

## **Promoting treatment access following pediatric primary care depression screening: Evaluation of web-based, single-session interventions for parents and youths**

Study Protocol Summary, July 20 2019

**BACKGROUND AND SPECIFIC AIMS.** Psychiatric disorders are the leading cause of disability worldwide, and 40.5% of this burden is attributable to major depression (MD).<sup>i</sup> Rates of MD increase markedly in adolescence, with nearly 20% of youth experiencing MD between ages 11 and 18.<sup>ii</sup> Despite this early onset and protracted course, up to 70% of US youth with MD do not receive services.<sup>iii</sup> To help address this disparity, the American Academy of Pediatrics recently released new practice guidelines promoting screening of youth MD in primary care (PC) clinics across the country, with the goal of more consistently identifying youths in need of treatment.<sup>iv</sup> This is a critical step towards increasing MD detection; however, the challenge of bridging screening with services remains. Even when diagnosed by PC providers, less than half of youth with MD access treatment of any kind.<sup>4</sup> Thus, there is a need for youth MD interventions that are more feasible for youths and parents to access and complete—and that may also strengthen parents' likelihood of pursuing additional, longer-term services for their child in the future.

Single-session interventions (SSIs) may offer a promising path toward both of these goals. SSIs include core elements of comprehensive evidence-based treatments, but their brevity makes them easier to disseminate beyond traditional settings. Indeed, SSIs can successfully treat youth psychopathology: In a meta-analysis of 50 RCTs, we found that SSIs reduced youth mental health problems of multiple types (mean  $g = 0.32$ ), including self-administered SSIs (e.g., web-based SSIs; mean  $g = 0.32$ ).<sup>v</sup> To date, one SSI (developed by PI Schleider) has been shown to reduce youth MD symptoms: the growth mindset (GM) SSI, which teaches the belief that personal traits are malleable, as opposed to fixed.<sup>vi,vii,viii</sup> For instance, we found that an online GM SSI led to significant 9-month MD reductions in high-symptom youth ages 12-15, versus a supportive therapy control ( $N=96$ ;  $ds=0.60, 0.32$  per parent and youth reports, respectively).<sup>8</sup> Thus, the GM SSI represents a scalable, evidence-based strategy for reducing MD in youth.

GM SSIs can also help augment parent beliefs about the effectiveness of mental health treatment—beliefs that robustly predict whether youths ultimately access and benefit from psychological services.<sup>ix</sup> In a RCT including 430 parents of youth ages 7-17, we found that an online, 15-minute SSI teaching a growth mindset of emotion (viewing emotions as malleable) significantly increased parents' beliefs that psychotherapy could be effective, both for themselves ( $d=.51$ ) and their offspring ( $d=.43$ ), compared to a psychoeducation control).<sup>x</sup> Results suggest that a scalable, low-cost program can help reverse parents' low expectancies for treatment, and potentially increase their odds of accessing services for offspring with mental health needs.

**The overall goal of this project is to examine whether these empirically-supported SSIs can help bridge the gap between PC-based depression screening and access to MD services for high-symptom youth.** This possibility will be tested via a clinical-research partnership between the Lab for Scalable Mental Health (led by PI Schleider) and Stony Brook University's Division of Pediatric Primary Care (led by Co-I Pati), which serves over 22,000 youths annually and screens all patients 11 and older for self-reported MD symptoms. Youth patients reporting elevated MD symptoms at a PC visit ( $N = 200$ ) will be randomly assigned to one of two conditions: Information, Psychoeducation, and Referral (IPR; i.e., usual care) or IPR

enhanced with youth- and parent-directed online SSIs (IPR+SSI), designed to *reduce youth MD symptoms* and *improve parents' expectancies of mental health treatment*, respectively. **Aim 1** is to test whether IPR+SSI increases parents' treatment-seeking behaviors (e.g., researching or contacting mental health providers; making an initial appointment), compared to IPR alone, across a 3-month follow-up period. **Aim 2** is to test whether IPR+SSI helps to reduce youth MD symptoms across a 3-month follow-up period, relative to IPR alone. **Aim 3** is to test whether IPR+SSI reduces parental stress and psychological distress across the 3-month follow-up period, relative to IPR alone. Finally, **Aim 4** is to gauge the acceptability and feasibility of this service delivery model (connecting PC-based MD screening to online SSIs) via parent and youth feedback. Results may yield a disseminable, low-cost model for promoting youth MD treatment access after PC screening.

