Research Protocol

Comparative Effectiveness Trial to Reduce Child Maltreatment, Improve Client Outcomes and Examine Client Burden

NCT02549287

11/17/16

CER-1409-21178, Patient Centered Outcomes Research Institute

Georgia State University,

Daniel J. Whitaker, PhD, PI

Contents

A. PROJECT SUMMARY

Child maltreatment is a significant public health problem worldwide. National data indicate that in 2012, there were over 3.4 million reports to child protective service systems for suspected child maltreatment on over 6.3 million children. Official reports represent only cases reported to local CPS systems, however, and the number of cases of maltreatment is likely much higher. Child maltreatment leads to a number of negative health impacts. Social and psychological impacts of maltreatment are common and pervasive. Maltreated children have more problems than non-maltreated children in many areas, including anxiety, depression, aggression, poor school performance (Fergusson, Boden, & Horwood, 2008; Gilbert et al., 2009; Herrenkohl, Herrenkohl, Rupert, Egolf, & Lutz, 1995; Thornberry, Ireland, & Smith, 2001) and these problems often persist into adulthood. Findings among adults suggest that maltreatment is related to health conditions such as autoimmune diseases, lung cancer, heart disease, and a lower health-related quality of life (Felitti et al., 1998). Across health outcomes, maltreatment raises risk of experiencing negative outcomes by about 70% (Wegman & Stetler, 2009).

Most intervention studies conducted within child welfare have focused on safety and permanence: whether children experience repeated maltreatment and whether they are removed from the home. Little focus has been placed on families' experiences of services, or outcomes they might identify as important.

The goal of this project is to conduct a comparative effectiveness trial of two different interventions for parents referred by child protective service systems. The first intervention is *supportive case management* (SCM), which is a process oriented service aimed at building rapport, providing family support, crisis management, and provision of referrals to additional services. The second intervention is behavioral parent training using the *SafeCare* protocol, which focuses on teaching specific skills that help parents to avoid maltreatment. SCM is the dominant intervention model in child welfare settings, but behavioral parenting has shown promise in reducing recidivism of maltreatment. Neither has been extensively evaluated with respect to client outcomes of well-being, or service delivery burden, satisfaction, and perceived effectiveness.

The significance of this study is threefold. First, with multiple sites, the study will represent one of the broadest studies ever conducted in a child welfare setting. Second, the study will have a strong focus on metrics of family well-being, which are typically given little attention in child welfare research. This focus has the potential to uncover impacts that were not previously measured, and to change the way child welfare systems think about assessing intervention impact. Last, we will focus strongly on parents' and providers' experiences of these interventions. This is key because child welfare services are often involuntary, and parent engagement in services can be difficult. By assessing how parents and providers experience different interventions, we can better implement those interventions in a way that engages more parents.

B. BACKGROUND

B1. General Project information

Title: Comparative Effectiveness Trial to Reduce Child Maltreatment, Improve Client Outcomes and Examine Client Burden

Sponsor: Patient Centered Outcomes Research Institute, CER# 1409-21178

Research Site: Georgia State University, School of Public Health, Center for Healthy Development, National SafeCare Training and Research Center, P.O. Box 3995, Atlanta, Ga, 30302-3995

Principal Investigator: Daniel Whitaker, Ph.D., Professor, Director, Division of Health Promotion and Behavior, School of Public Health, Georgia State University, Director, *National SafeCare Training and Research Center*, dwhitaker@gsu.edu, 404-413-1282

Co-investigators:

Matthew Hayat, Ph.D., Associate Professor, Division of Epidemiology and Biostatistics, School of Public Health, Georgia State University, mhayat@gsu.edu, 404-413-9314

John Lutzker, Ph.D., Distinguished University Professor, Associate Dean, School of Public Health, Director, Center for Healthy Development, jlutzker@gsu.edu, 404-413-1284

Shannon Self-Brown, Ph.D., Professor, School of Public Health, Director, School of Public Health Ph.D. Program, Associate Director, *National SafeCare Training and Research Center*, sselfbrown@gsu.edu, 404-413-1283

Jenelle Shanley-Chatham, Ph.D., Assistant Professor, School of Public Health, Georgia State University, Associate Director of Training, *National SafeCare Training and Research Center*, jshanley@gsu.edu, 404-413-1340

Cathleen Willging, Ph.D., Senior Scientist, Pacific Institute for Research and Evaluation, Albuquerque, New Mexico, CWillging@PIRE.org

Research Staff:

Colleen McCarty, MPH, Research Coordinator, *National SafeCare Training and Research Center*, cmccarty3@gsu.edu, 404-413-1294

Erin McFry, MPH, Research Coordinator, *National SafeCare Training and Research Center*, emcfry1@gsu.edu, 404-413-1298

Matthew Lyons, Graduate Research Assistant, *National SafeCare Training and Research Center,* mlyons5@student.gsu.edu

Katie Franchot, Graduate Research Assistant, *National SafeCare Training and Research Center,* kfranchot1@student.gsu.edu

Patient Partners

Jessica Brown, President, Foster Love, Atlanta, Georgia, jsrbrown@gmail.com

Susanna Patterson, Executive Director, Middle Georgia CASA, Macon, Georgia, susanna.patterson@cgcasa.org

Jamy Still, Groundskeeper, Georgia State Capital, Atlanta, Georgia, kingjaim84@gmail.com

Stakeholder Partners

Nicole Perez, Service Provider, Parent Aid, Inc., Tucson, Arizona, nicole@parentaid.org

Julia Neighbors, JD, Director, Prevent Child Abuse Georgia, Atlanta, Georgia, jneighbors@gsu.edu

Kimberlee Shoecraft, Mentor, The Incredible Years Inc., Seattle, Washington, kimber75@hotmail.com

B2. Study goals and objectives

The study is designed as a multisite comparative effectiveness trial with randomization of teams of providers at each of 8 sites to SCM or SafeCare. We will recruit sites already conducting SCM, and randomize teams to continue SCM at the site, or to implement SafeCare. The study aims are as follows:

(1) Primary Aim 1: To identify and assess barriers and facilitators of implementation of a structured behavioral parenting program SafeCare (SC).

(2) Primary Aim 2: Understand parent and provider reactions to SC services and Supportive Case Management (SCM), especially parents' perceptions related to trajectory of burden, engagement, satisfaction, and perceived impact across intervention receipt.

(3) Secondary Aim 3: To examine the short-term impact of SC versus SCM on client-centered outcomes, namely parenting variables, parent mental health and well-being, and child behavioral, social, and emotional well-being.

B3. Background and rationale for study

Primary Aim 1. Identify and assess barriers and facilitators that influence implementation of a structured behavioral parenting program.

In child welfare services, structured behavioral parenting programs have been documented to reduce important child-welfare outcomes, including child maltreatment recidivism (Chaffin, Funderburk, Bard, Valle, & Gurwitch, 2011; Chaffin, Hecht, Bard, Silovsky, & Beasley, 2012; Prinz, Sanders, Shapiro, Whitaker, & Lutzker, 2009). Thus, from a child welfare system perspective, there is a clear rationale for the broad dissemination and effective implementation of such programs within child welfare systems. Many child welfare systems have adopted or attempted to adopt one or more evidence-based behavioral parenting programs with varying levels of success.

Theoretical models of implementation such as Exploration, Preparation, Implementation, and Sustainment conceptual model (Aarons, Hurlburt, & Horwitz, 2011) suggest systems, organizational, and individual variables that can positively or negatively affect implementation of evidence-based interventions in complex human service systems. In this model, many of the

drivers and barriers to implementation may be attributable to system-specific variables, and/or site-specific because of organizational and individual (e.g., provider) variables. The current project affords us a unique opportunity to study how this range of factors can impact implementation of SC in a diversity of child-welfare serving sites and systems.

Given our sample of ten sites (including one site that failed to implemented SC), we have a unique opportunity to conduct research that will inform implementation challenges across several different sites, systems, and states. The majority of all other implementation studies largely focus on how SC is carried out in a single state or child welfare system. Our study will contribute significantly to the available literature by illuminating key commonalities or differences across diverse settings that impinge on effective implementation of an evidence-based intervention. Our research design and data collection will be organized according to the EPIS conceptual model outlined by Aarons and colleagues (Aarons et al., 2011). More specifically, the EPIS conceptual model points to several classes of factors that can influence implementation across developmental phases of implementation, which we will investigate in greater depth. These include outer-context factors, such as funding and inter-organizational networks, and inner-context factors such as organizational culture, climate, and leadership. We will apply the EPIS conceptual model to examine these factors and other potential sources of influence on implementation.

We will use a qualitative research strategy that includes semi-structured interviews and focus groups with several levels of staff responsible for implementing the model: program administrators, supervisors, and frontline staff (providers). This strategy will yield insight into an array of stakeholder perspectives concerning implementation. We will also conduct interviews with the training staff at National SafeCare Training and Research Center (NSTRC) who oversee the implementation at each site. In contrast to most implementation studies, ours will be the first to conduct a complementary set of interviews and focus groups with staff who have *not* been trained in SC, the SCM providers. This second set of interviews and focus groups will serve two primary purposes: (1) to understand typical barriers to service delivery (not model specific) that are commonly experienced in order to identify unique barriers and facilitators to SC implementation; and (2) to assess from provider perspectives key factors that must be prioritized and addressed when implementing a new evidence-based program. These two foci will help us differentiate barriers and facilitators that may be associated largely with implementation of a new model from those that generally exist at a service agency or at the larger system level, and help to prepare for future expansions of SC at both the study sites as well as other settings.

Primary Aim 2. Understand parent and provider reactions to SC and SCM services, especially parent perceptions related to trajectory of burden, satisfaction, and perceived impact across intervention receipt

In testing intervention for child-welfare referred clients, most research has focused on the important outcomes mandated by child-welfare legislation, safety, permanence, and well-being (but, especially safety and permanence). There has been little effort to understand client responses or preferences for different. This is surprising because (1) clients can be and often are mandated to services and thus demonstrate resistance to services, and (2) program attrition in child welfare referred serviced has been documented to be very high, and poor service engagement and completion are critical barriers in child welfare service and research.

Because of these issues, it is critical to understand client perceptions of intervention services. In particular, it is key to understand client goals, satisfaction, and perceived benefit/effectiveness to understand client engagement. As noted in the original application, most child welfare services, including SCM are fairly unstructured, consisting of emotional support, service referrals, crisis management, and didactic parenting advice. In contrast, behavioral parenting (i.e., SafeCare) offers a very structured curriculum, training in a few, specific parenting skills that are seen as key to improving outcomes, and includes less of an explicit focus on emotional support as a primary service goal.

It is common practice for consumers to rate service satisfaction at the completion of services. However, ratings are typically made at the end of service, and thus (1) only clients who reach the end of services are able to offer ratings (dropouts do not), and (2) there is little understanding of client perception of services throughout the course of treatment. The goal of this aim is therefore to understand client reactions to the two interventions (SafeCare and SCM) offered in this trial across the course of treatment. We will employ mixed methods (both quantitative and qualitative data collection) to inform this question. Specifically, we will (1) conduct qualitative interviews with families at two time points during the course of service, and (2) collect session-by-session ratings from families on service reaction (perceived burden satisfaction, perceived effectiveness).

Aim 3. Compare SC to SCM on parent outcomes and child outcomes including parenting skill, parenting stress, and parent-child relationship, and child behavioral, social and emotional well-being

Child welfare systems have a legislative mandate to improve three aspects of child and family functioning: safety, permanency and well-being. Most research on these topics has focused on the outcomes of safety (cases of re-abuse) and permanence (child removals from the home). The third aspect of the child welfare system's mandate – well-being – has received much less attention with respect to intervention effectiveness, and client's preferences about important outcomes.

