

# Does Accelerated Partner Therapy" ( two new models of care which emphasise rapid treatment and which will be different from traditional clinic-based methods) reduce delays in the assessment and treatment of sexual partners of people with bacterial sexually transmitted infections

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<b>Registration date</b> 30/07/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 14/01/2016	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Rates of sexually transmitted infections (STIs) in the UK continue to rise each year. Successful control of STIs relies on reducing the spread of infection in the community. One way of doing this is to cut down the length of time an individual carries the infection before seeking treatment. Partner notification (PN) aims to do this by informing the infected person's sexual partners of the possibility of exposure, offering diagnosis and treatment, and providing advice about preventing future infection. However, the effectiveness of PN as it is currently practised in the UK is doubtful, and many sexual health/Genito Urinary Medicine (GUM) clinics struggle to reach national targets. We do not know the best ways of carrying out PN. The current system relies on the infected person informing their partners and advising them to attend a sexual health clinic or their GP for testing and treatment. This is known as patient referral. However, many sexual contacts are reluctant to come forward and new methods need to be tested. We believe that new methods of PN, which include assessment of the sexual partner by a healthcare professional but do not require clinic attendance, will be key to improving PN in the UK. We call these methods Accelerated Partner Therapy (APT). The aim of this study is to determine the acceptability and feasibility of two new models of APT for STI patients in UK clinics. We will also obtain evidence of the effectiveness of APT as compared with routine PN practice and find out for whom APT is best suited.

### Who can participate?

Patients who are 16 and older and have tested positive for Chlamydia and/or Gonorrhoea (men and women), and men who have been diagnosed with non-gonococcal urethritis, and have at least one contactable partner.

### What does the study involve?

Sexual health advisers in the participating clinics offer eligible patients a choice of three PN strategies:

1. APT Hotline (patient's sex partner calls the APT hotline for a telephone consultation with a clinic health adviser/nurse practitioner)
2. APT Pharmacy (patient's sex partner attends pharmacy for consultation)
3. Standard PN using patient referral (patient advises their sex partner to attend a sexual health clinic or their GP)

We then compare the outcomes for the APT interventions with standard PN. It is important to give the patient a choice because APT may be more effective if offered as part of a 'menu' of PN options, and so we can determine for whom APT is best suited. If APT is successful, it would also be offered as a choice alongside patient referral. Patients who test positive for Gonorrhoea are given antibiotics. Treatment packs include information sheets on the relevant antibiotics, including drug interactions and possible side effects. A study hotline number is also prominently displayed in each pack, which patients can use to obtain advice or support.

### What are the possible benefits and risks of participating?

If the approach we propose is successful, it could enhance the provision of care to partners of patients with STIs, particularly those less likely to access existing services. The net result would be a decrease in STIs in the community and fewer re-infections. Together this would reduce the complications of STIs, such as infertility and pelvic inflammatory disease and their costly health consequences.

### Where is the study run from?

Barts Sexual Health Centre in London and The Milne Centre in Bristol (UK).

### When is the study starting and how long is it expected to run for?

November 2007 to July 2008

### Who is funding the study?

Medical Research Council (MRC) (UK)

### Who is the main contact?

Dr Lorna Sutcliffe (L.j.sutcliffe@qmul.ac.uk)

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## Contact information

### Type(s)

Scientific

### Contact name

Dr Lorna Sutcliffe

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## Additional identifiers

### Protocol serial number

2564

## Study information

### Scientific Title

Can Accelerated Partner Therapy (APT) improve outcomes of partner notification? A feasibility study and exploratory trial

### Acronym

APT

### Study objectives

We propose to develop two models of Accelerated partner Therapy (APT) and then to determine acceptability and feasibility of these two models of APT for index patients with chlamydia and /or gonorrhoea and/or non gonococcal urethritis in the UK clinics and obtain preliminary data on effectiveness of APT as compared with routine PN.

#### Specific objectives:

1. To develop through qualitative research, consumer and stakeholder consultation, a feasible, replicable intervention for delivering APT in UK GUM clinics
2. To determine the acceptability and feasibility of APT to clinic attenders, their sexual contacts and staff
3. To obtain preliminary evidence of effectiveness of APT compared with routine PN by undertaking an exploratory trial in two contrasting GUM services
4. To obtain cost data for APT strategies to use in preliminary economic evaluation based on restricted outcomes such as cost per partner treated
5. To develop a protocol for a formal randomised controlled trial (RCT) comparing the outcomes of APT with standard PN.

Interventions that involve changing health services are complex, so detailed development work is needed to define appropriate study areas, study populations and potential interventions. This project comprises the first three stages of the UK Medical Research Council (MRC) Framework for Development of

Randomised Controlled trials for Complex Interventions to Improve Health. The project will take place in two contrasting areas in England; Bristol, in the South West, which includes both rural and urban areas, and in inner city London.

More details can be found at <http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=2564>

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

East London Research Ethics Committee 1, 26/11/2010, ref: 06/Q0101/3

### **Study design**

Non-randomised; Interventional; Design type: Treatment

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Topic: Infection; Subtopic: Infection (all Subtopics); Disease: Infectious diseases and microbiology

### **Interventions**

APT Hotline: Index diagnosed, treated & given APT PIN

1. Sex partner calls APT hotline for telephone consultation with clinic Health adviser/Nurse practitioner
2. Index takes or Sex partner collects APT Pack from clinic reception
3. Sex partner attends clinic for Human immunodeficiency virus (HIV) & test at later stage
4. Index & contact follow up call

APT Pharmacy, Index diagnosed, treated & given APT PIN

1. Sex partner attends pharmacy for consultation: trained pharmacist under Patient Group Directions (PGD) gives APT Pack
2. Sex partner attends clinic for HIV test at later stage
3. Index & contact follow up call

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome(s)**

Proportion of index patients having at least one partner treated 4-6 weeks after initial diagnosis

### **Key secondary outcome(s)**

1. Proportion of regular partners treated
2. Number of contacts treated per index patient

**Completion date**

01/07/2008

## Eligibility

**Key inclusion criteria**

1. Index patients who are 16 years and older
2. Have tested positive for Chlamydia and/or Gonorrhoea (men and women)
3. Men who have been diagnosed with non-gonococcal urethritis (NGU) and have at least one contactable partner

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

16 years

**Sex**

All

**Key exclusion criteria**

Will be determined by a suitably qualified health professional are:

1. Pregnancy
2. Symptoms of complicated infection, allergy or contraindications to Azithromycin and or Cefixime
3. Inability to read English
4. An inability to understand instructions and give consent
5. Co-existent infection with syphilis and/or HIV as these cases require different investigation and management

**Date of first enrolment**

01/11/2007

**Date of final enrolment**

01/07/2008

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**  
**St Bartholomew's Hospital**  
London  
United Kingdom  
EC1A 7BE

## **Sponsor information**

### **Organisation**

Barts and The London Trust (UK)

### **ROR**

<https://ror.org/00b31g692>

## **Funder(s)**

### **Funder type**

Research council

### **Funder Name**

Medical Research Council (MRC) (UK)

### **Alternative Name(s)**

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

### **Funding Body Type**

Government organisation

### **Funding Body Subtype**

National government

### **Location**

United Kingdom

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/02/2012		Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes