

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

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

Protocol serial number

N/A

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

M4N 3M5

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?
Results article	Results	01/10/2005		Yes	No