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A cluster randomized controlled trial to evaluate a resilience-based intervention for caregivers of HIV-affected children in China

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Abstract

Objectives: The Child-Caregiver-Advocacy Resilience (ChildCARE) intervention aims to enhance the psychosocial wellbeing of children affected by parental HIV by providing programming at three levels: child, caregiver, and community. The objective of the current study was to evaluate the intervention's efficacy in improving mental health and parenting outcomes for participating caregivers.

Design: A cluster randomized controlled trial was used to evaluate initial efficacy of the intervention.

Methods: A total of 790 caregivers of children affected by parental HIV were recruited from Henan, China. Caregivers and their children were randomly assigned to one-of-four intervention arms (control, child-only, child + caregiver, child + caregiver + community) to evaluate the multiple components of ChildCARE. Those assigned to receive the caregiver intervention participated in five 2-h intervention sessions designed to improve their parenting skills and enhance their ability to cope with daily stressors. Caregivers reported on their mental health and parenting behaviors at baseline, 12, 24, and 36 months, with mixed effect modeling used to examine intervention effects.

Results: Caregivers who participated in the intervention reported decreased anxiety and parental stress at 12 months ($P < 0.05$). Participants also reported increased use of structured parenting

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conception and development of the intervention was done by X.L., J.Z., G.Z. Design of the intervention trial was done by X.L. Coordination of the intervention trial was done by J.Z. Supervision of data acquisition was done by J.Z., G.Z. Conception and design of current study was done by S.E.H., X.L., J.Z. Statistical analysis was done by J.Z. Interpretation of the analysis was done by J.Z., X.L., S.E.H. Drafting of manuscript was done by S.E.H. with contributions from J.Z., X.L.

Conflicts of interest

There are no conflicts of interest.

skills (i.e., parental demandingness) at 12 and 24 months ($P < 0.05$). However, by 36 months, they reported significantly lower levels of parental competence ($P < 0.01$) than those assigned to the control condition.

Conclusion: Preliminary findings suggest that the caregiving component of ChildCARE yields initial improvements in some key parenting and mental health outcomes. However, the challenges of caring for children affected by HIV are complex and may require more intensive intervention to yield marked, positive changes across key caregiver outcomes.

Keywords

caregivers; China; HIV; psychological resilience; social support

In the past 2 decades, significant reductions in mother-to-child HIV transmission have been achieved through routine testing for pregnant women, increased uptake of antiretroviral therapy among pregnant and breastfeeding women living with HIV, and other recommended practices (e.g., prophylaxis for exposed newborns) [1,2]. These advances have prevented ~1.4 million children from acquiring HIV since 2000 [3], and reduced global incidence of HIV among children by 50% since 2010 [4]. Eliminating mother-to-child transmission is now recognized as a core strategy for ending the epidemic [5,6].

Thus this generation of children born to HIV-positive mothers has a greater chance than ever before of avoiding seroconversion. However, even children who remain uninfected often face complex challenges associated with parental HIV. As of 2016, an estimated 16.5 million children worldwide have been orphaned by AIDS (i.e., lost one or both parents) [7], with the majority (i.e., ~80%) residing in sub-Saharan Africa [8]. Few attempts have been made to calculate the total number of children who have HIV-positive parents, outside of sub-Saharan Africa [9], but with ~36.7 million people currently living with HIV across the globe – the largest portion of whom are of child-bearing age – the burden on youth is substantial [10]. Even within the context of the concentrated HIV epidemic in the United States, the first attempt to quantify the number of HIV-affected children estimated that 28% of HIV-positive adults in care in the United States were biological parents to a child under the age of 18 [11]. Despite these numbers, efforts to understand and support the needs of children affected by parental HIV remain in early stages, with most research to date focusing on risk factors associated with parental HIV rather than intervention development [12–14].

Children affected by parental HIV, defined in this paper as a child who has a living parent who is HIV-positive or who has been orphaned by the AIDS-related death of a parent, face a wide range of negative psychological, behavioral, and socio-economic outcomes [15,16]. Parental HIV – as studied primarily in low-income and middle-income nations – is linked with poorer mental health outcomes, including depression, anxiety, and stress [17]; reductions in economic assets [18,19]; and lower levels of educational attainment [19,20]. Affected children are more likely to undergo major transitions including disruptions in caregiving, permanent caregiver changes, and household moves [18,20]. They are more likely to be exposed to trauma, including witnessing the illness and death of their parents [21]. A majority of studies in a recent review found that children affected by parental HIV

also display more externalizing behaviors than unaffected peers, including conduct problems, disruptive behaviors, and social skill deficits [13,22,23].

