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Skin and needle hygiene intervention for injection drug users: Results from a randomized, controlled Stage I pilot trial

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Abstract

A new skin and needle hygiene intervention, designed to reduce high-risk injection practices associated with bacterial and viral infections, was tested in a pilot, randomized controlled trial. Participants included 48 active heroin injectors recruited through street outreach and randomized to either the two-session intervention or an assessment-only condition (AO) and followed for six months. The primary outcome was skin and needle cleaning behavioral skills measured by videotaped demonstration. Secondary outcomes were high-risk injection practices, intramuscular injection, and bacterial infections. Intervention participants had greater improvements on the skin ($d = 1.00$) and needle cleaning demonstrations ($d = .52$) and larger reductions in high-risk injection practices ($d = .32$) and intramuscular injection ($d = .29$), with a lower incidence rate of bacterial infections ($HR = .80$), at 6-months compared to AO. The new intervention appears feasible and promising as a brief intervention to reduce bacterial and viral risks associated with drug injection.

Keywords

injection drug use; bacterial infections; intervention; randomized controlled trial; risk reduction; heroin

1. Introduction

Injection drug use (IDU) is a major public health concern in the U.S. and around the world. Injection drug users (IDUs) are at increased risk for developing viral disease (e.g., HIV, HCV; Schoener et al., 2002), bacterial infections (e.g., skin abscesses, endocarditis; Ebright & Pieper, 2002; Kak & Chandrasekar, 2002), and overdose fatalities (Pollini et al., 2006). Since the HIV epidemic began in the U.S., IDU has directly and indirectly accounted for approximately one-third of AIDS cases (CDC, 2010). In addition, the majority of persons infected with HCV, an infection also transmitted through sharing of injection equipment, are IDUs (CDC, 2009).

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While there has been considerable research dedicated to HIV and HCV among IDUs, there is limited research on bacterial infections, a very common health problem for IDUs. Up to one-third of active IDUs report a current or recent skin abscess or infection and almost 70% report a lifetime history of past infection (Binswanger et al., 2000; Murphy et al., 2001; Morrison et al., 1997). These infections cause significant morbidity and drive health care costs for IDUs, a population often uninsured or underinsured (Stein & Sobota, 2001). Bacterial infections associated with drug injection are most typically caused by Staphyloccus aureus (S. aureus; Mertz et al., 2008; Bassetti & Battegay, 2004) and include skin infections such as abscesses, ulcers, and cellulitis, as well as life-threatening endocarditis, osteomyelitis, sepsis/bacteremia, tetanus, and pneumonia (Stein, 1999). Skin abscesses, the most common bacterial infection, are initially surface infections that can cause extreme pain. Although IDUs often attempt to self-treat when they contract an abscess (Binswanger et al., 2000; Roose et al., 2009), abscesses can develop into life-threatening infections that can lead to hospitalization requiring extensive IV antibiotics, the delivery of which is complicated in persons without adequate venous access. Greater numbers of methicillin-resistant Staphylococcus aureus (MRSA) and polymicrobial bacterial infections are being observed among IDUs (Lloyd-Smith et al, 2010; Hsieh et al., 2008; Al-Rawahi et al., 2008). These infections tend to be more severe and difficult to treat (Siegel et al., 2007).

