Study Protocol with SAP

Improving Satisfaction, Engagement and Outcomes Among Traditionally Underserved Children Through Cultural Formulation

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Objectives

The present randomized examination evaluated the incremental utility of augmenting Clinical Assessment with the CFI among culturally diverse families seeking services for child-externalizing problems. Initial analyses examined equity-informed implementation outcomes – i.e., CFI fidelity, clinical utility, caregiver feeling understood and satisfaction – which can inform broader CFI use, sustainability, and ultimate effects on inequities (Eccles & Mittman, 2006; Proctor et al., 2011; Woodward et al., 2019). Given the tendency for families from marginalized back grounds to feel misunderstood by their provider, initial analyses examined caregiver and provider perceptions at post-assessment regarding the extent to which the provider understood the family's values and what is important to them. Next, analyses examined the effects of the CFI on subsequent treatment engagement and ultimate clinical response. Treatment engagement was conceptualized through family behaviors (e.g., attendance and homework) and the family-provider relationship (Becker et al., 2018). We first hypothesized that incorporating the CFI would be clinically useful, that providers and caregivers would report high satisfaction with the CFI, and that they would perceive the CFI as fostering improved provider understanding of the family's values. We further hypothesized that caregivers randomized to receive the CFI as part of their child's intake assessment, relative to caregivers randomized to standard Clinical Assessment (CA), would show stronger subsequent treatment engagement (i.e., higher subsequent treatment session attendance, homework completion, working alliance, and first treatment module completion), and would show higher rates of ultimate treatment response. Exploratory analyses further examined whether the language of service delivery (English versus Spanish) moderated outcomes. Families receiving services in Spanish, may be particularly vulnerable to poor treatment engagement and outcomes due to lower levels of acculturation, and potential misalignment of ment with their background and explanatory models (Alegría et al., 2015; Burnett-Zeigler et al., 2018; Ho et al., 2007; La Roche, 2013; Yeh et al., 2005). Moreover, there is evidence that culturally adapted EBTs are more effective for families with lower levels of acculturation and those that receive services in their native language (Griner & Smith, 2006).

Methods

Participants

Participants were 89 children ages 2–7 (M = 5.10, SD = 1.6), and their primary caregivers ages 20–57 (M = 33.4, SD = 7.3) receiving services through a Miami- Dade County-funded initiative to provide free behavioral parenting intervention services to underserved communities (i.e., those with limited access to mental health services) and to assess various engagement strategies. The majority of primary caregivers were mothers (N = 85). The initiative serves English- and Spanish-speaking families of children with behavior problems (clinically elevated symptoms) and/or history of child maltreatment. Comorbid child disorders did not exclude eligibility, although caregivers actively abusing illegal substances were not eligible. There were no other exclusion criteria. Approximately two- thirds of the children were male and approximately 89% of the children were identified as a member of a racial and/or ethnic minority group by the caregiver. Sixty percent of participating caregivers did not have a college degree. Roughly half of the families (54.8%) had significant financial needs and fell in "extreme poverty," "poor," or "low-income" economic ranges (see Measures). Regarding housing security, roughly one-third of participating families. lived with more than two people per bedroom, and roughly one-fifth reported temporarily living with others due to economic difficulties. Nearly 33% of families received treatment and study activities in Spanish.

Procedures

This study was approved by the University of Miami and the Florida International University Institutional Review Boards. All services were provided in English or Spanish. Presenting families completed informed consent, then were randomized across two parallel pre-treatment assessment conditions: Clinical Assessment (CA) or CFI followed by CA (CFI+CA). A master random number table generator was used for randomization. Services were offered across three sites. The intake assessment included consent, an intake interview (CA or CFI+CA), completion of study questionnaires, and structured observations of parent–child interactions, generally over 2–3 one-hour sessions. Families were not informed of the assessment condition to which they were randomized. After intake assessment, patients were offered a course of Parent-Child Interaction Therapy (PCIT), a well-supported behavioral parenting intervention for child behavior problems and maladaptive family patterns (Eyberg & Funderburk, 2011). A full PCIT course entails completion of two sequential treatment modules; the first module teaches caregivers to use positive and differential social attention to improve child behavior and the parent–child relationship, and the second module teaches caregivers consistent limit setting and effective discipline strategies. The precise length of a PCIT course varies as a function of the quickness with which parents acquire the skills and the child's behavior falls within normal limits. The standard PCIT protocol was flexibly delivered across conditions. A power analysis assuming an alpha level = 0.05, beta = 0.2, and power = 0.8, identified a sample ≥82 participants was needed to identify small-to-medium effects (i.e., OR~2.5). Recruitment was closed within one month of reaching minimum sample size estimated by power analysis. Families were recruited and randomized from August 2017 to October 2018; data collection continued through March 2019.

