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ORIGINAL PAPER

Effects of a Multilevel Resilience-Based Intervention on Mental Health for Children Affected by Parental HIV: A Cluster Randomized Controlled Trial

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Abstract

The present study aimed to examine the efficacy of the *Child-Caregiver-Advocacy Resilience* (ChildCARE) intervention, a multilevel resilience-based psychosocial intervention, on mental health outcomes, including depressive symptoms, school anxiety, and loneliness, among children affected by parental HIV in central China. Seven hundred and ninety children (51.6% boys, 6–17 years of age) affected by parental HIV were randomly assigned by cluster to a control group or one of three intervention groups designed to test the three conditions of the ChildCARE intervention (child-only, child + caregiver, child + caregiver + community). Linear mixed-effects modeling was performed to test the intervention effect at 6, 12, and 18 months. The intervention did not yield significant changes in mental health outcomes in the child-only group at any follow-ups, whereas significant reductions in depressive symptoms and loneliness were observed in the child + caregiver group at 12 months. The observed intervention effects were not sustained at 18 months. Also, children who received the additional community component that, was implemented after 12 months did not show larger improvements in mental health outcomes than the control group at 18 months. Lastly, older children (i.e., ≥12 years) were found to benefit more from the intervention than their younger counterparts (i.e., <12 years). Overall, the findings provide some support for the promise of multilevel resilience-based interventions in improving mental health of children affected by parental HIV, but more research is needed to further determine whether multilevel resilience-based interventions can yield sustained effects on mental health.

Keywords Intervention · Resilience · Mental health · Parental HIV · Age

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Highlights

- Improvements in mental health outcomes were observed in children receiving child and caregiver intervention components.
- No significant changes in mental health were found in children receiving child intervention component only.
- Age differences were observed in the effect of the ChildCARE intervention on mental health.

The HIV epidemic has had direct adverse impacts on over 37 million people living with HIV worldwide (UNAIDS, 2021) and indirect impacts on their families and communities (Boutayeb 2009; Ji et al. 2007). As of 2020, approximately 15.4 million children under 18 years of age were orphaned by AIDS, with millions more affected by familial HIV (UNICEF, 2021). Children affected by parental HIV, defined as children who have lost one or both parents to AIDS-related illnesses or have one or both parents living with HIV (Chi & Li, 2013), have been found to have an increased risk for a variety of poor emotional, educational, and social outcomes (for reviews, see Chi & Li 2013; Guo et al., 2012; Skovdal, 2012).

Parental HIV and Mental Health Outcomes

In a systematic review of literature on the psychosocial well-being of children affected by parental HIV, Chi and Li (2013) indicate that overall, children affected by parental HIV are at greater risk of experiencing poor mental health outcomes, including depression, anxiety, and loneliness, compared to children from HIV-unaffected families. The elevated risk of poor mental health among this group of children is not only driven by parental illness and death but also by multiple contextual and family factors (Cluver & Orkin, 2009; Cluver et al., 2013; Tompkins & Wyatt, 2008). HIV stigma, defined as prejudice, discrediting, and discrimination towards people living with HIV and individuals they are associated with, such as their family members (Herek, 2002), has been linked to increased depression, anxiety, loneliness, and post-traumatic stress among children affected by parental HIV (Cluver & Orkin, 2009; Lin et al., 2010). For example, Cluver and Orkin (2009) indicated that children orphaned by AIDS in South Africa reported much higher levels of HIV stigma than their counterparts orphaned by other causes, putting them at higher risk of experiencing depressive and anxiety disorders. Exposure to poverty and community violence has also been reported to contribute to increased psychological distress among children affected by parental HIV (Cluver et al., 2013). Notably, these risk factors related to parental HIV may interact to result in cumulative adverse effects on mental health (Cluver & Orkin, 2009). Cluver and Orkin (2009) suggested that stigma and poverty were independently associated with elevated mental health disorders among children affected by parental HIV; stigma and poverty also interacted to intensity the risk of mental health problems. In addition, mental health in children affected by parental HIV may be indirectly impacted by the quality of parenting they receive. Parents living with HIV are at elevated risk for depression and parental distress, which may contribute to poor quality of parenting (Lachman et al., 2014). For example, in a study of mothers living with HIV, parental stress was found to be associated with poor parenting skills (e.g., parent-child communication), which, in turn, was associated with elevated children's problem behaviors, including depressive and anxiety symptoms (Murphy et al., 2010). Such a constellation of risk factors highlights the need for interventions that address factors at multiple ecological levels (e.g., individual, family, community) to improve mental health of children affected by parental HIV.

Resilience

Not all children affected by parental HIV exhibit clinically significant mental health symptoms or show chronically elevated levels of adverse developmental outcomes (Chi et al., 2014; Mellins et al., 2008). This phenomenon is illustrative of the construct of resilience, which is defined as "a dynamic process encompassing positive adaptation within the context of significant adversity" (Luthar et al., 2000; p. 453). The resilience framework provides a welcome alternative to the deficit-focused model for children facing adversity (Masten, 2001), and numerous recent efforts have sought to apply the resilience theory to children made vulnerable by HIV (Harrison & Li, 2018).

