

**Name of Program/Strategy: Healthy Living Project for People Living With HIV**

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**1. Overview and description**

The Healthy Living Project for People Living With HIV promotes protective health decision-making among individuals with HIV--heterosexual women, heterosexual men, gay men, and injection drug users--to reduce substance use and the risk of transmitting HIV. The Healthy Living Project is based on social action theory and targets the interactive psychosocial domains of the community environment, internal affective states, and self-regulation. Using a cognitive-behavioral approach, this manual-driven intervention is delivered by facilitators functioning as "life coaches" who work with clients individually to help them make changes in their health behavior, become active participants in their ongoing medical care, and achieve desired personal goals. The Healthy Living Project consists of 15 sessions, each 90 minutes in duration, presented in 3 modules: Stress, Coping, and Adjustment; Safer Behaviors; and Health Behaviors. During tailored counseling sessions, the client is encouraged to identify a life project and work with the coach to set attainable goals and build self- confidence, self-esteem, and motivation to increase protective health behaviors. Intervention strategies include psychosocial education, skills building to improve coping, and problem-solving training involving role-play exercises.

**2. Implementation considerations (if available)**

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## **3. Descriptive information**

<b>Areas of Interest</b>	Substance abuse prevention Substance abuse treatment Co-occurring disorders
<b>Outcomes</b>	1: Substance use 2: HIV sexual risk behaviors
<b>Outcome Categories</b>	Alcohol Drugs
<b>Ages</b>	18-25 (Young adult) 26-55 (Adult) 55+ (Older adult)
<b>Genders</b>	Male Female
<b>Races/Ethnicities</b>	Black or African American Hispanic or Latino White Race/ethnicity unspecified
<b>Settings</b>	Outpatient Other community settings
<b>Geographic Locations</b>	Urban Suburban
<b>Implementation History</b>	Since 2000, the intervention has been implemented at four sites in three States (California, New York, and Wisconsin) with at least 936 HIV-positive clients, as well as in China.
<b>NIH Funding/CER Studies</b>	Partially/fully funded by National Institutes of Health: Yes Evaluated in comparative effectiveness research studies: No
<b>Adaptations</b>	The intervention has been adapted and translated for use in China.
<b>Adverse Effects</b>	No adverse effects, concerns, or unintended consequences were identified by the applicant.
<b>IOM Prevention Categories</b>	Indicated

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## **4. Outcomes**

### **Outcome 1: Substance use**

<p><b>Description of Measures</b></p>	<p>The substance use measure was derived from scales used in the 1999 National Survey on Drug Use and Health (NSDUH). It measured self-reported days in the past 3 months that the client used each of the following substances: alcohol, barbiturates, cocaine/crack, gamma-hydroxybutyrate (GHB), hallucinogens, heroin, inhalants, ketamine, marijuana, 3,4-methylenedioxymethamphetamine (MDMA, or ecstasy), methadone, opiates, sedatives, speedballs, steroids, and stimulants (i.e., methamphetamine/amphetamine). Interviews were conducted in private settings on laptop computers using an audio computer-assisted self-interviewing format. The TimeLine Follow-back (TLFB) method was used to solicit information about use of each substance. The TLFB method uses a calendar to help the respondent reconstruct prior days of drinking and drug use over a specified time period.</p> <p>Reported days of use for each substance were rated on a 9-point categorical scale developed by researchers for use in this study: 0 (never), 1 (less than once per month), 3 (once per month), 7 (2-3 times per month), 12 (once per week), 30 (2-3 times per week), 60 (4-6 times per week), 90 (once per day), and 120 (more than once per day). Each substance was also assigned a severity rating according to a 5-point categorical scale developed by researchers for use in this study: 0 (none); 1 (alcohol); 2 (marijuana); 3 (barbiturates, methadone, inhalants, sedatives, and steroids); and 4 (cocaine/crack, GHB, hallucinogens, heroin, ketamine, speedballs, MDMA, opiates, and stimulants).</p> <p>The ratings for days of use and severity of the substance provided a weighted index for days of use by drug severity.</p>
<p><b>Key Findings</b></p>	<p>In a randomized clinical trial, HIV-positive clients undergoing outpatient medical care were assigned to an intervention group receiving the Healthy Living Project or to a wait-list control group.</p> <p>Assessments occurred at baseline and at 5-month intervals up to 25 months after randomization. Among the findings from this study were the following:</p> <ul style="list-style-type: none"> <li>• Compared with the control group, the intervention group</li> </ul>

