

Universal Test and Treat and the HIV epidemic in rural South Africa; a community cluster randomized trial.

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1. ANRS 12249 TasP Study group

The members of the ANRS 12249 TasP trial group during the course of the study are as follows:

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Sponsor representatives (Brigitte Bazin, Claire Rekacewicz)

2. Protocol amendments

Version	Approval
Protocol V1.1 – June 3, 2011	Feb 2, 2012: BREC approval to start trial in control clusters
Protocol V1.2 – March 8, 2012	June 28, 2012: MCC authorization July 6, 2012: BREC full approval until July 2013 June 26, 2013: BREC recertification until July 5, 2014
Protocol V2.0 – January 9, 2014	March 11, 2014: BREC approval for phase 2 Aug 13, 2014: BREC recertification until July 5 2015
Amendment 1 (<i>on social science component</i>)	Aug 2, 2012: BREC sub-committee approval Ratified by full committee on Aug 14, 2012
Social Science Ancillary Study	Sept 26, 2012: BREC sub-committee approval Ratified by full committee on Oct. 20, 2012
Amendment 2 (<i>test and pregnancy national guidelines</i>) (Submitted in July 2012)	Aug 3, 2012: BREC sub-committee approval Ratified by full committee on Oct. 9, 2012
Amendment 3 (<i>6 additional clusters, mobile clinics</i>) (Submitted in September 2012)	Dec 14, 2012: BREC sub-committee approval Ratified by full committee Feb. 19, 2013
Amendment 4 (<i>linkage with DOH data bases</i>) (Submitted in January 2013)	Jan 28, 2013: BREC approval Mar. 12, 2013
Amendment 5 (<i>contact to improve linkage to care</i>) (Submitted in January 2013)	Jan 28, 2013: BREC approval Mar. 12, 2013
Amendment 6 (<i>updating treatment guidelines</i>) (Submitted in April 2013)	Aug 13, 2013: BREC approval
Amendment 7 (<i>To add a co-investigator</i>) (Submitted to BREC 8 July 2013)	Oct 10, 2013: BREC Sub-committee approval
Amendment 8 (<i>for use of family assessment device</i>) (Submitted Sept 2013)	Nov 12, 2013: BREC Sub-committee approval Dec 10, 2013: BREC full committee approval
Amendment 9 (<i>to update protocol from v1.2 to 2.0</i>) (Submitted Jan 2014)	Mar, 11 2014: BREC approval
Amendment 10 (<i>Use of the Beliefs about medicines questionnaire</i>) (Submitted July 2014)	Aug 12, 2014: BREC full committee approval
Amendment 11 (<i>updating treatment guidelines</i>) (Submitted January 2015)	Mar 10, 2015: BREC full committee approval
Amendment 12 (<i>Interventions to improve the cascade of HIV care</i>) (Submitted March 2015)	July 30, 2015: BREC approval
Amendment 13 (Health care professionals' survey) (Submitted 9 Oct 2015)	Mar 08, 2016: BREC committee approval
Amendment 14 (Camera capture of rapid test results) (Submitted 22 April 2016)	June 14, 2016: BREC committee approval

BREC: Biomedical Research Ethics Committee of the University of KwaZulu-Natal, South Africa; MCC: Medicines Control Council, South Africa

3. Outcomes and definitions

Table S1a Secondary outcomes at the general population level

Outcome	Definition, indicators	Status of reporting
Acceptability of initial HIV counselling and testing	<ul style="list-style-type: none"> ● HIV testing history at baseline ● Attitudes towards HIV testing at baseline and at 12 months ● Different estimates of coverage/uptake of HIV testing per method of calculation, per round and according to time interval ● Social determinants of HIV testing uptake at individual and community levels (at baseline then cumulative and/or at 12 months) 	HIV testing uptake reported in manuscript. Attitudes towards HIV testing reported at community level (Orne-Gliemann et al, AIDS Care 2016). Patterns and determinants of repeat HIV testing to be reported in another publication (Larmarange J et al; AIDS Research and Human Retroviruses, 30 (Suppl. 1) abstract; manuscript in preparation)
Prevention practices (HIV, pregnancy)	<ul style="list-style-type: none"> ● Circumcision uptake over time ● Contraceptive use and pregnancies over time 	To be reported in another publication
Sexual behaviours	<ul style="list-style-type: none"> ● Sexual partnerships patterns over time, disinhibition ● Safe sex and condom use over time ● Conjugal relationships (disclosure) 	Condom use reported in table S12. Sexual behaviours over time presented at IAS 2017 (Orne-Gliemann et al) (manuscript in preparation). Disclosure among HIV+ to be reported in another publication (in preparation)
Quality of life	<ul style="list-style-type: none"> ● Quality of life at baseline and over time 	To be reported in another publication (in preparation)
Household health care expenditures Treatment/care cost	<ul style="list-style-type: none"> ● Cost analysis ● Economic impact of HIV infection on the household welfare (health care use and health care expenditures) ● Budget impact 	To be reported in another publication (in preparation)
Community awareness	<ul style="list-style-type: none"> ● Stigma toward PLWHA, perception of stigma ● Perception about ART preventing HIV infection 	To be reported in another publication (in preparation) Reported in Iwuji et al; PLoS Med 13(8): e1002107.
Molecular epidemiology	<ul style="list-style-type: none"> ● Use of phylodynamic framework to understand transmission networks between intervention and control clusters 	To be reported in another publication (in preparation)

