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CHAMPIONS study part 2: utilising the social networks of men who have sex with men to reach and better serve those not accessing care.

Submission date
14/09/2023

Recruitment status
No longer recruiting

Registration date
13/10/2023

Overall study status
Completed

Last Edited
16/04/2025

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Hepatitis C virus (HCV) is the second leading cause of liver disease in the UK, affecting 81,000 people in England alone. Whilst the availability of new well-tolerated oral medication provides an opportunity to eliminate this virus, it remains a problem within a subgroup of men who have sex with men (MSM) in the UK. In part, this is because MSM at risk of HCV either do not attend services or do not undertake HCV testing if they do, which means that many with HCV are undiagnosed with the consequence that sexual transmission continues. Furthermore, the MSM at the highest risk of HCV often has multiple anonymous sexual partners, which renders traditional partner notification ineffective for HCV control. Reinfection rates are high in this population, suggesting these MSM are part of a wider network with ongoing transmission of HCV. Risk for HCV is likely to cluster not only among sexual partners but within social networks too. The use of social network strategies, using MSM to recruit peers from their social networks, is an approach to identify and test hardly reached patients with and at risk of HIV, but no one has used this approach for HCV in the UK. A social network intervention which aims to penetrate through social networks might be effective at increasing testing for HCV among MSM with or at risk of HCV and could contribute to the HCV elimination effort. The CHAMPIONS II study aims to explore this concept, provide an evidence base for an intervention, and undertake a pilot study to decide whether to take this work further.

Who can participate?
Any man (born male or identifies as male) who has had sex with other men, aged over 16 years old and living in England

What does the study involve?
Participants will undertake each stage once.
1. Recruitment and online consent process
2. Online questionnaire completion
3. Complete self-sampling testing at home using a kit sent by the study team (which is posted to an address of your choice or can be collected). Test results will be sent by your method of choice.
4. Recruit peers- friends/partners/acquaintances who are men who have sex with men, aged 16

or over and live in England
5. Complete follow-up evaluation questionnaire (questionnaire B)
6. 1:1 interviews to evaluate the process (for some participants)

What are the possible benefits and risks of participating?
There are no direct benefits to the participants for taking part in the study. However, the opportunity to be able to undertake blood-borne virus testing in the comfort of their home may be perceived as a benefit by some participants.

The study team are sensitive to the potential concerns around privacy and to the needs of those who may not identify as MSM and/or are concerned about the stigma around HCV. Participants will be recruiting peers from within their own networks and therefore intrinsically selecting participants they may have already disclosed their sexuality to. There may be a potential for embarrassment or awkwardness in social situations but feel this is in keeping with any discussions around sexual health matters. As seed selection is broad and not restricted to participants with any (previous or current) blood-borne virus (e.g. HCV), this should minimise inadvertent disclosure of a particular infection.

Participants may find that undertaking fingerpricks to obtain the dried blood spot sample is uncomfortable but it rarely results in any significant problems. Participants will be informed of any potential risks relating to the study procedures in the Participant Information Sheet (PIS). The PIS will also include contact details in case participants need any further advice following answering the questionnaire, undertaking testing or in regards to their test results.
There is a risk that the study identifies infections but cannot engage participants in care. The study team will attempt to contact participants with positive results up to three times, using any contact details supplied for the participant, signpost participants to their closest appropriate services and provide documentation stating they are part of this study and have been diagnosed with a blood-borne viral infection. They will also provide basic information about the infection(s), the importance of confirmatory testing and accessing care and will also attempt to contact the participant to see if they have engaged with local services for ongoing care.

There is no incentive to recruit peers, which is envisaged will decrease any intended or unintended coercion from a financial point of view.
The study team are conscious of the dynamic process of qualitative interviews especially where subject matters may be delicate and emotive and so have compiled a list of organisations that can offer third-party support, should participants wish to receive it.

Participants interviewed in the 1:1 interviews will be offered a £20 shopping voucher in recognition of their time.

The community advisory group consists of members of, or representatives of the user population, who have consulted on the design from the proposal stage and will continue to advise in the publication and dissemination plan. Stakeholder dissemination events are budgeted for within the CHAMPIONS study to enable further dissemination of findings, and the advisory group will play a role in the timing (e.g. end of CHAMPIONS study, or interim) and method (e.g. online or in-person events).

Where is the study run from?
The Institute for Global Health at University College London (UK) and the Mortimer Market Centre (UK)

When is the study starting and how long is it expected to run for?
November 2021 to March 2024

Who is funding the study?
1. National Institute for Health and Care Research (NIHR) (UK)
2. An MRC clinical research training fellowship grant (UK)

Who is the main contact?
Dr Nina Vora, nina.vora@ucl.ac.uk

Study website
https://Youtu.be/hfZkLf1cmWU

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
318015

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 318015, CPMS 55769

Study information

Scientific Title
Capturing Hepatitis C diagnoses Amongst MSM using Peer networks to Improve liNkage to Services: part 2

Acronym
CHAMPIONS II

Study objectives
The overarching aim is to study the acceptability and feasibility of using social network-driven recruitment (SNDR) among men who have sex with men (MSM) and their peers in England to test for HIV, hepatitis C and hepatitis B.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 25/04/2023, London - Camden and Kings Cross Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon tyne, NE2 4NQ, United Kingdom; +44 (0)207 1048083; CamdenandKingsCross.REC@hra.nhs.uk), ref: 23/LO/0273

Study design
Single-centre mixed methods observational study

Primary study design
Observational

Secondary study design
Mixed methods

Study setting(s)
Community, Home, Hospital, Internet/virtual

Study type(s)
Other, Screening

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

Health condition(s) or problem(s) studied
Evaluating the utility of reaching men through social networks and testing for blood borne viruses (HIV, hepatitis B and hepatitis C)

Interventions
The overarching aim is to study the acceptability and feasibility of using social network-driven recruitment (SNDR) among men who have sex with men (MSM) and their peers in England to test for HIV, hepatitis C and hepatitis B. The secondary objectives will focus on assessing the effectiveness of the interventions.

DESIGN: The CHAMPIONS study is a mixed-methods observational study (after CHAMPIONS - Part 1 https://www.isrctn.com/ISRCTN16666223) piloting the feasibility of MSM recruiting through their peer networks to test other MSM for blood-borne viruses.

DEVELOPMENT: Prior qualitative work around tool development and methodology, suggested combining the offer of an HCV test with testing for HIV and hepatitis B -all blood-borne viruses with similar modes of transmission in MSM- as this may improve engagement and be an important opportunity to test MSM who we may not otherwise have tested.

The study has undergone scientific review and has been awarded funding from the Medical Research Council (MRC). The design, management and dissemination activities have received insight from patient public involvement during this funding application stage and from a community advisory group for the development of this stage.

OVERVIEW OF PARTICIPATION JOURNEY: Participants will undertake each stage once.
1. Recruitment and online consent process
2. Online questionnaire A completion
3. Complete self-sampling testing at home using a kit sent by the study team
4. Recruit peers- MSM from the participant's sexual and social networks, using personalised study coupons.
5. Complete follow-up evaluation questionnaire (questionnaire B)
6. Receive test results
7. 1:1 cognitive interviews (for some participants)

In detail:
1. RECRUITMENT and CONSENT: Initial participants (seeds) will be invited to participate and will undertake online consent and enrolment. This will include a short animation video outlining the study, a PDF copy of the participant information sheet and then an online consent form using REDCap within the UCL Data Safe Haven. All potential participants will have the opportunity to contact the study team with any queries. These seeds will then recruit additional participants (alters) who are MSM in their social and/or sexual networks. These alter participants will also undergo the same process from online consent to recruiting alters from their networks. Participants for 1:1 interviews will be selected from the participants who have already consented to take part in the study.
2. Online questionnaire A is self-administered online questionnaire (in REDCap, within the UCL data safe haven), which includes validated questions from questionnaires looking at sexual practices and risk, such as the National Survey of Sexual Attitudes and Lifestyles studies (Natsal-4), World Health Organisation Global HIV Strategic Information Working Group Biobehavioural Survey Guidelines, European Men who have Sex with Men Internet Survey (EMIS-2017), and Gay Men's Sexual Health Survey, as well as additional questions. It covers sociodemographic characteristics (age, biological sex, marital status, partial postcode, migration background, educational level, sexual orientation and disclosure of sexual orientation to others), lifetime and recent sexual behaviours (history of sex with men and/or women, role during sex with men, condom use, type of sex partners, group sex, drug use), lifetime and recent STI history, including STI prevention (e.g. PrEP/PEP and HPV, HBV and Mpox vaccination) and social network details. Skip questions will be used so that participants are not wasting time responding to questions that do not apply to them.
3 and 6: Home testing kit and results- Participants will be sent a home self-sampling dried blood spot test kit to test for HIV (antibody/antigen 4th generation test), HCV antibody (and reflex HCV viral load testing if antibody positive) and hepatitis B (anti-HBs antibody and total anti-HBc antibodies). There is an option for participants to collect these kits from our clinic if they prefer. Participants will post these samples to the research team and receive their results by their preferred contact method. All participants will be encouraged to engage with local testing services. Participants with new positive results will be contacted by a physician, informed of these results and assisted with engaging in confirmatory testing and care.
4. Peer recruitment- Participants will be sent coupons (electronic or paper) to enable their peers (from their social and sexual networks) to participate in the study. The coupons are uniquely numbered to enable linking through chains. This unique code is distinct from the participant number. There is no restriction on the number of coupons they can initially hand out as optimum coupon distribution is part of the process evaluation.
5. Evaluation of process- a link will be sent to all participants (whether a completed test kit has been received or not) to an online self-completed questionnaire hosted on REDcap within the UCL secure data safe haven. This questionnaire will collect data on the reason for acceptance of self-sample tests, experience of the test and experience of onward referral /recruitment of peers. This will include questions asking which members were approached, how they were selected and who they would like to have approached, in addition to what went well and what could be improved with the process.
6. 1:1 interviews: A sub-sample of participants (n=10-15) will be approached to take part in semi-structured interviews (SSIs). These participants will represent different age and ethnicity groups and the number of peers recruited. The study will explore acceptability from an end-user perspective including barriers to and facilitators of recruiting peers, which network members were and were not approached (and why), and the responses to offering coupons, as well as experiences of home testing and receiving results. Input regarding aspects of the process which did and did not work well and suggestions for improvement will also be sought. These areas will aid in further evaluation and development of the intervention.

