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“Test n Treat”: a feasibility trial of rapid STI testing and treatment

Submission date
05/04/2016

Recruitment status
No longer recruiting

Registration date
31/08/2016

Overall study status
Completed

Last Edited
16/03/2020

Condition category
Infections and Infestations

[X] Prospectively registered

[X] Protocol

[X] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Chlamydia and gonorrhoea are sexually transmitted infections affecting 150,000 young people in England and costing over £100 million each year. Despite this, very few young people seek testing (<30% annually), which is too low to reduce infection rates, and there are often delays in the time between diagnosis and treatment. Bringing new rapid 90 minute chlamydia/gonorrhoea tests and on-site treatment (“TnT=Test n Treat”) to the community might get more people treated faster. This could reduce infection rates and serious complications like infertility, and save NHS costs. The aim of this study is to see if it is feasible to conduct a trial to see if offering rapid testing for chlamydia/gonorrhoea and on the spot treatment can reduce infection rates in young people.

Who can participate?
Students aged between 16 and 24 who have had penetrative sexual intercourse at least once.

What does the study involve?
Six further education colleges are taking part in this study, with 80 students being recruited from each. Participating colleges are randomly allocated to one of two groups. One month after this, colleges in the first group are visited on two consecutive days by the TnT team. The participating students from these colleges are then sent a text message inviting them to come for on-site rapid chlamydia/gonorrhoea testing. At the testing, students provide self-taken urine or vaginal samples which are immediately tested. Negative results will be sent to participants by text or WhatsApp or whatever preferred method they prefer. Students with positive results are telephoned and invited to come to the college nurse’s room for treatment, partner notification, advice and follow up by a visiting nurse health adviser. After four months, this process is repeated. Participants attending colleges in the second group continue as normal, and receive text messages at one and four months, thanking them for taking part in the study. At the start of the study and then seven months later, participants provide samples which are all tested at seven months for chlamydia/gonorrhoea. At the same times, participants complete a questionnaire about their sexual health. The time it takes for 80 participants to be recruited at each college is recorded at the start of the study and at the end. The number of participants who gave samples and sought treatment is also recorded.

What are the possible benefits and risks of participating?
Students who provide samples for rapid Test and Treat in college will be checked for chlamydia and gonorrhea and treated if necessary. This might prevent infection spreading to the testicles or womb and causing long-term complications. All students who take part in the TnT study will be given £5 and a lollipop at recruitment and £10 and a lollipop at seven months follow up. Those who take part in interviews will receive £10 for their time. There are no notable risks involved with participating in the study.

Where is the study run from?
The study is run by St George's, University of London and takes place in six further education colleges in London (UK)

When is the study starting and how long is it expected to run for?
September 2014 to December 2017

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

Who is the main contact?
1. Professor Pippa Oakeshott (scientific)
2. Ms Sarah Kerry (scientific)

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
20672

Study information

Scientific Title
“Test n Treat (TnT)”: a cluster randomised feasibility trial of frequent, rapid testing and same day on-site treatment to reduce rates of chlamydia and gonorrhoea in high risk Further Education college students

Acronym
Test n Treat (TnT)

Study objectives
The aim of this study is to assess the feasibility of conducting a trial of "Test n Treat" (TnT) in further education (FE) colleges, and obtain estimates of key values to inform sample size estimates and timescales.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bromley NRES Committee London, 21/12/2015: ref: 15/LO/1929

Study design
Cluster randomised feasibility study

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Screening

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Chlamydia trachomatis and Neisseria gonorrhoeae infection

Interventions
Participating colleges are randomised to one of two groups using block randomisation to ensure three colleges are allocated to each group.

Intervention group: One month after recruitment each intervention college will be visited on two consecutive days by the "TnT" team. The 80 participating students in each college will be texted and invited to come for on-site rapid chlamydia/gonorrhoea TnT. They will be invited to provide a sample, but this time the sample will be tested immediately using the Cepheid GeneXpert system which takes 90 minutes. Negative results will be sent to participants by text or WhatsApp or whatever preferred method they indicated on the consent form. Participants with positive results will be telephoned and invited to come to the college nurse's room for treatment, partner notification, advice and follow up by a visiting nurse health adviser. (Students positive for gonorrhoea will have a confirmatory test and GUM referral). At four months participants in intervention colleges will again be invited to provide samples for TnT.

Control group: Participants from the three control colleges continue as normal for the duration of the study. They will receive texts one and four months after recruitment thanking them for being in the study.

At baseline and 7 months, participants in both groups complete questionnaires on their sexual health and provide genitourinary samples for chlamydia/gonorrhoea testing.

Intervention Type
Other

Primary outcome measure
1. Recruitment rate is measured as the time taken to recruit 80 participants at each site at recruitment end (1 month)
2. Testing and Treatment uptake rates at three intervention sites are measured by the proportion of the 80 participants at each site who take part in Test and Treat for chlamydia /gonorrhoea at 1 and 3 months after recruitment end
3. Follow up rate is measured at 7 months by:
3.1. Calculating the percentage of participants who provide samples at all sites
3.2. Calculating the percentage who complete the final questionnaires
3.3. Recording the time to treatment for participants who test positive
4. Prevalence of chlamydia/gonorrhoea is measured using PCR of genitourinary samples taken at baseline and 7 months

Secondary outcome measures
1. Acceptability of TnT in FE colleges is measured through qualitative interviews at 1-9 months after recruitment
2. Cost of implementing TnT in FE colleges compared with usual care (no TnT) is measured by estimating:
2.1. The cost per person screened and treated of implementing TnT in FE colleges compared

with usual care (no TnT)
2.2. The incremental cost per chlamydia and gonorrhoea infection averted
Costs will be classified as solely research; capital set-up costs; or on-going running costs. Data will be collected in months 1-9, and the analysis conducted in months 10 to 20.

Overall study start date
01/09/2014

Completion date
20/12/2017

Eligibility

Key inclusion criteria
1. Sexually experienced Further Education College student
2. Aged 16-24

Participant type(s)
Healthy volunteer

Age group
Mixed

Sex
Both

Target number of participants
80 students in each of 6 clusters - total 480

Key exclusion criteria
1. Students who have never had penetrative sexual intercourse
2. Students with severe learning disability

Date of first enrolment
20/09/2016

Date of final enrolment
20/12/2016

Locations

Countries of recruitment
United Kingdom

Study participating centre
St George's, University of London
Cranmer Terrace
London

United Kingdom
SW18 ORE

Sponsor information

Organisation
St George's, University of London

Sponsor details
Cranmer Terrace
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England
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SW17 0RE

Sponsor type
University/education

ROR
https://ror.org/040f08y74

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
Planned publication in a high impact peer reviewed journal.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The dataset will not be made available as it is sensitive data on sexual health and lifestyles. It will be held at St George's and may be available to researchers with ethically approved projects.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V5	01/06/2016	31/08/2016	No	Yes
Protocol article	protocol	05/06/2018		Yes	No
Statistical Analysis Plan	statistical analysis plan	05/06/2018		No	No
Results article	results	01/07/2019		Yes	No
HRA research summary			28/06/2023	No	No