Table S1b Secondary outcomes in HIV-positive individuals only

Outcome	Definition, indicators	Status of reporting
Acceptability / uptake entry into care	<ul style="list-style-type: none"> ● Expectations and perceptions of early treatment over time ● Knowledge of HIV care and treatment ● Time to initiation of treatment ● Socio-cultural and economic determinants of entry into care 	Factors associated with early linkage to care reported in Plazy M et al; Journal of the International AIDS Society 2016, 19:20913 Factors associated with ART initiation reported in Boyer et al; AIDS CARE, 2016 Vol. 28, NO. S3, 39–51. Factors associated with long-term linkage to care and the impact of enhanced linkage to care to be reported in another publication (in preparation)
Programme retention	<ul style="list-style-type: none"> ● Patterns of retention over time and their determinants 	Retention at 12 months reported in manuscript. Determinants of retention and change over time to be reported in another publication (in preparation)
Adherence to ART	<ul style="list-style-type: none"> ● Estimates, patterns and measurement of adherence over time ● Determinants of adherence by CD4 strata 	To be reported in another publication (under review)
Virological outcomes	Immunological and virological response Socio-economic determinants of response to treatment First-line treatment durability, switches to second-line treatment	Virological suppression reported in manuscript. Determinants and durability of first-line ART to be reported in another publication (in preparation)

Outcome	Definition, indicators	Status of reporting
Morbidity/mortality	<ul style="list-style-type: none"> ● Mortality and severe morbidity (leading to hospitalization) ● Tuberculosis (incidence) ● Other morbidity events (infectious or not) by CD4 strata ● Hepatitis B co-infection 	Mortality rate reported in manuscript. Morbidity to be reported in another publication.
HIV drug resistance	<ul style="list-style-type: none"> ● Prevalence and incidence of acquired and transmitted drug resistance and associated factors 	To be reported in another publication (Transmitted resistance under review, Acquired resistance in preparation)
Toxicity and adverse events	<ul style="list-style-type: none"> ● Renal and liver abnormalities ● Other adverse events 	All adverse events summarised in table S10. Detailed analysis to be reported in another publication.
Vertically-acquired HIV infection	<ul style="list-style-type: none"> ● Uptake of PMTCT intervention(s) and relation with care program ● Pregnancy outcomes with Efavirenz first-line ART and transmission ● Overall HIV paediatric testing/treatment patterns in sample 	To be reported in another publication

Table S2. Definitions of the ANRS 12249 TasP trial indicators and secondary outcomes

Outcome	Definition
Eligible	An individual is eligible if he/she was 16 years or older, member of a household and resident
Ever contacted	Individuals who have ever been contacted (seen and talked to) by a fieldworker at any given survey round.
Contact rate per round	Proportion of individuals contacted among eligible ones, computed per home-based survey round, i.e. an individual eligible in three survey rounds and fully contacted in two rounds will contribute three episodes in the denominator and two episodes in the numerator.
Ever ascertained HIV-positive	Participant whose HIV status has been ascertained (i.e. had a valid rapid test result or self-reported to be HIV-positive) at least once.
HIV ascertainment rate per round	Proportion of individuals HIV ascertained among contacted ones, computed per home-based survey round, i.e. an individual contacted in two survey rounds but HIV tested in only one round (test being refused in the second round) will contribute two episodes in the denominator and one episode in the numerator.
Ever linked to trial clinics	HIV-positive participant who ever visited a trial clinic after referral.
Entry into care within 6 months among individuals not in care	Among individuals (i) ever referred to a trial clinic (i.e. ever ascertained HIV-positive), (ii) not already found in DoH HIV care at the time of referral, and (iii) observed at least 6 months after referral, the proportion who ever visited a trial clinic within 6 months after referral.
Ever on ART in trial clinics	Ever initiated ART in trial clinics or already on ART at first trial clinic visit.
ART uptake in trial clinics	Proportion who initiated ART within trial clinics among those linked to a trial clinic and were ART-naïve at first trial clinic visit.
Ever virally suppressed in trial clinics	Viral load <400 copies/mL at least once after inclusion in trial clinics.
Residency status	Residency status of each participant was computed for each calendar day taking into account date of death, date of out-migration, 16 th anniversary and estimated date of in-migration.
Estimated HIV status	HIV status of each resident participant was estimated for each calendar day taking into account repeat DBS, repeat rapid tests, HIV+ self-reports and clinic visits. Date of seroconversion was estimated using a random point approach.
Estimated HIV prevalence	
	<i>At beginning of the trial</i>
	Considering all individuals included during the first survey round of each cluster and with an estimated HIV status at the date of inclusion in the population cohort, proportion being HIV-positive.
	<i>At a given date</i>
	Among resident participants at that date, proportion being HIV-positive (participants with an unknown HIV status excluded)
Estimated ART status	ART care status of each HIV-infected resident participant was computed using clinical data collected in trial clinics and additional data collected on ART prescription in government clinics (Hlabisa sub-district only) and on viral loads from National Health Laboratory Service (NHLS). With the authorization of the ethical committee, TasP, DoH and NHLS database have been linked at individual level using a probability score based on first, middle and last names, date of birth, South African ID and cell phone numbers.

