A STUDY OF THE EFFECTIVENESS, SCALABILITY, AND SUSTAINABILITY OF EARLY CHILDHOOD DEVELOPMENT SERVICES IN RURAL CHINA

Pre-analysis Plan

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Summary: This document outlines the plan for analyzing a dataset consisting of information on the rural families with infants and toddlers who had previously benefited from randomized psychosocial parenting and caregiver mental health promotion interventions. The aim of the project is to estimate the impact of these interventions on child development, parenting practices, and caregiver mental health. This document outlines the regression specifications and defines the outcome variables. We expect to conduct additional analyses beyond those presented here. Therefore, this document is not exhaustive and does not exclude further analysis.

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INTRODUCTION

Up to 250 million children under the age of 5 years in low- and middle-income countries (LMICs), accounting for 43% of the young children living in those countries, are estimated to be at risk of missing out on their developmental potential [1]. The brain develops most rapidly during the critical window between birth and age 3, which is foundational for future health, wellbeing, and skills formation. Delayed attainment of age-specific developmental milestones during this early stage of childhood has been associated with lifelong limitations in a wide range of outcomes that include academic achievement, adult earnings, and physical wellbeing [2–4]. In response to these concerns, an increasing number of early childhood development (ECD) projects has been implemented in LMICs since 2010 [5]. As a result, a large, rapidly expanding body of empirical research now shows that ECD programs focusing on caregiver-child interaction can elevate caregiver engagement in stimulating parenting practices and, as a result, benefit ECD outcomes [6,7].

In addition to the high prevalence of ECD delays, maternal mental health problems are common in LMICs. Up to 1 in 4 women living in LMICs experiences depressive symptoms during pregnancy or the first year postpartum (i.e., the perinatal period), yet over 90% lacks access to any type of social support or mental health services [8]. Evidence suggests that maternal mental health problems are associated with reduced engagement in stimulating parenting practices, an essential element to help children reach their developmental milestones [9–11]. Furthermore, studies have established a link between poor maternal mental health and low cognitive, language, social, and emotional development during early childhood [9,10,12]. In comparison to ECD programs, few interventions for maternal mental health promotion have been implemented in LMICs. The Thinking Healthy Program (THP) is one of the very few evidence-based programs (originally developed for use in Pakistan and India) that has been designed to reduce perinatal depression through modified cognitive behavior therapy [13]. It was later recommended by the World Health Organization (WHO) for global dissemination. Since then, adapted versions of the curriculum have been implemented in a number of other LMICs such as Bangladesh, Vietnam, and Peru [14–17]. Despite the promising progress, scaling the THP in under-resourced areas remains a major challenge [18]. Additionally, because mental health is highly culturally sensitive, more studies are needed to understand the cultural compatibility of the THP in a wider range of diverse cultural contexts [19].

Despite the rich literature calling for the integration of ECD and maternal mental health intervention components due to the potential synergies in delivery and program effects [6,20,21], evidence is both limited and mixed in terms of how and to what extent integrated interventions can have effects on child development and maternal mental health. For the limited number of earlier interventions with both ECD and caregiver mental health components, each finds significant improvements in child development. However, only a subset finds evidence of significant protective effects on maternal depressive symptoms, while others detect no impact on maternal depression outcomes [22–24]. Two separate trials integrated the THP into child health and development interventions [15,25]; however, since those trials used parallel designs, where all treatment arms had both a mental health component in combination with child health and ECD components, it remains unclear whether integrated interventions have significant effects relative to a single intervention model. Therefore, a factorial-design trial is needed to decompose the integrated effects of ECD and caregiver mental health interventions.

Even when an intervention program has been proven effective in a certain context, improving the scalability and sustainability of this intervention program is yet another challenge [26]. Considering that public programs often face the most stringent resource constraints in the areas that are most in need of such services, the literature has suggested to integrate new programs into existing public service systems that are present even in the most disadvantaged areas, in order to improve inclusiveness of the disadvantaged populations [27–29]. Many existing programs rely on community health workers (CHWs) for program delivery, which puts CHWs in the spotlight as a critical frontline resource for public service delivery in underdeveloped areas [29]. However, emerging evidence suggests that CHWs are often overburdened with their workload, which may constrain program sustainability [30]. For example, the THP was originally designed for delivery by CHWs, but the program was later adapted to be delivered by housewives because of implementation challenges due to the excessive workload requirements for CHWs, especially in resource-poor areas [31]. The Lancet Series on *Advancing ECD* suggested the possibilities of implementing ECD interventions through child and social protection services [29]; however, due to a lack of CHWs with a sufficiently high educational background, it remains unclear whether this channel can be effective.

To address these challenges, we developed a factorial, cluster-randomized controlled trial that integrates a previously field-tested ECD intervention (one that follows a loosely adapted version of the *Reach Up and Learn* curriculum) with a caregiver mental health intervention (that follows a loosely adapted version of the THP curriculum). Both of the interventions are delivered and supervised by local agents of the All China Women's Federation (ACWF), the nationwide, government-sponsored social protection organization that aims to safeguard the rights and interests of women and children in mainland China [32]. The ACWF has the ability to reach households in remote areas and bring the program to a large, even nationwide scale, mainly because of two reasons. First, in line with China's political administrative divisions, the ACWF has national, provincial, prefectural (i.e., at the level of prefectural cities), county-, township-, and village-level administrative infrastructures. Second, the ACWF plays an important role in the transmission and implementation of state policy and represents the interests of women and children to the state, making it a promising agency to advocate for effective programs via policy recommendations. Nevertheless, no study to date has examined the ACWF's ability to effectively deliver maternal and child health interventions.

OBJECTIVE OF THE STUDY

Primary objectives

In this study, we aim to address the research questions with four primary objectives:

- First, compare child development and caregiver mental health between three treatment groups and the control group respectively to estimate the impact of psychosocial stimulation parenting training, caregiver mental health promotion, and the combined intervention.

- Second, evaluate the synergistic effects of the psychosocial stimulation parenting training program and caregiver mental health promotion program on child development, caregiver mental health, and program compliance— the additional impact of the caregiver mental

health intervention when receiving both services comparing the treatment group only receiving the parenting training alone.

- Third, dose-response effect of all three treatment interventions.

Secondary objectives
To understand the mechanism of the research questions, we aim to have the following two secondary objectives:

- Evaluate the impact of parenting training, mental health promotions, and the combined intervention on secondary outcomes, including parental stress, parental investment, parental self-efficacy, parental quality. The details of the secondary outcomes can be found in the Outcome Variable of Interest section.
- Understand the impact heterogeneity of the three interventions across subgroups. The variable of subgroup choices can be found in the Outcome Variable of Interest section.

EXPERIMENT DESIGN

The study design is a 12-month, single-blind, factorial, cluster-randomized controlled, superiority trial, in which 120 villages were randomly allocated to one out of four arms (see Figure 1): (1) a parental training intervention focusing on child psychosocial stimulation, (2) a caregiver mental health promotion intervention, (3) a combined intervention of both parental training and caregiver mental health promotion interventions, and (4) a pure control arm that does not receive any intervention. The randomization was executed at the village-level on an almost 1:1:1:2 allocation ratio (i.e., with the control arm being twice the size of an intervention arm) — with 25 villages in parenting training arm, 25 villages in caregiver mental health promotion arm, 25 villages in the combined intervention arm and 45 villages in the control group. The study enrolled children aged 6–24 months at the time of baseline survey and their caregivers. The baseline survey was only given to the primary caregivers due to limitations to the survey administration capacity, but the endline survey after 12 months of intervention have been completed, will be administered to the each of the primary and secondary caregivers.

INTERVENTION

Parenting intervention
For each village assigned to the parenting or the integrated intervention arm, we will install a Child Center in an existing space at a central location in the community provided by a local village committee. The research team will provide all Child Centers with child-friendly decorations, an open area for one-on-one parenting sessions, as well as toys and books that are required for use during the parenting sessions. Child Centers will be operated by one or two CWWs, who deliver one-on-one parenting training sessions following a scripted curriculum called the *Parenting the Future* curriculum.

The *Parenting the Future* curriculum was adapted from the *Reach Up and Learn* curriculum [33,38,39]. Local ECD experts from China adapted the curriculum to fit the context of rural China. Weekly stage-based, age-appropriate sessions were developed targeted at children between 6 and 36 months of age. Each weekly session contains modules focusing on two out of four developmental modules: cognition, language, motor, and social-emotional skill development. At the end of each session, the CWW encourages caregivers to take toys and books home and to practice the activities at home as frequently as possible between two sessions. The *Parenting the Future* curriculum has been field tested and demonstrated effective at improving cognitive development of young children in multiple randomized controlled trials across China [40–42].

This study will employ a hybrid delivery strategy where caregiver-child dyads can attend weekly training sessions either at Child Centers (center-based format) or in their homes (home-visitation format). Compared to the home-visitation format, the center-based format is considered less labor-intensive and more efficient, as it reduces the costs of commuting for CWWs. However, previous literature suggests that the effect of center-based parenting interventions on child development can diminish due to lower compliance rates among the most disadvantaged children with relatively poor cognitive development at baseline [41]. Therefore, to promote compliance to the parenting intervention while keeping labor costs low, CWWs encourage caregivers to attend the weekly sessions at the Child Center. However, if caregivers cannot or choose not to come to the Child Center, CWWs will schedule home visits and deliver the sessions at the caregiver's homes.

Mental health intervention

The mental health intervention, called Thinking Healthy Extended Program (THEP), consists of 24 group sessions delivered once every two weeks. The THEP was developed by the research team, and is based on both the THP [14] and a series curricula of the THP named THPP+ [34]. The THP is an evidence-based psychosocial intervention designed to reduce perinatal (i.e., the period from pregnancy to 10 months after childbirth) depressive symptoms through modified cognitive behavior therapy (CBT). As a significant part of the WHO's flagship mental health gap action program (the mhGAP), the THP program has been shown to be effective in reducing depressive symptoms and has since been implemented in a number of LMICs [15,16,43]. However, since THP targets the perinatal period, much of its content is not compatible with caregivers of children aged 6-36 months old. THPP+, on the other hand, was developed by the same research team and aims to provide continued mental health support beyond the perinatal period. Although the THPP+ has been designed for caregivers of children in the same age range as the children targeted in the current intervention, no evidence of significant treatment impacts of the THPP+ on maternal depression was detected in earlier studies, possibly due to lack of modified CBT techniques, low intensity, and being delivered by lay community workers [34]. Therefore, instead of directly translating and adapting the THP or THPP+, the THEP combines the THP and THPP+ and integrates essential principles, elements, and activities from both curricula to develop a unique curriculum system.

The THEP was designed to be a low-intensity intervention, meaning the THEP has been modified for use with fewer resources than conventional psychological treatments by specialists such that the intervention is feasible also in less-resourced communities [14]. Each session of the THEP has a specific theme focusing on caregivers' personal health, caregiver-child relationship, or caregivers' relationships with close family members and friends (i.e., these are the three

pillars of the curriculum). The structured group activities consist of discussions and games to help caregivers learn and apply simplified CBT strategies, adopt healthy practices in daily activities, share personal experiences of childrearing, and gain peer support.
The THEP also has unique features that differentiate itself from the THP and THPP+. First, THEP was designed for both mothers and grandmother caregivers with a view to the universal phenomenon of intergenerational parenting in China [44]. We assign mothers and grandmothers to separate groups in light of their differences in childrearing practices and experiences [9,45]. Second, the THEP is a universal intervention that includes women regardless of their baseline mental health status, meaning that we do not screen caregivers for any mental health symptoms to determine the eligibility for the mental health intervention. A wide range of literature indicates that stigma in mental health is especially widespread in Asia and underdeveloped areas [46,47]. Screening for mental health symptoms at the community-level may increase the risk of discrimination against caregivers with mental health problems. Therefore, the THEP was designed to be a preventative intervention for mental health symptoms and caregivers who may be experiencing severe symptoms will be referred for additional treatment. Finally, the content of the THEP was carefully adapted to fit the cultural context of rural China.

Combined intervention
In the villages that receives the combined intervention, the parenting training and the caregiver mental health promotion are stacked together. Enrolled households are entitled to full access of both interventions described above.

