A RANDOMIZED EFFICACY TRIAL OF AN EARLY INTERVENTION IN LAOS

by

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DISSERTATION ABSTRACT

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Approximately half of all children in Laos fail to reach their full developmental potential as a result of exposure to poverty-related risks. Early interventions that encourage sensitive and responsive caregiving in the context of stimulating activities such as reading and playing have shown consistent benefits on children's developmental trajectories across diverse domains. However, to our knowledge, no such intervention has been implemented in Laos. As such, the overarching goal of this dissertation was to examine the acceptability and efficacy of a culturally adapted early intervention on caregiving practices and children's cognitive and language outcomes in rural Laos.

Our first aim was to culturally adapt an evidence-based responsive stimulation intervention and to assess the acceptability of the resulting intervention, *Phadthana Khong Dek* (PKD). Cultural adaptation included process adaptations (e.g., identification of local needs and relationship-building with stakeholders) and content adaptations (e.g., adaptations across several domains including language, persons, metaphors, content, concepts, goals, methods, context) following established models of cultural adaptation. Preliminary findings from 93 Lao families receiving the intervention suggested that the cultural adaptions resulted in an intervention that is relevant, useful, and easy to put into practice.

A second aim was to examine the efficacy of PKD on caregiving practices and children's cognitive and language development among 159 caregivers and their under-five children. Trial arms included control, family-, and community-level conditions of PKD. Controlling for sociodemographic risk (e.g., caregiver education level, caregiver depression, ethnicity) and baseline measures, both family- and community-level conditions evidenced medium to large effects on caregiving stimulation practices one-month post-intervention. There was also a positive effect of the family-level condition on the likelihood of child play with different types of stimulating toys. The family-level intervention also had significant short-term benefits with a large effect size on cognitive and language outcomes for children who received the intervention at the earliest ages, before 20 months of age, but not at later ages. Together, these findings point to PKD as one brief, low-cost, and scalable public health strategy for alleviating the enormous burden of children in Laos not reaching their full developmental potential.

This dissertation includes unpublished coauthored material.

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CHAPTER I

INTRODUCTION

How can we help children thrive, and not just survive? More than 90% of children live in low- and middle-income countries (Engle, Rao, & Petrovic, 2013). Very young children growing up in these contexts experience four co-occurring factors that increase risk for mortality and exert pernicious effects on development (Aboud & Yousafzai, 2015): (1) poor antenatal care, (2) infectious diseases such as malaria, (3) malnutrition, and (4) inadequate stimulation. The first three events have dominated the global health agenda in the past few decades, resulting in meaningful reductions in global childhood mortality rates, with the number of deaths in children under five reduced by half between 1990 and 2015, to approximately 6.3 million (Requejo & Bhutta, 2015; Yousafzai & Arabi, 2015). Now that most children survive past the critical first 1,000 days of life (UNICEF, 2016), global health focus has expanded to consider how to support child thriving for those children who do survive.

The UN Sustainable Development Goals have drawn global attention to supporting optimal early child development. Yet, 43% of children (250 million) under age five years in low- and middle-income countries are still at risk for not reaching their full developmental potential (Black et al., 2017). This is due in part to a failure to apply burgeoning scientific knowledge on nurturing caregiving to shape children's early development (Britto et al., 2017). We know that child survival is attained through an environment sensitive to children's health and nutritional needs, while optimal development is achieved through responsive, stimulating care (Bornstein & Putnick, 2012). This includes sensitive (understanding a child's signals)

and responsive (responding in a contingent and developmentally appropriate way to these signals) caregiving, as well as opportunities for stimulating, developmentally-appropriate activities such as reading, talking, and playing. These opportunities often help young children explore and interact with their environment, learn to solve problems, and engage socially and emotionally with others. Early interventions aimed at supporting this type of caregiving are effective at improving children's developmental outcomes (Aboud & Yousafzai, 2015; Britto et al., 2017; Rao et al., 2014). Importantly, these early benefits have lifelong effects including improved health and well-being, increased ability to learn, and greater educational and occupational attainment (Boivin et al., 2013; Gertler et al., 2014; Walker, Chang, Vera-Hernández, & Grantham-McGregor, 2011).

Decades of research have consistently shown that interventions implemented earlier in life provide maximal benefit in terms of child development (National Scientific Council on the Developing Child, 2010). However, there is a relative dearth of early interventions implemented in low-and-middle income countries, where such programs are most needed (Britto et al., 2017; Engle et al., 2007; WHO, 2012). Low- and middle-income countries like Laos in Southeast Asia, face incredible challenges providing healthy living conditions for children due to low economic prioritization of children's health and developmental needs; less than 1% of Laos' total government expenditures are spent on health (The World Bank, 2014). Among children in Laos under five years of age, 44% are stunted (low weight-for-age; UNICEF, 2016). Stunting in early childhood is associated with lower IQ and delays in psychomotor and social development (Grantham-McGregor et al., 2007). These deficits likely increase with age because early development sets a critical foundation for a child's entire life trajectory (Engle, Fernald, et al., 2011; Gertler et al., 2014). As such, it is

imperative to invest in evidence-based programs that promote optimal early child development.

Government investment in early interventions in low- and middle-income countries is low for several reasons. For example, the problem of children's loss of developmental potential, as well as its individual and societal cost, is not immediately visible and it may be difficult for governments to justify the long-term investment in early child development (Engle et al., 2007). Despite these hurdles, there is evidence of increasing awareness of the importance of early child development in low- and middle-income countries. For example, the World Bank invested $3.3 billion dollars from 2001 to 2013 in 116 early child development programs (Sayre, Devercelli, a, & Wodon, 2015). However, there are disparities in investments between regions. For example, Latin America and the Caribbean, followed by Sub-Saharan Africa, benefitted the most from World Bank commitments, receiving approximately 73% of The World Bank's total early child development investments (Sayre et al., 2015). Countries receiving less investment, such as those in Southeast Asia, must then maximize return on investment by prioritizing low-cost and effective early interventions.

Care for Child Development

One low-cost early intervention showing promising child and caregiver outcomes in low- and middle-income countries is Care for Child Development (CCD). CCD is an evidence-based program developed jointly by UNICEF and the World Health Organization (UNICEF & WHO, 2012). CCD is a responsive stimulation intervention for caregivers of children under age five years. Health workers implement CCD by counseling caregivers on age-appropriate child play and communication activities. These activities support children's development and also

build on caregivers' capacity to be sensitive and responsive. A recent cost-effectiveness analysis of a culturally adapted version of CCD implemented in Pakistan, estimated the cost of the intervention to be relatively low, at approximately $4 USD per month per child (Gowani, Yousafzai, Armstrong, & Bhutta, 2014).

The generic CCD includes a poster with play and communication recommendations that differ by child age. The poster includes illustrations of some recommended activities and is meant to be applicable in a broad number of contexts. In conjunction with this poster, the program uses a four-step counseling approach in which trained health workers (1) ask about and listen to caregivers describe how they play and communicate with their child. The health worker then (2) praises the actions of the caregiver that are positive, and (3) provides advice as needed using the poster of illustrated recommendations. Finally, the health worker (4) works to ensure that the caregiver remembers the information by encouraging the caregiver to try out activities and by providing feedback during the visit.

CCD was originally intended to be delivered to individual families, however researchers have also adapted the generic CCD for group delivery formats (Yousafzai, Rasheed, Rizvi, Armstrong, & Bhutta, 2014). Thus far, too few studies exist to conclude which delivery format produces the largest and most sustainable effect on children's developmental outcomes (Aboud & Yousafzai, 2015). At least two studies in Bangladesh (Hamadani, Huda, Khatun, & Grantham-McGregor, 2006) and Brazil (Eickmann et al., 2003) found that combined individual and group counseling produced better outcomes than individual family interventions alone. However, we do not yet know about the the relative efficacy of family-level and group-level interventions.

CCD does not provide recommendations about intervention dosage or intensity. The number of CCD sessions in efficacy and effectiveness trials have ranged from a single session lasting 12 minutes during a sick child visit (Ertem et al., 2006), to two 30- to 60-minute home visits two times over a six-month period (Jin et al., 2007), to monthly group and home visits over the period of the first two years of life (Yousafzai et al., 2014; Yousafzai, Rasheed, Rizvi, Armstrong, & Bhutta, 2015). Overall, CCD notes that "the time and investment…is relatively small" (UNICEF & WHO, 2012, p. 13), making it promising low-cost, and culturally adaptable intervention for vulnerable children in low- and middle-income countries.

Care for Child Development Outcomes

CCD has been implemented in 19 countries with pilot studies in Brazil and South Africa, efficacy trials in Turkey and rural China, and nationwide implementation assessment in Tajikistan, Kazakhstan, and Kyrgyzstan (Richter et al., 2017). Most recently, in a cluster-randomized effectiveness trial in Pakistan, children who received a culturally adapted CCD intervention until 24 months of age had higher cognitive, language, and motor skills at 12 and 24 months and higher social-emotional skills at 12 months, than those who did not receive the intervention (controls received routine health and nutrition services; Yousafzai et al., 2014). Studies in central Asia (Engle, Smeby, & Grover, 2011) and rural China (Jin et al., 2007) also showed enhanced psychosocial development among children receiving the intervention. Further, studies in Turkey (Ertem et al., 2006) and Brazil (dos Santos, Gonçalves, Halpern, & Victoria, 1999) also showed that caregivers receiving the intervention engaged in more play and communication activities, remembered health worker messages, and had more childcare skills.

Evidence from Turkey and China suggest that even one or two sessions of CCD can have a short-term impact on changes in caregiver behavior and child development (Ertem et al., 2006; Jin et al., 2007). In Turkey, a single CCD session was provided at a clinic visit by trained pediatricians to children age two, or younger (Ertem et al., 2006). On average, the CCD session lasted approximately 12 minutes. One week later, more families in the intervention group, compared to the control group, had made at least one toy for their children, reported reading to their child at least once per week, and had tried a new play activity with their children. In China (Jin et al., 2007), two CCD sessions were provided over a six-month period to children age two or younger. Children were assessed at baseline and six months post-intervention. In comparison to the control group, children in the intervention group had greater positive changes in adaptive functioning, language, and social development. Additionally, caregivers in the intervention group reported greater understanding of the counseling card recommendations in comparison to caregivers in the control group. Together, these findings suggest that a brief CCD intervention (i.e., one or two sessions) has short-term efficacy.

Thus far, CCD has not been implemented in Laos despite the fact that approximately half of all children in Laos fail to reach their full developmental potential (Grantham-McGregor et al., 2007; Lu, Black, & Richter, 2016). Further, only 25% of Lao mothers are involved in four or more play activities with their under-five child over a period of three days, and only 3% of households own three or more children's books (UNICEF, 2012). Promoting adequate opportunities for play and communication is essential for supporting children's healthy development. As such, making CCD accessible to families in Laos is an important step towards supporting optimal child development in the country.

Study Overview

The overarching objective of this dissertation is to improve the developmental potential of children under five years of age among rural populations in Laos through the implementation of a culturally adapted CCD. The first goal is to culturally adapt CCD for use in Laos and to assess the adapted program's acceptability. The second goal is to examine effects of the adapted intervention on caregiving practices and children's cognitive and language development. We test two delivery formats of the adapted intervention, an individual family format and a group-based community format.

The specific research questions of this dissertation are:

- **Research Question 1. Intervention Acceptability.** Is a single session of a culturally adapted early intervention acceptable in terms of caregivers' perceptions that the intervention delivers benefit?
- **Research Question 2: Intervention Effects on Caregiving Practices.** Do caregivers in the intervention conditions show greater increases on indicators of caregiver stimulation practices at one-month post-intervention, relative to the control condition?
- **Research Question 3: Intervention Effects on Children's Cognitive and Language Development.** Do children in the intervention conditions show greater increases on indicators of child cognitive and language development one-month post-intervention, relative to the control condition?
- **Research Question 4: Family- vs. Community-Level Intervention Effects.** What is the relative efficacy of the family-level intervention compared to the community-level intervention with respect to caregiving practices and children's cognitive and language development?

I attempt to address the research questions outlined above in the following chapters. Chapter II documents the systematic cultural adaptation of the generic CCD for Laos, and describes the resulting intervention, *Phadthana Khong Dek* (PKD; English translation: Child Development). Process adaptations (e.g., focus groups to identify parenting goals and needs, and relationship-building with stakeholders) and content adaptations (e.g., adaptations across several domains including language, persons, metaphors, content, concepts, goals, methods, context) following established models of cultural adaptation are described. The acceptability of the adapted intervention is assessed among 93 Lao families who received the adapted intervention. Implications and future directions are discussed.

In Chapter III, I examine whether a single session of PKD can improve caregiver stimulation practices and cognitive and language outcomes among 159 caregivers and their under-five children in Laos. Trial arms included control, family-, and community-level intervention conditions. Analyses controlled for sociodemographic risk factors (e.g., caregiver education level, caregiver depression, ethnicity) as well as baseline measures of caregiving and development. A primary question was whether changes in caregiving stimulation practices was greater for caregivers in the intervention groups compared to the control group. Similarly, a secondary question was whether changes in children's early cognitive and language development was greater for children in the intervention groups compared to the control group. A third question was whether caregiving practices mediated any intervention effects on children's cognitive and language development. For all three questions, the relative efficacy of the family- level and community-level intervention conditions against the control condition was identified. Results of this study have implications for intervention implementation and scaling.

Chapter IV summarizes findings across Chapters II and III and provides a general discussion of implications and future directions.

This dissertation contains unpublished co-authored material under review for publication. The studies described in Chapters II and III are co-authored with C. Lattanavong, O. Inthachith, D. Wright, and J. Measelle and are currently under review for publication.

CHAPTER II

CULTURAL ADAPTATION OF A RESPONSIVE STIMULATION INTERVENTION FOR USE IN LAOS

C. Lattanavong, O. Inthachith, D. Wright, and J. Measelle are co-authors on this manuscript, which is currently under review for publication. I wrote this manuscript with editorial assistance from J. Measelle. Data was collected with assistance from C. Lattanavang and O. Inthachith. All authors provided input on the adaptation procedure described.

Introduction

Early interventions that promote sensitive and responsive caregiving through age appropriate and stimulating play are associated with a host of positive developmental outcomes across cultures (Aboud & Yousafzai, 2015; Britto et al., 2017; Mesman, van IJzendoorn, & Bakermans-Kranenburg, 2011; Rao et al., 2014). Despite their clear public health benefit, early interventions are underutilized in addressing health disparities in low- and middle-income countries, where 250 million children under age five fail to reach their full developmental potential (Black et al., 2017; Collins et al., 2011). This is part of a pervasive problem termed the 10/90 gap (Saxena, Paraje, Sharan, Karam, & Sadana, 2006), where only 10% of the world's spending on health research is directed towards problems that affect the poorest 90% of the world's population. In research on infant mental health and development, the problem is even more pronounced; only 2.3% of articles include data from low- and middle-income countries (Tomlinson, Bornstein, Marlow, & Swartz, 2014). Given that 92% of the world's children live in low- and middle-income countries, the

imbalance is alarming and urgent progress is needed to increase the availability and implementation of early interventions in low-resource settings (Engle et al., 2013).

One step towards addressing health disparities that begin in early childhood is to culturally adapt effective, evidence-based early interventions for underserved populations. Culturally adapted interventions can produce considerably better outcomes than unadapted versions of the same intervention with medium effect sizes (Hall, Ibaraki, Huang, Marti, & Stice, 2016; Smith, Rodríguez, & Bernal, 2011). Additionally, given the extensive influence of culture on caregiving (Bornstein & Putnick, 2012), cultural adaptations are particularly pertinent with respect to interventions that target caregiving. We believe that increasing accessibility to culturally appropriate and effective early interventions is a scientific imperative that has the potential to halt the progression of poor outcomes, and to promote child development in low- and middle-income countries. As such, the primary goal for this paper is to describe the cultural adaptation process for an evidence-based responsive stimulation intervention aimed at supporting early development in Laos, a lower-middle income country in Southeast Asia.

Care for Child Development

Care for Child Development (CCD; UNICEF & WHO, 2012) is an early intervention designed to support children's development through age-appropriate play and communication activities that also build caregivers' capacity to be sensitive and responsive. CCD is based on evidence that basic caregiver skills, such as sensitivity and responsiveness, as well as cognitive stimulation, play a critical role in children's development, and can be taught to caregivers (Behrman & Urzúa, 2013; Bornstein & Putnick, 2012). The generic intervention includes a poster with play and communication recommendations that differ by child age. The poster includes

illustrations of some recommended activities and is meant to be broadly applicable to diverse contexts. In conjunction with this poster, the program uses a four-step counseling approach: (1) Ask and Listen, (2) Praise, (3) Advise, and (4) Check Understanding. Specifically, health workers (1) ask about and listen to caregivers describe how they play and communicate with their child. The health worker then (2) praises the actions of the caregiver that are positive, and (3) provides advice as needed using the poster's activity recommendations. Finally, the health worker (4) checks for understanding by encouraging the caregiver to try out activities during the visit.

To date, CCD has been used in 19 countries (Richter et al., 2017) including Brazil (dos Santos et al., 1999), Turkey (Ertem et al., 2006), China (Jin et al., 2007), and Pakistan (Yousafzai et al., 2014, 2015), with studies finding enhanced early cognitive and social-emotional development among children receiving CCD, as well as positive effects on caregiver knowledge and skills. Given these promising effects, CCD appeared well-suited for use in Laos, a country in which numerous hardships often focus caregivers' attention on basic issues of child survival and less so on issues of thriving (Phanjaruniti, 1994). Approximately half of all children in Laos fail to reach their full developmental potential (Grantham-McGregor et al., 2007; Lu et al., 2016). Further, Lao children are behind their peers in other low- and middle-income countries in terms of access to opportunities for cognitive stimulation and social-emotional learning. For example, only 25% of Lao mothers are involved in four or more play activities with their under-five child over a period of three days. In contrast, in neighboring Thailand, that figure is 68% (UNICEF, 2012). Further, only 3% of Lao households own three or more children's books, whereas 43% of Thai households own three or more children's books (UNICEF, 2012). Promoting

adequate opportunities for play and communication is essential for supporting children's healthy development (Behrman & Urzúa, 2013; Bornstein & Putnick, 2012). As such, making CCD accessible to families in Laos is an important step towards supporting optimal child development in the country.

Models of Cultural Adaptation

Recognizing the need for theoretical and practical frameworks to guide the cultural adaptation process, researchers have developed several models for cultural adaptation (see Zayas, Borrego, & Domenech Rodríguez, 2009 for a review of models). These models provide a guide for documenting adaptations and have utility for planning, replicating, and disseminating cultural adaptations of evidence-based practices (Bernal, Jiménez-Chafey, & Domenech Rodríguez, 2009). Broadly, there are two types of cultural adaptation models: those focused primarily on the *process* of adaptation (e.g., Cultural Adaptation Process Model; CAP; (Domenech Rodríguez & Wieling, 2004), and those focused on adaptations to intervention *content* (e.g., Ecological Validity Model; EVM; Bernal, Bonilla, & Bellido, 1995). The current study was guided by both the CAP and EVM.

The CAP specifies a three-phase approach to adaptation (Domenech Rodríguez & Wieling, 2004). Phase 1 involves pre-intervention activities, including evaluating intervention fit for the target population, relationship-building with community stakeholders, and assessing community needs via focus groups. Phase 2 includes implementing, field testing, and revising initial adaptations to intervention and research measures. Phase 3 involves formulating plans for replication and iterative adaptations. The CAP can be used in combination with the EVM (Bernal et al., 1995), which specifies eight overlapping areas for cultural adaptation: language, persons, metaphors, content, concepts, goals, methods, and context.

The CAP and EVM have been used in conjunction in research adapting a parent management training program for Latino parents (Domenech Rodríguez, Baumann, & Schwartz, 2011) and a family strengthening intervention for low-income Latino families (Hurwich-Reiss, Rindlaub, Wadsworth, & Markman, 2014). Both studies included process adaptations guided by the CAP and adaptations to the generic intervention content guided by the EVM. Initial evaluations of the adapted interventions suggest high acceptability by parents and practitioners, reduced parental stress, and improved parenting practices, as well as changes in child behavior. While more work is needed to empirically document the impact of culturally adapting existing evidence-based treatments using the CAP and EVM models, these initial findings suggest that cultural adaptations using the CAP and EVM have promise for interventions such as CCD.

Despite the existence of cultural adaptation frameworks, relatively few published papers document the actual process of cultural adaptation (Baumann et al., 2015; Reese & Vera, 2007; see Domenech Rodríguez et al., 2011; Hurwich-Reiss et al., 2014 for examples). As Baumann and colleagues (2015) highlight, efforts to implement evidence-based programs with diverse groups "must be complemented with evidence-based approaches to cultural adaptation if they are to be adopted, implemented, sustained, and scaled-up in community settings" (p. 118).

The current paper describes the process of culturally adapting CCD for use with Lao families. Data were also gathered to assess the acceptability of implementing the adapted intervention with Lao families. Our hope is to increase transparency about the process of cultural adaptation so that interventions for neglected populations in low- and middle-income countries might become more readily available and remain therapeutically effective.

Method

Participants and Procedure

Participants were 93 caregivers (90% mothers) who were enrolled in the study when the child was between birth and 60 months of age. Participants resided in the predominantly agricultural Pak Ou District in northern Laos. The current study used data collected immediately after the adapted intervention was delivered. All caregivers provided informed consent. Ethics approval for this study was obtained from the institutional review board at the University of Oregon (Protocol 04292016.050).

The process used to adapt CCD was not entirely linear as revisions were continually made at each stage (e.g., also see Domenech Rodríguez et al., 2011). However, for purposes of clarity, the adaptation process will be presented sequentially, guided by the CAP's three-phase model. Changes to intervention content are guided by the EVM and are embedded in the second phase of the CAP's three-phase approach. We attempt to document dynamic feedback loops throughout this linearly-described process (see Figure 1). The resulting program, *Phadthana Khong Dek* (PKD; English translation: Child Development), was developed using the CAP and EVM as frameworks.

Phase 1: Assessing Intervention Fit and Community Needs

The first phase of the cultural adaptation process centered on reviewing the fit of intervention concepts with relevant literature, identifying community needs, and creating collaborative relationships with intervention stakeholders.

Phase 1, step 1: Review of relevant literature. The fit of the intervention with Lao caregiving practices and the broader socioeconomic context was assessed initially through literature review. Laos has over 49 distinct ethnic

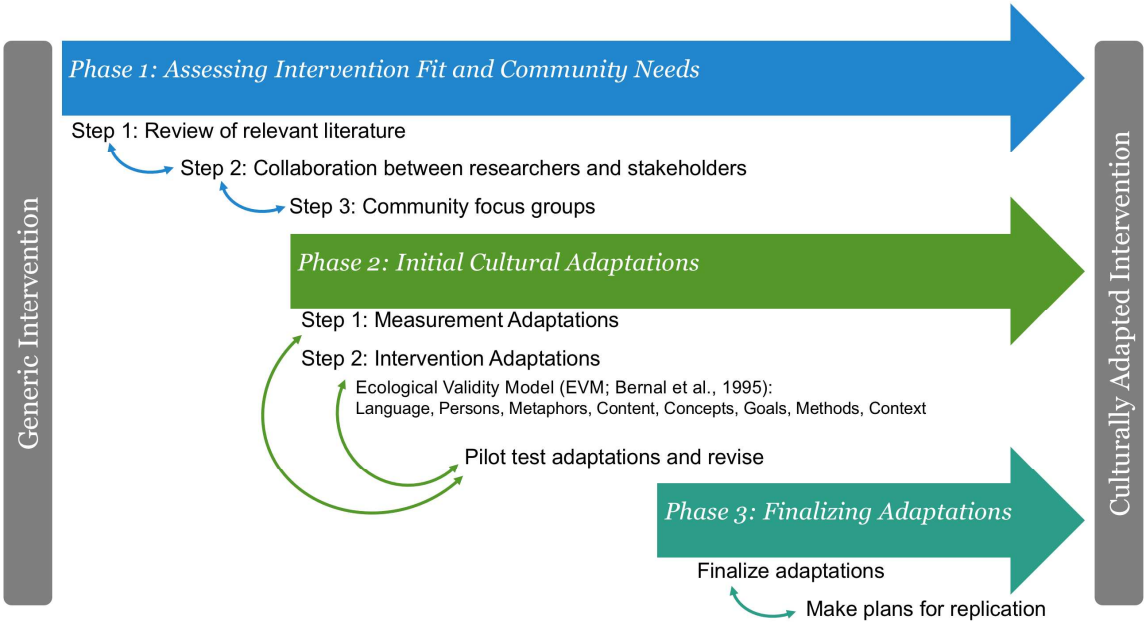

Figure 1. The general process for culturally adapting an intervention using the Cultural Adaptation Process Model (CAP; Domenech Rodríguez & Wieling, 2004) and the Ecological Validity Model (EVM; Bernal et al., 1995) as theoretical frameworks. The CAP specifies a process approach to adaptation while the EVM focuses more on adaptations to intervention content. Following the three-phase CAP approach, Phase 1 involves pre-intervention activities, including review of relevant literature, identifying community needs, and creating collaborative relationships with intervention developers, community leaders, and community members. Phase 2 included cultural adaptations to research measures and the intervention, including content adaptations guided by the EVM, and revisions to the adaptations based on field testing. Phase 3 focused on integrating the information and observations gathered in Phase 1 and 2 and finalizing adaptations to measures and the intervention. The process was not entirely linear, such that lessons learned within each step or phase were incorporated throughout the process of cultural adaptation. These iterative processes are represented by the double-headed arrows.

groups with different languages, practicing different spiritual beliefs, and with different histories and social status (Traditional Arts & Ethnology Centre, 2016). As there is little in-depth research into subgroup differences, it is challenging to discuss and explore culture in Laos without making overgeneralizations about the country. Below, we provide some of the cultural characteristics of Laos that were used to inform our adaption of CCD.

Of the nation's population of 6.6 million, 73% live in rural areas with poor road infrastructure and poor access to sanitation and electricity (WHO, 2015). The country is officially divided into 18 provinces, which are further divided into districts, and then villages. Most villages are ethnically homogenous. Lao are a majority, or about 53% of the population, followed by Khmu (11%) and Hmong (9%; Lao Statistics Bureau, 2016). Compared to Lao and Hmong, Khmu are at higher risk in terms of lower economic status (Vixathep, 2011) and higher rates of infant mortality (Intharack, 2009).

With respect to caregiving characteristics, mothers are typically the primary caregiver from birth to three months (Phanjaruniti, 1994). In general, the first year of a child's life is a precarious time for mothers and children, especially in rural areas where access to basic healthcare, clean water, and sanitation is limited. As such, many traditions associated with pregnancy and childbirth of different groups focus on protecting mother and infant. From three months to three years, mothers often work in the fields (around 80% of the workforce relies on subsistence agriculture; UNICEF, 2014). To keep infants close while leaving hands free to work, women carry infants in baby carriers that secure the child to the mother's back or torso (Traditional Arts & Ethnology Centre, 2016). When working parents cannot take their children with them, they often rely on grandparents or other village members for a supervisory form of childcare (Phanjaruniti, 1994; Traditional Arts & Ethnology Centre, 2016). However, recent data indicates that between 17 and 33% of Lao children are left alone or in the care of another child younger than 10 years of age (UNICEF, 2012).

Caregiving insights led to several initial adaptations to the CCD intervention. For example, we anticipated that caregivers would understandably prioritize child

survival over children's other developmental needs, such as cognitive and social-emotional development. Health workers were encouraged to validate these parental priorities, but to also broaden discussion to include the developmental needs of children that extend beyond survival and physical growth. Additionally, we also recognized the important role played by non-parental caregivers in raising healthy children, and as part of our adaptation, had health workers inquire about and invite other caregivers, including older siblings and grandparents, into the counseling session. Further, health workers were prepared with problem-solving solutions for caregivers who expressed concern over having a lack of time to spend with their children. For example, health workers helped these caregivers to find short periods throughout the day to spend interacting with their young children (e.g., during meal preparation or bathing). These changes are described further in Phase 2, Step 2.

Phase 1, step 2: Collaboration between researchers and stakeholders. In the second step of Phase 1, relationships were forged with stakeholders, including intervention developers, a community partner, government officials, and community leaders and members. The intervention developer, Dr. Jane Lucas, a social and clinical psychologist and consultant to UNICEF and WHO, provided formal CCD training to our research team. Dr. Lucas encouraged fidelity to the intervention's core components (e.g., encouraging caregiver-child play and communication), and also supported cultural adaptations that made CCD more useful for Lao families (e.g., allowing community and individual family delivery formats, language translation, expanding the number of play and communication activities, etc.).

We also established a relationship with our community partner, a local Lao organization with a history of collaborating with villages to support community

needs. Over the course of several meetings with the organization, the research team explained the rationale for the program and demonstrated the program. Interest and enthusiasm from the organization lead to discussions about a formal partnership, which included training of the organization's health workers. Our community partner was critical as a liaison to Lao government officials and helped the research team navigate cultural customs and relationship-building processes important for government partnerships. Lao representatives from the Ministry of Health and the Ministry of Education provided permission for the present study and granted access to villages. Village leaders also agreed on the need for an early childhood intervention for Lao families and allowed research members to engage directly with Lao families.

Phase 1, step 3: Community focus groups. Focus groups were conducted with parents of young children in four villages in Luang Prabang, Laos to assess community interest and needs, and to identify potential changes to intervention content and evaluation measures. Focus groups lasted one to two hours and included approximately 15 parents each, primarily mothers. Parents were asked to describe their desires for their child's future, ways they interacted and played with their child, and ways they helped their child learn.