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	<p>reported fewer days using alcohol, marijuana, methadone, inhalants, MDMA, stimulants, sedatives, barbiturates, steroids, heroin, cocaine/crack, and speedballs across the follow-up period (<math>p &lt; .0001</math>).</p> <ul style="list-style-type: none"> <li>• Compared with the control group, the intervention group reported fewer days of any substance use across the follow-up period (<math>p &lt; .0001</math>).</li> <li>• Among the 35% of clients who were homeless or marginally housed, those in the intervention group reported fewer days using alcohol or marijuana (<math>p = .002</math>) and fewer days using hard drugs (i.e., heroin, cocaine/crack, speedball, MDMA; <math>p = .042</math>) across the follow-up period compared with those in the control group.</li> <li>• Across the follow-up period, the intervention group had greater declines than the control group in the weighted days of use by drug severity index for alcohol, marijuana, methadone, inhalants, MDMA, stimulants, sedatives, barbiturates, and steroids (<math>p &lt; .0001</math>) but not for heroin, opiates, cocaine/ crack, ketamine, GHB, or hallucinogens.</li> <li>• Across the follow-up period, women in the intervention group reported fewer days of substance use than women in the control group and men in either condition for alcohol, marijuana, methadone, inhalants, MDMA, stimulants, sedatives, barbiturates, steroids, heroin, cocaine/crack, and speedballs (<math>p &lt; .0001</math>). Additionally, women in the intervention group had larger declines than women in the control group and men in either condition in the weighted days of use by drug severity index for all substances but heroin, cocaine/crack, and speedballs across the follow-up period (<math>p &lt; .0001</math>).</li> <li>• Men in the intervention group reduced their days using alcohol, marijuana, stimulants, and any substances more than men in the control group (<math>p &lt; .0001</math>) and showed a larger decline in the weighted days of use by drug severity index for alcohol and marijuana (<math>p &lt; .0001</math>) across the follow-up period.</li> <li>• Heterosexual men in the intervention group reduced their days of stimulant use more than heterosexual men in the control group (<math>p &lt; .0001</math>) and gay men in either condition (<math>p = .03</math>) across the follow-up period.</li> </ul>
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	<ul style="list-style-type: none"> <li>Gay men in the intervention group reported fewer days of hard drug use than gay men in the control group (<math>p &lt; .04</math>) and more days of hard drug use than heterosexual men in either condition (<math>p = .0002</math>) across the follow-up period.</li> </ul>
<b>Studies Measuring Outcome</b>	Study 1
<b>Study Designs</b>	Experimental
<b>Quality of Research Rating</b>	3.6 (0.0-4.0 scale)

### **Outcome 2: HIV sexual risk behaviors**

<b>Description of Measures</b>	<p>HIV sexual risk behaviors were measured as the number of self-reported unprotected sexual acts in the past 3 months with a partner whose HIV serostatus was negative or unknown to the client. An unprotected sex act was defined as any act of insertive or receptive anal or vaginal intercourse in which neither party used a condom. Interviews were conducted in private settings on laptop computers using a combination of audio computer-assisted self-interviewing and computer-assisted personal interviewing.</p>
<b>Key Findings</b>	<p>In a randomized clinical trial, HIV-positive clients undergoing outpatient medical care were assigned to an intervention group receiving the Healthy Living Project or to a wait-list control group. Assessments occurred at baseline and at 5-month intervals up to 25 months after randomization. Among the findings from this study were the following:</p> <ul style="list-style-type: none"> <li>From months 5 to 25 of follow-up, the number of self-reported unprotected sexual acts steadily declined for the intervention group compared with the control group (<math>p = .0069</math>), after controlling for baseline group differences in the number of unprotected sexual acts.</li> <li>Clients in both conditions reported reductions in the number of unprotected sexual acts from baseline through the follow-up period (<math>p &lt; .0001</math>). At the 20-month follow-up, however, intervention clients reported 36% fewer unprotected sexual acts than those in the control group (<math>p = .007</math>).</li> <li>Among the 35% of clients who were homeless or marginally housed, intervention clients reported fewer sexual partners who were HIV-negative or of unknown serostatus (<math>p &lt; .001</math>) and</li> </ul>

