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Parent-focused prevention of adolescent health risk behavior: Study protocol for a multisite cluster-randomized trial implemented in pediatric primary care

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ABSTRACT

Evidence-based parenting interventions play a crucial role in the sustained reduction of adolescent behavioral health concerns. Guiding Good Choices (GGC) is a 5-session universal anticipatory guidance curriculum for parents of early adolescents that has been shown to reduce substance use, depression symptoms, and delinquent behavior. Although prior research has demonstrated the effectiveness of evidence-based parenting interventions at achieving sustained reductions in adolescent behavioral health concerns, public health impact has been limited by low rates of uptake in community and agency settings. Pediatric primary care is an ideal setting for implementing and scaling parent-focused prevention programs as these settings have a broad reach, and prevention programs implemented within them have the potential to achieve population-level impact. The current investigation, Guiding Good Choices for Health (GGC4H), tests the feasibility and effectiveness of implementing GGC in 3 geographically and socioeconomically diverse large integrated healthcare systems. This pragmatic, cluster randomized clinical trial will compare GGC parenting intervention to usual pediatric primary care practice, and will include approximately 3750 adolescents; $n = 1875$ GGC intervention and $n = 1875$ usual care. The study team hypothesizes that adolescents whose parents are randomized into the GGC intervention arm will show reductions in substance use initiation, the study's primary outcomes, and other secondary (e.g., depression symptoms, substance use prevalence) and exploratory outcomes (e.g., health services utilization, anxiety symptoms). The investigative team anticipates that the implementation of GGC within pediatric primary care clinics will successfully fill an unmet need for effective preventive parenting interventions.

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1. Introduction

Adolescence is a developmental period characterized by significant physical and psychosocial changes, and often marks the onset of behaviors and symptomatology that can have lifelong impacts, including the initiation of substance use, antisocial behavior, and depression [1,2]. Fifty percent of adolescents will use some form of illicit drugs, and 52% will use alcohol before the end of high school [3,4]; 20% - 25% will meet criteria for depression [5,6], and some will engage in delinquency and violence [7,8]. Widespread prevention efforts to reduce the onset of these health-risking behaviors in diverse populations could improve adolescent health and wellbeing.

Guiding Good Choices (GGC) is a universal, anticipatory guidance curriculum for parents of early adolescents, with demonstrated impact on adolescent health outcomes from two randomized trials, including one longitudinal investigation [9–15]. Delivered to parents in groups in five 2-h sessions, GGC provides knowledge, tools, and skills that strengthen family bonds, promote adolescent health and wellbeing, and reduce risks for behavioral health problems. Because GGC targets risk and protective factors that are common predictors of adolescent behavioral health problems, it is expected to improve multiple outcomes. In prior community trials, GGC prevented adolescent alcohol, tobacco, and marijuana use, depressive symptoms, and delinquent behavior, including reductions in alcohol and marijuana use initiation by 41%, the progression to more serious substance misuse by 54%, and symptoms of depression by 28%, 4 to 6 years after families were exposed to GGC in middle school [9,10,16,17]. Furthermore, GGC strengthened parenting practices and parent-adolescent relationship quality [12,18–20], two components that are broadly protective for adolescent health [21,22].

The American Academy of Pediatrics' Bright Futures guidelines recommend that pediatricians offer developmentally tailored anticipatory guidance to all parents to support children's healthy development [23,24]. Although pediatricians are a trusted source of information about children's wellbeing, they often lack the time, resources, and self-efficacy to provide tailored guidance to parents of adolescents. Furthermore, although pediatric primary care is a favorable and appropriate setting for prevention programs to support parents and improve adolescent health [25], effective parenting programs that could provide this guidance are rarely offered through primary care. The current project, Guiding Good Choices for Health (GGC4H), tests the feasibility and effectiveness of implementing GGC with parents of 12- to 13-year-old adolescents in three large, integrated healthcare systems serving geographically and socioeconomically diverse families. The study uses the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework [26,27] to evaluate implementation outcomes, effectiveness, costs (now part of the RE-AIM framework), and cost effectiveness [28], including hypothesized reductions in the study's primary outcome of substance use initiation, secondary outcomes of substance use prevalence and frequency, antisocial behavior, and depression symptoms, and exploratory outcomes including substance use and mental health disorders, and health services utilization. The study is assessing costs in relation to value gained. The investigative team's partnerships with pediatricians and healthcare leaders ensures that the approach fits pediatric care workflows so that, if effective, it will be ready and appropriate for broad dissemination to pediatric primary care settings. Overall, the study fills an essential service gap in pediatric primary care and has the capacity to achieve population-level impact on adolescent health.

2. Materials & methods

2.1. NIH health care systems research collaboratory

This pragmatic investigation is part of the NIH Health Care Systems (HCS) Research Collaboratory ("Collaboratory"), which supports a series of pragmatic clinical trials across the United States addressing a range of public health concerns [29]. The overarching mission of the Collaboratory is to "strengthen the national capacity to implement cost-effective large-scale research studies that engage healthcare delivery organizations as research partners" [30]. Trials in the Collaboratory are conducted within real-world healthcare settings and aim to answer questions of crucial importance to patients, care providers, and researchers. A major goal is for findings from Collaboratory trials to affect clinical practice as quickly as possible, reducing the typically long lag from "bench to bedside" [31].

GGC4H is the only Collaboratory study targeting youth, and one of the few focused on prevention. It aligns well with Collaboratory goals in that most of the team members are healthcare system-embedded researchers and have a history of engagement with system stakeholders. The core team includes three pediatrician partners and regularly engages clinics and department heads. The pediatrician role within the investigation is also pragmatic, designed to be of minimal burden, and fit within typical clinic workflows. Importantly, GGC is a population-based universal intervention that is appealing to pediatricians because they can recommend it to all families of adolescents without the potential stigma of referring families to targeted interventions based on identifying individual risks. Finally, University of Washington Multiple Principle Investigators (MPI's) included one of the developers of the GGC curriculum prior to his retirement to aid curriculum adaptation to primary care delivery, and a group-randomized trial expert and health economist to aid in assessing the impact and cost effectiveness of GGC in the primary care setting.

2.2. Design

The current investigation employs a cluster-randomized design (Fig. 1) to test GGC effectiveness when implemented at scale within pediatric primary care practices across three large, geographically diverse, integrated healthcare systems: Kaiser Permanente Northern California (KPNC), Henry Ford Health System (HFHS) in Detroit, MI, and Kaiser Permanente Colorado (KPCO). The memberships of these systems have different sociodemographic profiles, and the systems themselves have distinct organizational, health plan coverage, and service delivery structures, offering the chance to evaluate GGC effectiveness across diverse systems and members.

Randomization is at the pediatrician level, with covariate constraint on three pediatrician panel characteristics that could affect adolescent outcomes or lead to unacceptable levels of imbalance across intervention and control arms: panel size, pediatrician gender, and a panel-level indicator of socioeconomic status (percentage of families on Medicaid) as a proxy for baseline levels of risk. Constraints ensure balance between arms after randomization, increasing statistical power and precision. The cluster-randomized design allows for ease of implementation around the pediatrician recommendation of GGC, and unlike randomization at the clinic level, cluster-randomization provides sufficient statistical power given the study's budgetary constraints.