Intervention Type
Mixed

Primary outcome measure
The following primary outcome measures will assess the feasibility and acceptability of the intervention:
1. The number of participants expressing interest as seeds, consenting to the process and recruiting alters (peers) measured from the total number of seeds who consented versus completed the process using an online self-completed questionnaire hosted on REDcap at the end of the study period
2. The number of participants (seeds or alters) going on to recruit their own alters – the number of waves in the different chains - measured using an online self-completed questionnaire hosted on REDcap at the end of the study period
3. The return rate of accepted test kits (to meet or exceed UKHSA Home HIV testing kit return rates of 0.54) measured using the number of kits sent versus returned by the end of the study period
4. The number of alters rejecting versus accepting participation (as reported by their recruiters) potential barriers to and facilitators to implementation within services measured quantitatively using the total number of coupons offered, as reported by participants, versus the number of peers who participate. Qualitative analysis will involve analysis of 1:1 interviews, by the end of the study period.

Secondary outcome measures
The following secondary outcome measures will assess the effectiveness of the interventions:
1. Network yield - newly diagnosed BBV infections divided by the number of alters and seeds at the end of the study period
2. Proportion of participants who:
2.1. Meet risk criteria but are not yet tested (participants who meet MOSAIC criteria for HCV testing but self-report as never having tested, by the end of the study period)
2.2. The number of participants who test positive for hepatitis C and self-report as not being hepatitis C positive by the end of the study period
2.3. The number of participants who self-report as having positive BBV infection but self-report as not being engaged in care at the time of enrolment, and then report engagement with services by the end of the study period
3. Ability of intervention to reach a less engaged at-risk population by exploring proportions of untested and undiagnosed MSM, comparing early recruitment waves (approximately waves 1-3) with later (4 onwards), by the end of the study period

Overall study start date
01/11/2021

Completion date
05/03/2024

Eligibility

Key inclusion criteria
1. Male who has had sex with another man within the last 12 months (sex can be oral or genital contact),
2. Aged 16 years old and over
3. Lives in England

Participant type(s)
Patient, Population, Service user

Age group
Mixed

Lower age limit
16 Years

Upper age limit
110 Years

Sex
Male

Target number of participants
300

Total final enrolment
40

Key exclusion criteria
1. Cis heterosexual women
2. Aged 15 years old or under
3. Not normally resident in England

Date of first enrolment
26/06/2023

Date of final enrolment
29/12/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Mortimer Market Centre
Mortimer Market
London
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Sponsor information

Organisation
University College London

Sponsor details
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Sponsor type
University/education

Website
http://www.london.ac.uk/

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
Medical Research Council

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. Planned publication in a high-impact peer-reviewed journal
2. Videos similar to the study explanation (see the study website)

Intention to publish date
05/03/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the study are not expected to be made available due to the sensitive nature of the data e.g. sexual practice, and drug use. Any access requests would be discussed with the team, including members of the PPI group on an individual basis.

IPD sharing plan summary
Not expected to be made available