Given these challenges, caregiving is particularly critical for the promotion of healthy development. High-quality caregiving and secure, stable attachments with caregivers may substantially mitigate risk and enable a vulnerable child to better cope with daily stress and adversity [24,25]. Multiple parenting interventions have been developed that aim to increase parents' behavioral skills and promote positive parent–child interactions [26]. Interventions such as the Triple P – Positive Parenting Program provide caregivers with structured lessons on effective parenting and behavior management strategies through a range of modalities, including didactic presentations, individual or small group activities, and task-based 'homework' [27,28]. Such interventions generally use social learning and behavioral principles to promote the development of positive parenting skills that are tailored to children's developmental needs, with meta-analyses and systematic reviews providing general support for the efficacy of structured parenting programs to yield improvements for a wide array of vulnerable child populations [29–31].

Although interventions have been developed and evaluated for children affected by parental HIV [32], few efforts have been made to tailor parenting interventions to the needs of adults caring for these children. Yet supportive caregiving – whether provided by a biological parent or another primary caregiver – is a key resilience factor for children coping with parental HIV, as highlighted in a recently proposed conceptual model of resilience for children affected by parental HIV (Fig. 1) [33]. The framework is informed by a socio-ecological model of human development [34,35] and resilience perspectives [36–38]. It posits that efforts to mitigate the risks associated with parental HIV should target modifiable individual and contextual factors including internal assets (i.e., self-efficacy, coping), family resources (i.e., caregiving, attachment), and community resources (i.e., school, peer, and neighbor support) [33].

Based on this framework, the *Child-Caregiver-Advocacy Resilience (ChildCARE)* intervention was developed with the aim of enhancing the resilience of children affected by parental HIV in Henan, China – the site of a rapid HIV outbreak in the mid-1990s that was driven by unhygienic commercial blood and plasma donation practices [39,40]. During this period, rural farmers in the region frequently supplemented meager incomes through recurring blood and plasma donation at commercial collection centers. HIV antibody testing of specimens was not routine before 1995, and other unhygienic practices, including reinjection of contaminated red blood cells after donation, rapidly spread HIV and yielded HIV prevalence rates among former plasma donors that range from 10 to 60% across local communities [41–43]. In 2005, members of the research team began a longitudinal study to understand the psychosocial impacts of HIV on affected families and then worked closely with local communities to develop the multilevel *ChildCARE* intervention. Content for the intervention was adapted from existing evidence-based interventions (i.e., PATHS [44], Second Step [45], Triple-P – Positive Parenting Program [46]) and tailored to the unique socio-cultural context of the Henan HIV epidemic, with the adaptation process guided by the *ADAPT-ITT* framework [47].

The intervention provides programming on three levels: child, caregiver, and community. At the child-level, *ChildCARE* aims to increase children's coping skills so they can better respond to demands associated with parental HIV. Specifically, children receive ten 2-h sessions of a manual-based peer-group intervention led by trained facilitators. Participating children set individual resilience-related goals at the initial session, and then participate in interactive sessions focused on specific topics (e.g., managing emotions, reframing negative thoughts, seeking social support, etc.). At the final session, children reflect on the progress they have made toward their goals and on the multiple resources (i.e., individual, peer, family, community) that can help them overcome adversity.

At the caregiver level, children's primary caregivers participate in five 2-h interactive intervention sessions led by trained facilitators, with the primary goals of enhancing parenting skills through structured parenting training and increasing the ability of caregivers to cope with the daily stressors associated with familial HIV. The five sessions addressed topics including creating a safe and engaging home environment; promoting a positive learning environment; enhancing parental discipline and monitoring; setting realistic expectations for children's behavior; and reducing caregiver stress and promoting self-care. For the current study, intervention facilitators consisted of masters level psychology and education students who were recruited and trained through a local university, and caregiver intervention sessions were delivered at 20 local school sites.

The third level of the *ChildCARE* intervention aims to enhance community support for families affected by HIV. Trained community advocates make supportive monthly home visits to families participating in the intervention and also provide a series of activities within the local villages to promote cohesion and offer visible support to impacted families.

Following development and pilot testing, *ChildCARE* was implemented and evaluated from 2012 to 2016 with a large cohort of children and caregivers in Henan, China. Initial efficacy evaluations indicate the intervention yields improvements for participating children in a number of resilience-related outcomes including self-reported coping skills, hopefulness, emotional regulation, and self-control [48]. Participating children also reported gains in school grades, school satisfaction, and school interest [49]; however educational gains largely faded by the end of a 3-year follow-up period [50]. The current study is the first to evaluate caregiver outcomes, and aims to examine the intervention's efficacy in improving mental health and parenting outcomes following receipt of the caregiver intervention component.

