

# Directly Observed antiretroviral Therapy for people living with Human Immunodeficiency Virus (HIV) and Acquired ImmunDeficiency Syndrome (AIDS): a randomised controlled trial

<b>Submission date</b> 01/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 02/03/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 06/11/2009	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

N/A

## Study information

### Scientific Title

**Acronym**

DOT-AIDS

**Study objectives**

Not provided at time of registration

**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

**Study type(s)**

Treatment

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

HIV/AIDS

**Interventions**

Intervention group:

Twice-weekly home visits performed by community-peer educators over a two month period. Thereafter, patients were visited once a week for four months. The purpose of the peer educators was to assist the patients in taking medication and provide information and support related to adherence, the importance of following physician recommendations and information related to healthy behaviour (e.g. safe sex, supportive measures related to stigma, and adherence strategies).

Control group:

Usual care provided by the outpatient clinics.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome(s)**

1. Adherence to highly active antiretroviral therapy (HAART) at the end of the study (6 months)
2. Diseases progression
3. Occurrence of AIDS-related disease/opportunistic infections

**Key secondary outcome(s)**

Not provided at time of registration

**Completion date**

31/12/2004

## Eligibility

**Key inclusion criteria**

1. HIV-1 infected individuals
2. 18 years old or older
3. Starting antiretroviral therapy in three AIDS clinics in Porto Alegre (Brazil)

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Not Specified

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/01/2004

**Date of final enrolment**

31/12/2004

## Locations

**Countries of recruitment**

Brazil

**Study participating centre**

Rua Landel de Moura, 1369

Porto Alegre

Brazil

91920-150

# Sponsor information

## Organisation

Ministry of Health (Brazil)

## ROR

<https://ror.org/02y7p0749>

# Funder(s)

## Funder type

Government

## Funder Name

Ministry of Health (Brazil)

# Results and Publications

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration