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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

Registration date
23/01/2004

Last Edited
08/12/2008

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Protocol serial number
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

Study type(s)
Not Specified

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(s)
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.

Key secondary outcome(s))

Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Male

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
United Kingdom

England

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)

Funder(s)

Funder type
Government

Funder Name
NHS Executive London (UK)

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?
Results article	results	16/06/2001		Yes	No