Method

Participants

Caregivers and children were recruited from five rural villages in Henan Province in central China. In collaboration with local antiepidemic centers, we identified villages with high HIV prevalence. We then generated a list of families caring for HIV-affected children in these villages with assistance of local school districts and social welfare systems. Children were eligible to participate if they were 6–17 years old and had a parent living with HIV or who had died from AIDS-related complications. HIV-positive children were not included in the

study, with HIV status confirmed by primary caregivers. Eligible families were invited to participate until the target sample size (i.e., ~800 dyads) was reached. The final sample included 790 child–caregiver dyads. Among the caregivers, 58.6% were women ($n = 463$) and 41.4% were men ($n = 327$). Mean age of caregivers was 42.7 years old ($SD = 12.6$ years), with a mean child age of 10.5 years. The majority (70.6%) of caregivers were biological parents of the participating child, with the remainder (29.4%) reporting another relationship (e.g., adoptive parent, kinship guardian). A small portion of enrolled children had experienced the death of one (9.3%) or both (3.1%) biological parents due to AIDS-related causes, and other factors including poverty and parental illness also were likely reasons for the participation of nonbiological caregivers. Caregivers reported low levels of education, with 45.1% of caregivers reporting elementary school to be the highest level of formal schooling. A majority (65.2%) of caregivers were farmers, and over half of the sample (52.5%) reported a yearly household income of less than 1000 yuan (equivalent to <160 USD). A majority of caregivers (61.6%, $n = 487$) were HIV-positive.

Procedures

The study used a four-arm cluster randomized controlled design. Child–caregiver dyads were grouped into 45 clusters based on the school the child was currently enrolled in (i.e., 45 total schools). These clusters were then randomly assigned to either a control arm or one-of-three intervention arms to assess the various levels of *ChildCARE* (i.e., child-only, child + caregiver, or child + caregiver + community). Caregivers and children participated in an initial baseline assessment in August 2012, and intervention content was then delivered according to schedule (Fig. 2), with intervention components delivered on a staggered basis. Caregiver and child intervention components were delivered at local schools; community components were delivered in participants' homes and various community settings. Children completed follow-up assessments every 6 months, and caregivers every 12 months (i.e., at 12, 24, and 36 months).

The current study compares self-reported mental health and parenting outcomes of caregivers who received the *ChildCARE* caregiving intervention (i.e., child + caregiver and child + caregiver + community arms) with caregivers who did not (i.e., control and child-only arms) at baseline, 12, 24, and 36 months to determine whether the caregiver intervention yielded improvements in mental health and parenting. Only measures and data collection procedures relevant to the caregiver assessment protocol will be reported here. The research protocol was approved by Institutional Review Boards at Wayne State University, the University of South Carolina, and Henan University.

Measures

Demographic information—Participants provided basic demographic information including their relationship with enrolled child (i.e., biological or nonbiological caregiver) and length of time the child had resided with them. Participants also reported on a number of other characteristics including age, sex, education level, occupation, marital status, income level, and HIV status.

Mental health measures

Several scales were used to assess caregivers' psychological functioning. *Depression* was measured with the 10-item short version of the *Center for Epidemiologic Studies Depression Scale* [51,52], which asked about depressive symptoms experienced in the past week. Higher scores indicate greater symptom severity; Cronbach's alpha at each wave were 0.71 at baseline, 0.75 at 12 months, 0.76 at 24 months, and 0.81 at 36 months. *Anxiety* was measured with a 6-item subscale from the *Depression Anxiety Stress Scale* [53]. Participants responded to questions about their anxiety in the past week using a four-point Likert scale. Higher scores indicated greater levels of anxiety, and Cronbach's alphas at each wave were: 0.87, 0.88, 0.83, and 0.92. *Resilience* was measured with 10 items from the *Connor-Davidson Resilience Scale* [54]. Participants indicated their endorsement of items such as 'I tend to bounce back after illness or hardship' or 'I can handle unpleasant feelings' on a five-point scale. Higher scores reflected greater resilience, and Cronbach's alphas at each wave were 0.84, 0.89, 0.91, and 0.90.

Parenting measures

Participants provided information on four constructs related to parenting style and skills. First, they completed modified items from the *Authoritative Parenting Index* [55] to assess parents' behaviors in the areas of responsiveness and demandingness (*Parental responsiveness*) was measured with a nine-item subscale designed to assess caregivers' ability to respond to their children in a sensitive and accepting manner (e.g., 'I listen to what my child has to say', 'I try to comfort my child when he or she is upset'). Higher scores indicated greater responsiveness, and Cronbach's alphas at each wave were 0.58, 0.67, 0.72, and 0.72. *Parental demandingness* was measured with a seven-item subscale that asked parents to report on parental monitoring/involvement in their child's lives. Sample items included, 'I know where my child is after school' and 'I set rules that I expect my child to follow'. Higher scores indicated more structured parenting (i.e., parental demandingness), and alphas at each wave were 0.69, 0.77, 0.77, and 0.83. *Parental competence* was measured with a six-item subscale from the *Parenting Sense of Competence* scale [56], which required caregivers to indicate the degree to which they felt confident in their ability to handle parenting challenges and solve common parenting problems. Higher scores indicated greater perceived competence, and Cronbach's alphas at each wave were 0.52, 0.51, 0.61, and 0.70. A second six-item subscale assessed *parental stress* and asked participants to rate frustration and anxieties associated with parenting. Higher scores indicated greater levels of stress; Cronbach's alphas at each wave were 0.78, 0.81, 0.81, and 0.83. Finally, participants completed a modified version of the *Trusting Relationship Questionnaire* [57,58] to assess the quality of the *trusting relationship* between caregiver and child. Participants responded to 19 items using a five-point Likert scale with sample items including 'Does your child seek out counseling or advice from you?' and 'Does your child talk to you about his or her problems?'. Higher scores indicated a more trusting caregiver-child relationship, and alphas at each wave were 0.84, 0.80, 0.84, and 0.87.

Statistical analysis

First, analysis of variance examined differences among control and intervention arms for demographic variables at baseline and for all outcome variables at 12, 24, and 36 months. Next, linear mixed effects modeling was used to examine intervention effects for caregiver vs. control arms, with correlations adjusted to account for clustering effects (i.e., repeated measures nested within participant; participants nested within community clusters). Fixed effects included in the model were age, sex, HIV status of the caregiver, and relationship of the caregiver to the child (e.g., biological vs. adoptive parent). Time was denoted as study period (i.e., 0, 12, 24, 36 months). Intervention effects were considered to be present if a significant interaction existed between time and exposure to the intervention (i.e., time $\times$ caregiver intervention). Data were analyzed using SPSS Statistics for Windows, version 17.0. Chicago, IL, USA: SPSS Inc. and SAS version 9.4. Cary, NC, USA: SAS Institute Inc.

Results

Demographic characteristics are presented in Table 1. Control and intervention groups were similar in terms of age, educational achievement, and family income. The groups were also similar in terms of caregiver HIV status, marital status, and relationship with the child (i.e., biological or nonbiological parent). Groups differed at baseline on occupation and sex. A total of 92.4% of caregivers completed all measures at baseline, and the subsequent retention rate was 77.1% at 12 months, 70.6% at 24 months, and 57.1% at 36 months.

A post-hoc mean comparison was completed to determine whether any baseline differences existed between caregivers who were retained over time and those who were lost to follow-up. Caregivers ($n = 451$) who were retained across all study waves were more likely to be farmers than another occupation ($P < 0.001$) and had lower levels of formal schooling ($P = 0.005$) than caregivers who were lost to follow-up ($n = 339$). A marginal difference ($P = 0.05$) was found at baseline for income, with 55.7% of retained participants reporting a yearly income of less than 1000 yuan, compared with 48.4% of those lost to follow-up. The inclusion of small participant incentives for completion of surveys at each wave may have contributed to this retention difference. No other baseline differences between retention groups were present for demographic or outcome variables.

Mental health outcomes at 12, 24, and 36 months

Means and SDs for depression, anxiety, and resilience are presented in Table 2. Mean scores for depression differed across arms at baseline ($P < 0.05$), 12 months ($P < 0.0001$), and 24 months ($P < 0.01$), and means for anxiety differed across arms at 12 months ($P < 0.01$). Results of the multiple mixed linear effects model are presented in Table 3. Examining the interaction effects (i.e., time $\times$ caregiver intervention) allows for evaluation of whether exposure to the caregiver intervention yielded improvements over the control arm across time. After controlling for relationship with child (i.e., biological or nonbiological parent), sex, age, and caregiver HIV status, interaction effects indicate that participants assigned to caregiving intervention arms reported fewer symptoms of anxiety at 12 months ($\beta = -0.106$, $P < 0.05$), though no significant effects on anxiety were present at 24 or 36 months. At 36

months, marginal intervention effects were present for increases in resilience ($\beta = 0.083$, $P = 0.05$). No intervention effects were present for depression.

Parenting outcomes at 12, 24, and 36 months

Means and SDs for parental responsiveness, parental demandingness, trusting relationship, parental competence, and stress are presented in Table 2. Significant between-arm mean differences were present for parental demandingness at 12 months ($P < 0.01$) and 24 months ($P < 0.01$). Arms also differed at baseline for parental competence ($P < 0.01$), and for parental stress there were between-arm differences at each time point, including baseline ($P < 0.0001$), 12 months ($P < 0.0001$), 24 months ($P < 0.01$), and 36 months ($P < 0.01$). Findings from the multiple mixed linear effect model for parenting variables are displayed in Table 4. At 12 and 24 months, participants assigned to the caregiver intervention reported significantly greater ($P < 0.05$) parental demandingness than participants assigned to the control condition ($\beta = 0.083$ and 0.076 , respectively). No intervention effects for parental demandingness were present at 36 months. At 12 months, participants assigned to the caregiver intervention reported lower levels of parental stress ($\beta = 0.099$, $P < 0.05$); however these effects were not present at 24 or 36 months. At 12 months, participants assigned to the caregiver intervention surprisingly reported lower levels of a trusting relationship with their child when compared with the control arm ($\beta = -0.060$, $P < 0.05$). In addition, at 36 months, caregivers who received the caregiving intervention reported less parental competence than those assigned to the control condition ($\beta = -0.099$; $P < 0.01$). Intervention and control participants did not differ on parental responsiveness at any time point.

Sensitivity analysis—To conduct an additional sensitivity analysis, sequential Bonferroni adjustments were first made for the eight mental health and parenting outcomes. Bonferroni adjustments were then made for to adjust for three groups (i.e., control, child, and caregiver). In the first reanalysis, the association between the caregiver intervention and parental competence remained significant, and in the second, the significant findings remained for the caregiver group for anxiety and parental demandingness at 12 months and parental competence at 36 months.

Additional fixed effects—Among the fixed effects included in the model, caregivers' relationship with child was found to have a significant effect on depression, with nonbiological parents reporting more symptoms of depression ($\beta = 0.044$, $P < 0.01$) than biological parents. Relationship with child also had significant effects on trusting relationship and parental competence, such that nonbiological parents reported a less trusting relationship ($\beta = -0.045$, $P < 0.01$) and less parental competence ($\beta = -0.032$, $P < 0.05$). Sex had a significant impact on caregivers' trusting relationship with their child ($\beta = -0.037$, $P < 0.01$), with men reporting a less trusting relationship. Caregivers' positive HIV status was significantly associated with increased depression ($\beta = 0.071$, $P < 0.001$) and anxiety ($\beta = 0.070$, $P < 0.001$), as well as with increased parental stress ($\beta = 0.066$, $P < 0.001$).

Discussion

ChildCARE is unique in its aim to enhance the resilience of children affected by parental HIV through multilevel psychosocial intervention. The manualized program offers intervention at child, caregiver, and community levels, and recent evaluations support its efficacy in – at least initially – improving a number of mental health, resilience, and educational outcomes for participating children [48–50]. This is the first study to examine whether *ChildCARE* also yields benefits for caregivers who take part in 10 h of intervention designed to improve their parenting skills and enhance their ability to cope with the daily stressors associated with familial HIV in Henan, China. Those randomized to participate in the caregiving sessions differed from the control group in a number of ways. They reported less anxiety and reduced parental stress following the intervention, as well as increased use of structured parenting practices (i.e. parental demandingness) at 12 and 24 months. However, unexpected findings were also present, with participating caregivers reporting less feelings of a close, trusting relationship with their child at 12 months and decreased parental competence at 36 months. These mixed findings highlight the need to better understanding unique aspects of caring for children affected by parental HIV and develop targeted intervention approaches that yield sustained improvements over time.

Compared with nonaffected children, Chinese children of HIV-positive parents have been shown to have increased rates of internalizing and externalizing adjustment problems [59,60], greater exposure to traumatic events [61], and more mental health disorders including anxiety and depression [62]. Caregiving for vulnerable children is a stressful, time-consuming, and challenging endeavor – even in the best of circumstances. Yet across the globe, caregiving for children made vulnerable by HIV frequently occurs within a context of extreme poverty and high HIV stigma – yielding additional challenges for affected families [63,64]. Providing direct services to affected children is critical but not sufficient; intervention and supportive services must also target the caregivers who set the foundation for children’s healthy development. Including caregivers in intervention and utilizing a family systems perspective may be particularly important in areas most severely affected by HIV [65]. In these areas, family often plays a central role not only in driving the epidemic (i.e., through sexual and vertical transmission), but also in supporting those affected by HIV and in delivering HIV messages and setting norms for HIV-related behaviors [65]. *ChildCARE* aims to leverage this influence in a positive manner by including caregivers of HIV-affected children in the resilience-promoting intervention.