A HIV-positive participant was considered as being on ART if he had an ART prescription (TasP or DoH) within the last 3 months or an undetectable viral load (NHLS) within the last 13 months.

Estimated population ART coverage

At beginning of the trial

Considering all participants registered during the first round of each cluster and being HIV-positive at the data of inclusion in the population cohort, proportion being actively on ART in trial or government clinics.

At a given date

Considering all participants being both resident and HIV-positive at that date, proportion being actively on ART in trial or government clinics at that date. By definition, population ART coverage is the product of the first and the second 90 (see below).

Population cascade of care at a given date

Diagnosed (first 90)

Considering all participants being both resident and HIV-positive at that date, proportion considered as being already diagnosed, taking into account rapid tests, self-reports and answers to home-based socio-demographic questionnaire in TasP and clinical visits in government clinics. Due to the fact that some individuals accepted to provide DBS but refused rapid HIV tests, we were able to identify individuals not yet diagnosed. In addition, knowing that some individuals were diagnosed at a later date allowed us to retrospectively estimate a period during which they were undiagnosed.

On treatment (second 90)

Considering HIV-positive resident participants already diagnosed at the given date, proportion who were actively on ART in trial or government clinics.

Virally suppressed (third 90)

Considering HIV-positive resident participants being on ART at that date, proportion whose last known viral load was undetectable (<400 copies/mL).

Sexual risk activity

Condom use at last round

Condom use with the last sexual partner within the last 12 months prior to the last round, among participants who completed a questionnaire at last round and who had at least one sexual partner during the last 12 months.

Sexual partner localisation

Localisation of the last sexual partner in the last 6 months prior to the last round among participants who completed a questionnaire at last round and who had at least one sexual partner during the last 6 months.

Retention in care at 12 months

Retention within trial clinics among all HIV-positive participants ever seen in trial clinics. It doesn't take into account the care trajectory within government clinics (or other places). A participant is defined as retained in care if he/she is not dead or transferred out and waiting for next appointment or less than 3 months late.

4. Study setting

Figure S1. Map of the ANRS 12249 trial clusters by arm and phased implementation.

