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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.**

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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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

[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. ☐

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