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The TARGET feasibility study: Can men and transgender people who have sex with men encourage others to have blood tests for HIV, HBV and HCV?

Submission date
23/09/2019

Registration date
30/09/2019

Last Edited
26/08/2020

Recruitment status
Suspended

Overall study status
Completed

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
There is a need to increase testing for viral infections that can be caught from body fluids, such as HIV, hepatitis B virus (HBV) and hepatitis C virus (HCV) in men and transgender people who have sex with men. They can be hard to reach in terms of healthcare because they might not want to discuss their sexuality, transgender status or sex life with healthcare professionals. Hard-to-reach groups can often respond better to approaches from people who are similar to them. This study aims to investigate whether 'Testing Champions' (men and transgender people who have sex with men who will be trained and paid a small amount to encourage them to provide information on testing and the offer of a free blood test to other men and transgender people who have sex with men) can increase rates of testing within these communities more than posters advertising testing, which will be placed in LGBTQ+ venues.

Who can participate?
The Testing Champions will be adult men or transgender people who have sex with men and who live in the Birmingham postcode region. They must be able to read and write in English. The people who request the online testing kit will be adult men or transgender people who have sex with men and are based in England, Scotland or Wales.

What does the study involve?
The Testing Champions will receive training on how to approach people and some answers to potential questions about the kit, for example how long it takes for the result to be sent out. They will be instructed to give business cards to other men or transgender people who have sex with men who they meet in their daily lives.The business card contains information on testing and a link where people can request a testing kit online.
When people request a testing kit, they will be invited to fill in a questionnaire that will ask them for information on how often they engage in risky sexual behaviour in order to help target future testing services to people at risk of sexually transmitted infections.

What are the possible benefits and risks of participating?
The potential benefit is that people might get tested who otherwise would not have otherwise had a test or they might be tested sooner. If they have an infection, they will be offered treatment, which is more likely to control or cure their infection the earlier the treatment is given.
If they get a negative result, this can provide peace of mind, especially if the person uses safe sex in the future.
The Testing Champions will receive a small amount a cash for every person who requests a kit and for every person who returns a kit.

The testing kit requires the person to prick their fingertip in order to provide a blood sample using a lancet (sharp blade) provided in the kit. This may cause some pain, and there is a possible chance of infection at the site – although this is reduced if the testing instructions are followed as described in the kit.
There is a risk of emotional distress if a person finds out that they are infected with HIV, HBV or HCV. The test results will contain information on care and support for people who have received positive test results.
The Testing Champions might be at increased risk of verbal and or physical abuse from people they approach about testing. As part of the recruitment process, Testing Champions will receive brief training regarding reducing the risk of this happening.

Where is the study run from?
Birmingham Heartlands Hospital (UK)

When is the study starting and how long is it expected to run for?
July 2017 to July 2020

Who is funding the study?
Gilead Sciences (USA)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
253425

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 253425

Study information

Scientific Title
A feasibility study to explore the acceptability and effectiveness of a peer-to-peer postal HIV and viral hepatitis testing intervention, targeted towards at-risk and hard to reach men who have sex with men (MSM) and transgender people who have sex with men (TPSM) compared with standard of care advertisement posters (SOCAP)

Acronym
TARGET

Study objectives
There is a need to expand blood-borne virus (BBV) testing in at risk and hard to reach testing in men who have sex with men (MSM) and transgender people who have sex with men (TPSM). By diagnosing these infections, we can enable access care and treatment, which in turn will reduce morbidity and mortality among these groups. This feasibility study aims to establish whether the

strategy of using recruited peer-referrers as advocates for bloodborne virus (BBV) testing for high-risk and hard-to-reach MSM and TPSM is feasible, when compared to the current standard of advertisement posters directing the target population to an online-based test request system.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/08/2019, NHS Health Research Authority: East Midlands - Nottingham 2 Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham NG1 6FS; +44 (0)207 104 8094; NRESCommittee.EastMidlands-Nottingham2@nhs.net), ref: 19/EM/0240

Study design
A single-centre feasibility study with an embedded qualitative process evaluation.

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Human Immunodeficiency Virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV) testing

Interventions
Intervention:
Testing Champions (TCs) or 'peer-referrers' comprise the complex intervention. They act as a peer provider of health promotion, signposting to a website from which the population (men who have sex with men and transgender people who have sex with men) can request a free BBV testing kit.

Two intervention sub-groups will be created (TCA and TCB) by a 1:1 randomisation of recruited TCs. TCs will be randomised 1:1 to group A or Group B using a specific randomisation function on Microsoft Excel, “=rand()”. Each TC will be randomised to a number between 0 and 1. The TCs will be allocated to a each group, starting with group A (i.e. the lowest number is assigned group A, then next lowest assigned group B, and so on). The randomisation group will be single-blinded to the TC, but not to the study team (as we will need to know to process remuneration amounts).

