Early ART Initiation in West Africa has no Adverse Social Consequences: A 24-Month Prospective Study

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Research Letter (1000 words)

Running head: Social impact of early ART initiation

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Main text: 979 words

ABSTRACT (70 words)

Based on social indicators collected within the TEMPRANO-ANRS12239 trial, we assessed the social consequences of early ART initiation in West Africa. We did not observe any significant differences in the levels or the time trends of various social indicators, including union status, HIV disclosure and HIV-related discrimination, between early and deferred ART initiation. Early ART does not carry detectable adverse social consequences that could impair its clinical and preventive benefits.

Key-words: HIV; antiretroviral therapy; sub-Saharan Africa; clinical trial; health care; early ART initiation; social integration.

MAIN TEXT (999 words)

Two randomized trials recently documented important clinical benefits of very early antiretroviral therapy (ART) [1,2]. These results complemented previous evidence of the preventive effect of early ART [3], so that treatment and prevention can now be seen as converging goals. Beyond preventive and clinical effects of early ART initiation, its possible consequences on social dimensions of patients' lives remain to be documented.

Pathways linking ART initiation to repercussion on various social dimensions are complex and partially understood. ART initiation is associated with HIV status disclosure to relatives [4–6], which can in turn lead to increased social support but also to rejection [7,8]. Similarly, the impact of ART on stigma and discrimination seems ambiguous [9–11]. Positive impact on professional activity has been more consistently documented [12,13]. However, these associations have been observed among people initiating ART at low CD4 count or with HIV-related symptoms. Negative events associated with ART may be more likely among people with high CD4 count, among whom treatment initiation may reveal a hitherto unapparent HIV infection.

With new international guidelines recommending ART for every HIV-infected person, trends should progressively move toward earlier treatment initiation [14]. The social repercussions of ART initiation among people perceiving themselves, or being perceived by their relatives, as healthy have not been documented yet, although they may have a substantial impact on acceptation and adherence, and ultimately on the public health impact of this strategy.

Relying on social data collected within the TEMPRANO-ANRS12136 randomized controlled trial, we aimed to assess the impact of early ART on various dimensions reflecting social inclusion and the experience of discrimination.

The present socio-behavioral study was nested in the TEMPRANO-ANRS12136 trial, a randomized trial of early ART that was conducted in Abidjan (Côte d'Ivoire) [1,15]. At inclusion, ART-naïve participants presenting no criteria for starting ART were randomized to initiate ART immediately ("early ART") or to defer ART until ongoing WHO criteria for treatment initiation were met ("deferred ART")

[16,17]. Standardized socio-behavioral questionnaires were completed during face-to-face interviews conducted at inclusion, and then during clinical visits occurring around 12 and 24 months after inclusion.

Questionnaires included items related to household composition, couple status, HIV status disclosure inside and outside the household, professional activity and experience of discriminations. From these items, we constructed the following indicators: living alone (yes/no), being in union (yes/no), having disclosed HIV status inside (yes/no) or outside (yes/no) the household, having had a regular professional activity in the last 6 months (yes/no) and having experienced HIV-related discriminations in the last 12 months (yes/no).

All trial participants having completed a questionnaire at one or more of the following timings were included in the analysis: i) M0 (inclusion visit), ii) M12 (12±3 months after inclusion), and iii) M24 (24±6 months after inclusion). For each indicator, levels and time trends from M0 to M24 were assessed and compared between deferred and early ART groups. Generalized Estimating Equations (GEE) with a logit link were used to account for multiple observations. Models included ART group and time period (coded as a three-level factor: M0/M12/M24) as covariates. Interaction terms between ART group and time period were added in order to test differential time trends between ART groups.

A total of 2061 participants (deferred ART: 1028; early ART: 1033) completed at least one socio-behavioral questionnaire (Table S1). Median baseline CD4 count was 469/mm^3 (IQR 379-577), 91% were WHO stage 1 or 2. After randomization, participants' socio-demographic and clinical characteristics distributions were balanced between both groups (Table S2).

