to 3 times during morning assessments and twice during evening assessments) 15 minutes later. EMA questions ask about current symptoms of anxiety and depression, medication use, current

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thoughts/affect/behaviors, social support, discrimination experiences, sleep quality, substance use, fast-food consumption, current location, fear of COVID-19, employment status, daily activities, and current COVID-19 symptoms. Participants are asked to rate their emotional state by indicating the extent to which they agree or disagree with each of 15 statements (using a 5-point scale from strongly disagree to strongly agree): I feel stressed, happy, angry, tired, afraid, relaxed, sad, bored, worried, lonely, calm, depressed, overwhelmed, energetic, and anxious (from the circumplex model of affect) [96]. Participants also indicate their current environment/social setting. In addition, participants are prompted to watch treatment videos twice per week (“A great way to get your day started is to watch a NEW short video that provides information and tips for handling stress. Would you like to watch the brief new video now? Note: Each video provides new information.”) and complete stress management exercises in the app (“Would you like to complete an exercise right now?”).

**Data Analysis**

**Overview**

Hypotheses for aims 1 and 2 will be examined using latent growth models (LGMs) [97], multilevel structural equation models (MSEMs) [98], and latent difference score models [99] using MPlus 8.0 [100]. Data will first be examined for multivariate normality and outliers to determine the most appropriate estimator. The maximum likelihood (ML) estimator will be used if data are approximately normal. Robust maximum likelihood (MLR) will be used if the data are not multivariate normal. LGMs will generally be used to model outcomes collected at major assessments. MSEMs will be used to further examine the longitudinal course of outcomes and hypothesized mechanisms of action as an MSEM is ideally suited for disentangling within and between individual variance in order to more precisely estimate main effects, lagged effects, and indirect effects in intensive longitudinal designs. Evaluation of the model fit in the LGMs/MSEMs will be examined using fit diagnostics (ie, standardized residuals) and common fit statistics (ie, root-mean-square error of approximation) following the associated cut-off criteria recommended by Hu and Bentler [101]. We will assess the equivalence of the treatment groups on key baseline variables (demographics and psychological variables); variables on which the groups differ will be used as covariates in the final analyses. We will also examine attrition from the study as a dichotomous outcome and use logistic regression to determine whether treatment assignment predicts attrition.

**Aims**

**Aim 1**

- **H1:** Participants randomized to the EASE intervention will have greater reductions in anxiety, depression, and functional impairment at 3- and 6-month follow-ups compared to those randomized to the mindfulness/relaxation-based comparison intervention. Multiple approaches to modeling changes in primary outcomes will be used to evaluate our hypothesis that the EASE app will result in greater reductions in the primary outcomes relative to the comparison app and that reductions will be similar across racial/ethnic groups. We will first estimate between-group differences by calculating Cohen d effect sizes (with a 95% CI) for anxiety, depression, and functional impairment at each major follow-up assessment. We will then conduct a series of conditional LGMs to examine the impact of the treatment condition on the trajectories of primary outcomes from baseline to the end of the follow-up period. First, an LGM will be specified using the assessments of primary outcomes at major assessments: baseline, 3 months, and 6 months. A dummy code representing the treatment condition will be included in the model as a predictor of the intercept and slope factors to quantify the effect of the EASE program on the longitudinal course of outcomes relative to the comparison group. The statistical significance (and magnitude of the effect size) of the main effect of treatment condition will test H1 (the EASE app will show greater reductions in anxiety [OASIS] and depression [ODSIS] symptoms and improved functional impairment). Separate models will be specified for anxiety, depression, and functional impairment.

- **H2:** Intervention effects of EASE relative to mindfulness/relaxation-based comparison will be equivalent across racial/ethnic groups. We will next conduct similar effect size and LGM analyses within each of the 4 racial/ethnic groups in order to test H2 (the effectiveness of EASE will be similar across racial/ethnic groups). We will then use MSEMs to examine the effects of the EASE app on the longitudinal course of outcomes, as measured by the EMA daily diary data. MSEM analyses will also be conducted both across and within the racial/ethnic groups to evaluate how effects vary across groups.

**Aim 2**

- **H3:** Intervention effects on study outcomes listed in aim 1 will be mediated by reductions in AS and changes in COVID-19–related stress and fear. Similar modeling procedures will be used to determine the impact of the treatment condition on AS and COVID-19–related stress and fear and whether improvements in primary outcomes are mediated by reductions in AS and the secondary mechanisms. We will first conduct separate LGMs for AS and the secondary mechanisms using methods such as those described for the primary outcomes. After conducting univariate LGMs to explore changes in AS and secondary mechanisms as a function of treatment condition, we will conduct a series of conditional process LGMs to examine how changes in AS and secondary mechanisms relate to changes in the primary outcomes. The effects of changes in AS and secondary mechanisms on changes in the primary outcomes will be examined by specifying the slope factor for each potential mechanism as a predictor of the slope factor for each outcome. Separate parallel process LGMs will be conducted for each primary outcome, and a series of parallel process LGMs will be evaluated to determine the unique effect of each mechanism when modeled simultaneously. The indirect effects of treatment on primary outcomes via AS and other potential mechanisms will be evaluated by calculated bootstrapped CIs of the indirect effect using the
MODEL indirect command in MPlus. These parallel process LGMs will not provide formal tests of mechanisms of change, as these models will be examining concurrent changes across the 6 months of assessment, but if the results from these models are promising, they will be followed by analyses that include the EMA measures of outcomes and mechanisms and will use models that permit more fine-grained examinations of temporal dependencies of change (ie, mediation models in SEMs and latent difference score models).

- H4: Perceived discrimination (worse intervention outcomes), social support (better intervention outcomes), or the SES (lower SES associated with worse outcomes) will moderate intervention effects on study outcomes listed in aim 1. The moderating influence of discrimination, social support, and SES will be evaluated using conditional LGMs in which condition, moderator, and conditionхmoderator interaction terms will be specified as predictors of the slope factor for primary outcomes using the XWITH command in MPlus. Separate models will be specified for each hypothesized moderator, and conclusions will be based on the CIs of the interaction terms.

Exploratory Aims
The brief qualitative interviews will be transcribed following completion and read to ensure accurate transcription. The transcribed interviews will be coded using NVivo v.12 (QSR International). The study team (2-3 project staff) will create the initial codebook and then code 2 interviews together. The codebook will then be revised (if needed), and a third interview will be coded as a team. If there is high coding agreement between team members, the remainder of the interviews will be coded independently by the staff and then checked by author MC. The team will meet to discuss any disagreements in coding and to create a final coded version for thematic analysis. Themes will be determined within and across codes. Comparisons will also be made across racial/ethnic groups and between the intervention and comparison groups. An additional team member will then review the coding and analysis for confirming and disconfirming evidence for the themes [102]. Participant responses will be integrated with quantitative usage data to identify inconsistencies in the participant’s perceptions and actual engagement with the app [103,104]. The team will make recommendations that can be used to improve app engagement and modifications for specific racial/ethnic groups. SEMs will then be used to further explore temporal patterns of COVID-19 outcomes and health behaviors using daily EMA data. Specifically, we will specify a series of models to examine interrelationships and concurrent and lagged effects among COVID-19 experiences (eg, treatments received, duration of symptoms), sequelae (eg, job loss, eviction, reduction in unemployment benefits), and health behaviors affected by COVID-19 (ie, physical activity, pain experience, sleep) among those who do and do not contract the virus.

Missing Data
We anticipate some participant attrition during the trial. Missing data will be handled in all analyses using direct ML techniques within MPlus under a missing-at-random (MAR) assumption [105]. Modern missing data techniques, such as direct ML, increase statistical power and provide more accurate estimates of model parameters and standard errors and are the recommended intent-to-treat approach for clinical trials.

Statistical Power
We calculated the sample size required to detect the treatment effect of EASE on the primary outcomes of anxiety, depression, and functional impairment at 3 and 6 months both across and within the racial/ethnic groups, the treatment effect of EASE on the longitudinal course of AS and secondary mechanisms, and the indirect effects of EASE on primary outcomes via the hypothesized mechanisms. Based on our pilot data and prior published research, we hypothesize moderate-to-large (d> .50) effects of EASE on primary outcomes and the hypothesized mechanisms and moderate-to-large associations (r>.30) between changes in mechanisms and primary outcomes. Power determinations based on these hypothesized effect sizes were conducted using GPower, RMASS [106], and simulation studies identifying the sample sizes needed to detect indirect effects [107]. Power analyses indicated that the targeted sample size of 200 participants for each of the 4 racial groups would yield greater than 80% power to detect effects for each study aim at α=.05, resulting in the overall target sample size of 800. Stratified block randomization was used to ensure equal allocation of adults across sex and racial/ethnic groups across treatment conditions.

Results
The study was funded by the National Institute of Mental Health (NIMH) in May 2021. The smartphone app was finalized in December 2021, and data collection began on December 22, 2021. Study staff have since been engaged in activities associated with study enrollment and data collection, including ordering and monitoring of gift cards and supplies; screening, consenting, and enrolling participants; dispersing intervention incentives; follow-up tracking/calls; maintaining an up-to-date Institutional Review Board (IRB) protocol and associated documents; and monitoring incoming data to identify and resolve problems early (ie, both EMA and traditional questionnaire data). As of June 17, 2022, 217 participants have been recruited into the study.

Discussion
Principal Results
Mental health disparities across racial/ethnic groups are projected to become more pronounced as a result of the COVID-19 pandemic [9]. Emerging evidence points to the utility of a digitally delivered, mobile transdiagnostic intervention that engages AS for ameliorating anxiety and depression [49]. Integrating theoretical and empirical models with a practical approach to treatment delivery, the proposed study aims to address emerging and downstream mental health disparities among BHAIP populations by testing whether our novel intervention (EASE) outperforms an active, credible comparison group. Data from this efficacy trial will determine whether EASE successfully improves symptoms of anxiety and depression.
depression and whether these improvements outperform an active comparison control app. If successful, EASE may be ready for implementation and dissemination into real-world behavioral health and social service settings consistent with the 4 objectives outlined in the NIH’s strategic plan [108]. Overall, this proposal has the potential to decrease anxiety and depression symptoms among all populations, including vulnerable populations determined to be most at risk of exacerbated, long-lasting negative health sequelae.

Notably, all study procedures are administered remotely. As such, this study may serve as a clinically important example for how to implement remote/virtual mental health research with BHAIs. Indeed, such flexible platforms for treatment delivery may have greater potential to reach and impact people of color, who constitute an underserved, hard-to-reach population. By providing a remote means of care, our study may be able to assist and assess a larger group of individuals who identify as BHAIs and remove potential barriers to treatment access, such as money needed to commute into the office/clinic or the need to take time off from work to attend appointments.

