Children with disruptive behavior difficulties reared by child welfare (CW)-involved families have an increased risk of future maltreatment and out-of-home placement. However, the lack of available providers and difficulties engaging families in mental health agencies frequently limit treatment access. Community-based organizations (CBOs) contracted by CW authorities to prevent out-of-home placement may be ideal locations to deliver child mental health Evidence-Based Practices (EBPs) as an adjunct to existing placement prevention services. As a result, CW-involved families' needs can be met comprehensively in one setting. Unfortunately, few EBPs have been successfully implemented in CW settings, especially those originally designed to be delivered by advanced mental health providers (i.e., Masters or PhDs). Given that CBO's typically employ bachelors'-level caseworkers who lack advanced mental health training, this is a significant barrier to implementation. As a potential solution, task shifting provides a practical and efficient strategy for facilitating implementation of EBPs where there are shortages of mental health professionals, involving (1) tailoring the EBP for provision by non-mental health providers; (2) training non-mental health providers in the tailored EBP; and (3) establishing regular supervision and monitoring of non-mental health providers by mental health specialists. The proposed R21 study will refine task-shifting strategies to implement an EBP to reduce child disruptive behavior difficulties, originally designed to be provided by advanced mental health practitioners (Masters or PhD), so that it can be delivered by bachelor's-level caseworkers in CBOs providing placement prevention services to CW-involved families. We will utilize the Multiple Family Group MFG (MFG) service delivery model to reduce child disruptive behavior disorders as the example EBP, because it has a beneficial impact on engagement, child behavior, and family processes when tested in community child mental health settings that provide services to CW-involved families. The proposed study aims are: (1) to use task shifting to tailor the content, training, and supervision of MFGs for delivery by bachelor's-level caseworkers in CBOs serving CW-involved families; and (2) to assess the feasibility and acceptability of the task-shifted MFGs in CBOs serving CW-involved families. The design and evaluation for this study are informed by the Practical, Robust, Implementation and Sustainability Model (PRISM) to support longer-term implementation efforts. We will use mixed quantitative and qualitative methods to assess for feasibility and acceptability from key stakeholders (caseworkers, supervisors, caregivers). By using the CW system as a non-specialty service sector platform to launch targeted mental health services, the proposed study will provide generalizable knowledge about using task shifting to facilitate cross-setting implementation for similar EBPs. Task shifting may also provide an innovative way to increase EBP access and reduce costs within transforming child-serving systems.

Children with disruptive behavior difficulties reared by families involved in the child welfare (CW) system have an increased risk of future maltreatment and out-of-home placement, yet have difficulty accessing and engaging with child mental health providers. The proposed R21 study will refine task-shifting strategies to implement an Evidence-Based Practice (EBP), originally provided by advanced mental health practitioners (Masters or PhDs) to reduce child disruptive behavior difficulties, so that it can be delivered by bachelors'-level caseworkers in Community Based Organizations (CBOs) providing placement prevention services to CW-involved families. In doing so, the proposed study will develop a strategy to increase access to needed mental health treatment for vulnerable families, thereby further reducing the risk for future maltreatment and out-of-home placement.

Impact: This proposed R21 will refine a "task-shifting" implementation strategy to implement a family-based Evidence-Based Practice (EBP) to reduce child mental health problems in low-resourced child welfare (CW) settings. The EBP, originally designed to be provided by advanced mental health practitioners (Masters or PhD), will be modified for delivery by bachelors'-level caseworkers in CW settings with appropriate training and supervision. We will utilize task-shifting strategies that involve "engaging non-specialists in the provision of effective psychosocial treatments under the supervision of mental health specialists" [1] to increase EBP access among CW-involved families. As an example EBP, the proposed project is built upon a recently completed, highly successful effectiveness study of a multiple family group (MFG) model to reduce child mental health problems among urban, low-income, minority families (R01 MH072649)[2-8]. Our study will advance implementation science by pilot testing the task-shifting approach for feasibility and acceptability. Moreover, this study will improve public health by making a promising EBP more available and disseminable to a highly vulnerable population. This study addresses the NIH goal of promoting "innovative approaches to identifying, understanding, and overcoming barriers to the adoption, adaptation, integration, scale-up, and sustainability of evidence-based interventions, tools, policies, and guidelines" (NIH PAR-13-054). Moreover, this project advances the NIMH strategic objective #4: "Strengthen the public health impact of NIMH-supported research" by promoting the widespread use of research-based interventions by those most in need.

Public Health Concern: Children who remain at home with their permanent caregivers following a CW investigation disproportionately manifest high rates of hyperactive, oppositional, disruptive, rule-breaking, and aggressive behavior[9], referred to as Disruptive Behavior problems. These difficulties increase children's risk for future maltreatment[10,11], out-of-home placement[12], and a host of other maladaptive consequences[13,14]. The proposed study focuses on community-based organizations (CBOs) contracted by CW agencies to prevent out-of-home placement by providing an array of services (or "Preventive" services). Mental health services are often subsequently subcontracted out to community mental health agencies that frequently lack sufficient capacity or providers to meet the serious needs of CW-involved families[15,16]. Not surprisingly, mental health providers frequently struggle to engage CW-involved families[17] who often lack the motivation and resources to follow through with multiple service providers[18,19]. CBOs may be ideal locations to increase access of child mental health EBPs as an adjunct to existing placement prevention services in order to meet families' needs comprehensively in one setting. Unfortunately, few EBPs have been successfully implemented in CW settings[20,21], especially those that were originally developed to be delivered by advanced mental health providers (i.e., Masters or PhDs). Given that CBOs contracting with CW services typically employ bachelors'-level caseworkers who lack advanced mental health training[22,23], this is a significant barrier to implementation.

Implementation Strategy: Task shifting provides a practical and cost-efficient strategy for facilitating EBP implementation where there are shortages of mental health professionals. Successful task-shifting models[1,24-26] emphasize: (1) tailoring the EBP for provision by non-mental health providers; (2) training non-mental health providers in the tailored EBP; and (3) establishing regular supervision and monitoring of non-mental health providers by mental health specialists. We will utilize MFG because it has a beneficial impact on engagement, child disruptive behavior problems, and family processes when tested in community child mental health settings that provide services to CW-involved families[2-8]. By using the CW system as a non-specialty service sector platform to launch targeted mental health services, the proposed study will provide generalizable knowledge about using task-shifting to facilitate cross-setting implementation for other similar EBPs. Task shifting may also provide an innovative way to increase EBP access and reduce costs within transforming mental health and CW service systems[27,28]. Consequently, the proposed study aims are:

AIM 1: *To use task shifting to tailor the content, training, and supervision of MFGs for delivery by bachelors-level caseworkers in CBO's serving CW-involved families*
AIM 2: *To assess the feasibility and acceptability of task-shifted MFGs in CBO's serving CW-involved families*

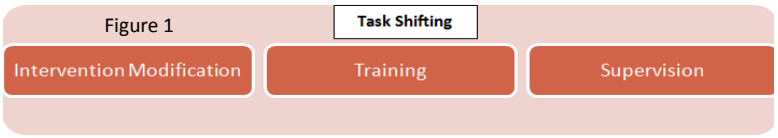
The design and evaluation for this study are informed by the Practical, Robust, Implementation and Sustainability Model (PRISM)[29] to support longer-term implementation efforts. For Aim 1, we will convene a research-community advisory team (1) to tailor MFGs to be delivered by bachelors'-level caseworkers within CBOs as an adjunct to placement prevention services; (2) to develop training to ensure treatment fidelity; and (3) to develop a protocol for mental health specialists to provide ongoing supervision of caseworkers.
For Aim 2, we will pilot test the task-shifted MFG delivered by n=4 caseworkers to n=20 caregivers and n=20 youth receiving CBO preventive services (where children manifest disruptive behavior problems). We will use mixed quantitative/qualitative methods to assess feasibility and acceptability. Results from this study will be used to support a larger-scale hybrid effectiveness-implementation trial (R01).

A. Significance

A.1. Children with disruptive behavior difficulties who remain at home with their permanent caregivers following a CW investigation are at high risk for future maladaptive outcomes. These difficulties (e.g., hyperactive, oppositional, disruptive, and/or aggressive behavior[9]), can result from, or be exacerbated by, multiple, co-occurring stressors (e.g., poverty, domestic violence, substance abuse) [10, 30-33] experienced by families investigated for maltreatment, as well as the impact of maltreatment itself. Consequently, children residing at home following a CW investigation manifest disproportionately higher rates of disruptive behavior problems compared to national rates[34, 35]. Untreated, such mental health problems are a costly (up to 10 fold increase) [36] public health concern as they also create additional service needs due to increased risk for future maltreatment[10, 11], and out-of-home placement[12], high school dropout[14], and delinquency[13].

A.2. Community-based organizations (CBOs), as non-specialty platforms, could increase access to child mental health EBPs. In many states, local CW authorities contract with CBOs to provide a comprehensive array of placement prevention services for families mandated or referred by CW authorities following maltreatment investigations[21, 37], as well as a small proportion of families with similar difficulties voluntarily seeking preventive services[38]. To meet CW contractual obligations, CBOs must subcontract with separately housed child mental health providers to offer treatment for children with mental health difficulties. However, mental health providers have frequent difficulties engaging and retaining CW-involved families[17, 39], many of whom lack resources to meet multiple service demands[18, 19]. A pervasive dearth of available child mental health providers in urban settings[16] further limits treatment access. It is imperative to investigate whether other service delivery platforms might ameliorate these concerns and conditions. Given that EBPs originally designed to reduce disruptive behavior problems also hold promise in reducing maltreatment risk[10, 37, 39], CBOs are logical platforms for effective services to reach CW-involved children with mental health problems. At the same time, many such EBPs were originally designed to be delivered by advanced mental health providers (i.e., Master's-level or PhD; e.g., Parent-Child Interaction therapy[39], Incredible Years[40]). This is a substantial barrier to implementation in CBOs, given that the typical workforce consists of bachelors'-level caseworkers[22, 23] who generally lack advanced specialized mental health training.

A.3. Task shifting is a practical, cost-efficient strategy for increasing EBP access in settings with limited professional resources[41]. Endorsed by the World Health Organization (WHO), task shifting involves redistributing tasks from professionally trained workers to those with less training and fewer qualifications[41]. As illustrated in Figure 1, successful task-shifting efforts[1, 24-26, 42] that focus on improving access to mental health treatment in the developing world have involved (1) modifying the intervention to be delivered by non-mental health workers, (2) training non-mental health workers, and (3) providing consistent supervision for task-shifted non-mental health workers by competent mental health providers. As a result, task-shifting strategies have successfully reduced adult depression using Cognitive Behavior Therapy and Interpersonal Psychotherapy in rural Pakistan, Uganda, Goa, India, and South Africa by a host of lay-level providers[1, 25, 26, 43, 44]. Most importantly, the beneficial effects were achieved by continuously supervised[43] workers with no mental health background and relatively short training (as little as 2 days[24, 25, 42]).



A.4. Task-shifting strategies can promote successful cross-setting implementation efforts for low-resource settings in high-income countries.[43] Specifically, this study focuses on implementing a child mental health EBP in the CW service sector, where there is a high level of child mental health need, but where mental health specialists are not typically employed. In states such as New York, which are undergoing substantial behavioral healthcare financing and child welfare service reform[27, 45], task shifting responds to calls for increased access to EBPs[27] delivered via cost- and resource efficient strategies[45]. Data gathered from this study will provide important information on how task shifting facilitates the broader issue of implementing child mental health EBPs in CW settings. Finally, this study will provide data on initial feasibility and acceptability, as well as solidifying methods to support a larger-scale R01 study[46] testing the effectiveness and implementation success of task shifting a child mental health EBP in CBOs.

B. Innovation

B.1. Task Shifting. This study innovatively utilizes task-shifting strategies drawn from international public health efforts to scale-up EBPs in low-resource countries. To our knowledge, task shifting has yet to be used to implement child mental health EBPs in CW settings. Refinement of task-shifting strategies proposed in this study can add to the growing arsenal of implementation strategies[47] such that task shifting could be used as one component within comprehensive, multi-level approaches to promote successful EBP implementation.

B.2. PRISM. As a methodological innovation, the proposed study will utilize PRISM[29] to guide this study's design and evaluation. PRISM is a practical, robust, and prescriptive model built upon multi-disciplinary implementation models. PRISM emphasizes: (1) organizational/patient perspectives on an intervention (e.g. burden, usability/adaptability, barriers); (2) external environment (e.g. CW authority performance indicators, community resources); (3) recipient (organizational/patient) characteristics (e.g., staffing and capacities, disease burden, competing demands); and (4) infrastructure (e.g. training/support). This study will focus on the first 3 categories, with a subsequent study developing the infrastructure for implementation and sustainability. Specifically, PRISM domains will specify aspects within the task-shifting approach (i.e., intervention modification, training, and supervision) that will be addressed to support implementation success across CBOs. Moreover, PRISM domains guide measurement of feasibility and acceptability in the proposed study.

B.3. Multiple Family Groups (MFG) to reduce child disruptive behaviors. As an additional innovation, the proposed study uses MFGs as an example EBP, which has demonstrated benefits for child mental health, functional capacities, and family processes[2-8] in a recently completed NIMH-funded effectiveness study (See Section C.2. Preliminary Studies and Appendix A for MFG materials). Weekly sessions of multiple family groups (6-8 families) are convened over 4 months, where engagement is promoted via extensive phone outreach, childcare, transportation expenses, and dinner provided at each session. MFG core treatment components integrate over 2 decades of research regarding behavioral parent training and family therapy strategies that address empirically supported family-level influences on disruptive behavior disorders[48-59]. MFG is an ideal example of an EBP to utilize in this study as MFGs (1) have already been successfully delivered by non-professional parent advocates (parent consumers of child mental health services) in collaboration with clinicians[2-8]; (2) address significant limitations in service capacity, (3) prioritize engagement and retention of low-income, minority families by targeting logistical (i.e., lack of transportation & childcare, conflicting demands) and perceptual barriers (i.e., stigma) to service use[60-62], (4) is manualized for straight-forward delivery by community-based providers, and (5) exemplifies similar EBPs well-known to reduce child disruptive behavior disorders. As providers can see multiple families simultaneously, MFGs may be recommended over those interventions requiring specialized placement, extensive provider investment (i.e., Multidimensional Treatment Foster Care[63]), and costly space/equipment requirements (i.e., Parent-Child Interaction Therapy[39]).

C. Approach:

C.1. Investigative Team: The investigative team for the proposed study possesses substantial experience in engaging organizations in NIH studies, intervention development and evaluation of MFGs, child mental health needs within the CW system, and EBP implementation in CW and child mental health systems (See Biosketches). Drs. Gopalan (PI) and McKay (Co-I) have spent the last 7 years evaluating MFGs, including Dr. Gopalan's focus on MFGs with CW-involved families. Moreover, they will have access to in-kind methodological support through the IDEAS Center (See Facilities and Resources). Dr. Barth (Advisor) will provide extensive expertise specific to national CW system implementation issues. Consultants will provide additional expertise on child mental health issues in the CW system, training CW caseworkers (Dorian Traube), and implementation expertise in publicly funded settings (Gregory Aarons).

C.2. Preliminary Studies. Findings for MFGs are summarized in 13 published manuscripts, 4 papers under review and numerous presentations. In addition, data from the study are central to the PI's (Gopalan) NIMH-funded post-doctoral fellowship (F32MH090614). The recently completed randomized effectiveness trial examining MFGs vs. standard care as usual (SAU) was conducted in 13 clinics in the greater New York City (NYC) area. A sample of 416 adult caregivers and children (ages 7-11) evidencing Oppositional Defiant Disorder or Conduct Disorder[64] were recruited. The vast majority of youth and families were of color (50% Latino; 30% Black/African American), 65% of families reporting living on less than $20,000 per year, and 40% indicated having prior or current CW involvement. Participants manifested very high attendance at initial meetings (75%) and strong rates of service involvement over a 4-month period (80% vs. 10% in comparison standard care)[2-8]. To date, random coefficient modeling has been used to examine change over time and differences between MFG and SAU across the first four time points (baseline, 8 week mid-test, 16 week post-test, and 6 month follow-up (10 months from baseline)). Compared to SAU participants at post-test, MFG participants had significantly reduced child disruptive behavior difficulties, and increased social skills. Compared to SAU participants at 6 months follow-up, MFG participants had significantly reduced child behavior difficulties, improved peer relationships, lower parent stress related to difficult child behavior, lower overall child rearing stress, and less negative/ineffectual discipline by caregivers. While CW-involved families perceived greater treatment barriers and less satisfaction with MFGs than non-CW-involved families, no differences were found in overall MFG attendance rates over time[65]. Significant benefits of MFG vs. SAU

among CW-involved participants included reduced child disruptive behavior difficulties and improved peer relationships, with greater effect sizes than those observed for the entire sample[66]. Qualitative findings from interviews with CW-involved caregivers in the MFG condition indicate a number of components which promoted retention, as well as recommendations to tailor MFGs for a CW population (e.g., home visiting)[67]. Findings from a recent state-wide implementation effort across n = 29 child mental health clinics in New York indicate that group facilitators and clinical staff overwhelmingly reported positive feelings about using MFGs, emphasizing "ease of use", "low preparation time" and "positive participant response".[68]

C.3. Research Design

This Exploratory/Developmental study has 2 main aims: (Aim 1) Use a task-shifting strategy to tailor the content, training, and supervision of MFGs for delivery by bachelors-level caseworkers in CBO's serving CW-involved families; and (Aim 2) Assess the feasibility and acceptability of task-shifted MFGs in CBO's serving CW-involved families.

C.3.1. Strategy: The proposed study is nested in a set of organizations in NYC that Drs. Gopalan and McKay have successfully collaborated with in the past. For Aim 1, we will convene a research-community advisory team from two participating CBOs (Catholic Guardian Society and Home Bureau, the Association to Benefit Children) and a CW parent advocacy organization (Child Welfare Organizing Project) to create guidelines for ensuring intervention quality and feasibility based on existing task-shifting literature[1, 24-26, 41-44, 69](See Letters of Support). The team will be charged with (1) tailoring the existing MFG intervention for delivery by CBO caseworkers, as well as (2) developing a protocol for training and (3) a mental health supervision framework of CBO caseworkers. This process will be informed by the following PRISM domains: Intervention perspectives (perceived burden, usability/adaptability, barriers), Recipient characteristics (existing staffing capacities, child/family mental health needs, competing demands and barriers), and External environment (CW authority performance indicators, community resources). To address Aim 2, we will involve n=4 bachelors'-level caseworkers at the participating CBOs who will be trained to deliver MFGs to n=20 caregivers/n=20 youth (2 MFGs) receiving placement preventive services at CBOs and whose children manifest disruptive behavior difficulties. Quantitative and qualitative approaches will be used to gather information from caseworkers, supervisors, and caregivers to assess feasibility and acceptability.

C.3.2. Aim 1: Refining task shifting strategy

C.3.2.a. Advisory Team: Relevant stakeholders invited to consult will include n=2 bachelors'-level caseworkers, n=2 supervisors, and n=2 agency administrators from the participating CBOs; n=2 parent consumers of placement prevention services; and n=2 MFG effectiveness study clinicians. Specifically, the team will meet regularly (weekly or bi-weekly) over 6 months (in person or phone) to refine the task-shifted MFGs. For those unable to attend, research staff will conduct individual phone check-in to report progress and receive feedback. We are confident that we will be able to recruit these consultants, as Dr. Gopalan has successfully convened similar advisory teams for past projects involving intervention development and adaptation. Research staff will take detailed written field notes of the advisory team process (e.g., decision-making, final products) with the goal of generalizing strategies for use with other EBPs.

