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Qualitative study looking at barriers to and facilitators for testing for hepatitis C among peer networks

Submission date
15/11/2021

Recruitment status
No longer recruiting

Registration date
29/11/2021

Overall study status
Completed

Last Edited
01/11/2023

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Hepatitis C virus (HCV) is a viral infection that can cause liver failure and liver cancer. We now have well-tolerated and effective drugs to treat HCV but up to 50% of the estimated 210,000 infected people in the UK do not know they are infected. If we find and treat all infected people we can decrease liver disease and stop HCV being spread to others. People who inject drugs (PWID) are the largest affected group in the UK. Most HCV testing strategies target PWID, but since 2000, increasing numbers of men who have sex with men (MSM), especially those with HIV, have been infected sexually with HCV. Their risk factors differ from PWID. More HIV-negative MSM are getting HCV now so MSM at risk of HCV infection should be tested when attending sexual health clinics, but this does not always happen and many MSM do not attend SH clinics, so testing in sexual health clinics will miss some MSM at risk. Traditional partner notification-testing partners of those diagnosed with HCV is often impossible to do as often there are many anonymous untraceable partners. The risk of HCV depends on the risk in the people one socialises with as well as has sex with. Social contacts influence behaviour and what is accepted as 'normal', including risky behaviour. More information about testing behaviours in these networks could allow better targeting of testing and a means to reach those not engaged with care. Studies have used a participant (known as a seed) to recruit social (including sexual) peers from their networks (alters) who in turn recruit their alters to reach 'hidden' populations. Adaptations to this method have helped find undiagnosed HIV cases in PWID in Athens for example. This study aims to develop and pilot a computer-based, peer-driven tool to recruit and test people at risk of HCV throughout social networks.

Who can participate?
1. MSM, over the age of 18 years, with a current or previous diagnosis of HCV infection
2. MSM, over the age of 18 years, who meet BASHH guidelines for HCV testing (at least one of the following):
2.1. HIV positive and have not had a hepatitis C test in the last year
2.2. Taking pre-exposure prophylaxis (PrEP) and HAS NOT had a hepatitis C test in the last 12 months
2.3. Has had sex with another man that is associated with trauma or injury and has not had a

hepatitis C test since then
2.4. Has used (or currently uses) recreational drugs and has not had a hepatitis C test in the last 12 months
2.5. Has (or has had) rectal lymphogranuloma venereum (LGV) infection and HAS NOT had a hepatitis C test since then
2.6. Has had condomless anal sex with a partner(s) whose HIV status is not known and has not had a hepatitis C test in the last 12 months
2.7. Has had condomless anal sex with more than 10 sexual partners over the last 12 months and has not had a hepatitis C test in the last 12 months
3. MSM over the age of 18 years who participated in focus group A or B
4. Healthcare workers (doctor of any grade, nurse of any grade, health advisors or clinical psychologists) who have direct involvement with MSM clinical care and testing

What does the study involve?
This study consists of three phases:
1. Focus group discussions (FGDs) with MSM: Group A (MSM with a previous diagnosis of HCV), group B (MSM who have not tested for HCV) and group C (a mix of participants from groups A and B). These participants will be recruited from clinics, using word of mouth, dating apps, previous studies and social media. The output from these will then help refine questions for the social-network-based peer-driven tool and then be used in phase 2
2. Interviews with MSM (end users) to ensure the refined questions are interpreted and answered correctly. The questions will then be refined further.
3. FGDs with healthcare professionals to explore the implementation of the tool and social network recruitment process
The researchers will undertake FGDs using Microsoft Teams which is widely available, which will allow for participants to be recruited from, and be based, anywhere in the England, with the advantage of allowing the study to explore barriers and facilitators for MSM in more rural settings where access to testing may differ from a central London setting.

What are the possible benefits and risks of participating?
The researchers are sensitive to the potential concerns around privacy and to the needs of those who may not identify as MSM and/or concerned about the stigma around HCV. Participants may have the option of using pseudonyms during the FGD and keeping their video off, and will therefore be afforded more anonymity than in a face to face FGD. The researchers are also conscious of the dynamic process of qualitative interviews, particularly in a focus group setting, where participants are engaging with others. The subject matters may be delicate and emotive and so they have also compiled a list of organisations that can offer third party support, should participants wish to receive it.

Where is the study run from?
University College London (UK)

When is the study starting and how long is it expected to run for?
February 2020 to March 2024

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Dr Nina Vora
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Contact information

Type(s)
Public

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Additional identifiers

Integrated Research Application System (IRAS)
293136

Central Portfolio Management System (CPMS)
51057

Study information

Scientific Title
Capturing Hepatitis C diagnoses Amongst men who have sex with men using Peer networks to Improve liNkage to Services: Part 1 (Qualitative) - CHAMPIONS (part 1)

Acronym
CHAMPIONS - Part 1

Study objectives
Rationale: In keeping with many other peer recruitment studies, key informants and focus groups help assess barriers and motivators to trial participation and the researchers envisage this will guide the pilot recruitment protocol.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/09/2021, East of England - Cambridge South Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA; +44 (0)207 104 8084; cambridgesouth.rec@hra.nhs.uk), REC ref: 21/EE/0198

Study design
Qualitative focus group discussions with cognitive interviews of key questions

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Hepatitis C

Interventions
This study is part of a larger body of work looking at alternative strategies to reach at-risk men who have sex with men (MSM) and their peers, to test and diagnose hidden cases of Hepatitis C (HCV). In the broader study, the aim is to utilise social networks as evidence suggests social contacts influence our behaviour, what is accepted as 'normal' and risk can therefore depend on social contacts too. In order to develop this strategy, the researchers will undertake focus group discussions (FGDs) with MSM who have been diagnosed with HCV, and MSM who do not currently test for HCV using traditional routes (e.g. GUM clinics). These FGDs will explore barriers and facilitators to testing and partner notification, as well as explore social networks and their influence. These in turn will be used to help refine a social network recruitment strategy tool. Further qualitative work will then take place in the form of a) cognitive interviews to review key new questions in the tool and b) FGDs with healthcare providers to look at the implementation and practicality of this tool. These findings will then be used to further develop the tool.

Intervention Type
Other

Primary outcome(s)
Participant insight into the phrasing of key questions around social network members, as explored in cognitive interviews at a single timepoint

Key secondary outcome(s))

1. Participant attitudes to HCV testing and disclosure, as measured using focus group discussions at a single timepoint
2. Participant insight into members of their social and sexual networks who are influential to risk-taking or protective behaviour as measured within focus group discussions at a single timepoint

Completion date
05/03/2024

Eligibility

Key inclusion criteria
1. MSM with HCV (current or previous)
2. MSM at risk of HCV but not undergoing regular testing (as per British Association for Sexual Health and HIV (BASHH) testing guidelines)
3. Healthcare workers involved in testing MSM for blood-borne viruses

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Cis and trans women are excluded from focus groups A-C and the cognitive interviewing as these sections focus on men who have sex with men
2. Participants under the age of 18 years will also be excluded
3. To allow for discussions within the group, participation will be restricted to those with a conversational level of English
4. Participants who decline to have audio recording during FGDs or cognitive interviews will not be eligible for the study

Date of first enrolment
19/10/2021

Date of final enrolment
29/12/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Institute for Global Health, UCL
4th floor Mortimer Market Centre
London
United Kingdom
WC1E 6JB

Study participating centre
Mortimer Market Centre clinics
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Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to the sensitive nature of the data and need to maintain participant anonymity.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No