Levels and time trends in social indicators according to ART strategy are presented in Figure 1. Twenty-four months after inclusion, we did not observe any significant differences in the level reported by participants between the early and deferred ART group for any of the indicators (Table S3). The interaction term between randomization group and time was not significant for any of the indicators (each $p>0.25$), suggesting that the observed time trends between M0 and M24 were not significantly different between ART strategies (Table S4). Results were similar when stratifying the analysis by sex (Table S5).

Motivation to start and adhere to ART may be difficult for people at early stage of HIV infection [18,19]. By increasing the visibility of HIV infection among apparently healthy people, one could have feared that early ART would lead to HIV disclosure, and potentially to discrimination, union breaking and loneliness. Moreover, adverse consequences on occupational activity could have been expected due to potential side effects of ART [20]. Documenting the absence of detectable associated negative social events is thus reassuring with regard to the social feasibility of very early ART and may help remove barriers to entry in treatment.

This study reports an absence of evidence supporting adverse social effect of early ART. Several elements suggest that, had substantial effects existed, this study would have successfully detected them. First, we relied on a large sample size that would have allowed detecting even small effect sizes. Second, information was collected face-to-face by trained interviewers using standardized questionnaires. Randomization ensured an equivalent distribution of confounders between the control and intervention groups. As follow-up was similar in both groups, differential report bias appears unlikely. However, the studied indicators did not cover key socio-behavioural issues such as intimate partner violence or mental health. Monitoring the implementation of the updated recommendations for ART initiation may help assess these issues.

To our knowledge, no previous study has addressed the issue of the repercussion of early ART on diverse social dimensions. These results have been obtained within a trial that documented strong clinical individual benefits of early ART alongside evidence for reduced sexual risk behaviours following early entry into care and decreased risk of transmission due to the effect of ART on viral load [1,15,22]. As a whole, these results show that early ART in a West African context appears to combine clinical and preventive benefits that are not impaired by potential adverse social effects. This reinforces the relevance of generalized recommendations of ART initiation as soon as possible for HIV-infected people in Africa.

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ADL, FL, RDS and CD designed the research and obtained funds. RM, GMK and AB contributed to acquisition of data. CD, RM, SE and XA supervised the study. KJ, SN, CD, RDS, FL and ADL

contributed to study concept and design. SN, KJ and DG prepared and analysed the data. KJ, SN and ADL performed the literature research and drafted the manuscript. CD, RM, RDS, SE, FL and XA critically revised the manuscript for important intellectual content.

Source of support: This trial was supported by the French Agence Nationale de Recherches sur le SIDA et les hépatites virales (ANRS), Paris, France [ANRS 12136 and ANRS 12239]. The sponsor of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