High-risk injection practices that lead to viral and bacterial infections occur at high rates among IDUs. Although similar in some ways, the practices that contribute to bacterial infections are somewhat distinct from those that lead to viral infection. The transmission of blood via shared needles, syringes, cottons, and water contributes to HIV and HCV acquisition (Chitwood et al., 1995; Hagan et al., 2001; Hagan et al., 2010; Patrick et al., 1997; Strathdee et al., 2001). While IDUs can pass bacterial infections to each other via shared equipment (Gordon & Lowy, 2005), other factors may be more important. Microbiologic research has established that an injector’s skin flora may be the most important source leading to bacterial infections among IDUs (Tuazon et al., 1974). In a Baltimore sample, Vlahov et al. (1992) found that frequency of injection was associated with presence of a skin abscess among IDUs, but only for participants who did not always clean their skin. When comparing IDUs with a current skin infection to injectors with no skin infection, Murphy et al. (2001) found that those without infections were more likely to report cleaning their skin with an alcohol wipe before injecting. More than three-quarters of IDUs do not always clean their injection site before injecting (Varga et al., 2006). Furthermore, several investigators have found a higher incidence of bacterial infections among HIV+ IDUs (Lloyd-Smith et al., 2005; Flanigan et al., 1999; Brettle, 1997; Gebo et al., 2006). It is likely that those with HIV have a higher likelihood of contracting these infections due to decreased immune functioning (Wilson et al., 2002).

Several additional factors also seem to increase the risk of infection. Use of black tar heroin may increase the likelihood that an IDU contracts a bacterial infection, although evidence is limited (Phillips & Stein, 2010; Kaushik et al., 2011). Black tar heroin is the predominant type of heroin used in Colorado and the western U.S., and it is known to be more difficult to inject than white powder heroin. The prevalence of abscesses appears to increase as the frequency of injecting subcutaneously (under the skin) increases (Binswanger et al., 2000; Murphy et al., 2001). Passaro and colleagues (1998) reported that injecting black tar heroin subcutaneously or intramuscularly heightened the risk of wound botulism. Based on our clinical work, IDUs appear to inject subcutaneously or intramuscularly (which may introduce bacterial skin flora more effectively) due to having difficulty injecting into their vein or because they are unable to find a usable vein. Others report accidentally missing their vein.

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Although the best way to prevent bacterial infections among IDUs would be to stop injecting and using drugs, many IDUs are not ready to make a change in their drug use. For those who continue to inject, reducing high-risk injection behaviors and learning new hygiene skills may substantially decrease risk. One of the most well-known and tested interventions to reduce injection risk includes needle exchange programs, which recommend use of a new syringe for every injection (Hagan et al., 2000; Huo & Ouellet, 2007). In addition to offering new syringes, needle exchanges also provide a range of services (e.g., HIV testing and counseling, substance abuse treatment referrals), educational materials (e.g., brochures on safer injection methods), and other risk reduction supplies (e.g., alcohol pads, cookers, condoms; Knittel, Wren, & Gore, 2010). Although needle exchange programs were initially designed as a form of HIV/HCV prevention, it is possible that using a new syringe for every injection may also decrease bacterial infections (Murphy et al., 2001). However, we were only able to find one study that examined the impact of needle exchange on bacterial infections. Hart et al. (1989) found that IDUs followed for three months after entry into a needle exchange program in London had a reduced incidence of abscesses.

Although many practitioners intervene with clients to reduce risk of bacterial infections, limited intervention studies have examined behavior change specifically related to bacterial infections (e.g., increase in skin cleaning practices or reduction in intramuscular injection) or bacterial infections as an outcome. Of note, Colon et al. (2009) recently developed a community-based intervention administered by outreach workers that focused on reducing infection risks associated with drug preparation. Although rates of bacterial infections weren't measured as part of the study, an initial pilot test of the intervention assessed changes in risky drug preparation practices among 37 IDUs from pre- to post-intervention. Among other strategies, one of the targeted practices included cleaning one's hands and skin prior to injection with hand sanitizer. Results indicated a significant increase in use of hand sanitizer prior to injection at the conclusion of the intervention, with 66% of IDUs adopting the practice. Similarly, Knittel et al. (2010) examined changes in skin cleaning practices among 88 IDUs participating in needle exchange from their first visit to six months after study entry. Although results were limited by a low follow-up rate, those who completed the follow-up interview were more likely to skin clean at the injection site compared to the baseline comparison group.

