Study protocol and statistical analysis plan
Testing Scalable, Single-Session Interventions for Adolescent Depression in the Context of COVID-19
NCT04634903

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Method

Ethics Information. Procedures were approved by the University of Denver institutional review board, and adolescents provided online assent prior to participating. To maintain adolescents' confidentiality and minimize access barriers (e.g., discomfort disclosing psychological distress, as parents are often unaware of their adolescents' depressive symptoms, including suicidal ideation, in up to 80% of cases),[27-28] parent permission was not required to participate in this study (waived by the University IRB). All procedures were pre-registered prospectively, before enrollment of the first participant (ClinicalTrials.gov: NCT04634903).

Recruitment and Resulting Sample. Participants learned about the study through Instagram advertisements following established ethics guidelines for passive, social media-based recruitment.[29] Posts included invitations to determine eligibility for a confidential, online psychology study, for which participants could earn up to $20 USD in gift cards. Instagram posts linked to a Qualtrics survey; the first page included study details and an invitation to complete an eligibility screener. Inclusion criteria were (1) being between 13-16 years old (inclusive); (2) comfort reading and writing in English; (3) internet and computer, laptop, or smartphone access; and (4) endorsement of elevated depressive symptoms, per a score of >=2 on the Patient Health Questionnaire-2 (this cut-off prioritizes sensitivity over specificity in identifying youth with elevated depressive symptoms).[30] Eligible adolescents then reviewed an online assent form inviting them to participate. Recruitment took place from November 19-December 6, 2020 (on which date >2,400 youth had been randomized to an intervention condition). Three-month follow-up surveys were completed by March 15, 2021 (youth received 3-week windows to finish their follow-up survey). Of 6,884 youths who completed the screener, 3,851 were eligible and agreed to participate; 2,452 completed the baseline survey and were randomized to an SSI; and 1,766 of those randomized were retained at follow-up. Rates of follow-up survey completion did not differ by intervention condition. Participants could complete the study from any U.S. location, using any internet-equipped device.

Procedures. Per the CONSORT Diagram (**Figure 1**), participants were invited to complete pre-SSI questionnaires; one of three 20-30 minute SSIs (youths were randomly assigned to one of three SSIs in a 1:1:1 ratio per a Qualtrics-embedded randomizer; youth and investigators were masked to condition assignment until after all data collection was complete); and post-SSI questionnaires, within one 50-to-60-minute session. Youths then received an email invitation three months later to complete a 10-minute follow-up questionnaire, also via Qualtrics, including a subset of measures from the baseline survey, to assess the SSIs' effects on primary and secondary outcomes. After all data collection was complete, the researchers learned each youth's condition assignment, and both active interventions were offered to all participants. Additionally, participants received a resource list of hotlines, textlines, and online psycho-educational resources to facilitate engagement with additional mental health supports, if desired. Adolescents were also invited to contact the research team at any time during the study with questions or for further support in accessing mental health support beyond the study's scope.

Interventions. *Behavioral Activation SSI (BA-SSI) — ABC Project*.[17] The BA-SSI includes 5 elements: (1) An introduction to the program's rationale: that engaging in values-based activities that build pleasure and accomplishment can combat sad mood and low self-esteem; (2) Psychoeducation about depression, including how behavior shapes feelings and thoughts; (3) A life values assessment, where youth identify key areas (family relationships, friendships, school, or hobbies) from which they draw (or once drew) enjoyment and meaning; (4) Creation of an activity "action plan," where youth identify (from

pre-generated lists) and personalize (in guided exercises) 3 activities to target for change; and (5) An exercise in which youths write about benefits that might result from engaging in each activity; an obstacle that might keep them from doing the activities; and a strategy for overcoming identified obstacles. Intervention materials are available here: https://osf.io/ch2tg/.

Growth Mindset SSI (GM-SSI) — Project Personality. The 30-minute, self-administered youth program includes: (1) An introduction to the brain and a lesson on neuroplasticity; (2) Testimonials from older youths who describe their views that traits are malleable, due to the brain's plasticity; (3) Further stories by older youths, describing times when they used "growth mindsets" to persevere during social/emotional setbacks; (4) Study summaries noting how/why personality can change; and (5) An exercise in which youths write notes to younger students, using scientific information to explain people's capacity for change. Intervention materials are available here: https://osf.io/a9uv2/

Supportive Therapy SSI (Placebo). The 30-minute, self-administered supportive therapy (placebo) is structurally similar to the other SSIs (e.g., it is length-matched; includes peer narratives; and contains the same number of writing activities), but is designed to control for nonspecific aspects of completing a generally-supportive online activity. The program encourages participants to express emotions to close others; it does not teach specific skills. In a previous trial, this program predicted smaller reductions in youth internalizing problems versus a GM-SSI. Intervention materials are available here: https://osf.io/u4axs/.

Outcomes. *Adolescent depressive symptoms (primary outcome).* Depressive symptom severity was assessed using the Children's Depression Inventory (CDI) 2 - short form (CDI-SF), a reliable, valid measure of youth depression severity. Twelve items are scored from 0-2, with higher summed scores reflecting greater overall depression symptom severity. Changes in CDI-SF scores from pre-SSI to three-month follow-up was the primary study outcome. Alphas were 0.77 and 0.85 at baseline and follow-up.

Adolescent anxiety symptoms. Generalized anxiety symptom severity was measured using the Generalized Anxiety Disorder 7 (GAD-7), which includes 7 items asking respondents how often, during the last 2 weeks, they were bothered by various anxiety symptoms. Items are rated on a 0-3 scale and averaged to yield an overall score. Changes in GAD-7 scores from pre-SSI to follow-up was a secondary outcome. Alphas were 0.89 and 0.90 at baseline and follow-up.

COVID-19-related Trauma Symptoms. Child Trauma Screen—Reaction Scale (CTS-RS) was administered at pre-SSI and 3-month follow-up. The CTS-RS is a reliable, valid self-report measure of traumatic stress symptom severity, including event-related somatic symptoms, intrusive memories, avoidance, sleep problems, and mood and behavioral changes. Here, instructions read: "For many, the COVID-19 (or 'coronavirus') pandemic has been scary or very upsetting. Sometimes, events that are scary or upsetting can affect how people think, feel, and act. The next questions ask how you have been feeling and thinking recently." Youth rated 6 statements describing traumatic stress symptoms per their past-month frequency, on a 0-3 scale (0 = *Never/Rarely*; 3 = *3+ times per week*). Responses were averaged to yield an overall severity score. Changes in CTS-RS scores from pre-SSI to follow-up was a secondary outcome. Alpha was 0.73 at both baseline and follow-up.

Perceived Agency. The "agency" subscale of the State Hope Scale (SHS) is a reliable, valid 3-item self-report measure of youth' perceived ability to generate plans and work towards one's goals. Pre- and post-intervention, youths rated 3 statements reflecting how they felt about themselves "right now" on an 8-point scale (1=definitely false; 8=definitely true). Alphas were 0.82, 0.83, and 0.80 at pre-SSI, post-SSI, and follow-up.

Hopelessness. The Beck Hopelessness Scale-4 (BHS-4) is a reliable, shortened version of the 20-item scale used to measure hopelessness in youth. Pre- and post-intervention and at follow-up, participants rated 4 statements reflecting their sense of hopelessness "right now, in this moment" on a 0-3 Likert scale (0="absolutely disagree"; 3="absolutely agree"). Alphas were 0.84, 0.87, and 0.88 at pre-SSI, post-SSI, and follow-up.

Intervention Acceptability. The Program Feedback Scale (PFS) asks youth to rate agreement with 7 statements indicating perceived acceptability of an SSI (e.g. "I enjoyed the program") on a 5-point

Likert scale (1="really disagree"; 5="totally agree").[17, 37] We pre-registered that scores of ≥3.5/5 on any given PFS item would reflect an "acceptable" rating on that item.

Power analysis. The pwr R package was used to calculate the Power for all planned contrasts detailed below. An *N*=2,400 (800 per group) and 2 time-points (pre-intervention and 3-month follow-up) yields 98% Power to detect a small effect size of *d*=0.20 on *all* outcomes when comparing SSIs.

Analysis Plan. We ran a series of linear regressions to test whether the GM-SSI and BA-SSI predicted (1) improvements in proximal post-SSI targets (perceived agency; hopelessness), and (2) reductions in adolescent depressive symptom severity (primary study outcome) from pre-SSI to 3-month follow-up, relative to (1) each other, and (2) the control SSI, when considered independently. SSI condition was a categorical predictor in these models, and parallel linear regressions were conducted to assess intervention effects on secondary, 3-month study outcomes. We imputed participant-level missing data using the expectation-maximization and bootstrapping algorithm implemented with Amelia II in R, allowing more conservative intent-to-treat analyses than other approaches (e.g., listwise deletion; last-observation carried-forward). We imputed as many datasets as there were percent of missing data for an outcome, rounding to the next-highest percentage (e.g., If 5.4% of data was missing on an outcome, we created 6 imputed datasets), allowing us to retain high power despite missing data. Cohen's *d* and 95% confidence intervals for analyses were calculated using *t*-values for treatment effects obtained from analyses with the MOTE package in R. The false discovery rate (FDR) was applied to identify potential false-positive results. Results from pre-registered tests described above were considered significant if FDR-corrected $p<0.05$. Lastly, for exploratory purposes, we computed effect sizes reflecting within-group intervention effects on depression (the primary outcome) for each SSI condition.

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Data availability. Anonymized participant-level data is available on the Open Science Framework (osf.io/8mk6x/)

Code availability. Analytic code is available on the Open Science Framework. (osf.io/8mk6x/)

Competing interests. JLS receives grant support from the National Institutes of Health (DP5OD28123),