TasP

Antiretroviral Treatment as Prevention • ANRS 12249
Ukuphila kwami, ukuphila kwethu (my health for our health)

AFRICA CENTRE
For Population Health

ISPED
Bordeaux school of public health
Institut de Santé Publique d'Epidémiologie et de Développement

The impact of Universal Test and Treat on HIV incidence in a rural South African population

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Inserm

anRS
France REcherche Nord & sud Sida-hiv Hépatites
Agence autonome de l'Inserm

UNIVERSITY OF Southampton

UCL

Disclosures

- Research grants from Gilead, MSD
- Study drugs were provided by Merck / Gilead

ART as prevention

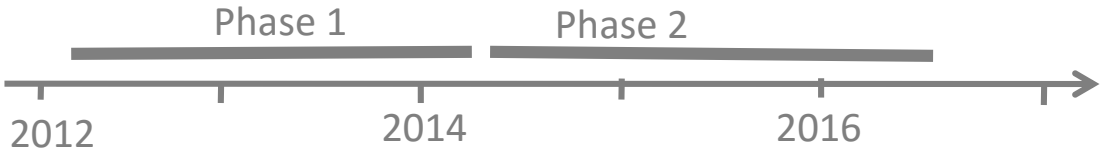
- Plasma HIV viral load: primary determinant of the risk of HIV transmission *(Quinn, NEJM 2000)*
- Good evidence that ART reduces sexual transmission of HIV in serodiscordant stable couples *(Cohen, NEJM 2011)*
- **What is the effectiveness of using ART as prevention (TasP) or Universal Test and Treat (UTT) at the population level in an HIV hyper-endemic community in rural KwaZulu-Natal?**
  - Population well characterized in terms of ART use and effect on transmission *(Tanser, Science 2013 & Oldenburg, CID 2016)*

ANRS 12249 TasP trial

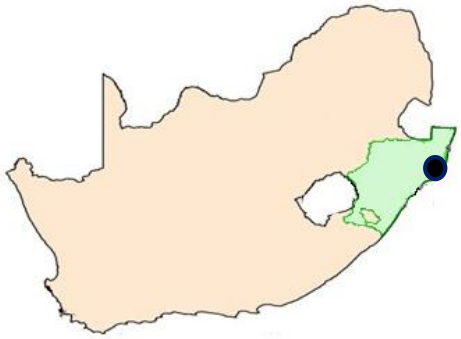
- **Objective:** To evaluate the effect of early ART, initated irrespective of CD4 count criteria, on HIV incidence in the general population in the same setting
- **Design:** Cluster-randomized trial *(Iwuji et al. Trials 2013; Orne-Gliemann et al. BMC Public Health 2015)*

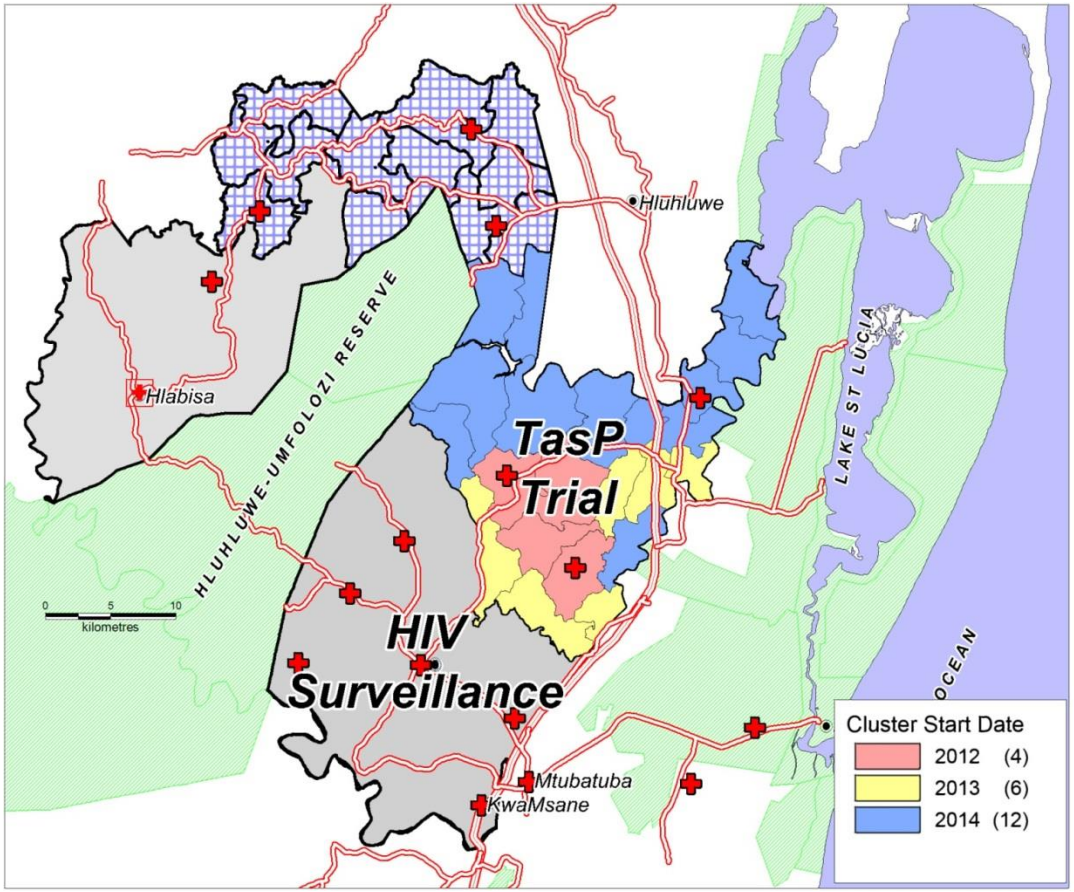
6-monthly rounds of home-based HIV-testing

