



## Original article

## 'Test n Treat' (TnT): a cluster randomized feasibility trial of on-site rapid *Chlamydia trachomatis* tests and treatment in ethnically diverse, sexually active teenagers attending technical colleges

P. Oakeshott<sup>1,\*</sup>, S. Kerry-Barnard<sup>1</sup>, C. Fleming<sup>1</sup>, R. Phillips<sup>2</sup>, V.M. Drennan<sup>3</sup>, E.J. Adams<sup>4</sup>, W. Majewska<sup>5</sup>, E.M. Harding-Esch<sup>6,7</sup>, E.C. Cousins<sup>6</sup>, T. Planche<sup>6</sup>, A. Green<sup>1</sup>, R.I. Bartholomew<sup>1,6</sup>, S.T. Sadiq<sup>6</sup>, F. Reid<sup>2</sup>

<sup>1</sup> Population Health Research Institute, St George's, University of London, London UK

<sup>2</sup> School of Population Health and Environmental Sciences, King's College London, London, UK

<sup>3</sup> Centre for Health & Social Care Research, Kingston University & St George's, University of London, London, UK

<sup>4</sup> Aquarius Population Health Limited, London, UK

<sup>5</sup> WEM Consultancy Ltd, London, UK

<sup>6</sup> Institute for Infection and Immunity, St George's, University of London, London, UK

<sup>7</sup> Public Health England, London, UK

## ARTICLE INFO

## Article history:

Received 6 June 2018

Received in revised form

24 October 2018

Accepted 25 October 2018

Available online 1 November 2018

Editor: C. Pulcini

## Keywords:

Cluster randomized

Feasibility trial

Rapid *C. trachomatis* tests

Screening

Technical colleges

Test and treat

Young people

## ABSTRACT

**Objectives:** We conducted a cluster-randomized feasibility trial of 90-minute *Chlamydia trachomatis* tests and same day on-site treatment ('Test n Treat/TnT') in six technical colleges in London, England, to assess TnT uptake rates; follow-up rates; prevalence of *C. trachomatis* at baseline and 7 months; time to treatment; acceptability of TnT.

**Methods:** Participants completed questionnaires and provided genitourinary samples at baseline and 7 months. Participants were informed that baseline samples would not be tested for 7 months and were advised to get screened independently. Colleges were randomly allocated 1:1 to intervention (TnT) or control (no TnT).

One month and 4 months post recruitment, participants at intervention colleges were texted invitations for on-site free *C. trachomatis* tests. A purposive sample of students who did/did not attend for screening were interviewed (n = 26).

**Results:** Five hundred and nine sexually active students were recruited: median age 17.9 years, 47% male, 50% black ethnicity, 55% reporting two or more sexual partners in the previous year. TnT uptake was 13% (33/259; 95% CI 8.9–17.4%) at 1 month and 10% (26/259; 6.7–14.4%) at 4 months with overall *C. trachomatis* positivity 5.1% (3/59; 1.1–14.2%). Follow-up at 7 months was 62% (317/509) for questionnaires and 52% (264/509) for samples. *C. trachomatis* prevalence was 6.2% (31/503) at baseline and 6.1% (16/264) at 7 months. Median time from test to treatment was 15 h. Interviews suggested low test uptake was associated with not feeling at risk, perceptions of stigma, and little knowledge of sexually transmitted infections (STIs).

**Conclusions:** Despite high *C. trachomatis* rates at baseline and follow-up, uptake of testing was low. Like many countries, England urgently needs better sex education, including making STI testing routine/normal.

Trial registration ISRCTN58038795 P. Oakeshott, *Clin Microbiol Infect* 2019;25:865

© 2019 The Authors. Published by Elsevier Ltd on behalf of European Society of Clinical Microbiology and Infectious Diseases. This is an open access article under the CC BY license (<http://creativecommons.org/licenses/by/4.0/>).

## Introduction

*Chlamydia trachomatis* is a common, often asymptomatic, bacterial sexually transmitted infection (STI) which can lead to pelvic

\* Corresponding author. P. Oakeshott, Population Health Research Institute, St George's, University of London, London SW17 0RE, UK.

E-mail address: [oakeshot@sgul.ac.uk](mailto:oakeshot@sgul.ac.uk) (P. Oakeshott).

inflammatory disease, ectopic pregnancy, and infertility [1,2] and may be associated with adverse pregnancy outcomes [3]. However, uptake of *C. trachomatis* testing by 16–24 year olds in many countries is too low to reduce infection rates [1,4–8], and there are often delays in treatment. Bringing novel 90-minute *C. trachomatis* tests [9,10] and same day on-site treatment ('TnT = Test n Treat') to the community might get more young people treated faster [6,10]. This could reduce rates of infection, onward transmission and adverse reproductive health effects, and save healthcare costs [7,11].

In order to address a number of unknown parameters required for the design of a future definitive study, we conducted a cluster randomized feasibility trial (or pilot study) of frequent, rapid TnT in six technical ('Further Education'/FE) colleges in London, England, over the academic year 2016–17. (FE colleges offer both academic and practical courses such as plumbing and hairdressing, and take many students from socio-economically deprived backgrounds. *C. trachomatis* positivity may be 6–8% [12–14].)

We assessed the following feasibility outcomes:

- recruitment rates
- TnT uptake rates
- follow-up rates
- prevalence of *C. trachomatis* at baseline and 7 months
- time to treatment
- acceptability of TnT.

