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LUSTRUM Accelerated Partner Therapy (APT) Chlamydia Trial V1.0

Submission date
13/08/2018

Recruitment status
No longer recruiting

Registration date
04/09/2018

Overall study status
Completed

Last Edited
03/10/2022

Condition category
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Public health control of Sexually Transmitted Infections (STIs) in the community depends on reducing transmission between sexual partners. One way to do this is through partner notification (PN), the process of identifying, testing, and treating exposed sex partners of a person with an STI. Currently this involves either the patient or a clinic health adviser (HA) contacting these sex partners and advising them to attend a clinic for testing and treatment, an approach that has limited success. A new PN option has been developed for patients with chlamydia called Accelerated Partner Therapy (APT), which could be offered at sexual health clinics alongside current standard PN. APT aims to improve the uptake of treatment by sex partners, and treat them more quickly, by providing a 'testing and treatment' pack to the sex partners, which may be delivered by the patient or by post. This pack is only provided after a HA has carried out a private telephone conversation with the sex partner to check it is medically safe for them to take the chlamydia treatment. In small studies, APT appeared to result in faster sex partner treatment and greater numbers of sex partners treated, but this has not yet been tested in a full trial. The aim of this study is to test the effectiveness and cost-effectiveness of APT compared with routine PN for patients with chlamydia.

Who can participate?
Patients aged 16 or older who have tested positive for Chlamydia and their sex partners from the past 6 months

What does the study involve?
The control phase is standard PN (enhanced patient referral and provider referral) and the intervention phase is offer of APT in addition to standard patient referral. All clinics take part in the control and the intervention phases, half the clinics do the intervention phase first and half do the control phase first. Before the start of the trial, clinics are randomly allocated to the control or intervention during phase 1 (6 months) (updated 16/07/2019, previously: 4 months). This is followed by a break of 2 weeks (updated 16/07/2019, previously: 2 months) during which clinics follow standard PN practice, before clinics cross over to the opposite (intervention or control) for phase 2 (6 months) (updated 16/07/2019, previously: 4 months). The cost-effectiveness of APT versus standard PN is assessed. The study also investigates how APT worked in practice during the trial (process evaluation), so that if APT is rolled out in the future,

procedures will be optimised to meet the needs of patients and clinic staff. Patients attending clinics offering APT during the trial are interviewed to talk about their experiences of APT in an interview of up to one hour.

What are the possible benefits and risks of participating?
Taking part will help shape sexual health services for the future if APT is successful. Participants will be given relevant information about how to follow the progress and findings of the study. It is hoped they will find the interview an interesting experience and benefit from sharing their opinions on APT. After the interview is completed, they will receive a £30 voucher as a token of thanks for taking part in the study. No risks or disadvantages are expected and participants will be advised to let the interviewer know if they do not wish to discuss any issue or wish to leave the discussion altogether.

Where is the study run from?
1. Barking Community Hospital
2. Ambrose King Centre
3. Sir Ludwig Guttmann Health and Wellbeing Centre
4. Florey Unit
5. Whittall Street Clinic
6. Royal Bournemouth Hospital
(removed 16/07/2019 7. Brighton and Hove Sexual Health and Contraception Service)
8. Brookside Sexual Health Clinic
9. Shaw Clinic
10. 10 Hammersmith Broadway
11. Croydon University Hospital
(removed 16/07/2019: 12. 4-5 Burrell Street, London)
13. Northampton General Hospital
14. Ashwood Centre
15. St Peter's Health Centre
16. The Hathersage Centre
17. Sandyford Sexual Health Service
18. Royal South Hants Hospital
19. St Mary's Sexual Health Service
20. Loughborough Sexual Health (added 16/07/2019)

When is the study starting and how long is it expected to run for?
April 2016 to May 2020

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

Who is the main contact?
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Study website
http://www.lustrum.org.uk

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
38402

Study information

Scientific Title
LUSTRUM cross-over cluster randomised controlled trial of Accelerated Partner Therapy (APT) to improve partner notification outcomes for heterosexual people with sexually transmitted Chlamydia trachomatis infection

Acronym
LUSTRUM

Study objectives
Public health control of Sexually Transmitted Infections (STIs) in the community depends on reducing transmission between sexual partners. One way to do this is through partner notification (PN), the process of identifying, testing, and treating exposed sex partners of a person with an STI. Currently this involves either the patient or a clinic health adviser (HA) contacting these sex partners and advising them to attend a clinic for testing and treatment, an approach that has limited success.