As conceptualized in the original proposal, there is a strong need to assess the impact of child welfare intervention on variables that are of importance to consumers in the child welfare system (parents). Here we will compare two interventions – SafeCare and SCM – on a number of aspects of parent and child well-being: parenting variables, parent mental health, and child behavioral, social, and emotional well-being. By focusing on measures of well-being and by engaging consumers in defining this focus, this study holds potential to expand the way in which the program effectiveness is conceptualized. This could be particularly important for dissemination of parenting programs to at-risk parents, who may be interested in different outcomes (e.g., improving their child's behavior) than child welfare systems, and findings may be useful for making interventions more appealing to consumers.

C. METHOD

C1. Site Recruitment

Several recruitment strategies will be employed. One-page information sheets will be distributed describing the purpose of the project and information about The National SafeCare Training and

Research Center (NSTRC), as well as site requirements and eligibility information. We will distribute information through personal contacts of the investigative team and a variety of email lists. Email lists targeted include:

- NSTRC's listserve (contains current and prospective sites)
- Child Maltreatment Researcher list (hosted by National Data Archive on Child Abuse and Neglect at Cornell University)
- American Psychological Association - Division 37 (Society for Child and Family Policy and Practice)
- The National Center for Community-Based Child Abuse Prevention
- ACF's listserve of Discretionary grantee
- FRIENDS, the National Center for Community-Based Child Abuse Prevention

Once we begin receiving inquiries about the study, we will organize a webinar to present project details which allows interested agencies to ask questions. Following our initial webinar, we will prepare for a second wave of recruitment. We will aim to target individuals involved in child welfare by sending information, including our flyer and recorded webinar, to Community-Based Child Abuse Prevention lead agency contacts across the country, as well as child welfare directors. During our third wave of recruitment, we will research child welfare agencies across the country and develop an extensive list of county and regional child welfare contacts. Each contact will be sent a personalized email explaining the opportunity, and how to proceed if interested.

C2. Site Application and selection

As sites express interest, we will engage them in our screening process, which will determine whether or not pursuing an application would be appropriate. Our initial conversations with interested sites will focus on team structure concerning randomization, number of referrals and their source, as well as whether or not the cases of maltreatment are substantiated. Upon successful completion of the screening process, potential sites will be required to complete our application. Completed applications will then be reviewed by our review team, comprised of a selection of research team members, partners, and stakeholders. Conference calls will be held with each site to clarify points of confusion, for example, what services are currently being conducted, specific target populations, and if and how randomization could be accomplished. Once applications are approved, we will begin readiness conversations with potential sites. During several of these calls we will discuss the randomization piece. Prior to the overview webinar, team randomization will be conducted.

C3. Interventions

C3.1 Supportive Case Management

SCM is a loosely defined, process oriented intervention in which providers engage families through relationship building and emotional support, assessing needs and linking families to local services, as well as troubleshooting and addressing day-to-day crises. SCM providers visit the home weekly to provide services. They do not have specific goals in mind for each particular session, but determine what needs to be addressed with the family in real time. There will likely be variability in SCM delivered at each site in terms of length of service and frequency of visits. For all clients receiving SCM, we will document number and frequency of visits, referrals, and

ancillary services utilized. We will incorporate these variables into the analyses of heterogeneity of treatment effects described below. We expect that SafeCare and SCM will be of similar dose and contact frequency, given that these dimensions drive CBO reimbursement. To the extent possible, we will encourage this equivalence within each site.

C3.2 SafeCare

SafeCare is a highly structured, empirically-supported parenting program that addresses the proximal behaviors that can lead to child neglect and physical abuse (Hecht, Silovsky, Chaffin, & Lutzker, 2008; Lutzker & Bigelow, 2002; Whitaker, Lutzker, Self-Brown, & Edwards, 2008). SafeCare was developed to help parents involved with the child welfare system, or who are members of high-risk populations. SafeCare is delivered weekly in the natural environment, usually the home, over an 18-20 week period. SafeCare contains three modules – health, safety, and parenting – that all families receive, and SafeCare providers utilize structured problem-solving on an as needed basis.

The *health* module uses standardized, validated scenarios to teach parents skills to care for their children's health. Parents are taught to recognize symptoms of illness and injury and to use a decision making process to choose the appropriate care for the child. The *safety* module aims to make homes safer and healthier for children while promoting parental supervision. In the safety module, parents are taught about ten categories of home hazards, and then learn to make the home safe by eliminating or securing the hazard. The *parent-child interaction (PCI)* module promotes positive relationships and limit setting by promoting positive parent-child interactions and preventing problem situations that can lead to harsh parenting. PCI teaches parents to increase positive interactions (talking, affectionate touching) with the child through play and daily interactions, and also how to manage the child's behavior using behavioral techniques, structuring interactions, and reinforcing positive behaviors. Parents of infants focus on behaviors that promote bonding (e.g.., looking, holding, talking, touching) versus behavior management.

The NSTRC is the main purveyor of the SafeCare program, along with other University-based sites, and provides training and implementation support to sites that choose to adopt SafeCare. Importantly, NSTRC employs a rigorous training and support model to ensure adoption and implementation of the program model with fidelity, which is needed to replicate outcomes.

Implementation of SafeCare

Once a site is selected, all providers and agency leadership are invited to attend a webinar describing the study, their involvement, and are given the opportunity to ask questions about the project. In addition to the project overview webinar, the in-person orientation is designed to address any questions or concerns expressed by agency staff and/or leadership. The orientation typically takes place two weeks before implementation and is led by the faculty member assigned to the site and the lead trainer.

Teams randomized to SafeCare will be assigned training specialists who will conduct the 4-day workshop training. The GSU research team will work with sites to schedule training and ensure that staff are prepared for implementation.

Due to the various locations of sites across the country, the GSU research team will request sites to determine which gift card should be distributed to families participating in the project at their site.