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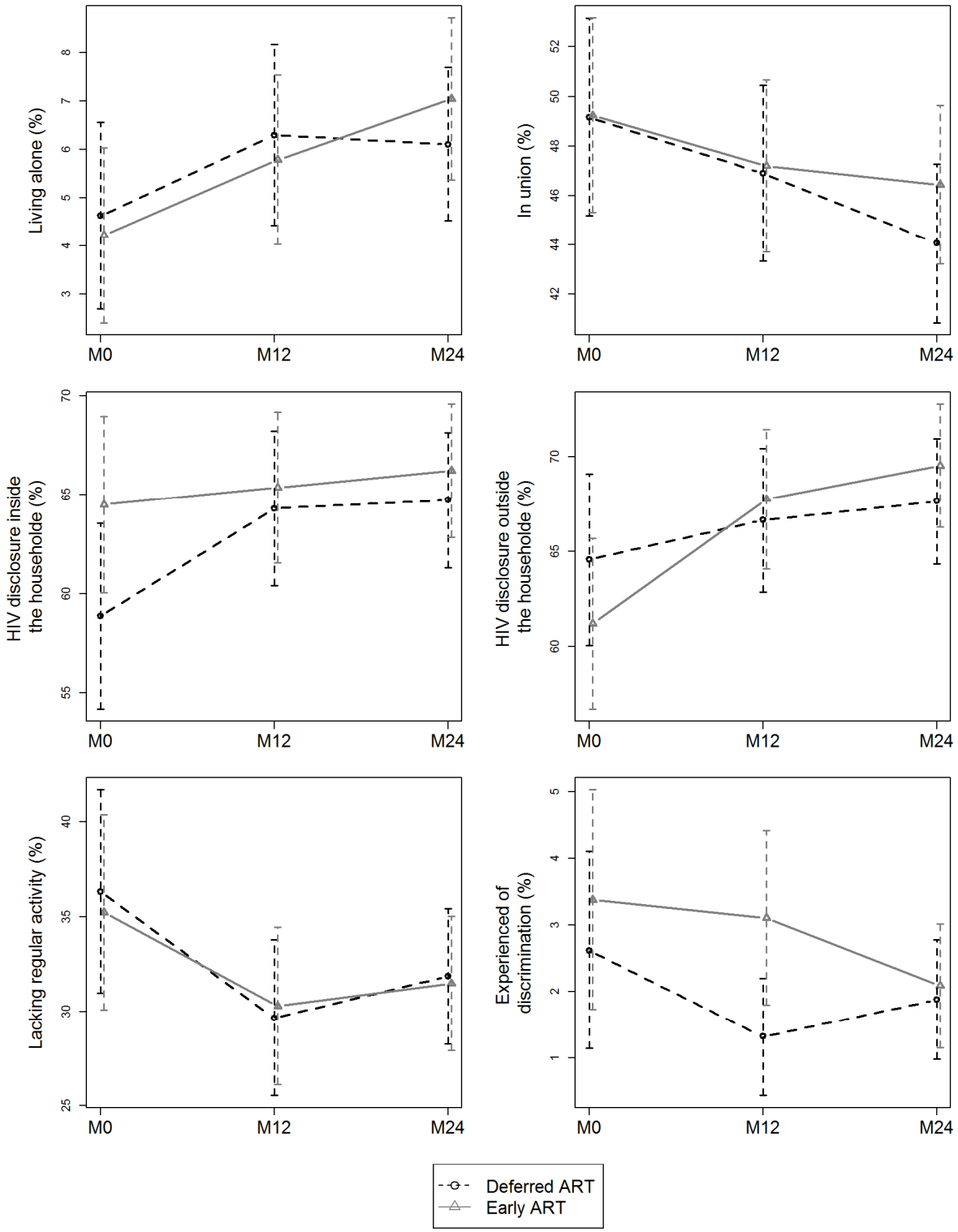

Figure 1 : Social indicators reported at inclusion (M0). 12-month (M12) and 24-month visits among participants on deferred vs. early antiretroviral therapy (ART).

Percentages and 95% Confidence Intervals are computed using Generalized Estimating Equations.

SUPPLEMENTARRY MATERIAL

Table S1 : Participants' baseline sociodemographic and clinical data according to randomisation group.

	Deferred ART (N=1028)	Early ART (N=1033)	p
Sex			**0.163**
Men	235 (22.9%)	210 (20.3%)	
Women	793 (77.1%)	823 (79.7%)	
Age	35 [30 – 42]	35 [30 – 42]	**0.563**
Educational level			**0.385**
None	245 (23.8%)	276 (26.7%)	
Primary	301 (29.3%)	293 (28.4%)	
Secondary	342 (33.3%)	341 (33.0%)	
>Secondary	140 (13.6%)	123 (11.9%)	
Religion			**0.620**
None	39 (3.8%)	35 (3.4%)	
Muslim	258 (25.1%)	263 (25.5%)	
Christian	720 (70.0%)	729 (70.6%)	
Other	11 (1.1%)	6 (0.6%)	
Nationality			**0.693**
Ivorian	916 (89.1%)	926 (89.6%)	
Other	112 (10.9%)	107 (10.4%)	
WHO clinical stage			**0.866**
1	673 (65.5%)	665 (64.4%)	
2	264 (25.7%)	272 (26.3%)	
3	91 (8.8%)	96 (9.3%)	
CD4 count cell (/mm3)	459 [360 - 568]	466 [373 - 578]	**0.202**

Counts (%) and Chi2 p-values are presented for categorical measures. Percent are computed as a fraction of non-missing observations. Medians (interquartile ranges) and t-test p-values are presented for quantitative measures.