Limitations
One notable limitation of our study is the reliance on Android smartphones to complete assessments and access app features. Study-provided Android smartphones will be loaned to eligible participants upon request; however, those who are unwilling to use a study-provided smartphone or their own personal Android smartphone will be unable to participate in the study. Additionally, recruitment of older populations may be hindered due to the lack of appropriate knowledge and familiarity with mHealth apps [109]. This study will focus on enrolling individuals who identify as either Black/African American, Hispanic, American Indian/Alaska Native, or NHW; therefore, those who identify their racial/ethnic identity as an identity other than Black/African American, Hispanic, American Indian/Alaska Native, or NHW, such as identifying solely as Asian, Native Hawaiian, or Other Pacific Islander, will be excluded from the study. Given that these groups have faced elevated levels of xenophobia [110] and discrimination (eg, microaggressions, hate crimes) [111] due to the COVID-19 pandemic, it is important that these groups—and the unique issues they face—be addressed in the development of future interventions. The experimental group targets 1 transdiagnostic factor (AS); however, future research would benefit from evaluating other factors associated with COVID-19-related anxiety, distress, and disability. Further, although the app includes videos on the disproportionate effect the pandemic has had on BHAIs, the cultural tailoring of the app and its features (ie, tailored treatment messages, resources) would benefit from further development. Finally, we will conduct exploratory analyses of how the frequency/duration of app feature use may relate to outcomes. Given that all app features are available simultaneously, these exploratory analyses will be confounded by the potential effect of using other app features. Future work would benefit from conducting a dismantling study of EASE to understand the potential for each component to improve outcomes.

Conclusion
Ultimately, the goal of this study is to target and reduce emerging and likely exacerbated mental health disparities among BHAIs. We aim to fill a void surrounding mental health treatment among all groups but particularly BHAIs by developing a digitally delivered, mobile, easy-to-use treatment for anxiety and depression. By addressing comorbid anxiety and depression symptoms through an intervention that targets an underlying transdiagnostic vulnerability factor (eg, AS), we hope that this intervention will help adults with anxiety or depression to reduce their symptoms.

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Data Availability
The data sets generated and analyzed during this study will be available from the corresponding author on reasonable request following the completion of the trial and publication of the main outcomes paper. Deidentified data also will be made available via the National Institute on Mental Health (NIMH) Data Archive (NDA).

Conflicts of Interest
MSB and DEK are inventors of the Insight mobile health (mHealth) platform, and they receive royalties related to use of this platform by investigators external to the University of Oklahoma Health Sciences Center (OUHSC). However, because MSB is a multiple principal investigator (MPI) on this study, neither MSB nor DEK will receive royalties in this case.

References
1. Karaca-Mandic P, Georgiou A, Sen S. Assessment of COVID-19 hospitalizations by race/ethnicity in 12 states. JAMA Intern Med 2021 Jan 01;181(1):131-134 [FREE Full text] [doi: 10.1001/jamainternmed.2020.3857] [Medline: 32804192]
2. Centers for Disease Control and Prevention (CDC). Health Equity Considerations and Racial and Ethnic Minority Groups. 2020. URL: https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html [accessed 2022-11-22]

3. Centers for Disease Control and Prevention (CDC). Demographic Trends of COVID-19 cases and deaths in the US reported to CDC. 2020. URL: https://www.cdc.gov/covid-data-tracker/index.html#demographics [accessed 2022-11-22]

4. Centers for Disease Control and Prevention (CDC). COVID-19 Cases, Hospitalization, and Death by Race/Ethnicity. 2020. URL: https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-race-ethnicity.html [accessed 2022-11-22]

5. Yancy CW. COVID-19 and African Americans. JAMA 2020 May 19;323(19):1891. [doi: 10.1001/jama.2020.6548]

6. Centers for Disease Control and Prevention (CDC). COVIDView: A Weekly Surveillance Summary of U.S. COVID-19 Activity. 2020. URL: https://covid.cdc.gov/covid-data-tracker/#demographicscovertime [accessed 2022-11-22]

7. Fitzpatrick KM, Harris C, Drawe G. How bad is it? Suicideality in the middle of the COVID-19 pandemic. Suicide Life Threat Behav 2020 Dec 14;50(6):1241-1249 [FREE Full text] [doi: 10.1111/slbt.12655] [Medline: 32589799]

8. Centers for Disease Control and Prevention (CDC). Percentages of Selected Mental Health Indicators for Adults Aged 18 and Over, by Race and Hispanic Origin: United States, January-June 2019. 2020. URL: https://www.cdc.gov/nchs/data/nhs/earlyrelease/ERmentalhealthbyrace-508.pdf [accessed 2022-11-22]

9. Thomeer MB, Moody MD, Yahirun J. Racial and ethnic disparities in mental health and mental health care during the COVID-19 pandemic. J Racial Ethn Health Disparities 2022 Mar 22;1:1-16 [FREE Full text] [doi: 10.1007/s40615-022-01284-9] [Medline: 35318615]

10. Sandoiu A. The Effects of COVID-19 on the Mental Health of Indigenous Communities. 2020. URL: https://www.medicalnewstoday.com/articles/the-effects-of-covid-19-on-the-mental-health-of-indigenous-communities [accessed 2022-11-22]

11. Urbatsch D, Robledo J. Native American Groups Address Mental and Behavioral Health as COVID-19 Wears On. 2020. URL: https://cronkitenews.azpbs.org/202006/19/native-american-mental-health-coronavirus/ [accessed 2022-11-22]

12. SAMHSA. Double Jeopardy: COVID-19 and Behavioral Health Disparities for Black and Latino Communities in the U.S. (Submitted by OBHE). 2020. URL: https://www.samhsa.gov/sites/default/files/covid19-behavioral-health-disparities-black-latino-communities.pdf [accessed 2022-11-22]

13. Johnson JL, Cameron MC. Barriers to providing effective mental health services to American Indians. Ment Health Serv Res 2001 Dec;3(4):215-223. [doi: 10.1023/a:1013129131627] [Medline: 11859967]

14. Fortuna LR, Tolou-Shams M, Robles-Ramamurthy B, Porche MV. Inequity and the disproportionate impact of COVID-19 on communities of color in the United States: the need for a trauma-informed social justice response. Psychol Trauma 2020 Jul;12(5):443-445 [FREE Full text] [doi: 10.1037/trta0000889] [Medline: 32478545]