We selected a cluster design for practical reasons for delivering screening, which would reflect the design of a definitive trial. This was a feasibility study and was not powered to assess the effectiveness of TnT. Although we used a combined *C. trachomatis*/*Neisseria gonorrhoeae* rapid test (Cepheid CT/NG GeneXpert® system [9]), on-site treatment (TnT) was for individuals with *C. trachomatis* only [15] as participants with *N. gonorrhoeae* (or *C. trachomatis*/*N. gonorrhoeae* dual infection) were referred to a sexual health clinic. Detailed qualitative and economic analyses will be presented elsewhere.

## Methods

### Recruitment and baseline samples

All technical colleges/clusters were eligible and all six approached agreed to participate. As previously described [15], researchers recruited students from public areas at the six colleges. Students were eligible if they were aged 16–24 years and had ever had sexual intercourse. The participant information leaflet and consent form provided information about STIs and the study design (please see [Supplementary Material](#)). Participants provided written informed consent. They were asked to complete questionnaires (see [Table 1](#) and [Supplementary material](#)), and to provide samples (for research purposes only) in the nearest washroom (urines for males, self-collected vaginal swabs for females) [15]. These samples were stored at –80°C and tested blind at St George's hospital after seven months using the Cobas 4800 CT/NG system (Roche diagnostics) [7]. All participants were warned of the risks of untreated *C. trachomatis*/*N. gonorrhoeae* and that their baseline samples would not be tested for seven months, and advised to get checked for STIs independently of the study.

### Randomization

After recruitment of all participants, the six colleges were randomly allocated 1:1 into the intervention group (TnT) or control

group (no TnT; [Fig. 1](#)) by the trial statistician using a computer-generated allocation sequence [15].

### Intervention colleges: TnT at 1 and 4 months

One month and 4 months after recruitment (to fit with college Autumn and Spring terms), each of the three intervention colleges were visited on two consecutive days by the research team. We advertised the visit on college websites and notice boards, and texted/emailed participating students the day before the visit and on both days inviting them to come for TnT. Attendees came to a private room to collect a test kit. When they returned with a sample, it was tested for *C. trachomatis*/*N. gonorrhoeae* immediately on-site in a pop-up laboratory in a classroom using a 90-min test [15] (one test/participant). Negative results were texted to participants. The research team's nurse health adviser telephoned participants with positive results and met them in another private room in college (same day whenever possible) for confidential treatment for *C. trachomatis*, partner notification and/or referral.

### Control colleges: no TnT

Participants from the three control colleges received texts 1 month and 4 months after recruitment thanking them for being in the study.

### Outcome assessment at 7 months

All six colleges were visited again on two consecutive days in the summer term using the same methods as in TnT above, and participants from both groups were invited to provide repeat questionnaires and samples for immediate testing. Same-day results and treatment were provided for all attenders (but these were not part of the TnT intervention). Non-attenders were followed up by text/email and telephone questionnaire and asked to give an address (e.g. home/work/college) if they were willing to provide a postal sample for testing [15].

### Honoraria

Participants received £5 in cash when they returned samples at recruitment and £10 after providing samples at the 7-month follow-up. Participants in intervention colleges did not receive honoraria for attending for TnT at 1 month and 4 months, as in the UK people are not usually paid for having an STI test.

### Masking

Recruitment of colleges and participants was conducted blind to group allocation. After the first TnT intervention, participants and researchers were no longer blinded.

### Main outcome measures

The key values to inform feasibility, sample size, and timescales of a definitive trial were

- recruitment rates
- TnT uptake in intervention participants at one and four-months
- follow-up rates at 7 months
- prevalence of *C. trachomatis* at baseline and 7 months
- time to receiving results and treatment (fidelity of TnT)
- acceptability of TnT in intervention colleges from thematically-analysed semi-structured interviews [16] with purposively

sampled students ( $n = 26$  to ensure a range of ages, genders and ethnicities) who did/did not attend for TnT (to be published elsewhere).

### Sample size and statistical analysis

Sixty to 100 subjects are sufficient to estimate an event rate with acceptable precision (i.e. sufficiently narrow confidence intervals) in a feasibility study [15,17]. As previously described [18], assuming a 30% recruitment rate [13], we aimed to approach 1600 students to recruit 480 overall (80 per college across six colleges).

Progression criteria to a definitive trial were TnT uptake  $\geq 60\%$  [13] at 1 and 4 months and TnT being acceptable to participants [16] (intervention colleges only), and follow-up rate  $\geq 70\%$  [12] at 7 months (all colleges).

Since this was a feasibility study, no significance testing was performed [19]. Descriptive statistics are presented, with corresponding exact 95% confidence intervals. Analyses [18] were performed in Stata version 14. As our analysis was of feasibility outcomes, the sample size and analysis were not adjusted for clustering.

### Ethics approval and consent to participate

Bromley REC reviewed the study (reference 15/LO/1929). Parental consent for 16–18 year olds was not required.

## Results

### Recruitment

Over 3 weeks in September/October 2016, we recruited 509 participants from six colleges (range 78–90 per college). We were unable to obtain information on all non-participants, but completed recruitment forms for 180 non-participants suggested that 67% (121/180) were ineligible due to never having had sexual intercourse, 14% (25/180) were ineligible for other reasons (e.g. not aged 16–24), and 19% (34/180) were eligible but declined.

Participants' median age was 17.9 years and 90% (458) were teenagers (aged 16–19 years). Participants described their ethnicity as black (50%), white (26%), or other ethnic groups (24%). Approximately half (47%, 240) were male, including 117 (23%) black male teenagers. Over half (55%) reported two or more sexual partners in the previous year, and a third (36%) said they had been tested for STIs in the past 6 months. Eligible non-participants ( $n = 34$ ) were similar to participants in age and ethnicity (median age 17, IQR 17–19; 53% black ethnicity), but a slightly higher proportion (67%) were male. Table 1 shows baseline characteristics of participants from intervention and control colleges.