In terms of hopes for their child's future, parents expressed a common goal of wanting to rear children who would be successful in school, so that they would have a strong foundation for achieving more later in life. This goal is consistent with prior work investigating Lao child rearing practices (Phanjarunti, 1994). In terms of how parents played with their children and helped them learn, parents spontaneously described many activities recommended by CCD. For example, many parents liked smiling and laughing with their children, teaching their children the names of

animals, showing their children how to greet people, and singing with their children. This suggested that many of the basic CCD recommendations were already familiar to parents.

Those themes that emerged from our focus groups with Lao caregivers were used to inform initial modifications to generic CCD materials. For example, based on the value parents placed on education, PKD emphasizes that playing early in life helps children develop important skills that support them in school, and throughout the lifespan. To encourage discussion around the links between early play and communication and later academic achievement, PKD health workers ask parents to answer the questions: "Why is early child development important?" and "How do we support early child development?". While guiding these discussions, PKD health workers explain how parents can help children learn by playing and talking with them, and stress that this early learning can help a child be successful in school. Further, during health worker training, PKD health workers were shown empirical evidence of the causal effects of play and communication on children's short- and long-term development (e.g., Gertler et al., 2014; Grantham-McGregor, Powell, Walker, & Himes, 1991; Tamis-LeMonda, Bornstein, & Baumwell, 2001). Discussion of results from empirical studies helped PKD health workers better understand the rationale and evidence base for the program. In turn, they were also more enthusiastic about conveying this information to caregivers.

In sum, Phase 1 of the CAP focused on several activities for (1) identifying community needs; (2) broadly evaluating the fit and flexibility of the generic CCD intervention for targeting community needs; and (3) relationship-building with intervention developers and community stakeholders. Community needs were identified through a review of the available literature and, importantly, by engaging

Lao families in a series of focus groups. Discussions with the intervention developer and review of the literature on Lao caregiving practices indicated that CCD was flexible and appropriate for targeting community needs. Throughout this process, relationships with our community partner and Lao government officials ensured that the research team and community partner could have access to Lao villages and families. Below, we expand on how findings that emerged across Phase 1 were used to inform Phase 2 cultural adaptations, and further detail cultural adaptations to the generic CCD content guided by the EVM.

Phase 2: Initial Cultural Adaptations

Phase 2 focused on cultural adaptations to research measures and intervention content, including adaptations as recommended by the EVM.

Phase 2, step 1: Measurement adaptations. Measures known to be sensitive to change based on prior studies of CCD in other countries were selected. Domains assessed by our measures include demographics, caregiving stimulation practices, children's cognitive and language development, and questions about the program's acceptability. Results on the program's acceptability are presented in this study; the effects of PKD on other outcomes are reported elsewhere (Fong, Lattanavong, Inthachith, Wright, & Measelle, 2018). As few measures were available in Lao or normed for Lao populations, measures were translated and back translated by a professional translational company, and by individuals with English and Lao fluency. Additionally, all measures were piloted and evaluated prior to use during data collection. For example, measures of early child development based on the UNICEF Multiple Cluster Index Surveys (UNICEF, 2016), were tested with over 800 Lao households as part of a large social determinants of health survey (Measelle, Mobasser, Fong, Soulalay, & Nijssen-Jordan, 2016). Additionally, a measure of

cognitive and language development for children under age three in developing countries (McCoy et al., 2017), was piloted with over 30 Lao families and revised prior to its inclusion in the present study.

Phase 2, step 2: Intervention adaptations – Ecological Validity Model. Cultural adaptations of the generic CCD based on information gathered in Phase 1 and initial field testing with health workers and Lao families, are summarized in Table 1. Below, adaptations to the generic CCD intervention are detailed following the EVM framework (Bernal et al., 1995).

Language. Language in the EVM refers to language translation as well as the use of *culturally syntonic language*. All PKD recommended play and communication activities were illustrated and most text eliminated from the PKD counseling card (Figure 2). The only text retained were headings describing the age group for each set of activities (e.g., 0 to 6 months) and a message at the top of the poster "Play and talk with your child for healthy development". This text was translated from English to Lao by a professional translation company and modified based on feedback by Lao health workers. The generic CCD counseling card, in contrast, includes illustrations and text describing recommendations. Text was eliminated after field testing revealed that extra text distracted caregivers and hindered health workers' ability to effectively convey program content. Illustrations to replace eliminated text were also critical given high rates of illiteracy in the area (27% illiteracy rate; (UNICEF, 2014). Finally, in contrast to the variety of families from different cultures depicted in the original CCD, PKD illustrations depicted Lao families only, to increase cultural relevancy.

Table 1
Summary of PKD Adaptations and Fit with Generic CCD, Organized by EVM Area

EVM	PKD adaptation	Fit with generic CCD
Language	Materials translated from English to Lao	Not available in Lao
	Intervention material conveyed in illustrations depicting Lao families. Most text removed from materials.	Intervention materials relied on text and some illustrations of multicultural families
Persons	PKD health workers selected from diverse ethnic groups	Interventionists and assessors typically selected from population of interest
	Social activities (e.g., ice breakers and movie nights) to build rapport between families and health workers	Social activities not mentioned in CCD
Metaphors	Metaphors evaluated for cultural relevance and appropriateness	Metaphors were essentially equivalent
Content	Caregiver-child activities were evaluated for relevancy	Activities were essentially equivalent
	Additional activities were generated for all age groups and activities were organized into four age bands to facilitate ease of use by caregivers and health workers	CCD included fewer activities and six age bands
	Distinction between “play” and “communication” activities was eliminated on PKD poster	CCD categorized activities as “play” or “communication”
Concepts	Framed concepts of sensitive and responsive caregiving and cognitive stimulation in terms of “play” and “communication” activities	CCD also framed these concepts as “play” and “communication” activities
Goals	Treatment goals evaluated for cultural relevance and appropriateness	Treatment goals were essentially equivalent
Methods	The number of sessions flexible depending on availability of caregivers and health workers.	Number of sessions not specified
	Family- or community-level treatment formats are available	Focused on individual family treatment format
	Retained four-step counseling approach	Four-step counseling approach
Context	Assessments and intervention conducted in village town hall or home to increase accessibility	Location of assessments and interventions were flexible, and conducted in primary care settings, homes, town halls, etc.
	Economic context was considered and Lao children’s books were given to families given the low availability of such books	Children’s books were not given to families

Figure 2. Culturally adapted *Phadthana Khong Dek* poster. The heading reads "Play and talk with your child for healthy development". Activities are divided into the following age bands: 0 to 6 months, 6 to 12 months, 12 to 24 months, 2 years and older, and activities for all ages.

Persons. Persons in the EVM refers to the client-therapist relationship, including *addressing ethnic and racial similarities and differences between client and therapist*. In our adaptation, this included consideration of ethnic differences between dominant (Lao) and minority ethnic groups (e.g., Hmong and Khmu), and the dynamics that might subsequently arise between health workers and caregivers of different ethnic groups. We attempted to select health workers from the three main ethnic groups to ensure some degree of cultural (including language) expertise. Further, PKD health workers spent additional time building rapport and trust in all villages by introducing themselves to families in the week before the start of the

intervention, and hosting social activities in villages, like movie nights. These relationship-building activities potentially contributed to increased interest in the program, participant retention, and engagement.

Metaphors. Metaphors in the EVM refers to the use of local *symbols*, including metaphors, in materials and during sessions. CCD included only one metaphor that was replaced in the adapted PKD. Instead of using a generic CCD metaphor, "a baby's brain is like a sponge", we added a new PKD demonstration meant to highlight the different skills babies learn by playing and talking with caregivers. For example, during the demonstration, PKD health workers ask a caregiver to give a baby a set of colorful plastic cups. As the baby plays with the cups, PKD health workers explain the different skills the child learns, such as how babies learn to reach and grab cups (e.g., motor skill development), learn to stack smaller cups into bigger cups (e.g., cognitive development associated with concepts of size and quantity), and learn social and emotional skills when sharing enjoyment or frustration with caregivers. We felt that this demonstration more vividly captured the skills infants learn compared to the generic CCD metaphor, and also utilized readily available materials (plastic cups).

Content. Content in the EVM includes consideration of the *cultural appropriateness of core intervention content*. More specifically, we considered the cultural appropriateness of the generic CCD play and communication recommendations. As described during Phase 1, Step 3, Lao caregivers participating in focus groups were familiar with many of the generic CCD play and communication activities. Additionally, when working with Lao translators and health workers, we found that every CCD play and communication activity was essentially equivalent in Lao and English. For example, in PKD, we retained the CCD recommendation for

children age 12 months to two years, “Give your child things to stack up, and to put into containers and take out”. Thus, consistent with studies of CCD implemented in other low- and middle-income countries (Ertem et al., 2006; Jin et al., 2007; Yousafzai et al., 2014), all generic CCD play and communication activities were retained. Importantly, caregivers understood the generic play and communication activities and found them to be congruent with ways they already interacted with their children. For example, many caregivers knew how to play “peek-a-boo” without needing a demonstration.

Although CCD’s primary emphasis on play and communication did not require conceptual modifications, based on feedback from focus groups, and work reported in Yousafzai et al. (2014) and Yousafzai et al. (2015), we expanded the number of play and communication recommendations to include more age-appropriate activities that can be made more or less complex for the child. We also organized activities into four age bands (0 to 6 months, 6 to 12 months, 12 to 24 months, and all ages) instead of the original six age bands to facilitate ease of use by caregivers and health workers. We also ensured that activities utilized locally available and low-cost resources (e.g., household items and homemade toys such as wooden or metal spoons and clean plastic cups or bowls).

In addition to increasing the number of activities and eliminating age bands, the explicit distinction between play and communication activities featured in the generic CCD poster was also eliminated from PKD. PKD health workers found significant overlap between play and communication activities and noted that the distinction was difficult to convey to caregivers. For example, book reading promotes both cognitive (e.g., literacy) and social-emotional development (e.g., through close caregiver-child contact and sharing of positive emotions). Similarly, singing also

promotes cognitive development (e.g., through communication with caregivers) and social-emotional development (e.g., through social interaction with others and shared enjoyment). Given that play and communication activities are often bundled and multidimensional, PKD health workers recommended several different activities that encompassed both play and communication (e.g., reading, singing, tossing or rolling a ball between caregiver and child, etc.).

Concepts. In the EVM, concepts refers to the degree to which treatment *constructs* are consistent with local values. Central concepts included early stimulation and sensitive and responsive caregiving. These concepts were framed as "play" and "communication" activities in PKD, which is also consistent with how the concepts are framed in CCD. For example, a PKD health worker might recommend that a caregiver of a baby "get a conversation going with your child by copying your child's sounds or gestures". This stimulating activity emphasizes both sensitivity (reading the child's cues) and responsivity (responding to the child).

Goals. Goals in the EVM refers to the framing of treatment *goals* to be consonant with Lao values. For example, the primary treatment goal in CCD, as in PKD, is to encourage caregivers to play and talk with their young children to support optimal early child development. Although understanding of what constitutes child development differs in Lao vs. Western culture, supporting healthy child development is in line with Lao values. Indeed, Lao caregivers and communities expressed wanting to see their children develop to their full potential; however, it is only recently that Lao caregivers have recognized developmental needs beyond survival and physical growth. For example, only two decades ago, a primary indicator of child success was survival, followed by the goals of having a healthy and physically big child (Phanjaruniti, 1994). Given potentially different understandings of child

development, PKD health workers spent time discussing the importance of other aspects of child development. Overall, this CCD treatment goal was in line with Lao values of raising children that reach their full developmental potential and was retained in PKD.

Methods. In the EVM, methods refers to procedures for achieving goals, including *intervention dosage, intervention delivery approach, and format*. We considered the cultural relevance of delivery methods with respect to session length, approach, and format. CCD does not specify treatment time with respect to the number or length of sessions. PKD was adapted for the rural Lao context, in which health workers may only have the opportunity for one contact with caregivers per year. Further, in recognition of the time constraints of caregivers and health workers, and restrictions on health workers' ability to reach villages during the rainy season when roads are often inaccessible, PKD can be delivered in as little as one session but can also be delivered at multiple time points throughout the child's development. Evidence from prior studies support the short-term efficacy of one and two sessions of CCD ranging from seven minutes to one hour in session length (Ertem et al., 2006; Jin et al., 2007), as well as the short-term efficacy of a higher intervention dosage comprising monthly sessions of CCD over the course a child's first two years of life (Yousafzai et al., 2014, 2015).

We also considered the cultural relevance of delivery methods with respect to CCD's four-step counseling approach described earlier: (1) Ask and Listen, (2) Praise, (3) Advise, and (4) Check Understanding. This approach was retained in PKD. In rural and urban areas, caregivers are typically familiar with hospital staff and visiting health workers that provide maternal and child health counseling, immunizations, and growth monitoring – CCD was explicitly developed to fit in with this approach

(UNICEF & WHO, 2012). Although caregivers may be familiar with health workers providing medical counseling, they may be less familiar with counseling on caregiving. As such, PKD health workers were encouraged to spend more time discussing the rationale behind PKD, and to take care to highlight and praise caregivers' specific strengths and assets. Further, as described above, PKD health workers also generate caregiver "buy in" to the intervention by rapport building (see "persons"), clarifying the problem and reason for the intervention (see "concepts"), and framing treatment goals to be consonant with cultural values (see "goals").

CCD was originally developed to be delivered to individual families. In the present study, we were interested in the comparative efficacy and acceptability of family- versus community-level delivery formats of PKD. We did not have a hypothesis about the comparative efficacy of family-level and community-level treatments given the different benefits and disadvantages for each treatment format. For example, we were curious about whether a community-level approach would be more acceptable given the communal approach to child rearing found in many Lao villages. Community-level treatment could also be valuable given that there are more individuals to identify with, disclose to, and to learn from in a group context. Individual family-level treatment also has its advantages. For example, family-level treatment has the benefit of allowing for greater individual attention to specific personal problems rather than problems of a larger group. Additionally, family-level PKD counseling is familiar to families as health care is often delivered in an individual or family format. Given these differences, we explored the comparative efficacy of family- and group-level delivery formats in a Lao context.

Context. Context in the EVM includes consideration of the *broader social and economic contexts*. For example, PKD sessions were held in accessible and

trusted locations, either in the family's home, or in the village town hall. Economic context was also considered. For example, although PKD recommended that caregivers read with their children, the activity did not hinge on having a children's book. We recognized the limited availability, accessibility, and affordability of children's books and encouraged caregivers to make simple picture books for their children with available materials. Children's books from Lao-based Big Brother Mouse (http://www.bigbrothermouse.com/) were also gifted to caregivers.

In sum, Phase 2 focused on cultural adaptions to measures and the intervention. Cultural adaptations to the intervention were guided by information gathered in Phase 1, as well as the EVM, and summarized in Table 1. PKD adaptations included several changes to the generic CCD poster including the addition of culturally relevant illustrations, an increase in the number of activities, and the elimination of the most text (Figure 2). Phase 3, described below, utilized adaptations from Phase 2 to finalize adaptations to measures and PKD.

Phase 3: Finalizing Adaptations

Phase 3 primarily refers to the iterative process of field testing the adapted intervention, and refining the adapted intervention using Phase 1 and 2 processes. After several iterations, finalized adaptations to the measures and intervention were tested in an efficacy trial (Fong et al., 2018). However, continual field testing of PKD is anticipated to generate some additional changes to future versions of PKD.

Measures

Acceptability. Seven items were used to assess the acceptability of the intervention in terms of caregivers' perceptions of (a) whether or not the health worker was clear and easy to understand during counseling; (b) whether or not the counseling was useful; (c) whether or not the counseling card was useful; (d) whether

or not the intervention was helpful for their child; (e) whether or not the intervention benefited the caregiver; (f) whether or not they believed the intervention would be difficult to put into practice; and (g) whether or not they would recommend the intervention to other families. Response options were dichotomous (yes/no).

Results

Preliminary results as measured by the acceptability of PKD provide initial support for the cultural adaptation process described above. Of the caregivers participating in PKD delivered at the family- or community-level, 100% (n = 93) reported that the health worker was clear and easy to understand during counseling. Additionally, 100% of caregivers reported that PKD counseling was useful and the PKD counseling card was useful. Further, 100% reported that PKD was helpful for their child and beneficial for the caregivers. Finally, 100% of caregivers reported that PKD recommendations were easy to put into practice and reported that they would recommend PKD to other families. Further, other outcome data show the impact of PKD on primary outcomes of interest such as caregiving practices and children's cognitive and language development (Fong et al., 2018), providing further support for the adaptation process and PKD.

Discussion

The cultural adaptation of evidence-based early interventions for young children is a valuable step towards reducing health disparities that begin in early life. Although cultural adaptation is relatively common, the process of adaptation is rarely reported. The overarching goal of this paper was to document the systematic cultural adaptation of the generic CCD for Laos, and the resulting intervention, PKD. The current paper outlined the ways in which two cultural adaptation frameworks (EVM and CAP) were used to inform process and content changes to the generic CCD

for the Lao context. Adaptations involved creating collaborative relationships with intervention and community stakeholders, and implementing changes in broad areas such as language, persons, metaphors, content, concepts, goals, methods, and context (i.e., areas outlined by the EVM). The entire cultural adaptation process was iterative such that continual field testing informed systematic revisions to PKD content and delivery. Preliminary findings suggest that this cultural adaptation process can result in an intervention relevant and useful for Lao families with young children. Further, it is likely that the generic CCD would not have worked as well in the Lao context. Future studies should test this assertion directly.

The cultural adaptation process highlighted the importance of (1) a local needs assessment and (2) trust-building. First, it was critical to establish upfront community needs through focus groups and literature review. These types of assessments were needed for making PKD relevant and useful for Lao families, and for guiding content and process adaptations. For example, focus groups revealed that a common goal among Lao parents was to raise children who were successful in school. While such a parental objective might seem universal or syntonic with most parents' beliefs, in Laos, this parenting aspiration may have inadvertently narrowed parents' choice of learning activities (e.g., activities that were immediately or unmistakably relevant to school) or caused parents to undervalue activities that undergird the development of learning capacity much earlier in life. Using this information, we encouraged PKD health workers to explain how playing and communicating with children from birth onward helps children learn and develop skills important for school. Increasing the relevance of PKD by focusing on goals important to caregivers (i.e., doing well in school) likely helped us gain caregiver "buy in" and PKD uptake. Focus groups with caregivers were also important, as the

most thorough report on Lao caregiving attitudes and practices is grey literature well over two decades old (Phanjarunti, 1994). Continual incorporation of feedback from families, village leaders, Lao health workers, and our local community partner was essential for adapting the intervention to meet local needs.

Second, the cultural adaptation process also underscored the importance of trust-building sessions with local community stakeholders, such as families, village leaders, community partners, and government officials. This type of collaboration allowed us to understand community needs and to align with communities. Trust-building at the start of a PKD session helped health workers build rapport, and likely helped to increase retention and program effectiveness.

Although results begin to support the acceptability of PKD with Lao families, results should be interpreted cautiously. Participants were limited by the dichotomous rating options for the acceptability questionnaire. Future evaluations should provide a Likert-scale for rating items and should also incorporate qualitative questions that allow caregivers to elaborate on their responses. Additionally, less subjective measures, such as retention rates could also be examined. To further substantiate the cultural adaptation process, future studies should examine PKD's effects on child and caregiver outcomes and compare the acceptability and feasibility of PKD with the generic CCD, and with a language translated version of the generic CCD.

The project described in the present report demonstrates how an evidence-based intervention can be culturally adapted systematically using two cultural frameworks (CAP and EVM). Further, this study provides an example of how to document the process of cultural adaptation in a manner that might assist with similar future efforts. In terms of future work to be completed with PKD, we or

others will need to compare PKD directly with the generic CCD to address questions about the circumstances in which cultural modifications are or are not warranted. An insistence on cultural adaptation may create barriers to the timely accessibility of effective interventions or may be less necessary if a program's therapeutic mechanisms are truly universal. On the other hand, the results of several meta-analyses show that culturally adapted treatments have a greater effect in comparison to traditional or unadapted treatments (Hall et al., 2016; Smith et al., 2011). A direct comparison of the adapted and generic version of this intervention will help address these uncertainties and illuminate specific areas more critical for adaptation.

It is our hope that cultural adaptation not only results in a program that is well-received by stakeholders and potential beneficiaries, but begins to ameliorate health disparities that begin in early child development. Disadvantaged children in low- and middle-income countries are less likely to be educated and productive members of society, with these inequities sustaining in future generations (Grantham-McGregor et al., 2007). When large numbers of children are affected, as is often the case in developing countries, national economic development is also adversely impacted. Thus, poor child development has a high cost, both economically and in terms of equity. Early interventions can help break this cycle. Ultimately, increasing accessibility to culturally appropriate and effective early intervention programs such as PKD is a social responsibility that has the potential to halt the progression of poor outcomes and promote optimal child development.

The next chapter of this dissertation examines the efficacy of PKD when delivered at the family-level (PKD-family) and at the village, or community-level (PKD-community). We examine the effects of PKD-family and PKD-community on caregiver stimulation practices and children's cognitive and language outcomes. The

relative efficacy of PKD-family and PKD-community on these outcomes is also explored.

CHAPTER III

EFFECTS OF A RESPONSIVE STIMULATION INTERVENTION ON CAREGIVING AND CHILDREN'S DEVELOPMENT IN LAOS

C. Lattanavong, O. Inthachith, D. Wright, and J. Measelle are co-authors on this manuscript, which is currently under review for publication. I wrote this manuscript with editorial assistance from J. Measelle. I designed the experiment described in this chapter with D. Wright. Data collection was organized by C. Lattanavang and O. Inthachith. I analyzed the data with input from J. Measelle.

Introduction

There is a need for affordable and scalable early interventions in low- and middle-income countries, where children's developmental needs are not an economic priority. In these countries, 43% of children under age five fail to reach their full developmental potential, resulting in an average deficit of 26% of adult annual income (Black et al., 2017; Richter et al., 2017). These children start disadvantaged, continue to fall behind, and are less likely to be educated and productive members of society by adulthood (Engle, Fernald, et al., 2011; Gertler et al., 2014). When large numbers of children are affected, there is also a detrimental impact on national economic development (Engle, Fernald, et al., 2011; Richter et al., 2017). Thus, the loss of developmental potential comes at a high cost, harming the futures of individual children, as well as the communities in which they live.

Early responsive stimulation interventions have shown consistent benefits on children's short-term developmental trajectories across diverse domains (Aboud & Yousafzai, 2015; Britto et al., 2017; Rao et al., 2014). These interventions encourage

caregiver sensitivity and responsiveness during play with their children. These stimulating activities also help young children learn from their environment. Few studies have examined longitudinal effects of responsive stimulation studies, but findings one landmark study in Jamaica showed early intervention effects that persisted through adulthood. In that study, undernourished infants who received two years of a stimulation intervention had improved earnings and reduced participation in violent crime 20 years post-intervention (Gertler et al., 2014; Walker, Chang, Powell, & Grantham-McGregor, 2005; Walker, Chang, et al., 2011). These findings suggest that early interventions can provide individual, social, and economic benefits in low- and middle-income countries, further justifying investment in early child development.

Despite clear and extensive evidence that early interventions reduce inequities in development, few developing countries have implemented early interventions at scale (Engle et al., 2007; Engle, Fernald, et al., 2011; Walker et al., 2007; Walker, Wachs, et al., 2011). Unless governments allocate more resources to effective early interventions for the youngest and most vulnerable populations, disparities in children's developmental potential will persist. Government investment in early interventions in low- and middle-income countries is low for several reasons. One is that the problem of children's loss of developmental potential and its individual and societal cost is not immediately visible (Engle et al., 2007). As such, it may be difficult for governments to justify the long-term investment in early child development. Additionally, policymakers may not implement and scale effective early interventions because they tend to be relatively labor intensive, with most requiring more than 50 hours of contact time with families (Aboud & Yousafzai, 2015), with an average intended duration of 11.5 months (Jeong, Pitchik, &

Yousafzai, 2018). Given these constraints, one way to further persuade governments and policymakers to invest in early child development is to document the effectiveness of interventions that are low cost and more easily scalable.

One low cost and scalable early intervention showing promising outcomes in low- and middle-income countries is Care for Child Development (CCD), a program developed jointly by UNICEF and WHO (Richter et al., 2017; UNICEF & WHO, 2012). CCD is a responsive caregiving and child stimulation intervention in which caregivers engage their young child in stimulating, age-appropriate activities while a health worker coaches and encourages caregiver sensitivity and responsiveness. Activities are low cost or no cost and include reading, singing, counting, stacking objects like bowls, and talking in developmentally appropriate ways. CCD has been scaled and implemented nationwide in three countries, Kazakhstan, Kyrgyzstan, and Tajikistan (Richter et al., 2017). Locally adapted versions of CCD have shown positive effects on early cognitive outcomes and caregiving practices in a number of developing countries. (Richter et al., 2017). Promisingly, two studies have demonstrated the effectiveness of only one or two sessions of CCD (Ertem et al., 2006; Jin et al., 2007), suggesting that a brief CCD is feasible. Further, the cost of implementing and delivering CCD is estimated to be relatively low, with one estimate of approximately $4 USD per month per child (Gowani et al., 2014).

Individual counseling sessions are the default treatment format in CCD (Ertem et al., 2006; Jin et al., 2007; UNICEF & WHO, 2012); fewer have assessed group-based approaches. The largest randomized control trial of CCD to date utilized a combination of individual family and community-level group delivery formats (Yousafzai et al., 2014, 2015), but none thus far have compared the relative efficacy of family- and community-level delivery formats of CCD. Information about the

relative efficacy of different delivery formats could have significant clinical implications and may also be helpful for policy makers seeking to maximize their return on investment in early interventions. The current study examined the relative efficacy of a single session of family-level vs. community-level adaptations of CCD on caregiving stimulation practices and children's early cognitive and language development in rural Laos. We also explored whether caregiving stimulation practices mediated any intervention effects on children's cognitive and language development.

Effects of Responsive Stimulation Interventions on Caregiving

Responsive stimulation interventions in low- and middle-income countries often target caregiving knowledge and practices as a way to support children's early development (Aboud & Yousafzai, 2015; Eshel, Daelmans, Mello, & Martines, 2006; Walker et al., 2007). The effects of responsive stimulation interventions on caregiving was recently summarized in a meta-analysis of 13 responsive stimulation interventions (Jeong et al., 2018). Jeong and colleagues (2018) identified medium to large benefits of these interventions on the home caregiving environment (e.g., availability of stimulating toys; pooled standardized mean difference [SMD] = 0.57), mother-child interactions (SMD = 0.44), and knowledge of early child development (SMD = 0.91).

For example, in Pakistan, in the largest randomized control trial to date (n = 1,125 children receiving the responsive stimulation intervention or control), an adapted CCD delivered in the first two years of life improved mother-child interaction quality (e.g., positive affect, scaffolding, child engagement) and parenting knowledge and practices at 12 and 24 months of age (Yousafzai et al., 2015). Notably, these effects were sustained at four years of age, two years post-intervention, as

caregivers in the responsive stimulation group continued to evidence better responsive caregiving behaviors and increased opportunities for stimulation (Yousafzai et al., 2016). These findings demonstrate the feasibility and effectiveness of delivering CCD at large scale and provided some of the first evidence for the longitudinal benefits of CCD. Evidence from Turkey suggests that even one or two sessions of CCD have a short-term impact on changes in caregiver behavior (Ertem et al., 2006). A single CCD session averaging 12 minutes was provided at a standard clinic visit by trained pediatricians to children age two or younger. One week later, more families in the intervention group, compared to the control group, had made at least one toy for their children, reported reading to their child at least once per week, and had tried a new play activity with their children. Together, these findings provide evidence for the beneficial effects of early responsive stimulation interventions on caregiving practices.

Effects of Responsive Stimulation Interventions on Cognitive Development

Several reviews of responsive stimulation interventions in low- and middle-income countries have also found positive effects of these interventions on children's cognitive and language development (Aboud & Yousafzai, 2015; Britto et al., 2017; Rao et al., 2014). Aboud and Yousafzai (2015) reviewed 21 responsive stimulation interventions delivered to children in the first two years of life and found a moderate effect of responsive stimulation interventions on children's early cognitive (average Cohen's d = 0.42) and language (average Cohen's d = 0.47) skills. Findings from these comprehensive reviews make clear that interventions aimed at encouraging responsive care and increasing opportunities for stimulation are effective at

improving children's short-term cognitive and language outcomes when delivered early in life.

Interestingly, the total amount of contact with caregivers is not related to effect size for interventions delivered to children under age two (Britto et al., 2017; Rao et al., 2014). For example, in rural China, children who received two CCD sessions had greater positive changes in language, adaptive functioning, and social development six months post-intervention, relative to children in the control group (Jin et al., 2007). This suggests that brief interventions may also be effective at inducing short-term change in children's development. Despite consistent evidence for the positive effects of early interventions on children's cognitive and language development, many basic questions about the mechanism for these effects have yet to be answered.

Caregiving and Cognitive Development

Responsive caregiver-child interactions provide important learning opportunities through which children develop cognitive and language capacities (Landry, Smith, & Swank, 2006). Indeed, links between responsive caregiving, the availability of a stimulating home environment, and improvements in children's cognitive outcomes have been well-established. For example, sensitive and responsive caregiving early in life is associated with cognitive and language competencies (Landry et al., 2006; Pearson et al., 2011). Cognitively stimulating environments, including the amount of time caregivers spend talking to their infants, are also well known to promote vocabulary and language development (Page, Wilhelm, Gamble, & Card, 2010; Pan, Rowe, Singer, & Snow, 2005).

Nevertheless, despite these well-documented links, relatively few studies have examined whether changes in caregiving behaviors and opportunities for stimulation

are related to improvements in child outcomes following exposure to intervention. In one study examining mediating effects, the quality of home stimulation and maternal scaffolding independently mediated the effects of CCD on executive functioning and IQ at age four in Pakistan (Obradović, Yousafzai, Finch, & Rasheed, 2016). Notably, CCD continued to have a significant direct effect on children's executive functioning and non-verbal intelligence. Given that both mediators tested in the study emphasized language stimulation, these findings suggest the likelihood that other dimensions of caregiving may further explain intervention effects on development (Obradović et al., 2017). Corroborating this idea, in rural China, Jin and colleagues (2007) found that maternal-child communication (e.g., self-reported use of language to communicate) was related to better motor, adaptive, and social outcomes, but was not related to better language outcomes after two sessions of CCD. This study also highlights the need to better understand mediators not based in language. To help further elucidate the mechanisms through which early interventions improve children's developmental potential, in the present study, we examined whether caregiving practices, as indexed by engagement in different forms of play and the availability of stimulating toys in the home, might mediate intervention effects on cognitive and language development.

Lao Context

Laos is one of the poorest countries in Southeast Asia, ranking 138 out of 188 countries on the 2016 Human Development Index, a proxy for standard of living based on a country's social and economic status (UNDP, 2016). Approximately 16.7% of the population lives below the international poverty line of $1.90 USD a day (UNDP, 2016). Laos is a primarily rural agricultural society, with 80% of the population living in rural areas with poor infrastructure and reliant on subsistence

farming (UNICEF, 2014). The average years of schooling is approximately 4.5 years for women and 5.6 years for men (UNDP, 2016). Literacy rates vary according to socioeconomic status, with 29% of women and 49% of men from the poorest quintile able to read (UNICEF, 2014). There are over 49 distinct ethnic groups in Laos, with the major ethnic groups being Lao (53%), Khmu (11%), and Hmong (9%; Lao Statistics Bureau, 2016). Compared to Lao and Hmong ethnic groups, Khmu are at higher risk in terms of infant mortality (Intharack, 2009) and lower economic status (Vixathep, 2011).

Approximately half of all children in Laos fail to reach their full developmental potential (Grantham-McGregor et al., 2007; Lu et al., 2016). There is a lack of opportunity for stimulation in the home as only 25% of Lao mothers are involved in four or more play activities with their under-five child over a period of three days, and only 3% of households own three or more children's books (UNICEF, 2012). Families in Laos also face incredible challenges to providing nurturing conditions for their children due to low economic prioritization of children's health and developmental needs; less than 1% of Laos' total government expenditures are spent on health (Denboba et al., 2014). Low economic prioritization of children's developmental needs in Laos, combined with inadequate stimulation opportunities, make it a context in which early intervention may be particularly beneficial.

Current Study

The current study randomized villages in northern Laos to participate in a culturally adapted CCD, *Phadthana Khong Dek* (PKD; Fong, Lattanavong, Inthachith, Wright, & Measelle, 2018). Villages were assigned to receive a single session of PKD delivered at the individual family level (PKD-family), the village or community-level (PKD-community), or a control condition. The outcomes of interest

included one-month post-intervention indicators of caregiving (*Aim 1*) that assessed engagement in stimulating play activities (*Aim 1a*) and the likelihood of child play with different toy types (*Aim 1b*). One-month post-intervention indicators of children's cognitive and language development were also of interest (*Aim 2)*. Another study aim was to determine whether caregiving practices mediated intervention effects on children's cognitive and language development (*Aim 3*). For all aims, we were also interested in the comparative efficacy of PKD-family and PKD-community. We hypothesized that both PKD-family and PKD-community would have an effect on caregiving practices and children's cognitive and language development one-month post intervention and that changes in caregiving stimulation would partially mediate intervention effects on children's outcomes. As studies thus far have not directly compared the relative efficacy of family- and community-level interventions, we did not have specific hypotheses about the comparative efficacies of the two delivery formats.

Method

Participants

Participants were 159 children (48% girls) and primary caregivers (94% mothers) who were enrolled in the study when the child was between birth and 60 months of age (M = 17.40 months, SD = 12.07). At baseline, caregivers were 25.75 years of age (SD = 5.57 years) and 17.9% of caregivers reported not completing preschool or primary school. The average number of children per family was 3.97 (SD = 1.16). Participants resided in northern Laos, in the predominantly agricultural Pak Ou District of the Luang Prabang Province. Cash crops and subsistence farming were the primary source of living for 94.2% of the sample. The majority of our

sample were Khmu (77%), followed by Hmong (19%). See Table 2 for additional descriptive statistics.

Table 2
Baseline Characteristics of Control and Intervention Groups

	Control (*n* = 42)		PKD-family (*n* = 79)		PKD-community (*n* = 38)	
Sociodemographic Characteristics	*n*	(%)	*n*	(%)	*n*	(%)
Child age (months)	18.12	(11.91)	17.76	(12.88)	15.84	(10.62)
Female gender of child	21	(50%)	37	(48%)	18	(47%)
Caregiver age (years)	25.27	(4.82)	25.86	(5.84)	24.90	(5.83)
Female gender of caregiver	39	(93%)	76	(100%)	31	(82%)
Caregiver's education level completed						
None	10	(24%)	16	(22%)	1	(3%)
Primary school	26	(63%)	17	(23%)	2	(5%)
Secondary school	3	(7%)	27	(36%)	27	(71%)
Higher than secondary school	2	(5%)	14	(19%)	8	(21%)
Negative screen for caregiver depression	9	(22%)	14	(19%)	5	(13%)
Ethnicity						
Khmu	21	(50%)	64	(85%)	37	(97%)
Hmong	19	(45%)	11	(15%)	0	(0%)
Other (Lao or Leu)	2	(5%)	0	(0%)	1	(3%)
Number of children in household	4.29	(1.29)	3.93	(1.19)	3.68	(0.84)
Number of children in household	4.29	(1.29)	3.93	(1.19)	3.68	(0.84)
Baseline caregiver stimulation scores	1.76	(0.35)	1.54	(0.74)	1.52	(0.53)
Baseline child play with homemade toys	25	(60%)	42	(56%)	7	(23%)
Baseline child play with manufactured toys	22	(52%)	37	(49%)	7	(23%)
Baseline child play with household objects	7	(17%)	24	(32%)	10	(26%)

Note. Values for child age, parent age, number of children in household, baseline caregiver stimulation scores, and baseline cognitive and language scores are presented as mean (standard deviation). Data are otherwise presented as *n* (valid percentage). Negative screen for caregiver depression was defined as "no" responses to both questions on the Patient Health Questionnaire-2 (Whooley et al., 1997).

Attrition prior to intervention delivery (n = 24) was primarily due to an inability to re-contact the family or to the family declining to participate in the intervention. Village leaders informally interviewed cited the harvesting season as a reason many families were unable or unwilling to participate in the intervention. At baseline, children in the attrited group were significantly more likely to play with household objects as toys ($\chi^2(1) = 4.06$, $p = .04$). There were no other significant differences between attrited families and non-attrited families on any other measures or sociodemographic variables (i.e., child age, child gender, caregiver age, caregiver gender, education level, caregiver depression, ethnicity, family size). A total

of 142 (89.3%) families completed the one-month follow up, including 13 of the families that received the baseline assessment, but attrited before receiving the intervention.

Procedures

Families living in four villages in the Pak Ou District of Laos were invited to participate in the study if they had at least one child under age five. Each village was randomly assigned to receive a single session of PKD-family or PKD-community or were assigned to the comparison control condition. Two villages were randomly assigned to receive PKD-family. There were no significant differences in the two villages assigned to receive PKD-family on any baseline measures, or sociodemographic variables. Subsequent analyses were collapsed across the two villages that received PKD-family.

The current study used self-report data collected at baseline prior to the intervention and at one-month post-intervention. All questionnaires were administered in the local language (Khmu, Hmong, or Lao) by the trained assessment team, or through the aid of an interpreter. All caregivers provided informed consent and could refuse an interview or assessment at any time. Ethics approval for this study was obtained from the institutional review board at the University of Oregon (Protocol 04292016.050).

Interventions

Health workers delivered PKD, an adaptation of CCD, to families in the two intervention conditions. PKD was developed following theoretically-driven models of adaptation focused on process (Domenech Rodríguez & Wieling, 2004) and content (Bernal et al., 1995) changes. Process adaptations centered on collaborating with stakeholders and identifying community needs. Content adaptations included

changes to language, such as the elimination of text from visual aids and the addition of illustrations capturing caregiver-child play within the Lao sociocultural context. Details of the cultural adaptation process are reported elsewhere (Fong, Lattanavong, Inthachith, Wright, & Measelle, 2018).

PKD promotes caregivers' sensitivity and responsiveness in the context of developmentally appropriate caregiver-child activities. Health workers suggest activities for caregivers to try with their child. While the caregiver tries activities with their child, the health worker observes and provides feedback to enhance the quality of the interactions. PKD-family was delivered in the home to individual families. PKD-community was delivered to all participating families within a village, typically in the village's town hall.

Measures

Intervention exposure. A dummy variable represented children's exposure to PKD-family (n = 79) vs. control (n = 42), and a separate dummy variable was created to represent children's exposure to PKD-community (n = 38) vs. control.

Caregiver stimulation. Caregiver's stimulation practices were assessed at baseline before the intervention and one-month post-intervention using items from the Early Child Development module of the UNICEF Multiple Cluster Index Surveys (UNICEF, 2016). Caregivers were asked to report on whether mothers, fathers, and/or other household members were engaged in any of the following six activities with their children in the past three days: (1) reading books or looking at pictures; (2) telling stories; (3) singing songs; (4) taking the child outside; (5) playing with the child; (6) naming, counting, or drawing with the child. A total score was created for mothers, fathers, and other household members, which ranged from 0 (no caregiver engagement in any stimulation activity) to 6 (caregiver engagement in all stimulation

activities within the last 3 days). The total score for mothers, fathers, and other household members was summed to create a single composite score ranging from 0 (no caregiver engagement in any stimulation activity) to 18 (engagement in all stimulation activities across all caregivers).

Toy play. Different types of toy play were also assessed at baseline and one-month post intervention using an item from the Early Child Development Module of the UNICEF Multiple Cluster Index Surveys (UNICEF, 2016). Primary caregivers were asked to report on whether their child plays with any of the following types of toys: (1) homemade toys (e.g., homemade dolls and cars); (2) toys from a shop or manufactured toys; (3) household objects (e.g., bowls or pots) or objects found outside (e.g., sticks, rocks, leaves). These items are a proxy for the availability of different toy types in the home. A dichotomous variable was created for each type of toy (0 = no, 1 = yes).

Cognitive and language development. Children's cognitive and language development was assessed at baseline and one-month post-intervention using the cognitive and language subscales of a language-adapted early version of the Caregiver Reported Early Child Development Index (CREDI; McCoy et al., 2017). The CREDI has been tested in more than 15 low- and middle-income countries, including Laos, and is designed to be culturally and linguistically neutral (McCoy, Fink, & Pierre-Louis, 2018). The 0 to 12 month, 13 to 24 month, and 25 months and older versions were used. For each item, caregivers responded "no" (0) or "yes" (1) to questions about their children's cognitive and language abilities. A cognitive and language development score was generated for each of the three age groups by summing up all items from 0 to 12 months (22 items), 13 to 24 months (32 items), and 25 months and older (31 items).

As recommended by a CREDI developer (D.C. McCoy, personal communication, April 11, 2018), a single composite score was generated by imputing "yes" responses (1) for items that were not asked of a child because they were too easy for the child's age. Similarly, "no" responses (0) were imputed for items that were not asked because they were too hard for a child's given age. There was overlap in the last 8 items of the 0 to 12 month scale and the first 8 items of the 13 to 24 month scale. Additionally, the first 26 items of the 25 months and older scale overlapped with the last 26 items of the 13 to 24 month scale and also overlapped with the last two items of the 0 to 12 month scale. Therefore, to generate the final composite score, a basal score of "14" was added to all 13 to 24 month scores and a basal score of "20" was added to all 25 month and older scores. The final composite CREDI score ranged from 0 to 51, with higher scores reflecting greater cognitive and language abilities.

Sociodemographic covariates. The following sociodemographic covariates were assessed by caregiver self-report at baseline: (a) child age; (b) child gender; (c) caregiver gender; (d) caregiver's highest level of education completed; (e) caregiver depressive symptoms; (f) ethnicity; and (g) family size as indexed by the total number of children in the household. The Patient Health Questionnaire-2 (PHQ-2; Whooley, Avins, Miranda, & Browner, 1997) was also used to screen for major depressive disorders. The PHQ-2 has been used successfully in a range of cultures and languages (Bosanquet et al., 2015; Manea et al., 2016). The PHQ-2 is comprised of two items that ask about depressed mood ("During the past month, have you often been bothered by feeling down, depressed, or hopeless?') and anhedonia ("During the past month, have you often been bothered by little interest

or pleasure in doing things?"). Participants responding "no" to both questions were identified as screening negative for depression.

Data Analytic Plan

All analyses were conducted in SPSS version 25 using an intention-to-treat design. Independent *t*-tests and chi-square tests were conducted to compare groups at baseline. Multivariate analyses consisted of hierarchical linear and logistic regression models that controlled for baseline measures to account for any potential baseline differences in outcomes of interest. Specifically, for each regression analysis, sociodemographic covariates and baseline measures of interest were included in Step 1 and intervention dummy codes were entered in Step 2. Baseline and outcome measures of caregiver stimulation and children's cognitive and language development were log-transformed to improve their distributional properties. Dummy codes were created for child and caregiver gender (male vs. female), caregiver's education level (primary school vs. no education, secondary school vs. no education, higher than secondary school vs. no education), parental depression (positive vs. negative screen for depression), ethnicity (Hmong, Lao, or Leu vs. Khmu), and intervention conditions (PKD-family vs. control and PKD-community vs. control). Effect sizes (Cohen's *d*) were calculated by taking the difference in estimated marginal means between intervention and control groups over the pooled standard deviation. Bootstrapping mediation analyses (Preacher & Hayes, 2008) based on 1,000 bootstrap samples at a 95% confidence interval were used to test the hypothesis that caregiver practices (i.e., caregiver stimulation and the availability of stimulating toys for child play) would mediate intervention effects on children's cognitive and language development. Sociodemographic variables and baseline cognitive and language scores were covariates in bootstrap mediation tests.

Results

Baseline Data and Bivariate Correlations

Descriptive statistics for baseline characteristics across intervention groups can be found in Table 2. At baseline, there were significant differences between intervention groups on caregiver gender ($\chi^2(2) = 14.38$, $p = .001$), caregiver education level ($\chi^2(8) = 59.14$, $p < .001$), and ethnicity ($\chi^2(4) = 32.52$, $p < .001$). As noted, we controlled for these sociodemographic variables across all analyses. Additionally, intervention condition was significantly related to baseline play with homemade toys ($\chi^2(2) = 17.48$, $p < .001$) and manufactured toys, ($\chi^2(2) = 12.12$, $p = .002$). Post-hoc comparisons using Bonferroni corrections indicated that a smaller proportion of families in the PKD-community condition reported play with homemade toys and manufactured toys at baseline, compared to PKD-family and control conditions. There were no significant differences between PKD-family and control conditions on baseline play with homemade toys or manufactured toys (Table 2). There were no other significant differences between groups on any other baseline measures or sociodemographic variables ($p > .05$).

Bivariate correlations among all study variables can be found in Table 3. Exposure to PKD-family was associated with higher levels of play with all three toy types post-intervention. In contrast, exposure to PKD-community was associated with lower levels of play with all three toy types at baseline and post-intervention. At baseline, higher caregiver stimulation scores were associated with higher levels of homemade toy and manufactured toy play, and unexpectedly, lower levels of post-intervention household object play. Higher caregiving stimulation scores at baseline

Table 3
Bivariate Associations for All Study Variables

Measure	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
1. PKD-family	-																			
2. PKD-community	-.56**	-																		
3. Child age	.03	-.07	-																	
4. Child gender	.01	.01	.01	-																
5. Caregiver gender	-.26**	.28**	-.04	-.06	-															
6. Caregiver primary edu	-.14	-.31**	.08	.08	-.11	-														
7. Caregiver secondary edu	-.02	.40**	-.14	-.04	.13	-.50**	-													
8. Caregiver > secondary edu	.09	.08	.06	-.04	.03	-.28**	-.33**	-												
9. Caregiver depression screen	-.02	.08	-.05	-.13	-.08	.01	.20*	-.16*	-											
10. Ethnicity	-.16	-.26**	-.09	.09	-.01	.08	-.34**	-.10	-.17*	-										
11. Num. of children	-.03	-.14	-.06	-.01	-.04	.23**	-.26**	-.13	-.10	.30**	-									
12. Caregiver stimulation (BL)	-.09	-.07	.30**	-.07	-.07	.10	-.12	.16	.10	-.10	.03	-								
13. Caregiver stimulation (PI)	-.03	.07	.13	.13	.27**	.01	-.18*	-.04	-.28**	.18*	.15	-.13	-							
14. Homemade toys (BL)	.16*	-.36**	.20*	.03	-.09	.15	-.18*	.09	.01	.07	.04	.24**	.00	-						
15. Homemade toys (PI)	.47**	-.36**	.31**	.03	-.17*	.00	-.25**	.10	.02	.03	-.03	.13	.16	.21*	-					
16. Manufactured toys (BL)	.13	-.28**	.21**	.01	-.07	.10	-.10	.13	-.04	-.07	-.02	.25**	-.07	.88**	.14	-				
17. Manufactured toys (PI)	.49**	-.42**	.30**	.10	-.12	.10	-.29**	.08	-.07	.01	-.14	.06	.13	.19*	.87**	.16	-			
18. Household objects (BL)	.12	.00	.09	-.10	-.10	-.07	.02	-.18*	.16*	.08	.08	-.02	.08	.13	.03	-.04	.00	-		
19. Household objects (PI)	.33**	-.20*	-.13	.15	-.10	.13	-.18*	-.18*	-.08	.20*	.12	-.30**	.35**	.02	.21*	-.10	.32**	.22**	-	
20. Child cog/lang (BL)	-0.02	-0.06	.70**	-0.02	-0.09	0.14	-.22*	0.00	-0.05	0.10	0.15	.32**	.29**	.21**	.31**	0.14	.25**	0.15	-0.05	-
21. Child cog/lang (PI)	0.11	-0.06	.76**	-0.01	-0.02	0.04	-.17*	0.11	-0.01	-0.03	-0.02	.28**	.21*	0.12	.36**	0.09	.32**	0.08	-0.06	.71**

Note. BL = baseline, PI = post-intervention
*p<.05, **p<.01

were also associated with higher cognitive and language scores among children at baseline and post-intervention. Post-intervention, higher caregiver stimulation scores were associated with increased household object play and higher cognitive and language scores among children. Increased levels of homemade and manufactured toy play at baseline were associated with higher cognitive and language scores at baseline and post-intervention.

Intervention Effects on Caregiver Stimulation Practices (Aim 1a)

A hierarchical linear regression was conducted to explore intervention effects on caregiver stimulation practices one month after treatment, controlling for sociodemographic covariates and baseline stimulation practices (Table 4). Approximately 35% of the variance in one-month post-intervention caregiver stimulation practices was explained by the full hierarchical linear regression model, $F(12,119) = 5.41$, $p = .001$. In the final model, older child age at baseline ($b = 0.01$, $p = .04$) and being a male caregiver ($b = 0.42$, $p < .001$) were significantly associated with higher post-intervention stimulation scores, whereas having a secondary level of education ($b = -0.34$, $p < .001$) or higher ($b = -0.35$, $p < .001$) and screening for depression ($b = -0.24$, $p = .007$) were significantly associated with lower post-intervention stimulation scores.

Together, the intervention conditions accounted for an additional 5% of variance in post-intervention stimulation scores, over and above sociodemographic variables and baseline stimulation scores ($p = .01$). Further, relative to control caregivers, PKD-family ($b = 0.19$, $p = .02$) and PKD-community ($b = 0.30$, $p = .003$) caregivers had significantly greater increases in caregiver stimulation scores, controlling for baseline scores and sociodemographic variables. A medium effect size was observed for PKD-family relative to control (Cohen's $d = 0.54$, adjusted

Table 4
Hierarchical Multiple Regression Analyses Predicting Post-Intervention Caregiver Stimulation

Predictor	*b*	*SE*	*β*	*t*
Step 1		F=5.20***, R^2=.30		
Child age (months)	0.01*	0.00	0.17	2.17
Child gender (0=female, 1=male)	0.11*	0.06	0.16	2.04
Caregiver gender (0=female, 1=male)	0.43***	0.11	0.30	3.85
Caregiver's education level completed				
Primary school vs. No education	-0.21*	0.09	-0.27	-2.35
Secondary school vs. No education	-0.29**	0.10	-0.39	-2.97
Higher than secondary school vs. No education	-0.28**	0.10	-0.30	-2.73
Screen for caregiver depression (0=negative)	-0.18*	0.08	-0.19	-2.32
Ethnicity (0=Khmu, 1=Hmong, Lao, or Leu)	-0.02	0.08	-0.03	-0.31
Number of children in household	0.03	0.03	0.10	1.19
Baseline caregiver stimulation	-0.07	0.05	-0.12	-1.40
Step 2		F=5.41***, R^2=.35, ΔR^2=.05**		
Child age (months)	0.01*	0.00	0.16	2.04
Child gender (0=female, 1=male)	0.09*	0.05	0.13	1.73
Caregiver gender (0=female, 1=male)	0.42***	0.11	0.30	3.81
Caregiver's education level completed				
Primary school vs. No education	-0.14	0.09	-0.18	-1.59
Secondary school vs. No education	-0.35***	0.10	-0.47	-3.62
Higher than secondary school vs. No education	-0.35***	0.10	-0.37	-3.39
Screen for caregiver depression (0=negative)	-0.20**	0.07	-0.22	-2.74
Ethnicity (0=Khmu, 1=Hmong, Lao, or Leu)	0.08	0.08	0.09	0.92
Number of children in household	0.03	0.03	0.08	1.02
Baseline caregiver stimulation	-0.04	0.05	-0.06	-0.68
Condition				
PKD-family vs. Control	0.19*	0.08	0.26	2.39
PKD-community vs. Control	0.30**	0.10	0.38	3.08

Note. Baseline and post-intervention caregiver stimulation scores are natural-log transformed.
*p<.05, **p<.01, ***p<.001

difference between means [ADM] = 0.19, 95% CI = [0.03, 0.35]), and a large effect size was observed for PKD-community relative to control (Cohen's d = 0.81, ADM = 0.30, 95% CI = [0.11, 0.49]; Figure 3).

Intervention Effects on Types of Toy Play (Aim 1b)

Three separate hierarchical logistic regression models (Table 5) were used to assess the effect of the intervention on children's likelihood of playing with three types of toys (i.e., homemade toys, manufactured toys, household or objects found outside) post-intervention, over and above sociodemographic covariates and baseline likelihood of playing with each toy type.

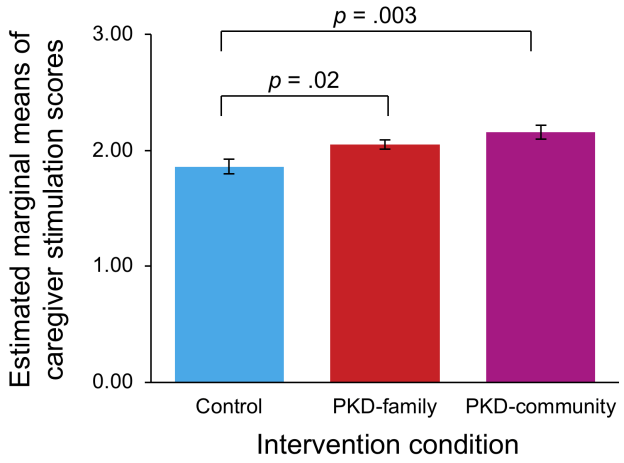

Figure 3. Estimated marginal means of post-intervention caregiving stimulation scores for each intervention condition, controlling for all covariates. PKD-family and PKD-community caregivers had significantly higher post-intervention caregiving stimulation scores in comparison to control group caregivers. Standard errors are represented in the figure by the error bars.

Homemade toys. The full model explained 53% (Nagelkerke R^2) of the variance in likelihood of homemade toy play, $\chi 2(12) = 66.96$, $p < .001$. In the full model, older child age at baseline ($OR = 1.07$, $p = .002$) was significantly associated with increased likelihood of homemade toy play whereas having a secondary level of education ($OR = 0.10$, $p = .009$) was significantly associated with decreased likelihood of homemade toy play. The addition of intervention conditions in the last step contributed significantly to the model, over and above sociodemographic covariates and baseline scores, $\chi 2(2) = 29.71$, $p < .001$. Controlling for baseline homemade toy play and sociodemographic variables, there was an increased likelihood of homemade toy play for families in PKD-family ($OR = 12.84$, $p < .001$) relative to control. The effect of PKD-community compared to control was not significant for this model.

Manufactured toys. The full model explained 58% (Nagelkerke R^2) of the variance in likelihood of manufactured toy play, $\chi^2(12) = 76.37$, $p < 0.001$. In the full model, older child age at baseline ($OR = 1.08$, $p = .002$) was significantly associated

Table 5

Hierarchal Logistic Regression Analyses Predicting Post-Intervention Likelihood of Play with Different Toys

	Types of toys child plays with at home								
	Homemade toys			Manufactured toys			Household or found objects		
Predictor	OR	95% CI		OR	95% CI		OR	95% CI	
Step 1		χ^2=37.24***			χ^2=36.20***			χ^2=33.64***	
Child age (months)	1.05**	1.02	1.09	1.06**	1.02	1.10	0.94	0.89	1.00
Child gender (0=female, 1=male)	1.27	0.56	2.85	1.78	0.79	4.01	2.28	0.69	7.51
Caregiver gender (0=female, 1=male)	0.20	0.02	1.89	0.50	0.09	2.88	0.00	0.00	.
Caregiver's education level completed									
Primary school vs. No education	0.23*	0.06	0.85	0.45	0.13	1.64	0.96	0.19	4.73
Secondary school vs. No education	0.11**	0.03	0.49	0.11**	0.03	0.45	0.11*	0.02	0.75
Higher than secondary school vs. No education	0.46	0.10	2.09	0.37	0.08	1.68	0.00	0.00	.
Screen for caregiver depression (0=negative)	2.33	0.74	7.36	1.13	0.37	3.39	0.42	0.09	1.98
Ethnicity (0=Khmu, 1=Hmong, Lao, or Leu)	0.71	0.23	2.22	0.67	0.21	2.07	0.72	0.17	3.15
Number of children in household	0.86	0.58	1.27	0.62*	0.41	0.93	0.96	0.59	1.57
Baseline score for types of toy play	2.56*	1.13	5.77	1.76	0.78	3.98	5.31*	1.32	21.38
Step 2		χ^2=29.72***			χ^2=40.17***			χ^2=24.92***	
Child age (months)	1.07**	1.03	1.12	1.08**	1.03	1.13	0.93	0.86	1.00
Child gender (0=female, 1=male)	1.25	0.48	3.25	1.75	0.64	4.81	2.25	0.51	9.85
Caregiver gender (0=female, 1=male)	0.78	0.07	8.59	2.98	0.39	23.00	0.00	0.00	.
Caregiver's education level completed									
Primary school vs. No education	0.37	0.09	1.60	0.92	0.21	4.10	3.32	0.38	28.89
Secondary school vs. No education	0.10**	0.02	0.57	0.10*	0.02	0.60	0.13	0.01	1.31
Higher than secondary school vs. No education	0.52	0.09	2.93	0.47	0.07	2.93	0.00	0.00	.
Screen for caregiver depression (0=negative)	3.80	0.93	15.55	1.74	0.43	7.03	0.13	0.01	1.31
Ethnicity (0=Khmu, 1=Hmong, Lao, or Leu)	1.44	0.39	5.35	1.28	0.35	4.70	2.58	0.33	20.41
Number of children in household	0.82	0.53	1.26	0.55*	0.35	0.87	1.03	0.57	1.87
Baseline score for types of toy play (0=no, 1=yes)	2.09	0.78	5.62	1.49	0.53	4.19	5.87*	1.00	34.35
Condition									
PKD-family vs. Control	12.84***	3.32	49.70	17.80***	4.06	77.93	79.96***	6.75	946.69
PKD-community vs. Control	0.82	0.14	4.69	0.48	0.08	3.00	7.25	0.28	191.03

*p<.05, **p<.01, ***p<.001

with increased likelihood of manufactured toy play whereas having a secondary level of education (*OR* = 0.10, *p* = .01) and greater number of children at baseline (*OR* = 0.55, *p* = .01) was significantly associated with decreased likelihood of manufactured toy play. $\chi^2(12) = 58.56$, $p < .001$. In the full model, play with household and found objects at baseline (*OR* = 5.87, *p* = .05) was significantly associated with increased likelihood of this type of play post-intervention. The addition of intervention conditions in the last step contributed significantly to the model, over and above sociodemographic covariates and baseline scores, $\chi^2(2) = 24.92$, $p < 0.001$. Controlling for baseline household and found object play and sociodemographic variables, there was an increased likelihood of household and found object play for families in PKD-family (*OR* = 79.96, p < .001) relative to control. The effect of PKD-community compared to control was not significant for this model.

Intervention Effects on Cognitive and Language Development (Aim 2)

A hierarchical linear regression model was conducted to explore intervention effects on children's cognitive and language scores one month after treatment, controlling for sociodemographic covariates and baseline cognitive and language development scores (Table 6).[1] Approximately 82% of the variance in post-intervention cognitive and language development scores was explained by the full hierarchical linear regression model, $F(12,77) = 28.55$, $p < .001$. In the final model, older child age at baseline (*b* = 0.03, *p* < .001) and higher cognitive and language scores at baseline (*b* = 0.52, *p* < .007) were significantly associated with higher cognitive and language scores post-intervention.

[1] There were 26 baseline and 24 post-intervention CREDI questionnaires administered at incorrect ages (e.g., the 25 month and older CREDI administered to a 6-month-old) secondary to miscommunication with the assessment team and were excluded from analyses. There were no significant differences on any variables between families who were administered the correct CREDI for their child's age and families who were not administered the correct CREDI for their child's age.

Table 6
Hierarchical Multiple Regression Analyses Predicting Post-Intervention Cognitive and Language Outcomes

Predictor	*b*	*SE*	*β*	*t*
Step 1		F=32.42***, R^2=.80		
Child age (months)	0.03***	0.01	0.40	4.04
Child gender (0=female, 1=male)	-0.11	0.11	-0.05	-0.94
Caregiver gender (0=female, 1=male)	0.18	0.19	0.05	0.95
Caregiver's education level completed				
Primary school vs. No education	0.06	0.17	0.03	0.34
Secondary school vs. No education	0.27	0.19	0.12	1.42
Higher than secondary school vs. No education	0.22	0.19	0.08	1.20
Screen for caregiver depression (0=negative)	0.14	0.14	0.05	0.99
Ethnicity (0=Khmu, 1=Hmong, Lao, or Leu)	0.06	0.15	0.03	0.42
Number of children in household	-0.03	0.06	-0.03	-0.60
Baseline cognitive/language scores	0.51	0.09	0.55	5.63
Step 2		F=28.55***, R^2=.82, ΔR^2=.01		
Child age (months)	0.03***	0.01	0.39	4.01
Child gender (0=female, 1=male)	-0.12	0.11	-0.06	-1.11
Caregiver gender (0=female, 1=male)	0.23	0.19	0.06	1.20
Caregiver's education level completed				
Primary school vs. No education	0.20	0.17	0.09	1.13
Secondary school vs. No education	0.26	0.20	0.11	1.33
Higher than secondary school vs. No education	0.19	0.19	0.07	1.01
Screen for caregiver depression (0=negative)	0.16	0.14	0.06	1.12
Ethnicity (0=Khmu, 1=Hmong, Lao, or Leu)	0.21	0.16	0.08	1.33
Number of children in household	-0.03	0.05	-0.02	-0.46
Baseline cognitive/language scores	0.52***	0.09	0.56	5.85
Condition				
PKD-family vs. Control	0.35*	0.15	0.15	2.26
PKD-community vs. Control	0.29	0.18	0.13	1.61

Note. Baseline and post-intervention cognitive/language scores are natural-log transformed.
*p<.05, **p<.01, ***p<.001

Although the full model was significant, the addition of intervention conditions in the last step did not significantly improve the model (ΔR^2 = .01, p = .08). In the final model, relative to control children, PKD-family children (b = 0.35, p = .03) had significantly greater increases in cognitive and language scores, controlling for baseline scores and sociodemographic variables. Children in PKD-community did not have significantly greater increases in cognitive and language outcomes relative to control. A medium effect size was observed for PKD-family relative to control (Cohen's d = 0.60, ADM = 0.35, 95% CI = [0.04, 0.66]; Figure 4).

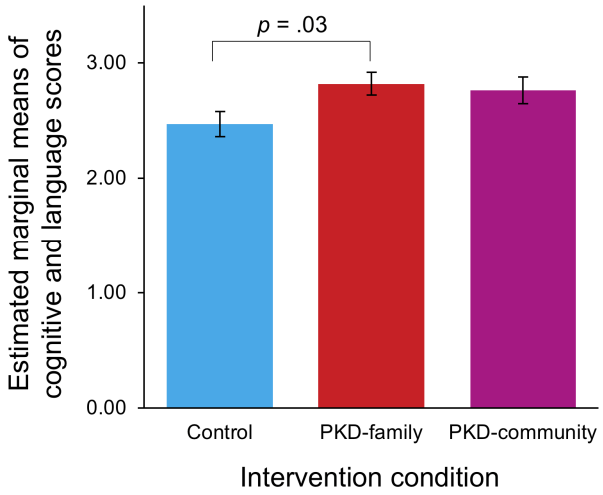

Figure 4. Estimated marginal means of post-intervention cognitive and language scores, controlling for all covariates. PKD-family children had significantly higher post-intervention caregiving stimulation scores in comparison to the control group. There were no significant differences between PKD-community and control group children. Standard errors are represented in the figure by the error bars.

Post-hoc moderation analyses. Given the significant main effects of child age on post-intervention cognitive and language scores (Table 6), post-hoc moderation analyses were performed. The interaction between children's age at baseline (grand mean centered) and PKD-family significantly improved the prediction of post-intervention cognitive and language scores, $\Delta R^2 = .01$, $F(1, 76) = 5.12$, $p = .03$. Overall, the model predicted 83% of the variance in cognitive and language scores, $F(13, 76) = 28.15$, $p < .001$. For both PKD-family ($b = .02$, $p = .01$) and control ($b = .04$, $p < .001$), older child age at baseline was associated with higher cognitive and language scores relative to baseline.

This interaction was further probed using the Johnson-Neyman technique (Bauer & Curran, 2005), which identified the ranges of the moderator (i.e., child age) in which the focal predictor (i.e., PKD-family vs. control) was a significant or nonsignificant predictor of the outcome (i.e., cognitive and language scores). There was a lower bound of significance such that significant differences between children

in PKD-family vs. control emerge at child ages below 19.63 months. Stated differently, among children younger than 19.63 months of age at baseline, there was a significantly greater improvement in cognitive and language scores relative to baseline for PKD-family children relative to control. For children above 19.63 months of age at baseline, there was no significant difference in cognitive and language scores relative to baseline, between PKD-family and control conditions. When data was restricted to children under 19.63 months of age, a large effect size was observed for PKD-family relative to control (Cohen's d = 0.78) on cognitive and language outcomes.

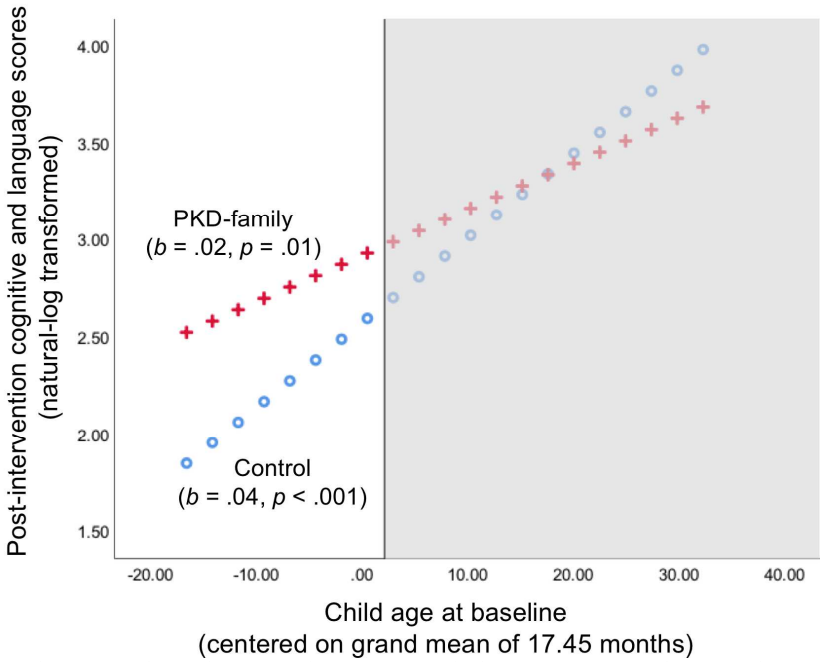

Figure 5. Post-hoc moderation analyses examining one-month post-intervention cognitive and language scores as a function of child age in months at baseline (centered on a grand mean of 17.45 months) and intervention condition. The Johnson-Neyman lower bound of significance is at 2.18, equivalent to a child age of 19.63 months. Shaded region is not significant.

Mediation (Aim 3)

Bootstrapping mediation tests (Preacher & Hayes, 2008) based on 1,000 bootstrap samples were used to test the hypothesis that caregiver stimulation

practices and children's play with different toys would mediate intervention effects on children's cognitive and language scores. Two separate mediation analyses controlling for sociodemographic covariates and baseline cognitive and language scores were used to test the hypothesis that caregiver practices (i.e., caregiver stimulation and the availability of stimulating toys for child play) would mediate intervention effects on children's cognitive and language development. Caregiving stimulation practices was not a significant mediator of PKD-family (estimate = -0.09, bias-corrected 95% CI = [-0.27, 0.003]) or PKD-community (estimate = -0.09, bias-corrected 95% CI = [-0.29, 0.01]) effects on post-intervention cognitive and language scores. In these tests, mediation is indicated when the bias-corrected 95% confidence interval for the indirect effect (e.g., intervention effects on cognitive and language scores through caregiving stimulation) does not include zero.

To test the hypothesis that the availability of stimulating toys for child play mediated intervention effects on children's cognitive and language outcomes, a single composite score for all three toy play items was created by summing up responses across all three items for total scores ranging from 0 (no toys available for child play) to 3 (homemade toys, manufactured toys, and household objects available for child play). This composite toy play score was tested as a mediator in a bootstrapping mediation test controlling for sociodemographic covariates and baseline cognitive and language scores. Composite toy play score was not a significant mediator of PKD-family (estimate = 0.09, bias-corrected 95% confidence interval = -0.10, 0.33]) or PKD-community (estimate = 0.01, bias-corrected 95% confidence interval = -0.17, 0.14]) effects on children's cognitive and language outcomes.

Discussion

The current study investigated the effects of a single session of a responsive stimulation intervention delivered at the individual family-level (PKD-family) or at the community-level (PKD-community) to rural Lao families with children under age five. Our results showed that by one-month post-intervention, significant benefits with moderate to large effects on caregiving stimulation practices were observed as a result of participation in either PKD-family or PKD-community (*Aim 1a*). Additionally, there was also a benefit of PKD-family on the likelihood of child play with different types of stimulating toys (*Aim 1b*). A single session of PKD-family had significant short-term benefits with a moderate effect on cognitive and language outcomes at one-month post-intervention (*Aim 2*). Importantly, child age moderated this effect such that relative to baseline, PKD-family children showed greater improvements in cognitive and language scores compared to control, but only for children who received the intervention before 20 months of age. For children under 20 months of age, there was a large effect of PKD-family on cognitive and language scores. Although there were intervention benefits for caregiving practices (i.e., stimulation and likelihood of child play with different toys) and children's cognitive and language scores, caregiving practices were not signification mediators of intervention effects on children's cognitive and language scores (*Aim 3*).

Intervention Effects on Caregiving (Aim 1)

Caregiver stimulation practices. Consistent with previous studies and our hypotheses, relative to control, both PKD-family and PKD-community caregivers had significantly greater improvements in stimulation practices, controlling for baseline scores and sociodemographic variables. Benefits on caregiving stimulation practices were also seen in other intervention studies in low- and middle-income

countries (Boivin et al., 2013; Cooper et al., 2002), including studies of CCD (Ertem et al., 2006; Yousafzai et al., 2015). Our finding that both family and community-level intervention formats had a positive impact on stimulation practices suggests that regardless of delivery method, caregivers were able to appreciate the importance of stimulation for their child's development after a single session. The recommended activities, which included telling stories and reading books, naming, singing, and playing, appeared to be simple enough for caregivers to report implementing one-month post-intervention; this was likely enhanced by our picture-only coaching card, which was specifically adapted for the Lao context.

We found different effect sizes for the delivery formats on caregiving stimulation practices, with a medium effect for PKD-family and a large effect for PKD-community. The larger effect size for PKD-community on caregiver stimulation practices may be attributable to the fact that, in the group condition, there are more individuals to observe and to learn from. In contrast, there may have been a greater focus in PKD-family on other aspects of caregiving, such as the provision of toys, rather than engaging the child with the toys.

Toy play. Although we found positive effects of participation in both PKD-family and PKD-community on caregiver stimulation practices, there was only a benefit of PKD-family on the likelihood of child play with different types of stimulating toys. It is not entirely clear as to why there was not an effect of PKD-community on likelihood of child play with toys. It may be that PKD-family allowed for greater focus on individual problem-solving, such as identifying objects in the home that could be used to create no cost toys, such as pots and pans for banging, or containers for sorting, counting, and making rattles. In support of this idea, the

largest effect of PKD-family among all toy types was on the likelihood of child play with household objects.

Intervention Effects on Cognitive and Language Development (Aim 2)

Our results provide clear support for the benefit of intervention on cognitive and language outcomes in the first 20 months of life. Children showed the greatest improvements in cognitive and language scores relative to baseline when they were enrolled in PKD-family before 19.63 months of age. Children who received the intervention after 19.63 months showed no differences in change in cognitive and language scores compared to control. These results are consistent with findings from basic and intervention science, which indicate that responsive stimulation early in life confers developmental advantages in part because of the high degree of early brain plasticity (Feldman, 2000; Marshall & Kenney, 2009). Children's early development is an ordered progression of perceptual, motor, cognitive, language, social-emotional, and self-regulation skills characterized by sensitive periods (Sameroff, 2009; Wachs, Georgieff, Cusick, & McEwen, 2014). During these early sensitive periods, there is rapid neuronal proliferation and pruning, synaptogenesis, and white matter development (Webb, Monk, & Nelson, 2001). As such, the brain and many of the body's other biological systems are highly receptive to environmentally stimulating inputs in the early years of life (Knudsen, 2004). In particular, the period between conception and age two years is sensitive to specific experiences. Studies suggest that after age two years, children are less sensitive to intervention effects (Wachs et al., 2014). For example, in Saint Lucia, children between ages 6 and 18 months at the start of the intervention evidenced cognitive improvements whereas no benefits were found for the cognitive development of children receiving the intervention between 18 and 30 months of age (Wint &

Janssens, 2008). Evidence in support of early intervention is also provided by studies of children reared in severely deprived environments, which show that the younger a child is when placed in foster care, specifically, before age two, the better the cognitive outcome (Nelson et al., 2007).

This early plasticity in the first two years means that it is easier to influence brain architecture and subsequent cognitive and language development earlier in life, and more difficult to influence and change brain and child development later in life. Thus, the effects of environments and experiences on the brain and development appear early and having lasting impact throughout the life course (Johnson, 2005; National Scientific Council on the Developing Child, 2007). These basic principles indicate that interventions earlier in life provide maximal benefit in terms of child development. Our findings support this.

Mediation (Aim 3)

Despite finding a direct effect of PKD-family on children's early cognitive and language outcomes and on caregiver stimulation practices, we were unable to find evidence that caregiver stimulation practices or the availability of different toys, mediated intervention effects on children's cognitive and language outcomes in this sample. In contrast, Obradović and colleagues (2016), found that measures of maternal scaffolding and quality of home stimulation mediated effects of CCD on cognitive skills at age four in Pakistan. However, there are several important differences in the study by Obradović and colleagues (2016) and the present study. For example, we used self-report measures whereas Obradović and colleagues (2016) utilized observational measures. In the present study, caregivers reporting higher engagement in stimulating activities with their children may not have necessarily been implementing those activities in practice.