The trialists have developed a new PN option for patients with chlamydia called Accelerated Partner Therapy (APT), which could be offered at sexual health clinics alongside current standard PN. APT aims to improve the uptake of treatment by sex partners, and treat them

more quickly, by providing a 'testing and treatment' pack to the sex partners, which may be delivered by the patient or by post. This pack is only provided after a HA has carried out a private telephone conversation with the sex partner to check it is medically safe for them to take the chlamydia treatment.

In small preliminary studies, APT appeared to result in faster sex partner treatment and greater numbers of sex partner treated, but this has not yet been tested in a randomised trial. This study will test the effectiveness and cost-effectiveness of APT compared with routine PN for patients with chlamydia, via:
1. A full-scale trial where 16 sexual health clinics will be randomised to either offer APT alongside standard PN or offer standard PN only
2. Economic evaluation studies to assess the cost-effectiveness of APT versus standard PN
3. Studies investigating how APT worked in practice during the trial (process evaluation), so that if APT is rolled out in the future, procedures will be optimised to meet the needs of patients and clinic staff

Ethics approval required
Old ethics approval format

Ethics approval(s)
London – Chelsea Research Ethics Committee, 23/07/2018, ref: 18/LO/0773

Study design
Randomised; Both; Design type: Treatment, Diagnosis, Process of Care, Psychological & Behavioural, Complex Intervention, Qualitative

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Chlamydia trachomatis infection

Interventions
This study has three components:
1. Cross-over cluster randomised controlled trial of Accelerated Partner Therapy (APT)
2. Cost-effectiveness sub-studies (within-trial economic evaluation and model-based economic evaluation)
3. Process evaluation sub-studies (quantitative analysis of trial data and in-depth interviews /focus group discussions with patients and clinic staff)

DEFINITION OF STAFF ROLES WITHIN THE STUDY

Sexual Health Adviser or other Healthcare Professional (HA/HCP): a member of the multi professional team in specialist sexual health services. They undertake a variety of roles including: training and education, counselling and risk reduction, and coordination of partner notification for individuals diagnosed with Sexually Transmitted Infections (STIs) and HIV.

Research Health Adviser (RHA) a clinical staff member employed by Barts Health as a Health Adviser who is working as part of the research team, responsible for patient follow-up, partner notification and providing centralised help and support for participants and staff involved in the trial.

Site Principal Investigator (Site PI): Each site (clinic) will have a senior member of clinical staff (either a doctor or a senior HA) who will oversee the study and delivery of the trial.

Chief Investigator (CI): The researcher who oversees the overall study (See section A3-1).

Research team: All named academic and trial management staff and individuals engaged in a contractual agreement with the sponsor, Central and North West London, or any of the study's collaborators who are involved in the collation and/or analysis of data.

DESIGN AND METHODOLOGY: CROSS-OVER CLUSTER RANDOMISED CONTROLLED TRIAL OF APT

Study setting

The trial will take place in 16 specialist sexual health/Genito-Urinary Medicine (GUM) services in England and Scotland with high rates of chlamydia and a mix of patient demographics. Clinics will be chosen from three groups: London, non-London metropolitan, and non-London urban areas. Two lead services will be:

1. Barts Health Sexual Health services, which serve an ethnically and socio- demographically diverse patient population of East London residents with varied healthcare needs;
2. Sandyford Sexual Health Services, which serve greater Glasgow and Clyde. Other clinics will be initially selected from other research–active services, supplemented by additional services to ensure broad geographical and demographic coverage.

The remaining 14 services will be chosen from Scotland's Sexually Transmitted Infections Surveillance System (STISS) and Public Health England's (PHE) GUM Network (GUMNet) of research-active services, enhanced by additional services to ensure broad geographical and demographic coverage. Selection will be informed by geographic and chlamydia diagnosis rates available from Genitourinary Medicine Clinic Activity Dataset (GUMCAD) (PHE's sexual health service surveillance system). This will give access to between 500 (smallest clinic) and 2000 (large urban centre clinics) cases of chlamydia per clinic per year, with a total study sample size of 5880 index patients.