Strengthening the capacity of caregivers to parent effectively is a cornerstone of efforts to prevent and reduce a wide variety of child behavior problems [66,67]. These preliminary findings indicate that *ChildCARE* helps caregivers set clearer standards of behavior, actively monitor their children, and maintain a structured home life. Such skills may be particularly important as parental HIV is associated with disruptions in family routines, shifts in caregiving, and changes in residence and/or caregiver that may challenge family stability [18,20]. In addition, existing literature suggests that children affected by HIV in low-income and middle-income countries are at higher risk than unaffected children to be victims of sexual violence, child abuse, labor exploitation, and other traumas [68,69]. Training

caregivers to closely monitor and take an active role in children's lives may reduce the risk for victimization.

Positive intervention effects of *ChildCARE* were not found for other key parenting outcomes including parental responsiveness and trusting relationship with the child. This may reflect the limitations of a brief, manual-based intervention to yield meaningful changes in attachment and interpersonal style, including how caregivers respond to the emotional needs of their children. Such needs may be more appropriately addressed through individual or family therapy than within the group-based format of *ChildCARE*. In future iterations of the intervention, a triage approach may be useful to identify child-caregiver dyads in need of intensive, individualized family therapy services that go beyond the standardized intervention.

In terms of mental health, the caregiving component yielded initial decreases in caregivers' anxiety and perceived stress. Having the opportunity to openly discuss with peers the challenges of caregiving in the context of HIV and learning positive parenting strategies may reduce caregivers' worries about their children and their parenting skills. The intervention also educates caregivers on the importance of self-care – critical for maintaining psychosocial wellbeing. However, the intervention did not yield decreases in symptoms of depression. This is perhaps not surprising given that the intervention focuses primarily on parenting skills.

Finally, some of the most surprising findings included no changes in resilience over time and reductions in caregivers' ratings of their trusting relationship with their child and their parental competence. Taking part in the caregiving intervention may have caused caregivers to reassess their relationships with their children, as well as their own parenting behaviors. In addition, they may have become more aware of the challenges facing families affected by HIV. Delivering the intervention in a peerbased format may provide additional opportunities for participants to seek and receive social support, as well as learn from others' experiences. However, bearing witness to the stories of neighbors and friends who have also been impacted by the widespread HIV epidemic in Henan and seeing families at different stages (i.e., who may have already experienced parental death, separation of siblings, etc.) may affect caregivers in unexpected – and even negative – ways, including becoming more aware of the challenges that lay ahead. Although caregivers' competence was lower postintervention, it should be noted that competence – as well as all other measures – was measured through self-report. Directly measuring parenting behaviors and evaluating the quality of caregiver-child interactions postintervention using a structured observation procedure would be a helpful addition to current findings.

There are a number of other limitations that should also be considered. First, while the use of cluster randomization may help to reduce the chance of contamination (i.e., sharing of intervention content) between control and intervention groups, the design yielded baseline differences between arms on several measures which could have impacted findings. In addition, attrition by 36 months was high, particularly among participants assigned to the control and child-only arms. Second, as is common among large randomized controlled trials, we assessed multiple study outcomes across multiple time periods. Thus some

significant findings may well be artifacts of multiple testing. Multilevel models such as the one used in the current study address this multiple comparison problem and are often superior to other correction procedures such as Bonferroni adjustments [70,71]. However, findings should be considered tentative and further replication is needed to confirm *ChildCARE*'s effects on caregiver outcomes. Third, we included both HIV-positive and HIV-negative caregivers in the evaluation trial. The psychosocial needs of these two groups are likely to be different. To account for this, HIV status was controlled for in our modeling. Future iterations of *ChildCARE* may wish to tailor content to the needs of a more homogenous group of caregivers (i.e., HIV-positive or negative, biological or nonbiological parents). Doing so may meet caregivers' needs more effectively and yield stronger intervention effects. Nonetheless, the study represents an important first step in evaluating *ChildCARE* caregiver outcomes and highlights the critical need to devote more resources to understanding the challenges of caregiving in the context of HIV and promoting psychological resilience for both children made vulnerable by HIV and their caregivers.

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Fig. 1. A conceptual framework of resilience promotion for children affected by parental HIV.
Reprinted from [33].

Intervention Arm	Months 1-6	Months 7-12	Months 13-18	Months 19-24	Months 25-30	Months 31-36
Control						
Child-only	Child Intervention Delivered					
Child +Caregiver		Caregiver Intervention Delivered				
Child +Caregiver +Community			Community Intervention Delivered			

Fig. 2. Timeline of the Child-Caregiver-Advocacy Resilience evaluation using a community-based four-arm cluster randomized design.