C.3.2.a.1. Intervention modification: Successful task-shifting efforts indicate the need to suitably modify an EBP (e.g., simplifying language, length, service delivery modality) in order to address the skill-set of non-specialist workers and fit with the CBO work context[43]. Modifications will be guided by PRISM domains of external environment (e.g., align with CW performance indicators), intervention perspectives (e.g., ensure relevance and flexibility with caseworker tasks, minimize burden on caseworker workload, reduce barriers to family's access), as well as recipient characteristics (e.g., facilitate delivery within existing staffing/supervision structure and caseworker/family competing demands, address CW-specific mental health issues). For example, modifications may include changes to overall intervention length and existing MFG fidelity measures, as well as well as incorporating suggestions from preliminary studies (See Section C.2 Preliminary Studies).

C.3.2.a.2. Training: PRISM will further inform the development of caseworker training for the task-shifted MFGs related to the external environment (e.g., identifying when to access community resources upon escalating mental health needs), intervention perceptions (e.g., enhancing caseworker familiarity, self-efficacy, and motivation to facilitate MFGs; providing training on family engagement), and recipient characteristics (e.g., aligns with existing training structure, provides information on CW-specific mental health issues). Existing training methods from prior effectiveness trial and state-wide dissemination of MFGs[2-4, 68] will be tailored for use with CBO caseworkers. Such methods involve training service providers and at least one supervisor per site. Based on recommendations from the extant literature on task shifting[43], implementation science[70, 71], and

training for EBPs[72, 73], training will include a mixture of (1) didactic workshops on child mental health issues and related family factors, engagement and group facilitation skills; (2) active and participatory learning strategies (e.g., practice, modeling, role-play, and vicarious learning); (3) provision of an easy-to-follow manual; and (4) ongoing clinical supervision (see Section C.3.2.a.3 Mental Health Supervision). Following training, we will administer a knowledge and skills assessment based on materials developed for the MFG effectiveness study (See Appendix A). Caseworkers who do not pass at the 80% level will be provided as-needed booster training and be allowed to re-take the test. Only those who pass the test will be allowed to be involved.

C.3.2.a.3. Mental health supervision: Task-shifting efforts emphasize the need for consistent supervision and monitoring of non-mental health workers provided by individuals with more extensive experience in mental health treatment[43] and the specific intervention[69]. Consequently, supervisory services for the proposed study will be provided by professional mental health clinicians with expertise in delivering MFGs, including the PI (Gopalan) and n=1 clinical supervisor from the MFG effectiveness study. Although we considered developing a supervision model intended for larger scale implementation and sustainment, this was judged to be beyond the scope of the proposed study, which seeks to establish initial feasibility and acceptability for task-shifting MFGs. However, supervision protocols (e.g., content and logistics, risk management, and clinical governance) and tools (e.g., MFG Supervision Tracking form) developed in the proposed study will be utilized for larger scale implementation. Such features will be developed along PRISM constructs for the external environment (e.g., ensuring linkages to higher-level mental health services when necessary), intervention perspectives (e.g., problem-solving around caseworker burden, importance of ongoing family engagement), and recipient characteristics (e.g., aligning with in-house supervision, education on clinical risk management).

C.3.3. Aim 2: Pilot testing for feasibility and acceptability

C.3.3.a. Population: This study will consist of 4 purposively selected samples: n=4 caseworkers, n=4 supervisors, n=20 youth with disruptive behavior difficulties, and their caregivers (n=20). Sample sizes for caregivers and youth account for an estimated 20% attrition rate (overestimating the 10% attrition from the MFG effectiveness study), so that each MFG group will contain at least 8 families. Although larger sample sizes were considered, smaller samples are sufficient in order to obtain detailed data to establish initial feasibility and acceptability. Such information will be subsequently utilized to revise task-shifted MFGs prior to testing in a larger scale study. A purposive sampling strategy was chosen rather than random selection due to the small sample sizes and desire to enroll engaged participants who can provide important information on feasibility and acceptability.

C.3.3.a.1. Caseworkers Inclusion Criteria: Eligible caseworkers (age 21 and older) include n=4 caseworkers who are (1) employed in a CBO contracted to provide placement prevention services within NYC; (2) English-speaking; (3) have completed a bachelor's-level degree.

C.3.3.a.2. CBO Supervisors Inclusion Criteria: Eligible CBO supervisors (age 21 and older) include n=4 supervisors who (1) supervise the caseworkers enrolled in the current study; (2) are English-speaking;

C.3.3.a.3. Youth Inclusion Criteria: Eligible youth include n=20 children whose permanent caregiver receives placement prevention services at a CBO. We will utilize multiple methods for screening children who manifest a range of disruptive behavior difficulties who might not be selected if we relied on a single screening tool. We will include English-speaking children ages 7-11 (based on original MFG effectiveness study criteria) who meet one or more of the following inclusion criteria:

(1) Caregiver report of the presence of serious disruptive behavior difficulties using the Disruptive Behavior Disorders Rating Scale[74] (e.g., meeting symptom criteria for Oppositional Defiant or Conduct Disorders)
(2) History of out-of-home placement in the past year due to the child's disruptive behavior difficulties

C.3.3.a.4. Caregivers Inclusion Criteria: Eligible caregivers include up to n=20 adult caregivers (age 21 and older) (1) who are receiving placement prevention services, (2) have a child meeting above criteria, and (3) are English speaking. If more than 1 caregiver or child is present and willing to participate in MFGs, they will be consented, but only 1 caregiver will be the data reporter for the family.

C.3.3.a.5. Exclusion criteria includes a significant cognitive impairment of child or caregiver that interferes with understanding the informed consent process. If participants with emergency psychiatric needs that require services beyond those within an outpatient setting (e.g. hospitalization, specialized placement outside the home), needed care will be secured, rather than study participation.

C.3.3.b. Setting. The proposed settings are CBOs offering placement prevention services to families in NYC. The Catholic Guardian Society and Home Bureau and the Association to Benefit Children are located in the

Bronx and East Harlem within NYC. Their general preventive programs focus on stabilizing families and reducing the likelihood of foster care entry. Services include case management, parenting classes, family counseling, advocacy, housing, and entitlement assistance to families referred as a result of maltreatment allegations, as well as families voluntarily seeking placement prevention services. Both CBOs and the NYC CW authority, Administration for Children's Services, have indicated their willingness to collaborate on this project (See Letters of Support).

C.3.3.c. Enrollment.

C.3.3.c. 1. CBO Caseworkers and Supervisors: To recruit caseworkers, research staff will present the project to caseworkers and their supervisors at each CBO during staff meetings, with the aim of recruiting those who were not part of the advisory team (See Section C.3.2.a Advisory Team). Interested caseworkers and their supervisors can contact research staff either in person or by the phone. Upon contact, research staff will schedule an in-person meeting to review study material and secure informed consent. Once enrolled, caseworkers and supervisors will receive the task-shifted MFG training (See Section C.3.2.a.2 Training).

C.3.3.c. 2. Youth and caregivers: Caseworkers and supervisors at each CBO will receive information about the proposed project and have printed materials to provide to their clients about participation in the proposed study. Recruitment strategies include: (1) a strong on-site presence at each CBO; (2) on-going reminder telephone contact with CBO staff to encourage planning to introduce the study to potentially eligible families; (3) presentation at staff meetings to problem solve any obstacles to recruitment; (4) meetings with families will take place during after school and evening hours and concerted efforts to follow-up with the family immediately upon their expression of interest will be made. Potentially eligible youth and their families (based on caseworker report of child disruptive behavior) will be informed of the study by their caseworkers first (Step I) and then, if the family is interested in learning more about the study, contacted by research staff (Step II). If the adult caregiver provides consent and the youth provides assent, then the research staff administers the screening instruments to determine study eligibility (Step III; See section C.3.3.a.3 Youth inclusion criteria). If the youth and family are screened as eligible, the family will be informed they will participate in the MFG.

C.3.3.d. Aim 2: Hypothesis: The task-shifted MFG intervention will be associated with a high degree of acceptability and feasibility.

C.3.3.e. Methodology: We will use a mixed methods approach to investigate the feasibility and acceptability of this task-shifted intervention delivered by caseworkers. Participants will provide demographic information following the consent process. Two MFG groups will be conducted (1 in each CBO, 2 caseworkers facilitating each group). Childcare, transportation expenses, and participant incentives will be provided at each session. During the MFG delivery, research staff will assess fidelity for 100% of sessions through use of web-based video conferencing, and document participant attendance. Upon completion of MFGs, meetings will be scheduled for participants to complete final quantitative and qualitative assessments concurrently. Quantitative and qualitative results will be integrated to complement each other in a QUANT→QUAL (given fidelity and attendance will be recorded first) design.[75]

C.3.3.e.1. Quantitative measures and analysis: Table 1 presents information on constructs, corresponding PRISM domains, measures, informants, timing, and methods of analyses. Univariate statistics (means, SD, frequencies) as well as percentages of participants reporting project-defined benchmarks for high feasibility (HF) and acceptability (HA) will be computed (See Table 1). The task-shifted MFGs will be considered feasible and acceptable if the majority of responses (>50%) exceed the HF and HA benchmarks.

C.3.3.e.2. Qualitative methods and analysis: We will conduct 4 separate focus groups with caregivers (2 groups 10 caregivers each), CBO caseworkers (1 group, 4 caseworkers), and their supervisors (1 group, 4 supervisors) to collect feasibility and acceptability data pertaining to the task-shifted MFGs and task shifting overall (See Table 1 for sample questions). If any participants are unable or reluctant to participate in the focus groups, we will conduct individual interviews. Efforts will be made to include caregivers who dropped out of MFGs. Data will be coded and analyzed using methods by Morgan and Kitzinger[76-78] as follows: Codes across respondents will be compiled based upon the topics of feasibility and acceptability. For example, we will include a content code "barriers" to identify any content reflecting obstacles to utilizing task shifting or implementing MFGs. Codes may be modified as new data are analyzed (i.e. dividing "barriers" into multiple codes such as "system barriers" regarding any organizational obstacles to delivery and "caregiver barriers" for any caregiver-related impediments). Coding will occur until reaching saturation, when data will be extracted by code and reviewed to determine main themes (feasibility, acceptability) by respondent (caregiver, caseworker, supervisor). We will compile a report detailing overall experiences and differences by respondent type.

