# Adherence to Antiretroviral Therapy in HIV-Infected Pediatric Patients Improves with Home-Based Intensive Nursing Intervention

## CITATION
Berrien VM, Salazar JC, Reynolds E, McKay K, for the HIV Medication Adherence Intervention Group. Adherence to Antiretroviral Therapy in HIV-Infected Pediatric Patients Improves with Home-Based Intensive Nursing Intervention. *AIDS Patient Care and STDs* 2004;18(6):355-63

## RESEARCH QUESTION
Does adherence to antiretroviral therapy in HIV infected pediatric patients improve with a home-based intensive nursing intervention?

## THE STUDY DESIGN
Randomised, non-blinded study

## STUDY SETTING
Hartford, Connecticut - referral center for HIV-exposed and -infected children and youth in the greater Hartford area, North Central, Northeast, and Southeastern Connecticut.

Connecticut Children's Medical Center's (CCMC) Human Subjects Review Board approved the study. Informed consent was obtained from each participant's legal guardian. Assent was obtained from all minors older than 7 years of age.

The study was conducted between April 2000 and April 2001.

## PARTICIPANTS
Included: HIV-positive children receiving care at CCMC

Excluded: No exclusion criteria listed

Sixty-seven percent (37/55) of the patients and their caregivers agreed to participate.

## INTERVENTIONS
Standard of care vs. home based intensive nursing intervention.

The intervention consisted of eight structured home visits over a 3-month period by the same home care experienced registered nurse. The intervention was designed to improve knowledge and understanding of HIV infection and HIV medications and to resolve or modify barriers to adherence.

Standard care: In the clinic setting, the physician, nurse, and social worker provided standard medication adherence education. Patient clinic appointments were generally scheduled at 3-month intervals.

## OUTCOMES
| | |
|---|---|
| Primary outcomes: | Changes in patient knowledge of HIV and their medications<br>Changes in adherence (self-report and pharmacy drug refill history) |
| Secondary outcomes: | Changes in viral load (Roche Amplicor HIV-1 Monitor Test) and CD4 T-cell percentages and counts. |

No information on power calculations was provided. Pre- and post-intervention questionnaires which assessed knowledge and understanding of HIV, ART, and adherence. Adherence was estimated objectively from medication refill history and subjectively from a self-report score. Also measured CD4 counts and viral load.

**RISK OF BIAS** (Risk Scale: Low – Moderate – High)

**SELECTION BIAS: moderate**
Patients were randomized 1:1 to either the home intervention or control group using the Small Table of Random Digits. The randomization process was number based, with patient names not identified. The randomization list was held by the clinical coordinator of the HIV Program and kept in a locked file. Unclear whether allocation concealment occurred. Baseline characteristics with regard to CDC diagnosis classification, receiving public assistance, high school education and ethnicity not balanced.

**PERFORMANCE BIAS: moderate**
No blinding. 64% of control group and 40% of intervention group had medication changes. NO drug resistance testing reported.

**DETECTION BIAS: moderate**
No blinding. Each caregiver and patient in the intervention and control groups completed pre- and post-study 21-point, multiple-choice questionnaires. With each question there were two to five possible responses with scores assigned to each answer. Twenty-eight would be a perfect score for knowledge and 37 would be a perfect score for adherence. The research nurse read each of the questions in similar fashion to caretakers. Questions were translated to Spanish for families whose primary language was Spanish. No mention of back translation. Individual scores were given for each of the two components of the questionnaire: knowledge and adherence. Adherence also was estimated by pharmacy refill records, and indirectly by viral load measurements and CD4 T cell measurements.

**ATTRITION BIAS: low**
Mentioned that ITT was performed however results not presented.

| | **Intervention** | **Control** |
|---|---|---|
| Started | 20 | 17 |
| Number loss to follow-up | 1 (5%) | 2 (11%) |

**STUDY FINDINGS**

**Changes in patient knowledge of HIV and their medications**

| *Mean (SE mean)* | *Intervention (n=19)* | *Control (n=15)* | *p-value* | *WMD* |
|---|---|---|---|---|
| Post test scores | 26.4 (0.22) | 23.9 (0.72) | | 2.50 (1.03 to 3.97) |
| Change in scores | 4.5 (0.71) | 1.5 (1.0) | 0.02 | 3.00 (0.60 to 5.40) |

**Changes in adherence**

- **self-report**

| *Mean (SE mean)* | *Intervention (n=20)* | *Control (n=17)* | *p-value* | *WMD* |
|---|---|---|---|---|
| Post test scores | 34.8 (0.41) | 31.9 (1.0) | | 2.90 (0.90 to 4.90) |
| Change in scores | 2.7 (0.88) | 0.2 (0.96) | 0.07 | 2.50 (-0.05 to 5.05) |

- **pharmacy drug refill history**

| | *Intervention* | *Control* | *p-value* |
|---|---|---|---|
| mean refill score | 2.7 | 1.7 | 0.002 |

**Changes in viral load and CD4 T-cell percentages and counts.**

| | *Intervention* | *Control* |
|---|---|---|
| Mean decrease in viral load | 0.5 log | 0.02 log |
| Mean post viral load values. | 3.19 log10 copies/ml | 3.69 log10 copies/ml |

There were no significant differences between the intervention and control groups in CD4 count or viral load, either immediately after the intervention or 6–11 months later.

**COMMENTS**
Poor quality small trial which showed that an intensive home based nursing intervention significantly improved self reported patient knowledge of HIV and medications, as well as adherence to medication as measured by pharmacy refill records but no change in CD4 and viral loads.

**Prepared by:** Taryn Young
**E-mail:** taryn.young@mrc.ac.za
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