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Urban community randomised trial for prevention of sexually transmitted diseases

Submission date	Recruitment status	[_] Prospectively registered
22/07/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/07/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/02/2015	Urological and Genital Diseases	

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
059131

Study information

Scientific Title
An urban community randomised trial of a multicomponent intervention for the prevention of sexually transmitted disease in female sex workers and the general population

Acronym
PREVEN

Study objectives
We aim to:
1. Determine the impact of a hybrid intervention on:
1.1. Prevalence of gonococcal, chlamydial, and trichomonal infection and syphilis seroreactivity in high-risk Female Sex Workers (FSW), bridging groups of clients of FSW, and the lower-risk young adult general population
1.2. The antimicrobial susceptibility and virulence-associated phenotypes of N. gonorrhoeae
2. Develop and employ mathematical models of gonorrhoea, chlamydial infection, syphilis and trichomoniasis to explain the observed impact of the interventions, and facilitate transfer of the intervention to other locations

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Universidad Peruana Cayetano Heredia, 07/12/1999, ref: #99084
2. University of Washington, 25/07/2000, ref: #99-2288
3. Naval Medical Research Center Detachment, 19/09/2002, ref: DOD#31556

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Sexually transmitted disease prevention

Interventions
Using data from a baseline survey in 24 Peruvian cities with populations more than 50,000, 20 cities were selected for the trial and placed into matched pairs based on region (coastal, jungle or Andean), size and STD prevalence. The pairs were then randomised into control or intervention groups, with the latter receiving a two-year hybrid intervention of:
1. Strengthened syndromic management through a network of physicians and pharmacists
2. STD screening and treatment of FSW
3. Social marketing of condoms

At the end of the two-year intervention, FSW and the young adult general population in all 20 cities will be surveyed again to evaluate its impact.

The anticipated end date of this trial has been extended to the 31st December 2006. The previous anticipated end date was 31/12/2005.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Gonorrhoea, chlamydia, trichomonas, bacterial vaginosis, syphilis and human immunodeficiency virus (HIV) infection
2. Demographic and behavioural information regarding sexual history and risk behaviours

Key secondary outcome(s)
No secondary outcome measures

Completion date
31/12/2006

Eligibility

Key inclusion criteria
1. General population survey: one adult per household ages 18 to 29 years, either sex
2. FSW: willing to participate
3. Clients of FSW: sex with a commercial sex worker

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. General population survey: over 29 years old
2. All surveys: under 18 years old

Date of first enrolment
24/08/2002

Date of final enrolment
31/12/2006

Locations

Countries of recruitment

Peru

United States of America

Study participating centre
University of Washington
Seattle, WA
United States of America
98104

Sponsor information

Organisation
University of Washington (USA)

ROR
https://ror.org/00cvxb145

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

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?
Results article	results	24/03/2012		Yes	No
Results article	results	01/10/2012		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes