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Feasibility of psychosocial interventions for preventing blood borne virus infection in people who inject drugs

Submission date
29/07/2014

Recruitment status
No longer recruiting

Registration date
24/09/2014

Overall study status
Completed

Last Edited
15/02/2018

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In the UK, between 33%-56% of people who inject drugs (PWID) suffer from one or more of the blood borne viruses (BBV) Hepatitis C, HIV or Hepatitis B as a result of sharing injecting equipment (needles and syringes, water, spoons, cotton etc) and also unsafe sex. New injectors, those who are homeless, prostitutes and women are more likely to become infected. Preventing PWID from getting or passing on these viruses is an important health issue. Opiate substitution therapy (methadone or buprenorphine) and needle exchanges have reduced BBV infections but behavioural interventions (treatments) such as individual or group therapy sessions that teach PWID how to reduce their risk of becoming infected could further prevent the spread of BBV. Most studies looking at behavioural inventions to reduce the risk of BBV infection have been carried out in the USA. There is therefore a need to develop treatments that are relevant to UK PWID and the UK drug treatment system. We need to find out what kind of behavioural intervention PWID would find useful, whether they would attend the intervention and whether it would stop them from behaving in ways most likely to lead to BBV infection.

Who can participate?
PWID aged at least 18 attending drug treatment clinics and needle exchange programs.

What does the study involve?
The project has a number of phases. These include a literature review to find out what type of intervention may work in different settings, collecting the views of PWID on what sort of interventions they would find useful (and are most likely to attend) and also collecting the views of drug treatment centres and relevant policy makers on how to provide possible psychosocial interventions and how successful they may be. Altogether, these findings are used to develop a new psychosocial intervention. In the last stage (phase 5), a trial takes place to see whether the newly developed intervention is feasible and acceptable to PWID. All participants taking part in this trial are randomly allocated into one of two groups. Those in group 1 attend a small number (1-4) of psychosocial group sessions while still getting their usual treatment. It covers

understanding BBV infection risks, motivation for change, and safer injecting and sexual practices. Those in group 2 (control group) are given an information leaflet on reducing the passing on (transmission) of BBVs as well as receive their usual treatment.

What are the possible benefits and risks of participating?
Possible benefits will be better knowledge on the transmission of BBVs

Where is the study run from?
King's College London (UK)

When is the study starting and how long is it expected to run for?
October 2015 to May 2016

Who is funding the study?
NIHR HTA (UK)

Who is the main contact?
Dr Gail Gilchrist
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title
Feasibility of psychosocial interventions for preventing blood borne virus infection in people who inject drugs: a feasibility randomised controlled trial

Study objectives
The proposed project will develop an evidence based psychosocial intervention to reduce blood borne viruses (BBV) and increase BBV transmission knowledge among people who inject drugs (PWID), and conduct a feasibility trial, comparing the psychosocial intervention to an information leaflet, to inform the future parameters of a large multisite RCT. The hypothesis for the full trial is that the psychosocial intervention will be more effective in reducing BBV risk behaviours and increasing BBV transmission knowledge than an information leaflet.

More details can be found at: https://www.journalslibrary.nihr.ac.uk/programmes/hta/131704/#/
Protocol can be found at: https://njl-admin.nihr.ac.uk/document/download/2007288

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Integrated Research Approval System will be used to gain ethical and R&D approval to conduct the study. This approval is not required till Phases 2 and 3 of the project (month 5 and 8 respectively) and for the feasibility trial in Phase 5 of the project (month 12); therefore, it is not possible to get ethical approval for the feasibility study until the intervention has been developed.

Study design
Feasibility randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Blood borne viruses among people who inject drugs

Interventions
All participants in the feasibility trial will receive treatment as usual in addition to the trial interventions. In community addiction treatment, treatment as usual in NHS/ 3rd sector Community Addiction treatment in the UK is fortnightly tier 3 key work/care planning (based on the National Treatment Agency models of care, 2006) delivered by a drug worker. In needle and syringe exchange programmes, injecting equipment and paraphernalia is supplied free of charge, and service users can exchange/ return used syringes. Injecting and harm reduction advice and physical health care (treatment of wounds etc) is provided as required. The HTA assesses the value of a health technology (i.e. the evidence based psychosocial intervention) compared to the best alternative (currently an information leaflet). Psychosocial interventions to reduce BBV risk behaviours and transmission are not standard practice in NHS and third sector treatment in the UK. Previous studies have compared psychosocial interventions to video and leaflet information sessions [e.g. 36,38], therefore we consider the proposed approach to be ethical.
1. Intervention arm:
A psychosocial intervention will be developed in Phase 4. Participants randomly allocated to the intervention arm will participate in a psychosocial group (brief) intervention (estimated 1-4 sessions) facilitated by a drugs worker. They will also receive treatment as usual from the service from which they are recruited. While the intervention to be used in the feasibility trial is not yet confirmed, we anticipate it will be brief (around 1-4 sessions) and will draw on the information motivation and behaviour skills model of health behaviour change:
1.1. Understanding BBV injecting and sexual transmission risks
1.2. Motivation for change
1.3. Skills building for safer injecting and sexual practices
1.4. Negotiating safer injecting and sexual practices
2. Control arm:
Participants randomly allocated to the control arm will be given an information leaflet on reducing the transmission of blood borne viruses by a drugs worker. They will also receive treatment as usual from the service from which they are recruited.

Intervention Type
Behavioural

Primary outcome measure
The proposed study will examine feasibility and is not powered to determine effect. Differences in number of risk events in past month will be assessed pre, end and 1 month post intervention using intention-to-treat analysis. The Blood Borne Virus Transmission Risk Assessment Questionnaire (TRAQ) will assess the frequency with which PWID have participated in specific injecting, sexual and other risk-practices in the previous month that may expose them to blood-borne viruses. The REDUCE questionnaire on Hepatitis C transmission knowledge and The brief HIV-Knowledge Questionnaire will measure transmission knowledge.

Secondary outcome measures
Quality of life will be measured using EQ-5D

Overall study start date
01/10/2015

Completion date
31/05/2016

Eligibility

Key inclusion criteria
1. PWID are aged 18 and older attending NHS and third sector community addiction and harm reduction clinics and needle exchange programmes (static and mobile)
2. Who have injected drugs at least once in the past 4 weeks
3. Who plan to stay in the area for the next 3 months
4. Who are able to complete the assessment (alone or with help of researcher) and communicate in a group intervention in English.
PWID are not routinely screened for BBV at drug treatment services & therefore do not always know their BBV status. As the focus of the proposed psychosocial intervention will be to increase knowledge about transmission/ reinfection & promote motivation/skills for safer injecting & sex practices, the intervention content will be the same regardless of BBV status.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
128 PWID for feasibility trial

Key exclusion criteria
PWID who are too intoxicated or in withdrawal to give informed consent.

Date of first enrolment
01/10/2015

Date of final enrolment
31/05/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Kings College London
London

United Kingdom
SE5 8BB

Sponsor information

Organisation
King's College and the Maudsley NHS Foundation Trust (UK)

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Maudsley Hospital
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/015803449

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	21/03/2017		Yes	No
Results article	results	01/11/2017		Yes	No