15. Lewis KJS, Lewis C, Roberts A, Richards NA, Evison C, Pearce HA, et al. The effect of the COVID-19 pandemic on mental health in individuals with pre-existing mental illness. BJPsych Open 2022 Mar 07;8(2):e59 [FREE Full text] [doi: 10.1192/bjop.2022.25]

16. Centers for Disease Control and Prevention (CDC). COVID-19 Cases, Hospitalization, and Death by Race/Ethnicity. 2020. URL: https://www.cdc.gov/coronavirus/2019-ncov/covid-data/hospitalization/data.html [accessed 2022-11-22]

17. Centers for Disease Control and Prevention (CDC). COVID-19 Data Tracker. 2020. URL: https://covid.cdc.gov/covid-data-tracker/index.html#demographics [accessed 2022-11-22]

18. Centers for Disease Control and Prevention (CDC). COVID-19 Cases, Hospitalization, and Death by Race/Ethnicity. 2020. URL: https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-race-ethnicity.html [accessed 2022-11-22]

19. Reiss S. Expectancy model of fear, anxiety, and panic. Clin Psychol Rev 1991 Jan;11(2):141-153. [doi: 10.1016/0272-7967(91)90092-9] [Medline: 20491001]

20. Schmidt NB, Lerew DR, Joiner TE. Anxiety sensitivity and the pathogenesis of anxiety and depression: evidence for symptom specificity. Behav Res Ther 1998 Feb;36(2):165-177. [doi: 10.1016/s0005-7967(98)80001-4]

21. Muris P, Schmidt H, Merckelbach H, Schouten E. Anxiety sensitivity in adolescents: factor structure and relationships to trait anxiety and symptoms of anxiety disorders and depression. Behav Res Ther 2001 Jan;39(1):89-100. [doi: 10.1016/s0005-7967(99)00179-5]

22. Olatunji BO, Wolitzky-Taylor KB. Anxiety sensitivity and the anxiety disorders: a meta-analytic review and synthesis. Psychol Bull 2009 Nov;135(6):974-999. [doi: 10.1037/a0017428] [Medline: 19883144]

23. Cox BJ, Enns MW, Freeman P, Walker JR. Anxiety sensitivity and major depression: examination of affective state dependence. Behav Res Ther 2001 Nov;39(11):1349-1356. [doi: 10.1016/s0005-7967(01)00106-6]

24. Cox BJ, Taylor S, W. Enns M. Fear of cognitive dyscontrol in relation to depression symptoms: comparisons between original and alternative measures of anxiety sensitivity. J Behav Ther Exp Psychiatry 1999 Dec;30(4):301-311. [doi: 10.1016/s0005-7967(99)00026-9]

25. Tull MT, Gratz KL. Further examination of the relationship between anxiety sensitivity and depression: the mediating role of experiential avoidance and difficulties engaging in goal-directed behavior when distressed. J Anxiety Disord 2008 Jan;22(2):199-210. [doi: 10.1016/j.janxdis.2007.03.005] [Medline: 17419002]

26. Stewart SH, Samoluk SB, MacDonald AB. Anxiety sensitivity and substance use and abuse. In: Taylor S, editor. Anxiety Sensitivity: Theory, Research, and Treatment of the Fear of Anxiety. Mahwah, NJ: Lawrence Erlbaum Associates; 1999:287-319.

27. Worden BL, Davis E, Genova M, Tolin DF. Development of an anxiety sensitivity (AS) intervention for high-AS individuals in substance use disorders treatment. Cogn Ther Res 2015 Jan 6;39(3):343-355. [doi: 10.1007/s10608-014-9666-0]
26. DeMartini KS, Carey KB. The role of anxiety sensitivity and drinking motives in predicting alcohol use: a critical review. Clin Psychol Rev 2011 Feb;31(1):169-177. [doi: 10.1016/j.cpr.2010.10.001] [Medline: 21074306]

27. Timpano KR, Buckner JD, Richey JA, Murphy DL, Schmidt NB. Exploration of anxiety sensitivity and distress tolerance as vulnerability factors for hoarding behaviors. Depress Anxiety 2009 Apr;26(4):343-353 [FREE Full text] [doi: 10.1002/da.20469] [Medline: 19123454]

28. Medley AN, Capron DW, Korte KJ, Schmidt NB. Anxiety sensitivity: a potential vulnerability factor for compulsive hoarding. Cogn Behav Ther 2013 Mar;42(1):45-55. [doi: 10.1080/1560677X.2012.738242] [Medline: 23505992]

29. Vujanovic AA, Farris SG, Bartlett BA, Lyons RC, Haller M, Colvonen PJ, et al. Anxiety sensitivity in the association between posttraumatic stress and substance use disorders: a systematic review. Clin Psychol Rev 2018 Jun;62:37-55. [doi: 10.1016/j.cpr.2018.05.003] [Medline: 29778929]

30. Drahovzal DN, Stewart SH, Sullivan MJL. Tendency to catastrophize somatic sensations: pain catastrophizing and anxiety sensitivity in predicting headache. Cogn Behav Ther 2006 Dec;35(4):226-235. [doi: 10.1016/j.cbt.2006.07.00898397] [Medline: 17189240]

31. Varela RE, Weems CF, Berman SL, de Bernal MCR. Internalizing symptoms in Latinos: the role of anxiety sensitivity. J Youth Adolesc 2007 Feb 13;36(4):429-440. [doi: 10.1007/s10964-007-9168-4]

32. Zvolensky MJ, McNeil DW, Porter CA, Stewart SH. Assessment of anxiety sensitivity in young American Indians and Alaska Natives. Behav Res Ther 2001 Apr;39(4):477-493. [doi: 10.1016/s0005-7967(00)00010-3]

