PARTNERSHIP FOR HEALTH

Good Evidence - Medication Adherence

INTERVENTION DESCRIPTION

Target Population

• HIV-positive clinic patients who are antiretroviral treatment-experienced

Goals of Intervention

- · Improve adherence to antiretroviral therapy
- Achieve undetectable viral load

Brief Description

Partnership for Health is a brief, clinic-based individual-level, provider-administered intervention emphasizing the importance of the patient-provider relationship to promote patients' healthful behavior. The medication adherence intervention includes the following components: (1) brochures that introduce the patient to the concept of partnership with the provider and messages about ART adherence; (2) posters conveying the partnership theme in the waiting room and posters with adherence messages in every examination room; and (3) communication from the medical provider during the medical examination to establish and solidify the partnership, present adherence messages, and discuss pill scheduling and adherence goals. At each clinic visit, the provider delivers a brief counseling session (3-5) minutes). Patients are given 1-page informational flyers on a monthly basis at subsequent clinic appointments; these serve to support provider messages and cover commonly asked questions about topics, including viral load and CD4 T-cell count, what HIV medications actually do, tips to help with adherence, how to keep from getting resistant virus strains, and information on support to help take medications. Intervention materials include printed and verbal information (the patient's regimen, potential side effects, and general importance of ART adherence), self-efficacy and skill building (problem solving, identifying barriers and ways to overcome them, identifying supportive people, and efforts to increase the patient's confidence in adhering to their regimen), and behavioral cues (tailoring of pill taking and establishing cues for when to take pills, including creating a detailed daily pilltaking reminder chart).

Theoretical Basis

• Mutual Participation Model of Patient Care

Intervention Duration

A 3- to 5-minute session at each clinic visit over 10 to 11 months

Intervention Setting

• HIV primary care outpatient clinics

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Deliverer

• Primary care provider (e.g., physician, physician assistant, nurse practitioner)

Delivery Methods

- · Brief counseling
- Discussion

- Printed material
- Problem solving

INTERVENTION PACKAGE INFORMATION

For information on training and intervention-related materials, please visit CDC's HIV
Effective Interventions website.

EVALUATION STUDY AND RESULTS

The original evaluation was conducted in 6 large HIV clinics in California between 1999 and 2000.

Key Intervention Effects

- Maintained medication adherence
- · Achieved undetectable viral load

Study Sample

The baseline study sample of 437 men and women is characterized by the following:

- 40% white, 39% Hispanic/Latino, 15% black or African American, 6% other
- 88% male, 12% female
- 76% MSM
- Mean age of 39 years
- 77% completed high school education or more
- 100% treatment-experienced
- 34% AIDS diagnosis
- 59% participants with undetectable viral load (< 500 copies/mL)

Recruitment Settings

HIV primary care outpatient clinics

Eligibility Criteria

Men and women were eligible if they were aware of their HIV-positive status for at least 3 months, sexually active during the previous 3 months (mutual masturbation and oral, anal, or vaginal sex), ≥18 years of age, fluent in English or Spanish, able to provide informed consent, on antiretroviral therapy, and intending to obtain care at the clinic for the next year.

Assignment Method

Six HIV clinics were randomly assigned to 1 of 3 groups: Medication Adherence Intervention (2 clinics; n = 149 patients assessed), Safer Sex Lost-frame comparison (2 clinics), or Safer Sex Gain-frame comparison (2 clinics); both Safer Sex Comparisons were combined for analysis (n = 288 patients assessed).

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Comparison Group

The Safer Sex comparison group received messages related to self-protection, partner protection, disclosure, and safer sex behaviors, rather than medication adherence. The intervention format and length (3 - 5 minute sessions delivered over a 10 to 11 month period by primary care providers) was identical to those of the Adherence intervention.

Relevant Outcomes Measured and Follow-up Time

- Medication adherence behavior was measured by self-reported number of pills missed or skipped during the previous 7 days, was categorized as < 95% or ≥ 95% prescribed doses taken, and was assessed at study entry and 11 18 months post-initiation of intervention.
- Viral load was measured at study entry and 11 18 months post-initiation of intervention, and was assessed as detectable (> 500 copies/mL) or undetectable.

Participant Retention

- Medication Adherence Intervention
 - 62% retained 11 to 18 months post-initiation of intervention*
- Safer Sex Comparison
 - o 63% retained 11 to 18 months post-initiation of intervention*

Significant Findings

- At 11 to 18 months post-initiation of intervention, the percentage of participants reporting ≥ 95% medication adherence was significantly greater in the intervention arm than in the comparison arm (85.9% vs. 69.8%, chi-square = 13.7, p < .01; missing data not imputed). This significant intervention effect was also found when the analysis was restricted to the subgroup of participants reporting ≥ 95% adherence at baseline (91.1% vs. 75.2%, chi-square = 12.59, p < .01; missing data not imputed).
- At 11 to 18 months post-initiation of intervention, intervention participants were more likely than comparison participants to report ≥ 95% adherence (OR = 2.39, p = .001; missing data not imputed). The intervention effect remained significant after controlling for other covariates (OR = 2.09, p < .01; missing data not imputed); after adjusting for whether providers counseled them on taking their ART medicines (OR = 2.30, p < .01; missing data not imputed); and after adjusting for whether providers counseled them on ways to make it easy to take ART medication (OR = 2.19, p < .01; missing data not imputed).
- When restricting the analyses to the subgroup of participants with ≥ 95% adherence at baseline, intervention participants in one medication adherence intervention clinic were more likely than participants in the 4 pooled safer sex comparison clinics to report ≥ 95% adherence at the assessment time point (OR = 5.26, p < .001; missing data not imputed). The effect in that adherence intervention clinic remained significant after controlling for covariates (OR = 5.39, p < .01; missing data not imputed).
- At 11 to 18 months post-initiation of intervention, intervention participants were less likely than comparison participants to have a detectable viral load, i.e., > 500 copies/mL (OR = 0.60, p = .04, adjusted for baseline detectable viral load; missing data not imputed).

Considerations

- This study did not meet the best-evidence criteria due to retention rate < 70% per arm and no imputation of missing data for the significant intervention effects.
- A subgroup analysis did not show any significant intervention effect for those who had less than 95% self-reported adherence to ART at baseline.

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- There were no significant intervention effects on detectable viral load at the follow-up assessment when controlling for both baseline detectable viral load (i.e., > 500 copies/mL) and baseline adherence levels.
- There were no significant intervention effects on self-reported medication adherence (p = .077) and viral load (p = .79) when adjusting for cluster allocation (i.e., clinics), although statistical power was limited due to only 6 clinics participating.
- Those lost to follow-up were more likely to have had a detectable viral load at baseline than those followed. However, the prevalence of a detectable viral load at baseline was comparable between the medication adherence intervention and safer sex comparison arms.
- Comparison participants were less likely to report unprotected sex than intervention participants over time because the focus of the Safer Sex comparison was to reduce unprotected sex behaviors. <u>See Risk Reduction</u> <u>version</u>.

REFERENCES AND CONTACT INFORMATION

Milam, J., Richardson, J. L., McCutchan, A., Stoyanoff, S., Weiss, J., Kemper, C., . . . Bolan, R. (2005). <u>Effect of a brief antiretroviral adherence intervention delivered by HIV care providers</u>. *JAIDS Journal of Acquired Immune Deficiency Syndromes*, 40, 356-363.

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^{*}Information obtained from author