Modification and evaluation of the DECIDE intervention to improve parent-provider interactions in low-income parents of adolescents with Disruptive Impulse Control, and Conduct Disorders

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DECIDE Parent-Provider Interaction
IRB Protocol

Modification and evaluation of the DECIDE intervention to improve parent-provider interactions in low-income parents of adolescents with Disruptive Impulse Control, and Conduct Disorders (DECIDE)

IRB #1911897011

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Table of Contents:

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1.0 Rationale

Interventions to optimize parent-provider interactions are urgently needed to ensure adolescents with Disruptive, Impulse-Control, and Conduct disorders (DIC) receive the behavioral health care they need. DIC affect 5 million (1 in 5) American adolescents aged 12 to 17 years.[1] DIC are characterized by emotional and behavioral dysregulation manifested by behaviors that are aggressive, infringe on the rights of others, violate social norms, and result in conflicts with authority figures.[2] For these adolescents, behavioral health care is complex, long-term, and requires parental participation.[3-5] Research by our team and others showed parents of these adolescents report that providers do not listen to them or involve them in their adolescents' care.[6-8] Research shows providers have biases and limited skills and confidence to communicate with these parents to encourage them to voice their concerns and care preferences.[9-12] Low income and/or minority parents are at greatest risk for not being involved in their adolescents' behavioral health care, having poor interactions with providers, being more likely to perceive poor quality of their adolescents' behavioral health care, and having low treatment engagement.[13-18] If unaddressed, poor parent-provider interactions interfere with adolescents' retention in behavioral health care.[19,20] No evidence-based interventions have targeted both parents and providers to optimize their interactions and improve behavioral health care for adolescents with DIC.[3,21]

To address these problems, we propose modifying the evidence-based DECIDE intervention to target low income and/or minority parents and providers of adolescents with DIC. DECIDE stands for Decide the problem; Explore the questions; Closed or open-ended questions; Identify the who, why, or how of the problem; Direct questions to your health care professional; Enjoy a shared solution. DECIDE was developed for ethnically/racially diverse adult patients with serious mental illness,[22] and the latest evidence-based iterations include intervention components targeted to and shown to increase patient activation, provider communication, and patient-provider interactions.[22] DECIDE has two primary components: 1) three patient training sessions designed to help patients effectively ask questions and participate in decisions about care: and 2) a 12-hour workshop and up to 4 individual coaching sessions for providers to improve perspective-taking, reduce attributional errors, and increase receptivity to patient participation. DECIDE has improved patient activation,[23,24] self-management,[23] perceived quality of care,[23]and collaborative treatment decision making.[22]

2.0 Background

Adolescents with disruptive, impulse-control, and conduct disorders (DIC), especially those in low income and/or minority families, present some of the nation's most pressing behavioral health care challenges. Five million (1 in 5) adolescents 12-17 years of age are diagnosed with a DIC that includes the following DSM-5 diagnoses: (a) Oppositional Defiant Disorder, (b) Conduct Disorder, (c) Intermittent Explosive Disorder, (d) Pyromania, (e) Kleptomania, (f) Other Specified DIC Disorder, and (g) Unspecified DIC.[1,2,26] DIC are characterized by emotional and behavioral dysregulation manifested in externalizing behaviors that are aggressive, infringe on the rights of others, violate social norms, and result in conflicts with authority figures.[2] Annual medical costs average $14,000 per child with Conduct Disorder compared to < $2300 per child without a mental disorder.[27] Annual direct medical costs range from $17 to 56 billion for those with DIC.[27-29] Parents incur financial costs associated with interruptions in employment due to caregiving responsibilities, increased healthcare needs for their own stress-related illnesses, and their child's treatment.[30-33] Approximately 57% of children with mental health disorders, including DIC, come from households living at or below the federal poverty level,[34] and low income and/or minority parents are particularly vulnerable to the negative effects of caregiving for adolescents with these disorders.[18,35-37] Problems associated with DIC are exacerbated during adolescence due to rapid developmental changes and increased substance abuse and criminal activities.[38]

The effective treatment of adolescents with DIC depends on their parents' active engagement with behavioral health care providers.[39,40] In addition to managing their adolescents' problem behaviors and their own distress over such behaviors,[31,32,36,41,42] parents of adolescents with DIC must attend frequent and often urgent meetings with providers.[6,7,43-45] Active parent involvement with the mental health system is required due to the complex treatment regimens needed by adolescents with these disorders and the high-risk nature of their behaviors.[32,44,46-48] Parents report that encounters with providers are often time-consuming, stressful, stigmatizing, exhausting, and unhelpful.[7,30] Negative interactions with providers contribute to parent disengagement from their adolescents' care and resistance to following provider recommendations, both of which lead to poor adolescent outcomes.[49,50]