Potential NHS services to be included are:

1. London: 10 Hammersmith Broadway (Chelsea & Westminster), Burrell Street (Guys & St. Thomas), Barking Havering and Redbridge (service TBC), Croydon Sexual Health Centre
2. Non-London metropolitan: Birmingham Whittall Street, Manchester Hathersage Clinic, St. Peter's Health Centre Leicester, Royal South Hants Hospital (Southampton), St Mary's Sexual Health Clinic (Portsmouth)

3. Non-London urban: Ashwood Centre for Sexual Health Kettering, Florey Unit Berkshire, Shaw Clinic High Wycombe and Brookside clinic Aylesbury, Royal Bournemouth Hospital, Brighton & Hove Sexual Health & Contraception service

N.B.

Cross-over cluster randomisation
This trial has a cross-over design. All clinics will take part in the control and the intervention phases, half the clinics will do the intervention phase first and half will do the control phase first. Before the start of the trial, clinics will be randomised to the control or intervention during phase 1 (6 months) (updated 16/07/2019, previously: 4 months). This will be followed by a washout period of 2 weeks (updated 16/07/2019, previously: 2 months) during which clinics follow standard Partner Notification (PN) practice, before clinics cross over to the opposite arm (intervention or control) for phase 2 (6 months) (updated 16/07/2019, previously: 4 months). This will allow clinics who took part in the intervention arm first to readjust to standard PN and avoid contamination between intervention and control phases. Clinics who started with the control phase will also take part in the two-week (updated 16/07/2019, previously: two-month) wash-out period to align the trial time periods. After the washout period, clinics cross over to the opposite arm (intervention or control) for phase 2 (6 months) (updated 16/07/2019, previously: 4 months) of the trial.

N.B. The control phase is standard PN (enhanced patient referral and provider referral); intervention phase is offer of APT in addition to standard patient referral.

Intervention (standard PN plus APT)
During the intervention phase, clinics will offer APT as an additional choice for patients diagnosed with chlamydia, pelvic inflammatory disease, or non-gonococcal urethritis (NGU) (see section A17-1 and A17-2) for detailed inclusion and exclusion criteria), alongside standard PN.

1. Index patient undergoes PN consultation with HA/HCP depending on clinic practice; eligibility for APT is assessed.
2. Eligible index patients who have ≥1 contactable sex partner in the last 6 months are offered APT alongside other standard PN options offered by that clinic. Note that for men with NGU or epididymo-orchitis (men), they must have ≥1 contactable sex partner(s) in the past 1 month instead of past 6 months in line with British PN standards (11). Each option is explained by HA /HCP, and the patient can choose different methods for different partners.
3. Index patient chooses APT for ≥1 sex partner and contacts sex partner (with or without HA /HCP present, according to preference) to offer immediate telephone assessment from HA/HCP. Index patient may use clinic telephone to contact sex partner if this is preferable.
4. Index patient waits in clinic while HA/HCP conducts APT telephone consultation with sex partner in private.
5. Index patient is informed about the follow-up telephone call at 2 weeks after the PN consultation and the chlamydia self-sampling postal kit to be sent 12-16 weeks after the PN consultation. They are given the option to opt-out of receiving the chlamydia self-sampling pack at this point and attend a sexual health clinic for re-testing in person instead (recommended clinical practice, which will be a requirement during the study).
6. Index patient receives follow up call from the RHA 2 weeks after PN consultation to collect clinical and PN outcomes (standard clinical practice).
7. Index patient receives a text at 12 weeks after PN consultation advising chlamydia self-sampling pack to be sent to their chosen address OR they can at this point choose to attend clinic in person for repeat testing by booking into their preferred clinic directly or provide the RHA an alternative address to which the self-sampling kit should be sent.

8. Index patient returns self-sample or attends clinic for repeat testing.
9. Index patient notified of results using routine clinic systems; positive results managed according to routine clinic protocol.

The RHAs will follow up index patients up to three times by telephone if they do not return a self-sample or attend clinic for repeat testing (this can take place up to 16 weeks after the PN consultation).