After stratifying on healthcare system and clinic and applying constraints, 75 pediatricians (KPNC $n = 21$, KPCO $n = 29$, HFHS $n = 25$), were randomized to either the intervention (GGC) or control arm (intervention arm $n = 38$, control arm $n = 37$). Importantly, pilot clinic data reviewed by the investigative team revealed that 85% of adolescents have a well-child visit with the provider with whom they are empaneled, suggesting limited crossover among providers. Additionally, research staff only enroll families in GGC who are empaneled with pediatricians randomized to the intervention condition. Based on other intervention studies carried out by various GGC4H partners [32–37], the study team estimates a recruitment rate of 50% of eligible adolescents (described in *2.3. Inclusion Criteria),* for a total sample of approximately 3750 adolescents, 1875 in each study arm.

Using the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework [27], this investigation evaluates

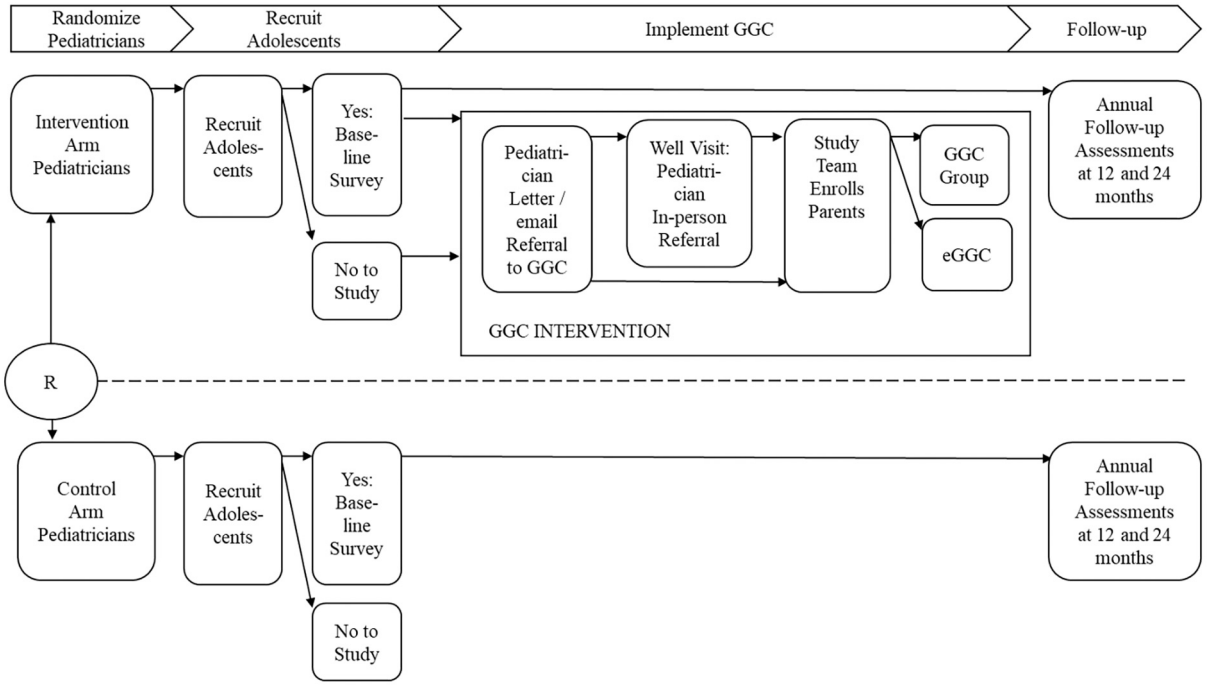

Fig. 1. GGC4H study design.
Note. R = Randomization. Pediatricians were stratified on healthcare system and clinic prior to randomization, which included covariate constraint on pediatrician panel size, pediatrician gender, and a pediatrician panel-level indicator of socioeconomic status (percentage of families insured through Medicaid) as a proxy for baseline levels of risk.

implementation and effectiveness of the GGC intervention across three large integrated healthcare systems. The RE-AIM framework allows the investigative team to measure GGC impacts on both individual and system levels, and ultimately aims to assess whether the intervention has the potential to achieve public health impact in real-world healthcare settings [27,38]. The investigative team hypothesizes that at the study endpoint, 24 months after baseline, adolescents in the GGC intervention will show reductions in the primary outcome of substance use initiation, secondary outcomes of substance use prevalence and frequency, depressive symptoms, and antisocial behavior, and exploratory outcomes including health services utilization and substance use and mental health disorders. Study hypotheses will be evaluated utilizing the RE-AIM framework, allowing the investigative team to assess implementation and effectiveness outcomes as well as implementation and dissemination potential. The Institutional Review Board (IRB) of Kaiser Permanente Colorado serves as the primary IRB of record for all sites and has approved all study procedures.

2.2.1. COVID-19 implications

Prior to COVID-19, the study timeline involved recruiting half of the sample in year 2 ("cohort 1") and half in year 3 ("cohort 2") and offering the GGC intervention to cohort 1 parents in year 2 and cohort 2 parents in year 3. The COVID-19 pandemic began prior to the implementation of GGC with cohort 1, ultimately delaying GGC implementation with cohort 1 and recruitment and GGC implementation with cohort 2 by a year. As a result, a second baseline assessment and implementation of GGC with cohort 1 was shifted to year 3, and recruitment and implementation of GGC with cohort 2 was shifted to year 4. Recruitment to the study is ongoing. Both cohorts complete follow-up surveys at 12 and 24 months post baseline (Fig. 1).

The COVID-19 pandemic also led to rapid evolution in healthcare delivery models, including telehealth delivery of services previously offered in person. With restrictions on in-person group-based behavioral interventions into the foreseeable future, the study team shifted implementation delivery to virtual live (synchronous) GGC groups using HIPAA-compliant technology. GGC experts and developers at the University of Washington developed a virtual delivery format that retains all core intervention components, including the large and small group discussions, modeling of skills, practice exercises that engage parents, and the opportunity for parents to connect with each other at a time when social distancing has limited such opportunities. These changes did not affect the overall study design and were approved by both the sponsor and the IRB of record.

2.3. Inclusion criteria

2.3.1. Adolescent inclusion criteria

Adolescents are eligible for the study if they are members of one of the three participating healthcare systems, are served by a participating pediatric primary care clinic at the time of the baseline survey, and would be 12 to 13 years old (date of birth 6/1/2007–5/31/2009) during the study's intervention period. They remain in the study even if they are no longer a health system member at the time of their follow-up surveys.

2.3.2. Pediatrician inclusion criteria

Pediatricians are included in the trial and randomized if they practice at a participating clinic in year 2 of the study, and do not opt out after reviewing the Pediatrician Information Form, or after an initial presentation by the study team describing the study and their role.

A total of 10 participating clinics (KPNC $n = 1$, KPCO $n = 5$, HFHS $n = 4$) were selected such that collectively they served a sociodemographically diverse patient population. None of the clinics or pediatricians approached to participate opted out. The final sample includes 75 pediatricians (intervention arm $n = 38$, control arm $n = 37$). Pediatrician panel sizes averaged 102.1 study-eligible adolescents ($SD = 49.1$, range: 12 to 299).

2.4. Exclusion criteria

Adolescents and parents are excluded if they have an intellectual,

developmental, or cognitive impairment that would prevent them from understanding the purpose of the study, study measures, or the GGC curriculum, or if they reside outside of the United States. For adolescents, exclusions are operationalized by specific ICD-9 or ICD-10 diagnostic codes documented in the electronic health record (EHR; e.g., ICD-10 F70-79 Intellectual disabilities, ICD-10 F84 Pervasive developmental disorders). For parents, impairment is identified by study team members at the time of recruitment into the study. Additionally, parents whose primary language is not English, as documented in the EHR or identified at study recruitment, are not included. EHR data suggests that exclusions for non-English speakers are small (approximately 7%). Non-study parents receiving care from an intervention arm pediatrician may also be excluded from the intervention at the discretion of pediatricians or GGC enrollment callers for impairment reasons or because English is not their primary language.

2.5. Recruitment and baseline interview

Prior to any intervention being offered, the study team contacts all parents, legal guardians, and/or caregivers (henceforward the term "parents" will refer to all types of caregivers) of eligible adolescents within participating clinics to recruit them to the study, which is called the "Promoting Adolescent Wellness Study" (PAWS) in parent and adolescent materials to distinguish it from the GGC intervention and help retain blinding among parents and adolescents. After obtaining parent consent and adolescent assent to participate and before parents in the intervention arm receive any intervention, adolescents complete a baseline behavioral health survey (called the PAWS Survey). Adolescents are resurveyed annually to assess intervention impacts on behavioral health outcomes in intervention arm participants compared to control arm participants.

Additionally, in order to assess intervention uptake more broadly, all study-eligible families receiving care from a pediatrician randomized to the intervention arm are offered the GGC curriculum, even if they choose not to participate in the study. However, intervention impacts will be assessed only among adolescents for whom consent and assent have been obtained (Fig. 1). Prior trials support a target enrollment rate of 33% in primary care [39,40].

2.6. Intervention and control conditions

The two conditions compared in the study are the GGC intervention, recommended by the pediatrician to parents of eligible adolescents empaneled with an intervention arm pediatrician, and control, in which parents of eligible adolescents empaneled with a control arm pediatrician experience usual pediatric primary care and are not offered GGC.

Prior to GGC initiation of enrollment calls by the study team, parents whose adolescents are empaneled with an intervention arm pediatrician receive a letter from their pediatric clinic or department briefly describing and recommending the GGC program. Pediatricians also offer an in-person recommendation to parents to enroll in GGC at eligible adolescents' 12- or 13-year-old well visits. The study team contacts parents within 1 week of their child's well visit or after receipt of the letter to enroll interested parents. GGC groups are expected to include 10 to 15 parents, and each healthcare system offers 10 to 12 groups to each cohort. Groups will be capped at approximately 20 parents to decrease the possibility of large enrollment numbers interfering with group dynamics and bonding. Parents in the intervention arm who opt not to enroll in GGC groups are offered a self-guided version of GGC (see *2.6.4. Guiding Good Choices Self-Guided Intervention)*.

2.6.1. Control

Control arm parents and adolescents receive care as usual and no GGC intervention. As in the intervention arm, control arm adolescents complete the baseline enrollment survey at the time of recruitment and at annual follow-up times.

2.6.2. Intervention: guiding good choices

GGC has been successfully implemented with culturally and ethnically diverse families throughout the United States [16]. GGC's efficacy was established as an in-person group-based intervention. An online, self-guided curriculum was developed for this trial as an alternative to the group modality to increase access to the intervention among those who experience barriers to in-person groups or prefer self-directed interventions.

2.6.3. Guiding good choices group intervention

GGC is a 5-session program for parents and their adolescents ages 9–14 (Grades 5–8). When delivered virtually, an introductory session is added to the curriculum prior to Session 1 to encourage virtual engagement and participation, orient families to the virtual platform, and provide technology support. GGC's overall goal is to promote adolescent wellbeing and healthy development through sustained preventive effects on adolescent health-risk behaviors. It also aims to strengthen protective factors that operate within the family (e.g., bonding, healthy communication) and peer contexts. GGC is theoretically grounded in the Social Development Model [41–44], which underscores the importance of strong bonds between parents and children, clear and explicit standards for healthy adolescent behavior, effective family management practices, and reducing family conflict as key mechanisms for reducing risk, strengthening protection, and preventing behavioral health problems in adolescence. Program content is delivered by two trained workshop leaders in weekly 2-h sessions for parents, each with a specific focus (Table 1). Adolescents join their parents at Session 4 to learn skills alongside their parents that can help them resist peer and other influences to engage in risky behavior. Sessions are interactive and skill-based, with opportunities to practice new skills and receive feedback from workshop leaders and other attendees. Video-based vignettes demonstrate parenting skills and adolescent risk resistance techniques through the portrayal of a variety of illustrative family situations. Families also receive Family Guides for each session, containing family activities, discussion topics, skill-building exercises, and information on positive parenting. Weekly home practice in the form of a family meeting is used to reinforce key concepts introduced at each session and to strengthen family bonds.

Table 1
Guiding Good Choices session objectives.

Introduction to Guiding Good Choices
Parents meet each other, learn about the structure and promise of Guiding Good Choices, talk about wishes for their children, and orient parents to participating in the online environment.
Session 1. Getting Started: How to Promote Health and Well-being During the Teen Years
Session 1 sets the context for increased risk of substance initiation and behavioral health concerns in adolescence. Parents learn about the Social Development Strategy, a framework for promoting adolescent well-being and preventing behavioral problems and decide how they want to prevent problems in their own families.
Session 2. Setting Guidelines: How to Develop Healthy Beliefs and Clear Standards
Session 2 focuses on the importance of establishing and effectively communicating clear family rules, monitoring behavior, and providing appropriate consequences. Parents use these skills to develop clear family guidelines and expectations for family substance use behavior.
Session 3. Managing Conflict: How to Deal with Anger in a Positive Way
Session 3 develops skills for managing anger and reducing family conflict. Parents learn to manage family conflict in a way that maintains and strengthens bonds with their children.
Session 4. Avoiding Trouble: How to Say No, Keep Your Friends, and Still Have Fun
Children and parents are invited to Session 4. They learn skills children can use for staying out of trouble and resisting peer influences while keeping their friends and still having fun.
Session 5. Involving Everyone: How to Strengthen Family Bonds
Session 5 discusses strategies for expressing positive feelings and involving children in developmentally appropriate family roles. Parents learn ways to strengthen family bonds and increase children's involvement in family tasks. They also discuss the importance of expressing love and appreciation to children.