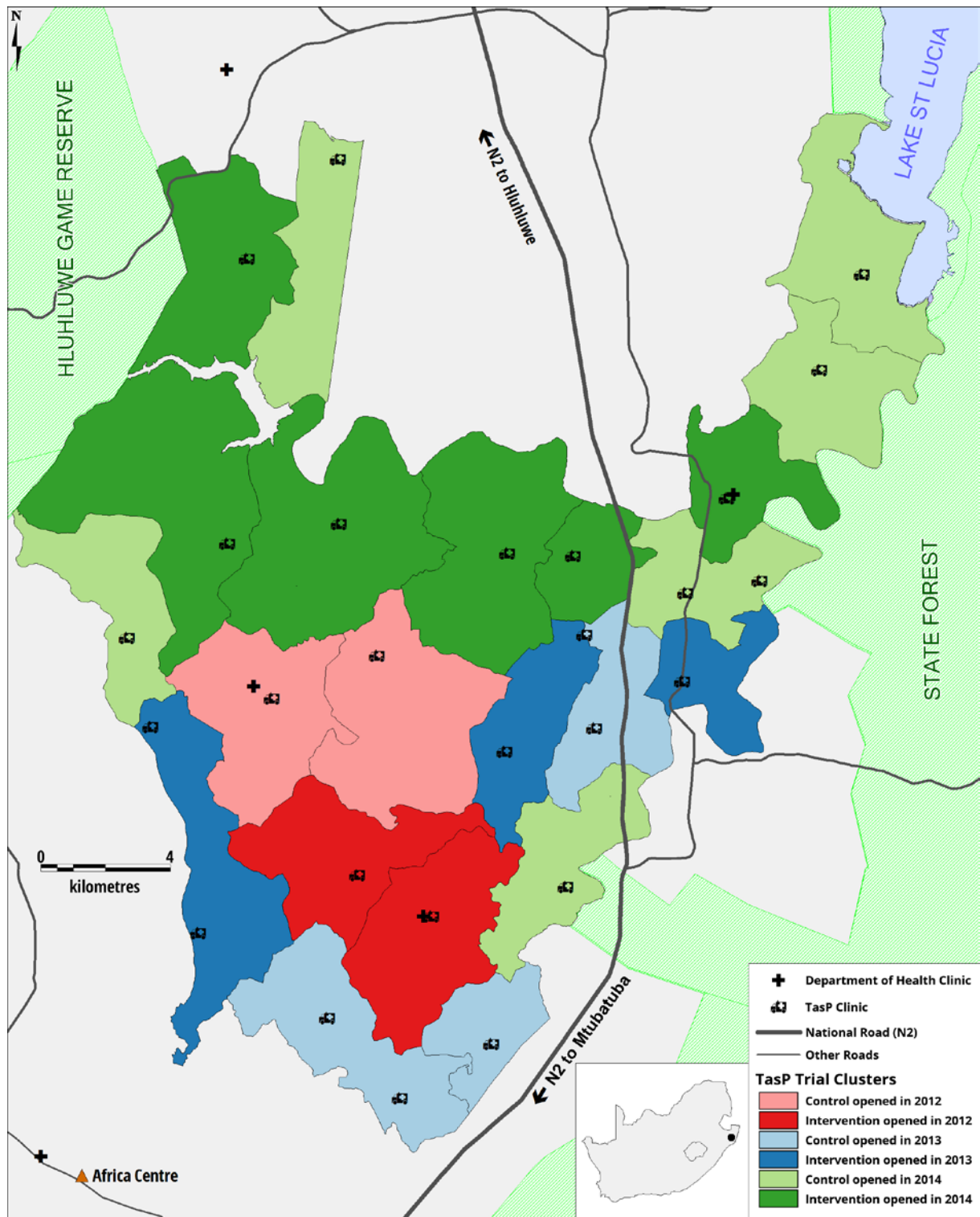
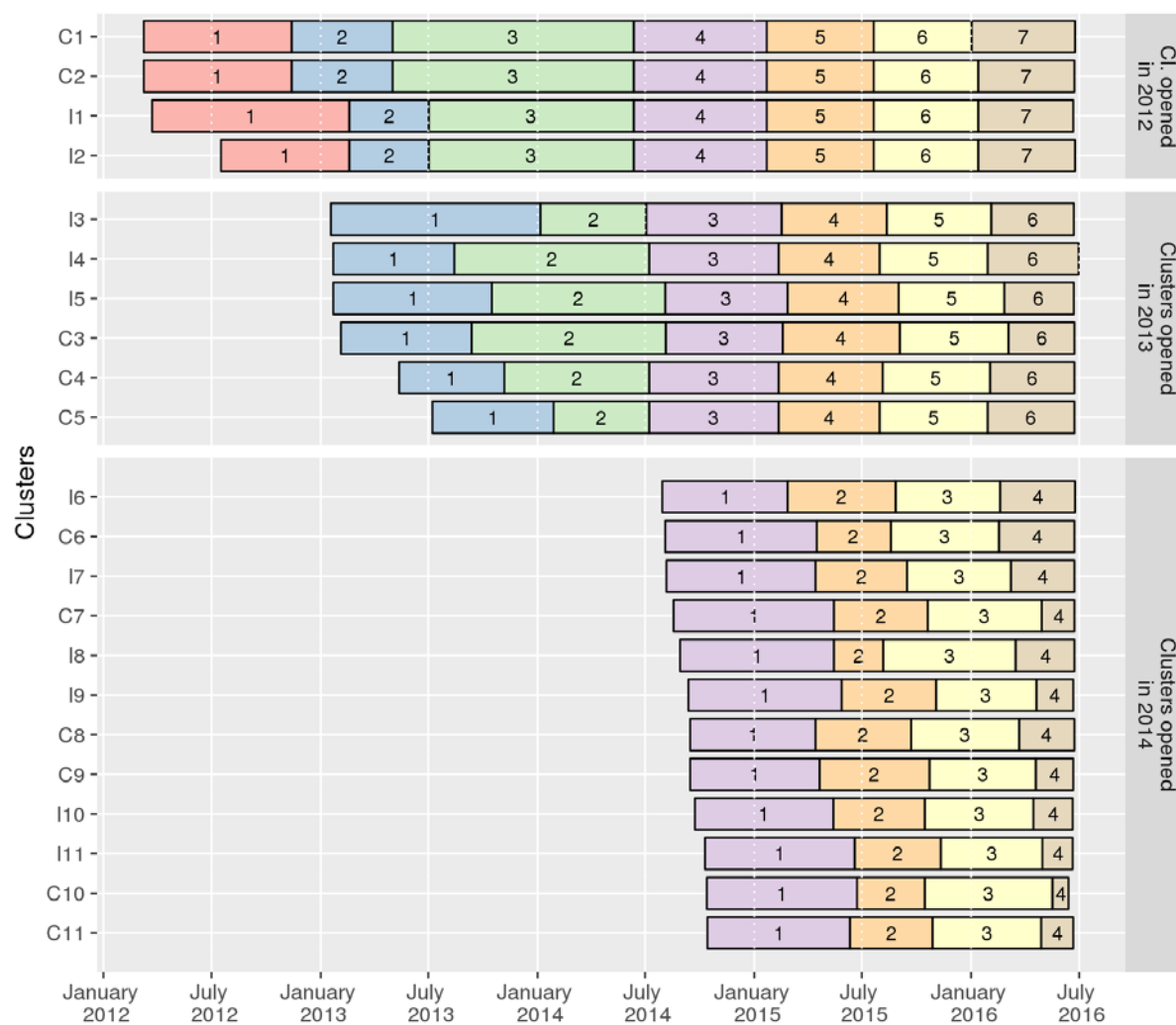


Figure S2. Dates of home-based survey rounds activities by cluster, ANRS 12249 TasP



5. Supplementary Analyses

Figure S3. Flow chart by trial arm. ANRS 12249 TasP trial (2012-2016).

