

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

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

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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?
Results article	results	16/06/2001		Yes	No