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A Trial to Reduce Hepatitis C Seroincidence In Drug Users

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Abstract

To test if a four-session motivational intervention would reduce hepatitis C virus (HCV) seroincidence among injection and non-injection drug users compared to an assessment-only condition, we performed a randomized 24-month clinical trial. At baseline 277 participants reported using heroin or cocaine at least three times weekly were HCV antibody negative, 65% male and 46% and 39% reported having injected drugs. Among the fifteen persons (5.4%) who seroconverted, all reported injecting drugs either at baseline or during follow-up. Seroconversion rates did not differ significantly by treatment assignment (p=.79). The annual HCV incident rate for injectors was 8.20 (95% CI 4.76-14.13) and for non-injectors was 0.74 (95% CI 0.19-2.98) per 100 person years. Significantly fewer participants in the intervention group initiated injection drug use behaviors (p = . 009). This intervention was no more effective at reducing HCV seroconversion than assessment alone, but did decrease injection initiation.

Keywords

Hepatitis C incidence; motivational intervention; injection drug use; noninjection drug use; prevention

Introduction

Hepatitis C virus (HCV) infection causes liver disease and affects more than 170 million people globally. HCV may be transmitted more efficiently than HIV1, and given the high prevalence of HCV in drug-using populations, injection drug users are at high risk for contracting the virus2›3. Factors influencing HCV infection include not only efficient blood-borne transmission, but also the frequency of sharing injection equipment (the dominant transmission mode) with infectious persons. HCV has also been associated with tattooing4 and unsafe sexual behavior5. Depending on the location and the population of drug users being studied, HCV incidence has been reported at 5.3-41.8 per 100 person-years, with the highest rates seen among those who were new initiates to drug injection6-12. HCV incidence rates may be lower in recent years especially among those injecting in areas with wider availability of needle exchange and HCV prevention programs[13].

Risk for HCV acquisition extends beyond the IDU population. Those who are not injecting but are using other drugs such as cocaine may also be at increased risk for HCV[14]. Some researchers have suggested that non-injecting drug users included in published studies are often injectors who fail to disclose injection drug use, or share drug equipment such as straws and crack pipes[15]. A recent review reported that prevalence of HCV in “never-injecting” drug users

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ranged from 2.3 to 17%, rates far higher than in a non-drug using population[14]. The one study to date that documented the annual incidence of HCV seroconversion in a non-injection drug user cohort reported HCV incidence as 0.4 per 100 person years[16].

Because HCV incidence is a continuing problem in both injection and non-injection drug using populations, we conducted a randomized clinical trial to reduce HCV seroconversion among a sample of such individuals. We chose a brief motivational interviewing intervention (MI), as developed by Miller and Rollnick[17], which focuses on enhancing an individual's intrinsic motivation to facilitate positive behavior change. Motivational interviewing interventions have primarily been shown to be effective in changing drinking behaviors[18-20]. When MI has been applied to drug-using populations, it has focused on drug dependent persons awaiting or receiving drug treatment[21-24] and has had modest effects improving engagement with care.

Motivational interventions for cocaine and/or heroin users have also been used as stand-alone treatments in two randomized trials that tested a single MI session, one trial based in the community, one in a medical settings. Marsden et al.25 enrolled 16-22 year old ecstasy or cocaine users in a clinical trial of a single MI session delivered in the community by youth drug outreach workers. They25 found no treatment effect on stimulant drug use beyond the control condition that only provided information, although dramatic behavior change was noted in both intervention and control condition participants as a result of this information. A second trial offering brief MI at a walk-in medical clinic for those not expressly seeking cocaine treatment[26], reported greater cocaine abstinence measured biochemically via hair sample 6-months post-intervention in the MI intervention group (22.3%) compared to the control group (16.9%).

In the BRAINE study, an MI was designed to reduce injection drug use risk behaviors among hazardously drinking IDUs[27]. This randomized clinical trial found that two brief MI sessions substantially reduced the number of injection risk days among the intervention group compared to an assessment-only control condition. However, the study was limited by its six-month follow-up and lack of biological testing for HIV or HCV infection.

