HELPING ENHANCE ADHERENCE TO ANTIRETROVIRAL THERAPY (PROJECT HEART)

Good Evidence – Medication Adherence

INTERVENTION DESCRIPTION

Target Population

- HIV-positive clinic patients who are antiretroviral treatment-naïve

Goals of Intervention

- Improve initial adherence to antiretroviral therapy
- Improve virologic outcomes (HIV viral load)

Brief Description

Project HEART is a social support/problem-solving intervention delivered one-on-one and through group sessions to HIV-positive clinic patients and their support partners. The core intervention consists of 5 individual/dyadic sessions delivered just before (2 sessions) and in the first two months after (3 sessions) initiation of antiretroviral therapy. In addition to the core intervention, there are five phone contacts between intervention sessions, 2-6 group educational sessions, and a booster session at 6 months after initiation of medication. Each patient identifies a support partner, who is required to attend at least 2 of the first 4 sessions, one of which needs to be a pre-medication session. For the core intervention, Session 1 consists of a structured needs assessment, detailed medication education, mapping the patient's daily schedule, and tailoring the medication regimen to correspond with regularly occurring events. Session 2 focuses on identifying adherence barriers, adjusting the regimen schedule if necessary, generating strategies to overcome the barriers, and developing an individualized adherence plan. At each subsequent meeting (Sessions 3-5 and the 6-month booster session), the interventionist follows the Semi-Structured Interview for Developing Medication Adherence Plans (SIDMAP) to review current circumstances, evaluate whether the strategies have been enacted and are working, generate new strategies if necessary, and update the list of barriers. An abbreviated version of the SIDMAP is also used in the brief follow-up calls and a MEMS SMART cap is used to provide participants with additional cues.

Theoretical Basis

- Problem-Solving Model
- Self-Determination Theory
- Social Support Theory

Intervention Duration

- Five sessions: two 2 – 3 hour sessions just prior to beginning medication; three 1.5 hour sessions (range, 45 minutes to 2 hours) at weeks 2, 4, and 8 following medication initiation, with 5 support phone calls between sessions (weeks 1, 6, and 10 and months 4 and 5 after) and a 1.5 hour booster session at 6 months.

Intervention Setting
- Public HIV primary care outpatient clinic

Deliverer
- A nurse interventionist, group discussion facilitator, and access to a peer advocate

Delivery Methods
- Discussion
- Individualized adherence plan
- Practice
- Video
- Problem solving

INTERVENTION PACKAGE INFORMATION

An intervention package is not available at this time. Please contact Linda J. Koenig, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop E-37, Atlanta, GA 30333.

Email: lkoenig@cdc.gov for details on intervention materials.

EVALUATION STUDY AND RESULTS

The original evaluation was conducted in Atlanta, Georgia between 1999 and 2002.

Key Intervention Effect
- Achieved medication adherence

Study Sample
The baseline study sample of 226 men and women is characterized by the following:
- *83% black or African American, 12% white, 3% other, 2% Hispanic/Latino*
- *64% male, 36% female*
- *58% heterosexual, 32% gay or lesbian, 8% were bisexual, 1% undecided*
- *Median age of 37 years, range: 31-43 years*
- *69% completed high school education or more*
- *100% treatment-naïve*
- *Median viral load = 145,890 copies/mL, range: 600-750,000*
- *100% participants with detectable viral load (>400 copies/mL)*

Recruitment Settings
Public HIV primary care outpatient clinic

Eligibility Criteria
Men and women were eligible if they were ≥18 years of age, receiving care for HIV at a local clinic, were newly prescribed HAART by their doctor but who had never previously taken a protease inhibitor, not currently self-reporting hard drug use, not pregnant or incarcerated, life expectancy of ≥12 months, and able to understand English and the consent form.

Assignment Method

Participants (N = 236) were randomly assigned to 1 of 2 groups: HEART Intervention (n = 116) or enhanced standard of care (n = 120).

Comparison Group

Comparison participants received standard-of-care adherence counseling, including a minimum of two preparatory sessions provided by education nurses, followed by dispensing of medications. Education nurses were available to meet with patients for additional sessions on patient or provider request. Participants also watched a 10-minute educational video with their support partner, the same activity that intervention participants received, which constituted the enhanced component.

Relevant Outcomes Measured and Follow-up Time

- Medication adherence behavior (recorded by MEMS caps) was defined as the proportion of doses taken among doses prescribed. Medication adherence was categorized as <90% or ≥90% and assessed monthly for 6 months post-initiation of intervention.
- Viral load was measured at 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

- HEART Intervention
  - 73% retained at 3 months post-initiation of intervention*
  - 70% retained at 6 months post-initiation of intervention*

- Enhanced Standard-of-Care Control
  - 70% retained at 3 months post-initiation of intervention*
  - 57% retained at 6 months post-initiation of intervention*

Significant Findings

- At 3-months post-initiation of intervention, a significantly greater proportion of intervention participants achieved ≥ 90% adherence, as assessed by MEMs caps, than comparison participants (46% vs. 28%, OR = 2.40, 95% CI = 1.35 to 4.27, p = .0028; missing data imputed; 61% vs. 42%; OR = 2.41, 95% CI = 1.24 to 4.67, p = .0094: without imputation).*

Considerations

- This study did not meet the best-evidence criteria due to assessment time point < 6 months post-initiation of intervention for the significant intervention effect. Also, the study did not find a significant positive intervention effect on either viral load measure.
- Several significant findings reported in the publication did not meet all the efficacy criteria:
  - A significantly larger proportion of intervention participants achieved ≥ 90% adherence than comparison participants (OR = 1.69, 95% CI = 1.08 to 2.64; p = .021: missing data imputed; OR = 1.66; 95% CI = 1.01 to 2.73; p = .04; missing data not imputed) using a weighted average across the 6 monthly assessments. However, this finding included the 6-month assessment, which had a retention rate for the standard-of-care comparison group that did not meet criterion.
  - A significantly larger percentage of intervention participants had undetectable viral load (<400 copies/mL) relative to comparison participants (OR = 1.65; 95% CI = 1.02 to 2.66; p = .04; missing data imputed) across 3- and 6-month post-initiation of intervention assessments. However, the retention rate for the standard-of-care comparison group at the 6-month assessment did not meet criterion. The re-analysis of this outcome at only the 3-month assessment provided by the authors did not show

statistical significance (OR = 1.38, 95% CI = 0.78 to 2.42, p = .27; missing data imputed).* The same analysis was also not significant when using observed data only.

- The proportion of 90% adherent participants declined steadily and significantly over time.
- MEMS caps were placed on one pill vial for each participant; protease inhibitor was the drug selected for 85% of participants.

***Information obtained from author**

REFERENCES AND CONTACT INFORMATION

Koenig, L. J., Pals, S. L., Bush, T., Pratt Palmore, M., Stratford, D., & Ellerbrock, T. V. (2008). Randomized controlled trial of an intervention to prevent adherence failure among HIV-infected patients initiating antiretroviral therapy. *Health Psychology, 27*, 159-169.

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