HEALTHY LIVING PROJECT

INTERVENTION MANUAL

MEDICAL COLLEGE OF WISCONSIN

CENTER FOR AIDS INTERVENTION RESEARCH (CAIR)

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During planning meetings held in 1999, the Manual and Guide benefited greatly from the input of all participating research sites:

- Center for AIDS Prevention Studies at the University of California San Francisco
- Center for HIV Intervention, Prevention, and Treatment Studies at the University of California Los Angeles
- HIV Center for Clinical and Behavioral Studies at Columbia University
- Center for AIDS Intervention Research (CAIR) at the Medical College of Wisconsin

In addition, we would like to express our gratitude to those who participated in the qualitative interviews and focus groups for openly sharing their personal experiences with us, and the Columbia University team for their exceptional work analyzing the qualitative data.

The following people at the Medical College of Wisconsin were responsible for the development of the Manual and Guide: Jeffrey A. Kelly, Kristin Hackl, Cheryl Gore-Felton, Sheryl Catz, Lance Weinhardt, and Troy Suarez.

We also are grateful to the following people at MCW for their extraordinary contributions to the development of the Manual and Guide: Thom Ertl, Margi Peterson, and Michael DiMarco.

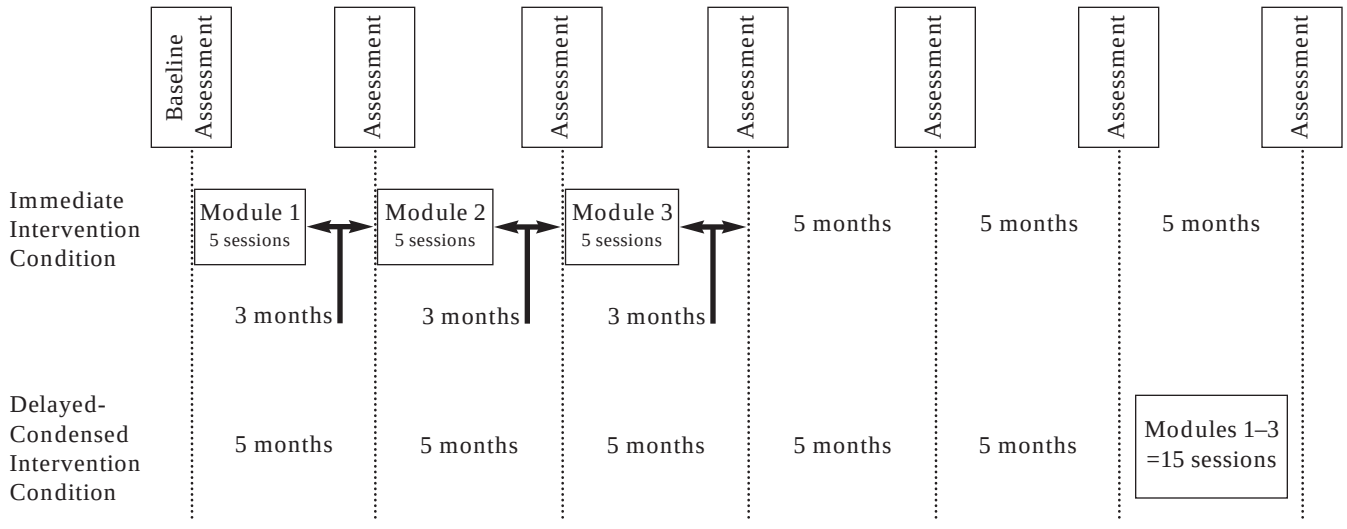
Welcome to the Healthy Living Project (also referred to as the R10 and Interactive R01). This Intervention Manual provides session-by-session instructions and is your primary source of information about how to conduct the intervention. It will also familiarize you with the study design. Additional information, including the preferred facilitation style, detailed instructions for specific intervention exercises, the basic skills that will be used in all sessions of the intervention, the diverse contextual issues that are expected to emerge, and how to handle specific procedural issues, is available in the Reference Guide, which is a companion to this Manual. Your role as a Facilitator will be critical to the success of the project. Please become familiar with both the Manual and the Guide and refer to them often.

OVERVIEW OF THE HEALTHY LIVING PROJECT

The Healthy Living Project (HLP) is a research investigation that tests the efficacy of a one-on-one multi-session intervention program designed to help people with HIV infection to improve their quality of life in three broad areas: mental, physical, and sexual health. More specifically, the HLP seeks to assist people who have HIV infection to develop 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. The HLP Participants will include women, injection drug users, and men who have sex with men. Overall, 1,200 Participants will be enrolled in the project, 100 from each subgroup at each of the four research sites: Los Angeles, Milwaukee, New York, and San Francisco.

Explanation of the Design. Because the HLP is designed to test the efficacy of an intervention, the intervention is conducted between multiple assessments. Figure 1 illustrates the study design described herein.

Figure 1. Healthy Living Project Study Design



Participants begin by completing a baseline interview. They are randomly assigned to either an Immediate or Delayed Intervention condition. The intervention is grouped in fifteen individual sessions, and each session is 90 minutes long. Sessions are delivered in three modules of five sessions each. Each module will take approximately two months to complete, with sessions occurring about every week. For the Immediate Intervention group, each module is separated from the next by three months to allow Participants time to incorporate the information from the program into their lives, and also to evaluate of the impact of each module on Participants' well-being. Thus, another assessment is conducted three months after each module is completed.

After Participants in the Immediate Intervention group complete the assessment following Module 3 and two subsequent follow up assessments, the Delayed Intervention group then begins participating in a condensed version of the intervention without the three month hiatus between modules. One additional assessment is conducted after they have completed the intervention. Participants in the Delayed Intervention condition complete assessments throughout the study at the same intervals as Immediate Intervention Participants, and those in the Immediate Intervention condition continue their assessments until the Delayed group completes the study.

Content of the Intervention. The content of the intervention is based on extensive qualitative interviews and focus groups, as well as on previous intervention research with people with HIV infection. Module 1 addresses stress and coping. Module 2 focuses on risky sexual and drug use behavior. Module 3 addresses treatment adherence. An outline and instructions for the 5 session in each module are contained in this Manual. Facilitators will help Participants address these topics by using a core repertoire of cognitive-behavioral techniques in each session, including trigger identification, problem solving, and goal setting. The rationale is that by teaching these skills, and how they can be used to address the diverse topics in each module, Participants will be able to use them independently to effectively meet challenges in their daily lives.

For the intervention to be most effective and appealing to Participants, the content of each session will need to be tailored to the life-context of individual Participants. Facilitators will encounter a wide range of ethnic, educational, and socioeconomic backgrounds among the Participants because the project targets diverse groups of HIV-positive people from distinct geographical areas. Although it is impossible for us to predict every viewpoint, challenge, and concern that Participants will bring to the study, many of the contextual factors that we anticipate are discussed on pages 43-58 of the Reference Guide, in the section entitled "Contextual Themes." It is imperative that you are well versed in these contextual factors prior to working with Participants.

RESPONSIBILITIES AND EXPECTATIONS OF THE FACILITATOR ROLE

Facilitator Responsibilities. On the most basic level, the responsibility of the Facilitator is to deliver the 15-session intervention described in the Manual in an ethical manner. However, the style in which Facilitators do this is important. The Reference Guide contains recommendations regarding the style of facilitation that we believe will be most successful. Facilitators are required to participate in centralized training, during which they will be tested on specific skills and "certified" to begin working with Participants.

In addition, Facilitators are responsible for maintaining a file documenting each participant's progress in the program. They will also audiotape and complete quality assurance paperwork at each session. They are required to participate in regular clinical supervision at their research site. Finally, they may be required to undergo additional training in the study protocol, based on results of quality assurance paperwork. These procedural topics are addressed in the Reference Guide.

Facilitator Expectations. It is expected that male Facilitators be able to deliver the intervention to male Participants; female Facilitators should be able to deliver the intervention to either men or women. Perhaps the most important point here is what is not expected of Facilitators. **FACILITATORS ARE NOT CLIENTS' THERAPISTS.** It may be useful to think of the Facilitator as a type of coach who helps Participants achieve goals and make changes in their lives. However, Facilitators are not expected to provide treatment for psychological disorders beyond what is contained in the intervention. Procedures for assisting Participants to obtain additional services when indicated will be covered at the centralized training. The specific services available will differ by research site, and a list of services will be provided to Facilitators by each site's study coordinator and/or clinical supervisors. In addition, an emergency protocol has been prepared by each site and will be reviewed with each Facilitator.

RESEARCH PROTOCOL VS. THERAPY

The goal of the HLP, in addition to helping the Participants directly, is to develop an intervention that can be used by others on a broader scale if it is found to be effective. Therefore, Facilitators need to adhere to the program as detailed in this Intervention Manual and the Reference Guide. To assist them in adhering to the study protocol, Facilitators will complete a checklist of required activities at the conclusion of each session, as described in detail in the "Procedural Issues" section of the Reference Guide.

At the same time, it is also important to the success of the project that Facilitators maintain the individual style that they have developed through years of prior experience as a social worker, counselor, or therapist, in order to connect with Participants. We anticipate that for some Facilitators, especially those with less experience delivering manualized interventions, combining the study protocol with existing clinical skills and style will be challenging. For this reason, although we have included core activities to be delivered as an active part of the program, we have left these activities open to be tailored to each participant, and, in addition, we have designated the beginning and end of each session to be adapted to each participant.

Nevertheless, based on your experience, you may feel that there is a better way to achieve the goals than the program described in this Intervention Manual and the Reference Guide. If you find that you are uncomfortable delivering the intervention according to protocol, it is important that you discuss this with your clinical supervisor rather than deviating regularly from the protocol.