By integrating perspectives from the resilience and ecological systems theory (Bronfenbrenner, 1989; Masten et al., 1990), Li et al., (2015) have developed an integrated resilience framework for children affected by parental HIV. This theoretical framework recognizes the unique HIV-related vulnerabilities experienced by this group of children and posits that enhancing supports from three key ecological systems, including the individual (e.g., coping skills), family (e.g., high-quality parenting), and community (e.g., social support) systems, may reduce the risk of developing poor outcomes among children affected by HIV. Consistent with this framework, some researchers have highlighted the importance of adopting an integrated ecological perspective

in research focusing on resilience and mental health of children affected by HIV, which can help provide important implications for developing resilience-based, multilevel interventions that aim to address the complex nature of adversities experienced by this pediatric group (Betancourt et al., 2013).

Impact of Resilience-Based Interventions on Mental Health

Resilience-based interventions—defined as interventions that focus on enhancing resilience at one or multiple ecological systems (Dray et al., 2017)— have shown promise in improving mental health of children affected by parental HIV, though some mixed findings have emerged (Skeen et al., 2017). In a systematic review of interventions for psychosocial well-being in children affected by HIV, Skeen et al. (2017) identified 17 intervention studies, with six resilience-based interventions aiming to reduce mental health problems, including depressive symptoms, anxiety, anger, and internalizing behaviors. For example, a post-test study found that enrolling in social support programs was significantly associated with fewer emotional symptoms among children 8–14 years of age in Kenya (Thurman et al., 2012). Similarly, a cluster randomized controlled trial (RCT) found that a peer-support intervention significantly reduced depression, anxiety, and anger among AIDS orphans 10-15 years of age in Uganda (Kumakech et al., 2009). However, three RCTs found that family-based interventions did not decrease internalizing problems or anxiety in children living in South Africa (Bell et al., 2008; Eloff et al., 2014) or the United States (Rotheram-Borus et al., 2012). In addition, a community-based intervention targeting self-efficacy found no significant effects on depression among children 8-18 years of age in South Africa (Mueller et al., 2011).

A few recent intervention studies in children affected by parental HIV have been published since the review of Skeen et al. (2017). A pilot RCT in children 7–17 years of age of caregivers living with HIV in Rwanda found that a family-based intervention significantly reduced depressive symptoms at the 3-month follow-up (Betancourt et al., 2017). Another pilot RCT showed that a family-based intervention significantly decreased depressive symptoms in children of 6–14 years old living with HIV-positive mothers in the United States (Murphy et al., 2017). These studies provide initial support for the promise of resilience-based interventions in improving mental health of children affected by parental HIV; however, research in this line is still limited. There is a lack of interventions targeting resilience-related factors at multiple ecological systems, and evidence regarding the efficacy of such interventions in improving mental health is limited.

The Present Study

The current study aimed to examine the efficacy of a multilevel resilience-based intervention, the *Child-Caregiver-Advocacy Resilience* (ChildCARE) intervention, in improving mental health in children affected by parental HIV in central China. The ChildCARE intervention, consisting of programming at three levels (i.e., child, caregiver, community), is a culturally tailored theory-guided psychosocial intervention that was developed to improve the psychosocial well-being and physical health of children affected by HIV in China (Li et al., 2015; Li et al., 2017). In previous reports of the efficacy of the ChildCARE intervention, improvements have been demonstrated in children's internal resilience resources (e.g., positive coping; Li et al., 2017) and educational outcomes (e.g., academic performance; Harrison et al., 2017; Harrison et al., 2018), as well as caregivers' mental health and parenting (e.g., parental stress; Harrison et al., 2019). The efficacy of the ChildCARE intervention on children's mental health, however, has not been examined. Specifically, this study examined the effect of the ChildCARE intervention on reducing depressive symptoms, school anxiety, and loneliness at 6, 12, and 18 months. We hypothesized that the ChildCARE intervention would result in improvements in mental health outcomes for participating children. We further hypothesized that participating children who were assigned to receive intervention components at multiple levels (e.g., child + caregiver) would gain greater mental health benefits than those who were assigned to receive the child-level intervention component only. A secondary aim was to explore potential gender and age differences in the intervention effects on mental health outcomes. Gender differences have been reported in the effects of resilience-based interventions on children's mental health (Dray et al., 2017). Also, older children affected by parental HIV have shown to be more responsive to resilience-based interventions than their younger counterparts (Li et al., 2017).

