

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.

Interesting Findings: We developed a measure of coping with HIV treatment side effects, the SECope, and provided support for the reliability and validity of the measure. Based in Stress and Coping Theory, the 20-item measure assesses strategies for coping with HIV treatment side effects, and includes scales of Positive Emotion Focused Coping, Social Support Seeking, Nonadherence, Information Seeking, and Taking Side Effect Medications. The factor structure was supported by exploratory and confirmatory factor analyses with two samples of HIV+ individuals on treatment (Ns = 173 and 233). The SECope has demonstrated reliability (internal consistency and test-retest), and its validity is supported through construct and criterion-referenced analyses. Nonadherence as a strategy for coping with side effects was associated with poorer provider relations, lower treatment knowledge, and higher beliefs of treatment effectiveness. Findings have the potential to inform investigations and interventions in the context of treatment of HIV and other medical conditions. (Johnson MO, Neilands TB. Coping with HIV treatment side effects: Conceptualization, measurement and linkages. *AIDS and Behavior*. 2007.)

Project End Date: February 2009