The Role of Non-pharmacologic interventions on HIV Outcomes

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Lay Abstract

a. Study Purpose:

The purpose of this study is to determine the effect of education and increased nursing visits on outcomes in HIV illness. Many HIV clinics around the country are adding similar programs to standard therapy with medications, in an effort to improve patients' outcomes. It is believed that such programs will help patients take their medications more reliably. Few centers have tested this hypothesis in a structure, scientific manner.

b. Study Subjects:

The study will be conducted at the Infectious Diseases (ID) Clinic at CPMC. Roughly 400 adult patients will be enrolled and randomized to the education and nursing visits versus just standard therapy. Doctors from the ID Clinic will be asked to refer patients who are beginning antiretroviral therapy for the first time. Once patients are referred, they will be approached at their current or next visit by a study nurse for enrollment.

c. Study Procedures:

Patients in both arms will be required to have a viral load and CD4 count drawn at least every 12 weeks. Patients in the control arm will have a nursing visit also every 12 weeks to determine adherence to current regimen. Patients in the intervention arm will have nursing visits every week and education sessions upon enrollment and every 2 months there after.

d. Issues:

All data collected for study purposes will be identified by unique codes only. No personal identifier will be used. Access to codes will be limited only to study personnel.

IRB Protocol

A. Study Purpose and Rationale:

The course of illness in HIV infected individuals has be dramatically altered by the introduction of highly active antiretroviral therapy (HAART). Enthusiasm for therapy has been tempered, however, by the patients' difficulty to adhere to complex medical regimens and by the emergence of drug resistance due to incomplete adherence. Many HIV centers have begun to implement nonpharmacologic interventions in an effort to improve adherence and consequently, clinical outcomes in HIV disease. Systematic assessment of the results of these interventions is lacking in the medical literature. The Infectious Diseases Clinic here at CPMC has initiated a program adding education and increased nursing visits to standard care in an effort to improve patient outcomes. These interventions have yet to be investigated in a prospective, controlled manner. It is hypothesize that the addition of educational sessions and additional nursing visits will improve the number of patients achieving viral suppression, improve CD4 count, and clinical outcomes with regard to opportunistic infections and hospitalization.

B. Study Design and Statistical Analysis

a. **1.Study Arms**
   i. Education and Nursing arm
   ii. Control
b. **2.Study Subjects: 400. Powered for a 15% increase in viral suppression from 40% to 55%**
   i. Patients will be randomized equally to each of the arms
c. **4.Statistical Analysis:**
   i. Chi Square analysis of undetectable viral load and drug resistance
   ii. t-test analysis of change in CD4 count, rate of Adherence
   iii. survival analysis to analyze duration of viral suppression
   iv. Power analysis performed with by chi square

C. Study Procedure:

Study is a prospective, randomized controlled trial comparing the rate of viral suppression to undetectable levels in patients receiving extra non-pharmacologic interventions in addition to usual care versus those receiving only standard care. Patients will be eligible for enrollment if they are infected with HIV, treatment naYve and being initiated on antiretroviral therapy. Patients must also have either a viral load greater than 30,000 copies/ml, a CD4 count less than 350 x 106/L or a viral load between 5,000-30,000 copies/nil and a CD4 between 350-500 x 106/L.1 Patients will be excluded if they cannot personally give informed consent or if they are taking a medication known to interact with any of the antiretroviral medications.

All patients will continue to be followed in the CPMC Infectious Diseases Clinic by one of the medical providers (include MD's, Physician Assistants and Nurse Practioners). Decisions regarding components of antiretroviral therapy will be left to the individual providers. Upon enrollment, patients will be randomized to one of two arms. The intervention arm will add weekly nursing visits and educational sessions to the provider visits. During these visits, the nurse will inquire about difficulties taking medications, side effects, emphasize need for adherence, dispense medications into a pillbox for the week and record doses missed in the prior week. The education will consist of an initial group session explaining the basics of HIV illness (ie. what is HIV, how is it contracted and spread, what effect does it have on the body, goals of treatment, importance of treatment/adherence). The group session is followed up by individual education sessions led by peer educators. Peer educators will use sessions to gauge each patients understanding of HIV and to reinforce gaps in knowledge. They will occur at enrollment and then

at 2 month intervals until the end of the study. The last group is a control group who will receive standard therapy in the clinic, which includes provider visits and ongomig follow-up with a social worker to whom they are assigned upon presentation to the clinic.

Patient will have a CD4 count and viral load done prior to enrollment to see if they meet entry requirements. Follow-up CD4 and viral loads will be drawn no less frequently than every 12 weeks, as is routinely done in practice. More frequent checks will be done at the discretion of the medical providers. Patients will be followed for 2 years.

The primary outcome will be achieving an undetectable viral load. Secondary outcomes will change in CD4 count,

D. Study Drugs:

None

E. Medical Devices:

None

F. Study Questionnaires:

None

G. Study Subjects:

a. Inclusion Criteria:

i. HIV positive by Western Blot
ii. Treatment Naive and started on antiretroviral therapy at time of enrollment or within past 4 weeks
iii. Viral Load greater than 30,000 copies/ml
iv. CD4 count less than 350 (x 106/L)
v. CD4 count 350-500 (x 106/L) and viral load 5,000-30,000 copies/ml

b. Exclusion Criteria:

i. drug interactions
ii. cannot give informed consent

H. Recruitment of Subjects:

Notification of Study protocol, objectives and inclusion/exclusion criteria will be sent to all medical providers and nurses in the Infectious Diseases (ID) clinic at CPMC.

1. Providers will be asked to refer current patients for the study.
2. A letter will be sent to the provider of all new patients to the ID clinic specifically asking if that patient would be appropriate for the study. Providers will be asked to discuss study with patient at the time of the next provider visit.
3. If provider and patient are agreeable to enrollment, patient will be approached during that same visit or at the time of their next provider or social work visit for enrollment.
4. Informed consent will be obtained from patients including permission to access their medical and electronic medical record to obtain necessary study data

I. Confidentiality of Study Data

1. All study data will be given a unique code number
2. records of unique codes will be stored in a secure location, accessible only to the investigators

J. Potential Conflict of Interest:

No investigator stands to benefit financially from the results of the Investigation

K. Location of Study:

All study activities will be carried out at the ID clinic on the sixth floor of Harkness Pavillion, CPMC

L. Potential Risks:

There are no additional risks to the participants beyond those of standard venipuncture that the patient would have done as part of the routine course of clinical treatment for HIV.

M. Potential Benefits:

Participants may or may not benefit as a result of participation in this study. The potential benefits are a decrease in viral load, an increase in CD4 count or a decrease in the number of hospitalizations and/or opportunistic infections.

N. Alternative Therapies:

None

O. Compensation to Subjects:

None

P. Costs to Subjects:

None

Q. Minors as Research Subjects:

Not Applicable

R. Radiation or Radioactive Substances:

Not Applicable

S. References:

1 Carpenter CCJ, Cooper DA, Fischl MA et al. Antiretroviral Therapy in Adults: Updated Recommendations of the International AIDS Society-USA Panel. JAMA. 2000;283:381-390