Study Protocol and Analytic Plan

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Title: Promoting Treatment Access Following Pediatric Primary Care Depression Screening

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RUNNING HEAD: SINGLE-SESSION INTERVENTIONS YOUTH PRIMARY CARE

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

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Stage 1 Registered Report

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 towards 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 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 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 ages 12-15 versus a supportive therapy control (N=96; ds=0.60, 0.32 per parent and youth reports).[6] Thus, GM SSIs represents a scalable, evidence-based strategy for reducing youth depressive symptoms.

GM-SSIs can also strengthen parent beliefs about the effectiveness of mental health treatment, which robustly predict whether youths ultimately access services.[9] A recent RCT including 430 parents of youth ages 7-17 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 their offspring (d=0.43), versus a psychoeducation control.[6] By helping 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 youth. Youths reporting elevated internalizing symptoms at a PC visit 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 internalizing symptoms and improve parents' mental health treatment expectancies, respectively. We predict that (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; (4) parents and youths will rate this service delivery model as acceptable.

Method Summary (see *Figure 1*). Per youth-reported internalizing symptom elevations during a PC visit (score ≥5 on the Pediatric Symptom Checklist internalizing subscale), eligible families (N=246; youth ages 11-16) 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 post-intervention. At 3-month follow-up, to assess SSI effects on parent treatment-seeking, parent stress and symptoms, and youth depressive symptoms, participating youths and parents will complete the same questionnaires administered at baseline.

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 (e.g., those that do not require new staff); involve both parents and youths to address the myriad factors that may undermine service access; and 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.

Clinicaltrials.gov registration: NCT04030897

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

Psychiatric disorders are the leading cause of disability worldwide, and 40.5% of this burden is attributable to major depression.[1] Depression symptoms and disorders increase markedly in adolescence, with nearly 20% of youth experiencing depression between ages 11 and 18.[2] Despite this early onset and protracted course, up to 70% of U.S. youth with depression never receive services.[2,3] To improve identification of youths in need of services, the American Academy of Pediatrics released practice guidelines promoting depression screening in primary care (PC) clinics.[4] However, even when identified by PC providers and offered community referrals, <50% of youth with depressive symptoms access treatment.[4] Thus, there is a need for interventions that are feasible for families to access and complete; can be offered via PC clinics efficiently and cost-effectively; and that encourage parents to seek out services for offspring in the future.

Single-session interventions (SSIs) may forward these goals. SSIs include core elements of comprehensive evidence-based treatments, but their brevity makes them easier to disseminate.[5,6] Indeed, SSIs can successfully treat youth psychopathology: In a meta-analysis of 50 RCTs, SSIs reduced youth psychiatric difficulties of multiple types (mean g=0.32), including web-based SSIs (mean g=0.32).[5] To date, one SSI has reduced youth depressive symptoms across multiple trials: the growth mindset (GM)-SSI, which teaches the belief that traits and attributes—such as sadness, shyness, and loneliness—are malleable rather than fixed.[7–9] A web-based, 30-minute GM-SSI has led to significant 9-month depressive symptom reductions in high-symptom youth ages 12-15, versus a supportive-therapy SSI (N=96; ds=0.60, 0.32 per parent and youth reports, respectively).[10] Separately, a GM-SSI significantly reduced depressive symptoms across 4 months in adolescent girls (N=222; d=0.23), versus an active control.[9] Thus, the GM-SSI may be a scalable, promising strategy for reducing youth depressive symptoms.

GM-SSIs may also strengthen parent *beliefs* about the effectiveness of mental health treatment, which robustly predict whether youths ultimately access and benefit from services.[11] In a RCT of 430 parents of youth ages 7-17, an online, 15-minute SSI teaching growth emotion mindset (viewing emotions

as malleable) significantly increased parents' beliefs that psychotherapy could benefit themselves (d=0.51) and their children (d=0.43) versus a psychoeducation control.[12] This low-cost, self-administered program may improve parents' treatment expectancies, potentially improving their likelihood of seeking support for their children's mental health needs.

