

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

Submission date 14/10/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 14/10/2005	Overall study status Completed	☐ Protocol
Last Edited 06/02/2015	Condition category Infections and Infestations	☐ Statistical analysis plan
		☒ Results
		☐ 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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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

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)

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

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