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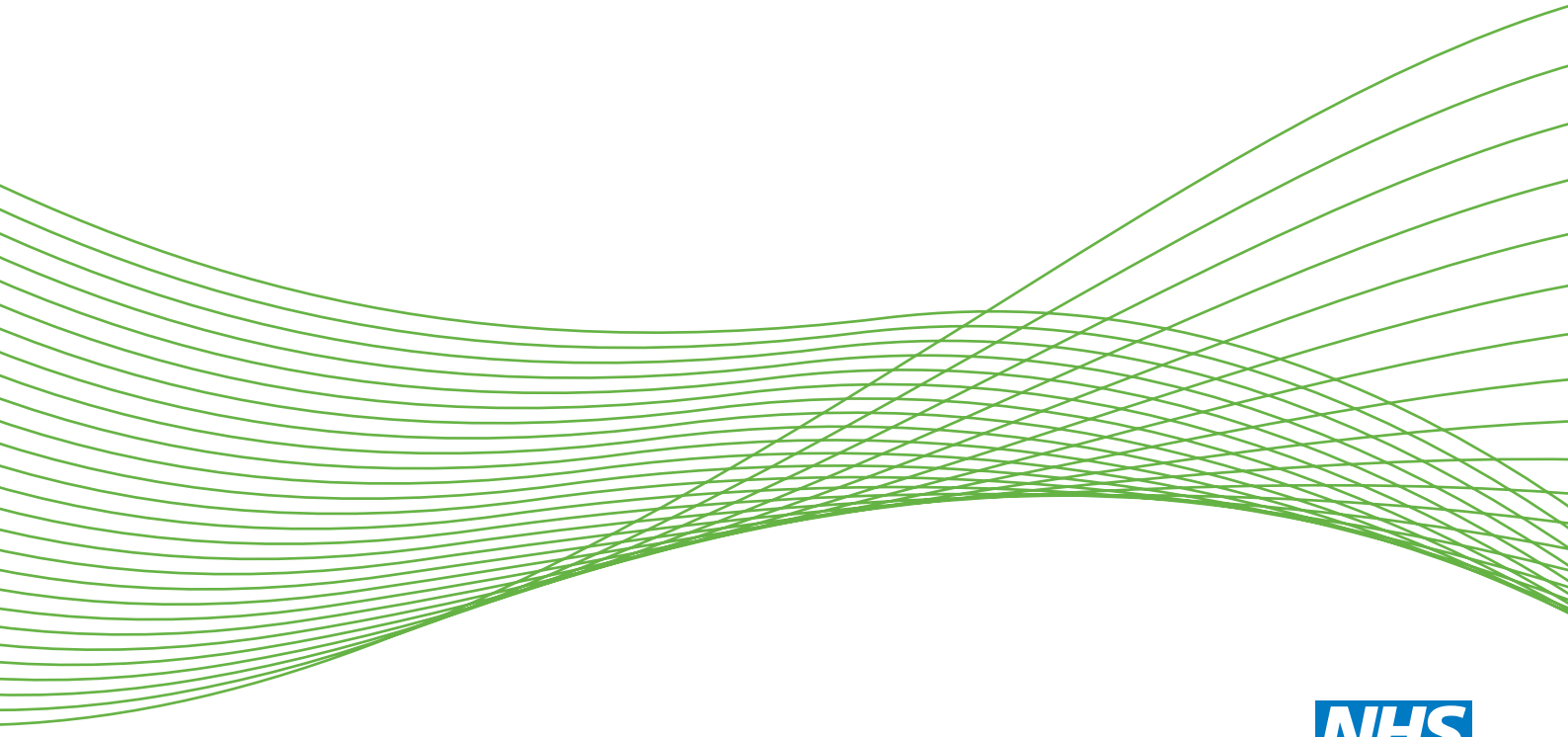

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Disclaimer: This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

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Abstract

Preventing blood-borne virus infection in people who inject drugs in the UK: systematic review, stakeholder interviews, psychosocial intervention development and feasibility randomised controlled trial

Gail Gilchrist,[1]* Davina Swan,[1] April Shaw,[2] Ada Keding,[3] Sarah Towers,[4] Noel Craine,[5] Alison Munro,[2] Elizabeth Hughes,[6] Steve Parrott,[3] Noreen Mdege,[3] John Strang,[1] Avril Taylor[2] and Judith Watson[3]

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Background: Opioid substitution therapy and needle exchanges have reduced blood-borne viruses (BBVs) among people who inject drugs (PWID). Some PWID continue to share injecting equipment.

Objectives: To develop an evidence-based psychosocial intervention to reduce BBV risk behaviours and increase transmission knowledge among PWID, and conduct a feasibility trial among PWID comparing the intervention with a control.

Design: A pragmatic, two-armed randomised controlled, open feasibility trial. Service users were Steering Group members and co-developed the intervention. Peer educators co-delivered the intervention in London.

Setting: NHS or third-sector drug treatment or needle exchanges in Glasgow, London, Wrexham and York, recruiting January and February 2016.

Participants: Current PWID, aged ≥ 18 years.

Interventions: A remote, web-based computer randomisation system allocated participants to a three-session, manualised, psychosocial, gender-specific group intervention delivered by trained facilitators and BBV transmission information booklet plus treatment as usual (TAU) (intervention), or information booklet plus TAU (control).

Main outcome measures: Recruitment, retention and follow-up rates measured feasibility. Feedback questionnaires, focus groups with participants who attended at least one intervention session and facilitators assessed the intervention's acceptability.

Results: A systematic review of what works to reduce BBV risk behaviours among PWID; in-depth interviews with PWID; and stakeholder and expert consultation informed the intervention. Sessions covered improving injecting technique and good vein care; planning for risky situations; and understanding BBV transmission. Fifty-six per cent (99/176) of eligible PWID were randomised: 52 to the intervention group and 47 to the control group. Only 24% (8/34) of male and 11% (2/18) of female participants attended all three intervention sessions. Overall, 50% (17/34) of men and 33% (6/18) of women randomised to the intervention group and 47% (14/30) of men and 53% (9/17) of women randomised to the control group were followed up 1 month post intervention. Variations were reported by location. The intervention was acceptable to both participants and facilitators. At 1 month post intervention, no increase in injecting in 'risky' sites (e.g. groin, neck) was reported by participants who attended at least one session. PWID who attended at least one session showed a trend towards greater reduction in injecting risk behaviours, a greater increase in withdrawal planning and were more confident about finding a vein. A mean cost of £58.17 per participant was calculated for those attending one session, £148.54 for those attending two sessions and £270.67 for those attending all three sessions, compared with £0.86 in the control group. Treatment costs across the centres vary as a result of the different levels of attendance, as total session costs are divided by attendees to obtain a cost per attendee. The economic analysis suggests that a cost-effectiveness study would be feasible given the response rates and completeness of data. However, we have identified aspects where the service use questionnaire could be abbreviated given the low numbers reported in several care domains. No adverse events were reported.

Conclusions: As only 19% of participants attended all three intervention sessions and 47% were followed up 1 month post intervention, a future definitive randomised controlled trial of the intervention is not feasible. Exposure to information on improving injecting techniques did not encourage riskier injecting practices or injecting frequency, and benefits were reported among attendees. The intervention has the potential to positively influence BBV prevention. Harm reduction services should ensure that the intervention content is routinely delivered to PWID to improve vein care and prevent BBVs.

Future work: The intervention did not meet the complex needs of some PWID, more tailoring may be needed to reach PWID who are more frequent injectors, who are homeless and female.

Limitations: Intervention delivery proved more feasible in London than other locations. Non-attendance at the York trial site substantially influenced the results.

Trial registration: Current Controlled Trials ISRCTN66453696 and PROSPERO 014:CRD42014012969.

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List of abbreviations

BBV	blood-borne virus
CBT	cognitive–behavioural therapy
CI	confidence interval
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CM	contingency management
CRN	Clinical Research Network
DMEC	Data Monitoring and Ethics Committee
DUIT	Drug Users Intervention Trial
EQ-5D	EuroQol-5 Dimensions
EQ-5D-5L	EuroQol-5 Dimensions, five-level version
GP	general practitioner
HBV	hepatitis B virus
HCV	hepatitis C virus
HIV	human immunodeficiency virus
HTA	Health Technology Assessment
IPED	image- and performance-enhancing drug
IT	information technology
ITT	intention to treat
MI	motivational interviewing
MMT	methadone maintenance treatment
MSM	men who have sex with men
NNEF	National Needle Exchange Forum
NICE	National Institute for Health and Care Excellence
NPS	novel psychoactive substance
NSP	needle and syringe programme/pharmacy
OST	opioid substitution therapy
PROTECT	PReventing blood-bOrne virus infecTion in people who injECT
PWID	people who inject drugs
QALY	quality-adjusted life-year
QR	quick response
R&D	research and development
RCT	randomised control trial
SD	standard deviation
SMD	standardised mean difference
SVR	sustained viral response
TALK	Timing is everything; Assert what you want; List your reasons for being safe; Keep to your bottom line
TAU	treatment as usual

Plain English summary

Opioid substitution therapy and needle exchanges have reduced blood-borne viruses (BBVs) among people who inject drugs (PWID). Interventions that provide PWID with skills, and strategies, to reduce risk behaviours are needed.

What we did

Interventions that reduced sharing of injecting equipment and unprotected sex, alongside the views of PWID and other key stakeholders, were used to develop a three-session, gender-specific group intervention to improve injecting techniques and BBV transmission knowledge, and to promote good vein care and strategies to avoid risky injecting and sex situations. A study was done to find out whether or not PWID would attend and take part in the intervention and what they thought about it. Ninety-nine PWID from harm reduction services in London, York, Glasgow and Wrexham were allocated at random to receive:

- the group intervention plus an information leaflet on BBV transmission ($n = 52$) or
- the information leaflet only ($n = 47$).

What we found

Twenty-four per cent of men and 11% of women attended all three sessions and 48% of men and 43% of women were interviewed 1 month after the intervention. The intervention was considered acceptable by both staff who delivered it and the people who attended it. PWID who attended at least one session tended to engage in fewer high-risk injecting behaviours, to plan more for withdrawal and to be more confident about finding a vein than those who did not attend any sessions.

Conclusions

More frequent injectors, and those who were homeless or female, were less likely to attend the intervention. Further development and testing is needed to meet the needs of all PWID.

Scientific summary

Background

Although opioid substitution therapy and needle exchanges are effective in reducing blood-borne virus (BBV) transmission among people who inject drugs (PWID), some PWID continue to share injection equipment, putting them at risk of acquiring or transmitting BBVs. Preventing BBV transmission among PWID remains a major public health concern. Psychosocial interventions (including cognitive–behavioural therapy, contingency management and skills training) may help reduce BBV transmission by informing PWID about transmission risks and providing them with the skills and strategies to reduce risky behaviours.

Objectives

The project contained six complementary phases to inform the development of an evidence-based psychosocial intervention to reduce BBV transmission risk behaviours among PWID and conduct a feasibility trial comparing the psychosocial intervention with an information leaflet. The main objectives were:

- to determine the efficacy of psychosocial interventions to reduce drug and sexual risk behaviours associated with BBV transmission and/or reinfection among PWID (phase I)
- to qualitatively explore PWID influences on BBV risk-taking behaviour and views on psychosocial interventions to address risks (phase II)
- to consult key stakeholders about the delivery and effectiveness of psychosocial interventions to reduce BBV transmission among PWID (phase III)
- to develop a psychosocial intervention to reduce BBV risk behaviours among PWID (phase IV)
- to determine the feasibility, and acceptability, of recruiting PWID to a trial comparing the intervention with control (phase V)
- to outline considerations for future research (phase VI).

Methods

Intervention design

The intervention was informed by findings from the following:

- A systematic review of the efficacy of psychosocial interventions compared with control interventions (interventions of lesser time or intensity) in reducing BBV transmission risk behaviours among PWID. Randomised control trials (RCTs) published from 2000 to May 2015 in MEDLINE, PsycINFO, Cumulative Index to Nursing and Allied Health Literature (CINAHL), the Cochrane Collaboration and ClinicalTrials.gov were included. A meta-analysis was performed, using a random-effects model.
- A scoping review of UK grey literature on the efficacy of psychosocial interventions, seeking sources not identified in the systematic review.
- A mapping exercise of psychosocial provision to address BBVs among PWID of all agencies responsible for alcohol and drug commissioning in the UK (i.e. alcohol and drug commissioners in England, alcohol and drug partnerships in Scotland, health- and social-care trusts in Northern Ireland and substance misuse area planning boards in Wales).
- In-depth interviews with a convenience sample of 60 PWID aged $\geq$ 18 years who had injected drugs (other than image- and performance-enhancing drugs) within the past 4 weeks from drug treatment and harm reduction centres, needle exchanges (including pharmacy and mobile), sexual health services and homeless hostels in Glasgow, London, Yorkshire and North Wales. Briefly, the interview covered

BBV transmission knowledge, perceptions of personal vulnerability to BBVs, influences on the sharing of injection equipment and sexual risk practices. Participants were also asked for suggestions on the psychosocial intervention being developed (content, format, venue, interventionist, duration, barriers/facilitators). Interviews were analysed using qualitative framework analysis.
- Telephone consultation with 40 key stakeholders with responsibility for delivering and commissioning services in BBV prevention in the UK identified any barriers to, or facilitators of, the delivery of psychosocial interventions in substance use treatment.

The manualised psychosocial intervention was co-developed by service users, service providers, policy-makers and academics and is available to download free of charge from the project website: www.kcl.ac.uk/ioppn/depts/addictions/research/drugs/bloodborneviruses.aspx. The COM-B ('capability', 'opportunity', 'motivation' and 'behaviour') theory of behaviour change was used to inform the intervention, that is, that capability (i.e. individual's psychological and physical capacity to engage in the activity concerned including having the necessary knowledge and skills), opportunity (i.e. factors outside the individual that make the behaviour possible or prompt it), and motivation interact to generate behaviour change. The Steering Group was responsible for final agreement of manual content. This group was supported by two development groups – an expert group (comprising practitioners, academics, policy-makers) and a service user group with lived experience of injecting drug use.

Feasibility trial

Design, participants and setting

A pragmatic, two-armed randomised controlled, open feasibility trial with equal randomisation delivered across four UK sites (Glasgow, London, York and Wrexham) was conducted among PWID in the last month (other than primary performance and image-enhancing drugs), who were aged ≥ 18 years and were attending NHS or third-sector community addiction, harm reduction clinics or needle exchange programmes.

Randomisation

To maintain allocation concealment, randomisation sequence generation was undertaken by an independent statistician at the University of York, and treatment allocation was performed by a secure and remote telephone randomisation service based there. Participants were randomised by block randomisation, ensuring balanced allocation within each location, service type and gender.

Interventions

Participants were randomised (1 : 1) to receive either:

- the intervention arm: a gender-specific psychosocial group (brief) intervention involving three 1-hour weekly sessions facilitated by trained drugs workers (and co-facilitated by a gender-matched peer educator in London), an information leaflet on reducing BBV transmission and treatment as usual (TAU) from the service from which they are recruited; or
- the control arm: an information leaflet on reducing BBV transmission and TAU from the service from which they are recruited.

Main outcome measures

Feasibility was measured by recruitment rates, retention in treatment and follow-up rates as well as the extent to which health economic data were completed with the required information, in order to inform the design and implementation of an economic evaluation of a full trial.

Secondary outcome measures

Differences in the number of injection risk events, BBV transmission knowledge, withdrawal planning, self-efficacy around finding a vein, not sharing equipment, safer sex, cleaning injection equipment and talking about safe drug use in past month were assessed at baseline, end of the intervention and 1 month post intervention (or equivalent time period for those in the control arm) using intention-to-treat analysis.

The economic analysis included intervention costing, calculation of NHS and wider social costs per patient, EuroQol-5 Dimensions, five-level version, results and assessment of the pilot questionnaires in preparation for a full, sufficiently powered RCT.

Acceptability

Intervention facilitators and participants completed feedback forms following each session and participated in focus group discussions to establish the acceptability of the intervention. Focus groups were analysed using thematic analysis.

Results

Intervention design

Thirty-two and 24 RCTS were included in the systematic review and meta-analysis, respectively. Psychosocial interventions appear to reduce the sharing of needles/syringes compared with education/information [standardised mean difference (SMD) –0.52, 95% confidence interval (CI) –1.02 to –0.03, $I^2 = 10\%$; $p = 0.04$] or human immunodeficiency virus infection testing/counselling (SMD –0.24, 95% CI –0.44 to –0.03, $I^2 = 0\%$; $p = 0.02$); however, moderate to high heterogeneity was reported for the sharing of other injecting equipment (SMD –0.24, 95% CI –0.42 to –0.06, $I^2 = 0\%$; $p < 0.01$) and unprotected sex (SMD –0.44, 95% CI –0.86 to –0.01, $I^2 = 79\%$; $p = 0.04$) compared with interventions of a lesser time/intensity. The main functions described in these interventions were education, training (imparting skills), enablement (increasing means/reducing barriers), incentivisation and persuasion (using communication to induce positive or negative feelings or stimulate action). Effective interventions were sourced and their content reviewed by the intervention development groups.

The scoping review of the UK grey literature, mapping exercise with drug and alcohol commissioners and the consultation with key stakeholders confirmed that no current intervention met the needs identified by PWID.

Analysis of 60 qualitative interviews with current PWID found that a range and combination of individual, situational and structural factors contributed to BBV risk behaviours in this population. Relationships and social networks are identified as crucial influences on risk behaviours, whereas access to needle exchanges and safe injecting environments is vital for maintaining safer injecting behaviours. However, drug states, such as withdrawal and craving, and the trajectory of drug use generate priorities of more immediate concern to PWID than BBVs. Furthermore, perceptions of BBV transmission risks change over time as knowledge is gained, and the interviews illustrate that there remains a great deal of uncertainty around BBV acquisition. Participants described managing risk situations by planning ahead and being more vigilant regarding hygiene practices when using with others. Although risk management strategies were not necessarily intentionally BBV-protective, they were employed to manage other risks such as overdose and soft-tissue infections. For many of those interviewed, any intervention aimed at reducing risk behaviours should include behavioural and skills components, such as health advice, hygiene promotion and injecting skills, as well as information about BBV transmission. Interventions that are delivered locally by informed trainers and are cognisant of the challenges PWID encounter in attending were considered important.

Based on these findings, the need to address symbiotic goals of PWID and develop strategies to avoid risk situations (e.g. withdrawal) and lack of preparedness were central to the intervention aims. Three weekly sessions of 1 hour were developed: improving injecting technique and good vein care (session 1); planning for risky situations (session 2); and understanding BBV transmission (session 3). The intervention was intended to be delivered to groups of eight participants of the same gender.

Feasibility trial

Participants were predominantly male, in their late thirties/early forties and had been injecting for between 14 and 22 years on average. Baseline characteristics were comparable between randomised treatment groups for males. Potential imbalances were observed in the smaller group of women (e.g. with a greater number of heroin users and homeless women in the intervention arm).

Primary outcomes

Fifty-six per cent (99/176) of eligible PWID were randomised into the feasibility trial: 52 were allocated to the intervention group and 47 to the control group. Only 24% (8/34) of male [ranging from zero men in York to 44% (4/9) in London] and 11% (2/18) of female participants (both from London) attended all three intervention sessions. More participants attended at least one intervention session in London (10/16, 63%) and Wrexham (7/13, 54%) than in Glasgow (3/12, 25%) and York (0/11). Compared with participants who attended at least one intervention session ($n = 20$), participants who did not attend any sessions ($n = 32$) were more likely to be homeless (56% vs. 25%; $p = 0.044$) and injected drugs for a greater number of days in the last month (median 25 vs. 6.5 days; $p = 0.019$). Follow-up at a minimum of one time point was also highest in London (83%) and Wrexham (63%), and significantly lower in Glasgow (55%) and York (43%), which may in part be linked to factors associated with higher homelessness and injecting frequencies in Glasgow and York. Follow-up attendance was associated with fewer days of injecting in the last month (median 14 vs. 27 days; $p = 0.030$) and fewer injections of cocaine (13% vs. 30%; $p = 0.063$). Women were more likely to attend follow-up in London and York than in Glasgow and Wrexham.

A mean cost per participant was calculated for attendance at one (£58.17), two (£148.54) and three (£270.67) sessions, and compared with the mean cost per participant in the control group (£0.86). Treatment costs across the centres vary as a result of the different levels of attendance, as total session costs are divided by attendees to obtain a cost per attendee.

The content of the intervention was considered acceptable by both facilitators and participants. Intervention participants welcomed the opportunity to talk about topics that are not normally discussed at harm reduction services, and the amount and variety of information provided. No adverse events were recorded as a result of participating in the feasibility trial. At 1 month post intervention, those who attended at least one intervention session reported no increase in injecting in more 'risky' sites (e.g. groin, neck) and no increase in the number of days in the past 28 days on which drugs were injected was observed.

Secondary outcomes

Improved (fewer) injecting risk practices, improved self-efficacy, better hepatitis C and hepatitis B transmission knowledge and greater use of withdrawal prevention techniques were reported in the intervention than in the control group. This was true at both follow-up time points and both analyses for randomised groups and groups based on attendance at the intervention. The economic analysis suggests that a cost-effectiveness study would be feasible given the response rates and completeness of data. However, we have identified aspects where the service use questionnaire could be abbreviated given the low numbers reported in several care domains.

Conclusions

Criteria were not predetermined regarding the feasibility parameters required for progression to a future definitive RCT of the psychosocial intervention. The recruitment (56%), intervention attendance (19% attended all three sessions) and 1 month post-intervention follow-up (47%) rates suggest that a future RCT of the intervention is not justifiable. Intervention delivery proved more feasible in London than at other sites. Potential reasons for differences in attendance and compliance across sites include payment in cash, reimbursement of travel and intervention co-delivery by peer educators in London, and higher homelessness and injecting frequencies in Glasgow and York. The findings suggest that the intervention did not meet the complex needs of some PWID, particularly in York and Glasgow. The intervention may

need to be more tailored to reach PWID who are more frequent injectors, who are homeless and who are female. Further development and testing of the intervention is warranted among other groups of PWID.

Although the findings suggest that the PReventing blood-bOrne virus infecTion in people who injECT (PROTECT) intervention has the potential to positively influence some PWID BBV risk behaviour, non-attendance at the intervention at the York trial site substantially influenced the results. Despite this, considerable and valuable insights have been obtained, showing the need for a greater embedding of BBV risk reduction in the work of substance misuse services and highlights an urgent unmet health need for PWID.

The study resulted in the co-production of an evidence-based brief psychosocial intervention that was acceptable to both facilitators and participants. Exposure to information on improving injecting techniques did not encourage riskier injecting practices or injecting frequency, and benefits were reported among those who attended at least one intervention session.

Implications for policy and practice

Although it was assumed by many policy-makers and practitioners that harm reduction information about BBV transmission is part of usual conversations with key workers in drug services and practitioners in needle exchange and specialist services, PWID confirmed this does not always happen. This may be a result of the deskilling of the substance use workforce as a result of cuts in service provision and/or the limited opportunity for harm reduction to be delivered in pharmacy needle exchanges. Alternatively, the recent drug policy shift from harm reduction to recovery may mean that the needs of those who are not engaged in treatment are not being addressed. Harm reduction services should ensure that the intervention content is routinely delivered to PWID to improve vein care and prevent BBV. The provision of drug consumption or injecting rooms should be considered in the UK.

Future research

- There remains a need to understand the needs of women who inject drugs and new injectors (especially those who were injecting novel psychoactive substances), to ensure that key BBV transmission messages are appropriately targeted. As it proved difficult to engage these groups of PWID in the research, we recommend that ethnographic research is undertaken to better understand the typology and potentially changing risks of contemporary drug use in the UK by exploring the specific concerns and barriers from the lived experience of PWID in terms of accessing help, advice and treatment, as well as what mode of delivery would work best for these groups.
- We propose to adapt the intervention to meet the needs of chemsex (the use of psychoactive substances either immediately before or during sex) injectors and test the intervention in a future feasibility trial.
- A future quasi-experimental trial of worker training is proposed to test the individual delivery of intervention content delivered at needle exchanges and tailored to individual PWID needs.

Trial registration

This trial is registered as ISRCTN66453696 and PROSPERO 014:CRD42014012969.

Funding

Funding for this study was provided by the Health Technology Assessment programme of the National Institute for Health Research.

Chapter 1 Introduction and background

This report presents the findings from a Health Technology Assessment (HTA)-funded programme of work to develop an evidence-based psychosocial intervention aimed at reducing blood-borne virus (BBV) transmission risk behaviours and increasing BBV transmission knowledge among people who inject drugs (PWID), and explore the feasibility of recruiting PWID to a trial comparing the intervention with control.

This first chapter provides the background and rationale for conducting this research, and describes the research objectives. The remainder of the report is divided into the following chapters representing the phases of the study: *Chapter 2, Determining the evidence base: a systematic review of psychosocial interventions to reduce drug and sexual blood-borne virus transmission risk behaviours among people who inject drugs*; *Chapter 3, Understanding people who inject drugs' influences on behaviour and views on psychosocial interventions*; *Chapter 4, Consultation with key stakeholders on the delivery and effectiveness of psychosocial interventions to reduce blood-borne virus transmission risks among people who inject drugs*; *Chapter 5, Intervention development*; *Chapter 6, Feasibility trial*; *Chapter 7, Protocol changes*; *Chapter 8, Implications and dissemination of findings*; and *Chapter 9, Discussion and conclusions*.

Background

Prevalence

Preventing the transmission of BBVs among PWID is a major public health issue. Hepatitis C virus (HCV) is the most prevalent BBV among PWID, with 56% in Scotland (61% among needle exchange attenders),[1] approximately 50% in England and Wales and 23% in Northern Ireland being HCV positive.[2] The rate of human immunodeficiency virus (HIV) and hepatitis B virus (HBV) infection among PWID in the UK is low, ranging from 0% in Wales and Northern Ireland to 1.4% in England for HIV and from 6% in Northern Ireland to 18% in England for HBV.[2]

Risk factors for blood-borne viruses

Hepatitis B virus and HIV are transmitted via blood or body fluids. Sharing injecting equipment poses the greatest risk of HCV transmission among PWID.[3] Although there is no increased risk of HCV transmission in a long-term heterosexual relationship, the risk of transmission increases with multiple sexual partners and among women who are infected with HIV or other sexually transmitted diseases.[4] Sex trading, younger age, cocaine injecting, depression, requiring help injecting, having unsafe sex with a regular partner and having an HIV-positive sexual partner are associated with HIV infection among PWID.[5–9] Risk factors for HCV among PWID include sharing needles and other injection equipment,[10] longer duration of injecting career,[11] increased frequency of injection,[11,12] requiring help injecting,[13] being female[14] and a history of imprisonment.[11,12] Research suggests that a gap in HCV transmission knowledge among PWID is contributing to the high prevalence.[15–17] Higher HIV and HCV infection rates have been reported among people with mental health disorders.[6,18,19] PWID with mental health disorders report greater sharing of injection equipment, lower rates of condom use, multiple sexual partners, sex trading and having sex with PWID.[5,6,20,21] Depressive symptoms are also associated with drug[21–23] and sexual risk behaviours.[23–25] The prevalence of intimate partner violence is high among people who use drugs.[23,26,27] Women who are survivors of intimate partner violence are less likely to use condoms and more likely to share needles, to have multiple sexual partners and to trade sex,[26,28] all of which increase susceptibility to BBV transmission.[28] BBV transmission risk behaviours should be understood in the context of PWIDs' sexual and drug-using relationships.[29] Some females who inject drugs share injecting equipment with their partners for trust and intimacy, perceiving less risk in such relationships.[30]

Current policy and practice

Policy and practice with regard to public health generally, and the management of BBVs specifically, are driven by different policies and agendas in the four nations of the UK, although the overarching recovery

agenda has dominated drug policy for a number of years.[31] In Scotland, *The Road to Recovery: A New Approach to Tackling Scotland's Drug Problem* was published in 2008,[32] and recovery became a central tenet of UK policy in 2010.[33] In a corresponding publication, *Putting Full Recovery First: The Recovery Roadmap*,[34] the authors outlined the roadmap for the ways in which recovery would be fostered in communities in England and Wales, including the creation and utilisation of 'recovery champions'.[34] Although the rhetoric of drug policy may have altered in the UK over the last 8 years from that of harm reduction to that of recovery, the extent to which the realities of drug treatment provision (including prevention) have changed remains largely unknown. Indeed, as commented by Duke 'at the level of practice, it will be interesting to examine how day-to-day practice develops and changes with drug users under the new framework'.[31]

With specific regard to the management and prevention of BBV infections, and HCV in particular, all four nations published their first action plans for the prevention and management of HCV around 10 years ago, and have had varying degrees of success. Very broadly, the action plans in all four countries set out key objectives that would need to be achieved in the realms of HCV prevention and treatment, with particular foci on PWID, in order to tackle the burden of HCV on individuals and on public health. Common objectives of the plans included developing a better evidence base for establishing prevalence figures through better monitoring and surveillance systems; increasing information on the disease; increasing the number of persons being tested and, therefore, diagnosed with HCV (as high numbers of people with the disease are undiagnosed); and increasing the number of people entering into treatment for HCV infection. It might be argued that harm reduction, rather than recovery, has been at the heart of the HCV action plans in the sense that other objectives of the plans involved not only providing more needle exchange outlets (including outreach distribution, as in Northern Ireland), but also increasing the number of needles, syringes and other injecting equipment that PWID can access.

Harm reduction approaches recognise that there is a need to reduce the risks associated with drug misuse (including injecting). This approach is facilitated in the UK by the provision of opioid substitution therapy (OST; e.g. with methadone or buprenorphine), key worker support, needle and syringe programmes that offer PWID free injecting equipment (and equipment), and information to reduce sharing behaviour and, therefore, the transmission of BBV, as well as support for stopping injecting. The use of psychosocial interventions to reduce risk behaviours among PWID is not routinely practised in the UK. Harm reduction messages are mainly provided by key workers, drug treatment staff and needle exchange staff, peer educators and BBV nurses.

Harm reduction approaches

Although advances have been made in treatment and pre-exposure prophylaxis for HIV infections and a vaccine is available for HBV, there is currently no vaccine available to prevent HCV infection. There is evidence to suggest that OST and needle exchanges[35–38] are effective in reducing HIV and HCV infection prevalence among PWID. However, recent research stresses that, although increasing the coverage of these interventions can reduce HCV prevalence among PWID, these reductions are modest and psychosocial interventions are required to further decrease HCV prevalence[36] by informing PWID about transmission risks and motivating them to reduce risky sexual and drug-taking behaviours. Although OST has been successful in reducing BBV, some PWID continue to inject and, therefore, may be at risk of acquiring or transmitting BBV. A meta-analysis found that the incidence of HCV reinfection following successful treatment for HCV among PWID was 2.4 per 100 person-years and 6.4 per 100 person-years among those who reported injecting drug use post sustained viral response (SVR).[39] A recent retrospective record linkage study in Scotland reported similar reinfection rates, 1.7 per 100 person-years among PWID and 5.7 per 100 person-years among those who had been admitted to hospital for injection-related causes.[40] Although there is a low risk of reinfection following successful treatment for HCV, a large cohort study in Scotland found that 10.6% of 1170 PWID who had achieved a SVR following treatment for HCV had been hospitalised for, or had died from, an injection-related cause in the first 3 years post SVR.[41] Moreover, findings highlight a rise in injection-related hospitalisation or death with time with increasing year of SVR attainment. In addition, women were more likely to have multiple injection-related

hospitalisations post SVR. These findings highlight that 'harm reduction interventions aimed at reducing the risk of HCV transmission should also continue to be promoted once treatment ceases'.[41]

Recent systematic reviews and meta-analyses of psychosocial interventions to reduce HIV and HCV risk behaviours among PWID have reported modest effects[42–44] and conclude that 'limited progress [has been made] in developing more effective interventions'[43] and that 'multi-component interventions are required'.[44] A recent Cochrane review on *Psychosocial Interventions for Reducing Injection and Sexual Risk Behaviour for Preventing HIV in Drug Users*[43] reported minimal differences identified between multisession psychosocial interventions and standard educational interventions for both injection and sexual risk behaviour. However, there were large pre–post changes for both groups, suggesting that both were effective in reducing risk behaviours. They also found evidence of benefit for multisession psychosocial interventions when compared with minimal controls. Moreover, people in formal treatment were more likely to respond to multisession psychosocial interventions, and single-gender groups were associated with greater benefit.

Harm reduction approaches mostly address risk factors associated with the sharing of injecting equipment and unprotected sex. Research has highlighted that PWID sometimes have different priorities, such as avoiding injecting-related scars or marks and maintaining venous access, which results in the use of sterile injecting equipment.[45] PWID have also stressed a need for 'non-judgemental venous care and access advice'.[45] PWID who plan ahead to ensure that they have access to sterile injecting equipment are more likely to store clean needles; avoid sharing needles and syringes and other injecting equipment; and provide clean needles to sex partners.[46] Therefore, it is vital that harm reduction interventions include protective practices and strategies to avoid and plan for injecting risk situations, such as withdrawal and lack of preparedness.[47,48]

Research has demonstrated that 'symbiotic' goals that are not directly focused on BBV risk reduction are important to PWID, such as avoiding withdrawal, maintaining social support, venous access and care, and image management,[45,49] and may help them to 'stay safe' and avoid BBV.[50] Strategies described to avoid withdrawal include 'back up methods, resorting to credit, collaborating with others, regimenting drug intake, balancing drug intake with money available, and/or resorting to treatment'.[47] PWID who have not become infected with HCV report protective practices, including principles about normative injecting practices; preparedness and contingency planning to avoid disruption to risk management; and the capacity for flexibility to adapt to changes in normative practices or intentions.[51]

Rationale

Research suggests that, although rates of HIV and HBV are low and stable among PWID in the UK, the prevalence of HCV remains high. There remain opportunities for BBV prevention among hard-to-reach groups who may not be engaged in drug treatment, such as new injectors,[52] women, black and minority ethnic PWID, those who are homeless[53] or those who are involved in prostitution.[6,20] Public Health England's *Shooting Up: Infections Among People Who Inject Drugs in the United Kingdom 2012* report[54] highlighted that, although needle and syringe sharing is lower than a decade ago, around one in seven PWID continue to share needles and syringes, and those who inject amphetamines and amphetamine-type drugs (e.g. mephedrone) are at increased risk of infection.[55] Therefore, the need to address the risks and increase knowledge to reduce infection and transmission among PWID remains priority. This research was a response to the commissioned call from the HTA programme.

Research objectives

The PReventing blood-bOrne virus infecTion in people who injECT (PROTECT) project contained six complementary phases to inform the development of an evidence-based psychosocial intervention to reduce BBV transmission risk behaviours and increase BBV transmission knowledge among PWID, and

conduct a feasibility trial, comparing the psychosocial intervention to an information leaflet, to inform the future parameters of a large multisite randomised control trial (RCT).

The main objectives were as follows.

Phase I: determining the evidence base

- To update recent systematic reviews of the efficacy of psychosocial interventions to reduce drug and sexual risk behaviours associated with HIV, HCV and HBV transmission and/or reinfection.
- To conduct a brief scoping exercise of the UK grey literature to identify ongoing research, information about current services relevant to preventing the spread of BBV and reducing risk behaviours among PWID.
- To survey all UK-commissioning drug partnerships (previously Drug Action Teams) for information on psychosocial interventions available and their effectiveness in reducing BBV risk behaviours among PWID.

Phase II: understanding people who inject drugs' influences on behaviour and views on psychosocial interventions

- To elicit why PWID engage in risk behaviours.
- To determine the type of psychosocial intervention acceptable and required by PWID to reduce BBV risk behaviours.

Phase III: key stakeholders' views on the delivery and effectiveness of psychosocial interventions

- To ascertain key local and national stakeholders' views on the delivery and effectiveness of psychosocial interventions.

Phase IV: intervention development

- To source and review content of all effective psychosocial interventions to reduce BBV risk behaviours among PWID.
- To develop a psychosocial intervention to reduce BBV risk behaviours among PWID.

Phase V: feasibility randomised controlled trial

- To demonstrate the feasibility of recruiting PWID to a group psychosocial intervention and delivering the intervention across four regions in the UK.
- To test the feasibility of training staff from existing services to deliver the developed intervention.
- To evaluate the level of intervention retention by participants randomised to the developed intervention.
- To explore staff and PWID views, acceptability and experiences of the intervention and the study process.
- To explore treatment effectiveness through quantitative outcome data.
- To explore the feasibility of collecting data for a large, definite RCT.
- To assess the feasibility of conducting a future large-scale effectiveness RCT.

Phase VI: considerations for future research

- To recommend specific interventions which could be tested in future research.
- To outline considerations for future research.

Chapter 2 Determining the evidence base: a systematic review of psychosocial interventions to reduce drug and sexual blood-borne virus transmission risk behaviours among people who inject drugs

Objectives

To identify effective psychosocial interventions to reduce drug and sexual BBV transmission risk behaviours among PWID by systematically reviewing the evidence from RCTs and a scoping review of the grey literature; and mapping drug and alcohol partnerships' provision of psychosocial interventions throughout the UK.

Review questions

To determine the efficacy of psychosocial interventions to:

- reduce BBV injection risk behaviours among PWID
- reduce BBV sexual risk behaviours among PWID
- increase BBV transmission knowledge among PWID.

Introduction

Several systematic reviews and meta-analyses of psychosocial interventions to reduce HIV and HCV risk behaviours among drug users have reported modest effects.[42–44,56] More recently, MacArthur *et al.*[37] published a review of reviews conducted during 2000–11 to determine the effectiveness of harm reduction interventions (including education, information and counselling interventions) in relation to HIV transmission, HCV transmission and injecting risk behaviour. The authors found that, although harm reduction interventions, especially OST and needle exchange programmes, can reduce injecting risk behaviours, the review or reviews found little evidence that such interventions prevented HCV transmission among PWID. In a systematic review and meta-analysis, Meader *et al.*[56] found that multisession psychosocial interventions had modest additional benefits compared with educational interventions and large positive effects compared with minimal interventions on the HIV sex risk behaviours by people who use drugs. This review included RCTs and quasi-experimental studies published during 1998–2012. Sacks-Davis *et al.*[44] conducted a systematic review of behavioural interventions (peer-intervention training and counselling interventions) for preventing HCV among PWID and included controlled trials until 2010. Authors concluded that it was 'unlikely that behavioural interventions can have a considerable effect on HCV transmission' (p. 176),[44] but suggested that multicomponent interventions were required to address HCV transmission. Hagan *et al.*[42] conducted a systematic review with meta-analysis of published and unpublished studies from 2000 to April 2010 of interventions (including behavioural and multicomponent interventions) to reduce unsafe drug injection and HCV seroconversion among PWID. This review found that combined substance use treatment and support for safe injection were the most effective interventions to reduce HCV seroconversion. Meader *et al.*[43] conducted a Cochrane review and reported minimal differences between multisession psychosocial interventions and standard educational interventions for preventing HIV infection among people who use drugs, for both injection and sexual risk behaviours. Randomised and quasi-randomised trials published until 2006 were included.

People who inject drugs are more likely to have BBVs than people who use drugs but do not inject.[57,58] As well as the elevated risks from sharing injecting equipment, PWID (especially polysubstance injectors), report high-risk sexual behaviours including sex trading, multiple sex partners and sex without a condom[20,57,59,60] than people who use drugs but do not inject. Despite this, there has been no recent systematic review focusing on the efficacy of psychosocial interventions to reduce injecting and sexual risk behaviours among samples of PWID, rather than people who use drugs, regardless of their injecting status. Thus, this review aims to address this evidence gap.

Aim

The aim of the present systematic review and meta-analysis was to determine the efficacy of psychosocial interventions in reducing injecting and sexual risk behaviours compared with usual care, education or information, HIV infection testing and counselling, or 'an intervention of lesser time or intensity'[44] (with and without OST). Psychosocial interventions including 'brief interventions, motivational interviewing (MI), cognitive behavioural therapy, contingency management (CM), graded exposure therapy and self-help groups' were defined as interventions that aimed 'to change behaviour through the exchange of information, typically delivered by a clinician or educator'.[61]

Methods

The review was registered with International prospective register of systematic reviews (PROSPERO 2014: CRD42014012969). A systematic review of RCTs was conducted and a meta-analysis performed, using a random-effects model. This systematic review and meta-analysis were undertaken in accordance with the principles recommended by the *Cochrane Handbook for Systematic Reviews of Interventions*[62] and the Centre for Reviews and Dissemination guidance for undertaking systematic reviews.[63] The reporting procedures followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[64] EndNote (X8; Thomson Reuters, CA, USA) was used for reference management and Microsoft Excel (2010; Microsoft Corporation, Redmond, WA, USA) was used for recording decisions.

The PICO (patient, intervention, comparison, outcomes) model was used to develop the search strategy, and is described below.

Participants/population

People who inject drugs aged ≥ 18 years. Studies of people who use drugs were included if the results were presented separately for PWID.

Interventions

Psychosocial interventions [e.g. cognitive–behavioural therapy (CBT), MI, CM, counselling, harm reduction, skills training] delivered to individuals, groups, couples or a mix of delivery methods.

Comparators/control

Usual care, education or information, HIV infection testing and counselling, or interventions of lesser frequency or intensity than the intervention (with or without OST).

Outcomes

- Any injecting risk behaviour (including sharing of needle/syringes or other injecting equipment), and frequency of injecting, reported separately or as an aggregated outcome.
- Any sexual risk behaviour (including unprotected sex or number of sexual partners), reported separately or as an aggregated outcome.

Search strategy

The following databases were searched for relevant RCTs published from 2000 until 26 May 2015: MEDLINE, PsycINFO, Cumulative Index to Nursing and Allied Health Literature (CINAHL) and the Cochrane Collaboration, with an update search in MEDLINE to 9 December 2016. Searches were restricted to trials from 2000 onwards to ensure that up-to-date information about BBV transmission was included.

Additionally, ClinicalTrials.gov databases were searched to identify additional publications, including any ongoing trials in this area and related publications. These databases were searched using the search strategy with keywords described in *Table 1*. In addition, forward and backward searching was conducted and the reference lists of recent relevant reviews and review of reviews[37,42–44,56,61] were cross-checked to verify that all relevant trials had been included in the current systematic review.

TABLE 1 Description of search terms

Database	Keywords
MEDLINE	Key words for population: people who inject; people who inject drugs; PWID; substance abuse; intravenous substance abuse; injecting drug use; intravenous drug use; IDU; injection drug use; injector; IVDU; intravenous drug abuse; injecting drug abuse; injection drug abuse
	Key words for BBV: blood-borne pathogens, BBV, blood-borne virus, blood-borne bacteria, HIV infection, human immunodeficiency virus, HIV, hepatitis C, hepatitis C virus, hep c, HCV, hepacivirus, hepatitis B, hepatitis B virus, HBV
	Key words for intervention: psychosocial *adjacent to* intervention, prevention, support, rehabilitation, treatment, or therapy; psychological *adjacent to* therapy, treatment, or intervention; CBT; cognitive *adjacent to* therapy, behaviour therapy, intervention, or remediation; behaviour *adjacent to* therapy, control, modification, change, or intervention; psychotherapy; counseling; social support; motivational *adjacent to* intervention, interview, or support; brief advice; brief intervention; family *adjacent to* therapy, intervention, or counselling, couple *adjacent to* therapy, intervention, or counselling; peer *adjacent to* therapy, intervention, or counselling; talking therapy; contingency management; psychoeducation; route transition; network therapy
	Key words for outcomes: risk *adjacent to* taking, reduction, protection, minimisation, prevention, decrease, avoidance, or behaviour; harm *adjacent to* reduction, protection, minimisation, prevention, decrease, avoidance; unsafe injecting; needle sharing; intravenous injection; injecting *adjacent to* equipment, paraphernalia, or risk; sexual risk behaviour; unsafe sex; multiple sexual partners; multiple casual partners; one time sex encounter; sex holiday; casual sex; casual partner; non-regular sex partner; unprotected intercourse; unprotected sex; condomless *adjacent to* sex or intercourse; condom free *adjacent to* sex or intercourse; barebacking; bareback sex; bug chase; anal intercourse; anal sex; condom; condom use; safe sex; health *adjacent to* knowledge, attitudes, or practice, or behaviour; transmission knowledge or understanding
PsycINFO	Key words for population: people who inject; people who inject drugs; PWID; substance abuse; intravenous substance abuse; injecting drug use; intravenous drug use; IDU; injection drug use; injector; IVDU; intravenous drug abuse; injecting drug abuse; injection drug abuse
	Key words for BBV: blood-borne pathogens, BBV, blood-borne virus, blood-borne bacteria, HIV infection, human immunodeficiency virus, HIV, hepatitis C, hepatitis C virus, hep c, HCV, hepacivirus, hepatitis B, hepatitis B virus, HBV
	Key words for intervention: psychosocial *adjacent to* intervention, prevention, support, rehabilitation, treatment, or therapy; psychological *adjacent to* therapy, treatment, or intervention; CBT; cognitive *adjacent to* therapy, behaviour therapy, intervention, or remediation; behaviour *adjacent to* therapy, control, modification, change, or intervention; psychotherapy; counseling; social support; motivational *adjacent to* intervention, interview, or support; brief advice; brief intervention; family *adjacent to* therapy, intervention, or counselling, couple *adjacent to* therapy, intervention, or counselling; peer *adjacent to* therapy, intervention, or counselling; talking therapy; contingency management; psychoeducation; route transition; network therapy
	Key words for outcomes: risk *adjacent to* taking, reduction, protection, minimisation, prevention, decrease, avoidance, or behaviour; harm *adjacent to* reduction, protection, minimisation, prevention, decrease, avoidance; unsafe injecting; needle sharing; intravenous injection; injecting *adjacent to*

continued

TABLE 1 Description of search terms (*continued*)

Database	Keywords
	equipment, paraphernalia, or risk; sexual risk behaviour; unsafe sex; multiple sexual partners; multiple casual partners; one time sex encounter; sex holiday; casual sex; casual partner; non-regular sex partner; unprotected intercourse; unprotected sex; condomless *adjacent to* sex or intercourse; condom free *adjacent to* sex or intercourse; barebacking; bareback sex; bug chase; anal intercourse; anal sex; condom; condom use; safe sex; health *adjacent to* knowledge, attitudes, or practice, or behaviour; transmission knowledge or understanding
CINAHL	Key words for population: people who inject; people who inject drugs; PWID; substance abuse; intravenous substance abuse; injecting drug use; intravenous drug use; IDU; injection drug use; injector; IVDU; intravenous drug abuse; injecting drug abuse; injection drug abuse
	Key words for BBV: blood-borne pathogens, BBV , blood-borne virus, blood-borne bacteria, HIV infection, human immunodeficiency virus, HIV, hepatitis C, hepatitis C virus, hep c, HCV, hepacivirus, hepatitis B, hepatitis B virus, HBV
	Key words for intervention: psychosocial *adjacent to* intervention, prevention, support, rehabilitation, treatment, or therapy; psychological *adjacent to* therapy, treatment, or intervention; CBT; cognitive *adjacent to* therapy, behaviour therapy, intervention, or remediation; behaviour *adjacent to* therapy, control, modification, change, or intervention; psychotherapy; counseling; social support; skills training; motivational *adjacent to* intervention, interview, or support; brief advice; brief intervention; family *adjacent to* therapy, intervention, or counselling, couple *adjacent to* therapy, intervention, or counselling; peer *adjacent to* therapy, intervention, or counselling; talking therapy; contingency management; psychoeducation; route transition; network therapy
	Key words for outcomes: risk *adjacent to* taking, reduction, protection, minimisation, prevention, decrease, avoidance, or behaviour; harm *adjacent to* reduction, protection, minimisation, prevention, decrease, avoidance; unsafe injecting; needle sharing; intravenous injection; injecting *adjacent to* equipment, paraphernalia, or risk; sexual risk behaviour; unsafe sex; multiple sexual partners; multiple casual partners; one time sex encounter; sex holiday; casual sex; casual partner; non-regular sex partner; unprotected intercourse; unprotected sex; condomless *adjacent to* sex or intercourse; condom free *adjacent to* sex or intercourse; barebacking; bareback sex; bug chase; anal intercourse; anal sex; condom; condom use; safe sex; health *adjacent to* knowledge, attitudes, or practice, or behaviour; transmission knowledge or understanding
Cochrane Collaboration	Key words for population: people who inject; people who inject drugs; PWID; substance abuse; intravenous substance abuse; injecting drug use; intravenous drug use; IDU; injection drug use; injector; IVDU; intravenous drug abuse; injecting drug abuse; injection drug abuse
	Key words for BBV: blood-borne pathogens, BBV, blood-borne virus, blood-borne bacteria, HIV infection, human immunodeficiency virus, HIV, hepatitis C, hepatitis C virus, hep c, HCV, hepacivirus, hepatitis B, hepatitis B virus, HBV
	Key words for intervention: psychosocial *adjacent to* intervention, prevention, support, rehabilitation, treatment, or therapy; psychological *adjacent to* therapy, treatment, or intervention; CBT; cognitive *adjacent to* therapy, behaviour therapy, intervention, or remediation; behaviour *adjacent to* therapy, control, modification, change, or intervention; psychotherapy; counseling; social support; skills training; motivational *adjacent to* intervention, interview, or support; brief advice; brief intervention; family *adjacent to* therapy, intervention, or counselling, couple *adjacent to* therapy, intervention, or counselling; peer *adjacent to* therapy, intervention, or counselling; talking therapy; contingency management; psychoeducation; route transition; network therapy
	Key words for outcomes: risk *adjacent to* taking, reduction, protection, minimisation, prevention, decrease, avoidance, or behaviour; harm *adjacent to* reduction, protection, minimisation, prevention, decrease, avoidance; unsafe injecting; needle sharing; intravenous injection; injecting *adjacent to* equipment, paraphernalia, or risk; sexual risk behaviour; unsafe sex; multiple sexual partners; multiple casual partners; one time sex encounter; sex holiday; casual sex; casual partner; non-regular sex partner; unprotected intercourse; unprotected sex; condomless *adjacent to* sex or intercourse; condom free *adjacent to* sex or intercourse; barebacking; bareback sex; bug chase; anal intercourse; anal sex; condom; condom use; safe sex; health *adjacent to* knowledge, attitudes, or practice, or behaviour; transmission knowledge or understanding
ClinicalTrials.gov	Key words for BBV: HIV, hepatitis
	Key words for intervention: psychosocial, behavioral

IVDU, intravenous drug user.

Eligibility

Citations were included if the full text was published in English, regardless of country of origin. Trials were eligible for inclusion if (1) they were published during 2000–15; (2) participants were all PWID or the results were presented separately for PWID and other study participants; (3) studies were RCTs; (4) the outcome(s) included (i) any injecting risk behaviour (including sharing of needle/syringes or other injecting equipment), and frequency of injecting, reported separately or as an aggregated outcome and (ii) any sexual risk behaviour (including unprotected sex or number of sexual partners), reported separately or as an aggregated outcome; and (5) the RCTs compared psychosocial interventions with a control group, who received usual care, education or information, HIV infection testing and counselling, or 'an intervention of lesser time or intensity'[44] (with or without OST).

Authors Gail Gilchrist and Noreen Mdege independently assessed all abstracts and potentially eligible full-text manuscripts against the eligibility criteria. Where there was disagreement, the decision whether to include or exclude each trial was reached through referral to additional reviewers (EH, DS or KW).

Data extraction

Authors Davina Swan, Kideshini Widyaratna, Julia Elena Marquez-Arrico and Gail Gilchrist independently extracted the following information for each study using a data extraction form specifically designed and piloted for use for this review. The following data were extracted, which included intervention description items from the TIDieR (Template for Intervention Description and Replication) checklist:[65] authors and publication year, country, aim of intervention, participants (percentage who were PWID, percentage of females, mean age), intervention delivery setting/staff who delivered intervention, description of intervention (intervention description, frequency and duration of sessions, adherence to intervention) and control interventions (intervention description, frequency and duration of sessions) and length of follow-up (see *Table 2*). Data were extracted independently by one reviewer and checked by a second. Differences in data extraction were resolved through discussion.

Assessment of methodological quality

Each study included in the review was independently assessed for methodological quality by two authors (from GG, DS, JM and JT) using the Cochrane risk-of-bias tool for RCTs.[66] These assessments were then compared with the quality assessment information in available reviews.[37,42–44] Differences in quality assessment decisions between the authors and published reviews were resolved through discussion and consensus with a third assessor (EH). The risk-of-bias tool produces a quality interpretation with ratings of 'yes' (low risk of bias), 'no' (high risk of bias), and 'unclear' (uncertain risk of bias) for six key domains: (1) sequence generation; (2) allocation concealment; (3) blinding of participants, personnel and outcome assessors; (4) incomplete outcome data; (5) selective outcome reporting; and (6) other sources of bias. For each domain a rating of low risk of bias equates to high methodological quality.

Describing the interventions

The behaviour change wheel was used to categorise intervention functions of the interventions included in the review.[67] Intervention functions were coded only where they related directly to the target behaviour of the intervention. The following intervention functions were coded: education (increasing knowledge or understanding, e.g. 'The 30 min pre-test counseling session provided basic information about AIDS and how to reduce the risk of HIV infection, as well as similar information about HCV');[68] persuasion (using communication to induce positive or negative feelings or stimulate action, e.g. 'The facilitators would often praise their effective communication strategies and offer additional'[69] and 'Reviewed progress, developed

strategies for overcoming obstacles, and reaffirmed commitment to change');[70] incentivisation (creating expectation of reward, e.g. 'Contingent vouchers were given when a participant provided a cocaine-negative urine specimen');[71] training (imparting skills, e.g. 'intervention included psychosocial training and skills building to teach personal risk reduction and negotiation skills'[72] and 'technical condom use and syringe disinfection skills');[73] modelling (providing an example for people to aspire to or imitate, e.g. 'model injection and sexual risk reduction behaviors with their risk network members'[74] and 'demonstration and rehearsal of syringe cleaning and condom application');[70] and enablement (increasing means/reducing barriers, e.g. 'women created a personalized risk reduction plan',[75] 'goal-setting for HIV risk reduction and outreach'[76] and 'a short role play was then used to help her identify barriers to safer injection'[77]). Gail Gilchrist and Davina Swan independently determined the intervention functions of the intervention conditions, with differences in intervention function coding resolved through discussion. In addition, the intervention functions determined by Gail Gilchrist and Davina Swan of five trials were validated by a behaviour change expert (see *Acknowledgements*).

Statistical analysis

The principal summary measure was the standardised mean difference (SMD). As outcome data were presented as dichotomous or continuous data across included trials, odds ratios were recalculated as SMDs to allow pooling of data.[78] The standard errors of the log-odds ratios were converted to standard errors of a SMD by multiplying by the same constant ($\sqrt{3}/\pi = 0.5513$). This allowed the standard error for the log-odds ratio and, hence, a confidence interval (CI) to be calculated.[79] For each RCT, the SMD and corresponding 95% CIs for the assessed outcome were retrieved or calculated. Data entry and statistical analysis were performed with the use of Review Manager software (version 5; The Cochrane Collaboration, The Nordic Cochrane Centre, Copenhagen, Denmark). Where trials reported data from various follow-up periods, data from the latest follow-up period were included in the meta-analysis, combining outcomes assessed at multiple time periods. To determine whether or not trials included in the meta-analysis were consistent, the degree of heterogeneity was calculated. An I^2 of 25% was considered low heterogeneity, 50% moderate heterogeneity and 75% high heterogeneity.[80] In the inverse variance method, individual effect sizes were weighted according to the reciprocal of their variance calculated as the square of the standard error.

Main and subgroup analysis

In line with a recent Cochrane review,[43] and in an attempt to address the complexity of clinical heterogeneity of interventions, subgroup analyses were conducted to compare psychosocial interventions with (1) treatment as usual (TAU); (2) education or information; (3) HIV infection testing and counselling; (4) control interventions of lesser time or intensity with OST; and (5) control interventions of lesser time or intensity without OST. As follow-up duration may affect intervention effectiveness, further subgroup analyses were conducted where possible, comparing length of time, in months, from the end of the intervention to the final follow-up of included trials (i.e. ≤ 3 months, 4–6 months and ≥ 9 months follow-up).

Injecting risk behaviour and sexual risk behaviour (as described in *Eligibility*) were used as outcomes of interest for meta-analysis. The Cochrane handbook (section 16.5) stresses that trials with multiple treatment arms 'that compare more than two intervention groups need to be treated with care' to avoid 'making multiple pair-wise comparisons between all possible pairs of intervention groups' in the meta-analysis.[62] Therefore, where trials included in the meta-analysis had more than one intervention group, data from the most relevant psychosocial intervention to address the aims of the systematic review were compared with the control intervention in the meta-analysis. For Booth *et al.*,[68] the most relevant intervention condition was considered TAU plus HIV/HCV infection counselling and education, rather than TAU plus a therapeutic alliance to facilitate treatment entry. For Sterk *et al.*,[81] the enhanced negotiation intervention was considered more relevant to the aims of the systematic review than the enhanced motivation intervention. For Schroder *et al.*,[71] TAU plus weekly CBT plus CM (CBT + CM) was considered superior to both weekly CBT plus

non-contingent vouchers and CM plus weekly group therapy and, therefore, was selected as the intervention condition for the meta-analysis. Go *et al.*[82] conducted a multilevel intervention using a 2 × 2 (four-arm) factorial design consisting of (1) standard of care (i.e. HIV infection testing and counselling); (2) a structural-level community stigma reduction programme; (3) individual-level post-test counselling and skill-building support groups; and (4) both individual-and structural-level activities. For the purpose of this systematic review, the individual-level post-test counselling and skill-building support groups will be compared with individual standard of care.

Random-effects models were applied to compare the following outcomes of interest for meta-analysis by type of control intervention, and by type of control intervention and length of follow-up post intervention: any injecting risk behaviour (see *Figures 3* and *4*), including sharing of needle/syringes (see *Figures 5* and *6*), or other injecting equipment (see *Figures 7* and *8*) and frequency of injecting (see *Figures 9* and *10*), reported separately or as an aggregated outcome; and any sexual risk behaviour (see *Figures 11* and *12*), including unprotected sex (see *Figures 13* and *14*) or number of sexual partners (see *Figure 15*), reported separately or as an aggregated outcome.

Results

Study selection and assessment

The electronic database searches to 26 May 2015 resulted in 2493 citations; an additional 77 citations were identified from 1 January 2015 to 9 December 2016 (*Figure 1*). One additional manuscript was identified from hand-searching other reviews' reference lists. After removal of duplicates, 1903 citations remained. In total 1771 abstracts were excluded as they did not meet eligibility criteria and 132 abstracts were selected for full-text assessment, including four related manuscripts referenced in these selected texts.[83–86] Eighty-nine articles were excluded for the following reasons: they were not RCTs ($n = 34$);[47,68,87–118] the outcomes of interest for this review were not assessed or presented at follow-up ($n = 29$);[86,119–146] outcomes were not presented by PWID ($n = 6$);[147–152] the number of PWID was not reported ($n = 4$);[153–156] or the intervention studied was not psychosocial ($n = 4$).[157–160] Additionally, 10 manuscripts were excluded as the results did not compare intervention groups[161–166] or did not evaluate the effect of the intervention.[167–170] One further manuscript was excluded because the same psychosocial intervention was delivered to each treatment group, and the difference between treatment groups was receipt of a coupon for 90 days of free methadone maintenance treatment (MMT).[171] One manuscript published in Chinese was excluded.[172]

In total, 42 manuscripts from 32 trials were eligible,[22,68–77,81–85,173–198] 41 originating from the electronic database searches, and one from hand-searching recent reviews and review of reviews[178] was added as a result of this process. Twenty-four trials were included in the meta-analysis.[22,68–73,75,76,81,82,173,175,179,180,182,186,188,189,192–195,197] The reasons for excluding eight trials from the meta-analysis were not providing the number of PWID for control and intervention groups at follow-up,[84,174,176,177,196] only providing risk ratios,[178] outcome combined HIV infections with sexually transmitted infections[77] and data for 'unsafe injection practices' were presented only at baseline.[74]

Quality and publication bias assessment

The summary of authors' judgements about the quality of each trial included in the systematic review is described in *Figure 2*. The risk of bias varied between trials. Incomplete outcome data was the most common risk of bias found in the trials included in the review, but selective outcome reporting also contributed to potential risk of bias for some trials. Other potential sources of bias included altering randomisation protocols depending on the number of participants enrolled on a particular day;[182] statistically significant differences between groups at baseline in the injecting subscale;[173] variation in the TAU group across sites;[68] possible crossover contamination between groups;[69,75,179,180,182,194] a high proportion of excluded individuals with the excluded individuals differing significantly to those included;[71] and large variations reported in the follow-up period.[74]

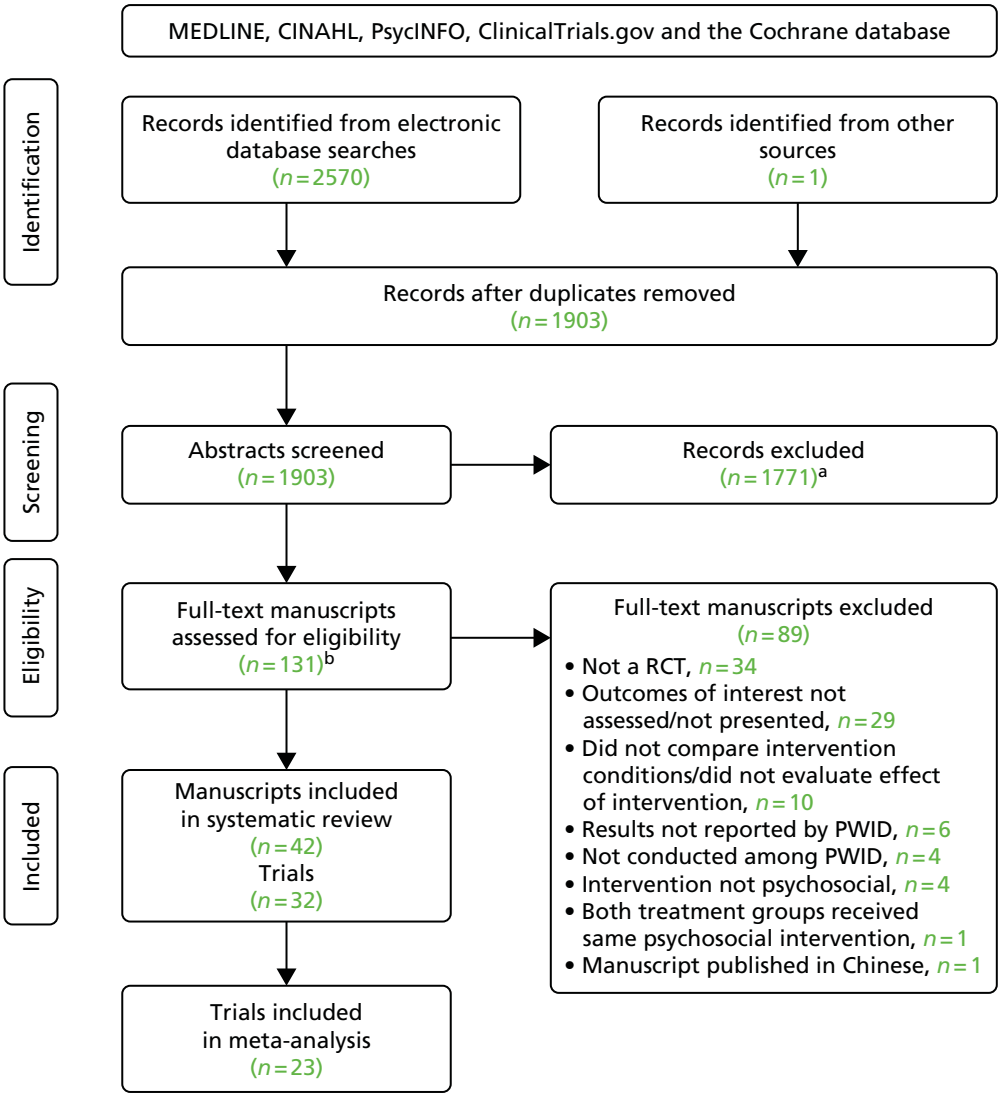

FIGURE 1 Flow chart. a, Includes six trials listed in the clinical trials database for which no published papers could be found; b, includes four related manuscripts references in potentially eligible manuscripts.

Study characteristics

The characteristics of the RCTs included in the systematic review are described in *Table 2*. In total, 12,840 participants (35% female, range 0–100%) were enrolled in the trials; the majority were PWID (84.5%) (the proportion of participants enrolled in the trials who were PWID ranged from 16% to 100%). The majority ($n = 18$) of trials were conducted in the USA,[22,68,70–72,76,81,84,174,176,177,179,182,186,189,193,195,196] three were conducted in Russia,[74,75,194] two were conducted in Canada,[175,178] two were conducted in Vietnam,[82,180] one was conducted in Kazakhstan,[73] one was conducted in Georgia,[188] one was conducted in Australia,[197] one was conducted in the UK,[173] one was conducted in Mexico,[77] one was conducted in Puerto Rico[192] and one was conducted in both the USA and Thailand.[69]

Trials included in the systematic review compared psychosocial interventions with usual care ($n = 4$),[22,68,178,195] education or information ($n = 9$),[70,76,77,175,176,180,188,196,197] HIV infection testing and counselling ($n = 5$),[69,82,84,192,193] interventions of lesser time or intensity with OST ($n = 12$)[72–74,81,173,174,177,179,182,190,194] and without OST ($n = 2$).[71,186] Of the 32 interventions delivered in the RCTs included in the systematic review, most ($n = 14$) were delivered to individual participants,[22,68,70,71,75,77,81,173,175,178,192,195–197] eight were delivered to groups of participants[69,74,174,176,179,180,182,193] and two were delivered to couples.[84,177] The remaining eight trials delivered interventions in more than one way (e.g. individual and couples sessions,[187,188] individual and group sessions,[69,76,186,190,194]

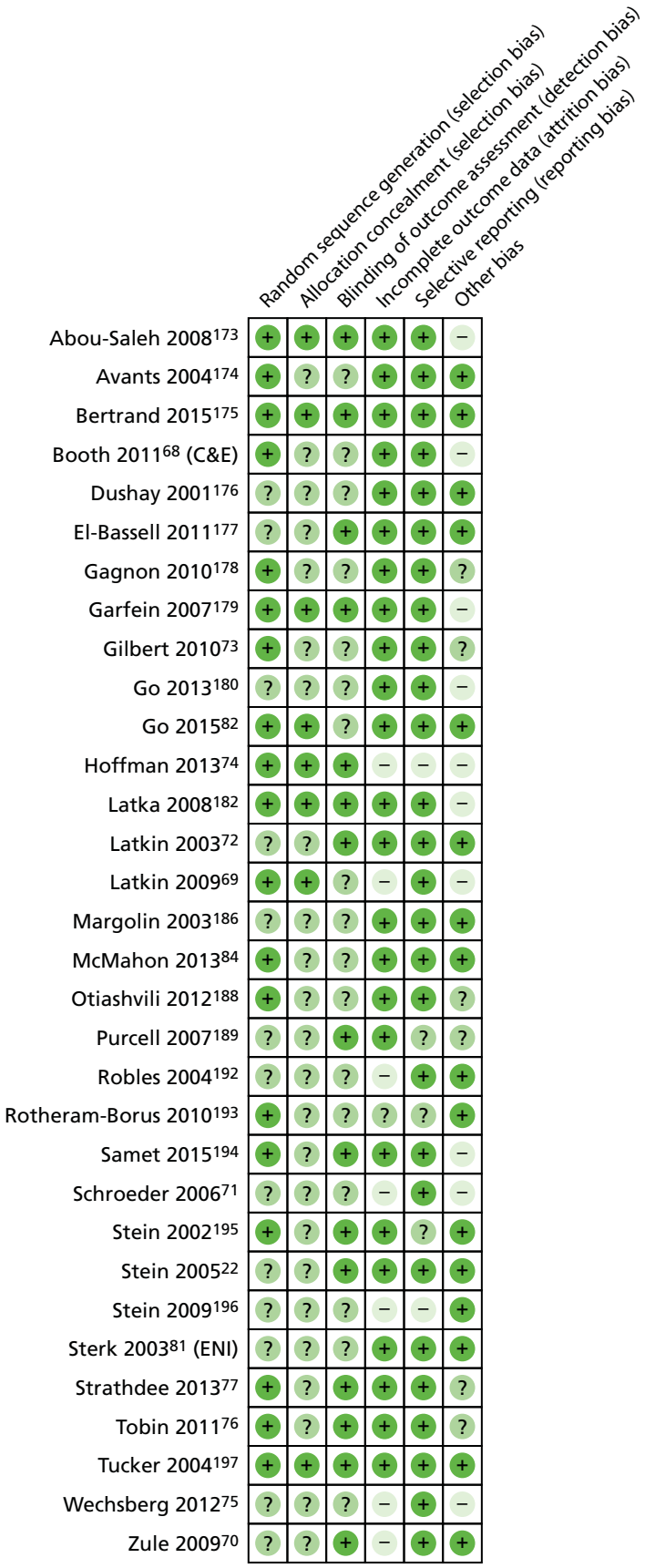

FIGURE 2 Risk of bias for included trials. C&E, counselling and education; ENI, enhanced negotiation intervention.

TABLE 2 Description of trials included in the systematic review

First author	Participants (% female)	Intervention delivery setting/staff	Description					Length of follow-up
			Intervention group			Control group		
			Intervention groups	Number of sessions	Intervention functions	Control intervention	Number of sessions	
Abou-Saleh *et al.*[173]	95 HCV –ve PWID (26%)	Outpatient drug treatment/treatment staff	Enhanced prevention counselling ($n = 43$)	Four 40- to 60-minute sessions	Education, enablement	Simple educational counselling ($n = 52$)	One 10-minute session	6 months post randomisation
Avants *et al.*[174]	220 PWID in MMT (69%)	MMT/clinician	Standard care + harm reduction group ($n = 108$)	Twelve 90-minute weekly group sessions	Education, enablement, training	Standard care + single HIV risk reduction session ($n = 112$)	One 2-hour session	Post intervention
Bertrand *et al.*[175]	219 PWID who shared drugs or injection equipment (18%)	Not specified/ researcher	MI ($n = 111$)	One session	Enablement, persuasion	Education intervention ($n = 108$)	One 30–45 minutes session	6 months post randomisation
Booth *et al.*[68]	632 PWID (24%)	Residential detoxification/ interventionist	TAU + HIV/HCV counselling and education ($n = 212$); TAU + intervention to facilitate treatment entry ($n = 209$)	Two individual sessions; individual session	Education, enablement, training	TAU: HIV/HCV infection risk assessment screening and referral for testing and counselling ($n = 211$)	HIV/HCV infection risk assessment screening and referral for testing and counselling	6 months post randomisation
Dushay *et al.*[176]	669 drug users (64% injecting) (27%)	Not reported	Ethnic cultural enhanced intervention ($n = 453$)	Five sessions	Education, enablement, training	AIDS video educational programme ($n = 216$)	Two video sessions	5–10 months post randomisation (20% interviewed 12 months post randomisation)
El-Bassell *et al.*[177]	282 HIV-negative drug-using couples (16% PWID) (50%)	Not reported/trained facilitator	Couple-based risk reduction ($n = 190$); individual-based HIV infection risk reduction delivered to male or female drug-using partner ($n = 183$)	Seven sessions	Enablement, training	Couple-based wellness promotion ($n = 190$)	Seven sessions	12 months post randomisation
Gagnon *et al.*[178]	260 PWID (31%)	Needle exchange/ computerised intervention	Standard intervention (needle exchanges, psychosocial support and social and health service referrals) + computer-tailored messages ($n = 130$)	Four sessions	Education, enablement, modelling, persuasion	Standard intervention ($n = 130$)	4 weeks	3 months post intervention

First author	Participants (% female)	Intervention delivery setting/staff	Description					Length of follow-up
			Intervention group			Control group		
			Intervention groups	Number of sessions	Intervention functions	Control intervention	Number of sessions	
Garfein *et al.*;[179] Purcell *et al.*;[191] and Mackesy-Amiti *et al.*[183–185]	654 HIV-negative and HCV-negative PWID (34%)	Not reported/trained facilitators	Peer education ($n = 431$)	Six sessions	Education, enablement, training	Video discussion ($n = 423$)	Six sessions	6 months post intervention
Gilbert *et al.*[73]	40 HIV-negative couples who inject drugs (50%)	Needle exchange/ facilitators	Couple-based HIV risk reduction (20 couples)	Three single gender group sessions + couple session	Education, modelling, training	Wellness promotion condition (20 couples)	Four group sessions	3 months post intervention
Go *et al.*[180]	419 index HIV-negative PWID (0%)	Not reported	Peer network oriented ($n = 210$)	Six sessions + three booster sessions	Education, enablement, training	TAU + HIV pamphlet ($n = 209$)	N/A	12 months post intervention
Go *et al.*[82]	455 HIV-positive PWID (0%)	Community intervention education sessions delivered by a trained community mobiliser; individual HIV knowledge and skill-building group sessions conducted by two facilitators	Individual level: HIV infection testing and counselling, plus two individual post-test counselling sessions, two small group sessions (HIV infection knowledge and skill-building) + optional dyad session ($n = 95$)	Four individual sessions + two group sessions + optional dyad session	Education, enablement, training, education	Individual level: HIV infection testing and counselling ($n = 89$)	Two sessions	24 months post randomisation
			Community and individual level: community-wide programme consisting of a two-part video and a series of six HIV education sessions ($n = 132$)	Two-part video and a series of six HIV education sessions		Community level: standard messages on HIV through village weekly public loudspeakers and educational pamphlets already being provided by community health stations ($n = 139$)		
Hoffman *et al.*[74]	432 PWID (33%)	Research centre/ facilitators	Psychological-communicative behavioural training; peer educator ($n = 99$); network members ($n = 127$)	Seven group + one individual session + four booster meetings	Education, modelling, persuasion, training	Group sessions devoted to areas of interest ($n = 92$); network members ($n = 114$)	Eight sessions	24 months post randomisation

continued

TABLE 2 Description of trials included in the systematic review (*continued*)

First author	Participants (% female)	Intervention delivery setting/staff	Description					Length of follow-up
			Intervention group			Control group		
			Intervention groups	Number of sessions	Intervention functions	Control intervention	Number of sessions	
Latka *et al.*;[182] Kapadia *et al.*[198]	418 HCV-positive PWID (24%)	Three research sites/ facilitators	Peer-mentoring behavioural intervention ($n = 222$)	Six sessions	Education, training	Video discussion ($n = 196$)	Six sessions	6 months post intervention
Latkin *et al.*[72]	250 (47% PWID) (39%)	Clinic/indigenous paraprofessional facilitators	Small group that encouraged peer outreach ($n = 81$)	10 group sessions	Enablement, education, training	Equal-attention control condition ($n = 36$)	10 sessions	6 months post intervention
Latkin *et al.*[69,199]	414 networks with 1123 HIV-negative participants (91% PWID) (3% in Thailand; and 20% in the USA)	Not reported/ facilitator	HIV C&T + group peer education ($n = 204$ networks)	Two individual + six group + two booster sessions	Education, enablement, persuasion, training	HIV C&T ($n = 210$ networks)	Two sessions	Up to 30 months (24 months in Thailand) post randomisation
Margolin *et al.*[186]	90 PWID HIV positive entering MMT (30%)	MMT/counsellor	Enhanced MMT (6 months of daily methadone and weekly individual substance abuse counselling and case management) + HIV harm reduction programme ($n = 45$)	Six sessions	Enablement, persuasion, training	Enhanced MMT + active control that included harm reduction components ($n = 45$)	Six sessions	9 months post randomisation
McMahon *et al.*[84,187]	330 HIV-negative drug users (48% PWID) (100%) and male partners	Field office/ interventionist	1. Couple-based HIV C&T ($n = 110$) (43% PWID) 2. Women only, relationship-focused HIV C&T ($n = 104$) (51% PWID)	Two sessions	Education, enablement	HIV C&T ($n = 116$) (51% PWID)	Two sessions	9 months post intervention
Otiashvili *et al.*[188]	40 drug users (98% PWID) (0%) and drug-free female partners	Research unit/ counsellor	MI for drug user and couple, CM + naltrexone ($n = 20$). Female partners invited to attend couples counselling	22 sessions	Enablement, incentivisation	Education sessions. Referral drug treatment ($n = 20$)	22 sessions	6 months post intervention

First author	Participants (% female)	Intervention delivery setting/staff	Description					Length of follow-up
			Intervention group			Control group		
			Intervention groups	Number of sessions	Intervention functions	Control intervention	Number of sessions	
Purcell *et al.*[189,190]	966 HIV-positive PWID (36%)	Not reported/peers	Peer-mentoring intervention ($n = 486$)	10 sessions: seven group sessions; two individual sessions; and one 'peer activity'	Education, enablement, training	Video discussion ($n = 480$)	Eight sessions	12 months post intervention
Robles *et al.*[192]	557 PWID (4%)	Assessment facility or drug treatment/nurse	HIV/AIDS infection risk intervention + counselling + case management ($n = 285$)	Two sessions; six sessions	Education, enablement, training	HIV/AIDS infection risk intervention ($n = 272$)	Two sessions	6 months post randomisation
Rotheram-Borus *et al.*;[193] and Hershberger *et al.*[181]	1116 drug users (65% PWID) (33%)	Field office/ counsellors/outreach workers	HIV C&T + HIV prevention programme (group skills-focused workshops, individual counselling, outreach/ social events) ($n = 558$; 359 PWID)	Two HIV C&T sessions + five sessions (two groups, one individual + two or more structured outreach)	Enablement, training	HIV C&T ($n = 559$; 364 PWID)	Two sessions	9 months post randomisation
Samet *et al.*[194]	700 HIV positive with risky sex and heavy alcohol consumption (60% PWID) (41%)	Hospital setting/peers	Healthy relationships intervention ($n = 350$; 212 PWID)	Two individual + three small group sessions	Education, enablement, modelling, training	Attention control ($n = 350$; 211 PWID)	Two individual + three group sessions	12 months post randomisation
Schroeder *et al.*;[71] and Esptein *et al.*[83]	81 drug users (96% PWID) (52%)	Research clinic/ counsellor	MMT + individual counselling followed by 12 weeks of intervention condition, followed by a 12-week standard treatment: 1. Weekly CBT + CM ($n = 16$) 2. Weekly CBT + non-contingent vouchers ($n = 19$) 3. CM plus weekly group therapy ($n = 22$)	29 weeks (methadone + 5-weekly individual counselling, 12 weeks of intervention, followed by 12 weeks standard treatment)	Education, enablement, incentivisation, modelling, training	Standard dose of methadone (70–80 mg/ day) + weekly individual counselling (5 weeks) followed by 12 weeks of control condition, followed by a 12-week standard treatment. Group therapy + non-contingent vouchers ($n = 24$)	29 weeks (methadone + 5-weekly individual counselling, 12 weeks of intervention, followed by 12 weeks standard treatment)	Post intervention

continued

TABLE 2 Description of trials included in the systematic review (*continued*)

First author	Participants (% female)	Intervention delivery setting/staff	Description					Length of follow-up
			Intervention group			Control group		
			Intervention groups	Number of sessions	Intervention functions	Control intervention	Number of sessions	
Stein *et al.*[195]	109 PWID who drink hazardously (38%)	Research site/social worker	Referrals for substance use and medical treatment + brief MI ($n = 60$)	Two sessions	Enablement	Referrals for substance abuse and medical treatment provided ($n = 49$)	N/A	6 months post randomisation
Stein *et al.*[22]	109 PWID (36%)	Outpatient academic research office/clinical psychologist	CBT + pharmacotherapy for depression ($n = 53$)	Eight CBT sessions + three pharmacotherapy visits	Education, enablement, training	Assessment ($n = 56$)	Assessment visit	9 months post randomisation
Stein *et al.*[196]	277 HCV-negative drug users (28% PWID) (37%)	Not stated/ interventionist	MI ($n = 140$)	Four sessions	Education, enablement, persuasion	Leaflet about local resources ($n = 137$)	N/A	24 months post randomisation
Sterk *et al.*[81]	68 HIV-negative PWID (100%)	Health intervention project house/ interventionists	Enhanced MI ($n = 20$); enhanced negotiation intervention ($n = 21$)	Four sessions; four sessions	Education, enablement, training	NIDA standard intervention ($n = 27$)	Two sessions	6 months (not clear if post intervention or post randomisation)
Strathdee *et al.*;[77] Vera *et al.*[85]	584 sex workers who inject drugs (100%)	Not reported/ counsellors	Interactive injection risk and didactic sexual risk intervention ($n = 146$); interactive sexual risk and didactic injection risk intervention ($n = 148$); interactive injection and sexual risk intervention) ($n = 146$)	One session; one session; one session	Education, enablement, modelling, persuasion, training	Didactic injection and sexual risk intervention ($n = 144$)	One 60-minute session	12 months post randomisation
Tobin *et al.*[76]	227 PWID (45%)	Research clinic/not reported	Peer-educator intervention ($n = 114$)	Seven sessions (five group + one individual + one with participant and enrolled risk network members)	Education, enablement, training	Group information ($n = 113$)	Five sessions	18 months post intervention
Tucker *et al.*[197]	145 PWID (26%)	Outpatient clinical and research organisation/clinical researcher	Tailored brief behavioural intervention ($n = 73$)	One session	Education, enablement	HCV educational leaflet ($n = 72$)	N/A	1 month post randomisation

First author	Participants (% female)	Intervention delivery setting/staff	Description					Length of follow-up
			Intervention group			Control group		
			Intervention groups	Number of sessions	Intervention functions	Control intervention	Number of sessions	
Wechsberg *et al.*[75]	100 PWID (100%)	Inpatient detoxification/ psychologist	Woman-focused intervention ($n = 51$)	Two sessions	Education, enablement, training	Nutrition intervention ($n = 49$)	Two sessions	3 months post randomisation
Zule *et al.*[70]	851 PWID (27%)	Not reported/lay community members	HCV risk reduction MI ($n = 423$)	Six sessions	Education, enablement, modelling, persuasion	Video HCV educational intervention ($n = 428$)	Six sessions	12 months post randomisation

AIDS, acquired immunodeficiency syndrome; C&T, counselling and testing; N/A, not applicable; NIDA, National Institute on Drug Abuse.

group and couples sessions[73]) and one trial provided both individual- and structural-level activities.[82] For interventions with more than one session, retention or adherence to the intervention ranged from 50%[68] to 95%.[81]

Eight interventions incorporated peer mentoring from an index participant to change the behaviours of other PWID.[69,72,74,76,179,180,182,190] The majority of interventions contained at least three sessions ($n = 25$),[22,69–74,76,81,82,173,174,176–180,182,186,188,190,192–194,196,197] four interventions contained two sessions,[68,75,187,195] and three interventions contained only one session.[77,175,197]

Most interventions were delivered in drug treatment settings, including outpatient and hospital clinics,[71,72,173,192–194] methadone maintenance clinics,[174,186] inpatient or residential detoxification units,[68,75,197] needle and syringe exchanges[73,178] or outreach[193] (settings not mutually exclusive). In addition, the vast majority of studies were delivered by clinic staff in the treatment setting rather than by a researcher (or not specified).

Assessed outcomes

Various validated and other purposely developed instruments were used to assess injecting risk behaviour in 32 trials[22,68–77,81,82,84,173–180,182,186,188,190,192–195,197] and sexual risk behaviour in 23 trials.[68–77,81,82,84,173,174,176,177,179,180,186,190,193,194,197] The most common reporting time frame for outcomes was in the past 30 days ($n = 19$),[22,68,69,73–77,81,174–176,186,188,192–195,197] followed by the past 3 months ($n = 10$),[74,82,84,174,177,179,180,182,190,194] or 6 months ($n = 3$),[72,76,196] past week ($n = 2$),[71,178] or behaviour at the last sexual encounter or injecting event ($n = 1$)[70] (answers not mutually exclusive as three trials reported a different reporting time frame for different outcomes).[74,76,194]

Results of individual studies not included in the meta-analyses

Of the eight trials not included in the analysis, three trials reported that psychosocial interventions were more effective than control conditions in reducing injecting risk behaviour[77,84,178] and three reported reductions in sexual risk behaviours[84,174,177] for participants receiving the psychosocial intervention. Avants *et al.*[174] found that, post intervention, the total number of weeks in which unsafe sex was reported by PWID receiving methadone treatment was significantly lower for participants in the harm reduction group (2.40 ± 3.42 weeks) than for those in the standard care group (3.67 ± 3.89 days) [$F(1,218) = 6.63$; $p = 0.01$]. In addition, 32% (14/44) of the participants in the harm reduction group reported using condoms, compared with 13% (6/48) in the standard care group [$\chi^2(1) = 5.04$; $p = 0.02$]. El-Bassel *et al.*[177] reported a 30% reduction in the incidence rate of unprotected sex acts with study partners for those who had received the couple-based risk reduction intervention compared with participants in the attention control arm over 12 months' follow-up. In addition, a 29% reduction was found in the same outcome in the couple arm compared with the individual arm, with a 41% reduction at the 12-month follow-up. Gagnon *et al.*[178] found that at the end of the 4-week intervention PWID who received the standard intervention plus the computer-tailored messages reported using fewer used syringes than PWID who received the standard intervention alone [relative risk 0.47, 95% CI 0.28 to 0.79; $p = 0.004$]. However, these changes were not sustained at 3 months' follow-up. McMahon *et al.*[84] found that, 9 months post intervention, women who attended a couples-based HIV counselling and testing intervention reported significantly less frequent receptive syringe sharing with primary partners (mean = 1.4 vs. 8.3; $p = 0.0002$) and less frequent unprotected anal intercourse with a primary male partner (mean = 0.7 vs. 5.7; $p = 0.005$) than women receiving standard care. In one trial, in two sites in Mexico among female drug-injecting sex workers, a significantly greater reduction in receptive needle sharing was reported by participants receiving an interactive intervention than among those receiving a didactic intervention in one site only (85% vs. 71%, respectively; $p = 0.04$).[77]

Meta-analyses

Any injecting risk behaviour

Twenty-two trials assessed any injecting risk behaviour. Psychosocial interventions independently reduced injecting risk behaviours more than control interventions in seven trials.[72,73,76,179,182,188,192] A total of 3096 PWID were included in the intervention groups and 2971 in the control groups. Overall, psychosocial interventions showed a greater reduction in any injecting risk behaviour (SMD –0.29, 95% CI –0.42 to –0.15, $I^2 = 61\%$; $p < 0.01$) than the control interventions (*Figure 3*). Psychosocial interventions also demonstrated greater reductions in any risk behaviours than education/information (SMD –0.41, 95% CI –0.79 to –0.04, $I^2 = 62\%$; $p = 0.03$), HIV infection testing and counselling (SMD –0.24, 95% CI –0.44 to –0.03, $I^2 = 0\%$; $p = 0.02$) and interventions of a lesser time or intensity (SMD –0.34, 95% CI –0.56 to –0.12, $I^2 = 75\%$; $p < 0.01$), but no difference was found when compared with interventions of a lesser time or intensity that included OST (SMD 0.23, 95% CI –0.51 to 0.97, $I^2 = 0\%$; $p < 0.01$) or TAU (SMD –0.09, 95% CI –0.32 to 0.15, $I^2 = 26\%$; $p = 0.54$). Where outcomes were assessed ≤ 3 months or 4–6 months post intervention, psychosocial interventions reduced any injecting risk behaviour when compared with interventions of lesser time or intensity. Where outcomes were compared ≥ 9 months post intervention, psychosocial interventions reduced any injecting risk behaviour more than interventions that provided education/information alone. (*Figure 4*).

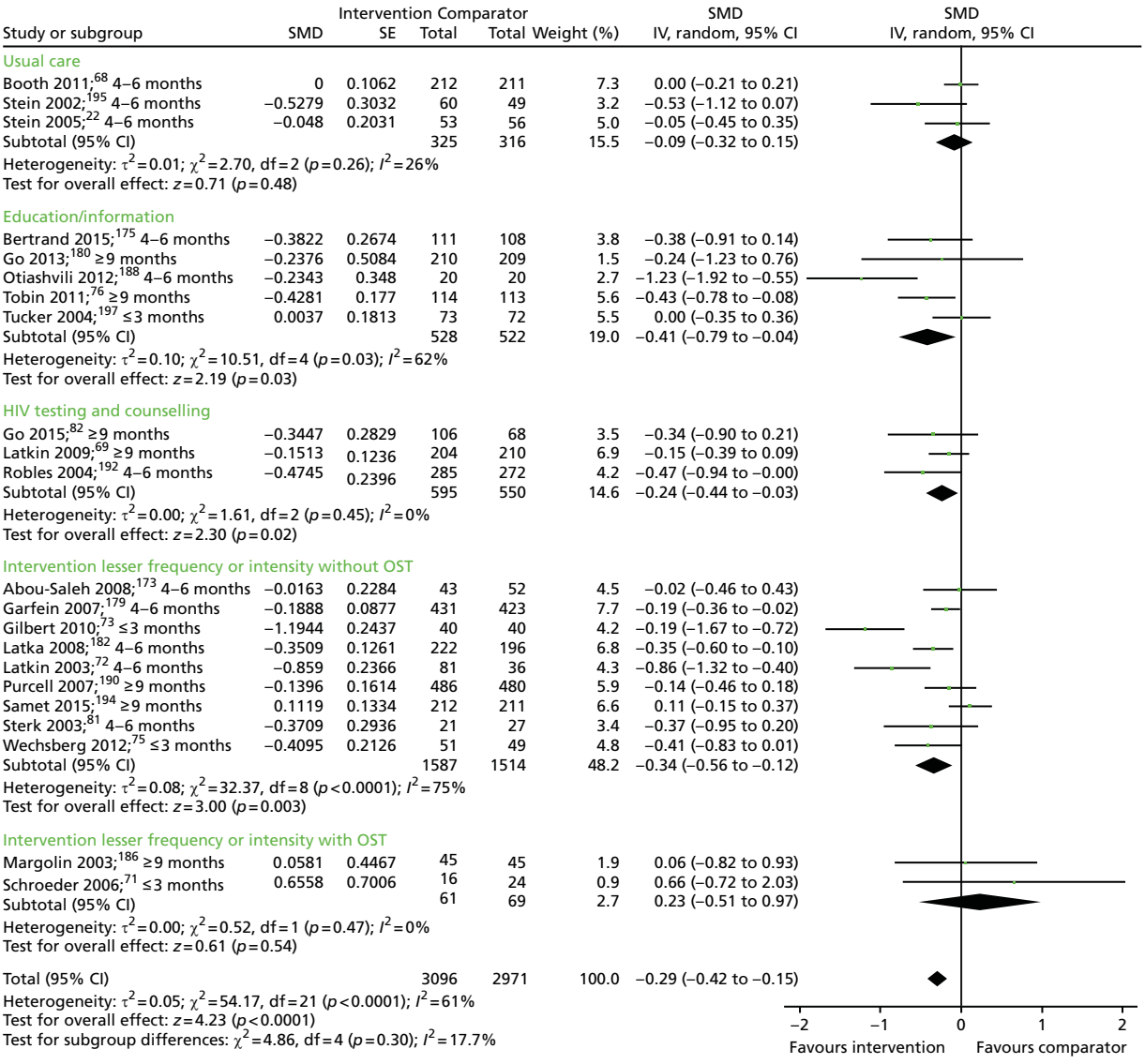

FIGURE 3 Efficacy of psychosocial interventions vs. control interventions in reducing any injecting risk behaviours among PWID. df, degrees of freedom; IV, inverse variance; SE, standard error.

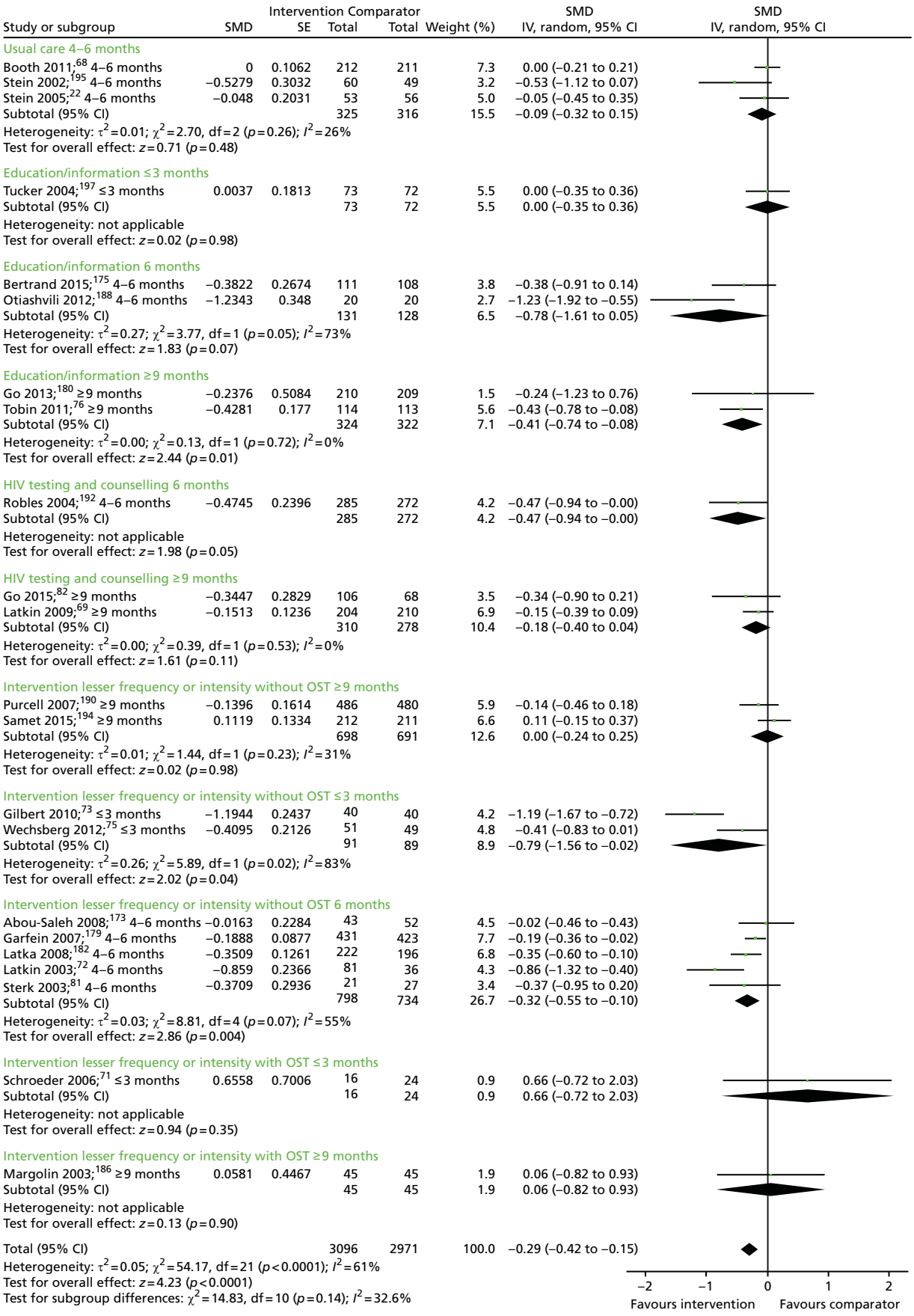

FIGURE 4 Efficacy of psychosocial interventions vs. control interventions in reducing any injecting risk behaviours among PWID by control intervention and length of follow-up post intervention. df, degrees of freedom; IV, inverse variance; SE, standard error.

Heterogeneity was moderate in psychosocial interventions compared with education/information ($I^2 = 62\%$), possibly as a result of the variations in the mode of delivery and intervention components (see *Table 2*). The education/information interventions in the control conditions included a pamphlet compared with a six-session education/enablement intervention[180] and ranged from comparing a one-session education intervention with a one-session motivational intervention[175] to comparing 22 education sessions with referrals to drug treatment with a 22-week intervention including MI counselling sessions for both the male participant and the couple, monetary incentives for drug abstinence and research-supported detoxification followed by naltrexone treatment.[188] There was high heterogeneity in the analysis of psychosocial interventions compared with interventions of a lesser time or intensity (without OST) ($I^2 = 75\%$), for similar reasons to those mentioned above. Six trials included equal-attention control conditions ranging from 2[75] to 10[182] sessions, and three included control interventions with fewer sessions, ranging from four sessions versus one session[173] to 10 versus eight sessions[190] (see *Table 2*). All but one trial[173] had at least two sessions in the control and/or intervention conditions. One trial compared a two-session woman-focused intervention with a two-session nutritional intervention.[75] The variation in intervention duration and content across conditions contributes to the high heterogeneity.

Sharing needles and syringes

Thirteen trials assessed the sharing of needles and syringes (*Figure 5*). Psychosocial interventions reduced with behaviour compared with the control interventions in five of those trials.[72,73,186,188,192] A total of 1411 PWID were included in the intervention groups and 1315 in the control groups. A total of 1411 and 1315 PWID were included in the intervention and control group, respectively. Overall, psychosocial interventions reduced sharing of needle/syringes (SMD –0.43, 95% CI –0.69 to –0.18, $I^2 = 68\%$; $p < 0.01$) compared with

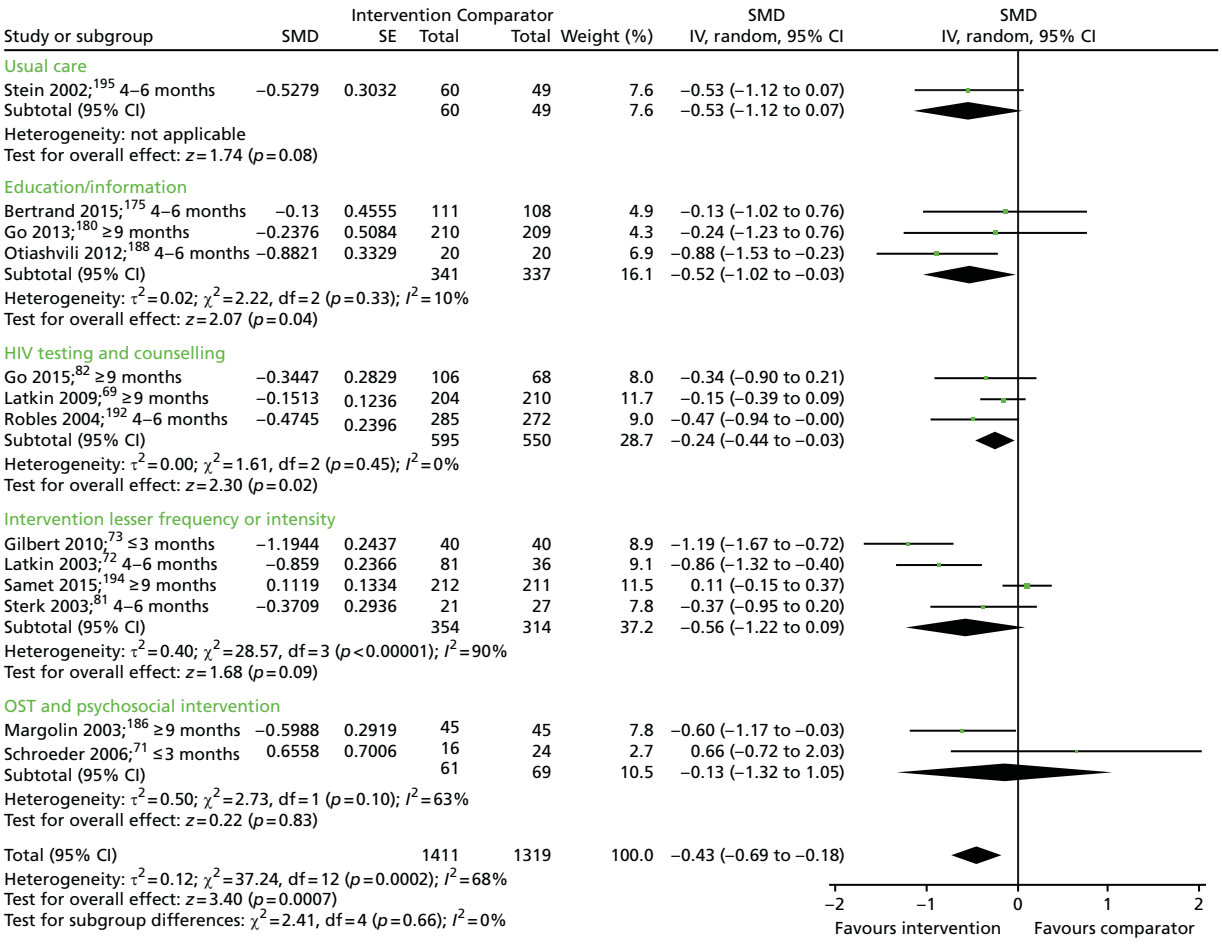

FIGURE 5 Efficacy of psychosocial interventions vs. control interventions in reducing sharing of needles or syringes among PWID by control intervention. df, degrees of freedom; IV, inverse variance; SE, standard error.

control interventions. Psychosocial interventions reduced needle and syringe sharing compared with education/information (SMD –0.52, 95% CI –1.02 to –0.03, $I^2 = 10\%$; $p = 0.04$), or HIV infection testing and counselling (SMD –0.24, 95% CI –0.44 to –0.03, $I^2 = 0\%$; $p = 0.02$). However, no difference was found when psychosocial interventions were compared with interventions of a lesser time or intensity (SMD –0.56, 95% CI –1.22 to 0.09, $I^2 = 90\%$; $p = 0.09$) or interventions of lesser time or intensity that included OST (SMD –0.13, 95% CI –1.32 to 1.05, $I^2 = 63\%$; $p = 0.83$) or TAU (SMD –0.53, 95% CI –1.12 to 0.07; $p = 0.08$; one trial[195]). Where outcomes were assessed ≤ 3 months or 4–6 months post intervention, psychosocial interventions reduced needle and syringe sharing compared with interventions of lesser time or intensity. Where outcomes were assessed 4–6 months post intervention, psychosocial interventions reduced any injecting risk behaviour compared with HIV infection testing and counselling (*Figure 6*). There was moderate and high heterogeneity in the analysis of psychosocial interventions compared with interventions of a lesser time or intensity with OST ($I^2 = 63\%$) and without OST ($I^2 = 90\%$), again potentially explained by the differences in intervention content and delivery. The two trials that compared psychosocial interventions with OST with interventions of a lesser time/intensity with OST varied in length of OST treatment. Both included a 12-week psychosocial intervention; however, the trial in which methadone was prescribed for 6 months independently reduced needle and syringe sharing[186] and the trial that prescribed methadone for 3 months did not.[71] Four trials compared psychosocial interventions with interventions of a lesser time or intensity without OST: the interventions that were delivered to couples[73] or encouraged peer outreach[72] independently reduced needle and syringe sharing, whereas those interventions delivered to individuals on their own or in groups did not.[81,194]

Sharing other injecting equipment

Seven trials assessed the sharing of injecting equipment (other than needles and syringes). None of these trials independently found the psychosocial intervention to be more efficacious than the control interventions. A total of 1209 and 1157 PWID were included in the intervention and the control group, respectively. Overall, psychosocial interventions reduced sharing of other injecting equipment (SMD –0.21, 95% CI –0.34 to –0.09, $I^2 = 0\%$; $p < 0.01$) compared with control interventions. Psychosocial interventions reduced the sharing of other injecting equipment compared with interventions of a lesser time or intensity without OST (SMD –0.24, 95% CI –0.42 to –0.06, $I^2 = 0\%$; $p < 0.01$), but were no different when compared with education/information (SMD –0.42, 95% CI –0.98 to 0.14; $p = 0.15$; one trial[175]) and HIV infection testing and counselling (SMD –0.17, 95% CI –0.34 to 0.00, $I^2 = 0\%$; $p = 0.05$) (*Figure 7*). Where outcomes were compared 4–6 months post intervention, psychosocial interventions reduced sharing of other injecting equipment compared with interventions of lesser time or intensity (*Figure 8*).

Frequency of injecting

Eight trials assessed the frequency of injecting (*Figure 9*). Psychosocial interventions independently reduced frequency of injecting compared with control interventions in four trials.[81,188,192,193] A total of 1168 PWID were included in the intervention group and 1177 in the control group. Overall, psychosocial interventions showed no difference in reducing frequency of injecting (SMD –0.17, 95% CI –0.35 to 0.00, $I^2 = 61\%$; $p = 0.05$). Psychosocial interventions reduced the frequency of injecting compared with education/information (SMD –1.05, 95% CI –2.07 to –0.03; $p = 0.04$; one trial[188]), but no showed difference when compared with interventions of a lesser time or intensity with OST (SMD 0.09, 95% CI –0.61 to 0.79, $I^2 = 76\%$; $p = 0.20$; one trial[71]) and without OST (SMD –0.46, 95% CI –1.02 to 0.21, $I^2 = 66\%$; $p = 0.80$), HIV infection testing and counselling (SMD –0.16, 95% CI –0.40 to 0.08, $I^2 = 76\%$; $p = 0.20$) and TAU (SMD 0.00, 95% CI –0.20 to 0.21; $p = 0.96$; one trial[68]). Where outcomes were compared 4–6 months post intervention, psychosocial interventions reduced the frequency of injecting compared with education/information (*Figure 10*). There was moderate to high heterogeneity in the analysis comparing psychosocial interventions with HIV infection testing and counselling ($I^2 = 76\%$) and with interventions of a lesser time/intensity with OST ($I^2 = 66\%$) and without OST ($I^2 = 66\%$), again potentially explained by the differences in intervention content and delivery described above (see *Study Characteristics*). All HIV infection testing and counselling intervention control groups received two sessions whereas in the intervention conditions the number of sessions ranged from seven[193] to 10.[69]

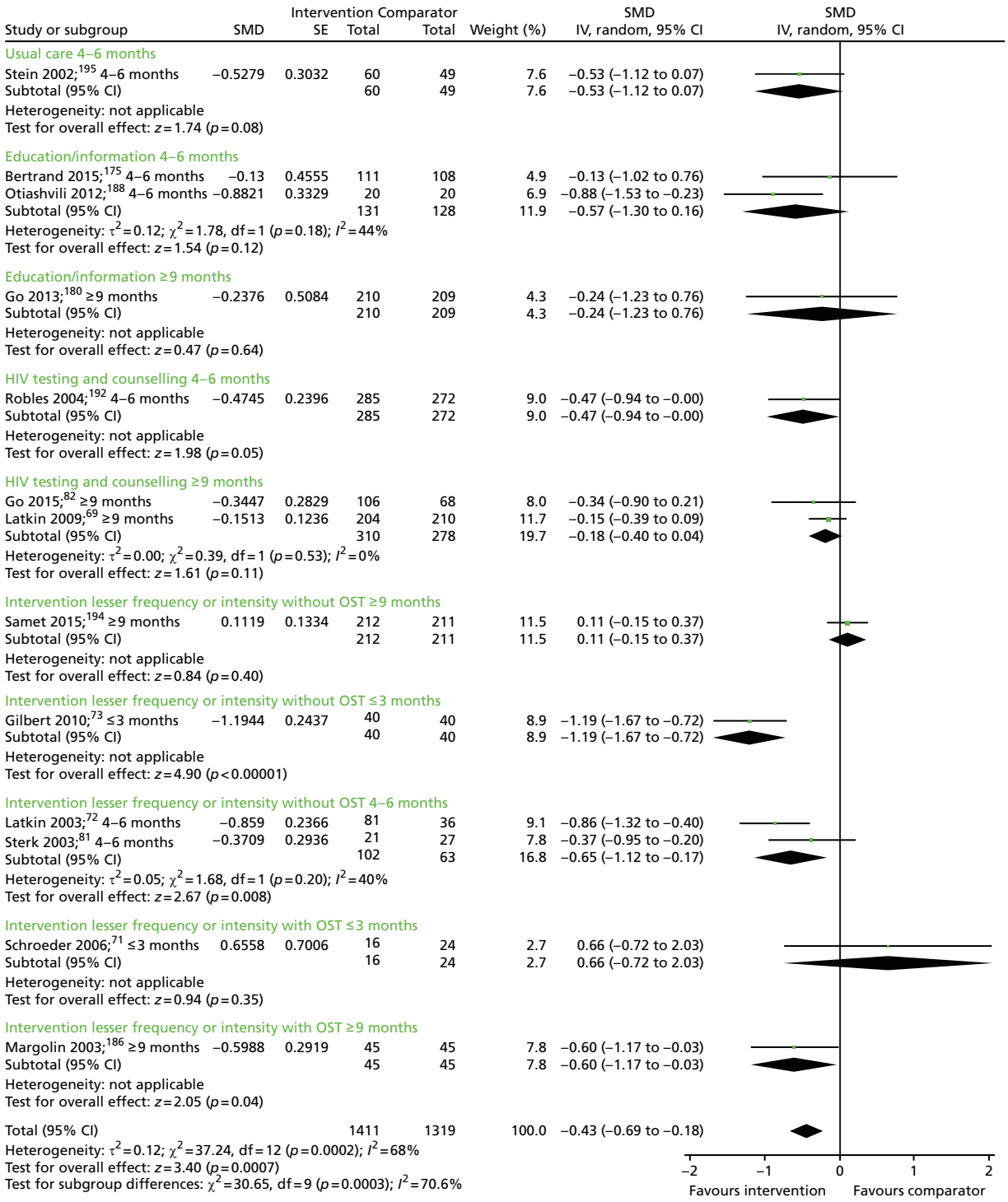

FIGURE 6 Efficacy of psychosocial interventions vs. control interventions in reducing sharing of needles or syringes among PWID by control intervention and length of follow-up post intervention. df, degrees of freedom; IV, inverse variance; SE, standard error.

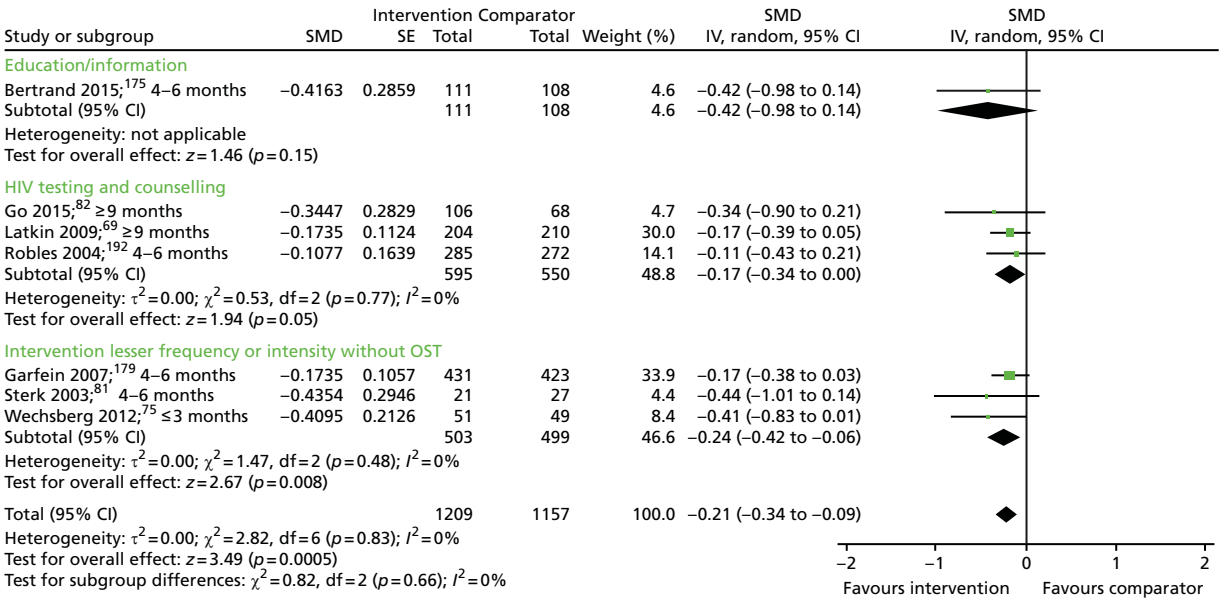

FIGURE 7 Efficacy of psychosocial interventions vs. control interventions in reducing sharing of other injecting equipment (not needle/syringes) among PWID by control intervention. df, degrees of freedom; IV, inverse variance; SE, standard error.

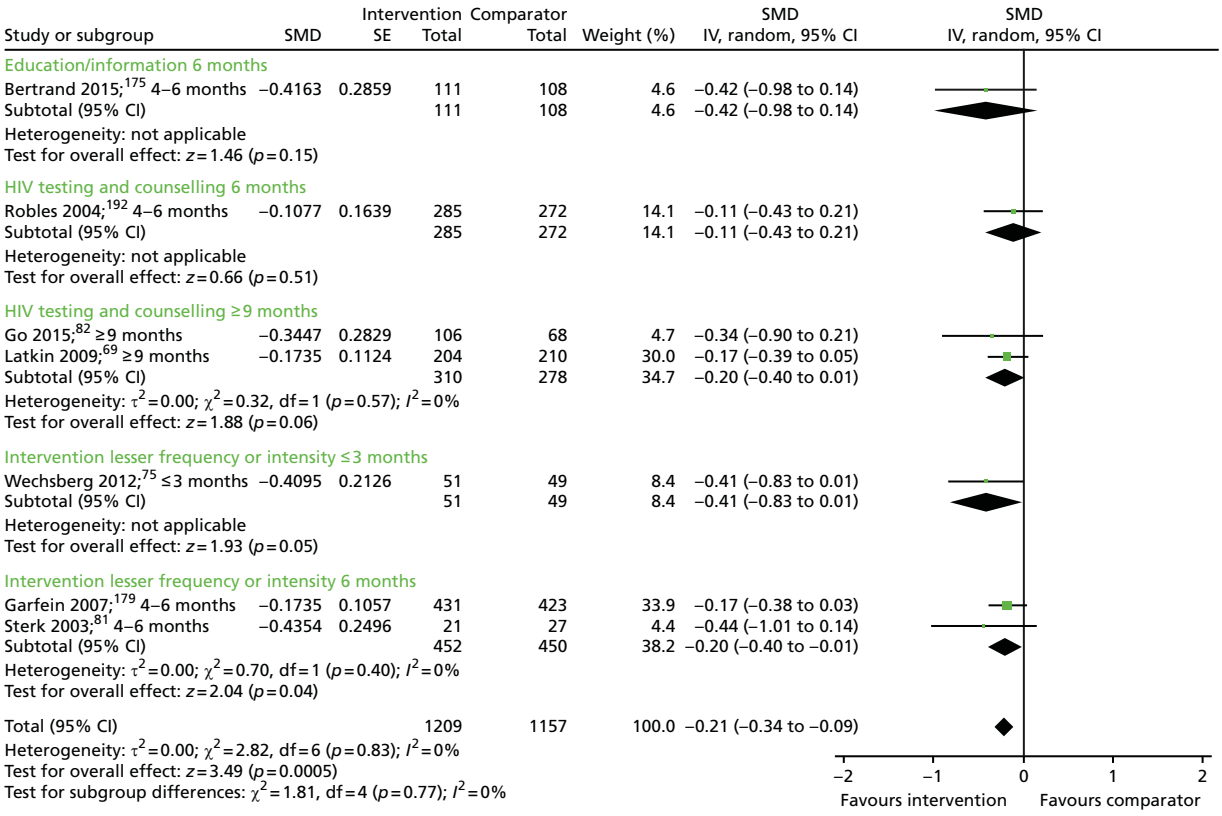

FIGURE 8 Efficacy of psychosocial interventions vs. control interventions in reducing sharing of other injecting equipment (not needle/syringes) among PWID by control intervention and length of follow-up post intervention. df, degrees of freedom; IV, inverse variance; SE, standard error.

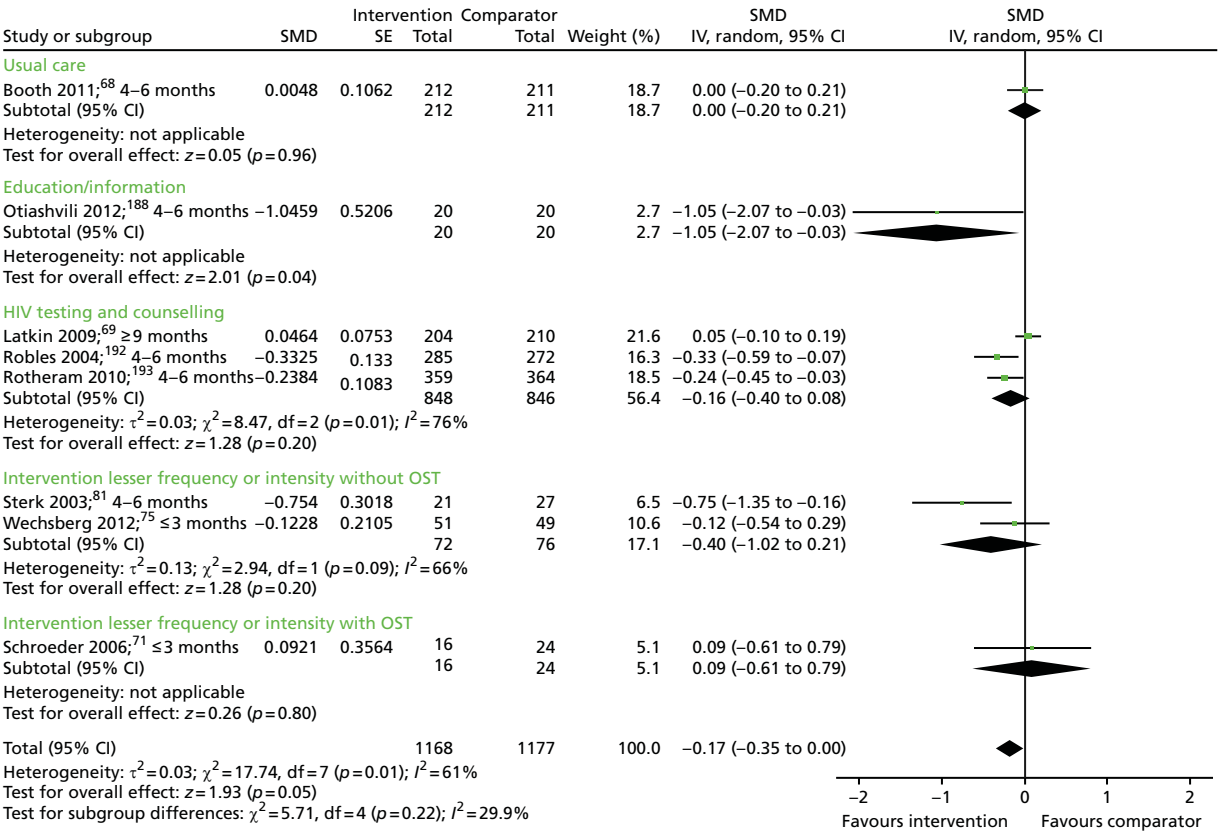

FIGURE 9 Efficacy of psychosocial interventions vs. control interventions in reducing frequency of injecting among PWID by control intervention. df, degrees of freedom; IV, inverse variance; SE, standard error.

Any sexual risk behaviour

Ten trials assessed any sexual risk behaviour (*Figure 11*). Psychosocial interventions were independently more likely to reduce any sexual risk behaviour than the control interventions in two trials.[73,75] A total of 1359 and 1409 PWID were included in the intervention and control groups, respectively. Overall, psychosocial interventions reduced any sexual risk behaviour compared with control interventions (SMD –0.19, 95% CI –0.39 to 0.01, $I^2 = 58\%$; $p = 0.07$). Psychosocial interventions were no different in reducing any sexual risk behaviours compared with education/information (SMD –0.12, 95% CI –0.32 to 0.09, $I^2 = 34\%$; $p = 0.27$), interventions of a lesser time or intensity with OST (SMD –0.26, 95% CI –0.67 to 0.15, $I^2 = 78\%$; $p = 0.21$), without OST (SMD –0.17, 95% CI –1.41 to 1.07, $I^2 = 72\%$; $p = 0.79$) and HIV infection testing and counselling (SMD 0.14, 95% CI –0.81 to 1.09; $p = 0.77$; one trial[82]). Where outcomes were compared ≤ 3 months post intervention, psychosocial interventions reduced any sexual risk behaviour compared with interventions of a lesser time or intensity (without OST) (*Figure 12*). The high heterogeneity in the analysis comparing psychosocial interventions with interventions of a lesser time or intensity with OST ($I^2 = 78\%$) and without OST ($I^2 = 72\%$) has already been discussed.

Unprotected sex

Eight trials assessed unprotected sex. Psychosocial interventions were more effective than control interventions in four trials.[73,75,81,186] A total of 876 and 930 PWID were included in the intervention and control group, respectively. Psychosocial interventions were independently more effective than the control interventions in four trials.[73,75,81,186] A total of 876 and 930 PWID were included in the intervention and control groups, respectively. Overall, psychosocial interventions reduced unprotected sex compared with control interventions (SMD –0.27, 95% CI –0.54 to –0.01, $I^2 = 68\%$; $p = 0.04$). Psychosocial interventions reduced unprotected sex compared with interventions of a lesser time or intensity (without OST) (SMD –0.44, 95% CI –0.86 to –0.01, $I^2 = 79\%$; $p = 0.04$), but there was no difference when compared with

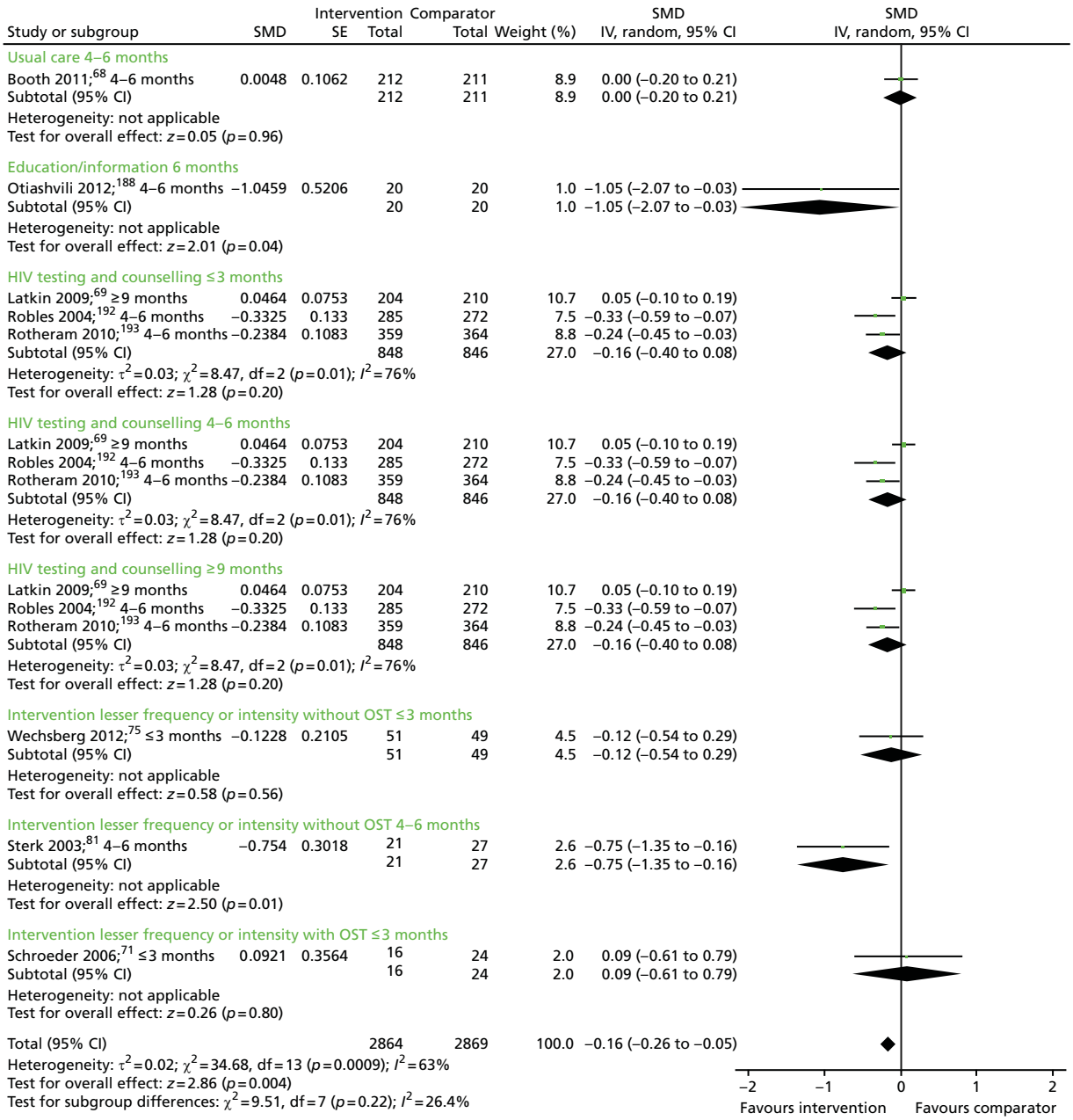

FIGURE 10 Efficacy of psychosocial interventions vs. control interventions in reducing frequency of injecting among PWID by control intervention and length of follow-up post intervention. df, degrees of freedom; IV, inverse variance; SE, standard error.

education/information (SMD 0.03, 95% CI –0.18 to 0.24; $p = 0.79$; one trial[70]), interventions of a lesser time or intensity with OST (SMD –0.13, 95% CI –1.21 to 0.94, $I^2 = 70\%$; $p = 0.81$) and HIV infection testing and counselling (SMD 0.14, 95% CI –0.81 to 1.09; $p = 0.77$; one trial[82]). (*Figure 13*) Where outcomes were compared ≤ 3 and 4–6 months post intervention, psychosocial interventions reduced unprotected sex compared with interventions of a lesser time or intensity (without OST). Where outcomes were assessed ≥ 9 months post intervention, psychosocial interventions reduced unprotected sex compared with interventions of a lesser time or intensity (with OST) (*Figure 14*).

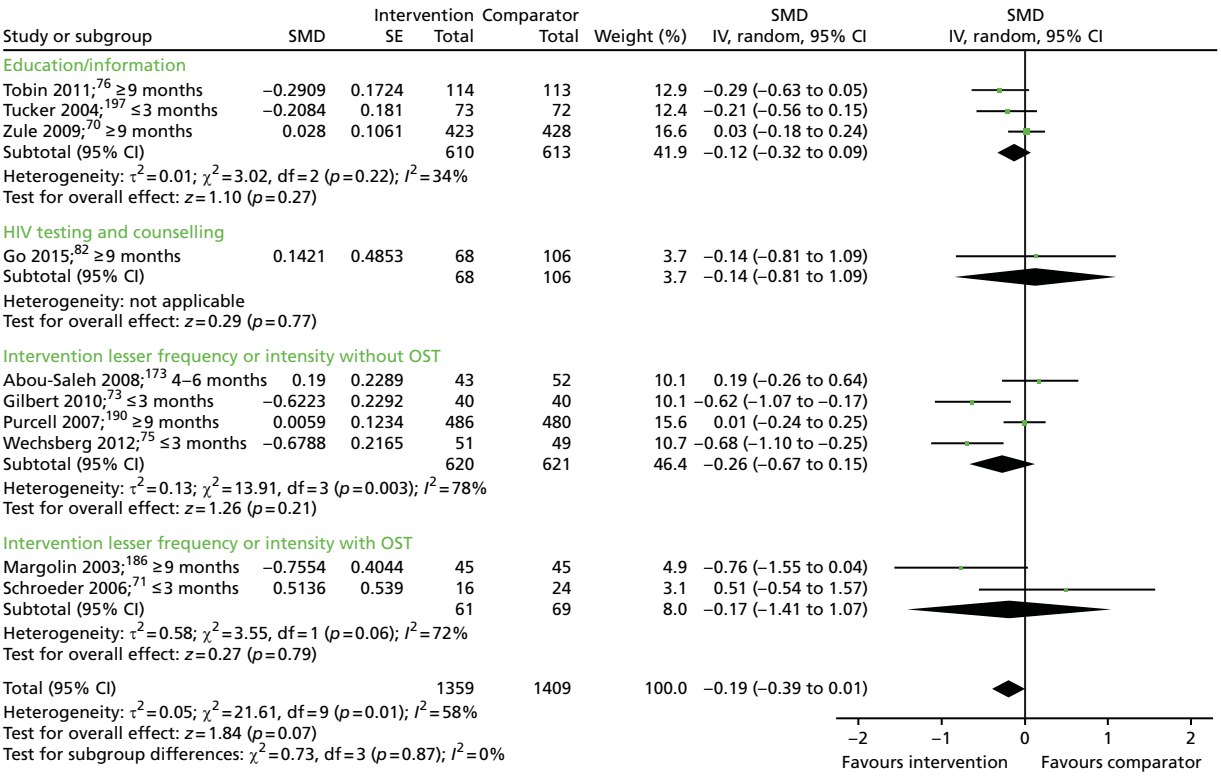

FIGURE 11 Efficacy of psychosocial interventions vs. control interventions in reducing ANY sexual risk behaviours among PWID by control intervention. IV, inverse variance.

Number of sexual partners

Two trials[76,81] assessed the number of sexual partners (*Figure 15*). A total of 135 PWID were included in the intervention group and 140 in the control group. There was no difference between psychosocial interventions and education/information in reducing the number of sexual partners (SMD 0.01, 95% CI –0.14 to 0.17; $p = 0.89$; one trial[76]). Interventions of a lesser time or intensity (without OST) reduced the number of sexual partners compared with psychosocial interventions (SMD 3.24, 95% CI 2.36 to 4.12; $p < 0.01$; one trial[81]).

Discussion

The aim of the review and meta-analysis was to identify and evaluate the impact of psychosocial interventions which were designed to reduce injecting risk and sexual risk behaviours among PWID. A total of 24 trials were included in the analysis. Overall, psychosocial interventions reduced some of the target injecting (sharing of needle and syringes and other injecting equipment) and sexual risk behaviour (unprotected sex) outcomes among PWID when compared with control conditions. More specifically, the meta-analysis found that psychosocial interventions reduced the sharing of needles and syringes compared with education/information or HIV infection testing and counselling, reduced the sharing of other injecting equipment compared with interventions of a lesser time or intensity, reduced the frequency of injecting compared with one trial of education/information, and reduced unprotected sex compared with interventions of a lesser time or intensity. Although psychosocial interventions targeted injecting risk behaviours rather than a reduction in injecting behaviour per se, one trial[188] reported that a significant effect ($p = 0.05$) was found with regard to reduced frequency of injecting. Psychosocial interventions were no more likely than control interventions to reduce the number of sexual partners. However, only two trials[76,81] were pooled in this specific meta-analysis, and many participants reported being in a steady relationship. Interestingly, they also reported a reduction in unprotected sex, a factor which may be more important in reducing BBV transmission than the number of sex partners.[76,81]

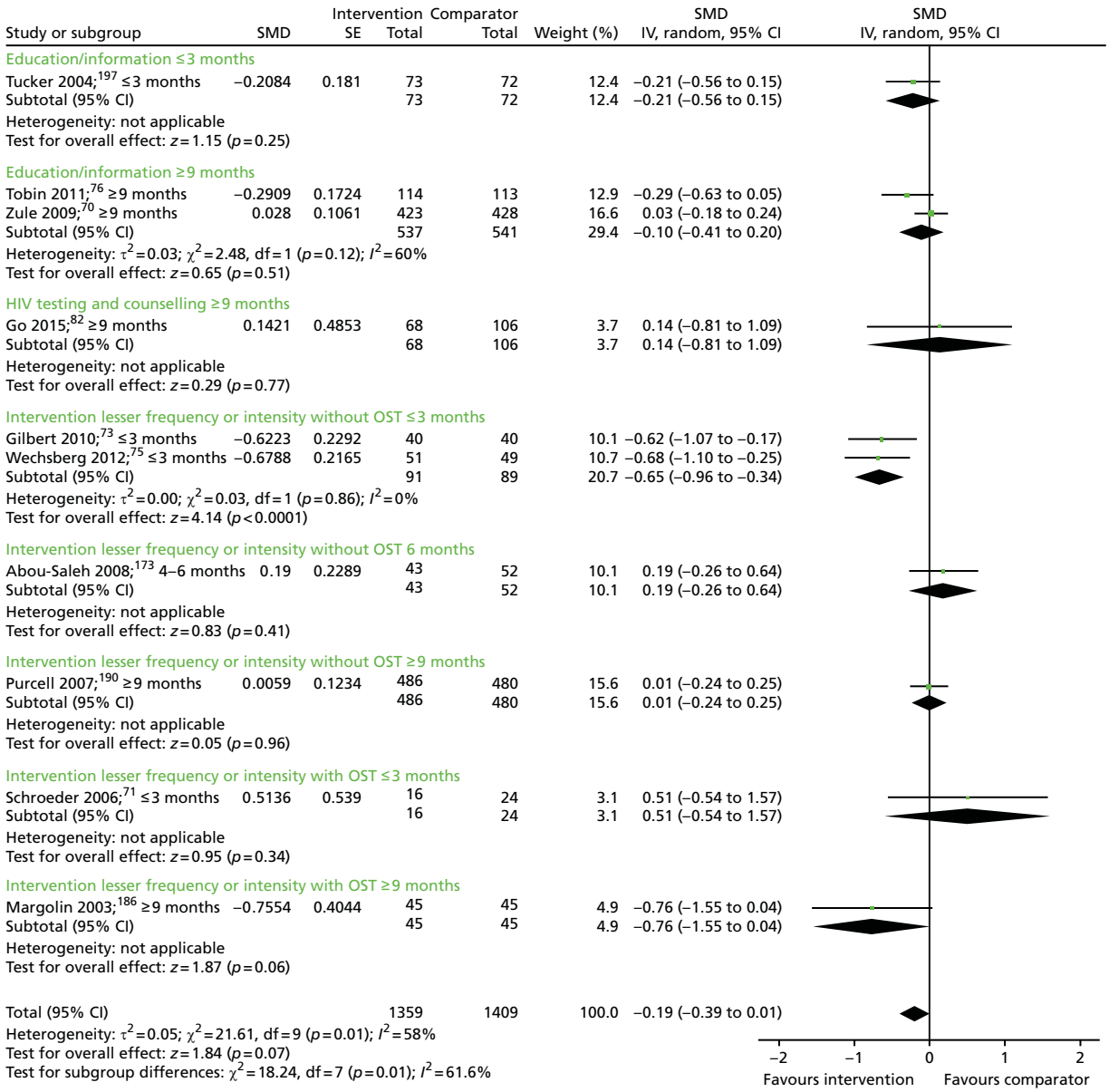

FIGURE 12 Efficacy of psychosocial interventions vs. control interventions in reducing ANY sexual risk behaviours among PWID by control intervention and length of follow-up post intervention. IV, inverse variance.

Individual, group and couple psychosocial interventions, but not mixed (individual + group session) interventions, reduced any injecting risk behaviour compared with control interventions. Psychosocial interventions of three sessions or more are more likely to reduce injecting risk behaviours, and psychosocial interventions of one or two sessions are more likely to reduce sexual risk behaviours. The meta-analyses using data on outcomes collected at ≥ 9 months post intervention found that psychosocial interventions produced more reported behaviour change than controls, suggesting that booster sessions may be required to sustain positive behaviour change.[200]

One study found reported that intervention effects were stronger for those who had known their HCV-positive status for at least 6 months than for those who had known their HCV-positive status for > 12 months,[182] suggesting that there may be a window of opportunity following HCV diagnosis to address transmission risks.

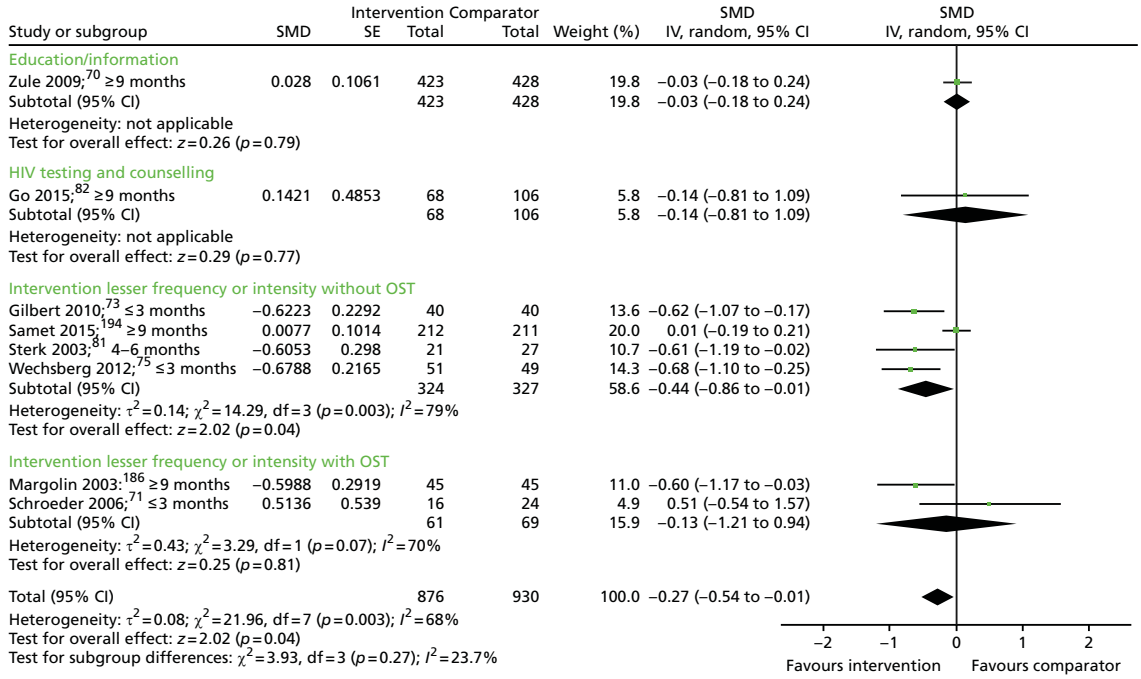

FIGURE 13 Efficacy of psychosocial interventions vs. control interventions in reducing unprotected sex among PWID by control intervention. IV, inverse variance.

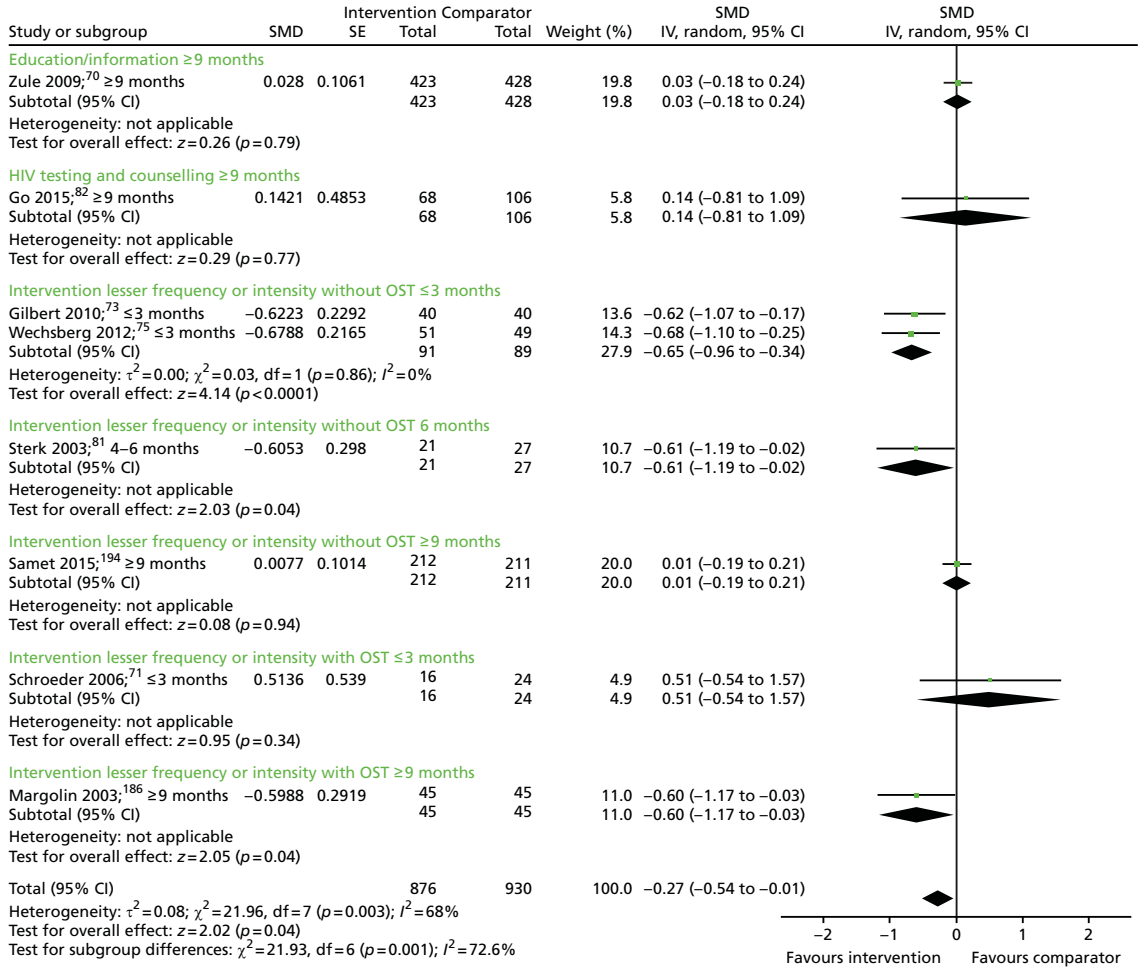

FIGURE 14 Efficacy of psychosocial interventions vs. control interventions in reducing unprotected sex among PWID by control intervention and length of follow-up post intervention. IV, inverse variance.

Study or subgroup	SMD	Intervention SE	Intervention Total	Comparator Total	Weight (%)	SMD IV, fixed, 95% CI
Education/information ≥9 months						
Tobin 2011;[76] ≥9 months	0.0109	0.079	114	113	97.0	0.01 (–0.14 to 0.17)
Subtotal (95% CI)			114	113	97.0	0.01 (–0.14 to 0.17)
Heterogeneity: not applicable						
Test for overall effect: $z = 0.14$ ($p = 0.89$)						
Intervention lesser frequency or intensity without OST 4–6 months						
Sterk 2003;[81] 4–6 months	3.2398	0.4514	21	27	3.0	3.24 (2.36 to 4.12)
Subtotal (95% CI)			21	27	3.0	3.24 (2.36 to 4.12)
Heterogeneity: not applicable						
Test for overall effect: $z = 7.18$ ($p < 0.00001$)						
Total (95% CI)			135	140	100.0	0.11 (–0.05 to 0.26)
Heterogeneity: $\chi^2 = 49.65$, df = 1 ($p < 0.00001$); $I^2 = 98\%$						
Test for overall effect: $z = 1.37$ ($p = 0.17$)						
Test for subgroup differences: $\chi^2 = 49.65$, df = 1 ($p < 0.00001$), $I^2 = 98.0\%$						

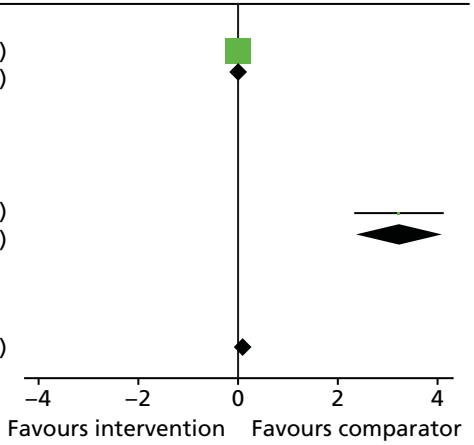

FIGURE 15 Efficacy of psychosocial interventions vs. control interventions in reducing number of sexual partners among PWID by control condition and length of follow-up post intervention. IV, inverse variance.

Overall and regardless of intervention or control content, 16 of the 32 trials included in the systematic review reported greater reductions in injecting or sexual risk behaviours in participants in the intervention compared with the control groups.[72,73,75–77,81,84,174,177–179,182,186,188,192,193] Only two trials[71,188] in the review (with small sample sizes) included CM (incentivisation). One of these trials reported that reductions in injecting risk behaviours were greater in the intervention group [22 sessions of MI for the male participant and couple (female partner drug free), plus CM and naltrexone] than in the control group (22 sessions of education, including referrals to a detoxification programme and aftercare that may or may not have included naltrexone).[188] The other reported no significant difference in injecting or sexual risk behaviours between the intervention [29-week intervention including 12 weeks of CBT and contingent vouchers as well as standard care (methadone + 5-weekly individual counselling), followed by 12 weeks of standard treatment] and the control groups [29-week standard care intervention (same as intervention group), including 12 weeks of group therapy and non-contingent vouchers][71] (see *Table 2*). However, only three[77,178,186] of the seven trials[69,70,77,175,178,186,196] of psychosocial interventions including MI found greater reductions in some injecting and sexual risk behaviours. As these three interventions varied in content and participant group [e.g. one interactive session for female sex workers,[77] computerised intervention (69% male),[178] and PWID entering OST (70% male)],[186] results about the effectiveness of specific intervention functions (e.g. incentivisation or persuasion) in reducing BBV risk behaviours among PWID are inconclusive.

Limitations

Limitations include the small number of studies for inclusion in some of the subgroup analyses of behavioural outcomes and intervention delivery modes. In addition, there was heterogeneity in terms of the interventions studied and their duration, as well as differences in sample sizes and characteristics, length of follow-up and assessment methods used to determine risk behaviours. This lack of consistency across studies may have contributed to the moderate levels of heterogeneity noted in the meta-analyses. The most common risk of bias in included RCTs was selective outcome reporting and possible crossover contamination between groups. A further limitation is that authors of the eight trials not included in the meta-analysis were not contacted to determine whether or not they could supply the additional data required to include the trial in the meta-analysis. It is acknowledged that this could have resulted in a potential source of bias in the findings. These limitations need to be considered when interpreting the results.

Conclusions

Although indications from the meta-analysis suggest that psychosocial interventions (when compared with control) reduce risk-taking behaviour outcomes, more research is needed. The findings highlight the difficulty and complexity involved in attempting to examine the effectiveness of interventions that include different content and functions, modes of delivery, dosage and number of sessions. This heterogeneity in both the control and intervention conditions resulted in challenges to fully interpret the findings. It will be important to determine what types of psychosocial interventions work for whom and in what settings.[56] Our findings suggest that psychosocial interventions could boost the impact of current harm reduction interventions delivered as routine care and could be included with other harm reduction approaches, including OST and needle and syringe exchange, to reduce BBV transmission risks among PWID. Further trials should address some of the limitations in terms of target populations, dose and frequency and timing of outcome measures.

Scoping review of grey literature

Methods

A scoping review of UK grey literature was conducted during April 2015 to determine if any unpublished evidence on the efficacy of psychosocial interventions was available that had not been identified through the systematic review. Thirty-one databases were searched to identify psychosocial interventions to reduce

injecting and sexual risk behaviours among PWID in the UK (*Table 3*). A combination of the following search terms were used to search for relevant interventions:

- UK/England/Scotland/Wales/Ireland
- Intervention/behavio*r/motivational counselling
- Inject*/intravenous
- Drug*/opiate/heroin/crack/cocaine
- Blood borne virus/hepatitis/HIV.

In addition, 64 academics/BBV experts identified by the Steering Group were sent requests for information on unpublished research in the UK that had taken place or that was ongoing on psychosocial interventions to reduce injecting and sexual risk behaviours associated with the transmission of BBV among PWID.

TABLE 3 Databases, search engines and websites

Databases, search engines and websites	Records (UK)
Grey literature sites	
Open Grey	0
CADTH Grey Matters	0
NYAM Grey Lit	0
Clinical trials	
UK Health Forum	0
UKCRN	0
EUCTR	0
Healthcare Improvement Scotland	0
NIHR Horizon Scanning Centre (via CADTH)	0
NIHR HTA programme	0
NIHR Evaluation, Trials and Studies	0
SIGN	0
MRC CTU	0
ClinicalTrials.gov	0
Theses and dissertations	
EThOs	0
ProQuest Dissertations and Theses	0
OATD	0
OpenThesis	0
BBV organisations	
Hepatitis Scotland	0
British Liver Trust	0
Hepatitis C Trust	2

TABLE 3 Databases, search engines and websites (*continued*)

Databases, search engines and websites	Records (UK)
Waverley Care	0
Hep C Positive	0
NHS Hepatitis C Resource Centre	0
Hepatitis C UK Forum	0
Positive Help	0
Lanarkshire HIV & Hepatitis	0
British HIV Association	0
Terrence Higgins Trust	0
C-Clear Peer Education Project Fife	0
Other	
Health Scotland	1
Drug and Alcohol Findings	0
Web of Science	0
Social Care Institute for Excellence	0
EMCDDA	0
BioMed Central	1
PLOS	0
SSRN	0
The British Library	0
Search engines	
Bing (Microsoft Corporation, Redmond, WA, USA)	0
Yahoo! (Verizon Communications, Sunnyvale, CA, USA)	0
Google Scholar (Google Inc., Mountain View, CA, USA)	0

CADTH, Canadian Agency for Drugs and Technologies in Health; EMCDDA, European Monitoring Centre for Drugs and Drug Addiction; EThOs, Electronic Theses Online Service; EUCTR, EU Clinical Trials Register; MRC CTU, Medical Research Council Clinical Trials Unit; NIHR, National Institute for Health Research; NYAM, New York Academy of Medicine; OATD, Open Access Theses and Dissertations; PLOS, Public Library of Science; SIGN, Scottish Intercollegiate Guidelines Network; SSRN, Social Science Research Network; UKCRN, UK Clinical Research Network.

Note

Other manuals identified from grey literature review outwith the UK.

Results

The search provided no UK-based reports, papers or study protocols (in progress or completed) directly related to psychosocial interventions aimed at preventing or reducing BBV transmission risk behaviours among PWID and delivered in the UK, although three evaluations of two peer-to-peer projects (in Scotland and Liverpool) were found (see *Table 3*).

During a grey literature search for UK-based interventions, a number of international manuals were found (*Table 4*).

TABLE 4 International manuals with potential utility in BBV intervention design

Manual	Outline	Criteria[a]	Ranking[b]	Origin	Evidence based/evaluated
REDUCE: Reducing Hepatitis C Risk Behaviours Among Female Drug Users in Europe[201]	Three-session group intervention for females who inject drugs: 1. understanding HCV transmission risks 2. HCV and sexual well-being: negotiating safety 3. HCV and emotional well-being: reducing negative mood	BBV (hepatitis/HIV); psychosocial intervention; risk behaviours (injecting/sexual); PWID; instructions	High	European	Yes/yes
Training Guide for HIV Prevention Outreach to Injecting Drug Users[202]	A package designed to aid the set-up of workshops designed to familiarise and train public health policy-makers, programme developers, programme managers, implementers and field workers in outreach to injecting drug users. It includes four workshop modules in a set order to enable the training of a wide range of participants, with varying training needs: 1. orientation workshop 2. programme development workshop 3. programme management workshop 4. field worker training	BBV (hepatitis/HIV); risk behaviours (injecting/sexual); PWID; instructions. (Requires CD-ROM for use with manual)	High	WHO	Yes/?
The NIDA Community-Based Outreach Model: A Manual to Reduce the Risk of HIV and Other Blood-Borne infections in Drug Users[203]	A manual containing information to assist community planners, policy-makers, programmers and service providers with developing and implementing programmes to better prevent the spread of HIV and other blood-borne infections. Specifically, the manual provides: • research-based principles of HIV prevention for drug using • populations not in drug treatment • background information on community-based HIV prevention, including how it works, why it works, where it works, and for whom it works • a discussion of the roles and personal characteristics of effective community-based outreach workers • step-by-step instructions for conducting community-based outreach and risk reduction • counselling sessions for out-of-treatment drug users and their sex partners	BBV (hepatitis/HIV); psychosocial intervention; risk behaviours (injecting/sexual); PWID; instructions	High	USA	Yes/yes

Manual	Outline	Criteria[a]	Ranking[b]	Origin	Evidence based/evaluated
	• information for programme managers on how to establish a community-based outreach HIV/AIDS risk reduction prevention programme locally, establish a field station and provide training and supervision to staff • cue cards to be used or adapted during educational and risk reduction counselling sessions				
UFO Model Replication Manual: A Hep C Intervention for Young Adult IDU[204]	The UFO model provides a 4-week education and support group for young adult IDUs who are at risk of or infected with HCV. These 1-hour group sessions takes place once a week for 4 consecutive weeks at a convenient time for participants. Ideally, the group should be offered on a regular basis, perhaps running the group three or four times per year. Participants may complete all sessions in one group, or may make up missed sessions during the next scheduled group. Participants are not required to complete all sessions, and may wish to return to certain sessions for boosters: • session 1: hepatitis ABCs • session 2: keeping you and your friends healthy – how to decrease HCV transmission risk • session 3: body and mind – how drugs, alcohol and HCV affect your physical and mental health • session 4: relationships and risk • add-on session: HCV treatment 101	BBV (hepatitis/HIV); psychosocial intervention; risk behaviours (injecting/sexual); PWID; instructions	High	USA	Yes/?
REMAS: A Gender-Focused HIV & Sexual Risk Reduction Intervention for Men in Substance Abuse Treatment[205]	Developed by the National Drug Abuse Treatment Clinical Trials Network Gender Specific HIV Prevention Intervention Protocol Development Team and used by male counsellors delivering the REMAS intervention to substance abuse treatment clients enrolled in protocol CTN-0018, 'Reducing HIV/STD Risk Behaviours: A Research Study for Men in Drug Abuse Treatment'. It is a five-session group-delivered intervention package designed to help clients in substance abuse treatment reduce their HIV risk [www.ctndisseminationlibrary.org/protocols/ctn0018.htm (accessed 10 October 2017)]	BBV (HIV); psychosocial intervention; risk behaviours (injecting/sexual); MWID; instructions	High	USA	Yes/yes

continued

TABLE 4 International manuals with potential utility in BBV intervention design (*continued*)

Manual	Outline	Criteria[a]	Ranking[b]	Origin	Evidence based/evaluated
Safety Counts Program Manual: A Cognitive–Behavioural Intervention to Reduce HIV/Hepatitis Risks Among Drug Users Who Are Not in Drug Treatment[206]	The Safety Counts intervention comprises nine sessions focusing on developing and implementing a personalised risk reduction plan. First, two individual standard pre- and post-test counselling sessions incorporate drug-focused prevention education to review basic HIV/AIDS information and provide optional HIV infection testing and counselling. Next, two interactive group workshop sessions, employing stages of change framework, are implemented with structured exercises involving three to seven clients to help them develop a personal HIV risk reduction plan, consider potential barriers and solutions, identify sources of social support through group discussion, view role model videos and complete two worksheet exercises to identify their own HIV risks and place themselves in on a stages-of-change continuum for each risk behaviour. Then a one-on-one individual counselling session is conducted to refine the client's personal risk reduction plan, strengthen commitment to personal goals, ensure availability of social support for risk reduction, and assess and arrange referral needs. One month after the client receives the individual counselling session, a minimum of two 15- to 20-minute field-based supportive follow-up outreach contacts are scheduled to reinforce progress towards risk reduction and encourage achievement and maintenance of personal risk reduction goals. Also, a minimum of two monthly social events, each lasting 2 hours, are provided, including lunch and planned HIV risk reduction activities, games and skits for clients and their peer-support buddies (15–25 clients and 10–15 guests), to provide support for HIV risk reduction, influence perceived social norms and increase self-efficacy for reducing HIV risks. Finally, food bank grocery bags and food coupons are made available to clients in storefront offices as a programme incentive every other week	BBV (hepatitis/HIV); psychosocial intervention; risk behaviours (injecting/sexual); MWID; instructions	High	USA	Yes/yes

IDU, injection drug user; MWID, men who inject drugs; REMAS, REal Men Are Safe; WHO, World Health Organization.

a Inclusion criteria: BBV (hepatitis/HIV); psychosocial intervention (e.g. MI, CBT, peer led); risk behaviours considered (injecting/sexual); PWID; instructions to facilitators.

b Ranking criteria: high, all criteria included; moderate, no instructions but includes psychosocial intervention for BBV risk reduction and includes evidence and references; low, no instructions, no psychosocial intervention for BBV risk reduction/no evidence and references.

Experts

Sixty-one per cent (39/64) of the academics/experts responded to the request for information about psychosocial interventions to reduce BBV transmission behaviours among PWID. A contact at the National Needle Exchange Forum (NNEF) cascaded the request to their membership via Facebook (Facebook, Inc., Menlo Park, CA, USA) and e-mail; however, no further responses were gathered from NNEF members. Two respondents provided relevant information:

1. Dr Magdalena Harris from the London School of Hygiene & Tropical Medicine shared publications, presentations and resources from three research studies:

    i. *Staying Safe: A Sociology of How People Who Inject Drugs Avoid Hepatitis C in the Long Term* [funded by the Economic and Social Research Council; RES-062-23-1766; www.youtube.com/watch?v%20=%20PsWn0_gOT4Q (YouTube, LLC, San Bruno, CA, USA; accessed 10 October 2017)][207]
    ii. *The Hepatitis C Treatment Journey: A Prospective Qualitative Longitudinal Study Addressing Patient, Provider and System Perspectives* (funded by National Institute for Health Research, PDF-2011-04-031)[208]
    iii. *HCV Treatment: Barriers and Facilitators to Hepatitis C Treatment For People Who Inject Drugs* (the European Commission Directorate of Health and Consumers and the World Health Organization's Regional Office for Europe; Grant Agreement 2008 52 02 work package 4).[209]

    These projects further highlighted the need among PWID for information about HCV prevention, transmission, diagnosis, testing, treatment, symptoms and natural history. Findings from Staying Safe determined the protective networks and environments for PWID and concluded that addressing pragmatic short-term meaningful goals for PWID could result in harm reduction (e.g. image management, venous access and care). Findings from this research were used to inform the intervention development and Dr Harris became a member of the PROTECT intervention development group. The following manuscripts were downloaded to inform intervention development from these studies: Harris and Rhodes,[45,210,211] Harris *et al.*[50,212,213] and McGowan *et al.*[51]

2. Alexis Llewellyn from the Centre for Reviews and Dissemination, University of York, provided a draft Cochrane review paper entitled 'Multi-Session and Brief Psychosocial Interventions For Preventing HIV in People Who Use Drugs'.

Further information was provided by five respondents, although none directly related to psychosocial interventions.

Drug and alcohol commissioning mapping exercise

Aim

To survey all agencies responsible for alcohol and drug commissioning in the UK for information on psychosocial interventions available and their effectiveness in reducing BBV risk behaviours among PWID.