Present study. We will examine whether these online GM-SSIs can bridge the gap between PC-based depression screening and service access for high-symptom youth. Youths ages 11-16 (N=246) reporting elevated internalizing symptoms at a PC visit will receive either Information, Psychoeducation, and Referral (IPR; usual care) or IPR enhanced with youth- and parent-directed online GM-SSIs (IPR+SSI), designed to *reduce youth depressive symptoms* and *improve parents' expectancies of mental health treatment*, respectively. Our primary hypotheses are two-fold. We predict that (1) IPR+SSI will increase parents' treatment-seeking behaviors, versus IPR alone, across 3-month follow-up; and we predict that (2) IPR+SSI will reduce youth internalizing symptoms across 3-month follow-up versus IPR alone. Hypotheses (1) and (2) are co-primary outcomes; both will help gauge whether GM-SSIs improve access to effective treatment, either as stand-alone interventions or by promoting increased service-seeking.

We expect that these co-primary hypotheses may relate to one another in at least two ways, although we do not have specific predictions as to how this interrelation may manifest (see *Figure 2*). First, the SSIs' effects on parent treatment-seeking and youth internalizing symptoms may relate *inversely* to one another, due to *differential* intervention effects on each outcomes. That is, the SSIs might positively influence youth problems *or* parent treatment-seeking, depending on which effects are more rapidly apparent to the family. For instance, if effects on youth internalizing symptoms emerge more rapidly and overtly than effects on parent treatment-seeking, parents may in turn be less inclined to seek additional care. Likewise, if effects on youth symptoms fail to emerge within a short period of time, parents may be *more* inclined to seek additional care after completing the parent-directed SSI. Thus, is it possible that effects may emerge for *either* parent treatment-seeking *or* youth symptoms, but not both. Conversely, it is possible that the SSIs may positively affect parent treatment-seeking and youth

internalizing symptoms *simultaneously*. If parents perceive initial symptom reductions in their child following the SSI, these initial improvements—indicating the potential for further gains—may *further* motivate them to seek additional care. We perceive both pattern of results as equally plausible in the present trial; either would help clarify the potential role(s) of these SSIs within pediatric primary care.

In addition to our co-primary hypotheses, we will also test two secondary hypotheses to further contextualize the intervention's effects and acceptability. We predict that (3) IPR+SSI will reduce parental stress and psychological distress across 3-month follow-up, versus IPR alone, and (4) families will rate this service delivery model as acceptable.

Method

Study Design. This study will be a two-arm randomized-controlled trial with 1 active intervention condition and 1 active control condition (1:1 allocation ratio). Procedures were pre-registered on ClinicalTrials.gov on 7/24/2019 (NCT04030897; anticipated date of first enrollment: 12/15/2019). The University Institutional Review Board (#IRB2019-00241) approved all study procedures on 7/8/2019. Project funding is provided by the Klingenstein Third Generation Foundation.

Youths and parents will complete all study procedures remotely via personal internet-equipped devices. After discussing procedures with a research team member via telephone, eligible families will receive a study link from which parents and youths may provide consent and assent and complete their respective study portions. In separate Qualtrics-based surveys, parents and youths will complete baseline questionnaires, the GM-SSIs (or 'waitlist' notification; IPR will be provided to all families at initial PC appointments), and post-intervention questionnaires within a single online survey lasting approximately one hour per family member. Parent-youth pairs will both be assigned to the same condition (GM-SSI or 'waitlist') via survey-embedded random-number generators; randomization will not be stratified. Subsequently, three-month follow-up questionnaires will be administered via Qualtrics-based surveys. Follow-up surveys will assess parents' treatment-seeking behaviors, youth symptoms, parental stress and psychopathology, and related variables (detailed below). Families who do not complete follow-up surveys

within 3 days of contact will receive ≤3 reminder messages. After completion of the 3-month follow-up, families who did not initially receive GM-SSIs will be granted intervention access.

Participants and Recruitment. We will recruit two-hundred youths ages 11-16 and one parent per youth from nine community-based branches of the University Hospital's Pediatric Primary Care service. Per the University Medical Center's policies, providers at all sites administer the youth-report Pediatric Symptom Checklist (PSC)[13] to patients 11 and older. Providers review patients' PSC scores during their appointments; all youths reporting symptom elevations receive an "Information, Psychoeducation, and Referral" folder, including contact information for local mental health providers and psychoeducational materials. In this study, youths with an elevated PSC-Internalizing Score (5/10 or higher, per 0-2 ratings of five items: *Feel sad or unhappy*, *feel hopeless*, *down on yourself*, *seem to be having less fun*, *worries a lot*) may be eligible for participation, per existing PSC-Internalizing cut-offs.[14] Because the PSC is already implemented and scored across participating clinics, and because PSC scores are used to direct distribution of "Information, Psychoeducation, and Referral" resource folders to patients, using the PSC as an eligibility screen creates no added clinical burden for providers. Within 3 weeks of the youth's PC appointment, a research team member will contact potentially eligible families by phone to introduce the study and invite them to participate. Additional inclusion criteria, assessed during this call, include English-language proficiency and comfort completing computer-based activities. Receipt of mental health services upon enrollment will be monitored but will not preclude participation.

The parent- and youth-directed interventions last approximately 15-30 minutes. Thus, there is no plan to discontinue interventions due to worsening symptoms, but participants will be informed that they may stop participating in the study at any time without penalty.

Sample size justification. First, using G*Power 3.1, we calculated samples needed to achieve 80% power to detect a small (per Cohen's recommendations: d=.2 or OR=1.49), medium (d=.5 or OR=3.45), and large effects (d=.8 or OR=9.00) effect on primary outcomes (parent treatment-seeking behaviors, per logistic regression, and youth depressive symptoms, per linear regression) at α=.05 for a two-arm RCT, including two covariates (baseline youth depression symptom severity; intervention

condition). *N*s were 392, 55, and 25, respectively, for a regression predicting, and 615, 89, and 50, respectively, for a logistic regression predicting parent treatment-seeking behaviors at 3-month follow-up. However, it is necessary in this study to consider our multisite recruitment structure (9 sites total). GM-SSIs have previously produced small-to-medium improvements in youth depressive symptoms and parent treatment expectancies; we thus used procedures outlined by Feaster, Mukulich-Gilbertson, and Brincks[15] to obtain more precise power estimates for a mixed-effects model predicting medium up ($d = 0.5$) changes in youth depressive symptom severity from baseline to 3-month follow-up, assuming low variability in treatment across sites (0.05). A target *N* of 246 (approximately 26-28 youths per site, although we cannot accurately project exact site-specific recruitment totals in advance) would ensure 92% power to detect an average intervention effect of $d = 0.5$ and 80% power to detect a minimum average effect size of $d = 0.42$. As such, a target *N* of 246 was selected for this study. Notably, participants will be randomized at the study level—not at the site level—ensuring an even number of families assigned to both study conditions overall.

Intervention Descriptions

Youth-Directed Growth Mindset (GM) SSI.[10] The web-based, youth-directed GM-SSI is delivered via Qualtrics and is approximately 30 minutes long. All activities are self-administered and delivered in a web-based format, including illustrations, graphics, and audio-recordings. Content is designed to maximize relevance for youths experiencing depressive symptoms (e.g., sadness, hopelessness) and includes five components: 1. A brief lesson on neuroplasticity, describing how behaviors are controlled by thoughts and feelings in the brain, and thus have potential for change; 2. Stories from older youths describing beliefs that their traits (e.g., sadness, anxiety) are malleable; 3. Further stories by older youths, describing times when they applied this knowledge to cope with emotional setbacks; 4. Scientific studies suggesting that personality can positively change over time; and 5. An exercise in which participants write notes to younger peers, using newly-gleaned knowledge to generate advice on coping with an emotional setback. Here, youths are presented with a hypothetical peer rejection scenario and 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, youths 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 that they can change, or things that are happening to them could change?"

Parent-Directed Growth Mindset (GM) SSI.[12] The web-based, parent-directed GM-SSI takes 15 minutes. Parents first read a brief passage, "Can We Change Our Emotions?" presenting data, quotations, and examples conveying the argument that emotions are inherently flexible in youths and adults. Parents then read another passage, "Is Failure a Friend or Foe?" illustrating the notion that failure promotes learning, growth, and self-reflection. After 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 exercise is designed to promote internalization of the passage's ideas.

To assess program completion, user-activity tracking markers will be embedded into our Qualtrics surveys for participants.

Information, Psychoeducation and Referral (IPR). IPR represents usual care in the University Hospital's Pediatric Primary Care Division; it is routine practice at all clinics in this study. All families of youths with elevated depressive 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 before enrollment, per University Medical Center policy.