Low income and/or minority parents of adolescents with DIC are at high risk for aversive interactions with providers due to socioeconomic disadvantages.[32,51,52] Research has shown that effective communication skills deployed by consumers in healthcare encounters, such as asking informed questions and clearly articulating opinions and needs, are associated with greater satisfaction with care and better health outcomes.[53-57] However, low income and/or minority persons often have less opportunity to acquire these skills due to low educational attainment, poor health literacy, disadvantaged social position, and limited resources.[47,58-60] Negative interactions are fostered by providers who perceive low income and/or minority health consumers to be uninvolved, uniformed, and unable to make complex health care decisions,[8,19,47,61,62] and lack of training about how to motivate low income and/or minority persons to voice treatment concerns and preferences. [18,59,60,63-65]

Scientific Premise: To address the above issues, research suggests appropriate target variables for parents and providers are parent activation, provider communication, and parent-provider interactions. Activation is a person's acquisition of knowledge, skills, and beliefs that facilitate active participation in health care.[66,67] High activation in adult patients with chronic illness,[68-77] such as diabetes,[78] HIV/AIDS,[79] hypertension;[80] and serious mental illness[81-85] such as schizophrenia[57] is associated with better health status and adherence to healthy behaviors.[57,67] Consumers who are well informed about health conditions and who are confident in their abilities to navigate the healthcare system and manage their care have better health outcomes.[47,57,86] In addition, improving provider communication increases satisfaction, adherence, and health outcomes in pediatric and adult populations with physical and mental health concerns.[86,87] Multiple factors contribute to the quality of patient-provider interaction including provider communication and institutional practices.[37,47,86,88,89] Effective provider communication is characterized by attentive, facilitative, and collaborative behaviors.[22,86]

Benefits of parent interventions will not be fully realized without collaborative parent-provider interactions.[90] Several parent support and skills training interventions have been shown to improve: 1) parent knowledge and management of their children and adolescents' behavior problems;[91-98] 2) parent mental health and stress levels;[93,94,99] and 3) parent self-efficacy in accessing and navigating adolescents' mental health services.[100,101] Moreover, activation interventions in adult behavioral health have demonstrated that patient activation in the absence of provider support can lead to harmful effects, including further exacerbation of tension in patient- provider relationships or diminished patient use of services particularly in low income and/or minority patients.[23] Patients' perception or belief that the provider is supportive (receptive) of the former's efforts to be actively involved in treatment may act as a mediator of intervention effects.[22,23] Alegria and colleagues suggested that patients' beliefs that providers will support their activation efforts may significantly contribute to benefits of patient-provider interactions, patient perception of management of care, perceived quality of care, and engagement and retention in care.[23]

Our proposed focus on both parents and providers is innovative in this field. In DIC and other mental health disorders, there are several support programs or interventions targeting parents. However, there are no (zero) interventions targeting providers, and no interventions targeting both parents and providers. This was confirmed in a PubMed search of all existing English-language literature using terms "parent, mental health, activation or empowerment, and intervention".

Our target variables are innovative in this field. Improving parent activation improves interactions with providers [17,21,102] yet only two studies to date have tested parent activation interventions in adolescent behavioral health care.[102,103] These two studies[102,103] showed positive effects on parent activation and perceived efficacy to work with mental health providers.[104] However, neither study intervened with providers. Similarly, improving provider communication increases satisfaction, adherence, and health outcomes,[86,87] Yet there are no such existing interventions for parents of children with DIC. This was confirmed in a PubMed search of all existing English-language literature using terms "parent - provider communication, mental health, and intervention. Provider communication interventions have been developed to improve encounters between healthcare providers and adult patients with physical health concerns,[58,105,106] and parents of children in pediatric primary care.[51,54,107,108] However, evidence-based parent-provider communication interventions for parents of children with mental health disorders, including DIC, have not been developed. Thus, this is the first intervention to improve interactions between parents and providers of adolescents with DIC.

Our inclusion of low income and/or minority parents addresses an understudied population. The existing parent activation intervention studies focused on military families[102,109] or Latino parents.[104] The military sample was majority white (73%) and middle income. Our study will include a more racial/ethnic diverse sample.