In the current study, we tested the effectiveness of a four-session motivational intervention to reduce HCV seroincidence among out-of-treatment heroin and/or cocaine users. While injection drug use is known to be the most important risk factor for the acquisition of HCV, we chose to include persons who were non-injecting heroin or cocaine users because 1) we presumed that some of the participants who denied drug injection at baseline had injected; 2) some non-injectors would transition to drug injection during the two-year follow-up period; and 3) HCV is known to be acquired through routes other than injection equipment sharing (e.g., sexually), albeit at lower efficiency. To enhance the effects from previous MI studies, we chose a multi-session approach with four motivational intervention visits over six months. We focused our intervention on reducing behaviors associated with HCV transmission, including the number of days of drug injection and equipment sharing for injectors, and the initiation of injection drug use for non-injectors.

Methods

Recruitment

Between April 2001 and December 2004, participants were recruited for a “Quality of Life Study for Drug Users” based in Providence, RI via advertisements in local newspapers and word of mouth. Initial eligibility included heroin or cocaine use in the past week, hepatitis C serology negative, English speaking, and 18 years of age or older. Of the 2356 persons who completed telephone screening, 559 callers were invited to the research office for further eligibility screening. Individuals were excluded during the initial screening if they reported

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hepatitis C (HCV) seropositivity (n=743); negative urine toxicology for heroin or cocaine use (n=425); psychotic symptoms (n=298); if they did not complete the screening, did not speak English, or for duplicate screening (n=331).

Of the 559 callers invited for further screening which consisted of HCV serological testing, 257 were excluded for: testing HCV antibody positive (n=130), not reporting drug use in the past month (n=20), failing to keep their appointment (n= 87) or being unable to participate for other reasons (unable to draw blood, chose to withdraw, comprehension problems (n=20). In addition, twenty-five eligible persons did not return for study enrollment which included the baseline interview.

The study sample consisted of 277 individuals who met the eligibility criteria described above and signed an informed consent. The study was approved by the Institutional Review Board of Rhode Island Hospital.

Following the baseline assessment, participants were randomized to an intervention group receiving the motivational intervention and were provided with a written informational handout about local treatment resources or to a control condition receiving only the informational treatment resource list handout. Randomization was overseen by the study methodologist.

Participants in both conditions completed self-report behavioral assessments at baseline and every six months thereafter for up to 24 months. In addition, HCV testing was performed at the 12 and 24 month follow-up assessments. Persons missing the 12-month assessment had HCV testing performed at 18 months. HCV serology was performed using third-generation enzyme-linked immunoabsorbent assays. Seroconverters were defined as participants who tested HCV antibody positive after having previously tested HCV antibody negative.

Intervention Condition

Schedule of the Intervention—The MI intervention consisted of four individual MI intervention sessions each lasting 30-45 minutes that were conducted at baseline, 1, 3, and 6-months post-baseline. Participants assigned to the control condition completed assessments only.

Intervention Manual Development—The manual for this study was adapted from Miller and Rollnick's[17] motivational interviewing approach, and the Brief Alcohol Intervention in Needle Exchangers (BRAINE)[27] project's motivational intervention therapy manual.

Initial MI Session—The goal of this first session was for the interventionist to guide participants in raising their awareness of behaviors that placed them at risk for HCV infection. Discussion points during this session were: the participant's values and goals, pros and cons of drug use, thoughts about drug use and cutting back/quitting, thoughts about the usefulness of substance abuse treatment, state of readiness to make changes around HCV risk activities, and creation of a change plan. The interventionist used motivational interviewing techniques to help the participant elicit self-generated goals to reduce drug use and/or HCV risk behaviors, explore internal or external obstacles/barriers in achieving the risk reduction goal, and discuss these barriers. HCV risk behaviors specifically discussed during the session were initiating injection drug use (for non-injectors), continued injection drug use, sharing both injection (e.g., syringe, cooker) and non-injection (e.g. straws) drug equipment, sharing drug in certain ways (e.g., backloading), receiving tattoos, and having unprotected sex.