33. Zvolensky MJ, Rogers AH, Bakhshaie J, Viana AG, Walker R, Mayorga NA, et al. Perceived racial discrimination, anxiety sensitivity, and mental health among Latinos in a federally qualified health center. Stigma Health 2019 Nov;4(4):473-479. [doi: 10.1037/sah0000160]

34. Glaser R, Kiecolt-Glaser J. Stress damages immune system and health. Discov Med 2009;5(26):165-169.

35. Mackey K, Ayers CK, Kondo KK, Saha S, Advani SM, Young S, et al. Racial and ethnic disparities in COVID-19–related infections, hospitalizations, and deaths. Ann Intern Med 2021 Mar;174(3):362-373. [doi: 10.7326/m20-6306]

36. Reitsma MB, Claypool AL, Vargo J, Shete PB, McCorvie R, Wheeler WH, et al. Racial/ethnic disparities in COVID-19 exposure risk, testing, and cases at the subcounty level in California. Health Aff (Millwood) 2021 Jun 01;40(6):870-878 [FREE Full text] [doi: 10.1377/hlthaff.2021.00098] [Medline: 33979192]

37. Centers for Disease Control and Prevention (CDC). What Is Health Equity?. 2022. URL: https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/racial-ethnic-disparities/index.html [accessed 2022-11-22]

38. Couch KA, Fairlie RW, Xu H. Early evidence of the impacts of COVID-19 on minority unemployment. J Public Econ 2020 Dec;192:104287 [FREE Full text] [doi: 10.1016/j.jpubeco.2020.104287] [Medline: 32952224]

39. Centers for Disease Control and Prevention (CDC). What Is Health Equity?. 2022. URL: https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/racial-ethnic-disparities/index.html [accessed 2022-11-22]

40. Gould E, Wilson V. Black Workers Face Two of the Most Lethal Preexisting Conditions for Coronavirus—Racism and Economic Inequality. 2020. URL: https://www.epi.org/publication/black-workers-covid/ [accessed 2022-11-22]

41. Hong S, Werner D. Economic Fallout from COVID-19 Continues to Hit Lower-Income Americans the Hardest. 2020. URL: https://www.pewresearch.org/social-trends/2020/09/24/economic-fallout-from-covid-19-continues-to-hit-lower-income-americans-the-hardest/ [accessed 2022-11-22]

42. Jeffrey CG, Cooper KM, DeWolfe J, Espiritu B, Hays R, Hwang S, et al. COVID-19 and racial/ethnic disparities: A report from the COVID-19 Racial/ethnic disparities workgroup. JAMA 2021 Mar 2;325(10):998-1008. [Medline: 33979192]

43. Clawson AH, Cole AB, Nwankwo CN, Blair AL, Pepper-Davis M, Ruppe NM. COVID-19 mental health impacts among Black workers: a systematic review. JAMA Netw Open 2020 Dec;3(12):e2029721. [Medline: 33349293]

44. Mishra V, Seyedzonoou G, Almohtadi A, Chowdhury T, Khashkhusha A, Axiาa G, et al. Health inequalities during COVID-19 and their effects on morbidity and mortality. J Healthc Leadersh 2021 Jan;13:19-26. [doi: 10.2147/jhl.s270175]

45. Gezici A, Ozay O. An intersectional analysis of COVID-19 unemployment. J Econ Race Policy 2020 Dec 15;3(4):270-281 [FREE Full text] [doi: 10.1007/s41996-020-00075-w] [Medline: 35300201]

46. Sheikh S, Furnham A. The relationship between somatic expression, psychological distress and GP consultation in two cultural groups. Couns Psychol Q 2012 Oct 31;25(4):389-402. [doi: 10.1080/09515070.2012.735860]

47. Otto M, Reilly-Harrington N. The impact of treatment on anxiety sensitivity. In: Taylor S, editor. Anxiety Sensitivity: Theory, Research, and Treatment of the Fear of Anxiety. The LEA Series in Personality and Clinical Psychology. Mahwah, NJ: Lawrence Erlbaum Associates; 1999:321-336.

48. Zvolensky MJ, Bogiaizian D, Salazar PL, Farris SG, Bakhshaie J. An anxiety sensitivity reduction smoking-cessation program for Spanish-speaking smokers (Argentina). Cogn Behav Pract 2014 Aug;21(3):350-363. [doi: 10.1016/j.cbpra.2013.10.005]

49. Papini S, Jacquet J, Zaizar ED, Telch MJ, Smits JA. Targeting anxiety sensitivity with evidence-based psychoeducation: a randomized waitlist-controlled trial of a brief standalone digital intervention. Cogn Behav Pract 2022 Apr:Online. [doi: 10.1016/j.cbpra.2022.04.001]
50. Keough ME, Schmidt NB. Refinement of a brief anxiety sensitivity reduction intervention. J Consult Clin Psychol 2012 Oct;80(5):766-772 [FREE Full text] [doi: 10.1037/a0027961] [Medline: 22468909]

51. Torous J, Jän Myrick K, Rauseo-Ricupero N, Firth J. Digital mental health and COVID-19: using technology today to accelerate the curve on access and quality tomorrow. JMIR Ment Health 2020 Mar 26;7(3):e18848 [FREE Full text] [doi: 10.2196/18848] [Medline: 3223476]

52. Zvolensky MJ, Kaufman BY, Garey L, Viana AG, Matoska CT. Interoceptive anxiety-related processes: importance for understanding COVID-19 and future pandemic mental health and addictive behaviors and their comorbidity. Behav Res Ther 2022 Sep;156:104141 [FREE Full text] [doi: 10.1016/j.brat.2022.104141] [Medline: 35752013]

53. Hollander JE, Carr BG. Virtually perfect? Telemedicine for Covid-19. N Engl J Med 2020 Apr 30;382(18):1679-1681. [doi: 10.1056/nejmmp2003539]