Because there have been limited studies examining the impact of interventions designed to reduce risk of bacterial infections, we recently developed and pilot tested a new risk reduction intervention aimed at reducing both bacterial and viral infections (Skin and Needle Hygiene Intervention or "Skin"). Much of this intervention was based on prior HIV risk reduction interventions, which have been found to be efficacious with IDUs (Copenhaver et al., 2006). Of importance, the Skin intervention was based on a widely-tested theoretical framework (Information-Motivation-Behavioral Skills or IMB, Fisher & Fisher, 1992) that incorporates multiple risk practices. In addition, our focus on increasing skills to reduce risk of bacterial infections and our measurement of skin and needle cleaning skills through a behavioral demonstration further contribute to the value of the study.

The pilot test of the Skin intervention was Stage 1 of a behavior therapy development research program (Rounsaville, Carroll, & Onken, 2001), where the goal was to develop a therapy based on research findings, including the development of a manual, and to perform an initial evaluation with a small number of participants. The primary aim of this study was to evaluate the feasibility of teaching skin and needle cleaning behavioral skills to IDUs and compare the efficacy of the Skin intervention to an assessment-only comparison group in a pilot, randomized controlled trial (RCT). Given the unresolved question concerning efficacy of various interventions in reducing risks associated with bacterial infections, we feel that the results from this pilot study can drive future work focused on bacterial infections.

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Furthermore, it is possible to incorporate brief skill-based interventions into community-based programs such as needle exchange programs to better serve IDUs.

2. Methods

2.1. Participants

Between Feb. 2010 and Sept. 2011, outreach workers recruited heroin injectors in Denver. IDUs were eligible for the study if they: 1) were 18 years of age or older, 2) reported injection of heroin on at least three different days in the last week, 3) reported injecting heroin for at least three months, 4) had visible track marks/puncture wounds from needles (as determined by the research interviewer) and 5) had a positive urine screen for heroin. IDUs were excluded if they: 1) were actively psychotic, 2) could not provide informed consent, 3) were unable to provide names and contact information for at least two verifiable locator persons who would know where to find them for retention/follow-up purposes, or 4) planned to move out of the Denver area over the subsequent six months.

2.2. Study Design and Procedures

The current RCT tested the Skin intervention versus an assessment-only control group. Because IDUs who are not enrolled in treatment services are at greatest risk for developing an infectious disease (Mark et al., 2006), street outreach was the primary method for recruiting participants. Outreach workers included staff members with extensive training on identifying and accessing active drug users. Training was based on the Indigenous Leader Outreach Model (ILOM; Wiebel, 1993). Although the ILOM utilizes former IDUs as outreach workers, we modified the model and employed staff who were familiar and comfortable with the target population, but who were not former IDUs. Outreach workers sought out locations frequented by drug users (e.g., bars, liquor stores, motels, shelters, etc.) where they could recruit participants. Potential participants were pre-screened on the street or by phone and those who were eligible were scheduled for an appointment. Participants in need of transportation were driven to the appointment from their home (or a location preferred by them) to the local study site at baseline and all follow-ups as needed. Upon presentation to the research office, eligibility was confirmed again verbally and with a urine screen. Following confirmation of eligibility, a research interviewer explained informed consent. Once enrolled and after the baseline assessment, participants were randomly assigned to the Skin intervention with one-month booster or to the assessment-only condition. All participants received rapid HIV testing, a review of testing results, and brief HIV prevention counseling and follow-up interviews at one and six months following the baseline interview.

After consent, participants completed a structured interview lasting approximately 60–90 minutes in a private room. During the interview itself, some questions were directly asked by the interviewer and some through use of an Audio Computer Assisted Self-Interview (ACASI; QDS Nova Software). To compensate them for their time, IDUs received $30 for completing the baseline assessment, $35 for the one-month follow-up assessment, and $40 for the six-month follow-up assessment (paid through a check, with a separate payment for each visit). The University of Colorado Multiple Institutional Review Board (COMIRB) and University of Northern Colorado IRB approved the study and all procedures.

