

AN INDIVIDUALIZED COMMUNICATION STRATEGY TO ENHANCE RETENTION IN CARE AND ART UPTAKE IN NAÏVE INDIVIDUALS: A RANDOMIZED CONTROLLED TRIAL

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BACKGROUND

Several strategies have been designed to improve retention in care in patients starting antiretroviral therapy (ART). In Latin America few strategies have been locally tested in a randomized way and evidence-based decisions are scarce.

MATERIAL AND METHODS

Between 2015 and 2018, we conducted a multicentric randomized controlled trial including naïve patients prescribed ART.

The main goal was to compare retention in care and VS between arms. Subjects were randomized to starting ART with standard of care follow-up (SOC) or SOC plus an individualized communication strategy (ICS). Patients were contacted using their method of preference to assess retention and adherence to treatment with a semi-structured interview, conducted by social workers and administrative assistants at weeks 2,4, and every 4 weeks up to 1 year. Among those randomized to receive the intervention, we measured number of effective contacts (NEC) during the first year after randomization. Poor NEC (PNEC) was defined as ≤ 4 contacts, and fair NEC (FNEC) as four or more.

The primary outcome was **successful linkage**, defined as ambulatory care in the last 6 months, with no ART interruption for a period longer than 7 days; secondary outcomes were: **viral suppression** (VS) defined as HIV-RNA <200 cps in the last measurement and **successful treatment** defined as the presence of both successful linkage and VS. Descriptive statistics were used for baseline characteristics. Risk differences (RD) and 95% confidence intervals (CI) were estimated using generalized linear models for primary and secondary outcomes. Crude and adjusted estimates were obtained for those outcomes. Secondarily, we wanted to assess, in the intervention arm, if FNEC was associated with successful linkage during the first year after randomization. Risk differences (RD) and 95% confidence intervals (CI) were estimated using linear regression for primary outcomes obtaining crude and migration-adjusted estimates.

RESULTS

A total of 207 participants were randomized (107 to SOC, 100 to SOC + ICT). Median age was 31 yrs. (IQR 26,40), 80% were male, 62% were men who have sex with men (MSM), 27% were immigrants. Median baseline HIV-RNA copies/ml (log) and CD4 count/mm³ were 4.44 (IQR 3.73,5.10) and 398 (IQR 220, 584) respectively. There were two reported deaths during follow up period, one in each arm.

Table 1: General characteristics of the enrolled population, overall and by study arm.

| | Total (n:207) | ARM A (n:107) | ARM B (n:100) |
|---|-----------------|-----------------|-----------------|
| Demographic Characteristics | | | |
| Age (median, IQR) | 31 (26,40) | 31 (26,40) | 31 (26,40) |
| Male at Birth | 0.8 | 0.79 | 0.83 |
| MSM | 0.62 | 0.61 | 0.64 |
| Non-Immigrant | 0.73 | 0.76 | 0.71 |
| Education Years (median, IQR) | 12 (10,14) | 12 (10,14) | 12 (9,13) |
| Informal work | 0.509 | 0.497 | 0.521 |
| Distance to clinic, mins (median, IQR) | 40 (20,90) | 40 (20,90) | 40 (20,90) |
| Comorbidities | | | |
| Recreational Drug User | 0.25 | 0.24 | 0.27 |
| Alcohol User | 0.52 | 0.5 | 0.55 |
| History of Psychiatric Treatment | 0.03 | 0.05 | 0.01 |
| Clinical and laboratory data | | | |
| Baseline Events | 0.03 | 0.04 | 0.02 |
| Baseline Viral Load (log) (median, IQR) | 4.44(3.73,5.10) | 4.60(3.86,5.17) | 4.37(3.63,5.07) |
| Baseline CD4 Count (median, IQR) | 398 (220,584) | 389 (196, 562) | 415 (266,604) |

Table 2: Crude and adjusted estimates for primary and secondary outcomes

| | ARM A (n:107) | ARM B (n:100) | Crude RD (95%CI) | Adjusted* RD (95%CI) |
|----------------------|---------------|---------------|-----------------------|----------------------|
| Successful Linkage | 0.607 | 0.670 | 0.063 (-0.068,0.193) | 0.076 (-0.064,0.217) |
| Viral Suppression | 0.542 | 0.470 | -0.072 (-0.208,0.064) | -0.039(-0.182,0.103) |
| Successful Treatment | 0.664 | 0.710 | 0.046 (-0.080,0.173) | 0.083(-0.044,0.210) |

*Estimates were adjusted by sex, transmission categories, age, migration status and baseline CD4 count.

There was not significant difference in successful linkage between arms (SOC=0.607, ICT=0.670, crude RD=0.063, 95%CI -0.068, 0.193). There was not significant difference in VS between arms (SOC=0.542, ICT=0.470, RD=-0.072, 95%CI: -0.208, 0.064). Successful treatment was lower among SOC (0.664) than among ICT (0.710) but not statistically significant (RD=0.046, 95%CI -0.080, 0.173). (Fig1a and 1b and Table 2)

Among those randomized to the intervention, 477 contacts were established. Mean number of contacts was 4.91. 64 participants had FNEC and 36, PNEC. FNEC and PNEC subgroups had not significant difference across covariates. Successful linkage was 0.396 higher among FNEC than among PNEC (95%CI:0.209,0.583; FNEC:0.813; PNEC:0.417). In the migration-status adjusted model, RD was 0.421 (95%CI:0.240,0.603; FNEC:0.610; PNEC:0.189). (Fig 1C and 1D))

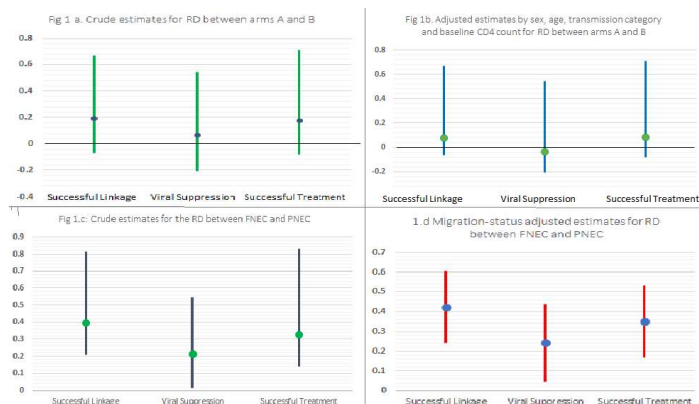


Fig. 1: RD estimates with 95% Confidence Intervals for: 1a. Crude and b. Adjusted estimates between 2 arms for primary and secondary outcomes (adjusted by sex, transmission category, age and CD4 count); 1c. Crude and d. Adjusted by migration status estimates between PNEC and FNEC

CONCLUSION

In a mostly male MSM cohort in Argentina, linkage was successful one year after ART initiation in approximately two thirds of the population. However, over one quarter was not linked to care at one year. The communication strategy showed increased linkage and treatment success, but not statistically significant. VS was similar in both arms. Among those receiving the intervention, only two thirds had at least three established contacts. FNEC was associated with higher probability of being retained in care, not suspending ARV and reaching viral suppression within a year of randomization. This difference is sustained after considering demographic and clinical factors. New strategies need to be developed to engage hard-to-reach patients, who ultimately are harder to retain, and to increase VS among those retained under care.