**Randomized controlled trial of motivational interviewing for reducing injection risk
behaviours among persons who inject drugs**

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ABSTRACT

Aim: We tested the efficacy of a brief intervention based on motivational interviewing (MI) to reduce high-risk injection behaviours over a 6-month period among people who inject drugs (PWID).

Design: A single site 2-group parallel randomized controlled trial comparing MI with a brief educational intervention (EI).

Setting: A study office located in downtown Montréal, Canada, close to the community-based harm reduction programs where PWID were recruited.

Participants: PWID who had shared drug injection equipment or shared drugs by backloading or frontloading in the month prior to recruitment were randomized to either the MI (112) or EI (109) group.

Intervention: The MI aimed to 1) encourage PWID to voice their desires, needs and reasons to change behaviours; 2) boost motivation to change behaviours; and 3) when the person was ready, support the plan he or she chose to reduce injection risk behaviours. The EI consisted of an individual session about safe injection behaviours.

Measurements: The primary outcome was defined as having any of these risk behaviours at 6 months: having shared syringes, containers, filters or water to inject drugs in the previous month, and backloading/frontloading; each behaviour was examined separately, as secondary outcomes.

Findings: The probability of reporting a risk injection behaviour decreased in both the MI and the EI groups. At 6-month follow-up, participants who reported any risk behaviours were 50% (OR=0.50; CI:0.13-0.87) less likely to be in the MI group than in the EI group as well as those who reported sharing containers (OR=0.50; CI:0.09-0.90). PWID who reported sharing equipment excluding syringes, were 53% less likely to be in the MI group (OR = 0.47; CI: 0.11-0.84).

Conclusions: A brief motivational interviewing intervention was more effective than a brief educational intervention in reducing some high risk injecting behaviours up in the subsequent 6 months.

INTRODUCTION

Injecting drug use is one of the most important causes of HIV transmission worldwide [1]. It is also the main mode of transmission of hepatitis C virus (HCV) in developed countries [2]. Both infections are very active in parts of Canada, especially in Montréal where, in 2010, HIV incidence was estimated to have been about 2.6 per 100 person-years (p-y) since 1995, and HCV incidence around 25 per 100 p-y since 1997 [3]. This study demonstrated that prevalence of HIV and HCV antibodies in persons who inject drugs (PWID) in Montréal was 26% and 75%, respectively. Sharing drug injecting equipment was one of the major modes of transmission behind these high transmission rates [4-5].

It is well established that needle exchange programs (NEP) significantly reduce self-reported injecting risk behaviours among PWID [6]. There is also strong evidence that NEP contribute to the control of HIV transmission and, to a lesser extent, to the prevention of HCV transmission among PWID. A consensus has emerged in the scientific literature that NEP are key harm reduction interventions that influence HIV and HCV control. In addition to distributing sterile injection equipment, NEP often provide other health services, including behavioural interventions. The latter present good opportunities to promote safer behaviours among PWID [7]. In a recent systematic review of reviews, Macarthur et al. concluded that there is only tentative review-level evidence to support the effectiveness of information, education and counselling, particularly in outreach settings, in reducing injecting risk behaviours in PWID [6]. Therefore, research must continue and innovative strategies in this field must be developed and tested.

Motivational interviewing (MI) is an individual intervention that has been shown to be effective in the field of substance abuse [8-11]. As defined by William R. Miller, MI is "a collaborative, goal-oriented style of communication with particular attention to the language of change (...) designed to strengthen personal motivation for and commitment to a specific

goal by eliciting and exploring the person's own reason for change (...) [12]. According to the literature, MI is effective when dealing with problematic substance use [8-11] and other health problems such as diabetes [13-15]. Its effectiveness has been statistically and clinically demonstrated for single sessions lasting 30 to 60 minutes [16-20]. Therefore, MI in a single session format is of particular interest in the context of needle exchange programs. Typically, NEP are for clienteles who come to a site on an irregular basis, and who are unable to and/or only marginally interested in engaging in longer term drug counseling services [21-22]. According to a recent Cochrane review, brief interventions are particularly well suited for the NEP context and have proved to be cost-effective compared to multi-session interventions [23].