2.3. Measures

The primary study outcome was improvement in skin and needle cleaning behavioral skills. Secondary outcomes included high-risk injection practices for bacterial and HIV infections, subcutaneous and intramuscular injection, and incidence of bacterial infections. Frequency of drug use and injection were also examined.

Skin and needle cleaning behavioral skills were measured four times total over the course of the study for all participants by videotaped demonstrations. Specifically, participants were tested first at baseline prior to any training associated with the intervention, at baseline after training, at the one-month follow-up (prior to Session 2 of the intervention), and at the six-month follow-up by a trained assessor. Based on the setup of the clinic, size of the trial, and use of only one research assistant, we opted not to blind the assessor. To verify that scoring was not biased, we had an independent rater who was not affiliated with the study (and unaware of participant group assignment) score a subset (81%) of baseline skin and needle cleaning videos. Interrater reliability of the skin and needle cleaning demonstrations suggested highly consistent ratings (*ICC, skin cleaning* = .950; *ICC, needle cleaning* = .955).

Assessor ratings were used to evaluate each participant's skill level. Participants were first asked to demonstrate the best way to clean their skin at the injection site before injecting. Following this demonstration, they were asked to demonstrate the best way to clean a used needle so that it was free from contamination. Each task in the demonstrations was scored as correct (1 point) or incorrect (0 points) and a sum total was calculated for each demonstration. For the skin cleaning demonstration, scores were based on 11 total steps using alcohol wipes, following a protocol created by our team that was adapted based on information from the Public Health Department of Seattle & King County (2002). For needle cleaning, we based scores on 34 steps that included three sequences of water and bleach rinses, following a revised version of a protocol endorsed by NIDA (Royer et al., 2004) and developed by Avants et al. (2004; personal communication). For all analyses, we used the percentage of correct steps used (total score/possible points) for skin cleaning and needle cleaning. A copy of the skill assessment checklists and scoring sheets are available from the first author.

To assess high-risk injection practices for bacterial infections, the Bacterial Infections Risk Scale for Injectors (BIRSI) was used to examine the proportion of time (0–100) that the participant engaged in high-risk behaviors for bacterial infections over the last 30 days, with a higher score indicating greater risk. This scale was created and piloted in past studies (Cronbach's alpha = .74; Phillips & Stein, 2010). Seventeen items contribute to a total score. Some examples of items include: "In the past month, how often did you clean your skin before you injected? In the past month, how often did you inject into your muscle (muscling)? In the past month, how often did you use a new, never-before used needle to inject?" The 9-item drug risk subscale of the Risk Assessment Battery (RAB) was used to examine high-risk injection practices for HIV (Metzger et al., 1993; Navaline et al., 1994).

Drug use, injection and subcutaneous and intramuscular injection were measured through Timeline Followback (TLFB; Sobell & Sobell, 1996) for the last 30 days at baseline and follow-up interviews. Because there were very few reports of subcutaneous injection in the sample, we chose to examine only intramuscular injection. For a more accurate measure of the degree of muscling, we used the total number of times a participant reported muscling over the last 30 days rather than days muscled. History of bacterial infections was assessed via self-report. Participants were asked detailed information about past and current bacterial infections, the location of any infections (skin abscesses primarily), when the infection occurred, and any history of self-treatment. When assessing history of abscesses, we provided a clear definition of abscesses, adapting language from Binswanger et al. (2000): "Have you ever had an abscess or other skin infection (such as an ulcer or cellulitis) at a place where you injected drugs – that is any pain, swelling, redness, hardness under your skin, heat, pus, or oozing anywhere you inject?" The baseline assessment also included demographic information about each participant, including age, race, living situation, and years of education.