Potential bias sources. Families will know whether they receive GM-SSIs immediately or after follow-up. To minimize other potential performance bias sources, families will be randomized remotely via online surveys; thus, the research team and PC providers will be blinded to condition. Second, some eligible families may have limited computer access, creating possible selection bias. We therefore designed study questionnaires and interventions to be completable on *any* internet-equipped device (smartphones, tablets, computers). Additionally, if an eligible youth with limited internet access is interested in participating in the study, research team members will work with the family to identify local venues where internet-equipped devices are accessible (e.g., public libraries/community centers).

Trial conduct. Data will be monitored on an ongoing basis (daily) for quality assurance purposes and to ensure protocol compliance. Further, we will follow University IRB policies for expedited adverse event (AE) reporting. The PI will review data for potential AEs in real-time throughout the trial; AEs occurring during the study will be reported to the IRB within 48 hours. Any protocol alterations that become necessary will be approved by the IRB before implementation.

Data confidentiality and sharing statement. Data will be collected via Qualtrics and stored on password-protected electronic servers meeting University security standards. After the funding period concludes, de-identified participant-level data will be posted publicly via Open Science Framework (OSF). Intervention materials are available from the first author upon request.

Measures (see **Table 1** for SPIRIT information).

Mental Health Treatment-Seeking Checklist (Co-Primary Outcome). At baseline and 3-month follow-up, parents will indicate their engagement ('yes'/'no') in four treatment-seeking behaviors for their child: researched local mental healthcare providers/agencies; contacted mental healthcare provider or agency about treatment; contacted child's school regarding mental health supports; and scheduled an appointment *or* placed child on waiting-list with a mental healthcare provider/agency (number of treatment-seeking behaviors ranges from 0-4). At baseline, parents will report whether they engaged in these behaviors since the child's PC appointment, and at follow-up, since their last survey. Parent treatment-seeking will be a primary outcome.

Children's Depression Inventory-2 (CDI-2; Co-Primary Outcome). Parents and youths will complete the CDI-2 scale at baseline (pre-intervention) and 3-month follow-up. The CDI-2 is a reliable, valid measure of youth depression severity, normed for youth age and sex and yielding raw and T scores, along with an index of functional impairment. The CDI-2 is highly sensitive to clinical change across treatment and is used routinely in clinical trials for treating youth depression.[3,7,10] Change in self-reported youth depressive symptoms will be a primary outcome; parent-reported youth depression symptoms is a secondary outcome.

Pediatric Symptom Checklist (PSC; Eligibility screener and secondary outcome). The PSC is a widely-used, validated measure of overall youth psychopathology, including internalizing, externalizing, attention, and total symptoms, based on 35 items rated 0-2.[15] Because participating clinics administer the PSC during all PC visits, the PSC will serve as the study's eligibility screener. Youth depressive symptoms will be indexed via the 5-item PSC Internalizing Subscale (score range 0-10).[16] A score of ≥5 will indicate possible trial eligibility. Receiver operating characteristics analyses suggest that the PSC-17 Internalizing subscale performs as well as competing screens (e.g., the Children's Depression Inventory and Child Behavior Checklist) in predicting depression diagnoses based on clinical interviews (AUC>0.80).[16,] Youths and parents will also complete the full PSC-17 at baseline and follow-up; changes in overall youth- and parent-reported youth psychopathology will be secondary outcomes.

Beck Hopelessness Scale-Short Version (BHS-4). The BHS-4[18] is a valid, reliable 4-item version of the 20-item BHS[19] assessing hopelessness in youths and adults.[20,21] Parent and youth self-reported hopelessness will be assessed at baseline, post-intervention (if assigned to the IPR+SSI group), and follow-up. Higher sum-scores (range: 0-12) reflect greater hopelessness.

Brief Symptom Inventory-18 (BSI-18). The BSI-18 is a reliable, validated measure of self-reported psychopathology and distress.[22,23] At baseline and 3-month follow-up, parents will rate endorsement of 18 physical and emotional complaints from 0-4. Sum scores yield a total distress score (range: 0-72).

Barriers to Accessing Care Evaluation (BACE). The BACE is a well-validated assessment of the degree to which beliefs, concerns, and circumstances have stopped or discouraged individuals from accessing youth mental health services.[24-26] At baseline and follow-up, parents will rate its 30 items on a 0-3 scale. Higher scores (range: 0-90) indicate greater service access barriers.