Eligible index patients who receive standard PN will receive the same follow-up contact as those who receive APT:
1. Index patient receives follow up call from the RHA 2 weeks after PN consultation to collect clinical and PN outcomes (standard clinical practice).
2. Index patient receives a text at 12 weeks after PN consultation advising chlamydia self-sampling pack to be sent to their chosen address OR they can at this point choose to attend clinic in person for repeat testing by booking into their preferred clinic directly or provide the RHA an alternative address to which self-sampling kit should be sent (see protocol, Appendix B).
3. The RHAs will follow-up index patients a maximum of three times by telephone if they do not return a self-sample or attend clinic for repeat testing (up to 16 weeks after the PN consultation).

APT and the Sex Partner
For the sex partner, the APT process is as follows:
1. Sex partner receives call from index patient to disclose chlamydial infection & offer immediate telephone assessment by a HA/HCP
2. If sex partner agrees to receive APT, sex partner receives call from a HA/HCP and has clinical assessment by telephone in private. From this point, the sex partner becomes a patient of the clinical service. If eligible, sex partner is offered APT testing and treatment pack (to be either delivered by the index patient of mailed to the sex partner directly, according to preference). If not eligible for APT or if the sex partner does not wish APT, the HA/HCP will advise the sex partner to attend clinic for further management. During the same call, sex partner is given the option to opt-in to being re-contacted about a telephone interview regarding their experiences of APT with a member of the research team.
3. Sex partner receives a text with their study number in (to be written on the STI self-sampling returned sample)
4. Sex partner receives APT pack either from index patient or via post as preferred (posted by the clinic HA), or from the trial RHAs for clinics who do not have postal testing). APT pack contains antibiotics (either azithromycin or Doxycycline, depending on clinic practice), condoms, information leaflets about chlamydia, gonorrhoea and HIV and how to take a sample, chlamydia and gonorrhoea self-sample test, HIV self-sample test, envelope for return of self-test kits, request form for the sample to be processed by the lab and APT pack packaging (coloured envelope, no branding or other identifiable markings, fits through standard letterbox).
1. Sex partner completes self-sampling kit, labels, and returns sample for testing
2. Sex partner takes antibiotic treatment immediately
3. Sex partner informed of test results by routine clinic processes & positive results managed according to routine care

If for any reason APT is not possible, standard PN will be offered instead. Such situations include:
1. If the index patient does not meet the eligibility criteria
2. If the index patient does not choose APT
3. If the sex partner does not answer their phone within an agreed timescale between the index patient and healthcare professional
4. If the sex partner declines the offer of a telephone consultation with the HA/HCP

5. If the sex partner declines the offer of the APT testing and treatment pack
6. If the sex partner has paid for or been paid for sex in the past 6 months

These inclusion/exclusion criteria for index patients and sex partners will be assessed by HA /HCP, who will be guided by the trial data collection tool, RELAY.

Control (standard PN only)
During the control phase, eligible patients will be offered standard PN for their sex partners as per usual clinic protocol. All patients will receive the same follow-up contact as during the APT phase:
1. Phone call 2 weeks after PN consultation to collect clinical and PN outcomes.
2. Text at 12 weeks after PN consultation advising chlamydia self-sampling pack to be sent to their chosen address OR they can at this point choose to attend clinic in person for repeat testing by booking into their preferred clinic directly or provide the RHA an alternative address to which the self-sampling kit should be sent (see protocol, Appendix B).
3. The RHAs will follow-up patients a maximum of three times by telephone if they do not return a self-sample or attend clinic for repeat testing (up to 16 weeks after the PN consultation).

Data collection and RELAY data collection tool
In routine clinical care, services collect PN data for clinical purposes, audit and service evaluation to a varying degree of detail [2]. Trial data will be collected using the RELAY data collection tool: a bespoke, secure web-based data collection platform. RELAY will incorporate different interfaces allowing different levels of access to HA/HCPs, RHAs, data manager, trial manager and the research team.