54. Smith AC, Thomas E, Snoswell CL, Haydon H, Mehrotra A, Clemens J, et al. Telehealth for global emergencies: implications for coronavirus disease 2019 (COVID-19). J Telemed Telecare 2020 Mar 20;26(5):309-313. [doi: 10.1177/1357633X20916567]

55. Zhou X, Snoswell CL, Harding LE, Babbling M, Edrippjutte S, Bai X, et al. The role of telehealth in reducing the mental health burden from COVID-19. Telemed J E Health 2020 Apr 01;26(4):373-379. [doi: 10.1089/tmj.2020.0068] [Medline: 32202977]

56. Lu SC, Xu M, Wang M, Hardi A, Cheng AL, Chang SH, et al. Effectiveness and minimum effective dose of app-based mobile health interventions for anxiety and depression symptom reduction: systematic review and meta-analysis. JMIR Ment Health 2022 Sep 07;9(9):e39454 [FREE Full text] [doi: 10.2196/39454] [Medline: 36069841]

57. Greenphire. Smarter Trials Begin and End with GreenPhire. URL: https://greenphire.com/ [accessed 2022-11-25]

58. Tzur Bitan D, Grossman-Giron A, Bloch Y, Mayer Y, Shiffman N, Mendlovic S. Fear of COVID-19 Scale: psychometric characteristics, reliability and validity in the Israeli population. Psychiatry Res 2020 Jul;289:113100 [FREE Full text] [doi: 10.1016/j.psychres.2018.08.115] [Medline: 25499982]

59. Smith AC, Thomas E, Snoswell CL, Haydon H, Mehrotra A, Clemens J, et al. Telehealth for global emergencies: implications for coronavirus disease 2019 (COVID-19). J Telemed Telecare 2020 Mar 20;26(5):309-313. [doi: 10.1177/1357633X20916567]

60. Lu SC, Xu M, Wang M, Hardi A, Cheng AL, Chang SH, et al. Effectiveness and minimum effective dose of app-based mobile health interventions for anxiety and depression symptom reduction: systematic review and meta-analysis. JMIR Ment Health 2022 Sep 07;9(9):e39454 [FREE Full text] [doi: 10.2196/39454] [Medline: 36069841]

61. Greenphire. Smarter Trials Begin and End with GreenPhire. URL: https://greenphire.com/ [accessed 2022-11-25]

62. Brooke P, Bullock R. Validation of a 6 item cognitive impairment test with a view to primary care usage. Int J Geriatr Psychiatry 1999 Nov;14(11):936-940. [Medline: 10556864]

63. Arozullah A, Yarnold P, Bennett C, Soltysik R, Wolf M, Ferreira R. Development and validation of a short-form, rapid estimate of adult literacy in medicine. Med Care 2007;45(11):1026-1033. [doi: 10.1097/mlr.0b013e3180616c1b]

64. Sternthal MJ, Slopen N, Williams DR. Racial disparities in health. Du Bois Rev 2011 Apr 15;8(1):95-113. [doi: 10.1017/s1357633x10916567]

65. Fisher C, Yip T. The Coronavirus Racial Bias Scale (CRBS): Fordham University Pathways to Health Study. 2020. URL: https://www.phenxtoolkit.org/toolkit_content/PDF/Fordham_CRBS.pdf [accessed 2022-11-22]

66. Kliem S, Moßle T, Rehbein F, Hellmann DF, Zenger M, Brühl E. A brief form of the Perceived Social Support Questionnaire (F-SozU) was developed, validated, and standardized. J Clin Epidemiol 2015 May;68(5):551-562. [doi: 10.1016/j.jclinepi.2014.11.003]

67. Zvolensky MJ, Garey L, Farebrother ET, Mayorga NA, Chavez J, Shepherd JM, et al. Evaluating the feasibility and acceptability of a mobile-based health technology for smoking cessation: mobile Anxiety Sensitivity Program. Br J Clin Psychol 2022 Jan 03;61 Suppl 1(S1):111-129. [doi: 10.1111/bjc.12294] [Medline: 33939190]

68. Patton MQ. Qualitative Research and Evaluation Methods: Integrating Theory and Practice. Los Angeles: Sage; 2014.

69. Arozullah A, Yarnold P, Bennett C, Soltysik R, Wolf M, Ferreira R. Development and validation of a short-form, rapid estimate of adult literacy in medicine. Med Care 2007;45(11):1026-1033. [doi: 10.1097/mlr.0b013e3180616c1b]

70. TSET Health Promotion Research Center. Mobile Health Technology. URL: https://healthpromotionresearch.org/Mobile-Health-Technology [accessed 2022-11-25]

71. Schmidt NB, Eggleston AM, Woolaway-Bickel K, Fitzpatrick KK, Vasey MW, Richey JA. Anxiety Sensitivity Amelioration Training (ASAT): a longitudinal primary prevention program targeting cognitive vulnerability. J Anxiety Disord 2007 Jan;21(3):302-319. [doi: 10.1016/j.janxdis.2006.06.002] [Medline: 16889931]

72. Garey L, Hébert ET, Mayorga NA, Chavez J, Shepherd JM, Businelle MS, et al. Evaluating the feasibility and acceptability of a mobile-based health technology for smoking cessation: mobile Anxiety Sensitivity Program. Br J Clin Psychol 2022 Jan 03;61 Suppl 1(S1):111-129. [doi: 10.1111/bjc.12294] [Medline: 33939190]