### TnT uptake at 1 month and 4 months in intervention colleges

Thirteen percent (33/259; 95% CI 8.9–17.4%) of intervention participants attended for on-site rapid tests and provided samples at 1 month and 10% (26/259; 95% CI 6.7–14.4%) at 4 months, despite implementing changes suggested by students and staff to increase uptake. These included brief information for tutors to give to their tutorial groups, educational posters (please see [Supplementary Material](#)), user-friendly texts, and free condoms. Five students provided samples at both 1 and 4 months. Of 59 tests, three (5.1%, 1.1–14.2) were positive for *C. trachomatis*. Two students with *C. trachomatis* only were treated on site (one same day, one next day), and one with dual *C. trachomatis*/*N. gonorrhoeae* infection was referred for treatment as per

**Table 1**

Baseline characteristics of 509 Further Education college students allocated to intervention and control arms of the Test and Treat *C. trachomatis* screening trial

Characteristic	Intervention	Control
	( $n = 259$ )	( $n = 250$ )
Male % ( $n$ )	49.8 (129)	44.4 (111)
Age median (IQR)	17.6 (16.8–18.6)	18.0 (17.3–18.9)
Ethnicity % ( $n$ )		
White	27.2 (70)	25.5 (63)
Black African/Black Caribbean/Black British	48.6 (125)	51.0 (126)
Asian/Asian British	5.1 (13)	6.1 (15)
Mixed/multiple ethnicities	15.2 (39)	12.6 (31)
Other ethnic group	3.9 (10)	4.9 (12)
Sexual Preference (females) % ( $n$ )		
Sex with men only	86.8 (112)	89.9 (124)
Sex with women only	3.9 (5)	1.4 (2)
Sex with men and women	4.7 (6)	7.2 (10)
Prefer not to say	4.7 (6)	1.4(2)
Sexual Preference (males) % ( $n$ )		
Sex with men only	3.9 (5)	2.7 (3)
Sex with women only	93.0 (120)	94.6 (105)
Sex with men and women	1.6 (2)	2.7 (3)
Prefer not to say	1.6 (2)	0.0 (0)
Age at first sexual intercourse <16 years % ( $n$ )	44.8 (112)	47.3 (112)
Two or more partners in past 12 months % ( $n$ )	56.6 (145)	53.5 (130)
New sexual partner in past 6 months % ( $n$ )	55.5 (141)	51.4 (128)
Female contraception % ( $n$ )		
Condoms	56.2 (73)	54.0 (75)
Pill	16.9 (22)	20.9 (29)
Implant/coil	15.4 (20)	17.3 (24)
None	20.0 (26)	15.1 (21)
Other	2.3 (3)	2.9 (4)
Condom use (male and female) % ( $n$ )		
Always	36.2 (92)	36.0 (89)
Usually	17.7 (45)	21.1 (52)
Sometimes	31.1 (79)	26.3 (65)
Never	15.0 (38)	16.6 (41)
Last STI check % ( $n$ )		
Never	46.1 (118)	41.9 (103)
In the past 6 months	36.7 (94)	35.8 (88)
More than 6 months ago	17.2 (44)	22.4 (55)
STI history ever % ( $n$ )		
<i>C. trachomatis</i>	7.5 (19)	8.9 (22)
<i>N. gonorrhoeae</i>	5.7 (14)	4.2 (10)
Other STI	0.9 (2)	1.3 (3)
NSU	0.4 (1)	1.3 (3)
Pelvic Inflammatory Disease in past 6 months (females only)	2.4 (3)	2.2 (3)
Symptoms in past 6 months (female) % ( $n$ )		
Bleeding between periods	17.5 (21)	15.9 (21)
Abnormal vaginal discharge	11.9 (14)	14.8 (19)
Pelvic discomfort other than normal period pain	7.0 (8)	13.2 (17)
Pain during sex	17.4 (20)	17.3 (23)
Symptoms in past 6 months (male) % ( $n$ )		
Pain/burning when urinating	6.5 (8)	7.4 (8)
Discharge from your penis	2.4 (3)	1.9 (2)
Pain or discomfort in testicles	6.5 (8)	4.7 (5)
Pain/burning from back passage	2.5 (3)	1.9 (2)
Smokes cigarettes % ( $n$ )	34.3 (87)	32.4 (81)
Alcohol-reports was drunk in past month % ( $n$ )	48.4 (123)	48.3 (119)
Visited GP in past 6 months % ( $n$ )	59.1 (149)	61.6 (151)
Visited Sexual health clinic in past 6 months % ( $n$ )	31.2 (79)	29.6 (72)
Visited Walk-in clinic in past 6 months % ( $n$ )	29.1 (73)	31.6 (77)
Visited A&E/hospital in past 6 months % ( $n$ )	36.0 (91)	31.8 (78)
Attended healthcare facility for sexual health reasons in the past 6 months % ( $n$ )	36.9 (94)	35.4 (87)
<i>C. trachomatis</i> at baseline <sup>a</sup> % ( $n$ )	7.1 (18)	5.2 (13)
<i>N. gonorrhoeae</i> at baseline <sup>a</sup> % ( $n$ )	1.2 (3)	0 (0)

Similar numbers of students were recruited from each college (intervention colleges  $n = 84, 85, 90$ ; total 259; control colleges  $n = 83, 78, 89$ ; total 250). NSU, non-specific urethritis; GP, general practitioner; A&E, Accident and Emergency department.