Interventionists send participating parents short emails encouraging attendance and containing Family Guides prior to each session. They also offer absent parents the chance for additional contact to address questions about missed content. Parents complete online pre-and post-test surveys to assess parents' understanding of key GGC skills and concepts and gauge their satisfaction with interventionist skills and delivery techniques as well as the curriculum in general.

2.6.4. Guiding good choices self-guided intervention

eGGC is a fully digital version of the GGC curriculum and is accessible via computer, tablet, or mobile phone. The eGGC website includes GGC session content, exercises, and online videos, as well as regular check-ins and coaching support from GGC interventionists intended to enhance parent engagement with the curriculum [45,46]. Parents who opt not to attend GGC groups are provided with a username and password so they can access the eGGC website. Parents in this modality are offered up to 12 weeks of supportive coaching by trained interventionists, including three supportive phone calls (an orientation to the curriculum and check-in calls after the completion of Sessions 1 and 2). They also receive bi-weekly short email or text messages intended to motivate use, enhance engagement, and address questions.

2.7. Intervention orientation, training, and supervision

2.7.1. Healthcare system orientation and engagement

Throughout the study, investigative team leaders at each site meet periodically with pediatric and adolescent medicine chiefs, clinic heads, and pediatricians to introduce them to GGC, its rationale and evidence, describe the study and their roles, offer pediatricians the chance to opt out of participation, and keep them apprised of study progress. These activities are intended to support ongoing engagement with the 5-year study. Separately, investigative leaders meet with pediatricians assigned to the intervention arm to orient them to their role in recommending GGC to parents at the adolescent well visit, offer them short scripts that they can use in making the recommendation, and provide them with "prescription pads" that they can give to parents which contain a brief description of GGC and contact information for enrollment.

2.7.2. Interventionist training

GGC is suitable for delivery by staff with a wide range of professional backgrounds, making implementation and dissemination in real-world healthcare settings more feasible. While the intervention requires specific GGC training, no advanced educational background is necessary to deliver the intervention (i.e., Ph.D., M.D., master's degree). Interventionists in this trial represent a wide range of professional backgrounds including bachelor's- and master's-level staff. Importantly, interventionist teams in this investigation are embedded within healthcare systems and mimic roles that exist within real-world settings and could be used in future implementation and efforts to scale up delivery (e.g., clinical health educator). Specific GGC intervention training is detailed below.

Prior to COVID-19, all interventionists completed a 22-h in-person training led by a GGC master trainer, which resulted in interventionist certification in GGC. Training covered session content, methods for engaging parents in each session, and issues that might arise in implementation. Interventionists practiced delivering sessions and were trained to complete fidelity rating sheets that track session adherence, dosage, participant responsiveness, and overall quality of delivery. Interventionists were also trained to administer anonymized GGC pre- and post-session surveys to parents. After the COVID-19 pandemic began, a GGC master trainer with experience delivering the curriculum held a series of virtual weekly meetings to orient interventionists to the virtual curriculum, provide strategies for engaging parents in the virtual environment, and offer feedback and tips to interventionists as they delivered GGC virtually in mock sessions.

Interventionists were also trained to provide supportive outreach to parents enrolled in the self-guided GGC modality to motivate use of the curriculum, assist in using the principles, tools, and skills with their families, answer questions, and troubleshoot barriers to progress. Interventionists also gather information about the usefulness of, satisfaction with, and time spent on GGC. In several bi-weekly virtual meetings, interventionists were oriented to the three semi-scripted outreach calls (orientation, post Session 1, and post Session 2) and their role in sending bi-weekly emails or texts encouraging use of the self-guided interventions. Parents can also request additional support through the GGC website's "Contact Us" feature, and protocols for responding to requests within 2 business days were discussed during training meetings.

2.7.3. Ongoing support and technical assistance

To further support high-quality delivery of virtual group and self-guided GGC, interventionists receive ongoing support from a GGC master trainer during the implementation phase. Meetings are oriented towards building a supportive interventionist community of practice, gaining further proficiency in GGC, answering questions and problem-solving issues from GGC sessions and outreach contacts, and sharing successes and strategies for reaching parents and keeping them motivated to use GGC to support their families. Meetings decrease in frequency from weekly to monthly as interventionists gain greater experience and fidelity with group and self-guided modalities.

2.7.4. Intervention observation

To assess both intervention implementation fidelity and parent engagement levels beyond interventionist self-report, trained observers attend one session for each group implemented, with the specific session observed varying over time. Observers use the same fidelity rating sheet used by interventionists so that two sources of data about dosage, quality of delivery, and parent engagement can be compared (Table 3).

3. Outcome measures

Data for Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) constructs will be collected from a variety of sources and measures (Tables 2 and 3).

3.1. Effectiveness: Adolescent Behavioral health outcomes

The main objective of this investigation is to improve adolescent behavioral health through the delivery of GGC. As was found in the prior longitudinal trial testing GGC, the investigative team anticipates impacts on multiple outcomes. To reduce the number of comparisons and control for the possibility of increased Type I error, the study team has prioritized primary, secondary, and exploratory outcomes (Table 2). The study's primary outcome of substance use initiation was selected because of intervention impacts on substance use initiation established in the prior efficacy trials. Adolescents who have already initiated substance use at baseline will be excluded only from analyses examining initiation outcomes. Importantly, recent epidemiologic data from the National Survey on Drug Use and Health [47] suggests that the majority of adolescents included in this investigation will not be excluded due to prior initiation. Secondary outcomes reflect additional areas of anticipated impact from the trial, including substance use prevalence, symptoms of depression, and antisocial behavior incidence and prevalence. Exploratory outcomes (e.g., anxiety symptoms, emergency department utilization) represent additional theoretically plausible areas of intervention impact not previously evaluated in GGC trials.

Because many of the study's outcomes are not uniformly captured in the EHRs of the three healthcare systems, the study team developed the PAWS Survey to assess risk, protection, and behavioral health outcomes, using previously validated items and scales (Table 2). After informed consent from parents and assent from adolescents have been obtained,

Table 2
Adolescent effectiveness outcomes.