73. Walters ST, Businelle MS, Sutchting R, Li X, Hébert ET, Mun E. Using machine learning to identify predictors of imminent drinking and create tailored messages for at-risk drinkers experiencing homelessness. J Subst Abuse Treat 2021 Aug;127:108417 [FREE Full text] [doi: 10.1016/j.sdt.2021.108417] [Medline: 34134874]
Hébert ET, Ra CK, Alexander AC, Helt A, Moisiuc R, Kendzor DE, et al. A mobile just-in-time adaptive intervention for smoking cessation: pilot randomized controlled trial. J Med Internet Res 2020 Mar 09;22(3):e16907 [FREE Full text] [doi: 10.2196/16907] [Medline: 32149716]

Businelle MS, Ma P, Kendzor DE, Frank SG, Vidrine DJ, Wetter DW. An ecological momentary intervention for smoking cessation: evaluation of feasibility and effectiveness. J Med Internet Res 2016 Dec 12;18(12):e321 [FREE Full text] [doi: 10.2196/jmir.6058] [Medline: 27956375]

Enkema MC, McClain L, Bird ER, Halvorson MA, Larimer ME. Associations between mindfulness and mental health outcomes: a systematic review of ecological momentary assessment research. Mindfulness (N Y) 2020 Nov 15;11(11):2455-2469 [FREE Full text] [doi: 10.1007/s12671-020-01442-2] [Medline: 35694042]

Brown KW, Ryan RM. The benefits of being present: mindfulness and its role in psychological well-being. J Pers Soc Psychol 2003 Apr;84(4):822-848. [doi: 10.1037/0022-3514.84.4.822] [Medline: 12703651]

Arch JJ, Landy LN. Emotional benefits of mindfulness. In: Brown KW, Creswell JD, Ryan RM, editors. Handbook of Mindfulness: Theory, Research, and Practice. New York, NY: Guilford Press; 2015:208-224.

McLeod JD, Kessler RC. Socioeconomic status differences in vulnerability to undesirable life events. J Health Soc Behav 1990 Jun;31(2):162-172. [Medline: 2102495]

Gallo LC, Matthews KA. Understanding the association between socioeconomic status and physical health: do negative emotions play a role? Psychol Bull 2003 Jan;129(1):10-51. [doi: 10.1037/0033-2909.129.1.10] [Medline: 12555793]

Matthews KA, Flory JD, Muldoon MF, Manuck SB. Does socioeconomic status relate to central serotonergic responsivity in healthy adults? Psychosom Med 2000 Nov;62(2):231-237. [doi: 10.1097/00006842-200003000-00015] [Medline: 10772403]

Businelle MS, Cuate EL, Kesh A, Poonawalla IB, Kendzor DE. Comparing homeless smokers to economically disadvantaged domiciled smokers. Am J Public Health 2013 Dec;103(S2):S218-S220. [doi: 10.2105/ajph.2013.301336]

Lantz PM, House JS, Mero RP, Williams DR. Stress, life events, and socioeconomic disparities in health: results from the Americans’ Changing Lives Study. J Health Soc Behav 2005 Sep;46(3):274-288. [doi: 10.1177/002214650504600305] [Medline: 16259149]

Browning MHEM, Larson LR, Sharaiyevksa I, Rigolon A, McNairin O, Mullenbach L, et al. Psychological impacts from COVID-19 among university students: risk factors across seven states in the United States. PLoS One 2021 Jan 7;16(1):e0245327. [doi: 10.1371/journal.pone.0245327]

Shiffman S, Hickcox M, Paty JA, Gnyis M, Richards T, Kassel JD. Individual differences in the context of smoking lapse episodes. Addict Behav 1997 Nov;22(6):797-811. [doi: 10.1016/s0306-4603(97)00063-4]

Wetter DW, McClure JB, Coffa-Woerpel L, Costello TJ, Reitzel LR, Businelle MS, et al. A randomized clinical trial of a palmtop computer-delivered treatment for smoking relapse prevention among women. Psychol Addict Behav 2011 Jun;25(2):365-371 [FREE Full text] [doi: 10.1037/a0022797] [Medline: 21500879]

Stone AA, Schwartz JE, Neale JM, Shiffman S, Marco CA, Hickcox M, et al. A comparison of coping assessed by ecological momentary assessment and retrospective recall. J Pers Soc Psychol 1998 Jun;74(6):1670-1680. [doi: 10.1037/0022-3514.74.6.1670] [Medline: 9654765]

Shiffman S, Paty JA, Gnyis M, Kassel JA, Hickcox M. First lapses to smoking: within-subjects analysis of real-time reports. J Consult Clin Psychol 1996 Apr;64(2):366-379. [doi: 10.1037/0022-006x.64.2.366] [Medline: 8871421]

Piatecki TM, Cooper ML, Wood PK, Sher KJ, Shiffman S, Heath AC. Dispositional drinking motives: associations with assessed alcohol effects and alcohol consumption in an ecological momentary assessment investigation. Psychol Assess 2014 Jun;26(2):363-369 [FREE Full text] [doi: 10.1037/a0035153] [Medline: 24274409]

Simons JS, Dvorak RD, Batien BD, Wray TB. Event-level associations between affect, alcohol intoxication, and acute dependence symptoms: effects of urgency, self-control, and drinking experience. Addict Behav 2010 Dec;35(12):1045-1053 [FREE Full text] [doi: 10.1016/j.addbeh.2010.07.001] [Medline: 20685044]

Swendsen JD, Tennen H, Carney MA, Affleck G, Willard A, Hromi A. Mood and alcohol consumption: an experience sampling test of the self-medication hypothesis. J Abnorm Psychol 2000 May;109(2):198-204. [doi: 10.1037/0022-006x.109.2.198]

Businelle MS, Ma P, Kendzor DE, Frank SG, Wetter DW, Vidrine DJ. Using intensive longitudinal data collected via mobile phone to detect imminent lapse in smokers undergoing a scheduled quit attempt. J Med Internet Res 2016 Oct 17;18(10):e275 [FREE Full text] [doi: 10.2196/jmir.6307] [Medline: 27751985]