To date, only two studies have been published on the effectiveness of MI, as described by Miller et al. [12,24], pertaining to reduction of injection behaviours at risk of transmitting HIV or HCV among PWID [25-26]. Only one of the two studies considered PWID who were not in drug treatment, and the results do not provide conclusive findings about MI [26]. There was no significant difference between the one-session MI and the non-intervention control groups, possibly due to high attrition rates (39.5% at three months and 54% at six months). Therefore, the effectiveness of MI to reduce injecting risk behaviours in PWID remains largely unexplored.

The specific aim of our study is to examine the efficacy of MI on high-risk injection behaviours among PWID. We compared PWID responses to MI with their responses to another brief intervention, which was based on an educational model. Both were individual interventions.

METHODS

Design

Study design was a 2-group parallel randomized controlled trial. Participants were allocated randomly to either MI (experimental group) or educational intervention (EI) (comparison group). Injection behaviours were assessed at baseline (T0) and reassessed at 3 (T1) and 6 months (T2) post-intervention.

Setting and participants

Participants were recruited by trained research staff during the latter's regular visits to the major community-based harm reduction programs located in downtown Montréal. The primary mission of those programs is prevention of HIV and HCV among drug users. One of their main activities is to provide clean drug preparation and consumption equipment to PWID and crack users. At time of visits, research staff screened individuals on site for eligibility using a 5-minute standardized questionnaire. To be eligible one needed to 1) have injected drugs in the month prior to recruitment; 2) have shared drug injection equipment (syringe, container, filter, water) or shared drugs by backloading or frontloading in the same month; 3) be 16 years old or older; 4) speak French or English; and 5) be able to provide informed consent. Individuals who agreed to participate were given an appointment at the study office located in the downtown area, the single site of this trial, generally within 48 hours. A process to confirm participants' eligibility began upon arrival at the study office. Once eligibility criteria were rechecked, the person was asked to complete the research questionnaire prior to randomization. The verification process resulted in the exclusion of 11 participants whose answers to the research questionnaire detected significant mismatches with the answers reported during recruitment.

Procedure

The baseline visit, which lasted approximately 90 minutes, began with the process of informed consent. Next, the research assistant collected contact information to trace the participant for follow-up visits. The randomization procedure was then carried out and either the EI or the MI was conducted. Different research team members conducted the interventions: three delivered EI and three others conducted MI. Participants received financial compensation (CAD \$20) at the end of the intervention. During follow-up interviews, a research assistant administered the questionnaire to participants, who were given the same amount of monetary compensation as at baseline. Ethical approval for the study was provided by the Comité d'éthique de la recherche en santé chez l'humain du CHUS (University of Sherbrooke).

Interventions: design and monitoring

MI intervention

Motivational interviewing as described by Miller and Rollnick [12, 24] was used in this study. The 30- to 45-minute MI specifically aimed to 1) encourage PWID to voice their desires, needs and reasons to change behaviours; 2) boost motivation to change behaviours; and 3) when the person was ready, support the plan he or she chose to reduce injection risk behaviours. Typically, MI is not intended to provide information or training unless participants ask for it. When information is given, a motivational style is used. This means that information is given only if participants agree and after they have explained what they already know about a given topic. Then participants' reactions and opinions about the given information are explored.

Motivational interviews were conducted by three different research team members: the principal investigator (PhD in psychology), an addiction specialized educator and a sexual health specialist (undergraduate degree). A consultant, who is a member of the *Motivational Interviewing Network for Trainers* (MINT) and psychiatrist specializing in addiction, trained and supervised the three individuals; the latter were given a minimum of 15 hours of MI training and had 27 90-minute supervision sessions over the entire data collection period. The consultant used Moyers et al.'s Motivational Interviewing Treatment Integrity Scale (MITI) [27] to assess the degree of fidelity of the intervention as delivered during the study. To this end, all MI sessions were recorded and 20% were coded using MITI. MI interventions lasted an average of 30.2 minutes (standard deviation (SD) = 12.4).

Educational intervention (EI)

Aside from the brief face-to-face format, EI differed from MI since the focus of the intervention was to provide information and training. The 30- to 45-minute educational intervention consisted of an individual session about safe injection behaviours using the document "One kit – One hit", a guide developed by Ministère de la Santé et des Services sociaux du Québec (MSSS) for people who want to reduce the risks associated with injection drug use [28]. The goal of the EI was to reduce risky injection behaviours and aimed specifically to give information about risky injection behaviours and how to use sterile injection equipment safely; and increase participants' awareness of their own lower-risk behaviours. The EI intervention was provided by three research team members (hereafter called "educators") trained for that purpose. There were three stages in the structured intervention: 1) participants described their injection behaviours; 2) the educator described sterile injection equipment items and provided relevant associated information about one item at a time to make connections with participants' descriptions and reinforce their knowledge

about safe and risky behaviours, occasionally reframing some of the participants' beliefs to reinforce safe behaviours; 3) the educator gave a demonstration of safe injection, simulating an injection event using sterile equipment but without using drugs. If a participant was uncomfortable with the demonstration, a pamphlet [29-30] could be substituted to explain the different steps involved in safe injection. Lastly, the educator gave the participant a copy of the MSSS guide that summarizes the information about safe injection and includes a list of useful resources for PWID.

Research staff members with academic backgrounds in relevant disciplines (undergraduate degrees in community health or criminology) were selected to provide the EI intervention. Two of the research investigators gave the staff a 3-hour training session on delivering the EI intervention. To ensure educators' compliance and give them ongoing feedback over the study period, all EI sessions were recorded and 20% were coded using a compliance tool developed by the investigators. EI lasted an average of 24.4 minutes (SD = 9.3).

Outcomes

Questionnaires typically took 30 minutes to complete at baseline interview and 20 minutes at follow-up visits. Outcomes variables included dichotomous measures of injection risk behaviours defined as having in the previous month, shared syringes, containers, filters or water, and backloading/frontloading. Primary outcome was defined as having any of those risk behaviours; each behaviour was also examined separately, as secondary outcomes. The questions used to assess injection risk behaviours came from the NIDA Risk Behavior Assessment (RBA) questionnaire, whose reliability and validity have been shown to be satisfactory [31]. Other variables included sociodemographic characteristics (age, sex, country of birth and aboriginal ethnicity, level of education and residential status), drugs

injected in the last month, and lifetime duration of drug injection in years. Based on our previous experience with studies on drug use and residential status trajectories among street-involved youth [32], we used techniques inspired from the life history calendar method to maximize recall and enhance the validity of participants' self-reported behaviours [33]. To reduce social desirability, special attention was paid to the training given to research assistants to ensure their attitudes were nonjudgmental.

Sample size

Assuming that 35% of participants in the EI group and 55% in the MI group would stop at least one injection risk behaviour, we estimated that we needed 250 participants (125 per group) to detect a 20% difference with at least 81% power at the significance level of 5% [34]. A 35% success rate was considered a reasonable, but at the same time relatively conservative, clinical threshold [35-36]. This calculation took into consideration an anticipated loss to follow-up of up to 20% over the 6-month follow-up period.

Randomization

Participants were randomized with Dacima™ Clinical software using permuted block randomization to obtain approximately equal numbers of MI and EI participants, that is, individual level randomization was used with no stratification. The randomization sequence was generated using SAS 9.2. A SAS macro was written that used the SAS block randomization function and random number generator syntax to generate random permuted blocks, with block sizes of 4, 6 and 8 to make the randomization sequence difficult to predict and to avoid major imbalance in numbers between MI and EI groups. The allocation sequence generated was then uploaded to the Dacima Clinical™ randomization module

stored on a server housed in a secure data storage facility in Montréal. Project staff based at the study office accessed the website using a unique log-on ID and password.

Blinding

Participants completed baseline questionnaires before being allocated to a group; therefore research staff were unaware of allocation at time of data collection. During follow-up, staff members who obtained outcome measurements were not informed of group assignments. Participants were blinded to the assignment, that is, they were not told whether they received motivational or education-based interventions. They did not know which was the experimental and which was the comparison intervention.

Statistical methods

Chi-square test, Fisher's exact test and t-test were used to compare baseline characteristics and behaviours of the two intervention group participants, as well as completers and those lost to follow-up at 3 and 6 months. Eligible and non-eligible subjects were also compared on sex and age. To test for group differences in proportions of participants reporting a given injection behaviour over the study period, intent-to-treat analyses were carried out. We used generalized linear mixed-effects model (GLMM) with an underlying logistic distribution for dichotomous outcomes [37]. By introducing random subject effects, this method explicitly considers interdependencies among repeated observations within subjects. Therefore, we were able to take into account all visits, allowing us to respect the intent-to-treat principle by keeping all participants in the analysis.

We examined seven models, one for each outcome under study. The models included intervention status as a dichotomous variable. Time and an interaction term between intervention and time were also included in the models to assess the effects of interventions

on injection behaviours over time. We estimated odds ratios (OR) using EI as the reference category.

RESULTS

Recruitment and follow-up

Recruitment for the study took place between February 2009 and August 2011. Follow-up visits were completed in February 2012. Given the feasibility issues related to recruiting among this hard-to-reach population, we chose to terminate data collection with a final sample of 219. Figure 1 outlines the recruitment and flow of participants throughout the trial. Overall, 537 persons were assessed for eligibility. Of the 261 individuals who qualified for the study, 221 (84.6%) were randomized. Eligible individuals were slightly younger than non-eligible ones (mean: 37.81 years versus 42.39 years; p -value <0.001), but there was no difference with respect to sex distribution (82.35% men among eligible and 84.7% men among non-eligible; p -value=0.48). One person was excluded from the database because he participated twice under two different identities, leaving 108 participants in the EI group and 111 in the MI group for the analyses. Follow-up rates were good: 72% of participants completed both T1 and T2 visits. At baseline, participants who completed follow-up were similar to those lost to follow-up regarding demographic variables (age, sex, ethnicity, schooling and residential stability) and all the outcomes variables except for backloading/frontloading (46.2% and 64.9%; $p=0.04$). To our knowledge, no adverse events occurred in either arm of the study.

FIGURE 1 ABOUT HERE

Baseline characteristics

There were no significant differences between MI and EI for socio-demographic characteristics and injection behaviours at baseline (Table 1). The majority of participants were male (82.2%) and Canadian-born (96.3%), and mean age was 37.85 years. Half had completed high school and 53% were homeless. Cocaine and opioids, and either heroin or prescription opioids were the main drugs injected.

TABLE 1 ABOUT HERE

Effects of the interventions

Results presented in Figures 2 to 8 show a decrease over time of the probability of all outcomes; this is true for both types of interventions.

FIGURES 2-8 ABOUT HERE

In our multivariate analyses, depending on the practice, the probability of reporting a risk behaviour decreased in the MI group (odds ratios varying between 0.13 and 0.26) and the EI group (odds ratios varying between 0.16 and 0.38) with all p-values <0.0001 except for any risk behaviour ($p=0.0006$). Table 2 presents the independent effects of interventions. After 6 months of follow-up and compared to the EI group, participants in the MI group were 50% less likely to report any risk behaviour ($OR=0.50$; $CI:0.13-0.87$, $p=0.0077$), 50% less likely to share containers ($OR=0.50$; $CI:0.09-0.90$, $p=0.0168$) and 53% less likely to share equipment, excluding syringes ($OR=0.47$; $CI:0.11-0.84$, $p=0.011$). Interaction terms were significant with p-values of 0.0013, 0.0003 and 0.006, respectively.

