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Title

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Permalink

https://escholarship.org/uc/item/3sf6m6zw

Journal

Health psychology : official journal of the Division of Health Psychology, American Psychological Association, 36(9)

ISSN

0278-6133

Authors

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Publication Date 2017-09-01

DOI

10.1037/hea0000503

Peer reviewed



HHS Public Access

Health Psychol. Author manuscript.

Efficacy of a Multilevel Intervention on the Mental Health of People Living with HIV and their Family Members in Rural China

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Abstract

Objective—HIV has a profound impact on infected individuals and their families. This study evaluated the efficacy of an intervention aimed at improving the mental health of people living with HIV (PLH) and their family members.

Methods—A randomized controlled trial of 475 PLH and 522 family members was conducted in Anhui, China. The intervention comprised of activities at individual-, family-, and community-levels. The study outcomes, which included depressive symptoms and coping with illness for the PLH and depressive symptoms and caregiver burden for the family members, were assessed at baseline and at 6-, 12-, 18-, and 24-month follow-up. We used a mixed-effects regression model with village- and participant-level random effects to assess the intervention effect on the improvement of outcome measures.

Results—Relative to the control condition, the PLH and family members of the intervention group reported a significant reduction in depressive symptoms. The largest difference in depressive symptoms was observed at the 6-month for the PLH and at the 12-month for family members. Decreases in perceived caregiver burden over time were observed for family members in both conditions; however, the group difference did not reach statistical significance. Significant intervention effect on the coping with illness was reported by the PLH.

Conclusions—The study highlights the importance of empowering families affected by HIV to confront the challenges together rather than individually. It may be optimal for future programs to include both PLH and their family members to maximize intervention effects through strengthening interactions and support within a family.

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Conflicts of Interest and Source of Funding: This work was supported by the National Institute of Child Health & Human Development/National Institutes of Health [grant number R01HD068165]. The funders had no role in study design, data collection and analyses, decision to publish, or preparation of the article. The authors have no conflict of interest to declare.

Keywords

HIV; intervention; family; depressive symptoms; China

Introduction

HIV has a profound impact on the mental health status of infected individuals and their families. Various studies have documented that people living with HIV (PLH) are more likely to develop mental health disorders, such as depression, compared with the general population (Chibanda, Benjamin, Weiss, & Abas, 2014; Lyons, Pitts, & Grierson, 2012). Depression is consistently found to be associated with non-adherence to HIV treatment (Gonzalez, Batchelder, Psaros, & Safren, 2011; Uthman, Magidson, Safren, & Nachega, 2014), and mental health challenges may accelerate HIV disease progression and lead to earlier mortality and increased HIV-specific morbidity (Chida & Vedhara, 2009; Leserman, 2008).

Literature has suggested that HIV disrupts the family structure and places stress on the entire family (Dejman et al., 2015; Li et al., 2012). Since the introduction of antiretroviral therapy (ART), HIV infection has become a lifelong chronic disease (Deeks, Lewin, & Havlir, 2013). As with other chronic illness, partners and families often take on the role of informal caregivers and perform a variety of roles that help PLH to adhere to treatment regimens, avoid unnecessary hospital admissions, and provide physical and emotional support (Okeke, 2016). The caregiving tasks can place a great strain on them and lead to individual stress and tensions between the members of the families (Vitaliano, Zhang, & Scanlan, 2003; Pinquart & Sorensen, 2003).

Additionally, HIV-affected families may become burdened not only by caregiving but also by social barriers attached to HIV infection, which are particularly true in family-oriented countries, such as China (Zhang et al., 2013). A study conducted in China showed that HIV brings shame to the whole family, damaging within family relations and the broader family social networks (Li et al., 2008). Both PLH and members of their families face fear of disclosure (Qiao, Li, Zhou, Shen, & Teng, 2016), financial uncertainty (Ama & Seloilwe, 2010), stigma and discrimination (Zhang et al., 2016), and social isolation (Kipp, Tindyebwa, Karamagi, & Rubaale, 2007; Zhang, Zhang, Hanko, & Fuller-Thomson, 2011). These psychosocial challenges may aggravate mental health issues among PLH and their family members. To minimize the psychological, physical, and social impact of HIV, program developers and researchers have increasingly recognized the important role played by family in reducing the vulnerability and coping with the devastating effects of the disease (Kuo et al., 2016; Rotheram-Borus et al., 2012). Some interventions have aimed to improve mental health functions of PLH and family members using family-based (Li et al., 2012), cognitive behavioral therapy-based (Carrico et al., 2009), and community-based approaches (Wu & Li, 2013).

