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# The impact of early ART initiation on HIV disclosure and social support among people living with HIV and followed within a universal test and treat programme in rural South Africa (ANRS 12249 TasP trial)

Cape Town, November 13th 2017

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# **Background**

 HIV status disclosure and social support have been associated with increased antiretroviral treatment (ART) adherence and better clinical outcomes.

- In September 2016, South Africa adopted the latest World Health Organization (WHO) guidelines on ART, recommending ART immediately after HIV diagnosis, regardless of CD4 count.
- The TasP cluster-randomized trial conducted in rural South Africa between 2012 and 2016 provided the opportunity to investigate HIV status disclosure and social support among patients who were offered early ART.



# **Objective**

To investigate the impact of early ART initiation on HIV status disclosure and social support among patients in care within the universal test and treat (UTT) cluster-randomized TasP trial.



## The TasP trial

#### Settings: The ANRS 12249 TasP trial

- Cluster-randomized trial implemented in the Hlabisa sub-district, northern KwaZulu-Natal
- Estimated HIV prevalence of 29%
- Trial <u>primary objective</u>: to estimate the impact of immediate ART just after positive diagnosis on HIV incidence among the population of the sub-district
- o **Two arms**: following home-based HIV testing, treatment initiation is offered in trial clinics:
  - i) Intervention arm: regardless of CD4
  - ii) Control arm: CD4≤500 since 01/01/2015 or CD4≤350 before 01/01/2015

#### The study population = all HIV-positive participants

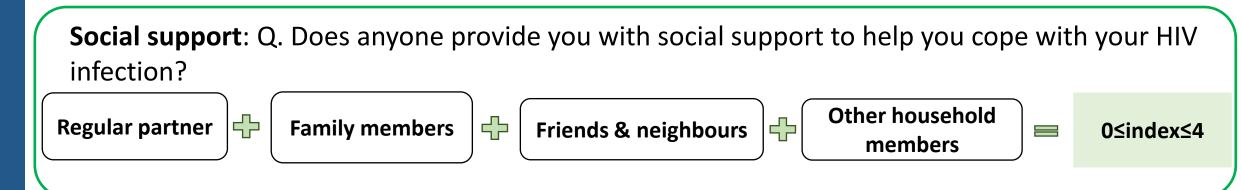
- Linked to a trial clinic
- Not ART treated at their first visit (baseline clinic visit)
- CD4 > 500 cells/mm³ (and no WHO stage 3 nor 4, nor pregnancy) at baseline
- Having at least two clinic visits over the trial period (March 2012 June 2016).



## Methods – Outcome variables

Estimated at baseline and every 6 months





## **Methods – Covariates**

**Covariates** (defined at baseline except ART status defined at each time point):

- Socio-demographic characteristics: sex, age
- Highest Education level reached
- Baseline professional status
- Care status before TasP (if ever been in care before the TasP trial)
- Time to link to a trial clinic
- ART Initiation in TasP
  - 0: as long as the individual has not « yet » initiated ART in trial clinics
  - 1: from the time the individual initiated ART in trial clinics
- Cluster HIV prevalence (<30%, ≥30%)</li>
- Having a regular partner
- Trial arm: intervention versus control