Table S2 : Levels of social indicators 24 months after inclusion according to ART strategy.

	At M24	
	OR $_{\text{Early/Deferred ART}}$	[CI 95%]
Living alone	1.16	[0.80 ; 1.70]
In union	1.10	[0.92 ; 1.32]
HIV disclosure inside the household	1.07	[0.86 ; 1.32]
HIV disclosure outside the household	1.09	[0.88 ; 1.35]
Lack of regular professional activity	0.98	[0.78 ; 1.24]
Experience of HIV-related discrimination in the last 12 months	1.11	[0.57 ; 2.18]

Odds Ratio have been estimated using Generalized Estimating Equations (GEE) accounting for ART group, time period, and an interaction term. OR: Odds Ratio; CI: Confidence Interval; M24: 24 months after inclusion.

Table S3 : Time trends in social indicators**.**

	Model with interaction term[1]					Model without interaction term[1]	
	Deferred ART		Early ART		Interaction p	Overall	
	$OR_{M24/M0}$	[CI 95%]	$OR_{M24/M0}$	[CI 95%]		$OR_{M24/M0}$	[CI 95%]
Living alone	1.34	[0.84 ; 2.14]	1.72	[1.08 ; 2.74]	0.582	1.52	[1.09 ; 2.12]
In union	0.81	[0.70 ; 0.94]	0.89	[0.77 ; 1.03]	0.534	0.85	[0.77 ; 0.94]
HIV disclosure inside the household	1.28	[1.04 ; 1.57]	1.08	[0.88 ; 1.32]	0.404	1.18	[1.02 ; 1.36]
HIV disclosure outside the household	1.15	[0.94 ; 1.40]	1.44	[1.19 ; 1.75]	0.245	1.29	[1.13 ; 1.48]
Lack of regular professional activity	0.82	[0.62 ; 1.07]	0.84	[0.65 ; 1.10]	0.928	0.83	[0.69 ; 1.01]
Experience of HIV-related discrimination in the last 12 months	0.71	[0.35 ; 1.42]	0.61	[0.33 ; 1.13]	0.253	0.65	[0.41 ; 1.04]

[1] Interaction terms between ART group and time period.
OR: Odds Ratio; CI: Confidence Interval; M0: At inclusion; M24: 24 months after inclusion.

Table S4: Social indicators according to ART strategy and time since inclusion (among women, men, and both sex).

	Deferred ART				Early ART				Interaction p[1]
Timing	%	$OR_{M24/M0}$	95%CI	p	%	$OR_{M24/M0}$	95%CI	p	
Women									
Living alone									0,605
M0	3.1	-	-	-	3	-	-	-	
M24	4.1	1,28	[0,68 ; 2,40]	0,447	5.1	1,85	[1,00 ; 3,44]	0,051	
In union									0,379
M0	47.1	-	-	-	47.4	-	-	-	
M24	39.2	0,76	[0,65 ; 0,90]	0,001	41.6	0,88	[0,75 ; 1,03]	0,101	
HIV disclosure inside the household									0,550
M0	60.5	-	-	-	68.2	-	-	-	
M24	63.5	1,17	[0,93 ; 1,46]	0,176	65.5	1,02	[0,82 ; 1,28]	0,833	
HIV disclosure outside the household									0,169
M0	68	-	-	-	59.8	-	-	-	
M24	69.3	1,16	[0,92 ; 1,47]	0,195	72.5	1,58	[1,27 ; 1,96]	0,000	
Lack of regular professional activity									0,856
M0	39.0	-	-	-	35.3	-	-	-	
M24	33.3	0,76	[0,55 ; 1,03]	0,077	31.3	0,82	[0,60 ; 1,10]	0,188	
Experience of HIV-related discrimination in the last 12 months									0,392
M0	2.8	-	-	-	4.1	-	-	-	
M24	2.2	0,81	[0,38 ; 1,72]	0,592	2.3	0,60	[0,32 ; 1,15]	0,122	

[1] Interaction terms between ART group and time period.

