




Substance Use Screening and Prevention for Adolescents in Pediatric Primary Care: A Randomized Clinical Trial using the Family Check-Up

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Abstract

This study evaluated acceptability, engagement in prevention, and efficacy of a primary care screening-and-referral-to-prevention program to reduce substance use in early adolescence. Screening tools were the Youth Risk Index and Transmissible Liability Index and prevention consisted of the Family Check-Up (FCU). Three hundred sixty-one 10- to 13-year-olds from low resource neighborhoods (85.9% African American; 52.4% female) screened “at risk” during primary care visits and were randomized to the FCU ($n = 123$) or usual care ($n = 238$). Screening was acceptable to parents and youths: nearly 95% of each rated it as important, about 90% of each were happy with or did not mind it, and only 2.4% of parents did not want their child to be screened at their next check-up. Of parents who had a chance to receive the FCU (or waitlist-control), 87.5% followed through with researchers while 93.5% who were offered FCU engaged in it. FCU efficacy primarily involved interactions such that youth with greater risk at baseline experienced larger benefits. At 12-month follow-up, FCU was associated with 11% reduced risk of initiating a new substance per substance that had been initiated before baseline; greater reductions in tolerance of deviance among those with higher tolerance of deviance at baseline; and a main effect of reduced anxiety, but no effect for conduct problems. Pediatric well-child check-up screening can identify high-risk youth before, or in the initial stages of, problematic SU; engage families in a preventive intervention; and reduce rates of substance use and related risk factors.

Keywords Screening · Primary care · Family Check-up · Adolescence · Substance use · Indicated prevention

Introduction

Despite over three decades of prevention efforts, early adolescent substance use (SU) remains highly prevalent. U.S. prevalence of SU in 8th graders is 25.6%, 14.8%, and 11.5%, respectively, for lifetime alcohol, cannabis, and cigarette smoking (Johnston et al., 2020). These rates are concerning as SU initiation before high school confers increased propensity for substance use disorder (SUD) and opioid misuse (Center for Behavioral Health Statistics and Quality, 2015; Green et al., 2016; Thrul et al., 2021). Thus, screening for

SU risk before high school and providing preventive interventions for at-risk youth has potential to avert short- and long-term harms from SUD, opioid overdose, and other substance use-related outcomes. To this end, this study tested the efficacy of coupling evidence-based innovative screening tools (youth-report and parent-report), with a family-based prevention, the Family Check-Up (FCU), to reduce risk of initiation and emerging SU in low-income youth recruited from pediatric primary care.

Pediatric primary care is an ideal setting for identifying at-risk youths. Advantages that pediatricians offer include long-term relationships with youth and parents, confidentiality and expertise, screening and prevention counseling to ensure healthy youth development, and parents generally trust pediatricians as the stewards of child healthcare (Leslie et al., 2016; Levy et al., 2016; Moseley et al., 2011). The American Academy of Pediatrics has prioritized SU screening and prevention for decades (AAP, 2010) and primary care before high school has potential for nearly universal

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reach, as the majority of children in the U.S., including those from low-income families, receive annual well-child visits (Child Trends Databank, 2018). However, because attendance of well-child check-ups drops substantially in mid- to late-adolescence (Nordin et al., 2010), screening for SU risk in early adolescence (ages 10–13) may be especially important. Many pediatricians do not screen for SU due to concern over low acceptability among patients or parents (Ozechowski et al., 2016; Ridenour et al., 2021), which was therefore evaluated in this study.

Theoretical Models for Screening and SU Prevention in Early Adolescence

Two well-established, multifactorial etiology models of SUD guided our conceptual approach, screening tools, and intervention selection. First, the liability-threshold model (Falconer, 1996) delineates how the manifold SUD risk factors combine in complex ways, change over time, and evolve with development to place individuals at their overall levels of SUD liability. When an individual's overall liability exceeds a theoretical threshold SUD is manifested, with less severe forms of SU occurring when liability surpasses their corresponding lower thresholds. Second, the common liability model posits that overall liabilities and specific risk factors are largely common across the SUDs that occur from using different substances (Kendler et al., 2007). These theories imply that (1) effective screening tools measure overall liability rather than specific sources of risk, (2) screening for ages 10–13 must quantify liability for SU initiation and escalation in early adolescence, and (3) prevention using family-based, evidence-based methods should be used to address the individual youth's particular risk factors (in contrast to a universal program).

Screening

Multiple brief screening tools for SU have been validated for adolescents, such as the Brief Screener for Tobacco, Alcohol, and Other Drugs (BSTAD; Kelly et al., 2014), Screening to Brief Intervention tool (S2BI; Levy et al., 2014), Car, Relax, Alone, Forget, Friends, and Trouble (CRAFT; Knight et al., 2002), Problem Oriented Screening Instrument for Teenagers (POSIT; Kelly et al., 2017), and NIAAA Screening Guide (NIAAA-SG; D'Amico et al., 2019). For screening liability of SU initiation in youths ages 10–13, they have considerable limitations. Foremost is that these instruments ask about some form of SU, whereas most at-risk early adolescents have not yet initiated SU or will not report their SU, and many pediatricians will not ask their patients about SU (Ozechowski et al., 2016; Ridenour et al., 2021). These tools require the primary care provider to administer, score, and/or interpret them, which is a barrier

for most pediatricians (Ozechowski et al., 2016; Ridenour et al., 2021). They also largely rely on written instruments, precluding accurate data from poor readers and illiterate youth who are at greater risk for SU on average and more likely than others to err or discontinue written surveys because of frustration, inattention and/or fatigue (Bennett et al., 2003).

The Youth Risk Index[®] (YRI) overcomes these barriers using youth-report items that ask about a range of risk factors (designed to quantify liability rather than SU per se – see Measures); a cartoon-based, audio, computer-assisted self-interview format for accessibility to illiterate youth; instant electronic scoring; and a protocol that can be administered and interpreted by a nurse or behavioral specialist as patients wait for appointments (thus requiring no time of a pediatrician; Ridenour et al., 2015). The YRI complements adolescent screening tools by detecting propensity for future problematic SU as early as age 8, allowing for early prevention well before SUD onset.

The Transmissible Liability Index (TLI) was used to cull parent ratings of youth liability for problematic SU (Kirisci et al., 2009; Vanyukov et al., 2009). The TLI measures a youth's heritable risk for SUD, potentially capturing sources of SU risk that the YRI misses. TLI items were each selected because they statistically distinguished 10- to 12-year-old youths who do (versus do not) (1) have fathers with a lifetime illegal drug SUD and (2) themselves experience a SUD by early adulthood during a prospective longitudinal study (Kirisci et al., 2009; Vanyukov et al., 2009).

The Family Check-Up (FCU)

The parent(s) of youth who were (1) identified at risk for SU and (2) randomly assigned to the intervention condition were referred to the FCU, a family-based intervention that addresses risk factors linked to early adolescent SU and other problem behaviors (e.g., low parental monitoring, deviant peer affiliation; Dishion et al., 2011; Shaw et al., 2019). Consistent with the liability-threshold model, the specific targets of intervention are selected by the parent(s) and informed by a thorough assessment of the youth and parents to identify the specific risk factors that contribute to the youth's liability.

The FCU included two or more sessions comprising an initial parent interview with a family assessment and a feedback session focused on assessment results. Following completion of the feedback, families also have the option to participate in follow-up treatment sessions focused on three domains of the caregiving environment: positive behavior support, limit setting and monitoring, and relationship quality, as well as other services that FCU counselors can help them access such as parental mental health or housing (Dishion et al., 2011). The focus on family management practices is directly derived from

Parent Management Treatment approaches to the treatment of antisocial behavior in children (e.g., Forgatch & Patterson, 2010). Modeled on the Drinker's Check-Up and grounded in motivational interviewing (Miller et al., 1988), the goal of the FCU is to motivate caregivers to change problematic behavior in their child, which is often achieved by modifying family management practices that compromise parenting quality. The FCU has been demonstrated to be efficacious for preventing youth behavioral problems and improving child and family adaptation from early childhood through adolescence, including yielding less growth in SU from ages 11 to 14 and pronounced intervention effects for the highest risk youth (Dishion et al., 2002, 2014; Shaw et al., 2016, 2019). In a separate sample, FCU youth reported significantly lower rates of antisocial behavior and alcohol, cannabis, and cigarette use from grades 6 to 8 compared to control youth (Stormshak et al., 2010). These outcomes are promising and highlight the effectiveness of the FCU model for reducing risk for SU in early adolescence.

Prior FCU trials with early adolescent youth have been delivered nearly exclusively in public school settings (Dishion et al., 2002; Stormshak et al., 2010). While these trials have been shown to be effective at reducing adolescent SU and conduct problems, the promise of disseminating the FCU in schools is tempered by low rates of family engagement in these settings (e.g., about 42% of Title 1 middle school students' parents, Van Ryzin et al., 2012). While there are numerous benefits of school-based prevention programs, to build youth resiliencies through parental involvement it is often challenging to engage parents in family-focused interventions in school contexts. These challenges are especially pronounced when working with families of low socioeconomic status who face significant barriers to school involvement (e.g., jobs without paid leave). Further, recommendations for adapting the Screening, Brief Intervention, and Referral to Treatment model for use with adolescents emphasize the importance of administering SU screening measures to both youth and parents (Ozechowski et al., 2016). Involving caregivers in the screening process may increase the likelihood of identifying youth at risk for SU initiation and help set the stage for subsequent parental involvement in treatment. As youth are often accompanied by their parents during well-child visits, primary care may be an ideal setting to identify and engage at-risk youth and their families (Leslie et al., 2016).

Study Hypotheses

This study tested the integrated YRI/TLI and FCU model in a sample of 10- to 13-year-old youth and their families recruited from primary care. First, we hypothesized the

screening protocol would be highly acceptable to youths and their parents based on preliminary evidence; their (lack of) acceptance has been a concern reported by, and a potential barrier for, pediatricians' adoption of SU screening (Ozechowski et al., 2016; Ridenour et al., 2021). We then tested the hypothesis that youth randomized to the FCU would show at one-year follow-up reduced initiation and frequency of alcohol, cannabis, and tobacco use as well as established correlates of SU: conduct problems, anxiety, and tolerance of deviance. Based on prior research with the FCU (Connell & Dishion, 2008; Shelleby et al., 2018), we expected that intervention effects would be particularly pronounced for higher risk youth with a history of problem behavior. Moreover, SU was expected to be positively skewed as most youths at ages 10–13 do not engage in SU further resulting in efficacy expected to be primarily detected among higher-risk youths who did initiate SU.

Methods

Participants

Participants were youth-caregiver dyads recruited from primary care clinics during well-child visits between July 2014 and May 2018. Follow-up data collection began in July 2015 and concluded in July 2019. Clinics were located in Pittsburgh, Pennsylvania, and predominantly served African American patients residing in low-resource, urban neighborhoods. After pediatric practice staff obtained verbal consent for research contact, study staff approached families in exam rooms to obtain parent consent and youth assent; study staff then administered screening tools to assess youth risk for SU and other problem behaviors. Screening tools were independently completed by parents and youth. Families were eligible to participate if a youth's or parent's screening score was in the elevated risk range, the child was 10–13 years old, and the child received need-based Medicaid or family income was at or below 150% of poverty guidelines. Exclusion criteria included an inability to speak English or the child having moderate or severe intellectual disability.

At baseline, parents were on average 35.82 years ($SD=6.31$), 96% female, and 82% Black/African American. Average gross annual household family income was \$24,705 ($SD=\$19,629$), and 44% of parents were unemployed. 74.5% of youth were Black/African American only and 11.4% were Black/African American and another race (e.g., Black and non-Hispanic White). Additional demographic information about participating youth is presented in Table 1.

