

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

¹Pippa Oakeshott oakeshot@sgul.ac.uk
¹Sarah Kerry-Barnard srkerry@sgul.ac.uk
¹Charlotte Fleming crdfleming@gmail.com
²Rachel Phillips r.phillips@imperial.ac.uk
³Vari M Drennan V.Drennan@sgul.kingston.ac.uk
⁴Elisabeth J Adams elisabeth.adams@aquariusph.com
⁵Wendy Majewska wendy@wemconsultancy.com
^{6,7}Emma M Harding-Esch Emma.Harding-Esch@lshtm.ac.uk
⁶Emma C Cousins E.Cousins@soton.ac.uk
⁶Tim Planche tplanche@sgul.ac.uk
¹Alastair Green m1400086@sgul.ac.uk
¹Rosalie I Bartholomew rosalie.bartholomew@nhs.net
⁶S Tariq Sadiq ssadiq@sgul.ac.uk
²Fiona Reid fiona.reid@kcl.ac.uk

¹Population Health Research Institute
St George’s, University of London, SW17 0RE

²School of Population Health and Environmental Sciences
King’s College London, SE1 1UL

³Centre for Health & Social Care Research,
Kingston University & St George's, University of London, SW17 0RE

⁴Aquarius Population Health Limited
58a Highgate High Street, London, UK N6 5HX

⁵WEM Consultancy Ltd.
96 Tantallon Road, London, SW12 8DH

⁶Institute for Infection and Immunity
St George’s, University of London, SW17 0RE

⁷Public Health England
61 Colindale Avenue, London, NW9 5EQ
Correspondence to Professor Oakeshott oakeshot@sgul.ac.uk

1 **Abstract**

2 **Objectives** We conducted a cluster-randomised feasibility trial of 90-minute *Chlamydia*
3 *trachomatis* tests and same day on-site treatment (“Test n Treat/TnT”) in six technical
4 colleges in London, England to assess:

- 5 • TnT uptake rates
- 6 • Follow-up rates
- 7 • Prevalence of *C.trachomatis* at baseline and 7-months
- 8 • Time to treatment
- 9 • Acceptability of TnT

10 **Methods**

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

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

18 **Results**

19 509 sexually active students were recruited: median age 17.9 years, 47% male, 50% black
20 ethnicity, 55% reporting ≥ 2 sexual partners in the previous year. TnT uptake was 13%
21 (33/259; 95% CI 8.9-17.4%) at one month and 10% (26/259;6.7-14.4%) at 4-months with
22 overall *C.trachomatis* positivity 5.1% (3/59;1.1-14.2%). Follow-up at 7-months was 62%
23 (317/509) for questionnaires and 52% (264/509) for samples. *C.trachomatis* prevalence was
24 6.3% (31/503) at baseline and 6.1% (16/264) at 7-months. Median time from test-to-
25 treatment was 15-hours. Interviews suggested low test uptake was associated with not
26 feeling at risk, perceptions of stigma and little knowledge of sexually transmitted infections
27 (STIs).

28 **Conclusions**

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

1 **Trial registration** ISRCTN58038795

2

3 **Key words**

4 Rapid *C.trachomatis* tests

5 Screening

6 Young people

7 Technical colleges

8 Test and treat

9 Cluster randomised

10 Feasibility trial

11

12

13

1 Introduction

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

11
12 In order to address a number of unknown parameters required for the design of a future
13 definitive study, we conducted a cluster randomised feasibility trial (or pilot study) of
14 frequent, rapid TnT in six technical (“Further Education”/ FE) colleges in London, England
15 over the academic year 2016-17. (FE colleges offer both academic and practical courses such
16 as plumbing and hairdressing, and take many students from socio-economically deprived
17 backgrounds. *C.trachomatis* positivity may be 6-8% [12-14].)

