DIRECTLY ADMINISTERED ANTIRETROVIRAL THERAPY (DAART) FOR DRUG USERS

Good Evidence – Medication Adherence

INTERVENTION DESCRIPTION

Target Population
- HIV-positive drug-using clinic patients who are antiretroviral treatment-experienced or -naïve

Goals of Intervention
- Improve adherence to antiretroviral therapy
- Reduce HIV viral load
- Increase CD4 cell counts

Brief Description

DAART for Drug Users is an individual-level intervention. Participants are provided with a pager that is programmed to remind them to report to a mobile Community Health Care Van (CHCV) during weekdays to take their medications. In the CHCV, a DAART specialist observes the patients taking their medications and also provides social support and case management services. Weekend doses are provided on Fridays, and 1-3 days of back-up medication is also provided in case a participant is unable to appear for a DAART visit. Participants are reminded to take evening doses through the pager. Reminders for other scheduled activities, such as medical appointments, are also programmed into the pager. Each patient receives a medication bottle with a MEMS cap to monitor non-observed doses. DAART is provided for 6 consecutive months, and patients are trained to package and self-administer their medications the month before transferring to complete self-administration of their therapy for an additional 6 months of monitoring.

Theoretical Basis
- None specified

Intervention Duration
- Every week day over 6 months

Intervention Setting
- Mobile community health care van

Deliverer
- DAART specialist, who is an outreach worker trained to supervise DAART

Delivery Methods
- Directly observed medication administration
- Pager reminder

INTERVENTION PACKAGE INFORMATION

An intervention package is not available at this time. Please contact **Frederick L. Altice**, Yale University, Sterling Hall of Medicine, PO Box 208022, New Haven, CT 06520-8022.

Email: frederick.altice@yale.edu for details on intervention materials.

EVALUATION STUDY AND RESULTS

The original evaluation was conducted in New Haven, CT between 2001 and 2006.

Key Intervention Effect
- Reduced viral load

Study Sample
The baseline study sample of 141 drug users is characterized by the following:
- *58% black or African American, 22% white, 19% Hispanic/Latino, 1% other*
- *69% male, 31% female*
- *Mean age of 44 years*
- *63% completed high school or GED*
- *88% treatment-experienced > 3 years*
- *25% participants with > 75% self-reported medication adherence*
- *36% participants with undetectable viral load (≤ 400 copies/mL)*

Recruitment Settings
Community health centers and hospital-based HIV clinics

Eligibility Criteria
Men and women were eligible if they were HIV-positive, eligible for and/or currently prescribed HAART, living in city of New Haven, history of heroin or cocaine use within the previous 6 months, and receiving a treatment regimen of ≤ 2 doses per day.

Assignment Method
Participants (N = 141) were randomly assigned 2:1 to one of two groups: DAART intervention (n = 88) or standard of care comparison (n = 53).

Comparison Group
Comparison participants received self-administered therapy (SAT) which included HIV treatment and medications through community-based physicians, with follow-up visits at routinely scheduled intervals.

Relevant Outcomes Measured and Follow-up Time
- Medication adherence behavior was measured using 3-day AIDS Clinical Trials Group (ACTG) self-reported adherence, was categorized as < 80% or ≥ 80% adherence, and was assessed at 1, 3, and 6 months post-initiation of intervention.

- Viral load was measured at 1, 3 and 6 months post-initiation of intervention. Virologic success was defined as undetectable (< 400 copies/mL) or achieving at least a 1-log10 drop in viral load.

Participant Retention

- DAART Intervention
  - Information not available for 1 month and 3 months post-initiation of intervention
  - 95% retained at 6 months post-initiation of intervention

- SAT Comparison
  - Information not available for 1 month and 3 months post-initiation of intervention
  - 98% retained at 6 months post-initiation of intervention

Significant Findings

- At 6 months post-initiation of intervention, a significantly greater proportion of intervention participants achieved virologic success (i.e., a viral load reduction of ≥ 1.0 log copies/mL or undetectable viral load of < 400 copies/mL) than comparison participants (70.5% vs. 54.7%, p = .017; OR = 2.6, 95% CI = 1.2 to 5.5, p = .017; missing data imputed).*
- Intervention participants achieved a significantly greater mean reduction in viral load from baseline to 6 months than comparison participants (-1.16 vs. -.29 log copies/mL, p = .03; missing data imputed).

Considerations

- This study did not meet the best-evidence criteria because the study did not find a significant positive intervention effect on medication adherence behavior.
- Several significant findings reported in the publication did not meet all the efficacy criteria:
  - A significantly greater proportion of intervention participants achieved undetectable viral load (< 400 copies/mL) across the 1-, 3- and 6-month assessment time points than comparison participants (OR = 2.3, 95% CI = 1.1 to 4.5, p = .02; missing data not imputed). This finding included data from the 1-month assessment, which does not meet the minimum assessment time point requirement.
  - Across the 1-, 3, and 6-month assessments, a significantly greater decline in viral load levels was observed for the intervention participants compared to comparison participants (-.53, 95% CI = -.88 to -.18, p = .003; missing data not imputed). This finding included data from the 1-month assessment, which does not meet the minimum assessment time point requirement.
  - In subset analyses (among patients with undetectable viral load at baseline), intervention participants were more likely to maintain virologic success (OR = 2.7, 95% CI = 1.1 to 6.9, p = .04) and reported a significantly greater mean viral load reduction (-1.6 vs. -.83 log10 copies/mL, p =.04) than comparison participants. These findings did not meet the minimum analytic sample size requirement of > 40 participants per arm.
- The mean change in CD4 count from baseline to the 6-month assessment was significantly higher in the intervention arm than in the comparison arm (+58.8 vs. -24.7 cells/uL, p = .002).

***Information obtained from author**

REFERENCES AND CONTACT INFORMATION

Altice, F. L., Maru, D. S., Bruce, R. D., Springer, S. A., & Friedland, G. H. (2007). Superiority of directly administered antiretroviral therapy over self-administered therapy among HIV-infected drug users: A prospective, randomized, controlled trial. *Clinical Infectious Diseases, 45*, 770-778.

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