

Turning Point
Alcohol & Drug Centre

**RANDOMISED CONTROLLED TRIAL
OF A BRIEF BEHAVIOURAL
INTERVENTION FOR REDUCING
HEPATITIS C VIRUS RISK PRACTICES
AMONG INJECTING DRUG USERS**

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Final report

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December 2002

Funded as part of the Disease Control & Research Program 2001, Communicable
Diseases Section, Victorian Department of Human Services

Randomised controlled trial of a brief behavioural intervention for reducing hepatitis C virus risk practices among injecting drug users (Final report)

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The study was funded by the Victorian Department of Human Services, Communicable Diseases Section, Disease Control & Research Program 2001.

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Published by Turning Point Alcohol and Drug Centre Inc on behalf of the Victorian Department of Human Services

July 2003

ISBN (print): 1 74001 004 3
ISBN (online): 1 74001 005 1

The correct citation for this report is:
Tucker, T., Fry, C. L., Baldwin, S., Lintzeris, N., Ritter, A., Donath, S., & Whelan, G. (2003), Randomised controlled trial of a brief behavioural intervention for reducing hepatitis C virus risk practices among injecting drug users. Fitzroy, Victoria: Turning Point Alcohol & Drug Centre Inc.

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Executive Summary

While public health initiatives such as Needle and Syringe Programs have significantly limited the spread of HIV among injecting drug users (IDU), they have had less of an effect on reducing the incidence of HCV in Australia. Efforts to reduce the spread of HCV must focus upon achieving a reduction in the risk behaviours of high-risk groups, particularly IDU. Brief behavioural interventions (BBIs) have been highlighted in the literature as a possible method for facilitating such behaviour change. The aim of this study was to design and evaluate the efficacy of a brief individually tailored intervention in reducing risk behaviours associated with the transmission of blood borne viruses (BBV).

The efficacy of the BBI was assessed using a two-group randomised design. One hundred and forty-five participants were recruited and randomised to 1) experimental BBI condition (n=73); or 2) the control condition (n=72). The BBI was based on the Blood-Borne Virus Transmission Risk Assessment Questionnaire (BBV-TRAQ) - a standardised blood-borne virus risk assessment questionnaire comprising injecting risk, sexual risk and other skin penetration risk subscales (Fry, Rumbold & Lintzeris, 1998). The BBV-TRAQ subscale scores were used as independent variables, with individually identified risk items used to tailor the 30-minute experimental BBI. Control condition participants received a standardised educational session on hepatitis C, using commonly distributed HCV educational materials.

One hundred and twenty-four participants (86%) were followed up at 4 weeks (+ 7 days). The primary outcome measure was injecting risk behaviour, assessed for both study groups at baseline and one-month follow-up via the BBV-TRAQ. Analyses revealed a significant reduction in BBV risk behaviours for both groups at one-month follow-up. While participants in the experimental BBI condition reported higher overall satisfaction with the intervention and an increase in HCV knowledge, the reduction in risk behaviour among this group was not significantly different from the control.

The current study meets a number of key objectives and principles of the current National HCV Strategy (Commonwealth Department of Health & Aged Care, 2000) and Victorian Hepatitis C Strategy (Victorian Department of Human Services, 2002) with respect to the goal of reducing HCV risk behaviour, and ultimately new infections, amongst the IDU target group. The study has shown that both interventions produced significant reductions in risk

behaviour, the implication of which is that BBI methods appear to hold promise as an additional element to the range of existing HCV education and prevention initiatives. Brief interventions certainly match the requirements of effective public health strategies – they are cost and time effective, can be administered by a range of people, and can be delivered to large numbers of the target group, in this case IDU. This study has also contributed important evidence showing persisting levels of HCV transmission risk behaviours that may help to explain continued high incidence rates in this country. In an indirect way, the study also highlights the potential value of standardised, comprehensive risk assessment instruments for augmenting current risk behaviour monitoring and surveillance mechanisms. Future research could evaluate the efficacy of the BBV-TRAQ as a risk behaviour intervention and counselling tool in clinical, NSP and peer education settings.

1.0 INTRODUCTION

1.1 - The hepatitis C virus

The prevalence of the hepatitis C virus (HCV) in Australia has been estimated at around 150,000 to 200,000 people infected, the majority of whom are thought to be current or former injecting drug users (IDUs) (Simmonds, Holmes, Cha et al., 1993; Wodak, 1997). Injecting drug use has been identified as the major contributor to the spread of the virus since the implementation of blood donor screening for antibodies. HCV incidence has been estimated at between 6,000 to 11,000 new infections each year (Australian National Council on AIDS and Related Diseases, 1998; Crofts & Aitken, 1997; Crofts, Hopper, Bowden et al., 1993; National Centre in HIV Epidemiology and Clinical Research (2001). However, recent estimates show an increase to 16,000 new cases of HCV in the year 2001 (Australian National Council on AIDS, Hepatitis C and Related Diseases, 2002).

HCV prevalence rates are disproportionately high among IDUs, with rates remaining around 50-70% since the 1970s (Australian National Council on AIDS and Related Diseases, 1998; Crofts, Jolley, Kaldor, van Beek, & Wodak, 1997). The highly infectious nature of HCV is of particular concern as the majority of individuals exposed to HCV become chronically infected (and infectious), with an estimated 10-20% of chronically infected individuals developing either cirrhosis of the liver or hepatocellular carcinoma (Australian Health Ministers Advisory Council, 1994). Six distinct genotypes of hepatitis C have been identified, each containing subtypes a, b, and c (Simmonds et al., 1993). Genotypes 1a, 1b, and 3a are the most common genotypes in the Australasian region (Simmonds et al., 1993). The genotype can influence the severity, level of viral replication, and natural history of the virus (Thompson & Locarnini, 2001). Given the high rates of HCV prevalence and incidence, the projected social, economic, and health costs to the community are considerable (Coutinho, 1998).

The recent surge in HCV incidence has been at least partly attributed to an increase in the number of people using injecting as their preferred method of taking drugs (Australian National Council on AIDS, Hepatitis C and Related Diseases, 2002). In support of this explanation convergent evidence suggests that HCV, unlike HIV, may be efficiently transmitted via a range of injecting risk practices supplementary to the sharing of used

needles/syringes (Crofts et al., 1997). First, HCV is more infectious than HIV, with transmission possible via the transfer of much smaller and even invisible volumes of blood (Gerberding, 1995). This implicates a wider range of risk practices (e.g. touching another person's injecting site) and injecting paraphernalia (e.g. using another person's spoon, filter, water, swab, etc). Further, case reports of HCV transmission via environmental contamination of hospital dialysis equipment (Chant, Kociuba, Munro et al., 1994; Heptonstall & Mortimer, 1995), and a recent case of transmission following a fist-fight, (Bourliere et al., 2000), together with video-taped footage of naturalistic injecting episodes showing clear opportunities for infection (Carruthers, 1997) demonstrate that environmental contamination leading to HCV transmission is plausible. A third source of evidence comes from studies that show that HCV transmission is possible via non-sterile tattooing and piercing (Strasser, Watson, Lee, Coghlan, & Desmond, 1995), through the sharing of personal hygiene equipment (Davis, 1995; Davis & Kowalik, 1996), and through sexual contact where blood is present (Bresters, Mauser-Bunschoten, Reesink et al., 1993; Sladden, Hickey, Dunn, & Beard, 1997). Finally, evidence of new HCV infections amongst IDUs who report no prior sharing of needles/ syringes (Crofts & Aitken, 1997; van Beek, Dwyer, Dore, Luo & Kaldor, 1998) further supports the hypothesis that HCV may be efficiently transmitted via a wide range of risk practices.¹

1.2 - IDU-targeted prevention strategies

The task of controlling the spread of HCV in this country depends on being able to control transmission within the IDU population (Crofts & Aitken, 1997; Wodak, 1997). Indeed, the aim of reducing the spread of HCV amongst this target group has been identified as a key objective of successive national policies, strategies and action plans, including:²

- National Drug Strategy (NCADA, 1993),
- National Hepatitis C Action Plan (Australian Health Ministers Advisory Council, 1994),
- 3rd National HIV/AIDS and Related Diseases Strategy (Commonwealth Department of Health & Family Services, 1996), and

¹ A more complete review of social and behavioural research may be found in the Australian Blood-borne Virus Risk and Injecting Drug Use Study (ABRIDUS), Dwyer, Fry, Carruthers et al., 2002.

² Prevention and control of HCV transmission, together with supporting research and surveillance have been two key priority areas also highlighted in the recent Victorian Hepatitis C Strategy 2002-2004 (Victorian Department of Human Services, 2002).

- National Hepatitis C Strategy 1999-2000 to 2003-2004 (Commonwealth Department of Health & Aged Care, 2000).

A range of interventions has been implemented as part of Australia's attempt to reduce the spread of HCV. This has included strategies with foundations in the HIV response of the preceding decades. Renewed attempts were made to increase the availability and uptake of sterile injecting equipment for drug users through Needle and Syringe Programs (NSPs) and to improve access to drug treatment options (National Drug Strategy, 1997). It was also recognised that a significant broadening of HCV-focused safe injecting messages was required, with the inclusion of the wider range of putative risk practices for HCV transmission. As a consequence, HCV education messages evolved to address the greater range of risks for HCV spread. More attention was directed at environmental contamination of the injecting process and injecting equipment by means of blood spread on fingers and hands (Dwyer et al., 2002).

There is sound evidence to show that Needle and Syringe Programs (NSPs) are effective in preventing HIV infection (Hurley, Jolley, & Kaldor, 1997; Health Outcomes International, 2002), with Australia's success in limiting the spread of this virus widely recognised. In contrast, the effectiveness of most strategies and interventions aimed at reducing the spread of HCV has not been systematically evaluated, with few published studies showing an association between NSPs and reduced HCV infection (Hagan, Jarlais, Friedman, Purchase, & Alter, 1995). However, the recent economic analysis of return for investment in NSPs in Australia (Health Outcomes International, 2002) has estimated that by 2000 around 21,000 HCV infections were prevented among IDU since the introduction of NSPs in 1988, together with significant treatment cost savings and quality of life gains.

Similarly, methadone maintenance treatment (MMT) has been shown to be an effective intervention for the management of opiate dependence, contributing to reductions in drug use, HIV risk behaviours, criminality and mortality (The Lindesmith Center, 1997; Ward, Mattick & Hall, 1998). However, evidence regarding the efficacy of MMT in reducing HCV risk behaviours, and incidence and prevalence is equivocal (Selvey, Denton & Plant, 1997; Crofts, Nigro, Oman, Stevenson & Sherman, 1997; Broers, Junet, Bourquin et al, 1998; Thiede, Hagan & Murrill, 2000; Ladewig, 2001).

Evidence of continuing high rates of HCV incidence among Australian injecting drug users (Australian National Council on AIDS, Hepatitis C and Related Diseases, 2002), despite relatively low HIV and HBV incidence in the same sub-population, raises concerns about the efficacy of current HCV prevention and education efforts (Loxley, 2000). Australian studies have also shown that many IDUs in this country continue to engage in a range of practices that increase the risk of HCV spread (Fry et al., 1998; Lenton, Kerry, Loxley, Tan-Quigley & Greig, 2000; Dwyer et al., 2002).

The incidence of HCV in this group will not be reduced without significant changes in the specific behaviours thought to be responsible for the spread of the virus. This requires an expansion of existing harm minimisation strategies, including improved education and support for IDUs to reduce or prevent the sharing of injecting equipment (Crofts, Caruana, Bowden, & Kerger, 2000). Given the need for more effective methods to limit the spread of HCV, it is critical that the impacts of new strategies are adequately evaluated. Brief behavioural interventions represent a potentially effective strategy for reducing such risk behaviours.

1.3 - Brief behavioural interventions

The brief behavioural intervention has long been recognised as an effective treatment modality for facilitating behaviour change. Several recent reviews have further strengthened the empirical support for these methods, particularly in the area of substance misuse (Moyer & Finney, 2002; Dunn, Deroo & Rivara, 2001). A major attraction of brief behavioural interventions is their cost-effectiveness. They have the potential to reach a large number of clients, are less time consuming than conventional methods, and can be conducted by non specialist workers (Heather, 1989). However, previous studies of brief interventions reveal that there may be significant temporal variations in what is considered 'brief', with interventions ranging from 15-20 minutes (Poikolainen, 1999) to several hours (Saunders, Wilkinson, & Phillips, 1995) and more extensive programs running over several months (Dunn et al., 2001).

Brief behavioural interventions typically involve a number of steps. To begin, an assessment is made of drug use, risk practices, symptoms and other problems. Motivational interviewing is often used during the assessment process, as a strategy for working with ambivalence about change. Motivational interviewing is designed to create a discrepancy between an individual's

current behaviour and the goals and values they hold deeply. It is also used for enhancing and maintaining a commitment to change. During brief interventions, motivational interviewing is often complemented by skills training - developing strategies to assist the client to commence change and to respond effectively to high-risk situations (Heather, 1995a). It has been suggested that regular check-ups and feedback improve the effectiveness of brief interventions as does the provision of written material. Referral information should also be provided to facilitate access to more intensive support should this be required (Heather, 1995b).

Some of the most successful brief interventions have been conducted with tobacco smokers. In an early study by Russell and colleagues (1979) the relative effectiveness of a simple intervention was demonstrated. Although only a small percentage of each group stopped smoking, the provision of advice and self-help materials was shown to increase the likelihood of stopping by a factor of seventeen. Therefore, whilst only a small proportion of clients stopped smoking, the simplicity of the intervention meant that it could be delivered to many clients, resulting in a large number of individuals benefiting overall - a substantial achievement for a small investment. The amenability of brief interventions to widespread application meets the public health goals of reducing HCV transmission in the population at large.

A number of brief intervention studies have been conducted with problem drinkers (Chick, Lloyd & Crombie, 1984; Heather, Robertson, MacPherson, Allsop & Fulton, 1987; Wallace, Cutler & Haines, 1988; Bien, Miller & Tonigan, 1993), proving to be effective in modifying a range of drug-related behaviours (Heather, 1989; Mattick & Jarvis, 1993). There is also growing evidence that targeted behavioural interventions can be effective in reducing the spread of HIV (Abraham, Sheeran & Orbell, 1998; Fishbein, 2000), and for treating problems associated with cannabis use (Copeland, Swift, Roffman & Stephens, 2001; Stephens, Roffman & Curtin, 2000; Lang, Engeland & Brooke, 2000). Recent work by Aitken, Kerger, and Crofts (2002) suggests that the provision of peer counselling and blood testing significantly reduces behaviours associated with the transmission of HCV.

Together, these studies offer a strong foundation and theoretical support for the development and evaluation of more structured forms of brief behavioural intervention that focus upon HCV risk behaviour. Whilst brief interventions have been demonstrated as an effective means of changing drug-related behaviour in a number of settings, to date this approach has

not been systematically developed or evaluated with regard to the HCV risk behaviour of IDUs. There is a clear need for behavioural research into the impact of brief interventions that aim to reduce HCV risk behaviour and subsequent transmission in the community, and it is essential that such interventions be evaluated rigorously.

1.4 - Evaluating brief interventions

There are a number of methods available for measuring the efficacy of an intervention in reducing the spread of HCV. The most precise approach is to compare HCV incidence rates in groups differentially exposed to an intervention over a period of time. However, this is a potentially expensive approach as it involves blood testing of intervention recipients over extended periods of time to examine for sero-conversion (i.e. new infections), and requires many person-years of follow up to detect meaningful differences between research groups. This would limit the ability to evaluate interventions of short duration (e.g. brief behavioural interventions, client literature, targeted education campaigns). Further, this evaluation approach would only be meaningful for IDUs who are HCV sero-negative (in order to identify sero-converters), thereby limiting the potential population from which to recruit for any study, and reducing the capacity to generalise findings to groups of HCV positive individuals – especially relevant given the existence of different HCV genotypes (Crofts, Thompson & Kaldor, 1999).

A potential cost and time effective method of assessing the efficacy of an intervention in reducing HCV transmission is to measure the extent to which it reduces high-risk transmission practices. The value of this method is that it may be applied to all individuals exposed to the intervention. Such approaches have been consistently used to assess the efficacy of interventions aimed at reducing HIV risk practices. For example, the HIV Risk Behaviour Scale, developed by Darke and colleagues (Darke, Heather, Hall, Ward & Wodak, 1991; Darke, Ward, Zador & Swift, 1991), has been widely used in Australia and abroad for the evaluation of methadone maintenance programs. The key to approaches relying on the measurement of putative risk practices is that they require sensitive, validated and reliable instruments to identify participation in specific risk practices - particularly those practices associated with injecting drug use and HCV transmission.

Available HIV injecting risk instruments such as Darke's HIV Risk Behaviour Scale (Darke, et al., 1991), and other recent injecting risk questionnaires (Stimson, Jones, Chalmers &

Sullivan, 1998) have been shown to have acceptable reliability and validity (Adelekan, Green, Dasgupta et al., 1996; Hunter, Stimson, Judd, Jones & Hickman, 2000). However, these have proven to be unsuitable for the purposes of measuring HCV risk behaviour as they do not provide sufficient coverage of the full range of HCV risk practices implicated due to the plausibility of environmental contamination.

1.5 - The Blood-Borne Virus Transmission Risk Assessment Questionnaire

In response to the lack of standardized BBV risk assessment instruments covering HCV practices, members of the current project team developed the Blood-Borne Virus Transmission Risk Assessment Questionnaire (BBV-TRAQ) (Fry et al., 1998). The BBV-TRAQ consists of 34 items comprising three sub-scales, and measures the prevalence of recent (previous month) injecting, sexual and skin penetration risk practices. The instrument incorporates questions regarding risk practices for the transmission of HCV, HBV and HIV. The BBV-TRAQ is brief and easy to administer, with a simple scoring procedure. The administration time for the instrument is short (around 15 minutes), and it has been shown to have good reliability and validity (Fry & Lintzeris, 2003).

The authors of the BBV-TRAQ have noted that the instrument is suitable for use by clinicians working within the alcohol and drug setting as an ongoing indicator of client risk behaviour, as well as for the purpose of developing brief interventions that aim to reduce BBV risk behaviour (Fry et al., 1998).

1.6 - Aims of the study

The specific aims of this project were to develop a brief intervention to reduce hepatitis C (HCV) risk practices among injecting drug users, and to evaluate the efficacy of this intervention. The efficacy of the intervention was evaluated using a randomised controlled trial. Risk assessment plus a brief tailored intervention around individual risk practices (experimental group) was compared to risk assessment plus a general educational session on HCV (control group) in reducing HCV risk practices as measured by the BBV-TRAQ. It was hypothesised that the experimental group would have significantly lower scores on the BBV-TRAQ (indicating a reduction in HCV risk practices) than the control group at one-month follow-up.

2.0 METHOD

2.1 - Participants

Participants were 145 injecting drug users (IDUs) recruited via the display of advertisements at local Community Health Centres, Needle Syringe Programs (NSPs), at VIVAIDS (Victorian Injecting Drug Users Association) and through snowballing. Information regarding the study was provided along with the contact details for the study Research Assistant. Interested persons contacting the Research Assistant were screened for eligibility and study entry either face-to-face or via a brief telephone assessment. In total, 239 individuals were screened for entry to the study. The inclusion and exclusion criteria used to determine eligibility are detailed below. Volunteers had to meet all of the inclusion criteria and none of the exclusion criteria in order to be eligible for the study.

Inclusion criteria

- Aged 18 years and above
- Must have injected drugs at least once per week (on average) for the previous 6 months: The purpose of the study was to measure the effect of the experimental and control interventions in a sample at risk for the transmission of blood borne virus (BBV). Persons injecting drugs of any kind may be at risk for the transmission of BBV. For the purposes of this study, 'drugs' means anything the person has injected.
- Must agree to be contacted for a one-month follow-up interview and provide follow-up locater information
- Must be able to give informed consent: Intoxication and mental state were assessed to determine whether or not the potential participant was able to understand the information about the study and provide informed written consent.

Exclusion criteria

- Enrolment in a current clinical trial and ceased participation, or terminated from participation.

- Currently enrolled in another clinical trial that is related to drug use or BBV risk practices.

145 people made up the final sample who were screened, deemed eligible to participate, and who were enrolled and randomised. Of this sample of 145, 73 were randomised to the experimental condition and 72 were randomised to the control condition. The total sample consisted of 108 males and 37 females, aged between 18 and 59 years. Of the 73 participants randomised to the experimental condition, 53 (72.6%) were male and 20 (27.4%) were female, with a mean age of 32 years. In the control group of 72 participants, 54 (75.0%) were male and 18 (25.0%) were female, with a mean age of 30.04 years.

2.2 - Materials

The following describes the various materials and data collection instruments utilised in the current study. Copies of each may be obtained from the Principal Investigator (CF) on request.

Brief Screen

The Brief Screen listed each of the inclusion and exclusion criteria, which were checked off by the Research Assistant to determine the volunteer's eligibility status. If the volunteer answered 'yes' to each of the Inclusion criteria and 'no' to each of the Exclusion criteria, they were deemed eligible for the study.

Consent forms

The consent form recorded the participant's name but not their ID number, and was not stored with the data.

Demographic, Treatment and Drug Use History Survey

This instrument was designed to collect demographic, treatment history, and drug use history data. It also included questions on blood borne virus status and testing.

The Blood-Borne Virus Transmission Risk Assessment Questionnaire (BBV-TRAQ)

The BBV-TRAQ instrument consists of 34 items comprising three sub-scales measuring the prevalence of recent (previous month) injecting, sexual and skin penetration risk practices (Fry et al., 1998). The BBV-TRAQ is brief, self-administered by participants, with a simple scoring procedure. The administration time for the instrument is short (around 15 minutes), and it has been shown to have good reliability and validity (Fry & Lintzeris, 2003).

The BBV-TRAQ Tally Sheet

The BBV-TRAQ Tally Sheet was designed for the experimental BBI condition to represent visually each of the risk practices on the BBV-TRAQ. The tally sheet was organized into five hepatitis C risk categories: mouth contact with injecting equipment, using contaminated injecting equipment, blood exposure and spread, sexual risk practices, and other skin penetration risk practices. The first three categories all related to injecting behaviour. The BBV-TRAQ Tally Sheet was used during the experimental intervention (Intervention A) to record risk practices the participant had engaged in during the last 4 weeks. This enabled a focused discussion of risk practices and protective factors during the intervention and provided structure for thinking about strategies for reducing risk.

The HCV-BBI Evaluation form

The HCV-BBI Evaluation form was designed to record participant feedback about the interventions received. Three questions used numeric Likert scales from 1 to 5, and the fourth used a verbal Likert scale ranging from “strongly agree” to “strongly disagree”.

Liver First (Australian Intravenous League – AIVL, April 2000)

Liver First is a 16-page booklet produced by the national drug user representative group, AIVL, which was chosen as the focus of the control intervention. The project team reviewed a number of current publications about hepatitis C and chose Liver First. It is a current, concise and informative booklet about hepatitis C and risk practices for the transmission of the virus. All participants received a copy of Liver First to take home.

Impact (Hepatitis C Council of Victoria, July 2000)

Impact was chosen to complement the Liver First booklet as it covers additional information about testing for hepatitis C, treatment options, complementary therapies, disclosure, and discrimination. There is also a list of agencies at the back of the booklet for further information and support about hepatitis C. All participants received a copy of Impact to take home.

Safer Injecting (AIVL, June 2000)

The Safer Injecting pamphlet was also given to participants from both treatment groups, as it includes harm minimisation strategies for safer injecting.

Intervention A Checklist

The Intervention A Checklist was designed to record what happened during the experimental intervention. The checklist recorded the duration of the intervention, the participant's response to the tally sheet, the educational materials used to provide education about hepatitis C, the categories of risk behaviour the participant wanted to think about and change, the categories of behaviour for which strategies for change were devised, any barriers to change which were identified by the participant, and the participant's general response to the intervention.

Intervention B Checklist

The Intervention B Checklist was designed to record what happened during the control intervention. If a participant asked any specific questions during the brief educational session, these were recorded, as was their general response to the written information.

2.3 – Procedures

This section describes the procedures followed in conducting the study. For clarity, these are represented graphically in Figure 1.

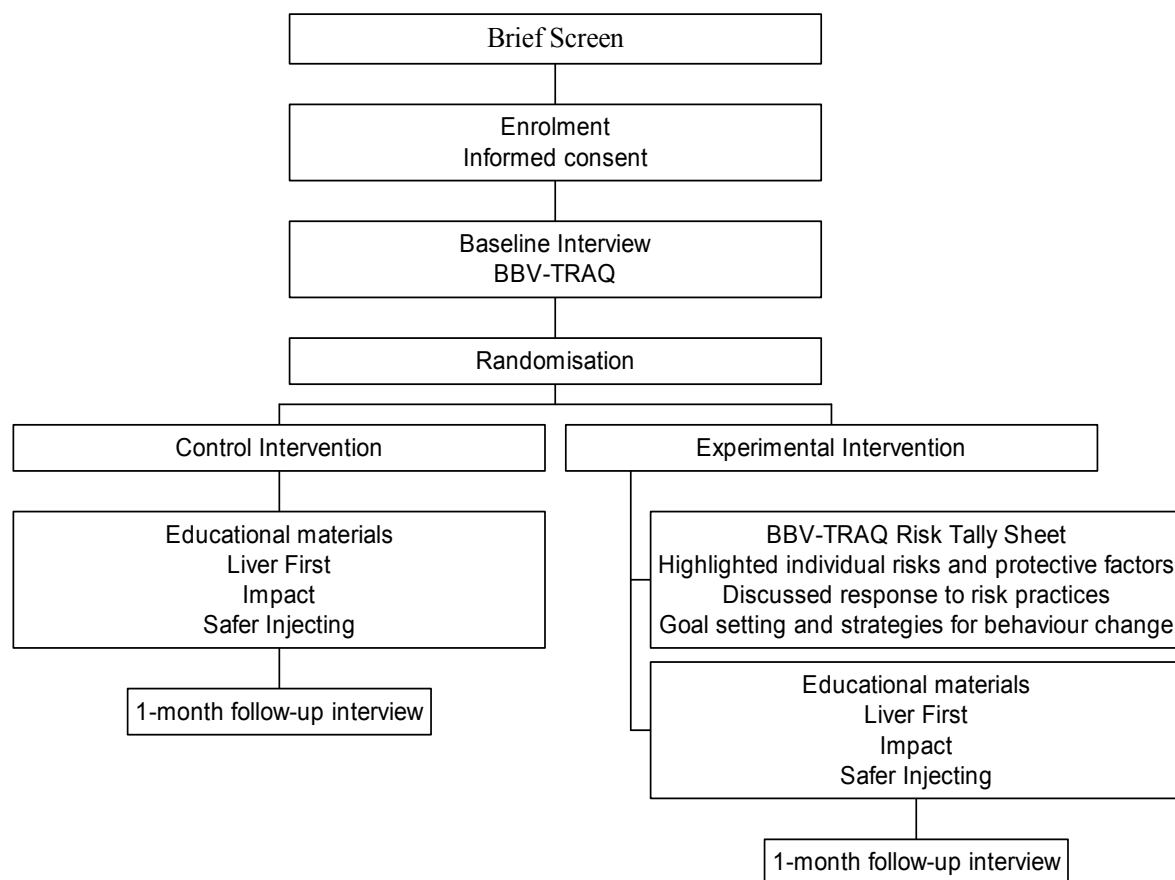
Ethics Clearances

Approval to conduct the study was obtained from the Victorian Department of Human Services Human Research Ethics Committee (Application No. 94/01).

Brief Screen

All volunteers were screened for initial eligibility (over the phone or in person) using the Brief Screen questionnaire. The study Research Assistant explained briefly what was involved in the study and the procedures for enrolment, using the “About This Project” information sheets as guides. The Brief Screen was conducted such that the volunteer was not informed explicitly about the criteria for inclusion in the study. If the Research Assistant deemed them ineligible for the study, an explanation was offered as to why they were ineligible. If the individual was interested in participating in the trial and was deemed eligible, he/she was booked in for the next available interview.

Figure 1. Flow diagram of procedures for the study.



Enrolment/Intervention session

The purpose of this session was to introduce the project to the volunteer, to confirm eligibility, obtain informed consent, collect baseline data, randomise, and deliver the randomised intervention. Firstly, the clinical researcher explained the study in detail using the “About This Project” plain language statement, ensuring that the procedures were understood and any questions answered. Written consent was obtained along with follow-up contact information, and the baseline research questionnaires and BBV-TRAQ were administered. Once the research interview had been completed, the clinical researcher then randomised the participant to an intervention condition by opening the next available envelope. The clinical researcher then delivered either the experimental or control intervention to the participant. At the completion of the intervention, participants were told they would be contacted in 4-weeks for the follow-up interview. The payment of \$20.00 was made and participants were asked to sign to acknowledge receipt of payment.

Randomisation procedure

Each participant was randomised to either the individually tailored (experimental) intervention or the standardised educational (control) intervention. A randomisation schedule was created by an independent researcher, with blocks of varied size (6, 8, and 10); such that there would be equal numbers of experimental and control participants in the final enrolled sample. Prior to study commencement, each randomisation was enclosed in a sealed envelope, to conceal intervention allocations.

When a volunteer was accepted for the trial, and had completed the informed consent and baseline interview, the clinical researcher opened the next available randomisation envelope to allocate the participant to an intervention. Whilst participants were informed about the randomisation procedure and the existence of two different hepatitis C discussions, the differences between the two interventions were not discussed with the participant.

All participants were randomised separately, regardless of their relationship (sexual, injecting, friendship) to other trial participants. Half of the participants enrolled in the trial were randomised to the individually tailored (experimental) intervention, with the other half (control group) randomised to the standardised educational intervention.

Experimental Intervention

Immediately following randomisation, those in the experimental group participated in the individually tailored brief behavioural intervention. The purpose of the 30-minute intervention was to increase awareness about specific risk practices for the transmission of hepatitis C and to increase motivation to change risk practices. For each intervention, the clinical researcher worked through the following procedures:

1. Completed the risk tally sheet for the BBV-TRAQ.
2. Reminded the participant that the focus of this intervention is hepatitis C, not hepatitis B or HIV.
3. Recorded the time at which the brief behavioural intervention began.
4. With the participant, went through each area of risk on the BBV-TRAQ Tally Sheet (injecting, sexual, and other skin penetration) and highlighted the specific practices which could place them at high risk for contracting or transmitting hepatitis C.
5. Also highlighted, in each section, what the participant was doing that was protective against contracting or transmitting hepatitis C.
6. Elicited a response from the participant about their level of risk for contracting/transmitting hepatitis C for each of the aforementioned categories. The clinical researcher provided relevant educational material where appropriate and explained the consequences of engaging in the high-risk behaviours using the Liver First booklet.
7. The participant was then asked whether or not they wanted to change any of their risk behaviours. If the participant expressed no desire to change any of their risk behaviours, the clinical researcher continued the motivational interview, exploring with the participant why they did not desire change. At times this involved the provision of more educational material. The Impact and Safer Injecting pamphlets were sometimes used in combination with Liver First for the provision of information. The clinical researcher was also clear, however, that 'no change' was a viable option.
8. If the participant expressed the desire to change any of their risk behaviours, the clinical researcher recorded this on the Intervention A Checklist and used the "Things I Can Do" sheet to record strategies for achieving this behaviour change.

9. If the participant mentioned any barriers to changing their behaviour, the clinical researcher discussed with them possible solutions and resources they may use to achieve their goals.
10. To complete the session, the clinical researcher provided the three selected pamphlets on hepatitis C and safer using (Liver First, Impact, and Safer Injecting) and highlighted the section on referrals for further information, support and counselling.
11. The clinical researcher then recorded the time at which the brief behavioural intervention was completed.

Control Intervention

1. The clinical researcher explained to the participant that she is not an expert on hepatitis C, but that there are resources and places where they can obtain information and support.
2. The clinical researcher recorded the time at which the control intervention began.
3. The clinical researcher presented the Liver First booklet to the participant, briefly highlighting the various sections in the booklet and pointing out the main facts about hepatitis C.
4. The clinical researcher responded to any specific questions about hepatitis C risk practices by referring the participant to the booklets or to one of the referral sources listed in the booklet. These questions (or at least the topic area) were recorded on the Intervention B checklist.
5. The other two pamphlets were shown to the participant and they were encouraged to read them at home. The clinical researcher did spend some time showing the participant (using the Impact booklet) where they could obtain further information and support if it was required.
6. The clinical researcher gave the participant the three booklets to take home, and recorded the time at which the control intervention was completed.
7. If the participant required further or more specific information to ensure their safety or the safety of others, the clinical researcher was able to provide the necessary support and/or information. There was no need to abandon any of the randomised

interventions or to provide much additional information, as the pamphlets were comprehensive.

One-month follow-up research interview

The purpose of the one-month follow-up appointment was for the Research Assistant to conduct the follow-up research interview and provide debriefing and referral details. Letters were posted out in the week prior to the proposed interview date, with participants asked to contact the Research Assistant on a free-call number to arrange a convenient date and time. If participants did not contact the Research Assistant, attempts were made at contact via telephone or via the people they had named and given consent for the Research Assistant to contact.

The Research Assistant (independent from the clinical researcher conducting the intervention sessions) conducted all of the follow-up interviews in an attempt to minimize respondent bias. The Research Assistant explained to participants that this was a different interview to the first, and that he did not wish to discuss what happened in the initial interview (the Research Assistant was blind to participant intervention status). Participants may have felt more pressure to answer in a sociably-desirable way had the clinical researcher conducted the follow-up interviews, given the implicit aims of the initial intervention (especially the experimental intervention) to increase hepatitis C knowledge and reduce risk behaviours.