Method

Setting and Participants

The implementation and evaluation of the ChildCARE intervention were conducted in a rural county in Henan Province in central China, where an outbreak of HIV infection emerged in the 1990s, primarily due to the unhygienic commercial blood and plasma collection practices (Li et al., 2009). The detailed information about the participant recruitment had been reported elsewhere (Li et al., 2017). In brief, researchers worked with local public health officials to compile lists of HIV-affected families in

the county and then randomly invited eligible children and their caregivers to participate in the study. Inclusion criteria for recruitment were (1) ages 6–17 years and (2) one or both biological parents were HIV-positive (i.e., alive or deceased). Children with known HIV infection (i.e., verified by caregivers or community officials) were excluded from the study, given that the psychosocial needs of children living with HIV might be different from children affected by parental HIV due to their health condition and that only a few young children were living with HIV at the time of the HIV outbreak in the study site. When multiple children from a family met the recruitment criteria, researchers randomly selected one to participate. The recruitment process was repeated until achieving the target sample size (i.e., about 800 child-caregiver dyads).

A total of 790 children (408 boys, 51.6%) participated in the study. The mean age of the sample was 10.51 ($SD =$ 1.99) years, with the majority of children (94.4%) between 8 and 15 years of age. Of the participating children, approximately 9.3% lost one biological parent to AIDS (i.e., "single death"), 3.1% lost both parents to AIDS (i.e., "double death"), 72.6% had one parent currently living with HIV (i.e., "singe infection"), and 15.1% had both parents currently living with HIV (i.e., "double infection"). The mean number of family members ever infected with HIV in the household was 1.07 ($SD = 1.01$), and the mean number of HIV-related death in the household was 0.45 ($SD =$ 0.78). Children reported a mean number of 1.77 ($SD =$ 1.20) siblings. In addition, 59.3% of fathers and 58.2% of mothers of participating children had less than high school education. The majority of parents were farmers (46.2% of mothers, 32.9% of fathers) and migrant workers (28.3% of mothers, 42.6% of fathers).

The ChildCARE Intervention

The ChildCARE intervention was developed upon a resilience framework proposed by Li et al. (2015), a conceptual framework illustrating the dynamic resilience process in shaping positive adaptation of children who experience parental HIV and associated risk factors (e.g., poverty, stigma, violence). Li et al. (2015) propose that resilience result from the interplay of multiple factors within and across three ecological systems: child internal assets (e.g., coping), family resources (e.g., parenting), and community resources (e.g., social cohesion). These resilience-related factors at the child, family, and community levels, together, play a critical role in influencing positive outcomes, including better mental health, among children affected by parental HIV. Accordingly, the ChildCARE intervention consists of intervention components at three levels: child, caregiver, and community. The child-level component was designed to enhance multiple intrapersonal skills, such as coping, emotional regulation, and positive thinking (for a detailed description of the intervention components, see Li et al. 2017). The caregiver-level component was designed for caregivers of children affected by parental HIV, with the goal of enhancing positive parenting skills and the capacity of self-care and support-seeking. The community-level component includes monthly home visits by intervention facilitators and a series of community-based activities (e.g., community sports events) that provide opportunities for children and their caregivers to meet and interact with community members, with the goal of reducing stigma and building community-level support for families affected by HIV.

Intervention Assignment and Delivery

The ChildCARE intervention was initially evaluated using a 4-arm community-based cluster RCT between 2012 and 2016. Participating children were clustered by the schools which they were currently attending. The school clusters ($n = 45$) then served as the unit of randomization for assignment to the control group (i.e., participated 10 2- hour sessions of after-school activities [e.g., games, crafts] but did not receive any intervention components) or one of the three intervention groups: a child-only group (i.e., received child component), a child + caregiver group (i.e., received both child and caregiver components), and a child + caregiver + community group (i.e., received all three intervention components, see Supplementary Figure 1). Due to the resource constraints, the three intervention components were implemented on a staggered six-month schedule. Specifically, the 10 2-hour child intervention sessions (i.e., a total of 20 h) were delivered between baseline and 6 months at the local schools, the five 2-hour caregiver intervention sessions (i.e., a total of 10 h) were delivered between 6 and 12 months at the local schools, and the home visits and community activities were delivered between 12 and 36 months in homes and local community settings, respectively. Children of similar age (or grade) were grouped to receive the intervention sessions so that the intervention facilitators could use age-appropriate language or materials during the intervention delivery. This implementation schedule allows examining the effect of the child-only component at 6 months, the effect of the child + caregiver components at 12 months, and the effect of the child + caregiver + community components at 18 months. Standardized training and the intervention manual were provided to intervention facilitators ($N = 104$) to increase the intervention fidelity. Sessions were audio-recorded for review if there were concerns about the deviations from the intervention manual.

Data Collection

After randomization, children were asked to complete a survey consisting of demographic and psychosocial scales

in Chinese. The same survey was also administrated at 6, 12, and 18 months. A forward and backward translation process was performed for scales that were initially developed in English by English-Chinese bilingual research team members (Fang et al., 2009). At each assessment, the survey was self-administered using a paper-and-pencil instrument individually or in small groups in the presence of two interviewers. A small portion of participants (i.e., about 2% of the sample) needed assistance from the interviewers to read survey items, either due to age or reading difficulties. For these participants, interviewers read the items aloud and recorded children's oral responses to the survey in a private room. Each child received an age-appropriate gift (e.g., a toy or school supply) at the end of each assessment. Prior to participation, appropriate informed consent was obtained from all children and their caregivers. The study protocol was approved by Institutional Review Boards at Henan University in China and Wayne State University and the University of South Carolina in the United States.

Measures

Depressive Symptoms

Depressive symptoms were measured using the 10-item *Center for Epidemiological Studies Depression Scale for Children* (CES-DC, Andresen et al., 1994; Fendrich et al., 1990). The reliability and validity of the CES-DC have been established in a large sample of children from urban and rural areas in China (Xiong 2015). Sample items were "I was bothered by things that usually don't bother me" and "I felt like something good was going to happen" (reversed coded). Children were asked to report how frequently they had experienced each of the 10 moods or symptoms during the past week on a 4-point scale (from 0 = not at all to 3 = a lot). A sum score for depressive symptoms was calculated by summing children's responses to the 10 items, with a higher score reflecting more severe depressive symptoms. For children with missing responses to one item (i.e., fewer than 3% of the sample), that missing item was imputed by replacing with the mean score of the remaining nine completed items, as recommended by Andresen et al. (1994). The Cronbach αs for the CES-DC were 0.62 at baseline, 0.69 at 6 months, 0.72 at 12 months, and 0.73 at 18 months.

School Anxiety

School anxiety was measured using the 6-item anxiety/withdrawal subscale adapted from the *Child Rating Scale* (CRS, Hightower et al., 1987). The CRS has been applied in previous studies among children affected by parental HIV in China (e.g., Li et al., 2009). Sample items were "I worry about things at school" and "I am nervous at school". Children were asked to assess how well each of the six items describes them on a 4-point scale ranging from 1 = "does not describe me at all" to 4 = "totally describes me." A mean score for school anxiety was calculated by averaging children's responses to the six items, with a higher score reflecting more severe school anxiety. The Cronbach αs were 0.51 at baseline, 0.64 at 6 months, 0.68 at 12 months, and 0.74 at 18 months.

Loneliness

Loneliness was measured using the 16-item *Loneliness Scale for Children* (Asher et al., 1984). This scale has also been applied in previous studies among children affected by parental HIV (e.g., Fang et al., 2009). Sample items were "I feel alone" and "I have nobody to talk to". Children were asked to report how well each of the 16 items describes them on a 4-point scale ranging from 1 = "does not describe me at all" to 4 = "totally describes me". A mean score for loneliness was calculated by averaging children's responses to the 16 items, with a higher score reflecting higher loneliness. The Cronbach αs were 0.77 at baseline, 0.79 at 6 months, 0.83 at 12 months, and 0.84 at 18 months.

Demographic Characteristics

Children were asked to provide information on their gender, age, household composition (e.g., number of siblings), parents' education and occupation, and HIV infection and HIV-related death in the household.

Statistical Analyses

All data analyses were performed in SPSS Version 25.0 for Windows (IBM Corp. Released 2017. Armonk, NY) using restricted maximum likelihood estimation (Gilmour et al., 1995). First, descriptive analyses were conducted for baseline demographic variables and outcome variables. Analyses of variance (ANOVA) for continuous variables and the Chi-square test for categorical variables were performed to test mean (or frequency) differences in baseline characteristics by intervention assignment. Multiple testing via the Bonferroni method was employed to determine where the differences occurred between the two intervention assignments. ANOVA was also performed to test whether there were any differences in baseline mental health outcomes between the intervention and control groups among children who had missing data at each follow-up.

Second, the linear mixed-effects model was used to test the intervention effects following the intention to treat principle, which allows adding a random intercept to account for the correlations among repeated measures and

the nesting of children within school clusters. In the model, the intervention conditions (e.g., control, child-only, child + caregiver, child + caregiver + community), time (e.g., 0 [baseline], 6 months, 12 months, 18 months), and the 2-way interaction terms between the intervention conditions and time were included as predictors of each mental health outcome. Gender and age were included as covariates in the model. The number of HIV infection in the household was also included as a covariate due to the observed inequivalence by intervention assignment (X. Li et al., 2017). Third, the linear mixed-effects model outlined above was used to test gender and age differences in the intervention effects. In the model, all possible two-way and three-way interaction terms among gender (or age), the intervention conditions, and time were included as predictors. Lastly, to interpret potential significant gender and age differences in the intervention effects, the analyses for linear mixed-effects models were stratified by gender (i.e., boys, girls) and age at baseline (i.e., under 12 years [67.7% of the sample], 12 years and older). Age 12 was chosen as the age cutoff because it marks a developmental transition from primary school to secondary school among Chinese children (UNICEF, 2014). Missing data were handled with full information maximum likelihood (Newman, 2003).

Results

Descriptive and Attrition Analyses

Table 1 displays the results for baseline demographic characteristics by intervention assignment. Results showed significant differences in age, parental vital status, and the number of HIV infection in the household between the intervention groups and the control group ($ps < 0.05$).

Table 2 displays the mean and standard deviations of mental health outcomes at baseline and follow-ups by intervention assignment. Overall, children had a mean score of 10.36 ($SD = 4.35$) on the 10-item CES-DC scale at baseline. When using the cutoff score of 15 for clinical depression recommended by Xiong (2015) in Chinese children, about 19.1% of children were at risk for clinical depression. Children had an overall mean score of 1.95 ($SD = 0.59$) for school anxiety and 2.13 ($SD = 0.47$) for loneliness at baseline. There were no significant differences in baseline mental health outcomes by intervention assignment ($ps > 0.05$). Data for three mental health outcomes were missing for 6.8% of children at 6 months, 14.2% at 12 months, and 16.6% at 18 months. Attrition analyses showed no significant differences in baseline mental health outcomes by intervention assignment among children with missing data at each follow-up ($ps > 0.05$, see Supplementary Table 1).

Intervention Effects

Table 3 displays the results of the intervention effects on mental health outcomes at 6, 12, and 18 months. Results showed that there were no significant changes in mental health outcomes at 6 months following the delivery of the child intervention component (unstandardized $b = 0.08$, $p = 0.32$ for depressive symptoms; $b = -0.01$, $p = 0.24$ for school anxiety; $b = 0.00$, $p = 0.82$ for loneliness). However, significant reductions in depressive symptoms ($b = -0.15$, $p = 0.009$) and loneliness ($b = -0.02$, $p = 0.002$), but not school anxiety ($b = -0.01$, $p = 0.27$), were observed for the child + caregiver group at 12 months (first time point of the assessment for the child + caregiver group). The observed intervention effects in the child + caregiver group at 12 months were not maintained at 18 months. In addition, there were no additional intervention effects on mental health outcomes at 18 months after the community intervention was delivered (first time point of the assessment for the child + caregiver + community group, $b = 0.07$, $p = 0.35$ for depressive symptoms, $b = 0.01$, $p = 0.54$ for school anxiety, $b = 0.01$, $p = 0.82$ for loneliness). A significant but negative intervention effect on school anxiety was observed for the child-only group at 18 months ($b = 0.01$, $p = 0.022$).

Gender and Age Difference in Intervention Effects

There was a significant three-way interaction term (gender by child-only intervention by time) on school anxiety at 6 months ($b = 0.06$, $p = 0.002$), but significant three-way interaction terms were not found for depressive symptoms or loneliness ($ps > 0.05$, see Supplementary Table 2). Stratified linear mixed models by gender showed a positive intervention effect on school anxiety for girls ($b = -0.05$, $p = 0.003$, see Supplementary Table 4), but not for boys ($b = 0.02$, $p = 0.22$) at 6 months. Sup. Figure 2a presents the changes in mean score of school anxiety across time and shows a graphical interpretation of gender differences in intervention effects at 6 months.

Significant three-way interaction terms (age by child + caregiver group by time) were observed for school anxiety at both 12 and 18 months ($b = -0.10$, $p = 0.018$; $b = -0.01$, $p = 0.011$; respectively, see Supplementary Table 3). Stratified linear mixed models by age showed that there was a significant reduction in school anxiety for children ages 12 years and older ($b = -0.04$, $p = 0.017$, see Sup. Figure 2b), but not for children under 12 years of age ($b = 0.00$, $p = 0.64$), in the child + caregiver group at 12 months. The observed positive intervention effect at 12 months in children ages 12 years and older did not maintain at 18 months ($b = -0.01$, $p = 0.13$), whereas a negative intervention effect was observed for children under

Table 1 Demographic variables by intervention assignment

Variables	Overall		Intervention groups		
		Control	Child-only	Child + Caregiver	Child + caregiver + community
N(%)	790 (100%)	195 (24.7%)	200 (25.3%)	198 (25.1%)	197 (24.9%)
Boys	408 (51.6%)	113 (57.9%)	96 (48.0%)	104 (52.5%)	95 (48.2%)
Age (SD)	10.51 (1.99)	10.62 (2.07)	11.24 (2.30)[a]	10.39 (1.64)	9.77 (1.59)[a]
# of siblings	1.77 (1.20)	1.80 (1.20)	1.73 (1.10)	1.81 (1.20)	1.74 (1.29)
Parental vital status					
Single death	72 (9.3%)	22 (12.1%)	20 (10.0%)	15 (7.6%)	15 (7.7%)
Double death	24 (3.1%)	7 (3.8%)	5 (2.5%)	9 (4.5%)	3 (1.5%)
Single infection	563 (72.6%)	134 (73.6%)	129 (64.5%)	135 (68.2%)	165 (84.2%)
Double infection	117 (15.1%)	19 (10.4%)	46 (23.0%)[a]	39 (19.7%)	13 (6.6%)
Familial HIV infection & death					
# of infection	1.07 (1.01)	1.14 (1.16)	1.18 (0.86)	1.15 (0.98)	0.80 (0.97)[a]
# of death	0.45 (0.78)	0.52 (0.88)	0.41 (0.78)	0.48 (0.70)	0.39 (0.72)
Father's education					
No formal schooling	19 (2.4%)	2 (1.0%)	6 (3.0%)	5 (2.5%)	6 (3.1%)
Elementary school	255 (32.5%)	66 (34.2%)	67 (33.5%)	66 (33.3%)	56 (29.0%)
Middle school	191 (24.4%)	50 (25.9%)	73 (36.5%)	37 (18.7%)	31 (16.1%)
High school	61 (7.8%)	16 (8.3%)	10 (5.0%)	17 (8.6%)	18 (9.3%)
College-level	51 (6.5%)	12 (6.2%)	8 (4.0%)	15 (7.6%)	16 (8.3%)
Do not know	207 (26.4%)	47 (24.4%)	36 (18.0%)	58 (29.3%)	66 (34.2%)
Mother's education					
No formal schooling	46 (6.0%)	11 (5.8%)	12 (6.1%)	14 (7.1%)	9 (4.8%)
Elementary school	249 (32.3%)	64 (33.7%)	71 (35.9%)	63 (32.1%)	51 (27.1%)
Middle school	154 (19.9%)	38 (20.0%)	55 (27.8%)	31 (15.8%)	30 (16.0%)
High school	59 (7.6%)	16 (8.4%)	12 (6.1%)	15 (7.7%)	16 (8.5%)
College	46 (6.0%)	8 (4.2%)	9 (4.5%)	12 (6.1%)	17 (9.0%)
Do not know	218 (28.2%)	53 (27.9%)	39 (19.7%)	61 (31.1%)	65 (34.6%)
Father's occupation					
Farmer	252 (32.9%)	65 (34.8%)	70 (35.2%)	68 (36.0%)	49 (25.8%)
Migrant worker	326 (42.6%)	73 (39.0%)	84 (42.2%)	76 (40.2%)	93 (48.9%)
Teachers/ village administrators/ business/others	186 (24.5%)	49 (26.2%)	45 (22.6%)	45 (23.8%)	48 (25.3%)
Mother's occupation					
Farmer	349 (46.2%)	85 (46.4%)	100 (50.0%)	88 (47.6%)	76 (40.6%)
Migrant worker	214 (28.3%)	49 (26.8%)	51 (25.5%)	52 (28.1%)	62 (33.2%)
Teachers/ village administrators / business/others	192 (25.5%)	49 (26.8%)	49 (24.5%)	45 (24.3%)	49 (26.2%)

The numbers for some demographic variables did not add to the total sample size due to missing data (i.e., about 2.5% missing)

[a] Represents any differences from Bonferroni post hoc tests between the control and intervention groups at $p < 0.05$

12 years of age ($b = 0.01$, $p = 0.028$). Lastly, there were significant three-way interaction terms among age, the intervention conditions (i.e., child-only group, child + caregiver group), and time in predicting loneliness at 18 months ($b = -0.00$, $p = 0.017$ in the child-only group; $b = -0.01$, $p = 0.015$ in the child + caregiver group). Stratified analyses showed that significant positive intervention effects on loneliness were found at 18 months for children ages 12 years and older in both the child-only ($b = -0.02$, $p < 0.001$, see Sup. Figure 2c) and child + caregiver

Table 2 Means and standard deviations for mental health outcomes by intervention assignment

Variables	Overall		Intervention groups				
	α	Mean (SD)	Control	Child-only	Child + Caregiver	Child + caregiver + community	*p*
Depressive symptoms							
Baseline	0.62	10.36 (4.35)	10.70 (4.42)	10.16 (4.29)	10.51 (4.02)	10.09 (4.67)	0.47
6-month	0.69	10.88 (4.77)	10.81 (4.81)	11.74 (4.38)	10.96 (4.95)	10.02 (4.82)	
12-month	0.72	9.81 (4.71)	10.19 (4.63)	10.50 (4.79)	9.72 (4.49)	8.86 (4.81)	
18-month	0.73	9.82 (4.80)	9.67 (4.92)	10.41 (4.61)	10.24 (4.49)	8.94 (5.06)	
School anxiety							
Baseline	0.51	1.95 (0.56)	1.99 (0.53)	1.89 (0.56)	1.97 (0.54)	1.94 (0.59)	0.32
6 months	0.64	1.95 (0.59)	2.05 (0.62)	2.01 (0.59)	1.89 (0.58)	1.86 (0.54)	
12 months	0.68	1.81 (0.58)	1.87 (0.61)	1.84 (0.58)	1.82 (0.54)	1.72 (0.57)	
18 months	0.74	1.80 (0.62)	1.81 (0.65)	1.91 (0.65)	1.83 (0.61)	1.66 (0.55)	
Loneliness							
Baseline	0.77	2.13 (0.47)	2.11 (0.49)	2.10 (0.47)	2.15 (0.42)	2.16 (0.48)	0.54
6 months	0.79	2.16 (0.48)	2.13 (0.46)	2.26 (0.44)	2.17 (0.49)	2.10 (0.50)	
12 months	0.83	2.02 (0.51)	2.10 (0.51)	1.99 (0.51)	2.02 (0.51)	1.99 (0.52)	
18 months	0.84	2.09 (0.52)	2.08 (0.54)	2.08 (0.51)	2.17 (0.44)	2.03 (0.56)	

