



## Abstract

**Grant Number:** 5R01NR004749-04

**PI Name:** ERLLEN, JUDITH A.

**PI Title:** PROFESSOR

**Project Title:** ADHERENCE TO PROTEASE INHIBITORS

**Abstract:** *DESCRIPTION (adapted from the Abstract): Protease inhibitors require persons with HIV (PWHIV's) infection to adhere strictly to the rigorous therapeutic regimen. Missing just a few doses or changing the intervals between doses may lead to increase in viral load, decreases in CD4 T-cell counts, and the development of drug-resistant mutant strains. Researchers are being challenged to demonstrate the efficacy of interventions to enhance adherence; however, no intervention studies with PWHIV's who are taking combination therapy including protease inhibitors have been published. Therefore, the primary aim of this study is to compare the effect of the habit-training and problem-solving intervention with usual care on adherence to combination therapy including a protease inhibitor. This 12-session telephone intervention and 12-week maintenance program is based on social learning and theory and self-efficacy theory. The sample of 200 PWHIV's who are taking combination therapy including protease inhibitor, and who are without cognitive dysfunction, alcohol and/or injection drug abuse, and/or chronic emotional disorders/personality disorders will be randomly assigned to one of two protocol arms. The intervention arm will receive a telephone-delivered 12-week intervention followed by a 3-month maintenance program of weekly telephone calls. Data will be collected at baseline, post-treatment, post-maintenance, and 6- months post-maintenance. Medication Electronic Monitoring System (MEMS) TrackCaps, daily diaries, and pill counts will be used to assess adherence. Efficacy moderators will be measured using the Medical Outcomes Study-HIV (mood and physical function), the Symptom Distress Scale, and the Beck Depression Inventory-II. Clinical response will be assessed using viral load and CD4 T-cell count. A repeated-measures model with planned comparisons will be used to test the hypotheses for the primary aim ( $p < .05$ , two-tailed).*

*Longitudinal data analytic techniques will be used. PWHIV's who adhere to therapy will live longer and require fewer hospitalizations, less skilled nursing care, and less home care, thus reducing the costs of their health care.*

**Thesaurus Terms:**

*AIDS therapy, antiAIDS agent, combination chemotherapy, human therapy evaluation, nursing intervention, protease inhibitor, therapy compliance  
health care cost /financing, longitudinal human study, mental health  
behavioral /social science research tag, clinical research, human subject, immunologic assay /test, patient monitoring device, personal log /diary*

**Institution:** UNIVERSITY OF PITTSBURGH AT PITTSBURGH  
4200 5TH AVE  
PITTSBURGH, PA 15260

**Fiscal Year:** 2001

**Department:** HEALTH PROMOTION & DEVELOPMENT

**Project Start:** 30-SEP-1998

**Project End:** 30-JUN-2003

**ICD:** NATIONAL INSTITUTE OF NURSING RESEARCH

**IRG:** ARRF

---