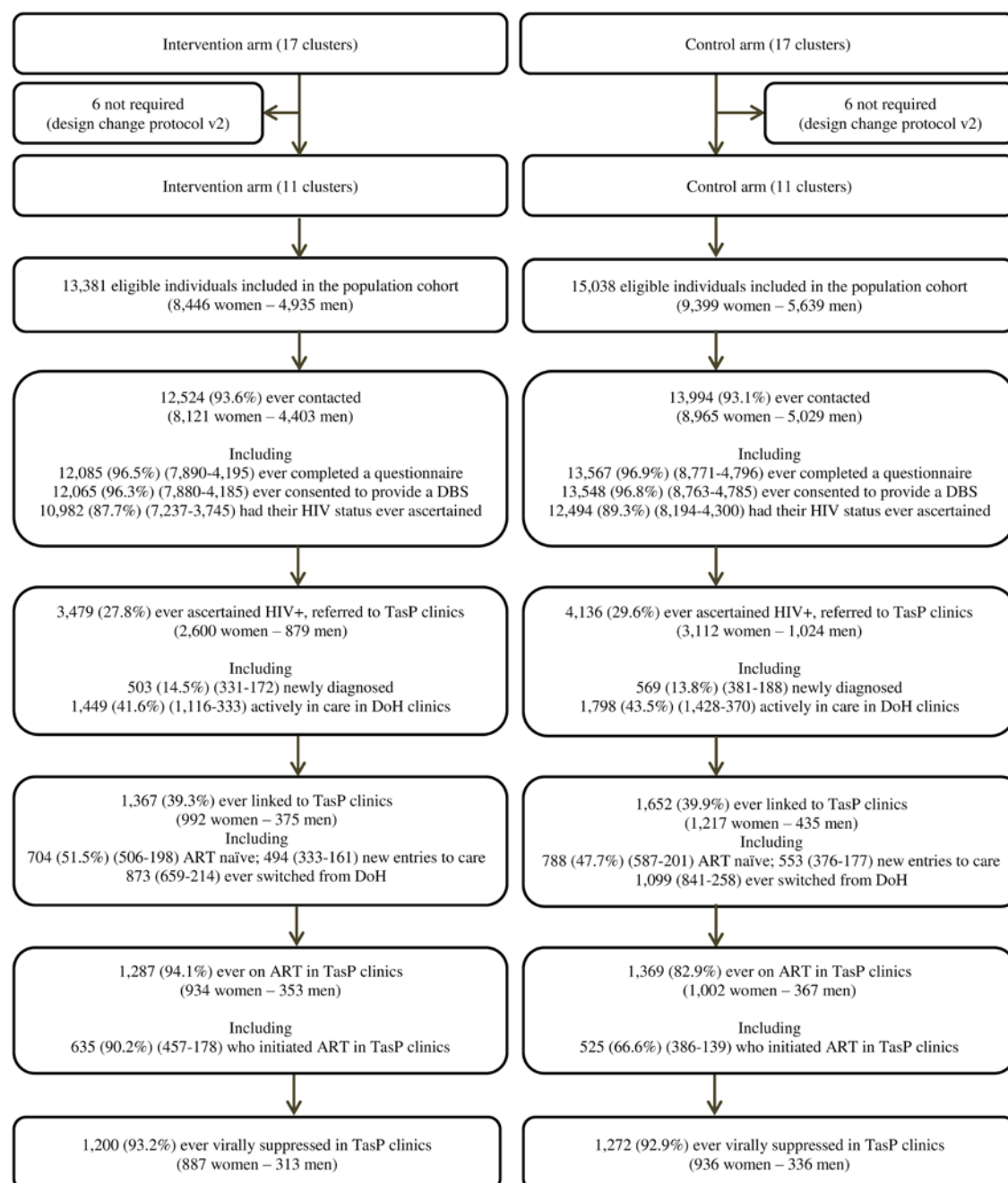


Table S3. Characteristics of individuals ever contacted compared to individuals never contacted. ANRS 12249 TasP trial (2012-2016).

		Individuals ever contacted	Individuals never contacted	p-value
In the intervention arm				
	N	12,524	857	
	Women (%)	8,121 (64.8)	325 (37.9)*	<0.0001
	Median age at inclusion (IQR)	30.2 (21.5-49.8)	26.6 (21.1-35.5)**	<0.0001
In the control arm				
	N	13,994	1,044	
	Women (%)	8,965 (64.1)	434 (41.6)*	<0.0001
	Median age at inclusion (IQR)	30.3 (21.4-49.5)	25.8 (20.5-33.4)**	<0.0001

* Proportion of female was not different between intervention and control arms among individuals not contacted (p=0.11)

** Median age was similar between the control and the intervention arm among individuals not contacted (p=0.43)

Table S4. Baseline characteristics of participants out-migrated at any point compared to participants never out-migrated among contacted. ANRS 12249 TasP trial (2012-2016).

	Never out-migrated (n=17,558)	Out-migrated at any point (n=8,960)	p-value
Women (%)	11,744 (66.9)	5,342 (59.6)	<0.0001
Age at inclusion in years (%)			<0.0001
16-29	5,993 (34.1)	5,813 (64.9)	
30-59	6,654 (37.9)	2,114 (23.6)	
60 and more	3,102 (17.7)	240 (2.7)	
Year of birth unknown	1,809 (10.3)	793 (8.9)	
Median age at inclusion (IQR)	38.0 (23.1-56.0)	24.5 (20.4-31.3)	<0.0001
Highest education level (%)			<0.0001
Primary or less	7,962 (45.3)	1,533 (17.7)	
Some secondary	6,043 (34.4)	3,498 (39.0)	
At least completed secondary	3,026 (17.2)	3,550 (39.6)	
Never documented	527 (3.0)	379 (4.2)	
Marital status (%)			<0.0001
Never been married	10,961 (62.4)	7,628 (85.1)	
Engaged	957 (5.5)	359 (4.0)	
Married	3,805 (21.7)	478 (5.3)	
Divorced/Separated/Windowed	1,312 (7.5)	124 (1.4)	
Never documented	523 (3.0)	371 (4.1)	
Professional status (%)			<0.0001
Employed	1,627 (9.3)	920 (10.3)	
Student	3,315 (18.9)	2,158 (24.1)	
Looking for work	3,100 (18.9)	2,874 (32.1)	
Other inactive	8,966 (51.1)	2,583 (28.8)	
Never documented	550 (3.1)	425 (4.7)	

Table S5a. Baseline characteristics of participants selected for the incidence analysis (at least two DBS with valid results documented and a first DBS as negative) compared to participants with only one sample documented (first DBS as negative). ANRS 12249 TasP trial (2012-2016).

