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# A cluster randomised controlled trial of an educational and organisational intervention to expand antiretroviral treatment access in public-sector primary care clinics in South Africa: the STRETCH (Streamlining Tasks and Roles to Expand Treatment and Care for HIV) trial

**Submission date**
26/04/2007

**Recruitment status**
No longer recruiting

**Registration date**
07/08/2007

**Overall study status**
Completed

**Last Edited**
21/01/2013

**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

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## Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
N/A

# Study information

### Scientific Title

### Acronym
STRETCH

### Study objectives
That the decentralisation of antiretroviral treatment services from doctors at hospitals to nurses at clinics, supported by appropriate training and supervision, expands treatment access, reducing mortality among enrolled patients waiting for HAART (Highly Active AntiRetroviral Treatment), without compromising HAART treatment outcomes.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
1. Ethics Committee of the Faculty of Health Sciences, University of the Free State (South Africa) (ref: ETOVS NR 75/07)
2. Ethics Committee of the Faculty of Health Sciences, University of Cape Town (South Africa), approval pending as of 16/07/2007

### Study design
Pragmatic, two-arm, cluster randomised controlled trial.

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Treatment

### Participant information sheet

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

HIV/ AIDS

## Interventions
Complex health systems intervention comprising:
1. Clinical algorithm to triage AntiRetroViral (ARV) patients for nurse- or doctor-managed care
2. Educational outreach training to nurses
3. Expanded prescribing provisions to permit trained nurse practitioners to prescribe ARVs
4. Re-defining roles of clinical staff:
4.1. Generalist nurses: pre-ARV HIV care
4.2. ARV nurses: monitoring of stable ARV patients, ARV initiation in selected adults
4.3. ARV doctors: review problem cases
5. Systems toolkit: a guideline for managers on how to implement STRETCH
6. Provincial STRETCH co-ordinators
7. STRETCH facility support teams - facilitate changes and provide support

## Intervention Type
Drug

## Phase
Not Specified

## Drug/device/biological/vaccine name(s)
antiretroviral treatment (HAART)

## Primary outcome measure
The following will be analysed at 1 year (interim analysis) and 2 years (final analysis):
Cohort 1: Survival
Cohort 2: Viral load suppression rates

## Secondary outcome measures
The following will be measured at 2 years (or 1 year if the trial should be discontinued):
Cohort 1:
1. Viral load suppression rates
2. Duration between enrolment and starting HAART
3. Proportion of patients with CD4 count <=350 who start HAART during the study period
4. Median baseline CD4 count of patients starting HAART
5. Tuberculosis (TB) case detection
6. Screening for TB (sputum tests)
7. Cotrimoxazole prophylaxis provision
8. Changes in CD4 and weight, hospital admissions
9. Number of nurse and doctor visits
Cohort 2:
1. Survival
2. Programme retention (the proportion of patients remaining alive and in care)
3. Duration of viraemia prior to switch to second-line treatment
4. TB case detection
5. Screening for TB (sputum tests)
6. Cotrimoxazole prophylaxis provision
7. Changes in CD4 and weight
8. Hospital admissions
9. Number of nurse and doctor visits

### Overall study start date
01/07/2007

### Completion date
30/06/2009

## Eligibility

### Key inclusion criteria
Clinics: All 31 public sector clinics currently offering antiretroviral treatment in the Free State province, South Africa.
Patients:
Cohort 1: All patients enrolled at the 31 facilities with a CD4 count of 350 cells/ul or less not yet on HAART.
Cohort 2: All patients enrolled at the 31 facilities already on HAART for 6 months or longer, and alive and in care at the start of the trial.

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
Clinics: 31; Cohort 1: 7000 patients; Cohort 2: 4000 patients

### Key exclusion criteria
Clinics: None
Patients: Patients younger than 18 years

### Date of first enrolment
01/07/2007

### Date of final enrolment
30/06/2009

## Locations

### Countries of recruitment
South Africa

### Study participating centre

**Knowledge Translation Unit**
Cape Town
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# Sponsor information

**Organisation**
Development Cooperation Ireland (South Africa)

**Sponsor details**
Embassy of Ireland
1st Floor
Southern Life Plaza
1059 Schoeman Street
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**Sponsor type**
Government

**Website**
http://www.embassyireland.org.za/

# Funder(s)

**Funder type**
Government

**Funder Name**
Canadian International Development Agency (02/2006) (Canada)

**Funder Name**
Irish Aid (Ireland)

# 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? |
|---|---|---|---|---|---|
| Other publications | process evaluation | 16/07/2012 | | Yes | No |
| Results article | results | 08/09/2012 | | Yes | No |