A Multi-Center Randomized Controlled Trial of Adding Brief Skill-Based Psychoeducation to Primary Needle and Syringe Programs to prevent Human Immunodeficiency Virus: Study Protocol

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Objectives: Our objective was to design an RCT in order to assess the effects of adding a brief skill-based psychoeducation (PE) to routine Needle and Syringe Programs to reduce injection and high risk sexual behaviors associated with Human Immunodeficiency Virus (HIV) infection among referrals of Drop-in Centers (DICs).
Method/design: This was a randomized control trial with the primary hypothesis that adding skill-based PE to the routine needle syringe program (NSP) provided in the DICs would be more effective in reducing injection and high risk sexual behaviors associated with HIV infection compared to the routine programs. We intended to randomly allocate 60 patients per group after obtaining informed written consent,. The intervention group receive a combination of brief psychoeducation consisting two individual sessions of skill-based education concerning blood borne viral infection, specifically HIV. The control group received the routine primary NSP services provided in DIC. Study assessments were undertaken by a psychologist at baseline, 1 and 3 months after recruitment. The primary outcome measure was the comparison of the trend of alterations in high risk sexual and injection behaviors associated with HIV infection during 3 months after the initiation of the intervention between the two groups. Secondary outcome measures included the comparison of HIV/AIDS related knowledge and client satisfaction in the participants .
Discussion: This paper presents a protocol for an RCT of brief skill-based PE by a trained psychologist to reduce the sexual and injection related high risk behaviors among drug users who received primary NSP services in DIC. This trial tried to investigate the efficacy of the intervention on increasing HIV/AIDS related knowledge and client satisfaction. The results of different indicators of high risk behaviors will be discussed.

Keywords: *Drop-in Center, High risk behavior, HIV, Needle and Syringe Programs (NSPs), Psychoeducation*

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Injecting drug use is closely linked with not only a more severe dependency syndrome, but also blood borne viruses' transmission through sharing syringes which pose a major public health concern (1). Based on the most recent available estimates in 2008, injection drug use was reported in 148 countries that comprise 95% of the world's population. It is estimated that there are 15.9 million (11.0 to 21.2 million) people who inject drugs (PWID) worldwide and 3 million (18.9%) of them live with the HIV infection (2). With the exception of sub-Saharan Africa, injecting drugs use accounted for approximately one third of all new HIV infections reported globally in 2010 (3). HIV infection can rapidly turn into an epidemic among people who inject drugs (PWID), especially in areas where extensive prevention activities are not delivered (4).

The "Rapid Situational Analysis of Drug Abuse in Iran" revealed that 18.1% of 1.2 million drug users reported injection as their main route of administration and 6.7% reported using needle, syringe or paraphernalia previously used by other drug users (5). Risk behaviors are quite common among PWID. In a study onPWID, it was demonstrated that the prevalence of syringe sharing by street drug users is up to 70% which can be alarming for the transmission of blood borne viral infections in Iran (6, 7). PWID are the most HIV affected population in Iran and have contributed to approximately 67% of the registered cases of HIV/AIDS (8).

According to a report by the Center for Disease Control of the Ministry of Health in 2007,

approximately 18% of the injection drug users in Iran are HIV positive (9). This rate is the highest concentration of HIV epidemics in a population subgroup in Iran. Therefore, it is especially important to reduce the risk of blood borne viral infections among IV drug abusers in Iran.

Evidence for Effectiveness of Brief Skill-Based HIV Prevention Intervention (skill-based HIV prevention psychoeducation)

Studies show that adding group counseling based on the behavior change model or cognitive behavioral therapy to methadone maintenance treatment has had a significant effect on decreasing the frequency of injection drug use, syringe sharing, unsafe sex and trading sex for money or drugs (10-12).

Psychoeducation designed for decreasing high risk behaviors in under treatment substance users increase their self-efficacy and promote their skills for using condoms and having safe sexual contacts (13). In the 3-month follow up, the intervention group showed a significant reduction in high risk sexual behaviors compared to control.

Segal et al. (1995) examined the effect of enhanced intervention on the behaviors of injection drug users in a 9-month follow-up and reported that subjects in the enhanced intervention group started to use safer injecting practices (14).

In another study, participants in the intervention group received a 6-hour group counseling aimed at enhancing their knowledge and improving their attitude towards AIDS, developing skills for cleaning syringes, use of condoms and changing high risk injection and sexual behaviors. After the intervention and at the 3-month follow up, subjects in the intervention group had a significantly more knowledge about AIDS and high risk behaviors, and their skills in using condoms improved (15).

Baker et al. (1994) evaluated and confirmed the effectiveness of a session of motivational interview (brief intervention) on decreasing high risk HIV transmission behaviors among injection drug users. The results showed a significant reduction in the score of injection-related high risk behaviors subscale. In this study, 3 and 6 months follow-ups did not reveal any significant change in the frequency of high risk sexual behaviors between the groups. Directing participants' attention to their high risk behaviors may have resulted in the reduction of high risk injections (16).

Eldridge et al. (1997) demonstrated the efficacy of behavioral skills training in reducing high risk sexual behaviors among female drug users. These women gained a more positive attitude towards HIV prevention after the intervention and reported a higher success rate on convincing their partners to use condoms (17).

Sterk et al. (2003) reported that enhanced intervention in a group of female drug users led to a significant reduction in the frequency of substance use, frequency of injections and syringe sharing. Also, exchange sex for money or drugs, sex under the influence of drug, and other high risk sexual behaviors decreased significantly (18).

According to the results of a systematic review, psychoeducation can effectively reduce high risk HIV-related behaviors. However, the effect size for these interventions was small (19). National Institute for Health and Clinical Excellence (2007) recommended further investigations on the efficacy of psychosocial interventions added to the needle and syringe programs. The main question is whether adding psychosocial content to the needle and syringe program can decrease the frequency of sexual and injection-related high risk behaviors or can it decrease HIV infection among drug users (19).

Overall Aim of the Study

The present study aimed at determining the efficacy of adding-up skill-based HIV prevention psychoeducation to the routine needle and syringe programs in DICs compared to needle and syringe programs alone.

Hypothesis

Adding-up skill-based psychoeducation to the routine needle and syringe programs offered in the Drop in Centers (DICs) results in a greater decrease in injecting and high risk sexual behaviors associated with HIV transmission compared to the needle and syringe programs (NSPs) alone.

The Study Objectives

-To determine whether adding-up skill-based psychoeducation to the routine NSPs will decrease the injection-related high risk behaviors compared to NSP alone.

-To determine whether adding-up skill-based psychoeducation to routine NSPs will decrease sexual-related high risk behaviors compared to NSP alone.

Method/Design

Study Design

This trial was designed in the Mental Health Research Center (MHRC) of Iran University of Medical Sciences (IUMS) and had two main goals. The first included determining the efficacy of adding skill-based psychoeducation to the routine needle and syringe programs in decreasing sexual and injection-related high risk behaviors. The second was determining the level of clients' satisfaction referring to these centers. It has been designed with equal allocation of participants between arms of the study (allocation ratio 1:1).

Trial Inclusion and Exclusion Criteria

A group of 120 consecutive clients, who met the inclusion criteria, meeting DSM-IV-TR criteria for opioid dependence with an age range of 18-65 years, were recruited to the study. They had positive

urinalysis for opioid drugs. Consent was required for participation in training sessions, performing the urinalysis and later follow ups. Eventually, a written informed consent was obtained from the participants who entered the study. The exclusion criteria were as follows:

- Having a severe mental disorder like schizophrenia, schizoaffective, bipolar disorder or mental retardation.
- Evidence of recent suicide attempt.
- Having debilitating cognitive disorders (these subjects could not understand to give an informed consent).
- Subjects who had received drug treatment (like methadone maintenance treatment or detoxification) or services (such as needle and syringe services or training sessions for risk reduction) during the past 30 days.

Setting

This clinical trial was conducted in two DICs (Azadi and Pardis-e Mehr) in Tehran, Iran. One of the centers was for males and another for females which were located in south-west and south of the city, respectively. Both centers offered the routine needle and syringe programs according to the Ministry of Health and Medical Education (MoHME) protocol.

Intervention Group

Subjects in the intervention group received 2 individual sessions of skill-based psychoeducation in addition to the routine needle and syringe programs offered in the center. These sessions were 30 minutes each and held with a one- week interval.

The content of the psychoeducation was developed by the extensive review of the international educational packages for HIV prevention developed for PWID. It was taught to the clinical psychologists of the DICs in an 8-hour workshop. In these workshops the emphasis was on using the demonstration method when teaching the skills to the clients. The topics of the educational content for each session were as follow:

First Session

In this session, necessary trainings about HIV/AIDS and decreasing the risks were offered. The focus was on risks of HIV and other infections transmitted through injection and sexual behaviors. Risk reduction education and skills training were provided. The following subjects were discussed in the first session:

- Basic information about HIV, HCV and HBV infections
- Transmission routes of HCV, HBV, HIV
- False beliefs about the HCV, HBV and HIV infections
- Risks associated with injecting drugs use and how to minimize them
- Risks associated with unsafe sexual practices and how to minimize them
- Benefits of cessation of drug use and entering to a treatment program particularly methadone maintenance treatments
- Risks associated with re-using syringe and other injecting paraphernalia and benefits of using sterile syringe
- How to clean syringe and injecting paraphernalia if you have to re-use them
- How to have a safer sexual contact with your partner
- Introducing voluntary counseling and testing (VCT).
- Information about the free distribution of condom and sterile needle and syringe in the center

The psychoeducation sessions were held individually in a quiet private place. The clinical psychologists who provided the services were from the same sex of the participants. The clinical psychologist first introduced himself/herself and explained his/her role as a drug counselor. At the beginning of the session, the psychologist provided an outline of topics which were going to be covered during a 30- minute session. Since the educational intervention aimed to develop safer injecting and sex skills, the trainer demonstrated the proper use of condoms and tried to show them how to clean syringes during the session. The participants were encouraged to ask their questions and discussed their concerns. By doing so, the intervention was tailored to respond to the educational needs of each participant. The clients were provided with some informative brochures at the end of the sessions.

Second Session

The second session was held one week after the first session and lasted for about 30 minutes. In this session, the clients who had participated in the first session were reminded of the complications and risks of injection drugs and unsafe sex and how to decrease these risks. The second session included:

- Review of information about the prevention and reduction of high risk behaviors discussed in the first session (reviewing the previously taught subjects through question and answer interactions)
- Information about services available in the center and encourage them to receive harm reduction packages
- Referral to other needed interventions including voluntary counseling and testing (VCT) and methadone maintenance treatment programs.

After the second session, follow up assessments were held 1 and 3 months after the intervention. If the clients did not show up for the follow up sessions, the patients' locations were detected from their files and a research assistant along with an outreach team member visited them to collect the data.

Control Group

The control group received routine needle and syringe program offered in the DIC centers. These programs include the distribution of sterile syringes and needles and other injection paraphernalia, collection of used syringes and needles, distribution of condoms and a meal. The clients also receive information through group trainings about safer injection and also a safe sex at the beginning of receiving services. Follow up assessments were also done for the participants of the control group 1 and 3 months later just like the intervention group. If they did not show up for the follow up, they were located and a research assistant with an outreach team member paid them a visit to obtain follow up data.

Follow up Strategy

Follow up of clients is hard and studies show that the rate of patients lost to follow up is high. Therefore, at the beginning of intervention, the personnel asked for the address and phone number of the subjects. If one was homeless, their whereabouts were asked and written down in their files. The clients were contacted by phone and reminded about their appointment one day before. For homeless subjects, this process was done by the outreach personnel.

If we were not able to contact a client, the personnel would keep trying to reach the client for 3 consecutive days. If the client was nowhere to be found or he was not willing to continue his participation in the study he would have been excluded from the study.

A strategy undertaken to minimize the number of patients lost to follow up was the use of monetary incentives. Study participants both in intervention and control group received 100,000 Rials (about 10 USD at that time) upon completion of baseline, 1 and 3 months assessments.

Primary Outcome Measure

In this study, the primary outcome measure was to assess the high risk sexual and injection behaviors associated with HIV transmission at 3 months follow-up and comparing the situation with the baseline assessment. For high risk injection behaviors 3 indices were considered including proportion of injecting to the total number of daily drug use (percent), the number of drug injection and the number of injecting drugs with a syringe used by another person during the last month. For high risk sexual behaviors, 5 indices were considered including the number of sexual partners, the number of new sexual partners, the number of partners with whom the participant had unprotected sex, the number of sex exchange for money or drugs and the number of sex after using drugs during the last month.

Data Collection/Management Process

High risk drug injection and sexual behaviors were measured using the author-made checklist. Data were gathered at baseline and during each follow up session (1 and 3 months after the onset of intervention) by a trained research assistant who was a clinical psychologist and completed a 4- hour training course on the application of data collection tools before beginning the study. The assessments were completed anonymously and specified with an identification code only. Data were entered into the database software with their specific ID code. Patients' information was kept private in a locked file in the DIC centers.

Sample Size Calculation

Previous studies demonstrated that the prevalence of safe behaviors in clients referring to the DIC centers such as the routine use of condoms in sexual contacts (before performing any intervention) was about 15% (20). In this study, we expected that at least 45% of the participants who received active intervention would have safe injection and sexual practices (15% versus 45%) 3 months after the intervention. Considering the 80% power of this study and the significance level of 0.05, sample size for each group was calculated as 48 subjects. On the other hand, considering the characteristics of this group of subjects and also the 25% drop-outs during the study, sample size for each group was estimated at 60 subjects.

$$n = 2\left[z_{(1-\alpha/2)} + z_{(1-\beta)}\right]^2 \times (SD^2)/d^2$$

Trial Recruitment Process (Figure 1)

Newly referred clients to the study sites were first assessed based on inclusion and exclusion criteria. Clients who met the inclusion and none of the exclusion criteria were enrolled to the study. The study design and objectives were thoroughly explained to the subjects in an informative session. After this session, the subjects who signed the written informed consent entered the study. It should be mentioned that patients' medical records were reviewed by the supervisor psychiatrist of the research team before the final inclusion of the patients into the study.