Construct [a]	Measurement	Representative items	Measure [b]
Primary outcome			
Incidence of lifetime substance use initiation at study endpoint	Dichotomous measure of any lifetime use (yes/no) of any of 4 substances (alcohol, marijuana, e-cigarettes, cigarettes) at any wave	Have you ever used marijuana (by used, we mean smoked, vaped, eaten, etc.) Have you ever used an e-cigarette or vaped (Juul, e-hookah, etc.)?	S2BI
Secondary outcomes			
Substance use at study end			
Prevalence of any past-year substance use	Dichotomous measure of past-year use (yes/no) of any of the 4 substances	How many times in the past year (if any) have you had alcoholic beverages – more than just a few sips?	CASI
Prevalence of any past-30-day substance use	Dichotomous measure of past-30-day substance use (yes/no) of any of the four substances	On how many days (if any) have you used marijuana in the past 30 days?	CASI
Lifetime incidence of antisocial behavior	Dichotomous measure of lifetime participation (yes/no) in any of 7 antisocial behaviors at the study endpoint	Have you ever stolen something from a store? Have you ever damaged or destroyed property? Have you ever been arrested? Have you ever attacked someone with idea of hurting them?	ASB
Prevalence of any past-year antisocial behavior	Dichotomous measure of engagement in any of the 7 antisocial behaviors	In the past year, have you ever stolen something from a store?	ASB
Mental health symptoms at study endpoint			
Depression symptoms	Total score on 9-item scale asking about depressive symptoms experienced over the past 2 weeks (range: 0–3, not at all, several days, more than half the days, nearly every day)	Over the past 2 weeks, how often have you been bothered by any of the following problems? Feeling down, depressed, irritable, or hopeless	PHQ-9
Exploratory outcomes			
Mental health			
Anxiety symptoms	Total score on 7-item scale asking about anxiety symptoms experienced over the past 2 weeks (range: 0–3, not at all, several days, more than half the days, nearly every day)	Over the past 2 weeks, how often have you been bothered by any of the following problems? Feeling nervous, anxious or on edge Trouble relaxing	GAD-7
Other substance use and mental health – dichotomized measure of lifetime prevalence (yes/no) at study endpoint			EHR
Substance use disorders	ICD-10 substance use disorder diagnoses		
Psychiatric disorder	ICD-10 depression, anxiety, and conduct disorder diagnoses		
Specialty substance use treatment service utilization	Service utilization documented in EHR for ICD-10 substance use disorder		
Specialty mental health services utilization	Service utilization documented in EHR for ICD-10 depression, anxiety, and conduct disorder diagnoses		
Emergency department utilization	ICD-10 substance use, depression, anxiety, and conduct disorder diagnoses		
Inpatient hospitalization utilization	ICD-10 substance use, depression, anxiety, and conduct disorder diagnoses		
Proximal parent and family process outcomes (risk and protection)			
Attachment to parents	Total score on 2-item scale (0 = no, 1-yes)	Do you feel very close to your parent(s)?	GGC/YDS
Relationship quality	Total score on 4-item scale (0 = no, 1-yes)	Do you enjoy spending time with your parent(s)?	GGC/YDS
Opportunities for positive involvement	Total score on 3-item scale (0 = no, 1-yes)	My parent(s) give me lots of chances to do fun things with them	GGC/YDS
Rewards for positive involvement	Total score on 4-item scale (0 = no, 1-yes)	My parent(s) notice when I am doing a good job and let me know about it.	GGC/YDS
Family management	Mean score on 4-item scale (range: 1–4; always, often, sometimes, never/almost never)	How often does your parent know who you are with when you are away from home?	GGC/YDS
Family conflict	Mean score on 3-item scale (range: 1–4; strongly agree, agree, disagree, strongly disagree)	We argue about the same things in my family over and over.	GGC/YDS
Parental attitudes favorable to substance use	Mean score on 4-item scale (range: 1–4; very wrong, wrong, a little bit wrong, not wrong at all)	How wrong do your parents feel it would be for you to… Use marijuana?	GGC/YDS

[a] The study's primary outcome reflects GGC's emphasis on preventing adolescent substance use. Secondary outcomes reflect impacts from GGC efficacy trials. Exploratory outcomes have not been previously examined but are plausibly linked to GGC. Proximal parent and family process outcomes reflect short-term impacts expected from exposure to GGC.

[b] S2BI = Screening to Brief Intervention [87]. CASI = Comprehensive Adolescent Severity Inventory [88]. ASB = Antisocial behavior [89]. PHQ-A = Patient Health Questionnaire for Adolescents [90]. GAD-7 = Generalized Anxiety Disorder 7-item scale [91]. EHR = Electronic health record. GGC/CYDS = Scales used in GGC efficacy trials [12,92] and/or Youth Development Survey [93].

adolescents complete the PAWS Survey online or by confidential telephone call with a trained study team member. The survey is administered at baseline (and a second baseline for cohort 1 due to delays from COVID-19), with annual follow-ups at 12 and 24 months. The EHR is the primary source of demographic data (e.g., race and ethnicity, gender, medical insurance) and information used for evaluating impacts on exploratory outcomes (e.g., emergency department and inpatient service utilization). Because race and ethnicity information is not always captured in the EHR, we also ask adolescents to report this information in the PAWS Survey.

Table 3
Implementation outcomes.

Construct	Measurement	Sample item	Source
Reach			
Reach	Percentage of parents who are not excluded from GGC due to impairment or because English is not their primary language		EHR, PAWS study records kept by recruiters, GGC enrollment records kept by enrollment callers
Enrollment	The number and percentage of eligible families who enrolled in the intervention		Study enrollment records, EHR for eligible families
Attendance	The number and percentage of families who attended at least one GGC group session or utilized self-guided GGC materials		GGC group attendance and self-guided utilization records
Adoption			
Healthcare systems adoption	The number and percentage of HCS approached who agreed to implement GGC and participate in the study		Study records
Clinic adoption	The number and percentage of clinics approached who agreed to implement GGC and participate in the study		""
Pediatrician adoption	The number and percentage of pediatricians approached who agreed to recommend GGC and participate in the study		""
Implementation			
Pediatrician recommendation to GGC	Dichotomous indicator that referral was made (yes/no); reported by parent during enrollment calls	At your child's last well check visit, did your pediatrician recommend that you enroll in GGC?	GGC enrollment records completed by enrollment callers
Group implementation	Number and percentage of groups held as planned		Session records kept by interventionists
Session implementation fidelity			
Dosage	Number and percentage of sessions held as planned		Session fidelity forms completed by interventionists, and trained observers
Adherence	Number and percentage of core content areas delivered as planned		""
Overall quality of delivery	Mean score across 5 sessions (range: 1–5; very ineffective to very effective)	How effective was your team's delivery of this session?	""
Parent response			
Attendance	Mean number of sessions attended		Attendance records kept by interventionists
Engagement	Mean score across 5 sessions of 2 items (range: 1–5; not at all active to very active)	How active was participation during group discussions? How active was participation during role plays?	Session fidelity forms completed by interventionists and trained observers
Satisfaction	Mean score across 5 sessions (range: 1–5; not at all satisfied to very satisfied)	Please rate your satisfaction with the overall session.	Post-session surveys completed by parents
Knowledge, skills, attitudes, and behavior	Difference between pre- and post-session survey item means (5-point Likert scales)	Good family management reduces the risk of substance use problems When parents get angry with their children, they should keep the specific reasons to themselves	Pre- and post-session surveys completed by parents

EHR = Electronic health record. HCS = ….PAWS = Promoting Adolescent Wellness Study.

3.2. Implementation outcomes

A second major objective of the investigation is to evaluate the feasibility of implementing GGC routinely while providing pediatric primary care to adolescents and their families by examining Reach, Adoption, and Implementation outcomes (Table 3). Data is collected from multiple sources identified in Table 3.

3.3. Maintenance

3.3.1. Maintenance of effectiveness

The study team will conduct repeated administration of the PAWS Survey (baseline, 12- and 24-month follow-ups) to provide data for evaluating adolescent behavioral health impacts and their maintenance over time.