Dotted lines indicate timeline for baseline and follow-up assessments with caregivers.

Table 1.

Demographic characteristics for overall sample and by intervention assignment.

	Overall	Control	Child-only arm	Caregiver arms
<i>N</i>	790 (100%)	195 (24.7%)	200 (25.3%)	395 (50.0%)
Caregiver's age	42.7 (12.6)	42.1 (14.0)	44.3 (10.9)	42.3 (12.5)
Caregiver's sex				
Male	327 (41.4%)	97 (49.7%)	79 (39.5%)	151 (38.2%) ^a
Female	463 (58.6%)	98 (50.3%)	121 (60.5%)	244 (61.8%)
Caregiver's education level				
No formal schooling	74 (9.4%)	19 (9.7%)	21 (10.5%)	34 (8.6%)
Elementary school	356 (45.1%)	95 (48.7%)	82 (41.0%)	179 (45.3%)
Secondary or above	360 (45.6%)	81 (41.5%)	97 (48.5%)	182 (46.1%)
Caregiver's occupation				
Farming	515 (65.2%)	121 (62.1%)	146 (73.0%)	248 (62.8%) ^a
Other	275 (34.8%)	74 (37.9%)	54 (27.0%)	147 (37.2%)
Caregiver's marital status				
Married/cohabitating	549 (69.5%)	131 (67.2%)	144 (72.0%)	274 (69.4%)
Other	241 (30.5%)	64 (32.8%)	56 (28.0%)	121 (30.6%)
Household income level				
<1000 yuan	415 (52.5%)	104 (53.3%)	113 (56.5%)	198 (50.1%)
>1000 yuan	375 (47.5%)	91 (46.7%)	87 (43.5%)	197 (49.9%)
Caregiver's HIV status				
HIV-positive	487 (61.6%)	114 (58.5%)	127 (63.5%)	246 (62.3%)
HIV-negative	303 (38.4%)	81 (41.5%)	73 (36.5%)	149 (37.7%)
Relationship with child				
Biological parent	558 (70.6%)	131 (67.2%)	142 (71.0%)	285 (72.2%)
Other	232 (29.4%)	64 (32.8%)	58 (29.0%)	110 (27.8%)
Follow-up rates				
12 months	78.2%	76.9%	79.0%	77.0%
24 months	71.5%	65.6%	67.0%	75.0%
36 months	57.3%	48.7%	48.0%	65.8%

^aSignificant differences ($P < 0.05$) existed at baseline between arms for distribution of sex and occupation.

Table 2.

Means and SDs of outcomes of interest by intervention assignment at baseline, 12, 24, and 36 months.

	Control arm		Child-only arm		Caregiver arms	
	<i>M</i>	<i>Std</i>	<i>M</i>	<i>Std</i>	<i>M</i>	<i>Std</i>
Depression						
Baseline	20.96	4.96	19.68	4.72	19.80	4.57 [*]
12 months	21.21	5.09	19.88	4.53	19.16	4.90 ^{****}
24 months	19.78	5.07	19.37	5.27	18.47	4.57 ^{**}
36 months	19.13	5.52	19.25	4.82	18.28	4.81 [*]
Anxiety						
Baseline	11.41	4.47	10.71	3.77	11.08	4.19
12 months	12.23	4.40	10.88	3.84	10.75	4.03 ^{**}
24 months	10.60	3.90	11.13	4.71	10.60	4.60
36 months	10.55	4.35	10.95	4.45	10.51	4.38
Resilience						
Baseline	31.49	7.93	31.33	7.78	30.72	7.82
12 months	31.37	7.86	30.80	7.83	31.14	8.48
24 months	31.72	7.81	31.10	8.56	30.41	8.53
36 months	29.84	9.56	32.53	7.56	30.20	8.78
Parental responsiveness						
Baseline	21.81	4.37	21.85	4.02	21.60	3.82
12 months	21.80	3.77	22.32	4.10	22.46	4.76
24 months	22.43	4.59	22.61	3.95	23.20	5.02 ^a
36 months	22.77	4.85	22.08	4.47	22.72	5.22
Parental demandingness						
Baseline	17.64	3.99	18.09	4.01	17.59	3.98
12 months	17.17	3.81	18.49	3.92	18.71	4.67 ^{**}
24 months	17.86	3.83	18.39	4.21	19.23	4.54 ^{**}
36 months	18.34	4.93	17.77	4.53	18.38	4.54
Trusting relationship with child						
Baseline	56.53	11.23	57.41	11.61	56.97	11.50
12 months	59.20	10.99	56.17	11.84	57.23	13.42
24 months	56.61	13.27	57.73	13.04	57.03	14.22
36 months	58.52	15.26	59.06	13.53	57.08	14.78
Parental competence						
Baseline	19.69	4.11	20.98	3.96	20.96	4.14 ^{**}
12 months	21.02	4.52	21.23	4.14	21.65	5.11
24 months	20.98	3.78	21.17	4.24	21.51	3.75
36 months	21.46	4.25	21.21	3.96	20.70	4.40
Parental stress						

