



Protocol Document for: Coping and Emotional Development for Adolescents to Reduce Stress for Adolescents (CEDARS) Intervention Study

NCT NUMBER: NCT04958694

DATE: APRIL 14, 2025

I. Design.

The CEDARS intervention was initially an existing in-person positive emotion intervention, which was adapted to be a self-paced, online, live-action/animation hybrid video-based intervention for adolescents. This protocol outlines the intervention component of the “ACHiP: Aces and Cardiometabolic Health in Pediatrics Study.”

This study will pilot the revised *CEDARS* intervention via online platform for adolescents with and without Adverse Childhood Experience (ACEs) exposure and determine the feasibility and acceptability (primary outcomes) of intervention in a clinical population. Secondary outcomes will include mental and behavioral health outcomes (i.e., depressive and anxiety symptoms, positive and negative affect, perceived stress, and flourishing and resilient coping).

The intervention will be conducted via SkyPrep, a HIPPA-compliant module delivery platform, with the PI serving as a supervisor. Sessions will consist of short videos with questionnaires to assess/practice skills learned (See Table 1).

Table 1. *CEDARS* Intervention Content/Skills with Rationale, by Module

Module	Content/Skills and Rationale
1	Introductions: Youth review stress, health, and emotional literacy. They complete the ACEs and CMH surveys.
2	Positive Reappraisal: Reframing an individual's understanding of the personal significance of an event has been consistently and empirically associated with increased positive affect. ^{71–73}
3	Amplifying Gratitude: Scheduling “positive events” is a key component of some forms of treatment of mental health. ^{61–63} After experiencing a positive event, capitalizing on the event and savoring it can strengthen the association between the event and positive affect. Keeping a gratitude journal has been associated with less negative affect, fewer physical symptoms, better sleep quality, and greater satisfaction with life. ^{70 64}
4	Mindfulness: Involves deliberately focusing on the present-moment experience, and bringing an attitude of nonjudgmental acceptance to the experience. ^{65,66} Both trait and state mindfulness are associated with higher positive affect and lower negative affect. ^{67,68} Mindfulness may also allow people to tolerate and reflect on strong emotions rather than responding impulsively. ⁶⁸
5	Acts of Kindness: Altruistic behavior may lead to positive affect because it provides a sense of self-efficacy, increases self-esteem, or provides a reprieve from one's own problems. ⁷⁶
6	SMART Goal Setting: Higher levels of positive affect and greater life satisfaction are found among people who perceive they are making progress toward their goals. ^{71,74,75}
7	Wrap-Up: Youth plan for continued practice and give feedback on the <i>CEDARS</i> intervention. Youth will complete the ACEs and CMH surveys used for baseline assessments.

II. Participant Eligibility and Recruitment.

Adolescent participants (Goal N=40) will be recruited from social media and repository from previous studies. Participants must be fluent English-speaking, adolescents, between the ages of 14 and 19. Due to the virtual nature of the intervention, participants will need to have a reliable internet connection.

III. Intervention Protocol.

Enrolled youth will be block stratified and assigned to a treatment group via using ACE scores (cut point ACEs ≥ 3). Youth will be enrolled in either a waitlist control or the CEDARS treatment group. We will allow self-paced CEDARS intervention modules over 7-9 weeks via SkyPrep and Zoom. After each session, adolescents will be assigned “homework” to try to apply their coping skills in their daily lives. There will be multiple follow-up sessions with participants. Participants (N=20) will go through the videos in a sequential format. The other participants (N=20) will be waitlisted controls and will be asked to go through the same assessment and have the same incentive opportunities. As part of the assessments, we will measure participant satisfaction as well as mental and behavioral health outcomes. They will be taken at baseline, midway (week 4) and after the intervention has concluded and 1 month after the intervention has ended.

IV. Intervention.

Videos were previously developed under the guidance of Drs. Heard-Garris and Moskowitz. The materials prepared by Drs. Heard-Garris and Moskowitz will be imported and uploaded to SkyPrep where they will be administered to run the intervention to participants.

V. Fidelity.

To ensure fidelity to the CEDARS intervention, we will have the same materials for all research participants administered to complete at their own pace. To ensure rigor and reproducibility, we will use consistent materials across the SkyPrep platform created and approved by Drs. Heard-Garris and Moskowitz.

V. Outcomes.

Primary outcomes: feasibility and acceptability.

We will have three measures of feasibility. This will include successful enrollment of target number or participants, mean intervention modules completed, and proportion of participants completing 4 or more modules.

