# Pragmatic Cluster Randomised Controlled Trial of the Practical Approach to Lung Health and Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS) in South Africa (PALSA PLUS) Educational Outreach Intervention

Submission date	<b>Recruitment status</b> No longer recruiting	Prospectively registered		
09/09/2005		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
10/02/2006	Completed	[X] Results		
<b>Last Edited</b> 27/04/2011	Condition category Infections and Infestations	[] Individual participant data		

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Lara Fairall

#### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

#### IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers** N/A

# Study information

Scientific Title

#### **Acronym**

**PALSA PLUS** 

#### **Study objectives**

Educational outreach, based on symptom and sign-based guidelines, improves the quality of respiratory and HIV/AIDS primary care in comparison with usual training.

PALSA PLUS Western Cape trial: This is an offshoot of the primary PALSA PLUS trial that will be taking place in the Western Cape province of South Africa. The hypothesis is the same as for the intial PALSA PLUS trial, but will also include the following hypotheses:

1. Educational outreach, based on symptom and sign-based guidelines, improves the quality of Tuberculosis (TB) respiratory illness and Sexually Transmitted Infections (STI) in comparison with usual training.

Any other differences can be seen under the heading PALSA PLUS Western Cape trial. This trial took place between the dates of 06/03/2006 and 15/10/2007.

# 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)

Hospital

#### Study type(s)

Treatment

#### Participant information sheet

#### Health condition(s) or problem(s) studied

HIV/AIDS, Tuberculosis (TB), and STIs.

#### **Interventions**

The trial is comparing educational outreach (based on guidelines) to passive dissemination of these guidelines to all nurses in control clinics combined with traditional off-site didactic training of selected nurse practitioners working directly in the ARV programme (i.e. usual training).

#### Intervention Type

Other

#### **Phase**

**Not Specified** 

#### Primary outcome measure

- 1. TB case detection
- 2. Voluntary counselling and testing uptake
- 3. Cotrimoxazole prophylaxis provision

#### Secondary outcome measures

- 1. TB screening (sputum sampling)
- 2. Proportion of ART patients with undetectable viral loads at 6,12 and 18 months
- 3. Health-related quality of life
- 4. Hospitalisation
- 5. Mortality
- 6. Antiretroviral treatment interruptions

#### Overall study start date

01/08/2004

#### Completion date

01/08/2006

# **Eligibility**

#### Key inclusion criteria

Clusters: primary care clinics participating in the first phases of the rollout of the national AntiRetroviral Treatment (ART) programme in the Free State province, South Africa Patients: All patients enrolled in the national ART programme at these clinics

#### PALSA PLUS Western Cape trial:

In addition to the above inclusion criteria, the PALSA PLUS Western Cape trial will also include primary care facilities where care for HIV and TB is provided.

Patients: all patients 15 years or older attending these facilities for the trial duration (36 weeks).

# Participant type(s)

Patient

#### Age group

Adult

#### Sex

Both

# Target number of participants

15 clinics (PALSA PLUS) and 45 clinics (PALSA PLUS Western Cape)

#### Key exclusion criteria

None

#### Date of first enrolment

01/08/2004

#### Date of final enrolment

01/08/2006

# Locations

#### Countries of recruitment

South Africa

# Study participating centre University of Cape Town Lung Institute

Cape Town South Africa 7937

# Sponsor information

#### Organisation

University of Cape Town Lung Institute (South Africa)

#### Sponsor details

University of Cape Town Lung Institute PO Box 34560 Groote Schuur Cape Town South Africa 7937 +27 21 4066919 Ifairall@uctgsh1.uct.ac.za

#### Sponsor type

University/education

#### ROR

https://ror.org/03p74gp79

# Funder(s)

## Funder type

Charity

#### Funder Name

International Development Research Centre Canada (Grant no: 102770-001)

# **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?
Results article	results	21/04/2011		Yes	No