C3.3 Tracking interventions received and utilization

We will capture basic service utilization data from providers to track client use of services. Data will be tracked with a smartphone/tablet app that is made available to all providers. The app allows providers to enter a new session, enter services offered, and for SafeCare clients, track behavior change. The app will provide information for each client on number of sessions (including dates), program completion, and types of services offered. SafeCare sessions are scripted and thus the content delivered is very clear and consistent across sessions. Sessions delivered in the SCM intervention will include a variety of content. For non-SafeCare sessions, providers will indicate from a list of activities what was done during the session. They will include the number of minutes spent on each activity, in order to describe the overall services delivered across sessions. We will also collect information on additional service referrals provided to parents and whether or not they attended additional programs/services.

C4. Aim 1. Identify and assess barriers and facilitators that influence implementation of a structured behavioral parenting program

C4.1 Overview

The approach to this aim will be primarily a qualitative approach with individual semi-structured interviews and focus groups conducted with staff at the sites. We will invite staff at all sites to participate, including Montgomery County MD, who dropped out immediately after training. We will recruit all administrators and supervisors to participate in individual interviews. For providers, we will conduct focus groups at each site with the SafeCare teams (10 focus groups; one at each implementing site plus Montgomery County) and non-SafeCare teams (9 focus groups; one at each implementing site).

The team, including both researchers and partners, will jointly develop a semi-structured interview and focus group guide. Dr. Cathleen Willging will lead the effort as the team's qualitative research expert; participation will also include the current members of the Georgia State University (GSU) research team (e.g., Whitaker and Self-Brown), and partners representing the perspectives of administrators (e.g., Shoecraft, Neighbors-Day), agency supervisors/providers (Perez), and parents (Still). Development of the interview will be an iterative process in which the team will brainstorm domains of interest. Willging will then develop specific questions and pass them on to the team for review and revision.

Several domains of initial interest will be drawn from the implementation science literature. We will consult the EPIS conceptual model to spell out specific concepts to explore in the interviews and focus groups. Initial domains we will target are:

- Funding agency role in implementation
- Engagement of implementation developers
- Organizational leadership and alignment across staffing levels
- Organizational structure, culture, and climate
- Fit of service model (SC) with client needs
- Time pressures/caseload issues/competition demands

- Individual attitudes, beliefs, and expectations about services

Data collection will be conducted entirely by Dr. Willging's team. This is important because Willging and her team are not part of the NSTRC, and this will reduce the pressure on participants to respond favorably regarding the SafeCare intervention. It is possible there are "fit" issues between SafeCare and the client needs, and provider must feel free to voice those concerns.

C4.2 Qualitative

Provider, supervisor, and administrative recruitment

Providers, supervisors, and administrators will be informed of the opportunity to participate in qualitative interviews over a series of conference calls and webinars. Those interested will be asked to sign a consent form and work with the GSU research team for scheduling purposes.

Assessment Procedures

We will conduct focus groups at each site with the SafeCare teams (10 focus groups; one at each implementing site plus Montgomery County) and non-SafeCare teams (9 focus groups; one at each implementing site). A total of 19 focus groups (n = 4-8 providers in each) and up to 45 individual interviews (average of 5 per site) will be conducted. The GSU-based research team will coordinate the recruitment of participants and the scheduling of the interviews. Dr. Willging will train research team members (Masters- or BA-level staff) to conduct focus groups and qualitative interviews. Team members will travel to each of the sites to conduct focus groups and individual interviews. If all individual interviews cannot be conducted at the same trip as focus groups, we will conduct remaining interviews via phone or video chat.

Data Analysis

Data will be transcribed and analyzed as follows. First, open coding will be conducted to locate themes/issues. Codes will be assigned to segments of text ranging from a phrase to several paragraphs based a priori on topical domains and questions from the interview guides. New codes not previously considered will be identified and defined. Second, "focused coding" will be used to determine which of these themes/issues emerge frequently and which represent unusual or particular concerns to the participants. All qualitative data will be independently coded by at least two members of the research team, and inter-rater reliability tested against a Kappa benchmark.

C5. Aim 2. Understand parent and provider reactions to SC and SCM services, especially parent perceptions related to trajectory of burden, satisfaction, and perceived impact across intervention receipt

We will assess both family and provider response to the interventions. For family responses, we will employ mixed methods for assessing family responses collecting data via both qualitative interviews and survey data. For provider data, we will rely primarily on the quantitative surveys collected periodically throughout services. Baseline data for families and providers will allow us to examine potential effect moderators.

C5.1 Family burden, satisfaction and perceived impact

For the qualitative component with this study, we will conduct semi-structured interviews with 72 families (36 SC, 36 SCM) at two time points, the first at approximately 4-5 sessions (of 18-20) into service, and then again at the end of service. The selection of four sessions into service as the first assessment point was chosen to allow parents to get a sense of the services that will be provided, and thus represents their initial impressions of services.

We will also collect sessions-by-sessions data from all families enrolled in the study. Providers will use a smartphone app that is provided as part of the study to collect data on quantitative measures. At the end of each session, families will be asked to respond to 10 questions via the app that assess their perceptions of burden, satisfaction, and service effectiveness. Once a parent submits responses, the app locks the survey and thus providers cannot access parent responses.

The results of the quantitative and qualitative data for this Aim will be integrated by the research/partner team. Specifically, we will compare findings from the quantitative and qualitative analyses, and specifically to look for convergences and divergences in findings (do both methods similar or different findings?), and we will use the qualitative responses to expand on the quantitative findings to provide deeper meaning (Palinkas et al., 2011). For example, we may find in both sets of data that burden, satisfaction, and service effectiveness change over time. The qualitative data will also be used to inform the quantitative data on specific of burden, satisfaction, and effectiveness. The quantitative data assess the extent of burden, satisfaction, and effectiveness, but the qualitative data will be used to assess why (or why not)?

Quantitative assessments of burden, satisfaction, and program effectiveness

Family perceptions of service burden, satisfaction, and program effectiveness will be captured in two ways: (1) during receipt of service through quantitative data collection and, (2) post-service through qualitative interviews from a select number of participants.

After each session, participants will complete a brief 10-item survey that assesses perceived service burden, satisfaction, and program effectiveness. Participants will complete the survey on a smartphone or tablet that the provider will bring to each session (the provider will use it to collect service data). The specific questions were developed for this study as there has been little assessment of these constructs in a child welfare setting. Questions are included in the Appendix.

Qualitative interviews to assess burden, satisfaction, and effectiveness

A subset of participants in the research study (n=72; 36 who received SafeCare and 36 who received SCM) will be asked of their interest in participating in the qualitative portion of the study, consisting of in-depth interviews via a separate consent process. The interviews will be conducted with parents at two time points, the first at approximately 4-5 sessions (of 18-20) into service, and then again at the end of service. Interviews will focus on how parents experienced the intervention, in addition to their initial expectations and perceived short-term outcomes. Eight families from each site, 72 total, will be included in the qualitative study. We will purposely choose families representing diversity in gender, race/ethnicity, and other demographics to capture a full range of perspectives.

Interview guides comprised of approximately 10 to 12 open-ended questions will be developed based on input from our provider and patient partners, pilot tested, and then revised. The guide will be designed to assess key issues that bear upon implementation (e.g., characteristics of the

model, modules, or provider behaviors found most or least helpful) and will include follow-up probes. Interviewers will be trained to examine novel or emergent issues that were not considered previously but which arose in the course of their discussions with parents. All interviews will be recorded and professionally transcribed with a final accuracy review undertaken by the interviewer, who will also take detailed notes during each interview. These notes will be organized according to a standard format (or "debriefing form"), with information on date, time, length of the interaction, physical setting, and preliminary themes.(Miles, Huberman, & Saldaña, 2013) The typed notes and transcripts will be converted into analyzable text and imported into a password protected NVivo 10 database for organization and analysis via iterative readings or codings. Discussion of preliminary themes during team meetings will lead to revisions of the interview guide. Parents will be compensated $25 for their time participating in each interview.

C5.2 Provider burden, satisfaction and perceived impact

Providers who consent to the study will be surveyed at baseline (prior to implementation), then quarterly over the course of the next year, and will complete a final survey one year post-baseline.

The initial (baseline) and final surveys are comprehensive, including measures of demographics, work experience, organizational factors (culture, climate, leadership) and individual attitudes and beliefs, that may affect implementation and service quality. The quarterly surveys are brief and focus on service implementation, burden, quality, and perceived effectiveness. Thus, we will have longitudinal survey data from providers at four time points during implementation regarding intervention burden, satisfaction, and perceived effectiveness.

All providers were recruited to participate in surveys conducted at the beginning and end of implementation. Providers willing to participate will sign a consent form, complete two organizational surveys (one prior to implementation and one at the end), and the brief quarterly surveys assessing program satisfaction, burden, and perceived effectiveness of the intervention they are delivering (SCM or SafeCare).

Providers who consent to the study are surveyed at baseline (prior to implementation), then three times quarterly over the course of the next year, and complete a final survey one year post-baseline. The initial (baseline) and final surveys are comprehensive, including measures of demographics, work experience, organizational factors (culture, climate, leadership) and individual attitudes and beliefs, that may affect implementation and service quality. The quarterly surveys are brief and focus on service implementation, burden, quality, and perceived effectiveness. All provider data will be collected using web-based surveys developed through Qualtrics. The GSU-based project coordinator will track providers who consent to the study. Providers will be emailed and called if necessary when it is time to complete the next survey. Providers who leave the organization before the end of the 12-month period will be asked to complete the follow-up survey of organization and individual characteristics at the time of their departure.

Analyses of provider responses will be done using GLMM as responses are nested within providers. We will have up to five responses for providers. Analyses will focus on understanding mean differences between SC and SCM providers, as well as time trends, and whether differences follow any time trends.

C6. Aim 3. Compare SC to SCM on parent outcomes and child outcomes including parenting skill, parenting stress, and parent-child relationship, and child behavioral, social and emotional well-being

Families will complete self-report measures at two time points (baseline and 6- months) to assess major outcomes. Assessments will be done via tablet-based surveys in the parents' home conducted by blinded assessors.

C6.1 Target population

The target population for this aim are families (caregivers/parents and children) who are being served by child protective service systems or their contractors for maltreatment. We will include both families who have cases of maltreatment that are substantiated and those who are not substantiated but referred to CPS systems for possible maltreatment. Research has shown identical risk profiles and likelihood of recidivism for CPS-referred families regardless of whether a referral is formally substantiated (Kohl, Jonson-Reid, & Drake, 2009), and the two populations are typically served with identical interventions.

A total of 376 parents/ caregivers will be recruited by the end of the study based on our current recruitment rate of families recruited per provider per month.

C6.2 Family Recruitment

The research team will work with local service providers to gain family interest in the project. All families enrolled in the study will already be receiving services from providers. For the study, we will ask providers to briefly describe the project, including that it is completely voluntary, and request permission to pass the family contact information to the GSU-based project coordinator. The GSU team will contact interested participants, fully explain the study procedures, and review the consent form with interested families. If a family consents to the project, the GSU-based research coordinators will contact a local assessor and provide the family name and phone number. An assessor, who will be a GSU contract-based employee and blinded to study conditions will be sent to conduct the face to face assessment. Assessments will be done in the home and will consist of an electronic survey and a home safety assessment. The survey will use standardized questionnaires delivered to clients on a tablet. The local assessor will schedule the assessment prior to the next visit by the service provider.

C6.3 Family assessments of outcomes

Families will complete in-home assessments at baseline and 6-months. Each assessment will consist of a computer-assisted self-interview and a home safety scan to be conducted by the assessor.

All constructs identified below will be assessed via self-reported survey conducted on tablet, except for the assessment of home hazards, which will be assessed via the safety scan. Parents will be compensated with a $40 gift card for each assessment completed.

