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An HIV self-testing public health intervention

Submission date
10/08/2016

Recruitment status
No longer recruiting

Registration date
24/10/2016

Overall study status
Completed

Last Edited
18/11/2024

Condition category
Infections and Infestations

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
HIV is a virus that attacks the immune system and weakens the body's ability to fight infections and disease. It is most commonly caught by having sex without a condom. This study is looking at whether the offer of free HIV self-tests could help reduce the spread of HIV in men who have sex with men (MSM). The annual rate of HIV diagnosis in MSM is increasing in the UK, but many MSM do not regularly test for HIV and as many as 1 in 4 may never have been tested. Currently, most HIV tests are conducted in genito-urinary medicine (GUM) clinics. HIV self-testing is where a person carries out the test themselves. They take a sample of blood or saliva and process it themselves using a self-testing kit. Some people may be more likely to test for HIV using this method than others because it is more private, quick and convenient than visiting a clinic. This study aims to investigate the potential impact of self-testing in the UK, how MSM feel about using self-testing, whether free self-testing could increase HIV diagnosis and lead to more people receiving treatment for HIV, and whether the NHS should provide free HIV self-testing.

Who can participate?
Men (including trans men), aged 18 or over, who have had anal sex with a man, and have not been diagnosed HIV positive

What does the study involve?
Participants are recruited via social media, other internet advertisements, and publicity in the gay press. Participants do not need to attend clinics or other healthcare settings in order to take part. Participants are randomly allocated to receive either a free HIV self-test or no free self-test. For those who receive one, the free self-test is delivered directly by the kit provider. All participants in this part of the study are asked to complete a survey at 3 months. These include questions about their experience with the self-test and the test results (if they received a test), their sexual behaviour and their HIV and STI testing since the start of the study. After 3 months, some of the people who received a test before are able to receive additional tests at regular intervals until the end of the study. This is only for people who used the test they received, found that they were HIV negative, and tell us they would be interested in receiving more tests. Whether or not they do receive more is decided by random allocation. All of the people who could have received additional tests – whether they do or not – are asked to complete regular surveys until the end of the study. The study is looking to compare the numbers of HIV diagnoses in the different groups (that is, those who receive tests and those who don’t). This information is collected in two ways: when people tell us in survey responses that they have

been diagnosed HIV positive, and using the Public Health England database that records all new HIV diagnoses in the UK.

What are the possible benefits and risks of participating?
Most participants in the study receive at least one free HIV self-test kit. This would otherwise cost £30. Some people might prefer the experience of testing on their own or with someone they trust, instead of having to go to a clinic. Being diagnosed as HIV positive, while distressing, has important benefits for long-term health compared to being undiagnosed. It is possible that participants may find the process of taking the self-test, or more likely the results, difficult. This may lead to other potential problems, such as with mental health or self-harm, or negative reactions towards partners.

Where is the study run from?
The study is run by researchers at the Royal Free Hospital, Sigma Research at London School of Hygiene and Tropical Medicine, University College London (UCL), the Medical Research Council Clinical Trials Unit at UCL and Public Health England. We have also had input from HIV iBase and a community advisory group.

When is study starting and how long is it expected to run for?
March 2014 to January 2020

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
1. SELPHI study team (mrcctu.selphi@ucl.ac.uk)
2. Chief Investigator: Dr Alison Rodger

Study website
http://www.selphi.org/

Contact information

Type(s)
Public

Contact name
Dr Alison Rodger

Contact details
Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
9233/001

Study information

Scientific Title
An HIV SELf-testing Public Health Intervention (SELPHI): a randomised controlled trial

Acronym
SELPHI

Study objectives
1. Is the online promotion and postal delivery of free HIV self-test kits (with testing reminders) feasible and acceptable?
2. Will the offer of a single free HIV self-test at enrolment lead to the confirmed diagnosis of prevalent HIV infections and entry to standard HIV clinical care?
3. Among seronegative men at high risk of acquiring HIV Infection, will the offer of regular free self-tests with testing reminders result in more rapid confirmed diagnosis of an incident HIV infection and entry into standard HIV clinical care?
4. Generate data to inform key parameters for cost-effectiveness models

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/09/2016, University College London Research Ethics Committee (Office of the Vice-Provost (Research), University College London, 2 Taviton St, London WC1E 6BT, UK; Tel: +44 (0) 20 7679 8717; Email: ethics@ucl.ac.uk), ref: 9233/001

Study design
Internet-based randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
HIV

Interventions
Internet-based study with two randomisations: at baseline, 10,000 eligible men randomised to receive either one free HIV self-test vs none in a 60:40 ratio, then at 3 months 3,000 eligible men at ongoing risk who have expressed an interest in receiving more kits randomised to either a regular (3-monthly) offer of additional self-tests vs none in a 1:1 ratio.

Intervention Type
Other

Primary outcome measure
Confirmed HIV diagnosis, identified through the Public Health England Diagnoses Database, supplemented with data from Genitourinary Medicine Clinic Activity Database (GUMCADv3) and participant self-report. For the first randomisation, the outcome will be a confirmed HIV diagnosis within 3 months of enrolment. For the second randomisation it will be time, from time of randomisation when participants are HIV negative, to a confirmed diagnosed HIV diagnosis.

Secondary outcome measures
1. The overall frequency of HIV testing irrespective of testing modality i.e. where and how individuals test
2. Frequency of STI screening
3. Markers of the recency of infection at the time of HIV diagnosis, where available e.g. CD4 count, antibody avidity assays
4. Frequency of condomless sex, either self-reported or as reflected in new STI diagnosis

Outcomes will mainly be measured in surveys, which are 3-monthly after the first randomisation. Additional information will come from data linkage with Public Health England – in particular this will give us data on CD4 counts and other biological information. The exactl timelines for this linkage are not yet decided, but we will have linked data for all trial participants by the time of final analysis.

Overall study start date
31/03/2014

Completion date
31/01/2020

Eligibility

Key inclusion criteria
For first randomisation (A):
1. Male (including trans men)
2. Has ever had anal sex with a man
3. Is not known to be HIV positive
4. Aged ≥18 years old
5. Resident in England or Wales
6. Willing to provide name, date of birth, and a valid email address
7. Consent for linkage of survey responses to surveillance and clinic databases held by PHE

8. Willing to complete online surveys
9. Has not been previously randomised to the study

For second randomisation (B):
1. Allocated to baseline self-test (BT) in randomisation A
2. Has completed the 3-month survey and:
2.1. Reports using self-test sent at baseline
2.2. Remains HIV negative
2.3. Expresses interest in using HIV self-test kits in the future
2.4. Is considers to be at high-risk for HIV infection. Defined as reporting condomless anal sex with ≥1 male partners (in previous 3 months)

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
10000

Total final enrolment
10111

Key exclusion criteria
None (all criteria are based on inclusion)

Date of first enrolment
01/11/2016

Date of final enrolment
31/10/2017

Locations

Countries of recruitment
United Kingdom

Study participating centre
No centres in this trial as it is internet-based
United Kingdom
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Sponsor information

Organisation
University College London (UCL)

Sponsor details
MRC Clinical Trials Unit at UCL
Aviation House
125 Kingsway
London
England
United Kingdom
WC2B 6NH

Sponsor type
University/education

Website
http://www.ctu.mrc.ac.uk

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
National Institute for Health 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

Intention to publish date
31/10/2020

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?
Protocol article	protocol	23/10/2018		Yes	No
Interim results article	feasibility and acceptability results	08/08/2019	04/11/2019	Yes	No
Interim results article	Experiences and attitudes of participants of colour	22/04/2022	25/04/2022	Yes	No
Results article		01/12/2022	05/12/2022	Yes	No
Other publications		22/08/2023	25/08/2023	Yes	No
Other publications	Accessing and utilising gender-affirming healthcare in England and Wales: trans and non-binary people's accounts of navigating gender identity clinics.	28/06/2021	18/11/2024	Yes	No
Other publications	HIV self-testing intervention experiences and kit usability: results from a qualitative study among men who have sex with men in the SELPHI (Self-Testing Public Health Intervention) randomized controlled trial in England and Wales	10/12/2019	18/11/2024	Yes	No
Other publications	Impact and acceptability of HIV self-testing for trans men and trans women: A mixed-methods subgroup analysis of the SELPHI randomised controlled trial and process evaluation in England and Wales	01/02/2021	18/11/2024	Yes	No