3.3.2. Maintenance of implementation

Data from implementation of GGC with parents in cohorts 1 and 2 will be used to examine maintenance of reach, adoption, and implementation outcomes across cohorts. To better understand the complexities of sustained GGC implementation in pediatric primary care from the perspectives of healthcare system (HCS) leaders, pediatricians, and clinic staff, and to assess continued engagement, the study team will conduct 30-min semi-structured key informant interviews with pediatricians and other relevant clinic staff (n = ~5 per HCS) at the beginning of study years 4 and 5.

3.4. Costs and cost savings

3.4.1. Costs of delivering GGC

The study team will use the Ingredients Method [48,49] and an activities-based costing approach to identify, measure, and value resources (e.g., personnel, materials and supplies, office space, parent-incurred costs) needed to implement GGC, including capacity building, intervention delivery, and ongoing support for high-quality delivery. Staff time sheets, calendars, meeting records, and project invoices will be used to estimate resources needed to build capacity to prepare for implementation, deliver GGC, and provide ongoing support to involved staff. Unit prices for each resource (e.g., staff hourly wage plus fringe benefits rate, GGC training costs) will come from project administrative records and the healthcare systems' administrative databases.

3.4.2. Cost savings

Inflation-adjusted [50] charges obtained from healthcare systems

billing records will be used to estimate costs of emergency and inpatient service use by adolescents in the intervention and control arms and calculate potential savings in the intervention arm.

4. Data analyses

4.1. General analytic issues

RE-AIM analyses will use data pooled across the three healthcare systems sites. Analysts at each healthcare system site will regularly implement quality control procedures established in year 1 to ensure the ongoing availability and validity of PAWS and EHR data and resolve any issues proactively.

4.2. Analysis of behavioral health outcomes

4.2.1. General issues

4.2.1.1. Nested design. Parents and adolescents are clustered within pediatricians at the three healthcare system sites. Analyses involving data from parents and adolescents will use multilevel modeling to account for the nested data structure and produce unbiased estimates [51–53]. Moreover, the multilevel design and data are partially cross classified [54]. GGC group participants are cross classified by two random factors (pediatrician and GGC groups), as those who have the same pediatrician may be in different GGC groups and those in the same GGC groups may have different pediatricians. eGGC participants and those in the control arm have nesting within one random factor (pediatrician).

4.2.1.2. Intent-to Treat (ITT) framework. Analyses of adolescent outcomes will use an intent-to-treat (ITT) design, comparing outcomes among adolescents in intervention and control groups as assigned by randomization. Because pediatricians will be randomized to condition, the effect of the intervention will be measured at the pediatrician level by the inclusion of a dummy variable comparing the two conditions (intervention = 1, control = 0).

4.2.1.3. Covariates. All analyses will adjust for a prespecified set of covariates and baseline measures to improve estimate precision [53,55,56]. For adolescents, models will adjust for age, gender, race/ethnicity, health insurance status (Medicaid vs. other), and baseline health condition (mental health diagnoses, other significant chronic medical conditions using Pediatric Medical Complexity Algorithm [57]). Because the study will intervene with two cohorts of families 1 year apart, analyses will also adjust for cohort. This variable will be interpreted as providing evidence of generalizability across different groups of parents as well as maintenance of implementation across 2 years. Due to the relatively small sample of pediatricians ($N = 75$), models will include a parsimonious set of pediatrician characteristics (gender, clinic, panel size, proportion of panel insured through Medicaid) at the pediatrician level. The pediatrician level will also include an indicator of clinic size, as it may be easier to fill and run GGC groups when drawing from larger pediatrician panels with more eligible parents.

4.2.1.4. Missing data. The investigative team expects to collect data from 85% - 90% of consented adolescents in the longitudinal follow-up. There will be some missing data due to nonparticipation in follow-up surveys, item nonresponse, member care received outside the system and not captured through claims data and therefore not in the EHR, and data lags, coding errors, and incomplete capture of relevant medical information. To deal with potential bias, multiple imputation techniques will be used [58–61].

4.2.1.5. Power. Prior to the start of the trial, a power analysis simulation was performed in the R programming language, based on the study's planned pediatrician and adolescent sample sizes, partially cross-classified nested design, and standardized mean difference effect sizes (ES) ranging from 0.19 to 0.31 (approximating the 0.314–0.512 log-odds effect size range found in GGC's efficacy trials [17]) at the study's primary endpoint. The analysis was carried out on 2000 simulated cohorts of 3636 parent-adolescent dyads nested within 72 pediatricians (64 dyads per pediatrician) using mixed-effects logistic regression modeling [62]. Half of the pediatricians (and associated dyads) were randomized to the intervention arm. Approximately one third of the dyads assigned to the intervention were randomly clustered into GGC-level groups, with no more than 15 subjects per GGC intervention group, reflecting study team assumptions about the proportion of intervention participants choosing each GGC delivery mode. The binary outcome for each subject was simulated according to the mixed-effects logistic regression model, with separate random effects for pediatrician and GGC-level clustering. Intraclass correlation coefficients (ICCs) for pediatricians were expected to be small (0.10 or less) because families in each clinic are randomly assigned to pediatricians, and changing empaneled physicians is burdensome. ICCs for GGC, which are less consequential for study power, were also expected to be small because GGC is a manualized intervention in which all instructors receive the same training by a GGC master trainer. To be conservative, the simulations were conducted with ICCs ranging from 0.03 to 0.20.

Power analyses demonstrated that the sample size of 72 pediatricians and 64 parent-adolescent dyads per pediatrician has adequate coverage and at least 0.80 power to detect the lowest effect size of 0.314 (log-odds) or greater at $ICC_{PED} = 0.10$ and at all of the ICC_{GGC} levels considered. Results suggested that 72 pediatricians are more than adequate for 0.80 power to detect hypothesized main intervention effects. Sensitivity analyses in which recruitment rates were lowered to 30% also indicated 0.80 power to detect hypothesized main intervention effects.

4.2.2. Primary outcome analysis

Substance use initiation (one or more of alcohol, marijuana, e-cigarette, and tobacco use) at the study's endpoint (24-month follow-up) is the study's primary outcome; at the 24-month follow-up assessment, adolescents in cohorts 1 and 2 will be 14 to 15 years old on average. The study team hypothesizes that, compared to control arm adolescents, GGC arm adolescents will report lower rates of substance use initiation (refer to Table 3 for the operationalization of this and other adolescent health outcomes described here and below). Mixed-effects logistic regression will be used for estimation of the covariate-adjusted substance use initiation odds ratio (and 95% confidence interval), intervention vs. usual care, and associated likelihood ratio test of significance, with the specification of random physician and GGC group effects accounting for the partial cross classification as described above. This regression model is a straightforward extension of that presented by Luo et al. [54] for a partially cross-classified study design where all study participants in one treatment arm are cross classified on two random factors (e.g., pediatrician and GGC group) and all participants in the other arm are nested on one random factor (e.g., pediatrician). We extend Luo's regression model to accommodate nesting on one random factor (pediatrician) in the eGGC subset of the intervention arm in addition to the entire usual care arm. The model can also be used to examine other questions of interest including, for example, symptom counts using Poisson regression with a log link function and differences in scale scores or means using linear regression with an identity link function.