Table 1 Demographic Characteristics and Baseline Descriptive Statistics of Analytic Sample

Study Variables		Entire Sample (<i>n</i> = 361)	Treatment arm		<i>p</i> - value ^b
			Family Check Up (<i>n</i> = 123)	Control (<i>n</i> = 238)	
Child sex	Male	47.6%	41.5%	50.8%	0.091
	Female	52.4%	58.5%	49.2%	
Child age (years)		11.93 (1.17)	12.00 (1.09)	11.89 (1.21)	0.423
Child race	Black/African American	74.5%	76.4%	73.5%	0.191
	White, Non-Hispanic	9.7%	6.5%	11.3%	
	Multiracial ^a	13.6%	16.3%	12.2%	
	Unknown	3.0%	0.8%	4.2%	
Number of 0		67.6%	65.6%	70.1%	0.296
substances 1		18.6%	19.7%	18.4%	
used 2		7.2%	10.7%	5.6%	
(ALEXSA) ^c 3		5.3%	4.1%	6.0%	
Number of 0		85.0%	83.8%	85.7%	0.694
occasions 1		7.9%	9.4%	7.1%	
drank alcohol 2		2.6%	1.7%	3.1%	
(ALEXSA) ^c 3		1.8%	2.6%	1.3%	
4		0.6%	0.0%	0.9%	0.216
5+		2.1%	2.6%	1.8%	
Number of 0		91.1%	95.8%	93.5%	
occasions 1		1.7%	0.8%	2.2%	
used tobacco 2		0.8%	0.8%	0.9%	0.216
(ALEXSA) ^c 3		0.8%	0.0%	1.3%	
4		0.6%	1.7%	0.0%	
5+		1.7%	0.8%	2.2%	
Anxiety (SCARED)		25.79 (14.05)	26.09 (15.03)	25.63 (13.57)	0.771
Tolerance of deviance (ALEXSA) ^c		0.46 (0.69)	0.37 (0.55)	0.51 (0.75)	0.088
Parent depression (CES-D) ^c		16.75 (8.79)	18.21 (8.19)	16.00 (9.03)	0.020
Parental attachment (ALEXSA) ^c		2.22 (0.72)	2.34 (0.60)	2.15 (0.77)	0.010
Parent monitoring interview (PMI) ^c		2.88 (0.60)	2.97 (0.54)	2.83 (0.63)	0.029

ALEXSA Assessment of Liability and Exposure to Substance use and Antisocial behavior, SCARED Screen for Child and Anxiety-Related Emotional Disorder, CES-D Center for Epidemiological Studies, Depression. Percentages may not sum to 100% due to rounding error.

^a Of the 49 youth identified as multiracial or biracial, 41 were Black/African American.

^b *p*-values for either *t*-test (continuous variables) or Fisher's Exact χ^2 test (categorical variables).

^c Variable is not over-dispersed, indicating a Poisson regression model is needed.

^d Variable is over-dispersed, indicating a negative binomial model is needed.

^e Welch's test, due to significant heterogeneity of variances between control and FCU groups.

Study Design

A staged recruitment process spanning three years (Fig. 1) was used to ensure the planned ratio of participants in three subgroups having two-year follow-ups: those with two years of FCU exposure, with one year of control waitlist followed by FCU, and true controls. Thus, some families were offered the FCU upon recruitment and those in the control wait-list condition were offered the FCU after a one-year wait period, with both groups participating in assessments of youth and family functioning at baseline and annual follow-ups. During

Year 1, 297 families were randomly assigned, stratified by child sex, to the FCU (*n* = 123) or a control wait-list condition (*n* = 127) using a 1:1 allocation. Random assignment occurred prior to screening using a computerized random number generator. In Year 2, all eligible families (*n* = 60) were assigned to the control wait-list condition, and Year 3 participants (*n* = 51) were recruited as “true” controls who received care-as-usual (i.e., Year 3 families were never offered the FCU). Thus, control wait-list families provided control data for one-year follow-up and were combined with “true” controls for the purposes of this study. Due to the