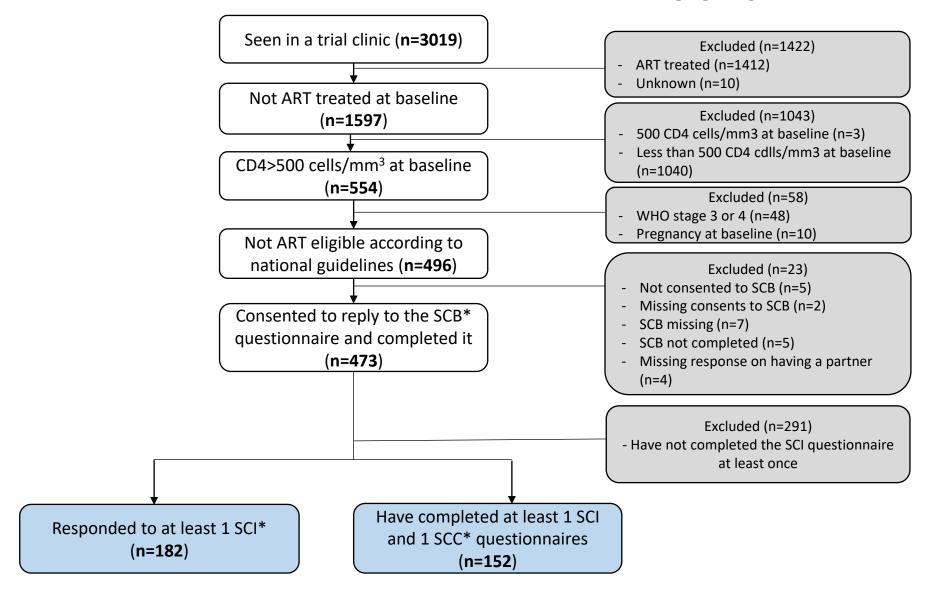


# Methods – Statistical analysis

- Poisson mixed effects model adjusted on individual factors
  - Multivariate analyses
    - Stepwise forward selection to adjust for individual characteristics (alpha=5%)
- 4 models have been built for each outcome:
  - Model 1 (arm): Is there any effect of the arm (Control vs. Intervention) on the outcome?
  - Model 2 (arm\*time): Does the evolution of the outcome over time differ according to the trial arm?
  - O Model 3 (ART): Is there any effect of initiating ART on the outcome?
  - Model 4 (ART\*arm): Is there a different effect of ART initiation on the outcome according to the trial arm?



# **Results** — Flowchart of the study population

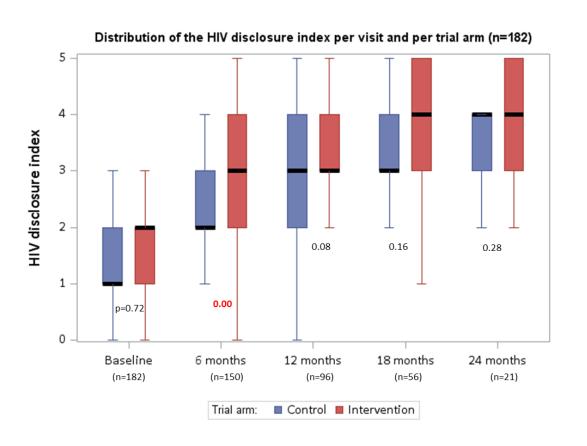


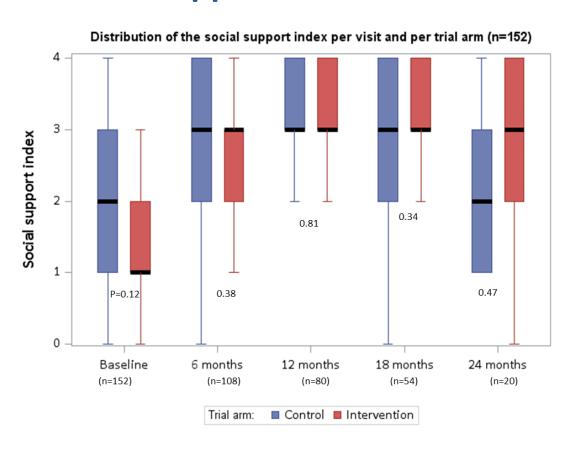


# **Results** - Main characteristics of the study population

| Covariates                       | Total (n=182)     |
|----------------------------------|-------------------|
| Sex                              |                   |
| Female                           | <u>84%</u>        |
| Age                              |                   |
| Median [IQR]                     | <u>32</u> [25-48] |
| Care status before TasP          |                   |
| Yes (ever been in care in DoH)   | <u>52%</u>        |
| Baseline highest education level |                   |
| Primary or less                  | 46%               |
| Some secondary                   | 32%               |
| At least completed secondary     | 22%               |
| Baseline professional status     |                   |
| Student                          | 12%               |
| Employed                         | 7%                |
| Inactive                         | 81%               |
| Cluster HIV prevalence           |                   |
| 30% or more                      | <u>82%</u>        |
| Time to link to a trial clinic   |                   |
| 0 - 1 month                      | 61%               |
| 1 month – 6 months               | 26%               |
| More than 6 months               | 13%               |

#### Distribution of the HIV disclosure and social support index over time





- Increase in the HIV disclosure and social support index over time
- The median of the HIV disclosure index was significantly different between trial arms; people from the intervention arm had a higher median index of HIV disclosure at 6 months.



1. Model 1: Is there any effect of the arm (Control vs. Intervention) on the outcome?

Yes

No

| Covariates                              | HIV disclosure index<br>IRR [95% CI] | Social Support index<br>IRR [95% CI] |
|---|--------------------------------------|--------------------------------------|
| Years from baseline                     | 1.46*** [1.35 ; 1.58]                | 1.33*** [1.21 ; 1.45]                |
| Trial arm  Control (ref.)  Intervention | 1<br>1.26**[1.12 ; 1.41]             | 1<br>1.03 [0.90 ; 1.17]              |

Note: Models adjusted on Cluster HIV prevalence, Care status before TasP, having a regular partner. \*\*\*p<0.001 \*p<0.05

All other things being equal,

- Increase in the HIV disclosure and social support index over time.
- Participants from the intervention arm disclosed their HIV status to more categories of people.



2. Model 2: Does the evolution of the outcome over time differ according to the trial arm?

No

Yes

| Covariates                              | HIV disclosure index<br>IRR [95% CI] | Social support index<br>IRR [95% CI] |
|---|--------------------------------------|--------------------------------------|
| Years from baseline                     | 1.45 *** [1.29; 1.62]                | 1.20** [1.06 ; 1.37]                 |
| Trial arm  Control (ref.)  Intervention | 1<br>1.24*[1.04;1.48]                | 1<br>0.87 [0.71 ; 1.06]              |
| Years * Intervention                    | 1.02 [0.87 ; 1.19]                   | 1.22*[1.02 ; 1.46]                   |

Note : Models adjusted on Cluster HIV prevalence, Care status before TasP, having a regular partner. \*\*\*p<0.001 \*\*p<0.05

All other things being equal,

- Both trial arms had a similar increase over time in the HIV disclosure index.
- People from the intervention arm showed a higher increase over time in the social support index.



#### 3. Model 3: Is there any effect of initiating ART on the outcome?

Yes

Yes

| Covariates                             | HIV disclosure index<br>IRR [95% CI] | Social support index IRR [95% CI] |
|--|--------------------------------------|-----------------------------------|
| Years from baseline                    | 1.24 *** [1.12 ; 1.38]               | 1.17* [1.03 ; 1.32]               |
| Trial arm  Control (ref.) Intervention | 1<br>1.05 [0.92 ; 1.20]              | 1<br>0.90 [0.78 ; 1.05]           |
| Initiated ART in TasP  No (ref.)  Yes  | 1<br>1.50 ***[1.28 ; 1.75]           | 1<br>1.35** [1.12; 1.62]          |

Note : Models adjusted on Cluster HIV prevalence, Care status before TasP, having a regular partner. \*\*\*p<0.001 \*\*p<0.05

All other things being equal,

 Initiating ART lead to an increase in the HIV disclosure and the social support index.



4. Model 4: Is there a different effect of ART initiation on the outcome according to the trial arm?
No
Yes

| Covariates                           | HIV disclosure index<br>IRR [95% CI] | Social support index IRR [95% CI] |
|--------------------------------------|--------------------------------------|-----------------------------------|
| Years from baseline                  | 1.24 *** [1.12 ; 1.37]               | 1.15* [1.02 ; 1.30]               |
| Trial arm                            |                                      |                                   |
| Control (ref.)                       | 1                                    | 1                                 |
| Intervention                         | 0.98 [0.80 ; 1.18]                   | 0.73** [0.58 ; 0.91]              |
| Initiated ART in TasP                |                                      |                                   |
| No (ref.)                            | 1                                    | 1                                 |
| Yes                                  | 1.40**[1.14 ; 1.71]                  | 1.11 [0.88 ; 1.40]                |
| Initiated ART in TasP * Intervention | 1.15 [0.89 ; 1.48]                   | 1.50** [1.12 ; 2.01]              |

Note: Models adjusted on Cluster HIV prevalence, Care status before TasP, having a regular partner. \*\*\*p<0.001 \*\*p<0.05

All other things being equal,

- Initiating ART lead to an increase in the HIV disclosure index
  - That effect was similar in both trial arms.
- The effect of initiating ART on the social support was stronger in the intervention arm.



# CONCLUSION

- Besides clinical benefits, early ART initiation at high CD4 cell count was associated with HIV disclosure and social support.
  - For the social support index: a longer time of follow-up may however be required to observe this benefit.
- Findings encouraging for the countries that have implemented the UTT strategy.

#### **Study Limits:**

- × All categories had a same weight in the definition of the index
- × A small proportion of our population had attended 18 months of follow-up at the end of the study.







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#### ANRS 12249 Study Group (by alphabetical order):

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