Methods

A brief survey was sent by e-mail to all agencies responsible for alcohol and drug commissioning in the UK (i.e. alcohol and drug commissioners in England, alcohol and drug partnerships in Scotland, health- and social-care trusts in Northern Ireland and substance misuse area planning boards in Wales). The survey was sent up to three times during January and February 2015, 1 week apart, to maximise response rates. Where contacts were out of date, telephone contact was made in an attempt to update the contact details.

Results

Surveys were emailed to 164 alcohol and drug commissioners in England from 150 commissioning teams. In Scotland, surveys were sent to 30 alcohol and drug partnerships. In Northern Ireland, surveys were sent to five health- and social-care trusts and, in Wales, surveys were sent to seven substance misuse area planning boards. In England, 93 surveys from 84 alcohol and drug commissioners were returned (84/150, 56%). In total, 26 surveys from 21 alcohol and drug partnerships in Scotland were returned (21/30, 70%). Two of the five health- and social-care trusts in Northern Ireland responded to the survey (2/5, 40%). In Wales, seven surveys were returned from five substance misuse area planning boards (5/7, 71.4%).

Table 5 describes the proportion of alcohol and drug commissioners by country that reported providing psychosocial interventions to PWID to reduce BBV risk behaviours. The most common psychosocial interventions used were CBT, coping skills training, relapse prevention training and MI/enhancement therapy.

If alcohol and drug commissioners reported providing any psychosocial interventions, they were asked whether or not it was evidence based (*Table 6*) and available as a manual or in written form (*Table 7*).

A review of the manuals/written materials identified suggested that no UK areas were currently delivering interventions (group or individual) that focused exclusively on BBV and injecting/sexual risk behaviours, although the interventions that were delivered could include discussion of BBV transmission risks and prevention within the wider context of substance use reduction or abstinence. The majority of interventions were delivered on a one-to-one basis by a key worker to a client. Group work primarily involved family members/significant others. Several areas had adapted toolkits from other instruments.

TABLE 5 Psychosocial interventions provided to reduce BBV risk behaviours in the UK

	Location in the UK (%)			
Psychosocial intervention	England ($n = 93$)	Scotland ($n = 26$)	Northern Ireland ($n = 2$)	Wales ($n = 7$)
CBT	82.8	53.8	50	71.4
Coping skills training	66.7	76.9	100	71.4
Behavioural self-control training	39.8	23.1	50	42.9
Relapse prevention therapy	87.1	73.1	100	85.7
MI/motivational enhancement therapy	95.7	96.2	100	85.7
Contingency management	53.8	23.1	50	42.9
Some family approaches	64.5	30.8	100	28.6
Psychoeducation	57.0	69.2	100	57.1
Behavioural couples therapy	31.2	65.4	50	–
Social behaviour and network therapy	32.3	11.5	50	42.9
Other (please describe)	16.1[a]	34.6[b]	–	14.3[c]

ITEP, International Treatment Effectiveness Project.

a Coaching, goal-setting, e-therapy, information, volunteering and self-help groups, structured groups (ITEP/5 Ways to Well-being/CBT), harm minimisation, harm reduction, life skills course, mindfulness, mindfulness-based relapse prevention, node-link mapping, peer support, pre- and post-testing support and Making Every Contact Count framework.

b Break the cycle, community reinforcement approach, cognitive–behavioural integrated therapy, complimentary therapies, sleep hygiene, facilitate entry to mutual aid and self-help, counselling, integrated therapy, mindfulness (based) approaches, reality therapy.

c No details provided.

TABLE 6 Evidence-based psychosocial interventions provided to reduce BBV risk behaviours

Psychosocial intervention	Not evidence based (%)	Yes, evidence known from service data[a] (%)	Yes, evidence known from outcome evaluation/trial[a] (%)	Do not know (%)
CBT ($n = 90$)	25.6	30.0	36.6	7.8
Coping skills training ($n = 82$)	28.0	32.9	25.6	13.4
Behavioural self-control training ($n = 44$)	18.2	38.6	34.1	9.1
Relapse prevention therapy ($n = 100$)	21.0	34.0	32.0	13.0
MI/motivational enhancement therapy ($n = 113$)	24.8	29.2	34.5	11.5
Contingency management ($n = 58$)	20.7	37.9	36.2	5.2
Some family approaches ($n = 64$)	21.9	37.5	35.9	4.7
Psychoeducation ($n = 70$)	27.1	35.7	24.3	12.9
Behavioural couples therapy ($n = 29$)	24.1	31.0	41.4	3.4
Social behaviour and network therapy ($n = 36$)	13.9	41.7	36.1	8.3

a If a respondent marked evidence from both service data and outcome evaluation/trial, their response was recorded as evidence known from outcome evaluation/trial, as the weight of the evidence was considered greater if an evaluation or trial had been conducted.

TABLE 7 Psychosocial interventions available as manuals or in written form

Psychosocial intervention	Available as manual/written form (*n*)
CBT	38
Coping skills training	37
Behavioural self-control training	24
Relapse prevention therapy	57
MI/motivational enhancement therapy	50
Contingency management	21
Some family approaches	23
Psychoeducation	35
Behavioural couples therapy	15
Social behaviour and network therapy	19

Figure 16 describes that, although 116 manuals/written materials (56 after duplicates removed) were identified from the survey, only 11 were considered potentially useful to the design of a BBV risk reduction intervention for PWID. *Table 8* provides links and information to potentially useful content currently used in the UK.

Summary

A scoping of the UK grey literature provided no UK-based reports, papers or study protocols (in progress or completed) directly related to psychosocial interventions aimed at preventing or reducing BBV transmission risk behaviours among PWID and delivered in the UK. An information request about psychosocial interventions to reduce BBV transmission behaviours among PWID was sent to 64 UK academics/experts and the information provided was used in the development of the PROTECT intervention. In addition, a brief survey was sent by e-mail to all agencies responsible for alcohol and drug commissioning in the UK for information on psychosocial interventions available and their effectiveness in reducing BBV risk behaviours among PWID. A range of evidence-based psychosocial interventions were reported, with the most commonly used being CBT, coping skills training, relapse prevention training and MI/enhancement therapy. A review of the manuals/written materials suggested that there are currently no interventions that focus exclusively on BBV and injecting/sexual risk behaviours, although a small proportion was considered potentially useful to the design of the PROTECT intervention.

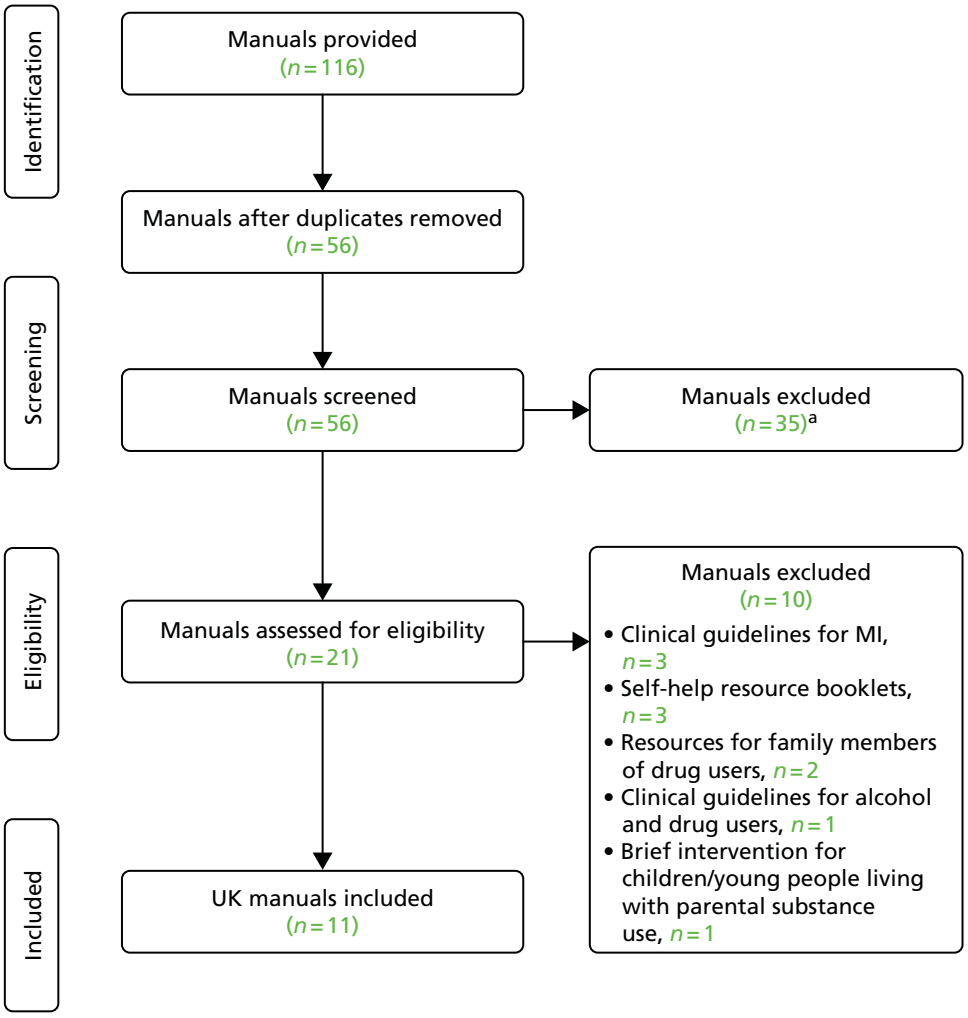

FIGURE 16 Flow diagram of drug and alcohol partnership survey. a, No BBV information or PSI included in manuals. PSI, psychosocial intervention.

TABLE 8 Manuals/written materials, from the UK, with potential utility in BBV intervention design

Manual	Outline	Criteria[a]	Ranking[b]	UK areas utilised	Evidence based/evaluated
Common Sense Ideas for HIV Prevention and Sexual Health[214]	Based on TCU mapping-enhanced counselling manuals for adaptive treatment. Handouts and activities used in the HIV/AIDS module incorporate node-link mapping, a visual representation system for helping clients improve personal problem-solving and decision-making skills. Its goal is to present workable approaches for educating clients about HIV/AIDS and helping them develop the skills needed for effective, consistent reduction of HIV-risky behaviours	BBV; psychosocial intervention; risk behaviours (injecting/sexual); PWID; instructions	High	Torbay and Torquay	Yes/yes
Routes To Recovery 1, 2, 4, 5, 6[215]	Routes to recovery ITEP 1 and 2: based on a cognitive approach known as node-link mapping. Provides a model for systematic cause-and-effect thinking and problem-solving, which clients can begin to adopt. Based on cognitive therapy and MI. Parts 4, 5, 6 and 7, 'The BTEI Manuals', are tools for implementing the full BTEI intervention – covering care planning, building motivation (for individuals and groups) and treatment exiting	Health awareness maps; brief mention of BBV instructions; no specific mention of PWID, injecting/ sexual risk behaviours	Moderate	Telford, Walsall, Leicester, Shropshire, Staffordshire, Solihull, Kensington and Chelsea, Hammersmith and Fulham, Enfield, Maidenhead, Kirklees, Bury, Gloucestershire, Durham, Knowsley, Cheshire and Halton	Yes/yes
Routes to Recovery Via the Community: Mapping User Manual[216]	MI and cognitive–behavioural approaches. Node-link mapping is used as a unifying element, presenting clinical tools in a simple to use map format	PWID; BBV; risk behaviours; no instructions	Moderate	Middlesbrough, Walsall, Gloucester, Kirklees and Solihull	Yes/not known
Routes to Recovery Psychosocial Interventions for Drug Misuse. A Framework and Toolkit For Implementing NICE-Recommended Treatment[217]	Framework and toolkit including: classifying psychosocial interventions; framework for the delivery of psychosocial interventions for drug misuse; delivery of competence-based psychosocial interventions for drug misuse	Mentions BBV and assessing risk and risk behaviour CM	Moderate	Grampian region and Durham	Yes/not known

continued

TABLE 8 Manuals/written materials, from the UK, with potential utility in BBV intervention design (*continued*)

Manual	Outline	Criteria[a]	Ranking[b]	UK areas utilised	Evidence based/evaluated
Criminal Justice Drugs Brief Intervention Tool Kit	Designed to help workers carry out a structured 6-week brief intervention following screening using ASSIST Includes: • ASSIST screening tool, which gives a score for each substance used in the last 3 months and helps discuss substance use with a criminal justice worker. The core tells clients where their level of use is (low risk, moderate risk or high risk) and what support might be best for their level of use • Drugs quiz: knowledge about different substances • Drug diary to help clients get an accurate picture of how much they are actually using • Making the decision to change explores clients' reasons for starting to use drugs and the reasons that they use now • To change or not to change: table to fill which helps reach a clear decision to change • Cues for drug use: identifies triggers and risk factors and works towards assisting clients with a relapse prevention plan/ trigger solution plan • Tips for cutting down • Keeping yourself safe: safe injecting/sex tips • Reduce the risk of overdose • Readiness to change questionnaire	BBV (hepatitis/HIV); risk behaviours (injecting/sexual); PWID; instructions	Moderate	Angus	Not known

Manual	Outline	Criteria[a]	Ranking[b]	UK areas utilised	Evidence based/evaluated
Straight Ahead: Transition Skills for Recovery[218]	Based on TCU mapping-enhanced counselling manuals for adaptive treatment. A 10-part workshop to reinforce key recovery concepts. The module is best suited for those who are not in deep crisis, who seem to be making progress in recovery, and who have made optimal use of individual and group counselling services and other opportunities for resolving their problems with substance use. Ideally, it can be used as an aftercare 'readiness' package for helping clients frame and focus their goals for continued recovery and the steps needed to realise those goals	No specific mention of PWID, injecting/sexual risk behaviours, BBV	Low	Staffordshire, Torbay and Torquay	Yes/not known
Tools For Change[219]	Self-assessment of substance and associated problems. Workbook on decision to change and steps	No mention of BBV, PWID, risk behaviours; no instructions for workers	Low	Northern Ireland and SEHT	Workbook is based on work from the Syracuse University and originally funded through NIAAA grant number 5R01AA13655 – 04
The Bouncing Back Workbook: Building Skills That Strengthen Resilience[220]	Workbook that includes: • information on seven identified factors that support resilience • pillars of change: skills that build resilience – pillar 1, believe change is possible; pillar 2, habits can be broken: even thinking habits; pillar 3, make a committed decision to change • positive steps to emotional health and well-being	No mention of BBV, PWID, risk behaviours	Low	Northern Ireland and SEHT	Some of the material in this booklet has been taken from the work of researchers at the University of Pennsylvania. Karen Reivich and Andrew Shatte are authors of *The Resilience Factor: 7 Keys to Finding Your Inner Strength and Overcoming Life's Hurdles*[221]
Drug and Alcohol Recovery and Treatment Tool (DARTT)[222]	Based on *Medications in Recovery Re-Orientating Drug Dependence Treatment* [URL: www.nta.nhs.uk/uploads/medications-in-recovery-main-report3.pdf (accessed 10 October 2017)]. Treatment within context of a behaviour change model	Requires subscription	Unable to rank	Kensington and Chelsea and Hammersmith and Fulham	

continued

TABLE 8 Manuals/written materials, from the UK, with potential utility in BBV intervention design (*continued*)

Manual	Outline	Criteria[a]	Ranking[b]	UK areas utilised	Evidence based/evaluated
Core Behavioural and CBT Skills for Relapse Prevention and Recovery Management: Facilitator Handbook and Portfolio Exercises	Overview and step-by-step guide for core behavioural and CBT skills for relapse prevention and recovery management: • motivational enhancement • functional analysis • relapse prevention and controlling impulsive behaviour • overview of reinforcement management and recovery • recovery management	No mention of BBV, PWID, risk behaviours	Low	Greater Glasgow and Dumfries and Galloway	Yes/not known
Core Behavioural and CBT Skills for Relapse Prevention and Recovery Management: Portfolio Exercises	Exercises cover a range of skills, which are included in motivational enhancement, coping and social skills to prevent relapse, and reinforcement management. Training and exercise worksheets (also designed to be used collaboratively with service users) include: • identifying problems • identifying things to work on • daily routine worksheet • exploring the relationships between substance use and mental health • exploring the pros and cons of using this substance • exploring the pros and cons of making a change • exploring the pros and cons of changing • discovering triggers • self-management plan • problem-solving worksheet • seemingly irrelevant decisions	No mention of BBV, PWID, risk behaviours,	Low	Greater Glasgow and Dumfries and Galloway	Yes/not known

AIDS, acquired immunodeficiency syndrome; ASSIST, Alcohol, Smoking and Substance Involvement Screening Test; BTEI, Birmingham Treatment Effectiveness Initiative; ITEP, International Treatment Effectiveness Project; NIAAA, National Institute on Alcohol Abuse and Alcoholism; SEHT, South Eastern Health and Social Care Trust; TCU, Texas Christian University.

a Inclusion criteria: BBV (hepatitis/HIV); psychosocial intervention (e.g. MI, CBT, peer led); risk behaviours considered (injecting/sexual); PWID; and instructions to facilitators.

b Ranking criteria: high, all criteria included; moderate, no instructions but includes psychosocial intervention for BBV risk reduction and includes evidence and references; and low, no instructions, no psychosocial intervention for BBV risk reduction/no evidence and references.

Chapter 3 Understanding people who inject drugs' influences on behaviour and views on psychosocial interventions

Aims

To inform the development of a psychosocial intervention to reduce BBV risk behaviours among PWID in the UK, a qualitative interview study was conducted exploring:

- why PWID engage in BBV risk behaviours
- the type of psychosocial intervention acceptable to, and required by, PWID to reduce BBV risk behaviours.

Methods

Settings

People who inject drugs aged ≥ 18 years who had injected drugs within the past 4 weeks were recruited from drug treatment and harm reduction centres, needle exchanges (including pharmacy and mobile), sexual health services and homeless hostels in Glasgow, London, Yorkshire and north Wales during May–July 2015. Settings were chosen to reflect the range of settings that PWID attend for substance use and sexual health-related issues and settings attended by particular at-risk PWID who are not engaged with addiction treatment.

Sample

A convenience sample of 60 PWID (15 from each locality) were recruited using a purposive sampling approach to ensure that a variety of perspectives were accessed, including those most at risk (*Table 9*). Sampling was thus stratified according to known BBV risk variables, including gender, length of time injecting, drugs injected, involvement in sex trading and homelessness.

Service users at each setting were eligible to participate if they were aged ≥ 18 years, had injected illicit drugs [other than image- and performance-enhancing drugs (IPEDs)] within the past 4 weeks and were able to speak English well enough to complete a 45-minute interview. Given inability to provide informed consent, service users were not recruited if/when experiencing withdrawal or intoxication.

Data collection

A number of recruitment approaches were taken to achieve the purposive sampling parameters. Flyers were left in participating services to promote the study to service users. Staff at each of the services also informed eligible service users about the study and either passed on the researcher's details to those who were interested or, with the service user's permission, passed their contact details to the researcher, who rang potential participants to discuss the study. Researchers also recruited participants from the waiting rooms in services (except sexual health clinics) using a short screening questionnaire to ascertain study eligibility. All participants received a written study information leaflet (see *Appendix 1*) and verbal explanation of the study from the researcher, and were given an opportunity to ask any questions. Participants indicated their consent to participate in the study by signing a consent form (see *Appendix 1*). Participants received a £20 voucher in compensation for their time and expenses on completion of the interview.

TABLE 9 Sampling framework and number of participants ($n = 60$)

Sampling parameter	Number of participants	% of the total
Gender		
Male	35	58
Female	25	42
Length of time injecting		
< 2 years (new PWID)	17	28
≥ 2 years	43	72
Drugs injected		
Mostly heroin/opiates	35	58
Mostly stimulants (cocaine/crack/methamphetamines)	13	22
Mostly both	12	20
Living situation		
Alone	18	30
With sexual partner and children	8	13
With sexual partner alone	6	10
With children alone	1	2
With parents	2	3
With family	5	8
With friends/flatmates	6	10
Homeless	22	37
No stable arrangements	1	2
Other living arrangements	2	3
Involvement in sex trading (previous/current)	9	15

Semistructured in-depth interviews were conducted with individual participants within a private room at each setting by trained researchers (DS, AS, NM and ST). Interviews lasted approximately 45 minutes and were audio-recorded with the interviewee's permission. The interview topic guide (see *Appendix 2*) included questions on participants' knowledge and perceptions of BBV transmission (HIV, HCV and HBV), perceptions of personal vulnerability to BBV, influences on the sharing of needles, syringes and other drug-using equipment, influences on sexual risk taking (such as non-condom use), and past interventions they had received on safer drug use and safer sex. Participants were also asked for their suggestions on how to support safer drug use and safer sex in the light of the influences on risk identified and their preferences for the PROTECT psychosocial intervention (content, format, venue, interventionist, duration, barriers/facilitators).

Ethics approval

The study was approved by the National Research Ethics Service Committee South East Coast – Brighton & Sussex (reference number 15/LO/0387).

Data coding and analysis

Interviews were transcribed by professional transcription services and analysed using qualitative framework analysis.[223] The framework approach allows the description and interpretation of what is happening among a predesigned sample with a set of a priori issues. The approach involves five key steps: familiarisation with

the data; identifying a thematic framework; indexing the data; charting categories and themes; and mapping and interpretation. The framework approach was developed to answer policy-relevant research questions and can facilitate inductive, deductive or combined approaches to analysis. It is especially amenable to projects where analysis will be conducted by more than one researcher.[224]

The research team (DS, GG, AS, AM, NM, EH, ST and NC) independently coded the first six interview transcripts, then reviewed the coding at a face-to-face team meeting and collaboratively generated an initial thematic framework. This coding framework was applied to the remaining interviews (indexing) by Davina Swan, April Shaw, Noel Crane and Kideshini Widyaratna. Weekly Skype (Microsoft Corporation, Redmond, WA, USA) meetings were held between the analysts to ensure consistency of coding across the interviews and to agree new codes to be added to the framework. This also included the researchers analysing one interview independently and reviewing how each had coded it to ensure validity. When first-level coding had been completed, Davina Swan and April Shaw reviewed all coding and charted and mapped the data.

Qualitative software (NVivo 10, QSR International, Warrington, UK) was used to manage and code the interviews. Several methods were utilised to enhance the validity of our findings: (1) triangulation of data across multiple settings and localities; (2) triangulation of coding across several co-researcher perspectives; (3) presentation of analysis and supporting quotes to service user representatives for feedback/critique (credibility); and (4) identification and questioning of researchers' underlying assumptions at the weekly skype meetings between analysts (reflexivity).[225]

Patient and public involvement

Two service user representatives from London, two from Wales and two peer educators from Glasgow helped develop the patient information leaflet and consent form, to ensure that appropriate language was used and the aims of the research were clear and jargon free. In addition, they helped develop the topic guide for use in the in-depth interviews with PWID.

Results

Factors influencing risk behaviour for blood-borne viruses

Drug states

Withdrawal/craving: balancing need and availability of equipment

When asked under what circumstances the sharing of needles, syringes and injecting equipment was most likely to take place, most participants cited the experience of withdrawal when they were without their own injecting equipment. Reasons for being without injecting equipment were varied, including lack of preparedness and running out of needles because of a 'drug binge' or repeated unsuccessful attempts to access a vein. Participants explained that the 'desperation' and urgency induced by withdrawal means that their main priority is about taking the drug 'as quick as possible' and they will use equipment belonging to anyone else that is available and to hand. Participants also noted that chemists and needle exchanges are not open during evening times or at weekends, so there is no opportunity to obtain sterile equipment if experiencing withdrawal at these times:

> *Normally when you're desperate, when you're needing your drug and the diarrhoea's comin' out ye', and you're being sick. They're not, people, myself, I don't want tae be runnin' tae the chemist, you know, and havin' tae run tae the chemist tae get new stuff. Maybe it's a Sunday and the chemist isn't open. Maybe I'm gonnae miss out in havin' drugs if I don't take them there and then. So that's the way I put myself at risk.*
>
> *Scotland ID4, female, aged 45 years, cocaine*

> *. . . when I have no needles and there's no, sort of, access to a needle exchange, it's after, like, sort of, 6 or 7 o'clock in the evening and there's no way you feel you can get any fresh needles and you're starting to feel that, sort of, withdrawal and you know you want the heroin and the person has needles and so you take the risk.*
>
> *York ID2, male, aged 42 years, heroin*

Some participants reported that the sickness of withdrawal had deterred them from accessing an open needle exchange because the distance and effort required to get there was too great. Thus, convenient access to equipment in situations in which the need to use drugs is high is important:

> *. . . it comes to times, you know, if you're in (name of place/area) you can't get no works unless you're in (name of street/road) and that's like a 20, 30 minute walk and if you ain't got money for a bus or Oyster card you know you have to walk. If you're sick you don't want to do that so you use your old ones you know what I mean, I'll share them if you're really that desperate.*
>
> *London ID5, male, aged 25 years, heroin/crack cocaine*

> *After 5 [pm]? You have to share, or use ones you've already used. So I break into my sin bin. I actually cut my sin bin open and I get my used needles out. Don't get me wrong, I clean them out with hot water and everything, but I have to re-use what I've already used.*
>
> *York ID9, female, aged 31 years, heroin/crack cocaine*

> Interviewer: *Because you can't access . . .*
>
> Interviewee: *Yeah. The same as weekends, it's closed. And a lot of people don't like going to chemists. They'd rather come to the drug worker and ask for help, but it's closed.*
>
> Interviewer: *OK. So when you go in you cannot access the needles. The only option there is to re-use.*
>
> Interviewee: *Re-use or share.*

The urgency to inject generated by withdrawal was also reported to expose people to other risks as they may to continue to inject even if they are having difficulty finding a vein, increasing their risk of getting abscesses.

Craving was similarly described as exerting a pressure to use drugs, which led participants to share equipment, including needles, when without their own. Cocaine and crack cocaine, with their shorter euphoric effect, were thought to increase the sharing of needles as a result of more frequent injection:

> *. . . like wi' coke you get a, you get a, a . . . what do you call it, euphoria . . . you get a high. And then you come doon. But wi, so you're, you're ****, you're going through a lot o' needles. But whereas heroin, you know, having one hit and you're, you're no chasing that high a' the time because you, you feel the same. You know what I mean, you're doon.*
>
> *Scotland ID 15, male, aged 41 years, heroin*

> Interviewee (London ID1, male, aged 42 years, heroin/crack cocaine): *. . . crack or cocaine could make you do it. Because if you get so high and wired, you might really, really need to calm down, and come down. So you could take that chance of, of, of sharing or using, just so you can get that, phew, that release off, off your brain, you know?*
>
> Interviewer: *Yeah, yeah.*
>
> Interviewee: *Just to calm yourself down. Hmm.*

Participants noted that in situations where they use others' equipment, they are reliant on others to be open and honest about their BBV status. However, there is scepticism about whether or not others are always honest about their status:

> *And obviously not a lot of people are truthful as well, a lot of people wouldn't say, I've got it, some people do and they're the people you look at and think I admire this person because at least he's honest. 95% of the people say no I'm clean I ain't got nothing, really they might have do you know what I mean and you're taking someone's word on it.*
>
> *London ID2, male, aged 28 years, heroin*

> Interviewer: *And do people tell other people if they have Hep C or HIV for instance?*
>
> Interviewee (York ID10, male, aged 26 years, heroin): *Not all the time, not everyone's . . . not honest, because it's something you don't want anyone to go broadcasting, is it, it's not like you want to go on the radio station and shout out, I've got Hep B so, you know, please don't share my needle.*

Intoxication: clouded judgement and reduced inhibitions

Participants reported that drug- and/or alcohol-induced intoxication undermined their ability to manage injection-related risks. Similar to cocaine/crack cocaine, alcohol and/or benzodiazepines were reported to cloud judgement and reduce inhibitions, leading to intentional sharing of equipment and also to inadvertent risks:

> *. . . if . . . I'd been drinking all day, and I was with, well, a few of my friends in the hostel, I could be a bit laxy in my way of thinking. I would never share a needle or that, but I could draw up from the same cook pot.*
>
> *London ID1, male, aged 42 years, heroin/crack cocaine*

> *They just get sloppy don't they. They forget tae dae things. They forget tae put caps on things.*
>
> *Scotland ID10, male, aged 30 years, heroin*

Trajectory of drug use

Addiction progression: increased willingness to take risks

Some participants described how, as their drug use progressed into addiction, their lifestyle began to revolve around drug use and they became willing to take greater risks and there was a loss of personal standards held in the past:

> *. . . once you become physically addicted, I don't know it just changes everything and using needles changes everything, er, so much that you I don't know like morals that you kept in the past seem to just go and, er, yeah I've shared needles, I've had unsafe sex and I knew that I could be at risk of that and it wasn't important anymore.*
>
> *London ID14, female, aged 32 years, heroin/crack cocaine*

> *I've seen people like, smoking it and then going to inject it and change their way of everything, from their hygiene to who they bother with to not caring how they get it or where they're digging [injecting] it.*
>
> *Wales ID4, female, aged 25 years, heroin*

Needing help injecting: dependence on others and risk of injury, rather than blood-borne virus transmission, are paramount concerns

In the early stages of their injecting drug use, particularly at injecting initiation, participants lacked the experience and skill to inject themselves and were reliant on others to inject them. Needing help injecting lessened participants' control over the injecting process. When being injected, participants' main concerns

were the risk of injury (e.g. if the person injecting them missed the vein or hit an artery or nerve) and their dependence on others to obtain their drug/hit, rather than any risk of BBV transmission:

> *I was obviously a bit scared if they missed me and if they knew what they were doing . . . well they obviously knew what they were doing but sometimes it would miss me. You know you give them a lot of responsibility.*
>
> *Wales ID14, female, aged 39 years, heroin/crack cocaine*

> Interviewer: *. . . when you first started, OK. How did you feel about somebody else injecting you, were you happy about that?*
>
> Interviewee (Wales ID13, female, aged 30 years, amphetamines): *Not really got really anxious and nervous.*
>
> Interviewer: *OK, were you worried about somebody else transmitting blood-borne viruses to you or was it about . . .*
>
> Interviewee: *. . . it was more about me going over [overdosing] at the time.*

In addition, when people had difficulties with venous access because of collapsed veins, they would need others to inject them as their viable injecting sites might be in awkward places and/or it could be a long and laborious process to try and 'get' themselves:

> *Yeah, well, where I'm going in my neck is a massive risk, I wouldn't dare do it to myself, I only trust one person to do it, but they don't like doing it to me, you know, but I know the risk in your neck is really high, it's not a good place to go. I've been everywhere else, I can't get nowhere else, it's like the last place left, you know.*
>
> *York ID4, female, aged 36 years, heroin*

> *. . . there are people that cannae get tae theirselves. But there's a vein that they cannae get tae. Maybe like the back of the knee or something, I don't know. Somebody would need to go and dae it for them.*
>
> *Scotland ID10, male, aged 30 years, heroin*

At time of interview, nine participants (seven females and two males) currently required injecting assistance and four had been injecting for < 2 years (three females, one male).

Injecting others: pressure and risk of legal ramifications, rather than blood-borne virus transmission, are paramount concerns

Most participants reported being asked by others to administer drug injections at some point although just five participants (three females and two males) reported currently injecting others and all had been injecting for ≥ 2 years. A couple of interviewees were very willing to assist others with injections:

> *I have injected other people before because I'm really good at getting . . . I know it sounds bad but if someone's got bad veins I'm very good at getting them first time so I often get asked. [. . .] I've even been walking down the road and someone I know from my group said oh [participant's name], I'm not well, can you help me, can you help me, I can't get myself and gone in a block, injected her and then she's fine and I've gone off or she's gone off so if someone can't do it and they need help . . .*
>
> *London ID6, female, aged 27 years, heroin*

Other interviewees had mixed feelings about injecting others and avoided doing so where possible as where venous access was an issue it could be a high-stress situation:

> *As a general rule, I don't like doing it 'cause it's just – it's an unpleasant thing to do, because if somebody needs you to inject, it's generally because they've got bad veins in the start and then it becomes a whole kind of nightmare as well. It becomes very stressful . . . if you can't kind of get it immediately.*
>
> *London ID7, male, aged 50 years, heroin/crack cocaine*

> *Aye well I've done loads o' people. I mean I've, I mean see if I'm being honest, I mean I've injected people in the neck and everything. You know it's . . . very very dangerous. Very, very dangerous.*
>
> *Scotland ID9, male, aged 41 years, heroin*

Besides the stress of missing the other's vein, participants' main concerns when injecting others were the legal ramifications if the recipient overdosed, rather than BBV transmission. As the participant below explained about injecting his friend who was HIV positive:

> Interviewer: *Do you feel it's safe for you to do it and say, for him to be injected? [IV sighs] I just want to get your thoughts on it, I suppose – how you feel about it.*
>
> Interviewee (London ID7, male, aged 50 years, heroin/crack cocaine): *It's not – you know, deep down, it's not an ideal situation. [OK.] I would really, I would kind of rather not do it. I know I shouldn't be doing it.*
>
> Interviewer: *Like, what risk might there be to you doing it, in terms of blood-borne viruses?*
>
> Interviewee: *The risk is, if he drops down dead, I'm in trouble. [OK, OK.] I'm in trouble, you know, legally and morally. I'm in trouble.*

As the above extracts illustrate, when participants injected others it was usually out of pressure or because it was relatively easy to do so.

Relationships and social networks

Intimate relationships: the primacy of trust and familiarity

Although not universal, the sharing of equipment and needles was more likely within couples, based largely on trust and familiarity. Many participants felt comfortable sharing injecting equipment with their partners but not with anyone else. Participants were confident that they knew their intimate partner's BBV status, which was in contrast to their scepticism generally regarding others' honesty about their BBV status. Thus, trust often took precedence in intimate relationships over safer practice:

> *I share with him but only because he's clean. Like we both got tested but I wouldn't share with anyone else.*
>
> *York ID12, female, aged 19 years, heroin*

> *I've been with my partner 20 years, and if she used a needle I'd use it after her, because I know that she hasn't got anything, do you know what I mean? If you know that somebody hasn't got 'owt, and they've always been clean, then you're at a higher percentage to use their needle, than you are somebody's who you know who has.*
>
> *York ID5, male, aged 36 years, heroin*

When disclosure of a positive BBV status was made, some couples continued to share equipment regardless, as they were already engaged in a sexual relationship without the use of condoms:

> *. . . because we sleep together, it doesnae matter if we share needles. Same again. 'Oh you take drugs, I take drugs so there's nae use taking a condom'.*
>
> *Scotland ID5, male, aged 45 years, heroin*

Sharing within couples was not always consensual, however. One participant related her experience of being in a violent relationship where she lacked control over her injecting practice:

> *I was in a domestic violence relationship [. . .] If he had one needle I had no choice of getting anyone's. I had to have what he had. He would actually do his and instead of washing it out, the blood would be still in the end of it and he'd suck mine up. I had to have it. I was ill.*
>
> *York ID9, female, aged 31 years, heroin/crack cocaine*

It was noted that inadvertent sharing can also happen when couples are using drugs together as they are less careful with each other and their equipment can become mixed up.

Injecting in groups: negotiating safe practice is challenging for injectors who are less assertive

Negotiating drug preparation and injecting practices within group injecting situations could be challenging. Some participants reported feeling under pressure to go along with unsafe practices, including sharing equipment, as they felt intimidated by others or feared causing offence:

> *I've been in those situations where I've felt uncomfortable saying to the person about sharing spoons, because I don't know how they're going to take it, you know, they might be, like, well what are you trying to say, are you trying to say that I've got HIV or hepatitis? And some of them are dangerous people, you know, they've been in prison for violence and stuff, so, you know, it can be intimidating.*
>
> *York ID2, male, aged 42 years, heroin*

> Interviewee (Scotland ID4, female, aged 45 years, cocaine): *I've felt a bit intimidated wi', at being in somebody's house and somebody's saying well, you know, I . . . I dae everythin' on this table and that's his personal space. So, and they take control and sometimes I've felt intimidated tae say, you know, get a bit too, a bit, felt a bit intimidated and I've not wanted tae say, you know, halt. I want tae do my own thing wi' my own drugs, and I want tae take control of my own . . .*
>
> Interviewer: *Preparation.*
>
> Interviewee: *Yeah. And . . . I've just felt that because I'm in that person's house that I've got tae go with their rules.*

Those selling drugs were considered to be the ones with the power ('powder power') within a group, and some participants reported that you do what they want to get what you need:

> Interviewee (Scotland ID3, male, aged 30 years, heroin): *Aye I have been in situations like that myself just because they're the mair dominant one. They're buying it and so you'll just sit back and they go and get the drugs. They'll make it up. And . . . they'll gie you it, what they think you should have instead o' me going 'oh you've got it, let me see what you've got and de de de de'.*
>
> Interviewer: *And like they sort of control, like you're saying like they control sort of how much you get. They, they might prepare it and . . .*
>
> Interviewee: *Aye and there's another risk. They prepare it so you're using the exact same filter, spoon, water.*

The pressures of using drugs within a group influenced drug preparation. For example, some participants reported that, when dividing up drugs within a small group, the spoon and filter may be shared to ensure fair distribution:

> *. . . if there's like three of you and you've only got like two bags of heroin then it would be like we'll put them all in together into the spoon. Even though we've all got our own pins we still share the spoon and the filter to separate it out evenly.*
>
> *London ID15, female, aged 34 years, heroin*

When injecting in groups, equipment can also become inadvertently contaminated:

> *. . . if you're using with other people there's always going to be a risk when you turn your back he might stick his needle in the water do you know what I mean and draw up and then you turn around, anything could happen.*
>
> *London ID2, male, aged 28 years, heroin*

> *. . . but sometimes if there's two bottles o' water opened you get mixed up. So I don't know if he's sometimes took water oot the wan' I've used, and I sometimes took water oot the wan' he's used. You know what I mean? So that's what I'm saying. No intentionally but you get mixed up.*
>
> *Scotland ID11, male, aged 41 years, heroin*

Access to resources: homelessness and limited opening hours of needle and syringe programme/pharmacies restricted opportunities for safer injecting

Homelessness

Homelessness was highlighted by most participants as an important risk factor for the sharing of injecting equipment, as people who were homeless lacked access to resources and to control over their injecting environments. Sleeping rough or living in a hostel often meant people had to inject outdoors or in public places. To avoid being caught injecting outside, PWID might inject in small groups (while someone keeps lookout) and the process was often rushed, leading to the intentional sharing of needles, syringes and equipment, as well to injection site wounds:

> *. . . it's more when we've got naewhere tae go. So we're doing out o' quickness . . . in car parks, in closes . . . You're trying no tae get caught. That's when you will just go into at least do it quickly, you know in and out . . . That's when you just go, '**** it, I'll share that needle with you'. You know, 'oh just give me yours'.*
>
> *Scotland ID14, female, aged 30 years, heroin*

> *When you're homeless you tend to go about in twos or threes. You have a little clique of people so if you're going to use you're more likely to use together and then the chances are it's all going to be on the same spoon.*
>
> *York ID15, female, aged 33 years, heroin*

The unsuitability of many of these environments (e.g. stairwells, public toilets) for drug preparation and drug use meant there were also risks of needlestick injury or equipment becoming accidently contaminated with another's blood:

> *. . . if you were doing it in, erm, housing, tower blocks, and things like that, erm, because I know hepatitis C stays quite alive outside the bloodstream for a while . . . [I]f the, like, you, you, you put the filter in the spoon and it rolled off, you don't know if it's rolled on an old, a bit of blood, from someone else whose used on the thing. You put it back in your thing, thinking there's nothing on it – bosh, you've got hepatitis C.*
>
> *London ID1, male, aged 42 years, heroin/crack cocaine*

Interviewee (Scotland ID4, female, age 45, cocaine): *Maybe when I was out prostituting. I would score the drugs there and then and I wouldn't want tae be waiting tae I got the bus or a taxi up tae [area] or wherever I'd came fae. And I went in tae maybe a hotel toilet or, and you're rushing, you know, and you're, and you're rushing that much that you're maybe leaving the needle in the toilets.*

Interviewer: *So you might be rushing the injection?*

Interviewee: *Yes, definitely. Which then can lead tae, rushin' can lead tae not getting' in the vein, which then leaves ye' poppin'. It then leaves ye' not getting' your, not getting' your fix right, which then leads tae abscesses and things like that. And I'm puttin' other people at risk by just leavin' my stuff behind . . . because I've not been compos mentis enough tae, tae grab everythin' and make it, make sure everythin's, I've got everythin.*

Access to the resources necessary for safer drug use (e.g. sterile water) was difficult when people were homeless and homelessness was also linked by some to a sense of apathy or hopelessness which fostered risk taking:

. . . when you're on the streets you know . . . you can't exactly put a tap on or something to get your own water, you know you have to share water from a bottle.

London ID5, male, aged 25 years, heroin/crack cocaine

Interviewee (Scotland ID10, male, aged 30 years, heroin): *Dae I take risks injecting outside?*

Interviewer: *Yeah, yeah.*

Interviewee: *Definitely, aye. I've used dirty water oot a puddle oot o' desperation. Couldnae get water. And that was ma best thinking. Water oot a puddle!*

Interviewer: *And you said you've picked up needles from outside.*

Interviewee: *Aye, aye, aye.*

Interviewer: *Did you clean them at all?*

Interviewee: *See if I've been, this is embarrassing, if I'm being honest. And it's just, I've done it oot a desperation, oot o' pure desperation. Don't get me wrang, there's times that I've been fine where I've no went tae them lengths. But there's other times I've went tae them lengths.*

Access to needle and syringe programme/pharmacies

Many participants highlighted evenings and weekends as times when needle and syringe sharing were more likely as pharmacies and needle and syringe programmes/pharmacies (NSPs) were closed, so there was no possibility of obtaining sterile injecting equipment. Some interviewees also felt there were not enough pharmacies offering needle exchange and not enough NSPs in smaller cities:

Interviewee (Wales ID10, male, age unassigned, heroin/amphetamines): *I just reckon rattling, or on a Sunday where places are shut, most places are shut and then you can't get anything, so you're more likely to share. You've got no choice but to ask someone else.*

Interviewer: *Are there any certain situations which you think people who inject drugs might be more likely to share needles and equipment?*

Interviewee (York ID13, male, aged 38 years, heroin): *When chemist shut or when certain places shut where they can't get their supply from and if they're ill and someone's got some stuff what he's already used and if it's been used and after that not clean them up properly or sterilise them then . . . It's mainly when they can't get any of the equipment because why else would they need to share?*

One participant highlighted stigma and fear of exposure as barriers to obtaining sterile equipment from pharmacies.

Values: compassion and the individualisation of responsibility influenced risk behaviour

The role of values in risk behaviour was implicit in many narratives.

Compassion

Compassion for others was cited as driving distributive sharing and willingness to inject others:

Interviewer: *How did you feel when you were helping them inject, in terms of the risk?*

Interviewee (York ID8, female, aged 37 years, heroin): *Very nervous, but it was somebody that was very poorly at the time, they couldn't get any methadone, they were absolutely desperate, it was a close friend, and I just felt I had to help.*

Interviewer: *OK, so you were feeling like sympathy to them?*

Interviewee: *Yes.*

Interviewer: *Because, of what they were going through?*

Interviewee: *Yes.*

Interviewer: *. . . is there a bit of a pressure on you to kind of give your stuff or is it easy to say sorry I don't . . .*

Interviewee (London ID6, female, aged 27 years, heroin): *No, my first reaction would be I don't really feel comfortable, is there like anybody else, can you not find one and then if like it really comes down to it then I'd have to because I couldn't really say no if they're not well or if they've been out grafting and they're tired or whatever but what I do is if you're going to use someone else's works boil a kettle, hold it over the kettle the needle bit like and it sanitises it as much as possible and then to run boiling hot water through it as well.*

Individualisation of responsibility

Many participants rationalised their distributive sharing by viewing the risk taken by those who re-use equipment as their own responsibility:

. . . so if I've got my equipment and someone else aint if they want to use it after me that's your, that's up to you but I know I'm going first.

London ID15, female, aged 34 years, heroin

I've got a routine. I, I open up a pin [mhmm], a 1-ml packet, I take half of the paper off and then I fill up that pin what I've just opened up – that packet, with water [mhmm] straight from the tap. That's what I use. Whoever uses it after that, I don't give a shit. It's their problem. They, they should know what they're doing.

London ID4, male, aged 39 years, heroin/crack cocaine

Mental health

Poor mental health promotes lack of self-care

Poor mental health (e.g. psychosis, depression and low mood) was reported to cause indifference to one's health and reduced care around safe injecting. Some participants reported that being diagnosed with a BBV, having serious injuries or conditions or experiencing a traumatic event were points at which they had little regard for their own safety in terms of drug use and risk behaviours:

> *My sister died and I've been so depressed . . . that I've thought, you know, who cares? You know. I don't want to be here anyway so . . . What does it matter if I use her set, her syringe, you know.*
>
> *Scotland ID4, female, aged 45 years, cocaine*

> *I think I probably started out more, yeah it's, er, it kind of depends I guess how – how sick I was, er, how depressed I was, how desperate I was, how bad things were. Er, you know I'd go through waves of – of being maybe having more money, using more drugs, being more functional, er, when there'd be periods of no money and no drugs, I'd be an absolute mess. So I'd be more desperate. So when it came to hitting up I'd use something dirty or I wouldn't prepare it properly or you know so it would it very much depended on where my mindset was I think yeah. So throughout the years it would kind of peak and I don't know yeah – yeah it was all to do with self care and you know if I was with it and together, you know, the self care kicks in, it's like once I don't know that can go very quickly, that always surprised me because I never thought I'd live like that.*
>
> *London ID14, female, aged 32 years, heroin/crack cocaine*

One participant reported experiencing a psychotic and suicidal episode in the past, when he actively made sure he went last when sharing equipment.

Perceptions of risk

Perceptions of risk are not only based on knowledge of BBV transmission routes, but also on the physical appearance of others and the trust and familiarity which has been built up over time with injecting partners. In addition, other injecting-related risks are often more paramount than BBV transmission.

Knowledge of transmission risk

Participants reported that in the past they had unknowingly placed themselves at risk of contracting a BBV as they had not known that sharing equipment was risky:

> *I mean I don't think people realise how easy it is to catch, I didn't know how easy it was to catch. I thought like if you share a pin that is how you catch it but I know that's not, it can be through saliva, it can be left on a filter from someone else you know because it can stay alive.*
>
> *London ID15, female, aged 34 years, heroin*

> *Well I contracted hepatitis C so I know more now than before I contracted it. Before I contracted it I really didn't know much you know, I didn't know that shaving, using someone's razor or somebody using your razor could give it, I didn't know that, I didn't know about the toothbrushes, didn't know about the water, when you're injecting sharing water, I knew you couldn't share needles but I didn't know you couldn't share water so that's obviously how I contracted it. I didn't know that, it just didn't come into my head, I didn't know, no one told me, you just didn't know.*
>
> *London ID6, female, aged 27 years, heroin*

Participants thought that younger and/or new injectors were especially vulnerable, as they may be less aware or informed about BBVs:

> *. . . if you're only new to injecting, you don't really have any clue about, like, the life, you know, so you would be more vulnerable.*
>
> *York ID4, female, aged 36 years, heroin*

Interviewee (Scotland ID8, female, aged 40 years, heroin): *Just, I thought at that point [novice injector] I thought, 'if you did it with a new needle you were fine'. Do you know what I mean?*

Interviewer: *Yeah.*

Interviewee: *I didnae think aboot the filter, the spoon, the water. Nothing like that. Do you know what I mean.*

Some participants noted that, although they had since been educated regarding BBV transmission routes, some of this information had been conflated or forgotten with the passing of time. Current knowledge of HBV was poor, and some interviewees were uncertain how long the HCV could live outside the body. Some participants who had HCV reported sharing equipment with others who had HCV as a few held the belief that if both you and your injecting partner have HCV then it is OK to share equipment.

Human immunodeficiency virus is considered the worst blood-borne virus to contract

Human immunodeficiency virus is still considered the worst BBV to contract, partly because HCV is considered curable, whereas HIV infection requires lifetime treatment, and partly because HIV infection is considered more stigmatising. This hierarchy of BBVs is evident in the description by one participant of an agreed dynamic with his friend who is HIV positive, whereby the participant draws up drugs first to avoid contracting HIV. However, the participant has HCV and so also poses a risk to his friend:

I always use mine first, I draw mine up first then his one, I wouldn't put his used works in it first, then I use it because I know I'd get HIV and even he told me that he was aware, he said yeah no you do your bit first because if we share the spoon you know. So yeah we are aware you know what I mean.
London ID5, male, aged 25 years, heroin/crack cocaine

Hepatitis C virus is considered the easiest blood-borne virus to contract

Hepatitis C virus is considered, by most participants, to be the easiest virus to contract because there is a greater prevalence of this virus within their social networks ('it's more virulent in the drug community') and because the virus lives longer outside the body.

Hepatitis C virus infection may be seen as inevitable

A couple of participants thought that there is an attitude that 'everyone has the [hepatitis C] virus anyway' and so people may be more willing to take risks as they assume they must have already contracted it:

. . . some o' them just say I've probably got it anyway, you know. Everybody I meet's got hepatitis C.
Scotland ID4, female, aged 45 years, cocaine

Interviewee (Scotland ID7, male, aged 44 years, heroin): *Yes if there's a group o' people sharing is more likely to take place, yeah, definitely.*

Interviewer: *How's that then?*

Interviewee: *Because people are, people are sitting there, you know. They're no really, you know, I think…there isn't really that fear factor about blood-borne viruses any more. I mean it ain't as scary as what it used to be, do you know what I mean, is what I've found is when I was dain' ma job as well, I found that people ain't as scared o' it as what, what it used to be, you know, because they know wi' hepatitis C it doesn't really, might, you could live wi' it forever and it might never affect you. And it'll take 30, 40 year before it does kill your liver and whatever, whatever it's gonnae dae tae you. And I think that fear factor's gone about it.*

Hierarchy of risk: blood-borne virus infection is not the paramount risk concerning people who inject

Throughout the discussions of risk situations above, it was clear that BBV transmission risks were not always the paramount risk in participants' minds. Participants were concerned with risks of abscesses, collapsed veins, hitting an artery or a nerve, bacterial infections, amputation, overdose and the legal ramifications of injecting others.

Hierarchy of importance: other priorities besides blood-borne virus protection may be paramount

Similarly, in situations where risk behaviour happens, it is often because other priorities take precedence (e.g. alleviating withdrawal/craving, sustaining trust and intimacy).

How risks are currently being reduced/managed

Managing injecting risks

Most participants managed their own injecting risks by using clean needles and equipment, although some reported sharing equipment with injecting partners. Managing injecting risks are closely tied with levels of trust engendered in long-term relationships and may also be contingent on the outward appearance of fellow injectors, as illustrated by the two excerpts below:

> Interviewer: *You mentioned earlier that you never inject in a group, you inject with your partner. So with your partner would you ever share like a needle or . . . ?*
>
> Interviewee (York ID7, female, aged 47 years, heroin): *No, never.*
>
> Interviewer: *OK. What about the cooking pans or . . . ?*
>
> Interviewee: *We have . . . I mean I know you can spread it through the cooking pans but to be fair we just . . . I've been with her 9 years now, but we do share stuff but I know she's got nothing, she knows I've got nothing because we've all been tested, you know, and we don't bother with anybody else really. We keep ourselves to ourselves. You know, we don't really socialise with anybody really, you know?*
>
> *Yeah, people I've shared, felt more comfortable sharing with, are people that I've known for a long time, I, kind of, look at their, sort of, general, sort of, state and if they physically look healthy I'm more comfortable, kind of like, taking that risk and also how honest they are and I'll ask them, like, have you got any diseases? You know, and if they're honest people, then they're more likely to tell the truth, you know, and then you have an informed decision to make . . . So I'm more willing to share with people who are honest, I've known for a long time and they look healthy.*
>
> *York ID2, male, aged 42 years, heroin*

A few participants reported planning ahead and collecting enough new equipment to ensure that a clean injection each time required or not injecting at all until new equipment could be obtained:

> *When I come [to the needle exchange] I always get, like, 40 to 50 to last me a couple of days and then I know for a fact that I won't need to go scraping around in a sin bin or whatever . . .*
>
> *York ID10, male, aged 26 years, heroin*

> *I've never, ever, ever, ever shared a pin. I've been that desperate, I've been that poorly where someone says, look, you can use mine, and I still haven't resorted to . . . I had to wait until the morning. So I had a night of hell but I would not because I was scared of taking that blunt needle . . .*
>
> *York ID7, female, aged 47 years, heroin*

The use of OST to alleviate withdrawals until clean equipment could be sought was reported, whereas alternative routes of administration, such as smoking or snorting, were substitutes to injecting if no sterile needles/syringes were available:

> *I might use once a fortnight and put it down and I won't touch it again [OK], but that's because I've got a methadone script and I don't need to use on top of that any more.*
>
> *London ID7, male, aged 50 years, heroin/crack cocaine:*

> Interviewer: *So for you if you cannot inject it, then you will just . . .*
>
> Interviewee (York ID10, male, aged 26 years, heroin): *Smoke it. [. . .] Yeah, or if you don't have no foil, just put it in a Rizla and smoke it like that.*

For those unable to defer use until clean equipment could be sought, previously used needles (either their own or another person's) would be cleaned using water (boiling and/or cold), bleach, washing-up liquid or alcohol swabs:

> *Stick it [needle/syringe] in the kettle and boil it.*
>
> *Wales ID9, male, aged 31 years, amphetamines*

> *Water, bleach, remember Vaporub, alcohol in the hospital, they bottles o' Vaporub. [I: Yep] That. I've used Fairy Liquid before.*
>
> *Scotland ID12, male, aged 30 years, heroin*

Vigilance was used when injecting in company to ensure that equipment did not become mixed up, with some participants keeping their equipment close to hand, marking their barrels or using colour-coded syringes:

> *I just don't let mine oot ma sight. If I was going tae the toilet I would take it wi' me.*
>
> *Scotland ID12, male, aged 30 years, heroin*

> *Sometimes if I've got a bit of tape I'll tape round the end or burn the end of the syringe with a lighter and then it's, you can distinguish it.*
>
> *London, ID9, male, aged 19 years, mephedrone*

Other BBV avoidance strategies included drawing up first (or, in the case of participants wo are HCV positive, allowing the injecting partner to draw up first) or asking injecting partners their HCV status before sharing equipment. A small number of participants mentioned having BBV tests to monitor their status, particularly if they considered that they might have put themselves at risk either sexually or through drug use.

A few participants reported being at low risk of BBVs because they injected alone or with their intimate partner only. Participants who injected in their own homes, as opposed to on the street, perceived themselves to be at less risk and hygiene practices (such as using sterile wipes or cleaning hands, surfaces and/or injection sites before injecting) were mentioned by a small number of participants:

> *You see I've got like sterile wipes and then there's a little thingy in shed so I wipe it all down, put the little pan, I do all me hands and wipe everything, I've got all my wipes, I wipe all myself down. I'm a bit of a clean freak so there's no worries there. I have all that at home, sterile stuff it's all sterile.*
>
> *York ID11, female, aged 38 years, heroin*

Protecting others

Participants mitigated BBV transmission risk to others by disposing of equipment, breaking equipment to avoid re-use and refusing people use of their used equipment. However, refusing to lend people used needles/syringes could be difficult for some participants, as they were aware of the effect of withdrawals/cravings, so in some cases they would disclose their BBV status and leave the decision to use to the recipient:

> *I try not to (share needles/syringes), but if they were pestering me and pestering me and . . . on and on and on at me and I just want to chill out, I tell them, I say, listen, I'm positive for Hep C, if you want to use it, it's your problem.*
>
> *York ID3, male, aged 31 years, heroin*

> *Well I use it first. If they want tae use it after me they're mair than welcome tae but I tell them no tae. I tell them I've got hepatitis C. They go like that, 'so what'.*
>
> *Scotland ID1, female, aged 28 years, heroin*

More unusually, some participants reported refusing to lend equipment to others despite direct requests in order to protect them from onward transmission as illustrated in the quotations below:

> Interviewer: *What about when people are injecting in groups? Does that carry a certain amount of risks?*
>
> Interviewee (Scotland ID8, female, aged 40 years, heroin): *It depends who it is. There is, I know a lot o' people still to this day . . . now for instance the other day there's a guy and . . . he knew I had . . .*
>
> Interviewer: *Say it a bit louder.*
>
> Interviewee: *. . . he knew I had done a hit and he says to me, 'have you done that [NAME]?' And I was like that, 'aye'. He was like that, 'wantae gie me your tools'. And I was like, 'no I don't'. And he's like that, I said 'there's nothing in them', do you know what I mean. He went, 'aye even if you've done a flush and you cannae get at it I can dae that'. And I mean there is people out there like that, do you know what I mean.*
>
> Interviewer: *What do you mean there's nothing in it? What do you mean? Like any residual drugs?*
>
> Interviewee: *Mmhmm. He's like that, 'aye but you says you never get your flush'. I went, 'aye cause I was dain' the flush and the door went and it was you so I just done that, oh bugger it'. He went like that, 'gie me that and let me thingwy it'. And I was like that, 'no'. And I says tae him. He's like, 'I don't care'. And I was like that, 'no, no'.*
>
> Interviewer: *No.*
>
> Interviewee: *I says, 'I will not be responsible'. I says, 'I wish somebody would have said no tae me [. . .] Or said something tae me rather than just let me get on wi' it. And I wouldn't gie him it.' I done it right doon the sink. He went like that, 'that's oot o' order, that's oot o' order'. I went, 'that's no oot o' order'. I said, 'that's probably saved your life', do you know what I mean.*
>
> *Scotland ID8, female, aged 40 years, heroin*
>
> Interviewer: *OK. Do you think you are at risk of passing hep C, for example, to another person?*
>
> Interviewee (York ID6, female, aged 25 years, heroin): *Oh yeah, you are. But that's just giving someone a death wish, that, if you share your kit with someone else and they haven't got it. I couldn't do that, no.*
>
> Interviewer: *OK. So how would you avoid . . . ?*

Interviewee: *There's people out there who don't give a shit and would share with someone that hasn't got anything and they've got it, but I'm not like that. I don't share with nobody. I've got my own equipment. I do everything myself. If they want to use they go get their own. I don't give them anything of mine.*

Interviewer: *OK. So if someone comes to you and says please may I share . . .*

Interviewee: *No, they've got no chance [. . .] No. It's a death wish on someone. It's wrong.*

York ID6, female, aged 25 years, heroin

Participants would often mention managing risks other than BBV transmission. For example, participants mentioned managing overdose risks by injecting with at least one other person; injecting in private settings to avoid stigmatisation, getting caught in public or protecting children; and managing infections or vein care by rotating injecting sites and avoiding groin injecting. As participants developed the skills to inject themselves, their control over the injecting process was improved; however, knowing how to inject could also lead to increased risks as participants would be asked to inject those who had difficulty finding veins or had not yet learned to inject. The main concern was the potential risk of fatal overdose:

Interviewer: *Would you ever help anyone else inject?*

Interviewee (London ID4, male, aged 39 years, heroin/crack cocaine): *I have done but . . . I wouldn't these days, man. There's too much risk; too much bullshit involved and too much red tape, yeah. [Yeah] That person will put it on you like, 'Oh, help me,' and they will put it on you, 'You bastard. You're not helping me.' It ain't like that though. Anything happens to that **** mate, I'm – it's me. That's my liberty mate or that's his death on my hands. I don't need shit like that, no. Don't need it. I've got enough bullshit of my own. Extra bullshit, I don't need it.*

Two participants noted that they were more careful about sharing equipment at the start of their injecting drug use, but as their addiction developed they became more 'lax' in their risk management. However, some participants reported being more careful as their drug use developed, and receiving a BBV diagnosis was often a catalyst for changes in risk behaviours:

Interviewee (York ID4, female, aged 36 years, heroin): *I always try now, well, I never share anything, I'm really, really careful now that everything is clean and new and I make sure, like, I must have had it years and years and, you know, when I've had partners in the past used old needles, you know, again and put them on the same spoon, now I won't do that, everything is totally new, you know, so I'm really aware now.*

Interviewer: *OK. So what is the motivation for you now not to share and to use clean?*

Interviewee: *Because I don't want to catch HIV.*

Interviewer: *OK.*

Interviewee: *You know, because now I know that I have got a . . . before you just think you're invincible, I thought I wouldn't get anything and now I have, I'm not invincible and now, obviously, there's something other than Hepatitis C I could get, you know, so now I'm more careful.*

Risk management strategies, however, may be dependent on the types of drug used. As explained here, stimulant drugs may complicate the user's capacity to manage injecting risks:

Well, when you inject the cocaine you get that much o' a rush, you're not really as much in tae, you're more involved in talkin' away and, and more engrossed in your . . . more engrossed in the buzz that

it's givin' ye', that you would just maybe put the needle down and in among the other people that are using. Whereas with heroin I would maybe take my injection and then I would scrape the numbers off ma', ma' injection, ma' needle. And I would normally scrape ma' numbers, or burn a wee bit of it, and that's generally how I would know mines from somebody else's.

Scotland ID4, female, aged 45 years, cocaine

Factors which promote change in risk behaviour (i.e. reduced risk behaviour)

Addiction progression

As drug use became more central in participants' lives, their level of preparedness increased, so they were more likely to have their own drug-using equipment and less likely to need to borrow others:

Interviewer: *OK, and what's changed that you have access to new equipment now and you didn't back then?*

Interviewee (London ID4, male, aged 39 years, heroin/crack cocaine): *Now, I would go to a chemist. I would make sure I would go to the chemist and pick up a bag of pins . . .*

Interviewer: *But you didn't before.*

Interviewee: *. . . whereas before, I wasn't really doing it all the time, so I was only around certain people. I was only doing it when I was around them people.*

Getting older and wiser

Experience and knowledge over time was reported to lead to safer behaviour. Also, some interviewees described maturing out of heavy drug use as they became older, leading to less frequent injection:

I don't use anywhere near as often, you know [OK]. I might use once a fortnight and put it down and I won't touch it again [OK], but that's because I've got a methadone script and I don't need to use on top of that any more. And I have lost the desire, you know – I just can't – I couldn't live like that any more.

London ID7, male, aged 50 years, heroin/crack cocaine

Addressing addiction

Where participants were addressing their addiction (e.g. went to rehab), had a 'recovery plan' or were on OST, their injection drug use decreased or (temporarily) ceased:

I'm trying to get off that, but I do every once in a while. I used to do it quite a bit more or less every day I used to inject heroin but do it once a month around here, trying to cut off altogether, the injecting, trying to stay clean.

Wales ID6, male, aged 34 years, heroin/amphetamines

Sometimes participants reported that this entailed distancing themselves from the people and places associated with their drug use. Being on OST not only reduced frequency of injection drug use but also facilitated participants to collect new injecting equipment while they picked up their OST, again increasing preparedness.

Life events

Health scares prompted some participants to change risk behaviour. For example, one participant described being in hospital with pneumonia and this provided the motivation for her not to share again:

I was in hospital a couple of years ago, and I had pneumonia, and it was then that I was tested for everything, because I had a strain of pneumonia that a lot of people with HIV get, and I was very

worried, obviously, about getting the results and stuff. But, I was so pleased when they came back all clean, for hepatitis as well, and from then on I've never shared.

York ID8, female, aged 37 years, heroin

Similarly, another participant who contracted HCV but cleared the virus was now very cautious. Other participants described experiencing needlestick injuries in the past which prompted greater mindfulness and care around injecting and safe disposal.

Other health scares, such as overdose or the risk of having an amputation, reduced or deterred injecting (at least temporarily):

I have just come out of hospital, this is from injecting, I had to sign a piece of paper to say that they might not be able to save my thumb, that if they can't save it, do I give them permission to amputate, it was bad, I almost lost my hand and everything, it was really bad [. . .] so since I had that scare I haven't been doing it (injecting) as much.

London ID6, female, aged 27 years, heroin

Other participants cited life events, such as having children or close relatives dying, as events that influenced them to change risk behaviours. As one participant described, the responsibility of family meant 'I've got to be clean and tidy.'

Stable housing/lifestyle

Having stable housing and a more stable lifestyle also facilitated safer drug use as people injected in their own homes:

I suppose when things changed for me was, you know, I – I thought – I moved away from the situation I was in. I moved away from my life being chaotic. I moved into my flat; I've lived there for ten years. I live a kind of fairly normal, stable life now [yeah]. I don't use anywhere near as often, you know.

London ID7, male, aged 50 years, heroin/crack cocaine

Intervention preferences for reducing blood-borne virus risk behaviours

Previous help and support for injecting behaviour change was mostly provided by key workers or nurses at drug treatment services, although information had also been provided through outreach services (specifically for sex workers and/or homeless), residential rehabilitation, prison services, drug treatment testing orders and drug rehabilitation requirement courses, and a BBV charity. Most information was provided through leaflets and usual treatment, although some had received information through BBV infection testing and HCV infection treatment. Although some participants reported attending group work sessions, few of these interventions focused specifically on BBVs or injecting/sexual behaviour change, but these were rather a component of the sessions. Information and advice on BBVs was generally well received and seen as useful, although some participants noted that it was not personally helpful as they were unable to retain the information, already knew the information or were not motivated to be informed:

I've done courses on this and I've read leaflets but actually when you ask me you know what are the differences and like how – how are these things transmitted, I don't really know, I forget. So yeah it's – it is quite important stuff isn't it to be telling people again and again and again.

London ID14, female, aged 32 years, heroin/crack cocaine

*I know the pros and cons o', I know the rights and wrongs. I've been educated . . . but it's doon tae desperation. Basically I couldnae give a ****. As long as I get the drugs I don't care.*

Scotland ID10, male, aged 38 years, heroin

Information and advice on overdose prevention strategies, where to access injecting equipment and help with housing and benefits were perceived to be helpful, as was practical information on safer injecting strategies, including how and where to inject safely on the body:

> *. . . when I done a medical trial in (hospital), the doctor there, he actually showed me, cos my arms are terrible and my injection sites were really bad and I've never gone in my groin but he actually showed me where to go if I was going to do it properly and safely yeah, so I don't know if that . . . but him showing me that that has helped me, it really has because I haven't got any luckily any abscesses or anything like that so people say well he shouldn't have showed you that but I think well he's helped me because I'm quite you know been doing it 8 years now touch wood I've not had anything major go wrong but before my arms were really bad, I had really bad like I did used to get bad abscesses, they weren't abscesses but really bad hard lumps and bruises all up my arm so yeah a doctor really showed me how to do it properly.*
>
> *London ID15, female, aged 34 years, heroin*

Intervention content

When asked for their views on the development of an intervention for PWID, almost all of the participants recommended the need for information on BBVs (including risk behaviours and consequences), safer sex information and equipment provision (needles and condoms, including supply of and information on where to access equipment):

> *. . . just find out all the different ways you can catch the Hep and HIV, just understanding more about how you can catch it and what might happen if you've got it, things like that.*
>
> *Wales ID6, male, aged 34 years, heroin/amphetamines*

The majority also recommended content that would inform behaviour and skills. Thirty-one participants recommended being taught injecting skills and techniques and nine of these wanted practical demonstrations of injecting in order to reduce risks such as skin and soft-tissue infections, amputations and venous damage:

> *Yes, you could maybe do groups where they show people how to inject properly, how to use the right things, like tourniquets, like damage limitation.*
>
> *York ID15, female, aged 33 years, heroin*

Health and hygiene, overdose training and relapse prevention were also mentioned. In terms of health and hygiene, participants suggested that promoting physical cleanliness, providing antibacterial hand wipes, showing people how to clean injecting equipment, providing dietary advice and emphasising liver health (particularly for those who have contracted a BBV), and encouraging PWID to move from injecting to smoking:

> *. . . there should be something involved in some scheme or whatever, to promote keeping clean physically, yourself, more than what there is. Because you don't see it. I've never been in a class or, in all my time of drug use, anything . . . and talking about keeping yourself clean, washing, blah, blah, blah, you know, hand washing.*
>
> *London ID1, male, aged 42 years, heroin/crack cocaine*

> *Yeah, if they have a solution that they can say, right, look, if a needle is being used, if you do this and clean it out in this way, this makes it much more likely to get rid of any blood-borne viruses, I think people would definitely take notice of that. You know, obviously it's not the safest thing, but if they're going to do it anyway, it's best to show them how to do it the safest way, I think people would take notice to that.*
>
> *York ID2, male, aged 42 years, heroin*

Just over one-third recommended various psychosocial content including help with motivation and self-esteem, assertiveness training and the involvement of family members and partners. A few participants mentioned the value of encouraging PWID to think of other injectors' safety when injecting in groups. Teaching people to be more assertive with injecting and/or sexual partners was recommended by a few participants:

> *Yeah, absolutely, you know, because there is a lot of bed hopping, there is a lot of, I'll do anything for a tenner, you know what I mean, but I'm sure half of these people aren't aware of the dangers they're putting themselves in, you know, and it's like . . . Alright, you might switch off when you're doing the business but, you know, you're putting yourself at risk, you're putting him at risk and you're putting anyone else at risk, you know, and that person could get into a relationship who's never been with anybody at all. It just takes one. You know, it's silly and they need . . . it's education, education, education, education, you know?*
>
> *York ID7, female, aged 47 years, heroin*

Delivery style

The style of delivery favoured by most participants was a group format. They thought that it was useful to share and learn from the experiences of others, although slightly fewer preferred one-to-one sessions as they were uncomfortable engaging in groups because they either had mental health issues or had concerns about other group participants. (This last concern was particularly prevalent among participants in Wales, who were recruited from a rural area where anonymity or privacy is more difficult to maintain.) A small number of participants in Scotland and London suggested separate groups for men and women, although four participants also advocated interventions for couples. Online sessions or applications were suggested, although most participants thought access may be limited (telephones sold or do not support applications, unfamiliar with computers). Some participants thought that leaflets would be a useful addition to face-to-face information delivery, although issues were raised around literacy and that some PWID may not bother to read. Visual information as opposed to written or lecture-style delivery was recommended so videos/digital versatile discs and leaflets with graphics were mentioned. Importantly, information on safer injecting would be preferable if it was demonstrated rather than given in a leaflet:

> *Keep it tight, keep it tae the point, keep it interestin', keep it relevant to their specific needs . . . Keep it relevant tae their situation, so they can identify wi' it. And if they identify wi' it they'll tune in tae it, ken. You know what I mean? . . . get them involved and, you know what I mean, keep them involved and interested.*
>
> *Scotland ID11, male, aged 40 years, heroin*

Duration, venue and personnel

The preferred length of sessions varied and ranged from < 30 minutes to 2 hours over one to six sessions, although the preference was for multiple sessions:

> Interviewer: *How many times do you think you would, you would need to go to get . . . the information? Would that be a on- off or . . .*
>
> Interviewee (Scotland ID2, male, aged 27 years, heroin): *No I'd need tae go quite a couple o' times anyway, for a couple o' weeks probably.*
>
> Interviewer: *Yeah, yeah.*
>
> Interviewee: *I dunno, I would need a few sessions o' it probably.*
>
> Interviewer: *Yeah OK. So be a few sessions though for a couple o' weeks or something yeah?*
>
> Interviewee: *Aye.*

Interviewer: *And how long do you think the sessions should last?*

Interviewee: *Don't know. Any time, anything between 15 minutes tae aboot half an hour or something.*

Scotland ID2, male, aged 27 years, heroin

Interviewer: *OK. And how many sessions would be realistic?*

Interviewee (York ID4, female, aged 36 years, heroin): *I don't know. See I don't think one would be enough, because I don't think people would listen. Maybe three or four, you know, like, one a week over a month or something.*

Interviewer: *OK. And how long do you think each session should be?*

Interviewee: *Oh, I don't know, about an hour.*

York ID4, female, aged 36 years, heroin

Drug services and needle exchanges were considered appropriate venues for intervention delivery by most participants, while outreach/street teams were also suggested:

Interviewer: *So where do you think it would be best delivered and who do you think it would be best delivered by? So this workshop you're talking about like where should we deliver it and who should we get to deliver it?*

Interviewee (London ID15, female, aged 34 years, heroin): *I think um at a treatment centre because that's where most people go um yeah most people that use drugs will come to a treatment centre to get their scripts so you've got them here already so you know they're going to turn up.*

London ID15, female, aged 34 years, heroin

Interviewer: *[W]here do you think this would be best delivered?*

Interviewee (York ID1, female, aged 32 years, amphetamines): *[name of service].*

Interviewer: *[name of service], you're saying [name of service], is that what you think?*

Interviewee: *Yeah.*

Interviewer: *So if [name of service] . . . why do you think [name of service] is the best place?*

York ID1, female, aged 32 years, amphetamines

Interviewee: *Because obviously that's where most users go, you know, to have their treatment or their, you know, just go for counselling or just for clean syringes, obviously, you know.*

Other venues included chemists, sexual health clinics/services for sex workers, gay men's services and homeless hostels/homeless services, probation/offender programmes, residential rehabilitation units, pre-existing groups (e.g. recovery cafes, Cocaine Anonymous, Narcotics Anonymous) and participants' homes:

Erm, centres like (name of service for women involved in prostitution), erm, they are – they are extremely good, and because the women that work there, erm, they really do care, like.

London ID13, female, aged 32 years, heroin/crack cocaine

[L]ocal housing estates just at the community centres, things like that. Maybe the chemists after they close. Put the seats doon and dae it there. Things like that.

Scotland ID12, male, aged 30 years, heroin

In rehabs and that. Know what I mean, when they're clean, getting clean. Or else see going intae homeless places. But I don't know. It's just, just need tae gie them information. It's whether they take that on board or not. Know what I mean. If there's two oot o' ten there's still, know what I mean, they take it in [laughs]. There's just places like that, homeless places and that.

Scotland ID13, male, aged 34 years, heroin

Although drug/needle exchange workers, health professionals and ex-drug users/sex workers were all recommended to deliver an intervention, there were some slight differences across the four areas. For example, in London and York, key workers, health professionals to teach safer injecting and ex-drug users/sex-workers were favoured:

Interviewer: *OK, and who do you think would be the best person to deliver this information?*

Interviewee (York ID12, female, aged 19 years, heroin): *Staff here could do it, couldn't they?*

Interviewer: *OK, so, you know, key workers?*

Interviewee: *Yeah, a key worker, yeah.*

Interviewer: *OK, and why do you think a key worker?*

Interviewee: *Because they know you, don't they, like they know most about you than anyone else here, so.*

I'm not a professional or anything, you know, I'm just picking up and going, oh like that. I should have some professional help, like you know proper nurse telling you how to do it with a tourniquet, you know what I mean, like how to let loose once it's like comes out, do it all, wipe your skin before you use you know with the alcohol wipes and all that so you don't get dirt in them, all that, you know what I mean like.

London ID5, male, aged 25 years, heroin/crack

Interviewer: *OK. And who do you think, for example, if we decide to do a workshop, who do you think would be the best person to give people this information, to talk to people about this issue?*

Interviewee (York ID14, male, aged 24 years, heroin): *People that had it happen to them. A person who's got HIV or Hepatitis, and that, for them to tell their story about how they caught it, and stuff like that.*

Interviewer: *OK. So you think it's important to get someone with lived experience of what they're talking about?*

Interviewee: *Yeah.*

The Welsh participants favoured drug workers to deliver the intervention:

Interviewer: *If there is somebody who is going to deliver it to you, who would you want to deliver it? Would you like drug workers, GPs [general practitioners], needle exchange . . . ?*

Interviewee (Wales ID12, female, aged 28 years, heroin/crack): *Needle exchange yeah.*

Wales ID12, female, aged 28 years, heroin/crack

Interviewer: *OK, and who do you think would be best to deliver it, so you know would it be like for instance harm reduction worker, needle exchange, GP [general practitioner], key worker, chemist?*

Interviewee (Wales ID6, male, aged 34 years, heroin): *Harm reduction or a key worker I think.*

Interviewer: *OK.*

Interviewee: *If you're not with a key worker, the harm reduction would do, but one or the other.*

Interviewer: *So why would you find them most beneficial?*

Interviewee: *It's cos you got partnership with them, you see them more often, doctor you only see when you're poorly but harm reduction you're always around them, you always see more, more often and listen to them more as well.*

Wales ID6, male, aged 34 years, heroin

In Scotland, ex-drug users or a combination of peers and drug workers, general practitioners (GPs) and needle exchange workers were recommended. Ex-drug users were considered relevant as they had 'lived experience' of injecting and/or BBVs:

I'd say people like . . . the street team or people like who work in the [drug service]. I think the, the street team are amazing . . . the street team are ex drug users.

Scotland ID14, female, aged 30 years, heroin

[I]t'd definitely have tae be somebody that's been there and done it because they're no gonnae really listen tae somebody that's like . . . nae offence or anything like that but I say you've never, you've never stuck a needle in yourself.

Scotland ID9, male, aged 41 years, heroin

Barriers to attending psychosocial interventions

The main barriers to PWID attending psychosocial interventions were considered to be being too busy earning money and using drugs, having a short attention span and being uninterested or considering the intervention irrelevant. Feeling stigmatised, not wanting to disclose their BBV status and learning difficulties were additional barriers. Travel to the intervention may be a barrier for some, especially those in rural areas, whereas family responsibilities could make it difficult to attend, particularly for women with child care responsibilities.

Facilitators of attendance

The most frequently suggested facilitators were cash or vouchers to incentivise attendance. Providing food and refreshment on the day was also important. In Scotland, additional suggestions included vouchers for haircuts, shoes or clothes, or gym passes. It was considered important to have an 'informal' and 'relaxed' atmosphere, and some suggested holding the sessions later in the day, keeping them short and interesting and making attendance mandatory. Further suggestions for improving uptake included holding the sessions on the same day as people are picking up their prescriptions or attending appointments and ensuring that staff are delivering consistent information:

I think in, like, a group setting, but, like, an informal thing. Don't make – cause it needs to be, kind of, a relaxed atmosphere so people can open up and that sort of stuff, and, like, not – like, although it's a serious subject, like, you've got to, kind of – no one wants to sit there and listen to a lecture because, at the end of the day, like I said, they're sitting there when they could be earning money or taking drugs. So, if they're not enjoying themselves to a certain extent, then, like, people are going to lose

concentration. Umm, so it kind of needs to be, like I said, with the concentration thing as well, like, relatively short, and informal, like, people will just, kind of – I don't know, just a relaxed atmosphere and obviously the person delivering it needs to be quite charismatic as well.

London ID13, female, aged 32 years, heroin/crack cocaine

Summary of key findings

The above analysis of 60 qualitative interviews with current PWID highlights that a wide range of individual, situational and structural factors contribute to injecting risk behaviours in this population, and thus preventing BBV infection and transmission among PWID is a challenge that will require a multilayered response. *Figures 17* and *18* summarise the identified themes and subthemes. Relationships and social networks are identified as crucial influences on risk behaviours, whereas access to needle exchanges and safe injecting environments are vital for maintaining safer injecting behaviours. Drug states, such as withdrawal and craving, and the trajectory of drug use generate priorities of more immediate concern to PWID than BBVs. Furthermore, perceptions of BBV transmission risks change over time as knowledge is gained and the interviews illustrate that there remains a great deal of uncertainty around BBV acquisition. The perceived seriousness of HCV infection may be undermined by the view that it is an inevitable consequence of injecting drug use, thereby leading to less safe injecting practices. Despite this, participants described managing risk situations by planning ahead and being more vigilant regarding hygiene practices when using with others. In addition, changes in life circumstances, such as access to stable housing, facilitated improvements in risk behaviours. Risk management strategies were not necessarily intentionally BBV protective, but were often employed to manage other risks such as overdose and soft-tissue infections. For many of those interviewed, any intervention aimed at reducing risk behaviours should include behavioural and skills components such as health advice, hygiene promotion and injecting skills. Functional content, such as BBV information and injecting equipment/condom provision, along with psychosocial content, such as assertiveness training, were also suggested. No consensus was drawn from the participants regarding the length of sessions, preferred venues or style of delivery, suggesting that one size will not necessarily fit all. However, interventions that are delivered locally by informed trainers and are cognisant of the challenges PWID encounter in attending were considered important by the participants.

Implications for intervention development

The wide range of factors identified, which contribute to risk behaviours for BBVs, highlights the importance of maintaining other efficacious interventions as well as developing psychosocial interventions (including OST, adequate access to NSP and harm reduction advice). Consideration should also be given to the provision of injecting rooms in the UK. The findings from the qualitative interviews with PWID were used to develop the PROTECT intervention focusing on increasing knowledge about BBV transmission and protective practices, and strategies to avoid risk situations such as withdrawal and lack of preparedness.

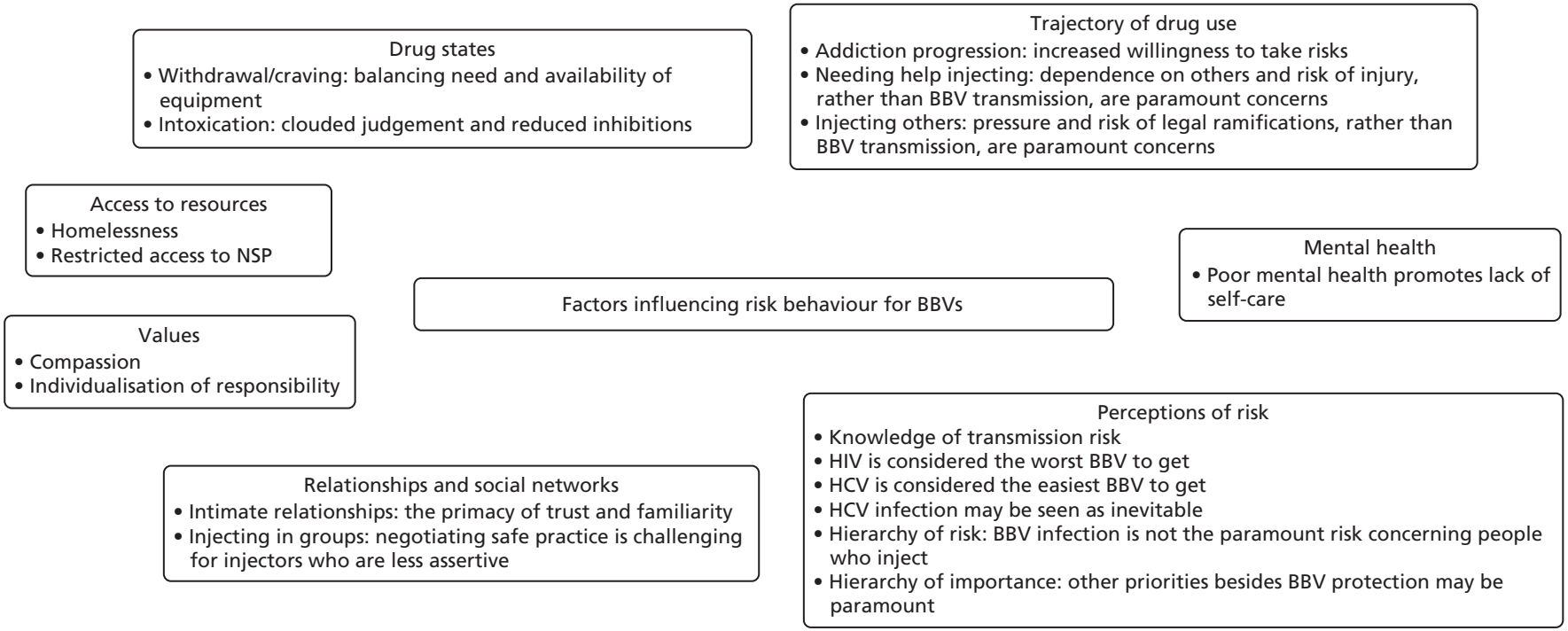

FIGURE 17 Themes and subthemes relating to factors influencing risk behaviours for BBVs.

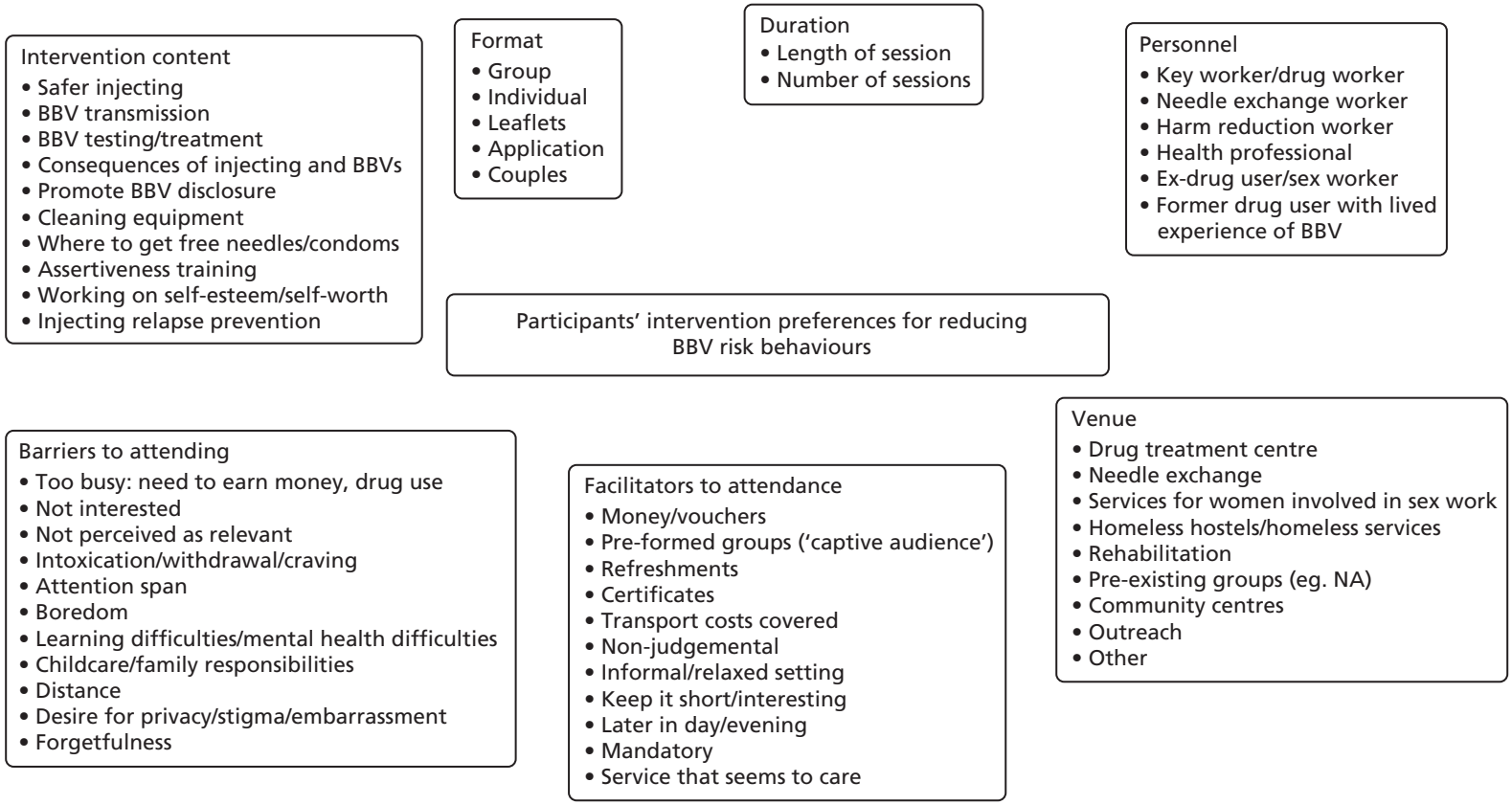

FIGURE 18 Themes and subthemes relating to participants' intervention preferences for reducing BBV risk behaviours. NA, Narcotics Anonymous.

Chapter 4 Consultation with key stakeholders on the delivery and effectiveness of psychosocial interventions to reduce blood-borne virus transmission risks among people who inject drugs

Aims

The main aims were to consult key stakeholders about the delivery and effectiveness of psychosocial interventions in reducing BBV transmission risks among PWID, including highlighting any barriers to, or facilitators of, delivery in substance use treatment in the UK to practically inform the implementation of the feasibility trial (see *Chapter 6*).

Methods

A telephone consultation was carried out with 40 national and local stakeholders (from Scotland, England, Wales and Northern Ireland), including service providers, policy-makers and commissioners. Selected stakeholders were key informants in the sense that they had responsibility for delivering and/or commissioning services in BBV prevention in the UK and would be in a position to identify the system barriers and facilitators necessary for successful implementation of the intervention in phase V, and beyond, in phase VI. In the first instance, key stakeholders in England and Wales were identified by Public Health England and Public Health Wales, respectively, which have responsibility for overseeing the delivery of BBV action plans. In Scotland, key stakeholders were identified by the co-applicants and selected from those people with responsibility for delivering the Sexual Health and Blood Borne Virus Framework. In Northern Ireland, key stakeholders were recruited through the Department of Health, Social Services and Public Safety, which has responsibility for BBV. Some of the stakeholders that were approached or interviewed referred the researchers to other appropriate colleagues who they felt would be well situated to respond to the consultation.

The consultation enquired about:

- key priorities for reducing BBV among PWID
- awareness of current delivery of psychosocial interventions to PWID in their area
- the need to develop psychosocial interventions to reduce BBV infections among PWID
- content of psychosocial interventions
- current barriers to, and facilitators of, delivering psychosocial interventions in harm reduction settings in their area.

The topic guides can be found in *Appendix 3*.

Analysis

Interviews were transcribed by professional transcription services and qualitative software (NVivo 10)[224] was used to manage and code the interviews. Thematic analysis of the data was conducted by Davina Swan and April Shaw. The researchers independently coded the first three interview transcripts, then reviewed the coding at a Skype meeting and collaboratively generated an initial thematic framework. This coding framework was applied to the remaining interviews (indexing) by Davina Swan and April Shaw.

Ethics approval

Ethics approval was not sought for this consultation, as it was not considered to be research. As such, to protect stakeholders' anonymity, the findings have been compiled together rather than separately across the four UK regions areas.

Results

Forty stakeholders, mostly policy-makers, from the four UK nations were consulted (*Table 10*).

Key priorities for reducing blood-borne viruses among people who inject drugs

At the time of the consultation, stakeholders identified a range of activities and target groups which they considered to be key priorities to reduce BBV transmission rates among PWID across the UK: BBV education, needle exchange provision and access to counselling were the most often cited, followed by stabilising and addressing client needs, OST, client-centred services and the reduction of sharing injecting equipment (*Table 11*). Screening and diagnosis for BBVs, reducing HCV and HIV incidence, and access to BBV/HCV infection treatment and HBV vaccinations were also key priorities. Stakeholders highlighted groups which need particular attention regarding BBV prevention, such as men who have sex with men (MSM), particularly chemsex injectors (i.e. MSM who inject psychoactive substances, such as crystal methamphetamine and mephredone, immediately before or during sex), and PWID who have limited engagement with services, novel psychoactive substance (NPS) users, migrant communities, IPED users and young people.

Issues in delivering on priorities

A number of issues were identified that impeded delivering on the priorities outlined above. These included funding and resources, staff capacity, access to services (particularly in rural areas), stigma in relation to drug use, and challenges with recruitment and retention of clients in services. Other difficulties identified included fractured care pathways, complex commissioning landscapes and lack of integrated services. Stakeholders identified a need for services to have a person-centred approach and it was suggested that service users be involved in the design of services. Finally, evidence is required to understand BBV transmission and identify gaps in service provision among people who inject NPSs.

Funding and resources were the most commonly cited, along with challenges around commissioning structures. A number of stakeholders suggested that it was challenging for different local authority structures to work together as there are often competing priorities within the same local authority area. Competing priorities within central government departments also present a challenge to commissioners and policy-makers. For example, it was mentioned that the recovery agenda (i.e. the focus on freedom from drug dependence, and improved well-being and citizenship) may threaten adequate provision of

TABLE 10 Sample of professional stakeholders

	Location in the UK (*n*)			
Role	Northern Ireland	Scotland	England	Wales
Policy	6	10	6	2
Practitioner	3	1	0	4
Policy and practice	0	0	5	3

TABLE 11 Key priorities for reducing BBV among PWID

Priority	Number of stakeholders who mentioned this
Priority activities	
BBV education	14
Needle exchange provision/coverage	11
Access to counselling/services	11
Stabilise PWID lifestyle/address multiple complex needs	7
Opiate substitution treatment	4
Client-centred services	3
Reducing sharing of needles and syringes	3
Priority BBVs	
BBV infection screening/diagnosis	13
HCV infection incidence	9
Access to BBV/HCV infection treatment	9
HIV infection incidence	7
HBV vaccination	3
Priority risk groups	
Chemsex injectors/MSM	7
PWID with limited engagement with services	7
NPS users	7
Young people (aged 18–24 years)	5
Migrant communities	4
IPED users	4
Recreational drug users	2
Prisoners	2
Ex-users	1
PWID's social networks/partners/children	1
Homeless	1
Lesbian, gay, bisexual, transgender	1

needle and syringe programmes and opiate substitution treatment in some areas. Co-ordinated and joined-up working between services, including pharmacy, statutory and voluntary organisations, was also an issue that needs addressing.

It was thought by some that there was an over-reliance on pharmacy needle exchanges, which may be detrimental to the needs of opiate users and MSM, in that the standard of care and assessment of needs may be better met at drug treatment services. Also, the sheer number of local authorities, all with different priorities, made delivering and maintaining extensive and effective high-quality needle and syringe programmes and adequate penetration of opiate substitution treatment across all areas challenging. Ensuring access to OST for PWID who prefer low-threshold services (i.e. services for drug users not in treatment that do not attempt to control drug use but endeavour to reduce barriers to service access and provide counselling and treatment only if requested), rather than therapeutic services, was deemed important.

A number of stakeholders suggested that there were issues regarding the offer of BBV infection testing and HBV vaccinations as there remains a substantial number of service users who do not take the opportunity to be tested and/or do not engage with services frequently enough to complete the full course of HBV vaccination. Moreover, access to HCV infection treatment was considered inadequate by some, as hepatology services were not appropriately structured for this client group and there needs to be more outreach into the community. Fractured care pathways between prisons and community services were another area of concern, particularly for prisoners with HCV infections post release.

Particular concerns were raised for those living in rural areas as it was often difficult to access harm reduction and hepatology services, as these could be some distance from the communities in which PWID live. Additionally, it is difficult to access the new and hard-to-reach groups who are not engaged with services (recreational users, MSM, IPED users, some migrant communities, club drug users, those aged 18–24 years, homeless groups and stimulant users). Providing access to harm reduction and hepatology services through outreach and 'embracing new approaches' may help increase access to HBV vaccines and HCV infection treatment for the hard-to-reach groups.

Current delivery of psychosocial interventions to reduce blood-borne virus transmission risk behaviours

Although some stakeholders were aware of psychosocial interventions that included BBV infection reduction components within a programme of harm reduction, most were unaware of any specifically designed to reduce BBV infection. Most stated that BBV information and education was incorporated into 'usual' harm reduction conversations by key workers in drug and alcohol services and practitioners in needle exchange and specialist services.

Support for the delivery of psychosocial interventions to reduce blood-borne virus transmission risk behaviours among people who inject drugs

Around half of the respondents agreed there was a 'need to develop psychosocial interventions to reduce BBV among PWID'; however, almost as many were unsure or were unconvinced. Lack of evidence of effectiveness or reservations around whether or not anything new could be added to existing BBV infection prevention strategies were the main reasons for the uncertainty. However, for those who agreed, some stressed that psychosocial interventions were one of a range of options within a holistic package of care.

There was a range of views on the delivery of psychosocial interventions for PWID. When asked for their views on the content, and development, of the psychosocial intervention for this project, most thought that it should be targeted to drug users at all stages of drug use and not at any particular point in the trajectory of drug use, although a few suggested targeting novice or new PWID. A few suggested some degree of tailoring of a psychosocial intervention, for example to the type of drugs injected, to the 'individual' and to the intervention setting. There was no consensus on the delivery format, with stakeholders suggesting a psychosocial intervention to reduce BBV infection among PWID should be brief and opportunistic, delivered one to one, a mix of individual and group work, group work only and as an online intervention. When specific settings were mentioned, they included needle exchanges and drug treatment services, sexual health services (for MSM), and gyms and fitness clubs (for IPED users). Other settings included outreach, BBV treatment services, homeless accommodation/hostels, satellite GP surgeries, ancillary services (e.g. housing/welfare support services), mental health services, pharmacies, hospitals, gay clubs/saunas, nightclubs and individuals' homes.

When asked who should deliver such psychosocial interventions, a variety of facilitators were suggested, including keyworkers, drug workers or harm reduction staff in drug treatment settings and needle exchanges; trained peer educators (in specific communities of users such as MSM and IPED users or, generally, within harm reduction services); pharmacists; allied health professionals (e.g. sexual health workers, hospital staff, health visitors, community nurses); GPs; and psychologists. Stakeholders were clear that any facilitators should be trained and supported to deliver the intervention.

Table 12 shows the content suggested by stakeholders. They can be categorised as (1) BBV specific (e.g. education on disease transmission); (2) addressing behaviour and skills (e.g. reducing risk behaviours, improving injecting skills); and (3) addressing individual needs (e.g. improving self-efficacy, addressing reasons for injecting). As well as ensuring any psychosocial intervention is 'culturally sensitive and culturally acceptable' for the range of PWID, a few stakeholders suggested content that achieves goals other than those directly related to BBV transmission reduction (e.g. good vein care and injecting technique to maintain vascular access).

There was some ambivalence regarding the provision of incentives for attendance at psychosocial interventions, with some stakeholders in favour of providing cash, vouchers or refreshment, whereas others thought it unnecessary or were undecided.

Facilitators of the delivery of psychosocial interventions to reduce blood-borne virus transmission risk behaviours among people who inject drugs

Stakeholders highlighted several key criteria to ensure the effective delivery of a psychosocial intervention specifically aimed at reducing BBV transmission risk behaviours for PWID both nationally and locally. The psychosocial intervention:

- should be evidence based for effectiveness and cost-effectiveness
- should have clear scope and clearly defined objectives for consistent delivery
- should have a practical time frame in terms of delivery and facilitator
- should be person centred and simple for staff to apply
- should include well-designed training and support materials
- should include appropriate pathways and management
- must meet the needs of the client group (peer input).

TABLE 12 Suggested content for psychosocial interventions

BBV specific	Behaviours/skills	Individual
Conducting/encouraging BBV infection testing	Reducing risk behaviour	Explore root cause of why injecting/having risky sex
Education on transmission, risk of infection, disease and disease progression, health effects	Preventing initiation of injecting	Looking at social support and social networks
Information on/support with BBV treatment	Identifying triggers of risk behaviour	Address self-efficacy/self-esteem/ motivation to change
	Hygiene, good vein care and injecting technique	Look at values (helping to support others not to share)
	Other routes of administration	Addressing impulsivity, ambivalence
	Drug tolerance/reduced tolerance	Assertiveness/negotiation skills training and preparedness for situations of peer pressure and enticement

At the system level, such interventions should:

- be integrated into current service delivery rather than separate commissioning
- require political, management, commissioner, worker and client buy-in
- be adequately funded
- be delivered by a trained workforce
- ensure capacity for staff to be released for training/delivery
- be marketed to PWID
- be monitored and evaluated (e.g. inclusion in the National Drug Treatment Monitoring System for reporting purposes).

In order to evaluate the effectiveness of a psychosocial intervention aimed at reducing BBV among PWID, stakeholders mentioned several outcomes that should be measured, such as:

- behaviour changes (e.g. changes in injecting behaviours/skills, drug use and risks)
- knowledge (transmission, risks prevention and BBVs)
- health benefits
- HBV vaccination rates
- self-esteem, confidence
- process outcomes (e.g. number of staff trained, intervention uptake)
- impacts on delivery in different environments
- facilitator competencies
- acceptability of the intervention
- review of PWID needs following the intervention.

Additionally, a small number suggested BBV infection prevalence/acquisition as a measure of effectiveness, but accepted that this would be difficult to do and the measures would need to be longitudinal. However, it was also suggested that injecting site problems could be used as a proxy measure in place of BBV infection prevalence.

Barriers to the delivery of psychosocial interventions to reduce blood-borne virus transmission risk behaviours among people who inject drugs

The barriers identified related to workforce, clients, structural issues and intervention design attributes (*Table 13*). Workforce barriers included concerns around staff resources and capacity to deliver psychosocial interventions within their current practice and ensuring that staff who deliver them are adequately skilled, trained and supervised. Although staff competencies were considered a workforce barrier, some stakeholders noted they already had highly skilled staff and workforce development teams in place.

Client barriers included client motivation and concentration, and some stakeholders were sceptical of the ability to recruit and retain clients to such interventions. Improving access and reducing stigma may help with the perceived client barrier to recruitment and retention, as might the provision of OST as an incentive for engagement. Involving service users and workers in the design, development and delivery of the intervention may ensure that it meets the needs of the clients and workers and is adaptable to different target groups and sites.

The most frequently cited structural barrier was ensuring funding was available. Commissioner, staff and client buy-in was also an issue for some, whereas others thought that BBVs were not considered as high a priority within the current treatment climate, which focuses on the recovery agenda. In terms of psychosocial intervention design attributes, the considered barriers were whether or not the intervention meets the needs of clients, fits into current treatment, and provides sufficient training and support.

TABLE 13 Barriers to, and facilitators of, delivering psychosocial interventions

Barriers	Facilitators
Workforce	
• Staff resources and capacity • Staff competencies • Staff perceptions of added value • Lack of experience among staff outside of treatment settings • Different levels of experience, knowledge, training and professional registration across the UK	• Existing skilled workforce in place • Existing local workforce development team • Existing outreach service/team • Proper training and supervision of staff • Staff engagement • Having a local workforce development team • Having suitable (e.g. nursing/social work) staff in an organisation who could be trained up
Client	
• Client recruitment and retention • Motivating clients to change • Client abilities to concentrate • Stigma	• Involve peers in design and delivery • Improve access to services • Reduce stigma • OST as 'incentive' for PWID engagement
Structural	
Funding Buy-in from clients and workers Complex commissioning landscape HCV (in general) does not integrate well with the recovery agenda Political climate does not support harm reduction but rather exiting of treatment as organisational target Commissioning cycles, difficult to change what is currently in contracts	• Client and worker buy-in • Existing appetite for brief interventions for risk behaviour • Local and national champions/opinion leaders • Effective community engagement • Joint working between services (e.g. police, NHS, voluntary services and education) • Pharmacies and needle exchanges to deliver intervention • Generally a positive strategic and political outlook on tackling BBVs and other drug-related harms • NICE backing/guidelines • Orange Guidelines/backing • Harm reduction philosophy exists within services, marginalised but still there • Governmental departmental buy-in • All commissioners should have leverage to be able to introduce this into existing contracts • Include it as a requirement in future tender contracts • Support of local authority chief executive and director of public council active members
Design attributes	
• Does the psychosocial intervention meet the needs of the clients? • Effective training with support • Adapting psychosocial interventions to different sites/clients • Quality of evidence (of effectiveness) • Systems in place to monitor and evaluate • How to fit it in current treatment pathways (not an add on)	• Evidence base • Look to/learn from work done in alcohol field • Tie in to human rights • Involve key workers in the design, development and delivery of the intervention • Involve peers in design, development and delivery • Not just delivered by drug and alcohol services but GPs and sexual health workers • Opportunistic intervention
Other	
Location/distance	

NICE, National Institute for Health and Care Excellence.

Ensuring local and national champions are on board may encourage buy-in from commissioners, managers, staff and clients.

The importance of monitoring and evaluation systems to measure effectiveness was highlighted.

Summary of stakeholder consultation findings

The findings from the consultations with 40 professional stakeholders highlight the current challenges and potential facilitators for the delivery of psychosocial interventions to PWID. Although there are a range of activities and priorities to reduce BBV transmission among this cohort of drug users, there are a number of structural and systemic issues that may impede delivering on those priorities. Although current activities and strategies include BBV components within harm reduction programmes, it was thought by a large minority that there was a need to develop psychosocial interventions specifically to reduce BBV transmission among PWID. Suggested content for future psychosocial interventions should include specific content on BBVs, and content that addresses client behaviours, skills and individual needs including the symbiotic goals identified by PWID. Although these may be related to goals other than BBV transmission, they may still have a positive impact on safer injecting behaviours and in turn, BBV transmission. In order to enable effective delivery of a psychosocial intervention, a range of workforce, client, structural and design barriers need to be addressed, but there was some indication that current and future facilitators could overcome some of these. The main criteria stakeholders required to ensure effective delivery of a psychosocial intervention nationally and/or locally were that any intervention should be evidence based, have clear objectives, be adequately funded and have clear buy-in from all relevant stakeholders. Ensuring staff are trained and supported and that the psychosocial intervention meets the needs of PWID was important, and any intervention development required input from peers and facilitators in its design and delivery.

Chapter 5 Intervention development

Intervention development

The intervention was co-developed by service users, service providers, policy-makers and academics. The intervention content was informed by (1) a review of the evidence about what works to reduce BBV risk behaviours among PWID (see *Chapter 2*); (2) qualitative interviews with PWID (see *Chapter 3*); (3) consultation with key stakeholders (see *Chapter 4*); and (4) expert opinion. There were three tiers of intervention development. The Steering Group was responsible for the final agreement of manual content. This group was supported by two development groups: an expert group (comprising practitioners, academics, policy-makers) and a patient and public involvement group with lived experience of injecting drug use. These two groups met separately three times during the process (*Figure 19*). Intervention development group members are listed in *Appendix 4* with their consent.

The process of reaching consensus on key intervention content was undertaken through debate and discussion to generate and prioritise ideas. At the first meeting, findings from the following phases of the research were presented:

- review of the evidence about what works to reduce BBV risk behaviours among PWID
- qualitative interviews with PWID
- consultation with key stakeholders.

The systematic review identified 16 effective interventions in reducing BBV risks or increasing knowledge about BBV among PWID. Authors of all these interventions were approached by e-mail and invited to share their interventions with the intervention development group. Only five of these manual authors agreed to provide the research team with a copy of their manual. Manual content was reviewed and described by the intervention groups (*Table 14*). Most effective interventions were multisession and delivered to groups. The main functions used in these interventions were education, training, enablement, persuasion, incentivisation and persuasion.[67] These findings and functions were used to inform the content of the PROTECT intervention.

Situations described by PWID during the qualitative interviews where they perceived they were more likely to engage in BBV injecting or sexual risk behaviours were listed and intervention content from existing interventions mapped against these risk situations. Where existing interventions did not include intervention content to address the specific risks identified by PWID, the intervention group developed appropriate materials using data from the qualitative interviews to illustrate risk behaviours, barriers and potential solutions (*Table 15*).

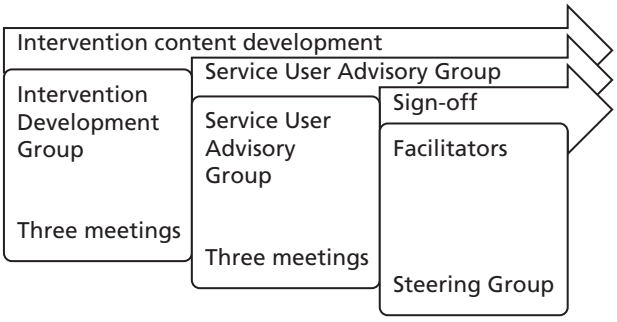

FIGURE 19 Intervention development process.

TABLE 14 Effective interventions

First author	Behaviour successfully changed in intervention compared with control group	Delivery format	Intervention functions[67]								
			Education	Persuasion	Incentivisation	Coercion	Training	Restriction	Environmental restructuring	Modelling	Enablement
[a]Avants *et al.*[174]	Reduction in unprotected sex	Individual	✗								✗
El-Bassell *et al.*[177]	Reduction inunprotected sex	Couple					✗				✗
Gagnon *et al.*[178]	Sharing syringes at 1 month not sustained to 3 months	Individual	✗				✗			✗	✗
[a]Garfein *et al.*[179]	Any injecting risk	Group/peer-education intervention	✗				✗				✗
[a]Gilbert *et al.*[73]	Sharing syringes/any sex risk behaviour/reduction unprotected sex	Couples	✗				✗			✗	
Latka *et al.*[182]	Any injecting risk	Group	✗				✗				
[a]Latkin *et al.*[72]	Any injecting risk/sharing syringes	Group	✗				✗				✗
Margolin *et al.*[186]	Sharing syringes/ reduction inunprotected sex	Individual		✗			✗				✗
[a]McMahon *et al.*[84]	Receptive syringe sharing with primary partners/ frequency of unprotected anal intercourse	Couple/ individual	✗								✗

First author	Behaviour successfully changed in intervention compared with control group	Delivery format	Intervention functions[67]								
			Education	Persuasion	Incentivisation	Coercion	Training	Restriction	Environmental restructuring	Modelling	Enablement
Otiashvilli *et al.*[188]	Any injecting risk/sharing syringes/frequency of injecting	Couple			✗						✗
Robles *et al.*[192]	Any injecting risk/sharing syringes/frequency of injecting	Individual	✗				✗				✗
Rotheram-Borus *et al.*[193]	Frequency of injecting	Group/ individual					✗				✗
Sterk *et al.*[81]	Frequency of injecting/ reduction inunprotected sex	Group	✗				✗				✗
Strathdee *et al.*[77]	In one site only, receptive needle sharing	Group	✗	✗			✗			✗	✗
Tobin *et al.*[76]	Any injecting risk	Group	✗				✗				✗
Wechsberg *et al.*[75]	Any sex risk behaviour/ reduction inunprotected sex	Group	✗				✗				✗

a Manuals sourced and content reviewed.

TABLE 15 Intervention to address risk factors for engagement in BBV risk behaviours identified by PWID

Risk factors for engagement in BBV risk behaviours identified by PWID (see *Chapter 3*)	Intervention content	Intervention function[67]
Withdrawal/cravings/intoxication	Develop strategies/plan to prepare for or avoid risk situations	Enablement
Access to/lack of sterile injecting equipment	Knowing where to access equipment	Education
	Develop strategies/plan to prepare for or avoid risk situations	Enablement
	Administration methods other than injecting in situations where there is no access to sterile injecting equipment	Education
Apathy/low mood	Awareness of context	Education
Homelessness	Develop strategies/plan to prepare for or avoid risk situations	Enablement
Inadvertent sharing	Develop strategies/plan to prepare for or avoid risk situations	Enablement
Lack of knowledge about transmission risks	Educate PWID about transmission risks for BBV	Education
	Video about cross-contamination of sharing injecting equipment	Education
Lack of assertiveness to insist on safer practices	Develop strategies/plan to prepare for or avoid risk situations	Enablement
	Develop assertiveness skills	Training
Sex trading	Develop strategies/plan to prepare for or avoid risk situations	Enablement
Requires help injecting	Skills building to learn to inject self	Training
'Symbiotic' goals that may impact on BBV risk behaviours		
Help finding a vein/image management	Video explaining how to inject safely	Modelling
	Education around how to find a vein and improve venous access and good vein care	Education
Requires help injecting/injects others	Skills building to learn to inject self	Training
	Administration methods other than injecting in situations where no access to sterile injecting equipment	Education

Based on the findings of interviews with PWID and the PPI intervention development group's views, it was decided that the intervention should therefore be brief, three 1-hour sessions and delivered once a week in a group format. The PROTECT intervention (as it was named) sessions, would address:

- session 1: improving injecting technique and good vein care
- session 2: planning for risky situations
- session 3: understanding BBV transmission.

Following this meeting, a logic model describing anticipated delivery mechanisms, intervention components, mechanisms of impact and intended outcomes was developed to further guide the intervention development process (*Figure 20*).[226] The COM-B ('capability', 'opportunity', 'motivation' and 'behaviour') model was the theory of behaviour change used to inform the intervention,[67] that is that capability (i.e. individual's psychological and physical capacity to engage in the activity concerned including having the necessary knowledge and skills), opportunity (i.e. factors outside the individual that make the behaviour possible or prompt it), and motivation to interact to generate behaviour change.

The research team drafted the intervention based on the discussion in the first meeting and sent the revised intervention to the groups to review as a homework task in advance of the second meeting. The refined draft intervention was discussed at the second group meeting to identify further areas in need of development. The remaining meeting was used to further refine the content. The intervention was also sent to facilitators prior to the training. During the training event, facilitators also contributed to intervention refinement.

Inputs	Target population	Theories and assumptions	Activities	Outputs		
Using these *resources* . . .	To *reach* . . .	To *guide* the intervention . . .	we will accomplish this . . .	and produce these *products*	Which will produce these *short-term outcomes* . . .	with these *long-term outcomes* . . .
Research/knowledge • Reducing BBV risk behaviours/what works • What influences PWID injecting/sexual risk behaviours • What PWID said want/need from an intervention Policies • Harm reduction • Recovery Partnerships • Clinical research networks Funding • NIHR HTA programme • NHS support and treatment costs • In kind support from third-sector organisations Staff • Academic • Drug treatment service staff • Peer educators (London)	Men and women who have injected drugs at least once in the past month and who are engaged with needle exchanges or harm reduction substance misuse treatment services	COM-B model of behaviour capability, opportunity and motivation interact to generate behaviour	Develop a group intervention and training manual Train staff/peer educators to deliver PROTECT group intervention Develop recruitment protocol for participants Gather outcome and process data	Training and intervention manuals	Increased understanding of BBV transmission risks Enhanced injecting skills and understanding of the implications of good vein care Reduction in risk behaviours • Sharing of needles and other injecting equipment • Unprotected sex Increased self-efficacy • Negotiating safer injecting and sexual behaviours • Finding a vein • Being prepared for risk situations Developed solutions/plan for ensuring safer injecting and sexual practices in risk situations	Reduced transmission of BBV

FIGURE 20 The logic model for PROTECT intervention. COM-B, 'capability', 'opportunity', 'motivation' and 'behaviour'.

Content of the intervention

The intervention was manualised, including instructions for facilitators and PowerPoint slides (Microsoft Corporation, Redmond, WA, USA) to accompany the manual. Handouts, as required, were prepared for participants. Manualised interventions are recommended as they promote consistent evidence-based practice, enhance treatment integrity and facilitate staff training.[227] This is important as 'the integrity and discriminability of the treatments delivered' are key components of internal validity of trials.[228] The final intervention content is outlined below.

Session 1: improving injecting technique and good vein care

Goals for session 1

- Introduce the PROTECT project and intervention.
- Build group cohesion.
- Establish group agreement.
- Engage participants.
- Increase knowledge about improving injecting techniques and good vein care.

Objectives

Participants will:

- understand what participating in the intervention requires
- feel a sense of group cohesion
- increase skills for injecting and achieving good vein care
- consider changing their risk behaviour.

Session 1 outline

- Introduction and welcome (10 minutes).
- Group agreement (10 minutes).
- Any questions about how to improve injecting techniques and good vein care? (10 minutes.)
- Skills building: how to improve injecting techniques (15 minutes).
- Skills building: how to achieve good vein care (15 minutes).
- Close.

Materials required

- PowerPoint presentation.
- Attendance register.
- Flipchart and pens.
- Participant folders.
- Name badges (ensure names written before sessions).
- Group agreement.
- Video: 'collapsed vein'.
- Video: 'how an abscess is formed'.
- Video: 'spot the difference'.
- Video: 'how to wash your hands'.
- Video: 'safer Heroin Injecting'.
- Video: 'how to clean a syringe'.
- Local needle exchange leaflet (localities and opening hours).

Handouts

- Timetable of sessions.
- Group agreement.
- Local needle exchange leaflet (localities and opening hours).

Session 2: planning for risky situations

Goals for session 2

- Identify situations where injection and sexual risk behaviours are more likely.
- Identify barriers to reducing injection and sexual risk behaviours.
- Identify solutions for reducing injection and sexual risk behaviours.
- Plan for avoiding situations where injection and sexual risk behaviours are more likely.
- Motivate participants to plan for risk situations.

Objectives

Participants will:

- increase their awareness of situations where injection and sexual risk behaviours may be more likely
- understand why, in certain situations, some people who inject may engage in injection and sexual risk behaviours
- be able to identify and provide solutions to injection and sexual risk behaviours
- use the TALK (Timing is everything; Assert what you want; List your reasons for being safe; Keep to your bottom line) model to negotiate safer injecting and sexual practices
- develop a 'be prepared' plan for risk situations.

Session 2 outline

- Welcome and feedback on session 1 (5 minutes).
- Why do people do risky things that can put them at risk of BBVs? (20 minutes.)
- Skills building: using TALK to negotiate safer sex and injection.
- Behaviours (15 minutes).
- Developing a 'be prepared' plan for risk situations (20 minutes).
- Review and close.

Materials required

- PowerPoint presentation.
- Attendance register.
- Flipchart and pens.
- Participant folders.
- Name badges.
- Group agreement.
- Potential risk scenario cards.
- TALK poster.
- Be prepared plan.

Handouts

- TALK poster.
- Be prepared plan.
- Example of preparedness plan.

Session 3: understanding blood-borne virus transmission

Goals for session 3

- Increase knowledge about BBVs and transmission injecting risk behaviours.

Objectives

Participants will:

- increase their knowledge about BBVs and transmission risk behaviours.

Session 3 outline

- Introduction and welcome (10 minutes).
- Myths and facts (game) about BBVs (20 minutes).
- Any questions about how BBVs are transmitted (10 minutes).
- Injecting risks: cross-contamination (video) (15 minutes).
- Close (certificate awards, 5 minutes).

Materials required

- PowerPoint presentation.
- Attendance register.
- Flipchart and pens.
- Participant folders.
- Name badges.
- Myths and facts cards.
- 'Dye demo' video.

Handouts

- Myths and facts cards.
- Certificates.

We are grateful to the following for their permission to use or adapt their resources for the PROTECT intervention:

- The Drug Users Intervention Trial (DUIT) for permission to reproduce and adapt some sessions from its intervention.[179]
- Exchange Supplies for permission to use extracts from its booklets/videos in this resource.[229]
- The Australian Injecting and Illicit Drug Users League for permission to use extracts from its website/videos in this resource.[230]
- The London Joint Working Group on Substance Use and Hepatitis C for permission to use content from its *Booklet 1. Hep C Info. Understanding Hepatitis C and Staying Safe*.[231] This booklet has been developed through a joint working initiative between Dr Magdalena Harris at the London School of Hygiene & Tropical Medicine and the London Joint Working Group on Substance Use and Hepatitis C. The booklet draws on the research of Dr Harris and is written by Danny Morris and Magdalena Harris.
- Merchants Quay Ireland Homeless & Drugs Services.[232]
- Drugs and Health Development Project.[233]
- The Self-Help in Eliminating Life-Threatening Diseases (SHIELD).[72]
- The Staying Safe Intervention.[47]

Training in the delivery of intervention

Group training that follows a detailed treatment manual is best practice to ensure that interventionists acquire skills and demonstrate competence in intervention delivery during the trial(s).[228] A 1-day group training was delivered in London in January 2016 face to face, facilitated by the chairperson of the Steering Group who is also a clinical director for addiction services and a service educator. The training was attended by facilitators from all four sites included in the feasibility study. Participants at the training event were given the PowerPoint slides, videos and intervention manual in advance of the training event to familiarise themselves with content and aims of the intervention.

The training event began with a presentation of the findings from the evidence of what works, risk situations reported by PWID and the intervention development process. Thereafter, the principles of the intervention delivery were presented and then each session of the intervention was delivered as if the facilitators were the group members to allow the group to understand the group in practice. Facilitators were encouraged to contribute to the final refinement of the model.

Patient and public involvement in the intervention development

Four service user representatives (two from London and two from Wales) and three peer educators (two from Glasgow and one from England) were involved in co-producing the intervention content. Their guidance around existing harm reduction materials was instrumental in developing the intervention and in the choice of the intervention leaflet used in the feasibility trial. The use of an additional 'bonus' CM payment for attending all three PROTECT intervention sessions was suggested by one service user representative. Finally, one peer educator co-delivered the intervention training and another attended the training. Facilitators found the discussion with peer educators to be extremely useful because of the knowledge they shared on injecting practices.

Chapter 6 Feasibility trial

Trial design

The PROTECT trial was a pragmatic, two-armed, randomised controlled, open feasibility trial, with equal randomisation delivered across four UK sites. PWID aged ≥ 18 years, attending NHS or third-sector community addiction, harm reduction clinics or needle exchange programmes, who consented to participate were randomised (1 : 1) to receive either:

- the intervention arm: a psychosocial group (brief) intervention developed during the early phases of the project work, involving three sessions facilitated by a drugs worker/peer mentor, an information leaflet on reducing the transmission of BBVs and TAU from the service from which they are recruited
- the control arm: an information leaflet on reducing the transmission of BBVs and TAU from the service from which they are recruited.

The study summary can be seen in *Appendix 5*.

Sample size

As a feasibility study, the main purpose was to assess the acceptability, feasibility and to obtain information that would inform the design of a larger full-scale trial. Therefore, no formal sample size calculation was conducted. However, we aimed to recruit 16 participants within each of the four locations and two service settings (needle exchange or community drug service, i.e. 128 patients in total). Half were to be allocated to the intervention arm and half to the control arm (64 patients per arm). This sample size exceeded that recommended for feasibility studies of between 24 and 50[234–236] and allowed feasibility assessments within both community clinics and needle exchanges. Based on previous studies, retention was estimated around 60–88% at the 1-month follow-up (77–113 participants).[188,197,237]

Approvals obtained

East Midlands – Leicester South Research Ethics Committee approved the study on 3 November 2015 (reference number 15/EM/0413).

Local research and development (R&D) approval was obtained, as well as agreement to participate from the relevant services. The project was approved by South London and the Maudsley NHS Trust R&D (reference number R&D2015/094) on 12 November 2015; by Greater Glasgow & Clyde Health Board R&D on 11 December 2015; and by Betsi Cadwaladr University Health Board R&D Internal Review Panel on 16 December 2015.

The trial was assigned the International Standard Randomised Controlled Trial Number (ISRCTN) 66453696.

Trial sites

The study was conducted in four location services in England (London and York), Wales (Wrexham) and Scotland (Glasgow) in the UK, to ensure that a mix of urban and semirural sites were included, as well as different modes of service delivery.

London

Participants were recruited from three drug and alcohol services (in two districts in the south of the city) that provided a tier 2 service, including advice and needle exchange, and tier 3 treatment to people aged over 18 years who have substance misuse (drug and/or alcohol)-related problems, including a prescribing clinic within a hostel for homeless people. The intervention was delivered in one community drug and alcohol service. Transport costs to attend the intervention were reimbursed.

York

Participants were recruited from a third-sector substance misuse organisation that provides tiers 1–3 addiction treatment. The service provides counselling and advice, as well as offering free needles, syringes, condoms and specialist advice, assessment and referral to residential rehabilitation, specialist NHS drug units and other agencies providing treatment for addiction and BBV infection testing. The intervention was scheduled to be delivered in a third-sector service in the city centre.

Glasgow

Participants were recruited from a drugs crisis centre in the city centre which provides both treatment and needle exchange services. The intervention was delivered in the drugs crisis centre.

Wrexham

Participants were recruited from a number of services including a NHS drug service, a drop-in centre and needle exchange for homeless people and a mobile harm reduction service that reaches PWID who are not currently engaged in treatment. The intervention was delivered at the drop-in centre and needle exchange for homeless people. Transport costs for intervention participants were reimbursed where requested.

Patient and public involvement in the feasibility trial

Four service user representatives (two from London and two from Wales) and three peer educators (two from Glasgow and one from England) helped develop the patient information leaflet and consent form, to ensure that appropriate language was used and the aims of the research were clear and jargon free. In addition, they developed the 'risk vignettes' used in the evaluation and also advised on the instruments suitable to measure outcomes of interest. In London, two peer educators co-facilitated the male and female PROTECT groups.

Recruitment

Participant eligibility

Inclusion criteria

People who inject drugs who were aged ≥ 18 years and attending participating NHS and third-sector community addiction and harm reduction clinics and needle exchange programmes (static and mobile) were considered potentially eligible if they met all of the following criteria:

- have injected drugs at least once in the past 4 weeks
- plan to stay in the area for the next 3 months
- able to complete the assessment (alone or with help of researcher)
- can communicate in a group intervention in English.

Exclusion criteria

People who inject drugs were excluded if they met any of the following criteria:

- were too intoxicated to give informed consent
- were in withdrawal
- had injected only performance-enhancing drugs in the past 4 weeks
- did not plan to be in the area for the next 3 months.

Recruitment into the trial

All clients in the waiting rooms of drug treatment and needle exchange services of participating sites were considered potential participants by researchers and were screened for eligibility (see *Appendix 6*). In addition, staff at the drug treatment and needle exchange services informed their clients about the study. If interested, staff asked for permission to share their contact details with the researcher who then contacted the potential participant to discuss the study with them in more detail.

Eligibility assessment

All potential participants were given a participant information sheet (PIS) (see *Appendix 7*) by the researcher (London, Glasgow and Wrexham) or Clinical Research Network (CRN) nurse (York and London). Those interested were screened for eligibility by the researcher/CRN nurse and given the opportunity to ask any questions about participating in the research. If interested and eligible, they were invited to participate. Potential participants were assured of confidentiality, but also informed regarding limitations to it (see *Consent procedure*). They were also informed of what to expect during the study and given contact details in case of complaint or need for further information. They were informed that participation was not compulsory and that they could withdraw at any time without affecting their care.

Consent procedure

The researcher or CRN nurse fully explained the study to those eligible and interested in participating, providing an opportunity for the PWID to ask questions. Those willing to participate signed a consent form including a statement on limitations to confidentiality (see *Appendix 7*). These limitations referred to a need to revoke confidentiality should they, at any time during the study, express current or future harm to themselves or others, in which case their key worker would be informed by the researcher or CRN nurse. Potential participants who were clearly intoxicated or under the influence of drugs were not considered as able to give consent.

In addition, consent was gained from participants for their contact details (mobile, house telephone, e-mail) and those of a close friend/relative to be recorded, as well as e-mail and Facebook accounts (Facebook Inc., Menlo Park, CA, USA) to enable the researcher to call to remind participants of their appointments and to arrange follow-up interviews. Participants were also asked to consent to researchers liaising with the service from which they were recruited, should it not have been possible to contact them through details provided. This method had been successfully used in the *Reducing hepatitis C sexual and drug taking risk behaviours among female drug users in Europe (REDUCE): translating evidence into practice* study[237] to improve engagement and retention in research studies. In cases where participants did not show up three or more times for their follow-up research appointment, telephone follow-up interviews were offered.

Baseline data were collected by the researcher or CRN nurse (see *Appendix 8*) after written informed consent was obtained.

Outcomes

Participants in both arms were interviewed using structured questionnaires (see *Appendix 8*), administered by researchers and/or CRN nurse at baseline and follow-up. Follow-up interviews were conducted at:

- the end of intervention delivery (or equivalent time period by those in the control arm); and
- 1 month post intervention (or equivalent time period by those in the control arm).

Trial completion

Participants were deemed to have completed the trial when:

- their final follow-up had been completed.

Participants were deemed to have fully withdrawn from the trial when:

- they wished to exit the trial fully
- their service withdrew them fully from the trial.

Instead of withdrawing fully from the trial, participants had the option of:

- withdrawing only from receiving trial treatment, but continuing to complete follow-up data collection.

Participants electing to withdraw from both the trial treatment and the follow-up data collection were deemed as full withdrawals.

Measurement and verification of primary measure

In conjunction with the qualitative aspect of the study, the feasibility of this current study and the potential for a future large-scale study were measured by the following.

Recruitment rates

The quantitative assessment of the acceptability of the research was measured by numbers eligible and those agreeing to participate.

Retention in treatment

Retention in treatment was evaluated by number of sessions attended as a measure of acceptability of the interventions to participants.

Follow-up completion rates

A quantitative assessment of the number of follow-up questionnaires completed.

Secondary outcome assessment

The following outcome measures were collected at baseline, the end of intervention and 1 month post intervention in the intervention arm, and equivalent time period by those in the control arm (see *Appendix 8*).

Injecting risk behaviour in past 30 days

The frequency with which participants had participated in specific injecting risk behaviours, that may have exposed them to BBVs in the previous month, were assessed using questions from the Health Protection Agency's survey of PWID.[2]

Participants indicated whether or not they had engaged in nine different risk practices in the past month relating to the use of sharing injection equipment. Events summed to a total ranging from 0 (engaged in no risk events) to 9 (engaged in all of the risk events).

Self-efficacy around injecting and sexual behaviours

Using questions from the Injection Drug Users – Research and Evaluation (INSPIRE) study,[190] self-efficacy about injecting skills and about avoiding risk behaviours were measured. For example, 'I can avoid sharing a needle even if I am in withdrawal'.

Self-efficacy about injecting drug use

Participants indicated agreement with eight self-efficacy questions around finding a vein, sharing equipment, cleaning equipment and talking about safe drug use. Agreement was rated between 1 (absolutely cannot) and 4 (absolutely can). Responses were added up to arrive at a total score between 8 (low self-efficacy) and 32 (high self-efficacy).[190]

Number of sexual risk behaviours

Sexual risk behaviours were defined by seven items. The first two items related to having had sex with more than one partner in the past month and not always having used a condom when having sex in the past month. The remaining five items were based on the agreement with five self-efficacy questions about being able to use a condom with regular or casual partners while intoxicated or not and being able to talk about safe sex. Responses were counted as a risk behaviour if participants were not 'absolutely sure' they would use a condom in a given situation or that they would be able to talk about safe sex. Events were added up to a total ranging from 0 (no risk behaviours) to 7 (all risk behaviours).

Withdrawal Prevention Tactics scale

This five-item scale asks whether or not participants had done any of four listed tactics to avoid withdrawal episodes in the last 6 months: saved a bag for the next morning; put aside additional drugs; stored methadone; or put aside money for getting the next bag in an emergency.[238] A fifth item asked about use of other substances, such as painkillers, to avoid withdrawal symptoms until they are able to obtain their drug of choice. Participants were asked how frequently they have undertaken each of the withdrawal activities in the past month, with responses ranging from 0 (never) to 4 (very often). A total score was calculated by adding up responses, resulting in a total score from 0 (never taken any of the preventative actions) to 20 (taken preventative actions very often for all of the activities).

Blood-borne virus transmission knowledge

Human immunodeficiency virus transmission knowledge

Participants judged 14 statements about HIV transmission from the 18-item HIV Knowledge Questionnaire as true, false or do not know.[239] The total number of correct answers (range 0–14) was calculated.

Hepatitis C virus transmission knowledge

Participants judged 33 statements about HCV transmission as true, false or do not know. These statements were a reduced version of the HCV Transmission Knowledge Questionnaire used in the *Reducing Hepatitis C Sexual and Drug Taking Risk Behaviours Among Female Drug Users in Europe (REDUCE): Translating Evidence into Practice* study,[237] adapted from Balfour *et al.*[240] and updated to include gender-specific questions and questions that incorporated recent advances in sexual and vertical transmission.[4] Two questions were considered ambiguous and responses did not count towards the total. The total number of correct answers (range 0–31) was calculated.

Hepatitis B virus transmission knowledge

Participants judged 15 statements about HBV across four domains (transmission, natural history, epidemiology and prevention, and clinical management), as true, false or do not know.[241] The total number of correct answers (range 0–15) was calculated.

Motivation to change behaviour

Participants were asked to rate their motivation from extremely motivated to not at all motivated to protect themselves and others from acquiring BBVs. Motivation scores for the two items ranged from 1 (not at all motivated) to 5 (extremely motivated).

Vignettes

Three scenarios were presented to participants regarding risky situations. They were then asked to describe what they would do if they found themselves in these situations. Responses were recorded verbatim.

Health-related quality of life

The EuroQol-5 Dimensions, five-level version (EQ-5D-5L) is a standardised measure of health status developed by the EuroQol group in order to provide a simple, generic measure of health for clinical and economic appraisal, where health is characterised on five dimensions (mobility, self-care, ability to undertake usual activities, pain, anxiety/depression).[242]

Health and social resource used

The feasibility of collecting details regarding hospital and primary health care service use, drug service use, other health-related services and contact with the police and criminal justice system was tested in this participant group. The service use questionnaire covered a retrospective 1-month period. Current medications were also collected.

In addition, the following demographic data were collected at baseline: age, gender, age when they first started injecting and type of service they had been recruited from.

Participants received £10 for their time involved in completing the baseline and each of the follow-up questionnaires. Those in the intervention arm received a further £10 if they participated in a focus group about their experience of participating in the trial and the group intervention. In all sites except London, participants received a high-street gift voucher for their time. In London, participants received payment in cash.

Focus groups with participants who attended the intervention and staff who delivered the intervention

Researchers moderating the focus groups used topic guides to lead the group through a discussion of the key issues, allowing and encouraging elaboration of views by participants as seemed appropriate (see *Appendix 9*).

Gender-specific intervention focus groups were conducted in each region where the intervention was delivered (London, Glasgow and Wrexham), with intervention group participants who had attended at least one intervention session (see *Appendix 10* for consent form and PIS). These examined barriers to participation and what worked/worked less well within the intervention including:

1. overall impressions: views regarding the intervention as a whole and each individual session, reasons for attendance/non-attendance at sessions, and thoughts on the trial randomisation process
2. intervention content: most/least useful aspects of the intervention, whether or not they had learned anything new, whether or not any intervention content had been shared with others (if so, what and with whom), and any other information they would have liked provided
3. logistics: views regarding the location and timing of the intervention, ease of getting to the group sessions, whether or not anything would have made it more convenient, potential barriers to uptake of, and attendance at, the intervention, and suggestions to improve uptake and attendance
4. quality, safety and comfort: views regarding facilitators delivering the intervention, intervention materials used (videos, handouts), and whether or not they felt comfortable during the sessions and safe sharing their experiences within the group
5. gendered groups: views regarding single versus mixed gender groups
6. behaviour changes: whether or not there had been any changes in behaviour as a result of taking part in the intervention
7. final comments: whether or not they would recommend the intervention to others, including why/why not, and any final thoughts.

Focus groups were also conducted in each region with staff who had delivered or who intended to deliver the group intervention to determine the acceptability of delivering the intervention and to identify barriers to, and facilitators of, its uptake and delivery. Staff were provided with a PIS and asked to complete a

consent form (see *Appendix 11*). For the focus groups with intervention facilitators, the following topics were covered:

1. training event: overall views regarding usefulness, comments regarding format (venue, duration, delivery style), suggestions for improvement of training, what else facilitators did to prepare for intervention delivery
2. intervention materials: comments regarding intervention manual (content, clarity, flow, layout, ease of maintaining fidelity to manual), exercises/activities, videos, overheads and handouts
3. intervention delivery: time spent preparing for delivery of sessions, ease of incorporating intervention delivery into overall workload, which parts of intervention they felt most confident/comfortable delivering, which parts they found challenging to deliver, experience of staff/peer co-delivery in London, views regarding what worked well/less well about the intervention, suggestions for changes/additions to intervention, views regarding logistics of sessions (day/time, venue), whether or not they would use the intervention in its entirety in their own practice [if not, what elements would they use (why, with what clients)], other thoughts regarding how the intervention could be used or developed
4. facilitator learning: from intervention participants regarding injecting practices
5. participant engagement and attendance: views regarding participant engagement with intervention and suggestions to improve attendance.

The topic guide can be seen in *Appendix 12*.

Randomisation

People who inject drugs who fulfilled the eligibility criteria and who provided written consent to take part in the study were eligible for randomisation. In order to maintain allocation concealment, the generation of the randomisation sequence was undertaken by an independent statistician at the University of York, and treatment allocation was performed by a secure, remote, telephone randomisation service based at the University of York. Participants were randomised by block randomisation, ensuring balanced allocation within each location, drug service/setting (needle exchange or community drug service) and gender. The three strata and covert block size ensured that the allocation sequence remained concealed to recruiting staff. Periodic checks were made on the computerised randomisation system during the trial following standard operating procedures. Owing to the nature of the intervention, it was not possible to conceal treatment allocation from the participant or the professional delivering the intervention.

Trial interventions

Participants were randomised to receive either:

- psychosocial group intervention (information booklets plus TAU)
- the control arm (information booklets plus TAU only).

Intervention arm

Participants randomly allocated to the intervention arm were invited to attend three 1-hour sessions (ideally, one a week for 3 consecutive weeks). Session 1 covered improving injection skills and good vein care, session 2 covered planning for risk situations and session 3 aimed to increase participants' knowledge about BBVs and transmission risk behaviours. The content of the intervention was developed in an earlier phase of work (as detailed in *Chapter 5*). Each session was scheduled to last 1 hour and it had been anticipated that there would be up to eight people in the group. Separate groups were held for women and men. The delivery of the intervention varied across sites to reflect current service delivery in each area. In London the group was co-facilitated by a drugs worker and peer educator (gender of co-facilitators matched that of the gender of the group), in Glasgow groups were co-facilitated by one male group

worker and one female service co-ordinator, in Wrexham the groups were co-facilitated by one male and one female harm reduction worker and in York the groups were to be delivered by one male BBV nurse. Refreshments were provided at all sessions. The sessions used videos, games and exercise to facilitate discussion and build skills, and strategies to reduce and avoid risk. All sessions also included a didactic education session. Any questions that facilitators were unable to answer during the session were answered at the following session, to ensure that participants' needs were met.

In addition, at baseline assessment, all participants were provided with a booklet containing information on HCV and a one-page information sheet developed specifically for the trial about a recent HIV outbreak among PWID (see *Appendix 13*). The HCV booklet *Booklet 1. Hep C Info. Understanding Hepatitis C and Staying Safe*[231] was developed through a joint working initiative between Dr Magdalena Harris at the London School of Hygiene & Tropical Medicine and the London Joint Working Group on Substance Use and Hepatitis C. The booklet draws on the research of Dr Harris and was written by Danny Morris and Dr Harris.

Participants also received TAU from the service from which they were recruited.

Contingency management was used to try and retain participants in the psychosocial intervention. Contingency management, as recommended by the National Institute for Health and Care Excellence (NICE), offers incentives or rewards (usually vouchers or privileges such as take-home methadone doses) contingent on retention or positive engagement in treatment (e.g. drug-negative urine sample).[243] Participants allocated to the intervention arm received £10 for each of the three sessions attended. A 'bonus' £10 was given to those who attended all three sessions. Participants in London were rewarded in cash, in the other three sites payment was in the form of a high-street gift voucher.

Control arm

Participants randomly allocated to the control arm were given the same booklet containing information on HCV and the information about the HIV infection outbreak. They also received TAU from the service from which they were recruited.

Evaluation of each session

Intervention group participants anonymously self-completed evaluation forms immediately after each of the three sessions. Evaluation forms asked participants to indicate the extent to which they agreed or disagreed with a series of statements about the intervention materials and delivery, and the achievement of session goals (e.g. increased knowledge, self-efficacy or motivation). Participants indicated their agreement/disagreement with each statement on a five-point Likert scale from 1 (strongly disagree) to 5 (strongly agree). The higher the score, the more positively the session was rated. Participants were also asked to give an overall rating for the session ('in general how would you rate today's session') on a scale of 1 to 5, where 1 was poor and 5 was excellent. Finally, they were asked three open-ended questions: 'what did you like most about today's session?', 'what did you like least about today's session?' and 'how could today's session be improved?'.

Intervention facilitators also self-completed an evaluation form immediately after each of the three sessions. Similar to the participant evaluation forms, the facilitator evaluation forms asked facilitators to rate the extent to which they agreed or disagreed with a series of statements about the session materials and delivery, the achievement of session goals, how well prepared they felt to deliver the session and their ability to answer participants' questions. Responses were given on a five-point Likert scale from 1 (strongly disagree) to 5 (strongly agree). The higher the score, the more positively the session was rated. They were also asked to give an overall rating for the session ('in general how would you rate today's session') on a scale of 1 to 5, where 1 was poor and 5 was excellent. Finally, they were asked four open-ended questions: 'what do you think worked best in today's session?', 'what do you think worked less well in today's session?', 'how do you think today's session could be improved?' and 'any additional comments?'.

All sessions were observed by at least one researcher to assess the feasibility of the quality assurance methods proposed for the main trial, including acceptability to drug worker/nursing staff and service users. Following completion of this study, this information may also be used to inform refinement of the training manual and/or the intervention itself and is expected to suggest the level of supervision likely to be required. During each session, researchers completed a brief checklist to identify what aspects of the manual were implemented. Participants and staff were also asked to complete an evaluation after each session (see *Appendix 14*).

Adverse events

There were no anticipated risks arising directly as a result of the psychosocial intervention, but a mechanism for recording them was in place if any arose.

Statistical analysis

As a feasibility trial, this study was not powered to determine the effectiveness of the intervention, but used to estimate feasibility parameters for a future effectiveness trial. Therefore, outcomes were primarily summarised descriptively. All analyses were conducted using Stata version 13.1 (StataCorp LP, College Station, TX, USA).

Primary outcomes: feasibility parameters

Recruitment rates

The number of patients eligible and the number and proportion entering the study are presented with reasons for not entering the trial where known.

Baseline data

Baseline characteristics of all the participants are summarised descriptively by intervention arm using means, standard deviations (SDs), medians and minimum and maximum values for continuous measures, and number and percentage for categorical measures. These are summarised by location, gender and treatment arm. As compliance and retention became an issue during the trial, baseline characteristics are further compared between participants who did and did not attend at least one treatment session, and for participants who did and did not attend at least one follow-up session. On advice from the Data Monitoring and Ethics Committee (DMEC), statistical tests are performed comparing these groups in order to explore potential predictors of non-compliance and dropout. As numbers are small, non-parametric tests (Mann–Whitney *U*-test and Fisher's exact test) are used.

Follow-up completion rates

The flow of patients through the study is summarised by means of a Consolidated Standards of Reporting Trials (CONSORT) diagram.[244] The number and percentage of participants remaining in the study, attending sessions and follow-up at each time point are reported by allocated group, with reasons for discontinuation given where known.

Retention in treatment

The number of treatment sessions attended is presented by recruitment site and gender as a measure of retention in treatment.

Secondary outcomes: intervention effectiveness

Intervention effectiveness was explored for selected outcome measures (see *Outcome measures*). An overview of the time points at which trial data were collected is presented in *Table 16*. The original plan was to present descriptive statistics for all outcomes across all stratification factors. However, given the low

TABLE 16 Data collection schedule

Assessment	Time point		
	Baseline	End of intervention	1 month post intervention
Baseline characteristics			
Demographics/injecting history	✓		
Quantitative evaluation			
Injecting behaviours	✓	✓	✓
Sexual behaviours	✓	✓	✓
Self-efficacy	✓	✓	✓
HIV transmission knowledge	✓	✓	✓
HCV transmission knowledge	✓	✓	✓
HBV transmission knowledge	✓	✓	✓
Withdrawal prevention	✓	✓	✓
Motivation to change behaviour	✓	✓	✓
Qualitative evaluation			
Vignettes	✓	✓	✓
Economic evaluation			
EQ-5D	✓	✓	✓
Frequency of service use	✓	✓	✓

EQ-5D, EuroQol-5 Dimensions.

follow-up rates and small numbers for some strata, this was not deemed informative and average outcomes are presented in total and by gender only. Tables include summaries grouped by randomised allocation as well as grouped by attendance of intervention sessions.

Longitudinal regression analyses were conducted, predicting each outcome at the two follow-up points from the outcome at baseline and allocation by follow-up interaction, adjusting for gender and recruitment site. Estimated mean group differences from these analyses are presented by intention-to-treat (ITT) and per-protocol groups together with 80% and 95% CIs. As a feasibility trial, no *p*-values are presented.

Focus group analysis

An essential aim of this feasibility study was to establish the acceptability of the group psychosocial intervention to both the PWIDs and the services delivering the intervention.

Focus groups were digitally recorded and transcribed verbatim with participants' consent. Researchers checked the transcripts against the audio-recordings for accuracy and de-identified them. Service and personal names were removed and a letter/number used to denote each focus group participant (e.g. R1 = respondent 1).

Transcripts were analysed thematically. Qualitative software (NVivo 10) assisted with the management and coding of transcripts. Initially, one transcript from each set of focus groups (i.e. one participant focus group transcript and one facilitator focus group transcript) were independently coded by both Davina Swan and April Shaw to generate an initial coding framework for each set of focus groups and to ensure reliability of coding. Codes were derived deductively from the topic guide and inductively from focus group responses.

Differences in coding between Davina Swan and April Shaw were discussed and resolved through revisiting the relevant extracts. Then, Davina Shaw coded the remainder of the participant focus group transcripts and April Shaw coded the remainder of the facilitator focus group transcripts. New codes were added to the initial coding frameworks as additional transcripts were analysed. The developing analyses were discussed at Research and Steering Group meetings and codes revised and renamed appropriately as the analytic process continued.

Economic analysis methods

The economic component of the study assessed the feasibility of conducting an economic evaluation of an adequately powered trial.[245] The economic component evaluated whether or not data could be obtained and the extent to which questionnaires were completed with the required information, in order to inform the design and implementation of an economic evaluation of a full trial. The costs of providing the intervention were collected from local data sources to establish the incremental cost of the psychosocial intervention over and above TAU in each setting.

The study was not powered to perform a full economic evaluation at this stage, as the perspective adopted includes criminal justice costs, which are high-tariff, low-frequency events. In a feasibility trial such as this, the sample size is such that the distribution of these infrequent events between intervention and control would have a significant bearing on cost-effectiveness results, which would be misleading in a small sample: results that are likely to be more a result of chance than a demonstration of cost-effectiveness. Therefore, the health economic component of this feasibility study piloted the service use questionnaires in order to measure the use of health-care services, including primary and secondary care contacts. Data returned would enable the revision of these instruments to improve the collection of data through further development, with further information used to identify the major services and, hence, costs that are associated with this population.

The economic analysis for the PROTECT feasibility trial includes intervention costing, calculation of NHS and wider social costs per patient, EQ-5D-5L results and assessment of the pilot questionnaires in preparation for a full sufficiently powered RCT. We do not present a full cost-effectiveness analysis, as the feasibility trial is not powered to detect significant differences and conclusions, and cost-effectiveness ratios from a small feasibility trial are likely to be misleading and contain a wide degree of uncertainty as a result of the low-frequency, high-tariff items recorded in the wider health care and criminal justice system costs.

Results: statistical analysis

Trial progression

The flow of participants is shown in *Figure 21*. Of 176 eligible drug users, 99 individuals were randomised into the feasibility trial during January and February 2016. One person was erroneously randomised twice (therefore 100 randomisations); however, their second randomisation was subsequently withdrawn and the person remained in the trial according to their initial allocation. Of the 99 individuals randomised, 52 were allocated to the intervention arm and 47 were allocated to the control arm. A total of 20 participants attended at least one intervention session and just under half of participants were followed up until 1 month post intervention.

Participant randomisation was stratified by recruitment site (London, York, Glasgow or Wrexham), service type (needle exchange or community drug service) and gender (male or female). Balanced allocation across these factors was achieved (*Table 17*). Recruitment from needle exchanges was substantially lower than anticipated. Owing to the small number of these participants, result summaries will not be presented separately for these groups, as was originally planned. The focus of the results will be on the potential population differences between recruitment sites and any differences between male and female participants.

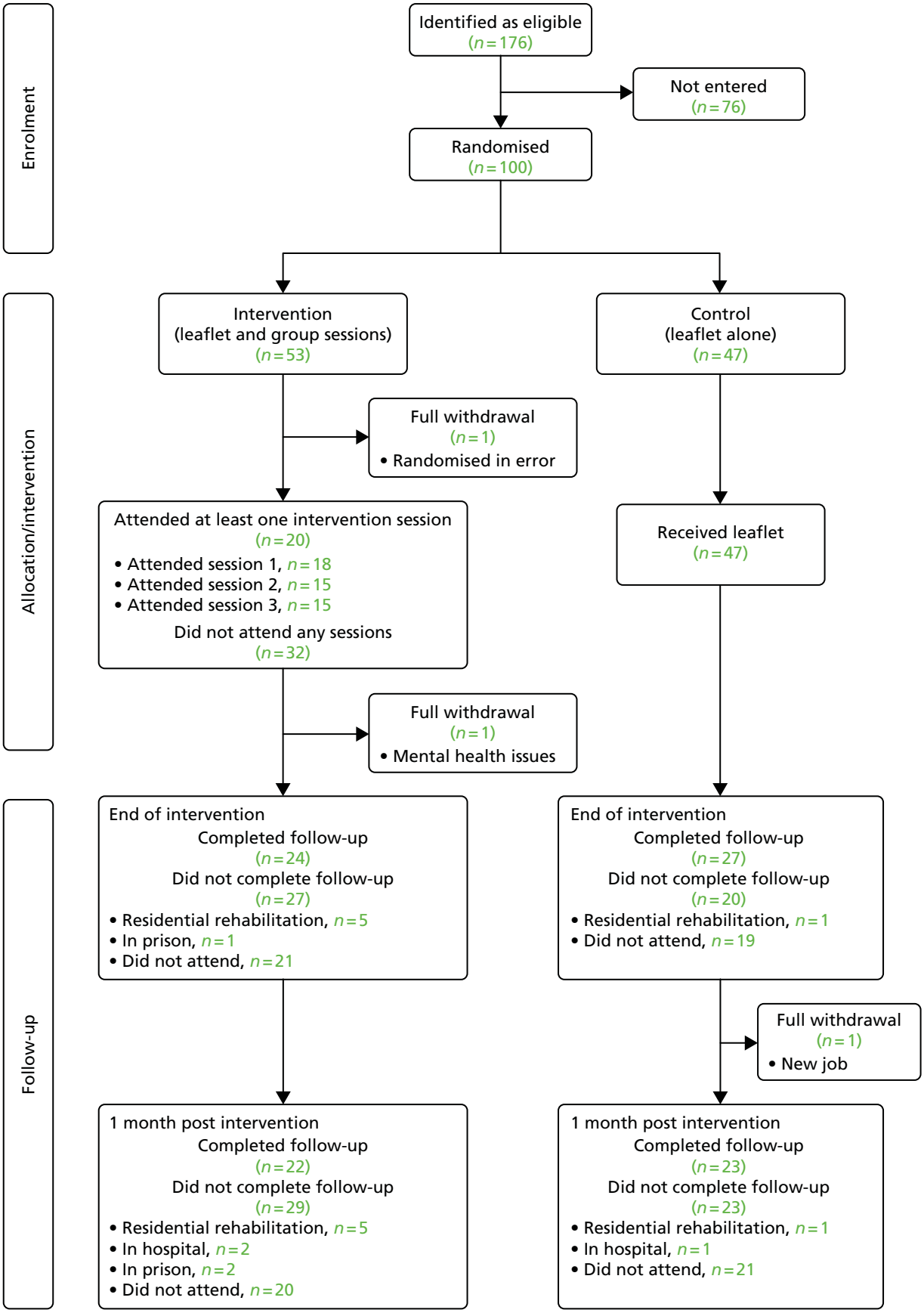

FIGURE 21 Study flow diagram.

TABLE 17 Randomisation by stratification factors

	Gender (*n*)					
	Male			Female		
	Trial arm			Trial arm		
Recruitment site	Intervention	Control	Total	Intervention	Control	Total
London	9 (CD, 8; NE, 1)	8 (CD, 8; NE, 0)	17	7 (CD, 6; NE, 1)	6 (CD, 6; NE, 0)	13
York	9 (CD, 9; NE, 0)	7 (CD, 7; NE, 0)	16	3 (CD, 3; NE, 0)	3 (CD, 3; NE, 0)	6
Glasgow	9 (CD, 6; NE, 3)	7 (CD, 5; NE, 2)	16	4 (CD, 3, NE, 1)	4 (CD, 3; NE, 1)	8
Wrexham	7 (CD, 3; NE, 4)	8 (CD, 6; NE, 2)	15	4 (CD, 4, NE, 0)	4 (CD, 3; NE, 1)	8
Total	34	30	64	18	17	35

CD, community drug service; NE, needle exchange.

Feasibility parameters

Feasibility was assessed as the proportion of patients consented and randomised, as well as compliance with the intervention and attrition throughout follow-up. Recruitment was relatively straightforward in most settings, with an expected number of presenting drug users being eligible for inclusion in the trial. Many service users were not eligible as they did not currently inject drugs. In general, women were harder to recruit, as fewer than anticipated attended the target services and not as many of those who did were injecting drugs. The rate of recruitment was 57% (99 participants of 175 eligible, excluding the participant who was randomised twice in error). Reasons for otherwise eligible drug users not being entered into the trial ($n = 76$) included that they were not interested ($n = 17$), too busy to discuss study/participate ($n = 18$), not able to (re)contact ($n = 14$), did not attend appointment ($n = 14$), intervention dates were not suitable ($n = 4$), they entered rehabilitation treatment ($n = 3$), they were worried regarding confidentiality of injecting status ($n = 2$), English was not their first language ($n = 2$), they were too ill ($n = 1$) or were with others on day of recruitment ($n = 1$).

Compliance and attrition by recruitment site are summarised in *Table 18*. Attendance for at least one intervention session was highest in London (63%) and Wrexham (54%), whereas only 25% attended in Glasgow and no participants attended in York. Follow-up at a minimum of one time point (at the end of the intervention or 1 month post intervention) was also highest in London (83%) and Wrexham (63%), and significantly lower in Glasgow (55%) and York (43%).

TABLE 18 Compliance and attrition by recruitment site

	Location in the UK, *n* (%)			
Compliance and attrition	London	York	Glasgow	Wrexham
Compliance (intervention arm only)	$n = 16$	$n = 11$	$n = 12$	$n = 13$
Attended at least one session	10 (63)	0 (0)	3 (25)	7 (54)
Attended no sessions	6 (38)	11 (100)	9 (75)	6 (46)
Attrition (both arms)	$n = 30$	$n = 23$	$n = 22$	$n = 24$
Attended at least one follow-up	25 (83)	10 (43)	12 (55)	15 (63)
Attended no follow-up	5 (17)	13 (57)	10 (45)	9 (38)

Compliance and attrition were further broken down by gender (*Tables 19–21*). Overall, men were more likely to attend at least one intervention session. Women were more likely to attend follow-up in London and York, but not in Glasgow and Wrexham. The possible reasons behind these gender differences were not clear. Possible associations of compliance and attrition rates with other characteristics of each population were explored as part of the next section (see *Baseline characteristics*).

TABLE 19 Compliance by gender (intervention arm only)

Recruitment site	Randomised to intervention, *n*	Compliance, *n* (%)			
		Attended one session	Attended two sessions	Attended three sessions	Attended at least one session
Males					
London	9	2 (22.2)	1 (11.1)	4 (44.4)	7 (77.8)
York	7	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Glasgow	9	0 (0.0)	1 (11.1)	2 (22.2)	3 (33.3)
Wrexham	9	0 (0.0)	3 (33.3)	2 (22.2)	5 (55.6)
Total	34	2 (5.9)	5 (14.7)	8 (23.5)	15 (44.1)
Females					
London	7	0 (0.0)	1 (14.3)	2 (28.6)	3 (42.9)
York	4	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Glasgow	3	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Wrexham	4	0 (0.0)	2 (50.0)	0 (0.0)	2 (50.0)
Total	18	0 (0.0)	3 (16.7)	2 (11.1)	5 (27.8)

TABLE 20 Compliance by gender: attrition (intervention)

Recruitment site	Randomised to intervention, *n*	Compliance, *n* (%)		
		Attended the end of intervention follow-up	Attended the 1-month post-intervention follow-up	Attended at least one follow-up session
Males				
London	9	8 (88.9)	8 (88.9)	8 (88.9)
York	7	3 (42.9)	1 (14.3)	4 (57.1)
Glasgow	9	5 (55.6)	3 (33.3)	5 (55.6)
Wrexham	9	2 (22.2)	5 (55.6)	5 (55.6)
Total	34	18 (52.9)	17 (50.0)	22 (64.7)
Females				
London	7	4 (57.1)	4 (57.1)	5 (71.4)
York	4	0 (0.0)	0 (0.0)	0 (0.0)
Glasgow	3	1 (33.3)	0 (0.0)	1 (33.3)
Wrexham	4	1 (25.0)	1 (25.0)	1 (25.0)
Total	18	6 (33.3)	5 (27.8)	7 (38.9)

TABLE 21 Compliance by gender: attrition (control)

Recruitment site	Randomised to control, *n*	Compliance, *n* (%)		
		Attended the end of intervention follow-up	Attended the 1-month post-intervention follow-up	Attended at least one follow-up session
Males				
London	8	6 (75.0)	6 (75.0)	6 (75.0)
York	8	2 (25.0)	2 (25.0)	3 (37.5)
Glasgow	7	6 (85.7)	2 (28.6)	6 (85.7)
Wrexham	7	6 (85.7)	4 (57.1)	7 (100)
Total	30	20 (66.7)	14 (46.7)	22 (73.3)
Females				
London	6	6 (100)	5 (83.3)	6 (100)
York	4	1 (25.0)	2 (50.0)	3 (75.0)
Glasgow	3	0 (0.0)	0 (0.0)	0 (0.0)
Wrexham	4	0 (0.0)	2 (50.0)	2 (50.0)
Total	17	7 (41.2)	9 (52.9)	11 (64.7)

Baseline characteristics

Characteristics of the trial population at baseline by allocation and gender are presented in *Table 22*. Participants were predominantly males in their late thirties/early forties, with an average history of between 14 and 22 years of injecting. Baseline characteristics were comparable between randomised treatment groups for males, despite the relatively small number of participants. Potential imbalances were observed in the smaller group of women (e.g. with a greater number of heroin users and homeless women in the intervention arm).

Following marked differences in compliance and follow-up at the four trial recruitment sites, population characteristics were additionally compared between sites (*Table 23*), between those attending at least one intervention session and those attending none [total including statistical test for differences (*Table 24*) and by gender (*Table 25*)], and between those attending at least one follow-up session and those attending none [including statistical test for differences (*Table 26*)].

Compared with participants who did attend at least one intervention session ($n = 20$), participants who did not attend any sessions ($n = 32$) were more likely to be homeless (56% vs. 25%; $p = 0.044$), injected drugs for a greater number of days in the last month (median 25 vs. 6.5 days; $p = 0.019$) and used a greater number of needles from a needle exchange in the last month (median 31 vs. 20 needles; $p = 0.056$). They were more likely to be predominant heroin injectors (69% vs. 40%; $p = 0.055$ for type of drug) and less likely to inject crack (31% vs. 55%; $p = 0.146$) (see *Table 24*). These differences were true for males and females, apart from homelessness, which did not show differences for women, although numbers were small (see *Table 25*).