18 We assessed the following feasibility outcomes:

- 19 • Recruitment rates
- 20 • TnT uptake rates
- 21 • Follow-up rates
- 22 • Prevalence of *C.trachomatis* at baseline and 7 months
- 23 • Time to treatment
- 24 • Acceptability of TnT

25
26 We selected a cluster design for practical reasons for delivering screening, which would
27 reflect the design of a definitive trial. This was a feasibility study and was not powered to
28 assess the effectiveness of TnT. Although we used a combined *C.trachomatis/Neisseria*
29 *gonorrhoeae* rapid test (Cepheid CT/NG GeneXpert® system [9]), on-site treatment (TnT)
30 was for individuals with *C.trachomatis* only [15] as participants with *N.gonorrhoeae* (or

1 *C.trachomatis/N.gonorrhoeae* dual infection) were referred to a sexual health clinic.

2 Detailed qualitative and economic analyses will be presented elsewhere.

3

4 **Methods**

5 *Recruitment and baseline samples*

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

18 *Randomisation*

19 After recruitment of all participants, the six colleges were randomly allocated 1:1 into the
20 intervention group (TnT) or control group (no TnT, **Figure 1**) by the trial statistician using a
21 computer-generated allocation sequence [15].

22

23 *Intervention colleges: TnT at both one and four months*

24 One and four months after recruitment (to fit with college Autumn and Spring terms), each
25 of the three intervention colleges were visited on two consecutive days by the research
26 team. We advertised the visit on college websites and notice boards, and texted/emailed
27 participating students the day before the visit and on both days inviting them to come for
28 TnT. Attendees came to a private room to collect a test kit. When they returned with a
29 sample, it was tested for *C.trachomatis/N.gonorrhoeae* immediately on-site in a pop-up lab
30 in a classroom using a 90-minute test [15] (one test/participant). Negative results were
31 texted to participants. The research team's nurse health-adviser telephoned participants

1 with positive results and met them in another private room in college (same-day whenever
2 possible) for confidential treatment for *C.trachomatis*, partner notification and/or referral.

3

4 *Control colleges: no TnT*

5 Participants from the three control colleges received texts one and four months after
6 recruitment thanking them for being in the study.

7

8 *Outcome assessment at 7 months*

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

16

17 *Honoraria*

18 Participants received £5 in cash when they returned samples at recruitment and £10 after
19 providing samples at seven months follow-up. Participants in intervention colleges did not
20 receive honoraria for attending for TnT at one and four months, as in the UK people are not
21 usually paid for having an STI test.

22

23 *Masking*

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

26

27 *Main outcome measures* (key values to inform feasibility, sample size and timescales of a
28 definitive trial)

- 29 • Recruitment rates
- 30 • TnT uptake in intervention participants at one and four-months
- 31 • Follow-up rates at seven-months

- 1 • Prevalence of *C.trachomatis* at baseline and seven-months
- 2 • Time to receiving results and treatment (fidelity of TnT)
- 3 • Acceptability of TnT in intervention colleges from thematically-analysed semi-structured
- 4 interviews[16] with purposively sampled students (n=26 to ensure a range of ages,
- 5 genders and ethnicities) who did/did not attend for TnT (to be published elsewhere).

6 7 *Sample size and statistical analysis*

8 Sixty to 100 subjects is sufficient to estimate an event rate with acceptable precision (i.e.

9 sufficiently narrow confidence intervals) in a feasibility study [17] [15]. As previously

10 described [18], assuming a 30% recruitment rate [13], we aimed to approach 1600 students

11 to recruit 480 overall (80 per college across 6 colleges).

12

13 Progression criteria to a definitive trial were: TnT uptake $\geq 60\%$ [13] at 1 and 4-months and

14 TnT being acceptable to participants [16] (intervention colleges only), and follow-up rate

15 $\geq 70\%$ [12] at 7-months (all colleges).

16

17 Since this was a feasibility study, no significance testing was performed [19]. Descriptive

18 statistics are presented, with corresponding exact 95% confidence intervals. Analyses [18]

19 were performed in Stata version 14. As our analysis was of feasibility outcomes, the sample

20 size and analysis were not adjusted for clustering.

21

22 **Ethics approval and consent to participate**

23 Bromley REC reviewed the study (reference 15/LO/1929). Parental consent for 16-18 year-

24 olds was not required.