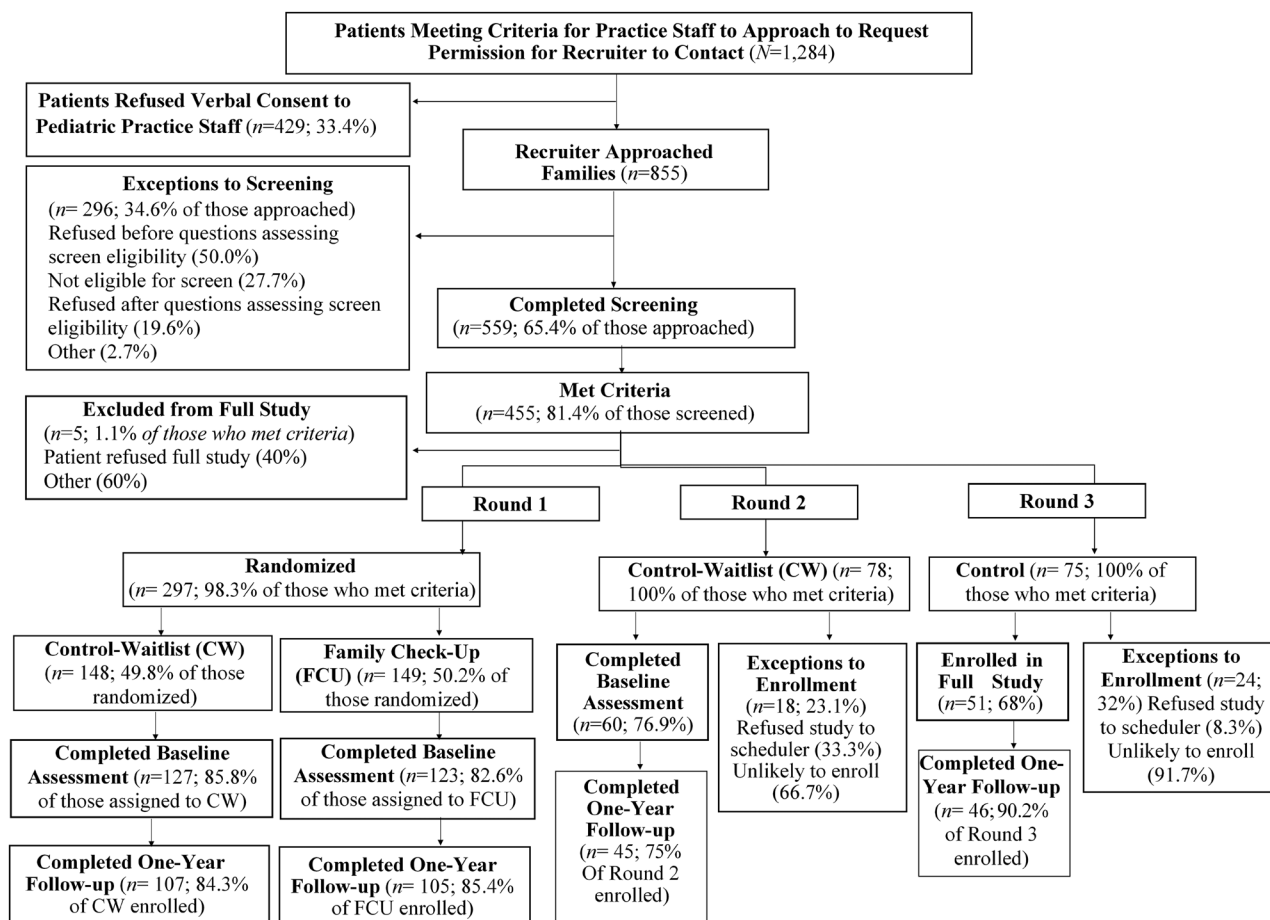


Fig. 1 CONSORT Diagram: Experimental Design and Flow of Participants through the Study

design of the trial, the Principal Investigator, treatment providers, and participants were aware of condition allocation.

Procedures

Study procedures followed the University of Pittsburgh IRB-approved protocols to conduct a randomized controlled trial to test the acceptability of the screening and referral program and FCU efficacy. Informed consent and assent were obtained for primary caregivers and youth, respectively, at the time of recruitment. Enrolled families completed surveys at study entry and at one-year follow-up. While the identification, screening, and referral of families occurred in primary care clinics, assessments and intervention services predominantly occurred in family's homes. As all families were of low socioeconomic status, a home visiting approach was adopted to reduce barriers to treatment and study engagement (e.g., lack of transportation, non-traditional work schedules). Home-based assessments at baseline and one year typically lasted 2 to 3 h in length and were focused on factors in youth's ecological context that have been linked to adolescent

problem behavior (e.g., parent well-being, parent-youth relationship quality, neighborhood risk/protective factors, peer relationships, exposure/accessibility to substances) and youth adjustment (e.g., substance use, antisocial behavior, depression, anxiety). Control and FCU families were compensated for completing assessments. The study protocol is available upon request.

The Family Check-Up (FCU)

The FCU consists of (1) a comprehensive, ecological assessment using normed measures of parenting, family dynamics, sociocultural contexts and resources, and child behaviors; (2) a rapport-building, "Get to Know You" (GTKY) initial interview which focuses on building a collaborative framework for subsequent intervention, and (3) a feedback session, during which the parent consultant uses motivational interviewing to summarize results from the ecological assessment. The primary goal of the feedback session is to generate dissonance for the parent between their current perception of their child's behavior and their aspirations for

their child by summarizing the family's strengths and challenges, suggesting areas that if addressed, could result in improved child behavior. Caregivers are offered a menu of intervention options, which may include follow-up parent training sessions using the Everyday Parenting Curriculum (EPC; Dishion et al., 2011). Parent consultants may also connect parents with community-based services, such as housing opportunities or youth extra-extracurricular activities, to address non-parenting needs. Of the 375 families with at-risk youths who were offered the FCU (either immediately or via control-waitlist), 87.5% engaged with researchers. Of the 123 families in the FCU condition, 115 (93.5%) completed the initial meeting, assessment, and feedback sessions and 42 (36.5%) completed follow-up sessions ($M=7.6$ sessions, $SD=9.1$). While the vast majority of families were given the option of engaging in follow-up sessions following the feedback, based on the FCU's collaborative structure that is grounded in the tenets of motivational interviewing (i.e., critical that parent maintains sense of control in making decisions about addressing needs salient to them), families were also encouraged to meet their goals independently or through referrals to external agencies to address family goals (e.g., housing, food insecurity, employment, to a psychiatrist for medication to address mental health concerns).

Parent consultants were primarily master's-level clinicians. Consultants received an initial 30 h of training in the FCU protocol, which incorporated didactic and experiential instruction and video observation of FCU-certified clinicians. After completing training, parent consultants submitted videotaped sessions for review by their supervisor to attain certification in the FCU model. FCU certification was determined by meeting the fidelity criteria established by the model developer using the COACH Rating System (Dishion et al., 2010). To further ensure fidelity and prevent drift, each parent consultant was required to be recertified on the COACH using a videotape of an FCU feedback and/or follow-up session every six months throughout the course of the project.

Measures

Assessment of Liability and EXposure to Substance use and Antisocial behavior© (ALEXSA) The ALEXSA is an illustration-based, audio, computer-assisted self-interview that measures early manifestations of, and risk factors for, youth SU and problem behaviors. The ALEXSA's 350 items are organized into ten domain scores and 39 subscales (based on factor analyses) which are reliable and valid for youth ages 7 to 15 of different races, sexes, and literacy levels (e.g., Chilenski et al., 2015; Ridenour et al., 2009). Study outcomes included ALEXSA questions regarding youth SU, conduct disorder criteria, and tolerance of deviance. Youth SU was a count of how many substances had been initiated of alcohol, tobacco, and cannabis,

using three items that were based on U.S. surveillance surveys: "Have you ever drunk alcohol, even just a sip?", "Have you ever used tobacco, even just to try it?", and "Have you ever used cannabis, even just to try it?" (response options were *yes* or *no*). Despite having few items, SU $\alpha=0.66$ at baseline and 0.72 at follow-up (α is heavily penalized for 3-item measures). If use of a substance was reported, a follow-up question inquired frequency of use (e.g., "How often do you [use tobacco/drink alcohol/use cannabis] right now?") with response options of *never*, *once in a while*, *every few days*, *most days*, or *every day*. Eleven items assessed DSM-5 conduct disorder behavior criteria such as vandalism and aggression. Items were scored using *yes* and *no* response options, and scale scores were criteria counts (baseline: $\alpha=0.71$; follow-up: $\alpha=0.70$). Seven items measuring tolerance of deviance asked how wrong it is for youths to behave in certain ways, such as skipping school or cheating on a test. The tolerance of deviance scale score equaled the mean of its 4-point Likert item scores and its internal consistency $\alpha=0.90$ at baseline and follow-up.

