COMPARISON OF EFFICACY OF TWO INTERVENTIONS TO ENHANCE ADHERENCE TO ANTIRETROVIRAL THERAPY

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Purpose

- The aim of this study was, at 6 month (M6) of intermediate analysis, to compare the efficacy of two interventions – Cognitive, Behavioral and Affective Strategy (CBAS) *versus* Cognitive Strategy Only (CSO) – both of them individual-level, leaded by pharmacists, to enhance medication adherence to HAART.
- CSO give tailored information about HAART to each patient.
- CBAS is a therapeutical education intervention, on medical prescription, permitting adherence feedback and monitor side effects.

Patients and methods

- A prospective study was conducted on outpatients with initiation of HAART, selected by chronological arrival to the pharmacy.
- Two groups were compared : group CBAS (2-sessions of 45min) and group CSO (1-session of 15 min) ; both of them in addition to standard of care.
- Adherence was assessed on March 2004 by patient self report using " adherence rule " and pharmacy refill.
- Outcome measures included 6 months follow up (M0 to M6) of virological and immunological responses to HAART.
- Data of barriers to and cause of adherence, medication regimens and tolerance were collected.

Results

Table 1. Baseline Caracteristics

	CBAS	CSO
N	14	13
Age (yr)	38 ± 7,8	43 ± 10,0
Men	43%	92%
Race/ethnicity		
White	29%	39%
African	71%	23%
Asiatic	0%	23%
North-african	0%	15%
Insurance		
Regime Général	64%	85%
CMU	7%	15%
AME	14%	0%
Precarity (PASS)	14%	0%
HIV RNA (log_{10} c/ml)	5,4 ± 0,66	5,2 ± 0,65
Mean CD4 (cell/mm3)	185	83

Table 3. Barriers to adherence at Baseline (M0) in CBAS group

Depression	36%
Social problems	29%
Treatment secret in family circle	29%
Organizational difficulties	7%
Illicitit drug use	7%

Figure 1. Proportion of patients with therapy efficacy (HIV RNA below detectable limits)

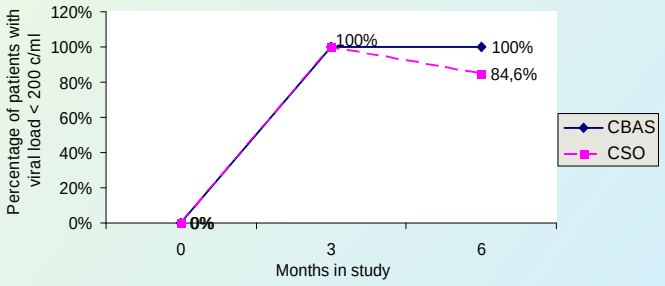


Table 2. Prescribed Antiretroviral Agents

	CBAS	CSO
NTRIs		
Combivir (AZT/3TC)	50%	56%
Trizivir (AZT/3TC/ABC)	14%	15%
Viread (TDF)	29%	23%
Epivir (3TC)	36%	38%
Zerit (D4T)	7%	23%
NNTRIs		
Sustiva (EFV)	36%	46%
PIs		
Crixivan + Norvir (IDV+RTV)	7%	8%
Kaletra (LPV/RTV)	36%	31%

Table 4. Pourcentage of subjects who developped adverse events at any time during the 6 months study in CBAS group

Gastrointestinal disorders	43%
Psychological and psychiatric disorders	29%
Dermatological disorders	29%
Neurological disorder	14%
Metabolic disorders	14%
Fatigue	7%

Figure 2. Mean CD4 cell count (/mm3)

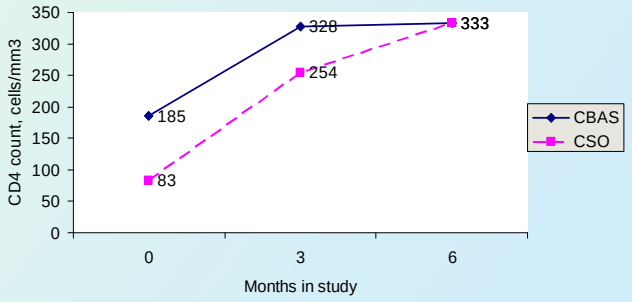


Figure 3. Reasons for poor ARV treatment adherence in CBAS group

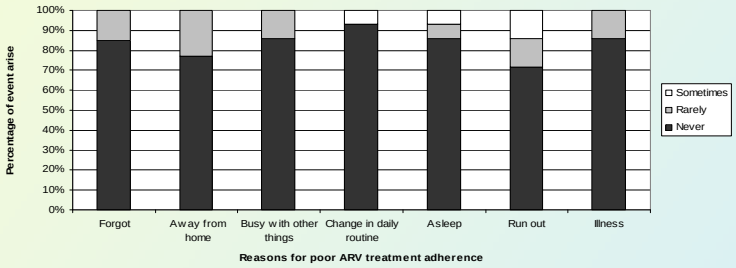
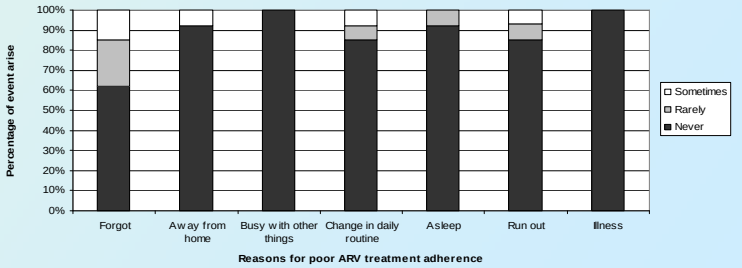


Figure 4. Reasons for poor ARV treatment adherence in CSO group



- This study suggests that the stated level of adherence at M6 was high in both groups (n_{cbas}=14 ; n_{cso}=13) : patients said they had taken 100% of doses over the last four days.
- During the six months follow up (M0 to M6), plasma HIV RNA levels decreased in both groups (mean $decrease_{CBAS}$ = 5.42 log; mean $decrease_{cso}$= 5.19 log).
- However, at M6, the proportion of patients with plasma HIV RNA levels below detectable limits (<200 copies/ml) was significantly higher in CBAS group (100% *vs.* 84.6%, p<0.05). HAART regimens were roughly the same in both groups.

Conclusion

Since there is no gold standard for determining treatment adherence, it is important to combine several methods to minimize errors of results. According to this intermediate analysis, 6 months after initiation of HAART, CBAS seems to be more efficient then CSO for increasing adherence. This study will continue beyond M6 to identify any regimen failure arise.