TasP

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

AFRICA CENTRE
For Population Health

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

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Inserm

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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)*

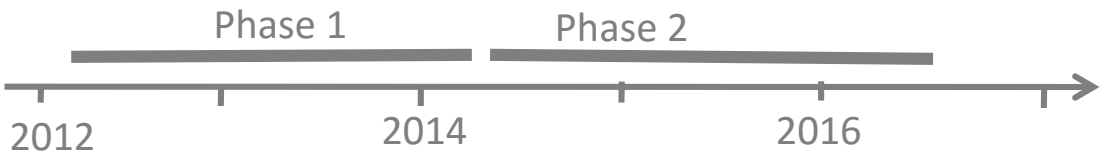
- **What is the effectiveness of using ART as prevention (TasP) or Universal Test and Treat (UTT) at the population level in an HIV hyper-endemic community in rural KwaZulu-Natal?**
  - Population well characterized in terms of ART use and effect on transmission *(Tanser, Science 2013 & Oldenburg, CID 2016)*

ANRS 12249 TasP trial

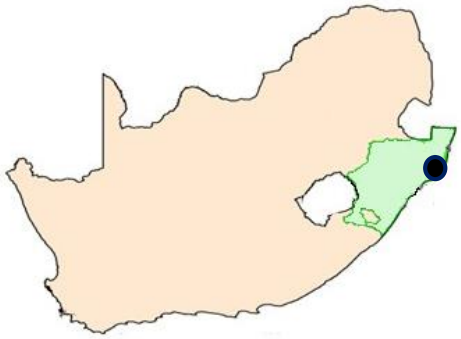
- **Objective:** To evaluate the effect of early ART, initated irrespective of CD4 count criteria, on HIV incidence in the general population in the same setting
- **Design:** Cluster-randomized trial *(Iwuji et al. Trials 2013; Orne-Gliemann et al. BMC Public Health 2015)*

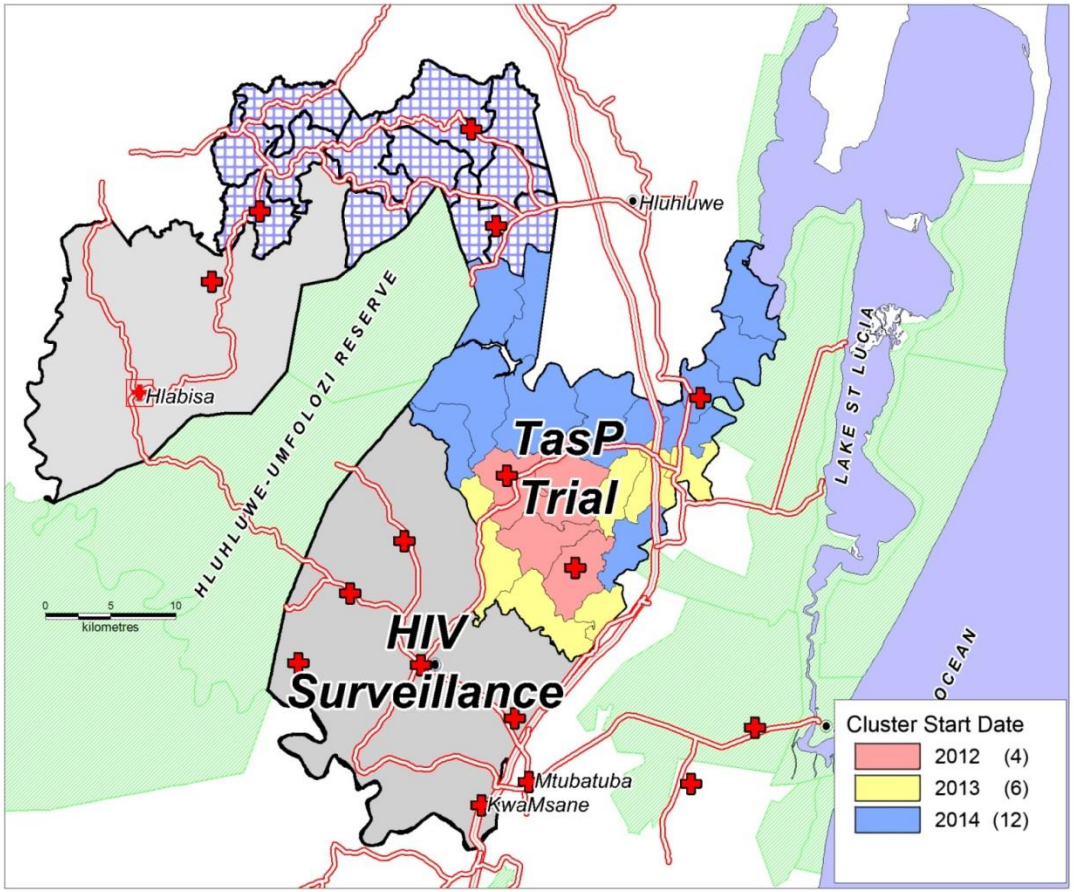
6-monthly rounds of home-based HIV-testing

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
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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

Homestead identification
(GPS)

Homestead visit every 6 months

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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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TasP clinic

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

HIV +

Referral to TasP clinics

HIV -

Repeat HIV test 6 mths later

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

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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

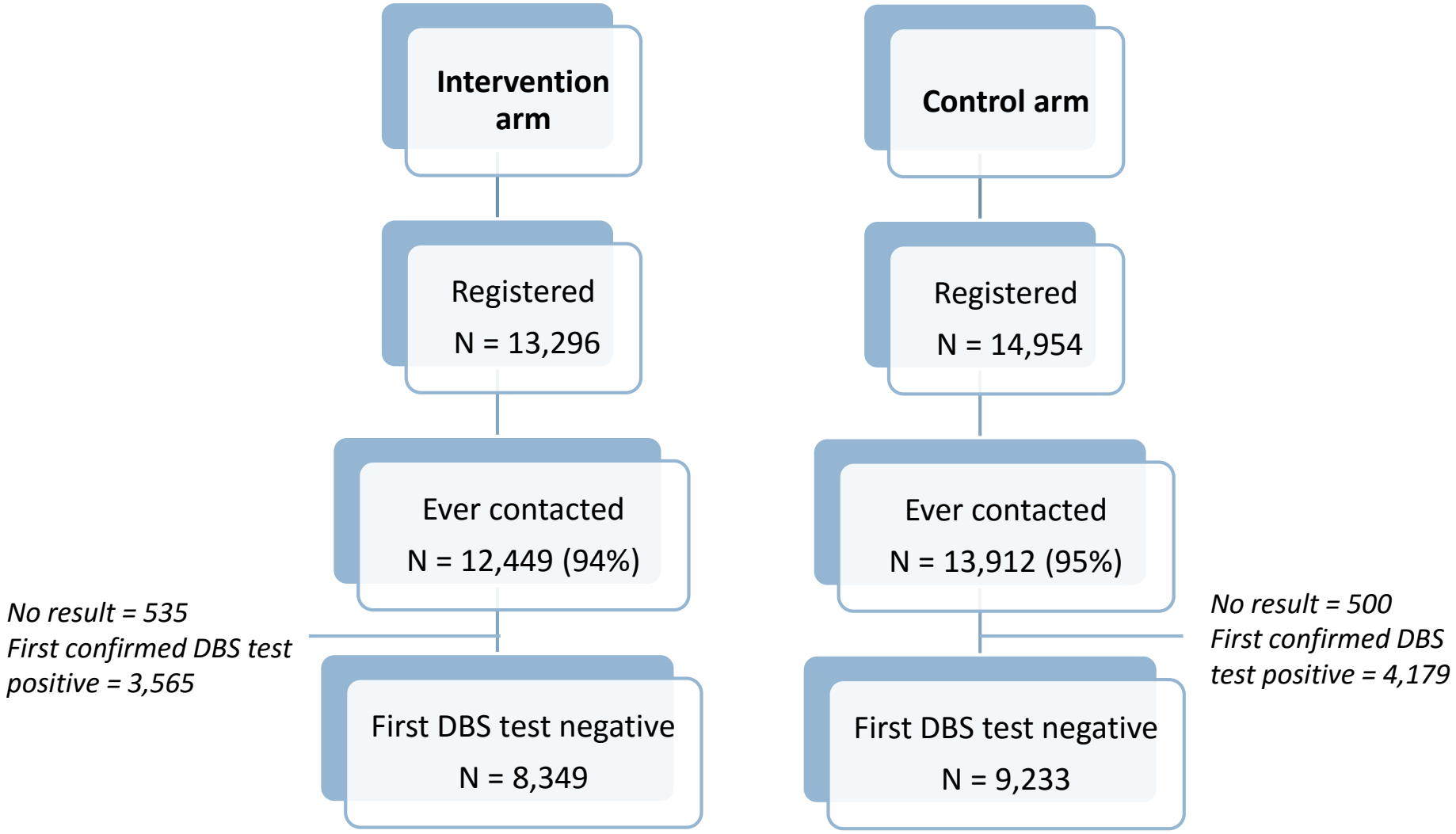
	Intervention	Control
Contact rate per survey round (range)	61% – 84%	66% – 90%
HIV ascertainment rate per survey round (range)	70% – 83%	77% – 88%
Entry into care among individuals not in care		
Within 3 months	28%	29%
Within 6 months	36%	37%
Within 12 months	**47**%	**47**%

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

Summary

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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

Acknowledgements

- Trial participants
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wellcome trust

ANRS France REcherche Nord & sud Sida-hiv Hépatites

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