DATA COLLECTION

The sample for this study consists of children aged 6-24 months at the time of the baseline survey and their caregivers, primarily mothers and grandmothers. Enrollment and the baseline survey were conducted in two waves based on specific strata. The first wave's enrollment and baseline survey was conducted between October to November 2022, while the second wave was conducted between late February to April 2023. Due to disruptions caused by the COVID-19 lockdown and reopening, the interventions for the first and second waves did not commence until May 2023 and October 2023, respectively. To evaluate the one-year impact of these interventions, the endline survey for the two waves is planned for May 2024 and October 2024, respectively.

EMPIRICAL STRATEGY

Evaluation of attrition
To assess whether attrition confounds our results, we proceed as follows.

First, we define $\text{attrit}_i = 1$ if individual *i* was surveyed at baseline but not at endline, and zero otherwise. We then assess the severity of attrition using three approaches. First, equation 1 estimates whether the magnitude of attrition is different for treatment and control participants:

(1) $$attrit_i = \beta_0 + \beta_1 T_i + \epsilon_i$$

Second, equation 2 assesses whether attrition participants are different in terms of a vector of baseline characteristics ($y_{i,t=0}$):

(2) $$y_{i,t=0} = \beta_0 + \beta_1 attrit_i + \epsilon_{i,t=0}$$

And third, equation 3 measures whether the baseline characteristics of attrition individuals in the treatment group are significantly different from those in the control group. The sample for regression will be restricted to attrition households:

(3) $$\left(y_{i,t=0} \middle| attrit_i = 1\right) = \beta_0 + \beta_1 T_i + \epsilon_{i,t=0}$$

If worrying levels of attrition are found, we will adjust for the potential effect of such attrition.

Estimation of treatment impacts

Provided that treatment assignment and attrition are random, comparing the means of primary and secondary outcomes between treatment arms results in unbiased estimates of the treatment effect on primary and secondary outcomes. We will use an ordinary least-squares (OLS) regression specification to estimate average treatment impacts on both primary and secondary outcomes. To increase power, and to account for the stratified randomization procedure, we will include controls for the randomization strata and baseline values of the outcome variables in our regression specification. In our analysis, we measure the treatment effect based on treatment assignment instead of a measure for effectively completed treatment. Therefore, our analysis is an intention-to-treat (ITT) analysis. The main regression specifications will be:

(4) $$Y_{ijt} = \beta_0 + \beta_1 PT_j + \beta_2 MH_j + \beta_3 Y_{ij(t-1)} + \tau_s + \varepsilon_{ijt}$$

Where Y_{ijt} is the primary or secondary outcome measure for child/household i in community j at follow-up time t. PT_j and MH_j are indicator variables for the treatment assignment of community j to child psychosocial stimulation and caregiver mental health promotion, respectively. $Y_{ij(t-1)}$ is the outcome measure at baseline. τ_s is a set of strata fixed effects. ε_{ijt} is the error term for child/household i in community j. Standard errors will be adjusted for clustering at the village-level.

To examine the synergy of the mental health promotion and the psychosocial stimulation parenting interventions, we use the additional specification:

(5) $$Y_{ijt} = \beta_0 + \beta_1 PT_j + \beta_2 MH_j + \beta_3 PT_j * MH_j + \beta_3 Y_{ij(t-1)} + \tau_s + \varepsilon_{ijt}$$

Where we also include the interaction term of PT_j and MH_j.

We will report estimates with and without baseline control variables for the robustness of the results. The baseline control variables include: 1) demographic information of children and their primary caregivers; 2) baseline information about households, including household size and asset level; 3) baseline measurement of primary outcomes child development and caregiver mental health. We also include indicator variables that takes value 1 if the above variables are missing.