C.3.3.e.3. Mixed-Methods Integration: Quantitative and qualitative data will be collected sequentially (quantitative followed by qualitative) and analyzed separately, but focused on answering the overarching and specific research questions being addressed. The PI, research staff, and Dr. Aarons will integrate both data types at the interpretation stage of analysis. Quantitative data will be visually juxtaposed (See Table 1) next to relevant qualitative themes in order to aid in interpretation of the combined findings. For example, a research question is whether MFGs in a task-shifted approach are feasible for CBOs providing CW services. Both quantitative and qualitative results will be placed side-by-side in order to compare and contrast, thus determining whether they support convergence (i.e., results confirm each other) or expansion (i.e., results generate additional information about what factors promote or limit feasibility and acceptability).

Table 1. Measurement and Analysis of Specific Aim #2

Aim 2: To assess the feasibility and acceptability of task-shifted MFG in CBO's serving CW-involved families from the viewpoint of key stakeholders (i.e., caseworkers, supervisors, caregivers).

HF: High Feasibility; HA: High Acceptability

Study Construct	PRISM Domain	Quantitative measure (see Appendix B)[79-81]	Sample Qualitative Questions (see Appendix B)
Demographics	Recipient	Project-developed survey[1,3,4; a]	Not applicable
Feasibility	External environment	CW performance indicators: % of enrolled families whom CW performance indicators for casework contacts and meeting child mental health service goals within 6 months of entry into services as entered into NYC ACS administrative data systems [2,c]	How was the process of meeting child mental health and casework contact performance indicator requirements affected by using task-shifting MFGs in your agency? [1,4; c]
Feasibility	Recipient	Client characteristics: Participant Flow: % of children/caregivers meeting inclusion criteria among those screened[2, c] Organizational capacities (ability of caseworkers to deliver MFG with fidelity): Caseworker Fidelity Ratings[2, b] **HF:** % of components scored as "Mostly met" or "Fully Met"	Describe the process of recruiting families for the task-shifted MFGs [1,4; c] What facilitated/hindered treatment fidelity? How does task shifting affect treatment fidelity for EBPs in general? [1,4; c]
Feasibility	Intervention perspectives	Client perspectives Attendance logs[2, c] **HF:** % of children/caregivers who attend ≥80-100% of sessions Kazdin Barriers to Treatment (KBT), [3, c] **HF:** % of participants with average score ≤ 2 Organization perspective Lyons Acceptability, feasibility, appropriateness scale (LAFAS)– feasibility subscale[1,4; c] **HF:** % of participants with average score ≥ 4	Please describe your experience with implementing the task-shifting MFGs in your agency[1,4; c]. Describe what made you stay or not stay in the task-shifted MFGs. What would you recommend to make MFGs easier for caregivers to participate? [3, c]
Acceptability	Intervention perspectives	Client perspectives Metropolitan Area Child Study (MACS) Treatment Program Satisfaction Scale[3, c] **HA:** % of participants with average score ≥ 3 Organization perspective on intervention LAFAS questionnaire – acceptability and appropriateness subscales[1,4, c] **HA:** % of participants with average score ≥ 4 Evidence Based Practice Attitude Scale[1,4, c] (EBPAS) **HA**: % of participants with average score ≥ 3	What facilitated/hindered your satisfaction with task shifted MFGs? [1,3,4; a] What are the benefits/challenges of using task shifting to implement EBPs in CW setting? [1,4, c]

Informant: 1. Caseworkers, 2. Research Assistants, 3. Caregivers, 4. Supervisors; **Timing:** a. Pre intervention; b. Ongoing, c. Post-intervention

C.4. Next steps: Information gathered from Phase I written notes will be compiled into preliminary guidelines documenting the process, successes, and "lessons learned" when utilizing task-shifting strategies. This study will provide data on initial feasibility and acceptability, as well as solidify methods (e.g., manual, training, supervision, enrollment) to support a larger-scale (R01) testing the effectiveness and implementation success of task shifting in CBOs. In the larger scale study, we will also address implementation and sustainability infrastructure, as well as average cost estimates across several CBOs, which we judge to be more salient and representative for a larger scale study. As MFG is an example EBP, the larger scale R01 will focus on the impact on task shifting versus services as usual (e.g., referral to child mental health clinics) on child and family outcomes, as well as uptake, integration, and sustainment in order to generalize the approach to other EBPs.

C.5. Timelines

	Mo 1-6	Mo 7-12	Mo 13-18	Mo 19-24
Start up/IRB				
Intervention and materials adaptation, Training and supervision development				
Enroll participants, train caseworkers, Baseline assessments, conducting MFGs				
Post-intervention assessment/focus group& interviews				
Analyses, Manuscript development, Develop/Submit R01				

Protection of Human Subjects
The University of Maryland, Baltimore (UMB) campus adheres to all federal regulations pertaining to studies involving human subjects. The proposed study will be administered through UMB, as the PI (Gopalan) will be officially employed as faculty of UMB School of Social Work at the time when proposed study activities will commence. All data collection activities will take place in New York City (NYC), facilitated with a subcontract with the New York University (NYU) Silver School of Social Work. Consequently, the PI (Gopalan) will obtain approval for the proposed project by the Institutional Review Boards (IRBs) of both UMB and NYU Washington Square Campus.

A. RISKS TO HUMAN SUBJECTS

A.1. Human subjects involvement, characteristics, and design

This proposed R21 will refine a "task shifting" implementation strategy to implement a family-based Evidence-based Practice (EBP) to reduce child mental health problems in low-resourced child welfare (CW) settings. The EBP, originally designed to be provided by advanced mental health practitioners (Masters or PhD), will be modified so it can be delivered by bachelors'-level caseworkers in CW settings with appropriate training and supervision. We will utilize task-shifting strategies, which involve "engaging non-specialists in the provision of effective psychosocial treatments under the supervision of mental health specialists" [1], in order to increase EBP access among CW-involved families. As an example EBP, the proposed project is built upon a recently completed, highly successful effectiveness study of a multiple family group (MFG) model to reduce child mental health problems among urban, low-income, minority families (R01MH072649) [2-8].

Following the completion of tasks to address Aim 1: *Use task shifting to tailor the content, training, and supervision of MFGs for delivery by bachelors'-level caseworkers in CBO's serving CW-involved families*, we will recruit n = 4 bachelors level caseworkers working in CBOs who will be trained to deliver MFGs over a 4 month period to up to n = 20 caregivers and n = 20 youth receiving placement prevention services at CBOs and whose children manifest behavioral difficulties. Caseworkers, their supervisors (n = 4), and caregivers will provide demographic data upon completing informed consent paperwork. Research staff will recruit caregivers and youth to complete informed consent paperwork, screen youth for eligibility in the study, and document the percent of families screened who meet study inclusion criteria. Two MFG groups will be conducted (1 in each CBO). During the MFG delivery, research staff will assess fidelity for 100% of sessions through use of web-based video conferencing, and document participant attendance. Upon completion of MFGs, meetings will be scheduled for participants to complete final quantitative and qualitative assessments concurrently. Research staff will collect quantitative information related to child welfare performance indicators. Additional quantitative measures will gather information from caseworkers, supervisors, and caregivers to assess for feasibility and acceptability. When possible, concurrently scheduled focus groups or individual interviews (approximately 60-90 minutes long) will be held with caregivers, caseworkers, and supervisors to further explore feasibility and acceptability of implementing task-shifted MFGs in CBOs, complementing information received from quantitative measures. If concurrent scheduling is not possible to complete both quantitative and qualitative assessments, separate meetings will be scheduled to complete quantitative and qualitative assessments separately.

A.1.a. Description of Sample

This study will consist of 4 purposively selected (deliberate, non-random) samples: n = 4 caseworkers, n = 4 supervisors, n = 20 youth with disruptive behavior difficulties, and their caregivers (n = 20). Sample sizes for caregivers and youth account for an estimated 20% attrition rate (overestimating the 10% attrition from the MFG effectiveness study), such that each MFG group will contain at least 8 families. Purposive sampling strategy was chosen rather than random selection due to the small sample sizes and desire to enroll engaged participants who can provide important information on feasibility and acceptability.

1. Sampling and recruitment of **service providers**

CBO Caseworkers Inclusion Criteria: Eligible caseworkers (age 21 and older) include n = 4 caseworkers who are (1) employed in a participating CBO that is contracted by the local CW authority to provide placement prevention services within New York City (NYC); (2) English-speaking; (3) have completed a bachelors'-level degree.

CBO Supervisors Inclusion Criteria: Eligible CBO supervisors (age 21 and older) include n = 4 supervisors who (1) supervise the caseworkers enrolled in the current study; (2) are English-speaking;

To recruit caseworkers, research staff will present the project to caseworkers and their supervisors at each site during staff meetings, with the aim of recruiting those who were not part of the advisory implementation team (See Research Strategy Section C.1.2.a). Interested caseworkers and their supervisors can contact research staff either in person after the meeting or by the phone. Upon contact, research staff will schedule an in-person meeting to review study material and secure informed consent. Once enrolled, caseworkers and supervisors will receive the task-shifted MFG training (See Research Strategy Section C.2.2.1.a.2).

2. Sampling and recruitment of **families**

Youth Inclusion Criteria: Eligible youth include n = 20 children between the ages of 7-11 whose permanent caregiver receives placement prevention services at one of the participating CBOs for the proposed study. We will utilize multiple methods for screening children who manifest a range of disruptive behavior difficulties which present significant risk for maltreatment or placement, who might not be selected if we relied on a single screening tool. We will include English-speaking children ages 7-11 (based on original MFG effectiveness study criteria) who meet one or more of the following inclusion criteria:

(1) Caregiver report indicating the presence of a serious disruptive behavior difficulties using the Disruptive Behavior Disorders Rating Scale[84]

(2) History of out-of-home placement in the past year due to the child's disruptive behavior difficulties

Caregivers Inclusion Criteria: Eligible caregivers include up to n = 20 adult caregivers (age 21 and older) (1) who are receiving placement prevention services, (2) have a child meeting above criteria, and (3) are English speaking. If more than 1 caregiver or child is present and willing to participate in MFGs, they will be consented, but only 1 caregiver will be the data reporter for the family.

Caseworkers and supervisors at each CBO will receive information about the proposed project and have printed materials to provide to their clients about participation in the proposed study. Recruitment strategies include: 1) a strong on-site presence at each CBO; 2) on-going reminder telephone contact with CBO staff to encourage planning to introduce the study to potentially eligible families; 3) presentation at staff meetings to problem solve any obstacles to recruitment; 4) meetings with families will take place during after school and evening hours and concerted efforts to follow-up with the family immediately upon their expression of interest will be made. Potentially eligible youth and their families (based on provider report of child behavior problem) will be informed of the study by their caseworkers first (Step I) and then, if the family is interested in learning more about the study, contacted by a member of the research staff (Step II). Informed consent materials provided to the family by the research staff will specify study details. If the adult caregiver provides consent, permission for youth, and the youth provides assent, then the research staff administers the screening instruments to determine study eligibility. If the youth and family are screened as eligible, then the project director is called and the family will be informed they will participate in the MFG.

Exclusion criteria includes a significant cognitive impairment of the child or caregiver that interferes with understanding the informed consent process. If participants with emergency psychiatric needs that require services beyond those within an outpatient setting (e.g. hospitalization, specialized placement outside the home), needed care will be secured, rather than study participation.

All participants will receive a stipend for their participation in this study. Caseworkers who will facilitate the MFGs will receive $20 per hour of time spent in training and in leading groups over a 4-month period. Caseworkers, supervisors, and caregivers will each receive $20 gift card for each quantitative (baseline, post-intervention) assessment and qualitative interview completed ($60 per person). Youth will receive $10 gift card for their participation in the MFGs. To promote retention of caregivers and youth at each session, all family members participating in MFGs will receive a $4.50 MetroCard (fare for public transportation), as well as participant incentives, and childcare, if needed.

A.1.b. Vulnerable populations

This study will enroll youth (ages 7-11) who present with disruptive behavioral difficulties. This special population is involved in this study as the intervention featured, MFG, focuses on reducing behavioral difficulties among children ages 7-11 through a family-based, multiple family group curriculum. As a result, it is imperative that this special population be enrolled given the focus of this study.

This study may also enroll pregnant women who are caregivers of youth enrolled in the study. Potential risks to participants are minimal. It is possible that participants may experience mild discomfort when talking about emotionally distressing matters, such as the nature of being involved in child welfare services and/or their child's behavior problems. However, as a precaution, research staff will be trained to be prepared to address any potentially serious issues which may emerge, such as suicide, physical/emotional abuse occurring within families, and clinical deterioration of the caregiver (or their child's) physical or mental health. Any potential risks associated with the study participant will be identified, and appropriate care will be immediately secured when needed (e.g., emergency psychiatric evaluation). Further, mandated reporting status as an intervention to interrupt harm to others will be taken seriously for this study.

A.1.c. Collaborating Sites and data protection

Human subjects research will be conducted in 2 community-based organizations (CBOs) which are contracted by CW authorities to provide placement prevention services, such as the Catholic Guardian Society and Home Bureau (CGSHB), and the Association to Benefit Children (ABC). CGSHB and ABC are located in the Bronx and East Harlem, respectively, within NYC. Their General Preventive programs focus on stabilizing families and reducing the likelihood of foster care entry. Services include case management, parenting classes, family counseling, advocacy, housing, and entitlement assistance to families referred as a result of maltreatment allegations, as well as families voluntarily seeking placement prevention services. Both sites and the NYC CW authority, Administration for Children's Services, have indicated their endorsement and willingness to collaborate on this project (See Letters of Support).

All data will be collected by research staff for the proposed project, and will only be housed at a secure NYU facility. Data collected at the CBO's will not be accessible to CBO staff or clients. Research staff will conduct informed consent, assessments and interviews at an NYU location, CBO setting where MFGs will take place, participants' home, or private community setting as needed. Hard copies (paper-and-pencil) of informed consent paperwork will be collected by research staff to be secured at an NYU location.

All quantitative data will be collected using Qualtrics, a web platform for the creation and distribution of online surveys. The platform also records response data to "the cloud" and allows analysis within the online tool or export to common formats like CSV and SPSS. Qualtrics servers have been tried and tested by most major corporations and government organizations that demand high level data security. Qualtrics offers Transport Layer Security (TLS) encryption (HTTPS) and survey security options like password protection and HTTP referrer checking. Qualtrics has SAS 70 Certification and meets the rigorous privacy standards imposed on health care records by the Health Insurance Portability and Accountability Act (HIPAA). All Qualtrics accounts are hidden behind passwords and all data is protected with real-time data replication. Qualtrics data is stored in data centers that are audited and SAS 70 certified. Qualtrics Research Suite allows all clients to control individual permissions of their accounts and their surveys. This means administrators can decide who creates, edits and distributes surveys, and analyzes data. Use of Qualtrics obviates the need for separate data entry, and mitigates the risk of hard-copies of information with participants' personally identifiable information being lost.

Additionally, caseworkers, supervisors, and caregivers will take in part in one 60-90-minute focus group or individual interview using semi-structured and open-ended questions. Research staff will receive specific training and instruction in focus group and in-depth interview methodology. All focus groups and interviews will be conducted in private rooms, and will be digitally audio-recorded and transcribed verbatim. All digital audio recordings and transcribed interviews will be coded with the unique coded identifiers used for quantitative measures.

To protect the integrity of the participants' data, the following procedures will be followed. First, all participants in the study are assigned a random code number by the Project Director. This code number is used on all information collected from participants, including informed consent, digital quantitative information, and digital audio files. To ensure that assessments and interviews are conducted with unique participants, we will maintain hard-copies and digital copies of lists of all participants with links between identifying information and code numbers at secure NYU facilities. Only the Principal Investigator and Project Director assigned to this study will have access to these lists. Hard copies of lists will be kept in locked file cabinets while digital copies of lists will be stored in password-protected computers at NYU. Additionally, digital files of the lists of participants will be password-protected and encrypted themselves. ID code numbers will be placed on the

consent forms, which will have the subjects' signature on the last page. Because ID codes will be placed on consent forms, hard copies of consent forms will be stored separately from all other forms as it could be used a key linking the ID code to the subject. Only the Principal Investigator and Project Director will have access to these lists, which are kept in locked files. Other study personnel will have access on an as-needed basis to individual participants' names and code numbers in order to adequately perform their duties (i.e., research staff must label the questionnaires with the correct code number of the participant whom they are interviewing). Research staff will return hard copies of the informed consent paperwork and digital files immediately to the NYU research office. All digital audio and questionnaire data will be inputted into encrypted data files, while hard copies of all identifying information (e.g., name, address, and phone number), informed consent documents will be stored in locked file cabinets.

After completion of assessments with study participants, digital audio recordings with code numbers will be uploaded onto an NYU password-protected, secure, computer to await transcription. All hard copies of data will be stored in locked cabinets at NYU to which only the Principal Investigator (Geetha Gopalan) and research staff have access. Digital audio files will be transcribed through a contracted transcription service, which will return recorded interviews on digital file, as well as transcribed interviews in digital word processing documents. To ensure confidentiality, digital audiofiles will be encrypted with password-protected software before being transferred through the use of "DropBox" (http://www.dropbox.com/features). Dropbox is an online, web-based data storage system which allows invited users to share files. Online access requires a username and password. Shared files are only viewable to invited individuals. Furthermore, all transmission of file data occurs over an encrypted channel (SSL). All files stored on DropBox are encrypted (AES-256) and are inaccessible without an account password. DropBox employees are not able to view any user's file, and DropBox website and client software have been hardened against attacks from hackers. Alternately, digital audiofiles will be encrypted with password-protected software before being emailed to a contracted transcription service. Similarly, the transcription service will return digital audiofiles and transcribed interviews in word processing documents through the DropBox service or on encrypted, password protected software to be emailed back to the Principal Investigator and Research Assistants assigned to the current study. Such procedures will expedite transcription and analyses of audio-recorded data, as well as minimize the risk of data being lost through the mail if stored on USB flashdrives. Data will be collected solely for the purposes of the current study.

All personnel must complete certain levels of training before they are granted access to this identifying information. They must complete the Human Subjects Training sponsored by the National Institute of Mental Health, which complies with federal guidelines delineated in 45 CFR Part 46. Personnel also sign confidentiality statements which specify that if the participants' confidentiality is breached unintentionally, personnel will follow the procedures for reporting this breach to the Principal Investigator. The confidentiality statements also declare that unintentional or deliberate violations of participants' confidentiality may result in demotion or termination depending upon the severity of the event. Personnel also participate in training with the Principal Investigator regarding data safety, maintaining confidentiality of participants, limits of confidentiality, and proper administration of the study protocol. Transcribers will also sign confidentiality statements.

All requests, current and future, to use the data are reviewed by the Principal Investigator. Any data files that are provided to other individuals are stripped of identifiers and contain only code numbers. Data will be stored for seven years after dissemination of research findings via publications. Within the informed consent documents, all participants are notified of the above procedures.

A.2. Sources of material

Description of the data to be collected from human subjects and records is in Table 1 below. All measures are provided in Appendix B.