**PARTICIPANTS AND RECRUITMENT.** Two hundred (200) youth ages 11-16 and one parent per youth will be recruited for this study, as depression markedly increases in adolescence. Further, youth (and parents of youth) in this age range have responded well to the GM SSI interventions described below. Participants will be recruited from nine pediatric primary care sites across Suffolk County, New York; all nine sites are community-based satellite branches of Stony Brook University Hospital's Pediatric Primary Care service. All 9 sites administer the youth-report Pediatric Symptom Checklist (PSC) to patients aged 11 and older, and total and subscale scores are indicated on youths' electronic medical record (EMR). All youth with a PSC-Internalizing Score of 5 (out of 10) or higher (based on five items rated from 0-2 indicating frequency: Feel sad or unhappy, feel hopeless, down on yourself, seem to be having less fun, and worries a lot) will be eligible for participation in the present study. A member of the research team will contact qualifying families by phone within 3 weeks of the family's PC appointment to invite them to participate in the study.

**OVERVIEW OF STUDY DESIGN.** After discussing the study and associated procedures with a member of the project team, eligible families will receive an electronic study link. This link will lead to a 'parent portal' and a 'youth portal' from which each may complete her individual study portion. In separate surveys (one for the parent and one for the youth), parents and youths will complete baseline questionnaires (*detailed below*), the experimental manipulation (IPR+SSI or IPR alone), and post-intervention questionnaires (*detailed below*), all within the same online survey. Parent-youth pairs will both be assigned to the same experimental condition (IPR+SSI or IPR alone). Following the baseline survey, follow-up questionnaires will be administered either via phone or electronically, depending on the family's preference, to assess service access, youth MD, parental stress, and related variables (*detailed below*). After completion of the 3-month follow-up, families not originally randomized to the IPR+SSI condition will receive the opportunity to complete both the youth and parent SSIs.

## ONLINE INTERVENTIONS

**Youth-Directed Growth Mindset (GM) SSI.** The web-based GM SSI for youth, called "Project Personality," is delivered entirely via Qualtrics and takes approximately 30 minutes to complete. All intervention activities are self-administered by youth and delivered in a web-based

format, including illustrations, graphics, and audio-recordings of text. Intervention content is designed to maximize relevance for youths experiencing symptoms of depression, including excessive sadness and hopelessness. The intervention includes five components: 1. An introduction to the brain, including a lesson on the concept of neuroplasticity, describing how and why our behaviors are controlled by thoughts and feelings in their brains, which have potential for change; 2. Testimonials from older youths who describe their beliefs that people's personal traits (e.g., sadness, anxiety) are malleable, given the brain's plasticity; 3. Further stories by older youths, describing times when they used "growth mindsets" to persevere through emotional setbacks; 4. A summary of selected scientific studies suggesting that personality can, and often does, positively change over time; and 5. An exercise in which participants write notes to younger children, drawing on scientific information to describe the malleability of personal traits (a "self-persuasion" exercise). First, participants are provided with a hypothetical peer rejection scenario and are asked to respond to the following prompt: "How do you think you would feel if this happened to you? What kinds of thoughts do you think you would have?" Next, participants are asked to "imagine that the same event you just wrote about happened to another kid just like you. What could you say to help them understand they can change, or things that are happening to them could change?"