3.0 Specific Aims

The **purposes** of this two-phase study are to modify and test the DECIDE intervention (referred to as DECIDE from now on) for parents and providers of adolescents with DIC. In phase I, our team in Indianapolis, IN (Drs. Oruche, Draucker, Perkins, parent and provider advisory boards) will work with two consultants to modify DECIDE. Dr. Nakash will help modify the DECIDE provider components to be relevant for DIC. Dr. Chacko will help modify DECIDE from patient to parent focused. In phase II, we will test modified DECIDE against usual care in parents and providers of adolescents with DIC using a two-group, pilot, randomized, controlled design. During phase II, Dr. Oruche became a Co-Investigator at the University of South Florida in Tampa, FL. Dr. Chacko (New York, NY) has clinical expertise in improving activation among parents of adolescents with DIC. Dr. Nakash (Northampton, MA) led the design and implementation of DECIDE components targeted to providers[25] Dr. Chacko will help modify DECIDE from patient to parent focused. Our setting is a large, safety net health system in the Indianapolis metropolitan area servicing primarily low income and/or minority persons.
Specific aims are to:

Phase I, Aim 1. Modify DECIDE for low income and/or minority parents and providers of adolescents with DIC.

Phase II, Aim 2. Evaluate the feasibility and acceptability of modified DECIDE.

Phase II, Aim 3. Estimate preliminary effects of modified DECIDE to improve parent, provider, and adolescent outcomes. We hypothesize that compared to usual care:

> **Hypothesis 3.1.** Modified DECIDE parents will show greater improvements in: 1) activation; 2) parent-provider interactions; 3) perceived management of adolescents' behavioral health care, 4) perceived quality of adolescents' behavioral health care, and 5) engagement in adolescents' behavioral health care.
> **Hypothesis 3.2.** Modified DECIDE providers will show greater improvements in: 1) communication skills and 2) parent-provider interactions.
> **Hypothesis 3.3.** Adolescents of modified DECIDE parents and providers will show higher rates of retention in behavioral health care.

If study findings are positive, we will be poised to test the modified DECIDE in a fully-powered R01 level randomized, controlled, multi-site clinical trial. If study findings are negative, we will have process and outcome information needed to further refine DECIDE or pursue different interventions. Either way, this line of research has potential to optimize parent-provider interactions and ultimately, ensure adolescents with DIC receive the behavioral health care they need.

4.0 Inclusion/Exclusion Criteria

Inclusion Criteria:

Inclusion Criteria for providers and interns: Providers will be regular paid staff members who are:

(1) Associate's or bachelor's or PhD prepared providers who work with parents **OR**

(2) Masters-prepared clinical social workers or mental health counselors **and**
(3) Provide behavioral health services to adolescents and their parents. OR
(4) Doctoral level interns (e.g. in psychology) **and**
(5) Provide behavioral health services to adolescents and their parents **OR**
(6) Providers who are bachelor's prepared interns must:
    (1) be currently working with a center or private practice to complete requirements for their Master's degree **and**
    (2) be providing behavioral health services to adolescents and their parents.

Inclusion Criteria for Guardians: Guardians will have a child or adolescent with DIC receiving services from a participating mental health provider. Parents/guardians meeting all the following criteria are eligible:

(a) are aged 21 or older
(b) speak English
(c) are the guardian (biological parent, adoptive parent, step parent, foster parent, or legal guardian) of the child or adolescent or a parent surrogate serving in a primary caregiver role (referred to as "parents"; if foster parent or legal guardian,).
(d) must have a child or adolescent aged 3 to 17 years with a diagnosis of Disruptive Impulse Control and Conduct Disorder (DIC) by a mental health professional. (This includes children with behavior problems, such as Oppositional Defiant disorder, Conduct disorders, or Intermittent Explosive disorders).
(e) Attends regular appointments with a provider
(f) Foster parents will be included if they have a child with DIC now or in the past, and regardless of whether that child is receiving services from a participating mental health provider or not.

Exclusion Criteria for parents:

- Show significant cognitive impairment or acute emotional distress on screening
- Have an incarcerated adolescent

No providers or parents will be excluded on basis of race/ethnicity, gender, or sexual orientation.

5.0 Enrollment/Randomization

Screening

Providers currently employed at Sandra Eskenazi Mental Health Hospital, Bowen Center, Centerstone, and other applicable mental health centers or private practice will be approached for inclusion on the study. Providers with at least one patient who is aged between 6-17 and diagnosed with DIC disorders will be screened for enrollment.

Informed Consent

A study investigator or research assistant will obtain informed consent from the provider either via a HIPPA compliant teleconferencing platform (ie Zoom Health) or via telephone contact. Parents who become enrolled will be approached via telephone contact. Informed consent for parents will be obtained virtually via a HIPPA compliant teleconferencing platform (i.e., Zoom Health) or telephone contact.

