

# 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

<b>Submission date</b> 09/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 10/02/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 27/04/2011	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<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

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## Additional identifiers

**Protocol serial number**

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 initial 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

### Study type(s)

Treatment

### 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(s)**

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

**Key secondary outcome(s))**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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)

### ROR

<https://ror.org/03p74gp79>

## Funder(s)

### Funder type

Charity

### Funder Name

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

## 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				

[Results article](#)

21/04/2011

Yes

No