Our findings do corroborate findings from Aboud and colleagues (2013), who found measures of home stimulation were significantly related with children's cognitive and language outcomes. Similarly, we also find that measures of caregiver stimulation and toy play were positively correlated with children's cognitive and language scores at baseline and post-intervention. Although these findings do point to stimulation practices as a mediator of intervention effects, we did not find evidence for this in our sample. The intervention effect found on younger children's cognitive and language skills could have instead been explained by other aspects of caregiving (e.g., sensitivity and responsiveness or paternal influences) not measured in the present study. Future work should examine alternative mediating processes as well as utilize observational measures of caregiving practices.

Implications

Together, findings from the present study have three important implications for intervention implementation. First, echoing others (Daelmans et al., 2017; Engle et al., 2007; Engle, Fernald, et al., 2011; Walker, Wachs, et al., 2011), interventions earlier in life have a greater effect on children's developmental trajectories than interventions delivered later in life. We found an intervention effect on cognitive and language outcomes for children under 20 months of age, but not at older ages, indicating that a single session was able to affect some short-term change in cognitive and language outcomes, but only among the youngest children.

Second, we add to the body of literature suggesting that even a brief intervention can produce measureable intervention effects on caregiving and children's cognitive development (Ertem et al., 2006; Jin et al., 2007; Rao et al., 2014). Given that our intervention was brief, relatively easy to implement, and low-cost, it lends itself well to reaching large populations with limited resources. Our

findings are also important in the context of what is feasible in developing countries such as Laos. In Laos, 80% of the population lives in rural areas that are often made inaccessible during the rainy season (UNICEF, 2014). As such, it may not be realistic to increase intervention dosage. The conditions in Laos are comparable to those in other low- and middle-income countries, in which there may be yearlong service gaps for routine health and nutrition programs (Black et al., 2017). Our results show that a single session can provide some momentum in improving short-term caregiving and cognitive and language outcomes, providing support for pursuing this approach in other settings.

Third, our findings point to differential effects of group vs. individual interventions. We found a greater effect of PKD-family on children's early cognitive and language outcomes and on child play with stimulating toys. Given that a single session of PKD-family was effective at improving short-term outcomes for children and caregivers, consideration should be given to the health sector as an entry point for PKD-family. Health services are well placed to reach children early (Richter et al., 2017) and to deliver interventions at the individual family level. Further, previous studies have shown benefits of integrating responsive stimulation interventions into primary care services (Chang et al., 2015; Ertem et al., 2006). Efforts to build PKD into existing services may also improve cost-effectiveness of the program and facilitate intervention scaling.

Limitations

The present study represents an initial step towards understanding the comparative short-term efficacy of family- and community-level versions of a brief responsive stimulation in Laos. While important, the current study has several limitations. First, measures used in this study are purely based on self-report rather

than observation. Self-report relies on caregiver's recall and subjective interpretation and could also be influenced by social desirability. Thus, it is possible that caregivers could have reported improved stimulation practices or improvements in their children's cognitive and language outcomes, without seeing actual changes. However, findings from this study are similar to those in other low- and middle-income countries that utilize observational methods or a combination of self-report and observational methods (Aboud & Akhter, 2011; Boivin et al., 2013; Walker, Chang, Powell, & Grantham-McGregor, 2004; Yousafzai et al., 2014). One reason the present study did not utilize more objective measures is due to the lack of culturally adapted and valid measures of caregiving and cognitive development in Laos. Future studies should consider using culturally adapted observational measures. Second, study findings are limited in generalizability. Our study is representative of high risk families in rural northern Laos and sociocultural factors unique to this group may not apply to other low- and middle-income settings. However, by showing the feasibility of a brief intervention in a rural and disadvantaged context, we hope others will continue to expand on this work in other low- and middle-income countries.

Conclusion

Our findings suggest that PKD, especially when delivered at the family level, is an effective way to improve short-term caregiving practices and children's cognitive outcomes. These findings replicate findings from many other studies of early responsive stimulation interventions in low- and middle-income countries (Aboud & Yousafzai, 2015; Rao et al., 2014; Richter et al., 2017). The time is now for the scale up of responsive stimulation interventions like CCD (Richter et al., 2017). A scale-up simulating the cost of 98% coverage of CCD in 73 low income to upper

middle-income countries by 2030, showed that the additional investment over the next 15 years would be the equivalent of $0.22 per person, per year (Richter et al., 2017). These data suggest that implementation of CCD represents value for little cost. Early childhood interventions are needed to address the global burden of loss of developmental potential among children in low- and middle-income countries. PKD represents one effective, low-cost, and brief intervention that can begin to address some of this loss among children in Laos.

CHAPTER IV

CONCLUSION

Summary of Findings

Recent estimates suggest that 250 million children in developing countries, or approximately a third of the world's children under age five, are at risk of not reaching their full developmental potential as a result of numerous poverty-related risk factors (Black 2017). Disadvantaged children with delays in development are likely to learn less in school and earn less as adults, thus perpetuating social and health disparities, and contributing to the intergenerational transmission of poverty (Engle, Fernald, et al., 2011; Gertler et al., 2014; Richter et al., 2017). Early responsive stimulation interventions that encourage sensitive and responsive caregiving in the context of stimulating, developmentally appropriate play have shown well-established benefits for the development of children living in low- and middle-income countries (Aboud & Yousafzai, 2015; Britto et al., 2017; Brown, van Urk, Waller, & Mayo-Wilson, 2014; Rao et al., 2014). Consequently, these interventions have drawn attention as a public health strategy for promoting optimal early child development (Britto et al., 2017; Engle, Fernald, et al., 2011; Jeong et al., 2018). However, to our knowledge, no such interventions have been implemented in Laos, a lower middle-income country in Southeast Asia with a high burden of developmental potential loss among children under age five (Lu et al., 2016).

The overarching goal of this dissertation was to examine the efficacy of a culturally adapted responsive stimulation intervention on caregiving practices and children's developmental outcomes in rural Laos. The relative efficacy of family- and

community-level delivery formats was compared. Specifically, at the outset of this dissertation (Chapter I), four specific research questions were identified:

- **Research Question 1. Intervention Acceptability.** Is a single session of a culturally adapted early intervention acceptable in terms of caregivers' perceptions that the intervention delivers benefit?
- **Research Question 2: Intervention Effects on Caregiving Practices.** Do caregivers in the intervention conditions show greater increases on indicators of caregiver stimulation practices at one-month post-intervention, relative to the control condition?
- **Research Question 3: Intervention Effects on Children's Cognitive and Language Development.** Do children in the intervention conditions show greater increases on indicators of child cognitive and language development one-month post-intervention, relative to the control condition?
- **Research Question 4: Family- vs. Community-Level Intervention Effects.** What is the relative efficacy of the family-level intervention compared to the community-level intervention with respect to caregiving practices and children's cognitive and language development?

Below, I address each of these research questions and summarize findings from this dissertation's substantive chapters.

Chapter II makes transparent the cultural adaptation process for Care for Child Development (CCD), an evidence-based, early responsive stimulation intervention that encourages activities known to promote early development, such as storytelling, singing, and playing, and also builds on the capacity of the caregiver to be sensitive and responsive (UNICEF & WHO, 2012). CCD has been evaluated in 19 countries (Richter et al., 2017), with findings showing improvements in caregiving

practices, home environment, and children's development (Ertem et al., 2006; Jin et al., 2007; Yousafzai et al., 2014, 2015). There have been several cultural adaptations of CCD, but the process of adaptation has yet to be documented in a full report. As such, the primary aim of Chapter II was to describe the systematic cultural adaptation of the generic CCD for Laos, and the resulting intervention, *Phadthana Khong Dek* (PKD; English translation: Child Development).

PKD was developed following two theoretically-driven models of cultural adaptation focusing on process (i.e., Cultural Adaptation Process Model; Domenech Rodríguez & Wieling, 2004) and content (i.e., Ecological Validity Model; Bernal, Bonilla, & Bellido, 1995) adaptations. Process adaptations centered on identifying community needs, creating collaborative relationships with intervention stakeholders, and field testing. Content adaptations were made across several overlapping domains, including language, persons, metaphors, content, concepts, goals, methods, and context. For example, in recognition of the country's low literacy rate, adaptations included the elimination of most text and the addition of illustrations capturing typical home environments in Laos. The cultural adaptation process was iterative such that continual field testing informed systematic revisions to PKD content and delivery. Preliminary findings from 93 Lao families receiving the intervention suggested that the cultural adaptions resulted in an intervention that is relevant, useful, and easy to put into practice (**Research Question 1**). By increasing transparency about the cultural adaptation process, our hope is that early interventions for neglected populations in low- and middle-income countries might become more readily available and remain therapeutically effective.

Chapter III presents findings from a study examining the effects of PKD on caregiver stimulation practices and children's cognitive and language development

among 159 caregivers and their under-five children in Laos. Trial arms included control, family-, and community-level conditions. Intervention condition was randomized at the village level. Analyses controlled for relevant sociodemographic (e.g., caregiver education level, child gender, ethnicity) and psychosocial risk factors (e.g., caregiver depression), as well as baseline measures of caregiver practices and cognitive and language development.

Our results showed that by one-month post-intervention, both family- and community-level conditions evidenced medium to large effects on caregiving stimulation practices. There was also a positive effect of the family-level condition, but not the community-level condition, on the likelihood of child play with different types of stimulating toys (**Research Question 2**). The family-level intervention also had significant short-term benefits with a large effect size on cognitive and language outcomes for children who received the intervention at the earliest ages, before 20 months of age, but not at later ages (**Research Question 3**). Although the intervention benefited both caregiving practices and children's cognitive and language outcomes for children under 20 months, caregiving practices did not mediate family-level intervention effects on children's cognitive and language development. Together, our findings suggest that PKD, particularly when delivered at the family-level, is an effective way to improve short-term caregiving practices and children's cognitive and language development in Laos (**Research Question 4**).

Implications

Taken together, the work presented in this dissertation provides support for the acceptability and feasibility of PKD as a brief intervention to enhance caregiving practices and child development in Laos. Three features of PKD are particularly notable and build on other studies demonstrating the efficacy of responsive

stimulation interventions in low- and middle-income countries (Aboud & Yousafzai, 2015; Britto et al., 2017; Rao et al., 2014). First, we demonstrate the acceptability of PKD, a culturally adapted intervention, among Lao caregivers. To our knowledge, this is the first early responsive stimulation intervention adapted for use in Laos. Although there have been many cultural adaptations of responsive stimulations, few have documented the process of adaptation, which may be a barrier to the proliferation of effective interventions in low- and middle-income countries. It is our hope to increase transparency about the process of cultural adaptation so that early interventions for populations in low- and middle-income countries might become more readily available and remain therapeutically effective.

Second, PKD is a brief intervention, effective at inducing short-term changes in caregiving and children's development after only a single session. Given that PKD is effective in the short-term, brief, and relatively easy to deliver, it lends itself well to reaching large populations with few resources. PKD's brief dosage, combined with its cost-effectiveness (Richter et al., 2017), represents little cost for value. We hope these results will encourage additional investment in this program from policymakers.

Third, we document differences in the relative efficacy of family- and community-level formats of PKD. Thus far, studies of CCD have included family-level (Ertem et al., 2006; Jin et al., 2007), or combined family- and community-level delivery formats (Yousafzai et al., 2014, 2015), but none thus far have examined the comparative efficacy of the two delivery formats. We found that both family- and community-level formats of PKD induced changes in caregiver stimulation practices, but only the family-level PKD affected change in measures of home stimulation and children's early cognitive and language development. Given the advantage of PKD-family over PKD-community, consideration should be given to integrating PKD into

primary health services, where interventions are already delivered at the family level. Overall, our findings point to PKD-family as one brief, low-cost, and scalable public health strategy for addressing the enormous burden of children in Laos not reaching their full developmental potential.

Future Directions

There are several potential avenues for future research. Three key considerations are highlighted. First is local adaptation of intervention services (Richter et al., 2017). Findings from several studies and meta-analyses (Hall et al., 2016; Kumar et al., 2015; Smith et al., 2011) have made clear the importance of understanding local needs and engaging community members as well as adapting intervention content to address existing beliefs and practices. We continue to advocate for formative adaptation research prior to formal evaluation of an intervention. In Chapter II, we document the process of cultural adaptation in the hopes that others will use it as a model for adapting intervention services for other underserved groups. Importantly, we also demonstrate the acceptability (Chapter II) and efficacy (Chapter III) of the adapted intervention services. Future work should also play close attention to the adaptation of evaluation tools to the local context. Cross-culturally comparable measures of children's early development and caregiving practices are scarce. Additional work is needed to develop culturally appropriate tools to quantify and monitor outcomes of adapted interventions.

Second is careful assessment of community-level barriers to implementation. In Chapter II, we reported on high acceptability of PKD by 93 caregivers who received the intervention. However, as noted in Chapter III, approximately 24 caregivers attrited prior to receiving the intervention. It is noteworthy then that our analyses identified intervention effects even with an intention-to-treat design, which

retained participants who did not receive the intervention. It is possible, given the communal nature of each village, that families who were not directly exposed to the intervention received some benefit from the intervention by talking with and learning from families who did receive the intervention. Additionally, each village in the intervention condition received a poster of recommended activities (Figure 2) and it is possible that families who declined to participate in the intervention received some intervention benefits through exposure to activities recommended in the poster. Future research should explore these possibilities and investigate more carefully the reasons for declining to participate in the intervention to further inform the local adaptation process.

Third is the sustainability of intervention effects over time. Chapter II documents short-term changes occurring one-month post-intervention. The longitudinal effects of PKD is unknown. It is likely that booster sessions will be needed for the intervention to produce longitudinal benefits, especially given evidence that cognitive delays worsen over time in children living in conditions of poverty (Fernald, Weber, Galasso, & Ratsifandrihamanana, 2011; Walker, Wachs, et al., 2011). A multi-sectoral approach may be one solution (Britto et al., 2017; Rao et al., 2014). As noted, given the brief nature of PKD, and its efficacy when delivered at the family-level, it may also be easy to add PKD to routine health services. Basic health services promote child survival, and adding an emphasis on responsive stimulation, would also help children develop optimally, beyond basic survival (Black et al., 2017). Given that adaptations of CCD have been integrated into various multi-sectoral programs, including day care, nutrition interventions, and child well-visits (Ertem et al., 2008; Richter et al., 2017; Yousafzai et al., 2014), a multi-sectoral approach to delivering PKD seems promising.

Evidence presented in this dissertation, combined with well-established evidence on the benefits of early interventions (Aboud & Yousafzai, 2015; Britto et al., 2017; Rao et al., 2014), make strong arguments for intervening in the first two years of life to support the development of children in low- and middle-income countries. Effective early interventions can help these children get better starts in life, increasing the odds they will become responsible, contributing members of society (Gertler et al., 2014). It is the basic right of every child to develop to their fullest potential and achieving this goal depends in part on ensuring responsive caregiving and learning opportunities for the youngest, most vulnerable, and most neglected populations.

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