Randomization

All participants will be assigned to the intervention arm and there will be no randomization. Instead, the intervention results will be compared to historical data.

Study Duration/Timeline

The study will consist of the provider completing baseline measures and then complete a 4.5 hours (max) workshop through Canvas Learning System, completed over the course of 2-3 weeks. After the provider completes the workshop, he/she will be contacted by study staff to complete the post-intervention measures (T2) and conduct a recorded qualitative interview. The parents will complete baseline (T1) study measures before meeting with the parent trainer. Then all will participate in up to three, hour-long sessions training sessions with a parent trainer. In total, participation in the study will last between 6-8 weeks.

6.0 Study Procedures

1. Theoretical Framework. DECIDE is grounded in mental health disparities frameworks[113, 24] and social cognitive principles.[114] The parent component is designed to increase parent activation, to help effectively ask questions and participate in decisions about care.[23,112 66,111] The provider component is designed to teach provider communication skills in listening, eliciting the patient's agenda, encouraging question, and providing management education.

2. Preliminary Studies. Drs. Oruche, Draucker, Perkins, and Chacko collaborated on the preliminary studies below. For this application, we added Dr. Nakash (Consultant) who is a nationally recognized researcher and clinician with expertise in racial/ethnic disparities related to provider level factors. Our preliminary work is below.

Preliminary study 1. Through this qualitative descriptive study (internal funding), Drs. Oruche and Draucker identified the most salient needs and challenges of parents of adolescents with DIC. Results indicated that parents' interactions with providers were often aversive, stressful, and nonproductive; suggesting need for an intervention.[7,115]

Preliminary study 2. Similar to the proposed study, we used a 2-phase study to develop and preliminarily test an intervention called FAME (Family Management Efficacy) for parents of adolescents with DIC. With funding (KL2TR001106, UL1TR001108), Oruche, Draucker, Chacko and a parent and provider advisory board, developed and tested this 6-week parent group-based, in-person intervention among low income African American parents of adolescents with DIC aimed at enhancing parent activation and improving interactions with behavioral health care providers.[116] The setting was the same as for the proposed study. FAME was acceptable but not feasible, and did not show preliminary efficacy on key outcomes because it did not have a provider component. Facilitators noted some parents struggled to develop effective communication skills (e.g., asking questions of providers, sharing ideas about the adolescents' treatments). The team gained valuable experience in intervention delivery to parents of adolescents with DIC and confirmed the importance of simultaneously targeting providers. These lessons inform modification of the evidence-based DECIDE intervention in this proposed study.[117]

Preliminary work for this application. Drs. Oruche, Draucker, and Perkins collaborated with Drs. Nakash (40 hours past 3 months) and Chacko (10 hours past 3 months), on the following components of this application: identification of target variables for the modified DECIDE, creation of the study conceptual model, selection of study measures, and overall study design.

3. Methods

DECIDE Parent-Provider Interaction
IRB Protocol

DECIDE Intervention. The evidence-based DECIDE intervention was developed for low income and/or minority adults with serious mental illness and their providers.[22] DECIDE has both patient and provider components. DECIDE has improved patient activation,[23,24] patient self-management,[23] perceived quality of care,[23]and improved collaborative treatment decision making.[22] Because DECIDE was designed for individuals who work with adult patients, we will adapt it for parents and providers of adolescents with DIC. For example, case examples need to be relevant to the clinical work with this population and accommodate individual or family therapy; we will also shorten the provider training – to increase feasibility of implementation and acceptability to participants. This fits with Stage 1A and 1B of the ORBIT model.[118]

The **modified DECIDE** will have parent and provider components.

The **parent component** is designed to teach parents how to effectively ask questions and participate in decisions about their adolescents' behavioral health care. It will include up to three 60 minutes sessions (the third session is optional). Session 1 (Decisions and Agency) is designed to increase awareness of their role in clinical interactions and encourage participation and decision making in care. Session 2 (Self-efficacy and Consolidation) encourages parents to ask questions about their adolescents' behavioral health and health care and treatment options . Session 3Optional Booster), which can discuss any previous topics the parent would like the trainer to review and can also include more practicing of asking questions).

The **provider component** is designed to improve provider communication in three key areas: 1) perspective taking to understand circumstances and perceptions; 2) attributional errors or attributing negative parent behaviors to character traits instead of considering the situational factors; and 3) receptivity to parent participation and collaboration. We will shorten the provider training to increase feasibility of implementation and acceptability to participants. The training will included one 4.5-hour (rather than 12-hour) group workshop.

Intervention Delivery. In addition to standard care, all participants will receive the modified DECIDE. Parents receiving intervention will receive up to three 60-minute sessions over the course of three weeks. The sessions will focus on increasing the parent's involvement in decision-making, increasing their understanding of the decision-making process, and training the parents to ask questions concerning their adolescent's care. These training sessions will be delivered by trained study staff virtually via HIPPA compliant video teleconferencing platform (ie Zoom Health) or via Telephone as approved by IRB.

Phase I, Aim 1

Recruitment of Parent Advisory Board. We will form a 5-member parent advisory board to guide modification of DECIDE. Inclusion Criteria. Parents of adolescents with DIC, who are receiving services at Midtown Child and Adolescent Program. We will invite parents sequentially in the clinic as well as parents from our previous study advisory board and who participated in preliminary study 2 that agreed to be contacted for future studies.

Recruitment of Provider Advisory Board. We will form a 5-member provider advisory board to guide modification of DECIDE. Inclusion Criteria. Midtown Child and Adolescent Program staffs who do not meet the inclusion criteria in phase II (i.e. manager and clinical coordinators or supervisors). We will invite two other direct care providers who work in the healthcare system but not at recruitment site. No parent or provider will be excluded on basis of race/ethnicity, gender, or sexual orientation.

DECIDE Modification. Dr. Oruche has met both Dr. Nakash and Midtown Chief Executive Officer, Program manager and clinical coordinators to discuss potential modifications to the provider intervention to increase acceptability and feasibility. We will invite their continued participation during phase I. The research team and provider advisory board will meet monthly for ~ 3 months to modify the intervention. At the initial meeting, the PI will share DECIDE and discuss what components need to be modified. The research team will prepare the modified intervention materials and present modifications to the provider advisory group for iterative feedback. The same process will be followed to modify the parent component of the DECIDE intervention. Together, research team and the parents' advisory group will meet twice during the first 4-months of study period. We will (a) share the parent component of the DECIDE intervention, (b) discuss what components need to be modified, (c) have the team do the modifications; and (d) present them back to the parent advisory group for iterative feedback.

Phase II, Aims 2 and 3.

Design. A pilot trial to assess feasibility and estimate outcomes in intervention vs. an historical control.

Setting. Similar to preliminary studies, we will conduct this trial at Sandra Eskenazi Mental Health Hospital in Indianapolis, IN, Bowen Center in Indianapolis, IN, Centerstone centers in Indiana, Florida and Tennessee, other applicable mental health centers and private practice in the US. Midtown is the largest publicly funded mental health center in Indiana and serves primarily low income and/or minority population (see Facilities and Resources). Child and Adolescent Program employs 22 masters-prepared mental health providers. Oruche also has clinical privileges at Midtown to facilitate recruitment (see support letter). Midtown has named treatment engagement as a top strategic priority.

Sample. First, we will recruit 16 providers and then work with them to invite parents (or parent surrogates) of adolescents aged 6 to 17 years who have been diagnosed with a DIC disorder. Ideally, we will enroll 80 parents (5 parents per enrolled provider).

Sample size justification. Because this is a feasibility pilot study, statistical models will be fit to estimate effect sizes for use in a future randomized trial. Any inferential testing is considered exploratory though effect sizes of ≥0.65 could be detected with 80% power in the models described below assuming pre/post exposure correlation of 0.5, intraclass correlation of 5%, and two-tailed test (α=0.05). We will follow the recommendation of Hertzog[119] that a minimum of 30 participants per group are needed for pilot studies to examine group comparisons.[119] To account for potential 20% dropout, we will recruit 40 parents to the intervention group with 1-5 parents per provider) for up to a total of 80 parents. Provider sample size is based on availability.

Procedures. Enrollment, consent, and baseline data collection. ***Providers***. PI will attend provider team meeting at Midtown to introduce the study, answer questions, and invite them to participate. Trained research assistants (RA) will obtain verbal informed consent from interested providers. ***Parents.*** To screen parents, we will enlist the help of providers and administrative assistants at the clinic, who have access to providers' caseloads, schedules, and adolescent patient demographics. To coordinate recruitment, we will ask the administrative assistants to select adolescents between 6 to 17 years who are diagnosed with DIC. PI and RAs will work determine provider schedules or enrolled parents' next visit. Parent eligibility and consent to participate will be determined by calling parents via telephone or a HIPPA compliant teleconferencing platform (ie Zoom Health). If RA does not make contact with parent, RA will send study flyer and recruitment letter co-signed by PI and Child and Adolescent Program Manager. RA will make follow-up contact within 7 days after the sending the study materials.. If parent express interest in participation, the RA will determine eligibility. Next, RA will obtain verbal consent from interested parents.. Following enrollment, RA will collect baseline data from all providers and parents.. Training for providers will occur as soon after baseline measures are collected.