The intervention described in this study, entitled Together for Empowerment Activities (TEA), was designed, developed, and implemented to target PLH and their family members' specific needs at individual, family, and community levels. The TEA intervention was

guided by the Social Action Theory (Ewart, 1991), which emphasizes social interdependence and its link to personal health. The intervention was piloted with promising outcomes (Li et al., 2011). Based on the pilot, a full scale randomized controlled trial was conducted between late 2011 and early 2016 to evaluate its efficacy to improve psychological wellbeing for both PLH and family members.

Methods

Study Design

The TEA intervention trial utilized a cluster-randomized controlled design with two arms. The study was conducted in Anhui providence, China, where many PLH were infected via commercial plasma donations, and HIV-affected families reside in poor rural areas (Ji, Detels, Wu, & Yin, 2006; Wu, Rou, Detels, 2001). A total of 475 HIV-affected families were recruited from 32 villages. The 32 villages were selected because they have the largest numbers of HIV-affected families in the study area as reported by the office of the Anhui Provincial Center for Disease Prevention and Control (CDC). After baseline assessment, the 32 villages were randomized into either an intervention condition or a control condition. We assessed the geographic information between the intervention and control villages to ensure that the distance between the villages was far enough to avoid potential contamination. The intervention and control villages were at least 10 kilometers (about 6.2 miles) apart and separated by hills or ranges. The intervention effects were evaluated at baseline and at 6-, 12-, 18-, and 24-month follow-ups. The study protocol was approved by the institutional review boards at the University of California, Los Angeles and the Anhui Provincial CDC. This trial was registered in the ClinicalTrials.gov protocol registration system (NCT01762553).

The Intervention

For villages in the intervention condition, the TEA intervention activities were delivered to target HIV-related challenges at these three critical levels: 1) at the *individual* level, TEA <u>Gathering</u> – six separate intervention sessions were conducted for PLH and their family members to deal with their specific HIV-related challenges. The sessions were conducted with approximately 10-12 participants in a group. Interactive group activities, such as games, pair-share, role plays, and discussions, were delivered to establish healthy daily routine, improve physical and mental health, improve family and parent-child relationships, and encourage community integration; 2) at the *family* level, TEA Time – six types of family activities were conducted at home after each TEA Gathering session. The family activities involved all members to strengthen family interaction and support. For example, "Fabric of Family" was an activity in which supplies were given to each family to make their own family carrying bag or blanket. The designs should represent things that were important to the family. The products were then shared with others during the next TEA Gathering session; and 3) at the community level, TEA Garden - three community events consisting of a health fair, an amusing sports event, and a family talent show were organized by both intervention participants and community leaders to enhance community and social integration. These initial intervention activities took place between six and eight weeks.

To maintain the intervention effect, reunions were held every two months during the first 12 months and every four months during the remainder of the study period (10 total reunion sessions). To ensure implementation fidelity, trained evaluators observed all the sessions and scored each session and the activity components according to an evaluation checklist. During the study period, 192 group sessions were carried out (96 for PLH and 96 for family members) and 18 community events organized. In addition, 202 reunion sessions were conducted in a group format. The overall participation in the TEA intervention activities was about 95% for the PLH and 94% for their family members.

Control Condition

PLH in the control group continued to receive the Chinese government's standard of care for the population. In addition, limited program activities were added to the control group to tease out intervention effects from the impact of attention. The intervention and control conditions differed in both contents and formats. There were three group sessions once a week, with the content areas focused on healthy daily routine, antiretroviral drugs adherence and side effects, nutrition, and personal and family hygiene. These control group sessions were didactic lecture-based health education, with no interactive activities between facilitators and participants nor between PLH and family members. In addition, village health workers visited the control group families once a week for the initial three weeks and once a month for 12 months.