Youth Risk Index© (YRI) To screen for youth risk status, the YRI was administered as youth waited in exam rooms for well-child visits. The YRI is composed items from other ALEXSA "risk factor" subscales that were highly associated with current or next-year SU initiation and/or 2+ conduct disorder behaviors (termed "conduct problems" herein) to quantify overall liability. Thus, no SU or conduct disorder criteria were queried during screening. Of the 23 YRI items, six query friends' conduct problems, five query tendency to cope with frustration through anger, four query distractibility, three measure impulsivity, three query susceptibility to peer pressure, and one each query access to tobacco and social disinhibition. The YRI has excellent test-retest reliability and good sensitivity and specificity for concurrent and later SU and conduct problems (Ridenour et al., 2015). Two YRI thresholds, set at 80% sensitivity and 80% specificity for predicting SU or conduct problems by one year later, identify ranges of low, moderate, and high risk. Moderate- or high-risk scores qualified for eligibility in the present study.

In our sample, the YRI demonstrated excellent internal consistency at baseline ($\alpha = 0.86$) and 12-month follow-up ($\alpha = 0.87$). YRI baseline scores correlated 0.51 ($p < 0.001$) with YRI scores 12 months later. Baseline YRI scores were associated respectively with baseline and 12-month follow-up using odds ratios (all p -values < 0.001) for use of any substance at 3.14 (95% C.I. = 2.02–4.90) and 2.09 (95% C.I. = 1.34–3.24); having 2+ conduct disorder behaviors at 7.64 (95% C.I. = 4.46–13.10) and 2.59 (95% C.I. = 1.65–4.06); and initiating sexual intercourse before age 15 (12-month follow-up only) at 4.20 (95% C.I. = 2.28–7.72). Baseline YRI scores correlated (Kendall's tau b) with baseline and 12-month counts of substances initiated (alcohol, tobacco, and cannabis) at 0.24 ($p < 0.001$) and 0.18 ($p < 0.001$) and

conduct disorder behaviors at 0.35 ($p < 0.001$) and 0.26 ($p < 0.001$). They also correlated (Pearson r) with baseline and 12-month Self-Reported Delinquency Scale (Piquero et al., 2002) at 0.45 ($p < 0.001$) and 0.29 ($p < 0.001$), Screen for Child Anxiety Related Disorders at 0.22 ($p < 0.001$) and 0.12 ($p = 0.02$), and tolerance of deviance at 0.32 ($p < 0.001$) and 0.23 ($p < 0.001$). Consistent with prior research on youth and parent reports, YRI scores correlated (Pearson r) less or not statistically with baseline and 12-month parent-rated Child Behavior Checklist Conduct Problems (0.16, $p = 0.001$; 0.12, $p = 0.02$); Oppositional Defiant Problems (0.12, $p = 0.01$, 0.11 $p = 0.03$); Anxiety Problems (0.08, $p = 0.06$; 0.03, $p = 0.30$); and Withdrawn/Depressed (0.04, $p = 0.26$; 0.02, $p = 0.34$).

Transmissible Liability Index (TLI) The Transmissible Liability Index's (TLI) parent-rated items to measure a youth's heritable risk for SUD was used as a parent-rating complement to YRI screening (Kirisci et al., 2009; Vanyukov et al., 2009), had excellent internal consistency ($\alpha = 0.85$) at baseline, and correlated 0.30 ($p < 0.001$) with the YRI, indicating they measure overlapping but different sources of risk. TLI items are based on items in the Tarter Childhood History Questionnaire, Schedule for Affective Disorder and Schizophrenia for School Age Children (K-SADS-E), Dysregulation Inventory, Child Behavior Checklist, and the Child Abuse Potential Inventory and are provided by Kirisci et al. (2009). Study eligibility was equivalent to 80% sensitivity in association with concurrent conduct disorder, oppositional defiance disorder, or SU in the sample first used to develop the TLI (Kirisci et al., 2009; Vanyukov et al., 2009).

TLI baseline scores correlated (Pearson's r , all $p < 0.001$) with baseline and 12-month parent-rated (Child Behavior Checklist scores) Conduct Problems (0.61 and 0.51); Oppositional Defiant Problems (0.60 and 0.50); Anxiety Problems (0.40 and 0.29); and Withdrawn/Depressed (0.32 and 0.34). Baseline TLI scores correlated respectively with baseline and 12-month values (Kendall's tau b) at 0.01 ($p = 0.47$) and 0.02 ($p = 0.34$) with number of child-reported substances initiated (alcohol, tobacco, and cannabis) and 0.06 ($p = 0.07$) and 0.07 ($p = 0.04$) with count of child-reported conduct disorder behaviors. Baseline TLI scores correlated (Pearson r) respectively with baseline and 12-month values at 0.16 ($p < 0.001$) and 0.17 ($p < 0.001$) with delinquent behaviors (Self-Reported Delinquency Scale), -0.02 ($p = 0.39$) and 0.02 ($p = 0.40$) with anxiety (Screen for Child Anxiety Related Disorders), and 0.09 ($p = 0.05$) and 0.03 ($p = 0.33$) tolerance of deviance. TLI baseline scores were not statistically associated (odds ratios) with baseline and 12-month follow-up, respectively, child-reported initiation of any substance at 1.10 (95% C.I. = 0.77–1.56, $p = 0.60$) and 1.09 (95% C.I. = 0.75–1.60, $p = 0.65$) or child-reported two or more conduct disorder behaviors at 1.44 (95% C.I. = 1.01–2.05, $p = 0.05$) and 1.35 (95% C.I. = 0.93–1.95, $p = 0.12$) but were

associated with initiating sexual intercourse before age 15 (12-month follow-up only) at 2.24 (95% C.I. = 1.30–3.86, $p = 0.004$).

Screen for Child Anxiety-Related Emotional Disorders (SCARED) Youth reported on their anxiety symptoms over the last 3 months using the SCARED, a 41-item inventory rated on a 3-point scale with well-documented internal consistency, test–retest reliability, and convergent and discriminant validity (Birmaher et al., 1997, 1999). Items were summed for analyses, with higher total scores indicating greater anxiety. Excellent internal consistency was observed in our sample (baseline: $\alpha = 0.92$; follow-up: $\alpha = 0.93$).