**Parent-Directed Growth Mindset (GM) SSI.** The web-based GM SSI for parents is also delivered entirely via Qualtrics and takes approximately 15 minutes to complete. In this program, parents first read a brief scientific passage, called "Can We Change Our Emotions?" that presents data, quotations, and real-life examples to convey the argument that emotions are, in fact, inherently flexible in children, adolescents, and adults. Parents also read a second passage, titled "Is Failure a Friend or Foe?" that presents data, quotations, and real-life examples to illustrate the notion that failure promotes learning, growth, and self-reflection. After reading each passage, parents are asked to write a brief summary of its main arguments "as though you were trying to convince a fellow parent why the passage's main arguments are true." This "self-persuasion" activity is designed to promote internalization of the passage's arguments and ideas.

**Information, Psychoeducation and Referral (IPR).** IPR represents usual care in the Stony Brook University Hospital's Pediatric Primary Care Division. Families of a youth with elevated MD symptoms during a PC visit receive a folder containing informational materials about the nature of depression and referrals to providers in their area. All families in this study will have received PC-based IPR.

### **Primary Outcome Measures:**

#### **1. Mental Health Treatment-Seeking Behavior Checklist**

At baseline and 3-month follow-up, parents will indicate whether they have engaged in each of four treatment-seeking behaviors for their child: researched local mental healthcare providers/agencies for their child; contacted a mental healthcare provider or agency about treatment for their child; contacted child's school regarding mental health supports for their child; and scheduled an appointment OR placed child on a waiting-list with a mental healthcare provider/agency. Total number of treatment-seeking behaviors between baseline and 3-month follow-up may range from 0 to 4. Individual behaviors are self-reported by parents on as 'yes' or 'no' (noting whether they engaged in the behavior during the study period). At baseline, parents will report on whether they engaged in these behaviors 'since the child's last doctor's

appointment.' At follow-up, parents will report whether they have engaged in these behaviors 'since their past survey, 3 months ago.'

[Time Frame: Baseline to 3-month follow-up]

## **2. Change in Pediatric Symptom Checklist - Youth-Report Internalizing Score**

Youth-report measure of youth depressive symptoms. Youth rate 5 items reflecting internalizing symptoms on a scale from 0-2. Total scores range from 0 to 10. Higher scores indicate higher internalizing symptom severity.

[Time Frame: Baseline to 3-month follow-up.]

### **Secondary Outcome Measures:**

#### **Change in Pediatric Symptom Checklist - Youth-Report Total score**

Youth-report measure of overall youth psychopathology. Youth rate 35 items on a 0-2 scale reflecting internalizing, externalizing, and attention-related symptoms. Scores range from 0 - 70. Higher scores indicate higher overall symptom severity.

[Time Frame: Baseline to 3-month follow-up.]

#### **Change in Pediatric Symptom Checklist- Parent Report Total score**

Youth-report measure of overall youth psychopathology. Youth rate 35 items on a 0-2 scale reflecting internalizing, externalizing, and attention-related symptoms. Scores range from 0 - 70. Higher scores indicate higher overall symptom severity.

[Time Frame: Baseline to 3-month follow-up.]

#### **Change in Pediatric Symptom Checklist- Youth Internalizing Score (parent report)**

Parent-report measure of overall youth psychopathology. Parents rate 5 items on a 0-2 scale reflecting internalizing symptoms in their child. Scores range from 0-10. Higher scores indicate higher overall symptom severity.

[Time Frame: Baseline to 3-month follow-up.]

#### **Change in Beck Hopelessness Scale - 4 (Youth Report)**

Respondents (youths) report agreement with 4 items indicating levels of hopelessness about the future. Higher summed scores reflect greater levels of hopelessness, and scores range from 0-12.

[Time Frame: Baseline to immediate post-online-intervention (in active intervention group only) and 3-month follow-up (between groups).]

#### **Change in Beck Hopelessness Scale - 4 (Parent Report)**

Respondents (parents) report agreement with 4 items indicating levels of hopelessness about the future. Higher summed scores reflect greater levels of hopelessness, and scores range from 0-12.