Follow-Up MI Sessions—During the three follow-up MI sessions, the interventionist guided the participant in (a) assessing progress on the goal(s) set during the previous intervention sessions, (b) discussing barriers in achieving the goal and identifying strategies

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for overcoming those barriers, and (c) helping the participant revise their previous behavior change goal or generate a new goal to reduce risk behaviors.

MI techniques were used to review the information from the first session in order to reevaluate the possibility for setting a drug goal. Cognitive-behavioral skills were offered as strategies that might be utilized once the participant becomes ready to make a change in their drug use/risk. Participants were also offered suggestions about interim steps which they might consider prior to setting an abstinence goal, such as gaining knowledge about trigger situations, reducing their drug use/drug risk, beginning to exercise, or using stress management techniques. For participants who were closer to taking action, this session focused on setting goals and developing concrete strategies for meeting those goals. For all participants, discussions during follow-up sessions also re-visited any specific areas the interventionist and participant discussed in previous MI sessions.

For individuals who had achieved their goals of reducing their risk by discontinuing drug use, the interventionists helped the participant identify strategies for avoiding relapse by helping the individual identify and cope with high risk situation and associated relapse triggers. Specifically, the interventionist helped the participant develop effective strategies to cope with lapse triggers, and in the event of a lapse, to avoid the abstinence violation effect in which a lapse triggers a full relapse. Cognitive behavioral skills training was emphasized, with a focus on removing barriers to achieve and/or maintain goals, identifying trigger situations, using stimulus control techniques to manage trigger situations, managing stress via relaxation, making positive lifestyle changes (e.g., exercise) and increasing social support for maintaining goals.

For those participants who did not set any goals in the first session, MI techniques were used to review the information from the first session in order to reevaluate the possibility for setting a drug use reduction goal.

Intervention Handouts—Handouts were used during intervention sessions to guide discussion. Handout topics at the first MI session included: 1) Values and Goals—Participants were asked to reflect on what they find important in their lives (e.g., values/ethics/relationships) and then on the meanings that drug use holds for them; 2) Decisional Balance—Participants were asked to describe positive and negative experiences related to their drug use and about their perception/experience of drug treatment, and concerns and benefits if they were to change their drug use or attend drug treatment; 3) Feedback—Compiled information from the baseline assessment, which highlighted the participants' reports of their perceived risk of Hepatitis C, any social support and environment factors that influence HCV risk-taking and drug use in general, and their readiness to make a change in their HCV risk or drug use; 4) Change Plan —Participants were asked to identify what goals they wanted to set, the steps necessary to achieve this goal, reasons why this goal was important for them, obstacles in obtaining that goal, ways to overcome these obstacles, and support from others for making this change.

At the follow-up sessions, additional handouts directed discussion. These handouts concerned: 1) drug use triggers and how to manage them as part of relapse prevention; 2) lists of pleasant activities, with a rationale for why increasing pleasant activities was important; 3) a positive and negative thoughts overview discussing ways to manage these thoughts. Specific techniques for decreasing negative thoughts and increasing positive ones were provided.

Therapist Integrity—We used a modified version of the Motivational Interviewing Skill Code 1.0 (MISC)[28] both to train the two study interventionists and to monitor the MI skills of the interventionists during biweekly supervision. The MISC 1.0 was chosen for a variety of reasons. First, this was the primary manual being used at the time to train and assess

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motivational interviewing skills. Second, our main purpose in using the MISC was to document interventionist adherence to MI, and provide structured feedback to the interventionists during supervision. Third, we were *not* interested in evaluating psychotherapy process issues29. We modified the MISC 1.0 according to the decision rules of Miller, et al.[22]. We used only those codes relevant to the interventionist's behavior (6 global therapist rating scales and 2 global interaction rating scales), as these would allow a general assessment of the interventionist's skills, and listened to the full session and not just a 20-minute section of the session, again, to allow a general assessment of the interventionist's skills, and an attention to key aspects of MI, such as change talk[30].

All intervention sessions were audiotaped and tapes were reviewed in biweekly supervision sessions. Five raters, trained in MI and with established inter-rater reliability (mean intraclass coefficients range: .55-.89), coded a random sample of intervention sessions. Intervention sessions were coded on the 7-point MISC scale. Mean scores across the 8 global scales for the intervention sessions were 5.73.

