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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

Registration date
10/02/2006

Overall study status
Completed

Last Edited
27/04/2011

Condition category
Infections and Infestations

[_] 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 Lara Fairall

Contact details
University of Cape Town Lung Institute
PO Box 34560
Groote Schuur
Cape Town
South Africa
7937
+27 21 4066919
lfairall@uctgsh1.uct.ac.za

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 intial 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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
01/08/2004

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

Age group
Adult

Sex
Both

Target number of participants
15 clinics (PALSA PLUS) and 45 clinics (PALSA PLUS Western Cape)

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)

Sponsor details
University of Cape Town Lung Institute
PO Box 34560
Groote Schuur
Cape Town
South Africa
7937
+27 21 4066919
lfairall@uctgsh1.uct.ac.za

Sponsor type

University/education

ROR
https://ror.org/03p74gp79

Funder(s)

Funder type
Charity

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

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	21/04/2011		Yes	No