Revised Study Schema:

Figure 2: Study Schema							
Providers	Recruitment	Screening	Consent	Baseline	Modified DECIDE intervention [workshop (1 @ 4.5 hrs)]	Time 2	DECIDE Oral Interview (all providers)

Parents	Recruitment	Screening	Consent	Baseline	Modified DECIDE sessions 2 @ 1 hr/week, with an optional 3rd booster session offered @ 1 hr/week	Time 2	DECIDE Oral Interview (subset of parents)
Green: Quantitative measures and oral interviews							
All participants will receive the DECIDE intervention. Results will be compared to historical control.							

Training for parents will be delivered remotely using telephone and/or Zoom Health for parents with video capability. The parents will be sent a Zoom Health invitation which include a toll free number they can call. This allows research staff to record sessions for fidelity checks.

Data collection. A trained study staff will collect baseline data (T1) before the provider takes the DECIDE Training and will schedule a follow-up assessment 1- 4 weeks post intervention training (T2). Providers will be instructed to think specifically about the most recent therapy session that he/she had with a parent of a child diagnosed with DIC in order to keep the parent provider interaction fresh in the provider's mind when completing the measures. Study staff will follow these same guidelines for scheduling the T2 data collection. Providers will complete and enter their surveys directly into REDCap. Providers will be contacted by study staff to remind them to complete their surveys and to answer any questions if necessary. Study staff will schedule an appointment with providers to collect the post-intervention (T2) measures in order to ensure the provider understands the instructions and also to conduct the post-intervention qualitative interview. Providers will be instructed to think specifically about the most recent therapy session that he/she had with a parent of a child diagnosed with DIC in order to keep the parent provider interaction fresh in the provider's mind when completing the measures. Parents will be contacted and asked to schedule a convenient time to complete the surveys with the study staff.

Measures.

Aim 2 measures. The research project coordinator will keep logs and field notes of feasibility including: 1) enrollment rates, reasons for ineligibility and declining participation; 2) attrition rate, reasons for missed session or intervention completion; and (3) measurement completion rates. We will measure parent and provider acceptability and satisfaction with modified DECIDE using Client Satisfaction Questionnaire (CSQ) and in-depth semi structured interviews at T2. RAs under Draucker's supervision will conduct in-depth semi-structured interviews including: All intervention providers (n = 8) and two of each of the parents (n = 16). To explore different levels of acceptability by parents, for each provider, one parent will be chosen who has a high score (> 3) on the CSQ and one parent who has a low score (< 3). Both parents and providers will be asked about their experience with the intervention, what was helpful or not, and how they would change the intervention.

Aim 3 measures. Parents, providers, and adolescents' socio-demographic factors will be assessed at T1; and outcomes will be assessed at T1 and T2. We will include three items (i.e., level of parent organization, involvement, and management of adolescents' care) from the Child and Adolescent Needs and Strengths (CANS) at Midtown's request. We will use self-administered questionnaires with read-aloud procedures to address issues of literacy. All measures have well-established psychometric properties, sensitivity to change, and acceptable response burden.[120-127] Multi-informant and mixed methods assessment of outcomes is a study strength. Given the change in design to one group pre and post intervention compared to historical group; we will use the Parent Participation Engagement Measure (PPEM). In lieu of Working Alliance Inventory or Kim Alliance Scale as our key measure of parent-provider interaction or engagement.