Odds Ratio have been estimated using Generalized Estimating Equations (GEE) accounting for ART group, time period, and an interaction term.

OR: Odds Ratio; CI: Confidence Interval; M0: At inclusion; M24: 24 months after inclusion.

Table S4 (continued): Social indicators according to ART strategy and time since inclusion (among women, men, and both sex).

	Deferred ART				Early ART				Interaction p[1]
Timing	%	$OR_{M24/M0}$	95%CI	p	%	$OR_{M24/M0}$	95%CI	p	
Men									
Living alone									0,751
M0	9.1	-	-	-	9.5	-	-	-	
M24	12.8	1,51	[0,75 ; 3,07]	0,25	14.1	1,35	[0,65 ; 2,79]	0,424	
In union									0,837
M0	60.6	-	-	-	71.6	-	-	-	
M24	61.7	1,03	[0,74 ; 1,44]	0,852	65.8	0,88	[0,60 ; 1,30]	0,529	
HIV disclosure inside the household									0,705
M0	60.0	-	-	-	66.1	-	-	-	
M24	75.0	1,94	[1,19 ; 3,16]	0,008	74.8	1,04	[0,66 ; 1,62]	0,870	
HIV disclosure outside the household									0,576
M0	53.2	-	-	-	56.4	-	-	-	
M24	59.8	1,07	[0,72 ; 1,59]	0,732	59.1	1,42	[0,82 ; 2,44]	0,207	
Lack of regular professional activity									0,989
M0	25.0	-	-	-	30.9	-	-	-	
M24	26.7	1,02	[0,58 ; 1,81]	0,931	31.5	0,96	[0,54 ; 1,72]	0,905	
Experience of HIV-related discrimination in the last 12 months[2]									
M0	2.0	-	-	-	1.4	-	-	-	
M24	0.5	-	-	-	1.1	-	-	-	

[1] Interaction terms between ART group and time period.

[2] GEE were impossible to fit due to insufficient numbers.

Odds Ratio have been estimated using Generalized Estimating Equations (GEE) accounting for ART group, time period, and an interaction term.

OR: Odds Ratio; CI: Confidence Interval; M0: At inclusion; M24: 24 months after inclusion.

Table S4 (continued): Social indicators according to ART strategy and time since inclusion (among women, men, and both sex).

	Deferred ART				Early ART				Interaction p[1]
Timing	%	$OR_{M24/M0}$	95%CI	p	%	$OR_{M24/M0}$	95%CI	p	
Both sex									
Living alone									0,605
M0	4.6	-	-	-	4.2	-	-	-	
M24	6.1	1,85	[1,00 ; 3,44]	0,051	7.1	1,28	[0,68 ; 2,40]	0,447	
In union									0,379
M0	49.2	-	-	-	49.2	-	-	-	
M24	44.1	0,88	[0,75 ; 1,03]	0,101	46.4	0,76	[0,65 ; 0,90]	0,001	
HIV disclosure inside the household									0,55
M0	58.9	-	-	-	64.5	-	-	-	
M24	64.7	1,02	[0,82 ; 1,28]	0,833	66.2	1,17	[0,93 ; 1,46]	0,176	
HIV disclosure outside the household									0,169
M0	64.6	-	-	-	61.2	-	-	-	
M24	67.7	1,58	[1,27 ; 1,96]	0,000	69.5	1,16	[0,92 ; 1,47]	0,195	
Lack of regular professional activity									0,856
M0	36.3	-	-	-	35.2	-	-	-	
M24	31.9	0,82	[0,60 ; 1,10]	0,188	31.5	0,76	[0,55 ; 1,03]	0,077	
Experience of HIV-related discrimination in the last 12 months[1]									0,392
M0	2.6	-	-	-	3.4	-	-	-	
M24	1.9	0,60	[0,32 ; 1,15]	0,122	2.1	0,81	[0,38 ; 1,72]	0,592	

[1] Interaction terms between ART group and time period.
Odds Ratio have been estimated using Generalized Estimating Equations (GEE) accounting for ART group, time period, and an interaction term.
OR: Odds Ratio; CI: Confidence Interval; M0: At inclusion; M24: 24 months after inclusion.