Participants

Baseline data were collected from October 2011 to March 2013. To be eligible for the study, the PLH had to 1) be 18 years or older, 2) be HIV sero-positive, 3) have a HIV sero-negative family member in the same household, 4) have a child between 6–18 years in his/her family, and 5) reside in one of the selected villages. The inclusion criteria for family members were that they had to 1) be 18 years or older, 2) be HIV sero-negative, 3) live with the PLH in the same household, and 4) have knowledge of the PLH's HIV sero-status. To recruit participants, information flyers about the study were posted in the village clinics where PLH obtained routine care. PLH who were interested in participating in the study could either directly contact the project staff using the contact information printed on the flyer or ask the clinic health workers to be referred to a project recruiter. The recruited PLH were asked to invite one of his or her family members to participate in the study. If the invited family member was also HIV sero-positive, then he or she will be recruited as a PLH participant, and an additional HIV sero-negative family member will be recruited from the same household. When recruiting participants, our trained recruiter explained the study purpose, procedure, potential risks and benefits, and guaranteed confidentiality and voluntary nature of their participation. Written informed consent was obtained from each participant. The refusal rate for the initial recruitment was less than 5%. Based on the epidemiological data reported by the Anhui provincial CDC office, the study has reached more than 85% of the eligible families in the study villages.

Procedures

At baseline and at each of the follow-up points, both the PLH and family member participants completed an assessment using the Computer Assisted Personal Interview

(CAPI) method. All the assessments were conducted in a private room of a village clinic or another private place where the participant preferred. Each assessment took approximately 45–60 minutes, and all the participants were compensated 50 yuan (8 USD) for each assessment. The participant did not receive incentives for participating in the intervention activities.

Outcome Measures

<u>Depressive symptoms</u> were measured for both the PLH and their family members using a shortened version of the Zung Self-Rating Depression Scale (Zung, 1965). The scale has been validated in our previous pilot study among PLH and their family members in China (Li et al., 2011). Participants were asked how often they felt each of the nine situations, including "I get tired for no reason", "I have trouble sleeping at night", and "I feel hopeful about the future". The responses ranged from (1) "a little of the time" to (4) "most of the time" with some items that were reverse coded. The overall score was the sum of each item, and a higher score implied a higher level of depressive symptoms (Cronbach's alpha = 0.81).

<u>Coping with illness</u> reported by the PLH was measured using an adapted version of Namir and colleagues' instrument that assesses active cognitive and behavioral efforts to cope with HIV (Namir Wolcott, Fayzy, & Alumbaugh, 1987). Two subscales, *active cognitive* and *behavioral coping*, were used in the study. The two scales consisted of 14 items. Participants responded to the question, "Which of these things have you used to help you deal with your illness?" using a five-point scale from (1) "never" to (5) "always". The active cognitive coping subscale includes items such as "thought about the positive changes in me since the illness" and "formed a plan of action in my mind"; the active behavioral coping subscale included items such as "went out more socially" and "tried to find out more about my illness". A higher summary score indicated a better ability to cope with the illness cognitively and behaviorally (Cronbach's alpha = 0.80).

<u>Caregiver burden</u> perceived by family members was measured using the Perceived Caregiver Burden Scale (Stommel, Given, & Given, 1990), which has been used in our previous study in Asia (Lee, Li, Lin, & Tuan, 2015). Family members' perception of having a PLH in the household and its impact on their finances, health, and feelings of entrapment were assessed using the modified 17-item scale. Sample items include "Caring for him/her has put a financial strain on the family", "My health has gotten worse since I have been caring for him/her", and "I feel trapped by my caregiving role". Responses to each item ranged from (1) "strongly disagree" to (5) "strongly agree", and a higher score reflected a higher level of overall burden perceived by family caregivers (Cronbach's alpha = 0.88).

In addition, the participants' age, gender, education level, marital status, family annual income and family size, and family members' relationship with the PLH were collected.