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	fewer unprotected sexual acts (p = .037) across the follow-up period compared with control group clients.
<b>Studies Measuring Outcome</b>	Study 1
<b>Study Designs</b>	Experimental
<b>Quality of Research Rating</b>	3.8 (0.0-4.0 scale)

5. **Cost effectiveness report (Washington State Institute of Public Policy – if available)**
6. **Washington State results (from Performance Based Prevention System (PBPS) – if available)**
7. **Who is using this program/strategy**

Washington Counties	Oregon Counties

## **8. Study populations**

The studies reviewed for this intervention included the following populations, as reported by the study authors.

Study	Age	Gender	Race/Ethnicity
<b>Study 1</b>	18-25 (Young adult) 26-55 (Adult) 55+ (Older adult)	79% Male 21% Female	45% Black or African American 32% White 15% Hispanic or Latino 8% Race/ethnicity unspecified

## **9. Quality of studies**

The documents below were reviewed for Quality of Research. Other materials may be available. For more information, contact the developer(s).

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## **Study 1**

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. *Journal of Acquired Immune Deficiency Syndromes*, 44(2), 213-221.

Rotheram-Borus, M. J., Desmond, K., Comulada, W. S., Arnold, E. M., Johnson, M., & the Healthy Living Trial Group. (2009). Reducing risky sexual behavior and substance use among currently and formerly homeless adults living with HIV. *American Journal of Public Health*, 99(6), 1100-1107.

Wong, F. L., Rotheram-Borus, M. J., Lightfoot, M., Pequegnat, W., Comulada, W. S., Cumberland, W., et al. (2008). Effects of behavioral intervention on substance use among people living with HIV: The Healthy Living Project randomized controlled study. *Addiction*, 103(7), 1206-1214.

## **Supplementary Materials**

Agrawal, S., Sobell, M. B., & Sobell, L. C. (2008). The Timeline Follow-back: A scientifically and clinically useful tool for assessing substance use. In R. F. Belli, F. P. Stafford, & D. F. Alwin (Eds.), *Calendar and time diary methods in life course research* (pp. 57-68). Washington, DC: Sage.

Gore-Felton, C., Rotheram-Borus, M. J., Weinhardt, L. S., Kelly, J. A., Lightfoot, M., Kirshenbaum, S. B., et al. (2005). The Healthy Living Project: An individually tailored, multidimensional intervention for HIV-infected persons. *AIDS Education and Prevention*, 17(1 Suppl. A), 21-39.

Gribble, J. N., Miller, H. G., Rogers, S. M., & Turner, C. F. (1999). Interview mode and measurement of sexual behaviors: Methodological issues. *Journal of Sexual Research*, 36, 16-24.

Kelly, J. A., Ehrhardt, A., Rotheram-Borus, M. J., & Chesney, M. (2002). NIMH Collaborative on Health-Related Interventions for People Living With HIV: Intervention quality assurance and quality control manual.

Turner, C. F., Ku, L., Rogers, S. M., Lindberg, L. D., Pleck, J. H., & Sonenstein, F. L. (1998). Adolescent sexual behavior, drug use, and violence: Increased reporting with computer survey technology. *Science*, 280(5365), 867-873.

## **Quality of Research Ratings by Criteria (0.0-4.0 scale)**

External reviewers independently evaluate the Quality of Research for an intervention's reported results using six criteria:

1. Reliability of measures
2. Validity of measures
3. Intervention fidelity
4. Missing data and attrition
5. Potential confounding variables
6. Appropriateness of analysis

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For more information about these criteria and the meaning of the ratings, see Quality of Research.

<b>Outcome</b>	Reliability of Measures	Validity of Measures	Fidelity	Missing Data/Attrition	Confounding Variables	Data Analysis	Overall Rating
<b>1: Substance use</b>	3.5	3.0	3.5	4.0	3.5	4.0	3.6
<b>2: HIV sexual risk behaviors</b>	4.0	3.5	3.5	4.0	3.5	4.0	3.8

## **Study Strengths**

The substance use outcome measure is considered the gold standard for self-reports. Sample reliability was provided for the measure of HIV sexual risk behaviors, and prior research has documented the reliability of computer-delivered interviews for reporting behaviors of a sensitive nature. Treatment fidelity was strong in this study, which used a detailed manual, systematic training, and an adherence instrument. Missing data rates were low and data that were missing were well managed with an intent-to-treat statistical approach and sophisticated data modeling. The study design included random assignment to conditions and a large sample size that provided statistical power to detect outcome differences between conditions. A sophisticated data analysis approach was used.

