

# Randomised controlled evaluation of the effectiveness of behavioural intervention in high risk gay men attending an sexually transmitted disease (STD) clinic

<b>Submission date</b> 23/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 08/12/2008	<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

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

RDC00058

## **Study information**

**Scientific Title**

### **Study objectives**

Despite clear evidence that gay men are at increased risk of HIV infection, there has been little rigorous evaluation of the effectiveness of behavioural intervention in reducing sexual risk behaviour in the group. We propose a randomised control trial (RCT) to examine the effectiveness of group work in promoting safer sex in gay men who have high risk sexual lifestyles, since they are at a high risk of transmitting and acquiring the HIV infection. Building on experience in this department, the feasibility of various forms of group intervention will be investigated during a pilot survey of gay men attending an STD clinic. In the subsequent RCT, high risk gay men will be randomly assigned to either the intervention under evaluation, or to standard management as currently provided in the clinic.

### **Ethics approval required**

Old ethics approval format

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

Not provided at time of registration

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Not specified

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

Not Specified

### **Participant information sheet**

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

Infection and infestations: Sexually transmitted diseases

### **Interventions**

One day 'safe' sex workshop vs standard management

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

Outcome measures will focus on the nature, as well as the number of sexual partnerships and the type of sexual practices within those relationships. STD rates will be a further outcome measure. Differences in outcome will be compared between intervention and control groups at 6 and 12 months after intervention.

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/05/1995

**Completion date**

01/07/2000

**Eligibility****Key inclusion criteria**

All participants will be gay men attending an STD clinic. In order to recruit gay men at high risk of human immunodeficiency virus (HIV) infection, those who present with an acute STD or who indicate that they are having unprotected anal sex will be invited to enter the trial (except those in stable monogamous relationships where both partners repeatedly test negative). Estimated sample size will be around 145 men in each group of the study.

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Male

**Target number of participants**

290

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/05/1995

**Date of final enrolment**

01/07/2000

# Locations

## Countries of recruitment

England

United Kingdom

## Study participating centre

**Department of Genitourinary Medicine**

London

United Kingdom

WC1 6AU

# Sponsor information

## Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

## Sponsor details

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

## Sponsor type

Government

## Website

<http://www.doh.gov.uk>

# Funder(s)

## Funder type

Government

## Funder Name

NHS Executive London (UK)

# Results and Publications

Publication and dissemination plan  
Not provided at time of registration

Intention to publish date

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	16/06/2001		Yes	No