Evaluation Of An Antiretroviral Adherence Intervention Among HIV Infected Patients

Introduction

The human immunodeficiency virus (HIV) is a lentivirus (a subgroup of retrovirus) that causes HIV infection and over time acquired immunodeficiency syndrome (AIDS) (Weiss, n.d,1993)(Douek, Roederer, & Koup, 2009). HIV infects vital cells in the human immune system such as helper T cells (specifically $CD4^+$ T cells), macrophages, and dendritic cells (Cunningham, Donaghy, Harman, Kim, & Turville, 2010). When the $CD4^+$ T cell numbers decline below a critical level, cell-mediated immunity is lost, and the body becomes progressively more susceptible to opportunistic infections, leading to the development of AIDS. In high prevalence settings, young women remain at unacceptably high risk of HIV infection. In lower prevalence settings, the majority of HIV infections occur among key populations like people who inject drugs, sex workers, transgender persons, prisoners, and gay men and other men who have sex with men and their sexual partners (Unaids, 2017).

According to a global survey, there were approximately 31.1–43.9 million people in 2017 who were living with HIV and 1.8 million people became newly infected with HIV. Whereas, Around 21.7 million people were accessing antiretroviral therapy (ART) (Sheet, Hiv, & Hiv, 2018). Global scale-up of antiretroviral therapy has been the primary contributor to a 48% decline in deaths from AIDS related causes, from a peak of 1.9 million in 2005 to 1.0 million in 2016 (Unaids, 2017).

In Pakistan, the number of adults and children living with HIV is 150 thousand. The prevalence of HIV among adults aged 15 to 49 is 0.1%. However, the coverage of adults and children receiving antiretroviral therapy is only 8% (Unaids, 2017).

One of the key challenges to antiretroviral therapy is the commitment and ability of HIV-positive individuals to adhere to long-term therapy. Adherence to antiretroviral therapy has been defined as “the ability of the person living with HIV/AIDS to be involved in choosing, starting, managing and maintaining a given therapeutic combination medication regimen to control viral treatment protocols results in individual treatment failure and can also lead to development of resistant strains of the virus.” (Beith & Johnson, 2006).

Center for disease control and prevention defines health related quality of life (HRQoL) as “an individual’s or group’s perceived physical and mental health over time’’. It includes physical and mental health perceptions and their correlates like health risks, socioeconomic status, functional status and social support on the individual level (FACIT.org, 2016b).

The relationship between QoL and adherence has not been well studied. ART adherence is known to contribute to improved HIV clinical outcomes, which could result in a better QoL. QoL may also influence adherence, as persons with better QoL may have a greater ability to adhere to their ART regimens. Studies have shown that adherence and QoL share some determinants. Both QoL and adherence have been associated with HIV RNA levels, HIV disease stage, and symptoms (Mannheimer et al., 2005).

ART involves several medications with potentially unpleasant side effects and complex dosing regimens, adherence is especially challenging. Thus, several studies indicate that ART adherence tends to decline over time, suggesting that patients become fatigued or discouraged because of these difficulties. Although interventions developed to improve ART adherence have shown promise, their effects may not be long lasting. Interventions are thus needed that not only attempt to increase adherence levels but help patients to maintain high levels during the course of their treatment.

Problem statement

The research problem set for this study is to identify the possible factors that could be responsible for poor adherence to ART and to measure the adherence and how interventional study helps improving the adherence to medication.

Significance of the Research Study

This study is of vital importance to determine the level of adherence to ART, and factors influencing adherence to highly active antiretroviral therapy (HAART). The research helps to provide results to serve as a launching pad for further work on adherence and quality of life and make recommendations. This research is to assist in the education and dissemination of information to HIV/AIDS patients in order to help them, adapt their social behavior towards improved adherence to ART and to develop measures that should prevent psychological and emotional apathy to the limited available antiretroviral (ARV) medication.

Aims

1. To find the effect of an antiretroviral adherence intervention delivered by HIV Care providers specially pharmacist.

Objectives

1. To measure level of adherence to antiretroviral therapy ACTG adherence baseline questionnaire will be used.
2. To identify reasons for non-adherence to antiretroviral therapy.
3. To integrate the intervention, a counseling and education session will be delivered to each patient.

Material and Methods

Study design:

Randomized controlled trial.

Study setting:

The study will be conducted in HIV Care Centre PIMS, Islamabad, Pakistan.

Study duration:

The estimated duration of proposed study is four to six months.

Sampling technique:

Simple Random Sampling techniques will be used.

Sample size:

66, in accordance with past published papers.

Inclusion criteria

1. Having the HIV diagnosis formally registered in their chart.
2. Being aware of one's HIV-positive status for at least 3 months.
3. Able to provide informed consent, and intending to obtain care at the clinic for the next year.
4. Already on antiretroviral therapy at least one month before or newly initiating an Antiretroviral Therapy.
5. Age > 18 years of age.

Exclusion criteria

1. Patients with cognitive impairment.

Methodology:

For developing a database of potential participants (preparatory to research) according to IRB-approved recruitment protocol, the consent will be taken from the participants/patients to take part in study and to be contacted for future research studies.

Data collection for adherence

A study will be conducted in a tertiary care hospital for a period of four to six months in HIV CENTRE PIMS with patients taking antiretroviral therapy. Antiretroviral treatment adherence will be assessed by self- reported adherence measures - the Adult AIDS Clinical Trials Group (AACTG) adherence instrument will be used.[1] Covariables of interest include age, sex, time since HIV diagnosis, ART duration, current ART regimen, HIV transmission route, comorbidity, HIV-1 RNA viral load (VL), and CD4 cell count.

For antiretroviral adherence intervention

The counseling for the adherence intervention will be consisted of 6 components: (1) background data and rationale for promoting adherence to ART, (2) behavior change theories and models, (3) communication skill building, (4) how to set up a tailored pill- taking regimen and reinforce medication adherence, (5) role play of adherence counseling (mainly primary care providers, including physicians, physician assistants, and nurse practitioners), and (6) implementing the program in the clinic. At follow-up, all patients who participated in the baseline survey will be contacted whether during their clinic appointment and/or by telephone.

Data analysis

Descriptive analysis will be performed along with univariate and multiple logistic regression to identify associated factors for non-adherence to antiretroviral therapy. Univariate and multivariate logistic regression will be performed to verify factors related to the QOL.

Ethics

Ethics approval for the study will be obtained from Quaid-e-azam university ethics committee and also from Pakistan institute of medical sciences, Shaheed Zulfiqar Ali Bhutto medical university ethical review board (ERB).

Publications

Evaluation Of An Antiretroviral Adherence Intervention Among HIV Infected Patients, The Lancet HIV.

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[1] https://www.ghdonline.org/uploads/ACTG_Adherence_Baseline_Questionnaire.pdf