HEALTHY LIVING PROJECT (HLP)

Best Evidence – Risk Reduction

Good Evidence – Medication Adherence

INTERVENTION DESCRIPTION

Target Population

- HIV-positive persons at risk of transmitting HIV

Goals of Intervention

- Eliminate or reduce sexual transmission risk behavior
- Eliminate or reduce injection drug use risk behaviors
- Improve health care practices and quality of life
- Improve adherence to antiretroviral therapy

Brief Description

Healthy Living is a 3-module/15-session intervention that is delivered one-on-one to people living with HIV. Each of the 3 modules consists of 5 sessions, and each is designed to improve quality of life in a different broad area of health: physical, mental, and sexual. More specifically, the modules focus on developing positive strategies for managing symptoms of depression, anxiety, complex medication regimens, injection drug use, and sexual risk behavior in order to avoid unwanted consequences for themselves, their friends, families, and partners. Module 1 (stress, coping, and adjustment) focuses on quality of life, psychological coping, and achieving positive affect and supportive social relationships. Module 2 (safer behaviors) centers on self-regulatory issues, such as avoiding risky sexual and drug use behavior. Module 3 (health behaviors) addresses accessing health services, adherence, and active participation in medical care decision making. Sessions have a standard structure and set of activities that are tailored to the individual participant. Psycho-education, skills-building exercises, and cognitive-behavioral techniques (trigger identification, problem solving, and goal setting) are included in each session so the participant can use these skills independently to effectively meet challenges in their daily lives.

Theoretical Basis

- Social Action Theory

Intervention Duration

- Fifteen 90-minute sessions were grouped into 3 modules of 5 sessions each. Each module was delivered over 2 months, with 3 months between modules for a total duration of 12 months.

Intervention Settings

- Private settings in community-based organizations and clinics

Deliverer

- Ethnically diverse, gender-matched female and male facilitators with experience as social workers, counselors, therapists, or community-based service providers

Delivery Methods

- Coping strategies
- Demonstration
- Goal setting
- Problem-solving
- Role plays

INTERVENTION PACKAGE INFORMATION

Intervention materials for risk reduction and medication adherence are available from **Center for AIDS Prevention Studies (CAPS)**, University of California San Francisco, 50 Beale Street, Suite 1300, San Francisco, CA 95105.

EVALUATION STUDY AND RESULTS

The original evaluation was conducted in Los Angeles and San Francisco, California; Milwaukee, Wisconsin; and New York, New York between 2000 and 2004.

Key Intervention Effects

- Reduce unprotected sex† with persons of HIV-negative or unknown serostatus
- Increased medication adherence

Study Sample

The baseline study sample of 936 HIV-positive men and women is characterized by the following:

- *45% black or African American, 32% white, 15% Hispanic/Latino, 8% other*
- *79% male, 21% female*
- *57% MSM (72% of men are MSM)*
- *Mean age of 40 years, range: 19-67 years*
- *81% completed high school education or more*

The analytic subsample of 204 HIV-positive men and women who were on ART and reported <85% adherence at baseline is characterized by the following:

- *56% black or African American, 31% white, 7% Hispanic/Latino, 6% other*
- *78% male, 22% female*
- *29% heterosexual, 52% homosexual, 16% bisexual, 2% other*
- *Mean age of 40 years*
- *83% completed high school education or more*
- *100% treatment-experienced*
- *Mean adherence of 61% (Adult AIDS Clinical Trials Group Scale; 3 day recall)*
- *20% participants with undetectable viral load (<50 copies/mL)*

Recruitment Settings
Community agencies and medical clinics

Eligibility Criteria
Men and women were eligible if they had medical documentation of their HIV infection, and were at least 18 years of age, free of severe neuropsychologic impairment or psychosis, not currently involved in another HIV-related behavioral intervention study, and self-reported unprotected sex† with an HIV-negative or unknown serostatus partner in the past 3 months, or with an HIV-infected non-primary partner.

Assignment Method
HIV-positive persons (N = 936) were randomly assigned to 1 of 2 groups: Healthy Living intervention (n = 467) or wait-list control (n = 469). Of the 633 participants that were on ART at baseline, 204 reported <85% adherence at baseline and are the analytical subsample used for the medication adherence analyses: Healthy Living intervention (n = 107) or wait-list control (n = 97).

Comparison Group
The wait-list control group received a delayed intervention following completion of the study.

Relevant Outcomes Measured and Follow-up Time
- HIV transmission risk acts during past 3 months (defined as unprotected insertive or receptive anal or vaginal sex† with partners of negative or unknown HIV serostatus) was assessed at 5, 10, 15, 20, 25 months post-baseline, which translates to assessments approximately 3 months after module 1, approximately 3 months after module 3, and approximately 3, 8, and 13 months after module 3.
- Medication adherence behavior (self-reported adherence measured as % of prescribed pills taken in the past 3 days) was assessed at 5, 10, 15, 20, 25 months post-baseline, which translates to assessments approximately 3 months after module 1, approximately 3 months after module 3, and approximately 3, 8, and 13 months after module 3.