Local data collectors will be hired and trained at each site to conduct family assessments, and will be paid on a contractual basis for each assessment. The GSU research team will work with sites to advertise and identify candidates for positions. Appropriate candidates will be naive to the intervention, hired by GSU directly via contract mechanism, and trained at their site by the

GSU research coordinator. GSU research staff will conduct a 1-day, in-person training for data collectors. Data collectors will be trained in scheduling, assessment, administrative, and follow-up procedures. They will be provided with a tablet for the duration of the study and will be trained on how to conduct in-home assessments. Local assessors will be required to complete CITI training and will be part of GSU's IRB application.

Computer assisted self-interview

Parents/caregivers will complete a survey on a tablet provided by the assessor. The survey will be developed with the Qualtrics program. The survey will use standardized questionnaires delivered to clients on a tablet. Parents will complete the electronic survey independent of the assessor to maintain privacy, while the assessor helps watch over children in the home to provide the parent additional uninterrupted time. If a parent needs assistance reading, the assessor will read the question aloud to the parent (using paper measures) and the parent will enter their responses directly into the tablet. The specific constructs to be measured include the following:

- *Parenting Behaviors* – the Parenting Young Children Scale (McEachern et al., 2012) assesses three dimensions of positive parenting: limit setting, proactive parenting, and supporting positive behavior.
- *Parent-child Relationship/Bonding/Attachment* – the quality of the relationship between the parent and child will be measured with the attachment subscale of the Devereaux Early Child Assessment (LeBuffe & Naglieri, 1999).
- *Parenting Stress* – the Parenting Stress Inventory – short form (Abidin, 1995) is a 36-item scale designed to measure stressors in parenthood including parental distress, dysfunctional interactions, and stressors related to having a difficult child.
- *Parent Emotional Well-being* – the Brief Symptom Inventory (Derogatis & Melisaratos, 1983) is a 53-item scale designed to measure a range of emotional health states including depression, anxiety, somatization, and others. We will also use the SF-12, (Gandek et al., 1998) a brief 12-item scale assessing physical and emotional health.
- *Child Well-being* – the Devereaux Early Child Assessment (DECA) (LeBuffe & Naglieri, 1999) is a validated behavioral rating scale that assesses child behavior in the domains of initiative, self-control, and behavioral concerns.
- *Caregiving Behaviors – the Mother-Child Neglect Scale* (MCNS) (Lounds, Borkowski, & Whitman, 2004) is a 20-item scale designed to assess caregiving behaviors in four domains: physical, cognitive, supervision, and emotional needs.
- *Home Environment* – the CHAOS scale (Confusion, Hubbub, and Order) (Dumas et al., 2005) is a 15-item scale that will be used to measure structure and chaos in the home environment, a common well-being related goal among parents.
- *Family Resources* – the Family Resources Scale – Revised (Van Horn, Bellis, & Snyder, 2001) assesses the adequacy of family needs in four domains: basic needs, money, time for self, time for family. Resource sufficiency is a common facet of parent well-being.
- *Drug/Alcohol Use* – the ASSIST (Humeniuk et al., 2008) measures drug and alcohol use and drug/alcohol related problems.

- *Relationship Violence* - the short form of the Conflict Tactics Scale II(Straus & Douglas, 2004) will be used to measure relationship violence victimization and perpetration.
- *Social Support* – a subscale of the Protective Factors Survey (Counts, Buffington, Chang-Rios, Rasmussen, & Preacher, 2010) will measure concrete and emotional support, each using a five item scale.
- *Standard Demographics* – standard demographics from the parent will be collected including age, sex, education, income, and marital status. We will also collect information about family structure, number of children, living situation, relationship partners, and prior social and mental health services.
- *Parental Supervision and Childhood Injury* – a questionnaire adapted for the current study which assess supervision in the home and injuries from hazards in the home

Home Safety Scan

Assessors will conduct a home safety scan designed to assess the hazards in the home. In the safety scan, assessors will look in three rooms in the house – the kitchen, bathroom, and living room – and count the number of accessible hazards in those rooms, using guidelines defined in the Home Accident Prevention Inventory-Revised.[58] The home safety scan is included in the Appendix.

C7. Data Management

All data cleaning and analysis will be handled at Georgia State University. Assessment data from families and providers will be collected via web-based surveys, and downloaded by the GSU research team, so no additional data transfer will be needed. Data on service utilization collected via tablets will be stored on a secure cloud-based server controlled by the GSU research team. The GSU research team will enter, clean, and analyze the data. Oversight of data entry and management will be done by the PI (Whitaker) and Self-Brown. Dr. Hayat (biostatistician) will oversee the data cleaning and analysis. This arrangement is purposeful and will allow the study analysts to maintain independence of the purveyors of SafeCare at NSTRC (Whitaker, Self-Brown, Lutzker).

C8. Data cleaning and missing data

Prior to analysis, data will be cleaned and inspected for missing data. Statistical analyses will be handled in a way that takes advantage of all available observed data (i.e. does not discard any cases) while not over-estimating precision. Missing data will be assumed to be missing at random (MAR). Although there is no complete, comprehensive method for handling missing data for general linear models, there are several approaches that we can draw upon to address this issue (Diggle, Heagerty, Liang, & Zeger, 2002). We will use multiple imputation of missing data whereby missing observations for individuals are estimated based on other covariates in the data set. If initial examination of the data and field reports suggest that the MAR assumption is not supported, we will conduct sensitivity analysis under the missing not at random (MNAR) assumption using pattern mixture models. However, the availability of only three longitudinal data points will limit the extent to which this is possible.

C9. Statistical power for quantitative analyses

In the initial proposal, we identified several standardized effects from prior studies for parenting skill (Carta, Lefever, Bigelow, Borkowski, & Warren, 2013) *d* = .81, parental depression (Chaffin, Bard, Bigfoot, & Maher, 2012) *d* = .33, changes in children's behavior (Carta et al., 2013) *d* = .29, and parent satisfaction (Damashek, Bard, & Hecht, 2012; Damashek, Doughty, Ware, & Silovsky, 2011; Silovsky et al., 2011) *d* = .52. Though there is variability in these effect, the median effect appears to be a medium-sized effect (Cohen, 1988).