Table 1. Measurement and Analysis of Specific Aim #2			
Aim 2: To assess the feasibility and acceptability of task-shifted MFG in CBO's serving CW-involved families from the viewpoint of key stakeholders (i.e., caseworkers, supervisors, caregivers). **HF: High Feasibility; HA: High Acceptability**			
Study Construct	***PRISM Domain***	***Quantitative measure* (see Appendix B)**[79-81]	***Sample Qualitative Questions* (see Appendix B)**
Demographics	Recipient	Project-developed survey[1,3,4; a]	Not applicable
Feasibility	External environment	CW performance indicators: % of enrolled families whom CW performance indicators for casework contacts and meeting child mental health service goals within 6 months of entry into services as entered into NYC ACS administrative data systems [2,c]	How was the process of meeting child mental health and casework contact performance indicator requirements affected by using task-shifting MFGs in your agency? [1,4; c]
Feasibility	Recipient	Client characteristics: Participant Flow: % of children/caregivers meeting inclusion criteria among those screened[2, c] Organizational capacities (ability of caseworkers to deliver MFG with fidelity): Caseworker Fidelity Ratings[2, b] ***HF:*** % of components scored as "Mostly met" or "Fully Met"	Describe the process of recruiting families for the task-shifted MFGs? [1,4; c] What facilitated/hindered treatment fidelity? How does task shifting affect treatment fidelity for EBPs in general? [1,4; c]
Feasibility	Intervention perspectives	Client perspectives Attendance logs[2, c] ***HF:*** % of children/caregivers who attend ≥80-100% of sessions Kazdin Barriers to Treatment (KBT), [3, c] ***HF:*** % of participants with average score ≤ 2 Organization perspective Lyons Acceptability, feasibility, appropriateness scale (LAFAS)– feasibility subscale[1,4; c] ***HF:*** % of participants with average score ≥ 4	Please describe your experience with implementing the task-shifting MFGs in your agency[1,4; c]. Describe what made you stay or not stay in the task-shifted MFGs. What would you recommend to make MFGs easier for caregivers to participate? [3, c]
Acceptability	Intervention perspectives	Client perspectives Metropolitan Area Child Study (MACS) Treatment Program Satisfaction Scale[3, c] ***HA:*** % of participants with average score ≥ 3 Organization perspective on intervention LAFAS questionnaire – acceptability and appropriateness subscales[1,4, c] ***HA:*** % of participants with average score ≥ 4 Evidence-based Practice Attitude Scale[1,4, c] (EBPAS) ***HA***: % of participants with average score ≥ 3	What facilitated/hindered your satisfaction with task shifted MFGs? [1,3,4; a] What are the benefits/challenges of using task shifting to implement EBPs in CW setting? [1,4, c]

Quantitative measures and analysis: Table 1 presents information on constructs, corresponding to PRISM domains, measures, informants, timing, and methods of analyses. Univariate statistics (means, SD, frequencies) as well as percentages of participants reporting project-defined benchmarks for high feasibility (HF) and acceptability (HA) will be computed (See Table 1). The task-shifted MFGs will be considered feasible and acceptable if the majority of responses (>50%) exceed the HF and HA benchmarks. All quantitative data will be collected using Qualtrics, a web platform for the creation and distribution of online surveys (See above Section A.1.c. "Collaborating Sites and data protection" for more information). Caseworkers, supervisors, and caregivers will be able to directly enter information personally (using secure and unique identification codes) on demographics, EBPAS, KBT, MACS, and LAFAS questionnaires. Research staff will directly input information CW performance indicators, attendance logs, and caseworker fidelity ratings.

Qualitative measures and analysis: We will conduct 4 separate focus groups with caregivers (2 groups 10 caregivers each), CBO caseworkers (1 group, 4 caseworkers), and their supervisors (1 group, 4 supervisors) to collect feasibility and acceptability data pertaining to the task-shifted MFGs and task shifting overall. Sample questions are included in Table 1. If participants are unable or reluctant to participate in the focus groups, we will conduct one-on-one, in-person interviews. Efforts will be made to include caregivers who dropped out of MFGs. Data will be coded and analyzed using methods by Morgan and Kitzinger[76-78] as follows: Codes across respondents will be compiled based upon the topics of feasibility and acceptability. For example, we will include a content code "barriers" to identify any content reflecting obstacles to utilizing task shifting or implementing MFGs. Codes may be modified as new data are analyzed (i.e. dividing "barriers" into multiple codes such as "system barriers" regarding any organizational obstacles to delivery and "caregiver barriers" for any caregiver-related impediments). Coding will occur until reaching saturation, whereupon data will be extracted by code and reviewed to determine main themes (feasibility, acceptability) by respondent (caregiver,

caseworker, supervisor). We will compile a report detailing overall experiences and differences by respondent type.

Mixed Methods Integration. We will use a mixed methods approach to investigate the feasibility and acceptability of this task-shifted intervention delivered by caseworkers. Quantitative and qualitative results will be integrated to complement each other in a QUANT→QUAL (given fidelity and attendance will be recorded first) design[75]. Quantitative and qualitative data will be collected sequentially (quantitative followed by qualitative) and analyzed separately, but focused on answering the overarching and specific research questions being addressed. The PI, research staff and Dr. Aarons will integrate both data types at the interpretation stage of analysis. Quantitative data will be visually juxtaposed (See Table 1) next to relevant qualitative themes in order to aid in interpretation of the combined findings. For example, a research question is whether MFG in a task-shifted approach is feasible for CBOs providing CW services. Both quantitative and qualitative results will be placed side-by-side in order to compare and contrast, thus determining whether they support convergence (i.e. results confirm each other) or expansion (i.e., results generate additional information about what factors promote feasibility/acceptability).

All data will be collected by research staff for the proposed project, and will only be housed at a secure NYU facility. Data collected at the CBO's will not be accessible to CBO staff or clients. Research staff will conduct informed consent, assessments, and interviews at an NYU location, CBO setting where MFGs will take place, participants' home, or private community setting as needed. Hard copies (paper-and-pencil) of informed consent paperwork will be collected by research staff to be secured at an NYU location.

All quantitative data will be collected using Qualtrics, a web platform for the creation and distribution of online surveys. The platform also records response data to "the cloud" and allows analysis within the online tool or export to common formats like CSV and SPSS. Qualtrics servers have been tried and tested by most major corporations and government organizations that demand high level data security. Qualtrics offers Transport Layer Security (TLS) encryption (HTTPS) and survey security options like password protection and HTTP referrer checking. Qualtrics has SAS 70 Certification and meets the rigorous privacy standards imposed on health care records by the Health Insurance Portability and Accountability Act (HIPAA). All Qualtrics accounts are hidden behind passwords and all data is protected with real-time data replication. Qualtrics data is stored in data centers that are audited and SAS 70 certified. Qualtrics Research Suite allows all clients to control individual permissions of their accounts and their surveys. This means administrators can decide who creates, edits and distributes surveys, and analyzes data. Use of Qualtrics obviates the need for separate data entry, and mitigates the risk of hard-copies of information with participants' personally identifiable information being lost. Caseworkers, supervisors, and caregivers will take in part in one 60-90-minute focus group or individual interview using semi-structured and open-ended questions. Research staff will receive specific training and instruction in focus group and in-depth interview methodology. All focus groups and interviews will be conducted in private rooms, and will be digitally audio-recorded and transcribed verbatim. All digital audio recordings and transcribed interviews will be coded with the unique coded identifiers used for quantitative measures.

To protect the integrity of the participants' data, the following procedures will be followed. First, all participants in the study are assigned a random code number by the Project Director. This code number is used on all information collected from participants, including informed consent, digital quantitative information, and digital audio files. To ensure that assessments and interviews are conducted with unique participants, we will maintain hard-copies and digital copies of lists of all participants with links between identifying information and code numbers at secure, NYU facilities. Only the Principal Investigator and Project Director assigned to this study will have access to these lists. Hard copies of lists will be kept in locked file cabinets while digital copies of lists will be stored in password-protected computers at NYU. ID code numbers will be placed on the consent forms, which will have the subjects' signature on the last page. Because ID codes will be placed on consent forms, hard copies of consent forms will be stored separately from all other forms as it could be used a key linking the ID code to the subject. Only the Principal Investigator and Project Director will have access to these lists, which are kept in locked files. Other study personnel have access on an as needed basis to individual participants' names and code numbers in order to adequately perform their duties (i.e., research staff must label the questionnaires with the correct code number of the participant whom they are interviewing). Research staff will return hard copies of the informed consent paperwork and digital files immediately to the NYU

research office. All digital audio and questionnaire data will be inputted into encrypted data files, while hard copies of all identifying information (e.g., name, address, and phone number), informed consent documents will be stored in locked file cabinets.

After completion of assessments with study participants, digital audio recordings with code numbers will be uploaded onto an NYU password-protected, secure computer to await transcription. All hard copies of data will be stored in locked cabinets at NYU to which only the Principal Investigator (Geetha Gopalan) and research staff have access. Digital audio files will be transcribed through a contracted transcription service, which will return recorded interviews on digital file, as well as transcribed interviews in digital word processing documents. To ensure confidentiality, digital audiofiles will be encrypted with password-protected software before being transferred through the use of “DropBox” (http://www.dropbox.com/features). Dropbox is an online, web-based data storage system which allows invited users to share files. Online access requires a username and password. Shared files are only viewable to invited individuals. Furthermore, all transmission of file data occurs over an encrypted channel (SSL). All files stored on DropBox are encrypted (AES-256) and are inaccessible without an account password. DropBox employees are not able to view any user’s file, and DropBox website and client software have been hardened against attacks from hackers. Alternately, digital audiofiles will be encrypted with password-protected software before being emailed to a contracted transcription service. Similarly, the transcription service will return digital audiofiles and transcribed interviews in word processing documents through the DropBox service or on encrypted, password protected software to be emailed back to the Principal Investigator and Research Assistants assigned to the current study. Such procedures will expedite transcription and analyses of audio-recorded data, as well as minimize the risk of data being lost through the mail if stored on USB flashdrives. Data will be collected solely for the purposes of the current study.

All personnel must complete certain levels of training before they are granted access to this identifying information. They must complete the Human Subjects Training sponsored by the National Institute of Mental Health, which complies with federal guidelines delineated in 45 CFR Part 46. Personnel also sign confidentiality statements which specify that if the participants’ confidentiality is breached unintentionally, personnel will follow the procedures for reporting this breach to the Principal Investigator. The confidentiality statements also declare that unintentional or deliberate violations of participants’ confidentiality may result in demotion or termination depending upon the severity of the event. Personnel also participate in training with the Principal Investigator regarding data safety, maintaining confidentiality of participants, limits of confidentiality, and proper administration of the study protocol. Transcribers will also sign confidentiality statements.

All requests, current and future, to use the data are reviewed by the Principal Investigator. Any data files that are provided to other individuals are stripped of identifiers and contain only code numbers. Data will be stored for seven years after dissemination of research findings via publications. Within the informed consent documents, all participants are notified of the above procedures.