		Selected for the incidence analysis	Only 1 sample	p-value
In the intervention arm				
	N	6,756	1,706	
	Women (%)	4,407 (65.2)	798 (46.8)*	<0.0001
	Median age at inclusion (IQR)	30.1 (19.9-56.7)	23.9 (19.8-31.4)**	<0.0001
In the control arm				
	N	7,467	1,879	
	Women (%)	4,749 (63.6)	900 (47.9)*	<0.0001
	Median age at inclusion (IQR)	29.7 (20.0-56.5)	23.2 (19.4-30.2)**	<0.0001
In both arms (combined)				
	N	14,223	3,585	
	Women (%)	9,156 (64.4)	1,698 (47.4)	<0.0001
	Median age at inclusion	29.9 (19.9-56.5)	23.5 (19.6-30.7)	0.036

* The proportion of women was not different between intervention and control arms among individuals with only one sample documented (p=0.50)

** Median age was similar between the control and the intervention arm among individuals with only one sample documented (p=0.06)

Table S5b. Baseline characteristics of participants selected for the incidence analysis (at least two DBS with valid results documented and a first DBS as negative) compared to participants with only one sample documented (first DBS as negative). ANRS 12249 TasP trial (2012-2016).

		Selected for the incidence analysis (n=14,223)	Only 1 sample (n=3,585)	p-value
In both arms (combined)				
Women (%)		9,156 (64.4)	1,698 (47.4)	<0.0001
Age at inclusion in years (%)				
	16-29	6,573 (46.2)	2,259 (63.0)	<0.0001
	30-59	3,798 (26.7)	583 (16.3)	
	60 and more	2,743 (19.3)	236 (6.6)	
	Year of birth unknown	1,109 (7.8)	507 (14.1)	
Median age at inclusion		29.9 (19.9-56.5)	23.5 (19.6-30.7)	0.036
Highest education level (%)				
	Primary or less	5,849 (41.1)	727 (20.3)	<0.0001
	Some secondary	5,329 (37.5)	1,304 (36.4)	
	At least completed secondary	3,033 (21.3)	1,338 (37.3)	
	Never documented	12 (0.1)	216 (6.0)	
Marital status (%)				
	Never been married	9,459 (66.5)	2,839 (79.2)	<0.0001
	Engaged	664 (4.7)	112 (3.1)	
	Married	3,064 (21.5)	324 (9.0)	
	Divorced/Separated/Windowed	1,032 (7.3)	98 (2.7)	
	Never documented	4 (0.0)	212 (5.9)	
Professional status (%)				
	Employed	1,000 (7.0)	414 (11.6)	<0.0001
	Student	3,989 (28.1)	968 (27.0)	
	Looking for work	2,473 (17.4)	939 (26.2)	
	Other inactive	6,745 (47.4)	1,021 (28.5)	
	Never documented	16 (0.1)	243 (6.8)	

Table S6. Baseline characteristics of participants selected in the incidence analysis (at least two DBS with valid results documented and a first DBS as negative) compared to participants with a first DBS as positive. ANRS 12249 TasP trial (2012-2016).

	Selected for the incidence analysis (n=14,223)	First DBS positive (n=7,775)	p-value
Women (%)	9,156 (64.4)	5,770 (74.2)	<0.0001
Age at inclusion in years (%)			<0.0001
16-29	6,573 (46.2)	2,706 (34.8)	
30-59	3,798 (26.7)	4,191 (53.9)	
60 and more	2,743 (19.3)	325 (4.2)	
Year of birth unknown	1,109 (7.8)	553 (7.1)	
Median age at inclusion (IQR)	29.9 (19.9-56.5)	33.6 (26.7-44.0)	<0.0001
Highest education level (%)			<0.0001
Primary or less	5,849 (41.1)	2,837 (36.5)	
Some secondary	5,329 (37.5)	2,811 (36.2)	
At least completed secondary	3,033 (21.3)	2,038 (26.2)	
Never documented	12 (0.1)	89 (1.1)	
Marital status (%)			<0.0001
Never been married	9,459 (66.5)	6,055 (77.9)	
Engaged	664 (4.7)	516 (6.7)	
Married	3,064 (21.5)	831 (10.7)	
Divorced/Separated/Windowed	1,032 (7.3)	283 (3.6)	
Never documented	4 (0.0)	90 (1.2)	
Professional status (%)			<0.0001
Employed	1,000 (7.0)	1,072 (13.8)	
Student	3,989 (28.1)	463 (6.0)	
Looking for work	2,473 (17.4)	2,459 (31.6)	
Other inactive	6,745 (47.4)	3,661 (47.1)	
Never documented	16 (0.1)	120 (1.5)	

Table S7a. Effect of the TasP intervention on HIV incidence estimated with GEE and augmented GEE adjusted for age, sex, modifications in WHO guidelines, initial ART coverage and initial HIV prevalence. ANRS 12249 TasP trial (2012-2016).