## **Study Weaknesses**

No biological measure such as urinalysis was used to strengthen the internal validity of self-reported drug use. Similarly, the validity of self-reported sexual behavior is an issue in this type of sensitive research; underreporting, both at pretest and follow-up, cannot be ruled out. As a result of minor problems with implementing random assignment, 9% of the study sample participated in the group to which they were not assigned.

## **10. Readiness for Dissemination**

The documents below were reviewed for Readiness for Dissemination. Other materials may be available. For more information, contact the developer(s).

### **Dissemination Materials**

Assessment interviewer guidelines. (2010). Assessment Quality Control Procedures

Center for AIDS Intervention Research (CAIR), Medical College of Wisconsin. (n.d.). Healthy Living Project intervention manual. Milwaukee, WI.

Center for AIDS Intervention Research (CAIR), Medical College of Wisconsin. (n.d.). Healthy Living Project reference guide. Milwaukee, WI.

Ehrhardt, A., Kelly, J. A., Rotheram-Borus, M. J., & Chesney, M. (2002). Data management protocols: The Healthy Living Project. Health-Related Interventions for Persons Living With HIV Protocol

Healthy Living Project: Baseline questionnaire. (2001). The Healthy Living Project Timeline and Study Design



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Kelly, J. A., Ehrhardt, A., Rotheram-Borus, M. J., & Chesney, M. (2002). NIMH Collaborative on Health-Related Interventions for People Living With HIV. Intervention quality assurance and quality control manual. Program Web site, <http://chipts.ucla.edu/projects/chipts/hlp.asp>

Sample In-Person Recruitment Script

## **Session forms**

Readiness for Dissemination Ratings by Criteria (0.0-4.0 scale)

External reviewers independently evaluate the intervention's Readiness for Dissemination using three criteria:

1. Availability of implementation materials
2. Availability of training and support resources
3. Availability of quality assurance procedures

For more information about these criteria and the meaning of the ratings, see Readiness for Dissemination.

<b>Implementation Materials</b>	<b>Training and Support Resources</b>	<b>Quality Assurance Procedures</b>	<b>Overall Rating</b>
2.8	1.5	2.8	2.3

## **Dissemination Strengths**

The materials include a series of highly detailed, well-developed guides and manuals to support implementation, and the role of the facilitator is clearly articulated. Customized training and telephone and email consultation are available for a fee. A well-developed quality control manual includes quality assurance checklists and screening criteria for both participants and program facilitators. A comprehensive data collection and data management system is also available to support quality assurance.

## **Dissemination Weaknesses**

Implementation materials and quality assurance tools have not been adapted for use outside a research setting. The training and support offered are not formalized.

## **11. Costs (if available)**

The information below was provided by the developer and may have changed since the time of review. For detailed information on implementation costs (e.g., staffing, space, equipment, materials shipping and handling), contact the developer.

<b>Item Description</b>	<b>Cost</b>	<b>Required by Program Developer</b>
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Intervention manual and other implementation materials	Free	Yes
2-week, onsite training	\$1,300 per participant plus travel expenses	Yes
30-minute phone consultation before training or implementation	Free	No
Intervention quality assurance and quality control manual and other quality assurance materials	Free	No
Technical assistance/consultation	\$50 per hour by phone	No

### **Additional Information**

The estimated cost for delivering the program to one client is \$412. Implementers should have a bachelor's degree, and program trainers must be experienced in behavioral management approaches.

### **Replications**

No replications were identified by the applicant.

## **12. Contacts for more information**

### **For information on implementation:**

Dallas Swendeman  
Ph.D. (310) 794-8128  
DSwendeman@mednet.ucla.edu

### **For information on research:**

Mary Jane Rotheram-Borus, Ph.D.  
(310) 794-8278  
rotheram@ucla.edu

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