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

• SAT Comparison
  o Information not available for 1 month and 3 months post-initiation of intervention
  o 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:
  o 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.
  o 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.
  o 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.
  o 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


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