	Control arm		Child-only arm		Caregiver arms	
	<i>M</i>	Std	<i>M</i>	Std	<i>M</i>	Std
Baseline	18.38	5.63	17.12	5.94	16.25	5.49****
12 months	19.28	5.56	16.99	5.16	15.89	6.10****
24 months	18.41	6.01	18.16	5.89	16.91	5.77**
36 months	19.72	6.36	18.90	6.18	17.39	5.75**

*
P < 0.05,

**
P < 0.01,

P < 0.001,

P < 0.0001,

^a
P < 0.10.

Table 3.

Fixed and random effect parameters for mental health outcomes at 12, 24, and 36 months.

Variable	Depression		Anxiety		Resilience	
	β	Std	β	Std	β	Std
Fixed effects						
Relationship with child	0.044	0.017 ^{**}	0.042	0.024 ^a	−0.002	0.021
Sex	−0.005	0.013	0.010	0.018	0.023	0.016
Age	0.000	0.001	−0.001	0.001	0.000	0.001
HIV status	0.071	0.014 ^{***}	0.070	0.019 ^{***}	0.022	0.017
Time × child intervention						
At 12 months	0.005	0.035	−0.047	0.049	−0.019	0.044
At 24 months	0.055	0.037	0.109	0.051 [*]	−0.033	0.047
At 36 months	0.100	0.041 [*]	0.117	0.057 [*]	0.137	0.051 ^{**}
Time × caregiver intervention						
At 12 months	−0.035	0.031	−0.106	0.043 [*]	0.023	0.039
At 24 months	0.006	0.032	0.027	0.044	−0.018	0.040
At 36 months	0.040	0.034	0.030	0.048	0.083	0.043 ^a
Random effects						
Intercept	0.014	0.002	0.028	0.003	0.019	0.002
Residual	0.049	0.002	0.094	0.003	0.077	0.003

*
P < 0.05,**
P < 0.01,***
P < 0.001,^aP < 0.10.

Table 4.

Fixed and random effect parameters for parenting outcomes at 12, 24, and 36 months.

Variable	Parental responsiveness		Parental demandingness		Trusting relationship with child		Parental competence		Parental stress	
	β	Std	β	Std	β	Std	β	Std	β	Std
Fixed effects										
Relationship with child	-0.012	0.014	-0.034	0.018 [*]	-0.045	0.017 ^{**}	-0.032	0.014 [*]	0.019	0.024
Sex	0.010	0.011	-0.012	0.014	-0.037	0.013 ^{**}	-0.006	0.011	0.021	0.019
Age	0.000	0.000	0.001	0.001	0.000	0.001	0.000	0.000	0.001	0.001 ^a
HIV status	-0.018	0.011	-0.027	0.014 ^a	0.009	0.014	0.014	0.011	0.066	0.019 ^{***}
Time $\times$ child intervention										
At 12 months	0.019	0.031	0.057	0.037	-0.081	0.034 [*]	-0.060	0.034 ^a	-0.081	0.053
At 24 months	0.009	0.033	-0.005	0.039	-0.010	0.036	-0.078	0.036 [*]	0.067	0.055
At 36 months	-0.032	0.037	-0.053	0.044	0.004	0.040	-0.071	0.040 ^a	0.044	0.061
Time $\times$ caregiver intervention										
At 12 months	0.035	0.027	0.083	0.033 [*]	-0.060	0.030 [*]	-0.035	0.030	-0.099	0.046 [*]
At 24 months	0.041	0.029	0.076	0.034 [*]	-0.018	0.031	-0.039	0.031	0.057	0.048
At 36 months	0.005	0.031	0.009	0.037	-0.033	0.033	-0.099	0.033 ^{**}	0.027	0.051
Random effects										
Intercept	0.007	0.001	0.013	0.002	0.016	0.002	0.005	0.001	0.025	0.003
Residual	0.040	0.001	0.056	0.002	0.046	0.002	0.047	0.002	0.110	0.004

^{*}P < 0.05,^{**}P < 0.01,^{***}P < 0.001,^aP < 0.10.