Intervention vs. control	HR	95%CI	P-value
Unadjusted GEE	0.95	0.75-1.20	0.68
Augmented GEE	1.01	0.87-1.17	0.89

Table S7b. Sensitivity analysis on the effect of the TasP intervention on HIV incidence estimated with GEE considering two scenarios. ANRS 12249 TasP trial (2012-2016).

For this sensitivity analysis, the 3 585 individuals with only one negative DBS sample (cf. Tables S4a and S4b) were included in the analysis, under two scenarios: (a) these 3 585 individuals seroconverted to HIV at a random date between their first negative sample and the date they exited the population (death or out-migration) or trial end (June 1st 2016); (b) these 3 585 individuals had a second negative DBS sample at a random date between their first sample and the date they exited population or trial end.

Scenario	HR	95%CI	P-value
(a) the 3 585 seroconverted	0.94	0.73-1.19	0.56
(b) the 3 585 remained HIV negative	0.92	0.81-1.05	0.20

Table S8. Characteristics of trial clusters. ANRS 12249 TasP trial (2012-2016).

	Estimated HIV prevalence at 1 st round (%)	Estimated ART coverage at 1 st round (%)	Age at inclusion <30 years (%)	Age at inclusion ≥60 years (%)	Proportion of females (%)
Cluster 1 (Madwaleni)	22.2	31.0	47.6	13.5	60.0
Cluster 2 (Shunqa)	26.0	32.7	43.2	13.1	62.3
Cluster 3 (Embongolweni)	22.4	31.8	49.5	15.0	59.5
Cluster 4 (Ntondweni)	21.7	28.8	47.0	14.5	65.6
Cluster 5 (kwaGxaba)	18.5	27.0	34.3	12.8	62.8
Cluster 6 (Makhambane)	23.8	36.6	36.8	12.6	59.5
Cluster 7 (Cakula)	20.6	45.3	30.6	18.4	69.8
Cluster 8 (kwaSqumbe)	35.7	39.8	37.9	10.2	59.6
Cluster 9 (Bhekamandla)	31.7	33.5	37.4	11.9	66.4
Cluster 10 (Egedeni)	39.7	30.4	38.9	11.8	60.4
Cluster 11 (Mchakwini)	37.6	29.1	38.2	9.0	62.4
Cluster 12 (Mfekayi)	35.0	36.8	33.2	12.0	64.1
Cluster 13 (Makhwela)	33.1	30.0	39.9	10.8	60.8
Cluster 14 (Esiphahleni)	32.3	22.9	37.5	10.9	64.7
Cluster 15 (Nkundusi)	26.8	28.5	38.8	15.6	62.6
Cluster 16 (Mazala)	35.5	28.5	40.3	10.3	65.2
Cluster 17 (Chwebeni)	31.2	29.4	36.0	11.7	59.5
Cluster 18 (Maqanda)	28.6	35.5	36.7	14.2	66.4
Cluster 19 (Danyini)	24.2	31.6	31.0	14.7	65.2
Cluster 20 (Esiqiwini)	17.0	39.1	28.4	17.7	69.5
Cluster 21 (Edwalaneni)	28.2	35.4	32.0	12.5	64.8
Cluster 22 (Gotshi)	26.3	30.5	32.3	12.6	63.1

Table S9. Patient cohort profile, by trial arm. ANRS 12249 TasP trial (2012-2016).

		Ever linked to trial clinics, intervention (n=1 367)	Ever linked to trial clinics, control (n=1 652)	Ever linked to trial clinics, total (n=3 019)
Sex (%)				
	<i>Women</i>	992 (72·6)	1,217 (73·7)	2,209 (73·2)
	<i>Men</i>	375 (27·4)	435 (26·3)	810 (26·8)
Age at inclusion in years (%)				
	<i>16-29</i>	424 (31·0)	438 (26·6)	862 (28·6)
	<i>30-59</i>	834 (61·1)	1,089 (66·0)	1,923 (63·8)
	<i>60 and more</i>	101 (7·4)	118 (7·2)	219 (7·3)
	<i>Year of birth unknown</i>	8 (0·6)	7 (0·4)	15 (0·5)
Median age at first clinic visit (IQR)		36·2 (28·1-48·1)	38·5 (29·6-49·6)	37·5 (28·8-49·0)
Highest education level (%)				
	<i>Primary or less</i>	635 (46·5)	831 (50·3)	1,466 (48·6)
	<i>Some secondary</i>	449 (32·9)	528 (32·0)	977 (32·4)
	<i>At least completed secondary</i>	279 (20·4)	280 (17·0)	559 (18·5)
	<i>Never documented</i>	4 (0·3)	13 (0·8)	17 (0·6)
Marital status (%)				
	<i>Never been married</i>	1,065 (77·9)	1,281 (77·5)	2,346 (77·7)
	<i>Engaged</i>	72 (5·3)	110 (6·7)	182 (6·0)
	<i>Married</i>	171 (12·5)	154 (9·3)	325 (10·8)
	<i>Divorced/Separated/Windowed</i>	55 (4·0)	93 (5·6)	148 (4·9)
	<i>Never documented</i>	4 (0·3)	14 (0·9)	18 (0·6)
Professional status (%)				
	<i>Employed</i>	181 (13·2)	206 (12·5)	387 (12·8)
	<i>Student</i>	58 (4·2)	52 (3·2)	110 (3·6)
	<i>Looking for work</i>	385 (28·2)	449 (27·2)	834 (27·6)
	<i>Other inactive</i>	737 (53·9)	928 (56·2)	1,665 (55·2)
	<i>Never documented</i>	6 (0·4)	17 (1·0)	23 (0·8)
Median time in weeks between first referral and first trial clinic visit (IQR)		3·0 (0·9-24·3)	2·4 (0·9-19·1)	2·7 (0·9-21·7)
ART status at baseline clinic visit (%)				
	<i>Ongoing ART</i>	611 (44·7)	801 (48·5)	1,412 (46·8)
	<i>Defaulted ART, ART experienced</i>	28 (2·1)	38 (2·3)	66 (2·2)
	<i>Not on ART, ART naïve</i>	704 (51·5)	788 (47·7)	1,492 (49·4)
	<i>Unknown status</i>	24 (1·8)	25 (1·5)	49 (1·6)
Initiated ART within trial (among ART-naïve at baseline clinic visit)		635	525	1,160
Median CD4 count at ART initiation in cells/μl (IQR)		401 (265-572)	320 (212-442)	356 (234-498)
Median viral load at ART initiation in log copies/ml (IQR)		4·4 (3·8-5·1)	4·5 (3·7-5·1)	4·4 (3·8-5·1)
Initiated ART within trial and on ART at least 12 months (%)		415 (65·4)	301 (57·3)	698 (60·2)
Median CD4 count at ART initiation in cells/μl (IQR) among ART-naïve on ART at least 12 months		394 (253-569)	304 (207-415)	345 (226-496)
On ART at least 12 months with VL data		363	265	628
Viral suppression among ART naïve treated >12 months (%)		352 (97·0)	259 (97·7)	611 (97·3)

Table S10. Mortality incidence and adjusted hazard ratio estimated with Poisson regression adjusted for age, sex, initial ART coverage and initial HIV prevalence, among HIV-positive patients seen in trial clinics. ANRS 12249 TasP trial (2012-2016).

	Intervention	Control	Total
Number of individuals seen in trial clinics	1 367	1 652	3 019
Number of deaths	33	58	91
Person-years	2 578	3 122	5 700
Crude incidence (95% CI)	1.28 (0.84-1.72)	1.86 (1.38-2.34)	1.60 (1.27-1.92)
Unadjusted HR (95% CI, p-value)	0.69 (0.45-1.06, 0.088)	1	
Adjusted HR (95% CI, p-value)	0.69 (0.42-1.15, 0.15)	1	

Table S11. Serious adverse events among HIV-positive patients seen in trial clinics. ANRS 12249 TasP trial (2012-2016).

	Intervention	Control	Total
No of HIV-positive patients seen in trial clinics	1 367	1 652	3 019
No of HIV-positive patients with one or more adverse events	59 (4.3%)	69 (4.2%)	128 (4.2%)
No of adverse events by category	84	105	189
Liver	11 (13.1%)	21 (20.0%)	32 (16.9%)
Digestive	16 (19.0%)	16 (15.2%)	32 (16.9%)
Renal	13 (15.5%)	15 (14.3%)	28 (14.8%)
Haematology	9 (10.7%)	17 (16.2%)	26 (13.8%)
Neurology	8 (9.5%)	9 (8.6%)	17 (9.0%)
Cardiovascular	4 (4.8%)	6 (5.7%)	10 (5.3%)
Musculoskeletal	4 (4.8%)	2 (1.9%)	6 (3.2%)
Others	19 (22.6%)	19 (18.1%)	38 (20.1%)

Table S12. Estimated cascade of HIV care and population ART coverage as of 1 January, 2016. ANRS 12249 TasP trial (2012-2016)

	Intervention	Control	Total
90-90-90 cascade of HIV care			
Diagnosed (first 90)	91.1% (2 632/2 888)	91.8% (3 065/3 338)	91.5% (5 697/6 226)
On treatment (second 90)	58.5% (1 541/2 632)	57.5% (1 763/3 065)	58.0% (3 304/5 697)
Virally suppressed (third 90)	86.6% (1 334/1,541)	84.1% (1 483/1 763)	85.3% (2 817/3 304)
Population ART coverage (first and second 90 combined)	53.4% (1 541/2 888)	52.8% (1 763/3 338)	53.1% (3 304/6 226)

Care status was estimated using trial and government clinic data, and computed among people still living in the trial area and alive (see Supplementary table 1 for more details)

Table S13. Sexual behaviours at population-level. ANRS 12249 TasP trial (2012-2016).

	Intervention	Control	Total	p-value
Condom use at last sex (%)				
In the first round*	38.0 (249/655)	29.4 (182/619)	33.8 (431/1,274)	0.001
In the last round**	45.4 (1 390/3 065)	43.3 (1 691/3 903)	44.2 (3 081/6 968)	0.084
Sexual partnerships (%)				
Outside trial area in the last round**	41.6 (1 271/3 055)	37.1 (1 444/3 893)	39.1 (2 715/6 948)	0.0001

* Questionnaires collected at home during the first round of each cluster

** Questionnaires collected at home during the last survey round