Measures

The baseline questionnaire assessed demographic characteristics age in years, gender, and race. We assessed years of drug use, current injection drug use (any injection drug use in the 6 months prior to study entry), and a history of ever injecting drugs using the Addiction Severity Index[31] at baseline, and the number of days on which participants used heroin, cocaine and other drugs during the prior 30 days at the baseline and all follow-up assessments. Drug equipment sharing behaviors was assessed at each interview with the question, “What is the number of times you shared needles or works in the last six months?”

Analysis Plan

We used the Pearson χ^2-test of independence and the t-test for differences in means to compare intervention groups on background characteristics, injection drug use history, and completion of follow-up assessments. Because the number of participants who became HCV-positive was small, we relied on small sample and nonparametric statistics to test most associations involving the primary outcome, HCV seroincidence. When expected cell sizes were small we report Fisher's exact p-value rather than the Pearson χ^2-statistic. A secondary outcome was reduction in drug injection days calculated as baseline minus follow-up. We report t-tests to compare the mean reduction in drug use-days between intervention groups. Although we report t-tests for differences in means we augmented these analyses with the nonparametric Wilcoxon rank-sum test; in all cases the nonparametric tests gave conclusions consistent with those we report.

Separate analyses are reported for those who reported never injecting drugs prior to baseline (n = 168) and those who had a positive lifetime history of ever injecting drugs (n = 109) at baseline. We used 12-, 18-, and 24-month HCV test results to estimate the incidence rate of HCV seroconversion for IDUs and non-IDUs. The HCV seroincidence rate is expressed as events per 100 person-years.

Results

The mean age of 277 participants was 37.2 (± 8.9) years, 62.5% were male, and 46.4% were Caucasian (Table 1). On average, participants reported they had used either heroin or cocaine for 16.2 (± 8.6, Median = 17) years. About 39.4% (n = 109) reported they had ever-injected drugs and 78 (28.3%) said they had injected in the 6-months prior to baseline.

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Overall follow-up completion rates were 80.1% at 6-months to 75% at the 24-month assessment. Only 24 (8.7%) of the participants who enrolled in the study were not located at any of the follow-up assessments. At least one HCV test result was available for 234 (84.5%) participants. Most participants were HCV tested at 12-months (n = 209) and 24-months (n = 199). Participants who were not located for their 12-month assessment were tested at 18-months (n = 16). Persons who did not have HCV testing at 24 months did not differ significantly with respect to age, gender, years of drug use, lifetime history of injection drug use, or sharing needs or work within the last six months from persons whose HCV status was tested at 24 months. IDUs were observed for an average of 21.13 person-months and non-IDUs were observed for a total of 22.33 person-months.

For those who reported a history of IDU at baseline, the intervention and controls groups did not differ significantly with respect to gender, age, ethnicity, years of drug use, frequency of heroin or cocaine use in the 30 days prior to baseline, probability of drug treatment in the 6 months prior to baseline, or likelihood of being located for follow-up at 6-, 12-, 18-, or 24-months (Table 1). Among participants who reported a history of IDU at baseline, 38 (67.7%) of those randomized to treatment and 40 (75.5%) of those randomized to control reported injection drug use in the 6-months immediately prior to baseline data collection; this difference was not statistically significant (Table 1).

Of the 168 participants who reported no history of injection drug use prior to baseline, 11 (6.5%) reported initiating IDU between the baseline and one of the follow-up sessions. As shown in Table 1, significantly fewer (one, 1.2%) of the participants randomized to the intervention condition reported initiating injection drug use during the two-year follow-up period than did those randomized to the control condition (ten, 11.9%) as evaluated with Fisher's exact test (p=.009).

Table 2 gives descriptive information on the 15 participants who became HCV+ during the 2 years of follow-up. Age ranged from 22 to 46 and averaged 32.0 (± 6.8) years. Twelve (80.0%) were male and 14 (93.3%) were white. Two (13.3%) participants reported no history of injection drug use at baseline, but reported injecting during the course of the study.

Seroconversion rates between the intervention and control conditions did not differ significantly (Table 3). Among those who reported never injecting drugs, one (1.7%) intervention condition participant and one (1.5%) control condition participant seroconverted (Fisher's exact p = .728). Among those reporting a history of IDU at baseline, six (14.3%) intervention participants and seven (21.9%) control condition participants seroconverted by the final follow-up at 24 months; this difference was not statistically significant (Fisher's exact p = .539). Additionally, we compared seroconversion rates among the 78 participants with a history of injection drug use in the six months prior to study entry; 4 (10.5%) participants randomized to intervention and 6 (15.0%) controls were observed to seroconvert (Fischer's exact p = .738). And, in the full cohort (n = 277) seroconversion rates were 5.0% and 5.8% (Fisher's exact p = .796) in the intervention and control arms, respectively.

We conducted auxiliary analyses to determine if MI significantly reduced injection drug use days. On average, participants with a lifetime history of injection drug use injected 47.3 (± 60.7) days in the 6-months prior to baseline. Mean injection drug use days were 38.8 (± 61.2), 21.6 (± 46.6), 24.9 (± 51.3), and 21.6 (± 44.6) at 6-, 12-, 18-, and 24-months, respectively. A Wilcoxon signed-rank test indicates that compared with baseline, the frequency of injection drug use days was significantly lower at 6-months ($z = 2.51$, $p = .012$), 12-months ($z = 3.61$, $p < .001$), 18-months ($z = 2.16$, $p = .031$), and at 24-months ($z = 4.00$, $p < .001$). There were no significant group differences, comparing intervention to control participants, in change in injection drug use days at any follow-up. This analysis was replicated using only participants

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who had injected in the six months prior to study entry (n = 78); again, there were no statistically significant group differences at any follow-up. Finally, we conducted analyses to determine if MI significantly reduced sharing of drug use equipment. Thirty-eight percent of injectors reported sharing equipment in the six months prior to study entry. There were no statistically significant group differences in change in sharing behavior at any follow-up.

The non-IDUs had a significantly different HCV seroincidence than the IDUs ($\chi^2 = 16.50$, df = 1, $p < .001$). Two individuals who reported no history of injection drug use prior to baseline, but reported initiating IDU during the study period seroconverted; the estimated incidence rate of HCV seroconversion among those with no prior history of IDU was 0.75 (95% CI 0.19-2.98) events per 100 person years (Table 4). Both of these participants reported injection drug use at one or more follow-up assessments. Thirteen individuals who reported a history of IDU at baseline seroconverted during the study period. The estimated incidence rate of HCV seroconversion among those with prior IDU history was 8.20 (95%CI 4.76-14.12) events per 100 person years. Note that this estimate is a lower bound estimate of the seroconversion rate among IDUs because HCV status at 24-months was not known for 19 (17.4%) of the 109 participants who reported injection drug use at baseline. Log rank tests comparing time to event yielded results consistent with those comparisons reported in Table 3.

Among those with a lifetime history of injection drug use, we tested selected background characteristics as possible predictors of seroconversion. Participants who became HCV+ did not differ significantly from HCV- participants with respect to age, gender, cocaine use, injection drug use, or sharing injection equipment in the six months prior to study entry. Caucasians (20.0%) were significantly (Fisher's exact p = .001) more likely to become HCV + during follow-up than racial and ethnic minorities (0.0%).

Discussion

The four-session MI tested in the present study did not significantly reduce HCV annual incidence rate among IDUs or non-IDUs compared to a control condition. However our cohort with a history of IDU had a low seroincidence rate (8.2 per 100 person years) compared to other studies of injectors (up to 41.8 per 100 person years), and thus there was little room to detect the hypothesized protective effects from this intervention. Similarly, our cohort without a history of IDU had a low HCV annual incidence rate (0.74 per 100 person years), nearly identical to one previously published cohort study[16].

Among those who reported never having injected drugs at study enrollment, eleven initiated drug injection and two seroconverted during the two years of follow-up. This 18% seroincidence rate is in keeping with previous studies describing unsafe injection practices and rapid seroconversion during period immediately following drug injection initiation[10]. Initiation of injection is an important transition in the life of drug user, and we found that this multi-session motivational intervention significantly decreased such initiations in our cohort. Discussion of the risk of HCV and other infectious disease and the self-reflection prompted by MI may have led to decreased uptake of this risky behavior. Although the number of new injectors was small, this finding may have important implications if replicated in larger sample of non-injectors given the substantial health impact (bacterial and viral infections) associated with drug injection.