Attitudes Toward Therapy Scale. This single-item scale assesses parents' perceptions that therapy/counseling would help reduce their child's mental health difficulties.[12] At baseline, post-intervention (if assigned to IPR+SSI), and 3-month follow-up, parents will rate the item from 0-10. Higher scores indicate stronger beliefs that therapy may help reduce mental health problems.

Mental Health Treatment Access. 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 follow-up).

Perceived Stress Scale. The PSS is a validated measure of one's appraisal of daily life as stressful, unpredictable, and uncontrollable.[27,28] At baseline and follow-up, parents will rate 10 items from 0-4, with higher scores indicating greater perceived stress (range: 0-40).

Implicit Theories of Emotion Scale. The ITE Scale[29,30] will serve as a manipulation check for the parent-directed GM-SSI. At baseline and post-intervention (IPR+SSI group only), parents will report the degree to which they view emotions as malleable (versus immutable) on a 1-6 scale across four items. Higher mean scores (range: 1-6) indicate stronger fixed emotion mindset, and lower scores, stronger growth emotion mindset.

Implicit Theories of Personality Questionnaire. The ITPQ[31] will be used as a manipulation check for the youth-directed GM-SSI. At baseline and post-intervention (IPR+SSI group only), youths will rate agreement with three statements linked to malleability of personality. Higher mean scores indicate stronger fixed personality mindsets, and lower scores, stronger growth personality mindsets (range: 1-6).

Intervention Feedback Scale. Immediately post-intervention, the Intervention Feedback Scale[32] will ask youth and parents receiving GM-SSIs to indicate how much they enjoyed, understood, felt helped by, would recommend, and agreed with the program's message. They will also be prompted to provide written feedback regarding their impressions of the program.

Adverse Childhood Experiences (ACEs). The ACEs questionnaire is a well-validated measure of exposure to violence, childhood emotional, physical, or sexual abuse, and household dysfunction during childhood.[33,34] Parents will complete the ACEs questionnaire at baseline in reference to their child and to themselves.[1]

[1] We do not plan to use the ACEs questionnaire in primary study analyses. Rather, we are including this questionnaire to allow for future tests of whether trauma exposure influences GM-SSI intervention

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

Analytic Plan

Manipulation check. Two paired-samples *t*-tests will assess whether youths and parents receiving GM-SSIs report significant pre-to-post-SSI increases in growth mindset of personality and emotion, respectively.

Intervention effects on parent treatment-seeking. We will run two mixed effects regressions (one mixed effects linear regression; one mixed effects logistic regression) to test whether IPR+SSI, versus IPR alone, increases parents' treatment-seeking behaviors (Hypothesis 1). Treatment-seeking will be operationalized in two ways: as a continuous outcome (total number of treatment-seeking behaviors), and a binary outcome (whether or not any treatment-seeking occurred). Both the linear and one binary logistic regression models will include intervention condition and baseline youth-reported depression symptom severity, with recruitment site included as a random effect. (Although randomization will occur at the patient level, our trial includes multiple sites, and current practice suggests that sites should be included in models as random effects.[15] While not strictly necessary for a balanced study in the absence of variability in intervention effects among sites, this is a more conservative, generalizable approach.) A significant effect of condition on the outcome would indicate that IPR+SSI, versus IPR alone, led to differential increases in the amount of treatment seeking (linear model), presence of treatment seeking (logistic model), or both. Significant effects per either or both models would suggest support for Hypothesis 1.

Intervention effects on youth internalizing symptoms. A mixed effects linear regression will include Intervention Condition and baseline self-reported youth depressive symptom severity, with recruitment site included as a random effect. A significant effect Intervention Condition would indicate

response. Any such analyses we decide to pursue will be pre-registered at a later date as exploratory, secondary tests.

that IPR+SSI, versus IPR alone, led to differential reductions in self-reported youth internalizing symptoms from baseline to 3-month follow-up (Hypothesis 2). An additional parallel model will be conducted to assess change in parent-reported youth depressive symptoms (a secondary outcome).

Intervention effects on parental distress and stress. Two additional mixed effects linear regressions, structured and interpreted in the same fashion as those for Hypothesis 2, will assess Hypothesis 3. Outcomes will be parent perceived stress and parent psychological distress.

Acceptability of service delivery model. Critical metrics will include SSI completion rates and ratings of SSIs as helpful, enjoyable, easy to understand, and worth recommending to others. Acceptable completion rates (≥60%: above mean completion rates for outpatient youth psychotherapy[36]) and mean ratings of ≥4/5 on acceptability items would suggest service model acceptability.

Missing data. We will apply multiple imputation (20 imputations) to address any item-level missing data and maximum likelihood estimation for subject-level missing data in regression analyses. Multiple imputation will be applied to all variables for which missing item- or subject-level data emerge.

Covariates. Potential covariates will include family income, youth age, and youth sex. Each covariate will be included only if it correlates significantly with condition assignment.

Correction for multiple tests. The false discovery rate (FDR)[37] will be applied to identify potential false-positive results. *Q*-values will be computed for *p*-values from regression models using an online calculator applying Benjamini and Hochberg's[37] approach (www.sdmproject.com/utilities/?show=FDR). Results will be considered significant if FDR-corrected $q<0.05$ (incurring maximum 5% false-positive rate amongst all tests meeting significance at $p<0.05$). To ensure rigorous tests of statistical significance, results of all pre-registered statistical tests of primary and secondary hypotheses (H1-H4) will be included in computations of FDR-corrected significance levels.

Study timeline. Recruitment is projected to begin by January 2020 and extend until the target sample is achieved. Recruitment, intervention administration, and follow-up assessments are projected to be complete by June 2021, and data processing and analysis, by August 2021 (end of the grant period).

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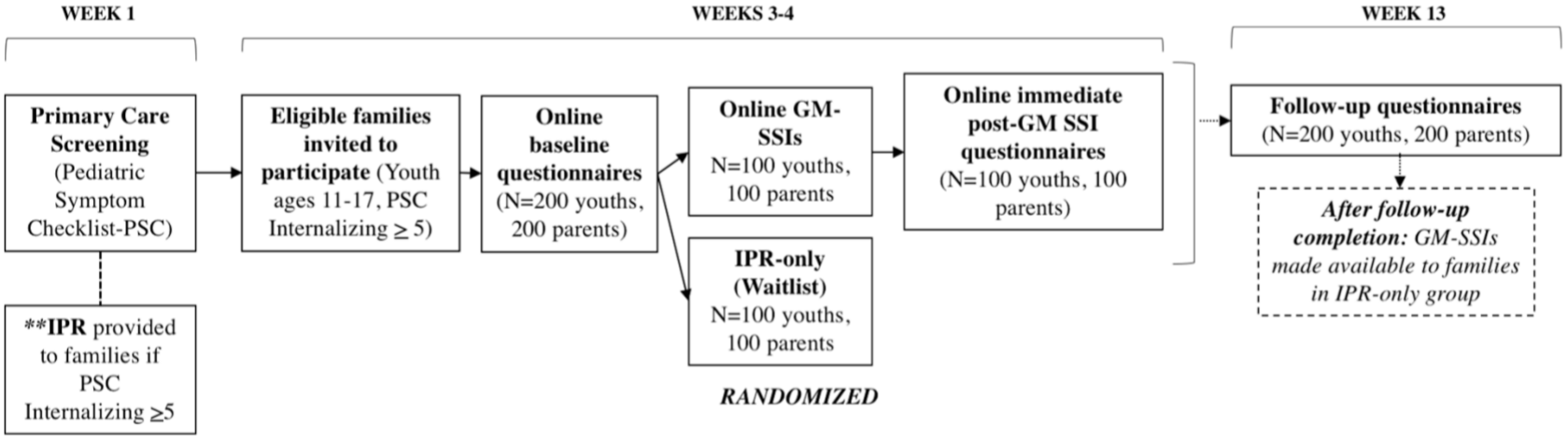
Table 1. Schedule of enrollment, interventions, and assessments.

Schedule	Study Period				
	Enrollment	Allocation (baseline)	Post-allocation		Follow-up (3-months)
			Intervention administration	Immediate post-intervention	
Enrollment					
Eligibility screen	X	- [a]	-	-	-
Informed consent/assent	X	-	-	-	-
Allocation	-	X	-	-	-
Interventions [b]					
Youth-directed GM SSI [c]	-	-	X	-	-
Parent-directed GM SSI [d]	-	-	X	-	-
IPR only (control) [e]	-	X	-	-	-
Assessments					
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	-

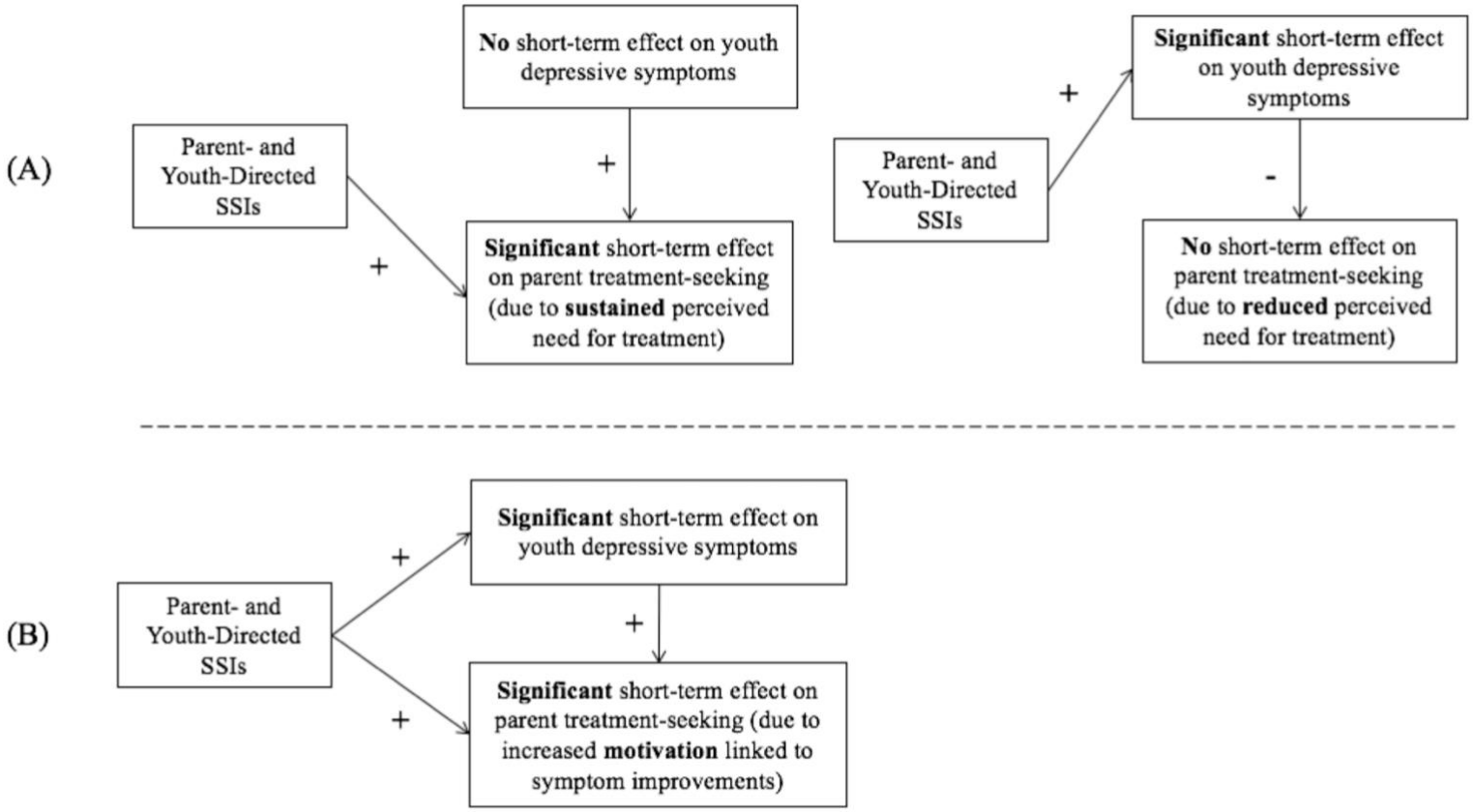
Note. [a] Not applicable. [b] Youth-directed SSI ~30 minutes; parent-directed SSI ~15 minutes; youth-parent pairs randomized to both receive interventions or both receive no intervention. [c] Youth-directed growth mindset intervention. [d] Parent-directed growth mindset intervention [e] Information, psychoeducation, and referral only (control).

Figure 1. Outline of Study Procedure



Note. IPR = Information, Psychoeducation, Referral. GM-SSI = 'Growth Mindset' Single-Session Intervention.

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.