

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 09/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 10/02/2006	Overall study status Completed	☐ Protocol
Last Edited 27/04/2011	Condition category Infections and Infestations	☐ Statistical analysis plan
		☒ Results
		☐ 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 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

Primary study design

Interventional

Study design

Randomised controlled trial

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

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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 article	results	21/04/2011		Yes	No