One possible reason that we found a relatively low HCV incidence rate in the IDU sub-group was that we enrolled an older group of drug users. There were relatively few new injectors, and participants had injected for a median of 17 years without acquiring hepatitis C, suggesting that the majority of our sample practiced risk reduction despite continued injection behavior. Older drug users, particularly injectors, could represent “healthy survivors” whose injection

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practices or injection network allowed this subpopulation to remain HCV free. The local epidemiology of IDU populations, at least those seeking drug treatment, suggests that HCV prevalence rates among those with a history of injection remains high[32]. In addition, during the study period in Rhode Island needle exchange was available, and in 2002 needles became available via over-the-counter pharmacy purchase. Nonetheless, some individuals seroconverted, suggesting the ongoing difficulty of having completely safe injection behaviors[33] among those who had previously remained HCV negative for long periods.

Why Caucasians had higher rates of seroconversion than minorities is unclear, has not been reported elsewhere, and would be worthy of further study, perhaps using anthropological methods. It is possible that race influences social network and Caucasians are in networks more densely infected with HCV. An alternative explanation is that Caucasians were more likely than other groups to misclassify themselves as non-injectors. We found no other demographic or drug use factor associated with seroconversion.

Our study was not limited to new injectors and took place in a small city, not in one of the major metropolitan centers usually associated with drug user studies, providing insight into the IDU and non-IDU groups recruited in parallel. However, our study had certain limitations. Because of the low HCV incidence rate in the population we had insufficient statistical power to see an intervention effect or to identify risk factors associated with seroconversion. In addition, our case definition was based on the presence of HCV antibody. We did not test for HCV viremia, which precedes the development of antibody, thus it is possible that some seroconversions were misclassified, but this should not have affected the presence of an intervention effect. Third, our reported seroconversion rates may not generalize to IDU and non-IDUs in the large drug-using community in our region or elsewhere. Fourth, because behavioral data were obtained by self-report, it is possible that under-reporting of risk behaviors occurred. We did not perform physical inspections for injection marks to confirm injection status. Some participants classified as non-IDU at baseline might have been surreptitious injectors, or might have become injectors during the two years of follow-up. Fifth, differential loss to follow-up of higher risk persons did not bias our results, but only 75% of participants had HCV testing at 24 months which could have influenced the absolute seroincidence. Our conversion estimates probably represent conservative estimates of incidence and risk behaviors in this population.

Summary

Our results demonstrate that injection drug users, even after years of use, remain at risk for HCV. Even low levels of injection risk behavior may lead to infection with this transmissible virus. Prevention efforts that highlight messages regarding the sharing of equipment, the accessibility of sterile injecting equipment, and the availability of substance abuse treatment need to continue. Because of the small window of opportunity to protect new injectors from HCV acquisition, our data suggests MI may be worth exploring as an intervention to prevent the initiation of injection drug use. More research is needed to understand whether geographic or temporal factors explain seroincidence, or whether local HCV prevention programs, specific risk behaviors, or the prevalence of HCV in the broader drug-using population predict changes in the HCV epidemiology of this and other regions.

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Table 1

Background Characteristics by Treatment Condition by History of Injection Drug Use.

