

Promoting Treatment Access Following Pediatric Primary Care Depression Screening: Randomized Trial of Web-Based, Single-Session Interventions for Parents and Youths

STUDY SYNOPSIS

Introduction Summary

Major depression in youth is a serious psychiatric illness with extensive acute and chronic morbidity and mortality.¹ In 2018, the American Academy of Pediatrics released updated practice guidelines promoting screening of youth depression in primary care (PC) clinics across the country, representing a critical step toward increasing early depression detection.² However, the challenge of bridging screening with service access remains. Even when diagnosed by PC providers, <50% of youth with elevated depressive symptoms access treatment of any kind.² Thus, there is a need for interventions that are more feasible for youths and parents to access and to complete—and that may strengthen parents' likelihood of pursuing future, longer-term services for their child.

Single-session interventions (SSIs) may offer a promising path toward these goals. SSIs include core elements of comprehensive, evidence-based treatments, but their brevity makes them easier to disseminate beyond traditional clinical settings.³ Indeed, SSIs can successfully treat youth psychopathology: in a meta-analysis of 50 randomized controlled trials, SSIs reduced youth mental health difficulties of multiple types (mean $g = 0.32$).³ To date, one SSI has been shown to reduce youth depressive symptoms in multiple Randomized controlled trials (RCTs): the online “growth mindset” (GM) SSI, which teaches the belief that personal traits are malleable rather than fixed.⁴⁻⁸ As one example, a 30-minute GM-SSI led to significant 9-month MD symptom reductions in high-symptom youths aged 12 to 15 years versus a supportive therapy control (N = 96; $d_s = 0.60, 0.32$ per parent and youth reports).⁶ Thus, GM SSIs represents a scalable, evidence-based strategy for reducing youth depressive symptoms.

The GM-SSIs can also strengthen parental beliefs about the effectiveness of mental health treatment, which robustly predict whether youths ultimately access services.⁹ A recent RCT including 430 parents of youths aged 7 to 17 years indicated that an online, 15-minute SSI teaching growth

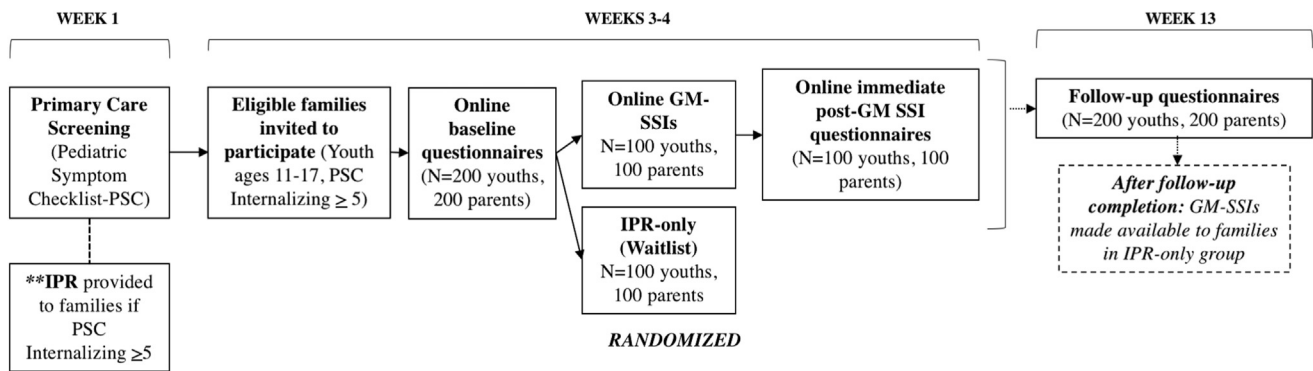
mindset of emotion (viewing emotions as malleable) significantly increased parents' beliefs that psychotherapy could be effective, both for themselves ($d = 0.51$) and for their offspring ($d = 0.43$), versus a psychoeducation control.⁶ By helping to reverse parents' low expectancies for treatment, this low-cost program may enhance parents' odds of seeking services for children with mental health needs.

Accordingly, this study will test whether empirically supported GM-SSIs can help bridge the gap between PC-based depression screening and access to depression services for high-symptom youths. Youths reporting elevated internalizing symptoms at a PC visit will be randomly assigned to one of two conditions: Information, Psychoeducation, and Referral (IPR; ie, usual care) or IPR enhanced with youth- and parent-directed online SSIs (IPR+SSI), designed to reduce youths' internalizing symptoms and to improve parents' mental health treatment expectancies, respectively. We predict the following: (1) IPR+SSI will increase parents' treatment-seeking behaviors, versus IPR alone, across 3-month follow-up; (2) IPR+SSI will reduce youth depressive symptoms across 3-month follow-up versus IPR alone; (3) IPR+SSI will reduce parental stress and psychological distress across 3-month follow-up, versus IPR alone; and (4) parents and youths will rate this service delivery model as acceptable.

Method Summary

Figure 1 provides an outline of the study procedure, and Figure 2 outlines the theoretical model for possible SSI effects. Per youth-reported internalizing symptom elevations during a PC visit (score ≥ 5 on the Pediatric Symptom Checklist internalizing subscale), eligible families (N = 246; youths aged 11–16 years) will be invited to participate in the study. In online surveys, parents will self-report recent treatment-seeking behaviors, expectancies for psychotherapy, stress and psychological symptoms, and youth mental health problems, along with family and demographic information; youths will self-report symptom levels. Within the same survey, youths and parents will then be randomized (1:1 allocation ratio) to one of two experimental conditions (IPR+SSI or IPR alone); those assigned to IPR+SSI will complete an intervention feedback form immediately postintervention. At 3-month follow-up, to assess SSI effects on parental treatment seeking, parental stress and symptoms, and youth depressive symptoms, participating youths and parents will complete the same questionnaires

FIGURE 1 Outline of Study Procedure



Note: IPR = Information, Psychoeducation, Referral. GM-SSI = “growth mindset” Single-Session Intervention.

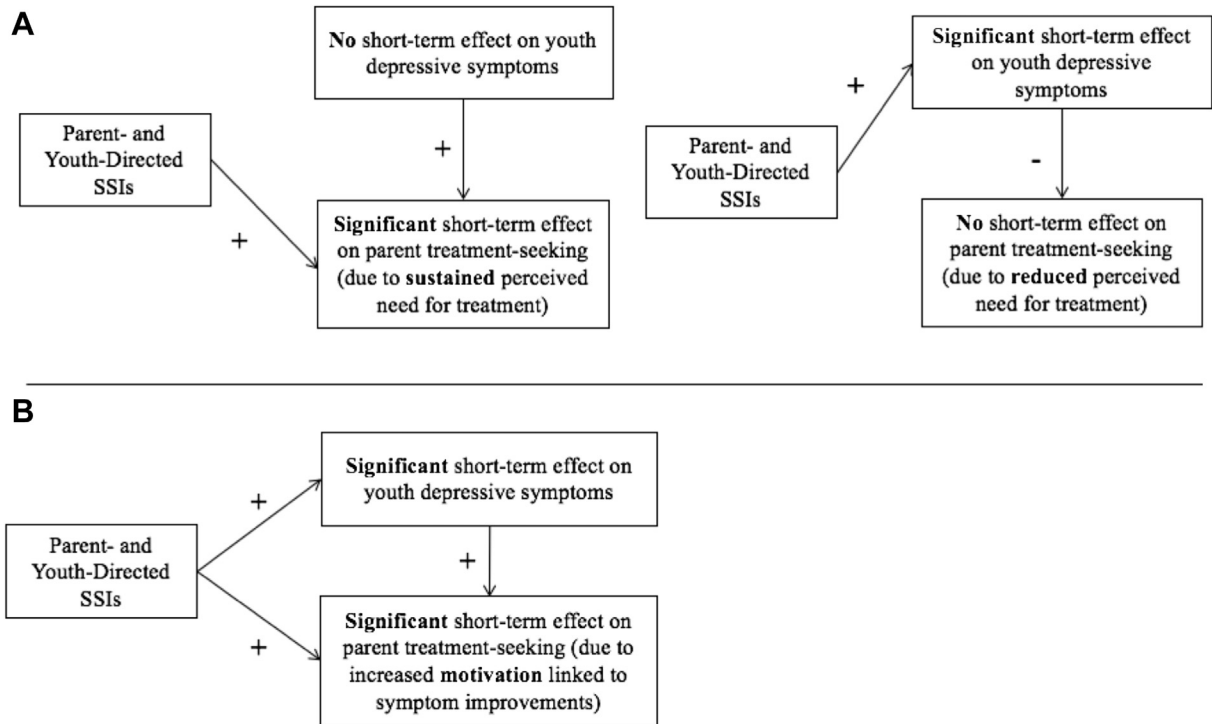
administered at baseline (see Table 1 for a timeline of all study procedures.).

Significance

There is a need for novel, potent strategies to increase families’ access to youth mental health services following PC-based symptoms screening. Ideally, such strategies would

be low cost (eg, those that do not require new staff), would involve both parents and youths to address the myriad factors that may undermine service access, and would impose minimal burdens on PC providers. Results will indicate whether one such strategy—providing online, low-cost SSIs to youths and parents—may help reduce youth depressive symptoms and promote treatment seeking in parents.

FIGURE 2 Theoretical Model Illustrating Potential Patterns of Single-session Intervention Effects



Note: Top panel (A) reflects potential differential intervention effects on co-primary outcomes. Lower panel (B) reflects potential simultaneously intervention effects on co-primary outcomes.

TABLE 1 Schedule of Enrollment, Interventions, and Assessments

Schedule	Study Period				
	Enrollment	Allocation (Baseline)	Postallocation		
			Intervention Administration	Immediate Postintervention	Follow-up (3 mo)
Enrollment					
Eligibility screen	X	—	—	—	—
Informed consent/assent	X	—	—	—	—
Allocation	—	X	—	—	—
Intervention^a					
Youth-directed GM-SSI ^b	—	—	X	—	—
Parent-directed GM-SSI ^c	—	—	X	—	—
IPR only (control) ^d	—	X	—	—	—
Assessment					
Youth self-report					
Pediatric Symptom Checklist	—	X	—	—	X
Children's Depression Inventory—2	—	X	—	—	X
Beck Hopelessness Scale—Short form	—	X	—	X	X
Implicit Theories of Personality Questionnaire	—	X	—	X	—
Intervention Feedback Scale	—	—	—	X	—
Parent report					
Demographics	—	X	—	—	—
Children's Depression Inventory—2	—	X	—	—	—
Adverse Childhood Experiences Questionnaire	—	X	—	—	—
Mental Health Treatment—Seeking Checklist	—	X	—	—	X
Pediatric Symptom Checklist	—	X	—	—	X
Brief Symptom Inventory	—	X	—	—	X
Barriers to Accessing Care Evaluation	—	X	—	—	X
Mental Health Treatment Access	—	X	—	—	X
Perceived Stress Scale	—	X	—	—	X
Attitudes Toward Therapy Scale	—	X	—	X	X
Beck Hopelessness Scale—Short form	—	X	—	X	X
Implicit Theories of Emotion Scale	—	X	—	X	—
Intervention Feedback Scale	—	—	—	X	—

Note: — = not applicable; GM-SSI = "Growth Mindset" Single-Session Intervention; IPR = Information, Psychoeducation, and Referral.

^aYouth-directed SSI, ~ 30 minutes; parent-directed SSI, ~ 15 minutes; youth–parent pairs randomized to both receive interventions or both receive no intervention.

^bYouth-directed growth mindset intervention.

^cParent-directed growth mindset intervention.

^dInformation, psychoeducation, and referral only (control).

Jessica L. Schleider, PhD
Mallory Dobias, BS
Julia Fassler, BA
Akash Shroff, BS candidate
Susmita Pati, MD, MPH

The funding source had no role in the design and conduct of the study; preparation, review, or approval of the manuscript; or the decision to submit the manuscript for publication. There are no additional funding sources for this work.

This work has been previously posted on a preprint server: <https://osf.io/c639z/>.

Clinical trial registration information: Promoting Treatment Access Following Pediatric Primary Care Depression Screening; <https://clinicaltrials.gov; NCT04030897>.

ORCID

Jessica L. Schleider: <http://orcid.org/0000-0003-2426-1953>

Mallory Dobias: <http://orcid.org/0000-0001-6814-3006>

Julia Fassler: <http://orcid.org/0000-0002-9598-6348>

Akash Shroff: <http://orcid.org/0000-0002-1778-3705>

Susmita Pati: <http://orcid.org/0000-0001-9927-3698>

Accepted April 20, 2020.

Dr. Schleider and Mss. Dobias, Fassler, and Shroff are with Stony Brook University, New York. Dr. Pati is with the Division of Pediatric Primary Care, Stony Brook University, New York.

This study is supported by a 2019 Access to Care Grant from the Klingenstein Third Generation Foundation, awarded to Dr. Schleider (PI) and Dr. Pati (Co-I).

Author Contributions*Conceptualization:* Schleider*Data curation:* Schleider, Fassler, Shroff*Formal analysis:* Schleider*Funding acquisition:* Schleider*Investigation:* Schleider*Methodology:* Schleider, Dobias, Pati*Project administration:* Schleider, Fassler, Shroff*Resources:* Schleider, Pati*Writing – original draft:* Schleider, Dobias*Writing – review and editing:* Schleider, Dobias, Fassler, Shroff, Pati

Disclosure: Dr. Schleider has received grant and research support unrelated to this study from the American Psychological Foundation, the Center on the Developing Child at Harvard University, Limbix Health, Inc., and the National Institutes of Health (NIH). Dr. Schleider and Ms. Dobias are under contract with New Harbinger Publications to coauthor a therapy workbook for adolescents. Dr. Pati has received grant and research funding unrelated to this study from NIH, the Health Resources and Ser-

vices Administration, the Agency for Healthcare Research and Quality, the Centers for Disease Control, the Slomo and Cindy Silvan Foundation, the New York State Office for People with Developmental Disabilities, the New York State Department of Health, the Commonwealth of Pennsylvania, the Department of Public Welfare, the American Lung Association, the Robert Wood Johnson Foundation, the Anne E. Dyson Foundation, the David E. Rogers Foundation, the Arnold P. Gold Foundation, and The Pew Charitable Trusts. Ms. Dobias has received research support from a Stony Brook University Graduate Council Fellowship. Ms. Fassler and Mr. Shroff have reported no biomedical financial interests or potential conflicts of interest.

Correspondence to Jessica L. Schleider, PhD, 100 Nicolls Road, Stony Brook University, Stony Brook, NY 11794-2500; e-mail: jessica.schleider@stonybrook.edu

0890-8567/\$36.00/©2020 American Academy of Child and Adolescent Psychiatry

<https://doi.org/10.1016/j.jaac.2020.01.025>

REFERENCES

- Whiteford HA, Degenhardt L, Rehm J, *et al.* Global burden of disease attributable to mental and substance use disorders: findings from the Global Burden of Disease Study 2010. *Lancet.* 2013;382:1575-1586.
- Zuckerbrot RA, Cheung A, Jensen PS, Stein REK, Laraque D; GLAD-PC Steering Group. Guidelines for Adolescent Depression in Primary Care (GLAD-PC): Part I. Practice preparation, identification, assessment, and initial management. *Pediatrics.* 2018;141.
- Schleider JL, Weisz JR. Little treatments, promising effects? Meta-analysis of single-session interventions for youth psychiatric problems. *J Am Acad Child Adolesc Psychiatry.* 2017; 56:107-115.
- Miu AS, Yeager DS. Preventing symptoms of depression by teaching adolescents that people can change. *Clin Psychol Sci.* 2015;3:726-743.
- Schleider JL, Weisz JR. Reducing risk for anxiety and depression in adolescents: effects of a single-session intervention teaching that personality can change. *Behav Res Ther.* 2016;87:170-181.
- Schleider JL, Weisz JR. Parent expectancies and preferences for mental health treatment: the roles of emotion mind-sets and views of failure. *J Clin Child Adolesc Psychol.* 2018; 47(Suppl1):S480-S496.
- Schleider JL, Burnette JL, Widman L, Hoyt C, Prinstein MJ. Randomized trial of a single-session growth mind-set intervention for rural adolescents' internalizing and externalizing problems. *J Clin Child Adolesc Psychol.* 2019 [Epub ahead of print].
- Schleider J, Weisz J. A single-session growth mindset intervention for adolescent anxiety and depression: 9-month outcomes of a randomized trial. *J Child Psychol Psychiatry.* 2018;59:160-170.
- Nock MK, Kazdin AE. Randomized controlled trial of a brief intervention for increasing participation in parent management training. *J Consult Clin Psychol.* 2005;73:872-879.