Intervention	Control
Treat all HIV+ individuals regardless of CD4 count and clinical stage	**Treat all HIV+ individuals according to South African guidelines** ***(≤350 CD4, WHO stage 3 or 4 until Dec 2014, ≤500 since Jan 2015)***



Trial area





Country: South Africa

Region: KwaZulu-Natal

Sub-district: Hlabisa

- 1 430 Km^2
- 228,000 Zulu speaking people

4 clusters
+ 6 clusters
+ 12 clusters

Total of 22 clusters

Trial procedures

Homestead identification
(GPS)

Trial procedures

Homestead identification
(GPS)

Homestead visit every 6 months

1. Head of household verbal consent
2. Registration of individuals

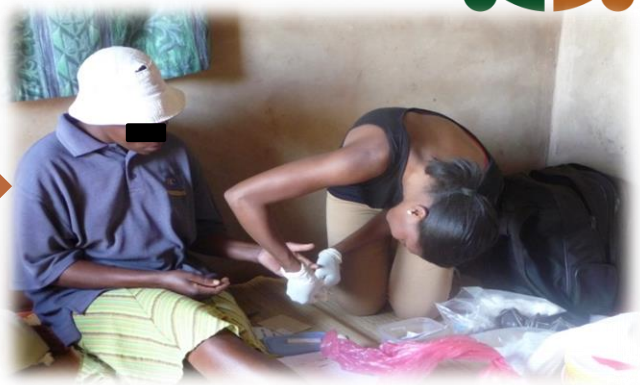
Inclusion criteria

- Resident member of a household
- 16 years or older
- Able to give informed consent

Exclusion criteria

- Untreated psychiatric disorder
- Neurological impairment

Trial procedures



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Homestead procedures

1. Household assets questionnaire
2. Individual questionnaire
3. DBS sample, rapid HIV testing
4. TasP card

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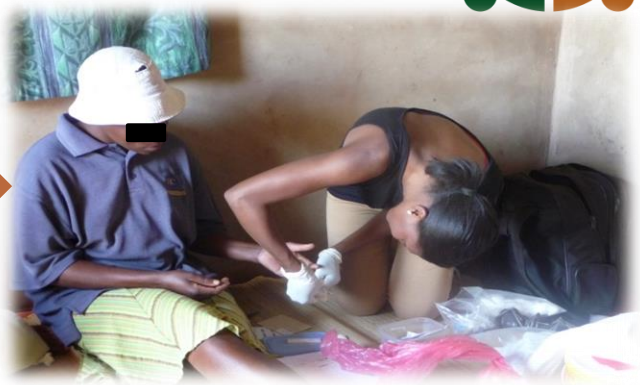

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HIV + → Referral to TasP clinics

HIV - → Repeat HIV test 6 mths later

TasP clinic

- One per cluster (45 min walk max)
- HIV care and treatment according to arm
- Study questionnaires

ANRS 12249 TasP trial primary outcome

- Cumulative incidence of new HIV infections
  - Powered to detect a 34% reduction in incidence in intervention arm vs control arm
- Measured on longitudinal/repeat Dried Blood Spot (DBS) using HIV-ELISA
- Computed among those individuals with a first HIV-negative test
- Compared by Poisson regression taking into account cluster effect

Results: UTT is feasible and acceptable

PLOS | MEDICINE August 9, 2016

RESEARCH ARTICLE

Uptake of Home-Based HIV Testing, Linkage to Care, and Community Attitudes about ART in Rural KwaZulu-Natal, South Africa: Descriptive Results from the First Phase of the ANRS 12249 TasP Cluster-Randomised Trial

