

# A pragmatic cluster randomised controlled trial of a guideline-based educational outreach intervention to improve quality of adult respiratory care in South African primary care clinics: the PALSA (Practical Approach to Lung Health in South Africa) trial

<b>Submission date</b> 03/05/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 22/08/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 20/12/2007	<b>Condition category</b> Respiratory	<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

# Study information

## Scientific Title

## Acronym

PALSA (Practical Approach to Lung Health in South Africa)

## Study objectives

The trial was undertaken to test whether PALSA improves the quality of respiratory care for patients with cough and/or difficult breathing in real world primary care clinics.

Priority respiratory diseases among adults attending primary care services, including tuberculosis (TB), lower and upper respiratory tract infections, obstructive lung disease (asthma and chronic obstructive pulmonary disease), and human immunodeficiency virus (HIV) co-infection.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Added as of 13/08/2007: The study was approved by the research ethics committee of the Faculty of Health Sciences, University of the Free State. The Free State Department of Health gave permission for the trial.

## Study design

Randomised controlled trial.

## Primary study design

Interventional

## Study type(s)

Treatment

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

Respiratory diseases

## Interventions

Educational outreach to groups of intervention clinic nurse practitioners, based on a clinical practice guideline on integrated adult respiratory case management and delivered with accompanying support materials.

Prescribing provisions for intervention clinic nurse practitioners will be expanded to include cotrimoxazole prophylaxis for symptomatic HIV infection, inhaled steroids for asthma (with review by a physician within one month) and a short course of oral corticosteroids for exacerbations of obstructive lung disease.

Control clinic nurse practitioners will receive no new training. Usual training, received by both intervention and control groups, includes short off-site training on the use of essential drugs including asthma medications and antibiotics, and the national TB protocol. Due to staff and budget restrictions, fewer than 5% of staff in any year attend these courses.

### **Intervention Type**

Drug

### **Phase**

Not Specified

### **Drug/device/biological/vaccine name(s)**

Inhaled corticosteroids, antibiotics, cotrimoxazole

### **Primary outcome(s)**

1. Sputum testing for tuberculosis
2. Inhaled corticosteroid prescriptions
3. Antibiotic prescriptions
4. Cotrimoxazole prescription among patients with tuberculosis

### **Key secondary outcome(s)**

1. TB case detection
2. Mortality
3. Smoking cessation advice received
4. Smoking cessation
5. Readiness to quit smoking
6. Frequency and severity of respiratory symptoms
7. Health-related quality of life (Euroqol)
8. Health care utilisation
9. Cost of care

### **Completion date**

29/11/2003

## **Eligibility**

### **Key inclusion criteria**

Forty primary care clinics in a high tuberculosis and HIV burden province of South Africa (Free State). Data will be collected from patients 15 years and older who provide written consent and who present with any one of the following:

1. Difficult breathing on the day of interview or during the last 6 months
2. Current cough for 7 days or more
3. Recurrent cough in the last 6 months
4. Current cough and a temperature in excess of 38°C and/or a respiratory rate of 30 breaths per minute or more

### **Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

Patients referred elsewhere urgently by their nurse practitioner will be excluded.

**Date of first enrolment**

08/04/2003

**Date of final enrolment**

29/11/2003

**Locations****Countries of recruitment**

Canada

South Africa

**Study participating centre****Institute for Clinical Evaluative Sciences**

Toronto

Canada

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**Sponsor information****Organisation**

University of Cape Town Lung Institute (South Africa)

**ROR**

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

**Funder(s)****Funder type**

Research organisation

**Funder Name**

International Development Research Centre (Canada) (IDRC File No. 101489)

**Alternative Name(s)**

Centre de recherches pour le développement international, IDRC.CRDI, le Centre de recherches pour le développement international (CRDI), el Centro Internacional de Investigaciones para el Desarrollo (IDRC), International Development Research Centre: IDRC, El Centro Internacional de Investigaciones para el Desarrollo, IDRC, CRDI

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Canada

**Funder Name**

Free State Department of Health (South Africa)

**Funder Name**

Medical Research Council (South Africa)

**Alternative Name(s)**

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

**Funder Name**

University of Cape Town Lung Institute (South Africa)

## Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	Results	01/10/2005		Yes	No