Covariates. Parental Depression, Parental Monitoring, Parent–Child Attachment To account for potential “third-variable” explanations, we included established measures of parental depression (Center for Epidemiological Studies – Depression (CES-D), $\alpha = 0.88$; e.g., “I had crying spells” and “I felt lonely”; Radloff, 1977), parent report of parental monitoring (Parental Monitoring Interview (PMI), $\alpha = 0.87$; “In the past year, to what extent did you really know who your child's friends are and what they do together?” and “How often do you usually obtain information from other sources about what your child does with his/her free time?”; Dishion et al., 1991), and youth report of attachment to the parent (subscale from ALEXSA $\alpha = 0.89$, “How often do you share your thoughts and feelings with your parent?” and “How often can you count on your parent for help with a problem?”; Ridenour et al., 2009).

Screening Acceptability This 10-item questionnaire queried participants' acceptability of the screening and referral to prevention protocol. It was based on past surveys of stakeholder acceptability of behavioral screening tools (Ridenour et al., 2015). Questions evaluated isolated aspects of the protocol rather than a summative score or overall index; thus, internal consistency is not computed for this measure.

Statistical Analysis

All analyses were conducted using SAS 9.4. Descriptive statistics were inspected to investigate the first hypothesis that the YRI and TLI screeners would be acceptable to youth and parents, respectively. Associations between the YRI or TLI and youth risky health behaviors were calculated using binary logistic regression, Kendall's tau b , or Pearson r based on the variable distributions (reported in Measures). Baseline differences between FCU and control groups were tested using t -tests for continuous variables and chi-square tests for categorical variables.

Regression analyses tested intervention effects, using the model that corresponded to distribution of each outcome

variable, controlling for the baseline level of the outcome. Tolerance of deviance and anxiety symptoms were normally distributed and thus analyzed using normal regression, with effect sizes reported as partial linear regression coefficients. Number of substances used and frequencies of alcohol and tobacco use were skewed but not overly dispersed and thus analyzed using Poisson regression with an effect size of risk ratio per unit increase in SU at baseline (risk ratio less than 1.0 represents less SU in the FCU group at follow-up). Conduct disorder behaviors was a count variable, right skewed, and slightly over dispersed and thus analyzed using negative binomial regression with an effect size of incidence rate ratio, with a ratio less than 1.0 representing fewer conduct disorder behaviors at follow-up in the FCU group.

Prior clinical trials of FCU documented interactions in which certain outcomes varied by participants' baseline level of risk. Thus, each outcome was first modeled using the following terms: hypothesized main effect (difference between intervention arms), baseline level of the outcome (to control for pre-study individual differences), an interaction term of treatment condition by baseline level of the outcome, and characteristics on which controls and FCU participants differed at baseline (Table 1). If neither the main effect nor interaction term reached $p < 0.10$, the interaction term was dropped and only the main effect result was reported.

Missing Data Consistent with the intent-to-treat philosophy, all participants were included in analyses, including those with completely missing follow-up data. Data were available for 301 of the 361 (83.4%) families at follow-up. SAS Proc MI was used to generate 20 imputed datasets for all variables that were analyzed at any time point. Imputed data were truncated to the observed minimum and maximum values. SAS Proc MIANALYZE was used to compile results across imputed datasets following statistical analyses. To estimate how sensitive results were to imputing values, analyses were repeating using only observed values with inverse probability treatment weighting to control for baseline differences between control and FCU participants. Results did not differ meaningfully; hence, the replicated results are reported in Supplementary Materials.

Attrition To assess whether participants lost to follow-up differed from those with complete data, their differences were tested across a range of baseline characteristics. None of the demographic or study outcome variables differed between them, supporting the assumption that data were missing at random. Moreover, retention rates did not differ between intervention and control families. However, randomization failed to equate study arms in terms of certain variables (Table 1); these variables were statistically controlled in outcomes analyses.

Results

Baseline Descriptive Statistics

Descriptive statistics for baseline outcome variables appear in Table 1. At baseline, lifetime alcohol, tobacco, and cannabis use were endorsed by 24.3%, 14.6%, and 12.3% of youth, respectively, and 19.4% of youth endorsed three or more conduct disorder behaviors, the diagnostic threshold for Conduct Disorder. The mean total score on the SCARED ($M = 25.6$, $SD = 14.1$) was above the cut point for indicating the presence of clinically significant anxiety (i.e., 25). Control and FCU participants differed statistically at baseline in terms of parental depressive symptoms, parental attachment, and parent monitoring, with trends toward statistical differences (i.e., $p > 0.10$) observed for youth's sex and tolerance of deviance; these five variables were statistically controlled for when testing follow-up outcomes.

Acceptability of YRI and TLI Screeners

Table 2 presents parents' and youths' acceptability of the screening and referral protocol. About 90% of parents and youths were happy with or did not mind the screening, considered it important, and had no trouble completing the screening tools. Nearly all parents and youths reported no concerns about confidentiality and gave no wrong answers on purpose; however, 19.1% of youth (compared to 5.2% of parents) reported that they struggled with answering screening items honestly. Only 2.4% of parents did not want their pediatrician to screen to their child during future visits, and over 90% of parents reported that they would seek help if their child was identified 'at risk.'

Intervention Effects on Primary and Secondary Outcomes

At 12-month follow-up, prevalence of alcohol, tobacco, and cannabis use was 27.2%, 18.6%, and 15.6%, respectively. Results from tests of whether the FCU would lead to reductions in SU and established correlates of SU (especially for youth with greater baseline levels of the outcome) appear in Table 3. There was no main effect of treatment condition on SU at follow-up. However, as hypothesized, among youth who had used a greater number of substances at baseline, FCU was associated with reduced risk of initiating a new substance by 11.0% per substance used at baseline (risk ratio = 0.89, 95% C.I. = 0.83–0.96, $p = 0.003$) (Figure S3A in Supplemental Materials). Also, no main effect was found for frequency of either drinking alcohol or using tobacco (in aggregate) whereas among youths who used either substance at baseline, those who received FCU used either substance 29.0% less

Table 2 Stakeholders' Acceptability of Screening and Referral Protocol

Characteristic of Screening Protocol	Parents	Youth
Happy with / did not mind screening	94.1%	88.7%
Pediatricians helping kids behave safer is important	94.8%	92.8%
Had no or little trouble completing screening	99.0%	92.2%
Child had no or little trouble completing screening	99.7%	- -
Easy or not hard to answer screening questions honestly	94.8%	80.9%
Concerned about confidentiality	1.7%	6.8%
Gave a wrong answer on purpose	2.1%	3.4%
Prefer paper form or computer to complete screening		
Paper and Pencil	3.5%	7.1%
Computer	60.5%	59.2%
Does Not matter	36.0%	33.7%
Prefer to take screening in reception area or exam room		
Reception Area	2.4%	9.2%
Exam Room	21.6%	22.4%
Does not Matter	76.0%	68.4%
Prefer that a nurse or doctor administer screening		
Nurse	1.7%	5.1%
Doctor	6.6%	7.8%
Does Not Matter	91.6%	87.1%
Does not want pediatrician to screen patients at child's next appointment	2.4%	- -
If child was 'at risk' would / probably would seek help	94.1%	- -
If child was 'at risk' AND doctor knew who could help, would / probably would seek help	93.3%	- -

frequently than controls at follow-up (risk ratio=0.71, 95% C.I.=0.56–0.92, $p=0.008$). Alcohol and tobacco use were sufficiently infrequent that the impact of FCU could not be detected statistically when testing the behaviors separately.

Treatment condition predicted less tolerance of deviance among youth with greater tolerance of deviance at baseline ($b=-0.32$, $p=0.003$), with the standardized difference being 0.33/0.11 or 3.00; Figure S3C). A main effect was

Table 3 Efficacy Estimates using Multiply Imputed Outcomes for Missing Data and Controlling for Baseline Level of Characteristic and Baseline Subgroup Differences

		Effect Size	95% C.I.	p -value
Number of substances used ^P (ALEXSA)	Main Effect	1.07	(0.95, 1.21)	0.28
	Interaction	0.89	(0.83, 0.96)	0.003
Number of occasions used alcohol or tobacco ^P (ALEXSA)	Main Effect	0.98	(0.59, 1.63)	0.94
	Interaction	0.71	(0.56, 0.92)	0.008
Number of occasions drank alcohol ^P (ALEXSA)	Main Effect	0.73	(0.50, 1.07)	0.10
Number of occasions used tobacco ^P (ALEXSA)	Main Effect	0.79	(0.39, 1.59)	0.58
Conduct disorder behaviors ^{NB} (ALEXSA)	Main Effect	1.06	(0.81, 1.38)	0.67
Tolerance of deviance ^{LR} (ALEXSA)	Main Effect	0.08	(0.00, 0.16)	0.33
	Interaction	-0.32	(-0.21, -0.43)	0.003
Anxiety symptoms ^{LR} (SCARED)	Main Effect	-3.15	(-4.63, -1.67)	0.03

Baseline differences that were statistically controlled for were youth sex, parent-reported depression, child-reported parental attachment, and parental discrimination based on income/education. Main effect=difference in Family Check-Up (FCU) recipients compared to controls. Interaction=adjusted FCU outcome per unit of baseline level of the outcome. ALEXSA=Assessment of Liability and Exposure to Substance use and Anti-social behavior; SCARED=Screen for Child and Anxiety-Related Emotional Disorder.

^{LR} Linear regression model with beta coefficient effect sizes.

^{NB} Negative binomial regression model with an incident rate ratio effect size.

^P Poisson regression with a risk ratio effect size.

found for FCU exposure on reducing youth anxiety symptoms compared to controls at follow-up ($b = -3.54$, $p < 0.01$; with a large standardized difference between FCU and control youth: 3.54/1.35 or 2.62). However, FCU exposure was not associated with change in conduct disorder symptoms at follow-up.

Discussion

This study tested the effectiveness of the integrated YRI/TLI and FCU model on emerging SU and other problem behaviors in 10- to 13-year-old youth recruited from pediatric primary care. Consistent with our first hypothesis, screening with the YRI and TLI was acceptable to nearly all early adolescents and parents. While the YRI was valid for screening and detecting risk for SU before high school, the TLI was unrelated to youth report of SU initiation. The second hypothesis, which predicted intervention effects on youth SU and established correlates of SU, particularly for higher risk youth, was partially supported. Compared to receiving care-as-usual, receiving the FCU was associated with reduced SU and tolerance of deviance at follow-up for youth with higher baseline SU. Unexpectedly, there were no main effects of the intervention on youth SU or tolerance of deviance, and the hypothesized effect of the FCU on youth conduct problems was not supported.

YRI and TLI Screeners

Results corroborate previous findings that the YRI detects youth who have initiated alcohol, tobacco, or cannabis use or are likely to over the next year (Ridenour et al., 2015). Moreover, while the YRI was designed to detect propensity of SU and conduct problems, it also predicted sexual debut before age 15 and was statistically, albeit weakly, correlated with youth anxiety. This finding, combined with the clinically significant levels of anxiety in the current sample, suggest that the YRI may be suitable as a transdiagnostic screening scale despite taking less than 8 min to complete. Thus, assessing risk for SU problems may have multiple advantages compared to querying actual SU in early adolescence. This approach, combined with the use of computer technology, may result in more honest reporting because of decreased concerns regarding the confidentiality of information disclosed. Additionally, based on common etiological factors underlying the development of youth SU, conduct problems, and internalizing problems, assessing risk factors appears highly informative for primary care screening for referral to selective / indicated prevention.

YRI scores in the moderate and high-risk ranges qualified youths for the FCU prevention program. However, the FCU's benefits were experienced primarily by youths

at greater levels of baseline risk. An additional preventive intervention may be more impactful specifically for youths at moderate risk for SU during early adolescence. To illustrate, serious videogames with efficacy for reducing various SU risk factors could be provided to youths while their parent(s) complete the FCU (Fiellin et al., 2017; Montanaro et al., 2015). Other programs that target specific sources of risky behavior could also be matched to youths who need them, such as Coping Power for youths experiencing aggression (Miller et al., 2020). Future research is needed to test a tiered approach to offering alternative interventions based on youth's level of risk.

Although the TLI – the parent-reported screening tool – failed to identify youth who had initiated SU, it served a critical function during screening by occupying parents' attention while youth completed the YRI. Further research is needed to develop and test parent-reported screening tools for youth SU liability to improve screening accuracy and prognosis. The TLI measures heritable risk which contributes less to initiation and early use compared to SUD (Hopfer et al., 2003) and so may capture less liability at ages 10–13 compared to YRI risk factors. It is possible that TLI validity was affected by parents who were motivated to engage in the FCU reporting greater child risk on the TLI than they otherwise would report. Alternatively, there could have been differential item functioning by race as the TLI was developed in a largely White, non-Hispanic sample whereas our sample was primarily Black, non-Hispanic.

Intervention Effects on Youth Adjustment

Our findings corroborate prior FCU studies and the broader literature showing that families at higher risk appear to benefit most from evidence-based prevention programs (Connell & Dishion, 2008; Shelleby et al., 2018). Specifically, FCU's reduction of SU was greater among youths who had initiated more substances or consumed alcohol or tobacco more frequently at baseline. These results are exciting as they point to the FCU's ability to interrupt early SU trajectories before long-term patterns of SU become established. Study findings are especially notable as the FCU only entailed sessions with parents, underscoring the feasibility of reducing SU and associated risks without intervening directly with youth for families whose teens are in the earlier stages of SU.

One unexpected result was a failure to find an intervention effect for youth conduct problems despite the FCU's past success in addressing this outcome (Dishion et al., 2014; Stormshak et al., 2010). Null findings may be due to the duration of the FCU in the current study. In past trials of the FCU using both adolescents and toddlers, more pronounced effects on children's conduct problems have been evident after repeated annual doses of the FCU (Shaw et al., 2016), versus the single dose offered in the present study. In

the FCU model, doses are defined as the number of annual initial interviews, assessments, and feedbacks rather than the number of treatment sessions a family has in a particular year to provide families with data and hopefully motivation for changing their parenting to promote their child's functioning. As a subset of families in the current study received a second dose of the FCU, we plan to follow-up on this issue in a future report.

The lack of significant intervention effects on youth conduct problems may also be related to the timing of intervention delivery or developmental status. Prevention programs may be most effective when delivered close to the period of symptom onset. Although early adolescence may be an optimal time for the prevention of SU because many youth first begin experimenting with substances during this developmental period, earlier intervention may be required for youth conduct problems which often have a much earlier onset (Galán et al., 2020; Shaw et al., 2019). For youth with early-onset conduct problems, by the time they reach early adolescence, more intensive intervention may be needed to address the likely increasing and more serious nature of their antisocial behavior.

Family Engagement

In addition to showing improvements in multiple types of youth behavior, our results support utilizing primary care as a platform for engaging families. Of those who screened at-risk and had a chance to receive the FCU, 87.5% followed up with researchers and 93.5% of the parents who were offered the FCU engaged in the intervention. The high engagement rate could be partially attributed to combining the initial interview and assessment components of the FCU into one meeting, making it possible to conduct the FCU in two versus three separate in-person meetings. Despite evidence-based interventions for preventing youth SU, availability and access to these programs are modest, particularly in disadvantaged areas. Primary care clinics are optimal settings for detecting youth at risk for SU and linking them to evidenced programs, such as the FCU. High engagement rates in our study are especially noteworthy given the historic challenges of engaging families whose teens are in the early stages of SU and are not seeking treatment. For these families, brief interventions such as the FCU may be most appropriate. FCU's use of motivational interviewing techniques may also be helpful in overcoming resistance from parents who do not believe that SU is a problem for their child or that monitoring their child's activities is necessary.

Study Limitations

Findings should be considered in the context of study limitations. First, participants were recruited from pediatric clinics

in one metropolitan area and families faced financial hardships. Although additional research is needed to examine whether findings generalize to higher SES families, the adaptive, tailored approach of the FCU makes it well-suited to be responsive to families' diverse needs and to be flexibly delivered in a variety of settings. Second, analyses were limited to one-year follow-up. Although findings suggest that the FCU was less beneficial for lower-risk youth in terms of SU reductions, intervention effects for these youth may become more evident as they transition to high school and have greater access to alcohol and other substances. Continued follow-up of the study sample is needed to formally test these speculations and to examine the endurance of intervention gains identified in the present study. Third, randomization of half the sample into a fully "control" condition is traditionally utilized. Nonetheless, a staged sampling approach allowed us to maximize statistical power and provide the most efficient use of funding as many participants provided both control and intervention data. This design will also permit us to examine possible dose–response effects in the future by comparing those who received one versus two doses (years) of the FCU. Finally, although families were identified in primary care, the FCU itself was delivered at parents' residence to reduce barriers to participation; this approach appeared to be effective based on families' high engagement in the FCU. However, to more fully integrate the FCU into pediatric care, parent consultants would ideally be regular staff members of the clinic and provide parents with the option of receiving the FCU as part of the well-child visit or if more convenient because of logistical concerns, at their family residence. In fact, the FCU is now being offered at the same pediatric clinic where the current study took place, as it has in other adaptations of the FCU to prevent pediatric obesity (Berkel et al., 2019).

Conclusions

Using brief youth- and parent-reports to identify at-risk youth in pediatric primary care, coupled with an established brief program in low-SES youth, is a much-needed preventive strategy with great potential for impacting future healthcare services. This approach demonstrates the ability to identify youth at risk for, or in the initial stages of, problematic SU; engage families in a preventive intervention; and reduce rates of continued SU and related problem behaviors utilizing modest resources and time. In sum, overall, evidence supports advancing screening and prevention of adolescent SU and continued research to optimize implementation in diverse settings, populations, and within broader strategies to reduce prevalence of SUD.

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Compliance with Ethical Standards

Informed Consent Informed consent was obtained from all study participants.

Clinical Trial Registration Registry Name: Substance Use Screening and Prevention for Adolescents in Pediatric Primary Care (SKY); Registration Number: NCT03074877.

Ethical Approval All procedures performed in studies involving human subjects were in accordance with the ethical standards of the IRB at the University of Pittsburgh (Protocol number 13070072; approved 10/2/2013) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This article does not contain any studies with animals.

Competing Interests Lori Ridenour, spouse of Ty Ridenour (last author), is copyright owner of the *Youth Risk Index* and *ALEXSA*. All other authors have no relevant financial or non-financial interests to disclose.

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