Table 1: Measures

Variables	**Measure**	**#items**	**Relibaility (α)**	**Schedule**	**Filled By**
Antecedents					
Parent Factors	Parent Information Form	10	N/A	T1	Parent
Provider Factors	Provider Information Form	10	N/A	T1	Provider
Adolescent Factors	Adolescent Information Form	7	N/A	T1	Parent
Feasibility/Acceptability					
% Eligible participants enrolled	Investigator Tracking Logs	N/A	N/A	T2	PI
% Eligible participants completed intervention	Investigator Tracking Logs	N/A	N/A	T2	PI
Provider Satisfaction with Intervention	Client Satisfaction Questionnaire; Semi-structured Interview	8; 10	0.93; N/A	T2	Intervention Parent
Parent Satisfaction with Intervention	Client Satisfaction Questionnaire; Semi-structured Interview	8; 10	0.93; N/A	T2	Intervention Provider
Mediators (Target Variables)					
Parent Activation	Parent Activation Measure-Mental Health (P-PAM-MH); Parent Needs and Resource Domain of CANS*	13; 3	0.89; N/A	T1, T2	Parent, Provider
Provider Communication Skills	Communication Subscale of Kim Alliance Scale (KAS)	11	0.94	T1,T2	Parent, Provider
Parent-Provider Interactions	Working Alliance Inventory - Short Form; Audio Tapes	12	0.9	T1, T2	Parent, Provider; Observer
Proximal Outcomes					
Parent Perceived Management of Adolescent Behavioral Health Care	Percieved Efficacy in Parent-Physician Interactions (PEPPI)-Short Form	5	0.83	T1, T2	Parent
Parent Perceived Quality of Adolescent Behavioral Health Care	Perception of Care Survey (POC)	18	N/A	T1, T2	Parent
Parent Engagement in Adolescents' Behavioral Health Care	Parent Participation Engagement (PPE); Proportion of Visits Attended of Scheduled	5; N/A	0.88; N/A	T1, T2	Observer; Medical Record
Distal Outcome					
Adolescent Retention in Behavioral Health Care	Attending at Least 4 visits in 6 Months Post-Baseline	N/A	N/A	T1, T2	Medical Record

*Midtown specific request; CANS- Child & Adolescent Needs & Strengths

Compensation. All parent participants will receive a $25 gift card for each assessment completed and $25 gift card if an oral interview is completed. They will receive a $10 gift card for each training session attended. We will offer continuing education credits (CE) for the 4.5-hr provider workshop. Dr. Oruche has arranged with her school's Center for Continuing Education and Lifelong Learning to offer the CE credits at minimal cost. Providers will also receive $100 upon completion of the T1 measures, the DECIDE Workshop, T2 measures and the qualitative interview **<u>if located at any center that is not Bowen or Eskenazi.</u>**

Intervention Fidelity. We will follow the treatment fidelity protocols developed for the original DECIDE trial and the NIH Treatment Fidelity Workgroup recommendations to ensure intervention integrity and minimize drift/group contamination.[128] *Design.* We are comparing an historical control data to intervention data gathered during the study.. Provider training. All study personnel will receive training specific to their role; regular supervision and retraining as needed. We will fully manualize the modified intervention similar to the original DECIDE intervention with standardized treatment protocols, training manuals, and training content,[25,129,130] modified from patients to parents of adolescents with DIC. *Treatment Delivery.* Parent and provider intervention delivery will be assessed using a random sample of recorded trainings and checklist of key intervention components. *Receipt and Enactment of Treatment.* Facilitators for parent component will complete a session-specific field note entry that summarizes parent responses (i.e., level of engagement and understanding) and any potential external factors (e.g., interruptions, noise) that may have influenced their response.

7.0 Reporting of Adverse Events

Participants will be monitored for adverse events on a daily basis. Any adverse events will be reported to PI immediately and IRB immediately. The research investigative team will be responsible for data and safety of this study and include Ukamaka Oruche, PhD, RN (Co-I)); Claire Draucker, PhD, RN (Co-I), Susan Perkins, PhD (PI), Ora

Nakash (Consultant), and Anil Chacko (Consultant). In addition to monthly research team meetings, the committee will meet as soon as possible following the occurrence of any adverse events.

Data. Parents and providers (participants) in this study will be assigned a participant identification number (PIN). Research materials such as parent and provider interviews will contain the PIN instead of the participants' names. A file containing a link between the PIN and the participants' names will be created and access to this file will be restricted to key research staff such as the Project coordinator and only for the purpose of scheduling interviews. All research staff will be required to complete training in Human Subjects protection sponsored by the Indiana University Office of Research Compliance. This includes basic human subjects' protection and advanced training on Health Insurance Portability and Accountability Act (HIPA) and Conflict of Interest. The staff will also receive additional training on working with participants or handling identifying information.

After obtaining consent from the parent, the research team will access their administrative data, and parent interviews for purposes of this study. Once at research team offices at the university offices, all documents that include identifying information (i.e. names, addresses and telephone numbers) will immediately be separated from the parent assessments, and recordings. These items will be stored by research staff authorized by the PI in a locked file and an identifying case number will be generated. The PI and authorized research staff will be the only persons with access to the locked filing cabinet and/or any information or files that link the case number with any parent identifying information. No reports will be made public using any names or identifying information. Raw data and accompanying research protocols will be kept for at least 7 years post publication of findings, as required by Indiana University. Strict measures to assure confidentiality of the data will be taken. Computerized data will be identified by participant number only. All research staff PCs are password-protected and have standardized, full featured, software and hardware configurations. Only research staff authorized by the PI will have access to the data.