groups ($b = -0.02$, $p = 0.004$, see Sup. Figure 2d), whereas there were no intervention effects for those under 12 years of age in the child-only group ($b = 0.00$, $p = 0.78$) and even negative intervention effects (i.e., increased loneliness) in the child + caregiver group ($b = 0.01$, $p = 0.013$).

Discussion

The complex challenges that children affected by parental HIV experience call for interventions to foster resilience using socio-ecological and theory-driven frameworks. This study is among one of the first studies to examine the efficacy of a multilevel resilience-based intervention on mental health outcomes in children affected by parental HIV in rural China. Overall, our results showed that the ChildCARE intervention contributed to reductions in depressive symptoms and loneliness for some participants at 12 months, although most of the intervention effects were not sustained at 18 months. The results also indicated gender differences in the intervention effects at 6 months and age differences in the intervention effects at 12 and 18 months, with girls and older children being more responsive to the intervention than boys and younger children.

This study showed that children who received only the child component of the ChildCARE intervention did not show significant improvements in mental health outcomes, whereas those who received both the child and caregiver intervention components showed more reductions in depressive symptoms and loneliness than children in the control group at 12 months. The results suggest that the child intervention component alone may not be sufficient to contribute to better mental health, as measured by self-reported depressive symptoms, school anxiety, and loneliness. Instead, addressing both individual- and family-levels factors may be necessary to produce meaningful changes in mental health outcomes. These findings echo previous studies emphasizing the need for intervention to enhance resilience across multiple ecological systems in HIV-affected children (Betancourt et al., 2013). Interestingly, our study did not observe intervention effects after the community intervention component was delivered at 18 months. This nonsignificant result may be due to the short duration between the delivery of the community intervention component and the evaluation time point. However, a more likely reason for the lack of findings is that the community intervention component was primarily designed to promote community cohesion and support. Although increased community support may indirectly impact children's mental health, the evaluation timeframe and the assessment measures used in the current study may not be sufficient to detect potential individual-level mental health impacts.

Our results further indicated that most of the intervention effects observed at 12 months were not sustained at 18 months. The lack of sustained changes in mental health may be due to multiple reasons. First, a time-limited, manual-based intervention may not be enough to result in sustained improvements in mental health among children affected by parental HIV, particularly given the tremendous challenges faced by this pediatric group (Betancourt et al., 2013; Chi & Li, 2013). More intensive interventions or repeated sessions (e.g., booster sessions) might be necessary

Table 3 Linear mixed effects models for mental health outcomes at 6, 12, and 18 months

	Depressive symptoms		School anxiety		Loneliness	
	b	*SE*	*b*	*SE*	*b*	*SE*
At 6 months						
Fixed effects						
Gender (Ref. Girl)	0.482	0.265	0.008	0.032	0.077	0.027**
Age	0.060	0.078	0.006	0.010	0.000	0.008
# of HIV infection in the household	0.026	0.136	0.003	0.016	−0.010	0.014
Child-only	−0.271	0.447	−0.045	0.064	0.039	0.052
Time	0.033	0.070	0.011	0.009	0.004	0.007
Child-only × time	0.081	0.081	−0.012	0.010	0.002	0.008
Random effects						
Intercept	0.578	0.289	0.019	0.007	0.012	0.004
At 12 months						
Fixed effects						
Gender (Ref. Girl)	0.680	0.243**	0.012	0.029	0.083	0.026**
Age	0.136	0.074	0.010	0.009	0.000	0.008
# of HIV infection in the household	0.030	0.124	0.008	0.015	−0.004	0.013
Child-only	−0.228	0.441	−0.061	0.062	0.058	0.050
Child + caregiver	1.193	0.617	−0.011	0.080	0.149	0.065*
Time	−0.045	0.037	−0.012	0.005**	−0.001	0.004
Child−only × time	0.077	0.049	0.005	0.006	−0.009	0.005
Child + caregiver × time	−0.154	0.059**	−0.008	0.007	−0.019	0.006**
Random effects						
Intercept	0.631	0.273	0.018	0.006	0.011	0.004
At 18 months						
Fixed effects						
Gender (Ref. Girl)	0.668	0.229**	0.029	0.028	0.087	0.025**
Age	0.140	0.071*	0.011	0.009	0.002	0.008
# of HIV infection in the household	0.142	0.117	0.013	0.014	−0.004	0.013
Child-only	−0.175	0.438	−0.054	0.062	0.058	0.050
Child + caregiver	0.274	0.546	−0.080	0.073	0.006	0.058
Child + caregiver + community	−1.439	1.113	−0.196	0.137	−0.160	0.113
Time	−0.057	0.025*	−0.012	0.003***	−0.002	0.002
Child-only × time	0.057	0.033	0.010	0.004*	−0.004	0.003
Child + caregiver × time	−0.003	0.040	0.005	0.005	0.002	0.004
Child + caregiver + community × time	0.067	0.072	0.005	0.009	0.008	0.007
Random effects						
Intercept	0.676	0.280	0.019	0.006	0.012	0.004