The Research Assistant was able to answer any questions the participants had about the research, and if a participant required further information or counselling about hepatitis C or their drug use, they were referred to Clinical Services at Turning Point Alcohol and Drug Centre or another appropriate service. Participants were reimbursed \$20.00 for their time and were asked to sign to acknowledge receipt of payment.

Intended Data Analyses

Power analysis indicated that a total sample of 120 was required (effect size = .25, power = .8, alpha = .05) (Cohen, 1992). The main variable that impacts upon the power analysis, and hence sample size, is the dropout rate (O'Brien, Volpicelli, & Volpicelli, 1996; O'Malley & Carroll, 1996). Therefore, a larger number of participants needed to be recruited in the first instance to ensure a final sample size of 120. Assuming a trial drop out rate of 30%, the required commencement sample size was estimated to be 180 (90 in each group).

Comparisons were to be made using chi square analyses between those who were enrolled and those who were only Brief Screened to determine whether or not there were baseline differences between these groups. Descriptive statistics were to be generated for the total enrolled sample. Differences between the two treatment groups (on the 4 major BBV-TRAQ variables and other relevant demographic and drug use/treatment variables at baseline) were to be examined using t-tests for the continuous variables, and chi-square or Fisher's Exact tests for the categorical variables. The major outcome variables (BBV-TRAQ Total Score, Injecting Subscale Score, Sex Subscale Score, and Other Skin Penetration Subscale Score) were to be examined at baseline and one-month follow-up, using independent samples t-tests to test for significant differences between the two groups. Time effects for the sample as a whole were to be examined using paired sampled t-tests.

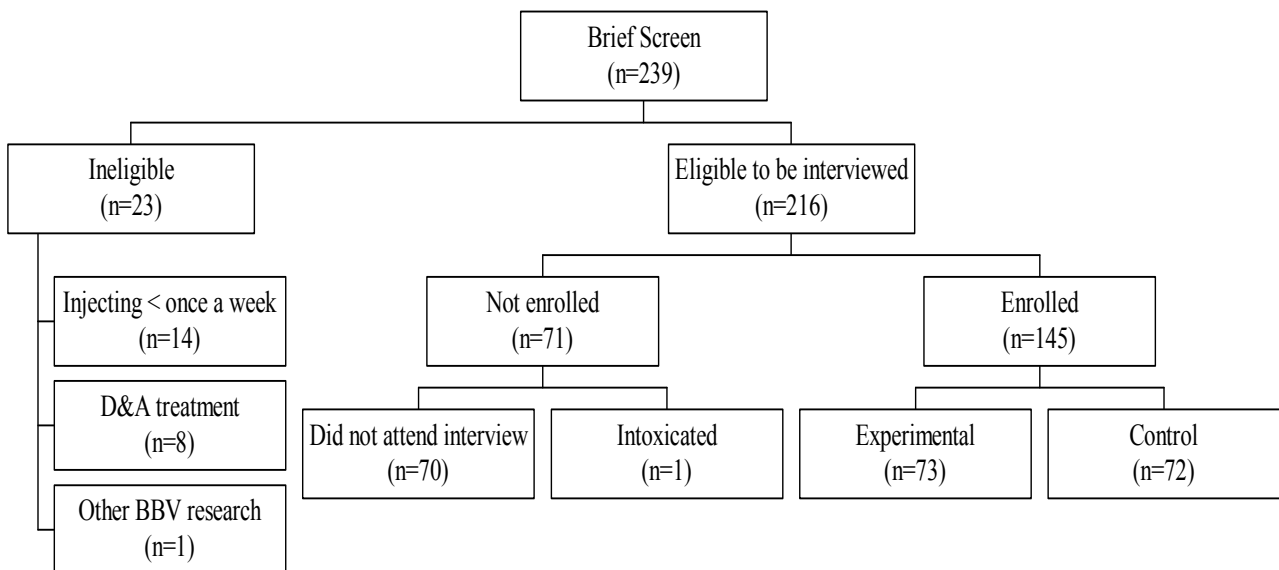
Participant satisfaction, as measured by the HCV-BBI Evaluation form, was to be compared between the two intervention groups using independent sample t-tests. Other variables for planned analyses examined at follow-up using independent-samples t-tests included: entry into drug treatment; changing levels of injecting drug use; and being tested for HCV post-intervention.

3.0 RESULTS

3.1 - Brief Screen.

Brief Screen outcomes are represented in the Figure 2 flow diagram. Of the 239 volunteers Brief Screened for the trial, 216 (90%) were deemed 'eligible' to be interviewed. There were 70 (30% of total number Brief Screened) people who were eligible but did not attend the interview appointment. For the 23 (9%) volunteers who were deemed ineligible at Brief Screen, 14 were excluded due to the infrequency of their injecting, having injected less than once a week over the previous 6 months. A further eight volunteers were excluded early in the study due to being currently engaged in drug and alcohol treatment. This criterion was abandoned after approximately 2 weeks of recruitment, as the project team re-evaluated its relevance to the research question. One volunteer was excluded due to their involvement in blood borne virus research and education. One other volunteer was deemed eligible at Brief Screen and attended for interview, but was not enrolled due to severe intoxication. Therefore, of the 239 people Brief Screened for the trial, 94 (39%) did not proceed to enrolment.

Figure 2. Flow diagram of the study procedures.



3.2 - Enrolled sample.

One hundred and forty five people (60% of the total sample Brief Screened) were enrolled in the trial. This sample comprised 107 males (73.8%) and 38 females (26.2%), with a mean age of 31 years. Thirty-eight participants (26.2%) had completed their high school education, with 22 (15.2%) reporting the completion of a university or college course. Forty-six participants (31.7%) reported completing a trade or technical training. Seventy participants (48.3%) were unemployed at enrolment. Eighteen (12.4%) reported being in some form of employment, with a further 47 people (32.4%) on a disability or sole parent pension. The remaining 10 participants (6.9%) were students, were performing home duties, or were independently wealthy. Tables A1 and A2 in Appendix A provide descriptive data for the enrolled sample on each of the demographic variables.

On average, participants reported first using drugs intravenously at the age of 19 years, with 76 (52.4%) participants reporting amphetamines as the first drug injected, and a further 57 (39.3%) reporting heroin as the first. Heroin was the drug of choice for 108 participants (74.5%), with 112 (77.2%) reporting it as the drug they most often injected in the last month. Eighty-nine participants (61.4%) reported injecting mostly in a private residence during the past month, 45 (31.0%) injected most frequently in a public place, and 11 (7.6%) injected in a car. Ninety-six participants (66.2%) usually injected in the presence of another person during this period, with the remainder usually injecting alone.

One hundred and forty-three participants reported previous testing for hepatitis C. Ninety-two participants (63.5%) reported being hepatitis C positive, with this group (98.6% of the total sample) having been tested a mean of 10.5 months prior to interview. Only 3 people reported being unsure of their hepatitis C status.

3.3 - Comparing the experimental and control groups at baseline

Age was the only continuous variable examined at baseline, with no significant difference observed using an independent-samples *t*-test, t ($df=144$) = 1.56, $p=0.12$. The categorical variables examined for baseline differences between the treatment groups are presented in Table 1 on the following page. No significant differences were observed on any of these variables at the 0.05 level of significance.

Table 1. Frequencies and percentages for each treatment group and results of chi square analyses for each of the categorical pre-treatment variables for the total enrolled sample ($n=145$)

Variable	Experimental group ($n=73$)		Control group ($n=72$)		Statistical results		
	<u>F</u> ¹	<u>P</u> ²	<u>F</u>	<u>P</u>	<u>χ^2</u>	<u>df</u>	<u>p</u>
Sex of participant							
Male	53	72.6%	54	75.0%	* ^b		0.851
Female	20	27.4%	18	25.0%			
Employment status							
Employed	7	9.6%	11	15.4%	1.132	3	0.769
Unemployed	37	50.7%	33	45.8%			
Pensioner	24	32.9%	23	31.9%			
Not seeking employment (home duties, pensioner, other)	5	6.8%	5	6.9%			
Level of education completed							
Did not complete high school	56	76.7%	51	70.8%	* ^b		0.455
Completed high school	17	23.3%	21	29.2%			
Who do you usually inject with?							
Inject alone	28	38.4%	21	29.2%	* ^b		0.293
Inject with other	45	61.6%	51	70.8%			
Where do you usually inject?							
Private home	44	60.3%	45	62.5%	0.117	2	0.943
Public place	23	31.5%	22	30.6%			
Car	6	8.2%	5	6.9%			
How often did you inject last month?							
Weekly or less	7	9.6%	3	4.2%	6.953	4	0.138
More that weekly but not daily	25	34.2%	36	50.0%			
Once a day	18	24.7%	19	26.4%			
2-3 times a day	16	21.9%	12	16.7%			
More that three times a day	7	9.6%	2	2.7%			
Received treatment for drug or alcohol use in the last month? ($n=136^a$)							
Not in treatment	32	47.1%	38	55.9%	* ^b		0.391
In treatment	36	42.9%	30	44.1%			
Drug injected most often last month							
Heroin	60	82.2%	52	72.2%	2.054	2	0.356
Amphetamine	7	10.7%	11	15.3%			
Other drug	6	8.1%	9	12.5%			

Hepatitis C status							
Never tested	2	2.4%	1	1.4%	2.105	3	0.551
Negative	22	30.5%	28	38.9%			
Positive	49	67.1%	43	59.7%			

Notes:

¹ = frequency

² = percentage

^a = Data regarding treatment were not collected for 9 participants

^b Fisher's Exact Test used as one or more cells contained less than the expected number of cases

The continuous drug use variables examined for baseline differences between the intervention groups are presented in Table 2. No significant differences were observed between the groups on the variables of age on day of first interview and age when first injected.

*Table 2. Means and standard deviations for each treatment group and results of independent samples *t*-tests for the continuous pre-treatment drug use variables (*n*=145)*

Major outcome variables		<i>n</i>	Mean	<u>SD</u>	<i>t</i>	<u>df</u>	<i>p</i>	95% <u>C.I.</u>	
								Lower	Upper
Age on day of first interview	Experimental	73	31.99	8.46	-1.566	143	0.120	-4.399	0.510
	Control	72	30.04	6.32					
Age when first injected	Experimental	73	19.47	6.26	-0.760	143	0.449	-2.478	1.102
	Control	72	18.78	4.47					

An examination of the four major outcome variables reveals that there were no significant differences between the treatment groups at baseline, with *p* values ranging from 0.12 to 0.69 (see Table 3). There is missing data for one participant on the BBV-TRAQ Injecting and Total scales, which has been omitted from analyses.

*Table 3. Means and standard deviations for each treatment group and results of independent samples *t*-tests for the four major outcome variables at baseline (*n*=145).*

Major outcome variables		<i>n</i>	Mean	<u>SD</u>	<i>t</i>	<u>df</u>	<i>p</i>	95% <u>C.I.</u>	
								Lower	Upper
BBV-TRAQ Injecting Score	Experimental	73	13.72	13.91	1.49	142	0.139	-1.15	8.24
	Control	71	17.26	14.61					
BBV-TRAQ Sex Score	Experimental	73	8.88	10.00	0.406	142.885	0.686	-2.63	3.99
	Control	72	9.56	10.14					
BBV-TRAQ Other Score	Experimental	73	2.68	3.65	1.553	143	0.123	-0.28	2.38
	Control	72	3.74	4.47					
BBV-TRAQ Total Score	Experimental	73	25.29	23.96	1.444	142	0.151	-2.01	12.93
	Control	71	30.74	21.37					

In summary, there were no significant differences between the treatment groups at baseline. All major outcome variables from the BBV-TRAQ were non-significant, as were the demographic variables and the variables relating to drug use. This indicates that

randomisation effectively distributed baseline differences equally between the two treatment groups.