Data analysis will be conducted with use of coded data to reduce the chance of inadvertent disclosure. Dr. Perkins and her statistical team working with the data are the only persons on-site with network level administrative password privileges. The original data and the encrypted data will not be transported or used at any other location and the data will not be copied onto other computers, discs, CDs etc. We will maintain all print-outs, electronic files, personal computers with restricted data on the hard drives, or other physical products containing data in locked cabinets, file drawers or other secure locations when not in use. Printed material that includes analyses based on restricted data will be promptly destroyed. At the end of the project, all files that include restricted data will be destroyed, including copies and subsets on the Indiana University server or any project computers.

Safety. The committee will monitor adverse events reported by participants and reasons for dropping out. Adverse events will be reported to the study PI or her designee within 24 hours, and any serious unexpected adverse events related to the study intervention will be reported to the Institutional Review Board within 5 working days. The relationship between adverse events and the study intervention will be determined based on PI and her research staff examination of the subject (research staff and/or patient) and subsequent clinical judgment. Both provider and parent participants will have several phone numbers to call should they have any concerns or questions about any aspect of the study, including contact numbers for the PI, the project coordinator, the IRB offices, and the parent/patient representatives at Midtown. All other adverse events will be reported annually with the continuing review. <u>Study Withdrawal/Discontinuation</u>. Taking part in the study is voluntary. A participant may choose not to take part in the study or to withdraw from the study at any time. If the participant withdraws from the study, he/she will not be penalized in any way and will not lose any benefits he/she is entitled. The participant may choose to contact the study PI to formally withdraw, or he/she may simply choose to stop coming to the study sessions. If the participant chooses to withdraw, a study representative will call the participant to make sure he/she is ok. The study representative will provide the participant with contact numbers to obtain other resources. For example, parents may be provided number to other Midtown programs or National Alliance on Mental Illness (NAMI) Indianapolis. In addition, the PI will meet monthly with the research project coordinator to review data collected to date in order to determine if there are any major problems in data collection procedures or data collected.

8.0 Study Withdrawal/Discontinuation

After signing the informed consent, participants can withdraw and leave the study at any time. Members of the study team will assist participants in withdrawing if that is the wish of the participant. Withdrawing from the study will not impact the participant's healthcare in any way.

9.0 Statistical Considerations

We will calculate the proportion eligible that enroll and proportion completing the intervention for both parents and providers. We will tabulate responses to Parent and Provider Satisfaction with Intervention items and calculate the proportion of parents and providers who have a mean ratings of at least 4 on the 5-point scale (satisfied or highly satisfied). Effect sizes will be estimated by fitting linear mixed models, with parent, provider, or observer target and outcomes variables, all measured at T2, as outcomes and treatment group (intervention or usual care) as the explanatory variable. All models will also include the T1 outcome as a covariate and random effects for provider and parent nested within provider to account for clustering. Effects sizes will be estimated with ω2. Analyses will be intent-to-treat and conducted using SAS Version 9.4 (SAS Institute Inc., Cary, N.C., Copyright 2002-2012).

Supplementary Analyses: We will investigate how the adjustment for covariates (age of child, sex of provider and parent, parent race and income, severity of child illness and duration in treatment) impacts effect size estimates by adding interaction terms to models and estimating effect sizes separately for different levels of the covariate (e.g. male and female for parent gender). *Missing Data*: We will compare baseline variables between subjects who drop out of the study to those who do not using two-sample *t* tests, chi-square tests or their non-parametric equivalents as appropriate. If we find that the missing data appear to be MNAR, this information will be used in designing the larger trial. Because of the relatively small sample size, we will not attempt to model the missing data mechanism in this pilot study. Sex as a biological variable: As noted above, we will estimate effect sizes by sex for all outcomes. Draucker will lead the qualitative analysis of the semi-structured interviews with input from PI and research team. The interviews will be coded with standard content analytic procedures.[13]

10.0 Privacy/Confidentiality

A secure web-based system (REDCap) will be used to capture study data. Participation in this research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers may not disclose or use any information, document, or specimens that could identify any participants in any civil, criminal, administrative, legislative, or other legal proceeding, unless participant consents to it.

11.0 Record Retention

Records will be retained for up to seven years post study completion.

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