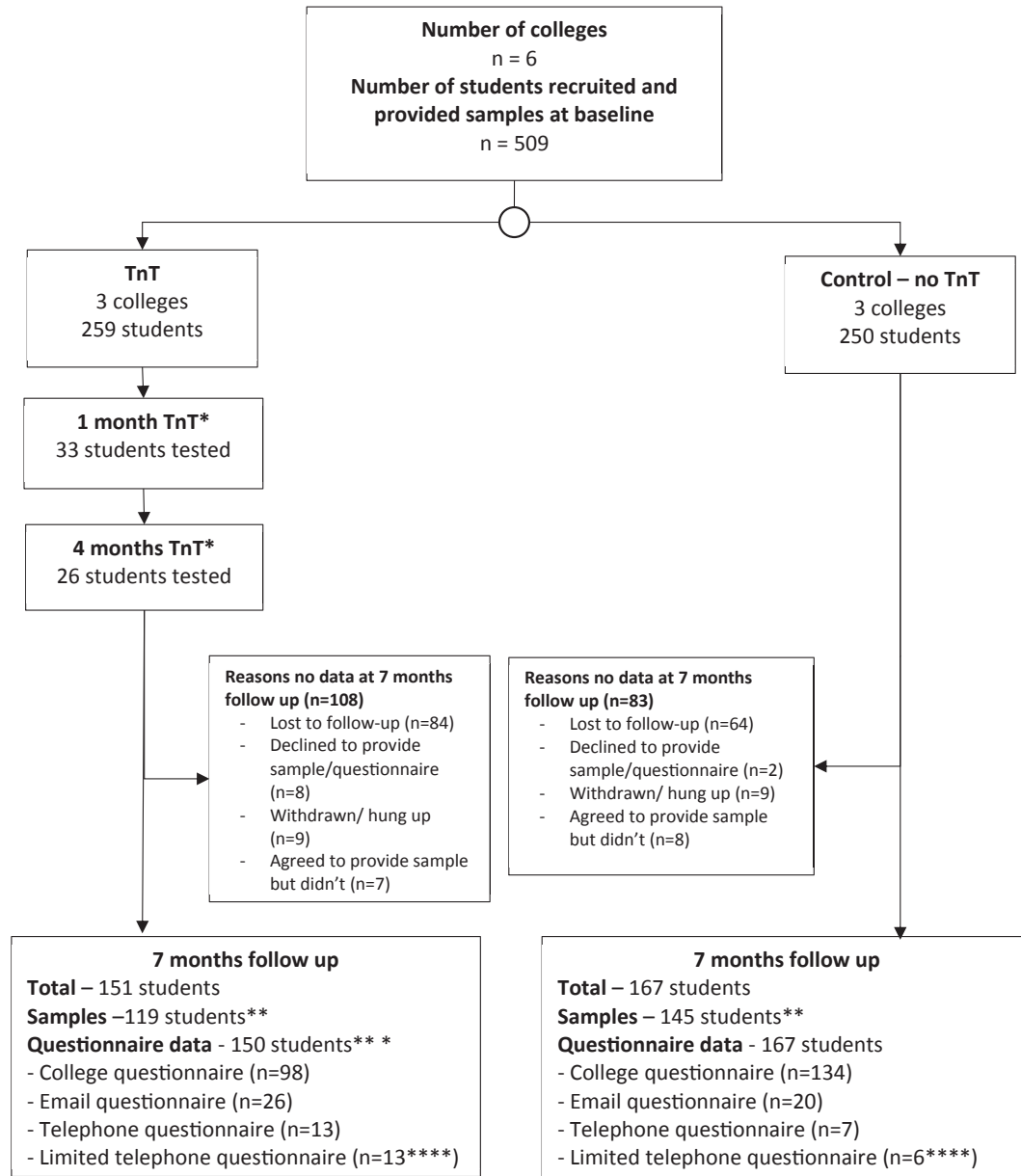
<sup>a</sup> Baseline samples were stored and tested after 7 months.

protocol. Table 2 shows baseline characteristics of participants who did/did not provide samples for TnT were broadly similar, although more TnT attenders than non-attenders had a history of *C. trachomatis* (13% versus 6%), and more were men who had sex with men (MSM, 15% versus 3%).

#### Follow-up

Overall follow-up at 7 months was 62% (317/509; 95% CI 58–67%) for questionnaires and 52% (264/509; 95% CI 47–56%)

for samples. (A further four participants provided invalid samples: three with no human DNA, one delayed postal sample.) Almost half the participants (46%, 232/509) completed follow-up questionnaires at college, a further 9% (46/509) subsequently completed an online questionnaire and 8% (39/509) a brief telephone questionnaire. These showed 29% of intervention participants and 25% of control participants reported STI testing outside the trial. (Other study-related behaviours reported at follow-up are shown in Table 3). Valid samples for testing were provided at college by 229 (45%) participants and later by post



\*Five participants provided samples at both one and four months.

\*\* Two additional samples from each arm did not give a valid result

\*\*\* One participant only returned a sample but did not complete a questionnaire

\*\*\*\* Limited questionnaire data were collected while informing participants by telephone of a positive baseline test for five and two individuals in the intervention and control groups respectively.

Fig. 1. Consort flow diagram for Test n Treat/TnT cluster randomised feasibility trial of rapid chlamydia tests and on-site treatment in six FE colleges.

**Table 2**

Baseline characteristics of 259 intervention students who either attended TnT and provided samples, or did not attend TnT at 1 month and/or 4 months

Baseline characteristic	Attended TnT	Did not attend TnT
	(n = 54 <sup>a</sup> )	(n = 205)
Male % (n)	48.1 (26)	50.2 (103)
Age median (IQR)	17.4 (16.7 to 18.7)	17.7 (16.8 to 18.5)
Ethnicity % (n)		
White	28.8 (15)	26.8 (55)
Black African/Black Caribbean/Black British	51.9 (27)	47.8 (98)
Asian/Asian British	1.9 (1)	5.9 (12)
Mixed/multiple ethnicities	13.5 (7)	15.6 (32)
Other ethnic group	3.8 (2)	3.9 (8)
Sexual Preference (females) % (n)		
Sex with men only	100.0 (27)	83.3 (85)
Sex with women only	0.0 (0)	4.9 (5)
Sex with men and women	0.0 (0)	5.9 (6)
Prefer not to say	0.0(0)	5.9 (6)
Sexual Preference (males) % (n)		
Sex with men only	7.7 (2)	2.9 (3)
Sex with women only	84.6 (22)	95.1 (98)
Sex with men and women	7.7 (2)	0.0 (0)
Prefer not to say	0.0 (0)	1.9 (2)
Age first sex <16 years % (n)	44.2 (23)	44.9 (89)
Two or more partners in past 12 months % (n)	50.9 (27)	58.1 (118)
New partner in past 6 months % (n)	50.9 (27)	56.7 (114)
Female contraception % (n)		
Condoms	67.9 (19)	52.9 (54)
Pill	14.3 (4)	17.6 (18)
Implant/coil	14.3 (4)	15.7 (16)
None	14.3 (4)	21.6 (22)
Other	7.1 (2)	1.0 (1)
Condom use (male and female) % (n)		
Always	41.5 (22)	34.8 (70)
Usually	17.0 (9)	17.9 (36)
Sometimes	30.2 (16)	31.3 (63)
Never	11.3 (6)	15.9 (32)
Last STI check % (n)		
Never	45.3 (24)	46.3 (94)
In the past 6 months	35.8 (19)	36.9 (75)
More than 6 months ago	18.9 (10)	16.7 (34)
STI ever % (n)		
<i>C. trachomatis</i>	13.2 (7)	6.0 (12)
<i>N. gonorrhoeae</i>	8.2 (4)	5.1 (10)
Other STI	0.0 (0)	1.0 (2)
NSU	0.0 (0)	0.5 (1)
Pelvic Inflammatory Disease in past 6 months	11.1 (3)	0.0 (0)
Symptoms in past 6 months (female) % (n)		
Bleeding between periods	25.0 (6)	15.6 (15)
Abnormal vaginal discharge	12.5 (3)	11.7 (11)
Pelvic discomfort other than normal period pain	8.7 (2)	6.6 (6)
Pain during sex	14.3 (3)	18.1 (17)
Symptoms in past 6 months (male) % (n)		
Pain/burning when urinating	4.0 (1)	7.1 (7)
Discharge from your penis	0.0 (0)	3.1 (3)
Pain or discomfort in testicles	8.0 (2)	6.1 (6)
Pain/burning from back passage	4.2 (1)	2.1 (2)
Smokes cigarettes % (n)	22.6 (12)	37.3 (75)
Alcohol-reports was drunk in past month % (n)	43.2 (22)	49.8 (101)
Visited GP in past 6 months % (n)	53.8 (28)	60.5 (121)
Visited sexual health clinic in past 6 months % (n)	39.2 (20)	29.2 (59)
Visited Walk-in clinic in past 6 months % (n)	30.0 (15)	28.9 (58)
Visited A&E/hospital in past 6 months % (n)	27.5 (14)	38.1 (77)
Attended healthcare facility for sexual health reasons in past 6 months % (n)	46.2 (24)	34.5 (70)
<i>C. trachomatis</i> at baseline % (n)	3.7 (2)	8.0 (16)
<i>N. gonorrhoeae</i> at baseline % (n)	0.0 (0)	1.5 (3)

<sup>a</sup> Five participants attended at both one and four months.**Table 3**

Reported behaviours during the study from 7-month follow-up questionnaires

Follow-up characteristics, % (n)	Intervention		Control	
	(n = 150)		(n = 167)	
Follow up method				
College questionnaire	65.3	(98)	80.2	(134)
E-mail questionnaire	17.3	(26)	12.0	(20)
Telephone questionnaire	8.7	(13)	4.2	(7)
Limited telephone questionnaire	8.7	(13)	3.6	(6)
Have they been tested for chlamydia or gonorrhoea outside the study?				
Yes	29.3	(44)	25.1	(42)
Where did they get tested?				
GP	21.2	(7)	12.8	(5)
Sexual health clinic	33.3	(11)	56.4	(22)
Walk in clinic	9.1	(3)	5.1	(2)
Hospital	3.0	(1)	2.6	(1)
College	27.3	(9)	17.9	(7)
Other	6.1	(2)	5.1	(2)
Smoking (cigarettes per day)				
None	69.7	(83)	65.5	(91)
1–10	25.2	(30)	30.9	(43)
More than 10	5.0	(6)	3.6	(5)
Vape (smoke electronic cigarettes)				
No	85.9	(110)	84.7	(133)
Yes	6.3	(8)	4.5	(7)
Occasionally	7.8	(10)	10.8	(17)
Alcohol (number of times drunk in past month)				
None	61.7	(79)	51.3	(80)
1–4 times	28.9	(37)	41.0	(64)
5 or more	9.4	(12)	7.7	(12)
Visited GP in past 6 months	56.4	(75)	49.4	(79)
Visited GUM clinic in past 6 months	22.1	(29)	25.8	(41)
Visited Walk-in clinic in past 6 months	22.1	(29)	25.6	(40)
Visited A&E/hospital in past 6 months	28.8	(38)	23.1	(37)
Attended healthcare facility for sexual health reasons	15.1	(39)	17.2	(43)

by a further 35 (7%) participants. [Table S1](#) gives baseline characteristics of those who did/did not provide samples at 7 months follow-up.