Statistical Analysis

Study populations by intervention assignment were characterized using descriptive statistics and frequencies. Baseline characteristics between the intervention and control conditions were compared using Chi-square tests and random-effects models for categorical and

continuous characteristics, respectively. Furthermore, we graphically examined the pattern of improvement for each outcome measure over time by plotting the mean score of each measure over time by intervention condition.

All the analyses were performed on an intent-to-treat basis. We used a mixed-effects regression model with village- and participant-level random effects to assess an intervention effect on the improvement of each mental health measure. The fixed-effects included the pre-selected individual characteristics (age, gender, marital status, and education) and family background (annual household income and size of family), group assignment (control vs. intervention), visit (baseline, 6-, 12-, 18-, and 24-month), and group-by-visit interaction. Two levels of random effects, village- and participant-level random effects, were included in the model to account for the dependence within the villages and the correlation between repeated observations for each participant. The intervention effect at each follow-up visit was defined as a difference in changes from baseline between the intervention and control groups and was estimated through model contrasts. All the statistical analyses were carried out using the SAS System for Windows 9.4 (Statistical Analysis Software, Cary, NC).

Results

Sample Characteristics

As shown in Figure 1, among the 475 families, 237 families (257 PLH and 237 family members) were randomized to the intervention condition and 238 families (265 PLH and 238 family members) to the control condition. The follow-up rate at the 24-month follow-up for the PLH was 91% in the intervention group and 84% in the control group. For family members, the 24-month follow-up rate for the intervention group was 88% and the control group was 81%. Participants' characteristics and their outcome measures at baseline are summarized in Table 1. The average age for the PLH in the intervention group was older than those in the control group (50 vs. 47, p = 0.0003). Less than 50% of the PLH were men (42% vs. 47% for intervention vs. control, respectively), approximately 40% had no education, and more than 80% of the participants were married. Approximately 65% of the family member participants were women, the average age was about 42 years old, slightly less than half were the PLH's spouse, and approximately 30% had an educational level of junior high school or above. The median annual income was 20,000 yuan (3,030 USD), and over one-third of the families had more than six members. At baseline, no significant differences were observed across the two study arms for gender, education, marital status or relationship to PLH, annual income, and family size. The PLH in the intervention group had a significantly higher coping with illness score than those in the control group (35.3 vs. 33.4, respectively; p = 0.008). Other outcome measures reported by the PLH and family members were comparable across the two intervention conditions.

Change in Measures over Time

The unadjusted mean plots of the outcome measures reported by the PLH and family members are presented in Figure 2A/2B and Figure 3A/3B, respectively. Figure 2A shows that the mean depressive symptoms reported by the PLH in both groups were similar at baseline, and the level of depressive symptoms reported by the intervention participants

decreased more rapidly than that reported by the participants in the control condition. The differences in the reduction in depressive symptoms were maintained across the rest of the follow-up visits. In Figure 2B, the coping with illness score for the PLH in the intervention and control groups were slightly different at baseline. The mean curve for the intervention PLH participants ascended at the 6-month follow-up and descended gradually after the one-year follow-up, whereas the mean curve for the control PLH participants decreased from baseline. The largest difference in the improvement in the coping with illness score occurred six months after the baseline. In Figure 3A, the pattern of the mean curves for the depressive symptoms of the family members was similar to those of the PLH (Figure 2A). The mean levels of caregiver burden decreased over time for both groups (Figure 3B). The rate of change in caregiver burden reported by the intervention participants was slightly faster than that reported by the control group.

Intervention Effects on the PLH's Measures

Table 2 shows that a significantly greater reduction in depressive symptoms reported by PLH in the intervention versus control conditions consistently over time, as seen in Figure 2A. Women reported a significant higher level of depressive symptoms on average than men (estimate= -2.15 ± 0.38 , p < 0.0001). Age was positively associated with depressive symptoms (estimate= 0.08 ± 0.02 , p = 0.0002). The PLH from the families in the lowest annual income category reported a higher level of depressive symptoms (estimate= 2.69 ± 1.02 , p = 0.007).

Similarly, we observed a significant intervention effect on the coping with illness reported by PLH consistently over time while the coping with illness reported by the intervention PLH was higher than the control PLH at baseline (difference = 2.18, SE = 0.71, p = 0.002). The largest intervention effect on coping with illness was occurred at the 6-month follow-up (difference = 4.44, SE = 0.84, p < 0.0001); the group difference slowly reduced over time, but remained significant up to the two-year follow-up period. Male participants (estimate=1.10±0.52, p = 0.035) reported a higher score in coping with illness. Having no formal education (estimate= -2.25 ± 0.78 , p = 0.004) and having five or six family members (estimate= -1.18 ± 0.52 , p = 0.025) were associated with a lower score in coping with illness.

Intervention Effects on the Family Members' Measures

Results from the adjusted analysis indicated that a significant intervention effect on depressive symptoms reported by family members was observed over time, similar to the reduction in depressive symptoms reported by PLH (in Table 3). The largest group difference in the reduction of depressive symptoms was observed at 12 months after baseline (difference = 2.17, SE = 0.44, p < 0.001). Older age (estimate= 0.09 ± 0.01 , p < 0.0001), female gender (estimate= 1.22 ± 0.40 , p = 0.003), and having no education (estimate= 1.55 ± 0.54 , p = 0.004) were associated with higher level of depressive symptoms. Those family members in the lowest annual family income category reported having the highest depressive symptoms (estimate= 2.61 ± 1.03 , p = 0.012).

We observed significant decreases in the perceived caregiver burden over time for both the intervention and control groups (Figure 3B) (both *p*-values < 0.005). The between-group

differences in reduction were not statistically significant. Those of older age (estimate= 0.17 ± 0.03 , p < 0.0001) and being female (estimate= 1.68 ± 0.78 , p = 0.031) were positively associated with a higher level of reported caregiver burden. Being the PLH's spouse (estimate= -3.94 ± 0.74 , p < 0.0001) was associated with a lower level of caregiver burden compared to being a non-spouse family member.

Discussion

This paper presents the efficacy of a multilevel large-scale randomized controlled intervention to improve the mental health of PLH and their family members. Overall, both target populations reported significant improvements in mental health indicators at the 6-, 12-, 18-, and 24-month follow-ups compared with those in the control condition. The findings suggest that both the PLH and family members could benefit from an intervention that addresses their common and specific challenges associated with HIV. The TEA intervention focused on family interconnection and supporting families impacted by HIV to confront the challenges together rather than individually. The inclusion of both the PLH and family members may have provided a unique environment to stimulate conversations and strengthen interactions within a family. During difficult times, it may become particularly important for family members to support each other, and their psychological wellbeing plays an important role in the process of overcoming challenges together. Furthermore, through community intervention activities, participants within the villages could become more aware of familiar challenges shared by other families in the neighborhood and come together to form a social network for community support. The multiple layers of intervention that happened concurrently may have synergized in achieving a greater overall impact on PLH and family members' mental health.

It is worthwhile to mention that although both the PLH and family members benefited from the intervention in regards to the alleviation of depressive symptoms, the patterns of change were different between the two populations. Both the PLH and family members in the intervention condition reported a steep reduction in depressive symptoms at the 6-month follow-up. However, the largest difference between the family members of the intervention and control groups occurred at the 12-month follow-up, and its magnitude was reduced at the 18- and 24-month follow-ups, whereas the intervention effects on depressive symptoms of PLH were sustained at a similar level. One explanation is that the intervention had the most direct impact on the PLH and family members after the initial, intensive activities. Family members in the intervention condition benefited the most after the initial intervention, but the effects lasted a shorter period of time than that for the PLH. It is of note that PLH and their family members in the control condition showed decreased depressive symptoms at the 6-month follow-up, which may be due to the perceived attention from the reoccurring surveys (Tourangeau, 2003).

Several demographic and family characteristics were found to be related to the mental health status of the PLH and their family members. Women reported more depressive symptoms than men, similar to the findings of other studies (Passos & Souza, 2015; Pereira & Canavarro, 2011). In traditional Chinese families, women are typically the primary caregivers (Stein et al., 2000). When a woman herself is infected, she struggles to balance

the stress and burden to take care of herself and the rest of her family. These results point to the importance of identifying and treating depressions as an essential element in the comprehensive care of women impacted by HIV. Families in the least income experienced the most mental health challenges. Financial hardships may induce more stress for HIV-affected families as they cope with illness and struggle to make ends meet. More resources are needed to provide care for those with limited financial resources to protect and promote mental health. Another area that deserves further investigation is caregiver burden perceived by the spouse vs. the non-spouse family members. Future intervention programs need to take these factors into consideration and address these issues in the program design and implementation.

Limitations

Several limitations should be considered when interpreting the results. First, our study was conducted in an area where a large proportion of PLH were former commercial plasma donors who were infected in the mid-1990s. Thus, the study results may not be generalizable to those PLH who were infected via other transmission routes and lived in different geographical regions. Second, the outcome measures relied on self-reports, which could be influenced by social desirability. The third limitation concerned eligibility criteria. For the PLH to be eligible for the study, they had to have disclosed their HIV status to at least one family member. It is possible that the mental health measures reported by those who had not disclosed their status to any family members were different from those who participated in our study. Fourth, the study faced measurement issues that only individual-level data were collected, so we would not be able to demonstrate the intervention effect on families and communities. Additionally, the individual-level outcomes were a combined effect of multilayered intervention activities, and data collected were insufficient to assess the within- and cross-level effects. With the data in hand, we would not be able to distinguish the key driving factor behind the results. Lastly, although some of the differences reached statistical significance, the small effect sizes may limit the implication of the findings.

Conclusion

Reduced depressive symptoms are attainable for both PLH and their family members with an intervention that involved the individual, their family, and their community. Although PLH and their family members have to deal with their specific issues (e.g., coping with the illness for the PLH, perceived caregiver burden for the family members), facing these challenges together as a family has been a powerful message from the intervention. This intervention model has the potential to be adapted to different cultures with family-oriented traditions. As the HIV epidemic transitions to a manageable chronic illness, PLH need the strength of their families more than ever. Future interventions should continue to target PLH as well as their family members and focus on family capital as an important component in the wellbeing of PLH. Family-based services, possibly integrating mental health services, need to be established to provide assistance to and address the specific needs of families affected by HIV.

Acknowledgments

This work was supported by the National Institute of Child Health & Human Development/National Institutes of Health under Grant [R01HD068165]. The authors would like to thank the project team members in Anhui, China for their contributions to this study.

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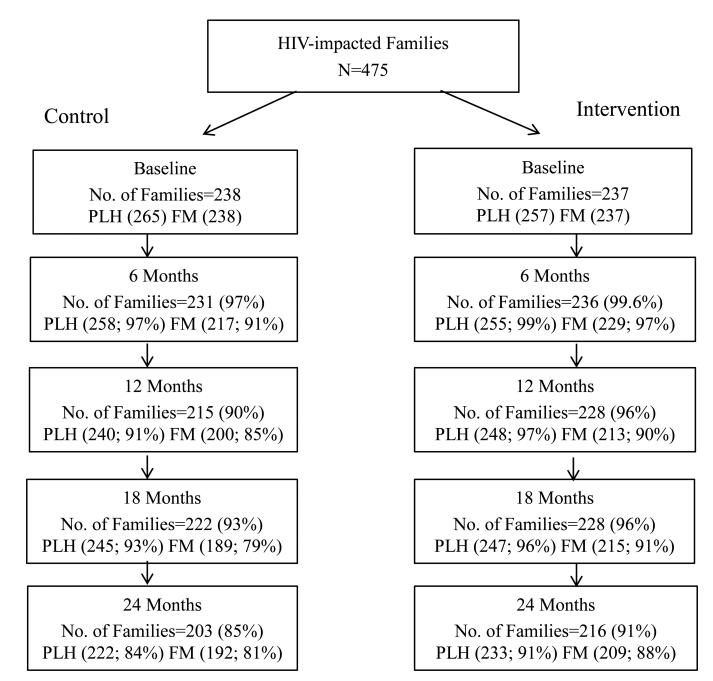
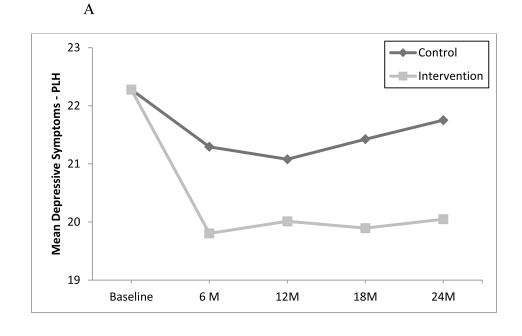


Figure 1.

Flow of study participants: TEA Intervention Trial; Anhui Province, China *Note*. PLH, people living with HIV; FM, family members

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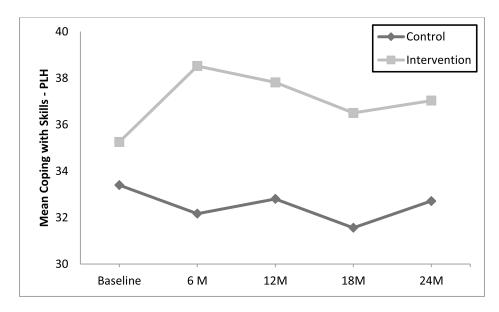
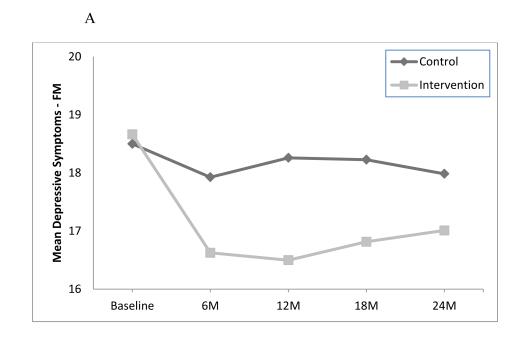


Figure 2.

A – Mean Depressive Symptoms over Time for PLH

B - Mean Coping with Illness over Time for PLH



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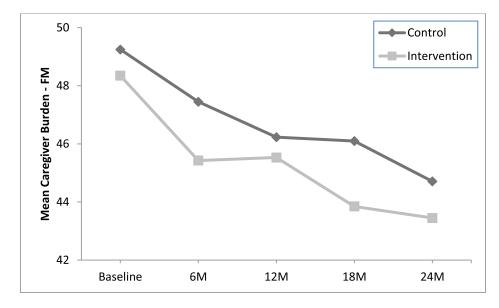


Figure 3.

A - Mean Depressive Symptoms over Time for Family Members

B – Mean Caregiver Burden over Time for Family Members

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Table 1

Sample Characteristics for PLH and Family Members

	Control	Intervention	
	Mean (SD) or N (%)	Mean (SD) or N (%)	Р
Individual Characteristics			
<u>PLH</u>	N=265	N=257	
Age (years), Mean (SD)	47.2 (9.1)	50.0 (8.3)	0.0003
Male, N (%)	125 (47.2)	109 (42.4)	0.27
Education, N (%)			0.52
None	102 (38.5)	108 (42.0)	
0 to 6 Years	123 (46.4)	118 (45.9)	
> 6 Years	40 (15.1)	31 (12.1)	
Married, N (%)	222 (83.8)	203 (79.0)	0.16
Family Member	N=238	N=237	
Age, Mean (SD)	43.3 (14.1)	41.0 (14.3)	0.07
Male, N (%)	91 (38.2)	77 (32.5)	0.19
Education, N (%)			0.58
None	71 (29.8)	61 (25.7)	
0 to 6 Years	96 (40.3)	104 (43.9)	
> 6 Years	71 (29.8)	72 (30.4)	
Relationship to PLH, N (%)			0.68
Spouse	117 (49.2)	112 (47.3)	
Other	121 (50.8)	125 (52.7)	
Family Characteristics	N=238	N=237	
Family Income, N (%)			0.16
Less than 5,000	6 (2.5)	8 (3.4)	
5,000 to < 10,000	22 (9.2)	34 (14.4)	
10,000 to < 20,000	83 (34.9)	90 (38.0)	
≥20,000	127 (53.4)	105 (44.3)	
Family Size, N (%)			0.54
4 or Less	59 (24.8)	49 (20.7)	
5 to 6	97 (40.8)	99 (41.8)	
More than 6	82 (34.5)	89 (37.6)	
Outcome Measures at Baseline			
PLH, Mean (SD)			
Coping with Illness	33.4 (8.3)	35.3 (7.7)	0.0083
Depressive Symptoms	22.3 (5.5)	22.3 (5.2)	0.99
Family Member, Mean (SD)			
Caregiver Burden	49.2 (11.2)	48.3 (11.7)	0.39
Depressive Symptoms	18.6 (5.3)	18.7 (5.2)	0.78

Table 2

Adjusted Regression Analyses for PLH on Mental Health Measures

	-			4	•	
	Estimate	SE	4	Estimate	SE	₄
Baseline Characteristics						
Age	-0.019	0.028	0.5114	0.081	0.021	0.0002
Male	1.096	0.520	0.0354	-2.152	0.388	<.0001
Education (REF: > 6 Years)						
None	-2.250	0.781	0.0040	-0.209	0.578	0.7177
6 or Less	-1.034	0.709	0.1446	-0.379	0.524	0.4698
Married	-0.753	0.612	0.2192	-0.166	0.457	0.7460
Family Income (REF: ≥20,000)						
Less than 5,000	-1.146	1.318	0.3847	2.691	1.002	0.0073
5,000 to $< 10,000$	-0.508	0.754	0.5000	0.629	0.580	0.2784
10,000 to < 20,000	0.001	0.508	0.9991	0.899	0.382	0.0186
Family Size (REF: > 6)						
4 or Less	-0.589	0.636	0.3544	-0.417	0.481	0.3864
5 to 6	-1.176	0.524	0.0249	0.339	0.393	0.3881
Comparison of Interest						
Baseline	2.184	0.707	0.0020	-0.428	0.563	0.4476
Intervention $Effects^I$						
6 Months	4.435	0.838	<.0001	-1.401	0.432	0.0011
12 Months	3.192	0.850	0.0002	-0.975	0.438	0.0262
18 Months	3.084	0.849	0.0003	-1.388	0.437	0.0015
24 Months	2.541	0.869	0.0035	-1.539	0.449	0.0006

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 I Estimated difference in changes from the baseline (Intervention - Control)

Table 3

Adjusted Regression Analyses for Family Members on Mental Health Measures

	Careg	Caregiver Burden	uen	Depress	Depressive Symptoms	ptoms
	Estimate	SE	4	Estimate	SE	_ ₽
Baseline Characteristics						
Age	0.165	0.027	<.0001	0.088	0.014	<.0001
Male	-1.680	0.777	0.0307	-1.219	0.402	0.0025
Education (REF: > 6 Years)						
None	1.345	1.043	0.1978	1.554	0.538	0.0040
6 or Less	-0.042	0.819	0.9594	0.360	0.422	0.3937
Relationship to PLH (REF: Others)						
Spouse	-3.944	0.740	<.0001	-0.731	0.381	0.0553
Family Income (REF: ≥20,000)						
Less than 5,000	3.701	1.982	0.0620	2.609	1.028	0.0113
5,000 to $< 10,000$	0.477	1.093	0.6622	0.755	0.571	0.1859
10,000 to < 20,000	1.828	0.729	0.0123	1.146	0.376	0.0024
Family Size (REF: > 6)						
4 or Less	-0.689	0.916	0.4520	-1.763	0.477	0.1100
5 to 6	-0.493	0.753	0.5128	-0.463	0.388	0.2329
Comparison of Interest						
Baseline	-0.725	0.891	0.4155	0.202	0.467	0.6650
Intervention Effects ¹						
6 Months	-1.007	0.944	0.2864	-1.329	0.430	0.0021
12 Months	-0.182	0.966	0.8504	-2.169	0.442	<.0001
18 Months	-1.657	0.974	0.0891	-1.510	0.445	0.0007
24 Months	-0.548	0.979	0.5756	-1.035	0.445	0.0202

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 I Estimated difference in changes from the baseline (Intervention - Control)