3.4 - Differences between attendees and non-attendees at 1-month follow-up

One hundred and twenty-three of the 145 participants attended their one-month follow-up research interviews. Using independent samples *t*-tests, a comparison was made between the baseline scores of those who attended the follow-up interview (*n*=123) and the baseline scores of those who did not attend (*n*=22), on each of the four major outcome variables. No significant differences or trends towards significance at the 0.05 level were discerned between the attendees and non-attendees, using the statistic for equal variance between the groups, with *p* values ranging from 0.38 to 0.71. Therefore, it appears that the follow-up attendees did not have significantly different scores at baseline compared to the non-attendees. Table 4 presents the means and standard deviations for the follow-up attendees and non-attendees, along with the results of the independent samples *t*-tests.

Table 4. Independent samples t-test comparing follow up attendees and non-attendees at baseline for the four major outcome variables

Major outcome variables		<i>n</i>	Mean	<u>SD</u>	<i>t</i>	<u>df</u>	<i>p</i>	95% <u>C.I.</u>	
								Lower	Upper
BBV-TRAQ Injecting	Did not attend	22	17.91	19.23	0.866	142	0.388	-3.688	9.441
	Attended	122	15.03	13.30					
BBV-TRAQ Sex	Did not attend	22	10.36	10.96	0.582	143	0.562	-3.251	5.961
	Attended	123	9.00	9.90					
BBV-TRAQ Other	Did not attend	22	2.91	4.91	0.369	143	0.713	-2.23	1.528
	Attended	123	3.26	3.95					
BBV-TRAQ Total	Did not attend	22	31.18	29.14	0.716	142	0.475	-6.663	14.223
	Attended	122	27.40	21.52					

A further comparison was made between the experimental and control participants who failed to attend (9 experimental participants and 13 controls) using independent samples *t*-tests. No significant differences were observed between the experimental and control non-attendees,

with p values ranging from 0.16 to 0.89. As may be observed from Table 5, the confidence intervals around the effect for each variable were extremely wide. The finding of no significant statistical difference is possibly due to the small sample used for the comparison. The direction of the effect varied, however, with no clear trend for one treatment group to be performing better than the other, in terms of those who did not attend the follow-up interview. On the baseline variable of BBV-TRAQ Other Skin Penetration subscale, the statistic for unequal variance between groups was used. Therefore, Mann-Whitney's U was also used to verify these findings without the assumption of normal distribution. There was still no significant finding observed between the experimental and control non-attendees for this variable, with a p value of 0.60.

Table 5. Independent samples t -test comparing experimental and control non-attendees on each of the four major outcome variables

Major outcome variables		n	Mean	SD	t	df	p	95% C.I.	
								Lower	Upper
BBV-TRAQ Injecting	Experimental	9	21.11	20.11	-0.64	20	0.529	-23.07	12.23
	Control	13	15.69	19.10					
BBV-TRAQ Sex	Experimental	9	6.33	12.10	1.475	20	0.156	-2.82	16.47
	Control	13	13.15	9.59					
BBV-TRAQ Other	Experimental	9	2.67	5.55	0.182	15.26	0.858	-4.13	4.96
	Control	13	3.08	4.65					
BBV-TRAQ Total	Experimental	9	30.11	33.23	0.140	20	0.890	-25.18	28.81
	Control	13	31.92	27.35					

3.5 - Major outcome variables: Between group differences at one-month follow-up

The four main outcome variables were derived from the BBV-TRAQ: Injecting Risk subscale (BBV-TRAQ Injecting), Sexual Risk subscale (BBV-TRAQ Sexual), Other Skin Penetration Risk subscale (BBV-TRAQ Other), and the Total BBV-TRAQ Score (BBV-TRAQ Total). The four main outcome variables were not normally distributed at baseline, each being negatively skewed, with risk scores being quite low. Therefore, for the comparison between the two groups at follow-up, difference scores were used. The difference score was calculated by subtracting the follow-up score from the baseline score for each of the four main variables.

The difference scores for each of the BBV-TRAQ subscales and Total score were normally distributed. Independent samples t-tests were then used to examine for differences between the treatment groups at one-month follow-up on each of the four major outcome variables. The means and standard deviations for each of the major outcome variables are shown in Table 6.

Table 6. Means and standard deviations for the four major outcome variables at baseline and follow up

Variable name and range of scores possible		<u>n</u>	Mean	<u>SD</u>
BBV-TRAQ Injecting (0-105)	Baseline	144	15.47	14.32
	F-up	123	7.42	9.17
BBV-TRAQ Sex (0-40)	Baseline	145	9.21	10.04
	F-up	123	7.42	9.17
BBV-TRAQ Other (0-30)	Baseline	145	3.21	4.10
	F-up	123	2.29	3.36
BBV-TRAQ Total (0-175)	Baseline	144	27.98	22.78
	F-up	123	19.09	19.61

There were no significant differences between the experimental and control groups on any of the four main variables, with p values ranging from 0.23 to 0.98. The statistical results of the t-tests are presented in Table 7. Figures 3 to 6 present these results graphically.

Table 7. Independent samples t-tests for the four major outcome variables difference scores (n=123).

Major outcome variables		<u>n</u>	Mean	<u>SD</u>	<u>t</u>	<u>df</u>	<u>p</u>	<u>95% C.I.</u>	
								Lower	Upper
BBV-TRAQ Injecting	Experimental	64	5.56	10.89	0.021	120	0.983	-3.81	3.89
	Control	58	5.60	10.55					
BBV-TRAQ Sex	Experimental	64	2.36	8.60	-1.160	121	0.248	-4.32	1.13
	Control	59	0.76	6.41					
BBV-TRAQ Other	Experimental	64	0.69	2.74	1.203	121	0.231	-0.39	1.59
	Control	59	1.29	2.80					
BBV-TRAQ Total	Experimental	64	8.61	16.28	-0.324	120	0.747	-6.29	4.53
	Control	58	7.72	13.61					

Figure 3. *BBV-TRAQ Injecting means and mean error bars for both the control and experimental groups at baseline and follow up.*

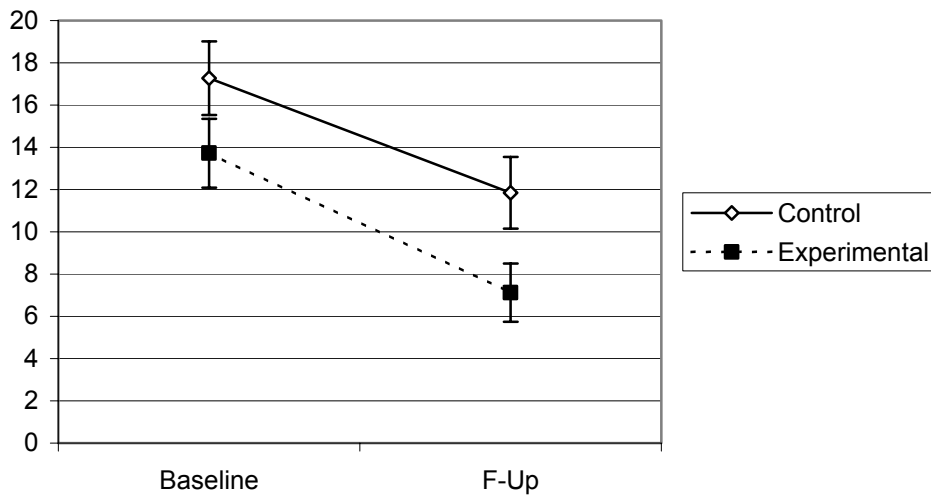


Figure 4. *BBV-TRAQ Sex means and mean error bars for both the control and experimental groups at baseline and follow up.*

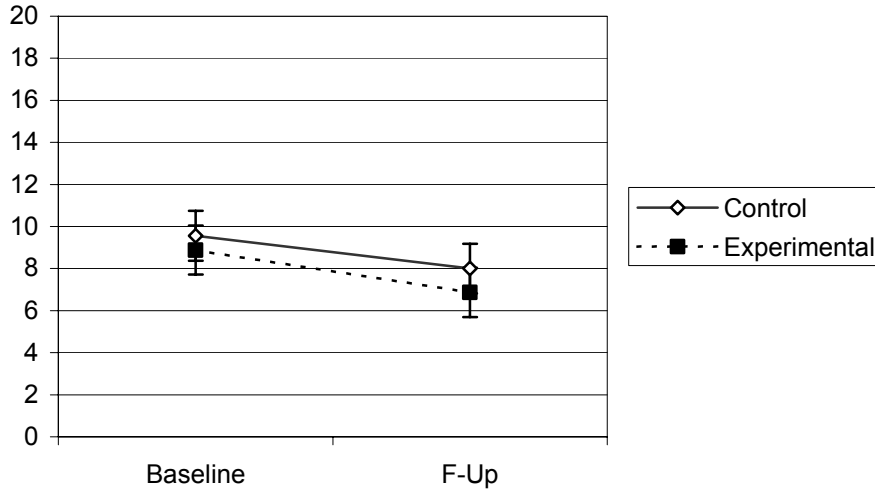


Figure 5. *BBV-TRAQ Other means and mean error bars for both the control and experimental groups at baseline and follow up.*

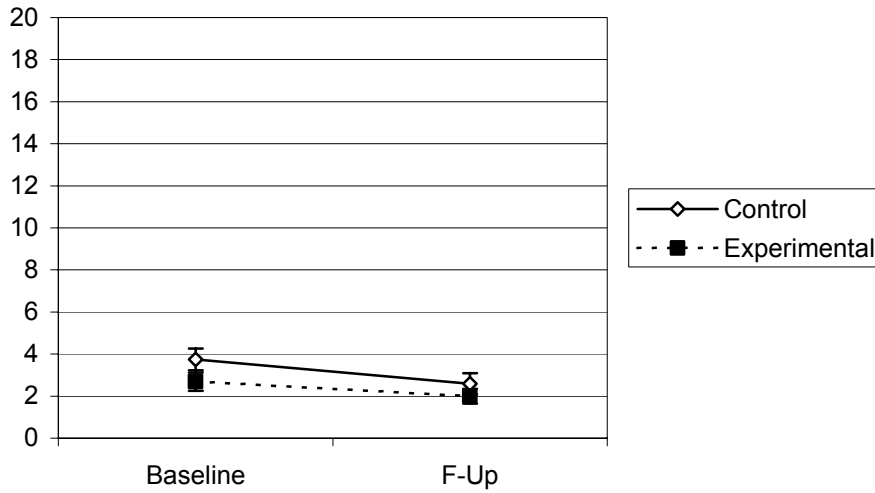
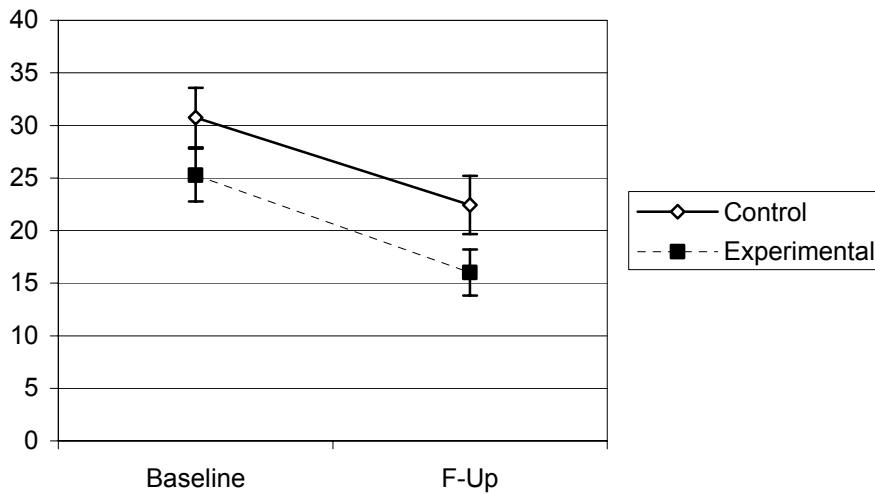


Figure 6. *BBV-TRAQ Total means and mean error bars for both the control and experimental groups at baseline and follow up.*



3.6 - Major outcome variables – Total Sample: An examination of within-group differences between baseline and one-month follow-up

There were no significant differences between the experimental and control groups on the four major outcome variables, enabling us to analyse the sample as a whole for changes in BBV-TRAQ scores over time. As may be observed in Figure 7, the sample as a whole appears

to have reduced their risk scores on each of the four main variables. Paired samples t-tests were used to examine whether any of these differences were significant. The statistical results of these tests are presented in Table 8. On all four variables, there was a significant difference between baseline and one-month scores, with p values ranging from 0.0 to 0.02, indicating that the sample reduced their risk practice scores over time.