2.4. Skin and Needle Hygiene Intervention

The Skin intervention involved two intervention sessions, four weeks apart, delivered immediately after the respective research assessments. A therapist manual was utilized by the interventionist in both sessions and a client workbook was provided so that clients could follow along and take the information with them at the end of the session. Session 1 included psychoeducational information on bacterial (skin abscesses/infections, endocarditis, etc.) and viral (HIV, HCV) infections that can result from injection, their causes, and preventive strategies to reduce risk of infection. The goal of providing this information was to inform participants about ways that they can reduce their risk of infection and to alter any unfounded beliefs about infections. Following this discussion, the interventionist and participant reviewed each of the participant's individual injection risk factors for bacterial infections (e.g., not cleaning skin) and HIV/HCV (e.g., sharing syringes), as well as the participant's current methods of hygiene. Based on this report, the interventionist evaluated the participant's stage of change in regard to each behavior and helped participants identify barriers (e.g., experiencing withdrawal or craving) to improving skin and needle use practices. Because the intervention was individualized for each participant, only those barriers and risk practices that applied to each participant were discussed during the risk assessment and design of the change plan. A decisional balance exercise was utilized to guide participants through the advantages and disadvantages of each risk reduction behavior. Although the major goal was to evaluate risk reduction, some participants set reduced drug use or abstinence goals. Participants who expressed interest in making changes set goals consistent with their readiness to change using a change plan worksheet in the client workbook.

Finally, step-by-step instructions for bleach-cleaning needles and skin cleaning were provided. Participants were asked to demonstrate the skills learned after observation and instruction. If a participant did not perform the skills correctly during his/her demonstration, he/she was asked to perform the procedure again until it was done without errors to ensure information transfer. Before ending this initial 60-minute session, intervention participants were provided with a hygiene kit to begin the practice of risk reduction, which included bleach and water kits for cleaning needles and injection equipment, alcohol-based cleanser to clean skin, alcohol swabs, cotton balls, a risk reduction workbook which included step-by-step instructions for bleach-cleaning needles and cleaning hands/skin, and referral information for obtaining HIV testing and counseling, needle exchange programs and drug treatment, pharmacy locations where needles could be purchased, and other health services.

Intervention participants also received a 30-minute booster session with the same interventionist one month after the initial intervention session. During the booster session, the interventionist reviewed the initial risk reduction change plan and progress towards goals or problems encountered. Risk reduction strategies, including use of skin and needle cleaning, were reviewed and failed attempts at risk reduction were discussed as learning experiences. The interventionist assisted the participant in setting new goals if needed. No additional skills training was offered during this session.

All of these described components were delivered using motivational interviewing (MI). Clients were encouraged to explore their ambivalence about changing risky behaviors. The interventionist employed basic principles of MI (expressing empathy, developing discrepancy, avoiding argumentation, rolling with resistance, and supporting self-efficacy to make changes; Miller & Rollnick, 2002) throughout the intervention, especially when reviewing individual risk factors and barriers to risk reduction. Clients were encouraged to set goals consistent with their stage of change.

In the current study, one interventionist conducted all Skin intervention sessions. The interventionist was a doctoral level clinician trained previously in MI. All sessions were audiotaped and a random sample of sessions were reviewed by a supervisor experienced in MI, who rated sessions using an adherence/competence scale. In addition, a client process measure was given to all clients after their second intervention session. Client and supervisor fidelity ratings were both high, indicating that the intervention was delivered appropriately and that clients found it favorable.

2.5. HIV Testing and Counseling

At the baseline appointment, all clients met with an HIV tester/counselor either immediately after completing their initial assessment (assessment-only participants) or after their Skin intervention session. The OraQuick Advance Rapid HIV-1/2 Antibody Test was used to determine HIV status. After collecting an oral saliva sample from participants, the HIV counselor educated the participant about HIV prevention using NIDA's HIV and HCV Counseling and Education (C&E) Intervention Training Manual (Royer et al., 2004).