[Time Frame: Baseline to immediate post-online-intervention (in active intervention group only) and 3-month follow-up (between groups).]

### **Change in Brief Symptom Inventory - 18**

The Brief Symptom Inventory-18 (BSI-18) assesses self reported parent psychopathology and distress. Adult respondents rate endorsement of 18 physical and emotional complaints on a 0-4 Likert scale. The total sum score yields an additional total distress score (range: 0-72). Higher scores indicate higher levels of overall psychological distress.

[Time Frame: Baseline to 3-month follow-up]

### **Change in Barriers to Accessing Care Evaluation (BACE)**

Parents rate the 30 items on a 0-3 scale indicating the degree to which various beliefs, concerns, circumstances, and logistical difficulties have stopped, delayed or discouraged them from getting professional care for their child's mental health problem. Higher total scores indicate greater perceived barriers to care. Scores range from 0-90, with higher scores indicating more overall barriers to accessing mental health care for their child.

[Time Frame: Baseline to 3-month follow-up]

### **Change in Attitudes Toward Therapy Scale - Parent**

One-item measure used to assess parents' perceptions that therapy/counseling would be useful in reducing their child's emotional or behavioral difficulties, rated on a 0-10 scale (total score range: 0-10). Higher scores indicate stronger beliefs that therapy may help reduce mental health problems, whereas lower scores indicate weaker beliefs that therapy may help reduce mental health problems.

[Time Frame: Baseline to immediate post-online-intervention (in active intervention group only) and 3-month follow-up (between groups).]

### **Mental Health Treatment Access at 3-month follow-up**

Parents will indicate (yes/no) whether their child has received (a) new and/or (b) continuing school-based, outpatient, or other mental health-related services since the child's recent PC appointment (at baseline) and since the baseline assessment (at 3-month follow-up).

[Time Frame: 3-month follow-up]

### **Change in Perceived Stress Scale**

The PSS is a well-validated measure of the degree to which situations in one's life are appraised as stressful, unpredictable, and uncontrollable. Higher total scores indicate greater overall perceived stress. The scale includes 10 items rated on a 0-4 scales, and scores range from 0-40.

[Time Frame: Baseline to 3-month follow-up]

### **Other Pre-specified Outcome Measures:**

#### **Change in implicit theories of emotion scale, parent-report**

This measure will be used as a manipulation check for parents assigned to the active intervention condition. Parents will be asked to report the degree to which they view emotions as malleable (versus immutable) at pre- and post-intervention using a previously validated, 4-item assessment of emotion mindsets in adults. Four items are rated using a 1-to-6 Likert scale. Higher mean scores on these items indicate a stronger fixed emotion mindset, a lower scores, a stronger growth emotion mindset (range: 1-6).

[Time Frame: Baseline to immediate-post-online intervention (active intervention group only)]

#### **Change in Implicit Theories of Personality Questionnaire, youth-report**

This measure will be used as a manipulation check for youths assigned to the active intervention condition. Respondents rate the extent of their agreement with three statements linked to the malleability of personality, using a 1-to-6 Likert scale (e.g. "Your personality is something about you that you can't change very much"). Higher mean scores on these three items indicate a stronger fixed personality mindset, a lower scores, a stronger growth personality mindset (range: 1-6).

[Time Frame: Baseline to immediate-post-online intervention (active intervention group only)]

#### **Intervention feedback scale.**

Immediately after completing the online intervention, youth and parents assigned to the IPT+SSI condition will be asked to indicate the degree to which they enjoyed, understood, felt helped by, would recommend, and agreed with the message of the SSI they complete. They will also be prompted to provide written feedback regarding their impressions of the programs; aspects they enjoyed; and aspects they would change. Additionally, we will invite parents and youths who complete the SSIs at the three-month follow-up point to provide feedback on the intervention materials.

#### **Demographics.**

Parents will report sociodemographic, family, and other background information (e.g. youth age, sex, race, mental health treatment history)..

