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

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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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Scientific summary

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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.

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