

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

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<b>Registration date</b> 14/10/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
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		<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

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**

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+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?
<a href="#">Abstract results</a>		01/01/2007		No	No