Collins C. Iwuji[1,2☯*], Joanna Orne-Gliemann[3,4☯], Joseph Larmarange[1,5], Nonhlanhla Okesola[1], Frank Tanser[1,6], Rodolphe Thiebaut[3,4], Claire Rekacewicz[7], Marie-Louise Newell[1,8‡], Francois Dabis[3,4‡], ANRS 12249 TasP trial group[¶]

Description of trial population, HIV burden and ART coverage at the beginning of the trial

	Intervention	Control	Total
Socio-demographics at registration	(n=13,236)	(n=14,917)	(n=28,153)
Men	37%	38%	**37%**
Median age in years (IQR)	30 (22-50)	30 (22-49)	**30 (22-50)**
Baseline cluster characteristics			
Average HIV prevalence (95% CI) (DBS)	30% (29-31)	31% (30-32)	**31% (30-31)**
ART coverage*	31%	36%	**34%**

** Estimated from Department of Health data*

Trial process indicators

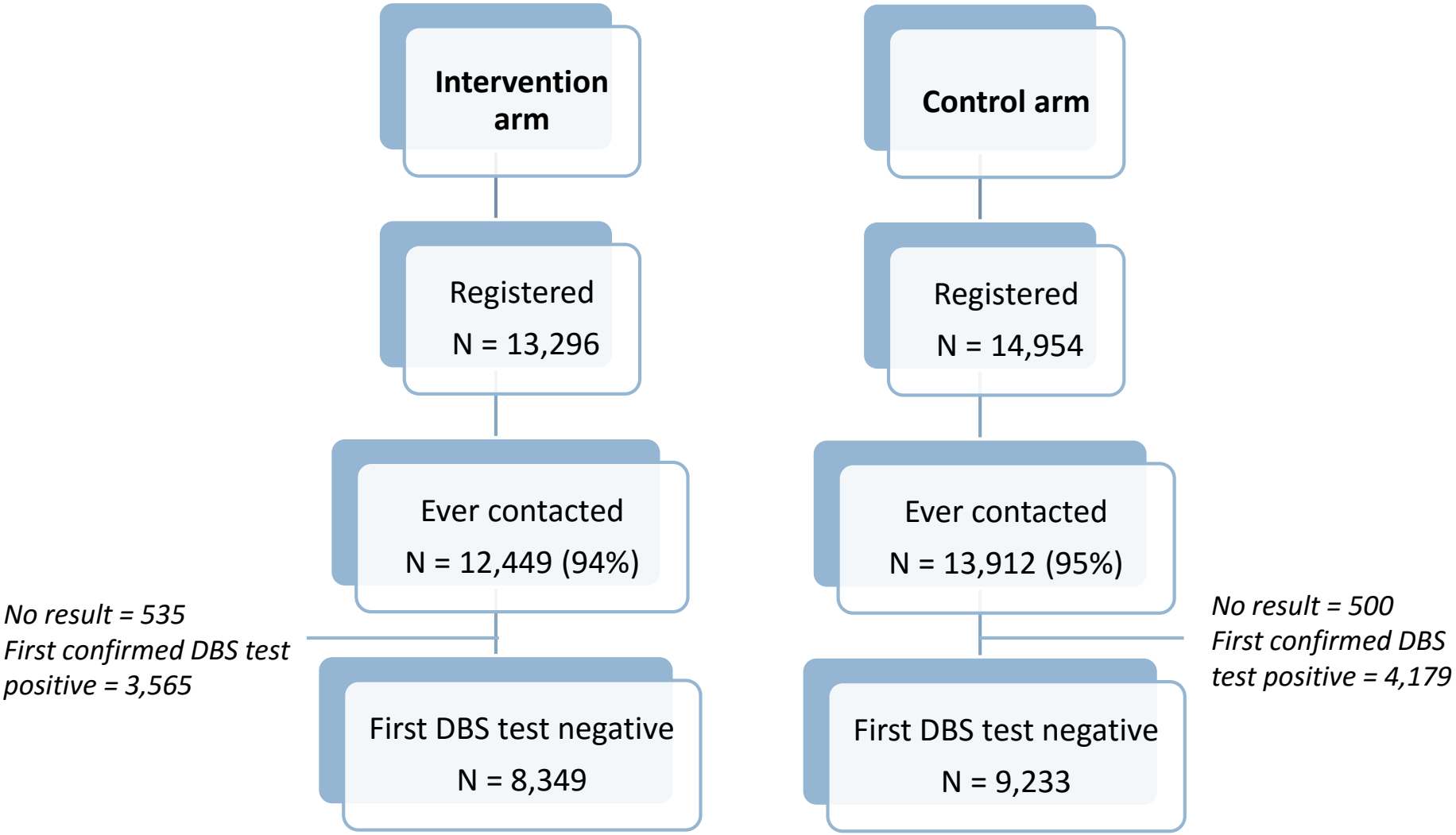
	Intervention	Control
Contact rate per survey round (range)	61% – 84%	66% – 90%
HIV ascertainment rate per survey round (range)	70% – 83%	77% – 88%
Entry into care among individuals not in care		
Within 3 months	28%	29%
Within 6 months	36%	37%
Within 12 months	**47**%	**47**%