	NEVER INJECTED DRUGS			EVER INJECTED DRUGS		
	Treatment (n = 84)	**Control (n = 84)**	**t (p =)**	**Treatment (n = 56)**	**Control (n = 53)**	**t (p =)**
Mean Age (Yrs)	38.5 (±9.7)	38.9 (±7.9)	0.28 (.781)	34.7 (±7.6)	35.1 (±9.8)	0.22 (.829)
Years Drug Use	16.0 (±9.7)	16.5 (±7.4)	0.37 (.708)	16.7 (±7.6)	15.4 (±9.8)	-0.75 (.457)
Heroin Use (0–30 Days)	2.5 (±7.5)	3.7 (±8.1)	1.04 (.297)	10.5 (±11.4)	13.5 (±12.3)	1.34 (.184)
Cocaine Use (0–30 Days)	13.4 (±10.5)	13.9 (±10.0)	0.31 (.759)	8.3 (±9.5)	10.5 (±9.9)	1.19 (.237)
n (%) Male	46 (54.7%)	46 (54.7%)	χ^2 (p =) 0.00 (1.00)	39 (69.6%)	42 (79.3%)	χ^2 (p =) 1.32 (.251)
n (%) Caucasian	30 (36.1%)	32 (38.1%)	0.07 (.794)	32 (58.2%)	33 (63.5%)	0.31 (.576)
n (%) Current Injector (Last 6-Months)	NA	NA	NA	38 (67.7%)	40 (75.5%)	0.78 (.378)
n (%) Any Drug Rx	21 (25.0%)	20 (23.8%)	0.03 (.857)	23 (41.1%)	26 (49.1%)	0.40 (.402)
n % Completed 6-Mo	71 (84.5%)	63 (75.0%)	2.36 (.124)	43 (76.8%)	45 (84.9%)	1.15 (.283)
n % Completed 12-Mo	68 (81.0%)	65 (77.4%)	.32 (.569)	42 (75.0%)	37 (69.8%)	.37 (.544)
n % Completed 18-Mo	63 (75.0%)	68 (81.0%)	.87 (.352)	39 (69.6%)	32 (60.4%)	1.03 (.310)
n % Completed 24-Mo	62 (73.8%)	68 (80.1%)	1.22 (.269)	44 (78.6%)	34 (64.2%)	2.78 (.095)
n % Initiated Inj. @ FU[a]	1 (0.7%)	10 (7.3%)	7.87 (.005)	NA	NA	NA

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Table 2

Description of Individuals who Became HCV+ During the 24-Month Follow-Up Period.

			Int.	Month	Ever	Recent (Past 6-Months) Injection Drug Use at Assessment				
Age	Gender	Race	Group	HCV+	Inject	Base.	6-Mo.	12-Mo.	18-Mo.	24-Mo.
40	M	W	I	24	Yes	Yes	Yes	Yes	Yes	Yes
35	M	W	I	24	Yes	Yes	No	No	No	No
29	F	W	I	12	Yes	Yes	No	No	Yes	Yes
30	F	W	C	24	Yes	Yes	No	Yes	Missing	No
28	M	W	C	24	Yes	Yes	Missing	Missing	Yes	Yes
32	M	W	I	12	Yes	Yes	Yes	Yes	Yes	Yes
24	M	O	I	12	No	No	Yes	Yes	Yes	Yes
37	M	W	C	12	Yes	Yes	Yes	Yes	Yes	No
46	M	W	I	12	Yes	Yes	Yes	Yes	Yes	Yes
40	M	W	C	24	Yes	No	Yes	Missing	Missing	Yes
28	M	W	I	12	Yes	Yes	Missing	Yes	Missing	Yes
24	M	W	C	24	Yes	Yes	Yes	Missing	No	Yes
22	M	W	C	12	Yes	Yes	Yes	Missing	No	No
35	F	W	C	24	Yes	Yes	No	Yes	No	Yes
30	M	W	C	12	No	No	Missing	No	Yes	No

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Table 3

HCV Seroconversion by Treatment Assignment at 24-Months.

	NEVER INJECTED DRUGS		EVER INJECTED DRUGS	
Seroconverted	**Intervention**	**Control**	**Intervention**	**Control**
Yes	1 (1.7%)	1 (1.5%)	6 (14.3%)	7 (21.9%)
No	59 (98.3%)	65 (98.5%)	36 (85.7%)	25 (78.1%)
Column Total	60 (100.0%)	66 (100.0%)	42 (100.0%)	32 (100.0%)
	Fisher's Exact p = .728		Fisher's Exact p = .539	

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Table 4

Comparison of HCV Seroconversion Rates between IDUs and Non-IDUs.

Cohort	No. Seroconverted	Incidence Rate	95% CI
Non-IDU	2	0.75	(0.19-2.98)
IDU	13	8.20	(4.76–14.12)