Figure 7. Within-group differences between baseline and one-month follow-up

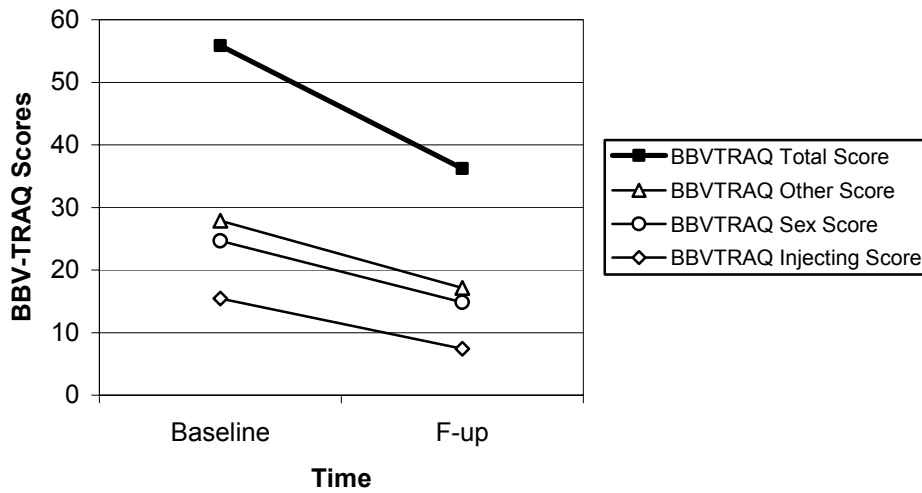


Table 8. Paired samples *t*-tests for the four major outcome variables at baseline and follow up (combined sample).

Major outcome variables	Mean (SD)		Paired differences		<i>t</i>	df	<i>p</i>	95% C.I.	
	Baseline (<i>n</i> =145)	Follow-up (<i>n</i> =123)	Mean	SD				Lower	Upper
BBV-TRAQ Injecting	15.03 (13.30)	9.45 (12.24)	5.58	10.69	5.767	121	0.000	3.67	7.50
BBV-TRAQ Sex	9.01 (9.90)	7.42 (9.17)	1.59	7.64	2.314	122	0.022	0.23	2.96
BBV-TRAQ Other	3.26 (3.95)	2.29 (3.37)	0.98	2.77	3.904	122	0.000	0.48	1.47
BBV-TRAQ Total	27.40 (21.52)	19.21 (19.64)	8.19	15.02	6.023	121	0.000	5.50	10.88

3.7 - Additional Measures of Outcome

Two other variables were examined for differences between the treatment groups at one-month follow-up, as they were considered relevant to measures of blood borne virus risk. Fisher's Exact Test showed that there was no significant difference in the proportion of each treatment group engaged in drug and alcohol treatment at one-month follow up ($p=0.38$), and a Chi square test showed no significant difference between the groups in terms of the frequency of injecting in the month prior to follow-up ($p=0.13$).

One other question examined at follow-up was the proportion of each treatment group who had undergone a blood borne virus test in the month following the intervention. A Fisher's Exact Test showed no statistically significant difference between the groups ($p=0.68$), with exactly 14 members of each treatment group having been tested.

Evaluation Forms were completed by 58 of the experimental group participants and 56 of the control group participants. These forms were designed to provide feedback about the usefulness and appropriateness of the interventions to participants. The following graphs show the responses of the surveyed participants to the following questions: "How useful was the program to your needs?" "How much did you learn from this program?" "How satisfactory did you find the program?" and "How useful do you think this program would be for other drug users?" As may be observed in Figures 8 to 11, those participants who received the individually tailored experimental intervention reported higher levels of satisfaction on each of the variables.

Chi square and Fisher's Exact Tests were then used to examine whether these differences between the treatment groups on each of the program evaluation questions were statistically significant. There was a significant difference between the groups on questions 1 and 3, "How useful was this program to your needs?" ($p=0.007$) and "How satisfactory did you find this program?" ($p=0.003$). Questions 2 and 4, "How much did you learn from this program?" ($p=0.08$), and "This program would be useful to other drug users' needs" ($p=0.07$), showed trends towards statistical significance. Therefore, it appears that the experimental intervention was considered significantly more useful and satisfactory to participants than was the control intervention.

Figure 8. Participant reports on usefulness of interventions to own needs (n=112)

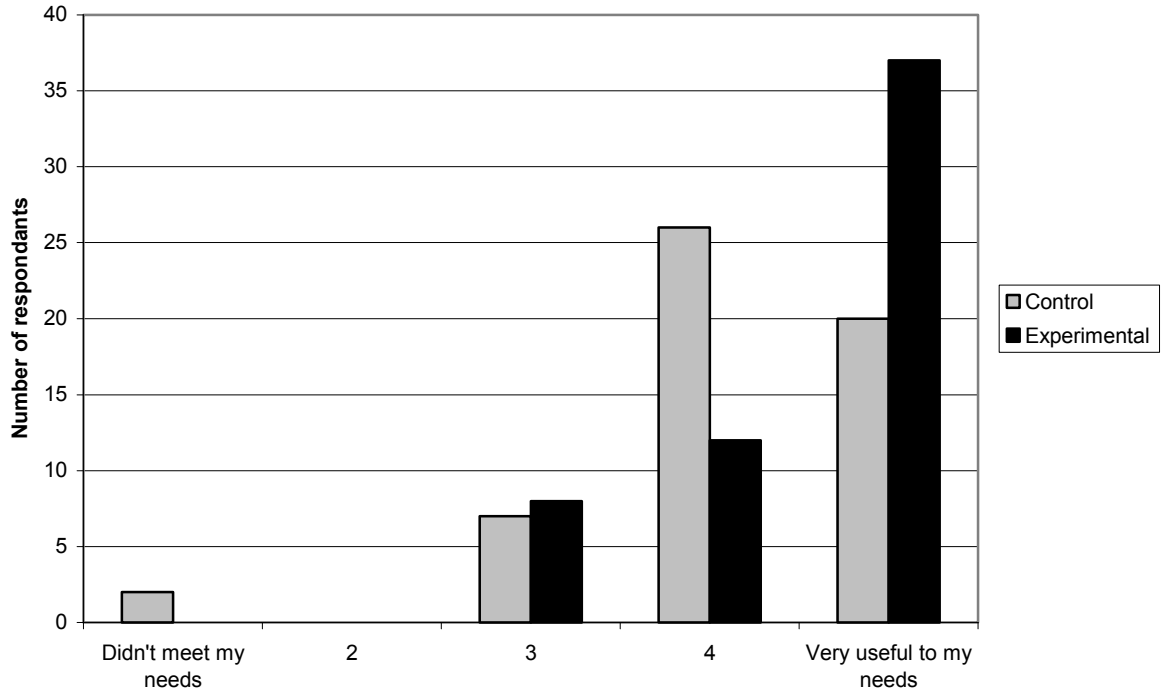


Figure 9. Participant reports on degree of learning from intervention conditions (n=112)

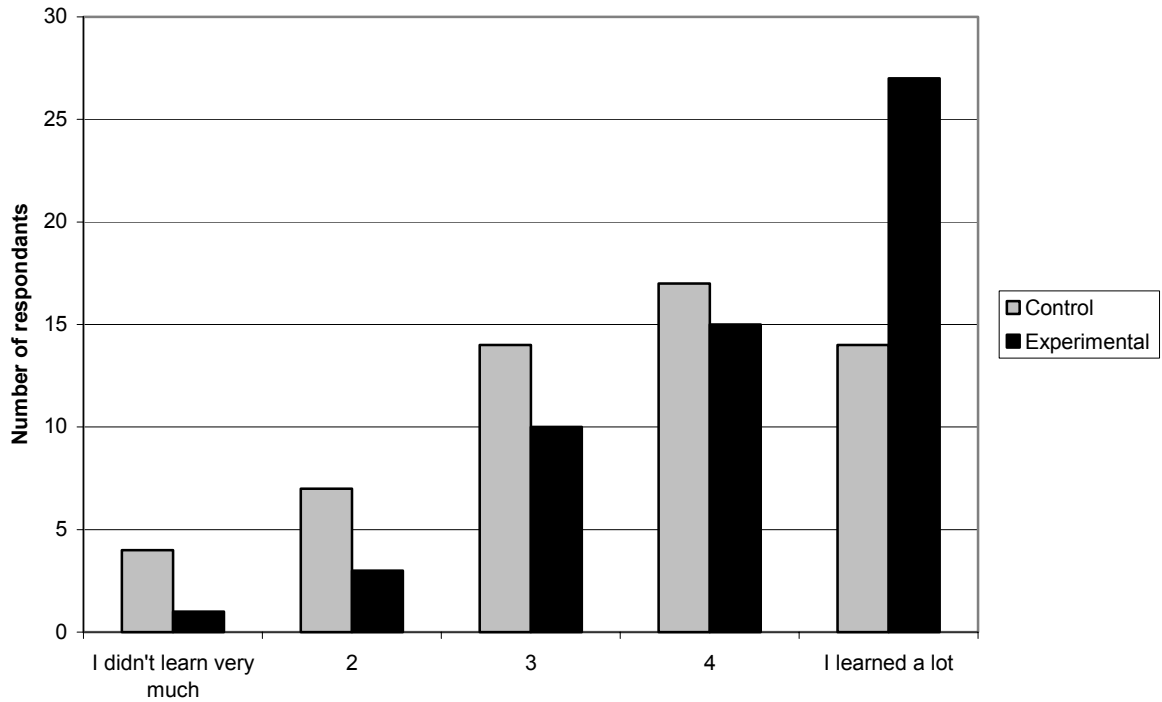


Figure 10. Participant reports on degree of satisfaction with intervention conditions (n=111)

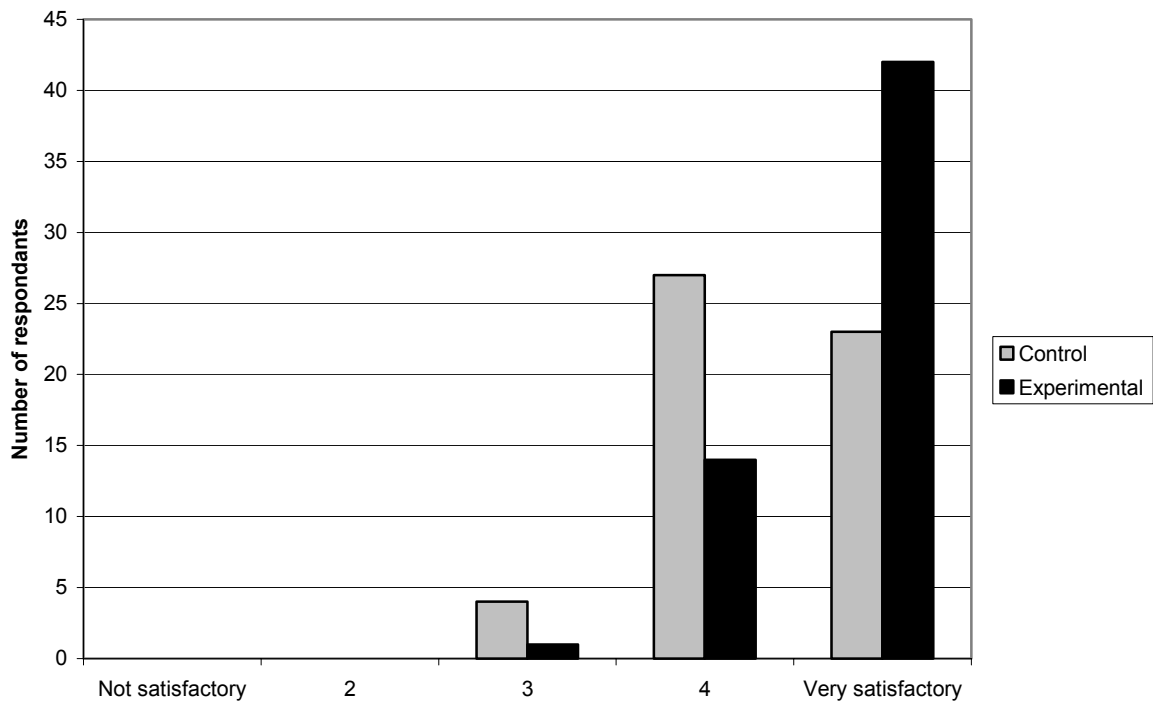
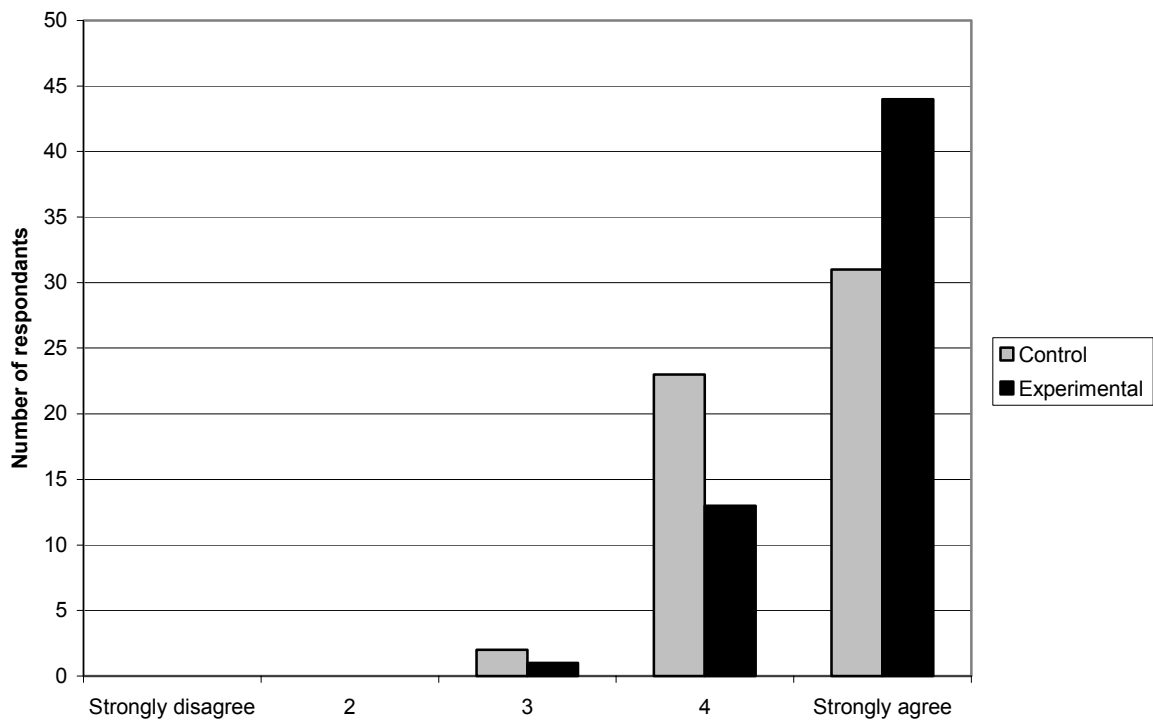


Figure 11. Participant reports on perceived usefulness of intervention conditions for other drug users' needs (n=114)



4.0 DISCUSSION

The current study examined levels of risk for the transmission of hepatitis C, before and after an experimental group and control group brief intervention. Experimental group participants received an intervention tailored to their individual HCV risk practices, and control group participants received a standardised educational intervention. The major goal of the research was to examine the efficacy of each of the experimental BBI in reducing HCV risk practices. The findings of this study did not support the primary hypothesis, that the experimental group would have significantly lower scores on the BBV-TRAQ than the control group (indicating a larger reduction in HCV risk practices) at one-month follow-up. There was, however, a significant reduction in BBV-TRAQ scores between baseline and one-month follow-up for both groups.

4.1 - Data integrity, reliability and validity

Before discussing the findings of the current study, it is important to consider the quality of the data on which the findings are based. The first section discusses the selection of the treatment samples, the prevention of bias through attention to randomisation, and the follow-up rate.

The research sample.

The current study attempted to recruit a broad sample of injecting drug users, in the sense that entry to the study was open to any injecting drug user who met the inclusion criteria. The study was advertised in a number of Community Health Centres and Needle Syringe Programs, at VIVAIDS (Victorian Injecting Drug Users Association), and via ‘word of mouth’ snowballing. While recruitment efforts targeted inner Melbourne suburbs of Fitzroy, Melbourne CBD, Collingwood and Richmond (to facilitate recruitment and follow-up rates), the broad socio-demographic characteristics of both study groups were similar to IDU samples (in service contact) drawn from wider metropolitan Melbourne in previous studies (e.g. Fry & Miller, 2001; Fry & Miller, 2002). The baseline average BBV-TRAQ risk practice scores of both the experimental and control groups was also similar to scores obtained from a sample of 142 Melbourne IDU recruited in the ABRIDUS study (see Dwyer et al., 2002). The

findings of this study may therefore be generalised to IDUs currently in contact with health services such as community health centres, NSPs and treatment agencies.

Close attention was paid to the randomisation of participants to the experimental and control conditions. An independent researcher, using random block sizes of 6, 8, and 10, generated the randomisation schedule. Each time a participant was enrolled, the clinical researcher opened the next available envelope, to be advised of the next allocation on the randomisation schedule. A randomisation schedule was held by the independent researcher, for comparison at the end of recruitment. Therefore, there was no possibility of bias on the part of the clinical researcher, with allocation to treatment condition completely random. No significant differences were discovered between the control and experimental groups pre-treatment, which indicates that the randomisation procedure was successful in evenly distributing the sample. Confidence can therefore be placed in the findings of the study, in respect to the effect of treatment condition.

Follow-up rates at one month were excellent, with 85% of participants followed up and interviewed. This high rate of follow-up resulted in very little missing data. Analyses conducted showed no obvious baseline differences between those who were and were not assessed at follow up and similar rates of drop out in the two groups. Again, we can be confident in interpreting the findings for those who were interviewed, and generalising them to the IDU population studied.

The research methodology

An independent Research Assistant who had no knowledge of the content of the first interview or the intervention received collected research data. This was to reduce the pressure participants can experience to answer in a socially desirable way, or to demonstrate improvement since the first interview, and also ensured that the interviewer was not biased in participant questioning and scoring. Whilst there is a need for caution when interpreting self-report data on risk practices, this is the best available method for assessing these behaviours.

The authors therefore conclude that the results of the current study may be considered a valid and reliable account of intervention effects, which have relevance to a wider IDU population in contact with health services. The following section will begin the discussion of the findings of the current study, paying attention to a comparison with previous research.

4.2 - Efficacy of the brief interventions

The main variables examined in this study were obtained from the BBV-TRAQ and relate to three different areas of risk behaviour associated with the transmission of hepatitis C – injecting risk practices, sexual risk practices, and other skin penetration risk practices. The main focus of the interventions was injecting risk; however the other two areas were included due to recent findings in the literature evidencing hepatitis C transmission via non-injecting means. The likelihood of sexual transmission of hepatitis C is thought to be extremely low (Lin, 1998), however, as this remains a possibility (Bresters et al., 1993; Sladden et al., 1997) this area was included in the intervention but was not the main focus.³ No significant differences were observed between the two intervention groups on the BBV-TRAQ subscales or total score. However, both groups significantly reduced their risk practice scores on each of the BBV-TRAQ scales at one month follow up. It appears that both interventions were effective in reducing hepatitis C risk practices, with a marked reduction in BBV-TRAQ scores over time for the sample as a whole.

A possible explanation for this is that the administration of the BBV-TRAQ prompted participants to question their level of risk for hepatitis C, before any formal intervention was attempted. Participants commented on specific items that related to them and that may have created a discrepancy between their perceived and actual levels of risk. Therefore, by the time the control participants received their educational materials, they often had specific questions in mind. It is likely therefore that the BBV-TRAQ (due to its specific focus) acted as a motivational and educational tool in its own right to direct the participant's attention and learning.

Similarly, it is possible that the additional effect of any formal intervention could not be detected on top of the improvements already effected by the BBV-TRAQ. It should be noted that baseline scores on the BBV-TRAQ were negatively skewed to begin with, possibly leading to a floor effect.

A factor that may explain the lack of significant difference in self-reported risk behaviour change between the two study groups is time spent with the clinical researcher conducting the interventions. There is evidence to suggest that simply spending time with any health provider, and developing a rapport, can be therapeutic (Ritter et al., 2002). While the

³ See Crofts, Thompson & Kaldor (1999) for a review of studies relating to HCV transmission pathways other than injecting drug use (e.g. nosocomial, sexual, vertical, household, tattooing and skin penetration).

intervention groups spent differing amounts of time in the actual intervention with the clinical researcher (e.g. experimental participants an average of 23 minutes, SD 8.4 min; control participants around 5 minutes), both groups actually spent approximately the same amount of total time (40-60 minutes) in the session (i.e. including time spent on the research interview and the BBV-TRAQ). Further, our experience was that both the research interview and the BBV-TRAQ prompted participant discussion and thinking around injecting behaviours and risks for hepatitis C.

