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

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