ISRCTN44114250 https://doi.org/10.1186/ISRCTN44114250

Intensified primary health care at the workplace: investigating the impact on human immunodeficiency virus associated morbidity and tuberculosis epidemiology

Submission date	Recruitment status	[_] Prospectively registered
14/10/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/10/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/02/2015	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr E Corbett

Contact details
London School of Hygiene and Tropical Medicine
Department of Infectious and Tropical Diseases
Keppel Street
London
United Kingdom
WC1E 7HT
+44 (0)20 7927 2116
elizabeth.corbett@lshtm.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
060983 LSHTM ITCR BA59

Study information

Scientific Title
Intensified primary health care at the workplace: investigating the impact on human immunodeficiency virus associated morbidity and tuberculosis epidemiology

Study objectives
1. To compare the acceptability of two Voluntary Counselling and Testing (VCT) strategies at the workplace
2. To test whether on-site availability of VCT linked to intensified primary health care at the workplace reduces HUman Immunodeficiency Virus (HIV)-associated morbidity, and if so, to an extent that is cost effective for businesses in high HIV prevalence areas

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)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Human immunodeficiency virus

Interventions
Cluster-randomised trial of Small and Medium size Enterprises (SMEs) in Zimbabwe.
Randomisation unit: each participating business site
Number of sites: 22

The randomisation was to provide Voluntary Counselling and Testing (VCT) through either:
1. On-site rapid HIV testing at occupational clinics
2. Use of free vouchers to an off-site testing centre

Open cohort, with active recruitment of all eligible new employees until the end of follow-up
Stratified randomisation according to pre-intervention absenteeism rates (low/medium/high).

The trial will provide the framework for an observational study of Tuberculosis (TB) epidemiology (impact of HIV on incidence, prevalence and duration of TB disease before diagnosis).

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Proportion of workers accepting VCT
2. Incidence rates of severe morbidity (composite: death, medical retirement, hospitalisation, TB, illness requiring five days or more off work) according to the VCT strategy allocated

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/09/2001

Completion date
01/07/2005

Eligibility

Key inclusion criteria
Site:
1. Has HIV prevention policy in place
2. Willing to supply access to workforce and to absenteeism data
3. Agreement of Workers Committee

Individuals within sites:
1. Based at the study site (not alternative workplace)
2. On a contract of six months or longer

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
6440

Key exclusion criteria
Individual:
1. Declined consent to participate
2. Sub-contracted or casual contract employee

Date of first enrolment
01/09/2001

Date of final enrolment
01/07/2004

Locations

Countries of recruitment
England

United Kingdom

Zimbabwe

Study participating centre
London School of Hygiene and Tropical Medicine
London
United Kingdom
WC1E 7HT

Sponsor information

Organisation
London School of Hygiene and Tropical Medicine (UK)

Sponsor details
Keppel Street
London
England
United Kingdom
WC1E 7HT
+44 (0)20 7636 8636
Penny.Ireland@lshtm.ac.uk

Sponsor type
University/education

Website
http://www.lshtm.ac.uk/

ROR
https://ror.org/00a0jsq62

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

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?
Abstract results		01/01/2007		No	No