The HA/HCP will use the RELAY data collection tool to assess eligibility of index patients/sex partners. The HA/HCP will enter details of all eligible index patients (in both control and intervention phases, and regardless of whether patients choose APT) and of sex partners managed through APT. Clinics will transfer clinical summaries produced by RELAY for these patients into their corresponding clinic electronic patient record as an ongoing clinical record of care. Information collected via the RELAY data collection tool will be available to the RHAs, who will enter data collected from index patients at the 2-week follow-up phone calls and the chlamydia re-test at 12-16 weeks post PN consultation. Data to be collected at all stages of the trial is listed in protocol, Appendix C. The information we collect on individuals who choose not to take up APT will be compliant with CONSORT (Consolidated Standards of Reporting Trials) [3] recommendations.

The RELAY data collection tool is based on previous versions used in earlier studies of APT [4,5], ethical approval granted from Norfolk REC 06/Q0101/3 and East London REC 1, ref: 10/H0703 /83). The system will be designed and supported by Epigenesys, a specialist software development company familiar with and certificated for NHS information governance compliance.

Analysis overview
The primary outcome being measured in this trial is the effect of offering APT on the proportion of patients who test positive for chlamydia 12-16 weeks after initial diagnosis. Secondary outcomes are the effect of offering APT on the proportion of sex partners treated, and whether offering APT is associated with faster treatment compared with standard PN. These analyses will be run on the total trial sample population and also stratified by sex partner type, to determine whether the effectiveness of APT varies according to partner type. Analysis will be on an ‘intention to treat’ basis, i.e. all eligible index patients whose initial visit was during the intervention phase will be included as ‘intervention’ patients, regardless of whether they chose

APT or not. Patients who were ineligible for APT, will be excluded from the APT analyses. A detailed analysis plan can be found in section A62.

DESIGN AND METHODOLOGY: COST-EFFECTIVENESS SUB-STUDIES

Within trial health economics evaluation
This will use data collected within the trial and will be based on an outcome of cost per case of re-infection avoided. The following data will be used:
1. Length of appointment with HA/HCP
2. Cost of contents of the APT pack
3. Number of telephone contacts and calls made.
4. Information on any additional related health service use (collected during the telephone assessment).

Unit costs will be attached to each of these in order that a cost can be calculated for each trial patient.

Model based economic evaluation
A transmission dynamic model will be used to do a full economic evaluation of the intervention, taking into account the potential effect of the intervention on transmission of chlamydia, and the corresponding impact on adverse clinical outcomes, within the population if rolled out. An economic evaluation will be carried out from the perspective of the health service based on the epidemiological outputs of this transmission dynamic model.

Both economic evaluations will use data collected during the trials to inform model parameters but will not involve additional data collection from participants. Full details of both economic evaluations can be found in section A62.

DESIGN AND METHODOLOGY: PROCESS EVALUATION SUB-STUDIES
The trialists will conduct an integral process evaluation which involves four sub-studies with index patients, sex partners and HA/HCPs to understand how APT has been operationalised, offered, and viewed. These sub-studies will examine:
1. The extent and quality of intervention delivery
2. The mechanism of delivery
3. The context of the intervention
4. Patients' response to the intervention

Quantitative process evaluation data
The following routinely-collected quantitative trial data will be used in the process evaluation:
1. Number of contacts tested for STIs and HIV per index patient
2. Proportion of sex partners who return an STI self-sampling kit
3. Time from first index case attendance to partner treatment
4. Proportion adhering to advice to abstain from sex until completion of therapy by both partners.

Qualitative process evaluation data

Interviews with Index patients' and sex partners about experiences of APT (process evaluation studies 1 and 2)
Semi-structured interviews will also be conducted by telephone with index patients (n=20) and sex partners of index patients (n=20) up to 8 weeks after APT consultation. The sampling frame will reflect trial participants' characteristics such as, number of contacts tested for STIs and HIV,

time from index patient clinic attendance to partner treatment, proportion adhering to advice to abstain from sex. The sample will also ensure diverse representation. The aim of the semi-structured interviews is to understand in detail the patient experiences throughout the intervention pathway and examine patient perspectives on its effects (whether planned or unanticipated outcomes). All interviews will be audio-recorded with informed consent prior to participation, transcribed verbatim and analysed using interpretative phenomenological analysis (23). The expected duration of interviews is 30-60 minutes.

