

ANRS 12249 TasP trial

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SCIENTIFIC CONTEXT

- Universal Test and Treat (UTT) aims to maximize PLWHIV on ART and virally suppressed in a community.
- According to mathematical modelling, UTT would lead to reduction in HIV incidence.



ART coverage
 (% of PLWHIV on ART)

Population Viral Suppression (% being virally suppressed)

↘ HIV incidence (new infections at population level)

THE ANRS 12249 TASP TRIAL

- One of 5 international trials aiming at evaluating UTT approaches
- > Design: cluster-randomised trial
- > Timeline: March 2012-June 2016
- > Study setting: Hlabisa sub-district
 - > ~28 000 individuals aged 16+
 - isiZulu speaking
 - > HIV prevalence ~30%
 - frequent migration
 - > low marital rates & late marriage
 - only 10% are employed





TASP TRIAL **PROCEDURES**



Homestead Identification



Local governmental clinics

- Matching between trial and governmental database at individual level
- CD4 and viral load results / clinic visits
- ART according to national guidelines



Homestead visit

- 1. Registration of resident adults
- 2. Update of resident members list
- 3. Exit forms



Homestead procedures

- 1. Individual questionnaires
- 2. DBS sample (lab tests)
- 3. Rapid HIV testing

repeated every ~six months



Trial clinics

- > Intervention arm: immediate ART
- Control arm: ART according to national guidelines

if ascertained HIV+ (rapid test or self-report) referred to trial clinic

TIMING OF FIELDWORK

- 4 clusters (opened in 2012)
- › 6 clusters (opened in 2013)
- 12 clusters (opened in 2014)

Light areas indicate the time required to complete the initial census of the population



PREVIOUS **RESULTS**

- Main results were presented in Durban in 2016 (Iwuji et al. Lancet HIV 2017)
- No significant difference in HIV incidence between trial arms



RESEARCH QUESTION

- Did population viral suppression improve during the course of the trial?
- > Differentially by arm?
- According to trial interventions or contextual changes?

APPROACH: COMPUTATION OF **DAILY STATUSES**



for each calendar day

RESIDENCY status

(resident / not resident)



among those residents

repeat DBS, repeat rapid tests, HIV-positive self-reports and HIV clinic visits seroconversion date imputed (random point approach)

HIV status (HIV positive / negative)

among those HIV-positive

clinic visits, ART prescription, CD4 counts and viral loads trial clinics and local governmental HIV clinics



CLUSTER-LEVEL POPULATION VIRAL SUPPRESSION

% being in care, on ART and virally suppressed

Computed at different time points (pre-intervention + daily)

POPULATION VIRAL SUPPRESSION **DENOMINATOR**



OVERALL **RESULTS**

- At baseline, population viral suppression
 slightly lower in intervention arm
- > Significant increase in both arms
- A slightly higher increase in intervention arm
- No significant difference between arms at the end of the trial



MODELLING POPULATION VIRAL SUPPRESSION

- > Mixed linear model
- > One record per cluster and per day
- Outcome: cluster-level population viral suppression
- > Factors:
 - calendar time
 - > time since cluster opening
 - trial arm
 - interaction between trial and time since cluster opening
 - socio-demographic characteristics (cluster-level)



MODEL RESULTS: POPULATION VIRAL SUPPRESSION, TASP ANRS 12249



LIMITATIONS

- Care received in governmental clinics probably underestimated due to participants not matched between governmental and trial datasets
- Care received in private sector or outside the trial area not captured
- 9.5% of trial population with no observed HIV status and excluded from the analysis
- > Sensitivity analysis: results unchanged



DISCUSSION

- Although suboptimal, the TasP strategy significantly improved population viral suppression over time.
- Mainly due to universal testing rather than universal treatment
- Increase similar between arms
 → explain the null effect of HIV incidence

Changes in treatment guidelines not enough to increase population viral suppression





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