Trial Consent Procedure

Consent procedures had been designed to inform patients about the trial and its objectives in a non technical language. It was matched to the literacy levels of the participants and caregivers and was designed in a manner to increase the intake of information. In this process, we tried to minimize the difficulties that persons with substance dependence commonly face in processing information for making an informed decision. The psychologist established a meeting for each client who met eligibility criteria. In the meeting, she/he explained the trial and its purposes and tried to respond to all their questions.

Then, the psychologist asked the client whether she/he were interested in participating in the trial. If they were interested to participate, the psychologist took written consent. If not, they were excluded from the trial and received routine services available in the center. The consent procedures have been approved by the Ethical Committee in Tehran University of Medical Sciences.

Trial Randomization Procedure

The randomization procedure was carried out by an independent statistician in the Mental Health Research Center (MHRC) of Tehran University of Medical Sciences (TUMS). He assigned the subjects into intervention and control groups by randomization method. After obtaining patients' consent in each of the centers, the DICs' personnel contacted the clinical trial research center and informed them about the enrollment of new subjects in the study. Then the statistician randomly specified study participant's code and their group via a computer generated randomization allocation sequence.

Blinding

The nature of such services prevents adequate blinding of the participants. Also, it is not possible to blind the psychologist who performed follow-up tools on cases and controls because she/he has a direct contact with the patients when filling out the questionnaires; therefore there is a great chance of interrupting the process of blinding. The statistician involved in data analyses was blinded to group allocation.

Planned Analysis

In this study, the primary end point was reduction in the frequency of high risk behaviors 3 months after trainings. In order to summarize the obtained data, descriptive statistical indices such as mean with 95% confidence interval were used. The first assessment was done at the time of the enrollment of patients in the study. For baseline evaluation and comparison of high risk behaviors and also the underlying variables such as gender, age groups, level of education, history of incarceration and occupational status between the two groups, ANOVA and independent t-test were used. Also, ANCOVA was used to eliminate the effect of primary measures. In order to assess the trend of alterations of indices between the two groups, repeated measures analysis of variance was used. A p-value of 0.05 was used to declare statistical significance and 95% confidence intervals of the estimated effects were reported.

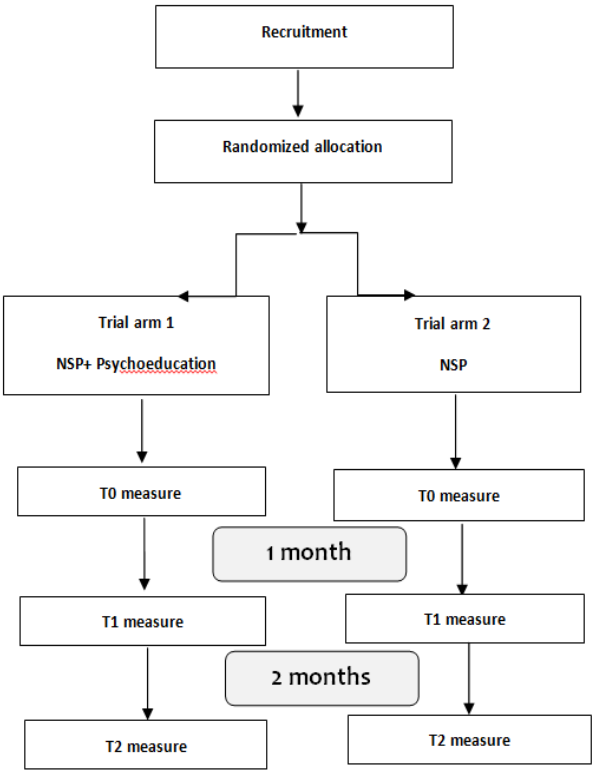

Figure 1: Flow of participants during the conduct of the trial

Considerations

Before the conduction of the study, patients were thoroughly informed regarding the services that were provided for them. Then, written informed consent was obtained from the patients and finally patients entered the study. The obtained data were strictly confidential. It was well explained to patients that they have the right to quit participation at any time. In this case, they could receive the routine services offered by the center. The clients did not pay any fee for receiving services and all the expenses were covered by the study's budget.

The study was approved at Mental Health Research Center, Iran University of Medical Sciences Ethics Committee ref: 86/11/1/11, and is fully compliant with the Helsinki declaration 2008.

Discussion

This paper presents a protocol for a RCT of adding on brief skill-based HIV prevention psychoeducation to the routine services of NSPs delivered to clients of drop-in-centers. Also, the trial sought to understand clients' satisfaction of receiving this form of intervention. Determining the effectiveness of this brief intervention to reduce the high risk sexual and injection behaviors compared to the control group will help policy makers for further planning. The results of subgroup analysis and implications of the results on

development of harm reduction programs in Iran will be discussed.

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