25

26 **Results**

27 *Recruitment*

28 Over three weeks in September/October 2016 we recruited 509 participants from six

29 colleges (range 78-90 per college). We were unable to obtain information on all non-

30 participants, but completed recruitment forms for 180 non-participants suggested that 67%

31 (121/180) were ineligible due to never having had sexual intercourse, 14% (25/180) were

1 ineligible for other reasons (e.g. not aged 16-24), and 19% (34/180) were eligible but
2 declined.

3

4 Participants' median age was 17.9 years and 90% (458) were teenagers (aged 16-19 years).
5 Participants described their ethnicity as black (50%), white (26%) or other ethnic groups
6 (24%). Approximately half (47%, 240) were male, including 117 (23%) black male teenagers.
7 Over half (55%) reported ≥ 2 sexual partners in the previous year, and a third (36%) said they
8 had been tested for STIs in the past 6 months. Eligible non-participants (n=34) were similar
9 to participants in age and ethnicity (median age 17, IQR 17-19; 53% black ethnicity), but a
10 slightly higher proportion (67%) were male. Table 1 shows baseline characteristics of
11 participants from intervention and control colleges.

12

13 *TnT uptake at one and four months in intervention colleges*

14 Thirteen percent (33/259; 95% CI 8.9-17.4%) of intervention participants attended for on-
15 site rapid tests and provided samples at one month, and 10% (26/259; 95% CI 6.7-14.4%) at
16 four months despite implementing changes suggested by students and staff to increase
17 uptake. These included brief information for tutors to give to their tutorial groups,
18 educational posters (supplementary files), user-friendly texts and free condoms. Five
19 students provided samples at both one and four months. Of 59 tests, three (5.1%, 1.1-14.2)
20 were positive for *C.trachomatis*. Two students with *C.trachomatis* only were treated on-site
21 (one same day, one next day), and one with dual *C.trachomatis/N.gonorrhoeae* infection
22 was referred for treatment as per protocol. Table 2 shows baseline characteristics of
23 participants who did/did not provide samples for TnT were broadly similar, although more
24 TnT attenders than non-attenders had a history of *C.trachomatis* (13% versus 6%), and more
25 were men who had sex with men (MSM, 15% versus 3%).

26

27 *Follow-up*

28 Overall follow-up at seven months was 62% (317/509; 95% CI 58-67%) for questionnaires
29 and 52% (264/509; 95% CI 47-56%) for samples. (A further four participants provided invalid
30 samples: three with no human DNA, one delayed postal sample.) Almost half the
31 participants (46%, 232/509) completed follow-up questionnaires at college, a further 9%
32 (46/509) subsequently completed an online questionnaire and 8% (39/509) a brief

1 telephone questionnaire. These showed 29% of intervention participants and 25% of control
2 participants reported STI testing outside the trial. (Other study-related behaviours reported
3 at follow-up are shown in Table 3). Valid samples for testing were provided at college by 229
4 (45%) participants and later by post by a further 35 (7%) participants. Supplementary Table
5 1 gives baseline characteristics of those who did/did not provide samples at seven months
6 follow-up.

7

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

9 Prevalences of *C.trachomatis* and *N.gonorrhoeae* respectively were 6.2% (31/503; 4.2-8.6%)
10 and 0.6% (3/503, 0.1-1.7%) at baseline (six samples were discarded as mislabelled).

11 Prevalences at follow-up were: *C.trachomatis* 6.1% (16/264, 3.5-9.7%, including 15
12 *C.trachomatis* only positive samples [13 college, 2 postal] and one dual infection); and
13 *N.gonorrhoeae* 1.1% (3/264, 0.2-3.3%, including the dual infection). The prevalence of
14 *C.trachomatis* in males and females was 6.8% (16/236) and 5.6% (15/267) at baseline; and
15 3.2% (4/125) and 8.6% (12/139) at follow-up. The three cases of *N.gonorrhoeae* at baseline
16 were in males, the three at follow-up were in females. Prevalence of *C.trachomatis* in those
17 tested at each college ranged from 1.3%-8.4% at baseline (intraclass correlation coefficient
18 0.002), and 2.4%-10.4% at follow-up (Supplementary Table 2).

