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2 **A cluster randomized trial evaluating a care**
3 **model adapted to people living with HIV in**
4 **Senegal**

32 **ABSTRACT**

Aims: To compare the retention rate of the ART-stable (on ART for ≥ 6 months with a stable condition) people living with HIV (PLHIV) between a care model adapted to PLHIVs (CMAP) combining task shifting and differentiated follow-up (intervention) .and the standard of care (control)

Study design: Cluster randomized trial with both quantitative and qualitative components

Place and Duration of Study: Between July 2017 and July 2019 in the 12 health districts of Saint and Tambacouda regions, Senegal

Methodology: We included 1014 PLHIVs (504 in the intervention arm, 510 in the control

arm). The mean age was 40.6 ± 13 years; 72% were female, 39.7% at WHO clinical stages 3-4. Arms were compared using Targeted Maximum Likelihood Estimation accounting for clustering.

A socio-anthropological survey was carried out among caregivers and PLHIVs through focus group discussions and interviews to elicit the perceptions on the CMAP. The interviews were subjected to thematic analysis with Atlas Ti

Results: After 18 months of follow-up, the retention rate was 94.4%(95% CI; = 93.8-96.2) in the CMAP arm versus 92.8% [95% CI = 90.2%-93.7%] in the control arm. The duration of the trip to the health facility (26 minutes vs 68 minutes; $p < 0.01$), the transport costs (1 US\$ vs 6 US\$; $p < 0.01$) and the time spent in the health facility (31 minutes vs 89 minutes; $p < 0.01$) were lower in the intervention arm.

Six (6) focus groups and 25 interviews involving 42 caregivers and 28 PLHIVs were conducted in the CMAP arm. The qualitative analyses revealed that caregivers and PLHIVs were supportive of CMAP.

Conclusion: The CMAP was associated with increased retention, shorter travel time and decreased cost in HIV care

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35 key words *Task shifting, differentiated care, HIV, Senegal*37 **Abbreviations**

ART	antiretroviral therapy
CI	confidence interval
CMAP	care model adapted to PLHIVs
IQR	interquartile range
PLHIV	people living with HIV
TMLE	targeted maximum likelihood estimation

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40 **1. INTRODUCTION**

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42 The effectiveness of antiretroviral therapy (ART) has been proven to be effective in
43 prolonging the lives of people living with HIV (PLHIV) and improve their quality of life.44 The HIV epidemic in Senegal is concentrated with a prevalence of 0.3% in the general
45 population but high among key or priority populations such sex workers , men who have sex
46 with men, and injection drug users(1).47 Senegal was the first country in Africa to set up a government program for the management
48 of PLHIVs with ART in 1998. After an initial pilot phase of eighteen months that showed
49 treatment effectiveness similar to results reported by Western countries (2), Senegal put in

50 place a national strategy for decentralization and facilitation of access to ART in 2001. ART
51 is currently offered free of charge across all regions in the country.

52 In Senegal, the health system is pyramidal with three levels: the central level is national in
53 character with the university hospitals; the intermediate or regional level is made up of
54 regional hospitals whilst the peripheral level with the health districts forms the operational
55 units of the system. Each health district coordinates the health centres and health posts.
56 Typically, the health posts are staffed by community health workers and managed by nurses.
57 A health centre may be responsible for and supervise several health posts. An assessment
58 in the country showed a shortage of health personnel, especially doctors. Doctors, until
59 recently, were the only health personnel authorized to prescribe ART. This created an
60 enormous workload on the existing staff thereby compromising the quality of services offered
61 to PLHIVs(3–5).

62 Task shifting is defined as a process of delegation whereby tasks are moved, where
63 appropriate, to less specialized health workers was recommended by the World Health
64 Organization (WHO) to deal with the human resource deficit(6) has been implemented in a
65 number of countries and has been reported to be effective(7–11) . In the context of HIV, the
66 adoption of a public health approach is central to the principle of task shifting. The public
67 health approach uses standardized, simplified, and decentralized systems that can maximize
68 the role of primary health care and community care workers (6).In Senegal, the Ministry of
69 Health (MOH) approved in 2014 the implementation of task shifting to address these
70 identified challenges(12). By delegating the care of PLHIV to health posts, Senegal would be
71 able to decentralize HIV care using a public health approach. After initial training, follow up
72 of stable PLHIVs was moved to the health posts.

73 PLHIVs on ART for more than six months without weight loss, serious comorbidity or
74 treatment failure were considered stable and were subject to non-medical follow-up,
75 particularly by nurses at health posts with differentiated care according to the profile of the
76 PLHIV. The benefits of the differentiated follow up has been documented(13–17). The
77 differentiated follow-up consisted of giving different appointment frequency depending on the
78 clinical profile. Appointment could be monthly, quarterly or six monthly. Appointment
79 reminders can be sent by text message if necessary, encouraging peer support and the
80 initiation of support groups related to HIV care.

81 We hypothesized that a care model adapted to PLHIVs (CMAP) combining tasks shifting of
82 PLHIV's care to paramedical/community staff and a differentiated follow-up of stable PLHIVs
83 would improve the PLHIVs care and the retention rate.

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85 **2. MATERIAL AND METHODS**

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87 We conducted a cluster randomized trial with both quantitative and qualitative components
88 from 2017 July to 2019 July. Two regions with different epidemiological profiles were
89 targeted to assess the CMAP in different contexts in Tambacounda and Saint Louis regions
90 located in the south-east and north of the country respectively. Tambacounda is designated
91 as a priority region in the fight against HIV/AIDS with a prevalence of 0.9%. The area of the
92 region is 42,706 km² (21.7% of the national territory) with an estimated population of
93 716,594. It is subdivided into seven health districts (Bakel, Dianké Makha, Goudiry, Kidira,
94 Koumpentoum, Maka Colibantang and Tambacounda). It has a regional hospital, eight
95 health centres and 104 health posts. The number of PLHIV on ART was 1137 in
96 2018(18,19). The Saint Louis region has 957,600 inhabitants in an area of 19,034 km². The
97 region had 111 health posts, 7 health centres and three hospitals in five health districts
98 (Dagana, Pètè, Podor, Saint Louis, and Richard Toll). The epidemic in the region is
99 concentrated with a prevalence of 0.4% and more accessible health facilities. The number of
100 PLHIV regularly monitored was 1205 in 2018(19,20).

101 The study had two (2) arms. Arm A received the intervention (CMAP) while the arm B
102 received the standard of care. After an initial (theoretical and practical) training in group A

103 districts, follow-up on ART including the provision of ART and differentiated follow-up of
104 stable PLHIV were shifted to the nurses, midwives, and community staff in the health posts.
105 frequency of follow-up according to the patient's profile, which can be quarterly or biannual.
106 Appointments reminders by text message were done as needed as well as an invitation to
107 peer support. In the standard of care, the care of PLHIV was provided by doctors with
108 monthly or bimonthly appointments. The randomization unit was the health district. The
109 package of services in the intervention arm (Arm A) included care was provided by
110 paramedical/community staff with differentiated follow-up (variable frequency of
111 appointments, peer coaching, appointment reminders as needed, participation in support
112 groups). In the arm B, all PLHIV were followed upon the basis of monthly or bimonthly
113 appointments. The consultation was done by the doctors. Their prescription was presented
114 at the pharmacy to take the ARVs. Social services could be called upon if necessary. In both
115 arms, a biological follow-up assessment was carried out every six months with a complete
116 blood count, blood glucose, transaminases, serum creatinine, CD4, CD8 and plasma viral
117 load
118 The study was carried out in all 12 health districts of the two (2) regions and all PLHIVs who
119 met the selection criteria during September 2017-July 2018 were included

120 The inclusion criteria were:

- 121 • Documented HIV infection (HIV-1 or HIV-2 or HIV-1 + HIV-2)
- 122 • on ART and stable
- 123 • Informed consent

124 The exclusion criteria were:

- 125
- 126 • Treatment failure
- 127 • Comorbidities like diabetes, poorly controlled hypertension, cancer
- 128 • Other comorbidity requiring medical management

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130 **2.1 QUANTITATIVE**

131 The primary outcome was retention in care. Geographical and financial accessibility was
132 a secondary outcome. Arms were compared using Targeted Maximum Likelihood
133 Estimation (TMLE), accounting for clustering. A sample of 982 patients was required to
134 show a 1.5% difference in retention rate between the arms, considering a population
135 retention rate of 90% with $\alpha = 5\%$, and $\beta \leq 20\%$.

136 All statistical tests were two-sided and considered statistically significant at a 5% threshold.
137 Statistical analyses were performed using version 16.1 of Stata.

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140 **2.2 QUALITATIVE**

141 A socio-anthropological survey was carried out among caregivers through focus group
142 discussions and semi-structured interviews. The interviews elicited the perceptions of
143 PLHIVs on the CMAP to guide its scaling up. The interviews were recorded, transcribed, and
144 subjected to thematic analysis with Atlas Ti.

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146 **2.3 ETHICAL APPROVAL**

147 The protocol was approved by the National Ethics Committee for Health Research (CNER)
148 on November 7, 2016 (N°0161MSAS/DPRS/CNER).

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3. RESULTS AND DISCUSSION

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3.1 RESULTS

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3.1.1 QUANTITATIVE

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Overall, 1014 PLHIVs in the 12 health districts of Saint Louis and Tambacounda were included. The mean age was 40.6 ± 13.5 years; 41.7 ± 13.4 years in the intervention arm; 39.8 ± 13.6 years in the control arm. A proportion of 72% (95% CI: 63.8-86.2) were female, 39.7% (95% CI: 33.8-46.2) at WHO clinical stages 3-4. Their characteristics are summarized in Table I.

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Table I. Characteristics of the population included in the cluster randomized trial comparing a care model adapted to people living with HIV with the standard of care in Senegal by study arm (CMAP arm, Control arm)

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Variables	CMAP ^a arm	Control arm	Total
	N=429	N=585	N=1014
	Median (IQR ^b) or n (%)	Median (IQR) or n (%)	Median (IQR) or n (%)
Age	42 (34 - 50)	40 (32 – 48.8))	41 (33 – 49)
Sex			
Female	298 (69.5)	430 (73.9)	728 (72.0)
Male	131 (30.5)	152 (26.1)	283 (28.0)
WHO clinical stage			
1-2	252 (61.9)	307 (59.0)	559 (60.3)
3-4	155 (38.1)	213 (41.0)	368 (39.7)
HIV serotype			
HIV-1	403 (93.9)	550 (94.0)	953 (94.0)
HIV-2	20 (4.7)	28 (4.8)	48 (4.7)
HIV1+HIV-2	6 (1.4)	7 (1.2)	13 (1.3)

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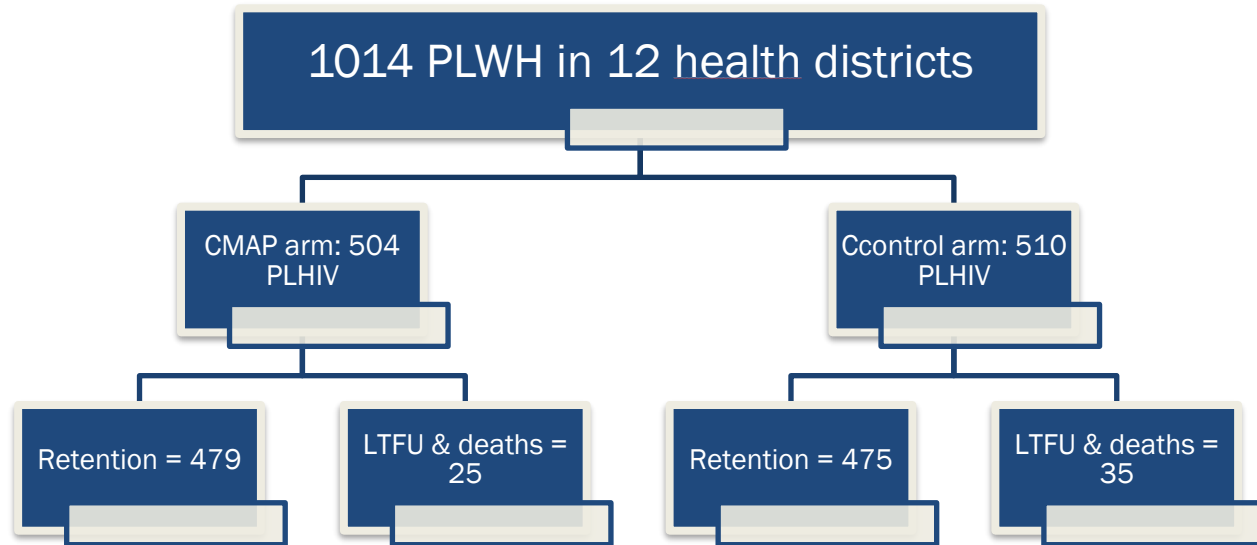
^acare model adapted to PLHIV

^b interquartile range

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166 The flowchart of the study is presented in figure 1.



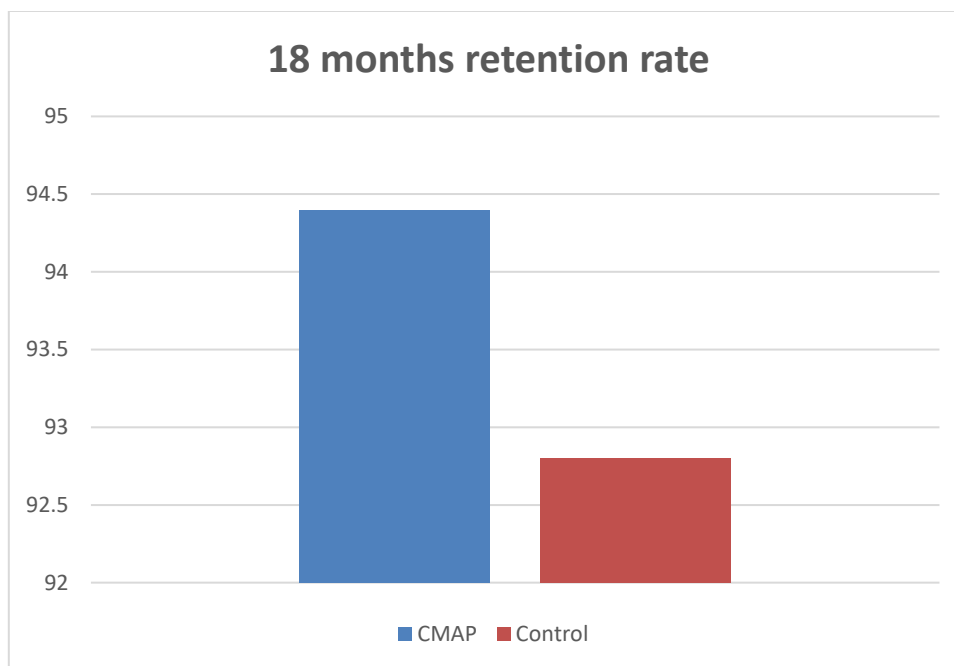
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168 Figure 1. Flowchart of the cluster randomized trial comparing a care model adapted to
 169 people living with HIV with the standard of care in Senegal

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171 **3.1.1.1 RETENTION**

172 After 18 months of follow-up, the retention rate was 94.4% [95% CI: 93.8-96.2] in the
 173 intervention group versus 92.8% [95% CI: 90.2-93.7] in the control group; $P = .04$ (figure 2).



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175 Figure 2. Retention rate by arm in the cluster randomized trial comparing a care model
176 adapted to people living with HIV with the standard of care in Senegal
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178 HIV viral load was measured for 411 PLHIV: 43.1% [95% CI = 41.28-48.13]. It was
179 undetectable for 79.6% [95% CI = 75.27-83.29] : 83.4% [95% CI = 77.19-88.53] in CMAP
180 arm versus 76.5% [95% CI = 70.50-81.84] in control arm; $P=.08$.
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182 **3.1.1.2 ACCESSIBILITY**

183 The duration of the trip to the health facility (26 minutes vs 68 minutes; $P <.001$), the
184 transport costs (1 US\$ vs 6 US\$; $P <.001$) and the time spent in the health facility (31
185 minutes vs 89 minutes; $P <.001$) were lower in the CMAP arm.
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187 **3.1.2 QUALITATIVE**

188 Six (6) focus groups involving 25 nurses; 17 semi-structured interviews with doctors, social
189 workers and community staff members; and 28 interviews with PLHIVs were conducted in
190 the CMAP arm in Saint louis and Tambacounda. The qualitative analyses revealed that
191 caregivers and PLHIVs were supportive of the CMAP and determined the ideal conditions for
192 successful scale-up: a) optimal communication and organization of caregivers between the
193 health centre and the health posts (clinicians, nurses, community staff); b) health districts
194 with limited access to physicians; c) initial training and supervision of the nurses and the
195 community staff.
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197 **2.2 DISCUSSION**

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199 This CMAP showed a higher retention rate than that obtained with
200 the standard of care for PLHIVs that existed in Senegal. Simple and
201 objective measures of outcomes were used. The study design and the
202 analyses carried out made it possible to control the confounding factors.

203 Several studies reported that nurse-initiated and monitored ART
204 was noninferior to clinician-initiated and monitored ART in adult
205 PLHIVs. (21–30). Some studies have reported, with the nurse’s model, a
206 reduction in the proportion of people lost to follow-up in South Africa,
207 Rwanda, Ethiopia and Swaziland (22,22,29,31–33) , and a higher rate of
208 retention on ART(31,32,34). One study in South Africa reported a higher
209 probability of lost to follow up(23) but that was not in line with our results. In
210 addition to the different epidemic contexts between Senegal and South
211 Africa, differences between this observational study and ours could help
212 explain this result. For example, in this study, PLHIV who had been on ART
213 for at least 16 weeks were eligible with clinical criteria like that of our study in
214 addition to having a last viral load< 50 copies/ml. It has been reported that
215 differentiated care models, including task-shifting had similar outcomes in
216 viral load suppression compared to the standard HIV care (23,33–35). These
217 results are in agreement with those of our study. Other studies have
218 reported that viral load suppression was higher in the community based
219 differentiated service delivery models(36,37).

220 As in our study, a lower cost was reported with task-shifting
221 (21,33,38,39) as well as with differentiated service delivery (40). The health-
222 related quality of life associated with task shifting was reportedly higher
223 compared with the standard of care (8). Consistent with our study, a reduced
224 patients' travel time, and visit time were reported with differentiated care
225 models as well as a higher adherence and enhanced social support in
226 Malawi, South Africa, Lesotho, Uganda, and Nigeria (40–44).

227 This study is the first one to demonstrate the effectiveness of task shifting
228 and differentiated service delivery in a context of concentrated epidemic.
229 Such a model could be replicated in countries with a similar context
230 (systemic and epidemiological) like that of Senegal.

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4. CONCLUSION

The CMAP was associated with increased retention, shorter travel time and decreased cost in HIV care. Expansion of this approach across the country will offer invaluable benefits to PLHIV

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268 **CONSENT (WHERE EVER APPLICABLE)**
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270 After a full reading of the information leaflet, the participants were required to provide
271 informed consent. If the candidate agreed to participate, together with the investigator, they
272 completed, dated, and signed two copies of the consent form. (Appendix I)
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274 **ETHICAL APPROVAL (WHERE EVER APPLICABLE)**
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276 Ethical approval was obtained from the National Ethics Committee for Health Research
277 (CNER) of the Ministry of Health (MOH) in Senegal on November 09, 2016
278 (N°00000161MSAS/DPRS/CNER)
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