Study Conditions

Clinical Assessment (CA)

CA entailed the standard intake assessment procedures used in the county-funded behavioral parenting program. This included a parent interview regarding the child's developmental milestones, educational history, medical history, disruptive behavior symptoms, previous treatment experiences, and current parenting strategies. A series of observational parent–child interaction tasks followed.

CFI+CA

Caregivers in CFI+CA participated in an augmented CA that also included the core CFI (CFI; American Psychiatric Association [APA], 2013). The CFI is a brief (16-item) semi-structured interview designed for providers to assess a patient's cultural identity and how it might affect key aspects of their understanding of mental health difficulties and clinical care. The CFI assesses the patient's individual symptom experience, their perceptions of mental health, and their perceptions and experiences of treatment via four domains: (1) cultural definition of the problem, (2) cultural perceptions of cause, context, and support, (3) cultural factors affecting self-coping and past help seeking, and (4) cultural factors affecting current help seeking (American Psychiatric Association [APA], 2013). See Table 2 for the domains of the CFI and the main component sections. For CFI+CA cases, providers administered the CFI prior to the CA, consistent with its implementation guidelines in DSM-5 (American Psychiatric Association [APA], 2013). This decision to deliver the CFI first was made to remain consistent with previous studies (Aggarwal et al., 2020), enhance fidelity by having a clear implementation plan (Aggarwal et al., 2014), center caregiver values and perspectives from the beginning of the intake (La Roche, 2018), and increase rapport (Aggarwal et al., 2015, 2016b).

Providers, Setting, and Training

Providers in the current study who conducted all baseline clinical assessments and subsequent services (N = 4) were master's- or doctoral-level community practitioners providing clinical services within three community clinics that were embedded within neighborhood centers regularly accessed by the community (i.e., afterschool care centers, family and neighborhood resource programs). The providers were employed by the medical center (i.e., not affiliated with the PI) to provide services within the neighborhood centers. Three out of the 4 providers had not delivered PCIT prior to the start of the study. They were trained by a certified trainer as part of the county-funded program to provide PCIT to underserved communities prior to delivering PCIT. These providers did not work for the PI or the study. The services were provided via a partnership between a medical center and the three neighborhood centers. Three of the providers were fluent in Spanish and delivered services in both English and Spanish. Providers conducted both CA and CFI+CA assessments. Randomization occurred at the patient rather than the provider level due to the providers working at three distinct community centers within distinct neighborhoods. Providers were masked to study hypotheses, but not study condition. For each family, the same provider conducted their intake assessment and their subsequent PCIT services. Providers and their supervisors at participating clinics completed a two-hour CFI training led by the study PI (who trained with one of the CFI developers) and another senior psychologist with CFI training experience. Per recommendations (Aggarwal et al., 2016a), training consisted of reviewing the CFI's written guidelines, a video demonstration, role-plays with feedback, a discussion of possible barriers to implementation, and peer debriefing exercises to consider implementation issues in their organizational climate. To prevent integrity drift and contamination across conditions, providers received structured feedback based on fidelity ratings from their first case prior to seeing study cases (Aggarwal et al., 2014). Three additional CFI booster trainings were implemented to problem solve any challenges with implementing the CFI (e.g., wording of the questions, using examples to increase caregiver responses).

Measures

Patient forms were administered through a secure online platform, or by paper when families preferred. Measures were available in English and Spanish.

Demographics

Primary caregivers reported on child and caregiver age, race, and ethnicity. Additionally, specific details regarding country of origin and immigration status were not collected to protect the privacy of families during a time of considerable increase in Immigrations and Custom Enforcement raids in the community where this study occurred. Caregivers also reported on their education, annual household income, and family size. Incometo- needs (INR) ratios were computed reflecting household income relative to the poverty threshold, and categorized as "extreme poverty" (INR ≤ .5), "poor" (.5< INR ≤1), "low-income" (1< INR ≤2), "adequate-income" (2< INR ≤4), and "affluent" (INR > 4). To assess housing security, caregivers were asked two items from the U.S. Department of Housing and Urban Development: 1) *During the past year, have you had more than 2 people per bedroom*, and 2) *In the past year, have you temporarily lived with other people because of economic difficulties?* In addition, the *Everyday Stressors Index* (ESI; Hall, 1990), a 20-item measure of daily stressors experienced by economically disadvantaged caregivers with young children, was administered at intake. Items are rated on a Likert-style scale ranging from 1 = "not at all bothered" to 4 = "bothered a great deal," as well as "I don't know" = 0, and tallied with higher scores indicating greater daily stress (maximum score = 80). The ESI has demonstrated good internal consistency and construct validity in English- and Spanish-speaking samples (Hall et al., 1996; Gómez et al., 2015; Hall, 1990) (α = .79 in present sample).

Intake Assessment Length

Providers recorded the total time, in minutes, spent completing each family's intake assessment. The pretreatment assessment sessions included the consent procedures, and CA or CFI+CA (depending on randomization). Time spent across the intake assessment was measured by provider report of the total length, in minutes, to complete these procedures. The pretreatment assessment typically lasted between 2 and 3 sessions.

Implementation Outcomes

Provider fidelity and condition integrity. To measure CFI fidelity and potential cross-condition contamination in CA, the CFI Fidelity Instrument (CFI-FI; Aggarwal et al., 2014) was used to code assessments in both conditions. Independent evaluators (IEs) masked to condition, study design, and study hypotheses coded recordings of all assessments. IEs met 80% reliability on a study video prior to coding further study videos. Consistent with previous research (Aggarwal et al., 2014), interrater reliability across IEs on a random 20% of study cases was high (i.e., agreement range: 80%–100% on Adherence items; mean agreement = 96.25%).

Provider perceptions of clinical utility. The *CFI Clinician Questionnaire* is a 4-item measure adapted from previous work (Aggarwal et al., 2015) to assess provider perceptions of CFI clinical utility. Directly following pretreatment assessment, providers rated 4 items related to content and quality of information, relationship with caregiver, treatment planning, and differential diagnosis (e.g., "*How much of an impact did using the CFI have on your relationship with your patient*") on a Likert-style scale ranging from 1 = "not at all" to 5 = "very much" (*α* in present sample =.84).

Perceptions of provider understanding of caregiver values and satisfaction. Two items developed for this study, administered directly after the intake assessment (but before treatment began), measured caregiver and provider perceptions of how well the provider understood the family's values and what is important to them, and how satisfied they were with the intake assessment. The items were rated independently by caregivers and providers on a 5-point scale (1 = *not at all*; 5 = *very much*). The items were translated into Spanish and then back translated into English to ensure semantic and cultural accuracy.

Treatment Engagement

The behavioral domains of engagement (e.g., attendance and homework) were measured for each family via provider logs recording: (a) initial treatment session attendance (i.e., did family attend a first treatment session after completing intake assessment?), (b) weekly session attendance rate (percentage of sessions attended across weeks in treatment), (c) completion of first treatment module (i.e., caregiver acquisition of positive-attending skills), and (d) homework completion (i.e., mean percentage of weekly homework completed across weeks engaged in treatment). While the average PCIT treatment length is between 12 and 20 sessions, the length of treatment varies based on family's specific needs, symptom reduction, and caregiver skill acquisition (PCIT International, n.d.).

The relationship domain of engagement was measured by the *Working Alliance Inventory-Short Form Revised* (WAI-SR; Hatcher & Gillaspy, 2006), administered at midtreatment. The WAI-SR is a 12-item caregiver-report of therapeutic alliance that assesses (a) perceived agreement with the provider on the tasks of therapy, (b) perceived agreement with the provider on the goals of therapy, and (c) the perceived affective bond between the provider and patient/ family. Items are rated on a 5-point Likert-style scale ranging from 1 = "never" to 5 = "always" and are summed for a total score. The WAI-SR has demonstrated strong internal consistency and construct and convergent validity in English and Spanish (Andrade- Gónzalez & Fernández-Liria, 2016; Hatcher & Gillaspy, 2006; Munder et al., 2010) (α = .94 in the present sample).

Treatment Response

Families were classified as Treatment Responders in accordance with formal PCIT graduation criteria (Eyberg & Funderburk, 2011), that is: (a) caregivers demonstrated skill acquisition, as coded against specific criteria in both phases of treatment; and (b) child behavior problems dropped into the subclinical range – i.e., *Eyberg Child Behavior Inventory* (ECBI) falls below 114; Eyberg, 1999).

Data Analysis

Intent-to-treat analyses were employed. Missing data were addressed through Multiple Imputation in Mplus (Enders, 2010). The majority of variables were completed for more than 90% of cases. Descriptive analyses were conducted to assess the implementation outcomes of fidelity, clinical utility, provider and caregiver perceptions of understanding the caregivers' values, and satisfaction with the intake. Additionally, linear regressions tested condition effects on caregiver and provider satisfaction, and the extent to which the provider understood the caregivers' values or what is important to them. Next, logistic and linear regressions examined condition effects on subsequent treatment engagement and response. Exploratory moderation analyses examined the main and interactive effects of language of service delivery (English versus Spanish) with study condition (CA versus CFI+CA) on dependent variables. To interpret effects, adjusted odds ratios and probabilities were calculated for logistic regressions and Cohen's *d* effect sizes were calculated for linear regressions. An alpha threshold of .25 determined inclusion of covariates. Due to condition differences all analyses controlled for length of intake assessment (in minutes), site, caregiver race/ethnicity, daily stress, and language of assessment delivery. Length of intake assessment is also controlled for to account for differences in effects solely related to differences in the amount of time the provider spent with the caregiver. Baseline ECBI score was included as a covariate for the treatment response analyses.