

# 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?

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<b>Registration date</b> 30/09/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 26/08/2020	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?

Dr Matthew Page, matthew.page@heartofengland.nhs.uk

## Contact information

### Type(s)

Scientific

### Contact name

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**Additional identifiers****EudraCT/CTIS number**

Nil known

**IRAS number**

253425

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

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; NRESCcommittee.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

### **Secondary study design**

### **Study setting(s)**

Other

### **Study type(s)**

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**

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 measure**

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)

### **Secondary outcome measures**

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.

**Overall study start date**

05/07/2017

**Completion date**

31/07/2020

## **Eligibility**

**Key inclusion criteria**

Testing Champion:

- 1. Aged  $\geq 18$  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  $\geq 18$  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

**Participant type(s)**

Mixed

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Male

**Target number of participants**

10-30 Testing Champions, 100-200 Online Kit Requesters

**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**

England

United Kingdom

**Study participating centre**

Heartlands Hospital, University Hospitals Birmingham NHS FT

Hawthorn House

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**Sponsor information****Organisation**

Birmingham Heartlands Hospital

**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

**Website**

<https://hgs.uhb.nhs.uk/research/>

**ROR**

<https://ror.org/01bd5gh54>

**Funder(s)****Funder type**

Industry

**Funder Name**

Gilead Sciences

**Alternative Name(s)**

Gilead, Gilead Sciences, Inc.

**Funding Body Type**

Government organisation

**Funding Body Subtype**

For-profit companies (industry)

**Location**

United States of America

**Results and Publications****Publication and dissemination plan**

Results of the study will be presented at relevant clinical meetings, form part of a PhD thesis and published in an appropriate peer reviewed journal. A lay report for the TC and members of the PPI group will also be produced, in addition to a lay report to be published on the Saving



Lives Charity website.

The data generated from this study may be used to produce:

1. A report document for Gilead Sciences ( funder of the study)
2. Part of Dr Matthew Page's PhD Thesis for the University of Birmingham
3. A lay report for the Saving Lives Charity website
4. A report document for R&D at Birmingham Heartlands Hospital, University Hospitals Birmingham NHS Foundation Trust
5. A lay report for the Testing Champions and members of the PPI group
6. A clinical presentation at a scientific meeting and/or an abstract in a peer-reviewed journal
7. A peer-reviewed publication

### **Intention to publish date**

01/03/2021

### **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**

<b>Output type</b>	<b>Details</b>	<b>Date created</b>	<b>Date added</b>	<b>Peer reviewed?</b>	<b>Patient-facing?</b>
<a href="#">HRA research summary</a>			28/06/2023	No	No