To compute power for nested data, we used the Optimal Design program (Sprybrook et al., 2011) which accounts for the nested structure of the data. In the initial proposal, we used provider as the nesting unit, with respondents/parents nested within providers, and time nested within respondent/parent.

We have generated power estimates based on each method of projecting sample size. The first method, the simple average of clients recruited per month, suggests a sample size of 144 families across the 23 teams; this would include 1 family per provider or about 6 families per team. The second method, using provider-months, suggests a sample size of 376 providers recruited across the 27 teams; this would include about 2 families per provider, or about 14 families per team. For Aim 2, understanding parent reactions to SC and SCM services, analyses are based on parents' session-by-session responses taken immediately after each intervention session. Each respondent should have as many responses as sessions (up to 20). For sample size determination, we have used a modest number of repeated measures – 10 – because some families may terminate services early. For a sample size of 376 families across 27 teams, with alpha set to .05, and power at .80, we are able to detect effects sized d = .31 to d = .45 for ICC values ranging from .01 to .10. For a sample of 144 families across 23 teams, under the same assumptions, minimally detectable effect sizes are *d* = .51 to *d* = .62.

For Aim 2, assessing provider perceptions of burden, satisfaction, and effectiveness, providers are the unit of analysis and measurement is repeated over four time points. To date, we have recruited 81% of providers into the study, and this projects to 139 providers over the total provider sample size of 172. To compute statistical power, we used G*Power (Faul, Erdfelder, Lang, & Buchner, 2007) to compute minimally detectable effect size given the sample of 139 providers with four assessment points, and assuming alpha = .05 and power = .80. For a sample of 139 providers, power is adequate to detect a small sized effect of *d* = .20, and if we assume attrition to be 20% (n = 111 providers), the detectable effect size is a small sized effect of *d* = .22.

For Aim 3, detecting differences in parenting skill, parent mental health and well-being, and child behavioral, social, and emotional development, the power analysis is based on 23 teams of providers, with each team providing family data on 14 families for the estimate using provider months to project enrollees (n = 376) and 6 families for the estimate using the average number of families enrolled per month to date (n =144). For the former estimate (27 teams; 14 families per team, n ~ 376), with a level of significance of .05, the cluster randomized design with two repeated measures, and power at .80, we are able to detect effect sizes in the range of *d* = .38 to *d* = .50 for values of ICC ranging from .01 to .10. For the latter estimate (23 teams; ~6 families per team, n = 144), with a level of significance of .05, the cluster randomized design with repeated measures provides power at 0.80 to detect effect sizes in the range of *d* = .62 to *d* = .70 for values of ICC ranging from .01 to .10. Thus, the former method of projecting sample size

appears to yield sufficient power to justify the study (medium sized effects), while the latter perhaps does not (greater than medium-sized effects).

C10. Ethical Considerations

We believe the risks of study participation to be very minimal. All survey data will be collected via web-based data collection. Web-based data will be collected using www.qualtrics.com, a secure online data collection system for surveys and psychological research, and through the SafeCare app. Responses obtained from participants will be collected only for the purposes of this research and this information will be kept strictly confidential to guarantee the protection of human subjects. Specifically, data will be kept secure using standard methods. Only the research team will have access to the data. Only code numbers will be used on data forms and in electronic databases and no identifying information will be associated with participants' responses. Responses obtained from the research study will be secured on a secured network drive or in a locked filing cabinet in a locked office. No individual data will be released.

D. REFERENCES

Aarons, G. A., Hurlburt, M., & Horwitz, S. M. C. (2011). Advancing a conceptual model of evidence-based practice implementation in public service sectors. *Administration and Policy in Mental Health and Mental Health Services Research, 38*, 4-23.

Abidin, R. R. (1995). *Parenting Stress Index: Professional Manual*. Lutz, FL: Psychological Assessment Resources.

Carta, J. J., Lefever, J., B., Bigelow, K., Borkowski, J., & Warren, S. F. (2013). Randomized Trial of a Cellular Phone-Enhanced Home Visitation Parenting Intervention. *Pediatrics, 132*(Supplement 2), S167-S173. doi:10.1542/peds.2013-1021Q

Chaffin, M., Bard, D., Bigfoot, D. S., & Maher, E. J. (2012). Is a Structured, Manualized, Evidence-Based Treatment Protocol Culturally Competent and Equivalently Effective Among American Indian Parents in Child Welfare? *Child Maltreatment, 17*(3), 242-252.

Chaffin, M., Funderburk, B., Bard, D., Valle, L. A., & Gurwitch, R. (2011). A combined motivation and parent–child interaction therapy package reduces child welfare recidivism in a randomized dismantling field trial. *Journal of Consulting and Clinical Psychology, 79*(1), 84-95.

Chaffin, M., Hecht, D., Bard, D., Silovsky, J. F., & Beasley, W. H. (2012). A Statewide Trial of the SafeCare Home-Based Services Model with Parents in Child Protective Services *Pediatrics, 129*, 509-515.

Cohen, J. (1988). *Statistical Power Analysis for the Behavioral Sciences* (2nd ed.). Hillsdale, NJ: Lawrence Erlbaum Associates.

Counts, J. M., Buffington, E. S., Chang-Rios, K., Rasmussen, H. N., & Preacher, K. J. (2010). The development and validation of the protective factors survey: A self-report measure of protective factors against child maltreatment. *Child abuse & neglect, 34*(10), 762-772.

Damashek, A., Bard, D., & Hecht, D. (2012). Provider Cultural Competency, Client Satisfaction, and Engagement in Home-Based Programs to Treat Child Abuse and Neglect. *Child Maltreatment, 17*(1), 56-66.

Damashek, A., Doughty, D., Ware, L., & Silovsky, J. (2011). Predictors of Client Engagement and Attrition in Home-Based Child Maltreatment Prevention Services. *Child Maltreatment, 16*(1), 9-20.

Derogatis, L. R., & Melisaratos, N. (1983). The brief symptom inventory: an introductory report. *Psychological medicine, 13*(03), 595-605.

Diggle, P., Heagerty, P., Liang, K.-Y., & Zeger, S. (2002). *Analysis of longitudinal data*: Oxford University Press.

Dumas, J. E., Nissley, J., Nordstrom, A., Smith, E. P., Prinz, R. J., & Levine, D. W. (2005). Home chaos: sociodemographic, parenting, interactional, and child correlates. *J Clin Child Adolesc Psychol, 34*(1), 93-104. doi:10.1207/s15374424jccp3401_9

Faul, F., Erdfelder, E., Lang, A. G., & Buchner, A. (2007). G*Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behavior Research Methods, 39*, 175-191.

Felitti, V. J., Anda, R. F., Nordenberg, D., Williamson, D. F., Spitz, A. M., Edwards, V., . . . Marks, J. S. (1998). Relationship of Childhood Abuse and Household Dysfunction to Many of the Leading Causes of Death in Adults The Adverse Childhood Experiences (ACE) Study. *American Journal of Preventive Medicine, 14*(4), 245-258.

Fergusson, D. M., Boden, J. M., & Horwood, L. J. (2008). Exposure to childhood sexual and physical abuse and adjustment in early adulthood. *Child abuse & neglect, 32*(6), 607-619.

Gandek, B., Ware, J. E., Aaronson, N. K., Apolone, G., Bjorner, J. B., Brazier, J. E., . . . Prieto, L. (1998). Cross-validation of item selection and scoring for the SF-12 Health Survey in nine countries: results from the IQOLA Project. *Journal of clinical epidemiology, 51*(11), 1171-1178.

Gilbert, R., Widom, C. S., Browne, K., Fergusson, D., Webb, E., & Janson, S. (2009). Burden and consequences of child maltreatment in high-income countries. *The Lancet, 373*(9657), 68-81.

Hecht, D. B., Silovsky, J. F., Chaffin, M., & Lutzker, J. R. (2008). SafeCare: An evidence-based approach to prevent child neglect. *The APSAC Adviser, Winter*, 14 - 17.

Herrenkohl, E. C., Herrenkohl, R. C., Rupert, L. J., Egolf, B. P., & Lutz, J. G. (1995). Risk factors for behavioral dysfunction: the relative impact of maltreatment, SES, physical health problems, cognitive ability, and quality of parent-child interaction. *Child abuse & neglect, 19*(2), 191-203.

Humeniuk, R., Ali, R., Babor, T. F., Farrell, M., Formigoni, M. L., Jittiwutikarn, J., . . . Monteiro, M. (2008). Validation of the alcohol, smoking and substance involvement screening test (ASSIST). *Addiction, 103*(6), 1039-1047.

Kohl, P. L., Jonson-Reid, M., & Drake, B. (2009). Time to Leave Substantiation Behind: Findings From A National Probability Study. *Child Maltreatment, 14*(1), 17.

LeBuffe, P. A., & Naglieri, J. A. (1999). The Devereux early childhood assessment. *Lewisville, NC: Kaplan Press Publishing*.

Lounds, J. J., Borkowski, J. G., & Whitman, T. L. (2004). Reliability and Validity of the Mother-Child Neglect Scale. *Child Maltreatment, 9*(4), 371.

Lutzker, J. R., & Bigelow, K. M. (2002). *Reducing Child Maltreatment: A Guidebook for Parent Services*. New York, NY: Guilford Publications.

McEachern, A. D., Dishion, T. J., Weaver, C. M., Shaw, D. S., Wilson, M. N., & Gardner, F. (2012). Parenting Young Children (PARYC): Validation of a self-report parenting measure. *Journal of Child and Family Studies, 21*(3), 498-511.

Miles, M. B., Huberman, A. M., & Saldaña, J. (2013). *Qualitative data analysis: A methods sourcebook*: SAGE Publications, Incorporated.

Palinkas, L. A., Aarons, G. A., Horwitz, S., Chamberlain, P., Hurlburt, M., & Landsverk, J. (2011). Mixed method designs in implementation research. *Administration and Policy in Mental Health and Mental Health Services Research, 38*(1), 44-53.

Prinz, R. J., Sanders, M. R., Shapiro, C. J., Whitaker, D. J., & Lutzker, J. R. (2009). Population-based prevention of child maltreatment: The US Triple P system population trial. *Prevention Science, 10*(1), 1-12.

Silovsky, J., Bard, D., Chaffin, M., Hecht, D. B., Burris, L., Owora, A., . . . Lutzker, J. (2011). Prevention of child maltreatment in high risk rural families: A randomized clinical trial with child welfare outcomes. *Children and Youth Services Review, 33*(8), 1435-1444.

Sprybrook, J., Bloom, H., Congdon, R., Hill, C., Martinez, A., & Raudenbush, S. W. (2011). *Optimal Design Plus Empirical Evidence: Documentation for the "Optimal Design" Software*. http://hlmsoft.net/od/.

Straus, M. A., & Douglas, E. M. (2004). A short form of the Revised Conflict Tactics Scales, and typologies for severity and mutuality. *Violence Vict, 19*(5), 507-520.

Thornberry, T. P., Ireland, T. O., & Smith, C. A. (2001). The importance of timing: The varying impact of childhood and adolescent maltreatment on multiple problem outcomes. *Development and psychopathology, 13*(04), 957-979.

Van Horn, M. L., Bellis, J. M., & Snyder, S. W. (2001). Family Resource Scale-Revised: Psychometrics and validation of a measure of family resources in a sample of low-income families. *Journal of Psychoeducational Assessment, 19*(1), 54-68.

Wegman, H. L., & Stetler, C. (2009). A meta-analytic review of the effects of childhood abuse on medical outcomes in adulthood. *Psychosomatic Medicine, 71*(8), 805-812.

Whitaker, D. J., Lutzker, J. R., Self-Brown, S., & Edwards, A. E. (2008). Implementing an evidence-based program for the prevention of child maltreatment: The SafeCare® program. *Report on Emotional & Behavioral Disorders in Youth, 8*, 55-62.