Businelle MS, Ma P, Kendzor DE, Reitzel LR, Chen M, Lam CY, et al. Predicting quit attempts among homeless smokers seeking cessation treatment: an ecological momentary assessment study. Nicotone Tob Res 2014 Oct;16(10):1371-1378 [FREE Full text] [doi: 10.1093/ntr/ntu088] [Medline: 24893602]

Kendzor DE, Shuval K, Gabriel KP, Businelle MS, Ma P, High RR, et al. Impact of a mobile phone intervention to reduce sedentary behavior in a community sample of adults: a quasi-experimental evaluation. J Med Internet Res 2016 Jun 25;18(1):e19 [FREE Full text] [doi: 10.2196/jmir.5137] [Medline: 26810027]

Reingle Gonzalez JM, Businelle MS, Kendzor D, Staton M, North CS, Swartz M. Using nHealth to increase treatment utilization among recently incarcerated homeless adults (Link2Care): protocol for a randomized controlled trial. JMIR Res Protoc 2018 Jun 05;7(6):e151 [FREE Full text] [doi: 10.2196/resprot.9868] [Medline: 29871852]
96. Russell JA. A circumplex model of affect. J Pers Soc Psychol 1980 Dec;39(6):1161-1178. [doi: 10.1037/h0077714]

97. Preacher KJ, Wichman AL, MacCallum R, Briggs NE. Latent Growth Curve Modeling. Thousand Oaks, CA: Sage; 2008.

98. Preacher KJ, Zyphur MJ, Zhang Z. A general multilevel SEM framework for assessing multilevel mediation. Psychol Methods 2010 Sep;15(3):209-233. [doi: 10.1037/a0020141] [Medline: 20822249]

99. McArdle JJ. Latent variable modeling of differences and changes with longitudinal data. Annu Rev Psychol 2009 Jan 01;60(1):577-605. [doi: 10.1146/annurev.psych.60.110707.163612] [Medline: 18817479]

100. Muthén L, Muthén B. Mplus: Statistical Analysis with Latent Variables (Version 3). Los Angeles: University of California; 2007.

101. Hu L, Bentler PM. Cutoff criteria for fit indexes in covariance structure analysis: conventional criteria versus new alternatives. Struct Equ Model 1999 Jan;6(1):1-55. [doi: 10.1080/10705519909540118]

102. Miles M, Huberman A, Saldaña J. Qualitative Data Analysis. Thousand Oaks, CA: Sage; 2014.

103. Creswell J, Clark V. Designing and Conducting Mixed Methods Research. Thousand Oaks, CA: Sage; 2017.

104. Cheney M, Gowin M. Using Legal Documents for Public Health Research: An Innovative Application of Qualitative Methodology to Document the Experiences of Transgender Asylum Seekers. Thousand Oaks, CA: Sage; 2020.

105. Enders C. Applied Missing Data Analysis. New York, NY: Guilford Press; 2010.

106. Hedeker D, Gibbons RD, Waternaux C. Sample size estimation for longitudinal designs with attrition: comparing time-related contrasts between two groups. J Educ Behav Stat 1999;24(1):70-93. [doi: 10.2307/1165262]

107. Fritz MS, Mackinnon DP. Required sample size to detect the mediated effect. Psychol Sci 2007 Mar 04;18(3):233-239 [FREE Full text] [doi: 10.1111/j.1467-9280.2007.01882.x] [Medline: 17444920]

108. National Institutes of Health (NIH). NIH-Wide Strategic Plan for Fiscal Years 2021-2025. URL: https://www.nih.gov/sites/default/files/about-nih/strategic-plan-fy2021-2025-508.pdf [accessed 2022-11-22]

109. Lee M, Kang D, Yoon J, Shim S, Kim I, Oh D, et al. The difference in knowledge and attitudes of using mobile health applications between actual user and non-user among adults aged 50 and older. PLoS One 2020 Oct 27;15(10):e0241350 [FREE Full text] [doi: 10.1371/journal.pone.0241350] [Medline: 33108792]

110. Gover AR, Harper SB, Langton L. Anti-Asian hate crime during the COVID-19 pandemic: exploring the reproduction of inequality. Am J Crim Justice 2020 Jul 07;45(4):647-667 [FREE Full text] [doi: 10.1007/s12103-020-09545-1] [Medline: 32837171]

111. Lee S, Waters SF. Asians and Asian Americans’ experiences of racial discrimination during the COVID-19 pandemic: impacts on health outcomes and the buffering role of social support. Stigma Health 2021 Feb;6(1):70-78. [doi: 10.1037/sah00000275]

Abbreviations

**6CIT**: 6-Item Cognitive Impairment Test  
**AS**: anxiety sensitivity  
**BHAi**: Black, Hispanic, and American Indian  
**CBT**: cognitive behavioral therapy  
**CRBS**: Coronavirus Racial Bias Scale  
**EASE**: Easing Anxiety Sensitivity for Everyone  
**EDS**: Everyday Discrimination Scale  
**EMA**: ecological momentary assessment  
**F-SozU K-6**: 6-Item Perceived Social Support Questionnaire  
**LGM**: latent growth model  
**mHealth**: mobile health  
**ML**: maximum likelihood  
**MSEM**: multilevel structural equation model  
**NHW**: non-Hispanic White  
**OASIS**: Overall Anxiety Severity and Impairment Scale  
**ODSIS**: Overall Depression Severity and Impairment Scale  
**RCT**: randomized controlled trial  
**REALM-SF**: Rapid Estimate of Adult Literacy in Medicine-Short Form  
**REDCap**: Research Electronic Data Capture  
**SES**: socioeconomic status  
**SSASI**: Short-Scale Anxiety Sensitivity Index
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