A.3. Potential Risks

Potential harms to participants are minimal. It is possible that children and caregivers in MFGs may experience mild discomfort when talking about emotionally distressing matters, such as youth behavioral difficulties, child welfare involvement, and family conflicts. However, as a precaution, caseworkers and research staff will be trained to be prepared to address any potentially serious issues which may emerge, such as suicide, physical/emotional abuse occurring within families, and clinical deterioration of the participants’ physical or mental health. Any potential risks associated with the children and caregivers will be identified, and appropriate care will be immediately secured when needed (e.g., emergency psychiatric evaluation). Further, mandated reporting status as an intervention to interrupt harm to others will be taken seriously for this study.

A second harm is the potential for loss of confidentiality. It is anticipated that participants in the study may reveal sensitive information within multiple-family groups and focus groups. All participants will be advised to keep information shared within the groups confidential. All participants will be offered the option of taking part in individual interviews rather than focus groups if they are concerned about revealing sensitive information to others. Any information provided by participants will not be shared to any other clients or staff at the collaborating CBO sites. Additional cautions to protect the confidentiality of participants’ responses include

coding all data with ID numbers to be stored on computerized datasets. Quantitative Data will be collected through Qualtrics, and qualitative data will be digitally audio recorded, and immediately uploaded onto password protected computers following the interview. The master list of names will be kept on password protected computer files available only to the PI and Project Director. Tracking information also will be kept on a password-protected computer. The master list will only be used to coordinate data collection. All research staff will sign confidentiality pledges and receive training through NIH courses in the protection of human subjects.

Participants will be informed that, as an alternative, they can withdraw their participation in this study without penalty. Participants will be informed that their decision will not affect services or employment at the participating CBO's from which they were recruited.

B. ADEQUACY OF PROTECTION AGAINST RISKS

B.1. Recruitment and informed consent

Recruitment plan

1. CBO Caseworkers and Supervisors: To recruit caseworkers, the PI will present the project to caseworkers and their supervisors at each CBO during regular staff meetings. Interested caseworkers and their supervisors can contact the team either in person after the meeting or by the phone. Upon contact, study staff will schedule an in-person meeting to review study material and secure informed consent.
2. Youth and caregivers: Caseworkers and supervisors at each CBO will receive information about the proposed project and have printed materials to provide to their clients about participation in the proposed study. Recruitment strategies include: 1) a strong on-site presence at each CBO; 2) on-going reminder telephone contact with CBO staff to encourage planning and to introduce the study to potentially eligible families; 3) presentation at staff meetings to problem solve any obstacles to recruitment; 4) meetings with families will take place during after school and evening hours and concerted efforts to follow-up with the family immediately upon their expression of interest will be made. Potentially eligible youth and their families (based on provider report of child behavior problem) will be informed of the study by their caseworkers first (Step I) and then, if the family is interested in learning more about the study, contacted by a member of the research staff (Step II). Informed consent materials provided to the family by the research staff will specify study details. If the adult caregiver provides consent and permission for youth, and the youth provides assent, then the research staff administers the screening instruments to determine study eligibility. If the youth and family are screened as eligible, then the project director is called and the family will be informed they will participate in the MFG.

All participants will receive a stipend for their participation in this study. Caseworkers who will facilitate the MFGs will receive $20 per hour of time spent in training and in leading groups over a 4 month period. Caseworkers, supervisors, and caregivers will each receive $20 gift card for each quantitative (baseline, post-intervention) assessment and qualitative interview completed ($60 per person). Youth will receive $10 gift card for their participation in the MFGs. To promote retention of caregivers and youth at each session, all family members participating in MFGs will receive a $4.50 MetroCard (fare for public transportation), as well as participant stipends, and childcare, if needed.

Informed consent

Research staff will enroll the first n = 4 caseworkers, n = 4 supervisors, and n = 20 families (20 caregivers, 20 children) who complete signed consent forms. Research staff will conduct informed consent in private rooms at an NYU location, CBO setting where MFGs will take place, participants' home, or private community setting as needed. All participants will be provided with blank copies of the most recently-approved IRB consent and assent forms to review. If the potential participants cannot read, an impartial witness will be recruited to be present during the entire consent/assent discussion to attest that the information in the consent form and any other information provided was accurately explained to, and apparently understood by, the subject, and that consent was freely given. The witness may not be a family member, friend, or a person involved in the design, conduct or reporting of the proposed research study. Research staff will read the consent/assent form to the subject and explain details so that the potential participant understands what it would be like to participate in the study. Potential participants will be allowed to ask questions and encouraged to discuss taking part in the research study with their family members. Research staff will invite and encourage potential participants to take the written information home to consider the information and discuss the decision to participate with family

members and others before making a decision. Potential participants will be asked if they understand the information provided, whether they feel pressured to make a decision, whether they understand that the choice to participate is voluntary, and whether they feel capable of making an informed choice. During the informed consent process, all participants will be assured that their decisions about participation (yes or no) will not affect their relationship with the CBO, NYU, or UMB. To encourage truthful responding on all assessments, confidentiality to all participants will be assured. To minimize any perception of coercion, all potential participants will be advised that their participation in the current study is completely voluntary, and will not affect services they receive through the CBO, NYU, or UMB whether they decide to participate in the current study or not. Written informed consent will be obtained for all adult participants. For youth participants, parental consent from 1 parent and 1 written youth assent form must be attained to enroll youth into the proposed study. Only those families where the legal guardian provides informed consent and parental permission, AND youth provides written assent, will be enrolled in the study. A copy of the signed and dated consent/assent form will be given to the person signing the document. Hard copies (paper-and-pencil) of informed consent paperwork will be collected by research staff to be secured at an NYU location.

B.2. Protections against risk

Potential harms to participants are minimal. It is possible that children and caregivers in MFGs may experience mild discomfort when talking about emotionally distressing matters, such as youth behavioral difficulties, child welfare involvement, and family conflicts. However, as a precaution, caseworkers and research staff will be trained to be prepared to address any potentially serious issues which may emerge, such as suicide, physical/emotional abuse occurring within families, and clinical deterioration of the participants' physical or mental health. Any potential risks associated with the children and caregivers will be identified, and appropriate care will be immediately secured when needed (e.g., emergency psychiatric evaluation). Further, mandated reporting status as an intervention to interrupt harm to others will be taken seriously for this study. The current study has instituted important safeguards to protect the welfare of study participants. The PI will train research staff and caseworkers to identify risk factors associated with suicide, homicide, worsening of participant physical health, new or escalating physical/emotional abuse occurring within families or clinical worsening of participant mental health that may or may not be related to treatment. Research staff will be instructed that if any adverse child outcomes are identified, participant involvement will be halted immediately and the appropriate personnel contacted, including emergency psychiatric personnel or the police. Study staff will be informed of the protocol of rescue procedures in the occurrence of adverse events, which begins with the notification of the Principal Investigator at an emergency number (917-224-2364) once emergency personnel have been notified, if necessary. All study personnel must complete this training before they are permitted to participate in the current study.

A second harm is the potential for loss of confidentiality. It is anticipated that participants in the study may reveal sensitive information within multiple-family groups and focus groups. All participants will be advised to keep information shared within the groups confidential. All participants will be offered the option of taking part in individual interviews rather than focus groups if they are concerned about revealing sensitive information to others. Any information provided by participants will not be shared to any other clients or staff at the collaborating CBO sites. Additional cautions to protect the confidentiality of participants' responses include coding all data with ID numbers to be stored on computerized datasets. Quantitative data will be collected either directly from participants or research assistants through Qualtrics, and qualitative data will be digitally audio recorded, and immediately uploaded onto password protected computers following the interview. The master list of names will be kept on password protected computer files available only to the PI and Project Director. Tracking information also will be kept on a password-protected computer. The master list will only be used to coordinate data collection. All research staff will sign confidentiality pledges and receive training through NIH courses in the protection of human subjects.

Participants will be informed that, as an alternative, they can withdraw their participation in this study without penalty. Participants will be informed that their decision will not affect services or employment at the participating CBO's from which they were recruited.

C. POTENTIAL BENEFITS

All participants will be paid for their participation. Caregivers and youth may experience reduction in children's behavioral problems and enhanced family relationships, as demonstrated in prior studies with this intervention. Participants may find that they enjoy sharing their opinions and experiences with research staff as their input

will be utilized to shape future services. No other immediate benefits to participants are expected. On balance, the potential risks are outweighed by the anticipated benefits to research participants and others.

D. IMPORTANCE OF KNOWLEDGE TO BE GAINED

By using the child welfare system as a non-specialty service sector platform to launch targeted mental health services, the proposed study will provide generalizable knowledge about using task shifting to facilitate cross-setting implementation for other child mental health interventions. Moreover, implementing MFGs in CBOs allows for effective services to reach and alter the negative trajectories for CW-involved children with behavioral difficulties. In doing so, the proposed study addresses the National Institutes of Health (NIH) goal of promoting "innovative approaches to identifying, understanding, and overcoming barriers to the adoption, adaptation, integration, scale-up and sustainability of evidence-based interventions, tools, policies, and guidelines" (NIH PAR-13-054). Moreover, this project fits with the NIMH strategic objective #4: "Strengthen the public health impact of NIMH-supported research" by promoting widespread use of research-based interventions by those most in need. Consequently, the importance of knowledge to be gained far outweighs the minimal risks this study imposes on participants.

E. DATA AND SAFETY MONITORING PLAN

The proposed study involves testing the feasibility and acceptability of a modified Evidence-Based Practice (EBP) which has already been successfully evaluated in an NIMH-funded effectiveness trial, the Multiple Family Group (MFG) service delivery model to reduce childhood disruptive behavior disorders (R01MH072649). As the original MFG intervention manifested no previous negative consequences, we do not expect any adverse events for the proposed study. However, as a precaution, the following Data and Safety Monitoring plan is in place.

E.1. Protection from Potential Safety/Clinical Risks

Potential participants are excluded from the study if, during the consenting process, they manifest mental health issues (e.g., risk of harm to self or others) which require immediate psychiatric attention. Moreover, research staff may be alerted to such risk by CBO staff, parent reports, or through direct observation of participants during delivery of the task-shifted MFGs or post-intervention assessments. The current study has instituted important safeguards to protect the welfare of study participants. The PI will train team members to identify risk factors associated with suicide, homicide, worsening of participant physical health, new or escalating physical/emotional abuse occurring within families or clinical worsening of participant mental health that may or may not be related to treatment. Staff members will be instructed that if any adverse child outcomes are identified, participant involvement will be halted immediately and the appropriate personnel contacted, including emergency psychiatric personnel or the police. Study staff will be informed of the protocol of rescue procedures in the occurrence of adverse events, which begins with the notification of the Principal Investigator at an emergency number (917-224-2364) once emergency personnel have been notified, if necessary. All study personnel must complete this training before they are permitted to participate in the current study.