Participant Retention
Risk Reduction
- Healthy Living Intervention
  - 84% retained at 3 months post-module 1 (5 months post-baseline)
  - 81% retained at 3 months post-module 2 (10 months post-baseline)
  - 78% retained at 3 months post-module 3 (15 months post-baseline)
  - 73% retained at 8 months post-module 3 (20 months post-baseline)
  - 73% retained at 13 months post-module 3 (25 months post-baseline)

- Wait-List Control
  - 88% retained at 3 months post-module 1 (5 months post-baseline)
  - 84% retained at 3 months post-module 2 (10 months post-baseline)
  - 83% retained at 3 months post-module 3 (15 months post-baseline)
  - 79% retained at 8 months post-module 3 (20 months post-baseline)
  - 81% retained at 13 months post-module 3 (25 months post-baseline)

Medication Adherence

- Healthy Living Intervention
  - 89% retained at 3 months post-module 1 (5 months post-baseline)
  - 84% retained at 3 months post-module 2 (10 months post-baseline)
  - 80% retained at 3 months post-module 3 (15 months post-baseline)
  - 75% retained at 8 months post-module 3 (20 months post-baseline)
  - 72% retained at 13 months post-module 3 (25 months post-baseline)

- Wait-List Control
  - 91% retained at 3 months post-module 1 (5 months post-baseline)
  - 84% retained at 3 months post-module 2 (10 months post-baseline)
  - 80% retained at 3 months post-module 3 (15 months post-baseline)
  - 79% retained at 8 months post-module 3 (20 months post-baseline)
  - 81% retained at 13 months post-module 3 (25 months post-baseline)

Significant Findings

- Intervention participants reported significantly fewer HIV transmission risk acts than control participants at 20 months post baseline (8 months after the completion of all three modules) (test statistic not reported; $p = 0.007$).
- Across the four assessments (5 to 25 months post-baseline), intervention participants reported significantly fewer HIV transmission risk acts than control participants ($X^2 = 16.0$; $p = 0.007$).
- Among participants who had <85% self-reported adherence at baseline and were still on ART at follow-up, intervention participants had an estimated 10% greater self-reported adherence than control participants at 15 months post-baseline (3 months after module 3) (88.6% versus 78.3%, respectively; F-test = 4.9579, $p = 0.027$).*

Considerations

For Risk Reduction:

- Despite randomized allocation to study arms, there were baseline differences between the intervention and control arms on transmission risk acts and unprotected sex† in the last 3 months and on race/ethnicity. These differences were statistically adjusted using propensity scores. The significant findings were consistent with and without propensity score adjustment.

For Medication Adherence:

- This study did not meet the best-evidence criteria due to no imputation of missing data and no measurement of viral load.
- The adherence findings are based on the analytic subsample of the 204 participants reporting <85% adherence at baseline who were still on ART at the specified follow up.
- Among participants with <85% self-reported adherence at baseline and on ART at follow up, there was an estimated 13% greater self-reported adherence among intervention participants compared to control participants (83.6% versus 70.3%, respectively; $p < 0.01$) at 5 months post-baseline (3 months after module 1). This finding did not meet the efficacy criteria because the assessment time period was during the intervention.
- The between-group difference on medication adherence was larger at 5 months post-baseline (3 months after Module 1: Stress, Coping, and Adjustment) than 15 months post-baseline (3 months after Module 3: Health Behaviors, which include medication adherence), 13% versus 10%, respectively (although no

statistical test compared the two differences). Module 1 addressed general stressors and taught problem solving, assertive communication, and strategies for dealing with stressful situations, which may include HIV-related stigma, depression, etc. Given that many of these factors are associated with HIV treatment adherence, it is possible that the content of this module was important for improving adherence.

- Self-reported adherence in the intervention arm declined at 20 months post-baseline (8 months after module 3) and increased at 25 months post-baseline (13 months after module 3), but was not statistically significantly different from the control arm at either assessment.
- At baseline, control participants had a slighter greater number of antiretroviral pills per day than intervention participants ($p = 0.05$), while mean baseline adherence did not statistically differ ($p = 0.54$).

***Information obtained from author**
†Unprotected sex measured as sex without a condom

REFERENCES AND CONTACT INFORMATION

RISK REDUCTION

Healthy Living Project Team. (2007). Effects of a behavioral intervention to reduce risk of transmission among people living with HIV: The Healthy Living Project randomized controlled study. *JAIDS Journal of Acquired Immune Deficiency Syndromes, 44*, 213-221.

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MEDICATION ADHERENCE

Johnson, M. O., Charlebois, E., Morin, S. F., Remien, R. H., Chesney, M. A., & National Institute of Mental Health Healthy Living Project Team. (2007). Effects of a behavioral intervention on antiretroviral medication adherence among people living with HIV: The Healthy Living Project Randomized Controlled Study. *JAIDS Journal of Acquired Immune Deficiency Syndromes, 46*, 574-580.

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