4.2.3. Analyses of secondary, exploratory and family process outcomes

Analyses of the intervention arm in relation to the study's secondary, exploratory, and family process outcomes (Table 3) will utilize generalized linear mixed regression, with probability distribution and link function as appropriate to the outcome of interest (e.g., Poisson

distribution and log link for symptom counts; normal distribution and linear link for scale scores). The approach to modeling random GGC group and pediatrician effects is as described for the primary outcome (4.2.2.). In general terms, the investigative team hypothesizes that, compared to adolescents in the control arm, adolescents in the GGC arm will have more favorable behavioral health outcomes (e.g., lower levels of antisocial behavior and violence, fewer depression or anxiety symptoms and diagnoses, lower prevalence of past-year substance use, lower levels of emergency department and inpatient utilization). With respect to family process outcomes, models will be used to evaluate hypotheses that, compared to control arm adolescents, intervention arm adolescents will report stronger bonds with parents, clearer standards for behavior, greater use of effective family management practices, and less favorable attitudes towards substance use.

4.2.4. Generalizability

To assess hypotheses that GGC impacts on adolescent health generalize across study cohort, adolescent gender and race/ethnicity, and healthcare system, the study team will conduct exploratory moderation analyses. Moderation will be evaluated by including a cross-level interaction term in analysis models (i.e., intervention at level 2 by individual characteristic at level 1) and testing the interaction term for statistical significance. Because power to detect cross-level interactions may be limited [63–66], the study team will also conduct exploratory subgroup analyses to provide additional information about the strength and direction of relationships that will aid in the interpretation of moderation.

4.3. Implementation outcomes analysis

4.3.1. General approach to implementation analyses

Implementation analyses focus on pragmatic questions about reach, adoption, and implementation of GGC that are of interest to healthcare systems. These analyses will generally be descriptive and focused on point and interval estimation of key constructs in the aggregate and, to assess generalizability, by healthcare system, clinic, and cohort (Table 3). Differences will be evaluated at a type 1 error rate of 0.05 using appropriate statistical tests (e.g., *t*-tests to evaluate differences in means, chi square to evaluate differences in proportions).

4.3.2. Parent response to GGC

Parent response to GGC will be evaluated in terms of session attendance, parent engagement, satisfaction, and gains in knowledge, attitudes, and skills that promote healthy parenting and positive youth development. Mean levels of attendance, engagement, and satisfaction will be reported as described as above. To evaluate hypothesized improvements in parents' knowledge and parenting skills, attitudes, and behavior after completing GGC, the study team will compare parent pre- and posttest scale scores (e.g., clear standards for adolescent behavior, proactive communication). The team will utilize the same multilevel modelling approach described previously (see *4.2.2. Primary Outcome Analysis* and *4.2.3. Analyses of Secondary, Exploratory, and Family Process Outcomes*), with posttest score as the dependent variable, adjusting for pretest score and participant-level (e.g., participant gender, educational attainment) and group-level (e.g., group, healthcare system) covariates.

4.3.3. Maintenance of healthcare system engagement in GGC

To better understand the complexities of sustained GGC implementation in pediatric primary care from the perspectives of healthcare system leaders and pediatricians/clinic staff, the study team will use a qualitative, inductive approach to analyzing detailed notes from stakeholder meetings and interviews with pediatricians. Meeting notes will be reviewed for completeness. Interview audiotapes will be transcribed. They will be analyzed using NVivo, Atlas.ti, or a similar software application that facilitates the organization and analysis of unstructured, qualitative data [67]. Data will be independently coded twice by trained coders in accordance with broad domains of the RE-AIM model. Differences among coders will be reconciled by consensus. Percentage coder agreement and a Kappa Coefficient will measure interrater agreement. Codes will be summarized within and across healthcare systems [68] to identify themes, which will inform the feasibility of implementing GGC and any tailoring needed across sites in the study.

4.4. Economic impact

4.4.1. Cost of implementing GGC

The study team will estimate the cost of resources required to implement GGC, *Ci*, as the product of the amount of each resource used, Q_i, and its unit price (adjusted for inflationary effects on prices incurred at different points in time), P_i. Total cost (ΣCi) and average cost per participant (ΣCi/n) across all healthcare system sites and within site will be estimated. The costs of key activities, such as capacity building, and costs borne by different stakeholders (healthcare system, clinic, parent) will be estimated by summing costs of resources relevant to each activity or stakeholder. The marginal cost of serving one more parent will be estimated by summing the costs of resources that vary on the margin (e.g., parent materials, engagement staff time, enrollment outreach).

4.4.2. Cost-effectiveness analysis

Cost-effectiveness analysis (CEA) will be used to evaluate the hypothesis that GGC is cost effective. Short-term cost-to-value will be indicated by the incremental cost-effectiveness ratio (ICER), which expresses the additional cost per unit of outcome (e.g., the cost per one fewer case of marijuana initiation or cost per one fewer case of depression in GGC relative to control). The primary outcome for the CEA will be substance use initiation at the study endpoint. Two sets of ICERs will be calculated to reflect costs from the healthcare system perspective and comprehensive costs [49]. To determine whether GGC is cost effective, ICERs will be compared to a range of values indicating willingness to pay (WTP) per unit of outcome (e.g., willingness to pay to reduce one case of depression).

If evidence for GGC impacts on emergency department and/or inpatient service utilization is found, the study team will also estimate short-term cost savings to the healthcare system experienced over the life of the project. Total cost savings for each service utilization domain will be calculated as the difference between inflation-adjusted [69] charges to adolescents in the intervention and control arms obtained from billing records. Differences across both domains will be summed to estimate total savings. Average cost savings (by domain and total) per participant will also be calculated as the difference in utilization cost per intervention arm adolescent less utilization cost per control arm adolescent. Cost savings can be compared to the cost of implementing GGC to ascertain the degree to which implementation costs are offset through savings in the short term.

4.4.3. Benefit-cost analysis

Benefit-cost analysis conducted from a societal perspective will be used to evaluate the hypothesis that GGC's long-term economic benefit will exceed comprehensive implementation costs. GGC's effects on adolescent outcomes will be monetized using models developed by the Washington State Institute for Public Policy [70] and previously applied to prevention benefit-cost studies [71,72]. Benefits will be projected over the lifetime of adolescents by linking intervention-attributable reductions in health-risk behaviors (e.g., drug use, depression, delinquency/crime) to benefits expected to accrue over participants' lifetimes (e.g., lower healthcare costs, increased earnings). GGC's net present value (NPV) will be estimated as the difference between discounted, inflation-adjusted benefits and costs on a per-participant basis. NPV greater than zero will indicate that GGC is cost beneficial. To account for sources of error in estimates, Monte Carlo methods will be used to estimate GGC's NPV under a range of assumptions.