Trial process indicators (ctd)

	Intervention	Control
ART initiation within 3 months in TasP clinics among patients not on ART at first TasP clinic visit	91%	52%
Viral load <400 copies/ml among patients not on ART at first TasP clinic visit		
At month 6	93%	92%
At month 12	**95%**	**95%**
Estimated ART coverage* (as of 1st January 2016)	**45%**	**43%**
ART coverage improvement since baseline	**+14**	**+7**

** Estimated from TasP + Department of Health data*

Incidence analysis - flowchart



HIV incidence

	Number of HIV-positive DBS tests	Person-years	Incidence for 100 person-years	95% CI
Control	268	11,787	**2.27**	2.00-2.55
Intervention	227	10,646	**2.13**	1.85-2.41
TOTAL	495	22,434	2.21	2.01-2.40

ANRS 12249 TasP: HIV incidence comparison

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Adjusted risk ratio*

	aRR	95% CI	P-value
Intervention vs control	0.95	0.79-1.14	0.5821

** Estimated with Poisson regression, adjusted on sex, age, change in national ART guidelines, baseline cluster HIV prevalence and ART coverage*

Estimated cascade of care

UNAIDS target

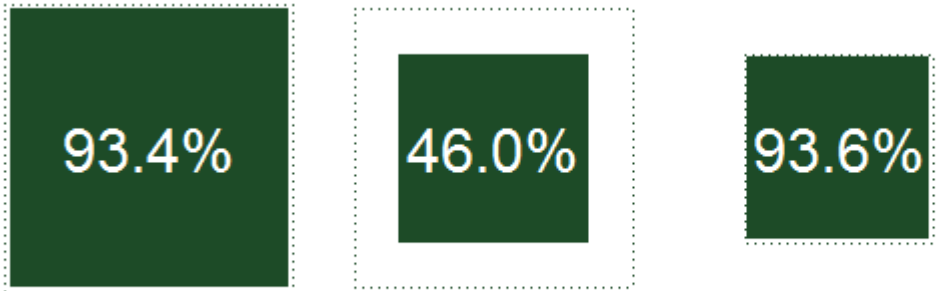
ANRS 12249 TasP - Estimated cascade of care

UNAIDS target

= 72.9%

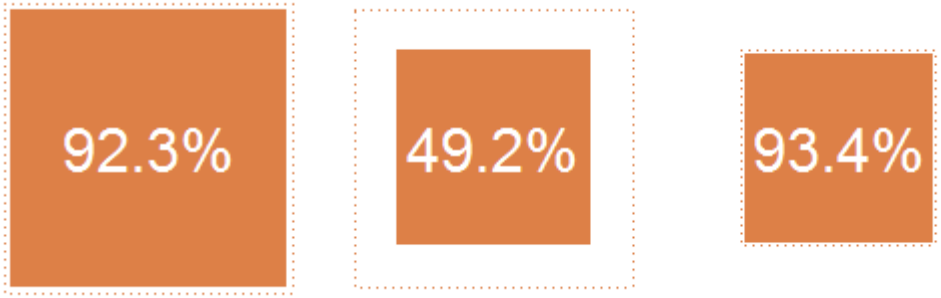
TasP trial (1st January 2016)

Control



= 40.2%

Intervention



= 42.4%

Summary

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- Nearly all individuals living with HIV in the trial communities are aware of their HIV status
- More than 90% individuals on ART achieved viral suppression

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- Nearly all individuals living with HIV in the trial communities are aware of their HIV diagnosis
- More than 90% individuals on ART achieved viral suppression
- Sub-optimal and delayed linkage to care
- Small ART coverage difference between arms

Further analyses

- Specific secondary outcomes: clinical, behavioural, socio-economic, health services

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- Profile of people reached and not reached by TasP intervention
- Reasons for non linkage
  - Models of care
  - Community attitudes and stigma….

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- In and out migrations
- Location of sexual partners
- Community viral load and phylogeny

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- Africa Centre staff
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