Can internet-based sexual health services increase diagnoses of sexually transmitted infections (STIs)? Evaluation of an internet-based sexual health service

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
11/11/2014		[X] Protocol		
Registration date 21/11/2014	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 15/01/2018	Condition category Infections and Infestations	[] Individual participant data		
13/01/2016	initections and initestations			

Plain English summary of protocol

Background and study aims

The London boroughs of Southwark and Lambeth have some of the highest rates of sexually transmitted infections (STIs) in England. Current face-to-face clinical services are unable to meet demand for sexual healthcare. Sexual Health 24 (SH:24) is an innovative internet-based sexual health service that aims to improve access to sexual healthcare in Lambeth and Southwark. We want to see whether this service can reduce the number of people diagnosed with at least one STI and increase the number of people asking to be tested for such an infection.

Who can participate?

Participants can be of either sex, aged between 16-30 and resident in the boroughs of Lambeth and Southwark. They must be sexually active (at least one partner in the last 12 months), have access to the internet and willing to take an STI test.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in group 1 (intervention group) are given access to the Sexual Health 24 website offering postal STI kits, test results via text message or by phone (HIV only) and details of local treatment clinics. Those in group 2 (control group) are given access to a website with details of local sexual health clinics where participants can get an STI test in person. Six weeks into the study, the number of participants diagnosed with at least one STI and complete at least one STI test in each group are compared.

What are the possible benefits and risks of participating?

Some participants may find this study helpful, particularly if they have been considering taking an STI test. Undetected cases will be diagnosed by those who follow through with the test, and infected participants will be signposted to treatment. It is possible that participants that do not have much privacy at home may risk possible consequences if they participate in internet-based STI testing. However, this risk will be minimised as we will ensure at recruitment that participants have sufficient privacy to participate in the study.

Where is the study run from?

- 1. King's College Hospital NHS Foundation Trust (UK)
- 2. Guy's and St Thomas' Hospital NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for? November 2014 to July 2015

Who is funding the study? Guys and St Thomas' Charity (UK)

Who is the main contact? Emma Wilson emma.wilson@lshtm.ac.uk

Study website

http://www.gettestednow.org.uk

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

v6

Study information

Scientific Title

Can internet-based sexual health services increase diagnoses of sexually transmitted infections (STIs)? Evaluation of an internet-based sexual health service

Acronym

N/A

Study objectives

Internet-based sexual health services offering postal self-administered STI kits can increase diagnoses of sexually transmitted infections when compared to standard care.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee London - Camberwell and St Giles, 09/09/2014, ref: 14/LO/1477

Study design

Interventional study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Internet/virtual

Study type(s)

Treatment

Participant information sheet

Available on our study website www.gettestednow.org.uk

Health condition(s) or problem(s) studied

Sexual health

Interventions

An internet-based sexual health service (intervention) versus standard face-to-face sexual health services (control)

Intervention Type

Other

Primary outcome measure

At 6 weeks we will assess:

- 1. % of participants diagnosed with at least one STI in each arm
- 2. % of participants who complete at least one STI test in each arm

Secondary outcome measures

At 6 weeks we will assess:

- 1. % of participants prescribed treatment in each arm
- 2. Time to test (from randomisation)
- 3. Time to treatment (from randomisation)
- 4. % of intervention group who agree that internet-based testing is acceptable
- 5. % of intervention group adhere to prescribed internet-testing pathway

Overall study start date

22/11/2014

Completion date

31/01/2017

Eligibility

Key inclusion criteria

- 1. Aged 16-30
- 2. Resident in the London boroughs of Southwark and Lambeth
- 3. Sexually active (at least 1 sexual partner in last 12 months)
- 4. Access to the internet (smart phone, PC or laptop)
- 5. Willing to take an STI test

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

3000

Key exclusion criteria

- 1. Non-English language speakers as the websites will be in English
- 2. Those unable to give informed consent such as people with severe learning disabilities

Date of first enrolment

22/11/2014

Date of final enrolment

31/08/2015

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Weston Education Centre

10 Cutcombe Road London United Kingdom SE5 9RJ

Sponsor information

Organisation

Kings College Hospital NHS Foundation Trust (UK)

Sponsor details

161 Denmark Hill London England United Kingdom SE5 8EF +44 (0)2032991980 kch-tr.research@nhs.net

Sponsor type

Hospital/treatment centre

ROR

https://ror.org/01n0k5m85

Funder(s)

Funder type

Charity

Funder Name

Guy's and St Thomas' Charity

Alternative Name(s)

Guy's and St Thomas' Charity, Guy's and St Thomas' Foundation, GSTTFoundation

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	15/01/2016		Yes	No
Protocol article	addendum to protocol	10/08/2016		Yes	No
Results article	results	27/12/2017		Yes	No
HRA research summary			28/06/2023	No	No