#### Prevalence of *C. trachomatis*/*N. gonorrhoeae* at baseline and 7 months

Prevalences of *C. trachomatis* and *N. gonorrhoeae* respectively were 6.2% (31/503; 4.2–8.6%) and 0.6% (3/503, 0.1–1.7%) at baseline (six samples were discarded as mislabelled). Prevalences at follow-up were *C. trachomatis* 6.1% (16/264, 3.5–9.7%, including 15 *C. trachomatis* only positive samples (13 college, two postal) and one dual infection); and *N. gonorrhoeae* 1.1% (3/264, 0.2–3.3%, including the dual infection). The prevalence of *C. trachomatis* in males and females was 6.8% (16/236) and 5.6% (15/267) at baseline; and 3.2% (4/125) and 8.6% (12/139) at follow-up. The three cases of *N. gonorrhoeae* at baseline were in males, the three at follow-up were in females. Prevalence of *C. trachomatis* in those tested at each college ranged from 1.3–8.4% at baseline (intraclass correlation coefficient 0.002), and 2.4–10.4% at follow-up ([Table S2](#)).

#### Time to results and treatment

For samples provided at college at 1, 4, and 7 months, most results (90%, 259/288) were received by participants the same day. Median time to being informed of a negative result ( $n = 267$ ) was 2.1 h (IQR 1.8–2.7 h, range 1.5 h to 23 days due to an administrative error). For the 15 cases of *C. trachomatis* only which were diagnosed in college (2 + 13 at months 1/4, and 7), ten were treated on-site (six same day, four next day), three were confirmed treated later



elsewhere (timing unclear for one), and two were not confirmed treated. Median time to confirmed treatment for *C. trachomatis* only ( $n = 12$ ) was 14.6 h (IQR 2.4–26.3 h, range 1.7 h to 27 days due to a problem with a mobile number).

### Acceptability

Semi-structured interviews in January–March 2017 with 13 students who attended for TnT and 13 who did not suggested that low uptake of TnT was associated with not feeling at risk, perceptions of stigma, and lack of knowledge about STIs. However, all were positive about TnT: 'I think the service you provide is actually very good because like most kids I think they would be too shy to like go out and get checked ....' (male, 16, black, TnT non-attender). Comments from attenders included: 'amazing', 'educational', 'friendly', 'helpful'.

## Discussion

### Principal findings

Rapid recruitment of sexually active teenagers was possible with £5 honoraria. However, despite high rates of *C. trachomatis* at both baseline and follow-up, the proportion of participants attending for non-incentivized college-based TnT was low: 13% at 1 month and 10% at 4 months. Although predetermined progression criteria for a definitive trial were not met, findings provide important insights for designing future studies and for public health policy.

### Strengths and weaknesses

This was a unique study in a group of often socio-economically deprived, ethnically diverse, inner-city teenagers. It included >100 black, sexually experienced teenage males, a group not often included in European STI research studies [4,7]. Participants had high rates of undiagnosed STIs including six participants with heterosexual *N. gonorrhoeae*, all from black and minority ethnic groups. It is also the first randomized study of rapid tests with on-site *C. trachomatis* treatment in FE colleges. It was a pragmatic study in a relevant setting to reach sexually active young people. Data on teenage lifestyles may inform future studies.

There are limitations. Opportunistic recruitment meant it was difficult to calculate a recruitment rate. We could not use the college population aged 16–24 (range approximately 500–3000 per college) as the denominator because assessment of eligibility required information on sexual history. As in other studies [4,20] we used self-reported data, which is subject to inaccurate recall. However, reported history of *C. trachomatis* was similar to rates in 16–24-year-old Londoners taking part in the population-based National Surveys of Sexual Attitudes and Lifestyles (8.2%, 41/502 in our study versus 7.0%, 19/273 in Natsal-3 UK data archive). Only two-thirds (10/15) of *C. trachomatis* only positives diagnosed in college were treated on-site. A faster 30-min test might have encouraged more students to wait for results [21], but no such suitable test was available. Although all participants diagnosed with infections were informed that their partners needed treatment, we did not have partners' consent to confirm notification. The study design meant TnT was only available to those already recruited. This would not happen if TnT were rolled out in routine practice. Follow-up rates were lower than the 81% in the recent 'Safetxt' pilot trial [22], but most of their participants were white, and/or aged 20–24. Our findings may not apply to such groups.

### Comparison with other studies

Rates of testing were lower than (54–60%) expected from our FE college-based pilot work [13,16,23], but similar to that in 16–29 year olds in a large Dutch register-based *C. trachomatis* screening trial: 16% in the first round decreasing to 11% in the second [8] with no substantial decrease in STI positivity rates. Another study from a Scottish FE college found 17% *C. trachomatis* testing uptake in teenagers [24], suggesting this is a challenging group to engage. By contrast, in the French Chlamyweb study [7] uptake by 18–24 year olds of an online offer of home-based *C. trachomatis* testing was 24% in males and 34% in females with positivity rates of 4.4% and 8.3% respectively. Similarly, in 'SH24', internet accessed postal testing almost doubled uptake of STI testing [20]. However, most participants were white and/or aged 20–30 years. As in other studies [7,16] many of our teenage participants did not want a test kit posted to their home. The high *C. trachomatis* positivity rates in Chlamyweb and our study were similar to those observed in STI clinics [7] and roughly double the rates in population-based studies in sexually experienced males and females aged 16–24 in England [5] (2.3% and 3.1%) and the USA [25] (1.7% and 3.2% respectively). Finally, there were more MSM among TnT attenders than non-attenders. MSM may be more aware of STI prevention [20].