4.5. Continuous quality improvement

To ensure continuous quality improvement, the study team regularly (monthly, semi-annually, or annually depending on the construct and measure) reviews data sources to identify (a) consistency with, adaptations to, departures from established engagement, enrollment, and implementation protocols; (b) possible barriers to engagement, concerns about workflow issues, and the like; and (c) possible low rates of GGC group enrollment and attendance, and self-study engagement/utilization. When concerns are identified, project investigators follow up with relevant staff to better understand the concern and respond appropriately (e.g., additional support to interventionists) or refine the approach where needed (e.g., tailoring protocols to better fit clinic workflow).

At the end of each implementation year, the study team will table descriptive statistics for RE-AIM constructs by healthcare system and clinic and, where relevant, by pediatrician and parent characteristics (e.g., enrollment rates, attendance by parent gender, ethnicity). The team will review all results and use them as the basis for recommendations for improving and refining the approach to implementing GGC. Some recommendations may apply to all healthcare systems while others may apply to a particular clinic or healthcare system.

5. Discussion

The current investigation is an innovative test of the feasibility and effectiveness of implementing GGC, a universal, evidence-based program that provides developmentally relevant anticipatory guidance to parents of young adolescents in three geographically diverse, large integrated healthcare systems. Prior studies have shown that evidence-based parenting interventions can achieve sustained reductions in health-risk behaviors and behavioral health concerns [73,74], but their public health impact has been limited by low rates of uptake when offered in community and agency settings [40]. Posited reasons for low uptake include stigma and concerns about being viewed as a "bad" parent, the appropriateness of the sponsoring organization to address parenting and parent education, and stable funding to provide reimbursement for services [39].

Pediatric primary care offers an opportune setting for implementing and scaling parent-focused prevention programs to better support parents and improve adolescent health and wellbeing. Pediatric primary care settings serve as patient-centered medical homes for children and adolescents where multidisciplinary care teams provide quality holistic care. These settings reach large numbers of demographically and economically diverse children and families and continue to expand their capacity to address and treat behavioral health issues [75,76]. Expansion of the Children's Health Insurance Program and passage of the Affordable Care Act has increased the availability of health insurance for children and thereby expanded access to pediatric preventive care [77]. Recent studies indicate that the proportion of children under age 18 without health insurance declined to 4.7% in 2020 [78], 96.4% had a pediatric medical home [39], and three quarters of those under age 18 accessed pediatric care within the past 6 months, nearly always accompanied by a parent [79]. Supporting parents in pediatric primary care is also increasingly becoming a clinical practice norm [80]. The American Academy of Pediatrics' Bright Futures guidelines recognize, for example, the critical role parents play in the process of preventing adolescent behavioral health problems, and recommend that providers offer developmentally tailored anticipatory guidance and education to all parents [24]. Several state Medicaid agencies allow for maternal depression screenings performed in pediatric care to be billed for and covered [81]. Parents have also expressed generally favorable attitudes towards prevention services offered in primary care, particularly in relation to mental health and substance use behavior [75].

Growth in integrated behavioral and primary healthcare, pediatric primary care reach among children and families, norms for supporting parents, and favorable parent attitudes towards preventive services all suggest strong potential for scaling evidence-based parent-focused prevention programs in pediatric primary care, and ultimately improving adolescent health trajectories. Although several reviews suggest prevention-focused parenting programs can be effective when offered in pediatric primary care [82–84], scaling effective parenting programs within pediatric primary care necessitates implementation protocols that fit within routine practice and varied organizational structures; are feasible to deliver; and appeal to diverse populations, including those who are marginalized, economically disadvantaged, and underrepresented [79]. With its emphasis on assessing feasibility and effectiveness of implementing GGC in 10 clinics located in three regional healthcare systems with distinct member profiles, the GGC4H trial is expected to generate new knowledge bearing on implementation at scale. The low-burden implementation strategy, in which pediatricians recommend GGC to parents but interventionists carry out the intervention, holds promise as a sustainable implementation approach that overcomes barriers of pediatrician time constraints, low provider self-efficacy in addressing behavioral health concerns, and perceptions about disciplinary scope and expertise [85,86].

The current investigation has a number of other advantages, which include assessing GGC effectiveness among a racially, ethnically, and socioeconomically diverse sample, and evaluating previously unexamined reductions in emergency department and inpatient service utilization—critical and costly outcomes particularly salient to health system leaders and policymakers—as well as broader adolescent health outcomes. It is also being conducted within the NIH Healthcare Systems Research Collaboratory, which provides the opportunity to examine study findings within the context of other pragmatic trials, to collaborate with other scientists engaged in pragmatic trials in healthcare systems, and to receive support from the Collaboratory's extensive network of methodological and topical (e.g., EHR data, patient-reported outcomes, ethics) experts.

5.1. COVID-19: An unexpected challenge

The novel coronavirus pandemic that began in early 2020 necessitated rapid modifications and adaptations to healthcare delivery. Telehealth service delivery has become a new standard of care in many healthcare settings, and clinical research studies like GGC4H were required to adapt to this new standard. Virtual adaptation of the intervention required swift work to ensure that intervention delivery retained all core curricular components and fostered meaningful engagement and parent relationships through a virtual modality. Although the adaptation process was unanticipated, the virtual modality provides unique benefits, including addressing potential barriers to participation, such as transportation costs and childcare needs. Technological barriers to participation (e.g., families lack a computer or internet service) will be at least partially mitigated by mobile phone access to virtual groups. The virtual modality may reduce intervention delivery cost, increase efficiency, and retain or even increase its appeal to healthcare systems leaders as it remains consistent with the current healthcare delivery approach. The virtual modality may become even more germane as health systems shift services, including many preventive psychoeducational programs, to virtual modalities in the wake of the COVID-19 pandemic.

5.2. Limitations

While this investigation is expected to yield important novel information about the feasibility and effectiveness of offering universal anticipatory guidance and education to parents of early adolescents in primary care settings, there are limitations. The study focuses on assessing generalizability across the three participating healthcare systems, but two of the three will implement GGC in multiple clinics; and variation in findings across clinics will not be fully explored due to budget and statistical (power) reasons. Moreover, because of the need to

demonstrate effectiveness before each healthcare system can broadly embrace a new service, the investigation will be implemented in a limited number of clinics within each large healthcare system. Due to budget constraints, the study is collecting limited data from parents, choosing to prioritize reports from adolescents. Additionally, the study team personally contacts all parents for recruitment and enrollment. This outreach method is not pragmatic and future implementation studies could adopt a more pragmatic approach to enrollment. Finally, though not a limitation per se, within the context of a pragmatic trial, the Adolescent Behavioral Health

(PAWS) Survey is not a pragmatic source of data relative to the EHR, requiring staff time to administer and incentives to thank adolescents for their participation. However, a survey was deemed necessary because EHRs of participating sites do not consistently capture data about this study's primary and secondary adolescent behavioral health outcomes.

5.3. Conclusion

The investigative team expects that implementation of Guiding Good Choices within primary care clinics will fill an unmet need for effective prevention programs for parents within pediatric primary care settings, increasing the program's reach and public health impact. Although the novel coronavirus pandemic has shifted the way GGC groups are offered to parents from in-person to virtual, the study design has remained intact, with potential to offer important new knowledge about parent response to and effectiveness of an intervention offered virtually within the course of routine pediatric primary care.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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