E.2. Data Management and Integrity to Protect Confidentiality

To protect the integrity of the participants' data, the following procedures will be followed. First, all participants in the study are assigned a random code number by the Project Director. This code number is used on all information collected from participants, including informed consent, digital quantitative information, and digital audio files. To ensure that assessments and interviews are conducted with unique participants, we will maintain hard-copies and digital copies of lists of all participants with links between identifying information and code numbers at secure, NYU facilities. Only the Principal Investigator and Project Director assigned to this study will have access to these lists. Hard copies of lists will be kept in locked file cabinets while digital copies of lists will be stored in password-protected computers at NYU. Additionally, digital files of the lists of participants will be password-protected and encrypted themselves. ID code numbers will be placed on the consent forms, which will have the subjects' signature on the last page. Because ID codes will be placed on consent forms, hard copies of consent forms will be stored separately from all other forms as it could be used a key linking the ID code to the subject. Only the Principal Investigator and Project Director have access to these lists, which are kept in locked files. Other study personnel will have access on an as needed basis to individual participants' names and code numbers in order to adequately perform their duties (i.e., research staff must label the questionnaires with the correct code number of the participant whom they are interviewing). Research

staff will return hard copies of the informed consent paperwork and digital files immediately to the NYU research office. All digital audio and questionnaire data will be inputted into encrypted data files, while hard copies of all identifying information (e.g., name, address, and phone number), informed consent documents will be stored in locked file cabinets. Quantitative data will be collected either directly from participants or research assistants through Qualtrics, and qualitative data will be digitally audio recorded, and immediately uploaded onto password-protected computers following the interview.

All personnel must complete certain levels of training before they are granted access to this identifying information. They must complete the Human Subjects Training sponsored by the National Institute of Mental Health, which complies with federal guidelines delineated in 45 CFR Part 46. Personnel also sign confidentiality statements which specify that if the participants' confidentiality is breached unintentionally, personnel will follow the procedures for reporting this breach to the Principal Investigator. The confidentiality statements also declare that unintentional or deliberate violations of participants' confidentiality may result in demotion or termination depending upon the severity of the event. Personnel also participate in training with the Principal Investigator regarding data safety, maintaining confidentiality of participants, limits of confidentiality, and proper administration of the study protocol. The consultant transcriber will also sign a confidentiality statement

All requests, current and future, to use the data are reviewed by the Principal Investigator. Any data files that are provided to other individuals are stripped of identifiers and contain only code numbers. Data will be stored for seven years after dissemination of research findings via publications. Within the informed consent documents, all participants are notified of the above procedures.

E.3. Monitoring and Responding to Adverse Events

Possible adverse events that are anticipated include the identification of any worsening of mental or physical health problems among children and caregivers, as well as the need to violate the confidentiality of the participants. All study personnel are trained regarding indicators of conditions that may jeopardize the welfare of participants and the limits of confidentiality. This training includes reviewing possible scenarios and knowledge of key questions used to assess risk. Research staff are trained to err on the side of caution and told to contact a clinical supervisor, who is always available, by telephone, in the event of the need to break confidentiality due to mandatory reporting or ethical concerns. Under the guidance of clinical supervisors, Research staff are trained either to contact the police to ensure safety of participants, or if appropriate, to have emergency personnel take the youth or family member to the nearest emergency room.

Reporting of adverse events will occur according to a project protocol. Staff will inform the Principal Investigator of the presence of a possible unanticipated adverse event, after which, these events will be immediately reported and brought to the attention of the UMB and NYU IRBs. The IRBs will determine whether it is appropriate to stop the study protocol temporarily or will provide suggestions/modifications to the study procedures. Possible modifications may include adding new risks to the consent form and re-consenting all study participants.

If preliminary outcome data indicates harmful impact of the program to youth, UMB and NYU IRB committees will be notified and it is possible that the study will be discontinued immediately. However, we do not anticipate any negative effects of participating at this time as this intervention has been tested previously without adverse events.

Inclusion of Women and Minorities

The families from which adult caregivers will be recruited for the proposed study are predominantly low-income, single-family households where mothers are the primary caregivers. The MFG effectiveness study estimates that 81% of adult caregivers are female. Therefore, women will be well-represented in the proposed study. Moreover, all families from which adult caregivers will be recruited are members of ethnic minorities, with the largest proportion likely to be Latino (with ties to Puerto Rico, the Dominican Republic, or Mexico) or African-American (with approximately 10% representing recent immigrants from Africa). Children recruited in the MFG effectiveness study were 69% male and 30% female. As the MFG effectiveness study reported recruitment of 50% Hispanic or Latino families and 30% of Black or African-American families, efforts will be made to recruit Hispanic/Latino and Black/African-American families with a similar ratio. Consequently, minorities will be well-represented in the current study. Based on reported characteristics from participating community-based organizations (CBOs) providing placement prevention services in this study, we also anticipate that 75% of caseworkers and supervisors recruited for this study will be women, with approximately 50% Black/African-American and 30% Latino.

Targeted/Planned Enrollment: Caregivers

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Improving child behavior using task-shifting to implement MFGs in child welfare

Total Planned Enrollment: 20

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	8	2	10
Not Hispanic or Latino	8	2	10
Ethnic Category: Total of All Subjects *	16	4	20
Racial Categories			
American Indian/Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American	5	1	6
White	11	3	10
Racial Categories: Total of All Subjects *	16	4	20

* The “Ethnic Category: Total of All Subjects” must be equal to the “Racial Categories: Total of All Subjects.”

Targeted/Planned Enrollment: Caseworkers

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Improving child behavior using task-shifting to implement MFGs in child welfare

Total Planned Enrollment: 4

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	1	0	1
Not Hispanic or Latino	2	1	3
Ethnic Category: Total of All Subjects *	3	1	4
Racial Categories			
American Indian/Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American	1	1	2
White	2	0	2
Racial Categories: Total of All Subjects *	3	1	4

* The “Ethnic Category: Total of All Subjects” must be equal to the “Racial Categories: Total of All Subjects.”

Targeted/Planned Enrollment: Supervisors

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Improving child behavior using task-shifting to implement MFGs in child welfare

Total Planned Enrollment: 4

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	1	0	1
Not Hispanic or Latino	2	1	3
Ethnic Category: Total of All Subjects *	3	1	4
Racial Categories			
American Indian/Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American	1	1	2
White	2	0	2
Racial Categories: Total of All Subjects *	3	1	4

* The “Ethnic Category: Total of All Subjects” must be equal to the “Racial Categories: Total of All Subjects.”

Targeted/Planned Enrollment: Children

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Improving child behavior using task-shifting to implement MFGs in child welfare

Total Planned Enrollment: 20

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	5	5	10
Not Hispanic or Latino	5	5	10
Ethnic Category: Total of All Subjects *	10	10	20
Racial Categories			
American Indian/Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American	3	3	6
White	7	7	14
Racial Categories: Total of All Subjects *	10	10	20

* The “Ethnic Category: Total of All Subjects” must be equal to the “Racial Categories: Total of All Subjects.”

Inclusion of Children

This study will enroll youth (ages 7-11) who present with disruptive behavioral difficulties. This special population is involved in this study as the intervention featured in this proposal, Multiple Family Groups (MFGs), focuses on reducing behavioral difficulties among children ages 7-11 through a family-based, multiple family group curriculum. As a result, it is imperative that this special population be enrolled given the focus of this study.

Recruitment strategies include: 1) a strong on-site presence at each site; 2) on-going reminder telephone contact with CBO staff to encourage planning to introduce the study to potentially eligible families; 3) presentation at staff meetings to problem solve any obstacles to recruitment; and 4) meetings with families will take place during after school and evening hours and concerted efforts to follow-up with the family immediately upon their expression of interest will be made. Potentially eligible youth and their families (based on provider/caseworker report of child behavior problem) will be informed of the study by their caseworkers first (Step I) and then, if the family is interested in learning more about the study, contacted by a member of the research staff (Step II). Informed consent materials provided to the family by the research staff will specify study details. If the adult caregiver provides consent and the youth provides assent, then the research staff administers the screening instruments to determine study eligibility. For youth participants, parental consent from 1 parent and 1 written youth assent form must be attained to enroll youth into the proposed study. Only those families where the legal guardian provides informed consent and parental permission AND youth provides written assent will be enrolled in the study. If the youth and family are screened as eligible, then the project director is called, and the family will be informed they will participate in the MFG.

Potential participants are excluded if they manifest mental health issues (e.g., risk of harm to self or others) that require immediate psychiatric attention. Research staff may be alerted to such risk by CBO staff, parent reports, or through direct observation of participants during the consenting process. The current study has instituted important safeguards to protect the welfare of study participants. The PI (Gopalan) will train team members to identify risk factors associated with suicide, homicide, worsening of participant physical health, new or escalating physical/emotional abuse occurring within families, or clinical worsening of participant mental health that may or may not be related to treatment. Over the last ten years, Dr. Gopalan has had extensive clinical and research experience working with children with mental health difficulties, as well as those involved in the child welfare system (see Biosketch). Dr. Gopalan is a licensed clinical social worker and has had substantial clinical experience conducting emergency psychiatric evaluations for children and youth, as well as serving as a clinical supervisor on a number of clinical research projects.

Staff members will be instructed that, if any adverse child outcomes are identified, participant involvement will be halted immediately and the appropriate personnel contacted, including emergency psychiatric personnel or the police. Study staff will be informed of the protocol of rescue procedures in the occurrence of adverse events, which begins with the notification of the Principal Investigator at an emergency number (917-224-2364) once emergency personnel have been notified, if necessary. All study personnel must complete this training before they are permitted to participate in the current study.

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