2.6. Data Analysis

We report simple descriptive statistics (means, standard deviations, percentages) to summarize sample characteristics. We were interested in determining whether Skin, compared to an assessment-only, resulted in: 1) improved skin and needle cleaning behavioral skills as measured through a skill demonstration, 2) less participation in high-risk injection practices for bacterial infections (as measured through the BIRSI) and HIV (as measured through the RAB drug risk subscale), and 3) reductions in intramuscular injection as measured through Timeline Followback (TLFB) recall. Injection and overall drug use days were also examined as secondary aims. Because of the small sample size, we focus on the substantive magnitude, as summarized by Cohen's (1988) standardized difference in mean gain scores. We also report the associated t-tests and p-values testing the null hypothesis of no difference in between-group means. Although not a major aim due to the short follow-up and small number of participants, we used all available 3- and 6-month data to estimate the incidence rate of bacterial infection per person year. Cox regression was used to compare the incidence rates of bacterial infection by intervention group. Seven individuals could not be located at the six-month follow-up. Therefore, statistical analyses were restricted to those who completed the baseline and six-month assessment sessions (n = 41).

3.0 Results

A total of 48 IDUs completed baseline assessments. Baseline participants averaged 43 (SD = 9.7) years of age, 36 (75%) were male, and most were Caucasian (54%) or Latino (27%). Over one-third of participants were homeless. Mean educational attainment was 11.6 (SD = 2.1) years. With the exception of one client who was already aware of his HIV-positive status, no other clients tested positive. Participants reported injecting drugs on 28.4 (SD = 4.3) of the 30 days prior to baseline. All clients tested positive for heroin per eligibility requirements, 52.1% also tested positive for cocaine and 12.5% for methamphetamine. No between group differences were found at baseline for any of the outcome variables.

Only one participant did not return for the one-month follow-up. Most intervention participants (98%) attended their second Skin session. Forty-one participants (85%) returned for their six-month follow-up. All intervention clients who presented to the six-month follow-up (n = 21) received both intervention sessions.

Effect sizes for our main outcomes at the six-month follow-up ranged from small to large (Table 1). The largest standardized differences in means were observed for needle (d = .53) and skin (*d* = 1.00) cleaning skills, which were moderate to large using Cohen's (1988) interpretation. Those randomized to the Skin intervention had significantly ($t = 3.21$, $p = .003$) and substantively ($d = 1.00$) larger (Table 1) improvements on the skin cleaning demonstration between baseline and the six-month follow-up. These analyses represent an 18.4% improvement among intervention participants from baseline to the six-month follow-up compared to a worsening of 2.8% among assessment-only participants. At baseline, intervention participants ($n = 21$) correctly performed 50% of the steps on the skin cleaning demonstration prior to training ($M = 51.9\%$, $SD = 10.3$). Following training at the baseline appointment, scores averaged 95.5% ($SD = 10.7$). This percentage decreased to an average of 82.0% ($SD = 21.0$) at the one-month follow-up and 70.2% ($SD = 22.7$) at the six-month follow-up.

On the needle cleaning skills test, participants randomized to the intervention ($n = 21$) had a 15.4% improvement on the needle cleaning skills behavioral test at the six-month follow-up compared to only a 2.8% improvement among assessment-only participants. Substantively, this difference represents a moderately strong ($d = .53$) intervention effect that is significant at the .10 level. Similar to changes in scores on the skin cleaning test, intervention participants scored an average of 33.6% ($SD = 16.5$) on the needle cleaning test at baseline pre-training, 83.7% ($SD = 17.2$) at baseline post-training, 61.8% ($SD = 21.13$) at the one-month follow-up, and 49.0% ($SD = 25.2$) at the six-month follow-up.

