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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

Registration date
22/08/2005

Overall study status
Completed

Last Edited
20/12/2007

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Merrick Zwarenstein

Contact details
Institute for Clinical Evaluative Sciences
G1 06
2075 Bayview Ave
Toronto
Canada
M4N 3M5
+1 416 4804055 ext. 7439
merrick.zwarenstein@ices.on.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
08/04/2003

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

Age group
Adult

Sex
Both

Target number of participants
40 primary care clinics, 1999 patients

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)

Sponsor details
P.O. Box 34560
Groote Schuur
Cape Town
South Africa
7937

Sponsor type
University/education

Website
http://www.lunginstitute.co.za/

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

Funding Body Type
Government organisation

Funding Body Subtype
Local 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, 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

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	01/10/2005		Yes	No