Interviews with HA/HCPs about experiences of APT (process evaluation study 3)
The trialists will conduct semi-structured interviews (either by telephone or face to face) with HA /HCPs (n=20) to supplement data generated from focus groups (see below) and to explore issues raised during the trial in more detail. Ten interviews will be conducted up to 16 weeks after the first phase of the trial for clinics who offered APT during this period. An additional 10 interviews will be undertaken up to 16 weeks after the second phase of the trial for clinics who offered APT during this period.

Interviews will be audio-recorded with informed consent prior to participation, transcribed verbatim and analysed using interpretative phenomenological analysis (23). Consent for telephone interview will be verbal, and will be audio-recorded at the start of the interview. Written consent will be obtained for face-to-face data collection (focus groups and face-to-face interviews). Data collected will assess intervention fidelity, for example cross-over effects, their APT training (the behaviour techniques they received), their APT delivery (the behaviour techniques they themselves delivered) in relation to a range of feasibility issues such as impact upon clinic flow and wider systemic and cultural issues raised within earlier phases.

Focus groups with HA/HCPs delivering APT (process evaluation study 4)
The trialists will undertake eight multi-professional focus groups drawn from the trial sites across the three strata (London, non-London metropolitan, non-London urban). Focus groups will be comprised of between three and eight professionals who have been involved in delivering the trial or who are usually involved in delivering or supporting the delivery of PN services or management of patients testing for and/or diagnosed with chlamydia. This will include HCPs, HAs, and other staff employed at the participating clinics including those who did not deliver APT.

Focus groups will take place during and after the trial to capture a range of experiences delivering APT. We will aim to conduct four focus groups with participants recruited from clinics who have delivered APT up to 16 weeks after the first trial phase and four focus groups up to 16 weeks after the second intervention phase with participants recruited from clinics who have delivered APT during the second trial phase. All potential participants will be given a participant information leaflet (either via email or a paper copy) and the researcher will discuss this information with participants before seeking informed consent to participate on the day of the focus group prior to participation. The focus group will be audio-recorded, transcribed verbatim and data will be analysed using the Framework approach.

Data collected will assess intervention fidelity, for example cross-over effects, their APT training (the behaviour techniques they received), their APT delivery (the behaviour techniques they themselves delivered) in relation to a range of feasibility issues such as impact upon clinic flow and wider systemic and cultural issues raised within earlier phases.

Recruitment process
Index patients: at the two-week telephone follow-up call the RHA will explain that the patient has the opportunity to participate in a telephone semi-structured interview with a researcher to

discuss their opinions of the APT intervention. If the patient is interested in learning more about the study, the RHA will request permission to pass on their mobile telephone number and email address to the researcher. The RELAY data collection tool will automatically email the patient the patient information leaflet containing full details of the study. If the patient does not have an email address, or if preferred, the RHA will post them a paper copy. The researcher will then contact the patient, explain about the study, check the patient has read and understood the information in the participant information leaflet and arrange a convenient time for the interview to take place

Sex partners: At the end of the APT consultation, the clinic HA/HCP will explain that the sex partner has the opportunity to participate in a telephone semi-structured interview with a researcher to discuss their opinions of the APT intervention. If the sex partner is interested in learning more about the study, the clinic health adviser/healthcare professional will request permission to pass on their mobile telephone number and / or email address to the researcher. At this point the RELAY data collection tool will automatically send the patient a link to the online patient information leaflet for information about the study. The researcher will then contact the sex partner, explain about the study, check they have read and understood the information in the participant information leaflet and arrange a convenient time for the interview to take place. Researchers will seek verbal informed consent before commencing the interview. The expected duration of interviews is 30-60 minutes.

HA/HCPs: Purposive and convenience sampling will be used to recruit HA/HCPs. Through regular clinic meetings and/or through the site PI, staff will be invited to take part in a process evaluation interview and/or focus group. During regular clinic meetings, the site PI will share details of the process evaluation and provide colleagues with an email address for the research team - so that interested staff members can contact the research team directly. The site PI will also be asked to provide contact details (first name, surname and work email address) for staff who have been involved in delivering the trial or who are usually involved in delivering or supporting the delivery of PN services or management of patients testing for and/or diagnosed with chlamydia.

Intervention Type
Other

Primary outcome measure
The primary biological outcome (the proportion of index patients positive for chlamydia 12-16 weeks after diagnosis) is a proxy for re-infection. This will be ascertained from the results of the follow-up chlamydia test at 12-16 weeks.

