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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)

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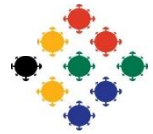
TasP
ANRS 12249

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 primary objective : to estimate the impact of immediate ART just after positive diagnosis on HIV incidence among the population of the sub-district
  - **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/mm^3 (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

HIV disclosure: Q. Have you disclosed to anyone that you are HIV-positive?

Regular partner + **Family members**: Male relatives, Female relatives, Children + **Friends** + **Neighbours** + **Others**: Employer, Traditional healer, Educational institution, Any other category = **0≤index≤5**

Social support: Q. Does anyone provide you with social support to help you cope with your HIV infection?

Regular partner + **Family members** + **Friends & neighbours** + **Other household members** = **0≤index≤4**

Methods – Covariates

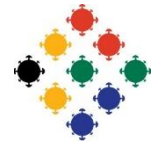
Covariates (defined at baseline except ART status defined at each time point):

- 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%)
- Having a regular partner
- Trial arm: intervention versus control

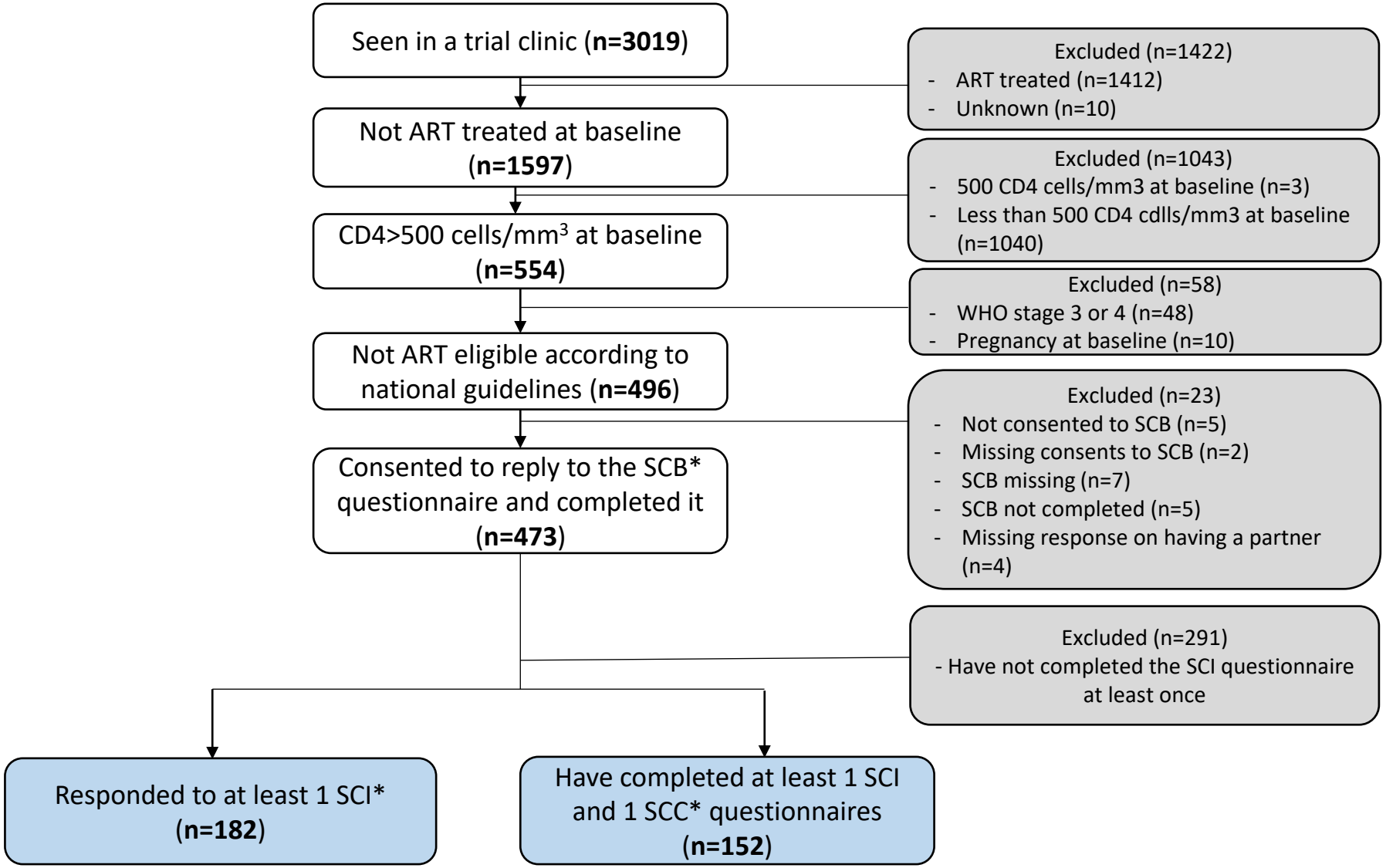
Methods – Statistical analysis

- **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?**
  - **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



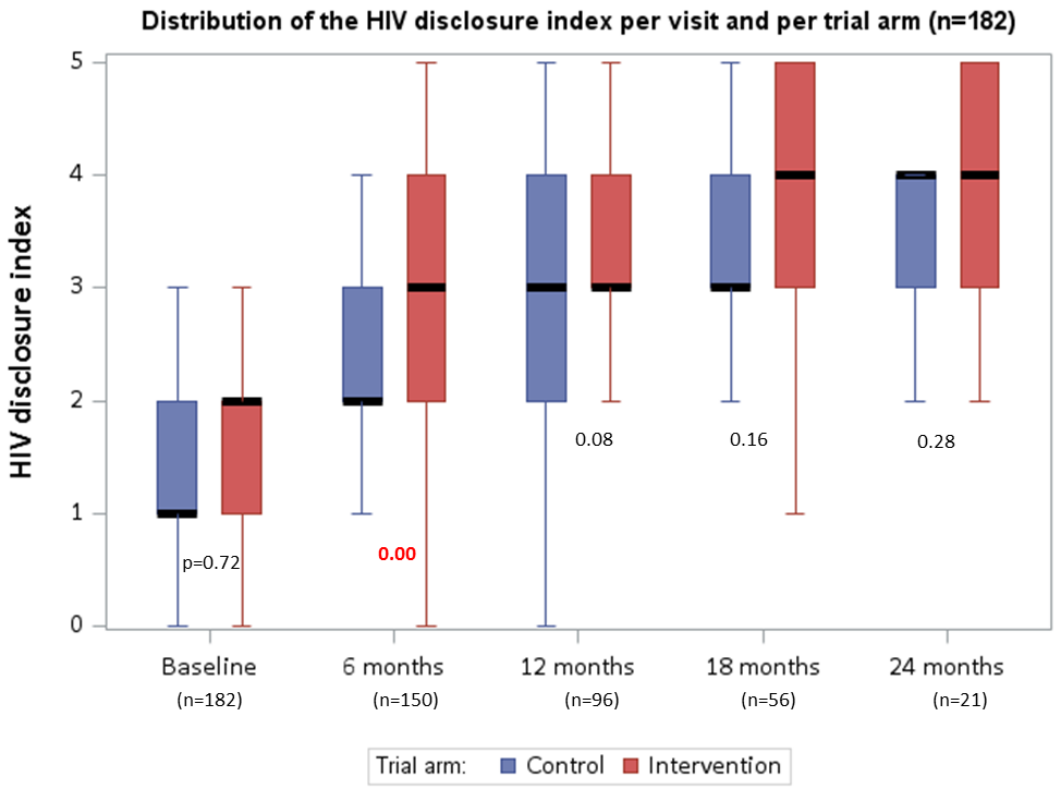
(*) SCB : social science baseline clinic-based, counsellor-administered questionnaire. SCI: social science clinic-based interviewer-administered questionnaire.
SCC: social science clinic-based follow-up counsellor – administered questionnaire.