It is plausible to suggest therefore that the control group received most of the active ingredients of the individually-tailored intervention: a standardised and very specific measure of hepatitis C risk practices (the BBV-TRAQ), which appears to have created dissonance between current practices and desired behaviours; high quality educational materials about hepatitis C; and time spent with another person talking and thinking about hepatitis C and risk practices for transmission. The intervention components the control group did not receive were the BBV-TRAQ Tally sheet, goal setting and problem-solving activities. It is important to note however that the experimental participants, who received these individualised components, reported significantly higher levels of satisfaction with their intervention, reporting it to be very useful to themselves and others.

Previous studies of brief interventions have examined interventions ranging from very brief (15-20 minutes) (Poikolainen, 1999) to several hours (Saunders, Wilkinson, & Phillips, 1995) and more extensive programs running over several months (Dunn et al., 2001). The findings of the current study support the efficacy of brief interventions, with neither intervention taking longer than 30 minutes. This will be an important factor if the intervention is to be feasible in the 'real world'.

4.3 - Limitations of the study

One limitation of this study alluded to earlier was that the two interventions may have been too similar. The control intervention was designed to replicate what is currently available within the community, within Needle and Syringe Programs and Community Health settings, namely generic educational materials about hepatitis C. It was considered unethical to provide an intervention to one group and nothing to the other, especially after the administration of a detailed and thought-provoking questionnaire such as the BBV-TRAQ. For the control participants, rather than simply handing over the written information, the clinical researcher

highlighted the key points from the Liver First booklet and encouraged participants to read the other materials at a later time, possibly contaminating the control intervention. It appears that both intervention groups received education that they were then able to implement to reduce their hepatitis C risks. Whilst this is an excellent outcome clinically, it does not demonstrate superior effectiveness of an individually tailored intervention; unless we conclude that the control group intervention did actually contain a degree of individual focus (e.g. BBV-TRAQ, time interacting with the clinical researcher).

A further limitation highlighted earlier is that of generalisability of the findings beyond the IDU group studied. The current study sample had similar socio-demographic and drug use history characteristics as previous samples of IDU in current contact with health services. It is plausible to expect that other IDU groups of different socio-demography and drug histories may respond differently to the interventions tested. The finding from this study that both groups significantly reduced risk behaviour at one-month follow up suggests that the brief interventions developed and employed here would be suitable for future application with other IDU groups to test this hypothesis.

Another factor to consider when reviewing the results of this study is the effect of social desirability on participant responses. The personal nature of the questions on the BBV-TRAQ, and the socially undesirable image of injecting drug use, may have affected the reliability of self-report, resulting in an under-reporting of risk behaviour. Every effort was made to reduce the pressure participants felt to answer in a certain way, with different researchers used at each time point, and much discussion around the importance of honest answers and the confidentiality of the data. However, interpretation of self-report data around very sensitive topics such as injecting and sexual behaviours must always proceed with caution.

Finally, whilst the BBV-TRAQ has been psychometrically tested and has been demonstrated to be a reliable and valid measure of hepatitis C risk behaviours (Fry & Lintzeris, 2003), it is possible that the demand characteristics associated with its use may have also influenced self-report. Because the BBV-TRAQ is designed for participant self-administration it is possible that some risk behaviours may be under- or over-reported due to misperceptions or misunderstandings about what is being asked in each item. Further, as participants become aware of the more subtle risk practices around the sharing or handling of equipment, they may respond differently to BBV-TRAQ items. At follow-up interviews some participants could be seen to have increased their risk practices when in fact they may have just increased their

awareness of what constitutes a risk for hepatitis C. Future applications of the BBV-TRAQ in developing BBIs should explore these issues further.

4.4 - Implications for intervention and future directions

The findings of the current study provide support for the application of brief interventions in initiatives aimed at reducing hepatitis C risk behaviour. Whilst the individually tailored intervention was not found to be more effective than the control intervention in terms of the degree of change measured on the four main outcome variables of interest, all participants did significantly reduce their injecting, sexual and other skin penetration risk practices. This is an important finding, which implies that varying degrees of educational interventions could be useful, and leads to harm reduction in the area of BBV. The commonality between the two interventions in the current study is the time spent with the health professional / clinical researcher (approximately equal total session times), completion of a standardised and specific assessment of risk practices (the BBV-TRAQ), and the educational materials provided.

Saunders and colleagues (1995) and others (Dunn et al., 2001) have noted the interpretive value of measuring subtle brief intervention effects (e.g. psychological or attitudinal changes) in addition to the usual overt effects (e.g. detectable behaviour change) in assessing the efficacy of such treatments. Despite equivalent reductions in risk behaviours observed in both groups in the present study, results from participant evaluation of the interventions showed that the experimental intervention was considered significantly more useful and satisfactory to participants than was the control intervention. These findings suggest that further developmental work with the experimental BBI is warranted.

The literature also suggests that an advantage of brief interventions is that they may facilitate maintenance of behaviour change beyond the intervention period (Heather, 1995a, 1995b). While significant risk practice reductions from baseline levels were detected at the one-month follow up period in the current study, the design did not permit an assessment of whether or not this would persist beyond this time. One hypothesis (based on an assumption of the value of individual tailoring and focused discussion) is that the experimental BBI group risk reduction would persist for longer than that seen for the control group. Further research will be needed to examine the factors that are important in effecting and maintaining change.

Another possibility is that the BBV-TRAQ is a powerful intervention in its own right. During the administration of the BBV-TRAQ, participants may begin to formulate their own ideas about their areas of risk practice for HCV, using the information obtained from the questionnaire, especially given the very specific nature of the questions. Whilst the questionnaire alone appears to provide educational material, it also encourages participants to think about the discrepancy between their previously perceived levels of risk and their actual risk for hepatitis C transmission. This may motivate, focus and direct their subsequent learning from the written materials provided. Future randomised controlled research could examine the effect of the BBV-TRAQ alone on hepatitis C risk practices, by comparing BBV-TRAQ scores between a group who completed the instrument at baseline interview and those who did not. All participants would complete the BBV-TRAQ at a follow-up time point. There are a number of areas of research and clinical work in which the BBV-TRAQ could be employed effectively. It appears to be the only available measure of BBV risk practices that comprehensively covers the behaviours specific to the transmission of hepatitis C (Fry & Lintzeris, 2003).

It would be useful for subsequent BBV and IDU research to use a standardised measure of risk to allow for comparison between studies. Clinically, the BBV-TRAQ provides a good basis from which to develop individually targeted HCV education in a number of different settings. Training could be provided to a range of services such as outpatient clinics, community health centres, general practice, NSPs, and peer education in the administration of the BBV-TRAQ and Risk Tally Sheet. This would facilitate discussion around BBV and risk practices and ensure that the information provided to clients is tailored and relevant to each individual. Further research could evaluate the use of the BBV-TRAQ in the aforementioned settings, taking into consideration the particular time constraints within each setting. The individually tailored intervention used in the current study could well be widely applied due to its short duration of approximately 20-30 minutes.

Participant feedback about the interventions provided indicates that the IDU population desires accurate information about hepatitis C and how it relates to them individually. Feedback also demonstrates that the individually tailored intervention, delivered with the use of the BBV-TRAQ Tally Sheet, was highly useful and satisfactory to participants. Whilst information appears to be readily available in the community, it may not be accessed or understood at the rate we might expect. It is important to continue research into what factors facilitate effective behaviour change. An instrument like the BBV-TRAQ seems to be an

effective and acceptable way to engage clients in thought and discussion about their risk behaviours.

The current study meets a number of key objectives and principles of the current National HCV Strategy (Commonwealth Department of Health & Aged Care, 2000) and Victorian Hepatitis C Strategy (Victorian Department of Human Services, 2002) with respect to the goal of reducing HCV risk behaviour, and ultimately new infections, amongst the IDU target group. The study has shown that both interventions produced significant reductions in risk behaviour, the implication of which is that BBI methods appear to hold promise as an additional element to the range of existing HCV education and prevention initiatives. Brief interventions certainly match the requirements of effective public health strategies – they are cost and time effective, can be administered by a range of people, and can be delivered to large numbers of the target group, in this case IDU. It has contributed important evidence showing persisting levels of HCV transmission risk behaviours that may help to explain continued high incidence rates in this country. In an indirect way, the study also highlights the potential value of standardised, comprehensive risk assessment instruments for augmenting current risk behaviour monitoring and surveillance mechanisms. Future research could evaluate the efficacy of the BBV-TRAQ as a risk behaviour intervention and counselling tool in clinical, NSP and peer education settings.

5.0 APPENDIX A

Table A1. Frequencies and percentages for the major categorical variables for the total enrolled sample (n=145)

Variable (<u>n</u> = 145, unless stated otherwise)	Frequency	Percent
Participants sex		
Male	107	73.8%
Female	38	26.2%
Employment status		
Employed	70	48.3%
Unemployed	18	12.4%
Pensioner	47	32.4%
Not seeking employment (home duties, pensioner, other)	10	6.9%
Type of accommodation currently living in		
Own house (includes renting)	65	44.8%
Parent/family house	24	16.6%
Boarding house/hostel	21	14.5%
Shelter/refuge	7	4.8%
No fixed address/homeless	11	7.6%
Staying with friends	12	8.3%
Squat	5	3.4%
Level of education completed		
Did not complete high school	107	73.8%
Completed high school	38	26.2%
Courses completed after school		
No courses completed	77	53.1%
Trade technical courses completed	46	31.7%
University or college courses completed	22	15.2%
Prison attendance in the last month		
No	142	97.9%
Yes	3	2.1%
How often did you inject last month?		
Weekly or less	10	6.9%
More that weekly but not daily	61	42.1%
Once a day	37	25.5%
2-3 times a day	28	19.3%
More that three times a day	9	6.2%
Who do you usually inject with?		
Inject alone	49	33.8%
Inject with other	96	66.2%
Where do you usually inject?		
Private home	89	61.4%
Public place	45	31.0%
Car	11	7.6%
Drug first injected		
Heroin	57	39.3%
Amphetamine	76	52.4%
Other drug	12	8.3%
Drug injected most often last month		
Heroin	112	77.2%
Amphetamine	18	12.4%
Other drug	15	10.3%
Drug of choice		

Heroin	108	74.5%
Amphetamine	17	11.7%
Other drug	20	13.8%
HIV status		
Never tested	4	2.8%
Negative	134	92.4%
Positive	2	1.4%
Don't know/not sure	5	3.4%
Hepatitis C status		
Never tested	2	1.4%
Negative	50	34.5%
Positive	92	63.4%
Don't know/not sure	1	0.7%
Hepatitis B status		
Never tested	4	2.8%
Negative	44	30.3%
Old infection	35	24.1%
Carrier	5	3.4%
Vaccinated	43	29.7%
Don't know/not sure	14	9.7%
Number of education sessions attended about blood born viruses ever		
No times	24	16.6%
Once	9	6.2%
Twice	11	7.6%
Three times	57	39.3%
More than four times		
Main type of treatment currently engaged (n = 136)		
Not in treatment	70	51.5%
Methadone	20	14.7%
Detoxification	8	5.9%
Narcotics Anonymous	3	2.2%
Drug counselling	8	5.9%
Buprenorphine	23	16.9%
Other	4	2.9%

Table A2. Descriptive statistics for the major continuous variables for the total enrolled sample

Variable	<u>n</u>	Mean	<u>SD</u>
Age on day of first interview	145	31.02	7.51
Age when first injected	145	19.12	5.44

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