Differences on the secondary outcomes were weaker as expected, but also favored those randomized to the intervention. Although not statistically different, those randomized to the intervention had larger reductions in high-risk injection practices for bacterial infections ($d = .32$) and lower incidence ($HR = .80$, 95% CI 0.37 – 1.74) of bacterial infections. Overall, 40% of participants reported at least one abscess during follow-up and estimated incidence rates were 1.15 and .93 infections per person year in the assessment-only and intervention arms, respectively. Mean time to first infection was 24% longer among intervention participants, although as expected given the small sample size, there were no statistically significant group differences.

Although the data for muscling was quite skewed, intervention participants reported a greater decrease in the number of times muscled compared to assessment-only participants ($d = .29$, *ns*). Both intervention and assessment-only participants reported slight reductions in HIV risk, with no significant differences between groups. Similarly, those randomized to the intervention had larger reductions in overall drug use frequency ($d = .29$, *ns*) and injection drug use days ($d = .12$, *ns*).

4.0 Discussion

As far as we are aware, this is the first study to evaluate whether drug injectors could be instructed in skin cleaning skills and retain these skills to lower their risk for bacterial infections, particularly skin abscesses, the most common infection in IDUs. Our data suggest that IDUs benefit from a brief intervention that focuses on behavioral skills training. The greatest impact of the intervention appears to be in relation to increasing skin and needle cleaning skills. Intervention clients improved their skin cleaning percentage score by almost 20 points, while assessment-only participants worsened. We also see intervention clients with greater improvements on needle cleaning skills. Effect sizes at the six-month follow-up were moderate to large for both demonstrations.

Needle cleaning behavioral skills, but not skin cleaning skills, has been examined in one other study. Avants et al. (2004) measured needle cleaning using a behavioral skills demonstration in a clinical trial with 220 participants randomized to either standard methadone care for 12 weeks plus a single individually-administered risk reduction session

(SC) or standard methadone care for 12 weeks plus a weekly group risk reduction intervention (HRG). Although participants in both groups received needle cleaning instruction, it is unclear whether the amount of time in training was equivalent across the groups. Injecting drugs and sharing needles did not differ by group when evaluated post-treatment, but there was a significant time × treatment interaction on needle cleaning behavioral skills acquisition. Participants in the HRG group showed greater improvement in needle cleaning. Overall, our data is consistent with Avants et al.'s needle cleaning findings, and with our longer follow-up, demonstrates that such behavioral skills can be maintained over time. Furthermore, both studies utilized behavioral skills observations, which appears to be a much more valid way of evaluating ability, particularly compared to relying on behavioral intentions or self-report.

Whether greater skin and needle cleaning skills translates into more frequent use of these risk reduction practices and reduction in bacterial infections is the critical clinical question. Given the small sample enrolled in this pilot study, we examined effect sizes as well as statistical differences for these secondary outcomes (Kraemer et al., 2006). Intervention group participants reported lower bacterial infection risk. Measured by the BIRSI, this effect was in the small to medium range at the six-month follow-up, although the two groups did not differ statistically. The BIRSI measure examines a wide range of injection risk practices that have been found to predict bacterial infections from a range of studies across geographic regions in the U.S. We also found a fairly high incidence of abscesses in our sample (40%) over the six-month follow-up. This figure is consistent with other estimates of abscesses in western U.S. states (e.g., Binswanger et al., 2000). While time to first infection was longer and the estimated rate of infections per year was lower among intervention participants, as expected, group differences were not statistically significant.

We did not find significant differences in HIV risk between the intervention and assessment-only groups. Offering HIV risk reduction to all of the study participants likely contributed to reduced HIV risk in both groups. Although both groups reported less HIV drug risk over time, the decrease in RAB scores was quite minimal. Overall, participants did not report substantial HIV risk at baseline, thus limiting how much scores could decrease. Furthermore, although we didn't find differences between groups in terms of overall drug use days, injection days, and times muscled, intervention participants did report greater reductions in these behaviors. Although this would need to be explored in future work, another possible advantage of the intervention is that it could impact drug use.

This study has limitations. A number of factors likely impacted the feasibility and results of our study including use of trained outreach workers, a highly-educated and formally trained interventionist, provision of transportation to follow-up assessments, and financial incentives for participation. Although we involved an interventionist who wouldn't require extensive training, we plan to train future interventionists of various backgrounds in future efficacy/effectiveness studies, with the ultimate goal of making this intervention readily usable by community-based organizations. In addition, the assessor rating the follow-up of the behavioral skills was not blinded to group assignment, although an independent rater re-evaluated 81% of baseline ratings and demonstrated excellent inter-rater reliability.

The sample was small and focused exclusively on heroin injectors. Although a large number of participants were also using cocaine, we don't know if our results would generalize to individuals injecting cocaine or methamphetamine exclusively. Most of our participants were men over 40 and all were injecting in the state of Colorado. We can't determine if intervening with new or younger injectors would produce different findings. Our past pilot data indicates that many injectors continue to have abscesses over time, particularly as they continue injecting black tar heroin. Type of heroin may influence how often IDUs develop abscesses and examining regional differences (e.g., western vs. eastern US) may help to better understand the relationship between injecting black tar heroin and subsequent abscesses. IDUs using black tar heroin have been known to rinse their syringes and heat the drug solution more often due to the thick consistency of the drug (Ciccarone & Bourgois, 2003). In addition, bacterial infections were self-reported and were not confirmed by visual inspection by study staff. Finally, because we were primarily interested in Skin's effects on bacterial and viral infections and injection risk practices, the two groups were not matched for the amount of time clients spent in each condition. The total contact time for the Skin intervention condition was approximately 90 minutes longer over two sessions than the assessment-only comparison condition. Both groups received an HIV Testing and Counseling (T/C) procedure. It is common in HIV-related behavioral research to have interventions of modestly unequal length and content, a study design endorsed by NIDA (Booth et al., 1998; Stephens et al., 2000) and the HIV Prevention Trials Network (Latkin et al., 2009). Using HIV T/C as part of an assessment-only condition with high-risk populations has been strongly encouraged by NIDA since 1995, as well as by the CDC, HRSA, and SAMHSA (Brigham et al., 2009).

Our findings point to future research. A larger sample, followed for a longer time, would allow a study powered to examine group differences in bacterial infection rates and possible mediators/moderators of any intervention effect. Overall, however, the new Skin intervention appears very promising as a brief intervention to reduce bacterial and viral risks associated with IDU. This study demonstrated that it is feasible to recruit and retain active IDUs for an intervention focused on bacterial infections. Importantly, we demonstrated sustained moderate to large intervention effects on skin and needle cleaning skills, the core of our intervention, as well as lower bacterial infection risk among intervention group participants. A successful Stage II test of the Skin intervention would provide more substantial support and could lead to multi-site Stage III trials that examine intervention effects in community settings.

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Table 1

Change in Behavioral Skills, Drug Use, and Injection Risk Behaviors (6-Months – Baseline) by Group Assignment

	GROUP			
	Skin (n = 21)	**Assessment-Only (n = 20)**		
Outcome	**Gain score M (SD)**	**Gain score M (SD)**	***t* (*p* =)**	**Cohen's *d***
Skin cleaning behavioral skills	18.38 (27.59)	−2.75 (10.43)	3.21 (.003)	1.00
Needle cleaning behavioral skills	15.38 (29.24)	2.75 (16.07)	1.70 (.10)	.53
Bacterial infection risk	−12.66 (13.48)	−8.75 (10.86)	1.02 (.31)	.32
HIV risk	−.10 (5.48)	−.15 (3.67)	0.04 (.97)	.01
Drug use days (last month)	−6.38 (10.36)	−3.25 (11.39)	0.92 (.36)	.29
Injection drug use days (last month)	−7.90 (11.47)	−6.50 (12.37)	0.38 (.71)	.12
Number of times muscled (last month)	−17.19 (32.06)	−7.1 (37.06)	0.94 (.36)	.29