#### **Adverse Childhood Experiences (ACEs) for parent and child.**

The ACEs questionnaire asks about exposure to violence, childhood emotional, physical, or sexual abuse, and household dysfunction during childhood. ACEs have shown robust associations with a range of adverse health and behavioral outcomes across the lifespan and may be important to consider in understanding barriers to youth MD treatment, parents' treatment-seeking behaviors, and youth and parent distress (including MD). Parents will complete the

ACES questionnaire twice at the baseline assessment only: once in reference to their child, and once in reference to themselves.

**STATISTICAL ANALYSIS PLAN. Power analysis.** G\*Power 3.1 was used to calculate the sample size needed to achieve sufficient power ( $1-\beta$ ) to detect mean group differences of small ( $d=.2$ ), medium ( $d=.5$ ), and large intervention effects ( $d=.8$ ) on the primary outcomes (total parent treatment-seeking behaviors and youth depressive symptoms), with  $\alpha=.05$  and power=0.80 for a two-arm RCT. Ns calculated were 786, 126, and 50, respectively, for an omnibus one-way analysis of variance (ANOVA). Power to detect a small effect is ideal, but logistical constraints necessitate a more conservative sample size. Further, the GM SSIs have previously produced small-to-medium sized improvements in youth depression and parent treatment expectancies,<sup>8-10</sup> and in the case of the proposed study, a medium effect size would likely present a more compelling case than a small effect size for practical implementation and clinical utility. Thus, a sample size of 200 (100 per condition) is proposed, which reflects power to detect small-to-medium effect sizes.

**Analytic plan.** To address Aim 1, we will use generalized estimating equations (GEE). A 2 (intervention condition) X 2 (time: baseline and 3-month follow-up) design will be used to test whether IPR+SSI, relative to IPR alone, increases parents' *treatment-seeking behaviors* (e.g., contacting mental health providers). GEE is an extension of linear mixed modeling permitting correlated repeated observations; it provides greater precision and power than alternate approaches and accommodates both binary and continuous outcomes. Treatment-seeking behaviors will be operationalized in two ways: first, as a continuous outcome (total number of treatment-seeking behaviors, from 0-4), and second, as a binary outcome (whether or not any treatment-seeking behavior occurred). Each of two GEE models (one, a linear model, and the other, a binary logistic model) will include time, intervention condition, and their interaction. We will use an autoregressive error structure for these and all other GEE models in the study, as responses cannot be considered independent. A significant ( $p < .05$ ) Time X Intervention interaction in the above two models would indicate that IPR+SSI, versus IPR alone, led to differential increases in the *total amount* of treatment seeking behavior (linear model), *the presence* of treatment seeking behavior (binary model), or both. Likewise, GEE will be used to address Aim 2. Here, linear GEE models will include time, intervention condition, and their interaction, and a significant Time X Intervention interaction would indicate that IPR+SSI, versus IPR alone, led to differential reductions in youth-reported youth internalizing problems from baseline to 3-month follow-up, per the Pediatric Symptom Checklist internalizing subscale score (Model 2). An additional, parallel model will be conducted to assess change in parent-reported youth MD symptoms (Model 3) across the follow-up, although parent-report youth internalizing symptoms is a secondary outcome in this study. Additional models, structured in the same fashion, will be used to address Aim 3; these GEE models will be identical in structure to those used for Aim 2, but the outcomes will be parent perceived stress (Model 5) and parent psychological distress (Model 6) and other secondary outcome variables in the study. Maximum likelihood estimation will be used to address missing data all GEE analyses. Finally, to address Aim 4 (model feasibility and acceptability), critical metrics will include online SSI completion rates and parent and youth ratings of SSIs as helpful, enjoyable, easy to understand, and worth recommending to others. Acceptable completion rates (above 60%: above mean completion rates for outpatient youth psychotherapy<sup>v</sup>) and mean ratings of 4 out of 5 or higher on each intervention acceptability item would support model acceptability and feasibility.

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