The difference between the two groups (TCA and TCB) will be the remuneration amount given to the TC for every kit requested and returned by their peers (OKRs) through their referrals. Both TCA and TCB will receive £1 for each peer they approach who successfully requests a sampling kit (which tests for HIV, HBV and HCV only) from the website https://takeatestuk.com/ but TCA will receive £2 for each kit returned by the peer while TCB will receive £4.

All TCs will be provided with a training document (in person, or electronically) detailing what is to be expected from them. This document will contain information about the BBV testing kit (how to use the kit, the expected duration of time taken to get a result, what happens if a result is positive) and some suggestions on how to approach a peer about using the kit. This document will be no more than two sides of A4 paper. The TCs will approach populations in their sexual or social environments.

Comparator:
This consists of the standard of care advertisement posters (SOCAP) which will signpost readers to an online BBV testing website. 10-20 posters will be positioned in known prominent gay, bisexual and transgender venues in Birmingham. The posters will contain the website address for the online kits and a QR code, signposting to sexual health clinics if they have any relevant symptoms, brief details about the BBV tested for, and a unique code specific to the SOCAP. All posters regardless of venue will have the same code. The online kit requesters (OKR) will need this code in order to gain access to the free sampling kit.

These posters will be checked on a weekly basis to ensure they are still in position. Posters which are not in position will be documented and replaced.

SOCAP will be positioned at the venues at the same time as the TCs onward referral begins.

Intervention Type
Behavioural

Primary outcome(s)
Feasibility outcomes of interest relate to:
1. Recruitment numbers for Testing Champions
2. Retention of Testing Champions
3. Kit request numbers and rates
4. Kit return numbers and rates
5. Participant evaluation and experience of process (qualitative)

Key secondary outcome(s))
Descriptive statistics will be used to derive:
1. The proportion (in %) of positive results for HIV, HBV and HCV from the 24 weeks
2. The proportion of individuals who have not tested for HIV, HBV and HCV for >12 months
3. The characteristics associated with Testing Champion performance (both well and poorly performing), by measures of estimated number of people approached, kit request and return numbers
4. The distribution of kit request numbers between each Testing Champion remuneration group and advertisement posters (out of 200 – as we are restricted to 200 available kits)
5. The distribution of kit returns for each Testing Champion remuneration group and advertisement posters
6. Summary demographics of the Online Kit Requesters collected when they request the kit over the 24-week period. This questionnaire will collect the following information:
6.1. Age at time of request (years)
6.2. First half of post code
6.3. Gender
6.4. Sexuality
6.5. Ethnicity
6.6. Educational level
6.7. When last tested for HIV
6.8. When last tested for hepatitis B
6.9. When last tested for hepatitis C
6.10. Number of sexual partners in last 12 months
6.11. Number of sexual partners in the last 12 months involving condomless sex
6.12. The frequency of sex under influence of alcohol
6.13. The frequency of sex under influence of recreational drugs

6.14. The frequency of intravenous drug use
6.15. Enquiry on the use of pre-exposure prophylaxis medication for HIV
7. A breakdown of costs for each TC intervention group and the advertisement poster comparator group. These will include costs incurred by remuneration, administrative costs of printing, TC monthly contact, dissemination of posters and cost associated with kit production and processing of samples.

Completion date
31/07/2020

Eligibility

Key inclusion criteria
Testing Champion:
1. Aged ≥18 years
2. Resident in the city of Birmingham
3. Willing to commit to the role of TC for the duration of the study
4. Able and willing to give informed consent to participate
5. Able to read and write in the English language
6. Identify as a man who has sex with men (MSM) or transgender person who has sex with men (TPSM) with at least one of the following conditions:
6.1. Engaged in condomless anal sex with 2 or more people in the last 24 weeks
6.2. Reported rectal chlamydia or gonorrhoea in the last 24 weeks
6.3. Reported a new diagnosis of syphilis in the last 24 weeks
6.4. Reported chemsex use in the previous 12 weeks
6.5. Attends sex sessions/venues where condomless anal sex or chemsex occurs, although does not have to be involved in any of the activities

Online Kit Requester:
7. Aged ≥18 years
8. Identify as MSM or TPSM
9. Resident in England, Scotland or Wales
10. Willing to give informed consent to provide a valid mobile phone number (does not have to be a UK phone number, but must be able to receive calls and text messages originating from England)
11. Able to read and write in the English language

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Male

Key exclusion criteria
Cis-gender female. Transgender females are also part of the gender inclusion criteria.

Date of first enrolment
13/10/2019

Date of final enrolment
29/05/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Heartlands Hospital, University Hospitals Birmingham NHS FT
Hawthorn House
Heartlands Hospital
University Hospitals Birmingham NHS Foundation Trust
Bordesley Green East
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Sponsor information

Organisation
Birmingham Heartlands Hospital

ROR
https://ror.org/01bd5gh54

Funder(s)

Funder type
Industry

Funder Name
Gilead Sciences

Alternative Name(s)
Gilead, Gilead Sciences, Inc., Oligogen

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes