



Correlated outcomes of a pilot intervention for people injecting drugs and their family members in Vietnam[☆]



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ABSTRACT

Background: The interrelationship between the well-being of injecting drug users (IDUs) and their family environment has been widely documented. However, few intervention programs have addressed the needs of both IDUs and their family members.

Methods: This study describes a randomized intervention pilot targeting 83 IDUs and 83 of their family members from four communes in Phú Thọ province, Vietnam. The IDUs and family members in the intervention condition received multiple group sessions, with the intent to improve psychological well-being and family relationships. The intervention outcomes (depressive symptoms and family relations) were evaluated at baseline, 3-month and 6-month follow-up assessments.

Results: Depressive symptoms and family relations reported by IDUs were found to be correlated to those reported by their family members. Overall, significant intervention effects on depressive symptoms and family relations were observed for both IDUs and family members. A similar improvement pattern in family relations emerged for both the IDU and family member samples, although the intervention effect of reducing depressive symptoms was more sustainable for family members at the 6-month assessment when compared to the IDU sample.

Conclusion: The intervention pilot addressed challenges faced by IDUs and their family members and revealed correlated outcomes for the two groups. Findings suggest a vital need to include family members in future drug prevention and harm reduction intervention efforts.

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1. Introduction

The interrelationship between the well-being of injecting drug users (IDUs) and their family environment has been identified in previous studies (Calabria et al., 2013; Fals-Stewart et al., 2005; Heinz et al., 2009; Lex, 1990; Mehta et al., 2012; Morita et al., 2011). Family contextual factors affect IDU behaviors, and IDU behaviors have fundamental consequences for a family's health and function (Calabria et al., 2013; Nagel and Thompson, 2010; Prado et al., 2012; Szapocznik and Coatsworth, 1999). In some countries, the family unit represents the principal source of financial support and care, which prevents IDUs from suffering serious social deprivation or ill health (Ogden and Nyblade, 2005; Rudolph et al., 2012;

Salter et al., 2010). Adverse family factors have been found to contribute to drug use initiation and relapse after treatment (Nomura et al., 2012; Ojeda et al., 2011; Sánchez-Hervás et al., 2012). Conversely, drug using behavior and its consequences also impact the well-being of the family as a whole (Salter et al., 2010). In Asian countries, which place more emphasis on family-oriented culture than Western nations, the link between drug treatment and family support is even more pronounced (Rudolph et al., 2012; Salter et al., 2010). Research has consistently suggested potential benefits for including families in an intervention for a drug-using population (Hammett et al., 2012; Maher et al., 2007).

Several interventions have been developed for the families of drug users. These interventions have proven the effectiveness of positive familial influences in reducing risky behavior and improving social and emotional well-being (Chau, 2006; Calabria et al., 2013; Miller and Wilbourne, 2002; Smit et al., 2008; Thompson et al., 2005). Although researchers usually acknowledge the important role family plays in a drug user's life and treatment outcomes (Thompson et al., 2005), studies often neglect to measure how the intervention affects the needs and well-being of family members.

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Given the close bond between most IDUs and their families, an intervention simultaneously targeting an IDU and his or her family members may result in improved well-being for both parties.

We conducted a pilot study to explore the complex and correlated outcomes of an intervention for both IDUs and their family members. The intervention contents were developed based on the Social Action Theory (Ewart, 1991) and Social Network Theory (Wasserman and Faust, 1994), which emphasize social interdependence and the impact of relationships on personal health. The study was conducted in Vietnam, which is experiencing a severe epidemic of drug use (Hoffman et al., 2011). In 2010, it was estimated that there were about 150,000 drug users in the country, 83% of whom were injecting heroin users (MOLISA, 2010). Vietnam has a strong family-oriented culture, and most IDUs live with their families (Rudolph et al., 2012; Salter et al., 2010). This is the first study to longitudinally analyze the correlated responses to an intervention from two separate yet related target populations: IDUs and their family members. We hypothesized that IDUs and family members might both benefit from the intervention, with possibly different trajectories in outcome measures.

2. Methods

2.1. Study design

The pilot study was conducted in Phú Thọ, a province in northern Vietnam with high rates of poverty, drug use, and HIV prevalence (Food and Agriculture Organization of the United Nations, 2013). The HIV prevalence among IDUs in Phú Thọ has been estimated to be about 20% (UNAIDS/WHO, 2008). We applied a cluster (or group) randomized trial (CRT) design with two study arms and three assessments (i.e., baseline assessment at study entry and 3-month and 6-month follow-up assessments). Four communes (a third-level administrative subdivision in Vietnam) were randomly selected from Phú Thọ. The number of IDUs in the communes was confirmed with local health institutes to ensure caseloads would be sufficient for the study. We also made an effort to make sure no other drug use or mental health intervention program was implemented at the selected study sites. The selected communes were matched into two pairs based on the number of IDUs in each commune. The two communes in each pair were randomized to either an intervention condition or a standard care condition after baseline using computerized random numbers. We considered the distance between the intervention and standard care communes to avoid potential contamination.

2.2. Participants

From August 2011 to February 2012, IDUs and their family members were recruited from the four communes with the assistance of healthcare providers at the local commune health centers (CHCs). In Vietnam, a large proportion of IDUs seek routine health service from their local CHC, thus the CHC health providers have direct contact with IDUs in their communes. Service providers at the CHCs introduced the study to their IDU clients through verbal explanation and a printed flyer. IDUs who were interested in participating called the project recruiter using contact information printed on the flyer; recruiters then met with prospective IDUs individually and screened them for eligibility. IDUs who were older than 18 years, had a history of injecting drug use, resided in the participating commune, and were willing to invite a family member to participate in the study were eligible for inclusion. Upon enrolling IDUs and with their consents, family members were recruited. The IDU chose the family member from spouse, mother, father, sibling (oldest to youngest), to other family members (oldest to youngest). To be eligible for inclusion, family members had to be an immediate or extended relation of the recruited IDU, be age 18 or over, live in the same household with the IDU, and have previous knowledge of the drug use status of the IDU.

Participants matching the inclusion criteria received detailed study information that included the study procedures, confidentiality agreement, and human subject protections. They were then asked to give written informed consent. Approval for the study design and data collection had already been obtained from the Institutional Review Boards of the University of California, Los Angeles, and the Vietnam National Institute of Hygiene and Epidemiology.

2.3. Intervention

The intervention was developed based on previous formative work with local commune stakeholders, service providers, and IDUs and their family members. Local health educators in Vietnam facilitated the intervention in order to ensure regional relevancy and cultural appropriateness. All facilitators received extensive training on research ethics, facilitation skills, intervention principles and delivery, and content-specific rehearsal. The intervention was conducted in a group format with

about 10 participants per group. Intervention activities were conducted in a private location such as a local CHC conference room. The IDUs and family members participated in intervention activities separately, each with four group sessions. Each group session was about 90 min. The group sessions featured interactive activities such as games, pair-share, discussion, and role-plays. Participants were taught how to overcome family challenges, manage negative emotion, build coping skills, deal with stigma, and integrate into communities. There were slightly different foci for the IDU and family member sessions. The sessions for IDUs mainly focused on setting realistic goals and making positive behavioral change, while the intervention for family members focused on coping with caregiver burdens and providing support. These contents reflected the challenges faced by the target populations that we identified in a previous formative study. The standard care group participants received routine health education and counseling services from the CHC. The dosage and time of services received by standard care group were not measured.

2.4. Baseline and follow-up assessments

The baseline assessments were administered face-to-face by trained interviewers in a private room of a local CHC or an alternative venue that the participant selected. Each assessment took about 45–60 min to complete. Study participants were followed up 3 and 6 months after the baseline assessment using the same questionnaire and the same format. For each assessment, participants received 80,000 dong (U.S. \$3.84) in compensation for their time. Fig. 1 illustrates the participant flow through the study.

2.5. Measures of background characteristics

Demographics and background characteristics included age, gender, marital status, employment, and annual income. For family members, we also recorded their relationship to IDU participants. The IDU's severity of drug use was measured using the Addiction Severity Index (ASI; McLellan et al., 1992). IDUs reported the frequency of their illicit substance use in the previous 30 days, and their perceived severity of drug using problem. A drug composite score was constructed, with a higher score indicating severer drug using behavior (McGahan et al., 1986).

2.6. Outcome measures

Depressive symptoms were measured using the short version of the Zung Self-Rating Depression Scale (Zung, 1965). This instrument consists of 10 items that record how often respondents feel a particular sentiment (e.g., "I feel down-hearted and blue" or "I get tired for no reason"). The participants evaluated the frequency of the sentiment using a four-point scale ranging from 1 (a little of the time) to 4 (most of the time). This measure has been utilized in our previous study in China (Li et al., 2011). An overall scale score was computed by summing all 10 items, with a higher score on the scale indicating a higher level of depressive symptoms ($\alpha = 0.84$ for IDUs and $\alpha = 0.75$ for family members).

Family relations were examined using questions adapted from the Family Functioning Scale (Bloom, 1985; Bloom and Naar, 1994). The original Family Functioning Scale consists of 15 subscales that represent various facets of a family relationship, including cohesion, expressiveness, conflict, intellectual-culture orientation, religious emphasis, and so on. For this study, we had a panel discussion with local experts and decided to only include the cohesion and conflict subscales because of their cultural relevancy. The two subscales contained a total of 10 items. Participants were asked how true each statement was for their family on a four-point Likert scale ranging from 1 (very untrue) to 4 (very true). Scores were determined by summing all 10 items, with a higher score indicating better family relation ($\alpha = 0.80$ for both IDUs and family members).

2.7. Statistical analysis

We found the study outcome measures reported longitudinally by both IDUs and their family members within families were likely to be correlated (Li et al., 2013). Thus, we used a hierarchical bivariate regression modeling approach (i.e., multi-level approach), rather than a stratified analysis approach, to assess whether the changes in the paired outcomes (i.e., those reported by IDUs and their family members) were different between the intervention and standard care groups at each follow-up assessment. The hierarchical modeling approach allowed us to address the following research questions simultaneously: (1) the overall intervention effects, (2) the intervention effects for IDUs and for family members, and (3) whether the intervention effects differed between IDUs and family members in a single model (with interaction terms) through the model contrasts. A stratified analysis approach is simpler for making inferences, but this approach did not allow us to address the three research questions in a single model. The modeling approach used in this study is essentially a bivariate longitudinal regression model (Weiss, 2005), which is a joint model for paired outcomes and useful to understand complex relationships between paired outcomes measured simultaneously over time (e.g., Comulada et al., 2010; Audrairie-McGovern et al., 2003). To provide valid analysis for a CRT study, a random intercept was included for each commune to account for clustering of individuals within the communes (Murray et al., 2004). In addition, the model included correlated random intercepts to account for the paired measures within

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