

## The Balance Project: A Randomized Clinical Trial of an HIV Treatment Side Effects Coping Intervention

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**Project Description:** The Balance Project is a randomized clinical trial that tests a counseling intervention to help HIV+ men and women achieve an active role in their health care. In particular, the intervention is designed to help individuals

- cope with the challenges of taking medications,
- deal with side effects and
- maintain an active collaboration with their health care providers.

The intervention consists of 5 individualized counseling sessions. We will enroll approximately 300 HIV+ adults taking antiretroviral medications, and will evaluate the impact of the intervention on quality of life and medication adherence. Participants are assessed at baseline and at 6-, 12-, and 18-month follow-up periods. Psychosocial and behavioral variables are assessed via computerized (ACASI/CAPI) interviews at the CAPS project offices.

**Significance:** While the life-extending benefits of highly active antiretroviral therapies (HAART) are well-documented, aversive side effects accompany drug benefit. Side effects are predictable, undesirable, dose-related pharmacologic effects that occur within therapeutic dose ranges. The most common side effects from HAART are gastro-intestinal problems such as diarrhea, nausea and vomiting and dermatological problems such as rashes. Additional “unseen” negative effects that become apparent over time include cardiac and liver problems, and increased triglyceride levels. Side effects are often cited when evaluating the impact of HAART on the HIV treatment arena. While researchers are actively attempting to develop new medications that have fewer side effects, the goal of a side effect-free, clinically effective regimen is far from realized. As such, HIV+ persons will have to face the realities of side effects in the foreseeable future.

**Project Recruitment Dates:** Enrollment began in February 2005 and is ongoing.

**Project End Date:** February 2009