

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 controlled trial that tests a counseling intervention to help HIV+ men and women achieve an active role in their health care. 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. We enrolled 250 HIV+ adults taking antiretroviral medications, and will evaluate the impact of the intervention on quality of life and medication adherence.

This study involves two phases:

- **Phase 1** is conducted over 12 months and includes two one-hour interviews with questions about personal life, family, friends, medications and medication side effects. After the first interview, participants may be invited to participate in Phase 2, which lasts 18 months.
- **Phase 2**, participants complete five two to three-hour interviews occurring at baseline and Months three, six, 12 and 18. Interviews include questions about personal life, friends, family, health-related activities, drug-using behaviors, emotions, mental state and educational background.

Participants are assigned randomly to one of two treatment groups:

- **Group 1** participants receive five individual sessions of cognitive behavioral coping training, beginning after the Month 3 interview. 90-minute sessions focus on coping with stress, dealing with medication side effects and staying on track with medications.
- **Group 2** participants receive standard care and one group session of coping training, which is held after the Month 18 interview. The group session covers the same material that is covered in the individual sessions.

After the last follow-up interview, some participants may also be asked to complete an exit interview about thoughts and feelings on study participation.

Significance

While the life-extending benefits of antiretroviral therapies (ART) are well-documented, adverse side effects accompany drug benefit. The most common side effects from ART 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. 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. HIV+ persons will have to face the realities of side effects in the foreseeable future.

Project End Date: February 2009