Secondary outcome measures
1. The key secondary outcome is the proportion of sex partners treated two weeks after the initial diagnosis. This will be ascertained by index patient reports at the 2-week follow-up phone call with the research health adviser
2. Patient acceptability, measured using process evaluation telephone interviews within 8 weeks of APT consultation
3. Number of partners treated per index patient, measured by telephone call with research health adviser at 2-week follow-up
3. Time to achieve partner treatment, measured by telephone call with research health adviser at 2-week follow-up
4. Number of partners notified per index patient, measured by telephone call with research health adviser at 2-week follow-up

5. STI and HIV testing in sex partners, measured by return of postal self-samples from test kits in APT pack
6. Sex partner positivity for STIs and HIV, measured by return of postal self-samples from test kits in APT pack
7. Adverse events, measured using local activity logs in each clinic
8. Costs associated with the intervention, measured by economic evaluation studies based on costings of trial

Overall study start date
01/04/2016

Completion date
02/05/2020

Eligibility

Key inclusion criteria
INDEX PATIENT INCLUSION CRITERIA
1. 16 years or older
2. Have tested positive for c. Trachomatis (Chlamydia) during the study period
3. Who had at least one sexual partner in the past 6 months (apart from men with non-gonococcal urethritis (NGU) or epididymo-orchitis (men) where the look-back period is 1 month)

Patients diagnosed with pelvic inflammatory disease (PID) or cervicitis (women) or non-NGU (men) on the day of first clinic attendance will also be eligible, as these patients will routinely be given treatment for chlamydia before definitive diagnostic test results are available.

Please note:
Re. PID & cervicitis: Chlamydia is a common cause of PID and cervicitis and it is routine practice to treat women with either condition as “presumptive chlamydia” until test results are known.

Re. NGU or epididymo-orchitis (men): urethritis (penile discharge and pain of passing urine) is a common presentation of chlamydia in men. Routinely men with urethritis will be microscopy of a urethral specimen performed at the initial clinic visit. If this does not show appearances suggestive of gonorrhoea, the man will be treated for “presumptive chlamydia at least until tests are known.

SEX PARTNER INCLUSION CRITERIA
Sex partners within the past 6 months who are selected by the index patient for APT will be eligible

STAFF INCLUSION CRITERIA
1. Involvement or role in delivering the LUSTRUM Chlamydia PN trial OR
2. Involvement or role in delivering or supporting the delivery of PN services OR
3. Involvement or role in the management of patients testing for and/or diagnosed with chlamydia

Participant type(s)
Mixed

Age group

Adult

Sex
Both

Target number of participants
Planned Sample Size: 5440; UK Sample Size: 5440

Total final enrolment
3639

Key exclusion criteria
INDEX PATIENT EXCLUSION CRITERIA
1. Patients aged under 16 years
2. Patients co-infected with other Sexually Transmitted Infections (STIs) including HIV, as these patients have Partner Notification (PN) requirements that will not be best met by Accelerated Partner Therapy (APT)
3. Men who had sex with one or more men in the past 6 months, as the epidemiology of STIs and HIV in this population is more complex and this form of APT may not be an appropriate intervention to meet all of their health needs
4. Any other clinical, social, or other circumstances which emerge during the consultation which mean that APT may not be suitable. This will include those whose diagnosis was the result of sexual assault
5. Patients who have paid for or who have been paid for sex in the past 6 months

SEX PARTNER EXCLUSION CRITERIA
1. Those aged under 16 years
2. Men who had sex with a man in the past 6 months
3. Those with insufficient English language competence to engage in a telephone consultation safely with adequate understanding.
4. Women who are pregnant
5. Women with symptoms of pelvic infection
6. Men with symptoms of testicular involvement
7. Men and women with likely-chlamydia-related extra-genital symptoms
8. Those with allergy or contraindications to azithromycin or doxycycline (first-line treatments for chlamydia)
9. Those with co-existent infection with T. pallidum and/or HIV as these cases require different investigation and management.
10. Any other extenuating circumstances which emerge during the consultation which mean that APT may not be suitable, including those who report sexual assault by the index patient or those reporting inter-partner violence
11. Patients who have paid for or who have been paid for sex in the past 6 months

These exclusion criteria will be assessed by the Health Adviser/Healthcare Professional during the telephone consultation, guided by the RELAY data collection tool.