Update

Journal of the American Academy of Child & Adolescent Psychiatry

Volume 59, Issue 12, December 2020, Page 1408–1410

DOI: <https://doi.org/10.1016/j.jaac.2020.09.012>

J Am Acad Child Adolesc Psychiatry 2020;59(12):1408–1410.

In the 2019 Scientific Proceedings supplement to *JAACAP*, New Research Poster 3.35, “Pediatric Acute-Onset Neuropsychiatric Syndrome and Autoimmune Family History” (2019;58:S206), the last name of author Sydney Rice, MD, was listed incorrectly.



0890-8567/\$36.00/©2020 American Academy of Child and Adolescent Psychiatry
<https://doi.org/10.1016/j.jaac.2020.10.006>

J Am Acad Child Adolesc Psychiatry 2020;59(12):1408–1410.

In the Translations article “Digital Phenotyping With Mobile and Wearable Devices: Advanced Symptom Measurement in Child and Adolescent Depression” by Lydia Sequeira, Marco Battaglia, Steve Perrotta, Kathleen Merikangas, and John Strauss, published in the September 2019 issue of the *Journal of the American Academy of Child and Adolescent Psychiatry* (2019; 9:841-845), there was a citation error involving quotations missing around the following text: *logged call events (ie, timel/date of the call, duration, and contact of both incoming and outgoing calls), short message service (SMS) text message events (ie, timel/date and contact), screen on/off events (ie, timel/date), app use (ie, what app was launched, when, and for how long)*. The text should read “*logged call events (ie, timel/date of the call, duration, and contact of both incoming and outgoing calls), short message service (SMS) text message events (ie, timel/date and contact), screen on/off events (ie, timel/date), app use (ie, what app was launched, when, and for how long)*.”¹



0890-8567/\$36.00/©2020 American Academy of Child and Adolescent Psychiatry
<https://doi.org/10.1016/j.jaac.2020.10.007>

REFERENCE

1. Asselbergs J, Ruwaard J, Ejdys M, Schrader N, Sijbrandij M, Riper H. Mobile phone-based unobtrusive ecological momentary assessment of day-to-day mood: an explorative study. *J Med Internet Res*. 2016;18:e72.

J Am Acad Child Adolesc Psychiatry 2020;59(12):1408–1410.

Revision to Stage 1 Registered Report, “Promoting Treatment Access Following Pediatric Primary Care Depression Screening: Randomized Trial of Web-Based, Single-Session Interventions for Parents and Youths”



We (J. Schleider, M. Dobias, J. Fassler, A. Shroff, S. Pati) have submitted a formal amendment to our recently-accepted Stage One Registered Report at *Journal of the American Academy of Child and Adolescent Psychiatry* (<https://doi.org/10.1016/j.jaac.2020.01.025>), “Promoting Treatment Access Following Pediatric Primary Care Depression Screening: Randomized Trial of Web-Based, Single-Session Interventions for Parents and Youths.” The COVID-19 pandemic has dramatically affected ongoing research endeavors, with especially large impacts falling on community-based studies. Our pediatric primary care-based RCT, outlined in this Registered Report, is no exception. The pandemic has substantially altered operations at our study recruitment sites (nine ambulatory pediatric primary care practices affiliated with Stony Brook University, located across Suffolk County, NY). Due to these uncontrollable changes, it has become necessary to modify our originally-intended recruitment approach in order to achieve our pre-registered sample size. In this letter, we outline the ways in which the COVID-19 pandemic has affected our original recruitment approach, along with changes we plan to incorporate to ensure its successful completion.