19

20 *Time to results and treatment*

21 For samples provided at college at one, four and seven months, most results (90%, 259/288)
22 were received by participants the same day. Median time to being informed of a negative
23 result (n=267) was 2.1 hours (IQR 1.8-2.7 hours, range 1.5 hours to 23 days due to an
24 administrative error). For the 15 cases of *C.trachomatis* only which were diagnosed in
25 college (2+13 at months one/four and seven respectively), ten were treated on-site (6 same
26 day, 4 next day), three were confirmed treated later elsewhere (timing unclear for one), and
27 two were not confirmed treated. Median time to confirmed treatment for *C.trachomatis*
28 only (n=12) was 14.6 hours (IQR 2.4-26.3 hours, range 1.7 hours-27 days due to a problem
29 with a mobile number).

30

31

32

1 *Acceptability*

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

9

10 **Discussion**

11 *Principal findings*

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

18

19 *Strengths and weaknesses*

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

27

28 There are limitations. Opportunistic recruitment meant it was difficult to calculate a
29 recruitment rate. We could not use the college population aged 16-24 (range approximately
30 500-3000 per college) as the denominator because assessment of eligibility required
31 information on sexual history. As in other studies [4, 20] we used self-reported data, which
32 is subject to inaccurate recall. However, reported history of *C.trachomatis* was similar to

1 rates in 16-24 year old Londoners taking part in the population-based National Surveys of
2 Sexual Attitudes and Lifestyles (8.2%, 41/502 in our study versus 7.0%, 19/273 in Natsal-3
3 UK data archive). Only two-thirds (10/15) of *C.trachomatis* only positives diagnosed in
4 college were treated on-site. A faster 30 minute test might have encouraged more students
5 to wait for results[21], but no such suitable test was available. Although all participants
6 diagnosed with infections were informed that their partners needed treatment, we did not
7 have partners' consent to confirm notification. The study design meant TnT was only
8 available to those already recruited. This would not happen if TnT were rolled out in routine
9 practice. Follow-up rates were lower than the 81% in the recent "Safetxt" pilot trial[22], but
10 most of their participants were white, and/or aged 20-24. Our findings may not apply to
11 such groups.

12

13 *Comparison with other studies*

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

30

31 The median time from diagnosis to treatment (within one day) was similar to a recent
32 feasibility study of online *C.trachomatis* management via an eSexual health clinic [26].

1 Overall rates of confirmed treatment for *C.trachomatis* (87%, 13/15) were similar to
2 ChlamywebII [7] (87%, 58/67) and 2014 English National Chlamydia Screening Programme
3 results (91% within six weeks of test date [27]). Participants' lack of knowledge about STIs
4 was in line with community-based studies from USA, Europe and Australia [28] [29] [16, 24,
5 30]. Sex education is optional in English state secondary schools.

6
7

8 *Conclusions and perspectives*

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

19

1 **Funding**

2 This independent research is funded by the National Institute for Health Research (NIHR)
3 under its Research for Patient Benefit (RfPB) Programme (Grant Reference Number **PB-PG-**
4 **1014-35007**). Value in kind funding was received from the UKCRC Translational Infection
5 Research Initiative supported by the Medical Research Council (Grant Number G0901608)
6 with contributions from the Biotechnology and Biological Sciences Research Council and the
7 NIHR. The views expressed are those of the authors and not necessarily those of the NHS,
8 the NIHR or the Department of Health. The funding body had no role in the design of the
9 study, the collection, analysis or interpretation of the data, or the write-up of the
10 manuscript.

11
12 **Availability of data and materials**

13 Data and materials may be obtained from trial manager SKB.

14
15 **Authors' contributions**

16 PO, FR, STS, VMD, EA and SKB designed the study and obtained the funding. FR and RP
17 designed the statistical analysis plan and analysed the data with trial manager SKB. PO
18 wrote the first draft of the paper to which all authors then contributed. All authors read and
19 approved the final manuscript.

20
21 **Competing interests**

22 Pippa Oakeshott is a member of the NIHR South London Collaboration for Leadership in
23 Applied Health Research and Care. PO, STS, EHE and EC are members of the eSTI²
24 consortium funded under the UKCRC Translational Infection Research Initiative. STS, EHE
25 and EC are members of the Applied Diagnostic Research and Evaluation Unit and have
26 received funding for projects from Cepheid, Atlas Genetics, TwistDx. Elisabeth Adams is
27 employed by Aquarius Population Health that receives grants and other funding to work on
28 projects relating to STIs and point of care tests. Fiona Reid is supported by the National
29 Institute for Health Research (NIHR) Biomedical Research Centre based at Guy's and St
30 Thomas' NHS Foundation Trust and King's College London.

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

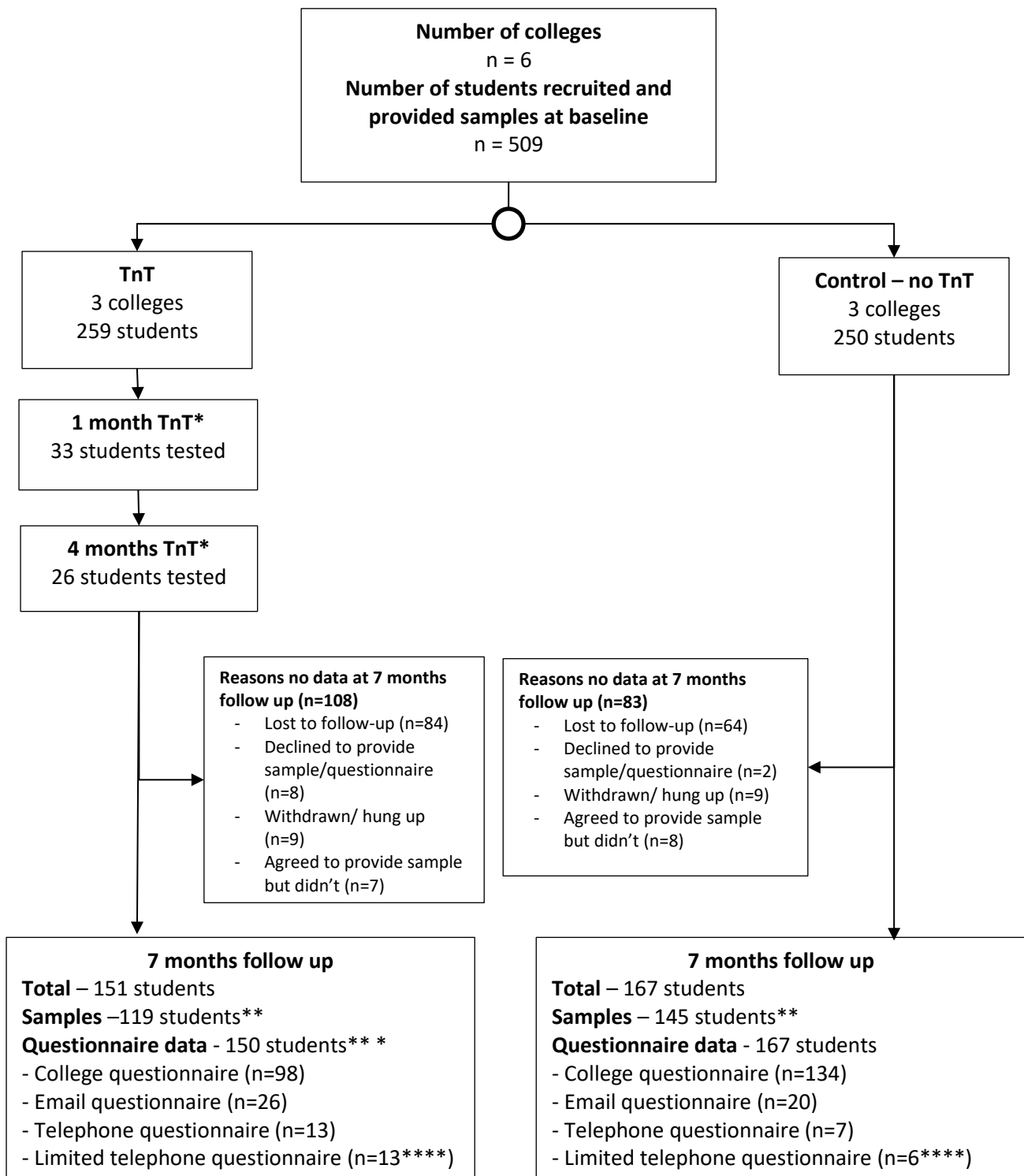
Reference List

- (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(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, 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(9907):1795-806.
- (5) Woodhall SC, Soldan K, Sonnenberg 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(3):218-27.
- (6) Guy RJ, Natoli L, Ward J, 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, 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(3):188-95.
- (8) van den Broek IV, van Bergen JE, Brouwers EE, 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, 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(6):1666-72.
- (10) Causer LM, Guy RJ, Tabrizi SN, 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.
- (11) Turner KM, Round J, Horner P, 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(2):104-11.
- (12) Oakeshott P, Kerry S, Aghaizu A, 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(4):283.
- (14) Sharman N, Sri T, Chow C, et al. Chlamydia testing: Reaching high-risk sexually active young people in the community. *Int J STD AIDS* 2016; 27(1):78-9.
- (15) Kerry-Barnard S, Fleming C, Reid F, 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(1):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* 2015; [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(1):312.
- (19) Leon AC, Davis LL, Kraemer HC. The role and interpretation of pilot studies in clinical research. *J Psychiatr Res* 2011; 45(5):626-9.
- (20) Wilson E, Free C, Morris TP, et al. Internet-accessed sexually transmitted infection (e-STI) testing and results service: A randomised, single-blind, controlled trial. *PLoS Med* 2017; 14(12):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, et al. Safetxt: a pilot randomised controlled trial of an intervention delivered by mobile phone to increase safer sex behaviours in young people. *BMJ Open* 2016; 6(12):e013045.
- (23) Holland J, Oakeshott P. Chlamydia testing in male further education college students. *Sex Transm Infect* 2015; 91(7):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(1):21-6.

- (25) Satterwhite CL, Torrone E, Meites E, et al. Sexually transmitted infections among US women and men: prevalence and incidence estimates, 2008. *Sex Transm Dis* 2013; 40(3):187-93.
- (26) Estcourt CS, Gibbs J, Sutcliffe LJ, 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(4):e182-e190.
- (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(6):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(2):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(11):831-4.

Figure 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



*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.

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 (n=259)	Control (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 mths % (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)

***C.trachomatis* at baseline* % (n)** 7.1 (18) 5.2 (13)

***N.gonorrhoeae* at baseline* % (n)** 1.2 (3) 0 (0)

*Baseline samples were stored and tested after seven months.

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

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 (n=54*)	Did not attend TnT (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)

* 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 (n=150)		Control (n=167)	
Follow up method	College questionnaire	65.3	(98)	80.2	(134)
	Email 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 had sex with anyone new since last visit?	Yes	49.3	(73)	54.5	(91)
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)

Supplementary Table 1. Baseline characteristics of 509 participants who did or did not provide a valid sample at 7 months follow-up.