More participants attended at least one intervention session in London (63%) and Wrexham (54%) than in Glasgow (25%) and York (0%) (see *Table 18*). Glasgow and York, however, had higher levels of homelessness, and participants injected for a greater number of days and used more needles from a needle exchange (see *Table 23*). As per the influential characteristics identified above, these factors may have contributed towards lower attendance rates. Specific contributing factors to non-attendance in Glasgow were that two female participants and three male participants had entered residential rehabilitation, and one male participant was

TABLE 22 Baseline characteristics by allocation and gender

Baseline characteristic	Gender			
	Male		Female	
	Intervention (*N* = 34)	Control (*N* = 30)	Intervention (*N* = 18)	Control (*N* = 17)
Age (years)				
Mean (SD)	41.7 (6.81)	41.4 (7.30)	35.8 (6.06)	37.9 (8.79)
Median	42.5	42	35	37
Minimum, maximum	26, 57	22, 54	26, 48	26, 62
Number of years injecting				
Mean (SD)	21.4 (8.00)	19.5 (9.01)	11.9 (7.58)	16.1 (12.14)
Median	22	19	11.5	14
Minimum, maximum	3, 36	1, 42	0, 34	0, 44
Used needle exchange in the last month, *n* (%)	31 (91.2)	26 (86.7)	16 (88.9)	16 (94.1)
Detox/maintenance drug use, *n* (%)	26 (76.5)	26 (86.7)	17 (94.4)	16 (94.1)
Most frequently injected drug, *n* (%)				
Heroin	15 (44.1)	23 (76.7)	15 (83.3)	10 (58.8)
Crack	1 (2.9)	2 (6.7)	0 (0.0)	0 (0.0)
Cocaine	4 (11.8)	1 (3.3)	0 (0.0)	1 (5.9)
Heroin and crack	8 (23.5)	2 (6.7)	3 (16.7)	3 (17.6)
Heroin and cocaine	1 (2.9)	0 (0.0)	0 (0.0)	1 (5.9)
Heroin and amphetamine	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.9)
Speedball	1 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)
Amphetamine	3 (8.8)	2 (6.7)	0 (0.0)	1 (5.9)
Methadone, mephedrone	1 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)
Homeless, *n* (%)	15 (44.1)	14 (46.7)	8 (44.4)	5 (29.4)
HIV positive, *n* (%)	1 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)
HCV positive, *n* (%)	17 (50)	15 (50)	5 (27.8)	6 (35.3)
HBV vaccinated, *n* (%)	27 (79.4)	22 (73.3)	18 (100)	14 (82.4)

incarcerated. In addition, in York, text messages were sent to remind participants of intervention session times and dates from the service (reported preference of participants), whereas in other sites the researcher contacted participants by telephone to remind them of session dates and times 1 day in advance and also sent a reminder text the day of the intervention. Thus, talking with the researcher and the additional reminder may have resulted in increased attendance at the other sites. Moreover, as a result of the dedicated researcher leaving their position at the University of York, four staff from the CRN York Teaching Hospitals NHS Trust were responsible for recruitment and follow-up of participants, whereas in other sites participants had contact with the same named researcher throughout the trial, and this established relationship could also have contributed to increased attendance. Additional potential contributing factors for the differences in compliance and attendance across trial sites include reimbursement of travel (bus ticket or receipt for bus travel), reimbursement of time and CM paid in cash (vs. high-street vouchers in other sites) and co-facilitation of the intervention by peer educators (in the London site only).

TABLE 23 Participant characteristics by recruitment site

Participant characteristic	Location in the UK			
	London (*N* = 30)	York (*N* = 23)	Glasgow (*N* = 22)	Wrexham (*N* = 24)
Gender, *n* (%)				
Male	17 (57)	15 (65)	15 (68)	16 (67)
Female	13 (43)	8 (35)	6 (27)	8 (33)
Transgender	0 (0)	0 (0)	1 (5)	0 (0)
Age (years)				
Mean (SD)	42.8 (7.53)	37.6 (6.13)	38.3 (6.85)	39.8 (8.33)
Median	42	37	40	42
Minimum, maximum	29, 62	27, 50	26, 50	22, 56
Number of years since first injected				
Mean (SD)	20.6 (11.27)	15.9 (9.05)	17.6 (8.97)	17.9 (8.10)
Median	22	17	16	18.5
Minimum, maximum	0, 40	0, 32	4, 35	1, 32
Homeless, *n* (%)	8 (27)	12 (52)	15 (68)	7 (29)
Number of days injected drugs in last month				
Mean (SD)	18.1 (9.87)	19.0 (10.28)	22.1 (9.48)	10.3 (8.83)
Median	20	26	28	8
Minimum, maximum	2, 28	2, 28	1, 28	1, 28
Most frequently injected drug, *n* (%)				
Heroin	15 (50)	16 (70)	16 (73)	16 (67)
Crack	2 (7)	0 (0)	0 (0)	1 (4)
Cocaine	0 (0)	0 (0)	6 (27)	0 (0)
Heroin and crack	11 (37)	3 (13)	0 (0)	2 (8)
Heroin and cocaine	2 (7)	0 (0)	0 (0)	0 (0)
Heroin and amphetamine	0 (0)	0 (0)	0 (0)	1 (4)
Speedball	0 (0)	1 (4)	0 (0)	0 (0)
Amphetamine	0 (0)	3 (13)	0 (0)	3 (13)
Methadone, mephedrone	0 (0)	0 (0)	0 (0)	1 (4)
Any drugs injected in the last month, *n* (%)				
Heroin	30 (100)	22 (96)	20 (91)	20 (83)
Crack	18 (60)	12 (52)	2 (9)	10 (42)
Amphetamine (speed)	0 (0)	7 (30)	1 (5)	7 (29)
Ketamine	1 (3)	0 (0)	0 (0)	1 (4)

continued

TABLE 23 Participant characteristics by recruitment site (*continued*)

Participant characteristic	Location in the UK			
	London (*N* = 30)	York (*N* = 23)	Glasgow (*N* = 22)	Wrexham (*N* = 24)
Methadone	0 (0)	0 (0)	0 (0)	0 (0)
Cocaine	2 (7)	2 (9)	12 (55)	3 (13)
Mephedrone	0 (0)	0 (0)	0 (0)	1 (4)
Methamphetamine	1 (3)	0 (0)	1 (5)	0 (0)
Other	3 (10)	1 (4)	1 (5)	0 (0)
Injected heroin and cocaine in last month (speedball), *n* (%)	15 (50)	11 (48)	5 (23)	9 (38)
Any drugs used in the last month, *n* (%)				
Cocaine	15 (50)	5 (22)	13 (59)	9 (38)
Amphetamine	1 (3)	7 (30)	1 (5)	10 (42)
Crack	29 (97)	14 (61)	12 (55)	19 (79)
Heroin	29 (97)	22 (96)	21 (95)	19 (79)
Mephedrone	2 (7)	0 (0)	3 (14)	5 (21)
Methamphetamine	1 (3)	1 (4)	2 (9)	0 (0)
Ecstasy/E	2 (7)	0 (0)	4 (18)	1 (4)
Cannabis	23 (77)	12 (52)	18 (82)	8 (33)
Solvents or glue	0 (0)	0 (0)	0 (0)	0 (0)
Ketamine	2 (7)	0 (0)	0 (0)	0 (0)
Benzodiazepines	12 (40)	10 (43)	20 (91)	17 (71)
Other drugs	5 (17)	6 (26)	5 (23)	3 (13)
Used needle exchange in the last month	28 (93)	21 (91)	22 (100)	18 (75)
Number of individual needles				
Mean (SD)	51.3 (50.43)	49.7 (48.73)	96.1 (176.05)	41.7 (50.11)
Median	34	40	48	28
Minimum, maximum	0, 220	8, 210	1, 840	0, 200
Current detox/maintenance drug use, *n* (%)	29 (97)	22 (96)	19 (86)	15 (63)
Length of time on current script, *n* (%)				
< 1 month	2 (7)	3 (13)	0 (0)	2 (8)
1–6 months	2 (7)	7 (30)	5 (23)	2 (8)
> 6 months	25 (83)	12 (52)	14 (64)	12 (50)
HIV positive, *n* (%)	0 (0)	0 (0)	1 (5)	0 (0)
HCV positive, *n* (%)	12 (40)	10 (43)	16 (73)	5 (21)

TABLE 24 Participant characteristics by compliance (total)

Participant characteristic	Compliance		*p*-value for difference[a]
	Attended at least one intervention session (*N* = 20)	Attended no intervention sessions (*N* = 32)	
Gender, *n* (%)			0.370
Male	15 (75)	19 (59)	
Female	5 (25)	13 (41)	
Transgender	0 (0)	0 (0)	
Age (years)			0.243
Mean (SD)	41.5 (7.29)	38.5 (6.85)	
Median	41.5	39	
Minimum, maximum	29, 57	26, 50	
Number of years since first injected			0.200
Mean (SD)	20.1 (8.12)	16.9 (9.45)	
Median	22	18.5	
Minimum, maximum	8, 36	0, 34	
Homeless, *n* (%)	5 (25)	18 (56)	0.044
Number of days injected drugs in last month			0.019
Mean (SD)	13.0 (11.00)	19.3 (9.49)	
Median	6.5	25	
Minimum, maximum	1, 28	3, 28	
Most frequently injected drug, *n* (%)			0.055
Heroin	8 (40)	22 (69)	
Crack	1 (5)	0 (0)	
Cocaine	2 (10)	2 (6)	
Heroin and crack	8 (40)	3 (9)	
Heroin and cocaine	0 (0)	1 (3)	
Speedball	0 (0)	1 (3)	
Amphetamine	1 (5)	2 (6)	
Methadone, mephedrone	0 (0)	1 (3)	
Any drugs injected in the last month, *n* (%)			
Heroin	18 (90)	30 (94)	0.634
Crack	11 (55)	10 (31)	0.146
Amphetamine (speed)	1 (5)	3 (9)	1
Ketamine	1 (5)	0 (0)	0.385
Methadone	0 (0)	0 (0)	
Cocaine	4 (20)	8 (25)	0.747

continued

TABLE 24 Participant characteristics by compliance (total) (*continued*)

Participant characteristic	Compliance		*p*-value for difference[a]
	Attended at least one intervention session (*N* = 20)	Attended no intervention sessions (*N* = 32)	
Mephedrone	0 (0)	1 (3)	1
Methamphetamine	0 (0)	0 (0)	
Other	1 (5)	1 (3)	1
Injected heroin and cocaine in last month (speedball), *n* (%)	9 (45)	12 (38)	0.772
Any drugs used in the last month, *n* (%)			
Cocaine	11 (55)	12 (38)	0.260
Amphetamine	2 (10)	4 (13)	1
Crack	16 (80)	23 (72)	0.743
Heroin	16 (80)	31 (97)	0.291
Mephedrone	1 (5)	2 (6)	1
Methamphetamine	0 (0)	0 (0)	
Ecstasy/E	2 (10)	2 (6)	0.623
Cannabis	13 (65)	17 (53)	0.237
Solvents or glue	0 (0)	0 (0)	
Ketamine	0 (0)	0 (0)	
Benzodiazepines	11 (55)	18 (56)	1
Other drugs	1 (5)	7 (22)	0.224
Used needle exchange in the last month	17 (85%)	30 (94)	0.361
Number of individual needles			0.056
Mean (SD)	31.3 (30.60)	61.5 (70.86)	
Median	20	31	
Minimum, maximum	10, 100	8, 280	
Current detox/maintenance drug use, *n* (%)	16 (80)	27 (84)	1
Length of time on current script, *n* (%)			0.374
< 1 month	1 (5)	1 (3)	
1–6 months	2 (10)	8 (25)	
> 6 months	14 (70)	18 (56)	
HIV positive, *n* (%)	1 (5)	0 (0)	1
HCV positive, *n* (%)	7 (35)	15 (47)	0.395

a Mann–Whitney *U*-test or Fisher's exact test as appropriate.

TABLE 25 Participant characteristics by compliance (by gender)

	Compliance			
	Attended at least one intervention session		Attended no intervention sessions	
Participant characteristic	Male ($N = 15$)	Female ($N = 5$)	Male ($N = 19$)	Female ($N = 13$)
Age (years)				
Mean (SD)	44.0 (6.45)	33.8 (3.03)	39.9 (6.69)	36.5 (6.84)
Median	44	35	41	35
Minimum, maximum	33, 57	29, 37	26, 50	26, 48
Number of years since first injected				
Mean (SD)	23.3 (6.66)	10.6 (2.70)	20.0 (8.82)	12.4 (8.84)
Median	23	9	21	12
Minimum, maximum	9, 36	8, 14	3, 32	0, 34
Homeless, *n* (%)	3 (20)	2 (40)	12 (63)	6 (46)
Number of days injected drugs in last month				
Mean (SD)	13.0 (10.42)	12.8 (13.95)	19.1 (9.56)	19.7 (9.76)
Median	8	5	25	28
Minimum, maximum	2, 28	1, 28	3, 28	4, 28
Most frequently injected drug, *n* (%)				
Heroin	5 (33)	3 (60)	10 (53)	12 (92)
Crack	1 (7)	0 (0)	0 (0)	0 (0)
Cocaine	2 (13)	0 (0)	2 (11)	0 (0)
Heroin and crack	6 (40)	2 (40)	2 (11)	1 (8)
Heroin and cocaine	0 (0)	0 (0)	1 (5)	0 (0)
Speedball	0 (0)	0 (0)	1 (5)	0 (0)
Amphetamine	1 (7)	0 (0)	2 (11)	0 (0)
Methadone, mephedrone	0 (0)	0 (0)	1 (5)	0 (0)
Any drugs injected in the last month, *n* (%)				
Heroin	13 (87)	5 (100)	17 (89)	13 (100)
Crack	9 (60)	2 (40)	7 (37)	3 (23)
Amphetamine (speed)	1 (7)	0 (0)	3 (16)	0 (0)
Ketamine	1 (7)	0 (0)	0 (0)	0 (0)
Methadone	0 (0)	0 (0)	0 (0)	0 (0)
Cocaine	4 (27)	0 (0)	6 (32)	2 (15)
Mephedrone	0 (0)	0 (0)	1 (5)	0 (0)
Methamphetamine	0 (0)	0 (0)	0 (0)	0 (0)
Other	0 (0)	1 (20)	1 (5)	0 (0)
Injected heroin and cocaine in last month (speedball)	7 (47)	2 (40)	8 (42)	4 (31)

continued

TABLE 25 Participant characteristics by compliance (by gender) (*continued*)

Participant characteristic	Compliance			
	Attended at least one intervention session		Attended no intervention sessions	
	Male ($N = 15$)	Female ($N = 5$)	Male ($N = 19$)	Female ($N = 13$)
Any drugs used in the last month, *n* (%)				
Cocaine	8 (53)	3 (60)	8 (42)	4 (31)
Amphetamine	2 (13)	0 (0)	4 (21)	0 (0)
Crack	11 (73)	5 (100)	13 (68)	10 (77)
Heroin	12 (80)	4 (80)	18 (95)	13 (100)
Mephedrone	1 (7)	0 (0)	2 (11)	0 (0)
Methamphetamine	0 (0)	0 (0)	0 (0)	0 (0)
Ecstasy/E	2 (13)	0 (0)	2 (11)	0 (0)
Cannabis	10 (67)	3 (60)	11 (58)	6 (46)
Solvents or glue	0 (0)	0 (0)	0 (0)	0 (0)
Ketamine	0 (0)	0 (0)	0 (0)	0 (0)
Benzodiazepines	8 (53)	3 (60)	9 (47)	9 (69)
Other drugs	0 (0)	1 (20)	5 (26)	2 (15)
Used needle exchange in the last month, *n* (%)	14 (93)	3 (60)	17 (89)	13 (100)
Number of individual needles				
Mean (SD)	30.0 (31.00)	36.0 (33.15)	62.9 (73.67)	59.6 (69.95)
Median	20	32	30	40
Minimum, maximum	0, 100	0, 80	8, 220	20, 280
Current detox/maintenance drug use, *n* (%)	11 (73)	5 (100)	15 (79)	12 (92)
Length of time on current script, *n* (%)				
< 1 month	0 (0)	1 (20)	0 (0)	1 (8)
1–6 months	0 (0)	2 (40)	3 (16)	5 (38)
> 6 months	12 (80)	2 (40)	12 (63)	6 (46)
HIV positive, *n* (%)	1 (7)	0 (0)	0 (0)	0 (0)
HCV positive, *n* (%)	6 (40)	1 (20)	11 (58)	4 (31)

Follow-up attendance (one or both times) was associated with fewer days of injecting drugs in the last month (median 14 vs. 27 days; $p = 0.030$) and fewer injections of cocaine (13% vs. 30%; $p = 0.063$), but none of the other characteristics identified for compliance above to a substantial extent (see *Table 26*). More participants were followed up in London (83%) and Wrexham (63%) than in Glasgow (55%) and York (43%) (see *Table 26*), which may in part be linked to factors associated with higher injecting frequencies in Glasgow and York. In addition, at the 1-month follow-up, two female participants in London were in hospital; one male participant was in prison in Wrexham; and in Glasgow, three female and three male participants were in residential rehabilitation, one male participant was in prison and one male participant was in hospital. As these participants were not contactable, it was not possible to conduct follow-up interviews.

TABLE 26 Participant characteristics by follow-up attendance (total)

Participant characteristic	Compliance		*p*-value for difference[a]
	Attended at least one follow-up (*N* = 62)	Attended no follow-up (*N* = 37)	
Gender, *n* (%)			0.153
Male	43 (69)	20 (54)	
Female	18 (29)	17 (46)	
Transgender	1 (2)	0 (0)	
Age (years)			0.347
Mean (SD)	40.5 (8.25)	38.8 (5.92)	
Median	41	40	
Minimum, maximum	22, 62	28, 50	
Number of years since first injected			0.097
Mean (SD)	19.4 (9.63)	16.2 (9.27)	
Median	19.5	15	
Minimum, maximum	0, 44	0, 35	
Homeless, *n* (%)	25 (40)	17 (46)	0.675
Number of days injected drugs in last month			0.030
Mean (SD)	15.8 (10.63)	20.1 (9.50)	
Median	14	27	
Minimum, maximum	1, 28	2, 28	
Most frequently injected drug, *n* (%)			0.591
Heroin	37 (60)	26 (70)	
Crack	3 (5)	0 (0)	
Cocaine	3 (5)	3 (8)	
Heroin and crack	10 (16)	6 (16)	
Heroin and cocaine	2 (3)	0 (0)	
Heroin and amphetamine	1 (2)	0 (0)	
Speedball	1 (2)	0 (0)	
Amphetamine	5 (8)	1 (3)	
Methadone, mephedrone	0 (0)	1 (3)	
Any drugs injected in the last month, *n* (%)			
Heroin	56 (90)	36 (97)	0.252
Crack	26 (42)	16 (43)	1
Amphetamine (speed)	10 (16)	5 (14)	0.781
Ketamine	1 (2)	1 (3)	1
Methadone	0 (0)	0 (0)	
Cocaine	8 (13)	11 (30)	0.063
Mephedrone	0 (0)	1 (3)	0.374
Methamphetamine	1 (2)	1 (3)	1
Other	1 (2)	4 (11)	0.063

continued

TABLE 26 Participant characteristics by follow-up attendance (total) (*continued*)

Participant characteristic	Compliance		
	Attended at least one follow-up (*N* = 62)	Attended no follow-up (*N* = 37)	*p*-value for difference[a]
Injected heroin and cocaine in last month (speedball), *n* (%)	24 (39)	16 (43)	0.677
Any drugs used in the last month, *n* (%)			
Cocaine	25 (40)	17 (46)	0.675
Amphetamine	13 (21)	6 (16)	0.609
Crack	46 (74)	28 (76)	1
Heroin	55 (89)	36 (97)	0.081
Mephedrone	7 (11)	3 (8)	0.739
Methamphetamine	2 (3)	2 (5)	0.623
Ecstasy/E	6 (10)	1 (3)	0.256
Cannabis	42 (68)	19 (51)	0.195
Solvents or glue	0 (0)	0 (0)	
Ketamine	2 (3)	0 (0)	0.530
Benzodiazepines	40 (65)	19 (51)	0.289
Other drugs	13 (21)	6 (16)	0.600
Used needle exchange in the last month	53 (85)	36 (97)	0.147
Number of individual needles			0.413
Mean (SD)	46.9 (43.6)	79.9 (144.23)	
Median	32.5	30	
Minimum, maximum	0, 210	2, 840	
Current detox/maintenance drug use, *n* (%)	53 (85)	32 (86)	1
Length of time on current script, *n* (%)			0.695
< 1 month	4 (6)	3 (8)	
1–6 months	9 (15)	7 (19)	
> 6 months	41 (66)	22 (59)	
HIV positive, *n* (%)	0 (0)	1 (3)	0.352
HCV positive, *n* (%)	24 (39)	19 (51)	0.287

a Mann–Whitney *U*-test or Fisher's exact test as appropriate.

Outcome measures

Outcome measures that were collected from participants at baseline and at the end of the intervention and 1 month post intervention are summarised by randomised allocation in *Table 27* (total) and *Tables 28* and *29* (by gender).

Following advice from the DMEC, outcomes were further grouped by compliance [i.e. participants who attended at least one intervention session compared with those who attended none (*Table 30*)]. See *Outcome measures* for a full description of the derivation and interpretation of each outcome.

TABLE 27 Trial outcomes: total – groups as randomised

Trial outcome	Trial arm					
	Intervention			Control		
	Baseline ($n = 52$)	End of intervention ($n = 24$)	1 month post intervention ($n = 22$)	Baseline ($n = 47$)	End of intervention ($n = 27$)	1 month post intervention ($n = 23$)
Injecting risk practices[a]						
Mean (SD)	2.5 (2.44)	1.9 (2.16)	1.7 (2.82)	2.7 (2.93)	2.6 (2.69)	2.6 (3.20)
Median (minimum, maximum)	2 (0, 9)	1 (0, 9)	1 (0, 9)	1 (0, 9)	1 (0, 9)	1 (0, 9)
Sexual risk behaviours[b]						
Mean (SD)	3.8 (2.08)	4.3 (1.31)	4.4 (1.92)	3.8 (1.80)	3.7 (1.98)	3.1 (1.73)
Median (minimum, maximum)	5 (0, 7)	4.5 (2, 7)	5 (0, 7)	4 (0, 7)	4 (0, 6)	3 (0, 6)
Self-efficacy[c]						
Mean (SD)	24.1 (4.76)	24.8 (3.23)	25.3 (3.24)	23.9 (4.75)	23.7 (5.55)	25.0 (5.26)
Median (minimum, maximum)	25 (10, 31)	26 (17, 31)	25 (17, 32)	23 (16, 32)	23 (14, 32)	25 (11, 32)
HIV transmission knowledge[d]						
Mean (SD)	10.4 (2.53)	11.3 (1.92)	11.4 (1.59)	10.5 (2.23)	11.3 (1.98)	11.1 (2.19)
Median (minimum, maximum)	11 (4, 14)	11.5 (7, 14)	12 (7, 14)	11 (4, 14)	12 (6, 14)	12 (4, 14)
HCV transmission knowledge[e]						
Mean (SD)	23.8 (3.98)	24.9 (3.49)	24.2 (3.75)	24.8 (3.15)	25.1 (2.18)	24.3 (2.99)
Median (minimum, maximum)	24.5 (13, 30)	26 (14, 29)	24 (15, 29)	25 (20, 29)	25 (20, 29)	25 (14, 28)
HBV transmission knowledge[f]						
Mean (SD)	10.2 (3.01)	11.1 (2.10)	11.0 (2.42)	10.4 (2.45)	10.6 (2.40)	10.0 (2.70)
Median (minimum, maximum)	11 (0, 14)	11 (7, 14)	11 (7, 15)	11 (4, 14)	11 (6, 14)	11 (3, 14)
Withdrawal prevention[g]						
Mean (SD)	6.2 (4.05)	6.5 (4.19)	5.8 (3.94)	6.9 (4.32)	6.3 (4.42)	5.6 (3.45)
Median (minimum, maximum)	6 (0, 19)	6 (0, 17)	6 (0, 13)	7 (0, 17)	4 (0, 17)	5 (0, 15)
Motivation to change (for self)[h]						
Mean (SD)	4.5 (0.83)	4.5 (0.66)	4.6 (0.49)	4.4 (0.80)	4.7 (0.45)	4.6 (0.58)
Median (minimum, maximum)	5 (2, 5)	5 (3, 5)	5 (4, 5)	5 (2, 5)	5 (4, 5)	5 (3, 5)
Motivation to change (for others)[h]						
Mean (SD)	4.4 (0.82)	4.3 (0.70)	4.5 (0.51)	4.4 (0.85)	4.9 (0.36)	4.7 (0.54)
Median (minimum, maximum)	5 (2, 5)	4 (3, 5)	4.5 (4, 5)	5 (0, 5)	5 (4, 5)	5 (3, 5)

a Range: 0–9 (higher number = more risk events).
b Range: 0–7 (higher number = more risk behaviours).
c Range: 8–32 (higher score = greater self-efficacy).
d Range: 0–14 (higher score = better knowledge).
e Range: 0–31 (higher score = better knowledge).
f Range: 0–15 (higher score = better knowledge).
g Range: 0–20 (higher score = better prevention tactics).
h Range: 0–5 (higher score = more motivation).

TABLE 28 Trial outcomes: males – groups as randomised

Trial outcome	Trial group					
	Intervention			Control		
	Baseline ($n = 34$)	End of intervention ($n = 18$)	1 month post intervention ($n = 17$)	Baseline ($n = 30$)	End of intervention ($n = 20$)	1 month post intervention ($n = 14$)
Injecting risk practices[a]						
Mean (SD)	2.6 (2.56)	1.8 (1.60)	1.5 (2.23)	2.2 (2.49)	2.4 (2.94)	2.3 (3.02)
Median (minimum, maximum)	1.5 (0, 9)	1 (0, 5)	1 (0, 9)	1 (0, 8)	1 (0, 9)	0.5 (0, 9)
Sexual risk behaviours[b]						
Mean (SD)	4.2 (1.98)	4.4 (1.34)	4.7 (1.53)	3.8 (1.89)	3.6 (2.14)	3.1 (1.59)
Median (minimum, maximum)	5 (0, 7)	4.5 (2, 7)	5 (1, 7)	5 (0, 7)	4.5 (0, 6)	3 (0, 6)
Self-efficacy[c]						
Mean (SD)	24.5 (4.97)	25.4 (2.85)	25.2 (3.41)	24.3 (4.38)	24.0 (5.71)	25.9 (4.55)
Median (minimum, maximum)	25 (10, 31)	26 (21, 31)	25 (17, 32)	23.5 (16, 32)	23.5 (14, 32)	23.5 (20, 32)
HIV transmission knowledge[d]						
Mean (SD)	10.2 (2.44)	11.2 (1.95)	11.2 (1.74)	10.8 (2.50)	11.3 (2.13)	10.7 (2.49)
Median (minimum, maximum)	11 (4, 13)	11 (7, 14)	11 (7, 14)	11 (4, 14)	11.5 (6, 14)	11.5 (4, 13)
HCV transmission knowledge[e]						
Mean (SD)	23.3 (3.87)	24.9 (3.33)	23.6 (3.66)	24.8 (3.53)	25.0 (2.08)	24.6 (3.46)
Median (minimum, maximum)	24 (13, 29)	26 (14, 29)	24 (15, 29)	26 (14, 30)	25 (20, 29)	25 (14, 28)
HBV transmission knowledge[f]						
Mean (SD)	9.9 (3.13)	11.1 (2.25)	11.2 (2.41)	10.3 (2.38)	10.9 (2.25)	10.2 (2.29)
Median (minimum, maximum)	10 (0, 14)	11.5 (7, 14)	11 (7, 15)	11 (4, 14)	12 (6, 14)	10.5 (6, 14)
Withdrawal prevention[g]						
Mean (SD)	5.6 (4.40)	6.3 (4.61)	5.5 (4.42)	6.7 (4.20)	6.5 (4.78)	5.6 (4.09)
Median (minimum, maximum)	5.5 (0, 19)	6 (0, 17)	6 (0, 13)	7 (0, 14)	5.5 (0, 17)	5.5 (0, 15)
Motivation to change (for self)[h]						
Mean (SD)	4.3 (0.94)	4.6 (0.61)	4.6 (0.51)	4.5 (0.63)	4.7 (0.47)	4.6 (0.50)
Median (minimum, maximum)	5 (2, 5)	5 (3, 5)	5 (4, 5)	5 (3, 5)	5 (4, 5)	5 (4, 5)
Motivation to change (for others)[h]						
Mean (SD)	4.4 (0.81)	4.3 (0.69)	4.4 (0.51)	4.6 (0.50)	4.8 (0.41)	4.8 (0.43)
Median (minimum, maximum)	5 (2, 5)	4 (3, 5)	4 (4, 5)	5 (4, 5)	5 (4, 5)	5 (4, 5)

a Range: 0–9 (higher number = more risk events).
b Range: 0–7 (higher number = more risk behaviours).
c Range: 8–32 (higher score = greater self-efficacy).
d Range: 0–14 (higher score = better knowledge).
e Range: 0–31 (higher score = better knowledge).
f Range: 0–15 (higher score = better knowledge).
g Range: 0–20 (higher score = better prevention tactics).
h Range: 0–5 (higher score = more motivation).

TABLE 29 Trial outcomes: females – groups as randomised

Trial outcome	Trial group					
	Intervention			Control		
	Baseline ($n = 18$)	End of intervention ($n = 6$)	1 month post intervention ($n = 5$)	Baseline ($n = 17$)	End of intervention ($n = 7$)	1 month post intervention ($n = 9$)
Injecting risk practices[a]						
Mean (SD)	2.1 (2.17)	2.4 (3.71)	3.0 (5.20)	3.5 (3.48)	3.0 (1.90)	3.0 (3.63)
Median (minimum, maximum)	2 (0, 9)	1 (0, 9)	0 (0, 9)	1 (0, 9)	3 (1, 6)	1 (0, 9)
Sexual risk behaviours[b]						
Mean (SD)	3.2 (2.15)	4.0 (1.26)	3.4 (2.88)	3.9 (1.68)	4.0 (1.53)	3.1 (2.03)
Median (minimum, maximum)	3 (0, 6)	4.5 (2, 5)	4 (0, 7)	4 (0, 7)	4 (1, 6)	3 (0, 6)
Self-efficacy[c]						
Mean (SD)	23.4 (4.38)	22.8 (3.76)	25.6 (2.88)	23.2 (5.40)	22.9 (5.43)	23.7 (6.24)
Median (minimum, maximum)	24.5 (12, 29)	22 (17, 27)	25 (22, 30)	23 (16, 32)	22 (17, 32)	24 (11, 31)
HIV transmission knowledge[d]						
Mean (SD)	10.8 (2.73)	11.7 (1.97)	12.0 (0.71)	10.0 (1.62)	11.3 (1.60)	11.7 (1.58)
Median (minimum, maximum)	12 (5, 14)	12.5 (8, 13)	12 (11, 13)	10 (7, 12)	12 (9, 13)	12 (9, 14)
HCV transmission knowledge[e]						
Mean (SD)	24.8 (4.09)	24.8 (4.26)	26.4 (1.67)	24.8 (2.44)	25.6 (2.57)	23.9 (2.20)
Median (minimum, maximum)	26 (16, 30)	26.5 (19, 29)	26 (24, 28)	24 (21, 30)	25 (22, 29)	25 (21, 27)
HBV transmission knowledge[f]						
Mean (SD)	10.7 (2.78)	11.0 (1.79)	10.4 (2.61)	10.5 (2.62)	10.0 (2.89)	9.7 (3.35)
Median (minimum, maximum)	12 (3, 13)	11 (9, 13)	10 (8, 14)	11 (7, 14)	10 (6, 14)	11 (3, 13)
Withdrawal prevention[g]						
Mean (SD)	7.3 (3.12)	7.2 (2.79)	6.8 (1.48)	7.2 (4.65)	6.0 (3.46)	5.7 (2.35)
Median (minimum, maximum)	8 (1, 11)	6.5 (4, 11)	7 (5, 9)	6 (0, 17)	4 (4, 12)	5 (3, 10)
Motivation to change (for self)[h]						
Mean (SD)	4.8 (0.38)	4.2 (0.75)	4.8 (0.45)	4.2 (1.03)	4.9 (0.38)	4.6 (0.73)
Median (minimum, maximum)	5 (4, 5)	4 (3, 5)	5 (4, 5)	5 (2, 5)	5 (4, 5)	5 (3, 5)
Motivation to change (for others)[h]						
Mean (SD)	4.4 (0.85)	4.3 (0.82)	4.8 (0.45)	4.1 (1.22)	5.0 (0.00)	4.7 (0.71)
Median (minimum, maximum)	5 (2, 5)	4.5 (3, 5)	5 (4, 5)	4 (1, 5)	5 (5, 5)	5 (3, 5)

a Range: 0–9 (higher number = more risk events).
b Range: 0–7 (higher number = more risk behaviours).
c Range: 8–32 (higher score = greater self-efficacy).
d Range: 0–14 (higher score = better knowledge).
e Range: 0–31 (higher score = better knowledge).
f Range: 0–15 (higher score = better knowledge).
g Range: 0–20 (higher score = better prevention tactics).
h Range: 0–5 (higher score = more motivation).

TABLE 30 Trial outcomes: total – groups by compliance

Trial outcome	Compliance					
	Attended at least one intervention session			Attended none of the intervention sessions		
	Baseline ($n = 20$)	End of intervention ($n = 14$)	1 month post intervention ($n = 16$)	Baseline ($n = 79$)	End of intervention ($n = 37$)	1 month post intervention ($n = 29$)
Injecting risk practices[a]						
Mean (SD)	2.3 (2.45)	1.7 (2.40)	1.4 (2.40)	2.6 (2.73)	2.5 (2.46)	2.6 (3.28)
Median (minimum, maximum)	1 (0, 9)	1 (0, 9)	1 (0, 9)	1.5 (0, 9)	1 (0, 9)	1 (0, 9)
Sexual risk behaviours[b]						
Mean (SD)	4.1 (2.04)	4.3 (1.07)	3.9 (1.89)	3.8 (1.92)	3.9 (1.90)	3.7 (1.97)
Median (minimum, maximum)	5 (0, 7)	4 (3, 6)	4 (0, 7)	4 (0, 7)	4 (0, 7)	4 (0, 7)
Self-efficacy[c]						
Mean (SD)	23.3 (5.14)	25.1 (3.12)	25.9 (3.47)	24.2 (4.64)	23.9 (5.04)	24.7 (4.76)
Median (minimum, maximum)	24.5 (12, 31)	26.5 (21, 31)	25.5 (17, 32)	24 (10, 32)	24 (14, 32)	25 (11, 32)
HIV transmission knowledge[d]						
Mean (SD)	10.8 (2.22)	11.9 (1.23)	11.4 (1.59)	10.4 (2.43)	11.1 (2.11)	11.1 (2.08)
Median (minimum, maximum)	11 (7, 14)	12 (10, 14)	12 (7, 14)	11 (4, 14)	11 (6, 14)	12 (4, 14)
HCV transmission knowledge[e]						
Mean (SD)	23.5 (3.78)	26.1 (2.53)	24.1 (3.55)	24.5 (3.59)	24.6 (2.89)	24.4 (3.06)
Median (minimum, maximum)	24 (15, 29)	26.5 (20, 29)	24 (15, 29)	25 (13, 30)	25 (14, 29)	25 (14, 29)
HBV transmission knowledge[f]						
Mean (SD)	10.3 (2.45)	11.1 (2.48)	11.1 (2.72)	10.3 (2.83)	10.7 (2.19)	10.2 (2.51)
Median (minimum, maximum)	11 (5, 13)	11.5 (7, 14)	11.5 (7, 15)	11 (0, 14)	11 (6, 14)	11 (3, 14)
Withdrawal prevention[g]						
Mean (SD)	5.4 (3.36)	6.5 (4.26)	5.9 (4.13)	6.8 (4.32)	6.4 (4.34)	5.6 (3.45)
Median (minimum, maximum)	5 (0, 12)	6.5 (1, 17)	6 (0, 13)	7 (0, 19)	6 (0, 17)	6 (0, 15)
Motivation to change (for self)[h]						
Mean (SD)	4.4 (0.82)	4.5 (0.52)	4.6 (0.51)	4.4 (0.81)	4.7 (0.58)	4.7 (0.55)
Median (minimum, maximum)	5 (2, 5)	4.5 (4, 5)	5 (4, 5)	5 (2, 5)	5 (3, 5)	5 (3, 5)
Motivation to change (for others)[h]						
Mean (SD)	4.4 (0.59)	4.2 (0.70)	4.4 (0.51)	4.4 (0.88)	4.8 (0.49)	4.7 (0.53)
Median (minimum, maximum)	4 (3, 5)	4 (3, 5)	4 (4, 5)	5 (1, 5)	5 (3, 5)	5 (3, 5)

a Range: 0–9 (higher number = more risk events).
b Range: 0–7 (higher number = more risk behaviours).
c Range: 8–32 (higher score = greater self-efficacy).
d Range: 0–14 (higher score = better knowledge).
e Range: 0–31 (higher score = better knowledge).
f Range: 0–15 (higher score = better knowledge).
g Range: 0–20 (higher score = better prevention tactics).
h Range: 0–5 (higher score = more motivation).

In addition to the summary statistics, outcomes were analysed by longitudinal regression analysis, predicting each outcome from treatment arm and follow-up point (and their interaction), the outcome at baseline, gender and recruitment site. Estimated group differences and CIs from these analyses are presented in *Table 31*. Following advice from the DMEC, both ITT and per-protocol analyses (by attendance of at least one intervention session) were conducted with both 95% and 80% CIs.

The summary of group differences for each outcome (see *Table 31*) is based on longitudinal regression analyses, adjusting for gender, recruitment site and the outcome in question at baseline. See *Outcome measures* for a full description of each outcome. Analyses revealed improved (fewer) injecting risk practices, improved self-efficacy, better HCV and HBV transmission knowledge and greater use of withdrawal prevention techniques in the intervention arm. This was true at both follow-up time points and both analyses for randomised groups and groups based on attendance of the intervention. Little change for any group was seen for HIV transmission knowledge.

A number of results appeared counterintuitive. Participants in the randomised intervention group engaged in a greater number of sexual risk behaviours at both follow-up time points, although group differences were reduced to minimal in the attendance-based analysis. Motivation to change both to protect the participant themselves and to protect others was greater for control arm participants/participants who did not attend any interventions. This outcome was highly skewed, with most participants indicated being highly motivated. There is no explanation for this high motivation, and this could potentially be a result of these participants hoping to be randomly allocated to the intervention group.

Sample sizes were too small to investigate possible interactions with baseline characteristics and outcomes (e.g. whether or not score changes can only be seen in a subset of the participant population). A larger pilot might have revealed meaningful trends for such subgroups.

All outcome measures were reviewed with regard to the number of missing items that contribute to each outcome (*Table 32*). Overall, data completeness was very high across all questionnaire responses, and most items were only missing sporadically. Notable exceptions were items 4 and 6 of the sexual risk behaviours. Both of these are questions relating to a casual sexual partner rather than a regular one, which may not have been applicable to some participants, although the question does ask to answer the question hypothetically if not applicable.

Adverse outcomes and events

Table 33 highlights that at 1 month post intervention no increase in self-reported injecting in more 'risky' sites (e.g. groin, neck) was observed among participants who had attended at least one session of the intervention.

Table 34 presents a trend towards injecting on fewer days in the past 28 days for those who had attended at least one session at 1 month post intervention. Therefore, exposure to sessions on improving injecting techniques as part of a BBV harm reduction psychosocial intervention does not appear to encourage riskier injecting practices or frequency of injecting.

No adverse events were recorded as a result of participating in the feasibility trial.

Results: health economics

The PROTECT intervention costs included a training event, which involved staff time and materials. We do not include travel time and cost as these costs would not be borne if the intervention was rolled out in practice, as training would take place at local facilities. The first stage of costing is the estimation of training costs. These costs are included in the cost per-session calculations. However, in this study the costs are higher per session because we have allocated training costs on a per-session basis, assigning the costs

TABLE 31 Summary of mean group differences for outcome measures[a]

	Analysis by					
	Randomised groups (ITT)			Attendance of at least one intervention session		
Trial outcome	Mean	95% CI	80% CI	Mean	95% CI	80% CI
Injecting risk practices[b]						
End of intervention	–0.45	–1.50 to 0.61	–1.14 to 0.24	–0.52	–1.78 to 0.74	–1.35 to 0.30
1 month post intervention	–0.25	–1.33 to 0.82	–0.96 to 0.45	–0.25	–1.51 to 1.01	–1.08 to 0.57
Sexual risk behaviours[c]						
End of intervention	0.57	–0.20 to 1.34	0.06 to 1.07	0.08	–0.85 to 1.02	–0.53 to 0.70
1 month post intervention	1.26	0.43 to 2.08	0.71 to 1.80	0.13	–0.80 to 1.06	–0.48 to 0.74
Self-efficacy[d]						
End of intervention	1.17	–0.71 to 3.05	–0.06 to 2.40	2.20	0.02 to 4.38	0.77 to 3.62
1 month post intervention	0.08	–1.90 to 2.07	–1.22 to 1.38	1.65	–0.51 to 3.82	0.24 to 3.07
HIV transmission knowledge[e]						
End of intervention	–0.06	–0.88 to 0.75	–0.60 to 0.47	0.04	–0.91 to 0.99	–0.58 to 0.66
1 month post intervention	0.18	–0.70 to 1.06	–0.39 to 0.76	–0.07	–1.00 to 0.87	–0.68 to 0.55
HCV transmission knowledge[f]						
End of intervention	0.16	–1.37 to 1.68	–0.84 to 1.15	2.13	0.41 to 3.85	1.01 to 3.26
1 month post intervention	0.12	–1.52 to 1.75	–0.96 to 1.19	0.30	–1.40 to 1.99	–0.81 to 1.41
HBV transmission knowledge[g]						
End of intervention	0.79	–0.31 to 1.89	0.07 to 1.51	0.79	–0.51 to 2.08	–0.06 to 1.63
1 month post intervention	0.75	–0.41 to 1.91	–0.01 to 1.51	0.88	–0.41 to 2.18	0.03 to 1.73
Withdrawal prevention[h]						
End of intervention	0.28	–1.37 to 1.93	–0.80 to 1.36	0.38	–1.54 to 2.31	–0.88 to 1.64
1 month post intervention	1.41	–0.34 to 3.17	0.26 to 2.57	1.83	–0.10 to 3.76	0.57 to 3.09
Motivation to change (for self)[i]						
End of intervention	–0.20	–0.47 to 0.07	–0.38 to –0.03	–0.21	–0.52 to 0.09	–0.42 to –0.01
1 month post intervention	–0.01	–0.30 to 0.28	–0.20 to 0.18	–0.21	–0.51 to 0.10	–0.41 to –0.01
Motivation to change (for others)[i]						
End of intervention	–0.40	–0.67 to –0.13	–0.58 to –0.22	–0.53	–0.84 to –0.23	–0.73 to –0.33
1 month post intervention	–0.14	–0.43 to 0.15	–0.33 to 0.05	–0.29	–0.59 to 0.01	–0.49 to –0.10

a Mean differences represent the estimated mean group difference following regression analysis adjusted for outcome at baseline, gender and recruitment site. Positive mean difference = higher score in the intervention arm; negative mean difference = higher score in the control arm.
b Range: 0–9 (higher number = more risk events).
c Range: 0–7 (higher number = more risk behaviours).
d Range: 8–32 (higher score = greater self-efficacy).
e Range: 0–14 (higher score = better knowledge).
f Range: 0–31 (higher score = better knowledge).
g Range: 0–15 (higher score = better knowledge).
h Range: 0–20 (higher score = better prevention tactics).
i Range: 0–5 (higher score = more motivation).

TABLE 32 Missingness for outcome measures

Trial outcome	Time point, *n* (%)		
	Baseline (*N* = 99)	End of intervention (*N* = 51)	1 month post intervention (*N* = 45)
Injecting risk practices			
Item 1	0 (0.0)	0 (0.0)	1 (2.2)
Item 2	0 (0.0)	0 (0.0)	0 (0.0)
Item 3	1 (1.0)	0 (0.0)	0 (0.0)
Item 4	0 (0.0)	0 (0.0)	0 (0.0)
Item 5	0 (0.0)	0 (0.0)	0 (0.0)
Item 6	1 (1.0)	0 (0.0)	0 (0.0)
Item 7	0 (0.0)	0 (0.0)	0 (0.0)
Item 8	0 (0.0)	0 (0.0)	0 (0.0)
Item 9	0 (0.0)	0 (0.0)	0 (0.0)
Sexual risk behaviours			
Item 1	2 (2.0)	1 (2.0)	2 (4.4)
Item 2	0 (0.0)	1 (2.0)	2 (4.4)
Item 3	4 (4.0)	1 (2.0)	0 (0.0)
Item 4	11 (11.1)	4 (7.8)	0 (0.0)
Item 5	6 (6.1)	1 (2.0)	0 (0.0)
Item 6	11 (11.1)	3 (5.9)	0 (0.0)
Item 7	0 (0.0)	1 (2.0)	0 (0.0)
Self-efficacy			
Item 1	0 (0.0)	0 (0.0)	0 (0.0)
Item 2	0 (0.0)	0 (0.0)	0 (0.0)
Item 3	0 (0.0)	0 (0.0)	0 (0.0)
Item 4	1 (1.0)	0 (0.0)	0 (0.0)
Item 5	0 (0.0)	0 (0.0)	0 (0.0)
Item 6	4 (4.0)	1 (2.0)	1 (2.2)
Item 7	0 (0.0)	0 (0.0)	1 (2.2)
Item 8	0 (0.0)	0 (0.0)	0 (0.0)
HIV transmission knowledge			
Item 1	0 (0.0)	0 (0.0)	0 (0.0)
Item 2	0 (0.0)	0 (0.0)	0 (0.0)
Item 3	0 (0.0)	0 (0.0)	0 (0.0)
Item 4	0 (0.0)	0 (0.0)	0 (0.0)
Item 5	0 (0.0)	0 (0.0)	0 (0.0)
Item 6	0 (0.0)	0 (0.0)	0 (0.0)

continued

TABLE 32 Missingness for outcome measures (*continued*)

Trial outcome	Time point, *n* (%)		
	Baseline (*N* = 99)	End of intervention (*N* = 51)	1 month post intervention (*N* = 45)
Item 7	1 (1.0)	1 (2.0)	0 (0.0)
Item 8	0 (0.0)	0 (0.0)	0 (0.0)
Item 9	0 (0.0)	1 (2.0)	0 (0.0)
Item 10	0 (0.0)	1 (2.0)	0 (0.0)
Item 11	0 (0.0)	0 (0.0)	0 (0.0)
Item 12	0 (0.0)	0 (0.0)	0 (0.0)
Item 13	0 (0.0)	0 (0.0)	0 (0.0)
Item 14	0 (0.0)	0 (0.0)	0 (0.0)
HCV transmission knowledge			
Item 1	0 (0.0)	0 (0.0)	0 (0.0)
Item 2	0 (0.0)	0 (0.0)	0 (0.0)
Item 3	0 (0.0)	0 (0.0)	0 (0.0)
Item 4	0 (0.0)	0 (0.0)	0 (0.0)
Item 5	0 (0.0)	0 (0.0)	0 (0.0)
Item 6	0 (0.0)	0 (0.0)	0 (0.0)
Item 7	1 (1.0)	0 (0.0)	0 (0.0)
Item 8	0 (0.0)	0 (0.0)	0 (0.0)
Item 9	0 (0.0)	1 (2.0)	0 (0.0)
Item 10	0 (0.0)	0 (0.0)	0 (0.0)
Item 11	1 (1.0)	0 (0.0)	0 (0.0)
Item 12	0 (0.0)	0 (0.0)	0 (0.0)
Item 13	0 (0.0)	0 (0.0)	0 (0.0)
Item 14	0 (0.0)	0 (0.0)	0 (0.0)
Item 15[a]	0 (0.0)	0 (0.0)	0 (0.0)
Item 16	0 (0.0)	0 (0.0)	0 (0.0)
Item 17	0 (0.0)	1 (2.0)	0 (0.0)
Item 18	0 (0.0)	0 (0.0)	0 (0.0)
Item 19	0 (0.0)	0 (0.0)	0 (0.0)
Item 20	0 (0.0)	0 (0.0)	0 (0.0)
Item 21	0 (0.0)	0 (0.0)	0 (0.0)
Item 22	0 (0.0)	0 (0.0)	0 (0.0)
Item 23	0 (0.0)	1 (2.0)	0 (0.0)
Item 24	0 (0.0)	0 (0.0)	0 (0.0)
Item 25	0 (0.0)	0 (0.0)	0 (0.0)
Item 26	0 (0.0)	0 (0.0)	0 (0.0)

TABLE 32 Missingness for outcome measures (*continued*)

Trial outcome	Time point, *n* (%)		
	Baseline (*N* = 99)	End of intervention (*N* = 51)	1 month post intervention (*N* = 45)
Item 27	0 (0.0)	1 (2.0)	0 (0.0)
Item 28	0 (0.0)	0 (0.0)	0 (0.0)
Item 29[a]	0 (0.0)	0 (0.0)	0 (0.0)
Item 30	0 (0.0)	0 (0.0)	0 (0.0)
Item 31	0 (0.0)	0 (0.0)	0 (0.0)
Item 32	0 (0.0)	0 (0.0)	0 (0.0)
Item 33	0 (0.0)	0 (0.0)	0 (0.0)
HBV transmission knowledge			
Item 1	0 (0.0)	0 (0.0)	0 (0.0)
Item 2	0 (0.0)	0 (0.0)	0 (0.0)
Item 3	0 (0.0)	0 (0.0)	0 (0.0)
Item 4	0 (0.0)	0 (0.0)	0 (0.0)
Item 5	0 (0.0)	0 (0.0)	0 (0.0)
Item 6	0 (0.0)	0 (0.0)	0 (0.0)
Item 7	0 (0.0)	0 (0.0)	0 (0.0)
Item 8	0 (0.0)	0 (0.0)	0 (0.0)
Item 9	0 (0.0)	0 (0.0)	0 (0.0)
Item 10	0 (0.0)	0 (0.0)	0 (0.0)
Item 11	0 (0.0)	0 (0.0)	0 (0.0)
Item 12	0 (0.0)	0 (0.0)	0 (0.0)
Item 13	0 (0.0)	0 (0.0)	0 (0.0)
Item 14	0 (0.0)	0 (0.0)	0 (0.0)
Item 15	0 (0.0)	0 (0.0)	0 (0.0)
Withdrawal prevention			
Item 1	1 (1.0)	0 (0.0)	0 (0.0)
Item 2	1 (1.0)	0 (0.0)	0 (0.0)
Item 3	0 (0.0)	0 (0.0)	0 (0.0)
Item 4	0 (0.0)	0 (0.0)	0 (0.0)
Item 5	0 (0.0)	0 (0.0)	0 (0.0)
Motivation to change			
Item 1	0 (0.0)	0 (0.0)	0 (0.0)
Item 2	0 (0.0)	0 (0.0)	0 (0.0)

a Items not used in the outcome calculation.

TABLE 33 Injection sites by session attendance

Injection site	Time point, *n* (%)					
	Baseline		End of intervention		1 month post intervention	
	Attended at least one session	Attended no sessions	Attended at least one session	Attended no sessions	Attended at least one session	Attended no sessions
Arms	8 (50)	13 (45)	9 (75)	14 (38)	8 (50)	13 (45)
Feet	1 (6)	1 (3)	2 (17)	3 (8)	1 (6)	1 (3)
Hands	1 (6)	8 (28)	2 (17)	8 (22)	1 (6)	8 (28)
Neck	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)
Groin	6 (38)	12 (41)	5 (42)	16 (43)	6 (38)	12 (41)
Genitals	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Legs	5 (31)	7 (24)	5 (42)	9 (24)	5 (31)	7 (24)

TABLE 34 Number of days injected by session attendance

Number of days injected	Time point					
	Baseline		End of intervention		1 month post intervention	
	Attended at least one session	Attended no sessions	Attended at least one session	Attended no sessions	Attended at least one session	Attended no sessions
n	20	78	14	36	16	29
Mean	13.0	18.6	18.4	15.3	11.6	15.4
SD	11.00	9.98	9.23	10.95	10.00	12.02
Median	6.5	22.5	21	14	9	17
Minimum	1	1	3	0	0	0
Maximum	28	28	28	28	28	28

to the 12 sessions delivered in the trial. In practice, the cost per session would be lower as those trained would deliver more sessions than within the trial, therefore reducing the cost of training per session. Summing the staff and other costs gives a total training cost of £2013. This cost is divided across the 12 sessions delivered to give a cost per session of £167.78.

A proportion of training cost is assigned to each session (*Tables 35* and *36*). Centre-specific costs are allocated to each centre and then a cost per attendee is calculated. *Table 35* details the items included in the costing. Total intervention costs are calculated per-session delivered. These included training costs, staff time (including contact and preparation time), costs of printed materials and text messages to patients.

Costs for sessions 1–3 are estimated for each of the treatment centres (see *Table 36*). The total cost of session delivery is calculated for each session at each service and divided by the number of patients to give a cost per patient. Each cost per patient is attributed to the patient, then the cost per session is added to derive a total cost of treatment. Total patient treatment costs are derived by summing the costs of the sessions attended (maximum = three).

TABLE 35 Training costs (£)

Category	Location in the UK							
	London	Cost per session	Glasgow	Cost per session	Wales	Cost per session	York	Cost per session
Intervention training event, 11 January 2016: staff time (£24.42 per hour)	Two people × 6 hours × 24.42	293.04	Three people × 6 hours × 24.42	439.56	Two people × 6 hours × 24.42	293.04	One person × 6 hours × 14.29; 1 person × 6 × 9.87	144.96
Intervention training event, 11 January 2016: peer educators' time (£100 for full day)	Two people × 100.00	200.00	N/A		N/A		N/A	
Intervention training event, 11 January 2016: (trainer) time	585.18 total	585.18	N/A		N/A		N/A	
Intervention training event, 11 January 2016: printing and binding intervention manuals	16 manuals × 65 pages × 0.04 per page (printing)	41.60	N/A		N/A		N/A	
	16 manuals × 1.00 (binding)	16.00						
Training costs		1135.82		439.56		293.04		144.96

N/A, not applicable.
Source of data: all data presented were collected by trial researchers.

TABLE 36 Intervention and control costs (£) per session by centre

Intervention session	Patients attending (*n*)	Cost		
		Total	Per patient	Excluding training
Location in the UK				
London				
Session 1	6	349.02	58.17	30.21
Session 2	5	333.35	66.67	33.12
Session 3	5	333.20	66.64	33.09
London (2)				
Session 1	2	316.56	158.28	74.39
Session 2	3	323.43	107.81	51.89
Session 3	2	316.44	158.22	74.33
Scotland				
Session 1	3	310.83	103.61	47.69
Session 2	3	310.38	103.46	47.54
Session 3	2	308.80	154.40	70.51
Wales				
Session 1	6	318.48	53.08	25.11
Session 2	4	313.16	78.29	36.55
Session 3	6	319.38	53.23	53.23
Control cost				
Cost item			*Unit cost*	
Staff time			0.81	
Leaflet			0.05	
Cost per patient			0.86	

We should note that the costs of these sessions are higher than would be expected in practice because the costs of the training are allocated only across the trial sessions delivered. In a pragmatic setting we would expect these training costs to be delivered to more patients, thus reducing the per-session costs as average cost is reduced as clinical centre throughput increases.

A mean cost was estimated based on number of sessions attended, whereby total cost of treatment is presented per patient based on the number of sessions attended. The mean cost was £58.17 (note that this is a coincidence that this figure is the same as the cost for London) for patients attending one session, £148.54 for those attending two sessions and £270.67 for those attending all three sessions in the intervention group. This is because costs are allocated on a per-patient basis. The overall session cost is not changed, but costs are allocated specifically to attendees. The control intervention included 2 minutes of staff time to hand out and briefly explain printed material. A cost of £0.86 was allocated to each patient in the control. No variability was observed in the control groups as treatment was provided as a standard 2 minutes of staff time plus a leaflet.

Further costs were incurred at one of the services in which six sessions were arranged but no patients attended. A total cost of £293 was estimated for each of these programmes of three sessions based on the staff time spent preparing for the sessions and waiting for no show clients.

EuroQol-5 Dimensions, five-level version

The EQ-5D-5L was completed at baseline and at follow-up time points.[242] *Table 37* shows the EQ-5D-5L scores valued using the social tariff at the three points using paired analysis. Both baseline and control show increases in scores on EQ-5D-5L across the time period. However, we should note that the change in the control group is greater than the intervention although starting from a lower initial health state valuation there is greater capacity for change.

The EQ-5D-5L responses were converted to health-related quality-of-life utility scores using the UK tariff (*Table 38*).[246] Differences in the changes between groups were calculated based on patients with complete EQ-5D scores at each time point. These differences were not significant for the change from baseline to the end of the intervention. The mean difference between groups was 0.04648 (95% CI –0.08172 to 0.17467) and from end of the intervention to 1 month post intervention the difference between groups was 0.10512 (95% CI –0.11455 to 0.32478). We do not present quality-adjusted life-years (QALYs) because of the short follow-up and the expectation that health utility gains would become evident over a period longer than 1 month.

For patients not attending any sessions the mean changes were –0.0254 ($n = 11$) between baseline and follow-up 1 and +0.0718 ($n = 13$) between follow-up 1 and follow-up 2. The changes for those attending at least one session were +0.0985 ($n = 4$) and +0.179 ($n = 13$), respectively. However, as a result of the small sample sizes available, statistical significance was not achieved.

TABLE 37 The EQ-5D-5L mean tariff scores at baseline and follow-up

	Time point		
Trial arm	Baseline	End of intervention	1 month post intervention
EQ-5D-5L mean tariff score (SD)			
Control	0.617 (0.323), $n = 46$	0.646 (0.314), $n = 27$	0.788 (0.258), $n = 23$
Intervention	0.672 (0.247), $n = 52$	0.754 (0.193), $n = 24$	0.775 (0.256), $n = 22$
	Baseline to end of intervention	**End of intervention to 1 month post intervention**	
EQ-5D-5L changes (paired cases)			
Control	+0.0738 (0.216), $n = 26$	+0.1420 (0.375), $n = 17$	
Intervention	+0.0273 (0.233), $n = 24$	+0.0369 (0.232), $n = 17$	
Difference between groups	0.04648 (95% CI –0.08172 to 0.17467)	0.10512 (95% CI –0.11455 to 0.32478)	

TABLE 38 The EQ-5D-5L mean tariff scores by number of sessions attended

	Mean tariff score by number of sessions attended (SD)		
Time point	One	Two	Three
Baseline	0.85800 (0.029698), $n = 2$	0.70938 (0.124112), $n = 8$	0.69220 (0.152066), $n = 10$
End of intervention	0.83750 (0.058690), $n = 2$	0.73700 (0.280407), $n = 4$	0.79775 (0.117116), $n = 8$
1 month post intervention	0.87400 (0.178191), $n = 2$	0.77517 (0.210201), $n = 6$	0.82075 (0.283898), $n = 8$

Service use

Service use questionnaires were completed at baseline and follow-up. Quantities of service use recorded were multiplied by the national average unit costs of health care and criminal justice contacts to derive a health-care cost. Follow-up costs are defined by summing costs at the end of the intervention and 1 month post intervention. The unit costs and sources of unit costs are presented in *Table 39*. The price year is 2014/15. Costs that were only available for previous years are inflated to 2014/15 prices using the Hospital and Community Health Services Index for health and social care and the retail prices index for criminal justice items.

TABLE 39 Unit costs (£) of service use (2014/15 prices)

Service use	Unit cost	Source
Health and social care		
GP consultation (in surgery)	38.00	Curtis[247]
GP consultation (home visit)	62.00	Curtis[247]
Practice nurse consultation (in surgery)	11.00	Curtis[247]
Practice nurse consultation (home visit)	18.00	Curtis[247]
NHS walk-in clinic	56.00	Curtis[247]
Inpatient admission (per night)	562.00	Department of Health[248]
Emergency medicine	124.00	Department of Health[248]
Ambulance convey	231.00	Department of Health[248]
Patient transport service	61.58	Curtis[249]
Hospital day case	704.00	Curtis[247]
Outpatient attendance	114.00	Department of Health[248]
Prescription cost per year (average per head)	£8.15	NHS Digital[250]
Social worker (at office)	55.00	Curtis[247]
Outreach worker	£34.0	Curtis[247]
Key worker	34.00	Curtis[247]
Mental health specialist	118.00	Curtis[247]
Pharmacy methadone	10.79	Curtis[251]
Needle exchange	24.00[a]	See notes[a]
Criminal justice service		
Arrest, caution or penalty disorder notice	2796	Curtis;[251] Field;[252] and HM Treasury[253]
Magistrates' court appearance	639[b]	See notes[b]
Crown Court appearance	11,586[b]	
Prison day	102.45	Ministry of Justice[254]

HMCTS, Her Majesty's Courts and Tribunals Service; NDTMS, National Drug Treatment Monioting System.

a Figures derived from the new economy unit cost (cost of needle exchange is per visit). Database URL: http://neweconomymanchester.com/downloads/2701-140207-Unit-Cost-Database-v1-2-xls (accessed 8 April 2016). Original source from the 'NDTMS Unit Cost Report – National And Regional Totals'.

b Phillips and Brown, 1998; HM Courts & Tribunals Service, 2013; Legal Services Commission, 2013; Crown Prosecution Service, 2013; HMCTS Governance and Assurance Data and Information Disclosures, Ministry of Justice, Freedom of Information request by e-mail (9 April 2014), Crown Prosecution Service, Freedom of Information request by e-mail (7 April 2014) (Steve Parrott, University of York, 7 April 2014, personal communication).

Table 40 shows the mean wider health-care costs, criminal justice costs and total social costs at baseline and follow-up points for the intervention and control groups. There were no significant differences between groups at any time point for any of the cost categories.

Health-care and criminal justice costs were also assessed at baseline and follow-up by compliance.

Table 41 shows no significant differences based on whether a patient had attended one or more treatment sessions compared with those who had attended no sessions.

Service utilisation questionnaires

Analysis of the service use questionnaires was undertaken to identify key areas where data collection could be improved or included in greater or less detail in a full trial. Twelve categories of cost were identified where > 90% of responses at all three time periods were zero (*Table 42*). Of these categories, six had > 95% of responses as zero. The results will enable the questionnaires to be revised for future use with areas with high positive response rates identified for more detailed questions and other items not collected as part of the routine data set. *Appendix 15* reports the service use utilisation scores based on treatment allocation (by ITT) and presents CIs around the mean difference for each item.

Conclusion

The mean cost was £58.17 for patients attending one session, £148.54 for those attending two sessions and £270.67 for those attending all three sessions in the intervention group. This is a cost weighted across centres by the numbers of patients attending as costs varied by centre as shown above. These costs compared with £0.86 in the control group. EQ-5D-5L scores in both groups improved from baseline through the two follow-ups showing potential for health improvement and associated QALY gains. However, any differences between groups must be treated with extreme caution because of the small sample size.

Wider NHS costs and criminal justice costs also showed a reduction from baseline through follow-up periods, suggesting a potential for a full randomised controlled trial to detect cost savings to society, although cost changes in this sample do not necessarily mean that such changes would be seen in a full trial. Again, caution must be exercised when interpreting these results because of the small sample sizes and the short follow-up period.

Analysis of the questionnaires identified several categories that could be excluded from the assessment battery in a full randomised controlled trial making the collection of data simpler and quicker. Other items, such as key workers and needle exchange services, were used by > 70% of the trial population indicating that these areas should be the subject of more detailed data collection in a full trial.

Results: qualitative analysis

Acceptability of the intervention to participants who attended at least one session and staff who delivered or intended to deliver the intervention

The participant focus groups lasted between 15 minutes and 1 hour, depending on the number of participants in the group. The facilitator focus groups lasted approximately 1 hour. Five focus groups were conducted with intervention participants (*Table 43*) and four focus groups with intervention facilitators (*Table 44*) across the four locations in the UK.

PROTECT study participant focus groups report

Most useful aspects of the intervention

When asked what they most liked or found most useful about the intervention, focus group participants cited content from all three sessions and also aspects of the delivery of the intervention. In terms of content, participants cited the information on BBV transmission, safer drug use, hygiene and handwashing,

TABLE 40 Wider health-care, criminal justice and societal costs (2014/15 prices): mean cost (£) (SD) per patient

	Time point								
	Baseline			End of intervention			1 month post intervention		
Category of cost	Intervention	Control	Difference in cost between groups (95% CI)	Intervention	Control	Difference in cost between groups (95% CI)	Intervention	Control	Difference in cost between groups (95% CI)
Total wider health-care cost	1109.00 (1696.14)	1257.00 (2177.61)	148.00 (–657.94 to 954.54)	705.00 (673.39)	997.00 (786.04)	292.00 (–137.81 to 721.34)	662.00 (682.47)	1466.00 (2885.66)	804.00 (–611.92 to 2220.61)
Total criminal justice cost	1239.00 (2581.51)	1284.00 (3953.47)	45.00 (–1344.95 to 1434.14)	439.00 (2060.80)	289.00 (1348.13)	–151.00 (–1191.45 to 890.34)	236.00 (1053.86)	521.00 (1465.97)	285.00 (–520.06 to 1091.05)
Total social cost	2489.00 (3397.65)	2494.00 (4498.24)	5.00 (–2107.85 to 2117.58)	1194.00 (2178.38)	1328.00 (1563.11)	134.00 (–1034.59 to 1303.28)	908.00 (1279.79)	1909.00 (3077.46)	1001.00 (–662.53 to 2665.44)

TABLE 41 Health-care and criminal justice costs (£) by compliance

Compliance	Number of patients	Mean cost (SD)	Difference in cost (95% CI)
Baseline			
Total wider health-care cost			
Attended no sessions	31	989.55 (1282.19)	150.76 (–1317.41 to 1015.89)
Attended at least one session	18	1140.31 (2189.63)	
Total criminal justice cost			
Attended no sessions	33	1251.55 (2483.27)	36.16 (–1725.08 to 1652.76)
Attended at least one session	17	1287.71 (2897.17)	
End of intervention			
Total wider health-care cost			
Attended no sessions	10	681.72 (515.14)	41.99 (–612.74 to 528.76)
Attended at least one session	13	723.72 (794.65)	
Total criminal justice cost			
Attended no sessions	9	0.00 (0.00)	743.54 (–2363.57 to 876.49)
Attended at least one session	13	743.54 (2680.87)	
1 month post intervention			
Total wider health-care cost			
Attended no sessions	5	501.67 (154.97)	49.20 (–334.15 to 235.75)
Attended at least one session	15	550.87 451.15)	
Total criminal justice cost			
Attended no sessions	4	1178.25 (2356.50)	1178.25 (–2571.47 to 4927.97)
Attended at least one session	15	0.00 (0.00)	

TABLE 42 Numbers (percentages) of patients recording positive contacts with each service use questionnaire item (all groups)

	Time point, *n* (%)		
Service use category	Baseline	End of intervention	1 month post intervention
A&E visits	17 (17.2)	7 (13.7)	6 (13.3)
Inpatient nights	**8 (8.1)**	**4 (7.8)**	**4 (8.9)**
Hospital outpatient visits	15 (15.2)	9 (17.6)	10 (22.2)
Day hospital attendances	5 (5.1)	3 (5.9)	6 (13.3)
Emergency ambulance	**5 (5.1)**	**3 (5.9)**	**2 (4.5)**
Hospital transport by PTA	5 (5.1)	6 (11.8)	1 (2.2)
GP surgery visits	49 (49.5)	27 (52.9)	22 (49.4)
GP home visits	**4 (4.0)**	**3 (5.9)**	**1 (2.2)**
Practice nurse surgery visits	17 (17.2)	10 (19.6)	7 (15.6)
Practice nurse at home	**2 (2.0)**	**1 (2.0)**	**1 (2.2)**
Prescriptions	81 (81.9)	47 (92.2)	41 (91.1)
Other health-care professionals	**9 (9.1)**	**3 (6.1)**	**2 (4.9)**
Key worker at drug service	87 (87.9)	43 (84.3)	37 (82.2)
Group work sessions	16 (16.2)	9 (17.6)	8 (17.8)

continued

TABLE 42 Numbers (percentages) of patients recording positive contacts with each service use questionnaire item (all groups) (*continued*)

Service use category	Time point, *n* (%)		
	Baseline	End of intervention	1 month post intervention
Specialist drug service	18 (18.2)	5 (8.8)	0 (0)
Pharmacist	78 (78.8)	44 (88.0)	37 (82.2)
Nurse at drug service	29 (29.3)	11 (22.0)	11 (24.4)
Needle exchange	84 (84.8)	42 (82.4)	32 (71.1)
Outreach worker	25 (25.3)	6 (11.8)	9 (20.0)
HIV or HCV test	13 (13.1)	5 (10.8)	9 (20.0)
HIV infection treatment	**0 (0)**	**0 (0)**	**0 (0)**
HCV infection treatment	**1 (1.0)**	**0 (0)**	**0 (0)**
HBV infection treatment	**1 (1.0)**	**0 (0)**	**1 (2.2)**
Mental health specialist	18 (18.2)	9 (17.6)	3 (6.7)
Social worker	**7 (7.1)**	**5 (9.8)**	**4 (9.1)**
Dentist	11 (11.1)	7 (13.7)	6 (13.3)
Family planning	1 (1.0)	0 (0)	1 (2.2)
Sexual health clinic	2 (2.0)	2 (3.9)	1 (2.2)
Arrest or caution	15 (15.2)	3 (6.0)	3 (6.6)
Magistrates' court appearances	15 (15.2)	3 (6.0)	4 (9.7)
Crown Court appearances	**3 (3.0)**	**0 (0)**	**0 (0)**
Prison	**1 (1.0)**	**0 (0)**	**0 (0)**

A&E, accident and emergency; PTA, patient transport ambulance.
Note
Figures in bold show categories where > 90% were zero at all baseline and follow-up time points.

TABLE 43 Number of intervention participants in each focus group per location in the UK

Location in the UK	Gender of focus group (*n*)	
	Male	Female
Wrexham	3	1
London	5	2
York	N/A[a]	N/A[a]
Glasgow	3	N/A[a]

N/A, not applicable.
a There was no PROTECT intervention group for females in Glasgow and no participants attended the intervention in York.

TABLE 44 Number of intervention facilitators in each focus group per location in the UK

Location in the UK	Number of facilitators
Wrexham	2
London	4
York	2
Glasgow	3

bleaching and preparedness planning as particularly useful. In terms of format and delivery, participants cited exposure to professional and service user points of view, intervention games and exercises, having the opportunity to talk about topics that are not normally discussed, and the amount and variety of information provided.

Information regarding blood-borne virus transmission risks

Participants in all five focus groups cited the information regarding BBV transmission ('how it's passed on') as particularly useful content and said they had gained new knowledge regarding transmission risks ('some new ways of catching BBVs'):

> *. . . the way like a drop of blood can be transferred from the water to the other needle . . . if you were using that day you could understand that better.*

> *. . . well I got to ask questions . . . I got to . . . find out even some, some of the . . . some information that I might not have brought up anywhere else. So it was helpful for me in that way. Like such as . . . contacting or picking up like viruses. How many different ways there were of picking up viruses. I wouldn't have known that unless I've come to the group.*

> M2: *It opened my eyes up(?) about Hep C.*

> M1: *Yeah it's definitely opened my eyes up a lot more about things, because I can assure you on some of them questions [BBV Knowledge questionnaires] I give at the beginning, when you have to do your questionnaire thing, I know that I got quite a few of them wrong, which now I know I would get right, you know what I mean, which I'm very happy about.*

One participant reported that information about the consequences of BBV infection was the most useful content:

> *I liked the third one the most likely 'cos you're giving more information on what would happen to you with the disease like and I just learnt more out of it.*

Safer using

The 'information on safer injecting' and 'safer using', generally, and in terms of BBV prevention, was highlighted as particularly useful and increasing knowledge:

> *And also the awareness of, you know, certain things you can do to prevent it, which is helpful, because I didn't know that before, you know.*

Hygiene

The material on hygiene and handwashing was particularly liked, with many participants referring to 'the cleanliness', 'using [a] clean surface', and 'washing your hands' as useful aspects of the intervention. The usefulness of this information was evident in reports by some participants that they had shared this information with their peers:

> *I think for me, you know, like cleaning sites before you inject, I didn't realise how relevant that was. I thought oh that's people being overcautious. But it's not, that's how you get abscesses.*

> *. . . for me anyway, anytime when I'm using drugs I never do it myself anyway. It's like me and my friend, you know. We're always together, you know what I mean, you know when we're having our hit. So any points o' view that I think that he doesnae know anything about, like I was talking about wi' the hygiene o' the hands, things like that, maybe talking about hep C, things like that, cleaning our tools. Just a' different wee points I would say tae him.*

Bleaching

Information on bleaching injecting equipment if re-using was considered useful by some participants and a couple had shared this information with others. The efficacy of bleaching was new learning for some:

> *And I think the bleach thing as well for me, that's very informative, 'cos I didn't know that can actually kill HIV and Hep C, like that I think it's really useful. [Focus group facilitator: And you said you told other people about that as well?] Yeah me and my partner.*

However, one participant in Wrexham disagreed that this was useful:

> Focus group facilitator: *. . . You know we talked about for instance the session about bleaching needles, was that new to anybody?*
>
> Person 2: *Yeh, never heard of it. Thought there would be trouble it you bleached the pin.*
>
> Focus group facilitator: *So that was new for you learnt if you did it properly you could bleach your equipment and its quite safe.*
>
> Person 1: *No, I don't think it is safe.*
>
> Focus group facilitator: *You don't?*
>
> Person 1: *Why bleaching needles with bleach when you can do it with cold water and it's alright. Do it with hot water and it's the same again.*
>
> Focus group facilitator: *So you didn't think that when we went through that session about bleaching equipment that it was useful?*
>
> Person 1: *No.*

Preparedness planning

The materials and discussions on preparedness planning were considered useful and participants felt they could draw on these strategies to reduce future risks:

> *. . . it was things like having a back-up plan, you know, of what you're gonna do if you run out of this, the risks, making me more aware of the risks that I put myself in sometimes when, you know, with sharing and not having a back-up plan. Just, you know, it was just certain situations, it made me more aware of what I would do that I could do more safely.*

Service user/professional point of view

Participants in London particularly liked that the intervention was co-delivered by a drug worker and a peer educator. Participants could relate to the peer educators as they had similar life experiences ('he's one of your own. He knows, he's been down the same trip as most of us'). In Glasgow, although the intervention was delivered by two drugs workers, hearing the perspectives of their peers within the intervention group, as well as the perspectives of the drugs workers, was considered one of the most useful aspects of the intervention:

> *. . . it was good hearing it from like . . . from like an addict's point o' view and from a professional's point o' view as well, you know. So from that point o' view I thought the group was really good.*

Games and exercises

Female participants in London preferred the games and exercises to the didactic parts of the intervention as they enabled more interaction and discussion:

> *Yeah I like interactive stuff. It was good, the sessions, if there were other things they could do to be interactive it would be a bit more . . . I like it that way, yeah.*

Opportunity to talk about topics not normally discussed

For the male participants in Glasgow, the opportunity provided by the intervention to discuss topics not normally talked about was one of the aspects most valued:

> *. . . fae my point o' view fae the group, what I got out of it was it was good tae talk about things that people don't usually talk about, you know what I mean.*

Variety and amount of information

One of the male participants in London noted that the variety, and the amount, of information provided in the intervention was good:

> *. . . there was a bit of everything there which I quite liked, a bit of variety.*

> *It was the right amount of sort of information that was needed.*

New learning from the intervention

Participants were asked what, if anything, they had learned from the intervention that was new. Their responses overlapped to a large extent with the content they most liked or found most useful above. Participants reported new learning on BBV transmission; how to use/inject drugs more safely; the importance of hygiene (especially handwashing – 'proper way to wash your hands', cleaning injecting sites before injecting and cleaning surfaces on which drugs are being prepared); how to bleach equipment ('found out about bleach and water'); and how abscesses are formed. Other learning points identified by participants were the prevalence of BBVs; the consequences of BBV infections; how long HCV can survive on a needle; how germs can transfer from one's mouth to injecting equipment' and to rub the injecting site after injecting.

Behaviour changes as a result of the intervention

Participants reported making behavioural changes as result of what they had been taught in the intervention.

Hygiene and handwashing

The most common changes reported were handwashing, wiping the injection site and making sure the surface area on which drugs are being prepared is clean:

> *I suppose the one thing that I got out of it was washing hands and stuff like that that. I never thought I would have done before so I do that now.*

> *. . . loads of things have been on my mind, making sure the area's clean, making sure I'm clean.*

Using sterile equipment

Participants in Wrexham reported that they had begun to ensure that they used new equipment for each injection since taking part in the intervention:

> *. . . just made sure I used new everything now, wouldn't use a spoon if I'd used it before, it if anybody else had used it. New everything every time.*

> *. . . make sure I go the (name of needle exchange) all the time, you know to get clean works.*

Planning ahead

In addition to the behavioural changes they had already made, some participants thought that they would implement more of the learning gained from the intervention in the future. For example, a couple of participants noted that the preparedness planning session had given them strategies which they would use in the future for reducing their risks:

> Focus group facilitator: *. . . Did you do anything sort of around the planning? Did you use any o' the kind of tools, you know, like that?*
>
> R1: *What any of these like advice sheets?*
>
> Interviewer: *Mmhmm.*
>
> R1: *Well I know, I know I will do. You know, it's there, you know, for me to use information that I've been taught.*
>
> Interviewer: *Yeah.*
>
> R1: *So but cause lately I've been using by myself. So I've not been in the sort of situations that we might have, I might have otherwise, you know. So when the time comes around then yeah I definitely will use the information.*

Sense of empowerment and control

As well as changes in behaviour, changes in motivation and self-efficacy were also reported. For example, participants in London reported gaining a sense of empowerment and self-efficacy regarding their ability to manage and prepare for risk situations:

> *It's empowering as well, knowing that you can take control back of a situation, do you know what I mean, you don't have to let the situation control you. You know that there is steps that you can take, you know, to prevent anything happening.*

Greater awareness

Similarly, some participants reported an increased sense of mindfulness or awareness around safer injecting practices as a result of taking part in the intervention:

> *I'm just a bit more, just a bit more switched on when it comes to like . . . what do you call it, like my hygiene and cooking up.*
>
> *I have learnt a lot more about blood-borne viruses . . . when you're in a mix and you're doing what you're doing every day, that don't really come to the forefront of your using, but in all consideration it should be . . . it has made me a bit more aware about things, it has yeah.*

Other changes

Other changes that participants reported were altering their tourniquet use, beginning to store methadone, reducing their benzodiazepine use and injecting less often with others:

> R3: *It's made me cut doon since I've started coming tae the sessions. My valium intake man is . . . the bit o' valium I've had in the last four days man, I'd have had that in the morning, one morning.*
>
> R2: *Same wi' me, I've cut down my benzos as well.*

Least useful aspects of the intervention

When asked what was least useful in the intervention, most participants reported that all of the intervention content was useful and nothing should be omitted ('it was all useful'; 'I don't think there's anything that should have been left out'; 'everything was alright for me . . . I liked it all.'). Exceptions to this were as follows.

Language in 'rate the risk' activity cards was confusing

The male participants in London disliked the verbatim language used in the 'rate the risk' activity cards:

> *. . . them little paper things, they was knacker. 'Yeah, but no, but 'em,' all that, whatever it was.*

Handwashing video was too long

One of the male participants in London thought that the handwashing video was too long:

> *Just like that the washing hands, OK do a video about washing hands but make it 30 seconds, a minute long, not 5 minutes long.*

Would have liked a bigger group for more input

Female participants in London would have liked a bigger group:

> F1: *Maybe bigger groups might have been better.*
>
> F2: *Yeah, bigger groups, yeah, there was like more of an input.*

Not enough information on blood-borne virus symptoms

One of the male participants in Wrexham thought that there was not enough information on the symptoms of BBV infections:

> Person 3: *There were parts when you kept repeating yourselves, like got to keep cleaning the spoon, got to keep boiling this, it could have gone further I thought.*
>
> Focus group facilitator: *So more in depth.*
>
> Person 3: *In depth into the symptoms of the disease that you could catch, it was more like skirting round them, you could catch this, you could catch that, but what would be the symptoms of catching that and how would you know if somebody else has catched that.*

Videos and handouts

Participants in Glasgow thought that the videos and handouts looked dated, although the content was considered useful:

> R2: *And I'm not saying it, it doesn't cover everything but I just think to make it look a wee bit more professional, I just think if you've got something that's maybe a wee bit more up to date. I think that would maybe help. I just felt that . . . it was an illustration thing that looked a bit dated. [. . .]*
>
> R1: *Yeah I think you got a point there [R2] cause especially like, not so much us but the younger bodies aye might look at that and think, 'I can't relate to that'. That was made in 19 bloody I wasn't even born then [interviewer laughs].*

Suggestions for improving the intervention/additional information required

Participants were asked for their thoughts on how to improve the intervention and whether or not there was anything important that we had left out.

Make more visual

The most common suggestion for improving the intervention was to make the content even more visual (i.e. more pictures, videos and animations):

> *. . . maybe more videos incorporated because I'm a visual person.*

More information on blood-borne virus prevention

Two participants suggested having more information on BBV infection prevention. However, one of the participants had missed session 3 on BBV transmission risks. The other noted a discrepancy between the questions asked at the baseline assessment (BBV knowledge questionnaires) and the material covered in the sessions:

> *On that questionnaire though, there's things you didn't go in to. It's like, you know, it asks you about the female condom and if you can get Hep C and all that if she uses that but I'm not quite sure, I weren't quite sure on that, but we've not gone into that, you know, there's been no mention of that really, you know what I mean, so . . .*

Potential injecting sites

In London, male participants indicated they would have liked more information and advice regarding potential injecting sites, as venous access was diminishing for some and several participants wanted to sustain their use for as long as possible:

> *I would liked to have got a bit more information about maybe places to go, you know . . . it's got to the stage where I'm using the sole of my feet and things like that, where it's like, you know, like even walking on it after is painful and all that, you know what I mean . . . I'd like someone to maybe, say like, you know like you get these doctors and that. 'Cos when I've been in jail and that before and the nurses or whatever can't take blood from me, the doctor 'll sit me down . . . I mean one time he done it, it wasn't in me groin, but it was up near here somewhere. And he stuck it, boom, within two seconds, boom, done. So it's things like that I'd like to know.*

More practical regarding injecting technique

In the women's group in London, participants felt that more practical hands-on demonstrations of injecting skills would have been beneficial:

> F1: *. . . yeah physical things, obviously you wouldn't be able to do it on the person but there must have been some kind of like module or that you can . . . I don't know . . . something like that.*
>
> Focus group facilitator 2: *More sort of hands on?*
>
> F2: *Yeah.*

More exercises and games

Female participants in London recommended making the intervention even more interactive:

> Focus group facilitator 1: *Did you find those good, the kind of exercises and games that we incorporated?*
>
> F2: *Yeah, I think a few more exercises [GF1: More of those, yeah] and that, yeah, so you're not just sitting here being talked at like, you know. But yeah I think for a trial, yeah, I think it was alright actually.*
>
> Focus group facilitator 1: *So on balance do you think there was a little bit too much of being talked to or at and not enough maybe of the interactive or the visual stuff, you'd like to see more of that and less of the . . .?*

F2: *Ahm no, I think they actually balanced it quite well to tell you the truth, considering the materials that they had, for me they done alright. I just think the videos for someone like myself, I just . . .*

F1: *Yeah I like interactive stuff. It was good, the sessions, if there were other things they could do to be interactive it would be a bit more . . . I like it that way, yeah.*

Use of scare tactics: graphic videos of injecting side effects instead of animations

Male participants in London thought that real-life depictions would be more motivational than animations:

That's one thing you should have done is to put more videos on of the side effects, you know, of say someone with a big abscess on their arms or on their groins, you know, to scare other people or show them what the side effects of injecting are, and make them think 'I better wash me hands or I better . . .' you know what I mean.

Use of social media: Facebook, YouTube

Male participants in Glasgow recommended making more use of social media to attract younger injectors to the intervention.

Maybe having a wee bit more up tae date, seeing if you could actually post things on YouTube or go ontae a Facebook. All these sorta things, you know.

Information on legal highs: relevant to younger injectors

They also advised including information on legal highs so that the intervention is more relevant to younger people:

R1: *. . . I've heard that people, you can inject legal highs, you know. I think maybe examples to do with that. [. . .]*

R1: *It's, a lot of these viruses are getting picked up by kids using legal highs.*

Other suggestions for improvement offered by participants included personalising the 'rate the risk' activity exercise, providing a bit more information on abscesses and vein collapse and also more information on BBV symptoms.

Logistics: venue/timing/duration

The intervention was held at different times of the day and in different settings at each of the three sites.

London

The intervention took place at a drug treatment service, which many of the participants attended for OST. The male group was held at 11 a.m. and the female group at 2 p.m., except for the final week, when the female session was held at 11 a.m. (because of room scheduling conflicts).

Both male and female participants reported that the venue was fine as they attend the service anyway ('where we get our scripts', 'come here anyway') and the location was relatively central. Male participants thought that the time the sessions were held at was fine; however, one of the two female participants who took part in the focus group noted that 11 a.m. was too early a start for her:

I'm just not used to doing things at this time of the morning, so I just know I'm a bit . . . If I was doing something every day, then obviously I would get used to it and be here at that time but yeah, if it's just randomly then obviously afternoon's better.

Wrexham

In Wrexham, the intervention was held at a homeless service and the male group took place at 11.30 a.m. and the female group at 2 p.m. Just one female participated in the focus group in Wales. She thought that the timing of the session was fine. One of the male participants found that the 11.30 a.m. start problematic and suggested having the intervention at 3 p.m. instead:

> Person 2: *Yeh a bit late in the day cos one of the appointments I actually came here and I spent the day trying to score first thing and I was actually wasted during one of the sessions.*
>
> Focus group facilitator: *So what do you think earlier or later?*
>
> Person 2: *Later, cos then I can get sorted and be awake for the actual lesson.*

Both male and female participants thought that the venue was fine. One participant who was homeless noted that she also appreciated the opportunity to get in somewhere warm.

Glasgow

In Glasgow, the intervention was held at 2.30 p.m. Three participants took part in the focus group. They reported that the time was fine. However, the venue was difficult for one participant to get to:

> *But me personally it's a wee bit o' pain in the arse tae get tae (name of street), you know what I mean. Cause it's like being on the edge o' the town, you know.*

Gendered groups

We were interested to know how participants found having a gender-specific intervention group and whether or not they would have preferred a mixed gender group. Males in all areas were open to having a mixed gender intervention group and some clearly thought that some degree of mixing of genders would have been beneficial:

> Focus group facilitator: *And were people happy that it was an all-male group?*
>
> M3: *I don't know. I don't know. I was a bit iffy about that one.*
>
> M4: *Like I said last week I think you should do two all-male and all-females group and one group where it's mixed. [. . .]*
>
> M2: *But it's the same thing though isn't it, it could be a man or a woman sitting here but Hep C is Hep C, no matter who transmits it or who gets it.*

However, one of the male participants in Wrexham noted that he would not have disclosed personal information regarding sexual behaviour/risk if the group was mixed gender:

> Focus group facilitator: *Was it easier to share stories or disclose personal information with the single sex groups, so do you think you would have disclosed as much as you did if there were females in the group?*
>
> Person 3: *I wouldn't not, not sexually anyway.*

In total, just three women participated in focus groups across the sites. Two of the three women 'didn't mind' if the group was mixed gender. However, one female participant said that she finds women-only groups 'safer':

> *I've done mixed groups before and sometimes it just stops you from talking about certain issues as such, like I don't get shy that often but I just prefer it, I think it's more safer being with women, yeah.*

Thoughts on intervention facilitation

Participants were asked what they thought of the facilitators' delivery of the intervention. Participants reported that the information had been well communicated by the facilitators and they had explained anything that participants did not understand. Participants appreciated that facilitators listened to them, looked up additional information for them and created a comfortable and relaxed atmosphere. London participants particularly liked that the intervention was co-facilitated by a peer educator and drugs worker.

Motivation for attending intervention

Participants were asked why they had attended the PROTECT study intervention. They cited a range of motivations and also a range of enabling influences.

New learning

Participants were motivated to participate in the study and to attend the intervention to avail of the learning opportunities it offered:

> *£10.00 voucher and I was in the area anyway and thought I might learn something.*

> *Personally I wanted to find out more about what I've been doing for so long that I might be missing out on that I could do better.*

> *I wanted to do this . . . Not just 'cos obviously it's a chance to get a bit of money but for the knowledge.*

Recovery aspirations

Some participants reported aspirations towards recovery and towards improving their lives and associated their engagement with the intervention with these broader goals:

> *Maybe it's just at the time you've got us all, you know what I mean. Maybe a time o' our lives that maybe we are wanting tae dae something wi' our lives.*

> *I'm also at a place where I'm ready I think to make changes, like I said I want to do the (name of a recovery intervention service), I want some structure, you know, I'm not happy just sitting at home getting high or whatever every day anymore.*

Cash or vouchers

As intended, the cash and voucher incentives were motivating factors in attendance at the intervention:

> *If I'm honest the extra tenner, yeah, that really motivated me . . . That really motivated you to make sure you get to all three. And I even changed one of my things, like, with my other trial, yeah [GF1: Ah did ya reshuffle things to be able to come to this?], yeah, come here, so money is a motivating factor for people in our circumstances, yeah.*

Social interaction/group dynamic

The group dynamic and social interaction afforded by the intervention was reported by some to have encouraged them to attend:

> *But now that I've started coming I've enjoyed, I enjoy the company cause I feel lonely at times.*

> *I enjoy doing groups, so I don't mind coming to them so, you know.*

> *it's good tae hear different points o' view.*

Something to do/break up routine

A couple of participants reported that the intervention offered a structure and a valued activity to fill their time:

> *Tae be honest just it was for something tae dae.*

> *I like to come and do something with my day, I have nothing to do.*

Reminders: text

Receiving reminders, including text reminders from the researchers, facilitated attendance at the intervention sessions. Additional motivators for attending the intervention were the desire to maintain one's veins to sustain drug use, wanting to improve one's injecting practices, wanting to protect oneself and others from HCV infection, wanting to help others through participating in the research, and not wanting to let people down who were investing their time and effort in the intervention. Additional enablers that facilitated engagement with the intervention were being more stable, and the fact that the intervention was not promoting abstinence and was not patronising.

What deterred others from attending

Participants were asked what they thought might have deterred others from attending the intervention.

Withdrawal

Some thought that withdrawal might have prevented others attending:

> *. . . if they are rattling and needed to score and they haven't got money . . .*

Not motivated/interested/ready to change

Participants highlighted the role that intrinsic motivation plays in willingness to engage with this kind of intervention. It was suggested that others may not have attended because they were not interested or ready to change:

> *You've got to remember a lot of people don't want to change. They're quite happy with where they are.*

> *. . . what I would maybe think is is maybe people have been put off. And the reason being is it's maybe having tae look at their own sorta lifestyle and maybe not too many people at this time in their life the now are ready tae maybe judge their selves or want tae go that other bit forward, you know, or do things like that.*

Do not perceive any benefit to them

It was also suggested that some people may not perceive that the intervention would be of any benefit to them or would offer anything new:

> *Nothing that they dae see that's gonnae benefit them.*

> *A lot of people think it's just the same old, same old.*

Other barriers to engagement, which people identified, were the prioritisation of drug use, legal issues and concealing drug use.

Suggestions for improving uptake of/engagement with the intervention

Participants' views were sought on how to improve uptake of and attendance at the intervention.

Better advertising: posters in women's hostel

Participants recommended more advertising of the intervention, particularly in women's hostels.

Cash

Participants in Glasgow thought that cash may provide more of an incentive than vouchers, but were concerned that cash may promote attendance without genuine engagement:

> R1: *They'd be turning up for the wrong reason yeah. And it's not gonna do, do . . . the person any favours. All this would go out the window and all their mind would be on is the cash. [. . .]*
>
> R2: *So they'd want tae do it as quick as they can and then out the door, you know.*

Bus fares

Participants in Glasgow also suggested covering people's bus fares:

> *I know like you reimburse us all, you know, wi' our vouchers, fantastic but I think another thing that would be good is if you'd reimbursed people for their bus fares as well.*

Nothing more we could do

Female participants in London thought that there was no more we could have done to facilitate attendance as we gave cash, covered transport costs and provided lunch ('I think you've done all you can really to get us here'). A summary of the main findings are shown in *Tables 45* and *46*.

TABLE 45 Summary of the findings regarding aspects of intervention

Most liked (*n*)	Least liked	Improvement (*n*)
• BBV transmission (5) • Safer drug use (3) • Hygiene (3) • Peer/staff views (3) • Preparedness planning • Consequences of BBVs • Bleaching • Games and exercises • Opportunity to talk • Variety of information	• Not in-depth enough on BBV symptoms • Videos/handouts look dated • Small group • Handwashing video too long • Language on 'rate the risk' activity cards • Prefer 'real-life' video instead of animation	• More visual (3) • More on BBV prevention (2) • Potential injecting sites • More practical regarding injecting technique • More exercises/games • Use of scare tactics: graphic videos instead of animations • Social/online media • Legal highs • Personalise rate the risk activity • More information on abscesses/vein collapse • More information on BBV symptoms

TABLE 46 Summary of the findings regarding aspects of participation

Motivation (*n*)	Improving uptake (*n*)
• New learning (4) • Recovery aspirations (3) • Cash/vouchers (3) • Group dynamic (2) • Break up routine (2) • Reminders (2) • To maintain veins • Improve injecting practices • HCV infection prevention • Was not promoting abstinence • Was not patronising • Not wanting to let people down • Help others through research	• Better advertising (2) • Cash (1) • Bus fares (1) • Nothing more we could do

PROTECT study facilitator focus group reports

The facilitators in Wrexham, London, York and Glasgow took part in focus groups following the delivery of the PROTECT study group sessions. The focus groups were facilitated by experienced researchers and views were sought on the PROTECT study training event, intervention materials and delivery, facilitator learning, and participant engagement and attendance.

Training event

The facilitators thought that the training event in London was useful and helped them prepare for the delivery of the intervention. They especially mentioned the benefits of being involved in the structure of the final intervention manual, with ideas from the day taken on board and added to the manual. This fitted well with the needs and practices of the different localities and service users. The training day also introduced new learning for the facilitators with regard to injecting practices, which could then be used in future discussions with needle exchange clients. The inclusion and input from the peer mentors provided new insights for the staff facilitators in relation to the differences in individual injecting practices and this combined with input from the clinician and project lead provided a good balance of information:

> *Yeah it was good. We were able to run through it as a group and make changes that suited each locality as well because obviously the people from, from Wales and London and obviously Glasgow, it meant we could change how we, the things we were saying. And we could suit it to our service users which was good.*

> *I really thought it was useful how they had service users involved in it and talking openly about it, I thought that was really good.*

Although the delivery and format of the training event was generally well regarded, the venue (a large lecture theatre) was considered inappropriate and limited interaction between the attendees. The training would have benefited from being held in a smaller room that would be more reflective of the local venues the intervention sessions would be delivered in. There was almost unanimous agreement that the training would also have benefited from being conducted over (at least) 2 days rather than 1 to allow equal time spent on each of the three intervention sessions and to provide time to conduct mock practice sessions:

> *I would prefer if, for example, if we can practice some of these exercises or some of the workshop, if we can practice it, because for me I would better know and better understand how for example how easy or difficult it is to deliver it and how long time I need for each exercise.*

One facilitator suggested that future training events could be held locally and that the facilitators from each area attending training could be introduced prior to the training event so they are familiar with who they will be training and delivering alongside. Other ideas included having a 'conversation café'-style format, which may help encourage more interaction and networking between the attendees, and a venue in a more central UK location. The consensus was that the training is better held face to face rather than delivery through video conferencing.

Intervention materials

Implementation of the intervention in keeping with the manual was not without some challenges. For some, the manual was considered well laid out and easy to follow ('Well the way the sessions were laid out was, you just ran with it. You didn't have to think about it. It was there, everything you needed was there'); however, for others it was more challenging. Although the manual was colour coded to indicate the facilitators' notes (blue font) and text to be read out verbatim (black font), it was difficult for those who only had black and white printed copies to distinguish between the two:

> FKW: *And I think me, I have to say it's the format a little bit I struggled – that it was written facilitator's section, then this section when we deliver – and when we were sometimes like [FPE: Yeah, that was a bit hard] 'So where are you . . . in which . . . ?' I would like to have two different – one s [. . .] One, it's that I just read out for the client, and then I have another one which is for me.*

FPE: *Yes. Because they got a bit mixed, they could get a bit mixed up if you were trying to look quickly and yeah that was a bit tricky.*

Perhaps it needs a bit of tweaking. We haven't got colour printing so it would have perhaps worked better to have the guidance and what you actually say separated out a bit more because it was all black and white to us so it wasn't easy to see on the day.

The content in session 1 was considered excessive for a 1-hour session and it was suggested that this could be split into two sessions to allow more time for participants to ask questions and engage in discussions. Sessions 2 and 3 were easy to follow and there was more time for participant feedback.

Reading out the text verbatim was considered too formal for some of the facilitators – as trainers or group workers they are used to following a looser format that encourages greater participant engagement. One facilitator thought that the sessions were more 'theoretical than practical' and that participants benefit more from practical information.

In terms of the teaching materials, the videos were generally thought to be relevant in terms of the information provided, although it was recommended they be updated. The cross-contamination video was almost unanimously criticised for the poor quality of filming (although the content was considered valid and useful). One site thought that the videos could have been grouped together to assist the flow of the session (e.g. hygiene, handwashing, abscesses, vein care) and only one video was needed for handwashing.

There was mixed opinion regarding the group activities. For instance, although some were thought to work well there were issues around the size of the groups. The activities were designed for groups of around eight participants, so there was some concern that these did not work as well as they could because the numbers attending sessions were lower, which inhibited a fuller discussion. There were also some reservations around discussing sexual risk behaviours in groups, although this related more to facilitators' confidence rather than the information/activities per se. The TALK activity was thought to be good by one site, but another changed the point at which it was delivered and a third site thought that it did not fit well with the rest of the material in session 2.

One criticism of the PowerPoint slides was that the key messages were not always clear. The handouts that were provided, on needle exchange sites and for the personal preparedness plan, were not as useful as anticipated, largely because the participants left them at the venues following the sessions. Nevertheless, one facilitator noted that, although the handouts were left behind, the participants had at least taken the information on board and returned the following week having made changes to their injecting practices. Moreover, he felt that the intervention should 'not be an exercise of work for them . . . You know, it should be more like information, informative'.

Despite reservations around some of the materials, overall the content and information provided in the manual and training materials were thought to be concise, up to date and informative, particularly the first session, which was centred on injecting practices. It was appreciated that, following the facilitator training event in London, elements of the manual were updated to include comments from the day and there was service user input in the content of the intervention:

It was well laid out, it was well thought up and you could see how much detail and how much time was put into it because it suited our service users straight away. You could see the service user input in it. As much as we don't know what their input was, you could see it in the design of it.

An unexpected outcome mentioned during the facilitator focus groups was the intention to use elements of the manual for staff training and for future use with clients.

Intervention delivery

The facilitators spent, on average, 1 hour preparing for the intervention – familiarising themselves with the session, and ensuring that information technology (IT) equipment was working and that the materials were ready for use. Incorporating the intervention into their existing workloads was relatively easy for those who had planned ahead and had block-booked the time needed to deliver the intervention and/or adjusted their workload accordingly. For one team it was more difficult as they had to include the intervention in an already busy schedule:

> *I don't think it made the 3 weeks any, feel any busier, because there was a lot of other things going on that made my workload heavier, it was just so hard to find two hours when there wasn't something else already booked in.*

Facilitators were most comfortable delivering the first session on safe injecting practices because this is a familiar topic for the workers and they also found this session interesting, particularly in relation to feedback from participants around bleaching and cleaning needles. Although they did not deliver the intervention to a group, the York facilitators also mentioned that they would be comfortable delivering the TALK activity.

The parts of the intervention that the facilitators found challenging to deliver were keeping to time in the first session as a result of the volume of content; discussions around sexual risk behaviours because of facilitators feeling less skilled to answer some questions; and reading verbatim from the manual (sometimes long sections of text), which the facilitators thought hindered their own natural style of delivery.

The first session worked well in Glasgow as it generated discussion, taught the participants the importance of hygiene, engaged the participants enough to attend the second session and resulted in safer injecting practices (e.g. handwashing, tourniquet use). In London, the facilitators thought that all of the content was important and the myths and facts and question/answer activities worked well. In Wrexham, the third session worked best as the facilitators reported a better balance between the narrative and interactive elements plus the activities opened up discussion among the group, allowing the facilitators and participants to talk more openly than they might when attending services for usual care.

The didactic elements of the intervention worked less well for the facilitators as they felt that participants engaged better with the interactive exercises. The 'rate the risk' activity cards used in session 2 used direct quotations from peers – these were considered ambiguous or not clear in the key message that was to be explored and some participants did not like the use of colloquial language. Repetition of the handwashing message and the flow of some of the sessions were criticised by the London team.

In London, the sessions were facilitated by one drug worker and one peer mentor in each of the gendered groups. The female facilitators were comfortable co-facilitating and appeared to have enjoyed the experience, with the key worker reporting that she learnt from the peer mentor during practice sessions. However, because of the narrative text the key worker felt that there was too little space to bring in the peer mentor's experiences during the actual sessions:

> *. . . you see because when we practised and you talked, even I just learned from her (referring to peer mentor) when we were practising, you know . . . But when it was in the session I felt almost like that there's so much stuff we didn't have time to . . . we didn't show our complementarity, we were just repeating you know the same kind of . . . The only maybe one passage when you started to say something, I remember that it was a little bit similar to when we practiced, but because we tried to follow the protocol it gives a little bit less space for the facilitator or the peer mentor to bring a little bit their person.*

When asked what they would change in the intervention, the Glasgow facilitators said they would ensure that participants were forewarned that the first session would take longer than 1 hour. In London, Wrexham and York they would make it less didactic and more interactive. The facilitators in Wrexham also suggested

updating the videos and having a video in the planning for risk situations section that relays a hypothetical situation that participants can discuss rather than having them talk about personal risk situations:

> *I think the session about planning, or the reasons why, there could be more to go on that. So maybe some videos. We don't want people to do role play but maybe we could see a little film that would give people a discussion point to say have you got any suggestions, what would you have done in her situation. And take it away from being personal, especially in the girls group, especially with people who may or may not get on with each other or trust each other. I think you need something impersonal, I don't think it really works people talking about themselves and in a group that people were made to go to and weren't getting paid to go to, I could see a service user turning round to someone else 'oh, that's like you, someone told me you never wear a condom'. I think it's to get away from it being personal. I think maybe something with actors, a couple of little scenarios done as a video.*

In London, the facilitators suggested bringing in BBV nurses, practitioners who can teach proper injecting techniques/demonstrate use of vein finders and sexual health workers to provide specialist knowledge for relevant sections of the intervention.

York, Wrexham and London held their men's groups in the morning and women's groups in the afternoon (no participants attended the groups in York); Glasgow held their men's group in the afternoon. All facilitators thought that the times allocated were reasonable and made sure that none was too early in the day. In York, London and Glasgow the interventions were held at a local drug service and in Wales at a homeless drop-in service. York thought that there may have been issues with the venue being in the centre of York and the cost of travel to attend. Wrexham and Glasgow both thought that the familiarity and centrality of the venues were good and London reported no concerns.

None of the facilitators would use the PROTECT study intervention in its entirety, but would use elements from the manual in their own practice. In Glasgow, the safe injecting practice videos, the TALK activity and the preparedness plan would be used on a one-to-one basis (the last two especially with female service users). Glasgow would not use the 'rate the risk' activity cards (session 2) and had some reservations regarding discussion of sexual behaviour risks and information on bleaching. Wrexham would use elements from the first session utilising the videos, but they would leave out the narrative and shorten it to the most salient points required by the individual clients. York would also use the videos and some of the PowerPoint slides.

When asked what clients they would target for the intervention, new referrals, new injectors and 'hidden clients' (those not accessing services) were suggested, as were people attending recovery groups, NPS users, IPED users, needle exchange attenders not accessing drug treatment, sex workers and people engaging in chemsex.

In addition to the changes already recommended, facilitators suggested that further development of the intervention could include the use of bite-size information for clients using the needle exchanges, use of mobile phone applications or quick response (QR) scanners, and an online resource for services to access with clients and/or as a staff training tool.

Facilitator learning

Attending the training and delivering the intervention was instructive for the facilitators. For example, in Glasgow the facilitators were surprised at the range of injecting techniques and risk behaviours that participants engaged in and the participants' lack of knowledge around risk behaviours and acceptance of conditions such as BBVs and soft-skin tissue infections:

> *People see abscesses, cellulitis, that kinda thing as part and parcel of being an injecting drug user as opposed to a, something that you can prevent . . . And I think that's why education's never been picked up because folk are still getting the end result of a hit and that they see it being part of, you know, part of being a drug user is that you're gonnae get abscesses and cellulitis.*

In London, the female key worker reported learning a lot from the peer mentors, particularly around use of citric acid and alcohol swabs. In Wrexham, as with Glasgow, they were surprised at the reluctance of participants to accept the information given on bleaching needles, but they were also pleased that they were able to engage in a dialogue with clients that normally would not happen during usual service contact, 'We kind of make lots of assumptions so it's good for them to have a little space to tell us things'. Although York did not deliver to participants, they had gained information on different injecting practices at the training event, particularly from the peer mentors, which they reported as useful to know and giving them more confidence when talking to needle exchange clients in future practice.

Participant engagement and attendance

Glasgow and Wrexham reported that the participants were engaged in the intervention, particularly during the first session. Suggestions for increasing attendance were widening out the services recruited from, and using, social media (Glasgow); changing the design of the recruiting leaflet; engaging with staff to enhance recruitment; and meeting briefly with prospective participants to introduce the facilitator(s) and intervention content (London); recruiting more people and widening the geographical area from which participants are recruited (Wrexham); moving to a community-based venue; and making staff more aware of the intervention and need to recruit (York). Overall, however, the facilitators felt there was little more that could have been done within the parameters of the recruitment strategy of the study.

PROTECT study session feedback questionnaires

Facilitators

Facilitator questionnaires were completed by two facilitators after each intervention session. Data are presented for only London and Glasgow (*Tables 47* and *48*), as no intervention sessions were conducted in York. Facilitator questionnaires were erroneously completed by participants in Wrexham.

TABLE 47 Overall evaluation

Evaluation of sessions	Gender, mean rating	
	Male	Female
Session 1 ($n = 6$)		
Preparedness	4.3	4.0
Ability to answer questions	4.0	4.5
Overall rating	4.5	4.0
Session 2 ($n = 6$)		
Preparedness	4.3	5.0
Ability to answer questions	4.5	3.5
Overall rating	4.5	4.5
Session 3 ($n = 6$)		
Preparedness	4.5	5.0
Ability to answer questions	4.0	4.5
Overall rating[a]	4.5	4.5

a Responses on a scale of 1 (very poor) to 5 (excellent).
Responses on a scale of 1 (strongly disagree) to 5 (strongly agree).

TABLE 48 Session-specific questions

Evaluation of sessions	Gender			
	Male		Female	
	Number of participants	Mean score	Number of participants	Mean score
Session 1				
Participants understood the purpose of the intervention	4	4.5	2	3.5
Participants understood the group agreement and the commitment to confidentiality	4	4.3	2	4.5
Participants increased their knowledge around injecting techniques	4	4.3	2	4.0
Participants increased their knowledge around good vein care	4	4. 3	2	4.0
Participants increased their motivation to improve their injecting techniques	4	4.0	2	3.5
The videos used were relevant and informative	4	4.5	2	3.5
Session 2				
Participants have a better understanding of injecting risk behaviours	4	4.5	2	5.0
Participants have a better understanding of sexual risk behaviours	4	4.0	2	3.0
I am confident participants can use some or all of the plan to avoid risk behaviours	4	4.3	2	4.5
I am confident participants can apply TALK to reduce/avoid risks	4	4.3	2	4.0
I am confident participants can prepare for and avoid risky situations	4	4.5	2	5.0
The handouts were helpful	3	4.7	2	5.0
The exercises used where relevant and informative	4	4.5	2	5.0
Session 3				
Participants have a better understanding of BBVs	4	4.8	2	4.5
Participants have a better understanding of BBV transmission risk	4	4.5	2	4.5
Participants enjoyed the myths and facts exercise	4	4.5	2	4.5
Participants appear confident they can reduce their BBV transmission risk behaviours	4	4.5	2	4.5
Participants showed increased their motivation for safer injecting	4	4.3	2	4.5
The handouts were helpful	4	4.3	2	4.5
The videos use were relevant and informative	4	4.5	2	5.0

Data are mean responses on a scale of 1 (strongly disagree) to 5 (strongly agree).

Intervention facilitator evaluation forms

Session 1

There were five responses to the question 'What do you think worked best in today's session?' Facilitators thought that the information on vein collapse ($n = 2$), vein care ($n = 2$) and the videos ($n = 2$) worked best (*Table 49*).

There were six responses to the question 'What do think worked less well in today's session?' (*Table 50*). Facilitators thought that there was too much content to be covered in this session ($n = 3$), leading to problems with timing ($n = 2$), parts of the session being rushed through ($n = 2$) and the session over running ($n = 2$). The handwashing video was considered unnecessary by two facilitators.

TABLE 49 Responses to question 'What do you think worked best in today's session?'

What worked best in the session	Number of responses
Vein collapse information	2
Vein care information	2
Videos	2
Questions (regarding injecting difficulties – section 1.3)	1
New learning for clients	1
Understanding of service users' injecting practices	1
Participant engagement	1
Attendance	1
Refreshments	1

TABLE 50 Responses to question 'What do think worked less well in today's session?'

What worked less well in the session	Number of responses
Too much content	3
Timing	2
Rushed parts	2
Session ran over	2
Handwashing video not necessary	2
Handwashing video not well received	1
Not well prepared	1
Omitted material	1

There were six responses to the question 'How do you think today's session could be improved?' (*Table 51*). Facilitators' suggestions for improvement involved shortening the session ($n = 3$) and having less content ($n = 2$). One facilitator suggested dividing this session into two sessions. Another facilitator suggested having a three-dimensional image of the body in the background when doing the section on injecting sites (section 1.5).

TABLE 51 Responses to question 'How do you think today's session could be improved?'

What could be improved in the session	Number of responses
Shorten session	3
Less content	2
Finish on time	1
Divide session into two sessions	1
Keeping an eye on the time	1
Being better prepared	1
Use a three-dimensional image of the body, with veins and arteries in background while doing injection sites (section 1.5)	1

Three facilitators offered 'additional comments', with two of the three noting that the session had been informative for them (*Table 52*).

TABLE 52 Responses to option of providing additional comments

Additional comments	Number of responses
Informative for facilitators/informative for facilitators regarding injecting drug use in area and participants' own injecting experiences	2
Simplify information in section on injecting sites (section 1.5)	1
Session went well	1
Participants contributed a lot to the session	1

Session 2

Table 53 shows the five responses to the question 'What do you think worked best in today's session?' Facilitators thought that the risk situations exercise and discussion worked best ($n = 2$) and also that participants were well engaged ($n = 2$).

There were five responses to the question 'What do think worked less well in today's session?' Facilitators thought that the 'rate the risk' activity cards worked less well (i.e. reading the cards was difficult or uncomfortable for participants) ($n = 2$) and the language used may be perceived to be stigmatising ($n = 1$) (*Table 54*). Two facilitators noted that there was 'nothing' that worked less well.

There were four responses to the question 'How do you think today's session could be improved?' (*Table 55*). Two facilitators suggested shortening the 'rate the risk' activity cards or having less cards.

TABLE 53 Responses to question 'What do you think worked best in today's session?'

What worked best in the session	Number of responses
Participant engagement	2
Discussion/dealing with risk situations	2
Discussion/exercises	1
Structure of session	1
Less content	1
Clock in room	1
Risk scenario exercise	1
TALK	1

TABLE 54 Responses to question 'What do think worked less well in today's session?'

What worked less well in the session	Number of responses
Reading the 'rate the risk' activity cards was difficult/uncomfortable for participants	2
Nothing	2
Language in 'rate the risk' activity cards is stigmatising	1
Timing	1
Too much content	1

TABLE 55 Responses to question 'How do you think today's session could be improved?'

What could be improved in the session	Number of responses
Shorten/sharpen the scenarios on 'rate the risk' activity cards/use less cards for rate the risk activity	2
Focus the session more on participant's own risks and solutions	1
Difficulty following the manual and not being able to use own notes	1
Not being ill	1

One facilitator offered 'additional comments', noting that session 2 had been better than session 1 as there was more time for participant discussion and interaction (*Table 56*).

TABLE 56 Responses to option of providing additional comments

Additional comments	Number of responses
Session was better as there was more time for discussion/interaction	1
No	1

Session 3

There were six responses to the question 'What do you think worked best in today's session?' All six facilitators thought that the myths and facts exercise about BBVs worked best (*Table 57*). The discussion and participants' questions ($n = 2$), and the timing of the session ($n = 2$) were also thought to work well.

There were six responses to the question 'What do think worked less well in today's session?' The main issue raised by facilitators was the poor quality of the DUIT cross-contamination video ($n = 3$) (*Table 58*).

TABLE 57 Responses to question 'What do you think worked best in today's session?'

What worked best in the session	Number of responses
Myths and facts cards	6
Questions/discussion	2
Timing	2
Statistics on prevalence of BBVs in UK	1
Participants had many questions	1
Video	1
Whole session worked well	1
Attendance	1

TABLE 58 Responses to question 'What do think worked less well in today's session?'

What worked less well in the session	Number of responses
Video was slow/difficult to see/poor quality	3
Had difficulty answering participants' BBV questions	1
Preparedness plan	1
Attendance	1

Table 59 shows the four responses to the question 'How do you think today's session could be improved?' Responses were varied and included having more visual presentation of information ($n = 1$), having less information on bleaching ($n = 1$) and having more time to prepare the room for the session ($n = 1$).

Three facilitators offered 'additional comments' (*Table 60*). Comments included that the intervention had gone well ($n = 1$) and the discussion had been valuable ($n = 1$). One facilitator noted that they had enjoyed delivering the intervention and one suggested having a greater focus on participants' own injecting difficulties.

TABLE 59 Responses to question 'How do you think today's session could be improved?'

What could be improved in the session	Number of responses
More visual presentation of information	1
Less on bleaching	1
Having time to prepare room for session	1
Not sure	1

TABLE 60 Responses to option of providing additional comments

Additional comments	Number of responses
Enjoyed facilitation	1
Went very well	1
Discussion was valuable	1
Focus more on participants own injecting difficulties	1

Participants

No intervention sessions were conducted in York. In Wrexham, feedback questionnaires were stored in one place; therefore, the appropriate gender group could not be determined. *Tables 61* and *62* show an overview of the feedback.

TABLE 61 Overall evaluation

	Gender, mean rating		
Evaluation of sessions	Male	Female	Unknown (mean)
Session 1 ($n = 17$)			
Trainer knowledgeable	4.4	5.0	4.8
Questions answered	4.6	5.0	4.8
Overall rating	4.4	4.3	4.8
Session 2 ($n = 13$)			
Trainer knowledgeable	4.6	4.7	4.5
Questions answered	4.5	4.7	5.0
Overall rating	4.5	4.7	4.0
Session 3 ($n = 15$)			
Trainer knowledgeable	4.7	5.0	5.0
Questions answered	4.7	5.0	4.8
Overall rating[a]	4.5	4.5	5.0

a Responses on a scale of 1 (very poor) to 5 (excellent).
Responses on a scale of 1 (strongly disagree) to 5 (strongly agree).

TABLE 62 Session-specific questions

Evaluation of sessions	Gender					
	Male		Female		Unknown	
	Number of responses	Mean score	Number of responses	Mean score	Number of responses	Mean score
Session 1						
I understood the purpose of the intervention	8	4.5	3	5.0	6	4.8
I understood the group agreement and the commitment to confidentiality	8	4.4	3	5.0	6	4.5
I have increased my knowledge around injecting techniques	8	4.0	3	5.0	6	4.2
I have increased my knowledge around good vein care	8	4.0	3	5.0	6	4.5
I have increased my motivation to improve my injecting techniques	8	4.3	3	5.0	6	4.2
I have increased my motivation to improve my vein care	8	4.3	3	5.0	6	4.7
The videos used were relevant and informative	8	4.0	3	5.0	6	4.5
Session 2						
I have a better understanding of injecting risk behaviours	8	4.1	3	4.7	2	4.0
I have a better understanding of sexual risk behaviours	8	4.0	3	4.7	2	4.0
I am confident I can use some or all of the plan to avoid risk behaviours	8	4.4	3	5.0	2	4.5
I am confident I can apply TALK to reduce/avoid risks	8	4.0	3	4.3	2	3.5
I am confident I can prepare for and avoid risky situations	8	4.3	3	4.7	2	4.5
The handouts were helpful	8	4.5	3	4.3	2	4.5
The exercises used where relevant and informative	8	4.4	3	4.3	2	4.5
Session 3						
I have a better understanding of BBVs	7	4.9	2	5.0	6	4.8
I have a better understanding of BBV transmission risk behaviours	7	4.9	2	5.0	6	4.8
I enjoyed the myths and facts exercise	7	4.6	2	5.0	6	4.8
I am confident I can reduce my BBV transmission risk behaviours	7	4.9	2	5.0	6	5.0
I have increased my motivation for safer injecting	7	4.7	2	5.0	6	5.0
The handouts were helpful	7	4.3	2	4.5	6	5.0
The videos use were relevant and informative	7	4.4	2	5.0	6	5.0

Data are mean responses on a scale of 1 (strongly disagree) to 5 (strongly agree).

Intervention participant evaluation forms

Session 1

There were 15 responses to the question 'What did you like most about today's session?' Responses were varied and referred to the content and process of the group intervention (*Table 63*). The most common responses were the opportunity afforded to learn new information ($n = 4$), the information on safer injecting/drug use ($n = 3$), the vein care information ($n = 2$) and the openness of the group ($n = 2$).

TABLE 63 Responses to question 'What did you like most about today's session?'

What was liked the most in the session	Number of responses
Learning new information	4
Safer using/injecting	3
Vein care information	2
Openness of group	2
Learning how to keep clean while injecting	1
Information was well explained	1
Group discussion	1
Unclear	1

There were 13 responses to the question 'What did you like least about today's session?' The most common response was that there was 'nothing' least liked ($n = 6$). Remaining responses varied greatly (*Table 64*). One participant thought that the session was too long, whereas another thought that it was too short. One participant thought that the handwashing video was condescending. Other comments referred to the circumstances of the session in particular localities on that day (e.g. delay before the session started, having to hurry at the end of the session).

There were 13 responses to the question 'How do you think today's session could be improved?' The most common response was that the session required no improvements ($n = 7$). Other responses included improving the sound quality of the videos ($n = 1$), making the session even more interactive ($n = 1$), having more people in the group ($n = 1$), making the session longer ($n = 1$) and having more information ($n = 1$) (*Table 65*).

TABLE 64 Responses to question 'What did you like least about today's session?'

What was liked the least in the session	Number of responses
Nothing	6
Handwashing video is condescending	1
People telling war stories	1
People talking out of the side of their neck	1
Session was too long	1
Session was not long enough	1
Lengthy delay before session started	1
Having to hurry at end	1
The ending	1

TABLE 65 Responses to question 'How do you think today's session could be improved?'

What could be improved in the session	Number of responses
Could not be improved on/nothing/good enough as is	7
Sound quality of videos	1
Make it more interactive	1
More people in group	1
Make the session longer	1
Have more information	1
Punctual attendance	1
On the whole it was OK	1
Maybe a lot cause I'm trying to stay clean (unclear)	1

Session 2

There were eight responses to the question 'What did you like most about today's session?' (*Table 66*). Participants most liked learning new information ($n = 3$) and the TALK exercise ($n = 2$).

There were seven responses to the question 'What did you like least about today's session?' The most common response was that there was 'nothing' least liked ($n = 6$). One participant disliked the language used in the 'rate the risk' activity cards (*Table 67*).

There were six responses to the question 'How do you think today's session could be improved?' Two participants noted that the session required no improvement. One participant suggested having 'better' 'rate the risk' activity cards, whereas another suggested removing 'slang' from the cards (*Table 68*). Other responses referred to the circumstances of the session in particular localities on that day (e.g. session starting late, room too warm).

TABLE 66 Responses to question 'What did you like most about today's session?'

What was liked the most in the session	Number of responses
Informative/learning new information	3
TALK/knowing your boundaries (bottom line – TALK)	2
All of it	1
Openness of group	1
Group discussion	1
Patience (unclear)	1

TABLE 67 Responses to question 'What did you like least about today's session?'

What was liked the least in the session	Number of responses
Nothing/enjoyed it all	4
Language in 'rate the risk' activity cards	1
Too quick	1
My motivation (unclear)	1

TABLE 68 Responses to question 'How do you think today's session could be improved?'

What could be improved in the session	Number of responses
Fine as is/nothing	2
Remove slang from 'rate the risk' activity cards	1
Better (rate the risk activity) cards	1
Allocate time to each section	1
Trainers ready to start session on time	1
Room could be cooler	1
Enough sleep beforehand	1

Session 3

Table 69 shows the 15 responses to the question 'What did you like most about today's session?' Participants most liked learning new information ($n = 3$), and the information about BBVs ($n = 2$), HCV transmission ($n = 2$) and safer drug use ($n = 2$).

There were 10 responses to the question 'What did you like least about today's session?' (*Table 70*). The most common response was that there was 'nothing' least liked ($n = 6$), followed by people talking over each other ($n = 2$). One participant disliked the DUIT video.

There were 12 responses to the question 'How do you think today's session could be improved?' (*Table 71*). Most participants thought that the session needed no improvement ($n = 7$). Two participants wanted more sessions or a longer session.

TABLE 69 Responses to question 'What did you like most about today's session?'

What was liked the most in the session	Number of responses
Informative/learning new information	3
Information about HCV/BBV	2
Learning how HCV is transmitted	2
Information on safer using/how to look after myself better	2
Learned how long HCV and HIV live outside the body	1
Video (cross-contamination)	1
Good to revisit information	1
Corrected misinformation	1
The questions that came up	1
Feedback was good	1
Revising material from earlier sessions	1
Politeness of group	1
It was all good	1
Enjoyable	1

TABLE 70 Responses to question 'What did you like least about today's session?'

What was liked the least in the session	Number of responses
Nothing	6
People interrupting and talking over each other	2
Video of woman using needle	1
Was interesting	1

TABLE 71 Responses to question 'How do you think today's session could be improved?'

What could be improved in the session	Number of responses
Fine as is/nothing/could not be improved on/good	7
More sessions/larger session for more information?	2
Make the (myths and facts) game more interesting	1
Bigger group	1
Ask group what refreshments they would like	1

Summary/discussion

Intervention group participants who attended the PROTECT study sessions rated the sessions highly. Participants reported that they had gained valuable knowledge on BBV transmission, safer drug use, hygiene and handwashing, cleaning equipment and preparing for risk situations such as withdrawal. Participants also valued being exposed to both service user and professional points of view, the opportunity afforded by the intervention to talk about topics not normally discussed and the variety of information included in the intervention. When asked how the PROTECT study intervention could be improved, participants suggested making the intervention more visual and interactive, and incorporating more practical instruction around injecting technique and injecting sites. It was also suggested that the videos illustrating the side effects of injecting should be more graphic and feature real people rather than animations. Incorporating online/social media (YouTube and Facebook) and including information on legal highs were also suggested to make the intervention more relevant and attractive to younger people.

Facilitators who delivered the PROTECT study intervention thought that the training event had prepared them for delivery. However, they suggested using a more suitable venue for the training and delivering the training event over 2 days, with equal time devoted to each of the three PROTECT study sessions and incorporating opportunities for mock delivery. Facilitators liked that peer educators were involved in the training event. They also appreciated that their input had been incorporated into the final version of the PROTECT study manual. Facilitators who delivered the PROTECT study sessions rated them highly and thought that the content was relevant and up to date. They reported that being involved in the intervention had improved their knowledge and led to changes in their practice with needle exchange clients. However, it was felt that session 1 had too much content and could not realistically be delivered within 1 hour. Facilitators were less comfortable delivering the didactic parts of the intervention and discussing sexual risk behaviour. When asked how the intervention could be improved, they suggested making it more interactive, improving the quality of the videos and including specialist workers for specific components (e.g. injecting instructors, BBV nurses or sexual health practitioners). Other potential modes of delivery for the PROTECT study intervention, which facilitators suggested, were delivery in bite-size pieces to clients, developing as an application or QR code scanner or as an online resource for staff training. It was also suggested that the preparedness plans could be incorporated into clients' care plans. Key target groups for the intervention, which facilitators identified, were new referrals to treatment, new injectors, sex workers, people who inject who engage in chemsex, people who inject IPEDs and people who inject NPSs.

The facilitator and participant evaluation forms reflected the findings from the focus groups in that there was an overall positive rating of each of the three sessions, with some suggestions for improvement around the timing of session 1 and some of the activities and visual imagery.

Chapter 7 Protocol changes

There were no changes to the protocol. Two minor amendments were submitted to the East Midlands – Leicester South Research Ethics Committee. The committee did not consider these to be substantial amendments, as defined in the Standard Operating Procedures for Research Ethics Committees. These amendments did not therefore require an ethics opinion from the committee and were implemented immediately following approval letters being signed by the Research Ethics Committee assistant.

Minor amendment 1

The first request for a minor amendment was submitted on 17 December 2015 and written permission was given on 31 December 2015 to implement the changes. The first minor amendment was to include the name of the drug treatment service where the intervention was being delivered in London and to change that participants would receive a 'shopping voucher' to 'a small sum of money' in the PIS for the feasibility trial for only London participants, as London was the only site to reimburse participants with cash rather than shopping vouchers.

Minor amendment 2

The second minor amendment was a request to include additional questions in the follow-up questionnaire for the feasibility trial. The request was submitted on 18 February 2016 and approved on 26 February 2016. The additional questions were included in an attempt to better understand the reasons for the low uptake of, and retention in, the PROTECT study intervention reported in some sites during the feasibility trial. The additional questions were as follows.

For all participants:

- Why did you decide to take part in the study?
- How did you find the randomisation process?

For intervention group participants only:

- Why did you decide to attend/not attend the sessions?

Chapter 8 Implications and dissemination of findings

Key findings from this study have been provided to a wide range of audiences described below.

Dissemination events

Key findings from the feasibility trial and presentation of the PROTECT study manual have taken place or are planned. Details of dissemination events and other presentations of study findings are described below.

- Lambeth Consortium Clinical Governance Meeting (the consortium being a partnership between South London and the Maudsley NHS Foundation Trust, Addaction, Phoenix Futures, Blenheim and Lambeth Local Authority) in London on 4 July 2016.
- Betsi Cadwaladr University Health Board Substance Misuse Service, North Wales. Two separate events on 20 and 21 July 2016.
- Commissioner and Provider Research Engagement Event in Huddersfield on 28 July 2016.
- Lambeth service user group meeting in London on 19 August 2016.
- London Joint Working Group on Substance Use and Hepatitis C Annual Conference in London on 24 October 2016.

Individual dissemination meetings to discuss implementation of the intervention in real-world settings and engagement in future research

The extensive stakeholder consultation carried out as part of this work clearly illuminated a wide range of service designs, resources and priorities across the NHS and voluntary sector service providers and the groups commissioning substance misuse services across the UK. We thus considered it as essential that the results and conclusions of this study, in terms of intervention design and trial feasibility, were considered against the real-world back drop of current and likely future funding to the health sector responsible for delivering BBV infection prevention initiatives.

To address this we conducted post-study consultations with the following key stakeholders from across the study regions, as well as regions that had stated an interest in being involved in a future trial of the PROTECT study intervention:

- The Hepatitis C Trust, 1 June 2016.
- London Joint Working Group on Substance Use and Hepatitis C, 3 June 2016.
- Cardiff & Vale University Health Board (Wales), 13 June 2016.
- Aneurin Bevan University Health Board (Wales), 13 June 2016.
- Betsi Cadwaladr University Health Board (Wales), 14 and 15 June 2016.
- Public Health England, 29 June 2016.
- Surrey and Borders Partnership NHS Foundation Trust (England), 6 July 2016.
- The University of Dundee (Scotland), 18 July 2016.

These consultations took the form of an informal presentation of the findings and discussion with senior management and staff from these organisations. The discussions sought to determine:

- any challenges with conducting the feasibility trial
- anticipated challenges and opportunities presented were the PROTECT psychosocial intervention to be introduced into their service
- development of the PROTECT study intervention
- key target areas for future research.

There was overall support for the approach and content of the intervention.

One service where dissemination took place had been a research site for the feasibility trial. They highlighted specific issues that had arisen with regard to lack of readily available technology within their organisation to deliver the intervention. Moreover, they highlighted, as did others from the other localities where dissemination took place, the need for local areas to have the flexibility to deliver the intervention content as they feel would best meet local service users' needs. Many services reflected that the group format and manualised delivery of the intervention content was not considered feasible if the intervention were to be rolled out. In some areas, groups were not considered the most appropriate method for the intervention delivery. Rather, individual, opportunistic discussions or bite-size messages with key workers, or when a client presents to needle exchange or to a service with an injection problem (e.g. abscess) may be more suitable. Given the considerable variation in risk profiles of PWID and in service profiles, a tailored bespoke intervention in each locality would be required.

During the feasibility trial, CM was used to encourage retention in the intervention and transport was reimbursed in some areas. This is not usual practice for most areas and additional funding would have to be sought to continue with this if the intervention were to be rolled out.

Other modes of delivery suggested were (1) weekly themes to be advertised and addressed at needle exchange sessions (e.g. finding a vein, abscesses, etc.); (2) delivering the three-session intervention in one session; (3) developing the intervention as a mobile application, QR code scanner or video resource; or (4) developing the intervention as an online training resource for harm reduction staff. It was also recommended that the development of preparedness plans could be incorporated into clients' care plans.

These harm reduction messages could also be given to new injectors at assessment or following BBV infection testing. These were considered windows of opportunity to address any BBV transmission risk behaviours. Other key target groups for this type of intervention were PWID who are engaged in sex work, PWID who are engaged in chemsex, people who inject performance-enhancing drugs and those who inject NPSs. Additional delivery sites suggested by facilitators, policy-makers, practitioners and academics were needle exchanges (including brief interventions delivered by pharmacy needle exchanges), opiate substitution treatment programmes, hostels for homeless people and in prison.

The intervention could also be used as a stand-alone training document for key workers and needle exchange staff. Those who delivered the intervention reported that being involved in the intervention had improved their knowledge and led to changes in their practice with delivering harm reduction messages and advice to needle exchange clients. However, with the budget for continuing professional development being cut by 40% by Health Education England, it is currently unclear who would be able to develop and deliver training courses related to this type of intervention. One of the key discussions going forward with public health and providers of services is how important staff development training can be delivered, by whom and how it is resourced.

All health authorities consulted during the dissemination phase were supportive of being involved in further development of the PROTECT study intervention to address the needs of other groups of PWID who may be at risk of acquiring BBVs, such as those involved in chemsex, sex work, new injectors and

those who were injecting NPSs. In addition, all health authorities offered to be research sites for future studies to test the feasibility and effectiveness of any modified PROTECT study intervention for these suggested groups of PWID.

Policy briefing

A briefing of key findings and recommendations has been e-mailed to all alcohol and drug commissioners in the UK.

Conferences

The following poster and oral presentations have been presented at conferences or have been accepted for presentation:

- Swan D. *The Efficacy of Psychosocial Interventions to Reduce Sexual and Drug Blood Borne Virus Risk Behaviours Among People Who Inject Drugs: A Systematic Review and Meta-Analysis* (poster presentation). Society for the Study of Addiction Annual Symposium. York, UK. 5 and 6 November 2015.
- Swan D. *Blood Borne Virus Risk Behaviours Among People Who Inject Drugs in the UK: A Qualitative Exploration* (poster presentation). Society for the Study of Addiction Annual Symposium. York, UK. 5 and 6 November 2015.
- Gilchrist G. *Feasibility of the PROTECT Group Intervention to Improve Injecting Skills and Reduce Bloodborne Virus Risk Behaviours Among People Who Inject Drugs.* Society for the Study of Addiction Annual Symposium. York, England. 9–10 November 2016.
- Swan D. *Blood Borne Virus Risk Behaviours Among People Who Inject Drugs in the UK: A Qualitative Exploration* (oral presentation). The 5th International Symposium on Hepatitis Care in Substance Users. Oslo, Norway. 7–9 September 2016.
- Swan D. *The Efficacy of Psychosocial Interventions to Reduce Sexual and Drug Blood Borne Virus Risk Behaviours Among People Who Inject Drugs: A Systematic Review and Meta-Analysis* (poster presentation). 5th International Symposium on Hepatitis Care in Substance Users. Oslo, Norway. 7–9 September 2016.
- Gilchrist G, Swan D, Shaw A, Towers S, Craine N, Munro A, *et al. Feasibility of the PROTECT Group Intervention to Improve Injecting Skills and Reduce BBV Risk Behaviours in People Who Inject Drugs* (poster presentation). Sydney, NSW, Australia. Australian Professional Society for Alcohol and other Drugs Scientific Alcohol and Drug Conference 2016. 30 October–2 November 2016.
- Gilchrist G, Swan D, Widyaratna K, Marquez JE, Hughes L, Mdege ND, *et al. Influences on Blood Borne Virus Risk Behaviours by People Who Inject Drugs in the UK: A Qualitative Exploration* (poster presentation). Australian Professional Society for Alcohol and other Drugs Scientific Alcohol and Drug Conference 2016. Sydney, NSW, Australia. 30 October–2 November 2016.
- Gilchrist G, Swan D, Shaw A, Towers S, Craine N, Munro A *et al. The PROTECT Study; A Feasibility Trial of a Psychosocial Intervention to Reduce Blood Borne Virus Risk.* Public Health Wales, Public Health Research, Policy and Practice: Working Together in Wales (Research Showcase Event). Cardiff, UK. 2 March 2017.
- Gilchrist G, Swan D, Widyaratna K, Marquez JE, Hughes L, Mdege ND, *et al. A Systematic Review and Meta-Analysis of Psychosocial Interventions to Reduce Drug and Sexual Blood Borne Virus Risk Behaviours Among People Who Inject Drugs.* Lisbon Addictions 2017. 2nd European Conference on Addictive Behaviours and Dependencies. Lisbon, Portugal. 24–26 October 2017.
- Gilchrist G, Swan D, Shaw A, Towers S, Craine N, Munro A, *et al. Improving Injecting Skills and Preventing Blood Borne Virus Infection in People Who Inject Drugs in the UK: A Feasibility Randomised Control Trial of a Psychosocial Intervention (PROTECT).* Lisbon Addictions 2017. 2nd European Conference on Addictive Behaviours and Dependencies. Lisbon, Portugal. 24–26 October 2017.

Published peer-review publications

- Gilchrist G, Swan D, Widyaratna K, Marquez-Arrico J, Hughes E, Mdege N, *et al.* A systematic review and meta-analysis of psychosocial interventions to reduce drug and sexual blood borne virus risk behaviours among people who inject drugs. *AIDS Behav* 2017;**21**:1791–11.
- Gilchrist G, Swan D, Shaw A, Keding A, Towers S, Craine N, *et al.* The acceptability and feasibility of a brief psychosocial intervention to reduce blood-borne virus risk behaviours among people who inject drugs: a randomised control feasibility trial of a psychosocial intervention (the PROTECT study) versus treatment as usual. *Harm Reduct J* 2017;**14**:14.

Peer-review publications in preparation

- Swan D, Shaw A, Towers S, Mdege N, Craine N, Widyaratna K, *et al.* Blood borne virus transmission risk behaviours among people who inject drugs in the UK: a qualitative exploration.
- Crank-Burnet N, Swan D, Gilchrist G. Chemsex and injecting drug use: an interpretative phenomenological analysis of blood borne virus risk behaviours.

Social media

Links to key publications and to the key outputs from the study will be tweeted via the National Addiction Centre at King's College London Twitter account (Twitter, Inc., San Francisco, CA, USA).

Website

The intervention manual and related materials are available to download free of charge on the project website [URL: www.kcl.ac.uk/ioppn/depts/addictions/research/drugs/bloodborneviruses.aspx (accessed 10 October 2017)].

Intervention recommended in other resources

Public Health England has included the link to the PROTECT study intervention manual and related materials in its Joint Strategic Needs Assessment Support Pack to assess and respond to local needs. The final HTA programme report and educational materials will be hosted on the Public Health Network Cymru internet site, R&D, resources, publications and report page [URL: http://research.publichealthnetwork.cymru/en/resources?keyword=&cat=1 (accessed 10 October 2017)].

Chapter 9 Discussion and conclusions

Main findings

We interviewed 60 PWID in depth from harm reduction services, pharmacy needle exchanges, hostels for homeless people and sexual health clinics in Glasgow, London, North Wales and York. Findings highlight that withdrawal and craving created an urgency to inject which led to needle, syringe and equipment sharing. Homeless PWID had difficulties accessing the resources needed for safer injecting (e.g. sterile water, hygienic environment). Inexperience in injecting and difficulties with venous access created dependence on others to administer injections. Trust in intimate relationships often took precedence over safer practice. In group injecting situations, younger, newer PWID may feel pressured to go along with unsafe practices. Needle exchange access, mental health, personal values and perceptions of risk also influenced risk behaviour. Participants ascribed risk behaviours to pressures of withdrawal, craving and intoxication. Lack of BBV transmission knowledge, inexperience in the physical process of injecting and poor vascular access also resulted in unsafe injecting practices. Interpersonal relationships based on trust, intimacy and/or dominance, and group norms and dynamics, also influenced risk. Unstable housing and sex work diminished participants' agency to manage risk.

Despite over a decade of national and UK plans to reduce BBV and strategies to reduce harm to PWID, PWID continue to engage in BBV injecting and sexual risk-taking behaviours.

Individual, situational and structural factors drive vulnerability to BBV infection among PWID. Priorities and risks other than BBV transmission are often paramount for PWID. BBV prevention initiatives should address 'symbiotic' goals for PWID, such as improving injecting techniques and maintaining venous access to promote the use of sterile injecting equipment. Protective practices and strategies to avoid risk situations, such as withdrawal, should also be considered.

We conducted a systematic review with meta-analysis that found that psychosocial interventions are effective in reducing sexual and drug risk behaviours among PWID.

We developed a three-session, gender-specific psychosocial group intervention to reduce BBV transmission behaviours among PWID, informed by evidence resulting from our research and expert opinion. The PROTECT study intervention included skills to improve injecting techniques and thus vein care, and strategies to avoid and plan for risk situations that PWID had themselves identified in in-depth interviews. Ninety-nine PWID from needle exchanges and harm reduction services in London, York, Glasgow and Wrexham were randomised to receive the intervention plus a BBV transmission leaflet ($n = 52$) or the leaflet only ($n = 47$). Contingency management, in the form of a small voucher or cash payment (£10 per session and additional £10 if all three sessions were attended), was used to encourage intervention attendance.

Baseline characteristics were comparable between randomised treatment groups for males, despite the relatively small number of participants. Potential imbalances were observed in the smaller group of women (e.g. with a greater number of heroin users and homeless women in the intervention arm). Although it is not known why attendance and compliance was lower among women, it may be that women were more likely to be responsible for child care and household duties than men. These competing priorities may have contributed to the lower attendance and compliance.

More participants attended at least one intervention session in London (10/16, 63%) and Wrexham (7/13, 54%) than in Glasgow (3/12, 25%) and York (0/11, 0%). Participants from Glasgow and York reported higher levels of homelessness, injected on a greater number of days and used more needles from a needle exchange in the last month which may have contributed towards lower attendance. Forty-five per cent

(45/99) were followed up 1 month post intervention. Follow-up was associated with fewer days of injecting in the last month. Follow-up attendance (one or both times) was associated with fewer days of injecting drugs in the last month (median 14 vs. 27 days; $p = 0.030$) and fewer injections of cocaine (13% vs. 30%; $p = 0.063$). Compared with participants who did attend at least one intervention session ($n = 20$), participants who did not attend any sessions ($n = 32$) were more likely to be homeless (56% vs. 25%; $p = 0.044$), injected drugs for a greater number of days in the last month (median 25 vs. 6.5 days; $p = 0.019$) and used a greater number of needles from a needle exchange in the last month (median 31 vs. 20 needles; $p = 0.056$). They were more likely to be predominant heroin injectors (69% vs. 40%; $p = 0.055$ for type of drug) and less likely to inject crack (31% vs. 55%; $p = 0.146$). These differences were true for males and females, apart from homelessness, which did not show differences for women, although numbers were small.

Analyses revealed improved (fewer) injecting risk practices, improved self-efficacy, better HCV and HBV transmission knowledge and greater use of withdrawal prevention techniques in the intervention arm. This was true at both follow-up time points and both analyses for randomised groups and groups based on attendance of the intervention. Little change for any group was seen for HIV transmission knowledge. Compared with those who attended no sessions, a trend towards greater reductions in injecting risk behaviours, increases in withdrawal planning and increased self-efficacy around finding a vein, not sharing equipment, cleaning equipment and talking about safe drug use was reported by those who attended at least one session. More importantly, we did not observe any increase in either self-reported injecting in more 'risky' sites (e.g. groin, neck) among participants who had been exposed to at least one session of the intervention, and a trend towards injecting on fewer days in the past 30 days for those who had attended at least one session was reported. No adverse events were recorded as a result of participating in the feasibility trial. Therefore, we conclude that the PROTECT study intervention, focusing on improving injecting techniques and providing strategies and skills to avoid and plan for risk situations where BBV transmission risk behaviours were more likely to occur, did not result in injecting in more risky injecting sites despite being taught the skills to do so.

Attendance at at least one intervention session was highest in London (63%) and Wrexham (54%), whereas only 25% attended in Glasgow and no participants attended in York. Follow-up at a minimum of one time point (at the end of the intervention or 1 month post intervention) was also highest in London (83%) and Wrexham (63%), and significantly lower in Glasgow (55%) and York (43%). Participants from Glasgow and York reported higher levels of homelessness, and participants injected for a greater number of days and used more needles from a needle exchange, which may have contributed towards lower attendance rates. In addition, in York, text messages were sent to remind participants of intervention session times and dates from the service (reported preference of participants), whereas in other sites the researcher contacted participants by telephone to remind them of session dates and times a day in advance and also sent a reminder text the day of the intervention. Thus, talking with the researcher and the additional reminder may have resulted in increased attendance at the other sites. Moreover, as a result of the dedicated researcher leaving their position at the University of York, four staff from the CRN: York Teaching Hospitals NHS Trust were responsible for recruitment and follow-up of participants, whereas in other sites participants had contact with the same named researcher throughout the trial and this established relationship could also have contributed to increased attendance. Additional potential contributing factors for the differences in compliance and attendance across trial sites include reimbursement of travel (bus tickets), reimbursement of time and CM paid in cash (vs. high-street vouchers in other sites) and co-facilitation of the intervention by peer educators in the London site only.

It appears that the intervention did not meet the complex needs of PWID, particularly in York and Glasgow, potentially resulting in limited engagement of those potentially most at risk of engaging in BBV transmission behaviours (e.g. homeless PWID, more frequent injectors, people who inject crack, women). These findings are supported from the reflections of staff and researchers in York, Glasgow and Wrexham who believed that the clients recruited to the feasibility trial often had complex social, mental and physical health needs and were often not well engaged with services. Irrespective, those hard-to-reach PWID were the target group for this intervention.

Although the PROTECT study intervention has the potential to positively influence some PWID BBV risk behaviour and improve vein care, non-attendance at the intervention at the York trial site substantially influenced the results, highlighting the need for flexible adaptation of the intervention delivery according to local need to ensure that all PWID are reached. Local service users should be involved in the decisions about how best to adapt the intervention to meet their needs. Alternative intervention delivery methods may achieve greater reach and suggestions are discussed below.

A number of challenges for trial implementation were highlighted. There are many factors that may have contributed to the different uptake of, and retention in, the feasibility study across sites and, therefore, it is not possible to provide a definitive explanation of the differences in rates reported.

Feasibility parameters and the decision whether or not to progress to a definitive randomised controlled trial

Progression criteria for a definitive RCT were not predetermined prior to undertaking the feasibility trial. However, stop/go criteria would include (1) that the intervention is acceptable to staff and participants; (2) recruitment is at least 60%; and (3) at least 70% of participants are followed up at 3 months. Acceptability was assessed by facilitators and participants completion of feedback forms at the end of each session, and their participation in focus groups about their experience of delivering and attending the PROTECT study intervention. Feasibility parameters assessed were the proportion of PWID who consented to participate in the trial and were randomised to treatments arms, as well as intervention compliance and attrition rates over the course of the study. These parameters were summarised by location, setting and treatment arm.

Despite full recognition of the need for the intervention, and high acceptability of the usefulness and interest of its content, the recruitment (56%), intervention attendance (19% attended all three sessions) and 1 month post-intervention follow-up (47%) rates suggest that a future RCT of the intervention, in its current format, is not warranted.

Only 24% (8/34) of male [ranging from no men in York to 44% (4/9) in London] and 11% (2/18) of female participants (both from London) attended all three intervention sessions. No women attended any sessions at the York or Glasgow trial sites and no men attended any sessions at the York trial site. More participants attended at least one intervention session in London (10/16, 63%) and Wrexham (7/13, 54%) than in Glasgow (3/12, 25%) and York (0/11, 0%). The delivery of the intervention proved more feasible in London than other sites, with high attendance at the intervention (44% of males and 29% of females attended all three sessions) and high follow-up rates (89% of males and 71% of females). Potential reasons for the marked differences in attendance and compliance across sites and by gender have already been mentioned.

Overall, 50% (17/34) of men and 33% (6/18) of women randomised to the intervention group and 47% (14/30) of men and 53% (9/17) of women randomised to the control group were followed up 1 month post intervention. Follow-up at a minimum of one time point was also highest in London (83%) and Wrexham (63%) and significantly lower in Glasgow (55%) and York (43%), which may in part be linked to factors associated with higher homelessness and injecting frequencies in Glasgow and York.

Despite the difficulties in recruitment and intervention attendance, the intervention content was considered acceptable and no adverse events were reported. Considering that 57% of eligible participants agreed to be randomised, this suggests support for addressing BBV risk behaviours among PWID. Evidence that the intervention increased injecting frequency, or resulted in riskier injecting practices or injecting in riskier sites (e.g. neck or groin), would stop progression to a definitive RCT. Providing participants with information and skills to improve injecting techniques did not result in riskier injecting practices or in injecting in riskier injection sites, such as the neck or groin.

In summary, although the intervention content was acceptable to both staff and participants, and those attending at least one session of the intervention reported a trend towards greater reductions in injecting

risk behaviours and increases in planning for withdrawal and increased self-efficacy around finding a vein, the feasibility parameters suggest that it would not be practical to proceed to a full definitive trial.

The need for current harm reduction services to incorporate the PROTECT study intervention to routine practice

Despite over 30 years of needle exchange provision in many parts of the UK, around one in seven PWID continue to share needles and syringes,[55] highlighting the need to improve harm reduction services to prevent PWID from acquiring BBV infection. A recent report concludes that 'Current drug policy is failing to protect people from the risks of blood-borne virus infection, at huge cost to drug users, the community and the taxpayer' and recommends 'All services (both pharmacy-based and specialist needle exchanges) should be staffed and equipped to provide: Information and practical advice on safer injecting practices, avoiding site infections, prevention of transmission, safe disposal of used equipment'.[255] Harm reduction approaches mostly address risk factors associated with the sharing of injecting equipment and unprotected sex. Our research confirmed that PWID sometimes have different priorities, from improving their injecting techniques and maintaining venous access to preparing for situations where they may be more likely to take risks. PWID and staff confirmed that such advice and support was not routinely available or provided in harm reduction services, despite the belief by some key stakeholders that it was part of these services' core business. Possible reasons for this are discussed later in this chapter.

Although the feasibility trial identified issues with retention in the intervention, this does not mean that the PROTECT study intervention, or components of the intervention, should not be taken on board as a routine intervention to offer PWID as part of harm reduction provision. Findings from this research indicate that the PROTECT study intervention could be delivered as part of routine advice and support to PWID by key workers and in needle exchange services. Preliminary findings suggest that the intervention has the potential to positively influence BBV infection prevention, with benefits reported among PWID who attended at least one intervention session. Furthermore, the content of the co-developed intervention was highly valued by both participants and facilitators, highlighting the need for flexibility to adapt the intervention to ensure that the needs of local PWID are met. Further detailed proposals are described below, including staff training to ensure that all harm reduction staff incorporate the PROTECT study intervention into their routine consultations and interactions with PWID to improve injecting techniques, venous access and care and prevent BBV.

Harm reduction services should ensure that the intervention content is routinely delivered to PWID to improve vein care and prevent BBV.

The qualitative research in this study identified circumstances that lead to risky injecting that may result in BBV transmission. The PROTECT study intervention responded with strategies on how to avoid or manage these situations and offers up-to-date evidence-based content and delivery approaches. Consideration of how best to train and motivate staff to deliver this intervention is required and, again, local solutions should be reached.

Current harm reduction services may be failing to address the needs of PWID, resulting in poor clinical outcomes and high health- and social-care costs for this client group. Therefore, there is a consequent benefit of offering this type of intervention adapted to local need as appropriate, including its routine delivery, whether in full to groups or individuals, or via more tailored information or advice offered by key workers, peer educators and needle exchange staff.

Specific lessons from the feasibility trial

Trial implementation

The importance of management and of service staff buy-in was stressed by the researchers. An approach used in some settings was a presentation of the study at staff meetings to facilitate recruitment of research participants. In addition, facilitators valued being involved in the development of the intervention. Training

of intervention facilitators should be delivered locally (we carried this out centrally in London, creating challenges for more distantly located staff), and we recommend that sufficient time be allocated to allow quality assurance of the delivery of the intervention, before the intervention is delivered in practice. Facilitators should have the competency to deliver the intervention, and services that use the intervention should ensure that sufficient resource is provided to ensure that interventions are comprehensively delivered and to maximise participant engagement.

Several sites that had previously offered to host the research had, by the time we came to start the trial, been retendered or had changes in management. This resulted in delays in order to find additional sites and secure buy-in with new management. In future, it may be useful to engage additional potential sites from the outset to address such eventualities.

It is important to consider the technology available at intervention sites in advance of trial implementation. Some sites did not have facilities to play the online YouTube videos that were part of the intervention and the use of a Dropbox (Dropbox Inc., San Francisco, CA, USA) was not permitted by IT at sites, making it difficult to share the video resources as these were too large to send by e-mail.

Offering the intervention on an individual delivery basis at the time of randomisation may have ensured that more participants received the intervention.

Delivery of intervention

The mapping exercise with drug and alcohol commissioners (see *Chapter 2*) and the consultation with policy-makers and practitioners (see *Chapter 4*) confirmed that there was no current intervention fit for purpose to meet the needs identified by PWID (see *Chapter 2*).

Although the separate focus groups with facilitators and intervention participants demonstrated the acceptability of the intervention, several key findings for its improvement were described.

Facilitators welcomed peer-educator involvement in the training event as they had gained new knowledge in the process. Although only one site (London) included peer educators as co-facilitators, it is recommended that this approach be used in future, as intervention participants highly valued the skill and experience mix of facilitators. However, it should be recognised that peer educators may also require support depending on where they are in their recovery. In York, peer educators were identified to co-deliver the intervention with staff; however, because of personal circumstances, they were not able to do so. In Glasgow, a service user organisation had agreed to deliver the intervention. However, this was not possible due to the resource requirements of this excess treatment cost.

Intervention participants in the feasibility trial welcomed gender-specific groups, reporting that they felt more comfortable discussing sensitive topics in a safe environments. Where groups are being delivered, services should consider the need to have gender-specific groups. Some participants and recent research[177] stressed the importance of delivering the intervention to reduce BBV transmission risks to couples. This may be appropriate for couples where domestic violence is not present.

Potential contributing factors for the differences in engagement, compliance and attendance across trial sites may include travel reimbursement, reimbursement of time and CM paid in cash compared with high-street vouchers. Where vouchers were used instead of money, it was because the services had requested this. However, to facilitate engagement and attendance at interventions and in research, we recommended that participants receive cash rather than vouchers for the reimbursement of time and CM, that refreshments are provided during intervention sessions and that travel costs are reimbursed. The small costs involved in encouraging engagement and retention are not comparable to the vast health- and social-care costs resulting from injection-related infection and BBVs.

There have been concerns raised in some ethics committees over the payment in cash to people who use substances that participate in research (as they believe this could facilitate illicit drug purchases). Instead, their preference would be for vouchers to be used to reimburse research participants. However, recent research has confirmed that modest cash payments increase participation in research among people who use substances, and very few participants reported they planned to spend the research cash payment on substances, rather they planned to spend it on food, cigarettes and transport/fuel.[256] More recently, Neale *et al.*[257] found that service users stressed there were many benefits of cash payments over vouchers for participating in research. They believed that 'on a practical level, cash was considered simple, easy, and convenient: you can spend it on what you want, when you want, and where you want'. In addition, cash has important symbolic value, signifying 'a genuine appreciation of the participant's time and contribution'. Furthermore, giving a research participant cash indicates 'respect' and 'trust' in the participant, so 'treating them like an adult'. As such, cash was perceived as 'empowering', 'non-stigmatising' and 'potentially encouraging of recovery', cash was 'king'. Although service users also accepted that cash from research participation could easily be spent on drugs or alcohol, they felt that the amounts of cash given for research participation were 'nearly always too small to raise any significant safety or ethical concerns, even when study payments were used to buy substances'. Therefore, we recommend that future studies offer cash rather than vouchers to research participants as our and other studies suggests this may enhance participation in research, and that this is supported by research ethics committees.

Intervention content

There was support for addressing symbiotic goals and teaching injecting skills to PWID. Indeed, some intervention participants stressed the need for more practical assistance on injecting technique, including observation and feedback on their own injecting technique.

Facilitators felt that session 1 had too much content and could not realistically be delivered within 1 hour. The manual could be improved by being more flexible and allowing facilitators to introduce and cover the information in each section, without having to follow the text verbatim.

Facilitators suggested that the intervention could be improved by making it more interactive, improving the quality of the videos and including specialist workers for specific components (e.g. injecting instructors, BBV nurses or sexual health practitioners).

When asked how the PROTECT study intervention could be improved, participants who attended at least one PROTECT study intervention session suggested making the intervention more visual and interactive and incorporating more practical instruction around injecting technique and injecting sites. It was also suggested that the videos illustrating the side effects of injecting should be more graphic and feature real people rather than animations. Making the intervention available online and including information on NPSs was also suggested to make the intervention more relevant and attractive to younger people.

The content of the intervention was rated highly by facilitators and intervention participants alike. We plan to seek funding to incorporate these suggestions into the PROTECT study intervention to further refine the intervention manual and materials.

Recruitment rates

We reported difficulties in recruiting particular groups of PWID, mainly women and new injectors. Future studies could consider the use of 'chain referral sampling' where existing study participants recruit future participants from among their acquaintances to target participants who may be hidden or difficult to reach for researchers. Participants who assist with the recruitment of other participants would be rewarded for every additional participant they helped recruit.

Retention rates

Feedback from trial participants suggests that payment for participating in the research and CM may be best given in cash rather than as vouchers, and that transport costs should be reimbursed because of the

distance often required to travel to attend the service for the intervention session or for follow-up interview. Provision of refreshments was also welcomed by trial participants.

Dedicated researchers are required to assertively follow up participants and remind them of intervention session times and dates. In all sites, except York (which was done by text from the service at the preference of the participants), the researcher rang participants' mobile phones the day before an intervention session or research follow-up and followed this up on the day of the intervention session or research follow-up with a text message, to increase attendance. However, this method was not without difficulties. In Wrexham, the researcher reported that many participants had lost or sold their mobiles, which hindered follow-up contact. However, as the researcher was also the line manager of the service, she had local knowledge of the service users that allowed her to call on participants at home or via other contact numbers, at the mobile unit or visit their regular meeting places in an attempt to follow them up. This relationship and familiarity may have resulted in greater participation in the intervention and retention in the feasibility trial.

Assessment

For those participants who attended the intervention sessions, all candidate outcome measures had very good completion rates. The number of injecting risk practices, and self-efficacy in particular, showed improvements in the intervention group that were maintained up to 1 month follow-up. These outcomes might be considered in a larger-scale study in the future. BBV transmission knowledge was more likely to show short-term improvements only, whereas withdrawal prevention questions had only limited applicability in this study population. Our systematic review highlights the need for a core outcome set to be developed to reduce selective outcome reporting issues when measuring BBV risk behaviours among PWID. Such a core outcome set could be used in future research including trials.

Recommendations for collection of data for health economics

Analysis of the questionnaires identified several categories that could be excluded from the assessment battery in a full RCT, making the collection of data simpler and quicker. The feasibility trial results suggest that some questionnaire items with low utilisation rates can be omitted.

Key workers and needle exchange services were used by > 70% of the trial population, indicating that these areas should be the subject of more detailed data collection in a full trial.

The mean cost was £58.17 for patients attending one session, £148.54 for those attending two sessions and £270.67 for those attending all three sessions in the intervention group. These costs compared with £0.86 in the control.

The EQ-5D-5L scores in both groups improved from baseline through the two follow-ups, showing potential for health improvement and associated QALY gains. Differences between groups must be treated with extreme caution because of the small sample size.

The use of case vignettes

Although the use of case vignettes, developed by service users, was considered a novel way to assess changes in risk behaviour, it was difficult to systematically and reliably analyse these data as many of the open-ended responses were ambiguous, creating a significant risk of researcher bias in coding. Therefore, the use of our case vignettes to assess changes in risk behaviour is not recommended.

Summary of implications for practice

Some PWID who were interviewed (see *Chapter 3*) and had been injecting long term reported that they still required help injecting, especially if venous access was difficult. Over half those participants interviewed recommended that the intervention include being taught injecting skills, requesting practical demonstrations of injecting to reduce risks such as skin and soft-tissue infections, amputations and venous damage. More importantly, they stated that although they had been given information about BBV

transmission, this had been in the past and had been conflated or forgotten over time, with many myths about transmission still being believed. This is important as older PWID may in turn influence the knowledge of younger, more recent-onset injectors. Few participants interviewed had ever attended interventions focused specifically on BBV transmission or injecting/sexual behaviour change. This finding is supported by the brief survey sent to all alcohol and drug commissioners in the UK, highlighting the lack of specific interventions to address BBV transmission risks.

People who inject drugs who attended at least one session of the intervention, many of whom also had long injecting careers, welcomed the opportunity to talk about topics in the intervention that they felt were not normally discussed. They liked that the intervention approach was not patronising and did not promote abstinence. The former finding is worrying, as it was assumed by many policy-makers and practitioners who we consulted both prior to the intervention, and post intervention in the dissemination phase of our project, that such BBV information and education were incorporated into 'usual' harm reduction conversations by key workers in drug and alcohol services and practitioners in needle exchange and specialist services. PWID have not confirmed this is currently happening. Therefore, clients' needs may not be currently being met by existing harm reduction services.

There are two potential reasons why this harm reduction advice may not be being delivered. First, this may be a result of the de-skilling of the substance use workforce as a result of the cuts in service provision. In some areas, needle exchanges that were previously staffed by experienced and specialist (BBV) nurses, were now staffed by unqualified drug workers with little training or experience. Moreover, needle exchange interactions in pharmacies had limited the opportunity for harm reduction. Second, as a result of the UK drug policy shift in recent years from harm reduction to recovery, it may be that the needs of those who are not engaged in treatment and who continue to inject drugs are being neglected. Our findings suggest that current harm reduction services may not meet the needs of all PWID, especially those not engaged in treatment.

The NICE quality standard for drug use disorders[258] recommends that people are given a range of information and advice about treatment options from harm reduction to abstinence, albeit that no definition of harm reduction is given. The guidance does not include advice on improving injecting techniques for PWID and strategies to avoid or plan for BBV risk behaviours.

Further development of the PROTECT study intervention

As described in *Chapter 7*, all services where the intervention was presented following the feasibility trial were supportive of the intervention content and aims, and believed that they could meaningfully use the intervention content messages and exercises with clients. All services wanted to be involved in further development of the intervention and suggested that there was benefit in refining the intervention further by adapting it for delivery in specific settings (e.g. needle exchange, pharmacy needle exchange, prison), and to specific groups of PWID including those living in homeless hostels, people receiving OST, young injectors when they are transferred from adolescent to adult addiction services, steroid injectors, those engaged in chemsex and those injecting NPSs. As previously discussed, the intervention delivery is required to be flexible to suit local needs.

Funding is being sought to further develop the intervention.

Summary of recommendations for further research

Three key areas for further research were identified.

Ethnography

Difficulties in recruiting females who inject drugs and new injectors, especially those who were injecting NPSs, had proved difficult despite recruiting from a variety of services (e.g. pharmacy needle exchanges, harm reduction services, sexual health clinics, homeless hostels). There remains a need to understand the needs of these injectors to ensure that key BBV transmission messages are appropriately targeted. As it proved difficult to engage these groups of PWID into the research (for both the in-depth interviews and the feasibility trial), we recommend ethnographic research is undertaken to better understand the typology and potentially changing risk of contemporary drug use in the UK by exploring the specific concerns and barriers from the lived experience of PWID in terms of accessing help, advice and treatment, as well as what mode of delivery would work best for these groups.

Feasibility of the intervention for males involved in chemsex who inject

'Chemsex' is used to describe the use of psychoactive substances (typically crystal methamphetamine, mephedrone and gamma-hydroxybutyric acid/gamma-butyrolactone) either immediately before or during sex.[259] High rates of injecting and other drug use and unsafe sexual practices[259,260] leading to increased rates of BBV infection have been reported among this group.[261,262]

We interviewed five males involved in chemsex who inject from London who had injected in the previous month, mostly crystal methamphetamine and mephedrone. They reported injecting risks such as being injected and injecting others, inadvertent mixing up of injecting equipment, potential needlestick injury and vein damage. Non-condom use ('bare backing') was driven by a desire for sexual intensity, but it was also reported that willingness to take sexual risks increased under the influence of drugs. These participants suggested outreach and online media as potential modes of delivering an intervention to address the needs of PWID and engaged in chemsex.

Current service provision around harm reduction for PWID may not address the 'specific and acute needs of gay men engaging in chemsex'.[263] We propose to adapt the PROTECT study intervention to meet the needs of chemsex injectors and develop a mobile application to be tested in a future feasibility trial.

Workforce development

This research has confirmed the need and support for providing interventions to PWID to improve their injecting techniques, vein care, strategies to avoid risk and to increase their knowledge about BBV transmission, even among people who have injected drugs over a long period of time. Several suggestions to increase the reach of the intervention were suggested by both staff and participants, including provision of information on an individual basis to PWID presenting to needle exchanges. This approach could be tested in a future trial of worker training on the intervention content for use in needle exchange consultations with PWID, using similar outcome measures as the current feasibility trial. A quasi-experimental design comparing areas with and without additional training is proposed.

Patient and public involvement

Working with service users to co-produce all study materials, the intervention and dissemination materials were invaluable and ensured that the key messages could be understood and reached participants. Having peer educators as co-facilitators to deliver the intervention was highlighted as beneficial by both facilitators at the training event, those co-delivering and by participants who attended a co-facilitated group.

Service users, service providers and policy-makers all participated in Steering Group meetings throughout the research study, including the final meeting where the results of the feasibility trial were presented and the implications for practice of the findings discussed to inform the conclusions presented in this report.

In London, service user representatives and peer educators were involved in developing a feedback summary of the key findings for service users. People who participated in the research were invited to attend a dissemination event in London (also open to other service users). These service user

representatives and peer educators assisted researchers in the delivery and discussion of the study findings at the dissemination event in London.

Copies of the feedback summary developed by service users in London were also made available to service users attending the site where the trial took place in Glasgow.

In Huddersfield, a dissemination event was held to present the study findings to key stakeholders. One ex-service user attended, who is now a harm reduction worker.

Conclusions

The research project has successfully developed and evaluated an evidence-based, group psychosocial intervention to reduce BBV risk behaviours among PWID. Although there was high satisfaction and acceptability of the intervention aims and content among participants and intervention facilitators, and the intervention showed the potential to positively influence BBV risk behaviours, the findings demonstrate that a future definitive RCT of the PROTECT study intervention is not feasible in the UK. Despite this, considerable and valuable insight has been obtained showing the need for a greater embedding of BBV risk reduction in the work of substance misuse services. In addition, this research highlights an urgent unmet health need for PWID. Furthermore, the research provides a body of evidence as to how this might best be achieved, and has generated important learning about the feasibility, delivery and implementation of the PROTECT study intervention, which should inform future studies in the field.

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Group membership

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Contributions of authors

All authors were involved in the design of all phases of the research, intervention development, data interpretation, drafting the report and have approved the final version of the report.

Gail Gilchrist (lead applicant) led on the design of all phases of the research in response to the commissioned call, developed the protocol for the feasibility study, led the systematic review and meta-analysis, led the intervention development and had overall responsibility for the conduct of all phases of the research. She led on the drafting of *Chapters 1*, *2*, *5* and *7–9*.

Davina Swan (post-doctoral researcher, London site) was responsible for the day-to-day running of the research in London. She contributed to the systematic review, collected data for all phases of the research, led on the analysis of the qualitative data, co-drafted *Chapter 3* and led on the drafting of the qualitative findings in *Chapter 6*.

April Shaw (research assistant, Glasgow site) was responsible for data collection for all phases of the research in Glasgow, led on the analysis of the qualitative data, co-drafted *Chapter 3* and led on the drafting of *Chapter 4*.

Ada Keding (co-applicant) was responsible for the statistical analysis for the feasibility trial presented in *Chapter 6*.

Sarah Towers (BBV nurse, Wales site) was responsible for data collection for all phases of the research in Wales.

Noel Craine (collaborator) was responsible for the day-to-day running of the research in Wales and contributed to analysis of the qualitative interviews with PWID in Wales presented in *Chapter 3*.

Alison Munro (co-applicant) was responsible for the day-to-day running of the research in Glasgow and contributed to the drafting of *Chapter 1*.

Elizabeth Hughes (collaborator) was responsible for the day-to-day running of the research in York, screened articles for the systematic review and led the development of the fidelity checklist.

Steve Parrott (co-applicant) was responsible for the health economics component of the feasibility trial presented in *Chapter 6*.

Noreen Mdege (research fellow, York site) undertook the searches and screening of articles for the systematic review and collected and coded qualitative data presented in *Chapter 3*.

John Strang (co-applicant) contributed to the design of all phases of the research.

Avril Taylor (co-applicant) contributed to the design of all phases of the research.

Judith Watson (co-applicant) was responsible for day-to-day trial management and the development of the feasibility trial protocol. She led on the drafting of *Chapter 6*.

Publications

Gilchrist G, Swan D, Shaw A, Keding A, Towers S, Craine N, *et al.* The acceptability and feasibility of a brief psychosocial intervention to reduce blood-borne virus risk behaviours among people who inject drugs: a randomised control feasibility trial of a psychosocial intervention (the PROTECT study) versus treatment as usual. *Harm Reduct J* 2017;**14**:14.

Gilchrist G, Swan D, Widyaratna K, Marquez-Arrico J, Hughes E, Mdege N, *et al.* A systematic review and meta-analysis of psychosocial interventions to reduce drug and sexual blood borne virus risk behaviours among people who inject drugs. *AIDS Behav* 2017;**21**:1791–1811.

Data sharing statement

All available data can be obtained from the corresponding author. We shall make data available to the scientific community with as few restrictions as feasible, while retaining exclusive use of the data until the publication of major outputs.

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Appendix 1 Patient information sheet and consent form for interviews with people who inject drugs

[Organisational logos and headers]

Information about the research (Phase 2)
Preventing blood borne virus infection in people who inject drugs in the UK

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. We would like to interview you about injecting and sexual risk behaviours among people who inject drugs and about what kind of intervention you think would be useful and acceptable to reduce blood borne virus risk behaviours that can lead to Hepatitis C, Hepatitis B and HIV. Interventions might include i) information to increase knowledge, ii) to teach skills to enable people to practice safer injecting and sex, and iii) to motivate people to practise safer injecting and sex. The information you provide will be treated confidentially unless you disclose intent to harm yourself or others. One of our team will go through the information sheet with you and answer any questions you have. **Explaining this information sheet to you should take about 5-10 minutes.** Do feel free to talk to others about the study if you wish.

What is the purpose of the study?

In the UK, around half of those who inject drugs have been infected with the Hepatitis C virus and around one in every 100 has HIV. Approximately one in six people who inject drugs have ever been infected with the hepatitis B virus. People who inject drugs may be at risk of these blood borne viruses (HIV, Hepatitis C and Hepatitis B) because of sharing injecting equipment (needles and syringes, water, spoons, cotton etc.) and unsafe sex (although the risk of sexual transmission of Hepatitis C is low). These blood borne viruses are preventable and we are looking to work with those at risk to identify ways to achieve this. We are doing this study to learn how best to help people adopt safer injecting and sexual behaviours and work out what kind of intervention (e.g. i) information to increase knowledge, ii) to teach skills to enable people to practice safer injecting and sex, and iii) to motivate people to practise safer injecting and sex) that you would find useful and acceptable.

This study is being conducted in London, Glasgow, Yorkshire and North Wales. This will allow the study to compare the results across different areas in the UK.

Why have I been invited?

People who have injected drugs (other than image or performance enhancing drugs) at least once in the past month are being invited to take part from drug treatment centres, harm reduction services, needle exchanges, sexual health clinics and homeless hostels. We wish to interview a total of 60 people who have recently injected drugs – 15 each from London, Glasgow, Yorkshire and North Wales.

Do I have to take part?

No, it is up to you to decide whether or not you want to take part in the research. If you agree to take part, we will then ask you to sign a consent form. This study is independent of your treatment. You are free to withdraw at any time, without giving a reason. This will not affect the care that you are receiving.

What will happen to me if I take part?

If you decide to take part, you will be interviewed face-to-face by a researcher about risk behaviours among people who inject drugs and about what kind of intervention you think would be useful and acceptable to reduce blood borne virus risk behaviours and increase transmission knowledge. You may refuse to answer some of the questions if you prefer not to. **The interview will take about an hour** and will be audio recorded with your consent. We can interview you today, or we can arrange a time that is suitable for you to be interviewed. You will receive £20 high street gift voucher to cover your time and expenses.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice **and all information about you will be handled in confidence**. The questionnaire and audio recording will contain only your study ID (not your name) and will be stored on a secure computer. Once we have done that, the audio recording will be deleted from the recording device. What you say in the interview will be typed out word for word. Only the researchers conducting the study will have access to these typed copies. The researcher will check them to make sure that neither you nor any other person is identifiable from what you have said; any references to names or addresses will be removed. The interviews and the data will be kept on a computer and will be stored separately from

your contact details. Data will be kept securely for 7 years after publication of the findings and then destroyed. Anonymised data (not individual interviews) will be stored with the UK data archive to allow other researchers to use the data in the future. Your data will only be included in the archive if you give your consent to this. If you do not give your permission for your data to be used in this way then it will not be shared.

Limitations to confidentiality

If you express current or future intention to harm yourself or someone who is specifically identified, there would be no grounds for maintaining confidentiality. Your key worker or a duty worker at the drug treatment service where the interview has taken place will be told by the researcher of your intentions and the worker will conduct a risk assessment.

What are the possible benefits of taking part?

Whilst there are no immediate benefits to yourself for taking part, this is your chance to use your experiences to help develop an intervention that has the potential to help people protect themselves from blood borne viruses.

What are the possible disadvantages and risks of taking part?

There is low risk of harm by taking part. However, talking about sensitive topics including potential risks for the transmission of blood borne viruses may make you feel worried or anxious. If you are worried or anxious or wish to find out more about blood borne viruses, you will be given the opportunity to speak to a member of staff at a local drug treatment service if you want to. We have also provided you with a range of contact numbers and websites that will be able to help.

Contact numbers

The Hepatitis C Trust Helpline [redacted] or [redacted]
http://www.hepctrust.org.uk/ *Open 10.30am to 4.30pm Monday to Friday (except*

Bank Holidays and the Christmas break, when dates and times may vary).Helpline is staffed solely by people with hepatitis C, some of whom have been through/or are currently undergoing treatment.

British Liver Trust [redacted]
www.britishlivertrust.org.uk (Free helpline, Mon-Fri 09.00-17.00) *The British Liver Trust is the national charity working to reduce the impact of liver disease in the UK through support, information and research.*

National Hepatitis Support Line [redacted]
http://www.hepbpositive.org.uk/ *Help the public and patients overcome hepatitis B. They clarify and reassure patients that hepatitis b is both easy to vaccinate against and caught early on an easy to manage common child acquired condition.*

National Sexual Health Line [redacted] **(24 hours)**
The National Sexual Health Line is UK-wide and provides confidential advice and information on all aspects of HIV, AIDS and sexual health. The Helpline can also provide UK wide referrals to specialist services. Open 24 hours a day, seven days a week. All calls are taken by trained and paid staff. It is not a counselling service, but gives you details of local helplines & services if needed.

Terrence Higgins Trust Direct Helpline [redacted]
(open 10am - 10pm Monday - Friday, and 12 noon - 6pm on Saturday and Sunday). Terrence Higgins Trust Direct Helpline can give you HIV information, advice and support over the phone.

Local services

Burrell Street Sexual Health Clinic, 4-6 Burrell Street, London [redacted]
Burrell Street offers tests and treatment for all sexually transmitted infections. Burrell Street has a sexual health counselling service which provides risk reduction interventions, sexual health advice, and an opportunity to discuss your relationships, sexual identity and concerns regarding your drug and alcohol use.

Community Drugs and Alcohol Service, 151 Blackfriars Road, London [redacted] *This service provides assessment, treatment and advice for people, aged over 18, who have substance misuse (drug and/or alcohol) related problems.*

What will happen to the results of the research study?

What you say will be used to help develop an intervention to reduce risky drug use and sexual practices among people who inject drugs. We intend to publish the results at the end of the study. A summary of the results will also be available on the project website

http://www.kcl.ac.uk/ioppn/depts/addictions/research/drugs/bloodborneviruses.aspx

and a brief summary of the results will be available in June at the services where the

research took place. It is possible that we would include your actual words in quotations in the report but we would not use your real name so that people will not be able to identify you in any report/publication.

Who is organising and funding the research?

The research is being led by Dr Gail Gilchrist, from the National Addiction Centre at King's College London, and is funded by the National Institute for Health Research. This study is being conducted in London, Yorkshire, Glasgow and North Wales. If you wish to talk to someone about the research please contact Dr Davina Swan on [telephone number].

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by NRES Committee South East Coast - Brighton & Sussex (Reference: 15/LO/0387).

Contact details

If you agree to take part in the research, we will arrange a time to meet with you again in the next couple of weeks. We can make this before or after your next visit to this service if that suits. We will contact you to remind you of the time we arrange today and also to check if you still wish to take part in the study.

Please can you fill out your contact details so that we can stay in touch. Thanks!

Name: _____

Mobile telephone number: _____

Home telephone number: _____

Email address: _____

Information sheet date of issue: 12 March 2015
Information sheet version number: 2

[Organisational logos and headers]

CONSENT FORM (Phase 2)

Title of Project: Preventing blood borne virus infection in people who inject drugs in the UK
Name of Researcher: Dr Gail Gilchrist

Please initial all boxes

1. I confirm that I have read and understand the information sheet dated 12/03/15 (version 2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my care or legal rights being affected. ☐

3. I understand the limitations to confidentiality. ☐

4. I understand the interview will be audio recorded. ☐

5. I understand that the data will be published at the end of the study and that completely anonymous quotations from the interview may be used in the report/publication. ☐

6. I agree to my anonymous interview data being shared with researchers at the four institutions where the research is being carried out – King's College London, University of the West of Scotland, University of York and NHS Wales. ☐

7. I agree to take part in the study ☐

Please initial the following box if you agree with the following statement. Your participation in this research study will not be affected if you do not agree with this statement

8. I agree to my anonymous interview data being stored with the UK data archive ☐

Name of Participant	Date	Signature
Name of researcher	Date	Signature

Consent form date of issue: 12 March 2015, Consent form version number: 2

Appendix 2 Topic guide for interviews with people who inject drugs

Feasibility of psychosocial interventions for preventing blood borne virus infection in people who inject drugs

ID number ☐

Type of service recruited from
☐$_1$ Drug treatment service
☐$_2$ Needle Exchange
☐$_3$ Sexual Health Clinic
☐$_4$ Hostel/ Homeless service

Gender
☐$_1$ Male
☐$_2$ Female
☐$_3$ Transgender

Age ☐

Time interview started ☐

Time interview finished ☐

As we previously discussed, we are doing this research to inform the development of an intervention to reduce blood borne viruses and increase knowledge about how you get or pass on HIV, Hepatitis C and Hepatitis B among people who inject drugs in the UK. Today I want to talk to you about injecting and sexual risk behaviours among people who inject drugs to work out whether there is a need for an intervention and also ask you about the kind of intervention you would find useful and acceptable.

Before we start, I just wanted to check

Have you injected drugs at least once in the past 4 weeks?

Yes ☐$_1$ No ☐$_0$ **(if no, thank and end interview)**

What drug/s have you injected at least once in the past 4 weeks?

(Interviewer: Read all options and mark all relevant responses)

Heroin	☐ 1	Cocaine	☐ 2	Crack cocaine	☐ 3
Methadone	☐ 4	Amphetamines	☐ 5	Methamphetamines	☐ 6
Hallucinogenics	☐ 7	Benzodiazepines	☐ 8	Novel Psychoactive Drugs	☐ 10
Cannabis	☐ 11	Steroids or other performance enhancing drugs	☐ 12	Other (specify)	☐ 13

Specify:

(Interviewer: Note if participant has only injected steroids or other performance enhancing drugs, thank participant and end interview)

What drugs did you inject most often in the past 4 weeks?

Heroin	☐ 1	Cocaine	☐ 2	Crack cocaine	☐ 3
Methadone	☐ 4	Amphetamines	☐ 5	Methamphetamines	☐ 6
Hallucinogenics	☐ 7	Benzodiazepines	☐ 8	Novel Psychoactive Drugs	☐ 10
Cannabis	☐ 11	Steroids or other performance enhancing drugs	☐ 12	Other (specify)	☐ 13

Specify:

How long have you been injecting drugs for?

< 2 years ☐ 0 ≥ 2 years ☐ 1

Are you currently receiving treatment for problems related to drug use?
(Interviewer: Mark only one response)

Yes, opiate substitution ☐ 1 Yes, other ☐ 2 No ☐ 0

What are your current living arrangements? (Interviewer: Read all options and mark relevant responses)

Alone ☐ 0	With sexual partner and children ☐ 1	With sexual partner alone ☐ 2
With children alone ☐ 3	With parents ☐ 4	With family ☐ 5
With friends/ flatmates ☐ 6	Homeless ☐ 7	No stable arrangements ☐ 8
Other living arrangements ☐ 10	Other ☐ 11	

Specify:

Section 1. Bloodborne viruses

I would now like to ask you about bloodborne viruses such as HIV, Hepatitis B and Hepatitis C

1.1. Can I ask you what you know or what you've heard about how people get blood borne viruses, like HIV, Hep C and Hep B? [probe for HIV, Hepatitis B and C]

1.2. From what you know or you've heard, which do you think is the easiest virus to get? Why is that?

1.3. From what you know or you've heard, which do you feel would be the worst virus to get/have? Why is that?

1.4. Do you feel you are at any risk of HIV, Hepatitis B and/or C? Why is that? Why not? [probe for personal risk perception/risk behaviours engaged in]

Section 2. Injecting drug use

I would now like to ask you about injecting risk behaviours.

2.1. Under what circumstances do you think people who inject drugs might be more likely to take risks when injecting (e.g. sharing needles, cookers, water etc in the preparation and administration of drugs for injection)?(Alternative phrasings if needed: Are there certain situations in which people who inject drugs might be more likely to share needles

or syringes? Are there certain situations in which they might be more like to share other equipment such as filters, cookers, or water? *Explore who injecting with/ context (location, intimate partner violence etc) in which risks occur – injecting couples, dyads, groups and therefore explore sharing of equipment/ preparation/'aftermath' – including potential cleaning and disposal of equipment and potential risk of transmission.* **[Explore any issues of power and/or dominance in injecting dyads/groups, gender, sex work, withdrawal and negative mood].**

Some probes I have found useful:
Where would you normally be when you are injecting? Would you ever inject anywhere else?
Would you ever inject in the company of other people?
Do you/have you ever needed help injecting? Why is/was that?
Have you ever had to help someone else inject? Why is/was that? How do you/did you feel about helping them?
Have you ever found yourself in a situation where you have had to share injecting equipment?
Are there certain people you'd feel comfortable sharing equipment with?
When you have had to share, would you always get an opportunity to clean the equipment?
How would you normally clean it?
Are there certain times when people are more likely to share injecting equipment?
Who disposes of the equipment and how is it disposed of?

2.2. Do you think there are different risks involved in preparing and injecting different drugs (e.g. heroin vs. cocaine or methamphetamine)? What are the different risks?

2.3. Are there times, however rare, when you think people who inject drugs lose control over how they inject? If so describe these circumstances/ drugs used etc

- *What about you, is that the same for you?*

2.4. What help or support [ie explore about more knowledge, more motivation, more skills?] do you think could be given to people who inject drugs to help them inject more safely? [PROBE: barriers/ what would motivate them]

Probes: Is there anything that might stop people from changing or make it difficult for them to change?
What might help people in that situation?

- *Have you ever had any help or support or education around safer injecting? Can you tell me about it and what you found most/least helpful*

Now I would like to talk about sexual risks for blood borne viruses

Section 3. Sexual behaviour

3.1. Do you have intimate relationships with….?

Men	☐1
Women	☐0
Both men and women	☐2

3.2. Under what circumstances do you think people who inject drugs might be more likely to have unsafe sex or engage in riskier sexual practice? (Alternative phrasing if needed: Are there certain situations in which people who inject drugs might be more likely to have unprotected sex or engage in riskier sex?) (Explore who having sex with/ context (sex trading, CHEMSEX, intimate partner violence, withdrawal, negative mood etc) in which risks occur. [Explore any issues of power and/or dominance, gender].

- *What about you, is that the same for you?*

Probes:
What do you think stops people using a condom or having safer sex in these situations?
Would it be easy do you think for you/others in that situation to use a condom if you wanted?

3.3. What help or support [ie explore about more knowledge, more motivation, more skills?] do you think could be given to people who inject drugs to help them have safer sex? [PROBE: barriers/ what would motivate them]

Probes: Is there anything that might stop people from changing or make it difficult for them to change?
What might help people in that situation?

- *Have you ever had any help or support or education around safer sex? Can you tell me about it and what you found most/least helpful*

Section 4. Development/need for intervention

The next stage of this project is to develop a specific intervention to help people who inject drugs reduce the risk of getting or passing on blood borne viruses such as HIV, and hepatitis B and C, by reducing drug and sexual risk

behaviours and increasing knowledge around transmission and re-infection. Interventions might include i) information to increase knowledge, ii)teach skills to practice safer injecting and sex, and iii)motivate people to practise safer injecting and sex. We would like to ask you whether you would find such an intervention useful and if so, what kind of intervention you would find useful.

4.1. What sort of information/skills do you think the intervention should focus on to help people who inject drugs to practice safer drug use and safer sex? [PROBE for whether this is already happening/ experience of interventions in the past they have attended]

4.2. Would you participate in something like that? Why/ why not?

4.3. Who do you think would be best to deliver it? [PROBE peer, drug worker, Needle Exchange, GP etc.] Why is that? Where do you think it would be best delivered?

4.4. How do you think it should be delivered? [PROBE in group, individual sessions, by leaflet, mobile app, online etc.] Why?

4.5. How many sessions do you think would be realistic? And how long should they be?

4.6. Sometimes it is difficult to get people to attend interventions, what do you think some of the barriers might be to people attending? What could be done to improve uptake of this type of intervention?

Thank you so much for taking part that is the end of the interview. Is there anything else you would like to add that we haven't covered?

Version 3 19 May 2015

Appendix 3 Topic guides for consultation with key stakeholders

TOPIC GUIDE POLICYMAKERS/GOVT (Phase 3)

Feasibility of psychosocial interventions for preventing blood borne virus infection in people who inject drugs

As we previously discussed, we are doing this research to inform the development of an evidence based psychosocial intervention to reduce blood borne viruses and increase blood borne virus transmission knowledge among people who inject drugs in the UK. By psychosocial intervention we mean any intervention that emphasizes psychological or social factors rather than biological[1]. We wish to speak to you about your views on the current priorities for reducing BBVs among PWID and delivery and effectiveness of psychosocial interventions to reduce blood borne viruses among people who inject drugs, as well as your views on any barriers or facilitators you can identify around their delivery.

1. **Can I ask what your job title is?**

2. **Could you describe what your job/role entails, and particularly in relation to BBVs?**

1. **In your opinion what are the key priorities for reducing BBVs among PWID in [country]?**
   a. What might be the issues, if any, in delivering on these priorities?

2. **Do you think there is a need to develop psychosocial interventions to reduce the spread of blood borne viruses among people who inject drugs?**
   a. Why/why not?
   b. (IF YES) How important is their development in relation to the priorities you've mentioned?

3. **How do you think a psychosocial intervention to reduce BBV risk behaviour would complement existing service requirements?**

4. **If a psychosocial intervention SPECIFICALLY AIMED AT REDUCING BBVs for PWID was developed what do you think would be the criteria (**e.g. evidence-based, funding, trained workforce, quality assessment etc.) **needed to ensure its EFFECTIVE delivery:**
   c. NATIONALLY
   d. LOCALLY?

5. **Are you aware of any current barriers (e.g. funding) /facilitators (e.g. joint strategic needs assessment) to delivering psychosocial interventions to people who inject drugs?**
   e. Nationally
   f. Locally?

6. **Are psychosocial interventions a priority in your joint strategic needs assessment?**
   g. (WHY/WHY NOT?)

9. **Are there any key performance indicators around BBV?**

As I said previously, the overall aim of the research is develop and test the feasibility of delivering a psychosocial intervention to reduce blood borne virus risk behaviours among people who inject drugs. The feasibility study will be conducted in London, Yorkshire, Glasgow and Wales. However, if the intervention is feasible we would apply for funding to conduct the study on a larger scale – throughout the UK.

10. **Can you envisage any issues with rolling out psychosocial interventions across all drug treatment settings locally or nationally? How could these be addressed?**

11. **How should we measure if the intervention was effective?**

TOPIC GUIDE STAFF (Phase 3)

Feasibility of psychosocial interventions for preventing blood borne virus infection in people who inject drugs

As we previously discussed, we are doing this research to inform the development of an evidence based psychosocial intervention to reduce blood borne viruses and increase knowledge of blood borne virus transmission among people who inject drugs in the UK. By psychosocial intervention we mean any intervention that emphasizes psychological or social factors rather than biological[1]*. We wish to speak to you about your views on the current delivery and effectiveness of psychosocial interventions to reduce blood borne viruses among people who inject drugs, get your views on how you think such interventions should be delivered and any barriers or facilitators you can identify around their delivery.*

3. **Can I ask what your job title is?**

4. **Could you describe what your job/role entails, and particularly in relation to BBVs?**

3. **Are you aware of,**
   a. Any psychosocial interventions to reduce BBV that are delivered to people who inject drugs within (NAMED COUNTRY)? (duration, content, mode of delivery, group based or individual based interventions, area delivered etc)
   b. To whom? (probe whether general IDU population or targeted groups e.g. prisoners/gender specific etc).
   c. By whom? Generalist or specialist delivered? Specify (If the intervention consists of different components, probe if these different intervention components are delivered by the same or different teams).
   d. In your opinion/or from evidence – are these effective? Why/why not?
   e. Can you talk us through what helps or hinders the delivery of the interventions
   f. Were/Are these interventions part of a research study or are they an ongoing intervention? (If ongoing are they being evaluated?)
   g. If you do not have all the details of these interventions could you signpost us to someone who may be able to provide more information?

4. **Do you think there is a need to develop psychosocial interventions to reduce the spread of blood borne viruses among people who inject drugs?**
    h. Why/why not?

5. **How do you think a psychosocial intervention to reduce BBV risk behaviour would complement existing service requirements?**

6. **What would they look like?**
    i. Content, duration (e.g., mode of delivery, group based or individual based interventions, how many sessions over what period of time and length of sessions).
    j. What behavioral, psychological or social factors should the interventions aim to promote or change for people who inject drugs in relation to blood borne viruses? Why?
    k. Who should deliver? generalist or specialist (e.g.staff, peers etc) delivered (When the intervention consists of different components, probe if these different intervention components should be delivered by the same or different teams).
    l. To whom should they be delivered (should they be targeted to specific groups of people who inject drugs) and should there be different interventions for different groups of people who inject drugs. If so why?
    m. Should they be delivered at a particular stage in the trajectory of an individual's drug use (e.g. whilst on opiate substitution treatment? whilst engaged in a pattern of chaotic behavior etc?)
    n. Where should they be delivered – in drug treatment services, needle exchanges etc
    o. Do you have any views on payments or incentives to encourage engagement in interventions?

7. **What are the current barriers (e.g. funding) /facilitators (e.g. joint strategic needs assessment) to delivering psychosocial interventions to people who inject drugs?**
    p. In your locality (if appropriate)
    q. Nationally

As I said previously, the overall aim of the research is develop and test the feasibility of delivering a psychosocial intervention to reduce blood borne virus risk behaviours among people who inject drugs. The feasibility study will be conducted in London, Yorkshire, Glasgow and Wales. However, if the intervention is feasible we would apply for funding to conduct the study on a larger scale – throughout the UK.

8. **Can you envisage any issues with rolling out psychosocial interventions across all drug treatment settings locally or nationally? How could these be addressed?**

9. **How should we measure if the intervention was effective?**

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Appendix 4 Intervention development group members

The PROTECT group intervention manual

[Organisational logos and headers]

Improving injecting skills and preventing blood borne virus infection in people who inject drugs in the UK

http://www.kcl.ac.uk/ioppn/depts/addictions/research/drugs/bloodborneviruses.aspx

This project was funded by the National Institute for Health Research Health Technology Assessment (project number 13/17/04)

Developed by:

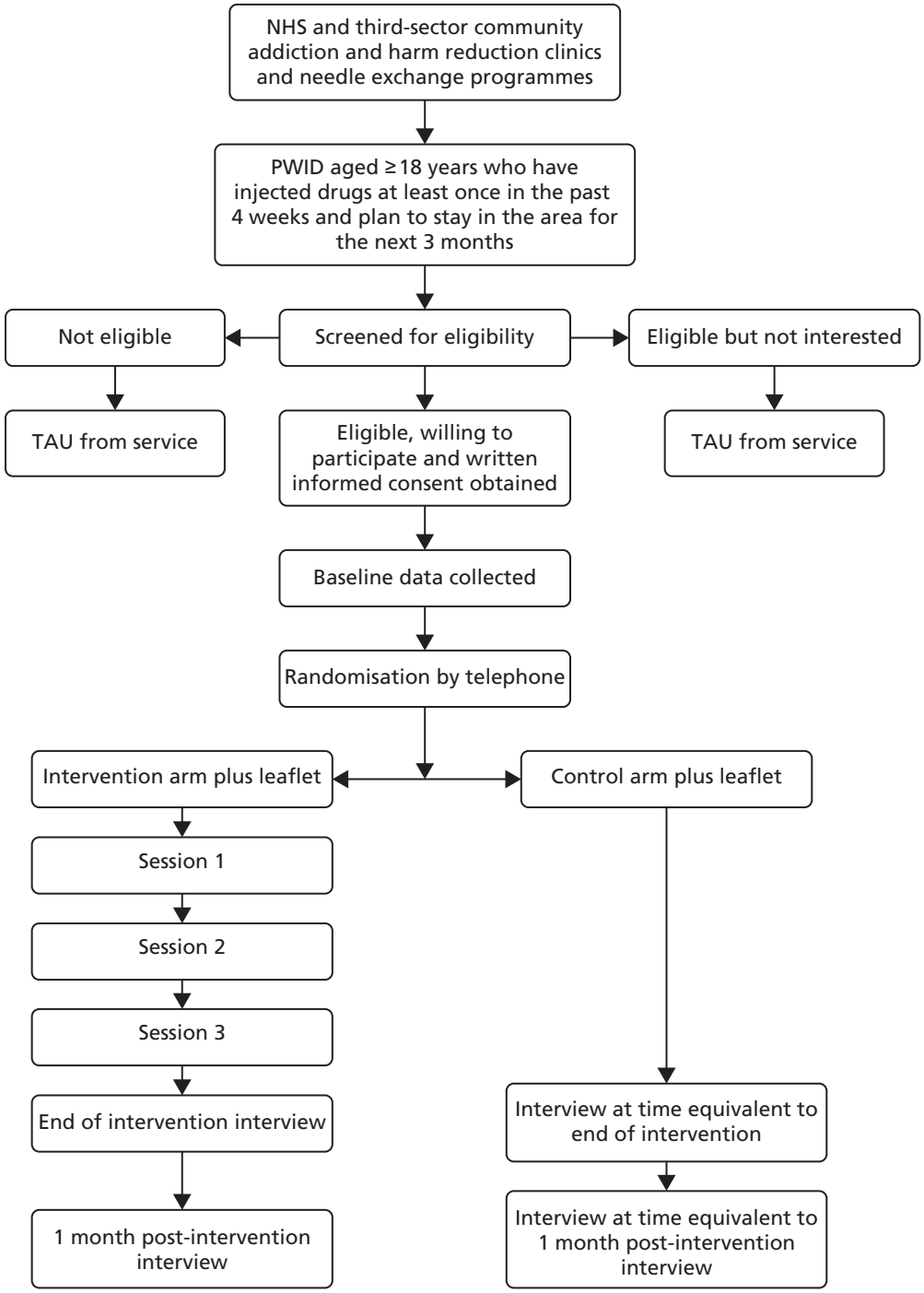
Research Team

Gail Gilchrist, John Strang, Davina Swan (King's College London); Alison Munro, April Shaw, Avril Taylor (University of the West of Scotland); Noel Craine (Public Health Wales), Sarah Towers (Betsi Cadwaladr University Health Board); Liz Hughes (University of Huddersfield).

Intervention development group (in alphabetical order)

Stephanie Brickwood (Wrexham Addiction Recovery Meeting); Archie Christian (The Hepatitis C Trust); Jon Derricott (Film Maker); John Dillon (University of Dundee); Paul Donachy (Scottish Drugs Forum); Magdalena Harris (London School of Hygiene and Tropical Medicine); Paul Lennon (Aurora Project); Martin McCusker (Lambeth Service User Council); Luke Mitcheson (South London and the Maudsley NHS Foundation Trust); Danny Morris (Drug Training & Consultancy); Terry Shields (South London and the Maudsley NHS Foundation Trust); Josie Smith (Public Health Wales); Carla Treloar (University of New South Wales); Jason Wallace (Scottish Drugs Forum)

Appendix 5 Study summary



Appendix 6 Eligibility screening questions

Eligibility criteria

Potential participants are eligible for the study if ALL of the following inclusion criteria apply.

Inclusion criteria

- Aged ≥ 18 years.
- Attending a participating site [i.e. NHS and third-sector community addiction/harm reduction clinics and needle exchange programmes (static and mobile)].
- Have injected drugs at least once in the past 4 weeks (if only injected performance-enhancing drugs they would not be eligible – therefore important to check what drugs injected).
- Plan to stay in the area for the next 3 months.
- Is able to complete the assessment and communicate in a group intervention in English.

Potential participants are NOT eligible for the study if ANY of the following exclusion criteria apply.

Exclusion criteria

- Is too intoxicated to give informed consent.
- Is in withdrawal.
- Has only injected performance-enhancing drugs in the past 4 weeks.

Screening questions

- Have you injected drugs at least once in the past 4 weeks?
- What drugs have you injected?
- What age are you?
- Do you plan to stay in the area for the next 3 months?

Appendix 7 Patient information sheet and consent form

[Organisational logos and headers]

Participant information sheet (Phase 5)

Improving injecting skills and preventing blood borne virus infection in people who inject drugs in the UK

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the study is being done and what it would involve for you if you decide to take part. One of our team will go through the information sheet with you and answer any questions you have. This should take about 10 minutes. Do feel free to talk to others (friends, family, staff) about the study if you wish. Thank you for taking the time to learn more about this study.

Why are we doing this study?

There is a high risk of blood borne viruses (e.g. HIV, Hepatitis C and Hepatitis B) as a result of sharing injecting equipment (needles and syringes, water, spoons, cotton etc.) and unsafe sex. It is in everyone's interest to prevent the spread of these viruses. Opiate substitution therapy (methadone or buprenorphine) and needle exchanges have helped to reduce blood borne viruses but programmes that give people the skills and knowledge to be able to avoid or reduce these risks could help prevent the spread of these viruses.

In order to address skills and knowledge around safer drug use, we have developed a 3-session group programme to help people who inject to learn how to improve their injecting skills in order to avoid or reduce their sexual and drug related blood borne virus risk behaviours. This has been based on what people who inject drugs have told us about what they think would help them be safer.

We are doing this study to see whether it is possible to deliver a programme like this in drug treatment services, whether people who inject drugs would come to such a programme and what they thought about taking part in it. We need to know if this new programme is any better than similar information provided in an information leaflet. We will also look at how the costs of the programme compares to the leaflet. This study is being conducted in London, Glasgow, Yorkshire and North Wales to allow the results to be compared across different areas in the UK.

Why have I been approached?

We are interested in talking to people who have injected drugs at least once in the past month and who are attending drug treatment or needle exchanges and inviting them to take part.

If you decide to take part

If you agree to take part in this research project you will be asked to complete the contact form (with your preferred ways of being contacted) and sign the consent form. The contact information will be used during the study to remind you of appointments for the study. If you consent to take part in the study, the researcher will then invite you to take part in an interview where you will be asked questions about your drug use, sexual practices, knowledge of blood borne viruses and use of services. This should take around 45 minutes. You will be interviewed two more times – in about one month and then one month after that. After completing the first interview with the researcher, you will have a 50/50 chance of being allocated to one of two groups:

- **Group one will receive an information leaflet about transmission risk behaviours for blood borne viruses AND will be invited to attend a 3 session group programme**
- **Group two will receive the information leaflet only.**

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As the allocation process is done by an independent researcher after the questionnaire is completed, we can't say at this stage whether you will get the group programme option or not. It is also important to mention that the research team have no influence over what group you are allocated to.

Why are we allocating people to the group by chance?

If we allowed people to choose, we may end up with more people who like group programmes specifically who would then find it more favourable and this could influence the findings. It makes for a fairer comparison if people are allocated to groups by chance.

How will I be allocated?

Following completion of the first questionnaire, we will call the University of York Clinical Trials Unit in your presence who will use a computer programme to allocate you by chance to one of the two options. To do this, they need a limited amount of information on you (your initials, sex and age) and your drug use (the main drug you inject). This information is confidential and protected. We will tell you immediately following the end of the phone call which group you have been allocated to.

Option 1 – GROUP PROGRAMME AND INFORMATION LEAFLET

If you are allocated to the group programme we will let you know the time, date and location of the first session shortly.

The intervention will be delivered by trained staff. The sessions will take place at the drug treatment service from which you are recruited and will include three one-hour interactive sessions to help you learn how to:

1) Improve your injecting skills to inject more safely
2) Learn good vein care
2) Understand blood borne virus transmission risks, and
3) Develop strategies to reduce these risks (e.g. when injecting with others, planning for withdrawal, being prepared, negotiating with others).

The group programme will last 3 weeks, with one session per week. There will be up to 8 people in the group and separate groups will be held for women and men.

A small number of you will also be invited to take part in a focus group to talk about your experience of taking part in the programme. Even if you agree to take part in the programme you are under no obligation to take part in the focus group.

You will also be given an information leaflet on injection and sex transmission risks for blood borne viruses. You will also still be able to receive the care that is offered to all people attending needle exchanges or drug treatment.

Option 2 - INFORMATION LEAFLET

If you are allocated to this group you will be provided with an information leaflet on injection and sex transmission risks for blood borne viruses. You will receive the care that is usually offered to all people attending needle exchanges or drug treatment. We will also be inviting you to complete the same questionnaire at 2 time intervals in order to compare the information from people in option 1 with option 2.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice **and all information about you will be handled in confidence**. The questionnaires will contain only your study ID (not your name) and will be stored on a secure computer. Only the researchers conducting the study will have access to these questionnaires (not the staff at the needle exchange or drug service). The information will be kept on a university

computer secure drive and will be stored separately from your contact details. Data will be kept securely for 7 years after publication of the findings and then destroyed.

Limitations to confidentiality

- **The safety of yourself and others is very important to us. If you express current or future intention to harm yourself or someone else, there would be no grounds for maintaining confidentiality**. Your key worker or a duty worker at the drug treatment service where the interview has taken place will be told by the researcher of your intentions and the worker will conduct a risk assessment. We will inform you that we need to breach confidentiality at the point of disclosure.

What are the possible benefits of taking part?
Whether you take part in option 1 or 2, you will have a chance to take part in an exciting new study which could influence future developments around safer injecting and sexual practices. No matter what option you are allocated to, you will receive leaflets on safer injecting and sexual practices, and information on blood borne virus risk behaviours. If you are allocated to the option 1 group, you will have an opportunity to take part in a new group and learn some new skills to keep yourself and your friends and loved ones safer. You will also have the opportunity to give some feedback on how useful it is.

What are the possible disadvantages and risks of taking part?
There is low risk of harm by taking part. However, you may find talking about sensitive topics including potential risks for the spread of blood borne viruses could make you feel worried or anxious. If during any stage of the study you become worried or anxious about these topics or wish to find out more about blood borne viruses, you will be given the opportunity to speak to a member of staff at a local drug treatment service should you want to. We have also provided you with a range of contact numbers and websites that will be able to help.

What will happen if I don't want to carry on with the study?
Taking part is completely up to you. It is voluntary and you are free to withdraw from the study at any time without giving any reason. There are no consequences to this and this will have no bearing on your treatment. If you do choose to withdraw from the study, we will delete your contact details from our records, but we will need to use the data collected up to the point of your withdrawal. This will not affect your rights or your future care in any way.

Expenses
You will receive a shopping voucher for each of the three interviews completed. In addition, you will receive compensation for your time and expenses to attend the group sessions and also if you attend a focus group.

Will I get to hear about the findings from the study?
Yes, this is important. Summaries of the findings will be made available in the drug treatment services involved in this study in June 2016. You will not be identifiable from any of the results presented. They will be presented in an easy to understand format.

If I am not happy with something related to the study who can I speak to?
In the first instance you can raise any queries or concerns with the local study lead [*local lead contact details*]. If you're not happy with the care or treatment you've received as part of this study, you have the right to complain. Your local Patient Advice and Liaison Service (PALS) will be able to help you make a complaint. Phone NHS 111 for details of your nearest PALS.

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Who has reviewed this study?
All research that takes place in the NHS and other healthcare providers is looked at by an independent group called a Research Ethics Committee. They make sure that the research is fair and that the research team are properly qualified and have plans to ensure the comfort and safety of all

participants. The study has been reviewed by the East Midlands – Leicester South Research Ethics Committee (reference: 15/EM/0413).

Who is organising and funding the research?

The research is being led by Dr Gail Gilchrist, from the National Addiction Centre at King's College London, and is funded by the National Institute for Health Research. If you wish to talk to someone about the research please contact Dr Gilchrist on [telephone number].

Useful contact numbers

For information about **local drug treatment services** call the Frank drugs helpline on [redacted] or visit the Frank website http://www.talktofrank.com/need-support?ID=108

The Hepatitis C Trust Helpline [redacted] or [redacted] http://www.hepctrust.org.uk/
Open 10.30am to 4.30pm Monday to Friday (except Bank Holidays and the Christmas break, when dates and times may vary).Helpline is staffed solely by people with hepatitis C, some of whom have been through/or are currently undergoing treatment.

British Liver Trust [redacted]
www.britishlivertrust.org.uk (Free helpline, Mon-Fri 09.00-17.00) *The British Liver Trust is the national charity working to reduce the impact of liver disease in the UK through support, information and research.*

National Hepatitis Support Line [redacted]
http://www.hepbpositive.org.uk/ *Help the public and patients overcome hepatitis B. They clarify and reassure patients that hepatitis B is both easy to vaccinate against and caught early on an easy to manage common child acquired condition.*

National Sexual Health Line [redacted] **(24 hours)**
The National Sexual Health Line is UK-wide and provides confidential advice and information on all aspects of HIV, AIDS and sexual health. The Helpline can also provide UK wide referrals to specialist services. Open 24 hours a day, seven days a week. All calls are taken by trained and paid staff. It is not a counselling service, but gives you details of local helplines & services if needed.

Terrence Higgins Trust Direct Helpline [redacted]
(open 10am - 10pm Monday - Friday, and 12 noon - 6pm on Saturday and Sunday). Terrence Higgins Trust Direct Helpline can give you HIV information, advice

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[Organisational logos and headers]

CONSENT FORM (Phase 5)

Title of Project: Improving injecting skills and preventing blood borne virus infection in people who inject drugs in the UK

Name of Researcher: Dr Gail Gilchrist, local lead [*local lead name*]

Please initial all boxes

1. I confirm that the researcher has explained the information sheet to me and that I understand the information sheet dated 20/10/15 (version 2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at from the study any time without giving any reason, without my care or legal rights being affected. ☐

3. The procedures regarding confidentiality have been clearly explained to me (e.g. anonymization of data, use of pseudonyms in reports etc.). I understand that if I express current or future intention to harm myself or someone else that the researcher will inform my key worker or a duty worker at the drug treatment service where the interview has taken place and the worker will conduct a risk assessment. ☐

4. I understand that I will be allocated to the group intervention or information leaflet at random. ☐

5. I understand that the findings will be published at the end of the study but that I will not be identified from the findings. ☐

6. I agree to my anonymous data being shared with researchers at the five institutions where the research is being carried out – King's College London, University of the West of Scotland, University of York, NHS Wales and University of Huddersfield. ☐

7. I agree to take part in the above study and be re-interviewed two more times – approximately one and two months from today. ☐

Name of Participant	Date	Signature
Name of researcher	Date	Signature

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[Organisational logos and headers]

CONSENT FORM (Phase 5)

Title of Project: Improving injecting skills and preventing blood borne virus infection in people who inject drugs in the UK
Name of Researcher: Dr Davina Swan

Please initial all boxes

1. I confirm that the researcher has explained the information sheet to me and that I understand the information sheet dated 10/12/15 (version 3) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw from the study any time without giving any reason, without my care or legal rights being affected. ☐

3. The procedures regarding confidentiality have been clearly explained to me (e.g. anonymization of data, use of pseudonyms in reports etc.). I understand that if I express current or future intention to harm myself or someone else that the researcher will inform my key worker or a duty worker at the drug treatment service where the interview has taken place and the worker will conduct a risk assessment. ☐

4. I understand that I will be allocated to the group intervention or information leaflet at random. ☐

5. I understand that the findings will be published at the end of the study but that I will not be identified from the findings. ☐

6. I agree to my anonymous data being shared with researchers at the five institutions where the research is being carried out – King's College London, University of the West of Scotland, University of York, NHS Wales and University of Huddersfield. ☐

7. I agree to take part in the above study and be re-interviewed two more times – approximately one and two months from today. ☐

Name of Participant	Date	Signature
Name of researcher	Date	Signature

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Appendix 8 Data collection forms

Baseline:

[Organisational logos and headers]

Improving injecting skills and preventing blood borne virus infection in people who inject drugs in the UK

ID number ☐

Type of service recruited from
- ☐1 Drug treatment service
- ☐2 Needle Exchange
- ☐3 Sexual Health Clinic
- ☐4 Hostel/ Homeless service

Interview ☐1 Baseline

Age ☐

Time interview started ☐

Time interview finished ☐

As we previously discussed, we are doing this research to test the feasibility of an intervention to improve injecting skills, reduce blood borne viruses risk behaviours and increase knowledge about how you get or pass on HIV, Hepatitis C and Hepatitis B among people who inject drugs in the UK. Today I would like to ask you some questions about your injecting practices and sexual behaviours, and about how you think HIV, Hepatitis C and Hepatitis B is spread.

***Please consider the following questions carefully and answer each one as accurately as you can. Remember that the information you provide will remain completely confidential unless* you express current or future intention to harm yourself or someone else.**

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1. How old were you when you **first** injected? _____

2. How old are you now? _____

3. Are you? Male ☐ 1 Female ☐ 2 Transgender ☐ 3

4. Have you used a Needle Exchange (*or a pharmacy exchange*) in the **last month** (28 days)?

Yes ☐ 1 No ☐ 0

If yes: How many *individual* needles (including ones attached to syringes) did you get from Needle Exchanges during the **last month** (28 days)? _____

How many of these needles were **already attached** to syringes (barrels)? _____

5. Are you currently being prescribed a detox or maintenance drug script?

Yes ☐ 1 No ☐ 0

If yes: how long have you been on your **current** script?

Less than a month ☐ 1 1 to 6 months ☐ 2 Over 6 months ☐ 3

6. In the **last month** (28 days), have you used any of these drugs by any means, including injecting? (*Tick **all** that apply*)

	Yes	No		Yes	No
Cocaine	☐ 1	☐ 0	Cannabis	☐ 1	☐ 0
Amphetamine (speed)	☐ 1	☐ 0	Solvents or Glue	☐ 1	☐ 0
Crack	☐ 1	☐ 0	Ketamine	☐ 1	☐ 0
Heroin	☐ 1	☐ 0	Benzodiazepines	☐ 1	☐ 0
Mephedrone (m-cat)	☐ 1	☐ 0	Other drugs not prescribed to you	☐ 1	☐ 0
Methamphetamine	☐ 1	☐ 0	*Specify:*		
Ecstasy/'E' (MDMA)	☐ 1	☐ 0			

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7. Have you injected drugs in the **last month** (28 days)? Yes ☐1 No ☐0

If yes: In the **last month** (28 days) which of the following drugs have you injected? (*Tick **all** that apply*)

Heroin	☐	Crack	☐	Amphetamine (speed)	☐	Ketamine	☐
Methadone	☐	Cocaine	☐	Mephedrone (m-cat)	☐	Methamphetamine	☐

Other Drugs ☐ *Specify:*

In the **last month** (28 days), have you **injected both heroin and cocaine together** ("speedball")?

Yes ☐1 No ☐0

In the **last month** (28 days), have you had:

	Yes	No
An abcess (swelling containing pus), sore, or open wound at an injection site?	☐1	☐0
Endocarditis (heart infection)	☐1	☐0
Swelling of hands or feet	☐1	☐0
Problems getting a vein	☐1	☐0
Prominent scarring or bruising	☐1	☐0
Septicaemia (blood infection)	☐1	☐0
Thrombosis (blocked veins)	☐1	☐0
Other	☐1	☐0

Specify:

In the **last month** (28 days), on how many days have you injected drugs? _____

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In the **last month** (28 days), into which parts of your body did you inject drugs? (*Tick **all** that apply*)

Arms ☐₂ Hands ☐₂ Groin ☐₂ Legs ☐₂

Feet ☐₂ Neck ☐₂ Genitals ☐₂ Other ☐₂

In the **last month** (28 days), which **drug/s** have you injected most often? _____

In the **last month** (28 days):

To **how many different people** have you passed on your needle or syringe to after you had used it (*including your partner*)? None ☐₀ 1 ☐₁ 2 or more ☐₂

How many different people's needle or syringe have you used after someone else had used it (*including your partner*)? None ☐₀ 1 ☐₁ 2 or more ☐₂

In the **last month** (28 days), did you use spoons or other containers for mixing which had previously been used by someone else (*including your partner*)?

Yes ☐₁ No ☐₀

In the **last month** (28 days), did you pass on spoons or other containers for mixing which you had previously used to someone else (*including your partner*)?

Yes ☐₁ No ☐₀

In the **last month** (28 days), did you inject with **your own** needle or syringe after it had been cleaned (e.g. with water, bleach or detergent)?

Yes ☐₁ No ☐₀

In the **last month** (28 days), did you inject with **someone else's** needle or syringe after it had been cleaned (e.g. with water, bleach or detergent)?

Yes ☐₁ No ☐₀

In the **last month** (28 days), did you use filters which had previously been used by someone else (*including your partner*)?

Yes ☐₁ No ☐₀

In the **last month** (28 days), did you pass on filters which you had previously used to someone else (*including your partner*)?

Yes ☐₁ No ☐₀

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In the **last month** (28 days), did you share rinse water with someone else (*including your partner*)?

Yes ☐1 No ☐0

8. In the **last month** (28 days), have you overdosed (OD-ed, gone-over, gone-under), used drugs to the point where you have lost consciousness?

Yes ☐1 No ☐0

If yes: How many times in the **last month** (28 days) have you overdosed?

1 ☐1 2-4 ☐2 5-9 ☐3 10 or more ☐4

In the **last month** (28 days), did you receive naloxone (the heroin overdose antidote) when you overdosed?

Yes ☐1 No ☐0 Not Sure ☐2

9. Have you **ever** been vaccinated for hepatitis B (hep B jab)?

Yes ☐1 No ☐2 Not sure ☐3

If yes: How many hep B jabs have you had?

1 ☐1 2 ☐2 3+ ☐3 Not sure ☐4

At which of the following services did you receive a hep B jab? (*Tick **all** that apply*)

Needle Exchange	☐2
Drug Treatment Service	☐2
Sexual Health, GUM or STI Clinic	☐2
In Prison	☐2
Hostel or Homeless Service	☐2
GP or Family Doctor	☐2
A&E or Casualty Department	☐2
Elsewhere	☐2

10. Have you **ever** had a blood test for HIV?

Yes ☐1 No ☐0 Not sure ☐2

If yes: In which year did you **last** have an HIV test? _____

What was the result of your **last** test?

Positive ☐1 Negative ☐0 Awaiting result ☐2 Not sure ☐3

11. Have you **ever** had a blood test for hepatitis C?

Yes ☐1 No ☐2 Not sure ☐3

If yes: In which year did you **last** have a hepatitis C test? _____

What was the result of your **last** test?

Positive ☐1 Negative ☐2 Awaiting result ☐3 Not sure ☐4

If tested positive, have you **ever** seen a specialist nurse or doctor (e.g. a hepatologist) about your hepatitis C?

No ☐1 Yes, but **not** given any medicine for hepatitis C ☐2

Yes, and been **given** medicine for hepatitis C ☐3

12. Have you been homeless in the **last month** (28 days) - that is living in a hostel, having no fixed abode, or living on the streets?

Yes ☐1 No ☐2

How sure are you that you could do what is said in each of the following statements?

13. I can always find a vein when I am injecting drugs

absolutely sure I cannot	pretty sure I cannot	pretty sure I can	absolutely sure I can
☐1	☐2	☐3	☐4

When someone is injecting and sharing drugs, it can be difficult to avoid sharing needles, syringes or other injecting equipment with other people. For the next set of questions, please tell us how sure you are that you could do what is described in each situation, even if you have never been in that exact situation.

14. I can avoid sharing a needle or syringe even if I am in withdrawal.

absolutely sure I cannot	pretty sure I cannot	pretty sure I can	absolutely sure I can
☐1	☐2	☐3	☐4

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15. I can refuse to lend out my used needle or syringe even if I am using drugs with people I don't know.

absolutely sure I cannot	pretty sure I cannot	pretty sure I can	absolutely sure I can
☐1	☐2	☐3	☐4

16. I can refuse to lend out my used needle or syringe even if I am pressured by someone who is in withdrawal

absolutely sure I cannot	pretty sure I cannot	pretty sure I can	absolutely sure I can
☐1	☐2	☐3	☐4

17. I can avoid sharing injecting equipment even if I have a very limited supply of filters, cookers/pans or rinse water.

absolutely sure I cannot	pretty sure I cannot	pretty sure I can	absolutely sure I can
☐1	☐2	☐3	☐4

18. I can take the time to clean my needles and syringes the best I can with bleach and water, even if I am in withdrawal

absolutely sure I cannot	pretty sure I cannot	pretty sure I can	absolutely sure I can
☐1	☐2	☐3	☐4

19. I can talk to other drug injectors about safer drug use/harm reduction even if I don't know them

absolutely sure I cannot	pretty sure I cannot	pretty sure I can	absolutely sure I can
☐1	☐2	☐3	☐4

20. I can talk to other drug injectors about safer drug use/harm reduction even if I really need to inject

absolutely sure I cannot	pretty sure I cannot	pretty sure I can	absolutely sure I can
☐1	☐2	☐3	☐4

Version 3. 30/12/15

21. In the last month (28 days), have you done any of the following to avoid withdrawal?

1. Saved a bag/wrap for the next morning

Never	Rarely	Sometimes	Often	Very often
☐ 0	☐ 1	☐ 2	☐ 3	☐ 4

2. Put aside additional drugs (e.g., stashing heroin//cocaine not as a wake-up bag/line) to resort to in an emergency

Never	Rarely	Sometimes	Often	Very often
☐ 0	☐ 1	☐ 2	☐ 3	☐ 4

3. Stored methadone/buprenorphine(Subutex)

Never	Rarely	Sometimes	Often	Very often
☐ 0	☐ 1	☐ 2	☐ 3	☐ 4

4. Put aside money for getting the next bag in an emergency

Never	Rarely	Sometimes	Often	Very often
☐ 0	☐ 1	☐ 2	☐ 3	☐ 4

5. How many times did you use other substances (painkillers, benzodiazepines, other drugs) to see you through until you could get your drug of choice?

Never	Once	2-5 times	6-10 times	11 or more times
☐ 0	☐ 1	☐ 2	☐ 3	☐ 4

The next set of questions cover sensitive issues about sexual practices. This is not to embarrass you, but it is important for us to know to help us with the research. Please let me know if you feel uncomfortable answering any of these questions.

22. Have you had sex in the **last month** (28 days)?

Yes ☐ 1 → *If yes:*

With how many **men** in the **last month** (28 days)?

None ☐ 0 | 1 ☐ 1 | 2-4 ☐ 2 | 5-9 ☐ 3 | 10 or more ☐ 4

No ☐ 2

With how many **women** in the **last month** (28 days)?

None ☐ 0 | 1 ☐ 1 | 2-4 ☐ 2 | 5-9 ☐ 3 | 10 or more ☐ 4

Did you use a condom?

Always ☐ 1 | Sometimes ☐ 2 | Never ☐ 3

Many people respond differently when it comes to using condoms in various situations. For the following situations, how sure are you that you could use a condom for sex, even if you have never been in that exact situation?

23. When you want to have sex with a regular partner, you can use a condom even if they don't want to

absolutely sure I cannot	pretty sure I cannot	pretty sure I can	absolutely sure I can
☐ 1	☐ 2	☐ 3	☐ 4

24. When you want to have sex with a casual partner, you can use a condom even if they don't want to

absolutely sure I cannot	pretty sure I cannot	pretty sure I can	absolutely sure I can
☐ 1	☐ 2	☐ 3	☐ 4

25. When you want to have sex with a regular partner, you can use a condom even if you have been taking drugs or drinking alcohol.

absolutely sure I cannot	pretty sure I cannot	pretty sure I can	absolutely sure I can
☐ 1	☐ 2	☐ 3	☐ 4

26. When you want to have sex with a casual partner, you can use a condom even if you have been taking drugs or drinking alcohol.

absolutely sure I cannot	pretty sure I cannot	pretty sure I can	absolutely sure I can
☐ 1	☐ 2	☐ 3	☐ 4

27. You can talk to people about safer sex even if you don't know them

absolutely sure I cannot	pretty sure I cannot	pretty sure I can	absolutely sure I can
☐ 1	☐ 2	☐ 3	☐ 4

Version 3. 30/12/15

28. Have you received money, goods or drugs in exchange for sex in the last month (28 days)?

Yes ☐1 No ☐0

If yes: **how sure are you that:**

When you receive money, goods or drugs in exchange for sex, how sure are you that you can use a condom even if they don't want to.

absolutely sure I cannot	pretty sure I cannot	pretty sure I can	absolutely sure I can
☐1	☐2	☐3	☐4

When you receive money, goods or drugs in exchange for sex, how sure are you that you can use a condom even if you have been taking drugs or drinking alcohol.

absolutely sure I cannot	pretty sure I cannot	pretty sure I can	absolutely sure I can
☐1	☐2	☐3	☐4

How sure are you that you can talk about safer sex to people who give you money, goods or drugs in exchange for sex?

absolutely sure I cannot	pretty sure I cannot	pretty sure I can	absolutely sure I can
☐1	☐2	☐3	☐4

NOW I'D LIKE TO ASK YOU SOME QUESTIONS ABOUT HOW YOU THINK HIV CAN BE TRANSMITTED

29. How would you describe your understanding about how the HIV virus can be transmitted?

Poor	Fair	Good	Excellent
☐0	☐1	☐2	☐3

Version 3. 30/12/15

I AM NOW GOING TO READ A SERIES OF STATEMENTS ABOUT HIV TRANSMISSION, SOME OF THESE STATEMENTS ARE TRUE AND SOME OF THEM ARE FALSE. WHEN I READ EACH STATEMENT PLEASE ANSWER IF YOU THINK THE STATEMENT IS TRUE (TRUE), FALSE (FALSE) OR IF YOU DON'T KNOW IF IT IS TRUE OR FALSE (DON'T KNOW)

		TRUE	FALSE	DON'T KNOW
1	Coughing and sneezing DO NOT spread HIV	☐	☐	☐
2	A person can get HIV by sharing a glass of water with someone who has HIV	☐	☐	☐
3	Pulling out the penis before a man climaxes/cums keeps a woman from getting HIV during sex	☐	☐	☐
4	A woman can get HIV if she has anal sex with a man	☐	☐	☐
5	All pregnant women infected with HIV will have babies born with AIDS	☐	☐	☐
6	People who have been infected with HIV quickly show serious signs of being infected	☐	☐	☐
7	There is a vaccine that can stop adults from getting HIV	☐	☐	☐
8	People are likely to get HIV by deep kissing, putting their tongue in their partner's mouth, if their partner has HIV	☐	☐	☐
9	A woman cannot get HIV if she has sex during her period	☐	☐	☐
10	There is a female condom that can help decrease a woman's chance of getting HIV	☐	☐	☐
11	Having sex with more than one partner can increase a person's chance of being infected with HIV	☐	☐	☐
12	Taking a test for HIV one week after having sex will tell a person if she or he has HIV	☐	☐	☐
13	A person can get HIV from oral sex	☐	☐	☐
14	Using Vaseline or baby oil with condoms lowers the chance of getting HIV	☐	☐	☐

Version 3. 30/12/15

NOW I'D LIKE TO ASK YOU SOME QUESTIONS ABOUT HOW YOU THINK HEPATITIS C CAN BE TRANSMITTED

30. How would you describe your understanding about how the hepatitis C virus is transmitted?

☐$_0$ Poor ☐$_1$ Fair ☐$_2$ Good ☐$_3$ Excellent

I AM NOW GOING TO READ A SERIES OF STATEMENTS ABOUT HEPATITIS C TRANSMISSION, SOME OF THESE STATEMENTS ARE TRUE AND SOME OF THEM ARE FALSE. WHEN I READ EACH STATEMENT PLEASE ANSWER IF YOU THINK THE STATEMENT IS TRUE (TRUE), FALSE (FALSE) OR IF YOU DON'T KNOW IF IT IS TRUE OR FALSE (DON'T KNOW)

		TRUE	FALSE	DON'T KNOW
1	People with hepatitis C can safely share their toothbrushes and razors with other people.	☐	☐	☐
2	There is a hepatitis C vaccine that can be used to prevent people from getting infected with hepatitis C.	☐	☐	☐
3	Hepatitis C can be spread from shared kitchen cups, plates or utensils.	☐	☐	☐
4	Once someone´s hepatitis C virus has been completely treated and cleared, they cannot get re-infected with hepatitis C.	☐	☐	☐
5	People can get infected with hepatitis C from tattoos and body piercings.	☐	☐	☐
6	People can get more than one type of hepatitis C.	☐	☐	☐
7	Hepatitis C usually enters the body through blood of another person.	☐	☐	☐
8	A single or one time exposure is not enough to contract hepatitis C - people usually are infected only if they have been exposed to the hepatitis C virus many times.	☐	☐	☐
9	No more than a tiny amount of blood (so small that it can`t be seen) is needed to pass on hepatitis C.	☐	☐	☐
10	People can get hepatitis C through needle stick injuries.	☐	☐	☐
11	There is some risk that hepatitis C can be given to someone by snorting cocaine with shared straws, rolled money, etc.	☐	☐	☐
12	Using `new` (e.g. never used before) needles, syringes, and equipment reduces the risk of being infected with hepatitis C.	☐	☐	☐
13	When people share needles, it`s easier to get HIV than hepatitis C.	☐	☐	☐

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		TRUE	FALSE	DON'T KNOW
14	Hepatitis C can be spread when injecting drug users share their rinse water.	☐	☐	☐
15	Bleaching needles is a safe way for injecting drug users to avoid getting hepatitis C.	☐	☐	☐
16	People can get hepatitis C from sharing filters.	☐	☐	☐
17	It's safe to share tourniquets.	☐	☐	☐
18	It's safe to share spoons in the preparation of drugs for injecting.	☐	☐	☐
19	Flushing injecting equipment with boiling water will destroy the hepatitis C virus and makes it safe for others to reuse.	☐	☐	☐
20	Sharing injecting equipment with others is safe as long as it`s with people you know.	☐	☐	☐
21	Using cotton filters when drawing up drugs into a syringe will filter out the hepatitis C virus.	☐	☐	☐
22	People are still at risk of catching hepatitis C from using a shared needle that has not been used for over a month.	☐	☐	☐
23	Washing hands before and after injecting will help people to prevent the risk of passing on hepatitis C.	☐	☐	☐
24	Hepatitis C can be spread by sharing drug preparing water.	☐	☐	☐
25	Hepatitis C can be spread by sharing pipes when smoking drugs.	☐	☐	☐
26	Hepatitis C can be spread by wiping one`s own injection site with an object (e.g. swab, tissue, hanky, towel) which had been used by another person.	☐	☐	☐
27	Babies born to hepatitis C pregnant women can be infected with Hepatitis C at birth.	☐	☐	☐
28	There is a low risk that hepatitis C can be given to someone during sexual intercourse.	☐	☐	☐
29	Hepatitis C positive mothers are at risk of transmitting hepatitis C to their child through breastfeeding.	☐	☐	☐
30	People can get hepatitis C by deep kissing, putting the tongue in the partner`s mouth, if the partner has hepatitis C.	☐	☐	☐
31	Using a condom lowers people`s chance of getting hepatitis C through sexual intercourse.	☐	☐	☐
32	People are more likely to get hepatitis C if they share sex toys.	☐	☐	☐
33	Anal sex increases the risk of acquiring hepatitis C.	☐	☐	☐

Version 3. 30/12/15

NOW I'D LIKE TO ASK YOU SOME QUESTIONS ABOUT HOW YOU THINK HEPATITIS B CAN BE TRANSMITTED

31. How would you describe your understanding about how the hepatitis B virus can be transmitted?

Poor	Fair	Good	Excellent
☐$_0$	☐$_1$	☐$_2$	☐$_3$

I AM NOW GOING TO READ A SERIES OF STATEMENTS ABOUT HEPATITIS B TRANSMISSION, SOME OF THESE STATEMENTS ARE TRUE AND SOME OF THEM ARE FALSE. WHEN I READ EACH STATEMENT PLEASE ANSWER IF YOU THINK THE STATEMENT IS TRUE (TRUE), FALSE (FALSE) OR IF YOU DON'T KNOW IF IT IS TRUE OR FALSE (DON'T KNOW)

Hepatitis B can be transmitted.....	**True**	**False**	**Don't know**
1. By having unprotected sex with a person with hepatitis B	☐	☐	☐
2. Through mother to child at birth	☐	☐	☐
3. By kissing a person with hepatitis B	☐	☐	☐
4. By eating food prepared by a person with hepatitis B	☐	☐	☐
5. Through the air when a person with hepatitis B coughs or sneezes	☐	☐	☐
6. By sharing eating utensils	☐	☐	☐
7. By sharing toothbrushes or razor blades	☐	☐	☐
8. By sharing injecting equipments, e.g. needles used in acupuncture, tattooing, body piercing or drug use	☐	☐	☐
Natural history			
9. Hepatitis B can cause liver damage, including liver cancer	☐	☐	☐
10. Most people infected with hepatitis B have no symptoms	☐	☐	☐
11. People with hepatitis B are infected for life	☐	☐	☐
Clinical management			
12. Hepatitis B can be cured	☐	☐	☐
13. There are effective treatments for hepatitis B	☐	☐	☐
Epidemiology and prevention			
14. There is a vaccination to prevent hepatitis B	☐	☐	☐
15. People with hepatitis B should use condoms when having sex	☐	☐	☐

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32a. How motivated are you to protect yourself from getting blood borne viruses?

Extremely motivated	Quite motivated	Neither motivated or not motivated	Not motivated	Not at all motivated
☐1	☐2	☐3	☐4	☐5

32b. How motivated are you to protect other people from getting blood borne viruses?

Extremely motivated	Quite motivated	Neither motivated or not motivated	Not motivated	Not at all motivated
☐1	☐2	☐3	☐4	☐5

VIGNETTES

Scenario 1

You are in a treatment service and you meet someone who tells you they have got some heroin. They ask you to try it out, but there is only one spoon. What would you do? Why?

Version 3. 30/12/15

Scenario 2

You are lying in bed and you've had no money for a few days. You are finally drifting off to sleep for the first time in days when a friend turns up at your door with a big bag of coke. They have no needles but you have one. What would you do? Why?

Scenario 3

You wake up in the morning withdrawing. Your flatmate offers to square you up as they can see you are suffering, you have no needles but the person you share a flat with has a used needle, and offers to let you inject after them. They say they are the only one that has used it and that they don't have Hepatitis C. What would you do? Why?

Version 3. 30/12/15

HEALTH SERVICES

This section asks about your use of health and social resources in the past month. Please read each question carefully and remember each question relates to the **past month only**.

Hospital and Primary Health Care Services

In the **past month** how many times have you visited an accident and emergency department as a patient?	
In the **past month** how many nights have you spent in hospital as an inpatient?	
In the **past month** how many times have you attended hospital as an outpatient?	
In the **past month** how many times have you attended a day hospital? (i.e. you have been admitted to hospital but not kept in overnight)	
In the **past month** how many times have you been taken to hospital in an emergency ambulance?	
In the **past month** how many times have you been taken to or from hospital using a patient transport service?	
In the **past month** how many times have you visited a doctor at your GP practice?	
In the **past month** how many times has a doctor visited you at home?	
In the **past month** how many times have you visited the nurse at your GP practice?	
In the **past month** how many times has a nurse visited you at home?	
How many times have you received a prescription in the **past month**?	

In the **past month** have you visited any other health care professional **other than** a doctor or nurse at your GP surgery?

Professional visited	No times
_____	
_____	

DRUG SERVICES

In the **past month** how many times have you visited a key worker at a drug service?	
In the **past month** how many times have you participated in group work at a drug service?	
In the **past month** how many times have you visited a specialist drug service for methadone dispensing?	
In the **past month** how many times have you visited a pharmacist for methadone dispensing?	
In the **past month** how many times have you visited a nurse at a drug service?	
In the **past month** how many times have you visited a needle exchange?	
In the **past month** how many times have you had contact with an outreach worker?	
In the **past month** how many times have you been tested for HIV, hepatitis B or hepatitis C?	

Version 3. 30/12/15

In the **past month** how many times have you had treatment for HIV? | | | |

In the **past month** how many times have you had treatment for hepatitis C? | | | |

In the **past month** how many times have you had treatment for hepatitis B? | | | |

OTHER SERVICES

In the **past month** how many times have you visited a mental health specialist? | | | |

In the **past month** how many times have you visited a social worker? | | | |

In the **past month** how many times have you visited a dentist? | | | |

In the **past month** how many times have you visited a family planning clinic? | | | |

In the **past month** how many times have you visited a sexual health clinic, GUM or STI clinic? | | | |

The next set of questions asks about criminal justice issues and therefore, may be considered sensitive. We want to remind you that your responses are confidential and for the purposes of the research only.

POLICE AND CRIMINAL JUSTICE SYSTEM CONTACTS

In the **past month** how many times have you been arrested, cautioned or received an on the spot fine? | | | |

Have you appeared in court in the **past month**? **Yes** | **No**

If yes how many times have you appeared in a magistrates court (days) | | | |

If yes how many times have you appeared in a crown court (times) | | | |

Have you been in prison in **past month**? **Yes** | **No**

If yes how many days in total? | | | |

MEDICATIONS

Please tell us below what medication(s) you are currently taking, filling in the table in the same way as the example given

Medication	Daily dose	Reason
E.G. Frusemide	E.G. 20MG	E.G. Heart Failure

Version 3. 30/12/15

HEALTH QUESTIONNAIRE

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

- I have no problems in walking about ☐
- I have slight problems in walking about ☐
- I have moderate problems in walking about ☐
- I have severe problems in walking about ☐
- I am unable to walk about ☐

SELF-CARE

- I have no problems washing or dressing myself ☐
- I have slight problems washing or dressing myself ☐
- I have moderate problems washing or dressing myself ☐
- I have severe problems washing or dressing myself ☐
- I am unable to wash or dress myself ☐

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

- I have no problems doing my usual activities ☐
- I have slight problems doing my usual activities ☐
- I have moderate problems doing my usual activities ☐
- I have severe problems doing my usual activities ☐
- I am unable to do my usual activities ☐

PAIN / DISCOMFORT

- I have no pain or discomfort ☐
- I have slight pain or discomfort ☐
- I have moderate pain or discomfort ☐
- I have severe pain or discomfort ☐
- I have extreme pain or discomfort ☐

ANXIETY / DEPRESSION

- I am not anxious or depressed ☐
- I am slightly anxious or depressed ☐
- I am moderately anxious or depressed ☐
- I am severely anxious or depressed ☐
- I am extremely anxious or depressed ☐

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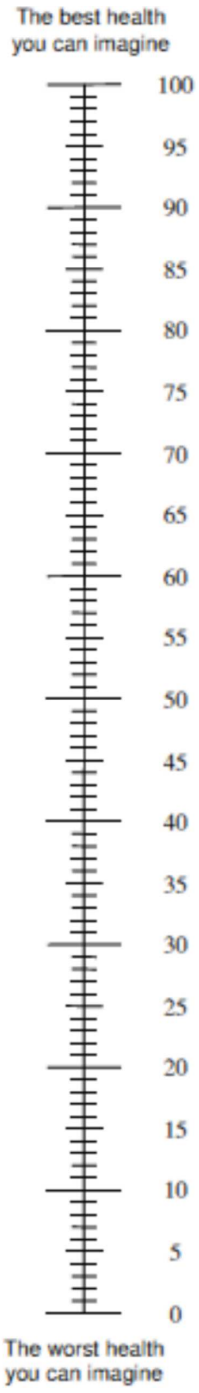
- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



Follow-up:

[Organisational logos and headers]

Improving injecting skills and preventing blood borne virus infection in people who inject drugs in the UK

ID number ☐

Interview ☐2 End of intervention
☐3 One month post intervention

Time interview started ☐

Time interview finished ☐

As we previously discussed, we are doing this research to test the feasibility of an intervention to improve injecting skills, reduce blood borne viruses risk behaviours and increase knowledge about how you get or pass on HIV, Hepatitis C and Hepatitis B among people who inject drugs in the UK. Today I would like to ask you some questions about your injecting practices and sexual behaviours, and about how you think HIV, Hepatitis C and Hepatitis B is spread.

***Please consider the following questions carefully and answer each one as accurately as you can. Remember that the information you provide will remain completely confidential unless* you express current or future intention to harm yourself or someone else.**

Version 4. 18/02/16

1. Have you used a Needle Exchange (*or a pharmacy exchange*) in the last month (28 days)?

Yes ☐1 No ☐0

If yes: How many *individual* needles (including ones attached to syringes) did you get from Needle Exchanges during the **last month** (28 days)? _____

How many of these needles were **already attached** to syringes (barrels)? _____

2. Are you currently being prescribed a detox or maintenance drug script?

Yes ☐1 No ☐0

If yes: how long have you been on your **current** script?

Less than a month ☐1 1 to 6 months ☐2 Over 6 months ☐3

3. In the **last month** (28 days), have you used any of these drugs by any means, including injecting? (*Tick **all** that apply*)

	Yes	No		Yes	No
Cocaine	☐1	☐0	Cannabis	☐1	☐0
Amphetamine (speed)	☐1	☐0	Solvents or Glue	☐1	☐0
Crack	☐1	☐0	Ketamine	☐1	☐0
Heroin	☐1	☐0	Benzodiazepines	☐1	☐0
Mephedrone (m-cat)	☐1	☐0	Other drugs not prescribed to you	☐1	☐0
Methamphetamine	☐1	☐0	*Specify:*		
Ecstasy/'E' (MDMA)	☐1	☐0			

Version 4. 18/02/16

4. Have you injected drugs in the **last month** (28 days)? Yes ☐1 No ☐0

If yes: In the **last month** (28 days) which of the following drugs have you injected? (*Tick **all** that apply*)

Heroin ☐2 Crack ☐2 Amphetamine (speed) ☐2 Ketamine ☐2

Methadone ☐2 Cocaine ☐2 Mephedrone (m-cat) ☐2 Methamphetamine ☐2

Other Drugs ☐2 *Specify:*

In the **last month** (28 days), have you **injected both heroin and cocaine together** ("speedball")?

Yes ☐1 No ☐0

In the **last month** (28 days), have you had:

	Yes	No
An abcess (swelling containing pus), sore, or open wound at an injection site?	☐1	☐0
Endocarditis (heart infection)	☐1	☐0
Swelling of hands or feet	☐1	☐0
Problems getting a vein	☐1	☐0
Prominent scarring or bruising	☐1	☐0
Septicaemia (blood infection)	☐1	☐0
Thrombosis (blocked veins)	☐1	☐0
Other	☐1	☐0

Specify:

In the **last month** (28 days), on how many days have you injected drugs? _____

Version 4. 18/02/16

In the **last month** (28 days), into which parts of your body did you inject drugs? (*Tick **all** that apply*)

Arms ☐2 Hands ☐2 Groin ☐2 Legs ☐2

Feet ☐2 Neck ☐2 Genitals ☐2 Other ☐2

In the **last month** (28 days), which **drug/s** have you injected most often? _____

In the **last month** (28 days):

To **how many different people** have you passed on your needle or syringe to after you had used it (*including your partner*)? None ☐0 1 ☐1 2 or more ☐2

How many different people's needle or syringe have you used after someone else had used it (*including your partner*)? None ☐0 1 ☐1 2 or more ☐2

In the **last month** (28 days), did you use spoons or other containers for mixing which had previously been used by someone else (*including your partner*)?

Yes ☐1 No ☐0

In the **last month** (28 days), did you pass on spoons or other containers for mixing which you had previously used to someone else (*including your partner*)?

Yes ☐1 No ☐0

In the **last month** (28 days), did you inject with **your own** needle or syringe after it had been cleaned (e.g. with water, bleach or detergent)?

Yes ☐1 No ☐0

In the **last month** (28 days), did you inject with **someone else's** needle or syringe after it had been cleaned (e.g. with water, bleach or detergent)?

Yes ☐1 No ☐0

In the **last month** (28 days), did you use filters which had previously been used by someone else (*including your partner*)?

Yes ☐1 No ☐0

In the **last month** (28 days), did you pass on filters which you had previously used to someone else (*including your partner*)?

Yes ☐1 No ☐0

Version 4. 18/02/16

In the **last month** (28 days), did you share rinse water with someone else (*including your partner*)?

Yes ☐1 No ☐0

5. In the **last month** (28 days), have you overdosed (OD-ed, gone-over, gone-under), used drugs to the point where you have lost consciousness?

Yes ☐1 No ☐0

If yes: How many times in the **last month** (28 days) have you overdosed?

1 ☐1 2-4 ☐2 5-9 ☐3 10 or more ☐4

In the **last month** (28 days), did you receive naloxone (the heroin overdose antidote) when you overdosed?

Yes ☐1 No ☐0 Not Sure ☐2

6. Have you **ever** been vaccinated for hepatitis B (hep B jab)?

Yes ☐1 No ☐2 Not sure ☐3

If yes: How many hep B jabs have you had?

1 ☐1 2 ☐2 3+ ☐3 Not sure ☐4

At which of the following services did you receive a hep B jab? (*Tick **all** that apply*)

Needle Exchange	☐2
Drug Treatment Service	☐2
Sexual Health, GUM or STI Clinic	☐2
In Prison	☐2
Hostel or Homeless Service	☐2
GP or Family Doctor	☐2
A&E or Casualty Department	☐2
Elsewhere	☐2

7. Have you **ever** had a blood test for HIV?

Yes ☐1 No ☐0 Not sure ☐2

If yes: In which year did you **last** have an HIV test? _____

What was the result of your **last** test?

Positive ☐1 Negative ☐0 Awaiting result ☐2 Not sure ☐3

8. Have you **ever** had a blood test for hepatitis C?

Yes ☐ 1 No ☐ 0 Not sure ☐ 2

If yes: In which year did you **last** have a hepatitis C test? _____

What was the result of your **last** test?

Positive ☐ 1 Negative ☐ 0 Awaiting result ☐ 2 Not sure ☐ 3

If tested positive, have you **ever** seen a specialist nurse or doctor (e.g. a hepatologist) about your hepatitis C?

No ☐ 0 Yes, but **not** given any medicine for hepatitis C ☐ 2

Yes, and been **given** medicine for hepatitis C ☐ 3

9. Have you been homeless in the **last month** (28 days) - that is living in a hostel, having no fixed abode, or living on the streets?

Yes ☐ 1 No ☐ 0

How sure are you that you could do what is said in each of the following statements?

10. I can always find a vein when I am injecting drugs

absolutely sure I cannot	pretty sure I cannot	pretty sure I can	absolutely sure I can
☐ 1	☐ 2	☐ 3	☐ 4

When someone is injecting and sharing drugs, it can be difficult to avoid sharing needles, syringes or other injecting equipment with other people. For the next set of questions, please tell us how sure you are that you could do what is described in each situation, even if you have never been in that exact situation.

11. I can avoid sharing a needle or syringe even if I am in withdrawal.

absolutely sure I cannot	pretty sure I cannot	pretty sure I can	absolutely sure I can
☐ 1	☐ 2	☐ 3	☐ 4

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12. I can refuse to lend out my used needle or syringe even if I am using drugs with people I don't know.

absolutely sure I cannot	pretty sure I cannot	pretty sure I can	absolutely sure I can
☐1	☐2	☐3	☐4

13. I can refuse to lend out my used needle or syringe even if I am pressured by someone who is in withdrawal

absolutely sure I cannot	pretty sure I cannot	pretty sure I can	absolutely sure I can
☐1	☐2	☐3	☐4

14. I can avoid sharing injecting equipment even if I have a very limited supply of filters, cookers/pans or rinse water.

absolutely sure I cannot	pretty sure I cannot	pretty sure I can	absolutely sure I can
☐1	☐2	☐3	☐4

15. I can take the time to clean my needles and syringes the best I can with bleach and water, even if I am in withdrawal

absolutely sure I cannot	pretty sure I cannot	pretty sure I can	absolutely sure I can
☐1	☐2	☐3	☐4

16. I can talk to other drug injectors about safer drug use/harm reduction even if I don't know them

absolutely sure I cannot	pretty sure I cannot	pretty sure I can	absolutely sure I can
☐1	☐2	☐3	☐4

Version 4. 18/02/16

17. I can talk to other drug injectors about safer drug use/harm reduction even if I really need to inject

absolutely sure I cannot	pretty sure I cannot	pretty sure I can	absolutely sure I can
☐1	☐2	☐3	☐4

18. In the last month (28 days), have you done any of the following to avoid withdrawal?

1. Saved a bag/wrap for the next morning

Never	Rarely	Sometimes	Often	Very often
☐0	☐1	☐2	☐3	☐4

2. Put aside additional drugs (e.g., stashing heroin//cocaine not as a wake-up bag/line) to resort to in an emergency

Never	Rarely	Sometimes	Often	Very often
☐0	☐1	☐2	☐3	☐4

3. Stored methadone/ buprenorphine(Subutex)

Never	Rarely	Sometimes	Often	Very often
☐0	☐1	☐2	☐3	☐4

4. Put aside money for getting the next bag in an emergency

Never	Rarely	Sometimes	Often	Very often
☐0	☐1	☐2	☐3	☐4

5. How many times did you use other substances (painkillers, benzodiazepines, other drugs) to see you through until you could get your drug of choice?

Never	Once	2-5 times	6-10 times	11 or more times
☐0	☐1	☐2	☐3	☐4

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The next set of questions cover sensitive issues about sexual practices. This is not to embarrass you, but it is important for us to know to help us with the research. Please let me know if you feel uncomfortable answering any of these questions.

19. Have you had sex in the **last month** (28 days)?

Yes ☐1 → *If yes:*

With how many **men** in the **last month** (28 days)?

None ☐0 1 ☐1 2-4 ☐4 5-9 ☐5 10 or more ☐6

No ☐2

With how many **women** in the **last month** (28 days)?

None ☐0 1 ☐1 2-4 ☐4 5-9 ☐5 10 or more ☐6

Did you use a condom?

Always ☐1 Sometimes ☐2 Never ☐3

Many people respond differently when it comes to using condoms in various situations. For the following situations, how sure are you that you could use a condom for sex, even if you have never been in that exact situation?

20. When you want to have sex with a <u>regular</u> partner, you can use a condom even if they don't want to

absolutely sure I cannot	pretty sure I cannot	pretty sure I can	absolutely sure I can
☐1	☐2	☐3	☐4

21. When you want to have sex with a <u>casual</u> partner, you can use a condom even if they don't want to

absolutely sure I cannot	pretty sure I cannot	pretty sure I can	absolutely sure I can
☐1	☐2	☐3	☐4

22. When you want to have sex with a <u>regular</u> partner, you can use a condom even if you have been taking drugs or drinking alcohol.

absolutely sure I cannot	pretty sure I cannot	pretty sure I can	absolutely sure I can
☐1	☐2	☐3	☐4

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23. When you want to have sex with a casual partner, you can use a condom even if you have been taking drugs or drinking alcohol.

absolutely sure I cannot ☐1 | pretty sure I cannot ☐2 | pretty sure I can ☐3 | absolutely sure I can ☐4

24. You can talk to people about safer sex even if you don't know them

absolutely sure I cannot ☐1 | pretty sure I cannot ☐2 | pretty sure I can ☐3 | absolutely sure I can ☐4

25. Have you received money, goods or drugs in exchange for sex in the last month (28 days)?

Yes ☐1 No ☐0

If yes: **how sure are you that:**

When you receive money, goods or drugs in exchange for sex, how sure are you that you can use a condom even if they don't want to.

absolutely sure I cannot ☐1 | pretty sure I cannot ☐2 | pretty sure I can ☐3 | absolutely sure I can ☐4

When you receive money, goods or drugs in exchange for sex, how sure are you that you can use a condom even if you have been taking drugs or drinking alcohol.

absolutely sure I cannot ☐1 | pretty sure I cannot ☐2 | pretty sure I can ☐3 | absolutely sure I can ☐4

How sure are you that you can talk about safer sex to people who give you money, goods or drugs in exchange for sex?

absolutely sure I cannot ☐1 | pretty sure I cannot ☐2 | pretty sure I can ☐3 | absolutely sure I can ☐4

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NOW I'D LIKE TO ASK YOU SOME QUESTIONS ABOUT HOW YOU THINK HIV CAN BE TRANSMITTED

26. How would you describe your understanding about how the HIV virus can be transmitted?

Poor	Fair	Good	Excellent
☐ 0	☐ 1	☐ 2	☐ 3

I AM NOW GOING TO READ A SERIES OF STATEMENTS ABOUT HIV TRANSMISSION, SOME OF THESE STATEMENTS ARE TRUE AND SOME OF THEM ARE FALSE. WHEN I READ EACH STATEMENT PLEASE ANSWER IF YOU THINK THE STATEMENT IS TRUE (TRUE), FALSE (FALSE) OR IF YOU DON'T KNOW IF IT IS TRUE OR FALSE (DON'T KNOW)

		TRUE	FALSE	DON'T KNOW
1	Coughing and sneezing DO NOT spread HIV	☐	☐	☐
2	A person can get HIV by sharing a glass of water with someone who has HIV	☐	☐	☐
3	Pulling out the penis before a man climaxes/cums keeps a woman from getting HIV during sex	☐	☐	☐
4	A woman can get HIV if she has anal sex with a man	☐	☐	☐
5	All pregnant women infected with HIV will have babies born with AIDS	☐	☐	☐
6	People who have been infected with HIV quickly show serious signs of being infected	☐	☐	☐
7	There is a vaccine that can stop adults from getting HIV	☐	☐	☐
8	People are likely to get HIV by deep kissing, putting their tongue in their partner's mouth, if their partner has HIV	☐	☐	☐
9	A woman cannot get HIV if she has sex during her period	☐	☐	☐
10	There is a female condom that can help decrease a woman's chance of getting HIV	☐	☐	☐
11	Having sex with more than one partner can increase a person's chance of being infected with HIV	☐	☐	☐

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		TRUE	FALSE	DON'T KNOW
12	Taking a test for HIV one week after having sex will tell a person if she or he has HIV	☐	☐	☐
13	A person can get HIV from oral sex	☐	☐	☐
14	Using Vaseline or baby oil with condoms lowers the chance of getting HIV	☐	☐	☐

NOW I'D LIKE TO ASK YOU SOME QUESTIONS ABOUT HOW YOU THINK HEPATITIS C CAN BE TRANSMITTED

27. How would you describe your understanding about how the hepatitis C virus is transmitted?

☐$_0$ Poor ☐$_1$ Fair ☐$_2$ Good ☐$_3$ Excellent

I AM NOW GOING TO READ A SERIES OF STATEMENTS ABOUT HEPATITIS C TRANSMISSION, SOME OF THESE STATEMENTS ARE TRUE AND SOME OF THEM ARE FALSE. WHEN I READ EACH STATEMENT PLEASE ANSWER IF YOU THINK THE STATEMENT IS TRUE (TRUE), FALSE (FALSE) OR IF YOU DON'T KNOW IF IT IS TRUE OR FALSE (DON'T KNOW)

		TRUE	FALSE	DON'T KNOW
1	People with hepatitis C can safely share their toothbrushes and razors with other people.	☐	☐	☐
2	There is a hepatitis C vaccine that can be used to prevent people from getting infected with hepatitis C.	☐	☐	☐
3	Hepatitis C can be spread from shared kitchen cups, plates or utensils.	☐	☐	☐
4	Once someone´s hepatitis C virus has been completely treated and cleared, they cannot get re-infected with hepatitis C.	☐	☐	☐
5	People can get infected with hepatitis C from tattoos and body piercings.	☐	☐	☐
6	People can get more than one type of hepatitis C.	☐	☐	☐
7	Hepatitis C usually enters the body through blood of another person.	☐	☐	☐
8	A single or one time exposure is not enough to contract hepatitis C - people usually are infected only if they have been exposed to the hepatitis C virus many times.	☐	☐	☐
9	No more than a tiny amount of blood (so small that it can`t be seen) is needed to pass on hepatitis C.	☐	☐	☐

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		TRUE	FALSE	DON'T KNOW
10	People can get hepatitis C through needle stick injuries.	☐	☐	☐
11	There is some risk that hepatitis C can be given to someone by snorting cocaine with shared straws, rolled money, etc.	☐	☐	☐
12	Using `new` (e.g. never used before) needles, syringes, and equipment reduces the risk of being infected with hepatitis C.	☐	☐	☐
13	When people share needles, it`s easier to get HIV than hepatitis C.	☐	☐	☐
14	Hepatitis C can be spread when injecting drug users share their rinse water.	☐	☐	☐
15	Bleaching needles is a safe way for injecting drug users to avoid getting hepatitis C.	☐	☐	☐
16	People can get hepatitis C from sharing filters.	☐	☐	☐
17	It`s safe to share tourniquets.	☐	☐	☐
18	It`s safe to share spoons in the preparation of drugs for injecting.	☐	☐	☐
19	Flushing injecting equipment with boiling water will destroy the hepatitis C virus and makes it safe for others to reuse.	☐	☐	☐
20	Sharing injecting equipment with others is safe as long as it`s with people you know.	☐	☐	☐
21	Using cotton filters when drawing up drugs into a syringe will filter out the hepatitis C virus.	☐	☐	☐
22	People are still at risk of catching hepatitis C from using a shared needle that has not been used for over a month.	☐	☐	☐
23	Washing hands before and after injecting will help people to prevent the risk of passing on hepatitis C.	☐	☐	☐
24	Hepatitis C can be spread by sharing drug preparing water.	☐	☐	☐
25	Hepatitis C can be spread by sharing pipes when smoking drugs.	☐	☐	☐
26	Hepatitis C can be spread by wiping one`s own injection site with an object (e.g. swab, tissue, hanky, towel) which had been used by another person.	☐	☐	☐
27	Babies born to hepatitis C pregnant women can be infected with Hepatitis C at birth.	☐	☐	☐
28	There is a low risk that hepatitis C can be given to someone during sexual intercourse.	☐	☐	☐
29	Hepatitis C positive mothers are at risk of transmitting hepatitis C to their child through breastfeeding.	☐	☐	☐
30	People can get hepatitis C by deep kissing, putting the tongue in the partner`s mouth, if the partner has hepatitis C.	☐	☐	☐

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		TRUE	FALSE	DON'T KNOW
31	Using a condom lowers people`s chance of getting hepatitis C through sexual intercourse.	☐	☐	☐
32	People are more likely to get hepatitis C if they share sex toys.	☐	☐	☐
33	Anal sex increases the risk of acquiring hepatitis C.	☐	☐	☐

NOW I'D LIKE TO ASK YOU SOME QUESTIONS ABOUT HOW YOU THINK HEPATITIS B CAN BE TRANSMITTED

28. How would you describe your understanding about how the hepatitis B virus can be transmitted?

Poor	Fair	Good	Excellent
☐0	☐1	☐2	☐3

I AM NOW GOING TO READ A SERIES OF STATEMENTS ABOUT HEPATITIS B TRANSMISSION, SOME OF THESE STATEMENTS ARE TRUE AND SOME OF THEM ARE FALSE. WHEN I READ EACH STATEMENT PLEASE ANSWER IF YOU THINK THE STATEMENT IS TRUE (TRUE), FALSE (FALSE) OR IF YOU DON'T KNOW IF IT IS TRUE OR FALSE (DON'T KNOW)

Hepatitis B can be transmitted…..	True	False	Don't know
1. By having unprotected sex with a person with hepatitis B	☐	☐	☐
2. Through mother to child at birth	☐	☐	☐
3. By kissing a person with hepatitis B	☐	☐	☐
4. By eating food prepared by a person with hepatitis B	☐	☐	☐
5. Through the air when a person with hepatitis B coughs or sneezes	☐	☐	☐
6. By sharing eating utensils	☐	☐	☐
7. By sharing toothbrushes or razor blades	☐	☐	☐
8. By sharing injecting equipments, e.g. needles used in acupuncture, tattooing, body piercing or drug use	☐	☐	☐
Natural history			
9. Hepatitis B can cause liver damage, including liver cancer	☐	☐	☐
10. Most people infected with hepatitis B have no symptoms	☐	☐	☐
11. People with hepatitis B are infected for life	☐	☐	☐

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Hepatitis B can be transmitted…..	True	False	Don't know
Clinical management			
12. Hepatitis B can be cured	☐	☐	☐
13. There are effective treatments for hepatitis B	☐	☐	☐
Epidemiology and prevention			
14. There is a vaccination to prevent hepatitis B	☐	☐	☐
15. People with hepatitis B should use condoms when having sex	☐	☐	☐

29a. How motivated are you to protect yourself from getting blood borne viruses?

Extremely motivated	Quite motivated	Neither motivated or not motivated	Not motivated	Not at all motivated
☐1	☐2	☐3	☐4	☐5

29b. How motivated are you to protect other people from getting blood borne viruses?

Extremely motivated	Quite motivated	Neither motivated or not motivated	Not motivated	Not at all motivated
☐1	☐2	☐3	☐4	☐5

VIGNETTES

Scenario 1

You are in a treatment service and you meet someone who tells you they have got some heroin. They ask you to try it out, but there is only one spoon. What would you do? Why?

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Scenario 2
You are lying in bed and you've had no money for a few days. You are finally drifting off to sleep for the first time in days when a friend turns up at your door with a big bag of coke. They have no needles but you have one. What would you do? Why?

Scenario 3
You wake up in the morning withdrawing. Your flatmate offers to square you up as they can see you are suffering, you have no needles but the person you share a flat with has a used needle, and offers to let you inject after them. They say they are the only one that has used it and that they don't have Hepatitis C. What would you do? Why?

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HEALTH SERVICES

This section asks about your use of health and social resources in the past month. Please read each question carefully and remember each question relates to the **past month only**.

Hospital and Primary Health Care Services

In the **past month** how many times have you visited an accident and emergency department as a patient?

In the **past month** how many nights have you spent in hospital as an inpatient?

In the **past month** how many times have you attended hospital as an outpatient?

In the **past month** how many times have you attended a day hospital? (i.e. you have been admitted to hospital but not kept in overnight)

In the **past month** how many times have you been taken to hospital in an emergency ambulance?

In the **past month** how many times have you been taken to or from hospital using a patient transport service?

In the **past month** how many times have you visited a doctor at your GP practice?

In the **past month** how many times has a doctor visited you at home?

In the **past month** how many times have you visited the nurse at your GP practice?

In the **past month** how many times has a nurse visited you at home?

How many times have you received a prescription in the **past month**?

In the **past month** have you visited any other health care professional **other than** a doctor or nurse at your GP surgery?

Professional visited	No times
_____	
_____	

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DRUG SERVICES

In the **past month** how many times have you visited a key worker at a drug service? | | |

In the **past month** how many times have you participated in group work at a drug service? | | |

In the **past month** how many times have you visited a specialist drug service for methadone dispensing? | | |

In the **past month** how many times have you visited a pharmacist for methadone dispensing? | | |

In the **past month** how many times have you visited a nurse at a drug service? | | |

In the **past month** how many times have you visited a needle exchange? | | |

In the **past month** how many times have you had contact with an outreach worker? | | |

In the **past month** how many times have you been tested for HIV, hepatitis B or hepatitis C? | | |

In the **past month** how many times have you had treatment for HIV? | | |

In the **past month** how many times have you had treatment for hepatitis C? | | |

In the **past month** how many times have you had treatment for hepatitis B? | | |

OTHER SERVICES

In the **past month** how many times have you visited a mental health specialist? | | |

In the **past month** how many times have you visited a social worker? | | |

In the **past month** how many times have you visited a dentist? | | |

In the **past month** how many times have you visited a family planning clinic? | | |

In the **past month** how many times have you visited a sexual health clinic, GUM or STI clinic? | | |

The next set of questions asks about criminal justice issues and therefore, may be considered sensitive. We want to remind you that your responses are confidential and for the purposes of the research only.

POLICE AND CRIMINAL JUSTICE SYSTEM CONTACTS

In the **past month** how many times have you been arrested, cautioned or received an on the spot fine? | | |

Have you appeared in court in the **past month**? **Yes** ☐ **No** ☐

If yes how many times have you appeared in a magistrates court (days) | | |

If yes how many times have you appeared in a crown court (times) | | |

Have you been in prison in **past month**? **Yes** ☐ **No** ☐

If yes how many days in total? | | |

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MEDICATIONS

Please tell us below what medication(s) you are currently taking, filling in the table in the same way as the example given

Medication	Daily dose	Reason
E.G. Frusemide	E.G. 20MG	E.G. Heart Failure

HEALTH QUESTIONNAIRE

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

- I have no problems in walking about ☐
- I have slight problems in walking about ☐
- I have moderate problems in walking about ☐
- I have severe problems in walking about ☐
- I am unable to walk about ☐

SELF-CARE

- I have no problems washing or dressing myself ☐
- I have slight problems washing or dressing myself ☐
- I have moderate problems washing or dressing myself ☐
- I have severe problems washing or dressing myself ☐
- I am unable to wash or dress myself ☐

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

- I have no problems doing my usual activities ☐
- I have slight problems doing my usual activities ☐
- I have moderate problems doing my usual activities ☐
- I have severe problems doing my usual activities ☐
- I am unable to do my usual activities ☐

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PAIN / DISCOMFORT

I have no pain or discomfort ❑
I have slight pain or discomfort ❑
I have moderate pain or discomfort ❑
I have severe pain or discomfort ❑
I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

I am not anxious or depressed ❑
I am slightly anxious or depressed ❑
I am moderately anxious or depressed ❑
I am severely anxious or depressed ❑
I am extremely anxious or depressed ❑

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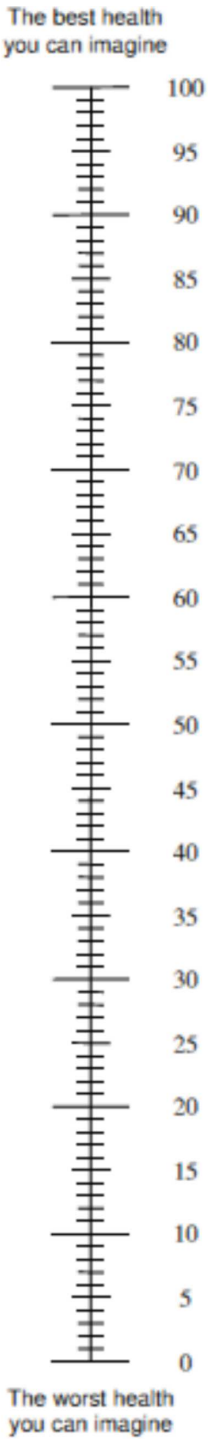
- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =



30a. On a scale of 0-10, where 0 is not useful at all and 10 is extremely useful, how would you rate the information leaflet you were given on hepatitis C and hepatitis B (the orange one)?

0 1 2 3 4 5 6 7 8 9 10

Any other comments on leaflet:

30b. Would you recommend it to other injectors you know?

Yes ☐1 No ☐0

31a. On a scale of 0-10, where 0 is not useful at all and 10 is extremely useful, how would you rate the information leaflet you were given on HIV?

0 1 2 3 4 5 6 7 8 9 10

Any other comments on leaflet:

31b. Would you recommend it to other injectors you know?

Yes ☐1 No ☐0

32. Why did you decide to take part in the study?

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33. How did you find the randomisation process?

For intervention group participants only:

34. Why did you decide to attend/not attend the sessions?

For control group participants only:

35. Did anyone who attended the group programme for this study discuss the content of the programme with you?

Yes ☐1 No ☐0

What did they tell you?

Version 4. 18/02/16

Appendix 9 Participant focus group topic guides

[Organisational logos and headers]

Participant Focus Group

1. Introductory Question
1.1 What did you think of the intervention as a whole?
Prompts: Individual Sessions 1, 2, 3.
Can you tell me what made you decide to attend the sessions you did? (or what made you decide not to attend?)

1.2 Do you have any comments or thoughts about the randomisation process?
2. Content
2.1 What did you find most/least useful about the intervention?

Prompts: Information provided (Injecting skills, risks, BBVs & Transmission risks)
The chance to Reflect on your own injecting behaviour and skills
Planning ahead etc.
Hearing about other people's experience

2.2 What did you learn if anything, that was new?
2.3 Have you shared any of the information you learnt with others? Who? Why?
2.4 Was there other information you would have liked us to provide/ that you think we've missed out?

3. Logistics
3.1 What did you think about the delivery of the intervention?
Prompts: How easy or difficult was it to get to group/fit in with life?
Was the location and timing ok?
What would have made it more convenient?
What might have put people off signing up/attending?
What would have helped more people attend/how could we improve uptake?

4. Quality, Safety and Comfort
4.1 What are your thoughts on the quality of the intervention?
Prompts: What did you think of the Facilitators? e.g. *Empathic, knowledgeable, confident, engaging, listening, etc.*
What did you think of the Materials? videos/handouts

4.2 Did you feel that the group was a safe place to be open about injecting behaviour?

Prompts: Did you have any worries about talking in the group about injecting?
Did any of the content make you feel uncomfortable, worried or embarrassed?
If so, were you able to talk about this in the group or with a worker afterwards?

5. Gendered Groups
5.1 How did you find having single sex groups rather than mixed?
5.2 Was it easier to share stories/disclose personal information in a single sex group?
5.3 Would it have mattered to you if it had been mixed sex?

6. Behaviour Changes

6.1 What changes in behaviour, if any, have you made as a result of taking part/what you've learned in the intervention? Why?

Finally

7. Would you recommend this intervention to others? Why/why not?

8. Any final comments

Appendix 10 Participant focus group consent form and patient information sheet

[Organisational logos and headers]

CONSENT FORM (Phase 5 Focus Group)

Title of Project: Improving injecting skills and preventing blood borne virus infection in people who inject drugs in the UK
Name of Researcher: Dr Gail Gilchrist

Please initial all boxes

1. I confirm that the researcher has explained and that I understand the information sheet dated 20/10/15 (version 2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw from the study at any time without giving any reason, without my care or legal rights being affected. ☐

3. The procedures regarding confidentiality have been clearly explained to me (e.g. anonymization of data, use of pseudonyms in reports etc.). I understand that if I express current or future intention to harm myself or someone else that the researcher will inform my key worker or a duty worker at the drug treatment service where the interview has taken place and the worker will conduct a risk assessment. ☐

4. I agree to the focus group being audio recorded. ☐

5. I understand that the data will be published at the end of the study and that completely anonymous quotations from the focus group may be used in the report/publication. ☐

6. I agree to my anonymous interview data being shared with researchers at the five institutions where the research is being carried out – King's College London, University of the West of Scotland, University of York, NHS Wales and the University of Huddersfield. ☐

7. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of researcher	Date	Signature

Version 2. 20/10/15

[Organisational logos and headers]

CONSENT FORM (Phase 5 Focus Group)

Title of Project: Improving injecting skills and preventing blood borne virus infection in people who inject drugs in the UK
Name of Researcher: Dr Davina Swan

Please initial all boxes

1. I confirm that the researcher has explained and that I understand the information sheet dated 26/01/16 (version 3) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw from the study at any time without giving any reason, without my care or legal rights being affected. ☐

3. The procedures regarding confidentiality have been clearly explained to me (e.g. anonymization of data, use of pseudonyms in reports etc.). I understand that if I express current or future intention to harm myself or someone else that the researcher will inform my key worker or a duty worker at the drug treatment service where the interview has taken place and the worker will conduct a risk assessment. ☐

4. I agree to the focus group being audio recorded. ☐

5. I understand that the data will be published at the end of the study and that completely anonymous quotations from the focus group may be used in the report/publication. ☐

6. I agree to my anonymous interview data being shared with researchers at the five institutions where the research is being carried out – King's College London, University of the West of Scotland, University of York, NHS Wales and the University of Huddersfield. ☐

7. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of researcher	Date	Signature

Version 3. 26/01/16

[Organisational logos and headers]

Participant information sheet (Phase 5. Focus group)

Improving injecting skills and preventing blood borne virus infection in people who inject drugs in the UK

Thank you once again for taking part in the study. We would now like to invite you to take part in a focus group about your experiences of taking part in the group programme. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. This should take about 5 minutes. Do feel free to talk to others about the study if you wish. We appreciate you taking the time to decide whether or not to participate.

Why are we doing this study?

People who inject drugs are at risk of blood borne viruses (e.g. HIV, Hepatitis C and Hepatitis B) as a result of sharing injecting equipment (needles and syringes, water, spoons, cotton etc.) and unsafe sex. Preventing people who inject drugs from getting or passing on these viruses is an important health issue. Opiate substitution therapy (methadone or buprenorphine) and needle exchanges have reduced blood borne viruses but programmes that give people the skills and knowledge to be able to reduce these risks could further prevent the spread of these viruses.

You took part in a study to see whether it was feasible to deliver the programme in drug treatment settings, whether people who inject drugs would come to the programme and what they thought about taking part in the programme. Therefore, we would like to ask you to participate in a focus group with other people who attended the programme to find out what you thought about it.

Why have I been chosen?

You recently took part in a 3-session group programme to help people who inject to be able to reduce sexual and drug related blood borne virus risk behaviours. Even if you only attended one session, we would like to hear about your experiences so that we can improve the programme if necessary.

If you decide to take part

If you agree to take part in the focus group you will be asked to complete and sign the consent form. If you consent to take part in the study, we will invite you to take part in a focus group that will last about 60 minutes. There will be about 8 people in the focus group with you so you can discuss your participation together as a group.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice **and all information about you will be handled in confidence**. The focus group will be audio-recorded with your consent. We cannot guarantee that others participating in the research will keep what you say confidential but we will encourage people to do so, so that people feel comfortable discussing their experiences. The focus group will be analysed as a whole and participants' names will not be used in any analysis of the discussion. The transcript and audio recording will be stored on a secure computer and the audio recording will be deleted from the recording device. What you say in the focus group will be typed out word for word. Only the researchers conducting the study will have access to these typed copies. The researcher will check them to make sure that neither you nor any other person is identifiable from what you have said. Any references to names or addresses will be removed. The data will be kept on a computer and will be stored separately from your contact details. Data will be kept securely for 7 years after publication of the findings and then destroyed.

Limitations to confidentiality

- **If you express current or future intention to harm yourself or someone who is specifically identified, there would be no grounds for maintaining confidentiality**. Your key worker or a duty worker at the drug treatment service where the interview has taken place will be told by the researcher of your intentions and the worker will conduct a risk assessment.

What are the possible benefits of taking part?
Your feedback on taking part in this programme will help us improve the programme that will potentially help people who inject drugs reduce the risk of blood borne viruses transmission.

What are the possible disadvantages and risks of taking part?
There is low risk of harm by taking part. However, talking about sensitive topics including potential risks for the transmission of blood borne viruses may make you feel worried or anxious. If you are worried or anxious or wish to find out more about blood borne viruses, you will be given the opportunity to speak to a member of staff at a local drug treatment service if you want to. We have also provided you with a range of contact numbers and websites that will be able to help.

Do I have to take part?
No. It is up to you to decide whether or not you want to take part in the focus group. If you agree to take part, we will then ask you to sign a consent form. This study is independent of your treatment. You are free to withdraw at any time without giving a reason. This will not affect the care that you are receiving.

Expenses
This study is funded by the National Institute for Health Research. You will receive a shopping voucher for participating in the focus group.

Results of the research study
The results of this research study will be available after we have analysed the data. Summaries of the results will be made available in the drug treatment settings involved in this study in June 2016. You will not be identifiable from any of the results presented.

What happens if something goes wrong?
If you're not happy with the care or treatment you've received as part of this study, you have the right to complain. Your local Patient Advice and Liaison Service (PALS) will be able to help you make a complaint. Phone NHS 111 for details of your nearest PALS.

Who reviewed the study
All research in the NHS is looked at by an independent group called a Research Ethics Committee. They make sure that the research is fair. The study has been reviewed by the East Midlands – Leicester South Research Ethics Committee (reference: 15/EM/0413).

Who is organising and funding the research?
The research is being led by Dr Gail Gilchrist, from the National Addiction Centre at King's College London, and is funded by the National Institute for Health Research. If you wish to talk to someone about the research please contact Dr Gilchrist on [telephone number]

Useful contact numbers

For information about **local drug treatment services** call the Frank drugs helpline on [redacted] or visit the Frank website http://www.talktofrank.com/need-support?ID=108

The Hepatitis C Trust Helpline [redacted] or [redacted] http://www.hepctrust.org.uk/
Open 10.30am to 4.30pm Monday to Friday (except Bank Holidays and the Christmas break, when dates and times may vary).Helpline is staffed solely by people with hepatitis C, some of whom have been through/or are currently undergoing treatment.

British Liver Trust [redacted]
www.britishlivertrust.org.uk (Free helpline, Mon-Fri 09.00-17.00) *The British Liver Trust is the national charity working to reduce the impact of liver disease in the UK through support, information and research.*

National Hepatitis Support Line [redacted]
http://www.hepbpositive.org.uk/ *Help the public and patients overcome hepatitis B. They clarify and reassure patients that hepatitis B is both easy to vaccinate against and caught early on an easy to manage common child acquired condition.*

National Sexual Health Line[redacted] **(24 hours)**
The National Sexual Health Line is UK-wide and provides confidential advice and information on all aspects of HIV, AIDS and sexual health. The Helpline can also provide UK wide referrals to specialist services. Open 24 hours a day, seven days a week. All calls are taken by trained and paid staff. It is not a counselling service, but gives you details of local helplines & services if needed.

Terrence Higgins Trust Direct Helpline [redacted]
(open 10am - 10pm Monday - Friday, and 12 noon - 6pm on Saturday and Sunday). Terrence Higgins Trust Direct Helpline can give you HIV information, advice and support over the phone.

version 2 (20/10/15)

[Organisational logos and headers]

Participant information sheet (Phase 5. Focus group)

Improving injecting skills and preventing blood borne virus infection in people who inject drugs in the UK

Thank you once again for taking part in the study. We would now like to invite you to take part in a focus group about your experiences of taking part in the group programme. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. This should take about 5 minutes. Do feel free to talk to others about the study if you wish. We appreciate you taking the time to decide whether or not to participate.

Why are we doing this study?

People who inject drugs are at risk of blood borne viruses (e.g. HIV, Hepatitis C and Hepatitis B) as a result of sharing injecting equipment (needles and syringes, water, spoons, cotton etc.) and unsafe sex. Preventing people who inject drugs from getting or passing on these viruses is an important health issue. Opiate substitution therapy (methadone or buprenorphine) and needle exchanges have reduced blood borne viruses but programmes that give people the skills and knowledge to be able to reduce these risks could further prevent the spread of these viruses.

You took part in a study to see whether it was feasible to deliver the programme in drug treatment settings, whether people who inject drugs would come to the programme and what they thought about taking part in the programme. Therefore, we would like to ask you to participate in a focus group with other people who attended the programme to find out what you thought about it.

Why have I been chosen?

You recently took part in a 3-session group programme to help people who inject to be able to reduce sexual and drug related blood borne virus risk behaviours. Even if you only attended one session, we would like to hear about your experiences so that we can improve the programme if necessary.

If you decide to take part

If you agree to take part in the focus group you will be asked to complete and sign the consent form. If you consent to take part in the study, we will invite you to take part in a focus group that will last about 60 minutes. There will be about 8 people in the focus group with you so you can discuss your participation together as a group.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice **and all information about you will be handled in confidence**. The focus group will be audio-recorded with your consent. We cannot guarantee that others participating in the research will keep what you say confidential but we will encourage people to do so, so that people feel comfortable discussing their experiences. The focus group will be analysed as a whole and participants' names will not be used in any analysis of the discussion. The transcript and audio recording will be stored on a secure computer and the audio recording will be deleted from the recording device. What you say in the focus group will be typed out word for word. Only the researchers conducting the study will have access to these typed copies. The researcher will check them to make sure that neither you nor any other person is identifiable from what you have said. Any references to names or addresses will be removed. The data will be kept on a computer and will be stored separately from your contact details. Data will be kept securely for 7 years after publication of the findings and then destroyed.

Limitations to confidentiality

- **If you express current or future intention to harm yourself or someone who is specifically identified, there would be no grounds for maintaining confidentiality**. Your key worker or a duty worker at the drug treatment service where the interview has taken place will be told by the researcher of your intentions and the worker will conduct a risk assessment.

What are the possible benefits of taking part?
Your feedback on taking part in this programme will help us improve the programme that will potentially help people who inject drugs reduce the risk of blood borne viruses transmission.

What are the possible disadvantages and risks of taking part?
There is low risk of harm by taking part. However, talking about sensitive topics including potential risks for the transmission of blood borne viruses may make you feel worried or anxious. If you are worried or anxious or wish to find out more about blood borne viruses, you will be given the opportunity to speak to a member of staff at a local drug treatment service if you want to. We have also provided you with a range of contact numbers and websites that will be able to help.

Do I have to take part?
No. It is up to you to decide whether or not you want to take part in the focus group. If you agree to take part, we will then ask you to sign a consent form. This study is independent of your treatment. You are free to withdraw at any time without giving a reason. This will not affect the care that you are receiving.

Expenses
This study is funded by the National Institute for Health Research. You will receive a small sum of money for participating in the focus group.

Results of the research study
The results of this research study will be available after we have analysed the data. Summaries of the results will be made available in the drug treatment settings involved in this study in June 2016. You will not be identifiable from any of the results presented.

What happens if something goes wrong?
If you're not happy with the care or treatment you've received as part of this study, you have the right to complain. Your local Patient Advice and Liaison Service (PALS) will be able to help you make a complaint. Phone NHS 111 for details of your nearest PALS.

Who reviewed the study
All research in the NHS is looked at by an independent group called a Research Ethics Committee. They make sure that the research is fair. The study has been reviewed by the East Midlands – Leicester South Research Ethics Committee (reference: 15/EM/0413).

Who is organising and funding the research?
The research is being led by Dr Gail Gilchrist, from the National Addiction Centre at King's College London, and is funded by the National Institute for Health Research. If you wish to talk to someone about the research please contact Dr Davina Swan on [telephone number]

Useful contact numbers

For information about **local drug treatment services** call the Frank drugs helpline on [redacted] or visit the Frank website http://www.talktofrank.com/need-support?ID=108

The Hepatitis C Trust Helpline [redacted] or [redacted] http://www.hepctrust.org.uk/
Open 10.30am to 4.30pm Monday to Friday (except Bank Holidays and the Christmas break, when dates and times may vary).Helpline is staffed solely by people with hepatitis C, some of whom have been through/or are currently undergoing treatment.

British Liver Trust [redacted]
www.britishlivertrust.org.uk (Free helpline, Mon-Fri 09.00-17.00) *The British Liver Trust is the national charity working to reduce the impact of liver disease in the UK through support, information and research.*

National Hepatitis Support Line [redacted]
http://www.hepbpositive.org.uk/ *Help the public and patients overcome hepatitis B. They clarify and reassure patients that hepatitis B is both easy to vaccinate against and caught early on an easy to manage common child acquired condition.*

National Sexual Health Line [redacted] **(24 hours)**
The National Sexual Health Line is UK-wide and provides confidential advice and information on all aspects of HIV, AIDS and sexual health. The Helpline can also provide UK wide referrals to specialist services. Open 24 hours a day, seven days a week. All calls are taken by trained and paid staff. It is not a counselling service, but gives you details of local helplines & services if needed.

Terrence Higgins Trust Direct Helpline [redacted]
(open 10am - 10pm Monday - Friday, and 12 noon - 6pm on Saturday and Sunday). Terrence Higgins Trust Direct Helpline can give you HIV information, advice and support over the phone.

version 3 (26/01/16)

Appendix 11 Staff focus groups consent form and patient information sheet

[Organisational logos and headers]

Participant information sheet (Phase 5. Staff focus group)

Improving injecting skills and preventing blood borne virus infection in people who inject drugs in the UK

Thank you for delivering the PROTECT group programme for our research study. We would now like to invite you to take part in a focus group about your experiences of delivering the programme. Before you decide whether or not to take part, we would like you to understand why the focus group is being done and what it would involve for you. One of our team will go through this information sheet with you and answer any questions you have. Do feel free to talk to others about the study if you wish. We appreciate you taking the time to decide whether or not to participate.

Why are we doing the focus group?

You recently delivered the PROTECT group programme to help people who inject to be able to reduce sexual and drug related blood borne virus risk behaviours. We would like to hear about your experiences so that we can improve the programme if necessary.

What will participation entail?

If you agree to take part in the focus group you will be asked to complete and sign the consent form. The focus group will last about 30 minutes and will include the other facilitator(s) in your locality who delivered the programme so that you can discuss your participation together as a group.

The focus group will be audio-recorded with your consent. The recording will be uploaded to a secure computer and deleted from the recording device. The recording will be typed out word for word by a professional transcriber. Only the researchers conducting the study will have access to these typed copies. The researcher will check the transcripts for accuracy and remove any references to names. A study number will identify you. The transcript and audio-recording will be stored on a secure computer separately from your contact details. Data will be kept securely for 7 years after publication of the findings and then destroyed.

What are the possible benefits of taking part?

Your feedback on delivering this programme will help us to improve the programme and potentially help people who inject drugs reduce the risk of blood borne viruses transmission.

What are the possible disadvantages and risks of taking part?

There is low risk of harm by taking part. In order to minimise the risk of your identity being revealed, once the focus group has been transcribed a code number will be assigned to the transcript to prevent identification. A study number will identify you. Your name will not be used. However, given the small number of people who delivered this group programme, it is possible that you may still be identifiable to some people. We will send the anonymised, password-protected transcript to you in advance of analysing it so that you have an opportunity to review and edit the information before we use it.

version 1 (24/02/16)

Do I have to take part?
No. It is up to you to decide whether or not you want to take part in the focus group. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time without giving a reason.

Results of the research study
The results of this research study will be available after we have analysed the data. We will present the results at conferences and in relevant scientific journals. Reports will contain quotes from the focus group to emphasise important points made by participants but your name will not be used.

Who reviewed the study
The study has been reviewed by the East Midlands – Leicester South Research Ethics Committee (reference: 15/EM/0413).

Who is organising and funding the research?
The research is being led by Dr Gail Gilchrist, from the National Addiction Centre at King's College London, and is funded by the National Institute for Health Research. If you wish to talk to someone about the research please contact Dr Gail Gilchrist on [telephone number].

version 1 (24/02/16)

[Organisational logos and headers]

CONSENT FORM (Phase 5 Staff Focus Group)

Title of Project: Improving injecting skills and preventing blood borne virus infection in people who inject drugs in the UK
Name of Researcher: Dr Gail Gilchrist

Please initial all boxes

1. I understand that my participation is voluntary and that I am free to withdraw from the study at any time without giving any reason. ☐

2. The procedures and limitations regarding anonymity have been clearly explained to me (e.g. use of study ID numbers in transcripts and reports instead of names) ☐

3. I agree to the focus group being audio-recorded. ☐

4. I understand that the data will be published at the end of the study and that anonymous quotations from the focus group may be used in the report/publication. ☐

5. I agree to the anonymized focus group data being shared with researchers at the five institutions where the research is being carried out – King's College London, University of the West of Scotland, University of York, NHS Wales and the University of Huddersfield. ☐

6. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of researcher	Date	Signature

Version 1. 24/02/16

Appendix 12 Staff focus groups topic guide

Staff Feedback

1. Training Event

1.1. How useful was the training event in London / how well did it prepare you to deliver the intervention?

1.2. Do you have any comments on the training format?
- Venue
- Duration
- Delivery style

1.3. Do you have any suggestions for alternative format/venue/delivery (e.g. video conference)?

1.4. Following the training, did you do anything else to prepare for the delivery of the intervention?

2. Intervention Materials

2.1. Do you have any comments on the Intervention Manual?
Prompts:
- Was it clear and easy to understand?
- Did it flow well?
- Was the lay-out/notes for facilitators helpful?
- Any comments on the content/information in each of the sessions?
- Any comments on the Activities?
- Any comments on the Videos?
- Any comments on the Overheads?
- Any comments on the Hand-outs?

2.2. How easy did you find it to implement the intervention in keeping with the manual (i.e., fidelity to content and timing)?
Prompt - What were the challenges, if any?

3. Intervention delivery

3.1. How much time did it take you to prepare for each of the sessions? Sessions 1, 2, 3.

3.2. Was it easy to incorporate the intervention into your workload?

3.3. What parts of the intervention did you feel most confident/comfortable delivering? Why?

3.4. Were there any parts of the intervention which you found challenging to deliver? Why?

3.5. FOR LONDON: How did you find co-facilitating the intervention with a peer worker/ drug worker?

3.6. FOR LONDON: How did you decide who would do what parts of the intervention?

3.7.What worked well about the intervention and why?

3.8. What worked less well and why?

3.9. What would you change and why?

3.10. Do you think anything was missing? What would you add?

3.11. What did you think of the day/time for the sessions?

3.12. What did you think of the venue for the sessions?

3.13. Would you use the PROTECT intervention in its entirety in your own practice?

Prompt: If no, would you use elements of the intervention? If yes, which ones and why?

3.14. Which clients would you target?

3.15. How else do you think the intervention could be used/developed? [examples: training of needle exchange staff, bite size info for needle exchange attenders, mobile phone apps]

4. Facilitator learning

4.1. Was there anything you learnt about injecting practices from the clients that you weren't aware of before delivering the intervention? *E.g. clients' knowledge, practice, BBV awareness*

5. Participant engagement and attendance

5.1.Do you feel those that attended were engaged?

*5.2.*As you are aware not everyone recruited to the intervention attended. What do you think we could have done differently to increase attendance?

Appendix 13 Human immunodeficiency virus: a 2016 update leaflet

[Organisational logos and headers]

HIV: a 2016 update

HIV is the virus that can cause AIDS.

HIV can be spread by injecting drug use; this may happen if someone uses a needle or syringe previously used by someone with HIV. Sharing other injecting equipment including cookers (e.g. spoons or stericups), filters, or water also carries a risk of HIV.

Recently in the UK there have been a number of HIV outbreaks amongst people who inject drugs; it is very important that anyone injecting drugs protects themselves.

HIV can also be spread by unprotected sex (sex without condoms).

The risks associated with unprotected sex are high amongst men who have sex with men, or where sex with different partners is common.

HIV can be diagnosed with a simple test; your drugs worker, drugs service, GP or your local GUM or sexual health service will be able to arrange an HIV test.

HIV is treatable; however it is important to diagnose HIV early as this improves the effectiveness of treatment. There is no vaccine to protect against getting HIV.

THE RISKS OF CATCHING HIV CAN BE REDUCED BY:

- **Always using clean needles and syringes**
- **Always using clean cookers (spoons, stericups), clean filters and clean water**
- **Not sharing ANY drug injecting equipment**
- **Using condoms**

Appendix 14 Participant and staff evaluation forms

Evaluation session 1 : Improving injecting techniques & good vein care [participant]

We would be grateful if you could give us some feedback on today's session to help us evaluate it and improve future sessions if necessary. ***Your answers are confidential, so we appreciate your honesty.***

Please answer all the questions indicating the degree of agreement or disagreement with each, with 5 being "strongly agree" and 1 being "strongly disagree". Circle the number that best describes your rating of the session today. ***The researcher can help you if you would prefer someone to read out the questions and ratings.***

	Strongly disagree				**Strongly agree**
1. I understood the purpose of the intervention	**1**	**2**	**3**	**4**	**5**
2. I understood the group agreement and the commitment to confidentiality	**1**	**2**	**3**	**4**	**5**
3. I have increased my knowledge around injecting techniques	**1**	**2**	**3**	**4**	**5**
4. I have increased my knowledge around good vein care	**1**	**2**	**3**	**4**	**5**
5. I have increased my motivation to improve my injecting techniques	**1**	**2**	**3**	**4**	**5**
6. I have increased my motivation to improve my vein care	**1**	**2**	**3**	**4**	**5**
7. The videos used were relevant and informative	**1**	**2**	**3**	**4**	**5**
8. The trainer was knowledgeable	**1**	**2**	**3**	**4**	**5**
9. Any questions I had were clearly answered	**1**	**2**	**3**	**4**	**5**

10. In general, how would you rate today's session? Circle the number that best describes your rating, where 5 is "excellent" and 1 is "poor"

Poor				**Excellent**
1	**2**	**3**	**4**	**5**

11. What did you **like most** about today's session?

12. What did you **like least** about today's session?

13. How do you think today's session **could be improved**?

Thanks

Evaluation Session 2: Planning for Risk situations [participant]

We would be grateful if you could give us some feedback on today's session to help us evaluate it and improve future sessions if necessary. ***Your answers are confidential, so we appreciate your honesty.***

Please answer all the questions indicating the degree of agreement or disagreement with each, with 5 being "strongly agree" and 1 being "strongly disagree". Circle the number that best describes your rating of the session today. ***The researcher can help you if you would prefer someone to read out the questions and ratings.***

	Strongly disagree				**Strongly agree**
1. I have a better understanding of injecting risk behaviours	**1**	**2**	**3**	**4**	**5**
2. I have a better understanding of sexual risk behaviours	**1**	**2**	**3**	**4**	**5**
3. I am confident I can use some or all of the plan to avoid risk behaviours	**1**	**2**	**3**	**4**	**5**
4. I am confident I can apply TALK to reduce/avoid risks	**1**	**2**	**3**	**4**	**5**
5. I am confident I can prepare for and avoid risky situations	**1**	**2**	**3**	**4**	**5**
6. The handouts were helpful	**1**	**2**	**3**	**4**	**5**
7. The exercises used were relevant and informative	**1**	**2**	**3**	**4**	**5**
8. The trainer was knowledgeable	**1**	**2**	**3**	**4**	**5**
9. Any questions I had were clearly answered	**1**	**2**	**3**	**4**	**5**

10. In general, how would you rate today's session? Circle the number that best describes your rating, where 5 is "excellent" and 1 is "poor"

Poor				**Excellent**
1	**2**	**3**	**4**	**5**

11. What did you **like most** about today's session?

12. What did you **like least** about today's session?

13. How do you think today's session **could be improved**?

Thanks

Evaluation of Session 3: Understanding Blood Borne Virus Transmission risks [participant]

We would be grateful if you could give us some feedback on today's session to help us evaluate it and improve future sessions if necessary. ***Your answers are confidential, so we appreciate your honesty.***

Please answer all the questions indicating the degree of agreement or disagreement with each, with 5 being "strongly agree" and 1 being "strongly disagree". Circle the number that best describes your rating of the session today. ***The researcher can help you if you would prefer someone to read out the questions and ratings.***

	Strongly disagree				**Strongly agree**
1. I have a better understanding of blood borne viruses	**1**	**2**	**3**	**4**	**5**
2. I have a better understanding of BBV transmission risk behaviours	**1**	**2**	**3**	**4**	**5**
3. I enjoyed the Myths and Facts exercise	**1**	**2**	**3**	**4**	**5**
4. I am confident I can reduce my BBV transmission risk behaviours	**1**	**2**	**3**	**4**	**5**
5. I have increased my motivation for safer injecting	**1**	**2**	**3**	**4**	**5**
6. The handouts were helpful	**1**	**2**	**3**	**4**	**5**
7. The videos used were relevant and informative	**1**	**2**	**3**	**4**	**5**
8. The trainer was knowledgeable	**1**	**2**	**3**	**4**	**5**
9. Any questions I had were clearly answered	**1**	**2**	**3**	**4**	**5**

10. In general, how would you rate today's session? Circle the number that best describes your rating, where 5 is "excellent" and 1 is "poor"

Poor				**Excellent**
1	**2**	**3**	**4**	**5**

11. What did you **like most** about today's session?

12. What did you **like least** about today's session?

13. How do you think today's session **could be improved**?

Thanks

Evaluation session 1 : Improving injecting techniques & good vein care [facilitator]

We would be grateful if you could give us some feedback on today's session to help us evaluate it and improve future sessions if necessary. ***Your answers are confidential, so we appreciate your honesty.***

Please answer all the questions indicating the degree of agreement or disagreement with each, with 5 being "strongly agree" and 1 being "strongly disagree". Circle the number that best describes your rating of the session today.

I think that….	**Strongly disagree**				**Strongly agree**
1. Participants understood the purpose of the intervention	**1**	**2**	**3**	**4**	**5**
2. Participants understood the group agreement and the commitment to confidentiality	**1**	**2**	**3**	**4**	**5**
3. Participants increased their knowledge around injecting techniques	**1**	**2**	**3**	**4**	**5**
4. Participants increased their knowledge around good vein care	**1**	**2**	**3**	**4**	**5**
5. Participants increased their motivation to improve their injecting techniques	**1**	**2**	**3**	**4**	**5**
6. The videos used were relevant and informative	**1**	**2**	**3**	**4**	**5**
7. I was well prepared to deliver the session	**1**	**2**	**3**	**4**	**5**
8. I was able to clearly answer any questions participants had during the session	**1**	**2**	**3**	**4**	**5**

9. In general, how would you rate today's session? Circle the number that best describes your rating, where 5 is "excellent" and 1 is "poor"

Poor				**Excellent**
1	**2**	**3**	**4**	**5**

10. What do you **think worked best** in today's session?

11. What do you **think worked less well** in today's session?

12. How do you think today's session **could be improved**?

13. Any additional comments

Thanks

Evaluation Session 2: Planning for Risk situations [facilitator]

We would be grateful if you could give us some feedback on today's session to help us evaluate it and improve future sessions if necessary. ***Your answers are confidential, so we appreciate your honesty.***

Please answer all the questions indicating the degree of agreement or disagreement with each, with 5 being "strongly agree" and 1 being "strongly disagree". Circle the number that best describes your rating of the session today.

I think,,,	**Strongly disagree**				**Strongly agree**
1.Participants have a better understanding of injecting risk behaviours	**1**	**2**	**3**	**4**	**5**
2. Participants have a better understanding of sexual risk behaviours	**1**	**2**	**3**	**4**	**5**
3. I am confident participants can use some or all of the plan to avoid risk behaviours	**1**	**2**	**3**	**4**	**5**
4. I am confident participants can apply TALK to reduce/avoid risks	**1**	**2**	**3**	**4**	**5**
5. I am confident participants can prepare for and avoid risky situations	**1**	**2**	**3**	**4**	**5**
1. The handouts were helpful	**1**	**2**	**3**	**4**	**5**
2. The exercises used were relevant and informative	**1**	**2**	**3**	**4**	**5**
3. I was well prepared to deliver the session	**1**	**2**	**3**	**4**	**5**
4. I was able to clearly answer any questions participants had during the session	**1**	**2**	**3**	**4**	**5**

5. In general, how would you rate today's session? Circle the number that best describes your rating, where 5 is "excellent" and 1 is "poor"

Poor				**Excellent**
1	**2**	**3**	**4**	**5**

6. What do you **think worked best** in today's session?

7. What do you **think worked less well** in today's session?

8. How do you think today's session **could be improved**?

9. Any additional comments

Thanks

Evaluation of Session 3: Understanding Blood Borne Virus Transmission risks [facilitator]

We would be grateful if you could give us some feedback on today's session to help us evaluate it and improve future sessions if necessary. ***Your answers are confidential, so we appreciate your honesty.***

Please answer all the questions indicating the degree of agreement or disagreement with each, with 5 being "strongly agree" and 1 being "strongly disagree". Circle the number that best describes your rating of the session today.

I think…	**Strongly disagree**				**Strongly agree**
1.Participants have a better understanding of blood borne viruses	**1**	**2**	**3**	**4**	**5**
2. Participants have a better understanding of BBV transmission risk behaviours	**1**	**2**	**3**	**4**	**5**
3. Participants enjoyed the Myths and Facts exercise	**1**	**2**	**3**	**4**	**5**
4. Participants appear confident they can reduce their BBV transmission risk behaviours	**1**	**2**	**3**	**4**	**5**
5. Participants showed increased their motivation for safer injecting	**1**	**2**	**3**	**4**	**5**
6. The handouts were helpful	**1**	**2**	**3**	**4**	**5**
7. The videos used were relevant and informative	**1**	**2**	**3**	**4**	**5**
8. I was well prepared to deliver the session	**1**	**2**	**3**	**4**	**5**
9. I was able to clearly answer any questions participants had during the session	**1**	**2**	**3**	**4**	**5**

10. In general, how would you rate today's session? Circle the number that best describes your rating, where 5 is "excellent" and 1 is "poor"

Poor				**Excellent**
1	**2**	**3**	**4**	**5**

11. What do you **think worked best** in today's session?

12. What do you **think worked less well** in today's session?

13. How do you think today's session **could be improved**?

14. Any additional comments

Thanks

Appendix 15 Mean service use values from the service use questionnaire

TABLE 72 Mean attendances for service use: control group

	Time point								
	Baseline			Follow-up 1			Follow-up 2		
Cost category	*n*	Mean	SD	*n*	Mean	SD	*n*	Mean	SD
A&E visits	47	0.468	1.0805	27	0.296	0.8234	23	0.261	0.6887
Inpatient nights	47	0.447	2.1245	27	0.296	0.8689	23	0.783	3.1328
Hospital outpatient visits	47	0.872	4.0946	27	0.667	1.1767	23	0.652	1.1123
Day hospital attendances	47	0.191	0.7413	27	0.111	0.4237	23	0.348	0.8847
Emergency ambulance	47	0.064	0.2471	27	0.185	0.6225	22	0.091	0.4264
Taken from hospital by PTA	47	0.149	0.6587	27	0.444	1.5525	23	0.043	0.2085
GP surgery visits	47	0.872	1.1348	27	1.074	1.1068	23	0.696	0.8221
GP home visits	47	0.064	0.2471	27	0.148	0.4560	23	0.000	0.0000
Practice nurse surgery visits	47	0.511	1.7178	27	0.296	0.5417	23	0.217	0.5184
Practice nurse at home	47	0.340	2.0566	27	0.037	0.1925	23	4.304	20.6429
Prescriptions	47	2.638	3.6856	27	2.481	1.3408	23	2.348	1.6127
Other health-care professionals	44	0.136	0.5099	26	0.038	0.1961	20	0.100	0.3078
Key worker at drug service	47	2.489	1.9322	27	2.370	1.2449	23	2.217	2.1941
Group work	47	0.830	2.7609	27	0.852	2.0325	23	0.783	1.9761
Specialist drug service	47	0.468	1.2132	27	0.296	1.0675	23	0.000	0.0000
Pharmacist	47	19.340	11.1887	26	19.962	9.0354	23	16.130	11.4507
Nurse at drug service	47	0.809	1.7525	26	1.231	4.6845	23	0.739	1.7637
Needle exchange	47	6.000	7.2891	27	4.630	6.8956	23	2.870	4.8082
Outreach worker	47	1.830	5.7760	27	0.852	2.4916	23	1.826	6.2570
HIV or HCV infection test	47	0.404	1.5695	27	0.111	0.3203	23	0.478	1.0388
HIV infection treatment	47	0.000	0.0000	27	0.000	0.0000	23	0.000	0.0000
HCV infection treatment	47	0.000	0.0000	27	0.000	0.0000	23	0.000	0.0000
HBV infection treatment	47	0.000	0.0000	27	0.000	0.0000	23	0.043	0.2085
Mental health specialist	47	0.340	0.8412	27	0.370	0.9667	23	0.043	0.2085
Social worker	47	0.043	0.2040	27	0.259	0.8590	23	0.217	0.5997
Dentist	47	0.085	0.3508	27	0.148	0.4560	23	0.261	0.6192
Family planning	47	0.021	0.1459	27	0.000	0.0000	23	0.087	0.4170

continued

TABLE 72 Mean attendances for service use: control group (*continued*)

	Time point								
	Baseline			Follow-up 1			Follow-up 2		
Cost category	*n*	Mean	SD	*n*	Mean	SD	*n*	Mean	SD
Sexual health clinic	47	0.149	0.8841	27	0.037	0.1925	23	0.087	0.4170
Arrest or caution	47	0.298	1.1017	27	0.074	0.3849	23	0.130	0.4577
Magistrates' court appearances	45	0.200	0.8146	26	0.115	0.4315	21	0.190	0.5118
Crown Court appearances	45	0.022	0.1491	26	0.000	0.0000	21	0.000	0.0000
Prison days	44	0.000	0.0000	27	0.000	0.0000	23	0.000	0.0000

A&E, accident and emergency; PTA, patient transport ambulance.

TABLE 73 Mean attendances for service use: intervention group

	Time point								
	Baseline			Follow-up 1			Follow-up 2		
Cost category	*n*	Mean	SD	*n*	Mean	SD	*n*	Mean	SD
A&E visits	52	0.269	0.9725	24	0.083	0.2823	22	0.091	0.2942
Inpatient nights	52	0.519	2.4454	24	0.208	1.0206	22	0.182	0.8528
Hospital outpatient visits	52	0.135	0.4441	24	0.083	0.4082	22	0.136	0.4676
Day hospital attendances	52	0.019	0.1387	24	0.083	0.4082	22	0.091	0.4264
Emergency ambulance	52	0.058	0.3076	24	0.000	0.0000	22	0.045	0.2132
Taken from hospital by PTA	52	0.058	0.3076	24	0.042	0.2041	22	0.000	0.0000
GP surgery visits	52	0.750	0.8828	24	0.500	0.6594	22	0.864	1.1253
GP home visits	52	0.019	0.1387	24	0.000	0.0000	22	0.091	0.4264
Practice nurse surgery visits	52	0.385	1.6821	24	0.125	0.3378	22	0.136	0.3513
Practice nurse at home	52	0.000	0.0000	24	0.000	0.0000	22	0.000	0.0000
Prescriptions	52	2.115	2.4387	24	2.250	1.5393	22	2.227	1.3428
Other health-care professionals	51	0.059	0.3106	23	0.130	0.4577	21	0.000	0.0000
Key worker at drug service	52	2.404	3.1390	24	2.083	2.1247	22	1.818	1.0065
Group work	52	0.519	1.7091	24	0.542	2.0637	22	0.273	0.7025
Specialist drug service	51	1.118	4.1214	24	0.375	1.4390	22	0.000	0.0000
Pharmacist	52	18.154	11.3593	24	20.125	8.3630	22	20.545	9.0118
Nurse at drug service	52	0.846	2.0711	24	0.167	0.3807	22	0.227	0.5284
Needle exchange	52	6.788	8.3157	24	3.833	4.7973	22	3.045	3.1393
Outreach worker	52	1.077	4.0041	24	0.042	0.2041	22	0.273	0.7025
HIV or HCV infection test	52	0.135	0.3446	24	0.167	0.6370	22	0.364	0.9021
HIV infection treatment	52	0.000	0.0000	24	0.000	0.0000	22	0.000	0.0000
HCV infection treatment	52	0.538	3.8829	24	0.000	0.0000	22	0.000	0.0000

TABLE 73 Mean attendances for service use: intervention group (*continued*)

	Time point								
	Baseline			Follow-up 1			Follow-up 2		
Cost category	*n*	Mean	SD	*n*	Mean	SD	*n*	Mean	SD
HBV infection treatment	52	0.019	0.1387	24	0.000	0.0000	22	0.000	0.0000
Mental health specialist	52	0.481	1.9851	24	0.292	0.8587	22	0.136	0.4676
Social worker	52	0.327	1.0426	24	0.083	0.2823	22	0.045	0.2132
Dentist	52	0.231	0.6141	24	0.292	0.6903	22	0.227	0.7516
Family planning	52	0.000	0.0000	24	0.000	0.0000	22	0.000	0.0000
Sexual health clinic	52	0.000	0.0000	24	0.042	0.2041	22	0.000	0.0000
Arrest or caution	52	0.231	0.4693	23	0.174	0.6503	22	0.045	0.2132
Magistrates' court appearances	51	0.176	0.4339	22	0.091	0.4264	20	0.150	0.6708
Crown Court appearances	51	0.039	0.1960	22	0.000	0.0000	20	0.000	0.0000
Prison days	51	0.137	0.9802	23	0.000	0.0000	22	0.000	0.0000

A&E, accident and emergency; PTA, patient transport ambulance.

TABLE 74 Mean scores on service use questionnaire items by treatment allocation (ITT): baseline

					95% CI of difference	
Baseline	Allocation	*n*	Mean	SD	Lower CI	Upper CI
A&E visits	Control	47	0.468	1.0805	–0.2131	0.6108
	Intervention	52	0.269	0.9725		
Inpatient nights	Control	47	0.447	2.1245	–0.9842	0.8393
	Intervention	52	0.519	2.4454		
Hospital outpatient visits	Control	47	0.872	4.0946	–0.4702	1.9456
	Intervention	52	0.135	0.4441		
Day hospital attendances	Control	47	0.191	0.7413	–0.0484	0.3930
	Intervention	52	0.019	0.1387		
Emergency ambulance	Control	47	0.064	0.2471	–0.1047	0.1170
	Intervention	52	0.058	0.3076		
Taken from hospital by PTA	Control	47	0.149	0.6587	–0.1188	0.3013
	Intervention	52	0.058	0.3076		
GP surgery visits	Control	47	0.872	1.1348	–0.2869	0.5316
	Intervention	52	0.750	0.8828		
GP home visits	Control	47	0.064	0.2471	–0.0369	0.1261
	Intervention	52	0.019	0.1387		
Practice nurse surgery visits	Control	47	0.511	1.7178	–0.5536	0.8056
	Intervention	52	0.385	1.6821		

continued

TABLE 74 Mean scores on service use questionnaire items by treatment allocation (ITT): baseline (*continued*)

					95% CI of difference	
Baseline	Allocation	*n*	Mean	SD	Lower CI	Upper CI
Practice nurse at home	Control	47	0.340	2.0566	–0.2634	0.9443
	Intervention	52	0.000	0.0000		
Prescriptions	Control	47	2.638	3.6856	–0.7414	1.7872
	Intervention	52	2.115	2.4387		
Other health-care professionals	Control	44	0.136	0.5099	–0.0987	0.2538
	Intervention	51	0.059	0.3106		
Key worker at drug service	Control	47	2.489	1.9322	–0.9454	1.1164
	Intervention	52	2.404	3.1390		
Group work	Control	47	0.830	2.7609	–0.6203	1.2414
	Intervention	52	0.519	1.7091		
Specialist drug service	Control	47	0.468	1.2132	–1.8573	0.5582
	Intervention	51	1.118	4.1214		
Pharmacist	Control	47	19.340	11.1887	–3.3157	5.6889
	Intervention	52	18.154	11.3593		
Nurse at drug service	Control	47	0.809	1.7525	–0.8008	0.7255
	Intervention	52	0.846	2.0711		
Needle exchange	Control	47	6.000	7.2891	–3.9016	2.3246
	Intervention	52	6.788	8.3157		
Outreach worker	Control	47	1.830	5.7760	–1.2548	2.7606
	Intervention	52	1.077	4.0041		
HIV or HCV infection test	Control	47	0.404	1.5695	–0.2001	0.7394
	Intervention	52	0.135	0.3446		
HIV infection treatment	Control	47	0.000	0.0000[a]		
	Intervention	52	0.000	0.0000[a]		
HCV infection treatment	Control	47	0.000	0.0000	–1.6195	0.5425
	Intervention	52	0.538	3.8829		
HBV infection treatment	Control	47	0.000	0.0000	–0.0578	0.0194
	Intervention	52	0.019	0.1387		
Mental health specialist	Control	47	0.340	0.8412	–0.7414	0.4607
	Intervention	52	0.481	1.9851		
Social worker	Control	47	0.043	0.2040	–0.5802	0.0114
	Intervention	52	0.327	1.0426		
Dentist	Control	47	0.085	0.3508	–0.3433	0.0519
	Intervention	52	0.231	0.6141		
Family planning	Control	47	0.021	0.1459	–0.0216	0.0641
	Intervention	52	0.000	0.0000		

TABLE 74 Mean scores on service use questionnaire items by treatment allocation (ITT): baseline (*continued*)

					95% CI of difference	
Baseline	Allocation	*n*	Mean	SD	Lower CI	Upper CI
Sexual health clinic	Control	47	0.149	0.8841	–0.1107	0.4085
	Intervention	52	0.000	0.0000		
Arrest or caution	Control	47	0.298	1.1017	–0.2796	0.4138
	Intervention	52	0.231	0.4693		
Magistrates' court appearances	Control	45	0.200	0.8146	–0.0772	0.2079
	Intervention	51	0.176	0.4339		
Crown Court appearances	Control	45	0.022	0.1491	–0.2476	0.2947
	Intervention	51	0.039	0.1960		
Prison days	Control	44	0.000	0.0000	–0.0871	0.0532
	Intervention	51	0.137	0.9802		

A&E, accident and emergency; PTA, patient transport ambulance.
a *t* cannot be computed because the SDs of both groups are 0.

TABLE 75 Mean scores on service use questionnaire items by treatment allocation (ITT): follow-up 1

					95% CI of difference	
Follow-up 1	Allocation	*n*	Mean	SD	Lower CI	Upper CI
A&E visits	Control	27	0.296	0.8234	–0.1302	0.5562
	Intervention	24	0.083	0.2823		
Inpatient nights	Control	27	0.296	0.8689	–0.4499	0.6259
	Intervention	24	0.208	1.0206		
Hospital outpatient visits	Control	27	0.667	1.1767	0.0923	1.0744
	Intervention	24	0.083	0.4082		
Day hospital attendances	Control	27	0.111	0.4237	–0.2066	0.2621
	Intervention	24	0.083	0.4082		
Emergency ambulance	Control	27	0.185	0.6225	–0.0611	0.4314
	Intervention	24	0.000	0.0000		
Taken from hospital by PTA	Control	27	0.444	1.5525	–0.2162	1.0217
	Intervention	24	0.042	0.2041		
GP surgery visits	Control	27	1.074	1.1068	0.0660	1.0822
	Intervention	24	0.500	0.6594		
GP home visits	Control	27	0.148	0.4560	–0.0323	0.3286
	Intervention	24	0.000	0.0000		
Practice nurse surgery visits	Control	27	0.296	0.5417	–0.0806	0.4232
	Intervention	24	0.125	0.3378		

continued

TABLE 75 Mean scores on service use questionnaire items by treatment allocation (ITT): follow-up 1 (*continued*)

Follow-up 1	Allocation	*n*	Mean	SD	95% CI of difference	
					Lower CI	Upper CI
Practice nurse at home	Control	27	0.037	0.1925	–0.0391	0.1132
	Intervention	24	0.000	0.0000		
Prescriptions	Control	27	2.481	1.3408	–0.5869	1.0499
	Intervention	24	2.250	1.5393		
Other health-care professionals	Control	26	0.038	0.1961	–0.3024	0.1185
	Intervention	23	0.130	0.4577		
Key worker at drug service	Control	27	2.370	1.2449	–0.7177	1.2917
	Intervention	24	2.083	2.1247		
Group work	Control	27	0.852	2.0325	–0.8456	1.4659
	Intervention	24	0.542	2.0637		
Specialist drug service	Control	27	0.296	1.0675	–0.8020	0.6446
	Intervention	24	0.375	1.4390		
Pharmacist	Control	26	19.962	9.0354	–5.1107	4.7837
	Intervention	24	20.125	8.3630		
Nurse at drug service	Control	26	1.231	4.6845	–0.8334	2.9616
	Intervention	24	0.167	0.3807		
Needle exchange	Control	27	4.630	6.8956	–2.5226	4.1152
	Intervention	24	3.833	4.7973		
Outreach worker	Control	27	0.852	2.4916	–0.1785	1.7988
	Intervention	24	0.042	0.2041		
HIV or HCV infection test	Control	27	0.111	0.3203	–0.3483	0.2372
	Intervention	24	0.167	0.6370		
HIV infection treatment	Control	27	0.000	0.0000[a]		
	Intervention	24	0.000	0.0000[a]		
HCV infection treatment	Control	27	0.000	0.0000[a]		
	Intervention	24	0.000	0.0000[a]		
HBV infection treatment	Control	27	0.000	0.0000[a]		
	Intervention	24	0.000	0.0000[a]		
Mental health specialist	Control	27	0.370	0.9667	–0.4349	0.5924
	Intervention	24	0.292	0.8587		
Social worker	Control	27	0.259	0.8590	–0.1806	0.5325
	Intervention	24	0.083	0.2823		
Dentist	Control	27	0.148	0.4560	–0.1163	0.1070
	Intervention	24	0.292	0.6903		
Family planning	Control	27	0.000	0.0000[a]		
	Intervention	24	0.000	0.0000[a]		

TABLE 75 Mean scores on service use questionnaire items by treatment allocation (ITT): follow-up 1 (*continued*)

					95% CI of difference	
Follow-up 1	Allocation	*n*	Mean	SD	Lower CI	Upper CI
Sexual health clinic	Control	27	0.037	0.1925	–0.1168	0.1075
	Intervention	24	0.042	0.2041		
Arrest or caution	Control	27	0.074	0.3849	–0.4137	0.2140
	Intervention	23	0.174	0.6503		
Magistrates' court appearances	Control	26	0.115	0.4315	–0.2257	0.2746
	Intervention	22	0.091	0.4264		
Crown Court appearances	Control	26	0.000	0.0000[a]		
	Intervention	22	0.000	0.0000[a]		
Prison days	Control	27	0.000	0.0000[a]		
	Intervention	23	0.000	0.0000[a]		

A&E, accident and emergency; PTA, patient transport ambulance.
a *t* cannot be computed because the SDs of both groups are 0.

TABLE 76 Mean scores on service use questionnaire items by treatment allocation (ITT): follow-up 2

					95% CI of difference	
Follow-up 2	Allocation	*n*	Mean	SD	Lower CI	Upper CI
A&E visits	Control	23	0.261	0.6887	–0.1501	0.4900
	Intervention	22	0.091	0.2942		
Inpatient nights	Control	23	0.783	3.1328	–0.7946	1.9962
	Intervention	22	0.182	0.8528		
Hospital outpatient visits	Control	23	0.652	1.1123	0.0001	1.0315
	Intervention	22	0.136	0.4676		
Day hospital attendances	Control	23	0.348	0.8847	–0.1620	0.6758
	Intervention	22	0.091	0.4264		
Emergency ambulance	Control	22	0.091	0.4264	–0.1619	0.2528
	Intervention	22	0.045	0.2132		
Taken from hospital by PTA	Control	23	0.043	0.2085	–0.0467	0.1336
	Intervention	22	0.000	0.0000		
GP surgery visits	Control	23	0.696	0.8221	–0.7647	0.4287
	Intervention	22	0.864	1.1253		
GP home visits	Control	23	0.000	0.0000	–0.2800	0.0981
	Intervention	22	0.091	0.4264		
Practice nurse surgery visits	Control	23	0.217	0.5184	–0.1850	0.3471
	Intervention	22	0.136	0.3513		

continued

TABLE 76 Mean scores on service use questionnaire items by treatment allocation (ITT): follow-up 2 (*continued*)

					95% CI of difference	
Follow-up 2	Allocation	*n*	Mean	SD	Lower CI	Upper CI
Practice nurse at home	Control	23	4.304	20.6429	–4.6223	13.2310
	Intervention	22	0.000	0.0000		
Prescriptions	Control	23	2.348	1.6127	–0.7706	1.0117
	Intervention	22	2.227	1.3428		
Other health-care professionals	Control	20	0.100	0.3078	–0.0441	0.2441
	Intervention	21	0.000	0.0000		
Key worker at drug service	Control	23	2.217	2.1941	–0.6312	1.4296
	Intervention	22	1.818	1.0065		
Group work	Control	23	0.783	1.9761	–0.3887	1.4084
	Intervention	22	0.273	0.7025		
Specialist drug service	Control	23	0.000	0.0000[a]		
	Intervention	22	0.000	0.0000[a]		
Pharmacist	Control	23	16.130	11.4507	–10.6020	1.7720
	Intervention	22	20.545	9.0118		
Nurse at drug service	Control	23	0.739	1.7637	–0.2786	1.3024
	Intervention	22	0.227	0.5284		
Needle exchange	Control	23	2.870	4.8082	–2.6161	2.2643
	Intervention	22	3.045	3.1393		
Outreach worker	Control	23	1.826	6.2570	–1.1661	4.2728
	Intervention	22	0.273	0.7025		
HIV or HCV infection test	Control	23	0.478	1.0388	–0.4697	0.6990
	Intervention	22	0.364	0.9021		
HIV infection treatment	Control	23	0.000	0.0000[a]		
	Intervention	22	0.000	0.0000[a]		
HCV infection treatment	Control	23	0.000	0.0000[a]		
	Intervention	22	0.000	0.0000[a]		
HBV infection treatment	Control	23	0.043	0.2085	–0.0467	0.1336
	Intervention	22	0.000	0.0000		
Mental health specialist	Control	23	0.043	0.2085	–0.3154	0.1296
	Intervention	22	0.136	0.4676		
Social worker	Control	23	0.217	0.5997	–0.1008	0.4446
	Intervention	22	0.045	0.2132		
Dentist	Control	23	0.261	0.6192	–0.3821	0.4493
	Intervention	22	0.227	0.7516		
Family planning	Control	23	0.087	0.4170	–0.0934	0.2673
	Intervention	22	0.000	0.0000		

TABLE 76 Mean scores on service use questionnaire items by treatment allocation (ITT): follow-up 2 (*continued*)

					95% CI of difference	
Follow-up 2	Allocation	*n*	Mean	SD	Lower CI	Upper CI
Sexual health clinic	Control	23	0.087	0.4170	–0.0934	0.2673
	Intervention	22	0.000	0.0000		
Arrest or caution	Control	23	0.130	0.4577	–0.1305	0.3005
	Intervention	22	0.045	0.2132		
Magistrates' court appearances	Control	21	0.190	0.5118	–0.3390	0.4199
	Intervention	20	0.150	0.6708		
Crown Court appearances	Control	21	0.000	0.0000[a]		
	Intervention	20	0.000	0.0000[a]		
Prison days	Control	23	0.000	0.0000[a]		
	Intervention	22	0.000	0.0000[a]		

A&E, accident and emergency; PTA, patient transport ambulance.
a *t* cannot be computed because the SDs of both groups are 0.

EME
HS&DR
HTA
PGfAR
PHR

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