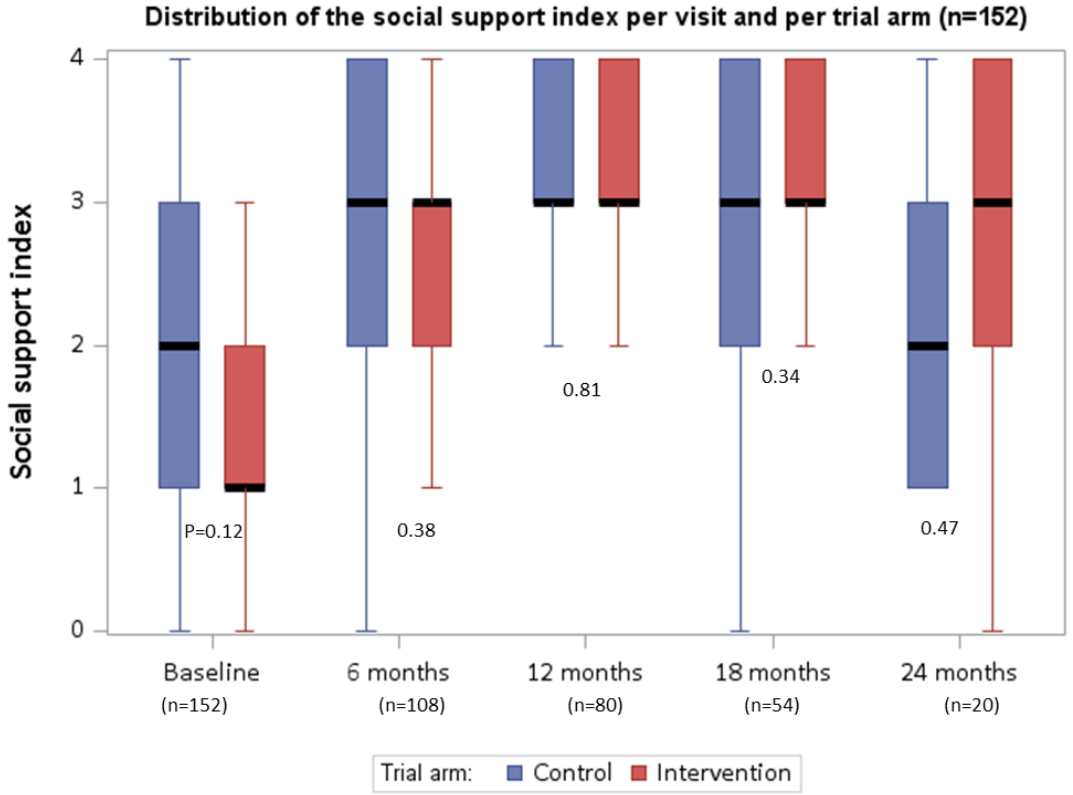
Results - Main characteristics of the study population

Covariates	Total (n=182)
Sex	
Female	84%
Age	
Median [IQR]	32 [25-48]
Care status before TasP	
Yes (ever been in care in DoH)	52%
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	82%
Time to link to a trial clinic	
0 - 1 month	61%
1 month – 6 months	26%
More than 6 months	13%

Results

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.

Results

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

	Yes	No
Covariates	**HIV disclosure index** IRR [95% CI]	**Social Support index** IRR [95% CI]
Years from baseline	1.46*** [1.35 ; 1.58]	1.33*** [1.21 ; 1.45]
Trial arm		
Control (ref.)	1	1
Intervention	**1.26**[1.12 ; 1.41]**	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<0.01 *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.

Results

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

Covariates	HIV disclosure index IRR [95% CI]	Social support index IRR [95% CI]
Years from baseline	1.45 *** [1.29; 1.62]	1.20** [1.06 ; 1.37]
Trial arm Control (ref.) Intervention	1 **1.24*[1.04;1.48]**	1 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<0.01 *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.**

Results

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

Covariates	HIV disclosure index IRR [95% CI]	Social support index IRR [95% CI]
	Yes	**Yes**
Years from baseline	1.24 *** [1.12 ; 1.38]	1.17* [1.03 ; 1.32]
Trial arm		
Control (ref.)	1	1
Intervention	1.05 [0.92 ; 1.20]	0.90 [0.78 ; 1.05]
Initiated ART in TasP		
No (ref.)	**1**	**1**
Yes	**1.50 ***[1.28 ; 1.75]**	**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<0.01 *p<0.05*

All other things being equal,

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

Results

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 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.) Intervention	 1 0.98 [0.80 ; 1.18]	 **1** **0.73** [0.58 ; 0.91]**
Initiated ART in TasP No (ref.) Yes	 **1** **1.40**[1.14 ; 1.71]**	 1 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<0.01 *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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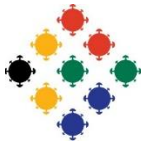


HIV DISCLOSURE


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SUPPORT
SUPPORT