Baseline characteristic	Sample provided at follow-up (n=264)	No sample at follow-up (n=245)
Male % (n)	47.3 (125)	46.9 (115)
Age median (IQR)	17.9 (17.1 to 18.7)	17.9 (16.9 to 18.7)
Ethnicity % (n)		
White	26.6 (69)	26.6 (64)
Black African/Black Caribbean/Black British	52.1 (135)	47.3 (116)
Asian/Asian British	6.2 (16)	4.9 (12)
Mixed/multiple ethnicities	10.4 (27)	17.6 (43)
Other ethnic group	4.6 (12)	4.1 (10)
Sexual Preference (females) % (n)		
Sex with men only	87.7 (121)	89.1 (115)
Sex with women only	1.4 (2)	3.9 (5)
Sex with men and women	6.5 (9)	5.4 (7)
Prefer not to say	4.3 (6)	1.6 (2)
Sexual Preference (males) % (n)		
Sex with men only	4.0 (5)	2.6 (3)
Sex with women only	92.8 (116)	94.8 (109)
Sex with men and women	2.4 (3)	1.7 (2)
Prefer not to say	0.8 (1)	0.9 (1)
Age first sex <16 years % (n)	42.3 (107)	50.0 (117)
Two or more partners in past 12 months % (n)	53.1 (136)	57.2 (139)
New partner in past 6 months % (n)	50.4 (132)	56.8 (137)
Female contraception % (n)		
Condoms	57.6 (80)	52.3 (68)
Pill	22.3 (31)	15.4 (20)
Implant/coil	14.4 (20)	18.5 (24)
None	16.5 (23)	18.5 (24)
Other	2.9 (4)	2.3 (3)

Condom use (male and female) % (n)		
Always	37.1 (99)	35.1 (85)
Usually	18.1 (47)	20.7 (50)
Sometimes	31.7 (82)	25.6 (62)
Never	13.1 (34)	18.6 (45)
Last STI check up % (n)		
Never	46.5 (121)	41.3 (100)
In the past 6 months	35.4 (92)	37.2 (90)
More than 6 months ago	18.1 (47)	21.5 (52)
STI history % (n)		
<i>C.trachomatis</i>	6.5 (17)	10.0 (24)
<i>N.gonorrhoeae</i>	3.1 (8)	6.9 (16)
Other STI	0.8 (2)	1.3 (3)
NSU	0.4 (1)	1.3 (3)
Pelvic Inflammatory Disease in past 6 months	2.9 (4)	1.6 (2)
Symptoms in past 6 months (female) % (n)		
Bleeding between periods	14.8 (19)	18.5 (23)
Abnormal vaginal discharge	16.0 (20)	10.7 (13)
Pelvic discomfort other than normal period pain	10.6 (13)	10.0 (12)
Pain during sex	18.3 (23)	16.4 (20)
Symptoms in past 6 months (male) % (n)		
Pain/ burning when urinating	7.4 (9)	6.4 (7)
Discharge from your penis	1.7 (2)	2.8 (3)
Pain or discomfort in testicles	5.0 (6)	6.4 (7)
Pain/ burning from back passage	2.5 (3)	1.9 (2)
Smokes cigarettes % (n)	27.5 (72)	39.7 (96)
Alcohol-reports was drunk in past month % (n)	46.3 (120)	50.6 (122)
Visited GP in past 6 months % (n)	62.0 (160)	58.5 (140)
Visited sexual health clinic in past 6 months % (n)	28.8 (74)	32.2 (77)
Visited Walk-in clinic in past 6 months % (n)	32.3 (83)	28.2 (65)
Visited A&E/hospital in past 6 months % (n)	31.5 (81)	36.5 (88)
Attended healthcare facility for sexual health reasons in past 6 months % (n)	35.1 (91)	37.2 (90)
<i>C.trachomatis</i> at baseline % (n)	3.8(10)	8.7 (21)
<i>N.gonorrhoeae</i> at baseline % (n)	0.4 (1)	0.8 (2)

Supplementary Table 2: Prevalence of *C. trachomatis* at baseline and final seven months follow-up in three intervention and three control colleges

	Intervention college 1	Intervention college 2	Intervention college 3	Control college 1	Control college 2	Control college 3
Prevalence of <i>C.trachomatis</i> at baseline % (n/N)	8.3 (7/84)	8.3 (7/84)	4.6 (4/87)	8.4 (7/83)	1.3 (1/77)	5.7 (5/88)
Prevalence of <i>C.trachomatis</i> at seven months follow up % (n/N)	5.1 (2/39)	7.7 (3/39)	2.4 (1/41)	4.1 (2/49)	6.3 (3/48)	10.4 (5/48)