Date of first enrolment
01/10/2018

Date of final enrolment
17/11/2019

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
Barking Community Hospital
Outpatients East
Upney Lane
Barking
United Kingdom
IG11 9LX

Study participating centre
Ambrose King Centre
Royal London Hospital
London
United Kingdom
E1 1BB

Study participating centre
Sir Ludwig Guttmann Health and Wellbeing Centre
Olympic Park
40 Liberty Bridge Rd
East Village
London
United Kingdom
E20 1AS

Study participating centre
Florey Unit
21A Craven Rd
Reading
United Kingdom
RG1 5LE

Study participating centre

Whittall Street Clinic
Umbrella Sexual Health Services
University Hospitals Birmingham NHS Foundation Trust
Whittall Street
Birmingham
United Kingdom
B4 6DH

Study participating centre
Department of Sexual Health
Royal Bournemouth Hospital
Castle Lane East
Bournemouth
United Kingdom
BH7 7DW

Study participating centre
Brookside Sexual Health Clinic
Station Way
Aylesbury
United Kingdom
HP20 2SR

Study participating centre
Shaw Clinic
Queen Alexandra Rd
High Wycombe
United Kingdom
HP11 2T

Study participating centre
10 Hammersmith Broadway
London
United Kingdom
W6 7AL

Study participating centre
Sexual Health Centre (GUM),
Croydon University Hospital
530 London Road
Croydon

United Kingdom
CR7 7YE

Study participating centre
Sexual Health Department
Northampton General Hospital
Area R
Cliftonville
Northampton
United Kingdom
NN1 5BD

Study participating centre
Ashwood Centre
St Mary's Hospital
Kettering
United Kingdom
NN15 7PW

Study participating centre
Haymarket Health
1st Floor
Haymarket Shopping Centre
Leicester
United Kingdom
LE1 3YT

Study participating centre
The Hathersage Centre
280 Upper Brook Street
Manchester
United Kingdom
M13 0FH

Study participating centre
Sandyford Sexual Health Service
2-6 Sandyford Place
Glasgow
United Kingdom
G3 7NB

Study participating centre
Dept of Sexual Health
Level B
Royal South Hants Hospital
Brintons Terrace
Southampton
United Kingdom
SO14 0YG

Study participating centre
St Mary's Sexual Health Service
2nd Floor
St Mary's Hospital
Milton Rd
Portsmouth
United Kingdom
PO3 6AD

Study participating centre
Loughborough Sexual Health
Pinfold Gate
Loughborough
United Kingdom
LE11 1DQ

Sponsor information

Organisation
Central and North West London NHS Foundation Trust

Sponsor details
Stephenson House
75 Hampstead Road
London
England
United Kingdom
NW1 2PL
+44 (0)20 3317 3535
sponsor.noclor@nhs.net

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05drfg619

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: RP-PG-0614-20009

Results and Publications

Publication and dissemination plan
Planned publication in high-impact peer reviewed journals. A lay protocol will be available on the study website (https://www.lustrum.org.uk/)

Intention to publish date
31/03/2022

Individual participant data (IPD) sharing plan
The researchers will be storing the final analysis ready blinded fully anonymised dataset with imputations in the UCL research data repository: https://www.ucl.ac.uk/library/research-support/research-data-management/ucl-research-data-repository. This will be available from 31/03/2021 or earlier if required by the journal where the main trial results will be published. The data is stored and remains available under the terms and conditions of the repository. A data search and access request can be made via the repository. The researchers will also upload the data dictionary and short meta summary of the intended purposes the data were collected for. Service level consent was obtained from all participating sites in the trial and patients could opt out of their data being used for research purposes in accordance to GDPR regulations.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V2.1	22/06/2018	04/09/2018	No	Yes
Participant information sheet	version V2.1	22/06/2018	04/09/2018	No	Yes
Participant information sheet	version V2.1	22/06/2018	04/09/2018	No	Yes
Protocol article	protocol	29/03/2020	02/04/2020	Yes	No
Results article		01/10/2022	03/10/2022	Yes	No

HRA research summary	28/06/2023	No	No