DIRECTLY ADMINISTERED ANTIRETROVIRAL THERAPY (DAART) IN A METHADONE CLINIC

Good Evidence – Medication Adherence

INTERVENTION DESCRIPTION

Target Population
- HIV-positive injection drug users in treatment who are antiretroviral treatment-experienced or -naïve

Goals of Intervention
- Improve adherence to antiretroviral therapy
- Improve virologic and immunologic responses to antiretroviral therapy (HIV viral load and CD4 cell count)

Brief Description

DAART in a Methadone Clinic is an individual-level intervention. A nurse or medical assistant observes patients taking their HIV medications in a private room that is distinct from the methadone-dispensing window each morning the patients attend the methadone clinic. Evening doses and doses to be taken on methadone take-home days are prepackaged and given to patients for self-administration. An emergency 3-day packet of medications is provided in case of a missed methadone visit. The treatment goal is to provide DAART for at least 1 year, but if patients wish, they can continue DAART for longer.

Theoretical Basis
- None specified

Intervention Duration
- Every morning of methadone clinic visit, over at least one year

Intervention Setting
- Methadone clinic

Deliverer
- Nurse or medical assistant

Delivery Methods
- Directly observed medication administration

INTERVENTION PACKAGE INFORMATION

An intervention package is not available at this time. Please contact **Gregory M. Lucas**, 1830 E. Monument St., Room 435A, Baltimore, MD 21287.

Email: glucas@jhmi.edu for details on intervention materials.

EVALUATION STUDY AND RESULTS

The original evaluation was conducted in Baltimore, MD between 2001 and 2003.

Key Intervention Effects
- Reduced viral load
- Achieved undetectable viral load

Study Sample
The baseline study sample of 891 men and women is characterized by the following:
- *79% black or African American*
- *65% male, 35% female*
- *Median age of 43 years, range: 38-49*
- *27% treatment-naïve*
- *Median viral load = 100,000, range: 20,000-250,000*
- *100% participants with detectable viral load (> 500 copies/mL)*

Recruitment Settings
Methadone clinic and HIV clinic

Eligibility Criteria
DAART intervention participants were HIV infected men and women ≥ 18 years of age who had a regular HIV treatment provider, had received methadone therapy for > 30 days with no plans to discontinue, were starting a first or subsequent HAART regimen in which doses were not administered more frequently than twice daily, had a detectable HIV-1 RNA viral load (> 500 copies/mL) at baseline, and did not have known triple-class antiretroviral drug resistance (as determined from a prior resistance test performed in clinical practice). All comparison participants were HIV infected men and women ≥ 18 years of age who were starting a first or subsequent HAART regimen on or after January 1, 2001, had a detectable HIV-1 RNA viral load (> 500 copies/mL) at baseline, and did not have known triple-class antiretroviral drug resistance (using the same genotypic criteria as the DAART intervention participants).

Assignment Method
Participants (N = 891) were from 1 of 2 groups: DAART Intervention (3 clinics; n = 82 participants) or a non-concurrent comparison (1 clinic; n = 809 participants). Participants in the non-concurrent comparison were divided into 3 groups based on participant characteristics: IDU-methadone group [n = 75], IDU-non-methadone group [n = 244], and non-IDU group [n = 490]).

Comparison Group
The IDU-methadone comparison group received methadone therapy, HAART, and usual clinical care. The IDU-non-methadone and non-IDU comparison groups received HAART and usual clinical care.

Relevant Outcomes Measured and Follow-up Time
- Viral load was measured at 6 and 12 months post-initiation of intervention and was assessed as log10 copies/mL and as undetectable (< 400 copies/mL).

Participant Retention

- DAART Intervention
  - 94% retained at 6 months post-initiation of intervention*
  - 74% retained at 12 months post-initiation of intervention*

- IDU-Methadone Comparison
  - 97% retained at 6 months post-initiation of intervention*
  - 83% retained at 12 months post-initiation of intervention*

- IDU-non-Methadone Comparison
  - 97% retained at 6 months post-initiation of intervention*
  - 86% retained at 12 months post-initiation of intervention*

- Non-IDU Comparison
  - 94% retained at 6 months post-initiation of intervention*
  - 82% retained at 12 months post-initiation of intervention*

Significant Findings

- The decrease from baseline in median log10 viral load level at 6 months post-initiation of intervention was significantly greater among the DAART intervention participants than the IDU-methadone comparison participants (2.5 vs. 1.3 log10 copies/mL, p = .001; missing data imputed).
- The proportion of participants achieving an undetectable viral load (< 400 copies/mL) was significantly higher in the DAART intervention arm than IDU-methadone comparison arm at 6 months post-initiation of intervention (74% vs. 41%, p < .001, missing data imputed; 78% vs. 52%, p = .002, without imputation).

Considerations

- This study did not meet the best-evidence criteria due to a quasi-prospective study design, non-concurrent comparison, non-randomized allocation with moderate bias, no adjustment for cluster allocation (i.e., clinic), and no measurement of medication adherence behaviors.
- Two significant findings reported in the publication did not meet all the efficacy criteria because the attrition plus missing data for the IDU-methadone comparison arm at the 12-month assessment were 47%, which exceeds the < 40% requirement.
  - At 12 months, the percentage of participants achieving an undetectable viral load (< 400 copies/mL) was significantly higher in the DAART intervention arm than the IDU-methadone comparison arm (56% vs. 32%, p = .009; missing data imputed)
  - At both 6 and 12 months, the DAART participants were significantly more likely to achieve viral suppression (< 400 copies/mL) than the IDU-methadone comparison participants (OR = 0.3, 95% CI = 0.2 to 0.6; p < .05; without imputation).
- The DAART Intervention participants had a significantly greater median increase in CD4 cell count at 12 months than IDU-methadone comparison participants (74 vs. 21 cells/mm3, p = .04; missing data imputed). No significant effect on CD4 cell count at the 6-month assessment.
- The DAART Intervention participants has a significantly greater median decrease in viral load at 6 months than the other two comparison arms (IDU-non-methadone arm, p = .001; non-IDU arm, p = .05).
- At baseline, a significantly larger percentage of the IDU-methadone participants took NNRTI than the DAART intervention participants (31% vs. 14%, p < .05).

***Information obtained from author**

REFERENCES AND CONTACT INFORMATION

Lucas, G. M., Mullen, B. A., Weidle, P. J., Hader, S., McCaul, M. E., & Moore, R. D. (2006). Directly administered antiretroviral therapy in methadone clinics is associated with improved HIV treatment outcomes among concurrent comparison groups. *Clinical Infectious Diseases, 42*, 1628-1635.

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