Recruitment Goal. Our recruitment goal is 40 adolescents, and we will measure feasibility based on the ability to attain 100% of the recruitment goal. During the recruitment process, approach rates and acceptance rates will be tracked, including staff reasons for missed approaches among eligible adolescents with ≥ 1 ACEs and adolescents' reasons for declining to participate. Information on missed approaches and refusals will be used to inform subsequent grant applications and modify approach and recruitment methods for subsequent proposals. Our goal is to enroll 50% of eligible participants.

Intervention Module completion. We will measure the mean number of modules that the treatment group completes and the proportion of participants who complete the recommended 4 of 7 modules (also a marker of fidelity to the intervention).

We will have two measures of acceptability. This will include the mean participant satisfaction score across intervention participants and the proportion of participants that rate the intervention at least 8 of 10 on our satisfaction survey.

Acceptability: A self-report feedback survey at session 4 (mid-intervention) and at session 7 (end of intervention) will be designed to assess acceptability of the intervention. Adolescents will be asked to report the degree to which they liked/disliked the intervention on a scale from 0 to 10 and respond to questions about the duration of session, content covered, perceived benefits, comfort level, and overall satisfaction. Outcomes of the pilot intervention will include baseline (session 1), mid-intervention (session 4), and post-intervention (session 7) measures of psychological well-being and stress.

We will examine secondary mental and behavioral health outcomes. We will use the PANAS-C-SF to assess positive affect, use the NIH PROMIS assessments PHQ9 & GAD-7 for depression and anxiety, respectively, the perceived stress scale to assess perceived stress, the Flourish Scale (Diener, et al. 2010) to assess flourishing, and Brief Resilient Coping Scale to assess resilient coping, and demographics (e.g., age, race, ethnicity, sex, and gender identity).

VI. Participant Incentives.

Participants will be compensated \$25 per assessment they complete, for up to \$100 per participant.

VII. Brief Statistical Analysis Plan

We will assess the feasibility and acceptability and also effects of the intervention on changes in the affect, stress and coping outcomes.

For each intervention outcome, as an exploratory analysis in this small sample with limited power, we will assess if we can fit a generalized linear model (for repeated within-subject observations) with each group as a fixed effect and the outcome's baseline value as an additional covariate. For the mental and behavioral health outcomes, we will use the Van Elteren Test to compare differences in change between the two groups, given its non-parametric properties. We will use this test to assess depression and anxiety symptoms, perceived stress, flourishing, and resilient coping.

Participant demographic indicators will be tested as predictors of the outcome variables.

Sample and Design

This pilot randomized controlled trial includes 40 participants assigned to either the CEDARS intervention (n=20) or a waitlist control (n=20). All analyses are exploratory given the small sample size and limited statistical power. A two-sided significance level of $\alpha=0.05$ will be used, though effect sizes may be emphasized over p-values given the pilot nature of the study.

Baseline Characteristics

Baseline characteristics of both arms will be described using standard summary statistics. To examine whether key variables, such as positive affect, negative affect, flourishing, and resilient coping, differ between groups at baseline, we will stratify descriptive analyses by ACEs category, gender/sex, and race/ethnicity, where appropriate.

Primary Outcomes: Feasibility and Acceptability

Feasibility will be assessed by (1) successfully meeting recruitment targets, (2) mean number of intervention modules completed, and (3) proportion of participants completing the minimum effective dose of 4 of 7 modules. Acceptability will be assessed by (1) mean participant satisfaction score and (2) proportion of participants rating satisfaction ≥ 8 out of 10. These outcomes will be reported descriptively with proportions and 95% confidence intervals where appropriate.

Secondary Outcomes: Intervention Effects

The secondary outcomes are depression symptoms, anxiety symptoms, perceived stress, flourishing, and resilient coping. For each outcome, we will use the Van Elteren test, a stratified non-parametric test, to compare change from baseline between the intervention and waitlist control arms, stratified by ACEs category. This approach is appropriate given the small sample size, potential non-normality of outcome distributions, and an a priori theoretical importance of ACEs as a stratification variable, given the prevalence of lower positive affect among youth with ACEs.

Exploratory Outcome Modeling

As an exploratory analysis, we will assess whether a regression model for repeated within-subject observations can be fit for each secondary outcome, with treatment arm as a fixed effect and the outcome's baseline value as a covariate. The specific model form including distributional family, link function, and within-subject correlation structure will be selected by the analyst based on the observed data properties and model diagnostics. Effect sizes will be reported alongside model estimates.

Missing Data

Missing data will be handled using complete case analysis. The extent and pattern of missingness will be reported descriptively.