*$p < 0.05$, **$p < 0.01$, ***$p < 0.001$

to make more robust improvements in mental health. Second, the delivery of the ChildCARE intervention was not embedded within the school system. Although schools served as the delivery site for the intervention, local school personnel were not involved in the intervention delivery, and the intervention content was not linked to or coordinated with other school-based services (e.g., school counseling services). In contrast, interventions embedded with school systems that provide a continuum of integrative care have been found to have sustained impacts on mental health improvement (Fazel et al., 2014).

Unexpectedly, the intervention yielded a negative effect on school anxiety in the child-only group at 18 months. One possible explanation for this unexpected result is that the intervention may raise awareness about the challenges experienced by this group of children, which in turn

contributes to increases in school anxiety. Another possible explanation is that some unmeasured events may have occurred during this follow-up period that led to increased school anxiety in the child-only group, given that no negative effects were found on school anxiety at 6 or 12 months.

Although no overall intervention effects were observed at 6 months, our study indicated that girls gained more benefits from the child intervention component than boys. One possible explanation for this result is the potential gender difference in school anxiety. Girls have been suggested to be more likely to experience anxiety at school than boys (Frawley et al., 2014; Freudenthaler et al., 2008), which, in turn, may make them more motivated to participate in the intervention and have more room to show symptom reductions (Stice & Shaw, 2004). However, such gender differences in the intervention effects were only limited to school anxiety at 6 months. Future studies are needed to confirm whether similar child-focused interventions may yield different outcomes in boys and girls.

The results also indicated that older children benefited more from the intervention than their younger counterparts. These findings are consistent with a previous resilience-based intervention for HIV-affected families in China that showed better improvements in behavioral outcomes for older children than younger ones (Li et al., 2017). One possible explanation for this result might be the developmental differences in understanding the curriculum and content of the intervention. Compared to younger children, older children might have a better understanding of the content of the ChildCARE intervention due to more mature cognitive skills (Burnett & Blakemore, 2009). Older children may also benefit more from the potential reductions in HIV stigma that the intervention may yield, as young children may not be as aware of the subtle acts of isolation and discrimination as their older counterparts. These age-related findings highlight the need for resilience-based interventions to be tailored to the developmental and cognitive stages of the targeted population to maximize intervention effects on mental health improvement.

The findings of this study, however, should be cautiously interpreted due to some limitations. First, schools, rather than individual children, were used as the unit of randomization in this study. Although cluster randomization could help reduce contamination between the intervention and control groups, it resulted in some significant differences in baseline demographic variables (e.g., age) across intervention assignments. Second, this study exclusively relied on children's self-reports of mental health outcomes, which may be subject to self-report bias. Also, some measures (e.g., school anxiety) were not previously validated among children in China and displayed relatively low internal consistency at baseline. Culturally validated measures for mental health outcomes should be considered in future studies. Third, a lack of data for an elaborate process evaluation, including children's and their caregivers' satisfaction with the delivered intervention, may limit our interpretations of the results reported in this study. Fourth, our results may not generalize to other cultural contexts. For example, the cause of the HIV outbreak in central China is largely distinct from the HIV outbreaks in other areas of the world—where the HIV infection is primarily driven by stigmatized behaviors (e.g., sexual activity, injection drug use). The impact of parental HIV on children in this study might be different from children from HIV-affected families that are stigmatized due to other modes of HIV transmission (Li et al., 2006). Despite these limitations, this study has several strengths. Our study is among one of the first RCTs to evaluate the efficacy of a multilevel resilience-based psychosocial intervention to improve mental health of children affected by parental HIV in rural China. Moreover, this study used a multi-arm design that allowed us to examine whether there were dose-response effects of the ChildCARE intervention on children's mental health. In addition, this study included a relatively large sample size of children affected by parental HIV, with high retention rates over the 18-month study period.

Conclusion

This study provides preliminary evidence to support the efficacy of a multilevel resilience-based intervention in improving some mental health outcomes among children affected by parental HIV. Our study also indicates that challenges remain in developing effective and sustained approaches to remedy the complex challenges encountered by children and families affected by HIV in rural China. Future studies are needed to examine whether more intensive, school-embedded, and age-tailored resilience-based interventions could achieve sustained and meaningful improvements in mental health for this group of children. Future studies are also needed to identify the active components in the ChildCARE intervention that are most responsible for improving mental health to provide insights for future intervention development.

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Compliance with Ethical Standards

Conflict of Interest The authors declare no competing interests.

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