Estimation of impact heterogeneity across subgroups
In addition to examining ITT effects, we will also investigate heterogeneity in treatment impacts across caregiver and child subgroups. We plan to use the following OLS regression specification to investigate impact heterogeneity:

$$(6) \quad Y_{ijt} = \beta_0 + \beta_1 PT_j + \beta_2 PT_j * S_{ij(t-1)} + \beta_3 S_{ij(t-1)} + \beta_4 MH_j * S_{ij(t-1)} + \beta_5 \beta_3 S_{ij(t-1)} + \beta_6 Y_{ij(t-1)} + \tau_s + \varepsilon_{ijt}$$

where $S_{ij(t-1)}$ is the relevant indicator defined using the baseline characteristics of the child, the caregiver, or the household. We will regress the outcome variable of interest on treatment dummies ($PT_j \; and \; MH_j$), the subgroup indicator ($S_{ij(t-1)}$), the interaction term between the treatment dummies and the subgroup indicator; the outcome measure at baseline ($Y_{ij(t-1)}$), and strata fixed effects (τ_s).

The variables of particular theoretical and conceptual interests include:

- Female children and their caregivers versus male children and their caregivers;
- Children with higher baseline (cognitive, noncognitive, or health) scores and their caregivers versus children with less good baseline outcomes) and their caregivers;
- Children and caregivers from families with high baseline parental investment versus children and caregivers from families with low baseline parental investment;
- Children and caregivers from families with high level of baseline parenting skills versus children and caregivers from families with low level of baseline parenting skills;
- Children and caregivers from families with parental migration at baseline and versus children and caregivers from families with parents staying close at baseline and their caregivers.

OUTCOME VARIABLES OF INTERERST

The effectiveness of the intervention will be evaluated on a range of child and caregiver outcomes. The primary and secondary outcomes will be measured at the time of baseline and endline data collection. Both surveys will be administered by trained enumerators. The details of the outcome measures are shown in Table 1. In addition to the two surveys, the comprehensive administrative data will be collected automatically by a tablet application.

Primary outcomes
The primary outcomes include a list of measures of child development and caregiver mental health outcomes. Child development in cognition, language, and motor is measured using the Bayley Scales of Infant and Toddler Development, third edition (Bayley-III) [48]; child development in social-emotional skills is measured using the Chinese version of the one-sided Strengths and Difficulties Questionnaire of 2-4 year olds reported by the primary caregiver and the Wolke Scale observed by the testers of the Bayley-III [49]. Child development is assessed using the standardized test scores each child receives. The proportion of the children whose score falls below a prespecified test-specific cut-off score is used to quantify the prevalence of developmental delay. Additionally, we will standardize raw test scores nonparametrically for age [78].

Caregiver mental health is measured using the eight-item version of the Patient Health Questionnaire (PHQ-8) to evaluate depressive symptoms and the 21-item version of the Depression Anxiety Stress Scale (DASS-21) to evaluate depressive, stress and anxiety symptoms [51,52]. Caregiver mental health is assessed using the continuous scores. In addition, the prevalence of the symptoms of mental health problems (e.g., symptoms of depression, anxiety, and stress) at both mild and severe levels, is assessed using the cut-off scores provided by each scale.

Secondary outcomes

The secondary outcomes consist of a combination of physical, psychological, and behavioral outcomes that can mediate the intervention effects on the primary outcomes of interest. The secondary outcomes include the following measures:

- Child health-related behaviors: child screen-time use measured by self-made items, and child sleep habit measured by the revised short form of Brief Infant Sleep Questionnaire (BISQ-R SF) [53].
- Stimulating parenting practices: Based on both self-reported and enumerator observed measures. The self-reported measurement include the Family Care Indicators (FCI) [54] and parenting quality.
- Three pillars of THEP sessions: Caregiver physical health measured by self-made items; caregiver relationship with their children measured with the short form of the Mother's Object Relations Score (MORS-SF) [56]; caregiver relationships with close family members and friends measured by Multidimensional Scale of Perceived Social Support (MSPSS) [57]; information on social interactions between households in the same villages.
- Parenting perceptions: Parenting stress measured by the short form of Parenting Stress Index (PSI-SF) [58], parenting self-efficacy, parenting daily hassles measured by the Parenting Daily Hassle Scale (PDH) [60], parenting belief measured by the self-made items, subjective well-beings, pro-social tendency, and household decision making.

Administrative records

The tablet application collects administrative data on parenting and mental health sessions, including the date, time, and location of each session, along with the participants' relationship with their children. For the parenting intervention, the tablet application also tracks records of each toy and book the household borrows from the Child Centers.

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