The median time from diagnosis to treatment (within 1 day) was similar to a recent feasibility study of online *C. trachomatis* management via an eSexual health clinic [26]. Overall rates of confirmed treatment for *C. trachomatis* (87%, 13/15) were similar to ChlamywebII [7] (87%, 58/67) and 2014 English National Chlamydia Screening Programme results (91% within 6 weeks of test date [27]). Participants' lack of knowledge about STIs was in line with community-based studies from the USA, Europe, and Australia [16,24,28–30]. Sex education is optional in English state secondary schools.

## Conclusions and perspectives

The low uptake of TnT despite high rates of STIs suggests that a definitive trial of TnT using this design is not feasible in FE colleges. It highlights both the difficulties of designing studies to reach sexually active young people, and the crucial need for better sex and relationships education [2]. This should include 'normalization' of STI testing [20] making it routine/acceptable to get checked. However, accessing testing is often problematic [1]. In the UK, funding cuts have closed many sexual health clinics, and relying on internet postal testing may disadvantage vulnerable teenagers [20]. Future trials might evaluate college-wide, multicomponent, combined Education/TnT interventions. This could include lessons offering user-friendly information on STIs, free condoms, and postal test kits perhaps followed by pop-up clinics offering confidential, on-site TnT.

## Transparency declaration

This paper presents independent research funded by the National Institute for Health Research (NIHR) under its Research for Patient Benefit (RfPB) Programme (Grant Reference Number PB-PG-1014-35007). Value in kind funding was received from the UKCRC Translational Infection Research Initiative supported by the Medical Research Council (Grant Number G0901608) with contributions from the Biotechnology and Biological Sciences Research Council and the NIHR. The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health. The funding body had no role in the design of the study, the collection, analysis or interpretation of the data, or the write-up of

the manuscript. Data and materials may be obtained from the trial manager S.K.B. Pippa Oakeshott is a member of the NIHR South London Collaboration for Leadership in Applied Health Research and Care. P.O., S.T.S., E.H.E., and E.C. are members of the eSTI<sup>2</sup> consortium funded under the UKCRC Translational Infection Research Initiative. S.T.S., E.H.E., and E.C. are members of the Applied Diagnostic Research and Evaluation Unit and have received funding for projects from Cepheid, Atlas Genetics, TwistDx. Elisabeth Adams is employed by Aquarius Population Health that receives grants and other funding to work on projects relating to STIs and point of care tests. Fiona Reid is supported by the National Institute for Health Research (NIHR) Biomedical Research Centre based at Guy's and St Thomas' NHS Foundation Trust and King's College London.

## Acknowledgements

We thank Georgie Timson and Alice Bonnissent of Cepheid International for providing the rapid *C. trachomatis*/*N. gonorrhoeae* tests, and Agata Lesniewska for doing *C. trachomatis*/*N. gonorrhoeae* tests on the stored baseline samples. We confirm Cepheid had no role in the design of the study, the collection, analysis or interpretation of the data, or the write-up of the manuscript. The Clinical Research Network nurses helped with consenting participants. Preventx tested postal samples. We also thank students and staff at the participating London FE colleges: Lambeth, Kingston, Merton, Wandsworth, Southwark, and Lewisham.

## Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.cmi.2018.10.019>.

## References

- [1] Centers for Disease Control. Sexually transmitted disease surveillance 2016. US Department of Health and Human Services; 2017.
- [2] Public Health England. Sexually transmitted infections and chlamydia screening in England 2016. Health Protection Report 2017;11:1–20.
- [3] Reid F, Oakeshott P, Kerry SR, Hay PE, Jensen JS. Chlamydia related bacteria (Chlamydiales) in early pregnancy: community-based cohort study. *Clin Microbiol Infect* 2017;23:119–24.
- [4] Sonnenberg P, Clifton S, Beddows S, Field N, Soldan K, Tanton C, et al. Prevalence, risk factors, and uptake of interventions for sexually transmitted infections in Britain: findings from the National Surveys of Sexual Attitudes and Lifestyles (Natsal). *Lancet* 2013;382:1795–806.
- [5] Woodhall SC, Soldan K, Sonnenberg P, Mercer CH, Clifton S, Saunders P, et al. Is chlamydia screening and testing in Britain reaching young adults at risk of infection? Findings from the third National Survey of Sexual Attitudes and Lifestyles (Natsal-3). *Sex Transm Infect* 2016;92:218–27.
- [6] Guy RJ, Natoli L, Ward J, Causer L, Hengel B, Whiley D, et al. A randomised trial of point-of-care tests for chlamydia and gonorrhoea infections in remote Aboriginal communities: Test, Treat AND GO- the "TTANGO" trial protocol. *BMC Infect Dis* 2013;13:485.
- [7] Kersaudy-Rahib D, Lydie N, Leroy C, March L, Bebear C, Arwidson P, et al. Chlamyweb Study II: a randomised controlled trial (RCT) of an online offer of home-based Chlamydia trachomatis sampling in France. *Sex Transm Infect* 2017;93:188–95.
- [8] van den Broek IV, van Bergen JE, Brouwers EE, Fennema JS, Gotz HM, Hoebe CJ, et al. Effectiveness of yearly, register based screening for chlamydia in the Netherlands: controlled trial with randomised stepped wedge implementation. *BMJ* 2012;345:e4316.
- [9] Gaydos CA, Van Der Pol B, Jett-Goheen M, Barnes M, Quinn N, Clark C, et al. Performance of the Cepheid CT/NG Xpert Rapid PCR Test for Detection of Chlamydia trachomatis and Neisseria gonorrhoeae. *J Clin Microbiol* 2013;51:1666–72.
- [10] Causer LM, Guy RJ, Tabrizi SN, Whiley DM, Speers DJ, Ward J, et al. Molecular test for chlamydia and gonorrhoea used at point of care in remote primary healthcare settings: a diagnostic test evaluation. *Sex Transm Infect* 2018;94:340–5.
- [11] Turner KM, Round J, Horner P, Macleod J, Goldenberg S, Deol A, et al. An early evaluation of clinical and economic costs and benefits of implementing point of care NAAT tests for Chlamydia trachomatis and Neisseria gonorrhoea in genitourinary medicine clinics in England. *Sex Transm Infect* 2014;90:104–11.
- [12] Oakeshott P, Kerry S, Aghaizu A, Atherton H, Hay S, Taylor-Robinson D, et al. Randomised controlled trial of screening for Chlamydia trachomatis to prevent pelvic inflammatory disease: the POPI (prevention of pelvic infection) trial. *Br Med J* 2010;340:1642.
- [13] Balendra A, Cousins E, Lamplough H, Oakeshott P, Majewska W, Kerry SR. Pilot study for the 'Test n Treat' trial of on-site rapid chlamydia/gonorrhoea tests and same day treatment. *Sex Transm Infect* 2017;93:283.
- [14] Sharman N, Sri T, Chow C, Pond MJ, Oakeshott P, Planche T, et al. Chlamydia testing: Reaching high-risk sexually active young people in the community. *Int J STD AIDS* 2016;27:78–9.
- [15] Kerry-Barnard S, Fleming C, Reid F, Phillips R, Drennan VM, Adams EJ, et al. 'Test n Treat (TnT)'- Rapid testing and same-day, on-site treatment to reduce rates of chlamydia in sexually active further education college students: study protocol for a cluster randomised feasibility trial. *Trials* 2018;19:311.
- [16] Normansell R, Drennan VM, Oakeshott P. Exploring access and attitudes to regular sexually transmitted infection screening: the views of young, multi-ethnic, inner-city, female students. *Health Expect* 2016;19:322–30. PM: 25703741.
- [17] Teare MD, Dimairo M, Shephard N, Hayman A, Whitehead A, Walters SJ. Sample size requirements to estimate key design parameters from external pilot randomised controlled trials: a simulation study. *Trials* 2014;15:264.
- [18] Phillips R, Oakeshott P, Kerry-Barnard S, Reid F. 'Test n Treat (TnT)': a cluster-randomised feasibility trial of frequent, rapid-testing and same-day, on-site treatment to reduce rates of chlamydia in high-risk further education college students: statistical analysis plan. *Trials* 2018;19:312.
- [19] Leon AC, Davis LL, Kraemer HC. The role and interpretation of pilot studies in clinical research. *J Psychiatr Res* 2011;45:626–9.
- [20] Wilson E, Free C, Morris TP, Syred J, Ahamed I, Menon-Johansson AS, et al. Internet-accessed sexually transmitted infection (e-STI) testing and results service: a randomised, single-blind, controlled trial. *PLoS Med* 2017;14:e1002479.
- [21] Harding-Esch EM, Cousins E, Sadiq ST. A 30-min nucleic acid amplification point-of-care test for genital chlamydia trachomatis infection in women: a prospective, multi-centre study of diagnostic accuracy. *eBiomedicine* 2018;28:120–7.
- [22] McCarthy OL, French RS, Baraitser P, Roberts I, Rathod SD, Devries K, et al. Safext: a pilot randomised controlled trial of an intervention delivered by mobile phone to increase safer sex behaviours in young people. *BMJ Open* 2016;6:e013045.
- [23] Holland J, Oakeshott P. Chlamydia testing in male further education college students. *Sex Transm Infect* 2015;91:496.
- [24] Lorimer K, Reid ME, Hart GJ. Willingness of young men and women to be tested for Chlamydia trachomatis in three non-medical settings in Glasgow, UK. *J Fam Plann Reprod Health Care* 2009;35:21–6.
- [25] Satterwhite CL, Torrone E, Meites E, Dunne EF, Mahajan R, Ocfemia MC, et al. Sexually transmitted infections among US women and men: prevalence and incidence estimates, 2008. *Sex Transm Dis* 2013;40:187–93.
- [26] Estcourt CS, Gibbs J, Sutcliffe IJ, Gkatzidou V, Tickle L, Hone K, et al. The eSexual Health Clinic system for management, prevention, and control of sexually transmitted infections: exploratory studies in people testing for Chlamydia trachomatis. *Lancet Public Health* 2017;2:e182–90.
- [27] Public Health England. Audit report on turnaround times: National Chlamydia Screening Programme. London: PHE; 2014.
- [28] Lindberg LD, Maddow-Zimet I, Boonstra H. Changes in adolescents' receipt of sex education, 2006–2013. *J Adolesc Health* 2016;58:621–7.
- [29] Samkange-Zeeb F, Mikolajczyk RT, Zeeb H. Awareness and knowledge of sexually transmitted diseases among secondary school students in two German cities. *J Community Health* 2013;38:293–300.
- [30] Lim MS, Bowring AL, Gold J, Aitken CK, Hellard ME. Trends in sexual behavior, testing, and knowledge in young people; 2006–2011. *Sex Transm Dis* 2012;39:831–4.