TABLE 2 ABOUT HERE

Discussion

Results of this randomized trial show that injection risk behaviours decreased significantly between T0 and T2 in both intervention groups. However, after six months, improvements in primary outcome (any risk behaviour), and two secondary outcomes (sharing containers and injection equipment excluding syringes) were more pronounced in the MI than in the EI group. Those changes could be attributed to passage of time or to the research process itself, including possible effects of answering questionnaires. Although plausible, we think this is unlikely. Based on the results of 59 randomized trials, a Campbell review on the effectiveness of MI to reduce substance abuse concluded that MI is more effective than no treatment [10]. Similarly, Gagnon et al.'s randomized trial of 260 PWID in Montréal and Québec (Canada) showed effects of a computer-tailored intervention to reduce needle sharing: the control group, which received no intervention, showed no changes at 1- and 3-month follow-ups [38]. Therefore it is probable that MI, as well as EI, are promising single-session interventions to lessen risky behaviours in PWID who use needle exchange programs.

At 6-month follow-up, MI appeared to have an advantage over EI when it came to any risk behaviour, sharing containers and sharing injection equipment, excluding syringes. This finding supports the clinical rationale for using MI, which is that this type of intervention encourages a person to resolve ambivalence about change [24]. There is also preliminary evidence that specific MI constructs and variables are related to better outcomes [39]. Studies have documented that PWID perceive the risks related to sharing needles to be greater than to sharing other injection equipment [40-41]. Motivational interviewing could have the effect of increasing a PWID's awareness of the importance of reducing sharing

other injection equipment, for instance by pointing out the divergence between the person's values and the risks associated with this behaviour.

Results of our randomized trial do not shed light on the processes that explain the possible effects of MI and EI. The significant and similar reduction in some injection risk behaviours in both groups could be due to numerous non-specific factors shared by MI and EI, such as comparable time of exposure to the intervention and therapeutic alliance. In an often-cited review of research on common factors in therapy, Asay and Lambert noted that only 15% of improvement is attributable to specific therapies, 30% to therapeutic relationship, 15% to the placebo effect and 40% to extratherapeutic factors [42]. In the field of drug addiction, compared with usual treatments or no intervention, the equivalent efficacy of “bona fide” intervention models—including MI and Cognitive Behaviour Therapy—has been demonstrated [43-45]. To be designated as “bona fide”, a treatment requires the following: a theoretical basis; an intervention guide with specific components; and appropriate training and supervision for individuals providing the intervention. The MI and EI interventions in this randomized trial meet these criteria, which is consistent with the fact that they have similar effects on some injection risk behaviours.

This trial demonstrates the feasibility of carrying out thorough studies of PWID in the community to assess the effectiveness of innovative strategies meant to reduce risky injection behaviours. Both interventions were conducted as planned and attrition rates were very low, given the target population's characteristics. Close partnerships with NEP contributed significantly to the success of this study. Moreover, the choice of closely monitoring the quality of the two interventions adds value to this randomized trial.

However, our study results need to be considered in light of the following limitations. Ideally, adding a third comparison group (no intervention) would have enhanced the

conclusions of the randomized trial. This was not possible for reasons of feasibility linked to difficulties recruiting individuals from this marginalized population as well as related budgetary issues. Secondly, data considered in this study were self-reported, which may have introduced the possibility of both recall and social desirability biases. We believe that the impact of such biases was limited by our use of the life history calendar method and the short time spans between interviews (3 months). Finally, we could not document long-term maintenance of change (beyond 6 months). Although the results of this trial open up avenues to improve our practices with PWID and to reduce HIV and HCV transmission risks, other randomized trials are needed to determine the effectiveness of MI and EI in this area.

Based on the trial results and review of the scientific literature, implementing brief and structured interventions that target injection risk behaviours can certainly be recommended. NEP are appropriate sites for these interventions since they are points of contact with PWID who are unlikely to engage in therapeutic processes that entail several sessions. To date, most behavioural interventions evaluated for HIV prevention have involved more than one session [46]. Although useful, multisession interventions are not appropriate for all PWID, or at least not suitable at certain moments in their lives. Brief interventions like MI and EI have the potential to complement services offered in NEP. EI are relatively easy to implement because their use requires less training than for MI; therefore EI could be used more widely by people working in NEP. MI could be considered for PWID who go to NEP regularly and who present recurrent injection risk behaviours. However, it is important to conduct effectiveness studies in a natural environment to look at the feasibility of applying this intervention model in the community [47-48].

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Figure 1. Flow chart

Figure 2. Probabilities of any risk behaviour estimated by mixed effects regressions, by type of intervention

Figure 3. Probabilities of sharing syringe estimated by mixed effects regressions, by type of intervention

Figure 4. Probabilities of sharing filter estimated by mixed effects regressions, by type of intervention

Figure 5. Probabilities of sharing container estimated by mixed effects regressions, by type of intervention

Figure 6. Probabilities of sharing water estimated by mixed effects regressions, by type of intervention

Figure 7. Probabilities of backloading/frontloading estimated by mixed effects regressions, by type of intervention

Figure 8. Probabilities of sharing equipment excluding syringe estimated by mixed effects regressions, by type of intervention

Table 1. Baseline sample characteristics

	EI (N=108)	MI (N=111)	Overall	p-value
Demographic characteristics				
Mean age (years)	38.22	37.49	37.85	0.565
% Male	84.3% (91/108)	80.2% (89/111)	82.2% (180/219)	0.430
% High school diploma	53.7% (58/108)	46.8% (52/111)	50.2% (110/219)	0.310
% Born in Canada ^a	94.4% (101/107)	98.2% (108/110)	96.3% (209/217)	0.167 ^c
% Aboriginal ^b	10.9% (11/101)	7.4% (8/108)	9.1% (19/209)	0.381
% Homeless in the last month	55.6% (60/108)	50.5% (56/111)	53.0% (116/219)	0.449
Drug injected in the last month				
% Cocaine	88.9% (96/108)	90.1% (100/111)	89.5% (196/219)	0.772
% Heroin	49.1% (53/108)	51.4% (57/111)	50.2% (111/219)	0.736
% Speedball ^d	23.1% (25/108)	17.1% (19/111)	20.1% (44/219)	0.265
% Other opioids	59.3% (64/108)	55.9% (62/111)	57.5% (126/219)	0.610
% Others	12.0% (13/108)	17.1% (19/111)	14.6% (32/219)	0.287
Lifetime mean duration of injection (years)	16.4	15.2	15.8	0.401
Risky injection behaviours in the last month				
% any risk behaviour	99.1% (107/108)	100% (111/111)	99.5% (218/219)	0.493
% sharing syringe	58.3% (63/108)	64.0% (71/111)	61.2% (134/219)	0.393
% sharing container	68.5% (74/108)	77.5% (86/111)	73.1% (160/219)	0.135
% sharing filter	40.7% (44/108)	53.2% (59/111)	47.0% (103/219)	0.066
% sharing water	59.3% (64/108)	64.0% (71/111)	61.6% (135/219)	0.474
% backloading/frontloading	50.9% (55/108)	47.7% (53/111)	49.3% (108/219)	0.638

^a 2 missing values; ^b 10 missing values; ^c Fisher's exact test; ^d Speedball also includes cocaine and Dilaudid mix.

Table 2. Comparison of injection risk behaviours between MI and EI groups over 6-month follow-up

	OR intervention					
	OR	T0 (95% CI)	OR	T1 (95% CI)	OR	T2 (95% CI)
Any risk behaviour	1.20	(0.16-2.24)	0.78	(0.37-1.19)	0.50	(0.13-0.87)†
Syringe	1.47	(0.48-2.46)	1.08	(0.46-1.70)	0.79	(0.06-1.53)
Container	1.67	(0.54-2.80)	0.91	(0.43-1.39)	0.50	(0.09-0.90)*
Filter	2.65	(0.36-4.94)	1.06	(0.21-1.91)	0.42	(0.12-1.49)
Dilution water	1.27	(0.46-2.08)	0.85	(0.40-1.29)	0.57	(0.09-1.04)
Backloading/Frontloading	0.99	(0.22-1.75)	0.69	(0.21-1.17)	0.48	(0.17-1.40)
Equipment, excluding syringe	1.42	(0.31-2.53)	0.82	(0.38-1.26)	0.47	(0.11-0.84)†

*p-values for significant OR † 0,0077, * 0,0168 ‡ 0,011*