Initially, and as written in our present Registered Report, we planned to recruit adolescents (ages 11-16) reporting elevated internalizing distress (per a youth-report Pediatric Symptom Checklist "Internalizing" score of ≥ 5) from 9 pediatric primary care offices affiliated with Stony Brook University. However, the COVID-19 pandemic caused all of our study recruitment sites to close to children >2 years old for 3.5 months, starting in March 2019—just 6 weeks after the trial was launched (we are located in New York, which was the nation's pandemic epicenter at that time, and these office closures were a public health necessity.) Thus, we paused recruitment during this 3.5 month emergency closure period. We recruited 23 families into our trial (of our target N of 246), using our original recruitment criteria, prior to COVID-related office closures.

When the 9 pediatric primary care offices re-opened in late June 2020, 3 of these offices were converted to "COVID-only and/or subspecialist-only" centers, and only 6 are now open for general pediatric "well visits", which are the type of visit during which the Pediatric Symptom Checklist is routinely administered in Stony Brook-affiliated PC offices in accordance with Bright Futures guidelines from the American Academy of Pediatrics. Thus, the maximum number of offices we could recruit from, among those specified in our original recruitment strategy, is now six—not nine.

To comply with new safety and social distancing requirements, these 6 offices can operate at a maximum of 75% patient capacity. Recruiting from just six offices operating substantially below-capacity will not allow us to achieve our target sample of $N=246$ within the time-period allotted by the grant that is funding this study—even after being granted a 12-month no cost extension (which we have already obtained from the Foundation supporting the project). Unfortunately, it is impossible for us to predict when (and if) these 6 offices will return to 100% operating capacity, and/or when the remaining 3 offices will re-open to non-COVID patients.

In order to increase our trial recruitment rate, while simultaneously ensuring that *all* youths who might benefit from our interventions receive the opportunity to participate, we now plan to expand our inclusion criteria for the trial. Specifically, we plan to broaden our definition of youths who qualify as "high-risk" for depression, such that youths meeting *one or more of the following criteria* will be eligible to participate in the trial:

1. **Youths aged 11-16 who report a PSC-Y score of ≥ 5** , reflecting self-reported clinical elevations in youth internalizing problems; AND/OR
2. **Youths aged 11-16 whose parent reports a PSC score of >5** , reflecting parent-reported clinical elevations in youth internalizing problems; AND/OR
3. **Youths aged 11-16 who have received *or* attempted to access treatment for depression** in the previous year, given that depression is likely to recur.

There are at least three advantages to broadening our inclusion criteria in this way. First, our new criteria maximize the odds that youths at-risk for depression will be identified and offered access to trial participation, which includes access to free, evidence-based interventions for adolescents and their parents. That is, if an adolescent does not report their depressive symptoms during their PC visit (e.g., due to privacy concerns or worries about the consequences of disclosing distress), youths may still be identified as "high-risk" should their parent or caregiver identify such symptoms. Likewise, youths who are at substantially elevated risk for major depression due to a recent history of depression (indexed by receipt treatment-seeking or treatment-involvement) may experience symptom reductions following completion of the intervention tested in this trial, per results of a previous test of the same intervention in at-risk youth (where the definition of 'at-risk' included recent receipt of treatment; Schleider & Weisz, 2018).

Second, criteria (2) and (3) will allow us to assess whether, and how, SBU-affiliated PC offices should expand their standard screening for adolescent depression, with the goal of identifying *all* youths who may benefit from mental health support. Criterion (1) is presently incorporated into the existing pediatric PC mental health screener at SBU-affiliated clinics; however, *prior treatment-seeking* and *parent-reports of adolescent internalizing problems* are *not* routinely assessed in adolescent patients. For the purposes of this trial, Criterion (1) will be assessed via medical record review, whereas Criteria (2) and (3) will be assessed via a follow-up phone call to potentially eligible families. By assessing *multiple* indices of potential youth depression risk, this study will allow us to quantify how many adolescents who might want or need mental health support (indexed by their interest in participating in this present trial, which evaluates a treatment for youth depression) are being *missed* by SBU's current screening practices.

Third, compared to our original inclusion criteria, our new inclusion criteria are more consistent with those utilized in current and past trials of the interventions tested in this trial [1-2]. This similarity will directly facilitate cross-trial comparison of intervention effects, facilitating a cumulative literature on the programs' effects in adolescents at-risk for and experiencing depressive symptoms.

We propose no changes beyond these expanded recruitment criteria. We plan to use the same measurement battery at all study time-points, the same 1:1 randomization structure, the same approach to consenting prospective families to take part in the study, the same measurement battery at pre-intervention, post-intervention, and follow-up, the same target sample size, and the same analytic approach (accounting for the new number of clinics we are able to recruit from in the study).

We appreciate the chance to update our planned approach to ensure our study's feasibility. Likewise, in keeping with the goal of the Registered Report model, we are grateful for the opportunity to maintain full transparency as to precisely when, why, and how we now must alter specific elements of our approach.

REFERENCES

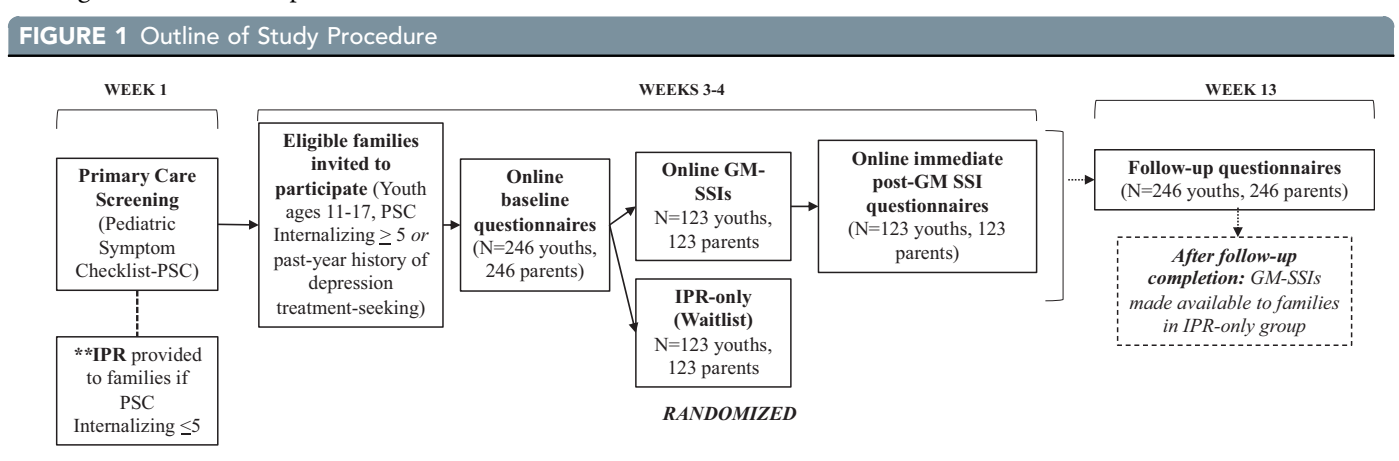
1. Schleider J, Weisz J. A single-session growth mindset intervention for adolescent anxiety and depression: 9-month outcomes of a randomized trial. *J Child Psychol Psychiatry*. 2018;59:160-170.
2. Schleider, J.L. (2019). Clinical Trial Pre-Registration, "Building Evidence-Based Supports for Teens Via Technology (BEST-TECH)" Retrieved from: <https://clinicaltrials.gov/ct2/show/NCT03858881>

Corrections to text:

In the fourth paragraph of the Introduction Summary, the following sentence has been corrected: "Youths **identified as at-risk for depression** at a PC visit will be randomly assigned to one of two conditions: Information, Psychoeducation, and Referral (IPR; ie, usual care) or IPR enhanced with youth- and parent-directed online SSIs (IPRpSSI), designed to reduce youths' internalizing symptoms and to improve parents' mental health treatment expectancies, respectively."

In the first paragraph of Methods Summary, the following sentence has been corrected: "Per youth- **or parent**-reported internalizing symptom elevations during a PC visit (score ≥ 5 on the Pediatric Symptom Checklist internalizing subscale), **or a past-year history of seeking treatment for youth depression**, eligible families (N = 246; youths aged 11–16 years) will be invited to participate in the study."

Figure 1 has been reprinted below:



Note: IPR = Information, Psychoeducation, Referral. GM-SSI = "growth mindset" Single-Session Intervention.